EUROPEAN CLIMATE, INFRASTRUCTURE AND ENVIRONMENT EXECUTIVE AGENCY (CINEA)

CINEA.C – Green research and innovation
C.1 – Horizon Europe Climate

GRANT AGREEMENT

Project 101156653 — ISMED-CLIM

PREAMBLE

This **Agreement** ('the Agreement') is **between** the following parties:

on the one part,

the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and

on the other part,

1. 'the coordinator':

UNIVERSITY OF CYPRUS (UCY), PIC 999835843, established in AVENUE PANEPISTIMIOU 2109 AGLANTZI, NICOSIA 1678, Cyprus,

and the following other beneficiaries, if they sign their 'accession form' (see Annex 3 and Article 40):

2. **THE CYPRUS INSTITUTE (CyI)**, PIC 965934440, established in CONSTANTINOU KAVAFI 20, NICOSIA 2121, Cyprus,

3. **ORGANISMOS ASFALISIS YGEIAS (HIO)**, PIC 881192427, established in KLIMENTOS 17 19, NICOSIA 1061, Cyprus,

4. **EBOS TECHNOLOGIES LIMITED (EBOS)**, PIC 997848022, established in ARCH. MAKARIOU III AND MESAORIAS 1 OFFICE 101, NICOSIA 2322, Cyprus,

5. **PANCYPRIAN FEDERATION OF LABOUR (EKYSY)**, PIC 940255630, established in ARCHERMOU ST 29, LEFKOSIA 1045, Cyprus,

6. **PANEPISTIMIO THESSALIAS (UTH)**, PIC 986152150, established in ARGONAFTON FILELLINON, VOLOS 38221, Greece,

7. **ETHNIKO KAI KAPODISTRIAKO PANEPISTIMIO ATHINON (NKUA)**, PIC 999643007, established in 6 CHRISTOU LADA STR, ATHINA 10561, Greece,

8. **DIMOS KORYDALLOS (KOR)**, PIC 917517763, established in GRIGORIOU LAMBRAKI 240, KORYDALLOS 18120, Greece,

9. **MINISTRY OF LABOUR AND SOCIAL AFFAIRS (MLSA)**, PIC 916252204, established in STADIOU 29, ATHENS 10437, Greece,

10. **ANAPTYXIAKI ETAIREIA DIMOU TRIKKAION ANAPTYXIAKI ANONYMI ETAIREIA OTA (TRIKALA)**, PIC 991940043, established in VALKANOY 6, TRIKALA 421 00, Greece,

11. **UNIVERSITA DEGLI STUDI DI CATANIA (UNICT)**, PIC 999874061, established in PIAZZA UNIVERSITA 2, CATANIA 95131, Italy,

12. **AZIENDA OSPEDALIERA DI RILIEVO NAZIONALE GARIBALDI CATANIA (ARNAS)**, PIC 888631163, established in PIAZZA SANTA MARIA DI GESU 5, CATANIA 95124, Italy,

13. **AZIENDA SANITARIA LOCALE ROMA 1 (DEASL)**, PIC 912924134, established in BORGO SANTO SPIRITO 3, ROMA 00198, Italy,

14. **UNIVERSIDAD DE LEON (ULE)**, PIC 999453372, established in AVENIDA FACULTAD 25, LEON 24004, Spain,

15. **FUNDACIO HOSPITAL UNIVERSITARI VALL D'HEBRON - INSTITUT DE RECERCA (VHIR)**, PIC 999541642, established in PASSEIG VALL D HEBRON 119-129 EDIFICIO DE RECERCA, BARCELONA 08035, Spain,

16. **AGENCIA ESTATAL CONSEJO SUPERIOR DE INVESTIGACIONES CIENTIFICAS (CSIC)**, PIC 999991722, established in CALLE SERRANO 117, MADRID 28006, Spain,

17. **UNIVERSIDADE NOVA DE LISBOA (UNL)**, PIC 960782479, established in CAMPUS DE CAMPOLIDE, LISBOA 1099 085, Portugal,

18. **UNIVERSIDADE DE AVEIRO (UA)**, PIC 999865331, established in CAMPUS UNIVERSITÁRIO DE SANTIAGO, AVEIRO 3810-193, Portugal,

19. **MUNICIPIO DE AGUEDA (AGUEDA)**, PIC 998359891, established in PRACA DO MUNICIPO, AGUEDA 3754 500, Portugal,

20. **ASSOCIACAO PORTUGUESA DE MEDICOS VETERINARIOS ESPECIALISTAS EM ANIMAIS DE COMPANHIA (APMVEAC)**, PIC 882219851, established in RUA AMERICO DURAO 18D, LISBOA 1900-064, Portugal,

21. **EUROPEAN CENTRE FOR MEDIUM-RANGE WEATHER FORECASTS (ECMWF)**, PIC 999916741, established in SHINFIELD PARK, READING RG2 9AX, United Kingdom,

22. **INSTITUT ZA MEDICINSKA ISTRA IVANJA (IMR)**, PIC 997623176, established in DR SUBOTICA 4 PRIZEMLJE, BELGRADE 11129, Serbia,

23. **AINIGMA TECHNOLOGIES (AIN)**, PIC 892135579, established in KAPELDREEF 60, LEUVEN 3001, Belgium,

24. **EDENTIFY FOUNDATION MTU (EF)**, PIC 881410095, established in NARVA MNT 7, TALLINN 10117, Estonia,

Unless otherwise specified, references to 'beneficiary' or 'beneficiaries' include the coordinator and affiliated entities (if any).

If only one beneficiary signs the grant agreement ('mono-beneficiary grant'), all provisions referring to the 'coordinator' or the 'beneficiaries' will be considered — mutatis mutandis — as referring to the beneficiary.

The parties referred to above have agreed to enter into the Agreement.

By signing the Agreement and the accession forms, the beneficiaries accept the grant and agree to implement the action under their own responsibility and in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

The Agreement is composed of:

Preamble

Terms and Conditions (including Data Sheet)

Annex 1 Description of the action[1]

Annex 2 Estimated budget for the action

Annex 2a Additional information on unit costs and contributions (if applicable)

Annex 3 Accession forms (if applicable)[2]

Annex 3a Declaration on joint and several liability of affiliated entities (if applicable)[3]

Annex 4 Model for the financial statements

Annex 5 Specific rules (if applicable)

[1] Template published on Portal Reference Documents.
[2] Template published on Portal Reference Documents.
[3] Template published on Portal Reference Documents.

TERMS AND CONDITIONS

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DATA SHEET

1. General data

Project summary:

Project summary
ISMED-CLIM aims to engage and mobilise regional stakeholders across the Mediterranean, in implementing a wide array of adaptation solutions to mitigate the health effects of climate change, and provide evidence for their feasibility, user acceptance and efficacy. Specifically, ISMED-CLIM will (i) enhance the understanding of climate change effects on non-communicable diseases (NCDs) and vector-borne infections across representative European countries within the Mediterranean; (ii) quantify, for the first time, how public health interventions integrating state-of-the-art technologies, public and social media, with vulnerable citizens' participation can reduce personal exposures to heat and air pollution and related health effects; (iii) validate the feasibility and user acceptance among high risk professionals of a regional early warning and risk prediction tool to mitigate the risk posed by exposure to sand flies and related diseases; (iv) employ open, participatory, and co-creative methodologies to locally adapt and refine existing evidence-based practices and prototype tools to increase the preparedness and ability of health systems in the Mediterranean to deliver safe, effective, and efficient care to citizens. We will test the proposed demonstration solutions initially in eight sites and coordinate ten replications in six sites in five European countries (Cyprus, Greece, Italy, Spain, Portugal), in alignment with Climate Change Adaptation Mission objectives. We will integrate the produced knowledge from epidemiology, forecasting, exposure and health data with insights from the demonstration and replication activities into a knowledge portal and policy decision-centric and action-oriented dashboard for policy makers, healthcare administrators, professionals and citizens. ISMED-CLIM's approaches will be readily applicable in other European regions affected by the same or other climate change-related stressors, such as forest fire smoke, floods, ozone, and cold.

Keywords:

- Climate change adaptation
- Early warning systems
- Environmental health
- Health monitoring systems
- Preparedness

Project number: 101156653

Project name: Innovative Solutions across the MEDiterranean for mitigation of Climate change-related heaLth rIsks and enhancing health systeM resilience

Project acronym: ISMED-CLIM

Call: HORIZON-MISS-2023-CLIMA-01

Topic: HORIZON-MISS-2023-CLIMA-01-03

Type of action: HORIZON Innovation Actions

Granting authority: European Climate, Infrastructure and Environment Executive Agency

Grant managed through EU Funding & Tenders Portal: Yes (eGrants)

Project starting date: fixed date: 1 November 2024

Project end date: 31 October 2028

Project duration: 48 months

Consortium agreement: Yes

2. Participants

List of participants:

N°	Role	Short name	Legal name	Ctry	PIC	Total eligible costs (BEN and AE)	Max grant amount
1	COO	UCY	UNIVERSITY OF CYPRUS	CY	999835843	1 026 250.00	1 026 250.00
2	BEN	CyI	THE CYPRUS INSTITUTE	CY	965934440	334 315.00	334 315.00
3	BEN	HIO	ORGANISMOS ASFALISIS YGEIAS	CY	881192427	98 750.00	98 750.00
4	BEN	EBOS	EBOS TECHNOLOGIES LIMITED	CY	997848022	587 000.00	410 900.00
5	BEN	EKYSY	PANCYPRIAN FEDERATION OF LABOUR	CY	940255630	50 650.00	50 650.00
6	BEN	UTH	PANEPISTIMIO THESSALIAS	EL	986152150	399 375.00	399 375.00
7	BEN	NKUA	ETHNIKO KAI KAPODISTRIAKO PANEPISTIMIO ATHINON	EL	999643007	334 375.00	334 375.00
8	BEN	KOR	DIMOS KORYDALLOS	EL	917517763	98 750.00	98 750.00
9	BEN	MLSA	MINISTRY OF LABOUR AND SOCIAL AFFAIRS	EL	916252204	51 400.00	51 400.00
10	BEN	TRIKALA	ANAPTYXIAKI ETAIREIA DIMOU TRIKKAION ANAPTYXIAKI ANONYMI ETAIREIA OTA	EL	991940043	50 500.00	50 500.00
11	BEN	UNICT	UNIVERSITA DEGLI STUDI DI CATANIA	IT	999874061	480 000.00	480 000.00
12	BEN	ARNAS	AZIENDA OSPEDALIERA DI RILIEVO NAZIONALE GARIBALDI CATANIA	IT	888631163	50 950.00	50 950.00
13	BEN	DEASL	AZIENDA SANITARIA LOCALE ROMA 1	IT	912924134	196 250.00	196 250.00
14	BEN	ULE	UNIVERSIDAD DE LEON	ES	999453372	354 375.00	354 375.00
15	BEN	VHIR	FUNDACIO HOSPITAL UNIVERSITARI VALL D'HEBRON - INSTITUT DE RECERCA	ES	999541642	405 000.00	405 000.00
16	BEN	CSIC	AGENCIA ESTATAL CONSEJO SUPERIOR DE INVESTIGACIONES CIENTIFICAS	ES	999991722	116 250.00	116 250.00
17	BEN	UNL	UNIVERSIDADE NOVA DE LISBOA	PT	960782479	155 500.00	155 500.00
18	BEN	UA	UNIVERSIDADE DE AVEIRO	PT	999865331	103 125.00	103 125.00
19	BEN	AGUEDA	MUNICIPIO DE AGUEDA	PT	998359891	49 750.00	49 750.00
20	BEN	APMVEAC	ASSOCIACAO PORTUGUESA DE MEDICOS VETERINARIOS ESPECIALISTAS EM ANIMAIS DE COMPANHIA	PT	882219851	51 175.00	51 175.00
21	BEN (IO)	ECMWF	EUROPEAN CENTRE FOR MEDIUM-RANGE WEATHER FORECASTS	UK	999916741	305 562.50	305 562.00
22	BEN	IMR	INSTITUT ZA MEDICINSKA ISTRA IVANJA	RS	997623176	110 350.00	110 350.00
23	BEN	AIN	AINIGMA TECHNOLOGIES	BE	892135579	567 500.00	397 250.00
24	BEN	EF	EDENTIFY FOUNDATION MTU	EE	881410095	368 750.00	368 750.00
25	AP	HSPH	HARVARD GLOBAL RESEARCH AND SUPPORT SERVICES INC.	US	953720200	0.00	0.00
26	AP	RG	RESILIENCE GUARD GMBH	CH	949987737	0.00	0.00
27	AP	ACARES	Americares Foundation Inc.	US	881117058	0.00	0.00
Total						6 345 902.50	5 999 552.00

Coordinator:

– UNIVERSITY OF CYPRUS (UCY)

3. Grant

Maximum grant amount, total estimated eligible costs and contributions and funding rate:

Total eligible costs (BEN and AE)	Funding rate (%)	Maximum grant amount (Annex 2)	Maximum grant amount (award decision)
6 345 902.50	100, 70	5 999 552.00	5 999 552.00

Grant form: Budget-based

Grant mode: Action grant

Budget categories/activity types:

- A. Personnel costs
  - A.1 Employees, A.2 Natural persons under direct contract, A.3 Seconded persons
  - A.4 SME owners and natural person beneficiaries

- B. Subcontracting costs

- C. Purchase costs
  - C.1 Travel and subsistence
  - C.2 Equipment
  - C.3 Other goods, works and services

- D. Other cost categories
  - D.2 Internally invoiced goods and services

- E. Indirect costs

Cost eligibility options:

- In-kind contributions eligible costs

- Parental leave

- Project-based supplementary payments

- Average personnel costs (unit cost according to usual cost accounting practices)

- Limitation for subcontracting

- Travel and subsistence:
  - Travel: Actual costs
  - Accommodation: Actual costs
  - Subsistence: Actual costs

- Equipment: depreciation only

- Indirect cost flat-rate: 25% of the eligible direct costs (categories A-D, except volunteers costs, subcontracting costs, financial support to third parties and exempted specific cost categories, if any)

- VAT: Yes

- Other ineligible costs

Budget flexibility: Yes (no flexibility cap)

4. Reporting, payments and recoveries

4.1 Continuous reporting (art 21)

Deliverables: see Funding & Tenders Portal Continuous Reporting tool

4.2 Periodic reporting and payments

Reporting and payment schedule (art 21, 22):

Reporting					Payments	
Reporting periods			Type	Deadline	Type	Deadline (time to pay)
RP No	Month from	Month to				
					Initial prefinancing	30 days from entry into force/10 days before starting date – whichever is the latest
1	1	18	Periodic report	60 days after end of reporting period	Interim payment	90 days from receiving periodic report
2	19	36	Periodic report	60 days after end of reporting period	Interim payment	90 days from receiving periodic report
3	37	48	Periodic report	60 days after end of reporting period	Final payment	90 days from receiving periodic report

Prefinancing payments and guarantees:

Prefinancing payment	
Type	Amount
Prefinancing 1 (initial)	3 199 561.08

Reporting and payment modalities (art 21, 22):

Mutual Insurance Mechanism (MIM): Yes

MIM contribution: 5% of the maximum grant amount (299 977.60), retained from the initial prefinancing

Restrictions on distribution of initial prefinancing: The prefinancing may be distributed only if the minimum number of beneficiaries set out in the call condititions (if any) have acceded to the Agreement and only to beneficiaries that have acceded.

Interim payment ceiling (if any): 90% of the maximum grant amount

Exception for revenues: Yes

No-profit rule: Yes

Late payment interest: ECB + 3.5%

Bank account for payments:

CY96018000060000200100341941 ERBKCY2N

Conversion into euros: Double conversion

Reporting language: Language of the Agreement

4.3 Certificates (art 24):

Certificates on the financial statements (CFS):

Conditions:

Schedule: only at final payment, if threshold is reached

Standard threshold (beneficiary-level):

- financial statement: requested EU contribution to costs ≥ EUR 430 000.00

Special threshold for beneficiaries with a systems and process audit(see Article 24): financial statement: requested EU contribution to costs ≥ EUR 725 000.00

4.4 Recoveries (art 22)

First-line liability for recoveries:

Beneficiary termination: Beneficiary concerned

Final payment: Each beneficiary for their own debt

After final payment: Beneficiary concerned

Joint and several liability for enforced recoveries (in case of non-payment):

Individual financial responsibility: Each beneficiary is liable only for its own debts (and those of its affiliated entities, if any)

Joint and several liability of affiliated entities — n/a

5. Consequences of non-compliance, applicable law & dispute settlement forum

Suspension and termination:

Additional suspension grounds (art 31)

Additional termination grounds (art 32)

Applicable law (art 43):

Standard applicable law regime: EU law + law of Belgium

Special applicable law regime:

– EUROPEAN CENTRE FOR MEDIUM-RANGE WEATHER FORECASTS (ECMWF): general principles governing the law of international organisations and the general rules of international law

Dispute settlement forum (art 43):

Standard dispute settlement forum:

EU beneficiaries: EU General Court + EU Court of Justice (on appeal)

Non-EU beneficiaries: Courts of Brussels, Belgium (unless an international agreement provides for the enforceability of EU court judgements)

Special dispute settlement forum:

– EUROPEAN CENTRE FOR MEDIUM-RANGE WEATHER FORECASTS (ECMWF): Arbitration

6. Other

Specific rules (Annex 5): Yes

Standard time-limits after project end:

Confidentiality (for X years after final payment): 5

Record-keeping (for X years after final payment): 5 (or 3 for grants of not more than EUR 60 000)

Reviews (up to X years after final payment): 2

Audits (up to X years after final payment): 2

Extension of findings from other grants to this grant (no later than X years after final payment): 2

Impact evaluation (up to X years after final payment): 5 (or 3 for grants of not more than EUR 60 000)

CHAPTER 1 GENERAL

ARTICLE 1 — SUBJECT OF THE AGREEMENT

This Agreement sets out the rights and obligations and terms and conditions applicable to the grant awarded for the implementation of the action set out in Chapter 2.

ARTICLE 2 — DEFINITIONS

For the purpose of this Agreement, the following definitions apply:

Actions — The project which is being funded in the context of this Agreement.

Grant — The grant awarded in the context of this Agreement.

EU grants — Grants awarded by EU institutions, bodies, offices or agencies (including EU executive agencies, EU regulatory agencies, EDA, joint undertakings, etc.).

Participants — Entities participating in the action as beneficiaries, affiliated entities, associated partners, third parties giving in-kind contributions, subcontractors or recipients of financial support to third parties.

Beneficiaries (BEN) — The signatories of this Agreement (either directly or through an accession form).

Affiliated entities (AE) — Entities affiliated to a beneficiary within the meaning of Article 187 of EU Financial Regulation 2018/1046[4] which participate in the action with similar rights and obligations as the beneficiaries (obligation to implement action tasks and right to charge costs and claim contributions).

Associated partners (AP) — Entities which participate in the action, but without the right to charge costs or claim contributions.

Purchases — Contracts for goods, works or services needed to carry out the action (e.g. equipment, consumables and supplies) but which are not part of the action tasks (see Annex 1).

Subcontracting — Contracts for goods, works or services that are part of the action tasks (see Annex 1).

In-kind contributions — In-kind contributions within the meaning of Article 2(36) of EU Financial

[4] For the definition, see Article 187 Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 ('EU Financial Regulation') (OJ L 193, 30.7.2018, p. 1): "**affiliated entities** [are]:
(a) entities that form a sole beneficiary [(i.e. where an entity is formed of several entities that satisfy the criteria for being awarded a grant, including where the entity is specifically established for the purpose of implementing an action to be financed by a grant)];
(b) entities that satisfy the eligibility criteria and that do not fall within one of the situations referred to in Article 136(1) and 141(1) and that have a link with the beneficiary, in particular a legal or capital link, which is neither limited to the action nor established for the sole purpose of its implementation".

Regulation 2018/1046, i.e. non-financial resources made available free of charge by third parties.

Fraud — Fraud within the meaning of Article 3 of EU Directive 2017/1371[5] and Article 1 of the Convention on the protection of the European Communities' financial interests, drawn up by the Council Act of 26 July 1995[6], as well as any other wrongful or criminal deception intended to result in financial or personal gain.

Irregularities — Any type of breach (regulatory or contractual) which could impact the EU financial interests, including irregularities within the meaning of Article 1(2) of EU Regulation 2988/95[7].

Grave professional misconduct — Any type of unacceptable or improper behaviour in exercising one's profession, especially by employees, including grave professional misconduct within the meaning of Article 136(1)(c) of EU Financial Regulation 2018/1046.

Applicable EU, international and national law — Any legal acts or other (binding or non-binding) rules and guidance in the area concerned.

Portal — EU Funding & Tenders Portal; electronic portal and exchange system managed by the European Commission and used by itself and other EU institutions, bodies, offices or agencies for the management of their funding programmes (grants, procurements, prizes, etc.).

CHAPTER 2 ACTION

ARTICLE 3 — ACTION

The grant is awarded for the action **101156653** — **ISMED-CLIM** ('action'), as described in Annex 1.

ARTICLE 4 — DURATION AND STARTING DATE

The duration and the starting date of the action are set out in the Data Sheet (see Point 1).

CHAPTER 3 GRANT

ARTICLE 5 — GRANT

5.1 Form of grant

The grant is an action grant[8] which takes the form of a budget-based mixed actual cost grant (i.e. a

[5] Directive (EU) 2017/1371 of the European Parliament and of the Council of 5 July 2017 on the fight against fraud to the Union's financial interests by means of criminal law (OJ L 198, 28.7.2017, p. 29).

[6] OJ C 316, 27.11.1995, p. 48.

[7] Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests (OJ L 312, 23.12.1995, p. 1).

[8] For the definition, see Article 180(2)(a) EU Financial Regulation 2018/1046: '**action grant**' means an EU grant to finance "an action intended to help achieve a Union policy objective".

grant based on actual costs incurred, but which may also include other forms of funding, such as unit costs or contributions, flat-rate costs or contributions, lump sum costs or contributions or financing not linked to costs).

5.2 Maximum grant amount

The maximum grant amount is set out in the Data Sheet (see Point 3) and in the estimated budget (Annex 2).

5.3 Funding rate

The funding rate for costs is 100% of the eligible costs for beneficiaries that are non-profit legal entities[9] and 70% of the eligible costs for beneficiaries that are profit legal entities.

Contributions are not subject to any funding rate.

5.4 Estimated budget, budget categories and forms of funding

The estimated budget for the action is set out in Annex 2.

It contains the estimated eligible costs and contributions for the action, broken down by participant and budget category.

Annex 2 also shows the types of costs and contributions (forms of funding)[10] to be used for each budget category.

If unit costs or contributions are used, the details on the calculation will be explained in Annex 2a.

5.5 Budget flexibility

The budget breakdown may be adjusted — without an amendment (see Article 39) — by transfers (between participants and budget categories), as long as this does not imply any substantive or important change to the description of the action in Annex 1.

However:

- changes to the budget category for volunteers (if used) always require an amendment
- changes to budget categories with lump sums costs or contributions (if used; including financing not linked to costs) always require an amendment
- changes to budget categories with higher funding rates or budget ceilings (if used) always require an amendment
- addition of amounts for subcontracts not provided for in Annex 1 either require an amendment or simplified approval in accordance with Article 6.2

[9] For the definition, see Article XX of the Horizon Europe Framework Programme and Rules for Participation Regulation (EU) XXX: '**non-profit legal entity**' means a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.

[10] See Article 125 EU Financial Regulation 2018/1046.

- other changes require an amendment or simplified approval, if specifically provided for in Article 6.2

- flexibility caps: not applicable.

ARTICLE 6 — ELIGIBLE AND INELIGIBLE COSTS AND CONTRIBUTIONS

In order to be eligible, costs and contributions must meet the **eligibility** conditions set out in this Article.

6.1 General eligibility conditions

The **general eligibility conditions** are the following:

(a) for actual costs:

(i) they must be actually incurred by the beneficiary

(ii) they must be incurred in the period set out in Article 4 (with the exception of costs relating to the submission of the final periodic report, which may be incurred afterwards; see Article 21)

(iii) they must be declared under one of the budget categories set out in Article 6.2 and Annex 2

(iv) they must be incurred in connection with the action as described in Annex 1 and necessary for its implementation

(v) they must be identifiable and verifiable, in particular recorded in the beneficiary's accounts in accordance with the accounting standards applicable in the country where the beneficiary is established and with the beneficiary's usual cost accounting practices

(vi) they must comply with the applicable national law on taxes, labour and social security and

(vii) they must be reasonable, justified and must comply with the principle of sound financial management, in particular regarding economy and efficiency

(b) for unit costs or contributions (if any):

(i) they must be declared under one of the budget categories set out in Article 6.2 and Annex 2

(ii) the units must:

- be actually used or produced by the beneficiary in the period set out in Article 4 (with the exception of units relating to the submission of the final periodic report, which may be used or produced afterwards; see Article 21)

- be necessary for the implementation of the action and

(iii) the number of units must be identifiable and verifiable, in particular supported by records and documentation (see Article 20)

(c) for flat-rate costs or contributions (if any):

(i) they must be declared under one of the budget categories set out in Article 6.2 and Annex 2

(ii) the costs or contributions to which the flat-rate is applied must:

- be eligible
- relate to the period set out in Article 4 (with the exception of costs or contributions relating to the submission of the final periodic report, which may be incurred afterwards; see Article 21)

(d) for lump sum costs or contributions (if any):

(i) they must be declared under one of the budget categories set out in Article 6.2 and Annex 2

(ii) the work must be properly implemented by the beneficiary in accordance with Annex 1

(iii) the deliverables/outputs must be achieved in the period set out in Article 4 (with the exception of deliverables/outputs relating to the submission of the final periodic report, which may be achieved afterwards; see Article 21)

(e) for unit, flat-rate or lump sum costs or contributions according to usual cost accounting practices (if any):

(i) they must fulfil the general eligibility conditions for the type of cost concerned

(ii) the cost accounting practices must be applied in a consistent manner, based on objective criteria, regardless of the source of funding

(f) for financing not linked to costs (if any): the results must be achieved or the conditions must be fulfilled as described in Annex 1.

In addition, for direct cost categories (e.g. personnel, travel & subsistence, subcontracting and other direct costs) only costs that are directly linked to the action implementation and can therefore be attributed to it directly are eligible. They must not include any indirect costs (i.e. costs that are only indirectly linked to the action, e.g. via cost drivers).

In-kind contributions provided by third parties free of charge may be declared as eligible direct costs by the beneficiaries which use them (under the same conditions as if they were their own, provided that they concern only direct costs and that the third parties and their in-kind contributions are set out in Annex 1 (or approved ex post in the periodic report, if their use does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants; 'simplified approval procedure').

6.2 Specific eligibility conditions for each budget category

For each budget category, the **specific eligibility conditions** are as follows:

Direct costs

A. Personnel costs

A.1 Costs for employees (or equivalent) are eligible as personnel costs if they fulfil the general eligibility conditions and are related to personnel working for the beneficiary under an employment contract (or equivalent appointing act) and assigned to the action.

They must be limited to salaries (including net payments during parental leave), social security contributions, taxes and other costs linked to the remuneration, if they arise from national law or the employment contract (or equivalent appointing act) and be calculated on the basis of the costs actually incurred, in accordance with the following method:

{daily rate for the person

multiplied by

number of day-equivalents worked on the action (rounded up or down to the nearest half-day)}.

The daily rate must be calculated as:

{annual personnel costs for the person

divided by

215}.

The number of day-equivalents declared for a person must be identifiable and verifiable (see Article 20).

The actual time spent on parental leave by a person assigned to the action may be deducted from the 215 days indicated in the above formula.

The total number of day-equivalents declared in EU grants, for a person for a year, cannot be higher than 215, minus time spent on parental leave (if any).

For personnel which receives supplementary payments for work in projects (project-based remuneration), the personnel costs must be calculated at a rate which:

- corresponds to the actual remuneration costs paid by the beneficiary for the time worked by the person in the action over the reporting period
- does not exceed the remuneration costs paid by the beneficiary for work in similar projects funded by national schemes (‘national projects reference’)
- is defined based on objective criteria allowing to determine the amount to which the person is entitled

and

- reflects the usual practice of the beneficiary to pay consistently bonuses or supplementary payments for work in projects funded by national schemes.

The national projects reference is the remuneration defined in national law, collective labour agreement or written internal rules of the beneficiary applicable to work in projects funded by national schemes.

If there is no such national law, collective labour agreement or written internal rules or if the project-

based remuneration is not based on objective criteria, the national project reference will be the average remuneration of the person in the last full calendar year covered by the reporting period, excluding remuneration paid for work in EU actions.

If the beneficiary uses average personnel costs (unit cost according to usual cost accounting practices), the personnel costs must fulfil the general eligibility conditions for such unit costs and the daily rate must be calculated:

- using the actual personnel costs recorded in the beneficiary's accounts and excluding any costs which are ineligible or already included in other budget categories; the actual personnel costs may be adjusted on the basis of budgeted or estimated elements, if they are relevant for calculating the personnel costs, reasonable and correspond to objective and verifiable information

and

- according to usual cost accounting practices which are applied in a consistent manner, based on objective criteria, regardless of the source of funding.

A.2 and **A.3 Costs for natural persons working under a direct contract** other than an employment contract and costs for **seconded persons by a third party against payment** are also eligible as personnel costs, if they are assigned to the action, fulfil the general eligibility conditions and:

(a) work under conditions similar to those of an employee (in particular regarding the way the work is organised, the tasks that are performed and the premises where they are performed) and

(b) the result of the work belongs to the beneficiary (unless agreed otherwise).

They must be calculated on the basis of a rate which corresponds to the costs actually incurred for the direct contract or secondment and must not be significantly different from those for personnel performing similar tasks under an employment contract with the beneficiary.

A.4 The work of **SME owners** for the action (i.e. owners of beneficiaries that are small and medium-sized enterprises[11] not receiving a salary) or **natural person beneficiaries** (i.e. beneficiaries that are natural persons not receiving a salary) may be declared as personnel costs, if they fulfil the general eligibility conditions and are calculated as unit costs in accordance with the method set out in Annex 2a.

B. Subcontracting costs

Subcontracting costs for the action (including related duties, taxes and charges, such as non-deductible or non-refundable value added tax (VAT)) are eligible, if they are calculated on the basis

[11] For the definition, see Commission Recommendation 2003/361/EC: micro, small or medium-sized enterprise (SME) are enterprises

- engaged in an economic activity, irrespective of their legal form (including, in particular, self- employed persons and family businesses engaged in craft or other activities, and partnerships or associations regularly engaged in an economic activity) and

- employing fewer than 250 persons (expressed in 'annual working units' as defined in Article 5 of the Recommendation) and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.

of the costs actually incurred, fulfil the general eligibility conditions and are awarded using the beneficiary's usual purchasing practices — provided these ensure subcontracts with best value for money (or if appropriate the lowest price) and that there is no conflict of interests (see Article 12).

Beneficiaries that are 'contracting authorities/entities' within the meaning of the EU Directives on public procurement must also comply with the applicable national law on public procurement.

Subcontracting may cover only a limited part of the action.

The tasks to be subcontracted and the estimated cost for each subcontract must be set out in Annex 1 and the total estimated costs of subcontracting per beneficiary must be set out in Annex 2 (or may be approved ex post in the periodic report, if the use of subcontracting does not entail changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants; 'simplified approval procedure').

C. Purchase costs

Purchase costs for the action (including related duties, taxes and charges, such as non-deductible or non-refundable value added tax (VAT)) are eligible if they fulfil the general eligibility conditions and are bought using the beneficiary's usual purchasing practices — provided these ensure purchases with best value for money (or if appropriate the lowest price) and that there is no conflict of interests (see Article 12).

Beneficiaries that are 'contracting authorities/entities' within the meaning of the EU Directives on public procurement must also comply with the applicable national law on public procurement.

C.1 Travel and subsistence

Purchases for **travel, accommodation** and **subsistence** must be calculated as follows:

- travel: on the basis of the costs actually incurred and in line with the beneficiary's usual practices on travel
- accommodation: on the basis of the costs actually incurred and in line with the beneficiary's usual practices on travel
- subsistence: on the basis of the costs actually incurred and in line with the beneficiary's usual practices on travel .

C.2 Equipment

Purchases of **equipment, infrastructure or other assets** used for the action must be declared as depreciation costs, calculated on the basis of the costs actually incurred and written off in accordance with international accounting standards and the beneficiary's usual accounting practices.

Only the portion of the costs that corresponds to the rate of actual use for the action during the action duration can be taken into account.

Costs for **renting or leasing** equipment, infrastructure or other assets are also eligible, if they do not exceed the depreciation costs of similar equipment, infrastructure or assets and do not include any financing fees.

C.3 Other goods, works and services

Purchases of **other goods, works and services** must be calculated on the basis of the costs actually incurred.

Such goods, works and services include, for instance, consumables and supplies, promotion, dissemination, protection of results, translations, publications, certificates and financial guarantees, if required under the Agreement.

D. Other cost categories

D.2 Internally invoiced goods and services

Costs for internally invoiced goods and services directly used for the action may be declared as unit cost according to usual cost accounting practices, if and as declared eligible in the call conditions, if they fulfil the general eligibility conditions for such unit costs and the amount per unit is calculated:

- using the actual costs for the good or service recorded in the beneficiary's accounts, attributed either by direct measurement or on the basis of cost drivers, and excluding any cost which are ineligible or already included in other budget categories; the actual costs may be adjusted on the basis of budgeted or estimated elements, if they are relevant for calculating the costs, reasonable and correspond to objective and verifiable information

and

- according to usual cost accounting practices which are applied in a consistent manner, based on objective criteria, regardless of the source of funding.

'Internally invoiced goods and services' means goods or services which are provided within the beneficiary's organisation directly for the action and which the beneficiary values on the basis of its usual cost accounting practices.

This cost will not be taken into account for the indirect cost flat-rate.

Indirect costs

E. Indirect costs

Indirect costs will be reimbursed at the flat-rate of 25% of the eligible direct costs (categories A-D, except volunteers costs, subcontracting costs, financial support to third parties and exempted specific cost categories, if any).

Contributions

Not applicable

6.3 Ineligible costs and contributions

The following costs or contributions are **ineligible**:

(a) costs or contributions that do not comply with the conditions set out above (Article 6.1 and 6.2), in particular:

(i) costs related to return on capital and dividends paid by a beneficiary

(ii) debt and debt service charges

(iii) provisions for future losses or debts

(iv) interest owed

(v) currency exchange losses

(vi) bank costs charged by the beneficiary's bank for transfers from the granting authority

(vii) excessive or reckless expenditure

(viii) deductible or refundable VAT (including VAT paid by public bodies acting as public authority)

(ix) costs incurred or contributions for activities implemented during grant agreement suspension (see Article 31)

(x) in-kind contributions by third parties: not applicable

(b) costs or contributions declared under other EU grants (or grants awarded by an EU Member State, non-EU country or other body implementing the EU budget), except for the following cases:

(i) Synergy actions: not applicable

(ii) if the action grant is combined with an operating grant[12] running during the same period and the beneficiary can demonstrate that the operating grant does not cover any (direct or indirect) costs of the action grant

(c) costs or contributions for staff of a national (or regional/local) administration, for activities that are part of the administration's normal activities (i.e. not undertaken only because of the grant)

(d) costs or contributions (especially travel and subsistence) for staff or representatives of EU institutions, bodies or agencies

(e) other :

(i) country restrictions for eligible costs: not applicable

(ii) costs or contributions declared specifically ineligible in the call conditions.

6.4 Consequences of non-compliance

If a beneficiary declares costs or contributions that are ineligible, they will be rejected (see Article 27).

This may also lead to other measures described in Chapter 5.

[12] For the definition, see Article 180(2)(b) of EU Financial Regulation 2018/1046: '**operating grant**' means an EU grant to finance "the functioning of a body which has an objective forming part of and supporting an EU policy".

CHAPTER 4 GRANT IMPLEMENTATION

SECTION 1 CONSORTIUM: BENEFICIARIES, AFFILIATED ENTITIES AND OTHER PARTICIPANTS

ARTICLE 7 — BENEFICIARIES

The beneficiaries, as signatories of the Agreement, are fully responsible towards the granting authority for implementing it and for complying with all its obligations.

They must implement the Agreement to their best abilities, in good faith and in accordance with all the obligations and terms and conditions it sets out.

They must have the appropriate resources to implement the action and implement the action under their own responsibility and in accordance with Article 11. If they rely on affiliated entities or other participants (see Articles 8 and 9), they retain sole responsibility towards the granting authority and the other beneficiaries.

They are jointly responsible for the *technical* implementation of the action. If one of the beneficiaries fails to implement their part of the action, the other beneficiaries must ensure that this part is implemented by someone else (without being entitled to an increase of the maximum grant amount and subject to an amendment; see Article 39). The *financial* responsibility of each beneficiary in case of recoveries is governed by Article 22.

The beneficiaries (and their action) must remain eligible under the EU programme funding the grant for the entire duration of the action. Costs and contributions will be eligible only as long as the beneficiary and the action are eligible.

The **internal roles and responsibilities** of the beneficiaries are divided as follows:

(a) Each beneficiary must:

(i) keep information stored in the Portal Participant Register up to date (see Article 19)

(ii) inform the granting authority (and the other beneficiaries) immediately of any events or circumstances likely to affect significantly or delay the implementation of the action (see Article 19)

(iii) submit to the coordinator in good time:

- the prefinancing guarantees (if required; see Article 23)
- the financial statements and certificates on the financial statements (CFS) (if required; see Articles 21 and 24.2 and Data Sheet, Point 4.3)
- the contribution to the deliverables and technical reports (see Article 21)
- any other documents or information required by the granting authority under the Agreement

(iv) submit via the Portal data and information related to the participation of their affiliated entities.

(b) The coordinator must:

(i) monitor that the action is implemented properly (see Article 11)

(ii) act as the intermediary for all communications between the consortium and the granting authority, unless the Agreement or granting authority specifies otherwise, and in particular:

- submit the prefinancing guarantees to the granting authority (if any)
- request and review any documents or information required and verify their quality and completeness before passing them on to the granting authority
- submit the deliverables and reports to the granting authority
- inform the granting authority about the payments made to the other beneficiaries (report on the distribution of payments; if required, see Articles 22 and 32)

(iii) distribute the payments received from the granting authority to the other beneficiaries without unjustified delay (see Article 22).

The coordinator may not delegate or subcontract the above-mentioned tasks to any other beneficiary or third party (including affiliated entities).

However, coordinators which are public bodies may delegate the tasks set out in Point (b)(ii) last indent and (iii) above to entities with 'authorisation to administer' which they have created or which are controlled by or affiliated to them. In this case, the coordinator retains sole responsibility for the payments and for compliance with the obligations under the Agreement.

Moreover, coordinators which are 'sole beneficiaries'[13] (or similar, such as European research infrastructure consortia (ERICs)) may delegate the tasks set out in Point (b)(i) to (iii) above to one of their members. The coordinator retains sole responsibility for compliance with the obligations under the Agreement.

The beneficiaries must have **internal arrangements** regarding their operation and co-ordination, to ensure that the action is implemented properly.

If required by the granting authority (see Data Sheet, Point 1), these arrangements must be set out in a written **consortium agreement** between the beneficiaries, covering for instance:

- the internal organisation of the consortium
- the management of access to the Portal
- different distribution keys for the payments and financial responsibilities in case of recoveries (if any)
- additional rules on rights and obligations related to background and results (see Article 16)

[13] For the definition, see Article 187(2) EU Financial Regulation 2018/1046: "Where several entities satisfy the criteria for being awarded a grant and together form one entity, that entity may be treated as the **sole beneficiary**, including where it is specifically established for the purpose of implementing the action financed by the grant."

- settlement of internal disputes
- liability, indemnification and confidentiality arrangements between the beneficiaries.

The internal arrangements must not contain any provision contrary to this Agreement.

ARTICLE 8 — AFFILIATED ENTITIES

Not applicable

ARTICLE 9 — OTHER PARTICIPANTS INVOLVED IN THE ACTION

9.1 Associated partners

The following entities which cooperate with a beneficiary will participate in the action as 'associated partners':

- **HARVARD GLOBAL RESEARCH AND SUPPORT SERVICES INC. (HSPH)**, PIC 953720200
- **RESILIENCE GUARD GMBH (RG)**, PIC 949987737
- **Americares Foundation Inc. (ACARES)**, PIC 881117058

Associated partners must implement the action tasks attributed to them in Annex 1 in accordance with Article 11. They may not charge costs or contributions to the action and the costs for their tasks are not eligible.

The tasks must be set out in Annex 1.

The beneficiaries must ensure that their contractual obligations under Articles 11 (proper implementation), 12 (conflict of interests), 13 (confidentiality and security), 14 (ethics), 17.2 (visibility), 18 (specific rules for carrying out action), 19 (information) and 20 (record-keeping) also apply to the associated partners.

The beneficiaries must ensure that the bodies mentioned in Article 25 (e.g. granting authority, OLAF, Court of Auditors (ECA), etc.) can exercise their rights also towards the associated partners.

9.2 Third parties giving in-kind contributions to the action

Other third parties may give in-kind contributions to the action (i.e. personnel, equipment, other goods, works and services, etc. which are free-of-charge) if necessary for the implementation.

Third parties giving in-kind contributions do not implement any action tasks. They may not charge costs or contributions to the action, but the costs for the in-kind contributions are eligible and may be charged by the beneficiaries which use them, under the conditions set out in Article 6. The costs will be included in Annex 2 as part of the beneficiaries' costs.

The third parties and their in-kind contributions should be set out in Annex 1.

The beneficiaries must ensure that the bodies mentioned in Article 25 (e.g. granting authority, OLAF,

Court of Auditors (ECA), etc.) can exercise their rights also towards the third parties giving in-kind contributions.

9.3 Subcontractors

Subcontractors may participate in the action, if necessary for the implementation.

Subcontractors must implement their action tasks in accordance with Article 11. The costs for the subcontracted tasks (invoiced price from the subcontractor) are eligible and may be charged by the beneficiaries, under the conditions set out in Article 6. The costs will be included in Annex 2 as part of the beneficiaries' costs.

The beneficiaries must ensure that their contractual obligations under Articles 11 (proper implementation), 12 (conflict of interest), 13 (confidentiality and security), 14 (ethics), 17.2 (visibility), 18 (specific rules for carrying out action), 19 (information) and 20 (record-keeping) also apply to the subcontractors.

The beneficiaries must ensure that the bodies mentioned in Article 25 (e.g. granting authority, OLAF, Court of Auditors (ECA), etc.) can exercise their rights also towards the subcontractors.

9.4 Recipients of financial support to third parties

If the action includes providing financial support to third parties (e.g. grants, prizes or similar forms of support), the beneficiaries must ensure that their contractual obligations under Articles 12 (conflict of interest), 13 (confidentiality and security), 14 (ethics), 17.2 (visibility), 18 (specific rules for carrying out action), 19 (information) and 20 (record-keeping)also apply to the third parties receiving the support (recipients).

The beneficiaries must also ensure that the bodies mentioned in Article 25 (e.g. granting authority, OLAF, Court of Auditors (ECA), etc.) can exercise their rights also towards the recipients.

ARTICLE 10 — PARTICIPANTS WITH SPECIAL STATUS

10.1 Non-EU participants

Participants which are established in a non-EU country (if any) undertake to comply with their obligations under the Agreement and:

- to respect general principles (including fundamental rights, values and ethical principles, environmental and labour standards, rules on classified information, intellectual property rights, visibility of funding and protection of personal data)

- for the submission of certificates under Article 24: to use qualified external auditors which are independent and comply with comparable standards as those set out in EU Directive 2006/43/EC[14]

- for the controls under Article 25: to allow for checks, reviews, audits and investigations

[14] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts or similar national regulations (OJ L 157, 9.6.2006, p. 87).

(including on-the-spot checks, visits and inspections) by the bodies mentioned in that Article (e.g. granting authority, OLAF, Court of Auditors (ECA), etc.).

Special rules on dispute settlement apply (see Data Sheet, Point 5).

10.2 Participants which are international organisations

Participants which are international organisations (IOs; if any) undertake to comply with their obligations under the Agreement and:

- to respect general principles (including fundamental rights, values and ethical principles, environmental and labour standards, rules on classified information, intellectual property rights, visibility of funding and protection of personal data)

- for the submission of certificates under Article 24: to use either independent public officers or external auditors which comply with comparable standards as those set out in EU Directive 2006/43/EC

- for the controls under Article 25: to allow for the checks, reviews, audits and investigations by the bodies mentioned in that Article, taking into account the specific agreements concluded by them and the EU (if any).

For such participants, nothing in the Agreement will be interpreted as a waiver of their privileges or immunities, as accorded by their constituent documents or international law.

Special rules on applicable law and dispute settlement apply (see Article 43 and Data Sheet, Point 5).

10.3 Pillar-assessed participants

Pillar-assessed participants (if any) may rely on their own systems, rules and procedures, in so far as they have been positively assessed and do not call into question the decision awarding the grant or breach the principle of equal treatment of applicants or beneficiaries.

'Pillar-assessment' means a review by the European Commission on the systems, rules and procedures which participants use for managing EU grants (in particular internal control system, accounting system, external audits, financing of third parties, rules on recovery and exclusion, information on recipients and protection of personal data; see Article 154 EU Financial Regulation 2018/1046).

Participants with a positive pillar assessment may rely on their own systems, rules and procedures, in particular for:

- record-keeping (Article 20): may be done in accordance with internal standards, rules and procedures

- currency conversion for financial statements (Article 21): may be done in accordance with usual accounting practices

- guarantees (Article 23): for public law bodies, prefinancing guarantees are not needed

- certificates (Article 24):

    - certificates on the financial statements (CFS): may be provided by their regular internal

or external auditors and in accordance with their internal financial regulations and procedures

- certificates on usual accounting practices (CoMUC): are not needed if those practices are covered by an ex-ante assessment

and use the following specific rules, for:

- recoveries (Article 22): in case of financial support to third parties, there will be no recovery if the participant has done everything possible to retrieve the undue amounts from the third party receiving the support (including legal proceedings) and non-recovery is not due to an error or negligence on its part

- checks, reviews, audits and investigations by the EU (Article 25): will be conducted taking into account the rules and procedures specifically agreed between them and the framework agreement (if any)

- impact evaluation (Article 26): will be conducted in accordance with the participant's internal rules and procedures and the framework agreement (if any)

- grant agreement suspension (Article 31): certain costs incurred during grant suspension are eligible (notably, minimum costs necessary for a possible resumption of the action and costs relating to contracts which were entered into before the pre-information letter was received and which could not reasonably be suspended, reallocated or terminated on legal grounds)

- grant agreement termination (Article 32): the final grant amount and final payment will be calculated taking into account also costs relating to contracts due for execution only after termination takes effect, if the contract was entered into before the pre-information letter was received and could not reasonably be terminated on legal grounds

- liability for damages (Article 33.2): the granting authority must be compensated for damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement only if the damage is due to an infringement of the participant's internal rules and procedures or due to a violation of third parties' rights by the participant or one of its employees or individual for whom the employees are responsible.

Participants whose pillar assessment covers procurement and granting procedures may also do purchases, subcontracting and financial support to third parties (Article 6.2) in accordance with their internal rules and procedures for purchases, subcontracting and financial support.

Participants whose pillar assessment covers data protection rules may rely on their internal standards, rules and procedures for data protection (Article 15).

The participants may however not rely on provisions which would breach the principle of equal treatment of applicants or beneficiaries or call into question the decision awarding the grant, such as in particular:

- eligibility (Article 6)

- consortium roles and set-up (Articles 7-9)

- security and ethics (Articles 13, 14)
- IPR (including background and results, access rights and rights of use), communication, dissemination and visibility (Articles 16 and 17)
- information obligation (Article 19)
- payment, reporting and amendments (Articles 21, 22 and 39)
- rejections, reductions, suspensions and terminations (Articles 27, 28, 29-32)

If the pillar assessment was subject to remedial measures, reliance on the internal systems, rules and procedures is subject to compliance with those remedial measures.

Participants whose assessment has not yet been updated to cover (the new rules on) data protection may rely on their internal systems, rules and procedures, provided that they ensure that personal data is:

- processed lawfully, fairly and in a transparent manner in relation to the data subject
- collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes
- adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed
- accurate and, where necessary, kept up to date
- kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data is processed and
- processed in a manner that ensures appropriate security of the personal data.

Participants must inform the coordinator without delay of any changes to the systems, rules and procedures that were part of the pillar assessment. The coordinator must immediately inform the granting authority.

Pillar-assessed participants that have also concluded a framework agreement with the EU, may moreover — under the same conditions as those above (i.e. not call into question the decision awarding the grant or breach the principle of equal treatment of applicants or beneficiaries) — rely on the provisions set out in that framework agreement.

SECTION 2 RULES FOR CARRYING OUT THE ACTION

ARTICLE 11 — PROPER IMPLEMENTATION OF THE ACTION

11.1 Obligation to properly implement the action

The beneficiaries must implement the action as described in Annex 1 and in compliance with the provisions of the Agreement, the call conditions and all legal obligations under applicable EU, international and national law.

11.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 12 — CONFLICT OF INTERESTS

12.1 Conflict of interests

The beneficiaries must take all measures to prevent any situation where the impartial and objective implementation of the Agreement could be compromised for reasons involving family, emotional life, political or national affinity, economic interest or any other direct or indirect interest (‘conflict of interests’).

They must formally notify the granting authority without delay of any situation constituting or likely to lead to a conflict of interests and immediately take all the necessary steps to rectify this situation.

The granting authority may verify that the measures taken are appropriate and may require additional measures to be taken by a specified deadline.

12.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28) and the grant or the beneficiary may be terminated (see Article 32).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 13 — CONFIDENTIALITY AND SECURITY

13.1 Sensitive information

The parties must keep confidential any data, documents or other material (in any form) that is identified as sensitive in writing (‘sensitive information’) — during the implementation of the action and for at least until the time-limit set out in the Data Sheet (see Point 6).

If a beneficiary requests, the granting authority may agree to keep such information confidential for a longer period.

Unless otherwise agreed between the parties, they may use sensitive information only to implement the Agreement.

The beneficiaries may disclose sensitive information to their personnel or other participants involved in the action only if they:

(a) need to know it in order to implement the Agreement and

(b) are bound by an obligation of confidentiality.

The granting authority may disclose sensitive information to its staff and to other EU institutions and bodies.

It may moreover disclose sensitive information to third parties, if:

(a) this is necessary to implement the Agreement or safeguard the EU financial interests and

(b) the recipients of the information are bound by an obligation of confidentiality.

The confidentiality obligations no longer apply if:

(a) the disclosing party agrees to release the other party

(b) the information becomes publicly available, without breaching any confidentiality obligation

(c) the disclosure of the sensitive information is required by EU, international or national law.

Specific confidentiality rules (if any) are set out in Annex 5.

13.2 Classified information

The parties must handle classified information in accordance with the applicable EU, international or national law on classified information (in particular, Decision 2015/444[15] and its implementing rules).

Deliverables which contain classified information must be submitted according to special procedures agreed with the granting authority.

Action tasks involving classified information may be subcontracted only after explicit approval (in writing) from the granting authority.

Classified information may not be disclosed to any third party (including participants involved in the action implementation) without prior explicit written approval from the granting authority.

Specific security rules (if any) are set out in Annex 5.

13.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 14 — ETHICS AND VALUES

14.1 Ethics

The action must be carried out in line with the highest ethical standards and the applicable EU, international and national law on ethical principles.

Specific ethics rules (if any) are set out in Annex 5.

14.2 Values

The beneficiaries must commit to and ensure the respect of basic EU values (such as respect for

[15] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

human dignity, freedom, democracy, equality, the rule of law and human rights, including the rights of minorities).

Specific rules on values (if any) are set out in Annex 5.

14.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 15 — DATA PROTECTION

15.1 Data processing by the granting authority

Any personal data under the Agreement will be processed under the responsibility of the data controller of the granting authority in accordance with and for the purposes set out in the Portal Privacy Statement.

For grants where the granting authority is the European Commission, an EU regulatory or executive agency, joint undertaking or other EU body, the processing will be subject to Regulation 2018/1725[16].

15.2 Data processing by the beneficiaries

The beneficiaries must process personal data under the Agreement in compliance with the applicable EU, international and national law on data protection (in particular, Regulation 2016/679[17]).

They must ensure that personal data is:

- processed lawfully, fairly and in a transparent manner in relation to the data subjects
- collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes
- adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed
- accurate and, where necessary, kept up to date
- kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the data is processed and
- processed in a manner that ensures appropriate security of the data.

[16] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).

[17] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (‘GDPR’) (OJ L 119, 4.5.2016, p. 1).

The beneficiaries may grant their personnel access to personal data only if it is strictly necessary for implementing, managing and monitoring the Agreement. The beneficiaries must ensure that the personnel is under a confidentiality obligation.

The beneficiaries must inform the persons whose data are transferred to the granting authority and provide them with the Portal Privacy Statement.

15.3 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 16 — INTELLECTUAL PROPERTY RIGHTS (IPR) — BACKGROUND AND RESULTS —ACCESS RIGHTS AND RIGHTS OF USE

16.1 Background and access rights to background

The beneficiaries must give each other and the other participants access to the background identified as needed for implementing the action, subject to any specific rules in Annex 5.

'Background' means any data, know-how or information — whatever its form or nature (tangible or intangible), including any rights such as intellectual property rights — that is:

(a) held by the beneficiaries before they acceded to the Agreement and

(b) needed to implement the action or exploit the results.

If background is subject to rights of a third party, the beneficiary concerned must ensure that it is able to comply with its obligations under the Agreement.

16.2 Ownership of results

The granting authority does not obtain ownership of the results produced under the action.

'Results' means any tangible or intangible effect of the action, such as data, know-how or information, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights.

16.3 Rights of use of the granting authority on materials, documents and information received for policy, information, communication, dissemination and publicity purposes

The granting authority has the right to use non-sensitive information relating to the action and materials and documents received from the beneficiaries (notably summaries for publication, deliverables, as well as any other material, such as pictures or audio-visual material, in paper or electronic form) for policy, information, communication, dissemination and publicity purposes — during the action or afterwards.

The right to use the beneficiaries' materials, documents and information is granted in the form of a royalty-free, non-exclusive and irrevocable licence, which includes the following rights:

(a) **use for its own purposes** (in particular, making them available to persons working for the granting authority or any other EU service (including institutions, bodies, offices, agencies, etc.) or EU Member State institution or body; copying or reproducing them in whole or in part, in unlimited numbers; and communication through press information services)

(b) **distribution to the public** (in particular, publication as hard copies and in electronic or digital format, publication on the internet, as a downloadable or non-downloadable file, broadcasting by any channel, public display or presentation, communicating through press information services, or inclusion in widely accessible databases or indexes)

(c) **editing or redrafting** (including shortening, summarising, inserting other elements (e.g. meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts, use in a compilation)

(d) **translation**

(e) **storage** in paper, electronic or other form

(f) **archiving**, in line with applicable document-management rules

(g) the right to authorise **third parties** to act on its behalf or sub-license to third parties the modes of use set out in Points (b), (c), (d) and (f), if needed for the information, communication and publicity activity of the granting authority

(h) **processing**, analysing, aggregating the materials, documents and information received and **producing derivative works**.

The rights of use are granted for the whole duration of the industrial or intellectual property rights concerned.

If materials or documents are subject to moral rights or third party rights (including intellectual property rights or rights of natural persons on their image and voice), the beneficiaries must ensure that they comply with their obligations under this Agreement (in particular, by obtaining the necessary licences and authorisations from the rights holders concerned).

Where applicable, the granting authority will insert the following information:

> "© – [year] – [name of the copyright owner]. All rights reserved. Licensed to the [name of granting authority] under conditions."

16.4 Specific rules on IPR, results and background

Specific rules regarding intellectual property rights, results and background (if any) are set out in Annex 5.

16.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such a breach may also lead to other measures described in Chapter 5.

ARTICLE 17 — COMMUNICATION, DISSEMINATION AND VISIBILITY

17.1 Communication — Dissemination — Promoting the action

Unless otherwise agreed with the granting authority, the beneficiaries must promote the action and its results by providing targeted information to multiple audiences (including the media and the public), in accordance with Annex 1 and in a strategic, coherent and effective manner.

Before engaging in a communication or dissemination activity expected to have a major media impact, the beneficiaries must inform the granting authority.

17.2 Visibility — European flag and funding statement

Unless otherwise agreed with the granting authority, communication activities of the beneficiaries related to the action (including media relations, conferences, seminars, information material, such as brochures, leaflets, posters, presentations, etc., in electronic form, via traditional or social media, etc.), dissemination activities and any infrastructure, equipment, vehicles, supplies or major result funded by the grant must acknowledge EU support and display the European flag (emblem) and funding statement (translated into local languages, where appropriate):

Funded by the
European Union

Co-funded by the
European Union

The emblem must remain distinct and separate and cannot be modified by adding other visual marks, brands or text.

Apart from the emblem, no other visual identity or logo may be used to highlight the EU support.

When displayed in association with other logos (e.g. of beneficiaries or sponsors), the emblem must be displayed at least as prominently and visibly as the other logos.

For the purposes of their obligations under this Article, the beneficiaries may use the emblem without first obtaining approval from the granting authority. This does not, however, give them the right to

exclusive use. Moreover, they may not appropriate the emblem or any similar trademark or logo, either by registration or by any other means.

17.3 Quality of information — Disclaimer

Any communication or dissemination activity related to the action must use factually accurate information.

Moreover, it must indicate the following disclaimer (translated into local languages where appropriate):

> "Funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or [name of the granting authority]. Neither the European Union nor the granting authority can be held responsible for them."

17.4 Specific communication, dissemination and visibility rules

Specific communication, dissemination and visibility rules (if any) are set out in Annex 5.

17.5 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 18 — SPECIFIC RULES FOR CARRYING OUT THE ACTION

18.1 Specific rules for carrying out the action

Specific rules for implementing the action (if any) are set out in Annex 5.

18.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such a breach may also lead to other measures described in Chapter 5.

SECTION 3 GRANT ADMINISTRATION

ARTICLE 19 — GENERAL INFORMATION OBLIGATIONS

19.1 Information requests

The beneficiaries must provide — during the action or afterwards and in accordance with Article 7 — any information requested in order to verify eligibility of the costs or contributions declared, proper implementation of the action and compliance with the other obligations under the Agreement.

The information provided must be accurate, precise and complete and in the format requested, including electronic format.

19.2 Participant Register data updates

The beneficiaries must keep — at all times, during the action or afterwards — their information stored in the Portal Participant Register up to date, in particular, their name, address, legal representatives, legal form and organisation type.

19.3 Information about events and circumstances which impact the action

The beneficiaries must immediately inform the granting authority (and the other beneficiaries) of any of the following:

(a) **events** which are likely to affect or delay the implementation of the action or affect the EU's financial interests, in particular:

(i) changes in their legal, financial, technical, organisational or ownership situation (including changes linked to one of the exclusion grounds listed in the declaration of honour signed before grant signature)

(ii) linked action information: not applicable

(b) **circumstances** affecting:

(i) the decision to award the grant or

(ii) compliance with requirements under the Agreement.

19.4 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 20 — RECORD-KEEPING

20.1 Keeping records and supporting documents

The beneficiaries must — at least until the time-limit set out in the Data Sheet (see Point 6) — keep records and other supporting documents to prove the proper implementation of the action in line with the accepted standards in the respective field (if any).

In addition, the beneficiaries must — for the same period — keep the following to justify the amounts declared:

(a) for actual costs: adequate records and supporting documents to prove the costs declared (such as contracts, subcontracts, invoices and accounting records); in addition, the beneficiaries' usual accounting and internal control procedures must enable direct reconciliation between the amounts declared, the amounts recorded in their accounts and the amounts stated in the supporting documents

(b) for flat-rate costs and contributions (if any): adequate records and supporting documents to prove the eligibility of the costs or contributions to which the flat-rate is applied

(c) for the following simplified costs and contributions: the beneficiaries do not need to keep specific records on the actual costs incurred, but must keep:

(i) for unit costs and contributions (if any): adequate records and supporting documents to prove the number of units declared

(ii) for lump sum costs and contributions (if any): adequate records and supporting documents to prove proper implementation of the work as described in Annex 1

(iii) for financing not linked to costs (if any): adequate records and supporting documents to prove the achievement of the results or the fulfilment of the conditions as described in Annex 1

(d) for unit, flat-rate and lump sum costs and contributions according to usual cost accounting practices (if any): the beneficiaries must keep any adequate records and supporting documents to prove that their cost accounting practices have been applied in a consistent manner, based on objective criteria, regardless of the source of funding, and that they comply with the eligibility conditions set out in Articles 6.1 and 6.2.

Moreover, the following is needed for specific budget categories:

(e) for personnel costs: time worked for the beneficiary under the action must be supported by declarations signed monthly by the person and their supervisor, unless another reliable time-record system is in place; the granting authority may accept alternative evidence supporting the time worked for the action declared, if it considers that it offers an adequate level of assurance

(f) additional record-keeping rules: not applicable

The records and supporting documents must be made available upon request (see Article 19) or in the context of checks, reviews, audits or investigations (see Article 25).

If there are on-going checks, reviews, audits, investigations, litigation or other pursuits of claims under the Agreement (including the extension of findings; see Article 25), the beneficiaries must keep these records and other supporting documentation until the end of these procedures.

The beneficiaries must keep the original documents. Digital and digitalised documents are considered originals if they are authorised by the applicable national law. The granting authority may accept non-original documents if they offer a comparable level of assurance.

20.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs or contributions insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 27), and the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 21 — REPORTING

21.1 Continuous reporting

The beneficiaries must continuously report on the progress of the action (e.g. **deliverables, milestones, outputs/outcomes, critical risks, indicators,** etc; if any), in the Portal Continuous Reporting tool and in accordance with the timing and conditions it sets out (as agreed with the granting authority).

Standardised deliverables (e.g. progress reports not linked to payments, reports on cumulative expenditure, special reports, etc; if any) must be submitted using the templates published on the Portal.

21.2 Periodic reporting: Technical reports and financial statements

In addition, the beneficiaries must provide reports to request payments, in accordance with the schedule and modalities set out in the Data Sheet (see Point 4.2):

- for additional prefinancings (if any): an **additional prefinancing report**
- for interim payments (if any) and the final payment: a **periodic report**.

The prefinancing and periodic reports include a technical and financial part.

The technical part includes an overview of the action implementation. It must be prepared using the template available in the Portal Periodic Reporting tool.

The financial part of the additional prefinancing report includes a statement on the use of the previous prefinancing payment.

The financial part of the periodic report includes:

- the financial statements (individual and consolidated; for all beneficiaries/affiliated entities)
- the explanation on the use of resources (or detailed cost reporting table, if required)
- the certificates on the financial statements (CFS) (if required; see Article 24.2 and Data Sheet, Point 4.3).

The **financial statements** must detail the eligible costs and contributions for each budget category and, for the final payment, also the revenues for the action (see Articles 6 and 22).

All eligible costs and contributions incurred should be declared, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Amounts that are not declared in the individual financial statements will not be taken into account by the granting authority.

By signing the financial statements (directly in the Portal Periodic Reporting tool), the beneficiaries confirm that:

- the information provided is complete, reliable and true
- the costs and contributions declared are eligible (see Article 6)
- the costs and contributions can be substantiated by adequate records and supporting documents (see Article 20) that will be produced upon request (see Article 19) or in the context of checks, reviews, audits and investigations (see Article 25)
- for the final periodic report: all the revenues have been declared (if required; see Article 22).

Beneficiaries will have to submit also the financial statements of their affiliated entities (if any). In case of recoveries (see Article 22), beneficiaries will be held responsible also for the financial statements of their affiliated entities.

21.3 Currency for financial statements and conversion into euros

The financial statements must be drafted in euro.

Beneficiaries with general accounts established in a currency other than the euro must convert the costs recorded in their accounts into euro, at the average of the daily exchange rates published in the C series of the *Official Journal of the European Union* (ECB website), calculated over the corresponding reporting period.

If no daily euro exchange rate is published in the *Official Journal* for the currency in question, they must be converted at the average of the monthly accounting exchange rates published on the European Commission website (InforEuro), calculated over the corresponding reporting period.

Beneficiaries with general accounts in euro must convert costs incurred in another currency into euro according to their usual accounting practices.

21.4 Reporting language

The reporting must be in the language of the Agreement, unless otherwise agreed with the granting authority (see Data Sheet, Point 4.2).

21.5 Consequences of non-compliance

If a report submitted does not comply with this Article, the granting authority may suspend the payment deadline (see Article 29) and apply other measures described in Chapter 5.

If the coordinator breaches its reporting obligations, the granting authority may terminate the grant or the coordinator's participation (see Article 32) or apply other measures described in Chapter 5.

ARTICLE 22 — PAYMENTS AND RECOVERIES — CALCULATION OF AMOUNTS DUE

22.1 Payments and payment arrangements

Payments will be made in accordance with the schedule and modalities set out in the Data Sheet (see Point 4.2).

They will be made in euro to the bank account indicated by the coordinator (see Data Sheet, Point 4.2) and must be distributed without unjustified delay (restrictions may apply to distribution of the initial prefinancing payment; see Data Sheet, Point 4.2).

Payments to this bank account will discharge the granting authority from its payment obligation.

The cost of payment transfers will be borne as follows:

- the granting authority bears the cost of transfers charged by its bank
- the beneficiary bears the cost of transfers charged by its bank

- the party causing a repetition of a transfer bears all costs of the repeated transfer.

Payments by the granting authority will be considered to have been carried out on the date when they are debited to its account.

22.2 Recoveries

Recoveries will be made, if — at beneficiary termination, final payment or afterwards — it turns out that the granting authority has paid too much and needs to recover the amounts undue.

Each beneficiary's financial responsibility in case of recovery is in principle limited to their own debt and undue amounts of their affiliated entities.

In case of enforced recoveries (see Article 22.4), affiliated entities will be held liable for repaying debts of their beneficiaries, if required by the granting authority (see Data Sheet, Point 4.4).

22.3 Amounts due

22.3.1 Prefinancing payments

The aim of the prefinancing is to provide the beneficiaries with a float.

It remains the property of the EU until the final payment.

For **initial prefinancings** (if any), the amount due, schedule and modalities are set out in the Data Sheet (see Point 4.2).

For **additional prefinancings** (if any), the amount due, schedule and modalities are also set out in the Data Sheet (see Point 4.2). However, if the statement on the use of the previous prefinancing payment shows that less than 70% was used, the amount set out in the Data Sheet will be reduced by the difference between the 70% threshold and the amount used.

The contribution to the Mutual Insurance Mechanism will be retained from the prefinancing payments (at the rate and in accordance with the modalities set out in the Data Sheet, see Point 4.2) and transferred to the Mechanism.

Prefinancing payments (or parts of them) may be offset (without the beneficiaries' consent) against amounts owed by a beneficiary to the granting authority — up to the amount due to that beneficiary.

For grants where the granting authority is the European Commission or an EU executive agency, offsetting may also be done against amounts owed to other Commission services or executive agencies.

Payments will not be made if the payment deadline or payments are suspended (see Articles 29 and 30).

22.3.2 Amount due at beneficiary termination — Recovery

In case of beneficiary termination, the granting authority will determine the provisional amount due for the beneficiary concerned. Payments (if any) will be made with the next interim or final payment.

The **amount due** will be calculated in the following step:

Step 1 — Calculation of the total accepted EU contribution

Step 1 — Calculation of the total accepted EU contribution

The granting authority will first calculate the 'accepted EU contribution' for the beneficiary for all reporting periods, by calculating the 'maximum EU contribution to costs' (applying the funding rate to the accepted costs of the beneficiary), taking into account requests for a lower contribution to costs and CFS threshold cappings (if any; see Article 24.5) and adding the contributions (accepted unit, flat-rate or lump sum contributions and financing not linked to costs, if any).

After that, the granting authority will take into account grant reductions (if any). The resulting amount is the 'total accepted EU contribution' for the beneficiary.

The **balance** is then calculated by deducting the payments received (if any; see report on the distribution of payments in Article 32), from the total accepted EU contribution:

{total accepted EU contribution for the beneficiary

minus

{prefinancing and interim payments received (if any)}}.

If the balance is **positive**, the amount will be included in the next interim or final payment to the consortium.

If the balance is **negative**, it will be **recovered** in accordance with the following procedure:

The granting authority will send a **pre-information letter** to the beneficiary concerned:

- formally notifying the intention to recover, the amount due, the amount to be recovered and the reasons why and
- requesting observations within 30 days of receiving notification.

If no observations are submitted (or the granting authority decides to pursue recovery despite the observations it has received), it will confirm the amount to be recovered and ask this amount to be paid to the coordinator (**confirmation letter**).

If payment is not made to the coordinator by the date specified in the confirmation letter, the granting authority may call on the Mutual Insurance Mechanism to intervene, if continuation of the action is guaranteed and the conditions set out in the rules governing the Mechanism are met.

In this case, it will send a **beneficiary recovery letter**, together with a **debit note** with the terms and date for payment.

The debit note for the beneficiary will include the amount calculated for the affiliated entities which also had to end their participation (if any).

If payment is not made by the date specified in the debit note, the granting authority will **enforce recovery** in accordance with Article 22.4.

The amounts will later on also be taken into account for the next interim or final payment.

22.3.3 Interim payments

Interim payments reimburse the eligible costs and contributions claimed for the implementation of the action during the reporting periods (if any).

Interim payments (if any) will be made in accordance with the schedule and modalities set out the Data Sheet (see Point 4.2).

Payment is subject to the approval of the periodic report. Its approval does not imply recognition of compliance, authenticity, completeness or correctness of its content.

The **interim payment** will be calculated by the granting authority in the following steps:

Step 1 — Calculation of the total accepted EU contribution

Step 2 — Limit to the interim payment ceiling

Step 1 — Calculation of the total accepted EU contribution

The granting authority will calculate the 'accepted EU contribution' for the action for the reporting period, by first calculating the 'maximum EU contribution to costs' (applying the funding rate to the accepted costs of each beneficiary), taking into account requests for a lower contribution to costs, and CFS threshold cappings (if any; see Article 24.5) and adding the contributions (accepted unit, flat-rate or lump sum contributions and financing not linked to costs, if any).

After that, the granting authority will take into account grant reductions from beneficiary termination (if any). The resulting amount is the 'total accepted EU contribution'.

Step 2 — Limit to the interim payment ceiling

The resulting amount is then capped to ensure that the total amount of prefinancing and interim payments (if any) does not exceed the interim payment ceiling set out in the Data Sheet (see Point 4.2).

Interim payments (or parts of them) may be offset (without the beneficiaries' consent) against amounts owed by a beneficiary to the granting authority — up to the amount due to that beneficiary.

For grants where the granting authority is the European Commission or an EU executive agency, offsetting may also be done against amounts owed to other Commission services or executive agencies.

Payments will not be made if the payment deadline or payments are suspended (see Articles 29 and 30).

22.3.4 Final payment — Final grant amount — Revenues and Profit — Recovery

The final payment (payment of the balance) reimburses the remaining part of the eligible costs and contributions claimed for the implementation of the action (if any).

The final payment will be made in accordance with the schedule and modalities set out in the Data Sheet (see Point 4.2).

Payment is subject to the approval of the final periodic report. Its approval does not imply recognition of compliance, authenticity, completeness or correctness of its content.

The **final grant amount for the action** will be calculated in the following steps:

Step 1 — Calculation of the total accepted EU contribution

Step 2 — Limit to the maximum grant amount

Step 3 — Reduction due to the no-profit rule

Step 1 — Calculation of the total accepted EU contribution

The granting authority will first calculate the 'accepted EU contribution' for the action for all reporting periods, by calculating the 'maximum EU contribution to costs' (applying the funding rate to the total accepted costs of each beneficiary), taking into account requests for a lower contribution to costs, CFS threshold cappings (if any; see Article 24.5) and adding the contributions (accepted unit, flat-rate or lump sum contributions and financing not linked to costs, if any).

After that, the granting authority will take into account grant reductions (if any). The resulting amount is the 'total accepted EU contribution'.

Step 2 — Limit to the maximum grant amount

If the resulting amount is higher than the maximum grant amount set out in Article 5.2, it will be limited to the latter.

Step 3 — Reduction due to the no-profit rule

If the no-profit rule is provided for in the Data Sheet (see Point 4.2), the grant must not produce a profit (i.e. surplus of the amount obtained following Step 2 plus the action's revenues, over the eligible costs and contributions approved by the granting authority).

'Revenue' is all income generated by the action, during its duration (see Article 4), for beneficiaries that are profit legal entities (— with the exception of income generated by the exploitation of results, which are not considered as revenues).

If there is a profit, it will be deducted in proportion to the final rate of reimbursement of the eligible costs approved by the granting authority (as compared to the amount calculated following Steps 1 and 2 minus the contributions).

The **balance** (final payment) is then calculated by deducting the total amount of prefinancing and interim payments already made (if any), from the final grant amount:

{final grant amount

minus

{prefinancing and interim payments made (if any)}}.

If the balance is **positive**, it will be **paid** to the coordinator.

The amount retained for the Mutual Insurance Mechanism (see above) will be released and **paid** to the coordinator (in accordance with the rules governing the Mechanism).

The final payment (or part of it) may be offset (without the beneficiaries' consent) against amounts owed by a beneficiary to the granting authority — up to the amount due to that beneficiary.

For grants where the granting authority is the European Commission or an EU executive agency,

offsetting may also be done against amounts owed to other Commission services or executive agencies.

Payments will not be made if the payment deadline or payments are suspended (see Articles 29 and 30).

If — despite the release of the Mutual Insurance Mechanism contribution — the balance is **negative**, it will be **recovered** in accordance with the following procedure:

The granting authority will send a **pre-information letter** to the coordinator:

- formally notifying the intention to recover, the final grant amount, the amount to be recovered and the reasons why
- requesting a report on the distribution of payments to the beneficiaries within 30 days of receiving notification and
- requesting observations within 30 days of receiving notification.

If no observations are submitted (or the granting authority decides to pursue recovery despite the observations it has received) and the coordinator has submitted the report on the distribution of payments, it will calculate the **share of the debt per beneficiary**, by:

(a) identifying the beneficiaries for which the amount calculated as follows is negative:

{{{total accepted EU contribution for the beneficiary

divided by

total accepted EU contribution for the action}

multiplied by

final grant amount for the action},

minus

{prefinancing and interim payments received by the beneficiary (if any)}}

and

(b) dividing the debt:

{{amount calculated according to point (a) for the beneficiary concerned

divided by

the sum of the amounts calculated according to point (a) for all the beneficiaries identified according to point (a)}

multiplied by

the amount to be recovered}.

and confirm the amount to be recovered from each beneficiary concerned (**confirmation letter**), together with **debit notes** with the terms and date for payment.

The debit notes for beneficiaries will include the amounts calculated for their affiliated entities (if any).

If the coordinator has not submitted the report on the distribution of payments, the granting authority will **recover** the full amount from the coordinator (**confirmation letter** and **debit note** with the terms and date for payment).

If payment is not made by the date specified in the debit note, the granting authority will **enforce recovery** in accordance with Article 22.4.

22.3.5 Audit implementation after final payment — Revised final grant amount — Recovery

If — after the final payment (in particular, after checks, reviews, audits or investigations; see Article 25) — the granting authority rejects costs or contributions (see Article 27) or reduces the grant (see Article 28), it will calculate the **revised final grant amount** for the beneficiary concerned.

The **beneficiary revised final grant amount** will be calculated in the following step:

Step 1 — Calculation of the revised total accepted EU contribution

Step 1 — Calculation of the revised total accepted EU contribution

The granting authority will first calculate the 'revised accepted EU contribution' for the beneficiary, by calculating the 'revised accepted costs' and 'revised accepted contributions'.

After that, it will take into account grant reductions (if any). The resulting 'revised total accepted EU contribution' is the beneficiary revised final grant amount.

If the revised final grant amount is lower than the beneficiary's final grant amount (i.e. its share in the final grant amount for the action), it will be **recovered** in accordance with the following procedure:

The **beneficiary final grant amount** (i.e. share in the final grant amount for the action) is calculated as follows:

{{total accepted EU contribution for the beneficiary

divided by

total accepted EU contribution for the action}

multiplied by

final grant amount for the action}.

The granting authority will send a **pre-information letter** to the beneficiary concerned:

- formally notifying the intention to recover, the amount to be recovered and the reasons why and
- requesting observations within 30 days of receiving notification.

If no observations are submitted (or the granting authority decides to pursue recovery despite the observations it has received), it will confirm the amount to be recovered (**confirmation letter**), together with a **debit note** with the terms and the date for payment.

Recoveries against affiliated entities (if any) will be handled through their beneficiaries.

If payment is not made by the date specified in the debit note, the granting authority will **enforce recovery** in accordance with Article 22.4.

22.4 Enforced recovery

If payment is not made by the date specified in the debit note, the amount due will be recovered:

(a) by offsetting the amount — without the coordinator or beneficiary's consent — against any amounts owed to the coordinator or beneficiary by the granting authority.

In exceptional circumstances, to safeguard the EU financial interests, the amount may be offset before the payment date specified in the debit note.

For grants where the granting authority is the European Commission or an EU executive agency, debts may also be offset against amounts owed by other Commission services or executive agencies.

(b) financial guarantee(s): not applicable

(c) joint and several liability of beneficiaries: not applicable

(d) by holding affiliated entities jointly and severally liable (if any, see Data Sheet, Point 4.4)

(e) by taking legal action (see Article 43) or, provided that the granting authority is the European Commission or an EU executive agency, by adopting an enforceable decision under Article 299 of the Treaty on the Functioning of the EU (TFEU) and Article 100(2) of EU Financial Regulation 2018/1046.

If the Mutual Insurance Mechanism was called on by the granting authority to intervene, recovery will be continued in the name of the Mutual Insurance Mechanism. If two debit notes were sent, the second one (in the name of the Mutual Insurance Mechanism) will be considered to replace the first one (in the name of the granting authority). Where the MIM intervened, offsetting, enforceable decisions or any other of the above-mentioned forms of enforced recovery may be used mutatis mutandis.

The amount to be recovered will be increased by **late-payment interest** at the rate set out in Article 22.5, from the day following the payment date in the debit note, up to and including the date the full payment is received.

Partial payments will be first credited against expenses, charges and late-payment interest and then against the principal.

Bank charges incurred in the recovery process will be borne by the beneficiary, unless Directive 2015/2366[18] applies.

For grants where the granting authority is an EU executive agency, enforced recovery by offsetting or enforceable decision will be done by the services of the European Commission (see also Article 43).

22.5 Consequences of non-compliance

[18] Directive (EU) 2015/2366 of the European Parliament and of the Council of 25 November 2015 on payment services in the internal market, amending Directives 2002/65/EC, 2009/110/EC and 2013/36/EU and Regulation (EU) No 1093/2010, and repealing Directive 2007/64/EC (OJ L 337, 23.12.2015, p. 35).

22.5.1 If the granting authority does not pay within the payment deadlines (see above), the beneficiaries are entitled to **late-payment interest** at the rate applied by the European Central Bank (ECB) for its main refinancing operations in euros ('reference rate'), plus the rate specified in the Data Sheet (Point 4.2). The reference rate is the rate in force on the first day of the month in which the payment deadline expires, as published in the C series of the *Official Journal of the European Union*.

If the late-payment interest is lower than or equal to EUR 200, it will be paid to the coordinator only on request submitted within two months of receiving the late payment.

Late-payment interest is not due if all beneficiaries are EU Member States (including regional and local government authorities or other public bodies acting on behalf of a Member State for the purpose of this Agreement).

If payments or the payment deadline are suspended (see Articles 29 and 30), payment will not be considered as late.

Late-payment interest covers the period running from the day following the due date for payment (see above), up to and including the date of payment.

Late-payment interest is not considered for the purposes of calculating the final grant amount.

22.5.2 If the coordinator breaches any of its obligations under this Article, the grant may be reduced (see Article 28) and the grant or the coordinator may be terminated (see Article 32).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 23 — GUARANTEES

Not applicable

ARTICLE 24 — CERTIFICATES

24.1 Operational verification report (OVR)

Not applicable

24.2 Certificate on the financial statements (CFS)

If required by the granting authority (see Data Sheet, Point 4.3), the beneficiaries must provide certificates on their financial statements (CFS), in accordance with the schedule, threshold and conditions set out in the Data Sheet.

The coordinator must submit them as part of the periodic report (see Article 21).

The certificates must be drawn up using the template published on the Portal, cover the costs declared on the basis of actual costs and costs according to usual cost accounting practices (if any), and fulfil the following conditions:

(a) be provided by a qualified approved external auditor which is independent and complies with Directive 2006/43/EC[19] (or for public bodies: by a competent independent public officer)

(b) the verification must be carried out according to the highest professional standards to ensure that the financial statements comply with the provisions under the Agreement and that the costs declared are eligible.

The certificates will not affect the granting authority's right to carry out its own checks, reviews or audits, nor preclude the European Court of Auditors (ECA), the European Public Prosecutor's Office (EPPO) or the European Anti-Fraud Office (OLAF) from using their prerogatives for audits and investigations under the Agreement (see Article 25).

If the costs (or a part of them) were already audited by the granting authority, these costs do not need to be covered by the certificate and will not be counted for calculating the threshold (if any).

24.3 Certificate on the compliance of usual cost accounting practices (CoMUC)

Not applicable

24.4 Systems and process audit (SPA)

Beneficiaries which:

- use unit, flat rate or lump sum costs or contributions according to documented (i.e. formally approved and in writing) usual costs accounting practices (if any) or

- have formalised documentation on the systems and processes for calculating their costs and contributions (i.e. formally approved and in writing), have participated in at least 150 actions under Horizon 2020 or the Euratom Research and Training Programme (2014-2018 or 2019-2020) and participate in at least 3 ongoing actions under Horizon Europe or the Euratom Research and Training Programme (2021-2025 or 2026-2027)

may apply to the granting authority for a systems and process audit (SPA).

This audit will be carried out as follows:

Step 1 – Application by the beneficiary.

Step 2 – If the application is accepted, the granting authority will carry out the systems and process audit, complemented by an audit of transactions (on a sample of the beneficiary's Horizon Europe or the Euratom Research and Training Programme financial statements).

Step 3 – The audit result will take the form of a risk assessment classification for the beneficiary: low, medium or high.

Low-risk beneficiaries will benefit from less (or less in-depth) ex-post audits (see Article 25) and a higher threshold for submitting certificates on the financial statements (CFS; see Articles 21 and 24.2 and Data Sheet, Point 4.3).

[19] Directive 2006/43/EC of the European Parliament and of the Council of 17 May 2006 on statutory audits of annual accounts and consolidated accounts or similar national regulations (OJ L 157, 9.6.2006, p. 87).

24.5 Consequences of non-compliance

If a beneficiary does not submit a certificate on the financial statements (CFS) or the certificate is rejected, the accepted EU contribution to costs will be capped to reflect the CFS threshold.

If a beneficiary breaches any of its other obligations under this Article, the granting authority may apply the measures described in Chapter 5.

ARTICLE 25 — CHECKS, REVIEWS, AUDITS AND INVESTIGATIONS — EXTENSION OF FINDINGS

25.1 Granting authority checks, reviews and audits

25.1.1 Internal checks

The granting authority may — during the action or afterwards — check the proper implementation of the action and compliance with the obligations under the Agreement, including assessing costs and contributions, deliverables and reports.

25.1.2 Project reviews

The granting authority may carry out reviews on the proper implementation of the action and compliance with the obligations under the Agreement (general project reviews or specific issues reviews).

Such project reviews may be started during the implementation of the action and until the time-limit set out in the Data Sheet (see Point 6). They will be formally notified to the coordinator or beneficiary concerned and will be considered to start on the date of the notification.

If needed, the granting authority may be assisted by independent, outside experts. If it uses outside experts, the coordinator or beneficiary concerned will be informed and have the right to object on grounds of commercial confidentiality or conflict of interest.

The coordinator or beneficiary concerned must cooperate diligently and provide — within the deadline requested — any information and data in addition to deliverables and reports already submitted (including information on the use of resources). The granting authority may request beneficiaries to provide such information to it directly. Sensitive information and documents will be treated in accordance with Article 13.

The coordinator or beneficiary concerned may be requested to participate in meetings, including with the outside experts.

For **on-the-spot visits**, the beneficiary concerned must allow access to sites and premises (including to the outside experts) and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the review findings, a **project review report** will be drawn up.

The granting authority will formally notify the project review report to the coordinator or beneficiary concerned, which has 30 days from receiving notification to make observations.

Project reviews (including project review reports) will be in the language of the Agreement, unless otherwise agreed with the granting authority (see Data Sheet, Point 4.2).

25.1.3 Audits

The granting authority may carry out audits on the proper implementation of the action and compliance with the obligations under the Agreement.

Such audits may be started during the implementation of the action and until the time-limit set out in the Data Sheet (see Point 6). They will be formally notified to the beneficiary concerned and will be considered to start on the date of the notification.

The granting authority may use its own audit service, delegate audits to a centralised service or use external audit firms. If it uses an external firm, the beneficiary concerned will be informed and have the right to object on grounds of commercial confidentiality or conflict of interest.

The beneficiary concerned must cooperate diligently and provide — within the deadline requested — any information (including complete accounts, individual salary statements or other personal data) to verify compliance with the Agreement. Sensitive information and documents will be treated in accordance with Article 13.

For **on-the-spot** visits, the beneficiary concerned must allow access to sites and premises (including for the external audit firm) and must ensure that information requested is readily available.

Information provided must be accurate, precise and complete and in the format requested, including electronic format.

On the basis of the audit findings, a **draft audit report** will be drawn up.

The auditors will formally notify the draft audit report to the beneficiary concerned, which has 30 days from receiving notification to make observations (contradictory audit procedure).

The **final audit report** will take into account observations by the beneficiary concerned and will be formally notified to them.

Audits (including audit reports) will be in the language of the Agreement, unless otherwise agreed with the granting authority (see Data Sheet, Point 4.2).

25.2 European Commission checks, reviews and audits in grants of other granting authorities

Where the granting authority is not the European Commission, the latter has the same rights of checks, reviews and audits as the granting authority.

25.3 Access to records for assessing simplified forms of funding

The beneficiaries must give the European Commission access to their statutory records for the periodic assessment of simplified forms of funding which are used in EU programmes.

25.4 OLAF, EPPO and ECA audits and investigations

The following bodies may also carry out checks, reviews, audits and investigations — during the action or afterwards:

- the European Anti-Fraud Office (OLAF) under Regulations No 883/2013[20] and No 2185/96[21]
- the European Public Prosecutor's Office (EPPO) under Regulation 2017/1939
- the European Court of Auditors (ECA) under Article 287 of the Treaty on the Functioning of the EU (TFEU) and Article 257 of EU Financial Regulation 2018/1046.

If requested by these bodies, the beneficiary concerned must provide full, accurate and complete information in the format requested (including complete accounts, individual salary statements or other personal data, including in electronic format) and allow access to sites and premises for on-the-spot visits or inspections — as provided for under these Regulations.

To this end, the beneficiary concerned must keep all relevant information relating to the action, at least until the time-limit set out in the Data Sheet (Point 6) and, in any case, until any ongoing checks, reviews, audits, investigations, litigation or other pursuits of claims have been concluded.

25.5 Consequences of checks, reviews, audits and investigations — Extension of results of reviews, audits or investigations

25.5.1 Consequences of checks, reviews, audits and investigations in this grant

Findings in checks, reviews, audits or investigations carried out in the context of this grant may lead to rejections (see Article 27), grant reduction (see Article 28) or other measures described in Chapter 5.

Rejections or grant reductions after the final payment will lead to a revised final grant amount (see Article 22).

Findings in checks, reviews, audits or investigations during the action implementation may lead to a request for amendment (see Article 39), to change the description of the action set out in Annex 1.

Checks, reviews, audits or investigations that find systemic or recurrent errors, irregularities, fraud or breach of obligations in any EU grant may also lead to consequences in other EU grants awarded under similar conditions ('extension to other grants').

Moreover, findings arising from an OLAF or EPPO investigation may lead to criminal prosecution under national law.

25.5.2 Extension from other grants

Results of checks, reviews, audits or investigations in other grants may be extended to this grant, if:

(a) the beneficiary concerned is found, in other EU grants awarded under similar conditions, to

[20] Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18/09/2013, p. 1).

[21] Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15/11/1996, p. 2).

have committed systemic or recurrent errors, irregularities, fraud or breach of obligations that have a material impact on this grant and

(b) those findings are formally notified to the beneficiary concerned — together with the list of grants affected by the findings — within the time-limit for audits set out in the Data Sheet (see Point 6).

The granting authority will formally notify the beneficiary concerned of the intention to extend the findings and the list of grants affected.

If the extension concerns **rejections of costs or contributions**: the notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings

(b) the request to submit revised financial statements for all grants affected

(c) the correction rate for extrapolation, established on the basis of the systemic or recurrent errors, to calculate the amounts to be rejected, if the beneficiary concerned:

(i) considers that the submission of revised financial statements is not possible or practicable or

(ii) does not submit revised financial statements.

If the extension concerns **grant reductions**: the notification will include:

(a) an invitation to submit observations on the list of grants affected by the findings and

(b) the **correction rate for extrapolation**, established on the basis of the systemic or recurrent errors and the principle of proportionality.

The beneficiary concerned has **60 days** from receiving notification to submit observations, revised financial statements or to propose a duly substantiated **alternative correction method/rate**.

On the basis of this, the granting authority will analyse the impact and decide on the implementation (i.e. start rejection or grant reduction procedures, either on the basis of the revised financial statements or the announced/alternative method/rate or a mix of those; see Articles 27 and 28).

25.6 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, costs or contributions insufficiently substantiated will be ineligible (see Article 6) and will be rejected (see Article 27), and the grant may be reduced (see Article 28).

Such breaches may also lead to other measures described in Chapter 5.

ARTICLE 26 — IMPACT EVALUATIONS

26.1 Impact evaluation

The granting authority may carry out impact evaluations of the action, measured against the objectives and indicators of the EU programme funding the grant.

Such evaluations may be started during implementation of the action and until the time-limit set out in the Data Sheet (see Point 6). They will be formally notified to the coordinator or beneficiaries and will be considered to start on the date of the notification.

If needed, the granting authority may be assisted by independent outside experts.

The coordinator or beneficiaries must provide any information relevant to evaluate the impact of the action, including information in electronic format.

26.2 Consequences of non-compliance

If a beneficiary breaches any of its obligations under this Article, the granting authority may apply the measures described in Chapter 5.

CHAPTER 5 CONSEQUENCES OF NON-COMPLIANCE

SECTION 1 REJECTIONS AND GRANT REDUCTION

ARTICLE 27 — REJECTION OF COSTS AND CONTRIBUTIONS

27.1 Conditions

The granting authority will — at beneficiary termination, interim payment, final payment or afterwards — reject any costs or contributions which are ineligible (see Article 6), in particular following checks, reviews, audits or investigations (see Article 25).

The rejection may also be based on the extension of findings from other grants to this grant (see Article 25).

Ineligible costs or contributions will be rejected.

27.2 Procedure

If the rejection does not lead to a recovery, the granting authority will formally notify the coordinator or beneficiary concerned of the rejection, the amounts and the reasons why. The coordinator or beneficiary concerned may — within 30 days of receiving notification — submit observations if it disagrees with the rejection (payment review procedure).

If the rejection leads to a recovery, the granting authority will follow the contradictory procedure with pre-information letter set out in Article 22.

27.3 Effects

If the granting authority rejects costs or contributions, it will deduct them from the costs or contributions declared and then calculate the amount due (and, if needed, make a recovery; see Article 22).

ARTICLE 28 — GRANT REDUCTION

28.1 Conditions

The granting authority may — at beneficiary termination, final payment or afterwards — reduce the grant for a beneficiary, if:

(a) the beneficiary (or a person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under this Agreement or during its award (including improper implementation of the action, non-compliance with the call conditions, submission of false information, failure to provide required information, breach of ethics or security rules (if applicable), etc.), or

(b) the beneficiary (or a person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed — in other EU grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (see Article 25).

The amount of the reduction will be calculated for each beneficiary concerned and proportionate to the seriousness and the duration of the errors, irregularities or fraud or breach of obligations, by applying an individual reduction rate to their accepted EU contribution.

28.2 Procedure

If the grant reduction does not lead to a recovery, the granting authority will formally notify the coordinator or beneficiary concerned of the reduction, the amount to be reduced and the reasons why. The coordinator or beneficiary concerned may — within 30 days of receiving notification — submit observations if it disagrees with the reduction (payment review procedure).

If the grant reduction leads to a recovery, the granting authority will follow the contradictory procedure with pre-information letter set out in Article 22.

28.3 Effects

If the granting authority reduces the grant, it will deduct the reduction and then calculate the amount due (and, if needed, make a recovery; see Article 22).

SECTION 2 SUSPENSION AND TERMINATION

ARTICLE 29 — PAYMENT DEADLINE SUSPENSION

29.1 Conditions

The granting authority may — at any moment — suspend the payment deadline if a payment cannot be processed because:

(a) the required report (see Article 21) has not been submitted or is not complete or additional information is needed

(b) there are doubts about the amount to be paid (e.g. ongoing audit extension procedure, queries about eligibility, need for a grant reduction, etc.) and additional checks, reviews, audits or investigations are necessary, or

(c) there are other issues affecting the EU financial interests.

29.2 Procedure

The granting authority will formally notify the coordinator of the suspension and the reasons why.

The suspension will **take effect** the day the notification is sent.

If the conditions for suspending the payment deadline are no longer met, the suspension will be **lifted** — and the remaining time to pay (see Data Sheet, Point 4.2) will resume.

If the suspension exceeds two months, the coordinator may request the granting authority to confirm if the suspension will continue.

If the payment deadline has been suspended due to the non-compliance of the report and the revised report is not submitted (or was submitted but is also rejected), the granting authority may also terminate the grant or the participation of the coordinator (see Article 32).

ARTICLE 30 — PAYMENT SUSPENSION

30.1 Conditions

The granting authority may — at any moment — suspend payments, in whole or in part for one or more beneficiaries, if:

(a) a beneficiary (or a person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under this Agreement or during its award (including improper implementation of the action, non-compliance with the call conditions, submission of false information, failure to provide required information, breach of ethics or security rules (if applicable), etc.), or

(b) a beneficiary (or a person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed — in other EU grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant.

If payments are suspended for one or more beneficiaries, the granting authority will make partial payment(s) for the part(s) not suspended. If suspension concerns the final payment, the payment (or recovery) of the remaining amount after suspension is lifted will be considered to be the payment that closes the action.

30.2 Procedure

Before suspending payments, the granting authority will send a **pre-information letter** to the beneficiary concerned:

- formally notifying the intention to suspend payments and the reasons why and
- requesting observations within 30 days of receiving notification.

If the granting authority does not receive observations or decides to pursue the procedure despite the observations it has received, it will confirm the suspension (**confirmation letter**). Otherwise, it will formally notify that the procedure is discontinued.

At the end of the suspension procedure, the granting authority will also inform the coordinator.

The suspension will **take effect** the day after the confirmation notification is sent.

If the conditions for resuming payments are met, the suspension will be **lifted**. The granting authority will formally notify the beneficiary concerned (and the coordinator) and set the suspension end date.

During the suspension, no prefinancing will be paid to the beneficiaries concerned. For interim payments, the periodic reports for all reporting periods except the last one (see Article 21) must not contain any financial statements from the beneficiary concerned (or its affiliated entities). The coordinator must include them in the next periodic report after the suspension is lifted or — if suspension is not lifted before the end of the action — in the last periodic report.

ARTICLE 31 — GRANT AGREEMENT SUSPENSION

31.1 Consortium-requested GA suspension

31.1.1 Conditions and procedure

The beneficiaries may request the suspension of the grant or any part of it, if exceptional circumstances — in particular *force majeure* (see Article 35) — make implementation impossible or excessively difficult.

The coordinator must submit a request for **amendment** (see Article 39), with:

- the reasons why
- the date the suspension takes effect; this date may be before the date of the submission of the amendment request and
- the expected date of resumption.

The suspension will **take effect** on the day specified in the amendment.

Once circumstances allow for implementation to resume, the coordinator must immediately request another **amendment** of the Agreement to set the suspension end date, the resumption date (one day after suspension end date), extend the duration and make other changes necessary to adapt the action to the new situation (see Article 39) — unless the grant has been terminated (see Article 32). The suspension will be **lifted** with effect from the suspension end date set out in the amendment. This date may be before the date of the submission of the amendment request.

During the suspension, no prefinancing will be paid. Costs incurred or contributions for activities implemented during grant suspension are not eligible (see Article 6.3).

31.2 EU-initiated GA suspension

31.2.1 Conditions

The granting authority may suspend the grant or any part of it, if:

(a) a beneficiary (or a person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed or is suspected of having committed:

(i) substantial errors, irregularities or fraud or

(ii) serious breach of obligations under this Agreement or during its award (including improper implementation of the action, non-compliance with the call conditions, submission of false information, failure to provide required information, breach of ethics or security rules (if applicable), etc.), or

(b) a beneficiary (or a person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed — in other EU grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant

(c) other:

(i) linked action issues: not applicable

(ii) the action has lost its scientific or technological relevance, for EIC Accelerator actions: the action has lost its economic relevance, for challenge-based EIC Pathfinder actions and Horizon Europe Missions: the action has lost its relevance as part of the Portfolio for which it has been initially selected

31.2.2 Procedure

Before suspending the grant, the granting authority will send a **pre-information letter** to the coordinator:

- formally notifying the intention to suspend the grant and the reasons why and
- requesting observations within 30 days of receiving notification.

If the granting authority does not receive observations or decides to pursue the procedure despite the observations it has received, it will confirm the suspension (**confirmation letter**). Otherwise, it will formally notify that the procedure is discontinued.

The suspension will **take effect** the day after the confirmation notification is sent (or on a later date specified in the notification).

Once the conditions for resuming implementation of the action are met, the granting authority will formally notify the coordinator a **lifting of suspension letter**, in which it will set the suspension end date and invite the coordinator to request an amendment of the Agreement to set the resumption

date (one day after suspension end date), extend the duration and make other changes necessary to adapt the action to the new situation (see Article 39) — unless the grant has been terminated (see Article 32). The suspension will be **lifted** with effect from the suspension end date set out in the lifting of suspension letter. This date may be before the date on which the letter is sent.

During the suspension, no prefinancing will be paid. Costs incurred or contributions for activities implemented during suspension are not eligible (see Article 6.3).

The beneficiaries may not claim damages due to suspension by the granting authority (see Article 33).

Grant suspension does not affect the granting authority's right to terminate the grant or a beneficiary (see Article 32) or reduce the grant (see Article 28).

ARTICLE 32 — GRANT AGREEMENT OR BENEFICIARY TERMINATION

32.1 Consortium-requested GA termination

32.1.1 Conditions and procedure

The beneficiaries may request the termination of the grant.

The coordinator must submit a request for **amendment** (see Article 39), with:

- the reasons why
- the date the consortium ends work on the action ('end of work date') and
- the date the termination takes effect ('termination date'); this date must be after the date of the submission of the amendment request.

The termination will **take effect** on the termination date specified in the amendment.

If no reasons are given or if the granting authority considers the reasons do not justify termination, it may consider the grant terminated improperly.

32.1.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit a **periodic report** (for the open reporting period until termination).

The granting authority will calculate the final grant amount and final payment on the basis of the report submitted and taking into account the costs incurred and contributions for activities implemented before the end of work date (see Article 22). Costs relating to contracts due for execution only after the end of work are not eligible.

If the granting authority does not receive the report within the deadline, only costs and contributions which are included in an approved periodic report will be taken into account (no costs/contributions if no periodic report was ever approved).

Improper termination may lead to a grant reduction (see Article 28).

After termination, the beneficiaries' obligations (in particular Articles 13 (confidentiality and security), 16 (IPR), 17 (communication, dissemination and visibility), 21 (reporting), 25 (checks,

reviews, audits and investigations), 26 (impact evaluation), 27 (rejections), 28 (grant reduction) and 42 (assignment of claims)) continue to apply.

32.2 Consortium-requested beneficiary termination

32.2.1 Conditions and procedure

The coordinator may request the termination of the participation of one or more beneficiaries, on request of the beneficiary concerned or on behalf of the other beneficiaries.

The coordinator must submit a request for **amendment** (see Article 39), with:

- the reasons why
- the opinion of the beneficiary concerned (or proof that this opinion has been requested in writing)
- the date the beneficiary ends work on the action ('end of work date')
- the date the termination takes effect ('termination date'); this date must be after the date of the submission of the amendment request.

If the termination concerns the coordinator and is done without its agreement, the amendment request must be submitted by another beneficiary (acting on behalf of the consortium).

The termination will **take effect** on the termination date specified in the amendment.

If no information is given or if the granting authority considers that the reasons do not justify termination, it may consider the beneficiary to have been terminated improperly.

32.2.2 Effects

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a **report on the distribution of payments** to the beneficiary concerned

(ii) a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, the financial statement, the explanation on the use of resources, and, if applicable, the certificate on the financial statement (CFS; see Articles 21 and 24.2 and Data Sheet, Point 4.3)

(iii) a second **request for amendment** (see Article 39) with other amendments needed (e.g. reallocation of the tasks and the estimated budget of the terminated beneficiary; addition of a new beneficiary to replace the terminated beneficiary; change of coordinator, etc.).

The granting authority will calculate the amount due to the beneficiary on the basis of the report submitted and taking into account the costs incurred and contributions for activities implemented before the end of work date (see Article 22). Costs relating to contracts due for execution only after the end of work are not eligible.

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 21).

If the granting authority does not receive the termination report within the deadline, only costs and contributions which are included in an approved periodic report will be taken into account (no costs/ contributions if no periodic report was ever approved).

If the granting authority does not receive the report on the distribution of payments within the deadline, it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that
- the beneficiary concerned must not repay any amount to the coordinator.

If the second request for amendment is accepted by the granting authority, the Agreement is **amended** to introduce the necessary changes (see Article 39).

If the second request for amendment is rejected by the granting authority (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the grant may be terminated (see Article 32).

Improper termination may lead to a reduction of the grant (see Article 31) or grant termination (see Article 32).

After termination, the concerned beneficiary's obligations (in particular Articles 13 (confidentiality and security), 16 (IPR), 17 (communication, dissemination and visibility), 21 (reporting), 25 (checks, reviews, audits and investigations), 26 (impact evaluation), 27 (rejections), 28 (grant reduction) and 42 (assignment of claims)) continue to apply.

32.3 EU-initiated GA or beneficiary termination

32.3.1 Conditions

The granting authority may terminate the grant or the participation of one or more beneficiaries, if:

(a) one or more beneficiaries do not accede to the Agreement (see Article 40)

(b) a change to the action or the legal, financial, technical, organisational or ownership situation of a beneficiary is likely to substantially affect the implementation of the action or calls into question the decision to award the grant (including changes linked to one of the exclusion grounds listed in the declaration of honour)

(c) following termination of one or more beneficiaries, the necessary changes to the Agreement (and their impact on the action) would call into question the decision awarding the grant or breach the principle of equal treatment of applicants

(d) implementation of the action has become impossible or the changes necessary for its continuation would call into question the decision awarding the grant or breach the principle of equal treatment of applicants

(e) a beneficiary (or person with unlimited liability for its debts) is subject to bankruptcy proceedings or similar (including insolvency, winding-up, administration by a liquidator or court, arrangement with creditors, suspension of business activities, etc.)

(f) a beneficiary (or person with unlimited liability for its debts) is in breach of social security or tax obligations

(g) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has been found guilty of grave professional misconduct

(h) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed fraud, corruption, or is involved in a criminal organisation, money laundering, terrorism-related crimes (including terrorism financing), child labour or human trafficking

(i) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) was created under a different jurisdiction with the intent to circumvent fiscal, social or other legal obligations in the country of origin (or created another entity with this purpose)

(j) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed:

  (i) substantial errors, irregularities or fraud or

  (ii) serious breach of obligations under this Agreement or during its award (including improper implementation of the action, non-compliance with the call conditions, submission of false information, failure to provide required information, breach of ethics or security rules (if applicable), etc.)

(k) a beneficiary (or person having powers of representation, decision-making or control, or person essential for the award/implementation of the grant) has committed — in other EU grants awarded to it under similar conditions — systemic or recurrent errors, irregularities, fraud or serious breach of obligations that have a material impact on this grant (extension of findings from other grants to this grant; see Article 25)

(l) despite a specific request by the granting authority, a beneficiary does not request — through the coordinator — an amendment to the Agreement to end the participation of one of its affiliated entities or associated partners that is in one of the situations under points (d), (f), (e), (g), (h), (i) or (j) and to reallocate its tasks, or

(m) other:

  (i) linked action issues: not applicable

  (ii) the action has lost its scientific or technological relevance, for EIC Accelerator actions: the action has lost its economic relevance, for challenge-based EIC Pathfinder actions and Horizon Europe Missions: the action has lost its relevance as part of the Portfolio for which it has been initially selected

32.3.2 Procedure

Before terminating the grant or participation of one or more beneficiaries, the granting authority will send **a pre-information letter** to the coordinator or beneficiary concerned:

- formally notifying the intention to terminate and the reasons why and
- requesting observations within 30 days of receiving notification.

If the granting authority does not receive observations or decides to pursue the procedure despite the observations it has received, it will confirm the termination and the date it will take effect (**confirmation letter**). Otherwise, it will formally notify that the procedure is discontinued.

For beneficiary terminations, the granting authority will — at the end of the procedure — also inform the coordinator.

The termination will **take effect** the day after the confirmation notification is sent (or on a later date specified in the notification; 'termination date').

32.3.3 Effects

(a) for **GA termination**:

The coordinator must — within 60 days from when termination takes effect — submit a **periodic report** (for the last open reporting period until termination).

The granting authority will calculate the final grant amount and final payment on the basis of the report submitted and taking into account the costs incurred and contributions for activities implemented before termination takes effect (see Article 22). Costs relating to contracts due for execution only after termination are not eligible.

If the grant is terminated for breach of the obligation to submit reports, the coordinator may not submit any report after termination.

If the granting authority does not receive the report within the deadline, only costs and contributions which are included in an approved periodic report will be taken into account (no costs/contributions if no periodic report was ever approved).

Termination does not affect the granting authority's right to reduce the grant (see Article 28) or to impose administrative sanctions (see Article 34).

The beneficiaries may not claim damages due to termination by the granting authority (see Article 33).

After termination, the beneficiaries' obligations (in particular Articles 13 (confidentiality and security), 16 (IPR), 17 (communication, dissemination and visibility), 21 (reporting), 25 (checks, reviews, audits and investigations), 26 (impact evaluation), 27 (rejections), 28 (grant reduction) and 42 (assignment of claims)) continue to apply.

(b) for **beneficiary termination**:

The coordinator must — within 60 days from when termination takes effect — submit:

(i) a **report on the distribution of payments** to the beneficiary concerned

(ii) a **termination report** from the beneficiary concerned, for the open reporting period until termination, containing an overview of the progress of the work, the financial

statement, the explanation on the use of resources, and, if applicable, the certificate on the financial statement (CFS; see Articles 21 and 24.2 and Data Sheet, Point 4.3)

(iii) a **request for amendment** (see Article 39) with any amendments needed (e.g. reallocation of the tasks and the estimated budget of the terminated beneficiary; addition of a new beneficiary to replace the terminated beneficiary; change of coordinator, etc.).

The granting authority will calculate the amount due to the beneficiary on the basis of the report submitted and taking into account the costs incurred and contributions for activities implemented before termination takes effect (see Article 22). Costs relating to contracts due for execution only after termination are not eligible.

The information in the termination report must also be included in the periodic report for the next reporting period (see Article 21).

If the granting authority does not receive the termination report within the deadline, only costs and contributions included in an approved periodic report will be taken into account (no costs/ contributions if no periodic report was ever approved).

If the granting authority does not receive the report on the distribution of payments within the deadline, it will consider that:

- the coordinator did not distribute any payment to the beneficiary concerned and that
- the beneficiary concerned must not repay any amount to the coordinator.

If the request for amendment is accepted by the granting authority, the Agreement is **amended** to introduce the necessary changes (see Article 39).

If the request for amendment is rejected by the granting authority (because it calls into question the decision awarding the grant or breaches the principle of equal treatment of applicants), the grant may be terminated (see Article 32).

After termination, the concerned beneficiary's obligations (in particular Articles 13 (confidentiality and security), 16 (IPR), 17 (communication, dissemination and visibility), 21 (reporting), 25 (checks, reviews, audits and investigations), 26 (impact evaluation), 27 (rejections), 28 (grant reduction) and 42 (assignment of claims)) continue to apply.

SECTION 3 OTHER CONSEQUENCES: DAMAGES AND ADMINISTRATIVE SANCTIONS

ARTICLE 33 — DAMAGES

33.1 Liability of the granting authority

The granting authority cannot be held liable for any damage caused to the beneficiaries or to third parties as a consequence of the implementation of the Agreement, including for gross negligence.

The granting authority cannot be held liable for any damage caused by any of the beneficiaries or other participants involved in the action, as a consequence of the implementation of the Agreement.

33.2 Liability of the beneficiaries

The beneficiaries must compensate the granting authority for any damage it sustains as a result of the implementation of the action or because the action was not implemented in full compliance with the Agreement, provided that it was caused by gross negligence or wilful act.

The liability does not extend to indirect or consequential losses or similar damage (such as loss of profit, loss of revenue or loss of contracts), provided such damage was not caused by wilful act or by a breach of confidentiality.

ARTICLE 34 — ADMINISTRATIVE SANCTIONS AND OTHER MEASURES

Nothing in this Agreement may be construed as preventing the adoption of administrative sanctions (i.e. exclusion from EU award procedures and/or financial penalties) or other public law measures, in addition or as an alternative to the contractual measures provided under this Agreement (see, for instance, Articles 135 to 145 EU Financial Regulation 2018/1046 and Articles 4 and 7 of Regulation 2988/95[22]).

SECTION 4 FORCE MAJEURE

ARTICLE 35 — FORCE MAJEURE

A party prevented by force majeure from fulfilling its obligations under the Agreement cannot be considered in breach of them.

'Force majeure' means any situation or event that:

- prevents either party from fulfilling their obligations under the Agreement,
- was unforeseeable, exceptional situation and beyond the parties' control,
- was not due to error or negligence on their part (or on the part of other participants involved in the action), and
- proves to be inevitable in spite of exercising all due diligence.

Any situation constituting force majeure must be formally notified to the other party without delay, stating the nature, likely duration and foreseeable effects.

The parties must immediately take all the necessary steps to limit any damage due to force majeure and do their best to resume implementation of the action as soon as possible.

CHAPTER 6 FINAL PROVISIONS

ARTICLE 36 — COMMUNICATION BETWEEN THE PARTIES

36.1 Forms and means of communication — Electronic management

[22] Council Regulation (EC, Euratom) No 2988/95 of 18 December 1995 on the protection of the European Communities financial interests (OJ L 312, 23.12.1995, p. 1).

EU grants are managed fully electronically through the EU Funding & Tenders Portal ('Portal').

All communications must be made electronically through the Portal, in accordance with the Portal Terms and Conditions and using the forms and templates provided there (except if explicitly instructed otherwise by the granting authority).

Communications must be made in writing and clearly identify the grant agreement (project number and acronym).

Communications must be made by persons authorised according to the Portal Terms and Conditions. For naming the authorised persons, each beneficiary must have designated — before the signature of this Agreement — a 'legal entity appointed representative (LEAR)'. The role and tasks of the LEAR are stipulated in their appointment letter (see Portal Terms and Conditions).

If the electronic exchange system is temporarily unavailable, instructions will be given on the Portal.

36.2 Date of communication

The sending date for communications made through the Portal will be the date and time of sending, as indicated by the time logs.

The receiving date for communications made through the Portal will be the date and time the communication is accessed, as indicated by the time logs. Formal notifications that have not been accessed within 10 days after sending, will be considered to have been accessed (see Portal Terms and Conditions).

If a communication is exceptionally made on paper (by e-mail or postal service), general principles apply (i.e. date of sending/receipt). Formal notifications by registered post with proof of delivery will be considered to have been received either on the delivery date registered by the postal service or the deadline for collection at the post office.

If the electronic exchange system is temporarily unavailable, the sending party cannot be considered in breach of its obligation to send a communication within a specified deadline.

36.3 Addresses for communication

The Portal can be accessed via the Europa website.

The address for paper communications to the granting authority (if exceptionally allowed) is the official mailing address indicated on its website.

For beneficiaries, it is the legal address specified in the Portal Participant Register.

ARTICLE 37 — INTERPRETATION OF THE AGREEMENT

The provisions in the Data Sheet take precedence over the rest of the Terms and Conditions of the Agreement.

Annex 5 takes precedence over the Terms and Conditions; the Terms and Conditions take precedence over the Annexes other than Annex 5.

Annex 2 takes precedence over Annex 1.

ARTICLE 38 — CALCULATION OF PERIODS AND DEADLINES

In accordance with Regulation No 1182/71[23], periods expressed in days, months or years are calculated from the moment the triggering event occurs.

The day during which that event occurs is not considered as falling within the period.

'Days' means calendar days, not working days.

ARTICLE 39 — AMENDMENTS

39.1 Conditions

The Agreement may be amended, unless the amendment entails changes to the Agreement which would call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

Amendments may be requested by any of the parties.

39.2 Procedure

The party requesting an amendment must submit a request for amendment signed directly in the Portal Amendment tool.

The coordinator submits and receives requests for amendment on behalf of the beneficiaries (see Annex 3). If a change of coordinator is requested without its agreement, the submission must be done by another beneficiary (acting on behalf of the other beneficiaries).

The request for amendment must include:

- the reasons why
- the appropriate supporting documents and
- for a change of coordinator without its agreement: the opinion of the coordinator (or proof that this opinion has been requested in writing).

The granting authority may request additional information.

If the party receiving the request agrees, it must sign the amendment in the tool within 45 days of receiving notification (or any additional information the granting authority has requested). If it does not agree, it must formally notify its disagreement within the same deadline. The deadline may be extended, if necessary for the assessment of the request. If no notification is received within the deadline, the request is considered to have been rejected.

An amendment **enters into force** on the day of the signature of the receiving party.

An amendment **takes effect** on the date of entry into force or other date specified in the amendment.

[23] Regulation (EEC, Euratom) No 1182/71 of the Council of 3 June 1971 determining the rules applicable to periods, dates and time-limits (OJ L 124, 8/6/1971, p. 1).

ARTICLE 40 — ACCESSION AND ADDITION OF NEW BENEFICIARIES

40.1 Accession of the beneficiaries mentioned in the Preamble

The beneficiaries which are not coordinator must accede to the grant by signing the accession form (see Annex 3) directly in the Portal Grant Preparation tool, within 30 days after the entry into force of the Agreement (see Article 44).

They will assume the rights and obligations under the Agreement with effect from the date of its entry into force (see Article 44).

If a beneficiary does not accede to the grant within the above deadline, the coordinator must — within 30 days — request an amendment (see Article 39) to terminate the beneficiary and make any changes necessary to ensure proper implementation of the action. This does not affect the granting authority's right to terminate the grant (see Article 32).

40.2 Addition of new beneficiaries

In justified cases, the beneficiaries may request the addition of a new beneficiary.

For this purpose, the coordinator must submit a request for amendment in accordance with Article 39. It must include an accession form (see Annex 3) signed by the new beneficiary directly in the Portal Amendment tool.

New beneficiaries will assume the rights and obligations under the Agreement with effect from the date of their accession specified in the accession form (see Annex 3).

Additions are also possible in mono-beneficiary grants.

ARTICLE 41 — TRANSFER OF THE AGREEMENT

In justified cases, the beneficiary of a mono-beneficiary grant may request the transfer of the grant to a new beneficiary, provided that this would not call into question the decision awarding the grant or breach the principle of equal treatment of applicants.

The beneficiary must submit a request for **amendment** (see Article 39), with

- the reasons why
- the accession form (see Annex 3) signed by the new beneficiary directly in the Portal Amendment tool and
- additional supporting documents (if required by the granting authority).

The new beneficiary will assume the rights and obligations under the Agreement with effect from the date of accession specified in the accession form (see Annex 3).

ARTICLE 42 — ASSIGNMENTS OF CLAIMS FOR PAYMENT AGAINST THE GRANTING AUTHORITY

The beneficiaries may not assign any of their claims for payment against the granting authority to

any third party, except if expressly approved in writing by the granting authority on the basis of a reasoned, written request by the coordinator (on behalf of the beneficiary concerned).

If the granting authority has not accepted the assignment or if the terms of it are not observed, the assignment will have no effect on it.

In no circumstances will an assignment release the beneficiaries from their obligations towards the granting authority.

ARTICLE 43 — APPLICABLE LAW AND SETTLEMENT OF DISPUTES

43.1 Applicable law

The Agreement is governed by the applicable EU law, supplemented if necessary by the law of Belgium.

Special rules may apply for beneficiaries which are international organisations (if any; see Data Sheet, Point 5).

43.2 Dispute settlement

If a dispute concerns the interpretation, application or validity of the Agreement, the parties must bring action before the EU General Court — or, on appeal, the EU Court of Justice — under Article 272 of the Treaty on the Functioning of the EU (TFEU).

For non-EU beneficiaries (if any), such disputes must be brought before the courts of Brussels, Belgium — unless an international agreement provides for the enforceability of EU court judgements.

For beneficiaries with arbitration as special dispute settlement forum (if any; see Data Sheet, Point 5), the dispute will — in the absence of an amicable settlement — be settled in accordance with the Rules for Arbitration published on the Portal.

If a dispute concerns administrative sanctions, offsetting or an enforceable decision under Article 299 TFEU (see Articles 22 and 34), the beneficiaries must bring action before the General Court — or, on appeal, the Court of Justice — under Article 263 TFEU.

For grants where the granting authority is an EU executive agency (see Preamble), actions against offsetting and enforceable decisions must be brought against the European Commission (not against the granting authority; see also Article 22).

ARTICLE 44 — ENTRY INTO FORCE

The Agreement will enter into force on the day of signature by the granting authority or the coordinator, depending on which is later.

SIGNATURES

For the coordinator

Marios DEMETRIADES with ECAS id ndmemari signed in the Participant Portal on 26/04/2024 at 12:23:50 (transaction id SigId-7318-O7So23oazRJ7NpUi1fjzZzJJUSy3eQJryrnfHPIzmVEoPFqPxOcwYmSQlsBBVYO2CIYeFuWjJajYMR6LlEIyg6q-jpJZscgsw0KZrf8dzSGvgE-k3tD1s6eaetmp96QeDnyvFd2Mj4b2XXw3nugAo8yGYokpkXWZlx1MzZK8uVCnsZ7QBWIFY36nJ9m9oDn9SuCgq). Timestamp by third party at 2024.04.26 12:23:54 CEST

For the granting authority

Signed by Tereza BUDNAKOVA with ECAS id koudete as an authorised representative on 29-04-2024 16:34:58 (transaction id SigId-28912-p10jkpQIxl1ztT2f2lw8wjZy5MKzJ0NNh9vQMvq1ZQxmoAZzf4a7zVrlQaHhxzhN2WflY1eHi02oo0GdDq05DwD-jpJZscgsw0KZrf8dzSGvgE-JTzkQUWzREqK1IC04NzwlDUV2RhJNLzt38U0Wt8iXYbTMG676xsCZ5ROjMVRClXkCxOHkt3xvLFImDjJvJc6eoe) 2024.04.29 16:35:03 CEST

ANNEX 1

Horizon Europe (HORIZON)

Description of the action (DoA)

Part A

Part B

DESCRIPTION OF THE ACTION (PART A)

COVER PAGE

Part A of the Description of the Action (DoA) must be completed directly on the Portal Grant Preparation screens.

PROJECT *Grant Preparation (General Information screen) — Enter the info.*	
Project number:	101156653
Project name:	Innovative Solutions across the MEDiterranean for mitigation of Climate change-related heaLth rIsks and enhancing health systeM resilience
Project acronym:	ISMED-CLIM
Call:	HORIZON-MISS-2023-CLIMA-01
Topic:	HORIZON-MISS-2023-CLIMA-01-03
Type of action:	HORIZON-IA
Service:	CINEA/C/01
Project starting date:	fixed date: 1 November 2024
Project duration:	48 months

TABLE OF CONTENTS

Associated with document Ref. Ares(2024)3060123 - 25/04/2024

PROJECT SUMMARY

Project summary

Grant Preparation (General Information screen) — Provide an overall description of your project (including context and overall objectives, planned activities and main achievements, and expected results and impacts (on target groups, change procedures, capacities, innovation etc)). This summary should give readers a clear idea of what your project is about.

Use the project summary from your proposal.

ISMED-CLIM aims to engage and mobilise regional stakeholders across the Mediterranean, in implementing a wide array of adaptation solutions to mitigate the health effects of climate change, and provide evidence for their feasibility, user acceptance and efficacy. Specifically, ISMED-CLIM will (i) enhance the understanding of climate change effects on non-communicable diseases (NCDs) and vector-borne infections across representative European countries within the Mediterranean; (ii) quantify, for the first time, how public health interventions integrating state-of-the-art technologies, public and social media, with vulnerable citizens' participation can reduce personal exposures to heat and air pollution and related health effects; (iii) validate the feasibility and user acceptance among high risk professionals of a regional early warning and risk prediction tool to mitigate the risk posed by exposure to sand flies and related diseases; (iv) employ open, participatory, and co-creative methodologies to locally adapt and refine existing evidence-based practices and prototype tools to increase the preparedness and ability of health systems in the Mediterranean to deliver safe, effective, and efficient care to citizens. We will test the proposed demonstration solutions initially in eight sites and coordinate ten replications in six sites in five European countries (Cyprus, Greece, Italy, Spain, Portugal), in alignment with Climate Change Adaptation Mission objectives. We will integrate the produced knowledge from epidemiology, forecasting, exposure and health data with insights from the demonstration and replication activities into a knowledge portal and policy decision-centric and action-oriented dashboard for policy makers, healthcare administrators, professionals and citizens. ISMED-CLIM's approaches will be readily applicable in other European regions affected by the same or other climate change-related stressors, such as forest fire smoke, floods, ozone, and cold.

LIST OF PARTICIPANTS

PARTICIPANTS

Grant Preparation (Beneficiaries screen) — Enter the info.

Number	Role	Short name	Legal name	Country	PIC
1	COO	UCY	UNIVERSITY OF CYPRUS	CY	999835843
2	BEN	CyI	THE CYPRUS INSTITUTE	CY	965934440
3	BEN	HIO	ORGANISMOS ASFALISIS YGEIAS	CY	881192427
4	BEN	EBOS	EBOS TECHNOLOGIES LIMITED	CY	997848022
5	BEN	EKYSY	PANCYPRIAN FEDERATION OF LABOUR	CY	940255630
6	BEN	UTH	PANEPISTIMIO THESSALIAS	EL	986152150
7	BEN	NKUA	ETHNIKO KAI KAPODISTRIAKO PANEPISTIMIO ATHINON	EL	999643007
8	BEN	KOR	DIMOS KORYDALLOS	EL	917517763
9	BEN	MLSA	MINISTRY OF LABOUR AND SOCIAL AFFAIRS	EL	916252204
10	BEN	TRIKALA	ANAPTYXIAKI ETAIREIA DIMOU TRIKKAION ANAPTYXIAKI ANONYMI ETAIREIA OTA	EL	991940043
11	BEN	UNICT	UNIVERSITA DEGLI STUDI DI CATANIA	IT	999874061

PARTICIPANTS

Grant Preparation (Beneficiaries screen) — Enter the info.

Number	Role	Short name	Legal name	Country	PIC
12	BEN	ARNAS	AZIENDA OSPEDALIERA DI RILIEVO NAZIONALE GARIBALDI CATANIA	IT	888631163
13	BEN	DEASL	AZIENDA SANITARIA LOCALE ROMA 1	IT	912924134
14	BEN	ULE	UNIVERSIDAD DE LEON	ES	999453372
15	BEN	VHIR	FUNDACIO HOSPITAL UNIVERSITARI VALL D'HEBRON - INSTITUT DE RECERCA	ES	999541642
16	BEN	CSIC	AGENCIA ESTATAL CONSEJO SUPERIOR DE INVESTIGACIONES CIENTIFICAS	ES	999991722
17	BEN	UNL	UNIVERSIDADE NOVA DE LISBOA	PT	960782479
18	BEN	UA	UNIVERSIDADE DE AVEIRO	PT	999865331
19	BEN	AGUEDA	MUNICIPIO DE AGUEDA	PT	998359891
20	BEN	APMVEAC	ASSOCIACAO PORTUGUESA DE MEDICOS VETERINARIOS ESPECIALISTAS EM ANIMAIS DE COMPANHIA	PT	882219851
21	BEN	ECMWF	EUROPEAN CENTRE FOR MEDIUM-RANGE WEATHER FORECASTS	UK	999916741
22	BEN	IMR	INSTITUT ZA MEDICINSKA ISTRA IVANJA	RS	997623176
23	BEN	AIN	AINIGMA TECHNOLOGIES	BE	892135579
24	BEN	EF	EDENTIFY FOUNDATION MTU	EE	881410095
25	AP	HSPH	HARVARD GLOBAL RESEARCH AND SUPPORT SERVICES INC.	US	953720200
26	AP	RG	RESILIENCE GUARD GMBH	CH	949987737
27	AP	ACARES	Americares Foundation Inc.	US	881117058

LIST OF WORK PACKAGES

Work packages

Grant Preparation (Work Packages screen) — Enter the info.

Work Package No	Work Package name	Lead Beneficiary	Effort (Person-Months)	Start Month	End Month	Deliverables
WP1	Project framework specification and requirements' elicitation	13 - DEASL	116.00	1	38	D1.1 – Climate change and health policy landscape review D1.2 – Regional Task Forces and stakeholder's mobilisation - Initial Version D1.3 – Regional Task Forces and stakeholder's mobilisation - Final version D1.4 – Proceedings of Regional Task Force workshop in Cyprus D1.5 – Proceedings of Regional Task Force workshop in Greece D1.6 – Proceedings of Regional Task Force workshop in Italy D1.7 – Proceedings of Regional Task Force workshop in Spain D1.8 – Proceedings of Regional Task Force workshop in Portugal D1.9 – Customised recommendations and alerts - Initial version D1.10 – Customised recommendations and alerts - Final version D1.11 – Platform architecture and digital tools specifications - Initial version D1.12 – Platform architecture and digital tools specifications - Final version
WP2	Climate change effects on non-communicable (NCDs) and infectious diseases across the Mediterranean Region	7 - NKUA	77.00	1	24	D2.1 – Administrative data sets D2.2 – Climate change effects on non-communicable diseases

Work packages

Grant Preparation (Work Packages screen) — Enter the info.

Work Package No	Work Package name	Lead Beneficiary	Effort (Person-Months)	Start Month	End Month	Deliverables
						D2.3 – Climate change effects on zoonotic diseases D2.4 – Vulnerability Assessment Framework and Knowledge Hub
WP3	Digital tools to disseminate forecasting information, evidence-based recommendations and obtain personal exposure and health data	4 - EBOS	151.00	6	41	D3.1 – Data processing - Initial report D3.2 – Data processing - Interim report D3.3 – Data processing - Final Report D3.4 – Early Warning and Response System (EWRS) - Initial Version D3.5 – Early Warning and Response System (EWRS) - Interim version D3.6 – Early Warning and Response System (EWRS) - Final version D3.7 – ISMED-CLIM integrated platform and digital tools delivery - Initial version D3.8 – ISMED-CLIM integrated platform and digital tools delivery - Interim version D3.9 – ISMED-CLIM integrated platform and digital tools delivery - Final version
WP4	Living Labs (LLs) based deep demonstrations	11 - UNICT	251.00	9	40	D4.1 – Living Lab planning and management - Initial report D4.2 – Living Lab planning and management - Final report D4.3 – LL1-3 results - Initial report D4.4 – LL1-3 results - Final report D4.5 – LL4 results - Initial report D4.6 – LL4 results - Final report D4.7 – LL5 results - Initial report D4.8 – LL5 results - Final report

Work packages

Grant Preparation (Work Packages screen) — Enter the info.

Work Package No	Work Package name	Lead Beneficiary	Effort (Person-Months)	Start Month	End Month	Deliverables
						D4.9 – LL material and replication guidelines - Initial report D4.10 – LL material and replication guidelines - Final report
WP5	Impact maximisation and sustainability through replications, trainings, policy uptake and evaluation	2 - CyI	156.00	13	48	D5.1 – Replications and scale-up D5.2 – Policy Dashboard and guidelines - Initial version D5.3 – Policy Dashboard and guidelines - Interim version D5.4 – Policy Dashboard and guidelines - Final report D5.5 – Health and socioeconomic impact assessment D5.6 – Training and capacity building
WP6	Dissemination, Communication, Exploitation	24 - EF	101.00	1	48	D6.1 – Project website D6.2 – DEC strategy 1 D6.3 – DEC strategy 2 D6.4 – DEC strategy 3 D6.5 – DEC strategy - Final report D6.6 – Proceedings of final conference D6.7 – Exploitation strategy and IPR management 1 D6.8 – Exploitation strategy and IPR management 2
WP7	Project Management	1 - UCY	72.00	1	48	D7.1 – Project operations handbook 1 D7.2 – Project operations handbook 2 D7.3 – Project operations handbook 3 D7.4 – Data Management Plan 1 D7.5 – Data Management Plan 2

Work packages

Grant Preparation (Work Packages screen) — Enter the info.

Work Package No	Work Package name	Lead Beneficiary	Effort (Person-Months)	Start Month	End Month	Deliverables
						D7.6 – Data Management Plan 3 D7.7 – Quality Assurance and Risk Management Plan 1 D7.8 – Quality Assurance and Risk Management Plan 2 D7.9 – Legal, ethical and gender issues manual 1 D7.10 – Legal, ethical and gender issues manual 2 D7.11 – Legal, ethical and gender issues manual 3

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Work package WP1 – Project framework specification and requirements' elicitation

Work Package Number	WP1	Lead Beneficiary	13 - DEASL
Work Package Name	Project framework specification and requirements' elicitation		
Start Month	1	End Month	38

Objectives

WP1 will assess the landscape in regard to the relationship between climate change and health as well as current relevant policy gaps and engage stakeholders through the creation of Regional Task Forces in an effort to elicit user needs and requirements under different climate change scenarios. In addition, WP1 will rely on co-creation methods and participatory approaches to set-up the customized recommendations for different population groups as well as streamline the design and specifications of the project's digital tools.
The specific objectives of WP1 are:
• Assess the current state of climate change effects on health across the Mediterranean region and map policies and action plans of regulatory authorities.
• Establish Task Forces to engage regional policy makers, patient groups, social stakeholders in surveys, focus groups and workshops to define user needs and requirements and generate refined tasks and actions of the project.
• Engage frontline professionals, policy and social stakeholders in customization and tailoring the recommendations to be tested in use cases for exposure reduction to heat, air pollution, and mitigation of related health effects.
• Define the specifications and the design for the set-up of electronic platform and technology applications.

Description

Task T1.1 - Climate change, health/disease, and policy landscape assessment and review (Lead: DEASL; Participants: UCY, NKUA, CSIC, CyI, IMR, UA [M01-M12]
DEASL will lead the assessment of the current state of research and innovation in relation to climate change effects on health across the Mediterranean by reviewing relevant scientific literature, and reports in order to: (i) identify key climate change-related exposures, such as heatwaves, droughts, wildfires, vectors' prevalence; (ii) identify climate-sensitive health outcomes, such as cardiovascular, respiratory, mental-psychiatric and vector-borne diseases; (iii) assess the climate change vulnerability of specific populations, including pregnant women, older adults, outdoor workers and subgroups with chronic conditions; and (iv) map and review existing policies and action plans of relevant regulatory authorities and stakeholders in charge of climate change and health policies in the Mediterranean, focusing on the implementation and effectiveness of measures targeting vulnerable groups at regional or local level. (Outputs: D1.1)

Task T1.2 – Regional Task Forces for engagement of stakeholders, user needs, scenarios, and requirements analysis (Lead: DEASL; Participants: ALL) [M01-M38]
DEASL with ALL partners will establish Regional Task Forces in all participating countries to mobilize support from a wider range of policy, civil society, and health system stakeholders and citizens in order to: (i) formulate details of the vision and transformative pathways towards climate resilience; (ii) identify best practices, innovative approaches, and successful case studies within the regions of interest; (iii) engage stakeholders in surveys, focus groups and workshops to define user needs, requirements and generate refined project tasks. Task T1.2 will follow a co-creative, bidirectional, and emancipatory participatory process to support stakeholders' mobilisation and promote capacity building, while enabling stakeholder accountability in the development of ISMED-CLIM innovative solutions. (Outputs: D1.2-D1.8)

Task T1.3 - Customised recommendations to be tested in use cases through methods of co-creation (Lead: UCY; Participants: ALL [M03-M38]
Concurrently with the requirements elicitation process described in Task T1.2, UNICT, UTH, ULE, VHIR and UCY will identify existing interventions already employed at the regional level through a scoping literature review, especially focusing on vulnerable groups' responses. For each type of recommendations to be tested in LL 1, 2 and 3, we will consider compatibility with user needs, adaptability to the specific context and assess the scientific evidence base. Following this initial configuration, final adaptation and tailoring of the recommendations to be tested in each LL will include assessment of intervention barriers, evaluation metrics and scalability potential, in consultation with the Regional Task Forces. For LL4, besides addressing the specified user requirements related to zoonotic diseases, UNL and APMVEAC will tailor the recommendations, building upon the decision support framework established in the CLIMOS project. In addition, these recommendations will consider potential challenges stemming from infrastructural, ethical and resource use considerations that may be relevant in environments where animals are kept or undergo treatment. For LL5,

beyond the scoping review of the literature, HSPH, ACARES and UCY will rely on a site-specific climate resilience and needs assessment and the employment of a modified OECD HSRQ. (Outputs: D1.9, D1.10)

Task 1.4 - Digital tools design and specifications (Lead: EBOS; Participants: EF, AIN) [M05-M38]
This task defines the design specifications for the project's digital solutions by extracting commonalities for the management of interventions, tailoring domain/intervention-specific components and complying with the overall project framework. Focus group discussions will evaluate the user needs questionnaires collected in T1.2, to co-creatively define information flows, user stories, and generic data types. EBOS along with AIN and EF will map user needs to (non-)/functional specifications in a live document, allowing for a seamless development of the tools in WP3. The system architecture of the ISMED-CLIM platform will embody data and processes' digital sovereignty, as well as architectural templates and blueprints to encompass the diverse nature of data collection, context, and scope, along with the stakeholders' interactions. The platform will encompass architectural principles of openness and transparency; interoperability, evolvability and integrate-ability of diverse data sources and services; trust, authenticity, and security; research compliance and reproducibility. (Outputs: D1.11, D1.12)

Work package WP2 – Climate change effects on non-communicable (NCDs) and infectious diseases across the Mediterranean Region

Work Package Number	WP2	**Lead Beneficiary**	7 - NKUA
Work Package Name	Climate change effects on non-communicable (NCDs) and infectious diseases across the Mediterranean Region		
Start Month	1	**End Month**	24

Objectives

WP2 will collect environmental and health data from the different project areas to establish a database for the study of different climate change stressors on both non-communicable and infectious diseases. The database will allow the epidemiological analysis of extreme climate change-related phenomena, such as heat and cold episodes, droughts, floods, and wildfires interacting with background air pollution and temperature in the Mediterranean region. Data on the presence and abundance of important disease vectors will be incorporated with gridded climate projections and vector dynamics to generate short- and long-term assessments of vector activity and associated disease risk. The specific objectives of WP2 are:
• Investigate the impact on NCDs' mortality and morbidity from the complex interplay of climate change parameters across the Mediterranean region. Enhance previous findings by updated data, extended outcomes and investigations of interactions between heat and cold with extreme events such as droughts, flooding and wildfires, as well as with air pollution for the whole region.
• Investigate the impact on zoonotic diseases and vector activity of various climate change parameters across the Mediterranean region.
• Feed results of the analysis into following WPs and form the basis of recommendations and mitigation strategies.

Description

Task T2.1 - Administrative data collection and curation (Lead: NKUA; Participants: UCY, DEASL, CSIC, CyI, IMR, UA) [M01-M12]
Under task T2.1, NKUA with DEASL, CSIC, UCY, UA will coordinate environmental and health data collection from main metropolitan areas across Greece, Italy, Spain, Cyprus, and Portugal and possibly from other Mediterranean countries to compile a wide database covering the period 2000-2023. Recent years' data when extreme events attributed to climate change have increased in the Mediterranean are particularly useful for the valid assessment of these associations. Specifically, daily data on temperature levels, humidity, wind direction and speed, occurrence of desert dust episodes, flooding, wildfires and air pollution levels will be collected along with age-specific daily counts on mortality and hospital admissions for all causes, cardio-respiratory, neurological and mental diseases. We will also collect data on preterm births and daily admissions in Neonatal Intensive Care Units for prematurity to assess the impact on pregnancy outcomes and inform Task 4.3 (LL on pregnant women). Data on the presence and abundance of important disease vectors, such as the common house mosquito (Culex pipiens), the Anopheles species, and the invasive Aedes mosquitoes, will be collected by IMR and CyI, as well as vector-borne disease prevalence, such as malaria, dengue, chikungunya, zika, West Nile, and leishmaniasis, as routinely monitored by regional health authorities. Specifically, data on sand fly

species presence, abundance, and sand fly-borne disease (SFBD) prevalence (leishmaniasis, sand fly fever, Sicilian virus, Toscana virus, etc.) in humans and dogs will be collected, harmonised, and archived based on routine monitoring by health authorities, ECDC open archives, the CLIMOS project and similar European efforts. (Output: D2.1)

Task T2.2 - Heat, cold, drought, air pollution, wildfire and flood health effects in NCDs (Lead: NKUA; Participants: UCY, DEASL, CSIC, CyI) [M01-M24]
Epidemiological analysis of extreme climate change-related phenomena, such as heat and cold episodes, droughts, floods, and wildfires interacting with background air pollution and temperature levels will include: (i) times-series analyses making use of T2.1 data to derive city-specific health effect estimates for independent and cumulative effects between examined parameters. NKUA, DEASL, CSIC, CyI, UCY will investigate in depth the shape of the underlying cumulative associations to identify any threshold effects. Analyses will be performed for all ages and by age groups, focusing on: a)18-65 age group that corresponds to the working age with more frequent outdoor exposure and b) 65+ age group to address impacts on susceptible older adults; (ii) Combination of city specific estimates, using meta-analytic techniques, to provide Mediterranean specific overall estimates and shapes for the outcomes. We will further explore effect modification patterns by area and build characteristics, such as urban green space, which may inform adaptation and mitigation actions related to urban design; (iii) Projections of climate change impact on NCDs will be performed by CyI, informed by results of sub-task (ii), under different (moderate, extreme and record-breaking) climate change scenarios and various population assumptions, for the next 50 years, using bias corrected climate projections. (Output D2.2)

Task T2.3 - Climate change impact on zoonotic diseases and vector activity (Lead: CyI; Participants: UCY, UNL, IMR) [M01-M24]
A database of infectious disease models with a specific focus on zoonotic and sand fly-borne diseases will be compiled by CyI, UNL, IMR and UCY based on published and unpublished open-source digital resources. Intelligence generated through relevant international initiatives, such as the CLIMOS project on sand fly-borne diseases, the IDAlert project on decision-support tools for infectious-diseases, and BlueAdapt on coastal pathogens, will be sought, and the repository will be co-developed with the relevant stakeholders. Models will be harmonised in an accessible standardised repository, and will be extended, if possible, to incorporate climate-sensitivity to the epidemiological and physiological processes described within. Specific focus will be given to vector dynamics and models will be assimilated with gridded global environmental datasets and climate projections to generate short- and long-term assessment of vector presence, population abundance, and associated disease risk. Sand flies and SFBDs, such as leishmaniasis, sand fly fever, Sicilian virus, and Toscana virus disease, will be tackled as an exemplary case study, to demonstrate the applicability and effectiveness of the predictive models and the early warning systems developed using these models. (Output D2.3)

Work package WP3 – Digital tools to disseminate forecasting information, evidence-based recommendations and obtain personal exposure and health data

Work Package Number	WP3	**Lead Beneficiary**	4 - EBOS
Work Package Name	Digital tools to disseminate forecasting information, evidence-based recommendations and obtain personal exposure and health data		
Start Month	6	**End Month**	41

Objectives

WP3 will ensure efficient data retrieval, curation, harmonization and develop the Data Management Middleware. In addition, under WP3, an AI-augmented Early Warning and Response System (EWRS) will be developed that would allow real-time personalized risk assessment and communication for heat exposure and thermal stress. The EWRS will also feature a sand fly-borne (zoonotic) diseases prompt, that will incorporate with disease modelling from the CLIMOS EWS, updated with recommendations for professionals working with animals and dog owners. Finaly, this WP will ensure the development and integration of the platfrom's Human Machine Interface (HMI) and related applications (such as the Citizen app) and tools based on agreed workflows so that all platform components satisfy requirements and Living Labs interfacing. The specific objectives of this WP are:
- Retrieve, orchestrate, fuse, and harmonise various data streams for integration and analysis.
- Develop the EWRS using machine learning and downscaling to account for person- and site-specific features.
- Develop user-friendly interfaces and Citizen Application using dynamic designs and short development cycles.
- Integrate all developed components and digital tools into a unified data platform.

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Description
Task T3.1 - Data retrieval, curation, harmonisation and management (Lead: AIN; Participants: UCY, UNICT, UTH, ULE, VHIR, UNL, NKUA, DEASL, CSIC, CyI, IMR, UA, ECMWF) [M06-M40] This task is responsible for retrieving and assessing the project datasets in terms of quality, considering technical aspects related to, inter alia, data consistency, integrity, and completeness. Where appropriate and possible, data corruption and missing/unbalanced information will be mitigated through data imputation and/or augmentation techniques. Some of the data variables collected by ISMED-CLIM will be mapped to a common data model following established standards (e.g., FHIR or OMOP) to facilitate future connection to European Health Data space. T3.1 will deliver the assembled multi-source datasets and be responsible for their curation over the course of the project, including the compliant release of certain of them (collected by the project) in open repositories (Zenodo). Furthermore, T3.1 is responsible for development of the Data Management Component and the respective pipelines from available open sources tools (e.g., Apache Kafka, Jenkins etc.) to collect, handle and aggregate exposure and health data from general population and vulnerable groups' studies, embracing FAIR standards for ensuring interoperability and accessibility. AIN will harmonize available datasets, EBOS will develop and integrate the Data Management Middleware, while ALL data providers will send their datasets for common data modelling and harmonization. (Outputs: D3.1 - D3.3) Task T3.2 - AI-augmented Early Warning and Response System development (Lead: AIN; Participants: UCY, EF, ECMWF, EBOS) [M06-M40] Task T3.2 is responsible for the development of an AI-augmented EWRS providing real-time personalized risk assessment for heat exposure and thermal stress. Forecasts and reanalysis from ECMWF products combined with observed weather data obtained from ISMED-CLIM partners will be analysed using a combination of ML techniques to post-process the forecasted products. Several ML techniques will be tested, starting from simple linear regression to LSTMS and hybrid time forecasting models such as ARIMA and Prophet. Temperature forecasts will be post-processed and downscaled to generate higher-resolution forecasts for the project sites, thus establishing a reliable and fine-resolution forecasting pipeline. Sequentially, the downscaled temperature forecasting products will be used as inputs (boundary and initial conditions) for dynamic urban micro-climate modelling to account for city-specific features. AI-augmented Risk Assessment Models: (i) Heat Exposure: weather forecasting output will be augmented with real time ambient temperature measurements, and spatiotemporal data to develop personalised exposure profiles; (ii) Thermal stress: The personalised heat exposure profiles will be combined in real time with additional meteorological, physiological and activity parameters to estimate indices such as the UTCI, as a comprehensive measure of thermal stress. The prompt from the successful employment of the two risk assessment models and personalized recommendations will be provided to the EWRS users. T3.2 is also responsible for the incorporation/replication/upgrade with disease modelling of CLIMOS EWS output to ISMED-CLIM EWRS, providing real-time personalized risk assessment for sand fly-borne (zoonotic) diseases, including recommendations for professionals and dog owners. The EWRS fosters continuous feedback loops soliciting passive user input, to identify trends, validate its predictions, identify areas for improvement, and refine its performance in a reinforcement learning schema. AIN will develop the EWRS with the support of EBOS; EF will incorporate the CLIMOS EWS; ECMWF will lead the optimisation and tailoring of the forecasting modelling process and together with UCY will undertake downscaling and post-processing of temperature forecasts. (Outputs: D3.4-D3.6) Task T3.3 - User interfaces and citizen application development (Lead: EBOS; Participants: UCY, EF, AIN) [M06-M41] EBOS with the support of AIN and EF will develop the Human Machine Interfaces (HMI) of the ISMED-CLIM platform's applications and tools (main portal, LL Management Portal, Citizen Application, Policy Dashboard). Specifically, this task will: (i) design the detailed low-level HMI after capturing the requirements and technical specifications from Tasks T1.2 and T1.4, and benefitting from the MEDena Health Hub platform provided by UCY; create a mapping of the descriptive list of all the LLs regarding the system functionality and requirements with the respective Unified Modelling Language diagrams; engage end-user actors to ensure that the HMI is user-friendly and that it is equipped with the necessary functionality; select the appropriate type of user interface components required, such as widgets, gauss controls, fusion charts, statistics and maps (as needed), and (ii) develop the HMI using open-source, web-based frameworks; create the necessary system development packages as a web-based service, to enable multi-tenancy and concurrency in use-case execution during the demos; match specific end-user configurations for easy deployment, by focusing on micro-service-oriented architecture and micro-services orchestration. This task will also develop a dedicated Citizen Application able to communicate the risk warnings and recommendations for self-management of exposures to climate change stressors. The trial versions of the Citizen Application will be available by M18 and M30 for LL validation. The final fully-fledged version (M41) compatible with Android and iOS will include modifications based on data analysis and interpretation, collected user feedback and complete integration of the components developed in T3.1-T3.3. (Outputs: D3.7 - D3.9)

Task T3.4 - Platform, application integration and Living Labs interfacing (Lead: EBOS; Participants: UCY, UNICT, UTH, ULE, VHIR, UNL, EF, ECMWF, AIN) [M12-M41]
EBOS with the support of AIN, ECMWF and EF will receive input from LLs leaders and set up the ISMED-CLIM platform by employing agile methodologies for orchestrating, homogenizing, and integrating the outputs of the above tasks, focusing on the interconnection between each module/component. Standards, protocols, and APIs will enable the integration of services and data that are needed for the creation of a single unified prototype platform to be extended and interfaced with the EU Climate-ADAPT platform. This task will set common tools and workflows for the development and integration of the all the platform components to satisfy requirements, and validation through dry-run testing of selected implemented scenarios. The platform will offer a secure environment with respect to legal/regulatory issues, as well as techniques and technologies to control access and handling of data in secure and trustworthy presented manner by inspecting organisational and technical measures that are put in place to ensure compliance with GDPR requirements, verifying their effectiveness, and recording all information related to the handling of personal data offering their accountability. (Output: D3.7 -D3.9)

Work package WP4 – Living Labs (LLs) based deep demonstrations

Work Package Number	WP4	**Lead Beneficiary**	11 - UNICT
Work Package Name	Living Labs (LLs) based deep demonstrations		
Start Month	9	**End Month**	40

Objectives

WP4 includes the performance of five Living Labs (LLs). Three of the LLs are designed as randomised controlled trials to examine the efficacy of interventions to reduce exposure to heat and air pollution and related health effects, one LL will assess the feasibility and user acceptance of an EWRS and an evidence-based set of prevention interventions for zoonotic diseases among high-risk professionals and citizen groups and one LL to assess current climate resilience of Health Systems in the region and adapt an existing prototype Climate Resilience for Frontline Clinics toolkit in the U.S. to the conditions and characteristics of Mediterranean Health Care Systems. Finally, under this WP, following the completion of LLs, the guidelines to be replicated in other sites will be tailored and finalized and a technical assistance and troubleshooting mechanism, hosted by UCY, offering direct consultation to the replicating regions will be established. The specific objectives of this WP are:
• Conduct three LLs designed as randomised controlled trials to examine the efficacy of interventions to reduce exposure to heat and air pollution and related health effects during summers in three vulnerable population groups: outdoor workers (OW), pregnant women (PW) and older adults with hypertension (OH).
• Conduct one LL to assess the feasibility and user acceptance of an EWRS and an evidence-based set of prevention interventions for zoonotic diseases among high-risk professionals and citizen groups.
• Conduct one LL to assess current climate resilience of Health Systems in the region and adapt an existing prototype Climate Resilience for Frontline Clinics toolkit in the U.S. to the conditions and characteristics of Mediterranean Health Care Systems.

Description

Task T4.1 - Living Labs (LL) lifecycle planning and management (Leader: UNICT; Participants: UCY, UTH, ULE, VHIR, UNL, UA, EBOS, AIN, HIO) [M09-M40]
This task focuses on the operational and lifecycle management of the LLs. UTH, UNICT and VHIR will lead the three efficacy LLs 1, 2, 3 in OW, PW and OH respectively and prepare complete study protocols, including SOPs in accordance with good clinical practice (GCP) standards. The trials will be performed in Trikala-Greece and León-Spain for OW, Catania-Italy and Limassol-Cyprus for PW, and in Barcelona-Spain and Nicosia-Cyprus for OH. UCY in collaboration with partners UNICT, UTH, ULE, and VHIR will submit applications and acquire ethical and administrative approvals for the performance of the randomised controlled clinical trials at the six sites. For LL4, UNL in collaboration with UA will prepare the tools and methods for testing the feasibility and user acceptance of an EWRS and an evidence-based set of prevention interventions for zoonotic diseases. For LL5, social scientists and healthcare specialists from UCY and UNICT in collaboration with HIO will prepare the methodology for the adaptation procedures of the prototype Climate Resilience for Frontline Clinics toolkit, taking into consideration the output of T1.3, while EBOS and AIN will provide horizontal technical support to all LLs. (Outputs: D4.1, D4.2)

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Task T4.2 - Reduce exposure to heat and air pollution and mitigate health effects in outdoor workers (LL1), (Leader: UTH; Participants: ULE, TRIKALA, MLSA) [M15-M39]
Task T4.3 - Reduce exposure to heat and air pollution and mitigate health effects in pregnant women (LL2) (Leader: UNICT; Participants: UCY, ARNAS) [M15-M39]
Task T4.4 - Reduce exposure to heat and air pollution and mitigate health effects in older adults with hypertension (LL3) (Leader: VHIR; Participants: UCY, EKYSY) [M15-M39]

The methodology for the three LL carried out in T4.2 (LL1), T4.3 (LL2) and T4.4 (LL3) is described below:
Study populations: In LL1, we will recruit 102 OW of municipality sector from Trikala Municipality-Greece and León Municipality-Spain. In LL2, we will recruit 102 PW from the Department of Obstetrics and Gynaecology of the ARNAS Garibaldi Hospital in Catania-Italy and the network of private Maternity Clinics in Limassol-Cyprus.
In LL3, we will recruit 102 OH from the roster of pensioners organizations or from primary care centers in Barcelona-Spain and in Nicosia-Cyprus, who have a physician's diagnosis of arterial hypertension and receive daily anti-hypertensive medication.
Design of randomised controlled trials (RCT): Subjects for each LL will be screened during Spring 2026 and 2027 for their eligibility to participate in the three randomized controlled trials. Inclusion criteria are distinct and specific for each LL and are described in detail in LLs descriptions in 1.2.2.8.2. Exclusion criteria will be the same for the three LLs and are also described in detail in 1.2.2.8.2.
In May of 2026 and 2027, we will enrol in each LL 102 eligible participants who fulfil the respective inclusion criteria and subsequently monitor them for two months during June-July of 2026 and 2027. At the beginning of each study period in May, participants of each LL will be randomized into three parallel study groups to a) receive no alerts for high temperatures nor recommendations for mitigation of health effects (business as usual scenario, n=34), b) receive timely personal alerts for high temperatures and specific recommendations to reduce exposure to heat and mitigation of health effects in written and animated format through mobile phones, web applications and tools to be developed by the program (WP3) (heat mitigation intervention, n=34), and c) receive alerts and recommendations as in group (b) and in addition continuously use air cleaners with HEPA filter for removing PM from indoor air in their residences and workplace (heat and air pollution mitigation intervention, n=34) to provide evidence for health benefits. Exposure assessment: Personal exposures of participants will be monitored continuously during the two months (June-July) of observation with wearable sensors to be worn all the time. Wristband actigraphy with 3-axis accelerometer, gyroscope, light, heart rate sensors will assess physical activity levels and sleep-wake patterns, while an iButton will assess personal exposure to ambient (outdoor and indoor) temperature and humidity. Wristband actigraphy and iButton will operate on battery and store data for one month. The time participants spend indoors/outdoors from their residence and work premises (where applicable) during the two months of the study will be assessed using the global positioning system (GPS) of their smartphone and transmitted wirelessly to the secure e-platform created by WP3 via the residence's Wi-Fi network or through 4G/5G. During Clinic Visits, at the end of study months 1 (June) and 2 (July), stored data will be downloaded and wearable devices will be re-charged for next use. Measurements of indoor exposures to PM at the residence and work premises will be provided continuously by commercial lightweight sensors (Alpha sense). The sampling devices will be placed in the residence living area and the work premise (where applicable), where participants spend most of their time indoors and collect data for the two months of observation. These monitors will enable the precise profiling of the participant's exposure to indoor-outdoor temperature, humidity, light and indoor PM levels. Health measures assessment: During Clinic Visits at baseline (May), middle (June), and end of two-month (July) study period, the Pittsburgh Sleep Quality Index (PSQI) questionnaire, the Sleep Regularity Index questionnaire and the Hamilton Anxiety Rating questionnaire will be administered. During each Clinic Visit, participants will be provided with advanced actigraphy for 24 hours that measures continuously blood pressure (BP), oxygen saturation, ECG, heart rate variability. The device will be returned to Clinic the next day and stored data will be downloaded. Finally, during each Clinic Visit blood and urine samples will be obtained. In LL1 specifically, OW at baseline, middle, and end of two-month study period will be administered the workers Heat Strain Score Index (HSSI) questionnaire and have for the next 24 hours continuous assessments of their body core temperature by swallowing eCelsius medical capsule. This design will enable repeated (x3) assessments of subjective (questionnaires) and objective (wearable sensors) health outcomes, as well as biomarkers of hydration and systemic inflammation of participant's randomised in the three parallel study groups at the beginning (May), middle (June) and end of the two-month (July) study period.
Outcome measures: The primary exposure outcome for the three LLs will be personal ambient temperature profile of all participants, as measured during the two months of observation with the iButton. Secondary exposure outcomes will include personal exposure of all participants to environmental conditions (temperature, humidity, wind, and sunlight), as well as to thermal stress indicators (i.e., wet-bulb globe temperature), physical activity levels, indoor levels of PM at the residence and work premises during the two months of observation.
The primary health outcomes will be assessed at baseline, middle and end of the study period. For LL1 in OW it will be the workers HSSI, for LL2 in PW it will be PSQI questionnaire score, and for LL3 in OH it will be night-time dipping systolic/diastolic BP and heart rate. Secondary health outcomes will include daily heart rate and sleep-

wake patterns during the two study months, and repeated assessments at baseline, middle and end of the study period of Sleep Regularity Index and Hamilton Anxiety Rating scores, 24 hour profiles of systolic/diastolic BP, ECG, heart rate variability, night-time dipping systolic/diastolic BP and heart rate, and core body temperature (in OW), as well as biomarkers of systemic inflammation, renal function and hydration in blood (high sensitivity C-reactive protein, urea, creatinine, sodium, potassium, chloride, osmolality) and urine (creatinine, sodium, potassium, osmolality) at baseline, middle and end of study period. The sample and power calculation relied on a 20% difference, in the mean score of HSSI (for LL1) and PSQI (for LL2), as well as 20% change in the disrupted non-dipper status for night-time BP (for LL3) between the intervention and control groups and is described in detail in 1.2.2.8.2. In each LL 1, 2 and 3, we will create a dataset from measurements collected during the observation months from the three parallel groups. Statistical analysis of LL1, 2, and 3 data will be coordinated by UCY with the support of UTH, ULE, UNICT, and VHIR, as described in detail in 1.2.2.8.2. (Outputs: D4.3, D4.4)

Task T4.5 – Feasibility and user acceptance of an EWRS and prevention interventions for zoonotic diseases (LL4) (Leader: UNL; Participants: IMR, UA, EF, APMVEAC) [M15-M39]
In LL4, UNL and APMVEAC with the support of IMR, EF, and UA will assess the feasibility and user acceptance of the zoonotic component of the EWRS (T3.3) and the proposed interventions among high-risk professionals and citizen groups (veterinarians, dog shelter workers/volunteers, dog owners) and collect feedback from them and other stakeholders on the proposed prototype (survey methods to be used). APMVEAC will (i) disseminate information about the project and its aims to its members; (ii) invite members to download the mobile application and take part in the study (50-100 participants for a follow-up period of three months - May-July 2026); (iii) ensure that enough veterinarians and dog owners have downloaded the application. At the end of the observation period, APMVEAC will circulate online surveys to the participants to assess the feasibility, and user acceptance of the EWRS and guidelines. After the end of the LL and data analysis, a refined version of the EWRS will be made freely available by APMVEAC to its members through its website. This task will build upon CLIMOS project and Climate and Health cluster EWS products and results of LL4 lab will be used for fine tuning the EWRS citizen app and improving existing surveillance and prevention plans for sand fly-borne zoonotic diseases. (Outputs: D4.5, D4.6)

Task T4.6 – Increase preparedness of health systems to climate change risks (LL5) (Leader: HIO; Participants: UCY, UNICT, VHIR, DEASL, HSPH, ACARES) [M15-M39]
LL5 will assess the current state of healthcare system preparedness to climate change risks in EU member states across the Mediterranean, identify current perceptions and practices of healthcare system administrators and first-line healthcare professionals, prioritize gaps in practice and infrastructure and eventually suggest broad areas for improvement. To achieve this, a scoping review followed up by an online international survey study, primarily targeting first-line healthcare professionals and administrators will be carried out. Subsequently, LL5 will bring together experts in climate and disaster resilience (HSPH, ACARES, DEASL), healthcare system administrators (HIO, VHIR) and professionals (UCY, UNICT) to carry out a detailed, region-specific climate resilience and needs assessment for the healthcare system by employing co-creation methodologies, such as focus groups and stakeholder interviews, while considering future projections for extreme events. This assessment will follow the methodology suggested by the EU Expert Group on Health System Performance Assessment and employ a modified OECD HSRQ. Thematic areas to be addressed are human resources, material resources, surveillance capacity, emergency care, reliability of information infrastructure, primary and referral care and emergency planning. Based on this assessment, and using as a prototype the Climate Resilience for Frontline Clinics toolkit that has already been developed by the HSPH and ACARES, LL5 will develop a Mediterranean-specific climate resilience toolkit for healthcare systems. Towards tailoring the existing toolkit to the Mediterranean, a series of consultation workshops, under the oversight of HSPH and ACARES, will take place. The tailored toolkit is expected to include a variety of instruments for ensuring continuation of healthcare delivery during extreme events, as well as tools to prioritize high risk patients, clinical checklists, case study examples, and patient tips sheets. Finally, the toolkit will be integrated into the Policy Dashboard and will be accompanied by training material and short courses to facilitate its replication and impact maximization. (Outputs: D4.7, D4.8)

Task T4.7 – Tailored replication guidelines for all LLs (Leader: UCY; Participants: UNICT, UTH, ULE, VHIR, UNL, HIO) [M24-M40]
UCY with the support of UTH, ULE, UNICT, and VHIR will fine-tune the alert algorithms, EWRS and recommendations and finalize them, considering the efficacy of the exposure reduction and health mitigation interventions, as demonstrated in T4.2, T4.3 and T4.4. For zoonotic diseases, the final tailoring of the recommendations will be done by UNL and will rely upon the feasibility and user acceptance of the EWRS and guidelines as assessed among high-risk professionals and citizen groups (veterinarians, dog shelter workers/volunteers, dog owners) in T4.5. Finally, for the healthcare system preparedness, the final tailoring of the proposed replication guidelines will be done by UCY with the support of HIO, UNICT and VHIR and will also rely on the site-specific climate resilience and needs assessment carried out in T4.6. In addition, replication guidelines for healthcare system climate resilience will be supported by clear documentation describing the key principles and best practices, as well as proposed pathways that allow further localization and

customization. Finally, replications for all LLs will be supported through a technical assistance and troubleshooting mechanism, hosted by UCY, offering direct consultation to the replicating regions. (Output: D4.9, D4.10)

Work package WP5 – Impact maximisation and sustainability through replications, trainings, policy uptake and evaluation

Work Package Number	WP5	Lead Beneficiary	2 - CyI
Work Package Name	Impact maximisation and sustainability through replications, trainings, policy uptake and evaluation		
Start Month	13	End Month	48

Objectives

WP5 will include replications to other sites and monitoring of re-applicability and adoption of the proposed guidelines and solutions. In this regard, and to support impact maximization, WP5 includes the development of a Policy Dashboard and of a Climate Risk and Vulnerability Assessment Framework to enhance policy uptake by local and other authorities. Finally, to quantify the expected benefits of implementing the proposed solutions WP5 includes the performance of a Health Impact Assessment (HIA) and Socioeconomic Impact Assessment (SEIA) studies. The specific objectives of WP5 are:

- Replicate proposed solutions to different regions within the Mediterranean biogeographical region and assess their re-applicability and adoption.
- Maximise policy uptake through the integration of disease surveillance, data visualization and community-level vulnerability mapping tools in a Policy Dashboard.
- Carry out health and socio-economic impact assessment studies for the proposed solutions across all (LL) sites.
- Ensure knowledge transfer and maximise capacity building

Description

Task T5.1 – LLs replications to other sites and monitoring of re-applicability and adoption (Lead: UCY; Participants: UNICT, UTH, VHIR, UNL, NKUA, DEASL, HIO, ARNAS, AGUEDA, KOR) [M41-M48]
The tools, services and recommendations developed as part of WP4 LL1 - LL5 address common challenges across the Mediterranean biogeographical region. To demonstrate the wide re-applicability of the proposed solutions, UCY with the support of UTH, UNICT, UNL, and HIO will coordinate ten replications in six Mediterranean sites (NKUA, ARNAS, VHIR, KOR, AGUEDA, DEASL). The replication sites for each proposed solution are presented below. Re-applicability will be assessed by quantifying EWRS usage and healthcare system resilience toolkit utilization and acceptability, as well as by collecting information on users' perceptions across the replicating sites. For this purpose, the replication activities will rely on user engagement, conversion and retention metrics, as well as surveys and questionnaires to gather feedback directly from users (citizens, clinicians, regulatory authorities and healthcare administrators). (Output D5.1)

LL Proposed solution

1 Adoption of EWRS and recommendations for heat and air-pollution exposure reduction in OW
Demonstration site(s): Trikala (Greece), León (Spain), Replication site(s): Korydallos Municipality (Greece), Agueda Municipality (Portugal)

2 Adoption of EWRS and recommendations for heat and air-pollution exposure reduction in PW
Demonstration site(s):Catania, Sicily (Italy), Limassol (Cyprus), Replication site(s): Alexandra University Hospital Athens (Greece)
3 Adoption of EWRS and recommendations for heat and air-pollution exposure reduction in OH
Demonstration site(s): Barcelona (Spain),Nicosia (Cyprus) Replication site(s): Korydallos Municipality (Greece), Agueda Municipality (Portugal)

4 Adoption of EWRS for zoonotic disease and guidelines for high-risk professionals/citizens
Demonstration site(s): Lisbon (Portugal), Replication site(s):Korydallos Municipality (Greece)

5 Adoption of climate resilience and healthcare system/unit preparedness toolkit
Demonstration site(s): Health System - Countrywide (Cyprus), Replication site(s): ARNAS Garibaldi Hospital Catania

(Italy), Hospital in ASL ROMA 1, Rome (Italy), Alexandra University Hospital Athens (Greece), Parc Sanitari Pere Virgili Hospital, Barcelona (Spain)

Task T5.2 – Climate Risk and Vulnerability Assessment Framework and Policy uptake (Lead: CyI; Participants: UCY, NKUA, DEASL, EF, EBOS, AIN) [M13-M48]
In this task, CyI, along with UCY, DEASL, and NKUA will lead the development of a Climate Risk and Vulnerability Assessment Framework to support authorities to (i) systematically assess climate-related hazards in their region, including extreme temperatures, air quality changes, vector-borne diseases, and extreme weather events; (ii) evaluate the vulnerability of their regions, communities, and demographic groups to climate-related stressors through a vulnerability profiling; (iii) quantify the potential health impacts considering both short-term and long-term effects on physical and mental health (derived from T5.3). Further, T5.2 aims to enhance policy uptake by designing and setting up an online Policy Dashboard focusing on climate change related health impacts to allow regional policy makers and healthcare administrators to explore data, make informed decisions and gain access to policy implementation tools. Beyond the tailored evidence-based recommendations developed in T4.7, EBOS, AIN, and EF will include in the Dashboard user friendly and interactive visualisations, including knowledge graphs for easier knowledge extraction and interpretation, as well as a series of policy implementation tools in the form of (i) digital workplaces supporting local multisectoral response networks of stakeholders; (ii) data queries to update resource allocation and utilization info, tailored for healthcare administrators; (iii) a series of alerts, data cards, data graphs and other communication templates to standardise risk communication across the Mediterranean. In addition, to support targeted actions at the local level, the Dashboard will include a Heat Vulnerability Index (HVI) map for each LL site to identify areas most at risk to experience heat-related health effects, depending on community level demographic, environmental and socioeconomic determinants. Finally, Dashboard users will be able to select and customise key performance indicators, generate gauge graphs and receive feedback from other users to evaluate regional policy uptake. Feedback on the utility of these tools and established best practices will be provided to the new Health Emergency Preparedness and Response Authority. (Outputs: D5.2 - D5.4)

Task T5.3 –Health and Socioeconomic impact assessment (Lead: CyI; Participants: UCY, DEASL, UA, RG) [M26-M48]
A Health Impact Assessment (HIA) modelling study will be carried out by CyI with the support of UCY, DEASL, UA, and RG across LLs sites, to quantify the expected benefits of implementing the proposed solutions on health and human wellbeing at the population level. It will rely on inputs from WP2 for exposure-response relationships and WP4 for the effectiveness of the proposed solutions. In addition, to evaluate the wide-reaching impacts of introducing the proposed solutions at the societal level, Task 5.3 also includes the performance of a Socioeconomic Impact Assessment (SEIA) study. The SEIA study will address different impacts across several societal fields, such as in governance, environmental sustainability, stakeholder engagement, infrastructural and services resilience, capacity building and labour market dynamics. Finally, the SEIA will include a cost-benefit analysis (CBA), as the primary quantitative framework to compare the costs and benefits of the introduction of the proposed solutions in monetary terms. The CBA will specifically consider purchase, maintenance, as well as direct energy, repair and replacement costs for the proposed solutions. (Output: D5.5)

Task T5.4 - Knowledge Hub for knowledge transfer, trainings and capacity building (Lead: UNICT; Participants: UCY, UTH, ULE, VHIR, UNL, NKUA, DEASL, UA, EBOS, RG) [M13-M47]
This task will entail integrating instructional resources and educational initiatives into the Policy Dashboard via the Knowledge Hub. These measures will aim at enhancing the capacity of authorities and healthcare systems within the Mediterranean region to bolster their climate resilience. The main goal is to empower local communities and healthcare facilities to take ownership of climate resilience initiatives by providing them with the necessary knowledge and skills. To this end, UNICT with the support of EBOS and RG and in collaboration with ALL academic partners will organize workshops, brainstorming and targeted surveys to identify levers and mechanisms of change that foster climate resilience in local communities. This will also help us to leverage existing knowledge by identifying practices that have historically helped the communities cope with environmental challenges. Specifically, the activities will encompass the development of a comprehensive array of educational and communicational tools, encompassing written and animated materials. Moreover, a tailored training curriculum will be curated for healthcare professionals. This curriculum will offer specialized training on climate-resilient healthcare practices and the integration of climate considerations into healthcare planning. It will be centered around the mitigation of heat and air pollution exposure, as well as addressing the health repercussions associated with events such as wildfires and flooding. This comprehensive educational framework will draw insights from the outcomes of WP2 and WP4, in conjunction with the findings of Task 5.3. The Knowledge Hub, interfaced with the European Climate and Health Observatory, will represent a central repository and one-stop-shop for project outputs, white papers, best practices and policy guidelines related to climate-health interactions, and will facilitate collaboration among researchers, policymakers, healthcare professionals, and the public through discussion forums, webinars, and workshops. (Output D5.6)

Associated with document Ref. Ares(2024)3060123 - 25/04/2024

Work package WP6 – Dissemination, Communication, Exploitation

Work Package Number	WP6	Lead Beneficiary	24 - EF
Work Package Name	Dissemination, Communication, Exploitation		
Start Month	1	End Month	48

Objectives

WP6 will drive the project dissemination and communication campaigns. More specifically, under WP6, communication channels with stakeholders, communities, other projects and other initiatives will be established and engagement and dissemination activities will be organized according to a Dissemination, Communication and Exploitation Strategy and Plan. Furthermore, as part of this WP, the project's market analysis, business modelling will be developed and exploitation opportunities will be assessed.

• Create and implement a multifaceted dissemination and communication (D&C) strategy. The specific objectives of WP6 are:

• Engage a scalable community and organise capacity-building activities to underpin skills development.

• Undertake stakeholder base building and engagement; orchestration with other relevant initiatives and organise clustering and joint activities.

• Develop a convincing and sustainable exploitation and business plan in addition to identifying and planning for commercially sound post-project opportunities.

Description

Task T6.1 - Dissemination, Communication plan and activities (Lead: EF; Participants: ALL) [M01-M48]
This task, with ALL partners involved, coordinates the creation and management of engagement channels and delivers effective D&C activities to targeted stakeholder groups (elaborated in Section 2.2). The DCM will design a Dissemination, Communication and Exploitation Strategy and Plan by M06 (D6.1). The task will establish the brand identity and set up the project's communication channels, including: the project website, the social media channels, and the bi-annual newsletter. It will collaborate with all the WPs to identify, develop and publish rich media content, presenting the ambition, activities and results of the project to the identified target groups (Table 2.1) in a timely manner. Dissemination actions will be developed to maximise promotion of non-confidential results of the project through scientific publications and event presentations. This will require a range of 'push' and 'pull' approach, and facilitation of two-way exchange of information with many different stakeholders. Finally, task T6.1 will oversee the organisation of events (see Section 2.2) and support the promotion and organisation of material and trainings led by task T5.4. (Outputs: D6.1 - D6.5, D6.6)

Task T6.2 - Clustering, liaison with projects, communities, and initiatives and scale-up activities (Lead: ULE; Participants: UTH, VHIR, DEASL, CyI, EF) [M01-M48]
Task T6.2 will undertake liaison activities to enable cross-fertilisation and establish synergies with other relevant EU-funded projects and initiatives e.g., projects funded under the same call or work programme or related to climate change and health in other clusters. ULE supported by UTH, VHIR, DEASL, CyI, and EF will strategically organise joint networking activities, such as workshops, focus groups for exchange of knowledge, best practices and lessons learned or joint communication activities with other projects funded under other topics in the Mission Climate Adaptation, as well as in other relevant Missions, and under Horizon Europe, in particular those funded under Cluster 1 and its destination 2 "Living and working in a health-promoting environment". This task will also foresee the participation in the Mission Community of Practice that will be established amongst the Mission Charter signatories by the Mission Implementation Platform in 2023, thus contributing towards establishing a network for coordinating activities amongst all projects. (Outputs: D6.2 - D6.5)

Task T6.3 - Market analysis, business modelling and exploitation (Lead: RG; Participants: EF, EBOS, AIN) [M01-M48]
In this task RG will collaborate with EBOS, AIN and EF to design practice applications of project outcomes, focusing on the emergence of new market opportunities to achieve sustainability for ISMED-CLIM platform and associated tools and services. Both post-project technological and market feasibility of the project's outcomes and KERs (see Section 2.2.1) will be analysed and promoted in this task. Further, actions will be implemented towards exploiting the project's outcomes with its stakeholders and related entities across the EU by developing detailed exploitation and sustainability plans, reflecting pathways to commercialization and value creation. The platform provider, as well as component developers, will continue to provide support and maintenance, so as the ISMED-CLIM platform and associated tools remain operational beyond the project's lifetime. Task T6.3 will select the appropriate business model

to incentivise, acquire, and retain profitable users, and enable subsequent commercial growth. Key considerations will include the target market, the competitive landscape, the licensing and revenue opportunity, and the customer value proposition. (Outputs: D6.7 - D6.8)

Task T6.4 – Innovation and IPR activities (Lead: EF; Participants: EBOS, AIN, RG) [M01-M48]
EF supported by EBOS, AIN, and RG will identify and manage project innovation, advising the PC and partners on the scope, paying attention to discerning IPR at regular checkpoints. All IP produced will be monitored and the potential IPR attached to them (e.g., copyright, patent) will be also verified and cleared for the project's smooth execution. Further activities include: (i) design the IPR protection strategy to promote the sustainability of project results, building on existing assets, considering aspects defined in Section 2.2.2; (ii) establish IPR management procedures and associated activities; (iii) conduct a search on prior art for potential inventions, trademarks and other IPRs when necessary and evaluate the costs for potential IP protection; and (iv) monitor the project from the IPR point of view so that confidentiality and all the partners' defined IPRs in the CA are fully respected. (Outputs: D6.7, D6.8)

Work package WP7 – Project Management

Work Package Number	WP7	**Lead Beneficiary**	1 - UCY
Work Package Name	Project Management		
Start Month	1	**End Month**	48

Objectives

WP7 focuses on the project's scientific coordination and administrative management according to the rules and regulations set by the EC. Furthermore, under WP7, monitoring of the technical process will be carried out as well as review of the resulting deliverables to ensure compliance with project quality procedures. Lastly, WP7 will include the Quality Assurance and Risk Management as well as FAIR Data Management Plan and will ensure GDPR compliance. The detailed objectives of this WP are:
• Ensure the project meets its contractual commitments (deliverables, quality, risk management, etc.).
• Report on project progress and ensure the effective use of resources for realising project activities.
• Plan and facilitate communication and interactions within the consortium and with the EC.
• Facilitate the scientific and research success of the project through careful monitoring of progress, management of resources and coordination of activities.

Description

Task T7.1 - Project & Scientific coordination and administrative management (Lead: UCY; Participants: ALL) [M01-M48]
Task T7.1 will provide the overall project coordination, management, and administration, ensuring that the project is managed according to the rules and regulations set by the EC and will coordinate the consortium partners, WPs and stakeholders involved in the technical and research/scientific activities. The Project Management Board (PMB), which consists of the Project & Scientific Coordinator (PC), the Technical Manager (TM), the Innovation & IPR Manager (IM) and Dissemination & Communications Manager (DCM), the Quality Assurance & Risk Manager (QARM), the Ethics Manager/DPO (EM) and the WP leaders – WP1: Dr. Francesca de'Donato (F), WP2: Prof. Evangelia Samoli (F), WP3: Dr. Loizos Christofi (M) , WP4: Prof. Antonella Agodi (F), WP5: Prof. Theodoros Zachariades (M), WP6: Dr. Nenad Gligoric (M), WP7: Prof. Panayiotis Yiallouros (M) will coordinate all scientific and impact creating activities beyond the confines of a WP, keeping the WPs in line and the project in focus. It will monitor partner performance and task fulfilment, propose corrective actions, and ensure a smooth collaboration between WPs. Other activities include project administration, budget controlling and administrative management for the legal, contractual, and financial project operations, including resources allocation monitoring, progress monitoring according to the contractual schedule, project meetings management and reviews preparation. Potential modifications to the project plan will be addressed in collaboration with the EC, where adjustments may be necessary in ensuring successful progress and completion of the project. (Outputs: D7.1-D7.3)

Task T7.2 – Technical Management (Lead: AIN) [M01-M48]
Execution of the overall technical and scientific management of the project including: (i) monitor the technical progress according to the contractual schedule; (ii) prepare technical project reviews; (iii) monitor the flow of technical information among the different WPs to develop a common understanding and technical coherence, avoiding deviations

resulting from lack of synchronisation between technical activities; (iv) monitor and control the technical progress per WP to ensure that objectives are met; (v) inform the PC in case of any deviation in the technical directions or delays in the developments; (vi) review technically the deliverables to ensure compliance with project quality procedures; (vii) provide support to external project affairs, centralising and compiling the available material from the different WPs. WP leaders will support the TM in fulfilling the task's obligations. (Outputs: D7.1-D7.3)

Task T7.3 - Quality Assurance and Risk Management (Lead: RG) [M01-M48]
This task entails the design and implementation of QA procedures with particular focus on monitoring review activities built into the work program and submitting quality review reports. A quality plan within the Project Quality Handbook will specify the quality procedures, internal and external peer reviews, control, monitoring and reporting activities to be implemented during the project to ensure satisfactory quality standards. Implementation of the plan includes the risk library and risk monitoring (several outlined in Table 3.1e), the processes and procedures for risk management. Reporting will be performed by all partners in each WP, coordinated by the QARM who will oversee project operational risks and framework level barriers/risks and monitor progress to ensure that proactive measures are taken to mitigate risks, which could jeopardize the planned project outcomes. (Outputs: D7.7, D7.8)

Task T7.4 – Data, GDPR, ethics, legal, gender and socioeconomic monitoring (Lead: UCY) [M01-M48]
A FAIR Data Management Plan (DMP) will be delivered by M06, and specify: (i) data formats and metadata collected, processed and/or generated; (ii) methodology and standards applied to ensure interoperability, following the Metadata Standards Directory by the Research Data Alliance; (iii) when and how data will be made openly accessible; (iv) how data and samples will be curated and preserved via storage and backup procedures; (v) how data reusability will be fostered; and (vi) how data security will be preserved, in accordance with Directive 95/46/EC, EU GDPR May 2018. Data handled during and after the project will follow the FAIR data principles. We will participate in the Open Research Data Pilot, enabling open access and reuse of the data generated by Horizon Europe projects. Also, the DMP, revised by M24, will include a data protection impact assessment and case validations, to ensure the project follows a data protection-by-design approach. The EM will ensure the project's foundation is ethically compliant and responds to the EC's ethics requirements, by delivering legal guidelines to create the baseline for a legally compliant project framework. Guidance will be provided on how key societal values are affected, i.e., equality, privacy, and data protection, and safeguarded, whilst remaining cognizant of public health research requirements. Security and privacy issues will be identified by conducting a thorough analysis of the building blocks to be utilized. T7.4 will lead to the identification of legislation, principles, and values regarding the sharing of personal and non-personal data, including data within the context of the LLs, such as participants' health data. The outcome will result in a description of legal requirements to be considered in development of the envisaged technologies and integrated into the system design. The resulting deliverable will explain how partners will approach de-identification of data (anonymization/pseudo-anonymization techniques); informed consent procedures and templates; opinions of ethics committees; data protection and transfer policies; and justification for processing different categories of sensitive data. (Output: D7.4 - D7.6)

STAFF EFFORT

Staff effort per participant

Grant Preparation (Work packages - Effort screen) — Enter the info.

Participant	WP1	WP2	WP3	WP4	WP5	WP6	WP7	Total Person-Months
1 - UCY	12.00	9.00	9.00	39.00	19.00	8.00	26.00	122.00
2 - CyI	4.00	16.00	2.00		25.00	4.00	1.00	52.00
3 - HIO	3.00		1.00	16.00	1.00	1.00	1.00	23.00
4 - EBOS	12.00		41.00	5.00	14.00	5.00	1.00	78.00
5 - EKYSY	2.00			8.00		1.00	1.00	12.00
6 - UTH	4.00		3.00	30.00	5.00	8.00	1.00	51.00
7 - NKUA	6.00	22.00	2.00		10.00	4.00	1.00	45.00
8 - KOR	2.00				16.00	4.00	1.00	23.00
9 - MLSA	2.00			6.00	2.00	1.00	1.00	12.00
10 - TRIKALA	3.00			6.00		2.00	1.00	12.00
11 - UNICT	5.00		3.00	44.00	11.00	3.00	1.00	67.00
12 - ARNAS	2.00			4.00	4.00	1.00	1.00	12.00
13 - DEASL	14.00	9.00	2.00	2.00	6.00	2.00	1.00	36.00
14 - ULE	4.00		3.00	23.00	4.00	8.00	1.00	43.00
15 - VHIR	4.00		3.00	34.00	12.00	8.00	1.00	62.00
16 - CSIC	4.00	10.00	2.00			1.00	1.00	18.00
17 - UNL	2.00	2.00	2.00	9.00	3.00	1.00	1.00	20.00
18 - UA	3.00	2.00	2.00	4.00	3.00	1.00	1.00	16.00
19 - AGUEDA	2.00				7.00	2.00	1.00	12.00

Staff effort per participant

Grant Preparation (Work packages - Effort screen) — Enter the info.

Participant	WP1	WP2	WP3	WP4	WP5	WP6	WP7	Total Person-Months
20 - APMVEAC	2.00			8.00		1.00	1.00	12.00
21 - ECMWF	2.00		14.00			1.00	1.00	18.00
22 - IMR	2.00	7.00	2.00	4.00		1.00	1.00	17.00
23 - AIN	4.00		40.00	5.00	5.00	4.00	11.00	69.00
24 - EF	6.00		20.00	4.00	2.00	16.00	1.00	49.00
25 - HSPH	2.00					1.00	1.00	4.00
26 - RG	3.00				6.00	11.00	11.00	31.00
27 - ACARES	5.00				1.00	1.00	1.00	8.00
Total Person-Months	116.00	77.00	151.00	251.00	156.00	101.00	72.00	924.00

LIST OF DELIVERABLES

Deliverables

Grant Preparation (Deliverables screen) — Enter the info.

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Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D1.1	Climate change and health policy landscape review	WP1	13 - DEASL	R — Document, report	PU - Public	12
D1.2	Regional Task Forces and stakeholder's mobilisation - Initial Version	WP1	13 - DEASL	R — Document, report	PU - Public	12
D1.3	Regional Task Forces and stakeholder's mobilisation - Final version	WP1	13 - DEASL	R — Document, report	PU - Public	38
D1.4	Proceedings of Regional Task Force workshop in Cyprus	WP1	1 - UCY	R — Document, report	PU - Public	12
D1.5	Proceedings of Regional Task Force workshop in Greece	WP1	7 - NKUA	R — Document, report	PU - Public	12
D1.6	Proceedings of Regional Task Force workshop in Italy	WP1	13 - DEASL	R — Document, report	PU - Public	12
D1.7	Proceedings of Regional Task Force workshop in Spain	WP1	15 - VHIR	R — Document, report	PU - Public	12
D1.8	Proceedings of Regional Task Force workshop in Portugal	WP1	17 - UNL	R — Document, report	PU - Public	12
D1.9	Customised recommendations and alerts - Initial version	WP1	1 - UCY	R — Document, report	PU - Public	14

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Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D1.10	Customised recommendations and alerts - Final version	WP1	1 - UCY	R — Document, report	PU - Public	38
D1.11	Platform architecture and digital tools specifications - Initial version	WP1	4 - EBOS	R — Document, report	PU - Public	14
D1.12	Platform architecture and digital tools specifications - Final version	WP1	4 - EBOS	R — Document, report	PU - Public	38
D2.1	Administrative data sets	WP2	7 - NKUA	DATA — data sets, microdata, etc	SEN - Sensitive	12
D2.2	Climate change effects on non-communicable diseases	WP2	7 - NKUA	R — Document, report	PU - Public	24
D2.3	Climate change effects on zoonotic diseases	WP2	2 - CyI	R — Document, report	PU - Public	24
D2.4	Vulnerability Assessment Framework and Knowledge Hub	WP2	7 - NKUA	R — Document, report	PU - Public	24
D3.1	Data processing - Initial report	WP3	23 - AIN	R — Document, report	PU - Public	14
D3.2	Data processing - Interim report	WP3	23 - AIN	R — Document, report	PU - Public	26
D3.3	Data processing - Final Report	WP3	23 - AIN	R — Document, report	PU - Public	40
D3.4	Early Warning and Response System (EWRS) - Initial Version	WP3	23 - AIN	OTHER	PU - Public	17

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Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D3.5	Early Warning and Response System (EWRS) - Interim version	WP3	23 - AIN	OTHER	PU - Public	29
D3.6	Early Warning and Response System (EWRS) - Final version	WP3	23 - AIN	OTHER	PU - Public	40
D3.7	ISMED-CLIM integrated platform and digital tools delivery - Initial version	WP3	4 - EBOS	OTHER	PU - Public	18
D3.8	ISMED-CLIM integrated platform and digital tools delivery - Interim version	WP3	4 - EBOS	OTHER	PU - Public	30
D3.9	ISMED-CLIM integrated platform and digital tools delivery - Final version	WP3	4 - EBOS	OTHER	PU - Public	41
D4.1	Living Lab planning and management - Initial report	WP4	1 - UCY	R — Document, report	PU - Public	15
D4.2	Living Lab planning and management - Final report	WP4	1 - UCY	R — Document, report	PU - Public	38
D4.3	LL1-3 results - Initial report	WP4	11 - UNICT	R — Document, report	PU - Public	25
D4.4	LL1-3 results - Final report	WP4	11 - UNICT	R — Document, report	PU - Public	37
D4.5	LL4 results - Initial report	WP4	17 - UNL	R — Document, report	PU - Public	25
D4.6	LL4 results - Final report	WP4	17 - UNL	R — Document, report	PU - Public	37
D4.7	LL5 results - Initial report	WP4	3 - HIO	R — Document, report	PU - Public	25

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Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D4.8	LL5 results - Final report	WP4	3 - HIO	R — Document, report	PU - Public	37
D4.9	LL material and replication guidelines - Initial report	WP4	1 - UCY	R — Document, report	PU - Public	25
D4.10	LL material and replication guidelines - Final report	WP4	1 - UCY	R — Document, report	PU - Public	38
D5.1	Replications and scale-up	WP5	1 - UCY	R — Document, report	PU - Public	48
D5.2	Policy Dashboard and guidelines - Initial version	WP5	4 - EBOS	OTHER	PU - Public	17
D5.3	Policy Dashboard and guidelines - Interim version	WP5	4 - EBOS	OTHER	PU - Public	29
D5.4	Policy Dashboard and guidelines - Final report	WP5	4 - EBOS	OTHER	PU - Public	48
D5.5	Health and socioeconomic impact assessment	WP5	2 - CyI	R — Document, report	PU - Public	48
D5.6	Training and capacity building	WP5	11 - UNICT	R — Document, report	PU - Public	37
D6.1	Project website	WP6	24 - EF	DEC —Websites, patent filings, videos, etc	PU - Public	3
D6.2	DEC strategy 1	WP6	24 - EF	R — Document, report	PU - Public	3
D6.3	DEC strategy 2	WP6	24 - EF	R — Document, report	PU - Public	18

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Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D6.4	DEC strategy 3	WP6	24 - EF	R — Document, report	PU - Public	36
D6.5	DEC strategy - Final report	WP6	24 - EF	R — Document, report	PU - Public	48
D6.6	Proceedings of final conference	WP6	24 - EF	R — Document, report	PU - Public	48
D6.7	Exploitation strategy and IPR management 1	WP6	24 - EF	R — Document, report	SEN - Sensitive	36
D6.8	Exploitation strategy and IPR management 2	WP6	24 - EF	R — Document, report	SEN - Sensitive	48
D7.1	Project operations handbook 1	WP7	1 - UCY	R — Document, report	SEN - Sensitive	6
D7.2	Project operations handbook 2	WP7	1 - UCY	R — Document, report	SEN - Sensitive	18
D7.3	Project operations handbook 3	WP7	1 - UCY	R — Document, report	SEN - Sensitive	36
D7.4	Data Management Plan 1	WP7	1 - UCY	DMP — Data Management Plan	SEN - Sensitive	6
D7.5	Data Management Plan 2	WP7	1 - UCY	DMP — Data Management Plan	SEN - Sensitive	18
D7.6	Data Management Plan 3	WP7	1 - UCY	DMP — Data Management Plan	SEN - Sensitive	48
D7.7	Quality Assurance and Risk Management Plan 1	WP7	1 - UCY	R — Document, report	SEN - Sensitive	18
D7.8	Quality Assurance and Risk Management Plan 2	WP7	1 - UCY	R — Document, report	SEN - Sensitive	36

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Deliverable No	Deliverable Name	Work Package No	Lead Beneficiary	Type	Dissemination Level	Due Date (month)
D7.9	Legal, ethical and gender issues manual 1	WP7	1 - UCY	R — Document, report	SEN - Sensitive	18
D7.10	Legal, ethical and gender issues manual 2	WP7	1 - UCY	R — Document, report	SEN - Sensitive	36
D7.11	Legal, ethical and gender issues manual 3	WP7	1 - UCY	R — Document, report	SEN - Sensitive	48

Deliverable D1.1 – Climate change and health policy landscape review

Deliverable Number	D1.1	**Lead Beneficiary**	13 - DEASL
Deliverable Name	Climate change and health policy landscape review		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	12	**Work Package No**	WP1

Description
Report reviewing health/disease related climate change impacts and effectiveness of existing policy measures across the Mediterranean

Deliverable D1.2 – Regional Task Forces and stakeholder's mobilisation - Initial Version

Deliverable Number	D1.2	**Lead Beneficiary**	13 - DEASL
Deliverable Name	Regional Task Forces and stakeholder's mobilisation - Initial Version		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	12	**Work Package No**	WP1

Description
Initial report on stakeholders' mapping, user needs and functional/non-functional requirements elicitation and analysis

Deliverable D1.3 – Regional Task Forces and stakeholder's mobilisation - Final version

Deliverable Number	D1.3	**Lead Beneficiary**	13 - DEASL
Deliverable Name	Regional Task Forces and stakeholder's mobilisation - Final version		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	38	**Work Package No**	WP1

Description
Final report on stakeholders' mapping, user needs and functional/non-functional requirements elicitation and analysis

Deliverable D1.4 – Proceedings of Regional Task Force workshop in Cyprus

Deliverable Number	D1.4	**Lead Beneficiary**	1 - UCY
Deliverable Name	Proceedings of Regional Task Force workshop in Cyprus		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	12	**Work Package No**	WP1

Description
Report describing participants, actions and outcomes of the Regional Task Force workshop in Cyprus

Associated with document Ref. Ares(2024)3060123 - 25/04/2024

Deliverable D1.5 – Proceedings of Regional Task Force workshop in Greece

Deliverable Number	D1.5	Lead Beneficiary	7 - NKUA
Deliverable Name	Proceedings of Regional Task Force workshop in Greece		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	12	Work Package No	WP1

Description
Report describing participants, actions and outcomes of the Regional Task Force workshop in Greece

Deliverable D1.6 – Proceedings of Regional Task Force workshop in Italy

Deliverable Number	D1.6	Lead Beneficiary	13 - DEASL
Deliverable Name	Proceedings of Regional Task Force workshop in Italy		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	12	Work Package No	WP1

Description
Report describing participants, actions and outcomes of the Regional Task Force workshop in Italy

Deliverable D1.7 – Proceedings of Regional Task Force workshop in Spain

Deliverable Number	D1.7	Lead Beneficiary	15 - VHIR
Deliverable Name	Proceedings of Regional Task Force workshop in Spain		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	12	Work Package No	WP1

Description
Report describing participants, actions and outcomes of the Regional Task Force workshop in Spain

Deliverable D1.8 – Proceedings of Regional Task Force workshop in Portugal

Deliverable Number	D1.8	Lead Beneficiary	17 - UNL
Deliverable Name	Proceedings of Regional Task Force workshop in Portugal		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	12	Work Package No	WP1

Description
Report describing participants, actions and outcomes of the Regional Task Force workshop in Portugal

Associated with document Ref. Ares(2024)3060123 - 25/04/2024

Deliverable D1.9 – Customised recommendations and alerts - Initial version

Deliverable Number	D1.9	**Lead Beneficiary**	1 - UCY
Deliverable Name	Customised recommendations and alerts - Initial version		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	14	**Work Package No**	WP1

Description
Initial report on customised recommendations and alerts to be tested and evaluated in LLs deep demonstrations

Deliverable D1.10 – Customised recommendations and alerts - Final version

Deliverable Number	D1.10	**Lead Beneficiary**	1 - UCY
Deliverable Name	Customised recommendations and alerts - Final version		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	38	**Work Package No**	WP1

Description
Final report on customised recommendations and alerts tested and evaluated in LLs deep demonstrations

Deliverable D1.11 – Platform architecture and digital tools specifications - Initial version

Deliverable Number	D1.11	**Lead Beneficiary**	4 - EBOS
Deliverable Name	Platform architecture and digital tools specifications - Initial version		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	14	**Work Package No**	WP1

Description
Initial report on the platform architecture and specifications of its associated digital tools

Deliverable D1.12 – Platform architecture and digital tools specifications - Final version

Deliverable Number	D1.12	**Lead Beneficiary**	4 - EBOS
Deliverable Name	Platform architecture and digital tools specifications - Final version		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	38	**Work Package No**	WP1

Description
Final report on the platform architecture and specifications of its associated digital tools

Associated with document Ref. Ares(2024)3060123 - 25/04/2024

Deliverable D2.1 – Administrative data sets

Deliverable Number	D2.1	**Lead Beneficiary**	7 - NKUA
Deliverable Name	Administrative data sets		
Type	DATA — data sets, microdata, etc	**Dissemination Level**	SEN - Sensitive
Due Date (month)	12	**Work Package No**	WP2

Description
Report on harmonised health and exposure data for epidemiological analyses

Deliverable D2.2 – Climate change effects on non-communicable diseases

Deliverable Number	D2.2	**Lead Beneficiary**	7 - NKUA
Deliverable Name	Climate change effects on non-communicable diseases		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	24	**Work Package No**	WP2

Description
Report presenting epidemiological analysis on NCDs

Deliverable D2.3 – Climate change effects on zoonotic diseases

Deliverable Number	D2.3	**Lead Beneficiary**	2 - CyI
Deliverable Name	Climate change effects on zoonotic diseases		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	24	**Work Package No**	WP2

Description
Report presenting epidemiological analysis on zoonotic diseases

Deliverable D2.4 – Vulnerability Assessment Framework and Knowledge Hub

Deliverable Number	D2.4	**Lead Beneficiary**	7 - NKUA
Deliverable Name	Vulnerability Assessment Framework and Knowledge Hub		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	24	**Work Package No**	WP2

Description
Report presenting results of regional vulnerability assessments and description of Knowledge Hub

Associated with document Ref. Ares(2024)3060123 - 25/04/2024

Deliverable D3.1 – Data processing - Initial report

Deliverable Number	D3.1	Lead Beneficiary	23 - AIN
Deliverable Name	Data processing - Initial report		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	14	Work Package No	WP3

Description
Initial report on Data Quality, Data Harmonization and Data Management Component

Deliverable D3.2 – Data processing - Interim report

Deliverable Number	D3.2	Lead Beneficiary	23 - AIN
Deliverable Name	Data processing - Interim report		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	26	Work Package No	WP3

Description
Interim report on Data Quality, Data Harmonization and Data Management Component

Deliverable D3.3 – Data processing - Final Report

Deliverable Number	D3.3	Lead Beneficiary	23 - AIN
Deliverable Name	Data processing - Final Report		
Type	R — Document, report	Dissemination Level	PU - Public
Due Date (month)	40	Work Package No	WP3

Description
Final report on Data Quality, Data Harmonization and Data Management Component

Deliverable D3.4 – Early Warning and Response System (EWRS) - Initial Version

Deliverable Number	D3.4	Lead Beneficiary	23 - AIN
Deliverable Name	Early Warning and Response System (EWRS) - Initial Version		
Type	OTHER	Dissemination Level	PU - Public
Due Date (month)	17	Work Package No	WP3

Description
Initial version and reporting of the Early Warning and Response System

Associated with document Ref. Ares(2024)3060123 - 25/04/2024

Deliverable D3.5 – Early Warning and Response System (EWRS) - Interim version

Deliverable Number	D3.5	**Lead Beneficiary**	23 - AIN
Deliverable Name	Early Warning and Response System (EWRS) - Interim version		
Type	OTHER	**Dissemination Level**	PU - Public
Due Date (month)	29	**Work Package No**	WP3

Description
Interim version and reporting of the Early Warning and Response System

Deliverable D3.6 – Early Warning and Response System (EWRS) - Final version

Deliverable Number	D3.6	**Lead Beneficiary**	23 - AIN
Deliverable Name	Early Warning and Response System (EWRS) - Final version		
Type	OTHER	**Dissemination Level**	PU - Public
Due Date (month)	40	**Work Package No**	WP3

Description
Final version and reporting of the Early Warning and Response System

Deliverable D3.7 – ISMED-CLIM integrated platform and digital tools delivery - Initial version

Deliverable Number	D3.7	**Lead Beneficiary**	4 - EBOS
Deliverable Name	ISMED-CLIM integrated platform and digital tools delivery - Initial version		
Type	OTHER	**Dissemination Level**	PU - Public
Due Date (month)	18	**Work Package No**	WP3

Description
Initial version of the integrated platform

Deliverable D3.8 – ISMED-CLIM integrated platform and digital tools delivery - Interim version

Deliverable Number	D3.8	**Lead Beneficiary**	4 - EBOS
Deliverable Name	ISMED-CLIM integrated platform and digital tools delivery - Interim version		
Type	OTHER	**Dissemination Level**	PU - Public
Due Date (month)	30	**Work Package No**	WP3

Description
Interim version of the integrated platform

Associated with document Ref. Ares(2024)3060123 - 25/04/2024

Deliverable D3.9 – ISMED-CLIM integrated platform and digital tools delivery - Final version

Deliverable Number	D3.9	**Lead Beneficiary**	4 - EBOS
Deliverable Name	ISMED-CLIM integrated platform and digital tools delivery - Final version		
Type	OTHER	**Dissemination Level**	PU - Public
Due Date (month)	41	**Work Package No**	WP3

Description
Final version of the integrated platform

Deliverable D4.1 – Living Lab planning and management - Initial report

Deliverable Number	D4.1	**Lead Beneficiary**	1 - UCY
Deliverable Name	Living Lab planning and management - Initial report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	15	**Work Package No**	WP4

Description
Initial report outlining the LL setup and approvals received from all bioethics/personal data protection committees in each participating site and data protection impact assessment reports.

Deliverable D4.2 – Living Lab planning and management - Final report

Deliverable Number	D4.2	**Lead Beneficiary**	1 - UCY
Deliverable Name	Living Lab planning and management - Final report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	38	**Work Package No**	WP4

Description
Final report outlining the LL operational management including approvals received from all bioethics/personal data protection committees in each participating site and data protection impact assessment reports

Deliverable D4.3 – LL1-3 results - Initial report

Deliverable Number	D4.3	**Lead Beneficiary**	11 - UNICT
Deliverable Name	LL1-3 results - Initial report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	25	**Work Package No**	WP4

Description
Initial report on the results obtained from testing and quantifying the efficacy of the EWRS and evidence based

interventions to reduce exposure to high temperature and air pollution and related health effects in vulnerable citizen groups.

Deliverable D4.4 – LL1-3 results - Final report

Deliverable Number	D4.4	**Lead Beneficiary**	11 - UNICT
Deliverable Name	LL1-3 results - Final report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	37	**Work Package No**	WP4

Description
Final report on the results obtained from testing and quantifying the efficacy of the EWRS and evidence-based interventions to reduce exposure to high temperature and air pollution and related health effects in vulnerable citizen groups.

Deliverable D4.5 – LL4 results - Initial report

Deliverable Number	D4.5	**Lead Beneficiary**	17 - UNL
Deliverable Name	LL4 results - Initial report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	25	**Work Package No**	WP4

Description
Initial report on the results obtained from testing and demonstrating the feasibility and user acceptance of the EWRS and a set of evidence-based interventions for animal handlers against climate-change prone zoonotic diseases.

Deliverable D4.6 – LL4 results - Final report

Deliverable Number	D4.6	**Lead Beneficiary**	17 - UNL
Deliverable Name	LL4 results - Final report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	37	**Work Package No**	WP4

Description
Final report on the results obtained from testing and demonstrating the feasibility and user acceptance of the EWRS and a set of evidence-based interventions for animal handlers against climate-change prone zoonotic diseases.

Deliverable D4.7 – LL5 results - Initial report

Deliverable Number	D4.7	**Lead Beneficiary**	3 - HIO
Deliverable Name	LL5 results - Initial report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	25	**Work Package No**	WP4

Description
Initial report on the adapted tailored toolkit for increasing healthcare systems' preparedness to climate risks across the Mediterranean region provided via the policy dashboard

Deliverable D4.8 – LL5 results - Final report

Deliverable Number	D4.8	**Lead Beneficiary**	3 - HIO
Deliverable Name	LL5 results - Final report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	37	**Work Package No**	WP4

Description
Final reports on the adapted tailored toolkit for increasing healthcare systems' preparedness to climate risks across the Mediterranean region provided via the policy dashboard

Deliverable D4.9 – LL material and replication guidelines - Initial report

Deliverable Number	D4.9	**Lead Beneficiary**	1 - UCY
Deliverable Name	LL material and replication guidelines - Initial report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	25	**Work Package No**	WP4

Description
Initial report on the activities carried out within the LLs (co-creation sessions, design thinking, design-tables etc.).

Deliverable D4.10 – LL material and replication guidelines - Final report

Deliverable Number	D4.10	**Lead Beneficiary**	1 - UCY
Deliverable Name	LL material and replication guidelines - Final report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	38	**Work Package No**	WP4

Description
Final report on the activities carried out within the LLs (co-creation sessions, design thinking, design-tables etc.), as well as guidelines to support replications.

Deliverable D5.1 – Replications and scale-up

Deliverable Number	D5.1	**Lead Beneficiary**	1 - UCY
Deliverable Name	Replications and scale-up		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	48	**Work Package No**	WP5

Description
Report on the outcome of replication activities

Deliverable D5.2 – Policy Dashboard and guidelines - Initial version

Deliverable Number	D5.2	**Lead Beneficiary**	4 - EBOS
Deliverable Name	Policy Dashboard and guidelines - Initial version		
Type	OTHER	**Dissemination Level**	PU - Public
Due Date (month)	17	**Work Package No**	WP5

Description
Initial version of the policy dashboard/tools and report on formulation of policy guidelines to contribute to policy shaping and supporting implementation of new policy decisions

Deliverable D5.3 – Policy Dashboard and guidelines - Interim version

Deliverable Number	D5.3	**Lead Beneficiary**	4 - EBOS
Deliverable Name	Policy Dashboard and guidelines - Interim version		
Type	OTHER	**Dissemination Level**	PU - Public
Due Date (month)	29	**Work Package No**	WP5

Description
Interim version of the policy dashboard/ tools and report on formulation of policy guidelines to contribute to policy shaping and supporting implementation of new policy decisions.

Deliverable D5.4 – Policy Dashboard and guidelines - Final report

Deliverable Number	D5.4	**Lead Beneficiary**	4 - EBOS
Deliverable Name	Policy Dashboard and guidelines - Final report		
Type	OTHER	**Dissemination Level**	PU - Public
Due Date (month)	48	**Work Package No**	WP5

Description
Final version of the policy dashboard/ tools and report on formulation of policy guidelines to contribute to policy shaping and supporting implementation of new policy decisions.

Deliverable D5.5 – Health and socioeconomic impact assessment

Deliverable Number	D5.5	**Lead Beneficiary**	2 - CyI
Deliverable Name	Health and socioeconomic impact assessment		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	48	**Work Package No**	WP5

Description
Report describing health and socioeconomic impact assessment.

Deliverable D5.6 – Training and capacity building

Deliverable Number	D5.6	**Lead Beneficiary**	11 - UNICT
Deliverable Name	Training and capacity building		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	37	**Work Package No**	WP5

Description
Report outlining the training material produced and realisation of bridging with Climate-ADAPT platform.

Deliverable D6.1 – Project website

Deliverable Number	D6.1	**Lead Beneficiary**	24 - EF
Deliverable Name	Project website		
Type	DEC —Websites, patent filings, videos, etc	**Dissemination Level**	PU - Public
Due Date (month)	3	**Work Package No**	WP6

Description
Delivery of ISMED-CLIM project website

Deliverable D6.2 – DEC strategy 1

Deliverable Number	D6.2	**Lead Beneficiary**	24 - EF
Deliverable Name	DEC strategy 1		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	3	**Work Package No**	WP6

Description
First report on dissemination, exploitation and communication strategy and periodic activities.

Deliverable D6.3 – DEC strategy 2

Deliverable Number	D6.3	**Lead Beneficiary**	24 - EF
Deliverable Name	DEC strategy 2		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	18	**Work Package No**	WP6

Description
Second report on dissemination, exploitation and communication strategy and periodic activities.

Deliverable D6.4 – DEC strategy 3

Deliverable Number	D6.4	**Lead Beneficiary**	24 - EF
Deliverable Name	DEC strategy 3		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	36	**Work Package No**	WP6

Description
Third report on dissemination, exploitation and communication strategy and periodic activities.

Deliverable D6.5 – DEC strategy - Final report

Deliverable Number	D6.5	**Lead Beneficiary**	24 - EF
Deliverable Name	DEC strategy - Final report		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	48	**Work Package No**	WP6

Description
Final report on dissemination, exploitation and communication strategy and periodic activities.

Deliverable D6.6 – Proceedings of final conference

Deliverable Number	D6.6	**Lead Beneficiary**	24 - EF
Deliverable Name	Proceedings of final conference		
Type	R — Document, report	**Dissemination Level**	PU - Public
Due Date (month)	48	**Work Package No**	WP6

Description
Report on the participants, actions and output of ISMED-CLIM final conference.

Deliverable D6.7 – Exploitation strategy and IPR management 1

Deliverable Number	D6.7	**Lead Beneficiary**	24 - EF
Deliverable Name	Exploitation strategy and IPR management 1		
Type	R — Document, report	**Dissemination Level**	SEN - Sensitive
Due Date (month)	36	**Work Package No**	WP6

Description

First report on ISMED-CLIM platform and digital tools exploitation including market-entry preparation plan, coherent business model(s) and intellectual property rights management

Deliverable D6.8 – Exploitation strategy and IPR management 2

Deliverable Number	D6.8	**Lead Beneficiary**	24 - EF
Deliverable Name	Exploitation strategy and IPR management 2		
Type	R — Document, report	**Dissemination Level**	SEN - Sensitive
Due Date (month)	48	**Work Package No**	WP6

Description
First report on ISMED-CLIM platform and digital tools exploitation including market-entry preparation plan, coherent business model(s) and intellectual property rights management

Deliverable D7.1 – Project operations handbook 1

Deliverable Number	D7.1	**Lead Beneficiary**	1 - UCY
Deliverable Name	Project operations handbook 1		
Type	R — Document, report	**Dissemination Level**	SEN - Sensitive
Due Date (month)	6	**Work Package No**	WP7

Description
First report providing management level overview of the activities carried out, including technical and scientific management and a quality handbook outlining risk registry, quality procedures, progress and actions to resolve issues.

Deliverable D7.2 – Project operations handbook 2

Deliverable Number	D7.2	**Lead Beneficiary**	1 - UCY
Deliverable Name	Project operations handbook 2		
Type	R — Document, report	**Dissemination Level**	SEN - Sensitive
Due Date (month)	18	**Work Package No**	WP7

Description
Second report providing management level overview of the activities carried out, including technical and scientific management and a quality handbook outlining risk registry, quality procedures, progress and actions to resolve issues.

Deliverable D7.3 – Project operations handbook 3

Deliverable Number	D7.3	**Lead Beneficiary**	1 - UCY
Deliverable Name	Project operations handbook 3		
Type	R — Document, report	**Dissemination Level**	SEN - Sensitive

Due Date (month)	36	Work Package No	WP7

Description
Final report providing management level overview of the activities carried out, including technical and scientific management and a quality handbook outlining risk registry, quality procedures, progress and actions to resolve issues.

Deliverable D7.4 – Data Management Plan 1

Deliverable Number	D7.4	Lead Beneficiary	1 - UCY
Deliverable Name	Data Management Plan 1		
Type	DMP — Data Management Plan	Dissemination Level	SEN - Sensitive
Due Date (month)	6	Work Package No	WP7

Description
First version of Data Management Plan ensuring data security, in accordance with Directive 95/46/EC, EU GDPR and FAIR data principles.

Deliverable D7.5 – Data Management Plan 2

Deliverable Number	D7.5	Lead Beneficiary	1 - UCY
Deliverable Name	Data Management Plan 2		
Type	DMP — Data Management Plan	Dissemination Level	SEN - Sensitive
Due Date (month)	18	Work Package No	WP7

Description
Second version of Data Management Plan ensuring data security, in accordance with Directive 95/46/EC, EU GDPR and FAIR data principles.

Deliverable D7.6 – Data Management Plan 3

Deliverable Number	D7.6	Lead Beneficiary	1 - UCY
Deliverable Name	Data Management Plan 3		
Type	DMP — Data Management Plan	Dissemination Level	SEN - Sensitive
Due Date (month)	48	Work Package No	WP7

Description
Final version of Data Management Plan ensuring data security, in accordance with Directive 95/46/EC, EU GDPR and FAIR data principles.

Associated with document Ref. Ares(2024)3060123 - 25/04/2024

Deliverable D7.7 – Quality Assurance and Risk Management Plan 1

Deliverable Number	D7.7	**Lead Beneficiary**	1 - UCY
Deliverable Name	Quality Assurance and Risk Management Plan 1		
Type	R — Document, report	**Dissemination Level**	SEN - Sensitive
Due Date (month)	18	**Work Package No**	WP7

Description
First version of Quality Assurance and Risk Management Plan with the design and implementation of quality assurance procedures, internal and external peer reviews as well as control, monitoring and reporting activities.

Deliverable D7.8 – Quality Assurance and Risk Management Plan 2

Deliverable Number	D7.8	**Lead Beneficiary**	1 - UCY
Deliverable Name	Quality Assurance and Risk Management Plan 2		
Type	R — Document, report	**Dissemination Level**	SEN - Sensitive
Due Date (month)	36	**Work Package No**	WP7

Description
Final version of Quality Assurance and Risk Management Plan with the design and implementation of quality assurance procedures, internal and external peer reviews as well as control, monitoring and reporting activities.

Deliverable D7.9 – Legal, ethical and gender issues manual 1

Deliverable Number	D7.9	**Lead Beneficiary**	1 - UCY
Deliverable Name	Legal, ethical and gender issues manual 1		
Type	R — Document, report	**Dissemination Level**	SEN - Sensitive
Due Date (month)	18	**Work Package No**	WP7

Description
First report on legal, ethical and gender issues including analytic ethics framework and templates for informed consent and data privacy regarding all participatory activities as well as socioeconomic and gender balance monitoring.

Deliverable D7.10 – Legal, ethical and gender issues manual 2

Deliverable Number	D7.10	**Lead Beneficiary**	1 - UCY
Deliverable Name	Legal, ethical and gender issues manual 2		
Type	R — Document, report	**Dissemination Level**	SEN - Sensitive
Due Date (month)	36	**Work Package No**	WP7

Description
Second report on legal, ethical and gender issues including analytic ethics framework and templates for informed consent and data privacy regarding all participatory activities as well as socioeconomic and gender balance monitoring.

Deliverable D7.11 – Legal, ethical and gender issues manual 3

Deliverable Number	D7.11	**Lead Beneficiary**	1 - UCY
Deliverable Name	Legal, ethical and gender issues manual 3		
Type	R — Document, report	**Dissemination Level**	SEN - Sensitive
Due Date (month)	48	**Work Package No**	WP7

Description
Final report on legal, ethical and gender issues including analytic ethics framework and templates for informed consent and data privacy regarding all participatory activities as well as socioeconomic and gender balance monitoring.

LIST OF MILESTONES

Milestones

Grant Preparation (Milestones screen) — Enter the info.

Milestone No	Milestone Name	Work Package No	Lead Beneficiary	Means of Verification	Due Date (month)
1	Start of project	WP7	1 - UCY	Launch of project and minutes of kick-off meeting	1
2	DEC plan	WP6	24 - EF	Submission of D6.2	3
3	Creation of an Advisory Board	WP7	1 - UCY	List of names participating in the Advisory Board	3
4	DMP Plan	WP7	1 - UCY	Submission of D7.4	6
5	Regional Task Forces and requirements	WP1, WP2	13 - DEASL	Submission of D1.2, D1.4, D1.5, D1.6, D1.7, D1.8	12
6	Yearly general assemblies	WP1, WP7	1 - UCY	Updates in M24, M36 and M48. Report on proceedings	12
7	Customized recommendations and specifications	WP1, WP3	1 - UCY	Submission of D1.9, D1.11, D3.1	14
8	LL preparedness and project review; Phase 1 completion	WP1, WP6, WP7, WP2, WP4, WP3, WP5	11 - UNICT	Submission D4.1, D7.1	16
9	Platform and digital tools initial delivery; Intervention cycle 1 start	WP4, WP3	4 - EBOS	Submission of D3.4 and D3.7	18
10	Intervention cycle 1 completion	WP4	11 - UNICT	Successful completion of first intervention cycle	21
11	LL interim results	WP4	11 - UNICT	Submission of D4.3, D4.5, D4.7	25
12	Platform and digital tools interim delivery; Intervention cycle 2 start	WP4, WP3	4 - EBOS	Submission of D3.5, D3.8	30
13	Intervention cycle 2 completion	WP4	11 - UNICT	Successful completion of second intervention cycle	33

Milestones

Grant Preparation (Milestones screen) — Enter the info.

Milestone No	Milestone Name	Work Package No	Lead Beneficiary	Means of Verification	Due Date (month)
14	LL final results	WP4	11 - UNICT	Submission of D4.4, D4.6, D4.8	38
15	Final platform and tools delivery; Phase 2 completion	WP3	4 - EBOS	Submission of D3.6 and D3.9	41
16	Final fully-fledged version of Citizen app compatible with Android and iOS	WP3	4 - EBOS	Submission of Deliverable D3.9	41
17	Replications, end of phase 3	WP6, WP7, WP5	1 - UCY	Submission of D5.1, D5.4, D6.6, D7.6, D7.11	48

LIST OF CRITICAL RISKS

Critical risks & risk management strategy

Grant Preparation (Critical Risks screen) — Enter the info.

Risk number	Description	Work Package No(s)	Proposed Mitigation Measures
1	Difficulty to obtain ethics clearance for LLs	WP4	ISMED-CLIM will have a dedicated Advisory Committee on Ethics and Data Protection during project execution. Furthermore, in WP7 we will provide support and guidelines for ethics committee approval procedures, regulatory affairs and legal issues to create the baseline for a legally compliant development of the framework, by fusing security and privacy by design mechanisms documented in D1.3.
2	Difficulty to mobilise stakeholders and recruit LL participants at each demonstration site	WP1, WP4	Recruitment of participants will be done through the roasters of the local hospitals, communities, municipalities at each demonstration site. The final study protocols will be tailored after interactions with the stakeholders to ensure better buy-in of LLs by the memberships of these organisations, thus enhancing success of recruitment. If any site fails to achieve the targeted number of recruitments per period, a contingency plan will be put in action to identify additional participants throughout the Regional Task Force countries.

Critical risks & risk management strategy

Grant Preparation (Critical Risks screen) — Enter the info.

Risk number	Description	Work Package No(s)	Proposed Mitigation Measures
3	Less than expected performance and results fail to match expectations	WP1, WP6, WP7, WP2, WP4, WP3, WP5	Periodical exchanges between the Project Management Board (PMB) will be conducted during the entire project. Any potential problems will be detected and addressed in early stages. The consortium foresees that the project management structure will also include an External Advisory Board of independent experts that will provide feedback and help to steer project activities.
4	Developed components are below the required level of maturity to sustain the digital tool requirements	WP3	Many platform and tool components are previous projects' assets or belong to partners' existing solutions. The risk minimises as ISMED-CLIM will perform incremental development, configuration, integration, and extension of such components. For all solutions, there will be alternatives and options, producing less risky implementations properly tested before deployment. Risk is monitored by Technical Manager.
5	Data and information security	WP3	The communication infrastructure of the data platform includes services for encryption, authorisation, pseudo-anonymisation, and secure information flows. These will be protected behind a secured access environment with appropriate security policies. Risk monitored by the Technical Manager.
6	Complexity of integration procedures and LL interfacing	WP4, WP3	We will apply prominent measures and methodologies to prevent extra complexity of the various modules developed. The partners that are responsible for the integration are in position to demonstrate a vast experience in successful integration from Horizon Europe actions. Attention will be given from early stages of integration to overcome early any obstacles. Careful planning for parallel duration of WP3 and WP4.
7	Inconsistency between partners of LL1-3 in handling, storage and analysis of biological specimens	WP4	The leaders of LL1-3 will define during the first 6 mo of the project SOPs for the collection, handling, storage and analysis of the blood and urine samples to be collected. The techniques and methods to be used for each assay will be defined and analysis of biological samples will be performed locally at the six sites by accredited laboratories. As the planned blood and urine tests are done by routine widely available assays, we do not foresee any technical biases to affect the accuracy of biological test results.
8	Lack of coordination due to large consortium: resulting in diverging results	WP1, WP6, WP7, WP2, WP4, WP3, WP5	The Project Management Board will meet regularly convening and monitoring progress and finding solutions to unexpected problems. Progress will be constantly monitored by the PC and managed by the Quality & Risk Manager.

Critical risks & risk management strategy

Grant Preparation (Critical Risks screen) — Enter the info.

Risk number	Description	Work Package No(s)	Proposed Mitigation Measures
9	LL not fulfilled	WP4	The PC will raise the issue urgently with the management of the partner organisation, as losing one of LL demonstration sites may decrease the quality of the outcome of the project. The consortium will seek to find a replacement site.
10	Underperformance and dropping out of a partner	WP1, WP6, WP7, WP2, WP4, WP3, WP5	Given the great reputation of the project Partners, most of them with proven success records in EU and related projects, we consider this possibility very unlikely. The GA would decide whether the uncovered project activities can be carried-out by one of the other partners, in which case activities would be reallocated amongst other partners. If this is not possible another partner would be recruited.
11	Delays due to unforseen events	WP1, WP6, WP7, WP2, WP4, WP3, WP5	Natural disasters, pandemics. The consortium is committed in intensifying the work once information and data are available to meet the expected deliverable schedule.
12	Associated partner funding issue	WP1, WP6, WP7, WP2, WP4, WP3, WP5	In the unlikely event that RG partner will not receive national funding, the remaining consortium members commit to absorb their duties as in-kind contribution. If required, the distribution of their duties could be discussed in the kick-off meeting and agreed within the first month of project execution. The PC will formulate a Memorandum of Understanding with HSPH and ACARES prior to GA, to solidify their commitment.
13	Weather extremes (colder weather) potentially affecting the randomised controlled trials which are concentrated within a short time period.	WP4	The possibility of having not enough heat or even cold weather during May-July at the study sites (Nicosia & Limassol-Cyprus, Trikala-Greece, Catania-Italy and Leon-Spain), where the Living Labs will be performed is very small. In the unlikely event that this is the case, the Living Labs performance can be prolonged and have assessments in August and September in the respective study years, which are also very hot months in the Mediterranean region.

PROJECT REVIEWS

Project Reviews

Grant Preparation (Reviews screen) — Enter the info.

Review No	**Timing** (month)	**Location**	**Comments**
RV1	21	tbc	
RV2	39	tbc	
RV3	48	tbc	

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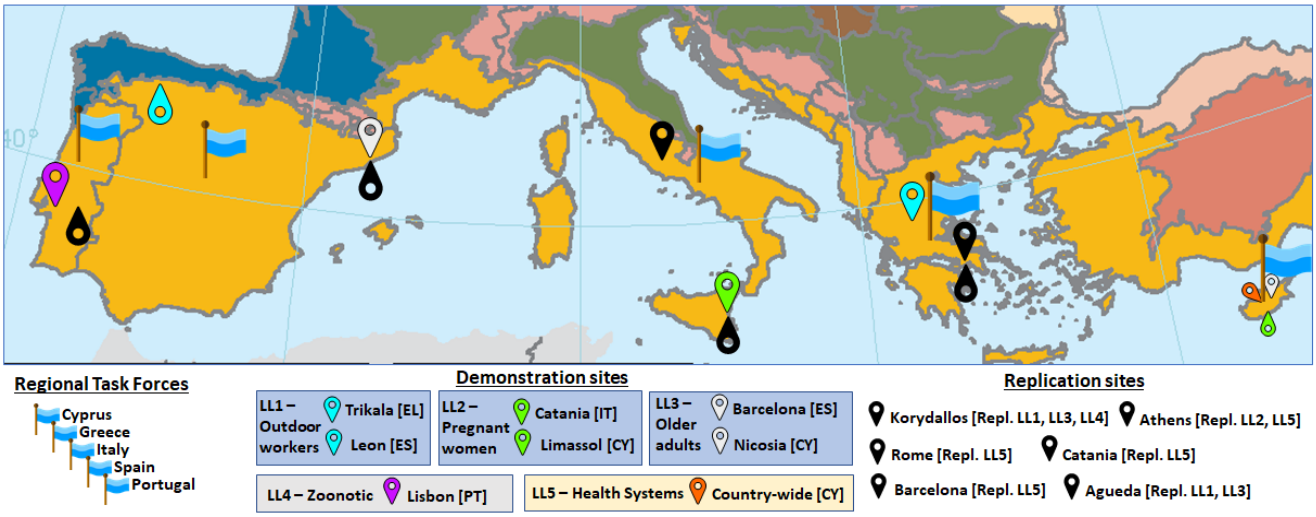
Version	Description of Changes	Submission Date
1.0	Development of Description of the Action (DoA) document	21/12/2023
2.0		22/01/2024
	Brief introduction for each WP was added in the objectives field (PART A)	
	All deliverables with initial, interim and final versions, have been separated as stand-alone deliverables with appropriates due dates	
	Original deliverable D6.1 has been split into new deliverables D6.1 – D6.2	
	New deliverables D1.4 – D1.8 have been added to describe the proceedings of the Regional Task Forces workshops in each of the five participating countries (Cyprus, Greece, Italy, Spain, Portugal).	
	Deliverable D7.1 has been split into separate deliverables D7.1 – D7.3	
	Deliverable D7.2 has been split into separate deliverables D7.4-D7.6 and D7.9-D7.11	
	The dissemination level of deliverables D2.1 has been changed from Public to Sensitive.	
	Added clarification statement after the titles of T4.2, T4.3 and T4.4.: “The methodology for the three LL carried out in T4.2 (LL1), T4.3 (LL2) and T4.4 (LL3) is described below:”	
	Two extra deliverables D6.7 (Exploitation strategy and IPR management 1) and D6.8 (Exploitation strategy and IPR management 2) have been added.	
	Added two extra deliverables D7.7 and D7.8 on Quality Assurance and Risk Management	
	Added new milestones M3 (Creation of an Advisory Board), M6 (Yearly general assemblies) and M16 (Final fully-fledged version of Citizen app compatible with Android and iOS)	
	Updated means of verification for each milestone	
	Original KPI O1.3 was replaced by new KPI O1.3 and KPI O1.4 (PART B, Section 1.1.2 Objectives)	
	Task 2.3 was updated with additional information on health impact assessment methodology (Part A)	
3.0	Updated information on the underlying basis for the sample size calculations for LL1, LL2, LL3 in Section 1.2.2.8 (Part B)	16/02/2024
	Updated scientific novelty under Section 2.1.3.2 to include the novel elements of the epidemiologic studies for non-communicable diseases and the EERS for zoonotic diseases (Part B)	
	Updated partners roles to demonstrate expertise in participatory research	
	Added an additional risk (#13) and mitigation strategy for unexpected weather in the Risk Table (PART A)	
	The dissemination level of deliverables D2.2, D2.3 and D4.3-D4.8 has been set to Public (PU)	
	Revised Figure 3.2 (Gantt chart updated)	
	The description and role of the associated partner 26- RH has been added in Section 3.2.2 (Part B)	



1. Excellence

1.1 Objectives and ambition

1.1.1 Motivation and strategic vision

Climate change presents one of the most important risks to human health as air pollution increases, surface temperatures rise, and extreme weather events become more frequent. The Mediterranean region is located at the **border between temperate and arid climates** and has been declared as one of **Europe's climate change hotspots** by the Intergovernmental Panel on Climate Change[1]. The rise in average temperature in the region exceeds the global average[2]. and the frequent extreme temperature events and forest fires, as identified in the International Disaster Database (EM-DAT), affect both mortality and morbidity[3,4]. Emerging evidence suggests that: (i) the **excess deaths and hospitalizations** attributed to extreme temperatures across Europe are **higher in Southern Europe**[5-8] and are enhanced with higher air pollution[9] especially in older adults, and the socially deprived sub-populations[10] (ii) heat waves in the Mediterranean region are projected to rise dramatically by the end of 21st century[11], **increasing the heat attributable fraction of deaths in the region**[12], which will exceed the reduction of deaths attributable to cold temperatures[13,14] (iii) exposure to heat causes a **wide spectrum of adverse health effects**, such as mental stress, heat stress, dehydration, sleep disturbance, hypertension, especially among vulnerable population groups, like outdoor workers, pregnant women and older adults, despite the recommendations and response plans that have been developed for preventing these effects[2,15-23]; (iv) vector-borne diseases account for 17% of all infectious diseases, and their **insect vectors are directly affected by external factors and climate change**[24] and finally, (v) **climate change threatens health care systems** by increasing demand, disrupting infrastructures, raising costs and compromising delivery of high-quality health care[25-27].

Main challenges towards addressing climate change impacts in the Mediterranean biogeographical region:

- **Challenge #1: Inform and mobilize local stakeholders and citizens** across the Mediterranean region about the extreme health risks posed by climate change and the pressing need to implement mitigation solutions.
- **Challenge #2: Insufficient scientific evidence on the effectiveness of existing alert systems** and **end users' compliance in implementing current recommendations** for reduction of exposure to heat and air pollution and mitigation of the related disruption of biological processes and heat stress.
- **Challenge #3: Utilization of existing vector disease models** with gridded Mediterranean environmental datasets and climate projections to generate short- and long-term assessment of vector presence, population abundance, and associated disease risk to alert and keep high risk populations and animals safe.
- **Challenge #4: Lack of risk assessment capacity, emergency plans and mitigation solutions** for climate change impact on health care systems at the local health authority and hospital levels within the region.
- **Challenge #5: Replication of effective evidence-based** forecast, early warning and early response systems and decision-making models for the health impacts of climatic stressors in vulnerable populations in the whole region.

The **vision** of **ISMED-CLIM** is to address the five main challenges and advance state-of-the-art knowledge about the effects of climate change on non-communicable diseases and vector-borne infections in the Mediterranean region. Towards this end, **ISMED-CLIM** will **engage and mobilize regional policy makers, social stakeholders, and citizens**, in implementing mitigation solutions. In addition, it will **evaluate and enhance the effectiveness of a set of interventions** to reduce climate sensitive extreme exposures and related health effects in vulnerable population groups. In a One Health approach, it will also develop and **test an integrated surveillance tool for high-risk professionals to manage zoonotic disease** prevention, control actions and interventions. Considering local characteristics, it will adapt existing evidence-based practices and prototype tools **to increase the preparedness and ability of health systems in the Mediterranean region** to deliver safe and effective care to citizens, in the context of the ongoing climate change. Finally, it will develop **knowledge, policy decision and action-oriented** tools and means for the **effective replication** of these solutions, **building systemic transformations.**

1.1.2 Objectives

Overall project objective: Our overarching goal is to engage and mobilize regional policy and social stakeholders,

as well as citizens, across the Mediterranean region in implementing a wide array of adaptation solutions to mitigate the health effects of climate change. Our strategy involves delivering state-of-the-art assessments of the regional health risks and providing field-based evidence for the feasibility, user acceptance and efficacy of a series of proposed solutions. To achieve this goal **ISMED-CLIM** will (i) enhance our understanding of climate effects on non-communicable diseases (NCDs) and vector-borne infections across representative Mediterranean countries; (ii) quantify, for the first time, how public health interventions integrating state-of-the-art technologies, personalized risk communication, with vulnerable citizens' participation can reduce personal exposures to heat and air pollution and related health effects; (iii) validate the feasibility and user acceptance among high risk professionals of a regional early warning and risk prediction tool to mitigate the risk posed by exposure to sand flies and related diseases; (iv) employ open, participatory, and co-creative methodologies to locally adapt and refine existing evidence-based practices and prototype tools to increase the preparedness and ability of health systems in the Mediterranean to deliver safe, effective, and efficient care to citizens. We will test the proposed demonstration solutions **initially in eight sites** and coordinate **ten replications in six sites** in **five EU countries (Cyprus, Greece, Italy, Spain, Portugal**) in the Mediterranean, in alignment with Climate Change Adaptation Mission objectives. We will integrate the produced knowledge from epidemiology, forecasting, exposure and health data with insights from the demonstration and replication activities into a knowledge portal and policy decision-centric and action-oriented dashboard for policy makers, healthcare administrators, professionals and citizens. Our approaches will be readily applicable in other European regions affected by the same or other climate change-related stressors, such as forest fire smoke, floods, ozone, and cold.

ISMED-CLIM Specific Objectives and Success Criteria

ISMED-CLIM will accomplish its overall objective by implementing **six SMART objectives** (*Specific, Measurable, Attainable, Realistic and Time bound*) divided into the three Pillars of Climate Change Adaptation Mission as follows:

- **Prepare and plan for climate resilience** by improving understanding of climate risks in the Mediterranean region and engaging regional stakeholders and citizens in **ISMED-CLIM** climate resilience actions;
- **Accelerate transformations to climate resilience** by developing the necessary technological infrastructure and by demonstrating the efficacy, feasibility and user acceptance of evidence-based solutions;
- **Build systemic transformations to climate resilience** by focusing on upscaling solutions, maximizing impact and building resilience across the Mediterranean biogeographical region.

Pillar 1: Prepare and plan for climate resilience

O1: Conduct state-of-the-art **epidemiological** and exposure **modelling studies** to **better understand** climate effects on NCDs and infectious diseases across the Mediterranean, inform **recommendations and response tools** and improve **citizens and stakeholders'** knowledge on climate change-related health risks, **enhancing their response**.

• Perform times-series analyses across the Mediterranean region to examine the associations of extreme climatic stressors with **mortality** and **hospital admissions** in citizens of all ages and among susceptible groups. We will use city-specific effects' estimates to obtain **overall Mediterranean estimates** and concentration-response functions.

• Perform across the Mediterranean region an extensive review of existing data and literature associating extreme climatic stressors with the presence and abundance of important infections' vectors, such as the ***Culex pipiens***, the ***Anopheles* species**, the invasive ***Aedes* mosquitoes**, and **phlebotomine sand flies**, as well as vector-borne infections prevalence, such as **Malaria, Dengue, Chikungunya, Zika, West Nile,** and **Leishmaniasis** in humans and dogs**.**

• **Forecast future climatic conditions** and assess **impacts** on **non-communicable diseases** and **vectors' dynamics.** As a case study, we will examine **sand flies and the pathogens** they carry, under different scenarios of climate change (moderate, extreme and record-breaking) for the next 50 years.

• Derive effects estimates and thresholds to **inform recommendations** for **intervention** to be tested in Livings Labs 1, 2, 3 (WP4). Subsequently, develop a **climate risk and vulnerability assessment framework** and a **Knowledge Hub interfaced with the European Climate and Health Observatory (WP5).**

Relation to the call: *Provide improved insights into short- and long-term health effects of climate-related stressors*

KPI O1.1: Effect estimates for the impact of at least **four (4)** climate-related stressors (temperature, air pollution, wildfires, flooding) on NCDs in **five (5)** Mediterranean EU countries (Cyprus, Greece, Italy, Spain, and Portugal).
KPI O1.2: Predictions for all-cause and cardiorespiratory mortality/morbidity for the next 50 years in **five (5)** Mediterranean EU countries (Cyprus, Greece, Italy, Spain, and Portugal) under **three (3)** climate change scenarios.
KPI O1.3: One literature review on climate change impacts on at least **six (6)** vector borne infections (Malaria, Dengue, Chikungunya, Zika, West Nile, and Leishmaniasis) and **four (4)** vectors' dynamics (Culex, Anopheles, and Aedes mosquitoes and phlebotomine sand flies)
KPI O1.4: Prediction of climate change impacts on sand fly dynamics and associated disease risk in **five (5)** Mediterranean EU countries (Cyprus, Greece, Italy, Spain, and Portugal) under **three (3)** climate change scenarios (SSP1-2.6, SSP2-4.5, and SSP5-8.5).

Means of verification / Deliverables: D2.1; **D2.2**; **D2.3**; **D2.4**.

Results: Enhanced region-specific awareness of societies regarding the effects of climate change on mortality and morbidity in European countries across the Mediterranean.

O2: Engage **ISMED-CLIM** partners in establishing **Regional Task Forces** to **increase support** from wider policy, civil society and health system stakeholders and citizens and develop a **vision and transformative pathways** for climate resilience.

• **Establish Regional Task Forces** and **increase support from** policy, civil society and health system stakeholders and citizens in **ISMED-CLIM** countries. Through inclusive and deliberative processes (workshops, focus groups, surveys) **steer co-production of data and knowledge** on climate effects on health across the Mediterranean region and identify best practices and gaps in practice and climate resilience policies.
• **Regional Task Forces** will **formulate details of the vision and the transformative pathways to climate resilience** by tailoring recommendations to be tested in the Living Labs (LLs), defining the specifications and the design for the project's digital solutions and tools, and by customizing domain/intervention-specific components.
• Identify existing information on **climate resilience of Healthcare Systems** in the Mediterranean region. Specifically, review literature and existing climate resilience policies, and identify gaps in practice to inform the pathway to relevant policy development and solutions to be proposed for Health Systems' resilience.

Relation to the call: *Mobilize support and engagement of regional stakeholders and citizens to formulate the vision and transformative pathways to user-friendly, locally tailored climate resilience solutions for healthcare*

KPI O2.1: Five (5) Regional Task Forces with at least **twenty (20)** stakeholders from **five (5)** Mediterranean countries (Cyprus, Greece, Italy, Spain, and Portugal).
KPI O2.2: Fifteen (15) co- participatory activities (workshops, focus groups, and surveys) towards the co-creation of recommendations, involving the Regional Task Forces members.
KPI O2.2: Five (5) sets of tailored recommendations to be tested at **eight (8)** demonstration sites.
KPI O2.3: One (1) scoping review focusing on the Mediterranean region and identifying gaps in practice for healthcare systems resilience to climate risks across **seven (7)** thematic areas.

Means of verification / Deliverables: **D1.1**; **D1.2**; **D1.3**; **D1.4**.

Results: Engagement of a wide array of policy, civil society and healthcare stakeholders across the Mediterranean in evaluation of baseline policy and health care landscape and in co-creation of the solutions to be tested.

Pillar 2: Accelerate transformations to climate resilience

O3: Create the **digital infrastructure and tools to enable** access of stakeholders and citizens to knowledge and data, disseminate forecasting and early warning, enhance implementation of evidence-based recommendations for managing climate risks, assess personal exposure and obtain health data and support healthcare resilience solutions.

• Develop the **Human Machine Interfaces** (HMI) of the applications and tools hosted in **ISMED-CLIM** platform (**LLs Management Portal, Citizen Application, Policy Dashboard).**
• Develop **a Data Platform** to assess the datasets of the project in terms of quality, considering technical aspects related to, inter alia, data consistency, integrity, and completeness.
• Develop an **AI-augmented Early Warning and Response System (EWRS)** for **real-time personalized risk assessment** for heat exposure and sensitivity, enabling **personalized risk communication**. Region-specific reanalysis and reforecast data will be used for accurate forecast, downscaled to higher-resolution for project sites.
• Set up **ISMED-CLIM platform** for orchestrating and integrating project outputs, focusing on interconnection between each module/component. Standards, protocols, and APIs will enable the integration of different services and data to a single unified prototype platform to be interfaced with the **EU Climate-ADAPT platform**.

Relation to the call: *Create key enabling conditions to facilitate access to knowledge and data, better forecast, early-warning and early response systems and decision-making models for the health impacts of climate change*

KPI O3.1: Development of one e-platform hosting the LLs Management Portal, Citizen Application and the Policy Dashboard with **six (6)** tools.
KPI O3.2: Roll-out the AI-augmented EWRS in LLs demonstration and replications sites.
KPI O3.3: **ISMED-CLIM** platform interfaced with at least **one EU platform** (Climate-ADAPT)

Means of verification / Deliverables: **D3.1**; **D3.2**; **D3.3**.

Results: Development of the necessary technological infrastructure and tools to enable evaluation of the program's evidence-based solutions and building of systemic transformation for climate resilience across the Mediterranean.

O4: Orchestrate the implementation of **five Living Labs (LLs) to test evidence-based solutions** aiming to curb the adverse effects of climate change on vulnerable population groups and enhance the preparedness and resilience of health systems at **eight sites across five European countries** in the Mediterranean region.

• Perform **three LLs** as prospective **randomized controlled trials** to quantify the **efficacy** of an Early Warning and Response System (EWRS) and a set of evidence-based interventions with the support of state-of-the-art technologies, and personalized risk communication to reduce exposure to high temperature and air pollution and related health effects during periods of extreme heat (summer) in three cohorts of vulnerable population groups: **outdoor workers (OW), pregnant women (PW)**, and **older adults with arterial hypertension (OH)**.
• Perform **one LL** as a **feasibility and user acceptance** study of an EWRS and an evidence-based set of prevention interventions for zoonotic diseases among **high-risk professionals** and citizen groups (**dog shelter workers and volunteers, and veterinarians).**
• Perform **one LL as an iterative co-creation activity** to **adapt the prototype** Climate Resilience for Frontline Clinics toolkit that has already been developed by associated partners HSPH and ACARES in the U.S. to a **Mediterranean-specific climate resilience toolkit for health care systems.**

Relation to the call: *Orchestrate and test innovative solutions to reduce impact of climate change on human health*

KPI O4.1: Three (3) randomized controlled trials quantifying the efficacy of EWRS and interventions in vulnerable populations **at six (6) sites (Trikala-Greece, León-Spain, Catania-Italy, Limassol-Cyprus, Barcelona-Spain, and Nicosia-Cyprus)** in the Mediterranean. Each trial will recruit **102** participants.

KPI O4.2: Reduction in ambient temperature exposure by **2 °C** and in PM level exposure by **40%**; improvement of ≧**20%** in health outcomes: heat strain in OW; sleep quality in PW; night-time dipping blood pressure in OH.
KPI O4.3: One feasibility study demonstrating the feasibility and user acceptance of an EWRS and prevention interventions for zoonotic diseases in **Lisbon-Portugal,** including **>50** veterinarians, dog shelter workers/volunteers, and dog owners.
KPI O4.4: One co-creation activity to develop the Mediterranean-specific climate resilience toolkit for **Cyprus' Health Care System.**

Means of verification / Deliverables: **D4.1**; **D4.2**; **D4.3**; **D4.4**; **D4.5**.

Results: Evidence-based tools and recommendations that: (i) reduce exposure to heat and air pollution and related health effects in three vulnerable populations; (ii) mitigate the risk of high-risk professionals and citizens for zoonotic diseases; and (iii) increase preparedness and resilience of healthcare systems in the Mediterranean to climate change.

Pillar 3: Build systemic transformations to climate resilience

O5: Ensure **impact maximization and sustainability** of proposed solutions through **replication** activities, development of **training materials**, introduction of **policy implementation** and **policy evaluation tools** to support **informed decision making**.

• Stimulate the implementation and adoption potential of the proposed solutions through **ten replications in six additional sites** within the Mediterranean biogeographical region.
• Accelerate adoption of **ISMED-CLIM** recommendations by the wider community through utilization of the online **Policy Dashboard** (O3) to: i) improve local monitoring and implementation of prevention plans for NCDs, zoonotic diseases and vectors; and ii) enhance resilience of healthcare systems and healthcare delivery during extreme events.
• Foster capacity building among stakeholders through development of **educational materials and training curricula** for healthcare professionals to be provided by the Policy Dashboard and disseminated through an effective Dissemination and Communication Plan.
• Increase **perception and awareness for the health effects** of climate change among vulnerable groups and the general public.
• Support policy making, including the digital version of the **Mediterranean-specific climate resilience toolkit** for healthcare systems, by **defining key performance indicators** to be collected to enable analysis of **user feedback**.
• Support policy evaluation and inform decision making through the performance of region-specific **Health Impact Assessment (HIA**) and **Socioeconomic Impact Assessment** Studies.
• Establish operational links and feed results to the **Climate-ADAPT platform.** This will monitor, support, and visualize the Mission progress in European Regions and will provide feedback and best practices to the new **Health Emergency Preparedness and Response Authority**.

Relation to the call: *Stimulate larger scale deployment of tested solutions for climate resilience and transformation of key community systems*

KPI O5.1: Ten (10) replications of tested solutions in **six (6)** additional sites within the Mediterranean region.
KPI O5.2: Utilization of the online e- platform by >**100** stakeholders, >**500** professionals and >**10,000** citizens
KPI O5.3: Five (5) short courses including digital handbook, explanatory videos and training curriculum (one per LL), in the languages of **five (5)** Mediterranean countries (Cyprus, Greece, Italy, Spain, and Portugal).
KPI O5.4: Definition and monitoring of **>14** KPIs (minimum two per thematic area of health system resilience) for analyzing user feedback and uptake of the Mediterranean-specific climate resilience toolkit for healthcare systems.
KPI O5.5: Five (5) Region-specific Health Impact Assessment and Socioeconomic Impact Assessment Studies.
KPI O5.6: Improvement in climate change health effects perception of general public by **>20%** and in vulnerable groups by **>30%**.

Means of verification / Deliverables: **D5.1**; **D5.2**; **D5.3**; **D5.4**.

Results: Maximize impact by delivering replication activities, training materials, policy implementation and policy evaluation tools to support informed decision making in the Mediterranean biogeographical region.

O6: Maximize cross-border impact of demonstrated resilience solutions across European regions by creating a multifaceted **dissemination and communication strategy,** implementing **capacity-building activities**, developing a sustainable **exploitation and business plan**, and identifying commercially sound **post-project opportunities**.

• Create and implement a multifaceted **dissemination and communication strategy** to maximize promotion of non-confidential knowledge generated by the project through scientific publications and presentations at relevant events.
• Undertake **liaison activities** to enable cross-fertilisation and exploit synergies with other relevant EU-funded projects and initiatives, e.g., projects funded under the Mission Climate Adaptation, same work programme, or related to climate change and health in other clusters (such as Cluster 1 and Cluster 6).
• Develop detailed **exploitation and sustainability plans** for continuation of operations beyond the project's lifetime by ensuring the provision of: (i) updates and maintenance to **ISMED-CLIM** knowledge portal and policy dashboard; (ii) forecasting data to support the citizen app and EWRS; (iii) project tools and methods for new research activities; (iv) market-oriented project outputs for commercialisation through market analysis and design of a business model.
• **Identify and manage innovation** from the project, advise the PC and partners on the scope, pay attention to discerning IPR at regular checkpoints.

Relation to the call: *Develop and implement common strategies for cross-border networking and cooperation activities in civil and health protection*

KPI O6.1: D-KPIs and C-KPIs (Section 2.2.1 and 2.2.2)

Means of verification / Deliverables: **D6.1**; **D6.2**.

Results: Create cross-border cooperation, fostering an additional set of cross-border demonstration activities for climate resilience to health risks of climate change across European regions and communities.

1.1.3 Ambition

1.1.3.1 Epidemiology and modelling of the impact of climate change on non-communicable diseases (NCDs)

Current State of the Art analysis & Challenges: Two recent multinational publications by partners of this consortium evaluated the excess deaths attributed to cold and heat across Europe and indicated an increasing north–south gradient in vulnerability[5]. In the largest risk assessment study to date, they attributed 37% of warm-season heat-related deaths to anthropogenic climate change, with the highest attributions estimated in Southern Europe[7] Partners of **ISMED-CLIM** have also demonstrated enhanced effects of heat on mortality by elevated levels of air pollutants, especially, in Mediterranean countries[9] and stronger effects among the elderly, the socially deprived[10], and in cities with urban heat islands and reduced greenness[28,29]. In contrast, evidence of the effects of high temperature on morbidity in the Mediterranean region comes mainly from small-scale local or national studies, showing comparatively smaller increases or inconsistent effects on total[30,31], cardiovascular and respiratory hospital admissions[32,33]. Similarly, evidence from the region of heat effects on important conditions, such as dementia[34], psychiatric disorders[35], children[32], and adverse pregnancy outcomes[16,36] comes from scarce small-scale local data. In the few studies that included data from multiple European cities, the impact of high temperatures on hospital admissions was greater in Mediterranean cities in comparison to Northern European cities[8]. Heat waves in the Mediterranean region are projected to increase seven times and last three times longer by the end of the 21st century[11] increasing dramatically the heat attributable fraction of deaths in the region[12], so that it will exceed the reduction of the cold attributable deaths in the second half of 21st century[13].

Ambition: In order to meet **Challenge #1 to inform and mobilize local stakeholders and citizens about the problem,** we propose to enhance the legacy of the recent large international projects (MCC Collaborative Research Network, EXHAUSTION 2021), and focus on representative EU countries across the Mediterranean to assess the complex interplay between various climate change parameters in the region with mortality, and morbidity outcomes. The consortium will collect data from five EU countries (Cyprus, Greece, Italy, Spain, and Portugal) across the Mediterranean for the past 24 years (2000-2023) on daily temperature, humidity, wind direction and speed, occurrence of desert dust episodes, flooding, wildfires and air pollution. In addition, the consortium will collect data on age- and cause-specific daily counts on mortality and hospital admissions for cardiovascular, respiratory and mental-psychiatric conditions, as well as data on preterm births and birth weight. Using an approach that allows the temporally aggregated effect from exposures, we will explore the complex interplay between increasing heat stress and air pollution, as well as the interactions between drought, flooding and wildfires events on the collected human health mortality and morbidity outcomes. Using open-source data (NOAA's global summary of the day and EU's Global Human Settlement layer), as well as Copernicus Land monitoring service data on land use and land cover in urban areas, we will also take into consideration characteristics of urban development, green space and densely populated Mediterranean cities[37]. We will apply the estimated concentration response functions from the baseline period to future projections using different scenarios of climate change for the next years based on Representative Concentration Pathway (RCP) framework, utilizing Copernicus Climate Change Service downscaled weather projections data, to estimate the attributable cases of health outcomes, while taking into account the population adaptation capacity and the region-specific socio-economic trajectories based on available Shared Socioeconomic Pathways (SSPs). ISMED_CLIM will use the Mediterranean-specific epidemiological and projection analyses to inform successful planning by local authorities. Also, it will mobilize citizens living in highly impacted regions, where adaptation solutions must be implemented immediately.

1.1.3.2 Disruption of biological processes by climate change-related stressors and evaluation of mitigation solutions through exposure reduction approaches

Current SoTA analysis & Challenges: Beyond increasing mortality and hospitalizations, exposure to extreme climate stressors is associated to a larger range of adverse health outcomes, especially among vulnerable population groups. These may suffer symptomatic exacerbations of pre-existing conditions or have sub-clinical effects and disruption of biological processes that may affect health and quality of life. High temperatures (>32 °C) during daytime normally reduce leisure outdoor activity and redistribute activity from noon and afternoon towards the mornings and evenings[38]. Activities of outdoor workers do not follow spontaneous adaptive changes, and occupational exposure to heat in the Mediterranean region frequently induces symptoms of thirst, excessive sweating, exhaustion, and headache[15]. **Occupational heat stress** disrupts physiological processes and increases core and skin temperatures, heart rate and urine specific gravity[39]. Few regional policy stakeholders across the Mediterranean (Cyprus, Spain, Greece) have adopted advanced occupational warning systems (such as those emerging from EU projects like HEAT-SHIELD and specific recommendations to: (i) reduce exposure to heat waves by **changing patterns of time spent and physical activity performed outdoors;** and (ii) mitigate related health effects **(hydration, light clothing, work breaks**)[22]. During heatwaves, night-time temperatures also increase and heat exposure during sleep can lead to **disruption of important sleep parameters** (sleep onset latency, total sleep time, sleep efficiency, wake after sleep onset), particularly among vulnerable populations such as older adults, children, pregnant women, and those with psychiatric conditions[17]. Similarly, air pollution, another important climate-related stressor, has independent detrimental effects on sleep quality[40]. Several recommendations for mitigation of sleep problems and their effects on general health during heatwaves have been proposed[21], including **reduction of indoor temperature with the use of fans and air conditioning (A/C), body cooling, hydration and light clothing.**

Pregnant women and developing fetuses are uniquely vulnerable to the impacts of extreme climate change-related events. Beyond the risk of preterm delivery and low birth weight, exposures to elevated temperatures and air

pollution[41,42] have been associated with negative behavioral changes and increased maternal mental stress[43], maternal hypertensive disease[18], heat stress and dehydration[44]. Moreover, sleep problems during pregnancy are known to be associated with maternal mental health problems (stress, depression)[19,20]. Stress, including heat stress, causes a rise in cortisol levels, which may lead to decreased blood flow to the placenta due to diversion of blood flow for other immediate action[45]. In the field of cardiovascular physiology, high ambient temperature during summers is known to decrease the mean daytime average and morning surge in blood pressure (BP), but **increases the nocturnal BP**[46]. Abnormalities in circadian BP variation, particularly the disappearance of the nocturnal BP fall (non-dipping) or rising of nocturnal BP vs. daytime BP, have been consistently reported to be associated with the incidence of cardiovascular diseases and subclinical organ damage, independently of daytime average BP levels[23,47]. The effect of high temperature on the increase of nighttime BP is more pronounced in older adults on hypertensive treatment[48]. Like sleep, airborne particulate matter (PM) is also known to acutely disrupt ambulatory blood pressure[49].

Ambition: In order to meet **Challenge #2** about the **insufficient scientific evidence on end users' compliance in implementing** the current recommendations and the **effectiveness of existing alert systems** to either reduce exposure to heat or mitigate the related disruption of biological processes[50-52], in **six sites across the Mediterranean** that are heavily exposed to the effects of climate change, we propose to apply, test, and demonstrate the **efficacy of timely personal alerts and a set of patient-specific, easy to implement exposure-reduction interventions** to reduce personal exposures to heat and air pollution towards protecting human health and wellbeing. Towards this end, we propose **three randomized controlled trials** in the main vulnerable population groups that have been found in observational studies to be severely affected. These include **outdoor workers** (LL1-Trikala-Greece, León-Spain), **pregnant women** (LL2–Catania-Italy, Limassol-Cyprus) and **older adults with hypertension** (LL3-Barcelona-Spain, Nicosia-Cyprus).

In the proposed clinical trials, we will randomize participants to intervention and control groups, and we will adapt and adopt telemedicine practices to support heat and air pollution reduction recommendations, employing: (1) communication media (web and smartphone written messages, animation videos detailing instructions) to foster interaction and deliver timely alerts to individuals on imminent heat and air pollution events; (2) AI-augmented early warning and response system (EWRS) providing downscaled forecasts and real-time personalized risk assessment for heat exposure and heat sensitivity; (3) wearable remote sensors to continuously measure exposure and health outcomes, and (4) cloud technologies to store and manage personal exposure and health data, with the **ultimate goal to quantify the efficacy of the exposure-reduction recommendations** on decreasing heat and air pollution exposure and adverse health outcomes vs the control groups. The **ISMED-CLIM** efficacy LLs will capitalize on: (i) our previous understanding of meteorology-based thermal stress indicators and physiology of heat strain [53] and (ii) our experience on behavioral responses to recommendations (physical activity, time outdoors) [54], engineering factors (commercially available wearable sensors)[55], and indoor air purification[56] that will enable us to design, execute and evaluate the proposed interventions. The LLs will provide quantitative evidence for the **health impact assessment of the proposed interventions** to the population level burden of disease, thus addressing simultaneously all aspects of a climate change adaptation public health policy, following the classic risk assessment paradigm of:

Ambient Levels → Human Exposures → Biological Outcomes → Population Mortality and Morbidity

1.1.3.3 Epidemiology and modelling of climate change impact on infectious diseases in the Mediterranean

Current SoTA analysis & Challenges: Leishmaniasis, caused by the protozoan parasite *Leishmania infantum*, is a zoonotic phlebotomine sand fly-transmitted disease endemic in southern Europe of great medical and veterinary importance. Dogs are the main hosts and reservoirs of human infection. Human and canine leishmaniasis is a multi-organ and potentially fatal disease, unless promptly treated. Many of the public health and veterinary authorities in the EU countries consider leishmaniasis a neglected, emergent, or re-emergent disease with insufficient resources dedicated to its prevention and control. Potential triggers include environmental and human-related changes affecting the risk of exposure to vectors, such as the movement of humans and dogs, urbanization of endemic rural areas and climate change. There is a clear need for integrated surveillance, in particular of animal leishmaniasis, and identification of areas with a high incidence, where effective control interventions should be intensified according to a One Health approach[57]. Like other disease vectors, sand flies are vulnerable to climate change and are therefore perfect indicators of how local climatic and microclimatic changes may affect not only their distribution, but also the spread of the diseases they transmit. The distribution of these vector species strongly depends on environmental changes which alter the landscape structure, although knowledge gaps still exist about the exact linkages of their appearance and spread with different combinations of climatic factors and/or land use types. Leishmaniasis, including its animal form, is thus a perfect example of a vector-borne disease for which informed One Health approaches to prevention and control might decrease the suffering of human and animal patients. At present, the range of operational usable, and accessible alert systems for infectious and vector-borne diseases, as well as availability of prevention recommendations is considerably limited[58].

Ambition: In order to meet **Challenge #3** about the **utilization of existing vector disease datasets and models** we will assimilate SSP1-2.6, SSP2-4.5, and SSP5-8.5 climate projections data, with existing vector population dynamics models to generate short- and long-term assessments of vector presence, population abundance, and associated disease risk across the Mediterranean, using sand fly-borne disease (leishmaniasis) as a case study. This output will support policy planning, as well as the development and validation of an effective EWRS and an evidence-based set of prevention interventions for zoonotic diseases among high-risk professionals and citizen groups (dog shelter workers and volunteers, and veterinarians). In addition, we will define: (i) key climate and environmental variables for sand fly abundance and related infections modelling; (ii) produce a range of parameters and critical values of climatic and environmental vector, pathogen and disease drivers, needed as inputs to the EWRS to be developed by

the project; (iii) upgrade the existing disease modelling of CLIMOS EWS output to ISMED_CLIM EWRS, providing real-time personalized risk assessment for sand fly-borne (zoonotic) diseases, including suggested guidelines interventions for concerned citizens; and (iv) test, provide feedback and validate the use of this tool in communication with end users. To this end, we will perform LL4 (Lisbon-Portugal) as a feasibility and user acceptance study of the EWRS and the developed evidence-based set of prevention interventions for zoonotic diseases among high-risk professionals and citizen groups (veterinarians, dog shelter workers and volunteers, and dog owners). This will lead to a tool that can be easily adopted by similar end users in Europe and internationally.

1.1.3.4 Improve resilience of health care systems to climate change across the Mediterranean region

Current SoTA analysis & Challenges: Beyond its direct health effects, climate change threatens the fundamental mission of health care systems to improve health and well-being. This challenge materializes through heightened demand, leading to overcrowding in emergency departments and hospitals. In addition, it disrupts critical infrastructures, causing damage, power outages, and closures. The financial strain is amplified by increased morbidity and heightened utilization, resulting in elevated costs. Most importantly, climate change compromises the delivery of high-quality healthcare, manifesting in poorer health outcomes and reduced health equity[25]. In 2012 and 2017, in targeted surveys of WHO Europe, most Member States reported generic actions to strengthen health systems to cope with climate change impacts, including strengthening early-warning systems and responses, infectious disease surveillance, and improved water and sanitation services[59]. Although climate change burden on health systems in Europe is widely acknowledged[60] detailed risk assessment, emergency plans and mitigation solutions at the local authorities and hospital levels are scarce or missing completely[26,27]. In contrast, regional hospitals, and facilities in the U.S., beyond the typical annual hazard vulnerability analyses, started recently to prepare mitigation plans under different forecasting projections and climate-related disaster scenarios and prioritized potential solutions, employing risk/benefit approaches to decision making[61]. Furthermore, in 2021 the Center for Climate, Health, and the Global Environment at Harvard T.H. Chan School of Public Health (**HSPH**) and Americares (**ACARES**), following nationwide surveys and focus groups with pilot frontline clinics that have experienced recurring emergencies due to climate crisis, created the Climate Resilience for Frontline Clinics Toolkit, which provides useful resources for health care providers, patients and administrators at clinics and community health centers to meet the challenges for health care from events, such as extreme heat, wildfires, hurricanes and floods[62].

Ambition: In order to meet **Challenge #4** about the **lack of risk assessment capacity, emergency plans and mitigation solutions** for the Health systems in Mediterranean EU countries, we propose an innovative **co-creation activity focusing on the adaptation of the existing U.S. toolkit (**tips for patients - guidelines for health care professionals - alert plans, checklists, and communication templates for health system administrators) to new uses in the Mediterranean healthcare conditions, and in parallel establish **processes for generation of entirely new approaches and innovative solutions** specific for the region. We will target this LL5 at first in the health system of Cyprus (HIO) and then replicate the toolkit in at least four hospitals (Alexandra University Hospital-Athens, APNAS Garibaldi Hospital-Catania, Hospital in ASL ROMA 1-Rome, Parc Sanitari Pere Virgili Intermediate Care Hospital and Primary Care Centers-Barcelona), and possibly others in EU countries across the Mediterranean. We will employ a scoping review and online international survey, targeting first-line healthcare professionals and administrators, to carry out a detailed, region specific climate resilience and needs assessment for the Mediterranean healthcare systems and by using co-creation methodologies such as focus groups, stakeholder interviews and open consultation workshops, we will tailor the existing Climate Resilience for Frontline Clinics prototype toolkit (HSPH, ACARES) to a **Mediterranean-specific climate resilience toolkit** for healthcare systems targeting administrators, healthcare professionals and end users. **ISMED-CLIM** LL5 will capitalize on our previous experience and understanding of modelling climate change effects on healthcare (CyI), building climate and disaster healthcare resilience in the U.S. health care system[62] (HSPH, ACARES) and adaptation of NICE U.K. guidelines for the Cyprus health system[63] (HIO, UCY). The tailored toolkit, including clinical checklists, case study examples, patient tip sheets and novel proposed tools will be integrated into the Experts and Policy Makers' Dashboard, accompanied by training material to facilitate climate sensitive awareness and capacity building among regional health care workforce.

1.1.4 R&I maturity

ISMED-CLIM will build on the **outputs and assets** of completed and ongoing EU and international projects, as well as other relevant commercial assets to seed its technology. The project partners are, in many cases, prior and/or current collaborators in relevant projects. **Table 1.1** outlines the most directly relevant assets.

Table 1.1: *Directly Relevant Assets from Previous Related Projects and Extensions*

Transferable asset	Partner	Reference Projects	Start TRL	End TRL
MEDena Health Hub platform	UCY	LIFE MEDEA	4	6
The MEDena Health Hub was developed as a bidirectional internet platform and application for early-personalised warning dissemination and collection of physical activity and health data from wearable sensors during LIFE MEDEA project. As part of the **ISMED-CLIM** project, parts of the application components (codes/user interface etc) will be used for the development of the EWRS.				
CLIMOS Early Warning System end user tools	EF	CLIMOS	5	**7**
Extending the work in the CLIMOS project to re-create a complete set of new user services and experience based on new requirements and co-creation.				
Heat stress indicators monitoring and forecasts	ECMWF, UCY	TRIGGER	4	**7**

Extend the current heat stress forecasts to include also other indicators developed within the project.				
Policy Dashboard	EBOS	NextGEM	4	7
ISMED-CLIM will integrate the developments of NextGEM's policy dashboard and extend towards a modularized dashboard incorporating a number of different tools and advanced visual analytics to improve policy making.				

1.2 Methodology

1.2.1 Concept

ISMED-CLIM will adopt a LL methodology approach in multiple settings across the Mediterranean region to create sustainable impact through iterative feedback processes of co-creation, prototyping, feasibility testing, multi-methods evaluation and scaling-up, with the involvement of multiple regional policy and civil society stakeholders, communities, workers and citizens together with clinical, environmental and social scientists and information technology (IT) experts. **ISMED-CLIM** aims at first to advance the understanding of how climate change affects health in the short and long-term in the Mediterranean region using climate modelling and epidemiology of non-communicable and infectious diseases, taking into consideration the effects of extreme temperatures in conjunction with air pollution and desert dust events, as well as the health impact of wildfires and extreme weather events, such as flooding. In addition, **ISMED-CLIM** envisions five Living Labs (LLs) to take place at **eight sites in five different EU member states** (Cyprus, Italy, Greece, Spain and Portugal) in the Mediterranean to demonstrate the effectiveness of a series of recommendations and tools in protecting vulnerable workers and citizens groups, the health systems and the society as a whole from the effects of climate change. Three randomized controlled trials will focus on tailoring and testing recommendations with the support of state-of-the-art technologies and personalized risk communication to reduce exposure and adverse health effects of heat and air pollution in outdoor workers, pregnant women, and older adults with hypertension and subsequently develop and validate an Artificial Intelligence (AI) based, personalized Early Warning and Response (EWR) system, which will be available as a citizens' app. One demonstration project, in a One Health approach, will focus on demonstrating the feasibility and impact of improved surveillance and modelling of zoonotic diseases and their vectors on high-risk professionals' and animals' health. One co-creation activity will evaluate a prototype toolkit on Health System preparedness and resilience to climate change effects already developed by ACARES and HSPH in the U.S. and adapt it to the prevailing conditions and characteristics of Cyprus' Health System and subsequently to the conditions of hospitals across the Mediterranean. **ISMED-CLIM** proposes the refinement of the five LLs outputs through **ten replications in six sites** in the Mediterranean, in parallel with the integration of the produced knowledge, forecasting, exposure and health data with insights from the LLs into a **knowledge portal** and **policy decision-centric and action-oriented dashboard** for policy makers, healthcare administrators, professionals and citizens. This Dashboard will provide a one-stop workplace that will allow users to access evidence-based policy proposals and public health recommendations, explore and visualize data, monitor area level vulnerability to climate change-related health risks, utilize digital policy implementation tools, participate, and carry out training activities and evaluate policy uptake by the community.

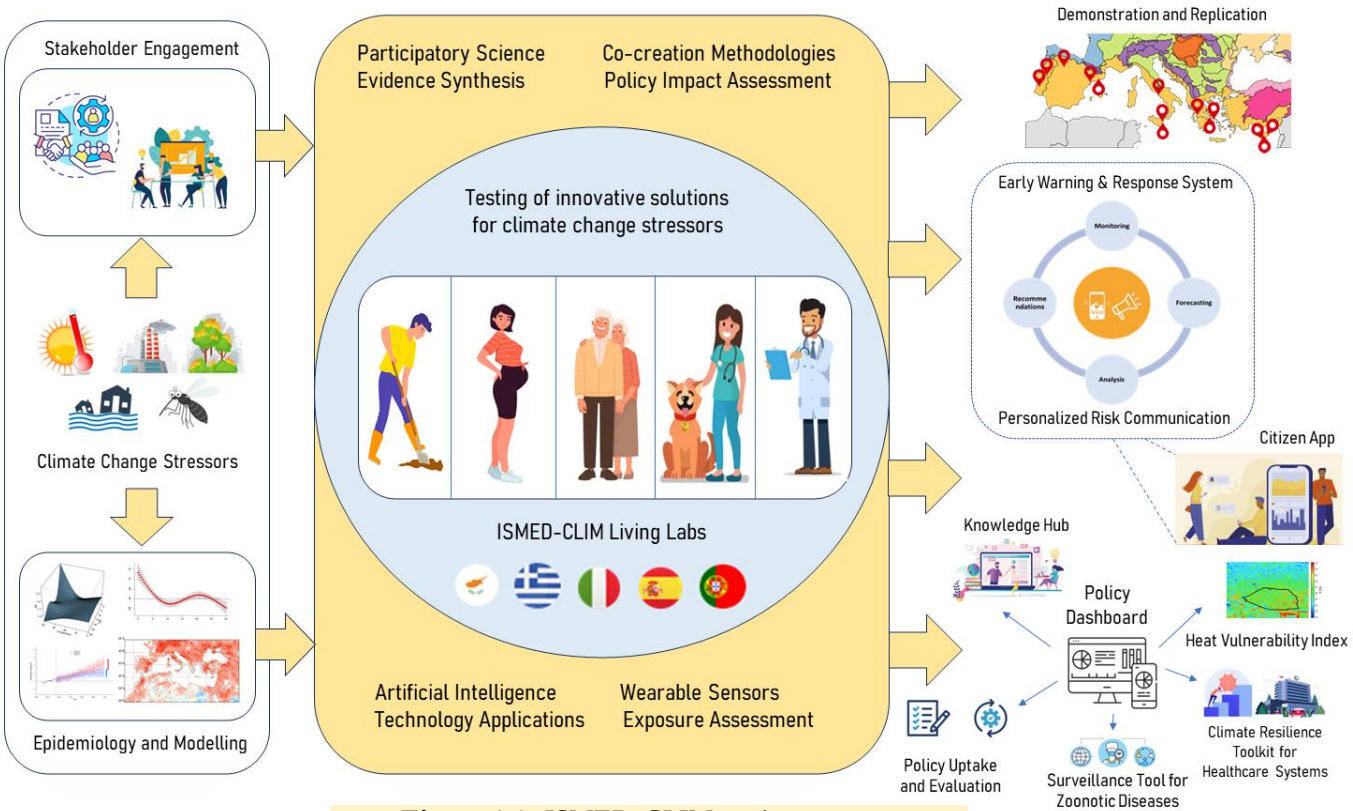


Figure 1.1: *ISMED-CLIM project concept*

1.2.2 Scientific and Technical methodology

1.2.2.1 Epidemiology of non-communicable diseases (NCDs) and climate change in the Mediterranean

The epidemiological analyses will enhance current knowledge on climate change health impacts in the region and fill related gaps. Mediterranean-specific results using recent data are necessary to inform successful planning by local authorities and allow citizens to understand how the region has disproportionately been experiencing extreme events related to climate change, compared with other regions in the world. The aim is to investigate the impact on NCDs mortality and morbidity outcomes in a cumulative approach to address the complex interplay between various climate change parameters (as temperature) and events (as wildfires) specifically for the Mediterranean region. We will further assess the exposure impact on pregnancy outcomes in areas with available registries to inform the work of LL2 in WP4. We will explore interactions between drought, flooding and wildfire events with increasing temperatures and air pollution for the area. Data collected will cover at least five EU countries, and possibly other member states, across the Mediterranean for 2000-2023 and will include daily data on temperature levels, humidity, wind direction and speed, occurrence of desert dust episodes, flooding, wild fires and air pollution levels along with age-specific daily counts on total and cause-specific mortality and hospital admissions (International Classification of Diseases, 10th Revision ICD-10 codes: All-cause–A00-Y84; natural–A00-R99; cardiovascular–I00-I99; respiratory–J00-J99; diseases of the nervous system: G00-G99). We will also collect data from available registries on preterm births (ICD10: P07.2–P07.3), low birth weight and daily admissions in Neonatal Intensive Care Units for prematurity to assess the impact of climate change parameters on pregnancy outcomes.

The analyses will apply a two-stage approach. In the first step, we will apply location-specific confounder-adjusted (Quasi-) Poisson distributed lag non-linear models[64] that flexibly account for the nonlinear shape of the association between temperature and health and the lag in the effects. Interactive effects with air pollution levels and dummy indicators for extreme events, such as droughts and wildfires will be examined by interaction terms between exposures[65]. Location-specific effect estimates will then be pooled in a second step using multivariate random effects meta-analyses to provide Mediterranean-specific overall estimates and shapes for the outcomes. We will further explore effect modification by area and build characteristics, as for example the green spaces in metropolitan areas.

1.2.2.2 Epidemiology of zoonotic diseases and vectorial capacity and climate change in the Mediterranean

Climate change not only causes the range expansion of vector species, but also facilitates the transportation and transmission of vector-borne diseases. In Europe, the recent establishment of the invasive mosquito species, *Aedes albopictus*, and its rapid range expansion have already led to local outbreaks of dengue and chikungunya in France, Italy, Croatia, and Spain. The common house mosquito, *Culex pipiens*, has already caused West Nile virus (WNV) outbreaks in Germany and Russia, and the emergence of Usutu virus (USUV), also transmitted by this mosquito, in Belgium, France, Germany, Switzerland, and The Netherlands[24]. At the same time, the number of human cases associated to WNV infection has dramatically increased in southern Europe during the last decade. In addition, re-emergence of ancient diseases becomes a plausible risk as climate changes. Local transmission of malaria resumed in Europe during the late 1990s, occurring sporadically in several countries of the region, including Greece, Cyprus, and Turkey[66]. Although classified as a neglected tropical disease, 1 million new cases of cutaneous leishmaniasis, the most common form of leishmaniasis, occur each year globally, with 70% of all cutaneous leishmaniasis cases worldwide coming from the Eastern Mediterranean and Middle East (EMME) region[67].

We will thoroughly review, collect and harmonize all the existent sand fly and sand fly-borne diseases (SFBDs) data available to us from project partners, or existing open datasets from previous or ongoing sand fly surveillance projects. We will go through the same review for the existing or currently developed climate and environment models to define those suitable for this project. We will do that to: (i) define the most important climate and environmental variables for sand fly abundance and SFBDs modelling; (ii) produce a range of parameters and critical values of climatic and environmental vector, pathogen and disease drivers, needed as inputs to the EWRS to be developed by the project; (iii) decide on the most appropriate algorithm for use in EWRS; and (iv) test, co-create and validate the use of this tool, in communication with end users – pet owners, dog shelter workers, activists and veterinarians. This will lead to a tool that can be easily adopted by similar end users in Europe and internationally.

1.2.2.3 Predictions of climate change effects on non-communicable and communicable diseases

For NCDs, we will apply the estimated concentration-response functions to future projections, using different scenarios of climate change for the next years based on the Shared Socio-economic Pathways (SSP) framework. SSPs represent a range of emission and radiative forcing scenarios, and here we will use SSP1-2.6, SSP2-4.5, and SSP5-8.5 to ensure a wide range of possible future climates (from SSP1-2.6 representing a very low emission scenario to SSP5-8.5 representing the highest emission scenario). We will utilise the Copernicus Climate Change Service downscaled weather projections data, which are high-resolution downscaled and bias-corrected projections, from multiple climate models that are structurally independent. The projected data will be used in conjunction with the estimated relationships between exposures and health outcomes from 1.2.2.1, to obtain projections of the attributable cases of health outcomes. The projections from the three SSP scenarios (from the best SSP1-2.6 to the worst SSP5-8.5) will be compared to the baseline period of 2001-2020, in order to understand the degree of projected risk.

Numerous studies project that suitable habitats for *Aedes albopictus* will expand globally, most significantly in the northern hemisphere, putting at least an additional billion people at risk of *Aedes*-borne diseases by the middle of the 21st century[68]. Several highly populated areas of the world will be suitable for *Aedes albopictus* populations, such as the northern parts of the USA, Europe, and India by the end of the century under the business-as-usual scenario. Ecological niche modelling predicts that future climate change will alter the geographic distribution of the existing *Phlebotomus* species in the Mediterranean and the EMME region[69]. It is also expected that these changes will allow certain sand fly species, such as *P. alexandri, P. neglectus, P. papatasi, P. perfiliewi, P. tobbi*, spread towards areas

currently not suitable for their survival (eventually reaching Western and Central Europe)[67]. Using the Copernicus projections data for the same SSP scenarios, assimilated with existing vector population dynamics models, we will generate short- and long-term assessments of vector presence, population abundance, and associated disease risk across the Mediterranean. Sand flies and related diseases will be tackled as the exemplary case study, to demonstrate the applicability and effectiveness of the predictive models and the developed early warning systems.

1.2.2.4 Optimization of operational forecasting for extreme weather events and regional downscaling

ECMWF will provide ensemble forecasts with different lead times (hours up to months) depending on application for several weather variables (temperature, humidity, precipitation, wind speed, cloud coverage, solar radiation) across all demonstration and replications sites. For each replication site, ECMWF will optimise the accuracy of the forecast for extreme weather events through machine learning (ML) using reanalysis, reforecasts and observed weather data to post-process the temperature forecasts to provide optimized and downscaled (1 km x 1 km resolution) forecasts. Furthermore, the downscaled temperature forecasting products will be used as inputs (boundary and initial conditions) for dynamical urban micro-climate modelling to account for city-specific features (e.g. heat island effects, urban canyons)[70,71] and provide personalized predictions of thermal stress during extreme events. The downscaling and micro-climate modelling of atmospheric data (e.g., temperature, humidity, wind speed, and direction) will resolve the significant biases that accompany the insufficient information of climate systems or low-resolution grids[72].

1.2.2.5 Recommendations development, tailoring and configuration

Although progress has been made by national/regional public health and environmental authorities in terms of adaptation plans and alert systems to improve response to climate-related stressors, there is limited evidence on the effectiveness of measures put in place, especially among high-risk population groups[50-52]. In addition, for other climate change-related health hazards, such as infectious and vector-borne diseases, the range of operational, usable, and accessible alert systems, and availability of recommendations is considerably limited[58]. Similarly, healthcare systems, especially in countries of the Mediterranean biogeographical region, are characterized by either lack of preparedness plans or disparities in the distribution of adaptation policies for climate change related risks[73,74]. **ISMED-CLIM** will engage frontline professionals, policy-makers, regulatory authorities, patient representatives and other social stakeholders in focus groups and surveys to configure the alert algorithms and tailor the recommendations to be tested in the proposed LLs. Identification and engagement of these stakeholders will serve a dual purpose: a) ensure representation of the required expertise from different implicated groups and b) ensure the buy-in and utilization of the outputs by end-users and subsequent adoption at the population level[75].

At first, we will identify existing action plans already employed or proposed at the regional level through a scoping literature review and active interviews with local authorities build on previous work done by WHO and EU projects, focusing on vulnerable groups' response. In particular for exposure to heat and air pollution, we will consider implementation across the Mediterranean region of recommendations that have been developed by others and partners of this consortium in previous projects, such as changes in behavioral[21,22] and activity patterns[54] of time spent and physical activity performed outdoors, hydration, body cooling and use of devices to reduce indoor temperature (fans, A/C)[21] and PM air pollution levels (HEPA air purifiers)[56]. We will seek each type of proposed solution, their range, applicability, as well as for gaps in practice and implementation. The scoping reviews will be carried out according to PRISMA extension[76] and will cover academic literature databases, as well as international and national institutional websites to capture unpublished grey literature. Subsequently, the engaged stakeholders will provide insight of their specific needs, integrate perspectives of vulnerable groups, assess intervention barriers, and provide suggestions on the evaluation and scalability of the proposed solutions and recommendations. Following this initial configuration and tailoring process, the alert algorithms, EWRS and recommendations will be adapted and finalized taking into consideration the output of WP2 (estimates of exposure-response relationships and effect thresholds) and WP4 LL1-3 (efficacy of exposure reduction and health mitigation interventions). For zoonotic diseases, the final tailoring of the recommendations will also rely upon the work of CLIMOS project and the feasibility and user acceptance of the EWRS and guidelines to be assessed among high-risk professionals and citizen groups (dog shelter workers and volunteers, veterinarians) in WP4 LL4. Finally, for the healthcare system preparedness, the final tailoring of the proposed recommendations will also rely on the site-specific climate resilience and needs assessment based on the methodology suggested by the EU Expert Group on Health System Performance Assessment. Current work carried out by WHO EUROPE[77] and the CATALYSE Horizon Europe project will be considered to tackle current barriers and gaps. We will employ a modified Health System Resilience Questionnaire (HSRQ) and built upon the prototype Climate Resilience for Frontline Clinics toolkit that has been developed in the U.S. by HSPH and ACARES. During the consultation workshops, the existing, as well as novel proposed resilience and preparedness tools and recommendations will be assessed and finalized, considering: (i) results of the region-specific climate resilience and needs assessment; (ii) comparison with international best practices (where available); (iii) assessment of resource constraints; (iv) geographical, cultural, and socio-economic characteristics of the region; (v) equity issues especially regarding healthcare access of vulnerable and marginalized groups; and (vi) technical feasibility.

1.2.2.6 Data Platform

ISMED-CLIM aims to create a data platform that manages and stores research and innovation outcomes produced by the project and involving coordination processes spanning from data management and analytics components to end-user applications and services. The platform will function as the cohesive element of the project's ecosystem, providing service interfaces for direct interactions with diverse components. Security-by-design, resource allocation, complete communication paths, spanning from end-devices and data sources to end-users (end-to-end communication), control mechanisms, seamless interaction between components, and data transfer integrity will be core principles embodied by the platform. **Data collection and storage within ISMED-CLIM and beyond**: We aim to create an extensive dataset, including cross-referencing capabilities, through integration of data generated within the project. The Open Access feature of the database facilitates effective data storage, retrieval, and updates, with the capacity for querying data and serving as a repository for the accumulated knowledge. There are plans to integrate and exchange data from external databases, broadening the accessibility of accumulated information, with the intention for knowledge to remain accessible and expandable for users beyond project's conclusion. **Engagement with stakeholders:** We aim to create a multimodal environment that facilitates interaction for both advanced users and simple viewers, emphasizing clarity over complexity and maintaining user control. An early phase of the project involves mapping controversies and identifying each actor and their knowledge base. The platform's architecture encompasses the following layers as outlined in **Figure 1.2**: ***Data orchestration and management***, ***Data ingestion and analytics***; and provision of ***Application tools and services*** for data collection, analysis, and utilization.

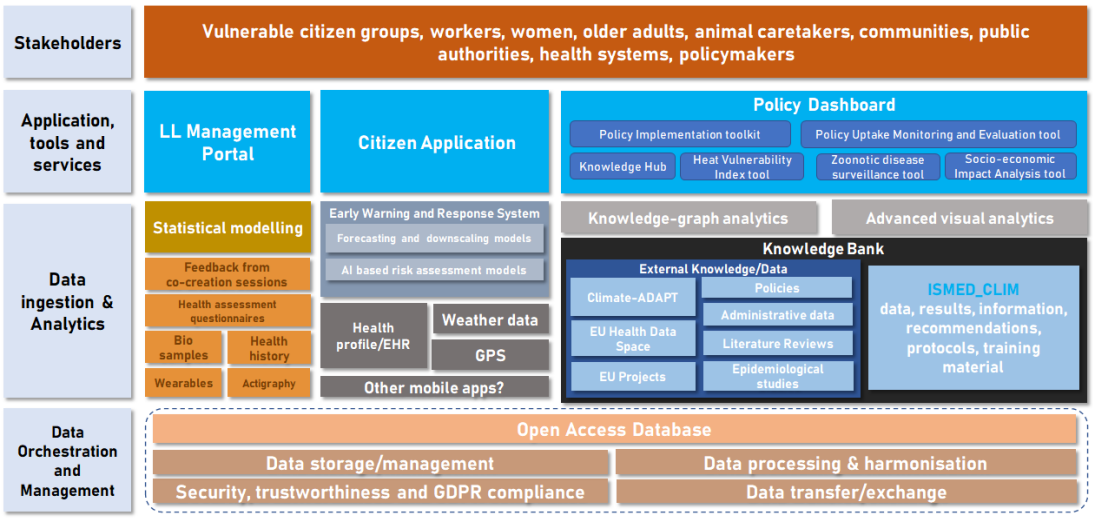


Figure 1.2: *ISMED-CLIM data platform*

Data processing, harmonization, and management: The layer responsible for data management and orchestration deals with the processing of data within the database, with a focus on ensuring trustworthiness, adherence to data ethics, and compliance with GDPR regulation (**T3.1**).

Data ingestion and analytics: The platform's database will be openly available and house an extensive repository of project activities and outcomes, including data from the LLs activities, protocols, public deliverables, publications, guidelines, policy recommendations, and articles closely tied to the project's core concepts. Data and information in the Knowledge Base will be readily accessible across various web browsers and devices via the Knowledge Hub, ensuring cross-browser and multi-device compatibility. Both during and beyond the entire lifespan of the project, users will retain the capability to continually enhance the content of the Knowledge Base. This collaborative contribution will result in the gradual expansion of this repository, evolving into a comprehensive one-stop reference for all stakeholders engaged in climate change and health domain. Furthermore, efforts will be directed towards managing access and ensuring the secure sharing of exported **ISMED-CLIM** data and registries, while maintaining privacy. In addition, secure interfaces will be established with EU Health Data Spaces and Climate-ADAPT platform through utilization of standards, protocols, and Application Programming Interfaces (APIs), enabling various services and data to be seamlessly integrated. ***Knowledge Graph-based analytics*:** A knowledge graph encodes data in the form of graph structures (nodes and edges) by capturing relationships between entities in a flexible manner and providing semantically structured information for question answering, recommendation systems and information retrieval and decision-making processes[78,79]. The proposed tool makes the decision-making process accessible in an interactive and explainable manner: Firstly, the information presented in policy guidelines produced during the project will be deconstructed and represented via a knowledge graph and secondly, an interactive suite of algorithms – the policy *recommender* - that commences with a set of initial domain values - the end user's starting point of query (starting node) e.g. *"Heat Alert Plan procedures to be followed when an extreme heat event is declared by the forecast agency"*. Using this prior knowledge and the knowledge graph representation, the algorithms prompt specific questions to the end user that the user has to answer. Responses to these questions enable the recommender to make progress and serve as input for the subsequent iteration, navigating progressively throughout the knowledge graph. The iterations persist until the domain expert is content with the outcome, and a final recommendation is reached.

1.2.2.7 AI models

1.2.2.7.1 Early Warning and Response System (EWRS) models: As a comprehensive measure of thermal stress, we will use state-of-the-art indices, such as the Universal Thermal Climate Index (UTCI), which was created as a composite index of air temperature, wind, radiation, and humidity, to describe synergistic interactions of the thermal environment and the human body, considering physical activity, metabolic rate and clothing insulation[80]. UTCI is a valid tool across all spatio-temporal scales and has been applied to settings such as occupational health[81],

heatwave hotspots forecasting[82] and heat-related health risk assessment in Europe and elsewhere[83].
The evolution of neural networks in the context of early warning systems is a significant advancement in leveraging AI for predictive capabilities. Traditional feedforward neural networks initially offered the ability to capture complex, non-linear relationships between (weather) variables and outcome of interest (UTCI index in our use case). However, it's important to note that in some cases, simpler methods like regression models may also be adequate for UTCI prediction, especially when the relationships are relatively linear or when computational resources are limited. For spatial data like weather patterns, Convolutional Neural Networks (CNNs) have been recently introduced to address the intricacies of image-like data, such as temperature maps[84]. While CNNs have shown great success in image classification tasks, their application to UTCI prediction can be suboptimal due to the unique characteristics of meteorological data. Weather data typically involve temporal dependencies and regional variations, which CNNs might not capture effectively. Within **ISMED-CLIM,** we will employ models like Long Short-Term Memory (LSTM) networks, which are recurrent neural networks designed for time series forecasting, which might be more suitable for predicting UTCI changes over time, as they can account for sequential patterns and temporal correlations within the data. The evolution of neural networks in this context reflects the importance of tailoring model selection to the specific data and problem at hand to achieve optimal results in early warning systems. Furthermore, Time Series Forecasting Models such as ARIMA and Prophet have emerged as valuable tools in this context because they excel at capturing temporal patterns and seasonality inherent in weather data. These models can outperform CNNs and traditional neural networks when it comes to predicting UTCI changes over time, making them a compelling choice for early warning systems, where accuracy and interpretability are crucial for timely and effective alerts.
ARIMA is a time series forecasting method that models a time series as a combination of autoregressive (AR) and moving average (MA) components after differencing the data to make it stationary[85]. Prophet is a forecasting model developed by Facebook for handling timeseries data with daily observations and strong seasonal patterns. It incorporates a flexible seasonal component, holidays, and trend changes[85]. Very recently hybrid combinations of LSTM and such Time Series Forecasting Models have been introduced[86]. Such models have not been tailored nor tested for weather data and will be explored for the first time within **ISMED-CLIM**.

1.2.2.7.2 Trustworthiness and robustness of AI: **ISMED-CLIM** aims to build novel EWRS models to power the data Platforms and the AI-enabled tools hosted within. In the design of any AI-enabled recommendation system meeting regulatory requirements and earning stakeholders' trust is challenging, yet paramount for uptake. Building trustworthy AI solutions is a multi-factorial process that requires systematic steps, from design to development and from deployment to management, as well as interdisciplinary collaboration. To this end, a procedural framework (recently termed as TrustAIOps) will be established based on the Assessment List for Trustworthy AI (ALTAI) (a cornerstone of the recently voted EU AI Act), functioning as guide and a checklist for building the AI-driven components of the project. The framework will be co-developed by data science, development, ethics, and legal (DBC) teams. The ALTAI will be amalgamated with regulatory requirements [FDA action plan on AI in SaMD], recommendations of relevant standards (ISO/IEC JTC1/SC42 umbrella) and guideline collections. We will also define a set of tools, metrics, and tests for building/evaluating AI components and underlying datasets according to trustworthy qualities. Considering the targeted TRL for the models (TRL 6) and associated software (TRL 7), emphasis will be given to aspects of trustworthiness pertaining to AI design, development, and deployment.

1.2.2.8 Living Lab Demonstrations

1.2.2.8.1 Overall LL concept: **ISMED-CLIM** envisions **five Living Labs (LLs) in WP4** to test and validate a series of recommendations, digital tools and solutions for mitigation of climate change impact on the health of vulnerable workers and citizen groups, the health systems and the society as a whole across the Mediterranean. **LLs 1, 2, 3** will assess in randomised controlled intervention trials **how early warnings, personalised risk communication and recommendations** (in written and animated format through web and smartphone applications) **with the support of advanced technologies** can reduce exposure to heat and air pollution and related health effects during summers in three vulnerable population groups: (i) outdoor workers; (ii) pregnant women; and (iii) older adults with hypertension. **LL4** will assess the **feasibility and user acceptance** of an EWRS and an evidence-based set of prevention interventions for zoonotic diseases among high-risk professionals and citizen groups. **LL5** will **adapt an existing protype Climate Resilience for Frontline Clinics toolkit** in the U.S. to be used by healthcare system administrators, healthcare professionals, and end users in the conditions and characteristics of Mediterranean Health Care Systems. The LLs will be performed during a first initial cycle of **eight demonstration sites** followed by a second refined cycle of additional **ten replications in six sites.**

These sites have been carefully selected and are distributed across the **five main EU countries** (Cyprus, Italy, Greece, Spain and Portugal) of the Mediterranean region, including two of the largest **islands (Sicily and Cyprus)** at the edge of southern Europe, that experience **very hot summers, prolonged heatwaves,** and exposure to **high particulate matter (PM) air pollution** from anthropogenic and natural sources (**desert dust, volcanic ash**)[87-89]. Among the demonstration and replication sites there are **socially underprivileged areas** (Korydallos-Greece) and sites eligible for **Cohesion funds** (Catania-Italy, Aveiro-Portugal, Trikala-Greece), as well as a **newly established national healthcare system** (HIO-GESY Cyprus).

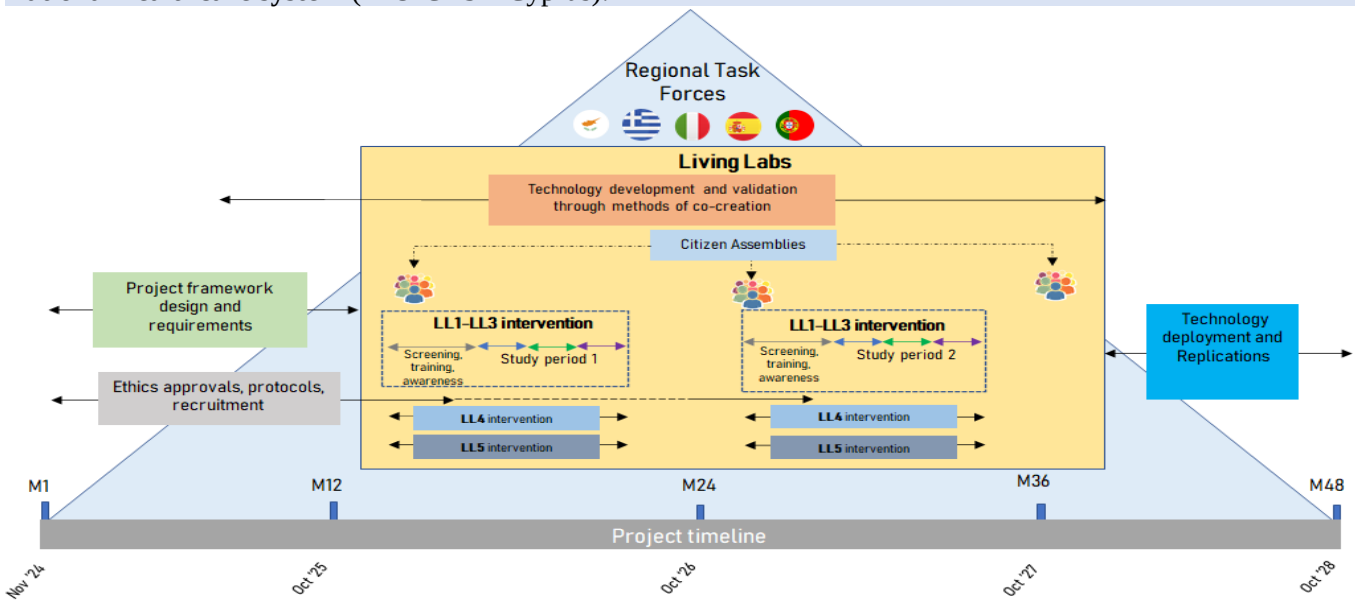


***Figure 1.3**: Roadmap for the development of all the phases of the LLs.*

1.2.2.8.2 Living Lab descriptions

LL1	**Target group: Outdoor workers**	**Leading partner: UTH**
Site 1: Trikala - Greece	**Site 2: León - Spain**	**Other partners: TRIKALA, ULE**

***Background and motivation*:** Occupational exposure of outdoor workers **(OW)** to heat in the Mediterranean region frequently induces symptoms of exhaustion, headache[15] disrupts physiological processes and increases core and skin temperatures, heart rate and urine specific gravity[53]. The scientific evidence on the effectiveness of existing alert systems and end users' compliance in implementing current recommendations for reduction of exposure to heat and mitigation of biological processes disruption and heat stress remains to date insufficient[22].

***Description of Site 1*:** **Trikala–Greece** is an underprivileged area with a hot and humid climate during summers. The Municipality of Trikala has a track record of participation in climate change projects and employs >500 OW who typically work in 30-40°C temperature and 40-80% relative humidity, with temperatures reaching 45°C during heatwaves.

***Description of Site 2*:** **León-Spain** has a hot and dry climate during summers. The Municipality of León has >300 OW, collaborates closely with ULE in research projects, and will facilitate the recruitment of participants in the trial.

Inclusion criteria and partner roles (see study design below*): **UTH** and **LEÓN** will recruit in a randomised controlled intervention trial **102** municipality **OW,** aged 18-65 years from Sites 1-2, who regularly work outdoors for at least 6 hrs[90], are not currently smokers, are clinically healthy and do not have diabetes mellitus type 2 (DM2) or arterial hypertension.

***Added value and impact towards climate change adaptation*:** Provide scientific evidence for the effectiveness of a set of OW-specific interventions that can reduce personal exposure to heat and air pollution and related health effects across two socially and climatically diverse sites in the Mediterranean.

LL2	**Target group: Pregnant women**	**Leading partner: UNICT**
Site 3: Catania - Italy	**Site 4: Limassol - Cyprus**	**Other partners: ARNAS, UCY**

Background and motivation: Pregnant women (PW) and developing fetuses are uniquely vulnerable to the impacts of extreme temperatures and air pollution which, besides the risk of preterm delivery and low birth weight, have been associated also with negative behavioral changes, sleep disruption[17] increased maternal mental stress[43], maternal hypertensive disease[18], heat stress and dehydration[44].

***Description of Site 3*:** **Catania-Italy** is an underprivileged area with a scorching, humid climate during summers, experiencing frequent intense heatwaves and high PM pollution. ARNAS Garibaldi Hospital in Catania is a public Hospital with a large Obstetrics Dept that is actively participating in mother-child cohort studies, registered in birthcohorts.net[91].

***Description of Site 4*:** **Limassol-Cyprus** has a hot, humid climate during summers and high PM pollution. A network of small private Maternity Clinics in Limassol has a previous record of participation in a pregnancy-birth cohort[92].

Inclusion criteria and partner roles (see study design below*): **UNICT** and **UCY** will recruit in a randomised controlled intervention trial **102 PW** aged 20 to 35 years from Regions 3-4, who are in the 2nd trimester of a singleton pregnancy, do not currently smoke, and do not have gestational diabetes, pre-eclampsia or severe pregnancy

complication.

Added value and impact towards climate change adaptation: Provide scientific evidence for the effectiveness of a set of PW-specific interventions that can reduce personal exposure to heat and air pollution and related health effects across two different hospitals settings (public-private) and socially diverse patients in the Mediterranean region.

LL3	Target group: Older adults with hypertension	Leading partner: VHIR
Site 5: Barcelona - Spain	Site 6: Nicosia - Cyprus	Other partners: EKYSY, UCY

***Background and motivation*:** High ambient temperature is known to decrease the mean daytime average and morning surge in blood pressure (BP), but increases the nocturnal BP[46]. Abnormalities in circadian blood pressure (BP) variation, particularly the disappearance of the nocturnal BP fall (non-dipping) or rising of nocturnal BP vs. daytime BP are associated with incidence of cardiovascular diseases and subclinical organ damage[23,47] which is more pronounced in elders on hypertensive (EH) treatment[48]. Particulate matter air pollution is also known to acutely increase ambulatory blood pressure[49] and incidence of complicated ST elevation myocardial infarction[93].

***Description of Site 5*: Barcelona-Spain** has a hot and humid climate during summers and high PM air pollution. The Aging research group of VHIR (REFiT) is set in Parc Sanitari Pere Virgili (PSPV), which manages an Intermediate Care Hospital, and four Primary Care Centers. PSPV and VHIR together with other eight institutions (among others, the Federation of Older People Associations in Catalonia) founded the Barcelona Aging CoLLaboratory (BALL) and will assist the recruitment of participants in the trial.

Description of Site 6: **Nicosia-Cyprus** has a very hot and dry climate during summers and high PM air pollution. EKYSY is the Pensioners Federation in Cyprus with over 60.000 members, and is a partner of **ISMED-CLIM**. They will actively promote recruitment of participants in the trial from their members roaster in Nicosia city.

Inclusion criteria and partner roles (see study design below*): **VHIR** and **UCY** will recruit in a randomised controlled intervention trial **102 EH** aged >65 years from Sites 5-6, who do not currently smoke, have a physician's diagnosis of arterial hypertension, receive daily anti-hypertensive medication and are otherwise clinically healthy.

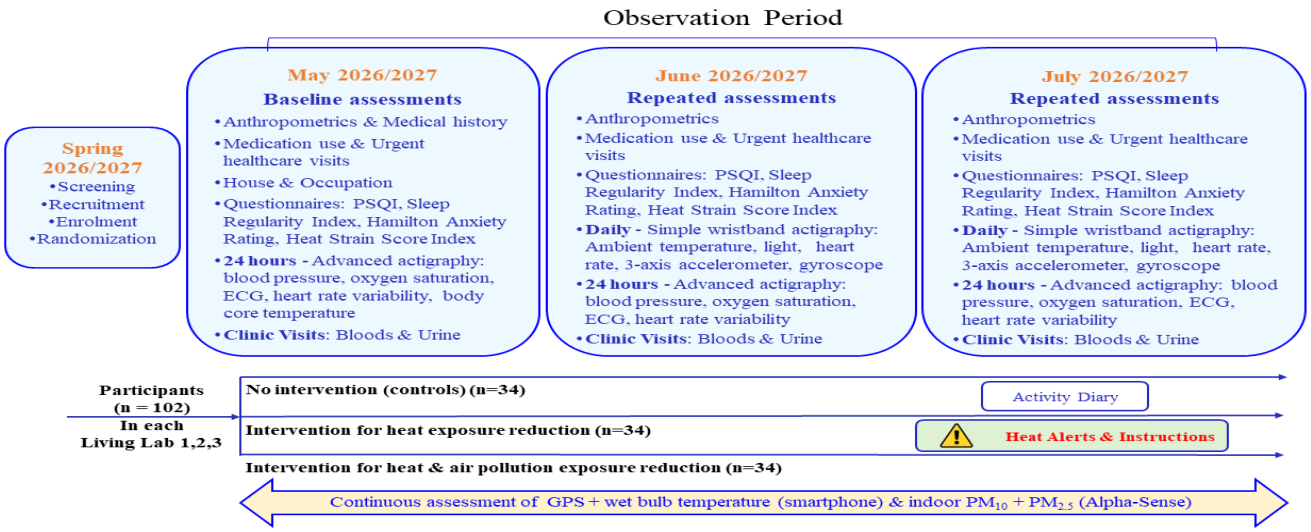
***Added value and impact towards climate change adaptation*:** Provide scientific evidence for the effectiveness of EH-specific interventions that can reduce personal exposure to heat and air pollution and related health effects across two sites with different climatic conditions in the Mediterranean.

Study Design: LLs 1, 2, 3 are randomized controlled intervention trials and will have the same study design **(Figure 1.4)**. Subjects for each LL1, 2 and 3 will be screened during ***Spring 2026 and 2027*** for their eligibility to participate in the three randomized controlled trials, based on the respective inclusion criteria, as described above. **Exclusion criteria will be the same for the three LLs:** Presence of any smoking residents in the household, not residing at the household for at least 5 days a week or family planning to move from the current home within the next two months, or no access to Wi-Fi or 4G/5G mobile phone. Also, participants will be excluded if they have severe chronic conditions (congestive heart failure, ischemic heart disease, significant valvular heart disease, DM2, inflammatory diseases, renal failure, or active cancer), abuse drugs or alcohol, have psychiatric disorders or severe mental disability that interferes with answering questions or following instructions.

In ***May 2026 and 2027***, we will enrol in each LL 102 eligible participants and monitor them for two months during upcoming ***June-July***. At baseline in May, participants of each LL will be randomized into three parallel study groups to a) receive no alerts for high temperatures nor recommendations for mitigation of health effects ***(business as usual scenario, n=34)***, b) receive timely personal alerts for high temperatures and specific recommendations to reduce exposure to heat by changing patterns of time spent and physical activity performed outdoors, regulating indoor temperature using fans and or A/C devices, as well as recommendations for mitigation of health effects (hydration, body cooling) in written and animated format, through mobile phone and web application tools to be developed by the program (WP3) (***heat mitigation intervention, n=34***), and c) receive alerts and recommendations as in group (b) and in addition continuously use air cleaners with HEPA filter for removing PM from indoor air in their residences and workplace (***heat and air pollution mitigation intervention, n=34***) to provide evidence for health benefits.

Exposure assessment: Personal exposures of participants will be monitored continuously during the two observation months with wearable sensors to be always worn and assess personal exposure to ambient (outdoor and indoor) temperature and humidity (iButton), as well as physical activity levels and sleep-wake patterns (wristband actigraphy with 3-axis accelerometer, gyroscope, light, heart rate sensors). Wristband actigraphy and iButton will operate on battery and store data for one month. The time participants spend indoors/outdoors from their residence and work premises (where applicable) throughout the study will be assessed using the global positioning system (GPS) of their smartphone. During Clinic visits stored data will be downloaded and devices will be re-charged for next use. Measurements of indoor exposures to PM at the residence and work premises will be provided continuously by

Figure 1.4: *LLs 1,2,3 Study design as randomised controlled intervention trials*



commercial lightweight sensors (Alpha sense). The sampling devices will be placed in the residence living area and the work premise (where applicable), where participants spend most of their time indoors and store data for the two months of observation. These monitors will enable the precise profiling of the participant's exposure to indoor-outdoor temperature, humidity, light and indoor levels of particulate pollutants. **Health measures assessment**: During Clinic visits at baseline (May), middle (June), and end of two-month (July) observation period, the Pittsburgh Sleep Quality Index (PSQI) questionnaire, the Sleep Regularity Index questionnaire and the Hamilton Anxiety Rating questionnaire will be administered. During each Clinic visit, participants will be provided with advanced actigraphy to use for 24 hours with sensors that measure continuously blood pressure (BP), oxygen saturation, ECG, heart rate variability. Finally, during each Clinic visit blood and urine samples will be obtained. In LL2 specifically, OW at baseline, middle, and end of two-month observation period will be administered the workers Heat Strain Score Index (HSSI) questionnaire and have 24 hours continuous assessments of body core temperature by swallowing eCelsius Medical capsule. This design will enable repeated (x3) assessments of subjective (questionnaires) and objective (wearable sensors) health outcomes, as well as biomarkers of hydration and systemic inflammation in the three parallel study groups in each LL at baseline (May), middle (June) and end (July) of observation period (**Table 1.1**).

Table 1.1: Exposure and health parameters to be assessed per participant and in total in the three LLs 1, 2, 3.

Parameters	LL1 OW (n=102)	LL2 PW (n=102)	LL3 EH (n=102)	Total Observations
Indoor-outdoor temperature, humidity & light exposure	60 Days	60 Days	60 Days	55.080 Obs Days
Activity levels	60 Days	60 Days	60 Days	55.080 Obs Days
Sleep wake pattern	60 Days	60 Days	60 Days	55.080 Obs Days
Indoor levels of PM	60 Days	60 Days	60 Days	55.080 Obs Days
PSQI, Sleep Regularity Index, Hamilton Anxiety Rating Q.	3	3	3	2.754 Obs
Heat Strain Score Index Q.	3	-	-	306 Obs
Blood pressure, oxygen saturation, ECG, heart rate variability	3 Days	3 Days	3 Days	2.754 Obs Days
Body core temperature	3 Days	-	-	306 Obs Days
Blood biomarkers (C-reactive protein, urea, creatinine, Na, K, osmolality)	3	3	3	2.754 Obs
Urine biomarkers (creatinine, Na, K, osmolality)	3	3	3	2.754 Obs

Exposure outcome measures: The **primary exposure outcome** for the **three LLs** will be the personal ambient temperature profile of all participants, as measured during the two months of observation with the iButton. Secondary exposure outcomes will include personal exposure of all participants to thermal stress indicators (i.e., wet-bulb globe temperature)[53], humidity, light, physical activity levels, indoor levels of PM at the residence and work premises during the two months of observation. **Health outcome measures**: The **primary health outcomes** will be assessed at baseline, middle and end of the study period and for **LL1 in OW** will be the workers HSSI[94] for **LL2 in PW** will be PSQI questionnaire score[95] and for **LL3 in EH** will be night-time dipping systolic/diastolic BP in relation to daytime BP[96]. Secondary health outcomes will include daily heart rate and sleep-wake patterns during the two observation months, and repeated assessments at baseline, middle and end of the study period of Sleep Regularity Index and Hamilton Anxiety Rating scores, daytime and night-time profiles of systolic/diastolic BP, ECG, heart rate, heart rate variability, and core body temperature (in OW), as well as biomarkers of systemic inflammation, renal function and hydration in blood (high sensitivity C-reactive protein, urea, creatinine, sodium, potassium, osmolality) and urine (creatinine, sodium, potassium, osmolality) at baseline, middle and end of the study period. **Sample Size and Power Calculation:** The three LLs in outdoor workers, pregnant women, and older adults are randomized intervention clinical trials employing a similar study design. Therefore, the estimation of the required sample size and the power calculation in each of the three LLs relied on a common repeated measures analysis involving three intervention groups and three visits and was carried out using G*power Software[97].For the power calculation in LL1 and LL2, the effect size assumed was a **20% difference, in the mean score of HSSI** (for LL1) **and PSQI** (for LL2) between the intervention and control groups. For HSSI, the employed novel heat strain score index, the few recent previous studies demonstrated that improvements of similar magnitude in HSSI were observed following interventions to reduce heat stress in both controlled[98] and real-life conditions[99]. For LL2, PSQL is a well-established outcome

measure for sleep quality, but its use in studies focusing on environmental exposures is very limited. However, differences in the range of 20% were reported in the two available observational and intervention studies evaluating the impact of thermal comfort, temperature and other parameters on sleep quality[100,101] in different population groups (young adults and elderly people). In the absence of comparative or intervention studies focusing on environmental exposures in pregnant women that used the PSQI as an outcome measure, the available evidence supports a 20% effect size for LL2.

For night-time dipping blood pressure in LL3, a **20% change in the disrupted non-dipper status** for night-time BP (compared to daytime BP) to a dipper status was found to be clinically meaningful in a recent prospective, observational study[102] while the nocturnal systolic BP fall is significantly less during the summer season in comparison to the cold seasons of the year. Based on the study by Kario K et al, patients with dipping and extreme dipping night-time BP were characterized by a lower risk of cardiovascular events compared to patients with non-dipping and rising night-time BP[102]. To date, no studies examined night-time BP dipping status as an outcome measure in intervention studies focusing on environmental parameters but there was some evidence related to physical activity and medication. In an observational study focusing on physical activity, being active was associated with a 18.6% change in the disrupted non-dipping status for night-time systolic BP and 22.2% in the disrupted non-dipping status for night-time diastolic BP[103], while, in a study focusing on the effect of medication (telmisartan and ramipril) the transition from one dipping category to another following 14-week treatment was much higher with the percentage of patients rising or non-dipping status moving to the non-dipping and dipping status respectively being greater than 30% and 20% respectively[104]. Overall, for a repeated measures analysis involving three intervention groups and three visits (time points of assessment) and assuming a 0.05 alpha error probability, 0.95 power (1-beta error probability) and a moderate effect size of 0.20, the required sample size is 81. Accounting for a dropout rate of 20%, a total of 102 subjects will be recruited in each LL.

Statistical Analysis: In each LL 1, 2 and 3, we will create a dataset from measurements collected during the observation months from the three parallel groups (business as usual scenario, heat mitigation intervention and combined heat and air pollution mitigation intervention). Heat mitigation intervention aims to **reduce personal exposure to mean ambient temperature by 2 ^{0}C** that will be measured continuously by the iButton wearable sensor. Air pollution mitigation intervention aims to **reduce mean indoor particle levels by 40%** using an air cleaner device with HEPA filter. To assess the effectiveness of this intervention on the cumulative personal air pollution exposure is important to a) determine indoor (household/work premise) particle levels, b) estimate the time participants spend indoors (household/work premise) and outdoors. Indoor particle levels will be measured continuously by Alphasense optical particle counters and ambient hourly outdoor $PM_{2.5}$ levels will be collected from local regulatory authorities (publicly available data). The time spent indoors/outdoors will be determined using the GPS signal of the participants smartphone and then assign exposure to indoor levels of $PM_{2.5}$ for the time spent indoors, whereas for the time spent outdoors we will assign levels of $PM_{2.5}$ measured by local central air pollution monitoring stations.
In term of primary health outcomes, the interventions aim to reduce the workers **HSSI by 20%** in **LL1 in OW**, the **PSQI questionnaire score by 20%** in **LL2 in PW,** and the **night-time non-dipping BP and heart rate by 20%** in **LL3 in OH**. To assess the impact of the heat and air pollution exposure reduction interventions on health outcomes, we will use a linear mixed effect model, which will be defined by fixed effects for the intervention group (categorical) and visit (time of assessment), an interaction term between intervention and visit (time of assessment), and by random effects for subject specific intercepts and slopes.

LL4	Target group: Animal care community	Leading partner: UNL
Site 7: Lisbon-Portugal		Other partners: APMVEAC, IMR, EF

Background and motivation: Vector-borne diseases account for 17% of all infectious diseases, and their insect vectors are directly affected by external factors and climate change[24].
Description of Site 7: **UNL in Lisbon** coordinates the ongoing CLIMOS project, which focuses on the effects of environmental changes on geographical migration and expansion of parasites, reservoirs and vectors, in particular in zoonotic leishmaniasis. APMVEAC is the professional association of >2.500 veterinarians across Portugal aiming to improve protection of its members and the veterinary care of companion animals.
Implementation and partner roles: **UNL** and **APMVEAC** will assess the feasibility and user acceptance of the zoonotic component of the EWRS (T3.3) and the suggested guidelines/interventions among high-risk professionals and citizen groups (dog shelter workers and volunteers, veterinarians) and collect feedback from them and other stakeholders on the proposed prototype (survey methods to be used). This will include conducting surveys to assess user satisfaction, needs, and preferences. This task will build upon CLIMOS project and Climate and Health cluster EWS products and results of LL4 will be used for fine tuning the EWRS citizen app.
Added value and impact towards climate change adaptation: Improve existing surveillance and prevention plans for sand fly-borne zoonotic diseases across a country-wide network of high-risk professionals and their animals.

LL5	Target group: Healthcare systems	Leading partner: HSPH
Site 8: Republic of Cyprus		Other partners: HIO, ACARES, UCY

Background and motivation: In Europe, detailed risk assessment, emergency plans and mitigation solutions for climate change impact at the local authorities and hospital levels are scarce or missing completely[26,27]. In contrast, regional hospitals, and facilities in the U.S., started recently to prepare mitigation plans under different forecasting projections and climate-related disaster scenarios[61] while since 2021 HSPH and ACARES, following nationwide surveys and focus groups with pilot frontline clinics, created the Climate Resilience for Frontline Clinics Toolkit, for

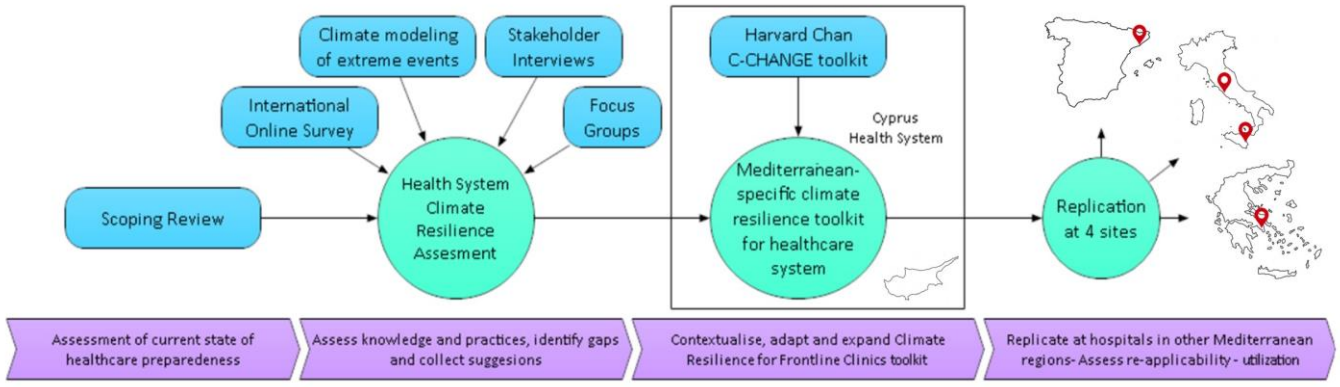
health care providers, patients and administrators.

Description of Region 8: **HIO-Cyprus** is the central organization that manages the newly established (2019) general healthcare system in Cyprus (GESY). HIO in collaboration with UCY and NICE International have been building local capability for contextualisation of NICE clinical guidelines to the conditions of GESY in Cyprus[63].

Implementation and partner roles: Experts in climate and disaster resilience **(associated partners HSPH, ACARES),** climate modelers **(CyI),** healthcare system administrators **(HIO)** and health care professionals **(UCY)** will assess the current state of healthcare system preparedness to climate change risks in EU countries across the Mediterranean and develop a detailed, region specific climate resilience and needs assessment for the healthcare system by employing co-creation methodologies, such as focus groups and stakeholder interviews, while considering future projections for extreme events. This assessment will follow the methodology suggested by the EU Expert Group on Health System Performance Assessment and employ a modified Health System Resilience Questionnaire (HSRQ). Based on this assessment, and using as a prototype the Climate Resilience for Frontline Clinics toolkit, already developed in the U.S., will develop a **Mediterranean-specific climate resilience toolkit** for healthcare systems, following a second series of consultation workshops, under the oversight of **HSPH** and **ACARES**.

Added value and impact towards climate change adaptation: A toolkit adapted to the conditions and characteristics of healthcare institutions, spanning from primary care through to tertiary care settings, in the newly established countrywide Health System in Cyprus and subsequently to the conditions of hospitals across the Mediterranean, integrated into the Experts and Policy Makers' Dashboard to facilitate its replication and impact maximization.

Figure 1.5: *Design and roadmap of LL5*



1.2.2.9 Applications and services

1.2.2.9.1 Citizen Mobile App: The Citizen Mobile App for self-management of exposure and climate change resilience will empower end-users, i.e. workers, patients, citizens, and communities to (i) easily and effectively receive forecasts, alerts and practical guidelines for exposure prevention and reduction; (ii) directly and coherently monitor their exposure based on their location, and (iii) assess additional resources and educational material through the **ISMED-CLIM** knowledge Hub. This will enable effective behavioural changes towards risk appreciation and mitigation in a logical manner. The application will be designed and implemented in the form of Open Geospatial Consortium (OGC) compliant web service, with front-end web-based Human Machine Interface (HMI) dashboard and APIs based on open standards. It will also pull processed data from wearable app, analyse and present meaningful mitigation steps and recommendations to users. It will also use open APIs for interfacing relevant data sources from external mobile app libraries and online platforms (local weather data, GPS location etc). The overall development of the citizen app involves adapting the GUI for mobile devices, implementing mobile-specific features, testing and refining the Mobile App, and submitting the App-to-app stores. By taking these steps, the Citizen App will provide an optimized user experience, support knowledge and innovation on-the-go. To design the Mobile App, functional and non-functional requirements will be derived from the **ISMED-CLIM** LLs. This input will be translated into technical specifications to create a detailed representation of the App and its supported software modules.

1.2.2.9.2 Policy Dashboard: The Policy Dashboard is a decision-centric, action-oriented interactive tool to enable policy makers, modelers, scientists, health administrators, professionals, and citizens to understand the impact of their choices and to facilitate discussions, decisions, planning and long-term evidence-based policymaking. Development of the Dashboard will follow a highly participatory process involving stakeholders and social scientists in the entire process, as well as in defining its use cases. Complex information, indicators and processes will be presented in a user-friendly way through interactive GUI, presenting summary statistics, charts of all indicators for each country and the Mediterranean as aggregate, in-depth country profiling, overviews of all progress indicators within a selected policy priority. The Dashboard will encompass the following **five main components**: (i) ***Knowledge Hub****;* (ii) ***Heat Vulnerability Index Tool***; (iii) ***Surveillance Tool for Zoonotic Diseases***; (iv) ***Policy Uptake and Evaluation tool****;* and (v) ***Mediterranean-specific Climate Resilience Toolkit for Healthcare Systems***. The Dashboard will draw data from the **ISMED-CLIM** platform's *Knowledge Bank;* a repository incorporating the latest scientific research, emerging data sources, changes in disease dynamics, recommendations and guidelines, news, project results, and training material and educational resources to main end-users.

i) Knowledge Hub: The Knowledge Hub will accelerate the **impact** of **ISMED-CLIM**, improve **citizen awareness,** and ensure the most efficient **visualization** of complex **data analytics** and processes, to provide an overview of key **metrics and indicators** on climate change-related health impacts in a user-friendly way. The Knowledge Hub will

also offer practical guidelines on **ISMED-CLIM** tools and applications, and present complex information and scientific evidence in a comprehensive and understandable manner (white-paper style), thus enabling citizens appreciate and comprehend the impact of their choices.

ii) Heat Vulnerability Index Tool: A primary feature of the Policy Dashboard will be the Heat Vulnerability Index (HVI) for each project site, which will identify and prioritize areas or communities that are most susceptible to heat-related risks, allowing policymakers and stakeholders to identify hotspots and more effectively target adaptation policies. Beyond demographic (e.g., age structure, ethnicity) and environmental (e.g. heat exposure, heat island effect, urban canyons, air pollution) determinants, the HVI will also rely on social determinants that influence capacity of individuals and communities to cope with extreme heat, such as poverty rates, language barriers, housing quality, social support, access to green spaces, access to cooling centers and access to emergency healthcare services.

iii) Surveillance Tool for Zoonotic Diseases: An integrated tool for healthcare/veterinary authorities and public health experts to manage zoonotic disease prevention, control actions and interventions. The tool provides prompt access to valuable data for awareness and effective surveillance of zoonotic diseases, taking well-informed decisions and proactive measures for early preparedness and prevention of their spread at local level. The tool also offers additional data, such as temperature and precipitation maps for the area(s), with short- and medium-term forecasts. It also offers interoperability across organizations to increase inter-sectional collaboration and coordination. It will be field-validated (within LL4) and easy to navigate by different groups of professionals and by the general public.

iv) Policy Uptake and Evaluation Tool: A series of policy implementation and evaluation tools will be prepared:

- Digital workplaces that bring together regulators, experts and stakeholders at each project site to form a local multisectoral **Regional Task Force.**
- Specific communication protocols, customized for each region, type and level of risk, so as to enhance interoperability and efficiency for public health agencies/authorities across the Mediterranean. A series of alert and communication templates, data cards and graph templates will be made available.
- Online training platform, which will include the library of evidence-based policy proposals (also summarized in policy briefs), as well as the tailored recommendations and relevant animation videos for targeting vulnerable groups and general population, and templates for emergency response plans at the municipality/regional level.

Furthermore, to facilitate evidence-based decision making, the users will have the option to generate custom reports, export data and create visualizations tailored to their specific needs. Finally, to further facilitate policy uptake, the Dashboard will include tools for monitoring and evaluating the progress and impact of policy interventions such as: (i) User-selected and customized key performance indicators; (ii) Generation of gauge graphs; and (iii) Feedback pathway from other users.

v) Mediterranean-specific Climate Resilience Toolkit for Healthcare Systems: The online version of this toolkit will include features that will enable healthcare administrators, professionals and patients to:

- Carry out data collection queries to update data on resource allocation and utilization (e.g., availability of hospital beds, ICU occupancy, hospital staff levels, stock levels of critical supplies, transport assets).
- Ensure rapid communication among hospital staff and between doctors and patients during emergencies.
- Prioritize high-risk patients and provide clinical checklists and patient tip sheets.

In addition, the toolkit will also include training materials and educational activities for healthcare professionals towards fostering capacity building.

1.2.2.10 Complying with the "Do no significant harm" principle

As part of the socioeconomic and health impact analysis of the proposed solutions, **ISMED-CLIM** will ensure that is fully compliant with the "Do no significant harm" (DNSH) principle. It is expected that the project activities, as well as the project recommendations and tools to be developed, will substantially contribute in a positive way and/or do not significantly harm any of the six environmental objectives set out in Art. 9 and 17 of the EU Sustainable Finance Taxonomy Regulation (Regulation EU No 2020/852), especially the environmental objectives "climate change mitigation", "climate change adaptation" and "pollution prevention and control". To this effect, the project will establish a life-cycle oriented procedure for checking compliance with the DNSH requirement, which will consist of the following steps: (i) Identify potential adverse impacts during the life cycle of proposed solutions (risk assessment); (ii) Address prevention and mitigation of adverse impacts (risk mitigation); (iii) quantify and ensure balancing of potential trade-offs; (iv) suggest monitoring approaches and communication to ensure transparency and accountability in decision making. As part of the socio-economic analysis of the proposed solutions, lifecycle greenhouse gas (GHG) emissions will be calculated using the Recommendation 2013/179/EU (T5.3).

1.2.3 Links to relevant national and international research projects and activities

Table 1.2 presents how we will leverage the accumulated experience and built upon research and policy tools **co-developed by ISMED-CLIM partners** in other EU, international and national projects.

Table 1.2: *Links of* **ISMED-CLIM** *to relevant national and international projects and activities*

Clinical & Public Health	**Projects: LIFE MEDEA, BeAT Heat, Italian Heat Plan, HEAT-SHIELD**
We will apply the LIFE MEDEA, and Italian Heat Plan experience in developing practical and sustainable guidelines and tools for climate change related stressors (Task 1.3). We will also take advantage of strategies for enhancing recruitment and compliance in health intervention and field trials, already tested in LIFE MEDEA, BeAT Heat and HEAT-SHIELD (Tasks 4.2, 4.3, 4.4). In addition, the MEDena Health Hub elements, used for alerting and activity data collection in LIFE MEDEA, will be upgraded for the EWRS development (Tasks 3.1, 3.2).	
Forecasting	**Projects: TRIGGER, SustUrbanClim, CLIMAAX, LIFE ASTI**

We will build upon downscaling methodologies for temperature (Task 3.2), developed by ECMWF for TRIGGER, while we will also apply SustUrbanClim and LIFE ASTI know-how and code in considering urban microclimate for thermal stress estimation in the built environment. Finally, through ECMWF, we will have access to CLIMAAX risk assessment utilities to inform the Policy Dashboard (Task 5.4).	
Resilience Projects	**HARVARD C-CHANGE/Americares Climate Resilience for Frontline Clinics, HIO-NICE International Project**
ISMED-CLIM and HIO will adapt and adopt a Mediterranean-specific climate resilience toolkit in GESY (Cyprus healthcare system) (Task 4.6), originally developed by Harvard Chan C-CHANGE and Americares in the U.S. We will follow a co-creative approach, as in the original methodology applied in the US, with surveys and focus groups led by the toolkit creators, associated partners HSPH/ACARES. HIO will capitalize on its expertise from the ongoing project on adapting guidelines for the Cyprus healthcare system in collaboration with NICE International.	
Zoonotic Projects	**CLIMOS, VEClim**
CLIMOS-developed pathogen and vector population models accounting for climatic variables will be used to inform the EWRS zoonotic component (Task 3.2). In addition, **ISMED-CLIM** partners experience in surveillance of infectious diseases and modelling impacts of vector-control measures (VEClim) will also be leveraged for the development of guidelines, tools and training materials (Tasks 1.3, 4.5 5.4).	
IT/AI Projects	**NextGEM, BIO-STREAMS**
Tools and methodologies on sharing and managing health data and enabling interconnection with the Health Data Space developed by the NextGEM, will be adapted and extended to facilitate the requirements of **ISMED-CLIM** (Tasks 3.1, 3.2), including the extension of NIKH dashboard into a modularized portal hosting multiple interactive tools with advanced knowledge-graph based analytics (Task 5.4). In addition, the reinforced learning schema supporting the AI-augmented EWRS will leverage elements from the AI-powered Risk Stratification Tool and Recommendation Engine developed in BIO-STREAMS (Task 3.2).	
Epidemiology Projects	**EXHAUSTION, EXPANSE, MCC network, EMME-CARE**
We will expand the methodology of projects EXHAUSTION, EXPANSE and the MMC network that formed a collaboration basis for epidemiology cohorts to provide a harmonized Mediterranean-wide surface for the study of climate change stressors and their health impacts. Future projections of climate and air quality datasets for the Mediterranean biogeographical region will be made available by EMME-CARE.	
Social Science & Humanities Projects	**LIFE Sirius, STEDI-RC, URBACT**
The decision-making approach and capacity building measures implemented as part of LIFE Sirius and URBACT will be taken into consideration in Policy Dashboard development (Task 5.4), while expertise accumulated through the STEDI-RC will be used to set-up the pathways linking new knowledge to public policy (Tasks 1.2, 1.4).	

1.2.4 Inter-disciplinary approaches and use of stakeholder knowledge

ISMED-CLIM adopts a strong **inter-disciplinary approach**, with **academic, industry, policy** and **civil society** partners employing a "four propeller" or "quadruple helix" model, integrating knowledge and methods, to generate credible scientific evidence, and inform sound policies.

ISMED-CLIM includes a number of **R&I inter-disciplinary elements**, aligned with the broad skills and complementary expertise of the large spectrum of consortium partners: **Climate scientists, epidemiologists, public health scientists, clinicians, occupational health experts, policy stakeholders, regional authorities, environmental engineers, weather forecasters, software, AI** and **health-tech developers,** and **experts in social sciences/innovation, citizen science** and **Living Labs.** These disciplines are interwoven within **ISMED-CLIM**'s activities and most experts will work in more than one WP to address the objectives in a truly collaborative and interdisciplinary way. The consortium has the relevant know-how (Section 3.2) to carry out interdisciplinary aspects of the project and incorporate knowledge from external stakeholders when necessary.

1.2.5 Integration of Social Sciences and Humanities (SSH)

ISMED-CLIM addresses a multifaceted issue with diverse implications for both citizens and society. Towards this direction, it will involve a wide array of authorities, professional associations and civil society organisations and therefore, an effective contribution of social sciences and humanities is required. This will allow, across all sites, the consideration of cultural dimensions, socioeconomic inequalities, and health seeking behaviour in the development and implementation of multilevel interventions for the health effects of climate change[105]. In addition, the integration of social sciences is expected to enhance community engagement and policy advocacy[106], guide policy uptake, long-term planning and evaluation[107], as well as lead to effective risk communication strategies through the development of multi-approach training curricula and educational materials for professionals and the public[108]. To this effect, **ISMED-CLIM** consortium includes partners with expertise in decision analysis, transformation and sustainability of public administration, policy evaluation, including socio-economic impact assessment, as well as experts in digital communication, social behaviour and education. Integration of social sciences will focus on the following activities:

• **Co-creation of proposed solutions based on the Responsible Research and Innovation (RRI) principles:** Social scientists **(UNICT, KOR, UCY)** will suggest a cartography of concerned stakeholders (formation of Regional Task Forces), set-up an effective toolkit of engagement methods (workshops, focus groups, surveys) and analyse all collected relevant datasets and materials.

• **Support the creation of the EWRS and Knowledge Hub:** The EWRS and Knowledge Hub will target a wide audience with varying degrees of health and IT literacy across countries. Cooperation between social scientists (**UCY, UNICT**) and IT experts will ensure that both systems reflect the expectations of their diverse end-users. This activity also includes the co-development of curricula, short digitalised courses (digital handbook/explanatory videos) and other hands-on educational materials **(UCY).** Improvement in perception of climate change related health effects between the start and end of the project will be assessed using social and digital media analysis by **UCY**.
• **Support policy implementation by local authorities and stakeholders (professional associations, civil society groups):** Support decision making and governance by developing evaluation frameworks and KPIs to measure the impact and outcomes of the proposed solution over time **(KOR, UNICT).**
• **Perform the SEIA and support HVI tool implementation:** Social scientists (**CyI, UCY**) will carry out the SEIA to address impacts across different societal fields and support the development of the HVI tool for each site.

1.2.6 Gender Dimension

Gender (as a social construct) and sex (as a biological factor) may affect exposure to climate-related stressors[109], the effective dose to target organs in case of inhaled or ingested pollutants[109,110], health vulnerability[111,112] and the health outcomes of interest[113]. In parallel, gender and sex may also affect applicability or feasibility of some of the proposed solutions and as such, we aim to address the diverse gender needs of EU citizens and enhance the societal relevance of the knowledge, recommendations, tools and other innovations produced by the project. To do so, the project will collect gender-sensitive data and incorporate gender analysis in its methodology, as follows:
• **Pregnant women will be assessed as a susceptible population:** LL2 will provide evidence for the effectiveness of interventions to reduce exposure to heat and air pollution and associated health effects in pregnant women.
• **Ensure gender balance among the research population:** To understand sex and/or gender differences in terms of exposure and health effects, as well as in terms of feasibility of the proposed solutions, we will use gender-balanced retrospective datasets and employ stratified sampling for participant selection in LL 1, 3 and 4.
• **Identify daily activities and quantify gender-associated factors:** Specific activities as well as other factors (e.g., body size, working outdoors, time spent indoors, household tasks) that may relate to differential heat and air pollution exposure and response or differential user acceptance and applicability of solutions across genders, will be quantified using a combination of research tools, including wearable sensors, surveys and questionnaires.
• **Incorporation of gender analysis:** Gender specific toolkits (Yellow Window, EIGE) will be used to integrate gender analysis into the project's methodology. As a minimum, we will incorporate gender analysis as part of the statistical methodology (sub-group analyses) to disaggregate the temperature and air-pollution exposure-response effects by gender and in prospective analyses, will explore the influence of multiple sex- and gender-associated factors on the effectiveness of the proposed solutions to reduce exposure and mitigate health effects.
• **Embed gender mainstreaming and positive gender norms in recommendations and risk communication:** Development of recommendations, policy materials and communication strategy will include social stakeholders and project scientists with expertise in gender-sensitive health communication programs that consider the different ways genders perceive environmental health risks and respond to risk communication messages.

1.2.7 Open Science practices

ISMED-CLIM fully supports an open scientific process that ensures efficient participation, transparency, knowledge sharing and open availability of findings and developed tools (Section 2.2.3). In line with the Open Science Policy Priority of the European Commission and abiding by the 'as open as possible' principle, appropriate open science practices will be implemented, as an integral part of the project's methodology as described below:
• **Co-creation approach:** In an open cooperative framework, we will bring together scientists, regional stakeholders and end-users for the co-creation of innovative solutions for climate change-related health risks. Active involvement of stakeholders will take place through the establishment of the **Regional Task Forces** at each demonstration site and will ensure both the continuous engagement and support to the project activities, as well as the inclusion of additional experiences and perspectives into recommendations development. The co-creation approach will rely on a deliberative decision-making process to maximize stakeholder involvement and accountability in the development of solutions in accordance with the Open Innovation 2.0 paradigm. The project will employ workshops, focus groups and surveys to ensure that the gaps in practice and climate resilience policies, as well as the real-word user needs are clearly understood and that the solutions provided are successful both at the replication and adoption stages. In this manner, an ecosystem-centric and **cross-organizational scheme** will emerge that will encompass the **quadruple innovation helix of government, industry, academia, and civil society**.
• **Open access to research output:** **ISMED-CLIM** partners will use the Open Research Europe publishing service for Horizon Europe to enable rapid publication times and open science practices. Alternatively, partners could choose between self-archiving ("green" Open Access) or other open access publishing ("gold" Open Access) to ensure open access to deposited publications. In the first case, partners will deposit the final peer-reviewed manuscripts in a repository of their choice (ResearchGate, Academia, etc.), ensuring open access to the publications within a 6-month period. This strategy is consistent with the open science policy and facilitates dissemination and reuse of the project's results. For this reason, a dedicated part of the budget will cover open access publication fees.
• **Promoting open data access and science literacy:** To further engage citizens, professionals and other civil society and academic actors, as well as to open up the innovation and replication process to additional actors, we will ensure that project datasets will be made available in open **data repositories under a Creative Commons Attribution Public License (CC BY),** in line with the Open Data Policy, the FAIR Data Principles. To this effect, by providing open access to research outputs and training materials, as well as through **citizen science** approaches employed in the replication stage, the project will improve science literacy and build expertise. Citizens and other actors will have

better access and understand scientific information. Aptitudes for research will be cultivated and in the case of young adults, will be steered towards a career in health, environment, or other related disciplines.

• **Open availability of training and educational materials:** Online training resources and educational materials produced by the project in Task 5.4 will be made publicly available through the project's website and will be posted in the public domain (SlideShare, YouTube, Spotify podcasts), also under the **CC BY** license.

1.2.8 Data management and management of research outputs

Types of data/research outputs: *Research data types* will at least include: raw experimental measurements from the LLs (e.g. tabular CSV-like data); aggregated epidemiological datasets; scripts used for the analysis of raw measurements; specific flow/service statistics for debugging purposes; detailed data traces; S/W source codes, technical reports and manuals. Raw data will be pre-processed at collection to remove any personally identifiable information, leaving only anonymous and unique machine identifiers, along with other parameters related to computations. *Data communication protocols* include http, MQTT, SQL, MongoDB. *Data training models*: supervised/unsupervised AI/ML. *Inference approach*: real-time responses, batched, on demand and stored. *Data analysis*: the data will be analyzed using tools such as R. **Estimated data size analyzed:** From 100s of GBs to a few tens of TBs. **FAIR principles:** Findability: Use of the European Open Science Cloud and the Open Research Europe scholarly fully open access publishing service for HEU to enable rapid publication of data, research integrity, reproducibility, transparency and open science practices. Make accessible its software through well-known trusted repositories for distributed version control and source code platforms, such as GitHub and GitLab. The project repository can be concentrated in reference sites, such as Stack Overflow, the largest online community for developers. Different types of persistent identifiers for digital objects will be used, such as Archival Resource Keys (ARKs), Digital Object Identifiers (DOIs) and Uniform Resource Names (URNs). Accessibility: The Consortium Agreement will define the details concerning the access rights for exploitation to background and results. Open access to publications: <6 months; Access to restricted data (e.g., sensitive deliverables): only to consortium partners, the EC PO and the project reviewers. Inter-operability: Standards: ISO/IEC 20547-4:2020, NIST SP 1500-4r2. Formats: Data from the LLs will be used for raw measurements (e.g., timestamps), stored in plain text format, such as comma separated values (CSV-like). Scripts to analyze the data will be stored in their respective source code formats. Logs that contain the history of various processing elements will be stored in plain text format. Artifacts such as analysis plots will be stored as plain or vector images. Data traces and SW source codes in numerical and text formats. All data gathered from end-users during the co-design process and demonstrations will be pseudo-anonymized using the OpenAIRE AMNESIA tool to ensure both accuracy and GDPR compliance. Vocabulary: The Logical Observation Identifiers Names, and Codes (LOINC) controlled vocabulary will be used for tests, observations and measurements metadata. Reusability: Creative Commons licenses (CC-By Attribution) will be employed for sharing research data and academic publishing, which permits sharing and reuse of the material, as long as the original authors are credited. **Curation and storage/ preservation**: Partner responsible for the project's Data Management and DMP: **UCY**. The DMP (part of D7.2) will reflect data and research output management in line with the FAIR principles. Knowledge and data will be securely stored and maintained in an internal document management system, such as TeamWork and/or ARGOS for at least 2 years after project conclusion. **UCY** will also serve as the project's Data Protection Officer (DPO) assisted by contact points in all consortium partners. **RG** will be responsible for the Quality Assurance.

2. Impact

2.1 Project's pathways towards impact

ISMED-CLIM pathway towards impact encompasses two key phases: **The initial phase** pertains to the project's duration and the immediate aftermath, during which the outputs are utilised by the stakeholder target groups **(§2.1.1),** leading to short and medium-term effects **(§2.1.2)**, until 2030. **The second phase** focuses on the period extending beyond 2030 by which the broader adoption of **ISMED-CLIM** will result in long-term impacts **(§2.1.3).** The driving force behind the expected projection of impact in the second phase is the momentum generated up to the end of the project (expected 2028), primarily achieved through a significant replication effort, impact maximisation and policy outreach, facilitated by an effective **Dissemination, Exploitation, and Communication (DEC) plan (§2.2).**

2.1.1 Stakeholder target groups

	Target groups description
A	**Regions:** regional, national, municipal authorities and organisations.
B	**Citizens and local communities:** Vulnerable groups, citizen associations, community groups, charities, NGOs.
C	**Healthcare systems:** Hospitals and administrators having in-depth knowledge of the regulatory framework governing patient care, direct the operation of healthcare organizations and shape the policy and budgets.
D	**Decision- and policymakers:** Setting priorities, developing policies, and allocating resources to ensure that the healthcare system is accessible, affordable, and effective.
E	**Private sector and entrepreneurial ecosystem:** Health technology companies aim to develop innovative solutions, products and services, digital health solutions to reduce heat and air pollution exposures and patient adverse outcomes, enhance efficiency, reduce costs, tackle complex challenges facing the healthcare industry.
F	**Knowledge providers:** Research, Academic Institutions, Social Innovators, EU project consortia: Interested in research activities public health research on the effect of climate change.
G	**Open-source initiatives, open data spaces:** Related to open access of information and essential for fostering collaboration and innovation to information with initiative, such as the European Climate and Health Observatory.

2.1.2 Medium-term project's contribution to Expected Outcomes

The project addresses the Expected Outcomes (EO) of topic CLIMA-01-03:

EO1: Regions, local authorities and communities have been involved in development and testing of a whole range of transformative solutions that will help to mitigate the effect of climate change on health and human wellbeing, including making the public health sector more climate resilient and better prepared to mitigate the climate change related health challenges.	
Target groups: A, B, C	**Linked to Obj.: 1-5**

The goals of **ISMED-CLIM** *align with the objectives of the Climate Change Adaptation Mission, which aims to engage at least 150 regions in testing locally relevant solutions and delivering a minimum of 75 in-depth demonstrations of systemic transformations towards climate resilience.* **ISMED-CLIM** will rally a number of stakeholders in various regional and social contexts throughout the Mediterranean region, and involve them in the co-development and testing of transformative solutions to **mitigate** the effects of climate change on health and human wellbeing and build more **resilient, sustainable, well-prepared** communities and health systems for the future. **ISMED-CLIM** will achieve this by offering advanced assessments of region-specific health risks and present on-the-ground evidence for the feasibility, acceptance, and effectiveness of the proposed solutions. **ISMED-CLIM** will follow a **step-wise approach towards impact**: ***Step 1:*** Assessment and Awareness (*Obj. 1*) *Assess the current state of climate change impacts on health and their mitigation in the Mediterranean region*, through literature and policy review at the local level to create awareness about the urgency of the matter. ***Step 2:*** Epidemiological and exposure modelling (*Obj. 1*) *Enhance the understanding* of the intricate relationship between rising temperatures, air pollution, drought, flooding, and wildfires, and how these factors impact mortality and morbidity outcomes across the Mediterranean region, considering the implications of health-related climate change predictions. ***Step 3:*** Regional Task Forces (*Obj. 2*) *Identify and engage key stakeholders* in **five (5) Regional Task Forces in Cyprus, Greece, Italy, Spain, and Portugal**, including local government officials, community leaders, healthcare providers and administrators, educators, businesses, communities to work together to define clear, measurable objectives, user needs and customized recommendations for mitigating climate impacts on health and wellbeing. Citizen Assemblies will facilitate community engagement, through focus groups to gather local insight and feedback and community workshops for trainings. ***Step 4:*** Innovative interventional tools in LL Demonstrations (*Obj. 3, 4*) *Assess the efficacy of an Early Warning and Response System (EWRS) and evidence-based interventions* to reduce exposure to high temperature and air pollution and related health effects during periods of extreme heat in: i) Healthy Outdoor Workers @ **Trikala-Greece** through the engagement of the local university (**UTH**), local authority (**TRIKALA**) and policymaker (**MLSA**), and **Leon-Spain** through the engagement of a university (**ULE**) and their network (Tragsa public company); ii) Pregnant Women @ **Catania-Italy** by the local university (**UNICT**) and hospital (**ARNAS**), and **Limassol-Cyprus** by **UCY** and local accessible network of maternity clinics; iii) Older adults with arterial hypertension @ **Barcelona-Spain** by local research institute and hospital (**VHIR**) and **Nicosia-Cyprus** by **UCY**, and national pensioners' association (**EKYSY**); *Demonstrate the feasibility and user acceptance of an EWRS and an evidence-based set of prevention interventions* against zoonotic diseases by animal handlers @ **Lisbon-Portugal** through the engagement of a university (**UNL**) and national veterinary association (**APMVEAC**). *Enhance healthcare systems' preparedness to climate risks* across the Mediterranean by tailoring a climate resilience toolkit and applying it in the national General Health System of Cyprus (**HIO**). ***Step 5:*** LL Monitoring and Evaluation: *Implement robust monitoring and evaluation systems* to track the progress of the demonstrations, collect data on health outcomes, and community engagement. Use this data to make informed decisions and fine tune the digital intervention tools. ***Step 6:*** Replications (*Obj. 5*) *Scale successful initiatives* by identifying and prioritizing successful initiatives at six sites and coordinating ten replications for the benefit of a larger portion of the community. *Empower communities* to take ownership of their health and wellbeing by providing them with the tools and resources to sustain and expand the initiatives they find effective. ***Step 7:*** Knowledge sharing and training (*Obj. 1,5*) *Share best practices, training and educational materials* with the wider Mediterranean regions and communities through the Knowledge Hub and further encourage formulation of Regional Task Forces and exchange of ideas to accelerate progress. Promote education and training programs to empower community members to adapt to climate change and improve their health. This may include workshops on energy efficiency, emergency preparedness, and sustainable living. ***Step 8:*** Resilience Building *Strengthen health system and community resilience* by developing robust emergency response plans, and social support networks (implemented via the Citizen Assemblies) that can withstand the challenges posed by climate change. ***Step 9:*** Impact assessment: *Assess health and socioeconomic impact* to continuously measure the impact of ISMED-CLIM, both in terms of improved health and reduced climate-related risks. ***Step 10:*** Policy implementation *(Obj. 5) Advocate for supportive policies at the regional and national levels* by engaging with policymakers to influence legislation and regulations that promote climate resilience, public health, and sustainable practices. ***Step 11:*** Contribution to Regional Action Plans **ISMED-CLIM** *commits to maintain ongoing engagement* with local authorities, communities, and stakeholders to collaboratively adapt their regional climate action plans, by integrating strategies for climate mitigation, adaptation, and health improvement with specific actions, responsibilities, timelines, and resource requirements.

Barriers	Measures to overcome

While climate change is widely recognized in EU, citizens and communities often experience desperation due to disinformation, limiting their willingness to engage. Mitigation measures against climate change are neither widely known nor understood by general public. Even where awareness exists, there are reservations on their effectiveness. There is lack of processes and measures specifically targeted to promote interventional solutions.	**ISMED-CLIM** socially driven activities, such as the knowledge transfer and impact pathways methodology, aim to strike at the root of the problem and establish ambitious engagement of citizens and communities. Moreover, the **DEC plan (§2.2)** and capacity building will ensure that stakeholders will obtain both the knowledge and means to act. The five LLs will ensure the field-based evidence on the efficacy and user acceptance of proposed solutions.

KPIs	Baseline, benchmark and assumption of estimate	Target values
Number of regions reached	At least one additional region at each of the five participating countries	>20
Number of local authorities involved	At least two additional authorities at each of the five participating countries	>15
Health systems /hospitals reached	At least one additional health system/hospital at each of the five participating countries	>15
# of citizens per group impacted	At least 5.000 additional outdoor workers, at least 25.000 additional pregnant women, at least 50.000 additional older adults, 2.000 additional veterinarians/animal handlers	>80.000

EO2: Climate resilience solutions protecting human health have been developed, tested and made widely available

Target groups: B, C | **Linked to Obj.: 1-5**

Achieving climate-resilient and environmentally sustainable health systems requires evidence-based interventions to protect those at greatest risk. There is an important gap in enabling effective and user-friendly technological interventions. **ISMED-CLIM** will provide innovative adaptation solutions to **eight demonstration sites** by employing cutting-edge communication and wearable sensor technologies. Towards this end, we will (i) evaluate the effectiveness of an early warning and response system (EWRS) and a series of sustainable interventions aimed at reducing heat and air pollution exposure and their associated health risks within three vulnerable population groups: outdoor workers, pregnant women, and older adults with hypertension; (ii) validate the feasibility and user acceptance among high risk professionals of a regional early warning and risk prediction tool to mitigate the risk posed by exposure to sand flies and related diseases; (iii) employ open, participatory, and co-creative methodologies to locally adapt and refine existing evidence-based practices and prototype tools to increase the preparedness and resilience of health systems in the Mediterranean. **ISMED-CLIM** will eventually scale-up climate resilience solutions to a total of **ten replications at six sites** in the Mediterranean biogeographical region to maximize impact, and re-applicability of the fully-fledged technological solutions and lessons learnt in these sites.

Climate resilience solution	Demonstration	Replication
An effective EWRS along with evidence-based recommendations to reduce heat and air pollution exposure and related health impacts. These will be tested in three vulnerable population groups, initially across six demonstration sites and subsequently in three replication sites.	Adoption of EWRS and recommendations by OW at Trikala (Greece) and León (Spain)	Korydallos Municipality (Greece), Agueda Municipality (Portugal)
	Adoption of EWRS and recommendations by PW at Catania, Sicily (Italy), Limassol (Cyprus)	Alexandra University Hospital Athens (Greece)
	Adoption of EWRS and recommendations by OH at Barcelona (Spain), Nicosia (Cyprus)	Korydallos Municipality (Greece), Agueda Municipality (Portugal)
An effective EWRS and surveillance tool for zoonotic diseases to be tested in high-risk groups in one demonstration site and one replication site.	Adoption of EWRS for zoonotic disease and guidelines by high-risk professionals and citizen groups at Lisbon (Portugal)	Korydallos Municipality (Greece)
Adoption of climate resilience and healthcare system/unit preparedness toolkit accessed via a digital Policy Dashboard initially tested within Cyprus' Healthcare System and subsequently replicated in four hospitals.	National Health System (Countrywide - Cyprus)	ARNAS Garibaldi Hospital, Catania (Italy), Hospital in ASL ROMA 1, Rome (Italy), Alexandra University Hospital, Athens (Greece), Parc Sanitari Pere Virgili Hospital, Barcelona (Spain)

Barriers	Measures to overcome
The primary constraint to climate change adaptation and resilience is limited investment, as well as identification of effective interventional solutions to manage the magnitude and pattern of climate-	**ISMED-CLIM** EWRS and tailored evidence-based recommendations are crucial adaptation strategies, allowing health sector to best manage impacts of climate stressors. Increasing effectiveness of strategies and interventions to best adapt and respond to current conditions will build capacity to manage additional climate change-related health effects and target groups, within an iterative risk management framework that supports decision makers' systematic responses to climate change, while allowing for adjustments, as new evidence emerges. **ISMED-CLIM** implementation science approach affords a valuable opportunity to take stock of challenges, identify knowledge gaps, and inform

sensitive health outcomes.	the design and successful deployment and uptake of adaptation interventions.

KPIs	Baseline, benchmark and assumption of estimate	Target values
Replicability	Sustaining the project's solutions for more than 2 years beyond the 8-month project replication period	10 regions; >7 local authorities; >7 hospitals
Public perception and awareness	Improved public perception and awareness of climate change related health effects through social media and digital media analysis	>20% improvement
User acceptance and satisfaction	User acceptance and satisfaction, conversion and retention metrics, evaluated through user feedback questionnaires	>75% user acceptance rating
Adaptive capacity	Incorporation of ISMED-CLIM solutions in new or updated public health/occupational health & safety legislations and regional climate change adaptation plans	At least 10 regions in 5 countries

2.1.3 Long-term impact

The project addresses the Expected Impacts *EI1: Accelerate the transformation to a climate resilient future in a number of regions* and *EI2: Deploy at full scale the systemic transformations locally needed to build climate resilience* in a multifaceted approach involving governments, businesses, communities, and individuals through contribution to policy (section 2.1.3.1) and science, economy and society (section 2.1.3.2).

2.1.3.1 Contributions to Climate Adaptation Mission and EU Policies

The outcomes of **ISMED-CLIM** will decisively contribute to the goals of the Climate Adaptation Mission, as well as to a number of other relevant EU policies.

Climate Change Adaptation Mission goal	Contribution
Support at least 150 European regions and communities Adaptation to Climate Change and become climate resilient by 2030	**ISMED-CLIM** will implement solutions in **eight** demonstration sites and **six** replication sites. Based on the projections detailed above, 20 regions, >15 local authorities, >15 hospitals and over 80.000 citizens will be engaged in **ISMED-CLIM** Regional Task Forces by 2030.
75 large scale demonstrations of systemic transformations	
Provide support to European regions & communities to better understand, prepare and manage climate risks and opportunities	**ISMED-CLIM** provides open access to explainable, harmonized, clear and actionable data, utilized to support data-driven policy making through its Policy Dashboard.
EU Policies/instruments	**Contribution towards policy implementation**
EU Adaptation Strategy to Climate Change	Accelerate the rollout of technologically driven solutions for adaptation of EU regions and forge smarter adaptation through digital innovation and data that bridge gaps in adaptation knowledge, reducing climate-related risks.
Health Emergency Preparedness and Response Authority	Provide feedback and share best practice from the LLs to the new Health Emergency Preparedness and Response Authority, including public awareness campaigns, identifying the warning communication chain, role, tasks and responsibilities of science advisors and decision-makers.
European Climate Law	Support regions to implement their Climate Adaptation Plans and provide confidence, motivation knowledge and realistic prospects for them to adhere to the legally binding objectives of the EU Climate Law.
EU Regulation on Governance and Climate Actions	Provide policy input on regulation and governance relevant for implementation of the National Energy and Climate Plans (NECPs).

2.1.3.2 Scientific, Technoeconomic and Societal Impacts, Scale and Significance

ISMED-CLIM will generate significant Scientific, and Technoeconomic Societal Impacts, that will result from its ambitious and extrovert strategy focused on replication.

Scientific: The project will provide Mediterranean specific exposure response coefficients for the relationship between climate-related stressors and health outcomes based on most recent data (2000-2023) and focusing on more detailed datasets with information on understudied exposures and various effect modifiers such as humidity, wind direction and speed, occurrence of desert dust episodes, flooding, wildfires as well as on age- and cause-specific daily counts on mortality and hospital admissions for cardiovascular, respiratory outcomes and outcomes for mental-psychiatric conditions, preterm births and birth weight that are also understudied. , followed by estimation of future NCD health impacts (and vector dynamics for vector-borne and zoonotic diseases) under different climate change scenarios considering the population adaptation capacity and the region-specific socio-economic trajectories. In addition, using wearable technology and validated tools, the project will quantify the efficacy of EWRS and evidence-based interventions to reduce exposure to high temperature and air pollution and related health effects, targeting at least **20%** improvement in primary health outcomes among vulnerable population groups: outdoor workers, pregnant women, and older adults with arterial hypertension. Finally, the feasibility and user acceptance of recommendations and EWRS providing real-time personalized risk assessment targeting professionals and other end users at risk of zoonotic diseases will be estimated for the first time and the **first** Mediterranean-specific climate resilience toolkit for health care systems will be made developed. By 2030, open access scientific knowledge will

be generated through at least **40** (>FWCI~3) publications, promotion of FAIR research data, and facilitate extensive capacity building in a pool of **~20,000** individuals. **ISMED-CLIM**'s open-source platform and tools will enhance both fundamental and implementation-based research on building climate resilience across Europe and the world.

Technoeconomic: **Technological Innovation:** Integration of state-of-the-art technologies in the form of improved and AI augmented forecasting and warning dissemination for extreme events, advanced communication, wearable sensor exposure assessment and health monitoring tools, and integration of digital policy implementation tools in enhancing population adaptation and healthcare system resilience to climate change. **Economic innovation**: Economic benefits of exposure reduction approaches and mitigation of related health effects of heat and air pollution outweigh the costs of implementing **ISMED-CLIM** proposed solutions by 30%. Measurable improvements in the job market and regional GDP growth (up to 0.2%), over **500** jobs created, over **150M€** of climate investment in participating regions and over **500M€** of additional investment in climate resilience will be leveraged.

Societal: **ISMED-CLIM** will significantly contribute towards improvement in public health, governance and climate resilience in different ways: **Governance and policy impact:** Increased decision-making capacity of public and local authorities through Policy Dashboard utilization by **>100 stakeholders** from at least **five Mediterranean countries** and introduction of digital innovation in public health protection across less privileged regions and municipalities. **Acceptance and Feasibility:** High user acceptance of EWRS in **>75% of participants** across all susceptible groups participating in **ISMED-CLIM** by integrating social and cultural aspects, characterizing the diverse populations and communities involved. **Community Engagement:** Establishment of broad risk communication strategy for educating professionals and citizen groups on the potential health effects of climate change stressors and how these can be mitigated. At the center of this risk communication strategy lies the EWRS, which will be utilized by **>500 professionals** and **>10000 citizens** alike. **Healthcare system resilience**: Climate resilience of regional healthcare systems will be fostered through replicating the Mediterranean-specific climate resilience toolkit for health care systems and establishing short courses and other training curricula for healthcare professionals and administrators. **Cross-Regional Applicability:** The solutions to be assessed will be adaptable and easily transferable in other European regions affected by climate change-related or other environmental stressors.

2.2 Measures to maximise impact - Dissemination, exploitation and communication

ISMED-CLIM **DEC** plan is based on **3 major pillars: 1. Dissemination; 2. Communication; 3. Exploitation strategy,** ensuring that the project activities and outcomes are widely spread among the appropriate target communities, in a timely manner, via suitable and effective methods, identifying potential contributors to the development, evaluation, uptake and exploitation of its outcomes.

2.2.1 Pillar 1: Project's dissemination plan and activities

The dissemination strategy aims to maximise the outreach of the project, diffusing scientific and technological knowledge to specific target groups. **Table 2.1** identifies specific dissemination measures and target values, which are tailored to the needs and profile of each target audience, mainly aiming to progress and improve their work.

***Table 2.1**: Dissemination Plan – Measures, Means, Target Groups and Target Values*

D1: Scientific publications ***[Target groups: F]***	***D2: Industrial Exhibitions, Business Conferences and Trade Fairs [Target groups: A, C, D, E]***
Scientific journals (indicative): Environment International, Environmental Pollution and Environmental Epidemiology, Nature Climate Change, Lancet Planetary Health, Environment International, Journal of Physiology, Journal of Applied Physiology, European Journal of Applied Physiology. **Conferences (indicative):** Annual Conference of the International Society of Environmental Epidemiology; EGU conference, International Workshop of Statistical Modelling, GEOMED conference; European Society of Vector Ecology (E-SOVE), European Mosquito Control Association (EMCA).	Global Congress on Climate Change (GCCC); Global Climate Action Summit; World Health Summit; Greenbuild International Conference and Expo; International Conference on Climate Change and Public Health; COP26; EcoHealth Conference; Healthcare Sustainability Symposium.

D3: Training Curricula, Workshops, Webinars ***[Target groups: A-D, F]***	**D4: Links with European spaces** ***[Target groups: F, G]***
Apropriate training curricula for healthcare professionals across Europe will be prepared, incorporated and trialled within Citizen Assemblies workshops and webinars in all the regions, attended by local authorities and communities. The tailored material will be made available in the Knowledge Hub, incorporating interactive and participatory elements to engage learners effectively.	**ISMED-CLIM** will include an appropriate mechanism to establish operational links with the Climate-ADAPT platform that will act as a central element for the monitoring, support and visualisation of the Mission progress in European Regions.

D5: Policy feedback measures through technical publications, presentations, workshops, white papers and initiatives ***[Target groups: A, D]***	**D6: Clustering and joint activities with related projects and initiatives, associations** ***[Target groups: F]***
ISMED-CLIM will translate relevant project results obtained in its work stream on e.g., technology deployment into formats and content that can contribute to policy debates and issue recommendations on the	**ISMED-CLIM** will pursue link, liaisons and strategies in various EU-wide initiatives, associations, alliances and clusters, such as the International Society of Environmental Epidemiology, International Society for

effectiveness of **ISMED-CLIM** digital interventions. **CyI** will lead on this activity and develop communication formats (such as policy briefs, contributions to webinars and policy campaigns) that can be disseminated among EU leaders in policy, industry, academia and civil society.	Environmental Ergonomics, other ongoing projects (see Section 1.2.5), the relevant and newly funded projects under the Mission to amplify the outreach of the project and to create synergies for promoting the outcomes among the broader community. **ULE** leads this activity.
Dissemination metrics (during the project)	
D1-KPIs: >**15** Peer-reviewed journal publications; >**20** Conference presentations	
D2-KPIs: ≥**6** Industrial exhibitions targeted; **2** Roll-up banners; >**1.000** Brochures to stakeholders	
D3-KPIs: ≥**5** Workshops; ≥**8** Pilot Workshops; **8** Online Training Tutorials; **6** Webinars	
D4-KPIs: >**3** Links with European platform and data spaces	
D5-KPIs: >**3** Policy briefs; >**2** Policy campaigns; >**5** Guidelines to enhance policy recommendations	
D6-KPIs: Clustering and joint activities with ≥**20** related projects, ≥**4** initiatives and associations, >**20** administrative or professional communities, and >**10** civil society networks.	

2.2.2 Pillar 2: Project's communication plan and activities

The communication strategy and plan focus on creating awareness amongst the full range of stakeholders, including the general public, as well as liaise with relevant initiatives for knowledge transfer, as outlined in **Table 2.2**. The aim is to foster the adoption of the project's results by industry and society at large.

Table 2.2: *Communication Plan – Communication Channels/Target Audience/Timeline and Target Values*

C1: Visual identity, website, social media	Target Group: **A-G**	From M03 to 7 years
Definition of the project's brand (logo, guidelines and templates) will guarantee its visual identity. The project's website will be the key channel for both communication and dissemination, divided into a public area (for external communication) and a private, secure, password-protected area for internal project management and communications. The first version will be online by M03, and will be constantly maintained and updated regularly, extending to 3 years post-project. **ISMED-CLIM** will build and maintain its online presence in several social media channels: Twitter and LinkedIn for interaction with R&I communities. **EF** leads this activity.		
C2: Newsletters, online publishing, blogposts	Target Group: **A-G**	From M12 to M48
Through these media project activities, achievements, and results, targeting cross-fertilisation, will be distributed to diverse mailing lists, to foster inter-communication with relevant research actions, projects and technical communities. Leveraging online publishing platforms (e.g. WIRED: Threat Level) and magazines (e.g. CORDIS Research*EU Magazine) and blogs, will enable the project to reach out to a broader audience and execute periodic broad promotion activities. All partners will disclose non-confidential information of the project to local/regional newspapers, media and press in their national language to promote the impact of the demonstrated pilots.		
C3: Promotional Material	Target Group: **A-G**	From M09 to M48
Reference promotional instruments, including brochures, catalogues, posters and any other laid out paper-based resource will be distributed when participating in events. Most of the material will be available as e-documents and printing will occur as required. **ISMED-CLIM** will also explore alternatives for labelling gadgets and merchandise, as an effective mean of promoting initiatives among a less specialized audience. **EF** undertakes this activity.		
C4: Multimedia and podcasts	Target Group: **B**	From M16 to M48
ISMED-CLIM will produce multimedia material, e.g., video animations, to deliver self-explanatory project exposure reduction and health effects mitigation recommendations, and appealing presentation of its scope, leveraging available promotion channels (e.g., YouTube, Vimeo). Video animations will provide the main project message and be available on **ISMED-CLIM** website, YouTube, LinkedIn and partners' websites. A set of interviews and Podcasts from scientific partners and citizens will be recorded to collect inputs, taking advantage of plenary meetings and relevant events. **EF** undertakes this activity.		
Target Values: No. of short videos**: 4**; Number of interviews/podcasts produced: >**6**; Number of views: >**10,000**.		
C5: Public awareness campaigns and Citizen Assemblies	Target Group: **B**	From M12 to M36
ISMED-CLIM envisions to find its way to the centre of the political priority-making process and involve citizens in a continuous way, through accessible communication and co-creation. Public awareness campaigns will disseminate **ISMED-CLIM** solutions' impact on citizens everyday life and create awareness on its societal benefits. In relation to climate change projections, **ISMED-CLIM** will highlight the warning communication chain, the role, the tasks and responsibilities of science advisors and decision-makers. This set of activities includes the use of social media, online video-clips, public talks, participation in events organised by local authorities, etc. Regional Task Force leaders will coordinate dissemination and stakeholder's engagement in the involved countries (Cyprus, Greece, Italy, Spain, Portugal). The Regional Task Forces will employ a bottom-up approach to connect and create networks at regional level and scale up of the mission engagement and peer learning by forming **Citizen Assemblies** to: (i) facilitate definition of the mission within their community/city/region; (ii) create a shared purpose and facilitate joint development; and (iii) exploit citizens' science tools i.e., collection of data, experimenting and create a library of conversations about climate adaptation and societal transformation. **UNICT** is responsible for this activity.		
Communication metrics (during the project)		
C1-KPIs: Website online by: **M01**; >**1.500** Website Unique Visitors by M18 and >**4.000** by M48; >**4.500** online community members (by M48); >**500** monthly average number of impressions		

C2-KPIs: >**7** e-Newsletters contributed/released (every 6 months); >**1.500** Mailing List Contact Points in total; >**25** Unique Publications/Contributions to Blogs; >**8** Different Blogs to Post
C3-KPIs: >**2,000** hard copies distributed to events; >**4** Roll-up Banners
C4-KPIs: **≥4** short animation videos; **≥6** podcast interviews produced; >**10.000** total number of total views
C5-KPIs: **≥10** Citizen Assembly events; >**80** participants per event

2.2.3 Pillar 3: Project's exploitation plan and activities

ISMED-CLIM consortium has the critical mass for successful exploitation, which is also facilitated by the planned open-source version of the platform. The deliverables are based on appreciation and understanding of climate change health effects, as well as the efficacy, user acceptance and health system preparedness of innovative digital interventions through the Mediterranean region, indicating the areas where policy efforts are required.

Exploitation plan and activities

Exploitation of the project's results is considered as a key enabler for the success and long-term sustainability of **ISMED-CLIM**. The project consortium has been carefully crafted to embrace complementary expertise and reach out to different domains. It includes industry, SME, research and academia partners, along with end-users; **ISMED-CLIM** can therefore establish the necessary relationships with many external players to ensure a widespread promotion and adoption of its results to a wide range of associations, clusters, industrial stakeholders and researchers. To orientate the outcomes of **ISMED-CLIM** towards viable open-source or commercial solutions and assets, the consortium will adopt a focused exploitation strategy with measurable outcomes by embedding commercial best practice into the project's lifecycle. The exploitation activities (**part of Task T6.3**) will focus on delivering solutions that have a clear market opportunity that can be tested, demonstrated and replicated by key commercial stakeholders and in close collaboration with end users. The completed business models and marketing plan **(Deliverable D6.2)** will aim to outline viable and commercially relevant solutions, assets and services from the project by taking a broad cross-consortium perspective, with credibility built on a foundation of embracing industry best practice for bringing new products to market. Partner exploitation intentions are described in Section 3.2.2.

ISMED-CLIM has set the objective of achieving sustainability, continuity, and eventually prepare the ground for market entry for the project's results. For this reason, the consortium has drafted and agreed upon its initial exploitation intentions, as depicted in **Table 2.3**. The plan consists of 3 phases: **Phase I** (M01-M16) sets the necessary conditions for the business plan; **Phase II** (M17-M41) formulates the exploitation, sustainability and go-to-market strategy; and **Phase III** (M42-two years post-project) featuring the sustainability plan for the uninterrupted operation of the system and the commercialization roadmap.

Table 2.3: *Exploitation planning approach*

Phase	Planned activities
Phase I: Exploitation planning	Identify innovation and development opportunities by defining **ISMED-CLIM**'s product(s) and services.
Phase II: Exploitation strategy agreement	Elaborate on market analysis, sustainability and business plans. Consortium members will reflect on individual exploitation intentions, the sustainability strategy, and reach a joint exploitation strategy agreement.
Phase III: Exploitation potential maximization and market readiness	Promote potential maximization and launch to market including the following activities: within one-year post-project end integrate **ISMED-CLIM** KERs into commercial or open-source products, continue capacity building trainings and promotion. Within 2-5 years post-project: launch results to industry, build customer base and provide extended services; acquire funding to cover joint venture costs and follow-up research.

Key Exploitable Results

The **Key Exploitable Results (KERs),** which will form the basis for the exploitation strategy and development of appropriate sustainability plans, are presented in **Table 2.4** below:

Table 2.4: **ISMED-CLIM** *KERs*

KERs	By whom	Type	Licensing	Services*	Time to market
LL Management portal	EBOS, UCY	Product	Open source	Su, T, C, E	Freely available by M48
Citizen's application	UCY, EBOS, AIN, EF	Product	Open source	Su, T, C, E	2-3y after project
AI models for EWRS	AIN, EF	Product	Commercial	T, E	2-3y after project
Policy Dashboard (interface)	UCY, EBOS	Product	Open-source	E	Freely available by M48
Knowledge Hub	UCY, EBOS	Product	Open-source	Su, T, C, E	2-3y after project
Policy Implementation Tool	UCY, EBOS	Product	Open-source	Su, T, C, E	2-3y after project
Policy Uptake Monitoring and Evaluation Tool	UCY, EBOS	Product	Open-source	Su, T, C, E	Freely available by M48
Heat Vulnerability Index tool	UCY, EBOS	Product	Open-source	Su, T, C, E	2-3y after project
Zoonotic disease surveillance tool	EF	Product	Open-source	Su, T, C, E	2-3y after project
Training and educational material	ALL	Demo	Open-source	C	Freely available by M48

**Services: Support (Su), Training (T), Consulting (C), Extension (E)*

2.3 Summary

SPECIFIC NEEDS	EXPECTED RESULTS	D & E & C MEASURES
• Mobilise at least 150 regions in testing the solutions most locally needed to build climate resilience and deliver at least 75 deep demonstrations of systemic transformations to climate resilience. • Improved prevention and policy-making against the adverse health effects of climate change • Improved health system preparedness • Need for better understanding of the immediate and prolonged impacts on health resulting from stressors associated with climate change, including the well-being of animals and humans, as encapsulated in the One Health framework. • Enhancing the effectiveness and accessibility of epidemiological surveillance, as well as improving modelling and predictive tools that encompass socio-economic trends, adaptation possibilities, and the assessment of exposure and vulnerability to climate-related factors.	• Enhanced region-specific awareness of societies towards the interplay between various climate change parameters with mortality and morbidity in 5 European countries across the Mediterranean • >50 policy, civil society and healthcare stakeholders engaged across the region in assessment of baseline policy and health care landscape and in co-creation of transformative solutions to be tested. • Development of the necessary technological infrastructure and tools to enable evaluation of the program's evidence-based solutions and building systemic transformation for climate resilience across the Mediterranean. • Evidence-based tools and recommendations that: (i) reduce exposure to heat and air pollution and related health effects in three vulnerable population groups; (ii) mitigate the risk of high-risk professionals and citizens for zoonotic diseases; and (iii) increase preparedness and ability of health care systems in the region to deliver safe, effective, and efficient care to citizens, in the context of the continuing climatic change. • Maximize impact by delivering replication activities, training materials, policy implementation and policy evaluation tools to support informed decision making in the Mediterranean region. • Cross-border cooperation, fostering an additional set of cross-border demonstration activities for climate resilience to health risks of climate change across European regions and communities.	>**15** Peer-reviewed journal publications; >**20** Conference presentations; **≥6** Industrial exhibitions targeted; **2** Roll-up banners; >**1.000** Brochures to stakeholders ≥**10** Workshops; **8** Online Training Tutorials; **6** Webinars; **>3** policy briefs; **>2** Policy campaigns; **>5** Guidelines to enhance policy recommendations Clustering and joint activities with ≥**8** related projects and ≥**4** initiatives, associations; >**4.500** online community members (by M48); >**500** monthly average number of impressions >**7** e-Newsletters contributed/released (every 6 months); >**1.500** Mailing List Contact Points in total; >**25** Unique Publications/Contributions to Blogs; >**8** Different Blogs to Post; >**2.000** hard copies distributed to events; >**4** Roll-up Banners; **≥4** short videos; **≥6** podcast interviews produced; >**2.500** total number of total views; **≥10** Citizen Assembly events; >**80** participants per event
TARGET GROUPS	**OUTCOMES**	**IMPACTS**
• **Regions:** Regional, national, municipal authorities and related organisations; • **Citizens and local communities:** Vulnerable groups, citizen associations, workers, community groups, charities, NGOs • **Healthcare systems:** Hospitals • **Decision- and policymakers:** Ministries • **Private sector and entrepreneurial ecosystem:** Health technology companies • **Knowledge providers:** Research, Academic Institutions, Social Innovators, EU project consortia • **Open-source** initiatives, open data spaces	• 5 countries, 8 demonstrations at 8 sites, 10 replications at 6 sites involved in the development and testing of a whole range of transformative solutions [ISMED_CLIM platform, Citizen App, Policy Dashboard] • that will help to mitigate the effect of climate change on health and human wellbeing, including making the public health sector more climate resilient and better prepared to mitigate the climate change related health challenges. • >20 regions reached; >15 local authorities involved; >15 health systems/hospitals reached; >80.000 vulnerable groups (outdoor workers, pregnant women, older adults, animal handlers) impacted by 2030	• Demonstrate effective use of digital interventional tools and achieve improved climate change risk mitigation and increased knowledge. • Incorporation of ISMED-CLIM solutions in new or updated public health/occupational health & safety legislations and regional climate change adaptation plans in EU • >15% of EU citizens in the Mediterranean region belonging to vulnerable groups will be positively affected

3. Quality and efficiency of the implementation

3.1 Work plan and resources

3.1.1 Outline of workplan and WP interdependencies

Figure 3.1 *PERT chart*

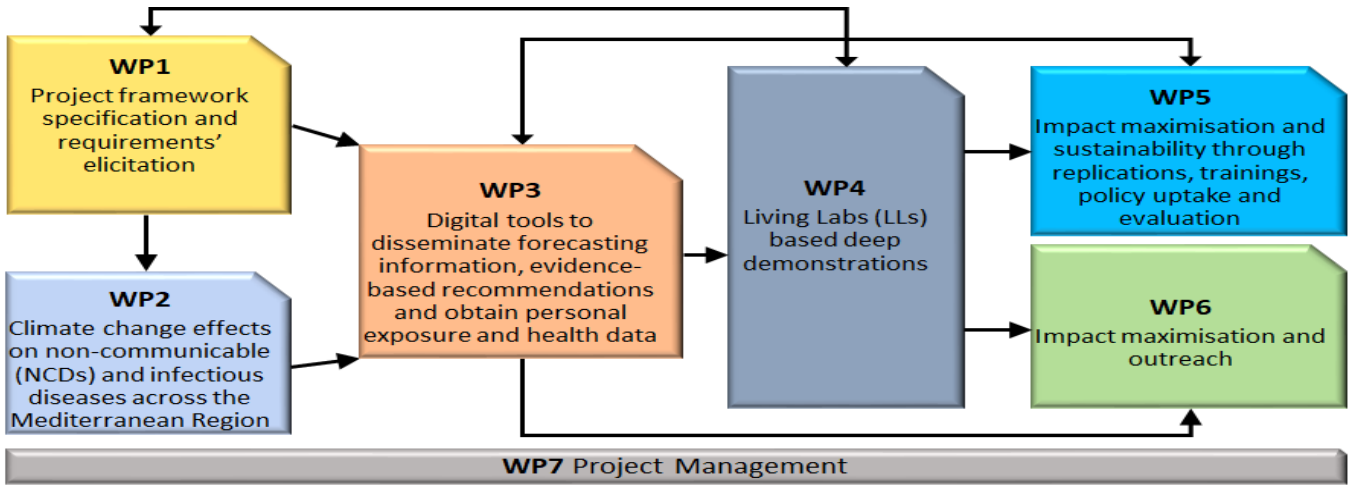
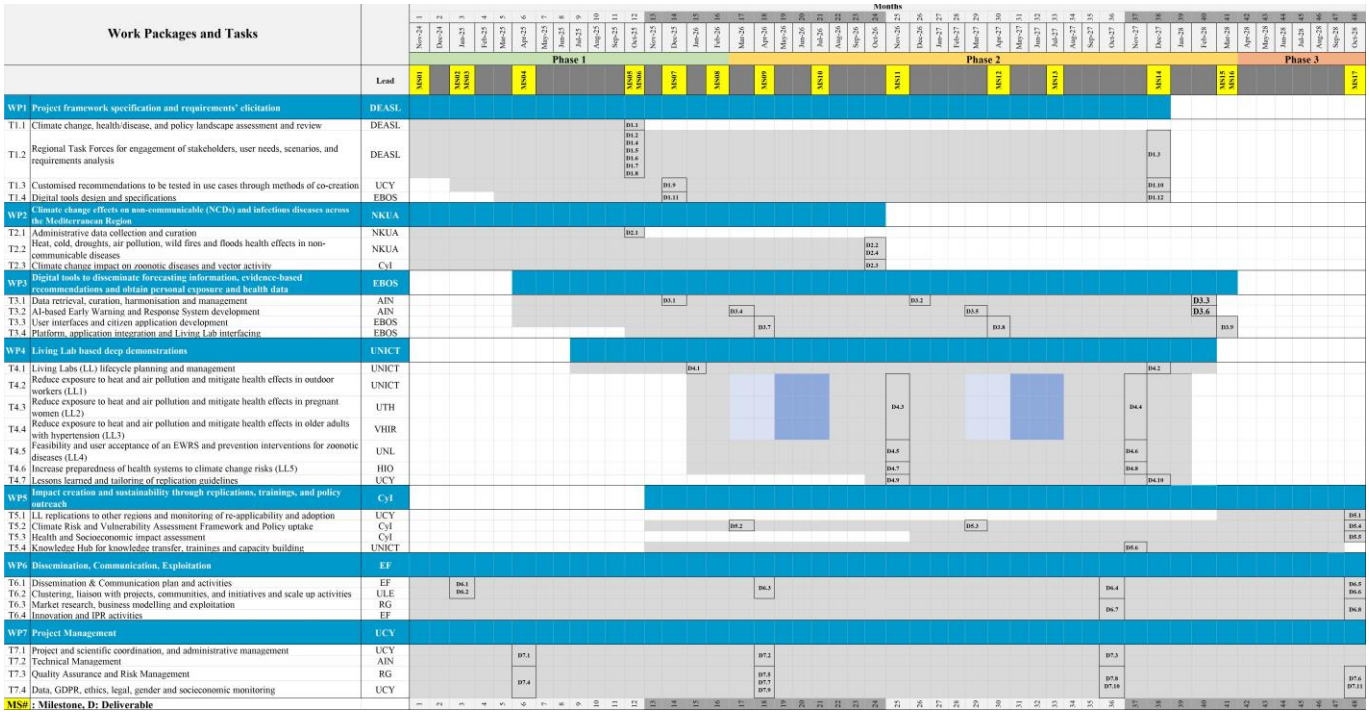


Figure 3.2 *Gantt chart*



3.1.2 Work Package descriptions and resources

Table 3.1h: 'Purchase costs' items (travel and subsistence, equipment and other goods, works and services)

1/UCY	Cost (€)	Justification	6/UTH	Cost (€)	Justification
Other goods, works and services	**108,000**	€18K for Simple Actigraphy Wristbands; €9K for I-buttons; €12K for Advance Actigraphy; €7K for Air Purifiers; €9K for Alpha Sense PM; €16K for project meetings; €10K for dissemination consumables; €21K for workshops; €1K for audit cost; €5K publication fees	**Other goods, works and services**	**75,000**	€9K for Simple Actigraphy Wristbands; €4.5K for I-buttons; €6K for Advance Actigraphy; €3.5K for Air Purifiers; €4.5K for Alpha Sense PM; €45K for Body Core Temperature Capsule; €2.5K to host meetings and workshops
Remaining purchase costs (<15%)	42,000		**Remaining purchase costs (<15%)**	15,000	
TOTAL	**150,000**		**TOTAL**	**90,000**	
14/ULE	**Cost (€)**	**Justification**	**15/VHIR**	**Cost**	**Justification**

Other goods, works and services	**75,000**	€9K for Simple Actigraphy Wristbands; €4.5K for I-buttons; €6K for Advance Actigraphy; €3.5K for Air Purifiers; €4.5K for Alpha Sense PM; €45K for Body Core Temperature Capsule; €2.5K to host meetings and workshops	**Other goods, works and services**	**31,000**	€9K for Simple Actigraphy Wristbands; €4.5K for I-buttons; €6K for Advance Actigraphy; €3.5K for Air Purifiers; €4.5K for Alpha Sense PM; €3.5K to host meetings and workshops
Remaining purchase costs (<15%)	15,000		**Remaining purchase costs (<15%)**	14,000	
TOTAL	**90,000**		**TOTAL**	**45,000**	

3.2 Capacity of participants and consortium as a whole

3.2.1 Partner complementarity

The **ISMED-CLIM** consortium includes **27** organisations from **9** HE-associated countries (CY, EL, IT, ES, PT, RS, EE, BE, UK) and **2** non-associated countries (US, CH), and it encompasses **6** Public Authorities, **7** Academic, **6** Research Technology Organisations, **5** SMEs, **3** NGOs. The consortium members have been carefully selected to provide significant interdisciplinary competency and complementarity in public and healthcare administration, clinical and epidemiological research for infectious and non-communicable diseases, occupational health, climate change and atmospheric modelling, advocacy, policy development and sustainability, and risk communication to adequately support all the project objectives and activities. Beyond the special skills, competences and expertise of each partner, we also considered their past collaborations and experience. All partners have been allocated with adequate resources based on their expertise and capacity to successfully fulfil their obligations during implementation of the project. The composition of the consortium, in relation to each partner's expertise and role, is presented below:

3.2.2 Partner roles

Public organisations

TRIKALA is a public administration authority (Trikala municipality) in the Thessaly Region of Greece. It has significant expertise in implementing European projects and in adopting innovative solutions, that made Trikala internationally known as the Greek flagship smart city, giving it the name of Greece's 'first digital city' in 2004. **Role:** TRIKALA will demonstrate the effectiveness of **ISMED-CLIM** interventions and ESWR in protecting municipal outdoor workers from extreme temperature. **Exploitation:** TRIKALA anticipate that the wide use and promotion of interventions and ESWR will positively impact its citizens and employees, and enrich its provided services.

HIO is the public organisation that manages the General Healthcare System (GESY) of the Republic of Cyprus. GESY was established in 2019, and since 2021, HIO is engaged in the adaptation of NICE U.K. guidelines to the conditions of the Cyprus health system. **Role: HIO** will build upon its experience on guidelines adaptation and develop a Mediterranean-specific climate resilience toolkit for healthcare systems. **Exploitation:** HIO anticipates to establish procedures, tools and KPIs across GESY of Cyprus, which will be evaluated on a regular basis.

KOR is Korydallos Municipality in the Attica Region of Greece. It has significant expertise in transformation and sustainability of public administration in less privileged urban areas. It is actively engaged in research and innovation actions to improve citizens mobility, healthcare access and wellbeing. Furthermore, KOR has extensive experience in the organisation of participatory workshops through nationally funded (DemoCU) and European funded projects (EUCIDIN, CLEAR-ERASMUS+). **Role**: KORYDALLOS will replicate the innovative solutions of LL 1, 3 and 4 among its outdoor employees, in older adults' day-care centres and in animal shelters under its jurisdiction. **Exploitation:** KORYDALLOS expects to increase the climate resilience of this urban and less privileged community and share these tools and experiences within the extended Development Associations for the region of West Attica and the EU URBACT network.

ARNAS Hospital Garibaldi in Catania-Sicily is a tertiary multidisciplinary hospital. Its Maternal and Child Department has been actively participating in ongoing mother-child cohort studies coordinated by UNICT, registered in birthcohorts.net. **Role:** ARNAS will adopt the Mediterranean-specific climate resilience toolkit co-created by LL5 for use by its hospital administrators, healthcare professionals and end users. **Exploitation:** Increase ARNAS climate resilience and system preparedness, and disseminate the toolkit to associated healthcare institutions in Italy.

AGUEDA is a public administration authority in central Portugal, engaged in the Green City Accord, the European Climate Pact in 2022 and member of the Covenant of Mayors. It has already launched the Agueda Smart City platform to enhance the wellbeing of its citizens. **Role:** AGUEDA will replicate LL1 recommendations among its outdoor employees, and LL3 in older adults' day-care centers. **Exploitation:** AGUEDA will adopt the new practices, make them accessible through Agueda Smart City platform and disseminate the solutions within the SMART CITIES network.

DEASL participates through the Department of Epidemiology (DE) and Hospital in ASL ROMA 1 that are part of the Lazio regional public Health Service. DE supports the Italian state and local authorities in the Italian Heat Plan and performs high quality research in environmental and clinical epidemiology. **Role:** DE will lead WP1, which will assess policy landscape across the Mediterranean countries, engage stakeholders, and provide key estimates for the project's digital tools. DE will also contribute to epidemiological modelling of climate change health effects. Finally, the Hospital in ASL ROMA 1 will adopt the Mediterranean-specific climate resilience toolkit co-created by LL5 for use by its hospital administrators, healthcare professionals and end users. **Exploitation:** DEASL expects to provide scientific evidence to Lazio regional public Health Service for innovative climate resilient solutions, enhance its research know-how and its collaborations with WHO EURO and Italian MOH on environment and health initiatives.

MLSA is the Ministry responsible for occupational health and safety legislation in Greece. It hosts the National Focal

Point of EU-OSHA, and is in the process of developing an integrated national protection framework to address occupational heat stress. **Role:** MLSA will participate in the development and tailoring of recommendations for the policy uptake tools in T5.2. **Exploitation**: MLSA will enhance its in-house capacity to address climate related health risks by leveraging the tools and recommendations of **ISMED-CLIM** to support its role as the regulatory authority for occupational health and safety in Greece.

Academic and Research Technology Organisations

UCY is the biggest university in Cyprus and has extensive research expertise from participating in 136 Horizon 2020 projects (55 as coordinating partner). It will participate in **ISMED-CLIM** through its: (i) Medical School (expertise in intervention clinical studies, sleep physiology, wearables' technology, environmental health and infectious diseases epidemiology); (ii) Department of Civil and Environmental Engineering (expertise in dynamical urban micro-climate modelling of environmental parameters); and (iii) Department of Social and Political Sciences (expertise in citizen and stakeholders' engagement, participatory research methodology, communication strategy and training curricula development). **Role:** UCY will be responsible for the overall project management and successful completion of technical tasks, network coordination, budget allocation and reporting. It will also undertake performance of LL2 and LL3 in Cyprus and support implementation of LL4 and LL5. Finally, it will also participate in the development of the EWRS and Policy Dashboard. **Exploitation:** UCY expects to provide new real-life evidence on the effectiveness of interventions for climate change adaptation and further contribute to advancement of public health and climate resilience in Cyprus.

UNICT is the oldest university in Sicily (Italy) and will participate through its (i) Department of Medical and Surgical Science and Advanced Technologies "GF Ingrassia"; and (ii) Department of Political and Social Sciences. "GF Ingrassia" has extensive expertise in maternal and perinatal health research and coordinates the ongoing birth cohorts "Mamma & Bambino" and "MAMI-MED," which participate in the international network Birthcohorts.net and contribute to LifeCycle Project. The Department of Political and Social Sciences has extensive research and consulting experience on public health policy evaluation, participatory research involving public and healthcare professionals, open government, and strategic planning. **Role:** UNICT will coordinate WP4 and lead the set-up and implementation of LL2 focusing on pregnant women, as well as support policy uptake by public authorities and development of educational material, through UNICT social scientists. **Exploitation:** UNICT expects to contribute to protection of maternal-fetal health from the impact of heat and air pollution by informing evidence-based policies and translating research findings into practical applications.

UTH is a public University in the region of Thessaly (Greece). It participates through its Department of Exercise Science that has acquired international fame through participation in European and international projects focusing on the effects of environmental factors, especially temperature and thermal strain, on human health and performance (e.g., HEAT-SHIELD, FP7 THERMOMICS). **Role:** Capitalizing on its previous expertise, UTH will lead LL1 focusing on testing recommendations to reduce exposure and adverse health effects of heat and air pollution in outdoor workers, as part of LL1 in Greece. **Exploitation:** UTH expects to further expand current understanding on the feasibility, acceptance and efficacy of interventions focusing on outdoor workers and in combination with findings from current projects such as ADAPTHEAT, will further update occupational health and safety directives.

ULE is a public university in Spain that has a strong record of participation in international R&D projects. It is part of the VALFIS Research Group that belongs to the Institute of Biomedicine (IBIOMED) and the Department of Physical Education and Sports. It has >15 years' experience in laboratory and on-field assessments of the effects of heat on thermo-physiological responses in occupational and sports settings. **Role:** ULE will test recommendations to reduce exposure and adverse health effects of heat and air pollution in outdoor workers, as part of LL1 in Spain, leveraging on expertise from previous H2020 (e.g., SIXTHSENSE) and national projects that utilized wearable sensors. **Exploitation:** ULE expects to advance knowledge and reinforce understanding of the effects of heat and PM exposure on workers´ health and generate insights that are useful from a policy and a scientific perspective.

NKUA is the biggest University in Greece. It participates through the: (i) Department of Hygiene, Epidemiology and Medical Statistics, which houses the Environmental Epidemiology Unit that has coordinated and participated in large EU and international projects focusing on health effects of environmental and climate change exposures, such as air pollution, heat and noise; and (ii) Alexandra General Hospital, which hosts one of the largest Maternity & Obstetrics units in Greece. **Role:** NKUA will lead WP2 and the study of the associations of climate change parameters with NCDs outcomes. In addition, through Alexandra General Hospital, it will serve as a replication site of the interventions for pregnant women tested in LL2 and of the Mediterranean-specific climate resilience toolkit co-created in LL5. **Exploitation:** NKUA expects to provide additional epidemiological insights related to climate change in the region and expand on the work carried out in EXPANSE and MCC network projects.

UNL is the NOVA University of Lisbon and participates through the NOVA Institute of Hygiene and Topical Medicine (IHMT-NOVA), which is the only Portuguese research centre totally dedicated to tropical diseases and public health. UNL coordinates the CLIMOS project, which focuses on the effects of environmental changes on geographical migration and expansion of parasites, reservoirs and vectors, in particular in zoonotic leishmaniasis. **Role:** UNL, capitalizing on CLIMOS work, will lead implementation of LL4. In collaboration with stakeholders of high-risk professionals, it will validate the feasibility and user acceptance of a regional EWRS tool to mitigate the exposure risk to sand flies and related diseases. **Exploitation:** UNL expects to strengthen its role in the development of a global health research agenda in zoonotic diseases and the implementation of evidence-based interventions.

VHIR participates through its aging research group REFiT of the Vall D'Hebron University Hospital Research Institute and the Parc Sanitari Pere Virgili (PSPV) Hospital. This is a large healthcare institution in Barcelona, which integrates geriatrics (hospital based and home-based services) and primary care in an area of around 900.000 citizens.

REFiT's research is oriented towards implementation of complex interventions for older adults, including innovative services and care pathways. **Role:** REFiT will test recommendations to reduce exposure and adverse health effects of heat and air pollution in older adults with hypertension within LL3 in Spain. The PSPV Hospital will adopt the Mediterranean-specific climate resilience toolkit co-created by LL5 for use by its hospital administrators, healthcare professionals and end users. **Exploitation:** VHIR team through its leader Dr. Inzitari, who is currently the coordinator of the geriatric masterplan of Catalonia, at the Catalan Ministry of Health, expects to integrate the new project tools in the action plans of the health and social systems in Catalonia and increase resilience to climate change.

HSPH is one of the world leading institutions in the field of public health and the design of interventions and policies with worldwide impact. Through the Center for Climate, Health, and the Global Environment (Harvard Chan C-CHANGE), HSPH has developed (2021) a US Climate Resilience for Frontline Clinics toolkit, which delivers useful resources for health care providers, patients and administrators to meet the challenges for health care from extreme climatic events. **Role:** HSPH, will scientifically oversee LL5 for adaptation of the U.S. toolkit to a Mediterranean-specific climate resilience toolkit, ensuring the quality and streamlining of the adaptation process. **Exploitation:** HSPH, as **ISMED-CLIM** associated partner, expects to maximise impact of the Harvard Chan C-CHANGE toolkit in the Mediterranean region and gain insight from its replication across multiple countries and diverse health systems.

IMR is a Serbian governmental research institute under the University of Belgrade. It participates in the CLIMOS project and has accumulated significant expertise, especially in studying the distribution of vectors, vector-borne diseases and zoonoses in relation to climatic parameters. **Role:** IMR will participate in the study of the impact of climate change on infectious diseases and vector activity in WP2 and support the implementation of LL4. **Exploitation:** Through its participation, IMR expects to expand the work undertaken by CLIMOS and access the real-life applicability of recommendations and EWRS for zoonotic disease, as part of **ISMED-CLIM**.

CSIC is Spain's largest public research institution, attached to the Spanish Ministry of Economy, Industry and Competitiveness. It plays a key role in scientific and technological policy in Spain and worldwide. Through the Environmental Geochemistry and Atmospheric Research (EGAR) group, CSIC will leverage its expertise gained from previous and ongoing research projects, focusing on environmental resilience and public health protection (H2020 FIRE RES and LIFE REMY). **Role**: CSIC will participate in WP2 in the study of the impacts of extreme climatic events on health effects in NCDs and support the estimation of future health impact on NCDs under different climatic change scenarios for the region. **Exploitation:** CSIC expects to advance knowledge by addressing understudied relationships and further inform evidence-based policy making in the field of public health.

CyI participates through its regional Centre of Excellence for Climate and Atmosphere Research in the Eastern Mediterranean and Middle East Region (EMME-CARE) and its Science and Technology Driven Policy and Innovation Research Centre (STEDI-RC). CyI has a long record of analysing extensive climate data and making climate projections in addition to developing advanced statistical/AI models for linking environmental data with impact data (e.g., health). It has also experience in assessing the impacts of climate change on vector-borne diseases, such as sand fly-borne leishmaniasis. Through STEDI-RC, CyI has experience in decision support methodologies and policy evaluation. **Role:** CyI will carry out a comprehensive assessment of sand fly-borne disease risk to inform the proposed EWRS, participate in the estimation of extreme events impacts on health and lead the project's health and socioeconomic impact assessments. **Exploitation:** CyI expects to inform its VEClim platform, a repository of mathematical disease risk models for vector-borne diseases and further expand on its capacity in development and maintenance of decision-support tools for climate change adaptation, providing insights to policymakers.

UA is a public university in Aveiro, Portugal and a founding member of the European Consortium of Innovative Universities. It participates in ISMED-CLIM through its Centre for Environmental and Marine Studies (CESAM) Research Unit, which has significant experience in the study of population and professional exposure to air pollution from wildfires. In addition, UA have experience in participatory research methodologies as it participated in projects engaging businesses, policy makers and municipalities (including technical workers and senior stuff) in co-creation methodologies to address environmental and climate change issues in projects DISTENDER and CLAIR-CITY (Horizon Europe). **Role:** UA will support the development of Regional Task Force in Portugal, participate in the implementation of HIA and SEIA studies and support the development of the Policy Dashboard. **Exploitation:** UA will exploit the project output to inform evidence-based policy making in the field of public protection in Portugal and link the ISMED-CLIM solutions with the FirEUrisk project integrated strategy for wildfire risk assessment.

Professional and civil society organizations

EKYSY (Federation of Cypriot Pensioners) operates within the structure of the Pancyprian Federation of Labor (PEO) and is the biggest pensioners organization (>60.000 members) in Cyprus. It has a long record of advocacy activities and projects for enhancing healthcare access and wellbeing of older adults. **Role:** EKYSY will facilitate the implementation of LL3 in older adults with hypertension in Nicosia-Cyprus. **Exploitation:** EKYSY expects to replicate **ISMED-CLIM** solutions across its membership and its country-wide community centers.

APMVEAC is the professional association of >2.500 veterinarians in Portugal. It fosters educational activities and initiatives aiming to improve professional development of its members and the veterinary care of companion animals. **Role:** APMVEAC will contribute in co-creation of **ISMED-CLIM** guidelines and will participate in LL4 to assess the feasibility and user acceptance of the zoonotic component of the EWRS through its application among its member veterinarians and pet owners. **Exploitation:** As a member of WSAVA Global Veterinary Community, APMVEAC expects to share the project output to the wider community of veterinarians and pet owners in Portugal and Europe.

ACARES is global health-focused relief and development NGO with expertise in disaster response, health crises and health systems resilience. Along with HSPH, it developed guidance to safeguard vulnerable patients from extreme heat, wildfires, hurricanes and floods. **Role:** As an associated partner, ACARES will have a consulting and support

role in LL5 for the adaptation of the U.S. Climate Resilience for Frontline Clinics' toolkit to the Mediterranean-specific climate resilience toolkit for healthcare systems. **Exploitation:** ACARES expects to increase the know-how and the capacity to support similar adaptation and replication activities of its toolkit in other regions adversely affected by climate change (Latin America, Caribbean and Southeast Asia).

International organizations

ECMWF is both a research institute and a 24/7 operational service, producing global numerical weather predictions and other data for its Member and Co-operating States and the broader community. ECMWF has one of the largest supercomputer facilities and meteorological data archives in the world and is a key player in Copernicus, offering quality-assured information on climate change (Copernicus Climate Change Service; C3S), atmospheric composition (Copernicus Atmosphere Monitoring Service; CAMS), flooding and fire danger (Copernicus Emergency Management Service; CEMS). **Role:** ECMWF will optimize weather forecasting algorithms and generate higher-resolution (downscaled) temperature forecasts for the project sites and advice on the development of the EWRS and Policy Dashboard. **Exploitation:** ECMWF expects to expand on the available information for the region in terms of health risks arising from climate and weather. The results will be shared to the community through the dedicated platform and if feasible also through the Copernicus and DestinE data sharing spaces.

Industrial Organisations and Small Medium Enterprises

EBOS has more than 20 years of expertise as a software powerhouse and has successfully participated in >50 previously EU-funded projects as an IT partner. **Role:** EBOS will lead WP3 and will be specifically responsible for developing the Data Management Middleware and support the platform and application integration for the LLs and the EWRS, as well as set-up the **ISMED-CLIM** Policy Dashboard. **Exploitation:** Apart from designing and maintaining the project's website, EBOS will also leverage its wide experience in the market, to contribute to the elaboration of **ISMED-CLIM** dissemination and sustainability plans and present project's results to key associations through its membership (e.g., DAIRO, AIOTI, NESSI).

AIN brings together a multidisciplinary team with a long track record in the development of Artificial Intelligence (AI) solutions for healthcare applications. AIN has been involved in large-scale European and national research and commercial projects with different roles. **Role:** AIN will be responsible for setting-up the data retrieval pathways, ensure data harmonisation of datasets and lead the development of the AI-augmented EWRS. **Exploitation:** AIN expects to extend the company's R&D activities, improve its services portfolio and expand its contact base for the development of international collaborations, especially within the public health and environmental sector.

EF is an NGO with significant expertise in open-source web protocols, open AI and other open source solutions. It is committed to conducting extensive outreach activities as part of research and innovation initiatives **Role:** EF will participate in the development of the project's sustainable exploitation and business plan, lead the design of the IPR strategy and establish the IPR management procedures and associated activities. Furthermore, EF will support the other IT partners on the incorporation of CLIMOS project elements in the **ISMED-CLIM** EWRS. **Exploitation:** EF aims to further advance its capacity as developer of open source protocols and tools, enable subsequent commercial growth of developed tools and further ccontribute to a knowledge-driven society.

RG is an experienced consulting firm with a strong background in training and research activities, including EU H2020 funded projects. RG activities focus on advocating and providing solutions to foster organisational resilience and quality assurance of organisations and system activities in the face of potentially disruptive environmental or other events. **Role:** RG will be primarily responsible for the business modelling, exploitation and quality assurance of the project but it will also support training activities (especially activities fostering climate resilience in local communities), and the development of the Health and Socioeconomic impact assessment. **Exploitation:** Through the **ISMED-CLIM** activities, RG will increase its experience in the development and exploitation of decision support systems for environmental risks, especially targeting local and healthcare administrators

4. Ethics self-assessment

Ethical dimension of the objectives, methodology and likely impact

ISMED-CLIM aims to (i) advance the understanding of how climate change affects health in the short and long-term in the Mediterranean region using climate modelling and epidemiology of non-communicable and infectious diseases (WP2); (ii) orchestrate the performance of five Living Labs (LLs) (WP4) at eight sites in five different EU member states (Cyprus, Italy, Greece, Spain and Portugal) in the Mediterranean to demonstrate the effectiveness of a series of recommendations and tools in protecting vulnerable workers and citizen groups, the health systems and the society as a whole from the effects of climate change; (iii) develop an electronic platform for collection and handling of data and validate an Artificial Intelligence (AI) based, personalized Early Warning and Response (EWR) system, which will be available as a citizens' app (WP3); and (iv) refine the five LLs outputs through ten replications in six sites in the Mediterranean, in parallel with the integration of the produced knowledge, forecasting, exposure and health data with insights from the LLs into a knowledge portal and policy decision-centric and action-oriented dashboard (WP5). The objectives and methodology of ISMED-CLIM have well defined ethical dimensions, which have been carefully identified in collaboration with experts in research methodology of the consortium and are described in detail for each WP below: • WP2 will investigate associations between climate change stressors and health in the short and long-term and will require data on temperature, air pollution, desert dust events, wildfires, and flooding together with mortality and morbidity data (specifically natural, cardiovascular, respiratory, neurological) from national population cohorts across the Mediterranean region. However, as this type of data is already anonymised and publicly available for use for public health purposes, their use for this project does not raise any ethical considerations. • WP4 encompasses: (i) LLs 1, 2 and 3 that are randomised controlled trials to examine the efficacy of interventions to

reduce exposure to heat and air pollution and related health effects for two months during summers in three vulnerable population groups: outdoor workers, pregnant women and older adults with hypertension. Each clinical trial will recruit 102 participants (in total 306) who will be randomised to intervention and control groups to evaluate low-level interventions, including implementation of behavioural recommendations for changes in time spent and activity performed outdoors and use of devices to reduce indoor temperature (fans, A/C) and PM air pollution levels (HEPA air purifiers). These studies will also involve the profiling of the participant's time spent indoors/outdoors using their smartphone's global positioning system (GPS) and use of wearable sensors to assess their personal exposure to ambient temperature (iButton), physical activity levels and sleep-wake patterns (wristband actigraphy) and important related health outcomes (advanced actigraphy: blood pressure, oxygen saturation, ECG, heart rate variability). The study interventions and the wearable sensor monitors have been used in previous studies and are not expected to confer any additional risk or severe burden to the patients included. The collected sensor and multiple questionnaire datasets from all study sites will be uploaded to the secure e-platform created by WP3 to be transferred centrally to UCY in Cyprus for harmonization and analysis; (ii) LL4 that will assess the feasibility and user acceptance of the zoonotic component of the EWRS (T3.3) and a set of preventive guidelines/ interventions among high-risk professionals and citizen groups (dog shelter workers and volunteers, veterinarians) in Portugal and collect feedback from them by conducting surveys to assess user satisfaction, needs, and preferences; and (iii) LL5 that will develop a detailed, Mediterranean-specific climate resilience toolkit for healthcare system administrators, healthcare professionals and end users in Cyprus, following a series of focus groups and consultation workshops. For both LL4 and LL5, data from interviews, and questionnaires will be anonymised and uploaded on the e-platform for curation and analysis. • WP3 & WP5 will develop an electronic platform to collect raw experimental measurements from the LLs; aggregated epidemiological datasets; scripts used for the analysis of raw measurements; specific flow/service statistics; technical reports and manuals. They will also develop Deep Learning and AI techniques to synthesise data and model outputs and transform them into early warnings, insights, and recommendations. Also, they will develop a user-friendly dashboard with flexible functionality to expose the data and modelling process to a wide group of stakeholders (policy makers, healthcare administrators, professionals and citizens) with tailored/customized view of the visualized data and decision outcomes.

Compliance with ethical principles and relevant legislations

ISMED-CLIM will have an Ethics Manager/DPO (EM) at UCY and a dedicated Advisory Committee on Ethics and Data Protection during project execution. Furthermore, in WP7 we will provide support and guidelines for ethics committee approval procedures, regulatory affairs and legal issues to create the baseline for a legally compliant development of the framework, by fusing security and privacy by design mechanisms documented in D1.3. The issues identified above are addressed below in detail for each WP: • WP4: (i) For LLs 1, 2 and 3 randomised controlled trials, UCY will supervise application procedures, order EudraCT number and submit applications to the scientific ethical committee system, Trial Registration (clinicaltrials.gov), and the Cyprus Bioethics Committee, including a separate section on ethical considerations and EudraCT. Partners UNICT, UTH, ULE, and VHIR in Catania-Italy, Trikala-Greece, Leon-Spain and Barcelona-Spain respectively, will consult with their local Ethics Committees experts with regards to the requirements of the national legislation for approval. Protocols will be translated for each country. All subjects selected for participation will receive an appropriate explanatory letter, together with detailed patient/volunteer information and informed consent forms. Consent will also be obtained for data collection, storage, transfer and analysis in agreement with national laws. The exact content of the patient information and informed consent forms will be worked out in collaboration of the ISMED-CLIM Data Protection Manager with the Advisory Committee on Ethics and will be adapted to the different countries and languages. The responsible PI of any of the participating centres holds the possibility for immediate exclusion of a patient, if continuing the study is considered a risk or burden to the patients of any kind. All identifying personal data (names, addresses) will remain in the partner country, and only totally anonymous data will be uploaded to the secure e-platform created by WP3 and transferred centrally to UCY in Cyprus. UCY will ensure protection and security of data in its central database and non-disclosure of personal data; (ii) For LL4; and (iii) For LL5, participating stakeholders, professionals and citizens will take part in the focus groups, workshops and questionnaire surveys on an entirely voluntary basis. Raw data from these procedures will be pre-processed at collection to remove any personally identifiable information, leaving only anonymous and unique machine identifiers along with other parameters related to computations, before uploading to the central database of the e-platform. • WP3 and WP5: A FAIR Data Management Plan (DMP) will be delivered by M06, and data security will be preserved, in accordance with Directive 95/46/EC, EU GDPR May 2018. The data handled during and after the project will follow the FAIR data principles. The partner responsible for the project's Data Management and DMP will be UCY. Knowledge and data will be securely stored and maintained in an internal document management system, such as TeamWork and/or ARGOS for at least 2 years after project conclusion. UCY will also serve as the project's Data Protection Officer (DPO) assisted by contact points in all consortium partners. RG will be responsible for the Quality Assurance. The DMP will be revised by M24 and will include a data protection impact assessment and case validations that will be used to ensure the project follows a data protection-by-design approach. The EM will ensure the project's foundation is ethically compliant and responds to the EC's ethics requirements, by delivering legal guidelines to create the baseline for a legally compliant development and framework. Security and privacy issues will be identified by conducting a thorough analysis of the building blocks to be utilized. D7.2 will describe the legal requirements to be considered in development of the envisaged technologies and integrated into the system design; how consortium partners will approach de-identification of data; the informed consent procedures and templates; opinions of ethics committees; data transfers, detailed data protection policy; a description of anonymization/pseudo-anonymization techniques; a justification for processing of each category of sensitive data. The layer responsible for data

management and orchestration will deal with the processing of data within the database, with a focus on ensuring trustworthiness, adherence to data ethics, and compliance with GDPR regulation. Partners AIN and eBOS will only use deidentified and aggregated health and exposure data for Deep Learning and AI transformations into early warnings, insights, and recommendations. We will abide by the Ethics Guidelines for Trustworthy AI for designing and developing lawful, ethical and robust AI models. Therefore, there are no major ethical or human rights considerations from this activity.

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ANNEX 2

ESTIMATED BUDGET FOR THE ACTION

	Estimated eligible[1] costs (per budget category)										Estimated EU contribution[2]			
	Direct costs								Indirect costs	Total costs	EU contribution to eligible costs			Maximum grant amount[6]
	A. Personnel costs			B. Subcontracting costs	C. Purchase costs			D. Other cost categories	E. Indirect costs[3]		Funding rate %[4]	Maximum EU contribution[5]	Requested EU contribution	
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons		A.4 SME owners and natural person beneficiaries	B. Subcontracting	C.1 Travel and subsistence	C.2 Equipment	C.3 Other goods, works and services	D.2 Internally invoiced goods and services	E. Indirect costs					
Forms of funding	Actual costs	Unit costs (usual accounting practices)	Unit costs[7]	Actual costs	Actual costs	Actual costs	Actual costs	Unit costs (usual accounting practices)	Flat-rate costs[8]					
	a1	a2	a3	b	c1	c2	c3	d2	e = 0,25 * (a1 + a2 + a3 + c1 + c2 + c3)	f = a + b + c + d + e	U	g = f * U%	h	m
1 - UCY	671 000.00	0.00	0.00	0.00	22 000.00	20 000.00	108 000.00	0.00	205 250.00	1 026 250.00	100	1 026 250.00	1 026 250.00	1 026 250.00
2 - CyI	237 952.00	0.00	0.00	0.00	20 000.00	0.00	9 500.00	0.00	66 863.00	334 315.00	100	334 315.00	334 315.00	334 315.00
3 - HIO	69 000.00	0.00	0.00	0.00	10 000.00	0.00	0.00	0.00	19 750.00	98 750.00	100	98 750.00	98 750.00	98 750.00
4 - EBOS	444 600.00	0.00	0.00	0.00	22 000.00	0.00	3 000.00	0.00	117 400.00	587 000.00	70	410 900.00	410 900.00	410 900.00
5 - EKYSY	35 520.00	0.00	0.00	0.00	5 000.00	0.00	0.00	0.00	10 130.00	50 650.00	100	50 650.00	50 650.00	50 650.00
6 - UTH	229 500.00	0.00	0.00	0.00	15 000.00	0.00	75 000.00	0.00	79 875.00	399 375.00	100	399 375.00	399 375.00	399 375.00
7 - NKUA	247 500.00	0.00	0.00	0.00	19 000.00	0.00	1 000.00	0.00	66 875.00	334 375.00	100	334 375.00	334 375.00	334 375.00
8 - KOR	69 000.00	0.00	0.00	0.00	10 000.00	0.00	0.00	0.00	19 750.00	98 750.00	100	98 750.00	98 750.00	98 750.00
9 - MLSA	36 120.00	0.00	0.00	0.00	5 000.00	0.00	0.00	0.00	10 280.00	51 400.00	100	51 400.00	51 400.00	51 400.00
10 - TRIKALA	35 400.00	0.00	0.00	0.00	5 000.00	0.00	0.00	0.00	10 100.00	50 500.00	100	50 500.00	50 500.00	50 500.00
11 - UNICT	335 000.00	0.00	0.00	0.00	18 000.00	0.00	31 000.00	0.00	96 000.00	480 000.00	100	480 000.00	480 000.00	480 000.00
12 - ARNAS	35 760.00	0.00	0.00	0.00	5 000.00	0.00	0.00	0.00	10 190.00	50 950.00	100	50 950.00	50 950.00	50 950.00
13 - DEASL	144 000.00	0.00	0.00	0.00	13 000.00	0.00	0.00	0.00	39 250.00	196 250.00	100	196 250.00	196 250.00	196 250.00
14 - ULE	193 500.00	0.00	0.00	0.00	15 000.00	0.00	75 000.00	0.00	70 875.00	354 375.00	100	354 375.00	354 375.00	354 375.00
15 - VHIR	279 000.00	0.00	0.00	0.00	14 000.00	0.00	31 000.00	0.00	81 000.00	405 000.00	100	405 000.00	405 000.00	405 000.00
16 - CSIC	81 000.00	0.00	0.00	0.00	12 000.00	0.00	0.00	0.00	23 250.00	116 250.00	100	116 250.00	116 250.00	116 250.00
17 - UNL	110 900.00	0.00	0.00	0.00	12 500.00	0.00	1 000.00	0.00	31 100.00	155 500.00	100	155 500.00	155 500.00	155 500.00
18 - UA	72 000.00	0.00	0.00	0.00	10 500.00	0.00	0.00	0.00	20 625.00	103 125.00	100	103 125.00	103 125.00	103 125.00
19 - AGUEDA	34 800.00	0.00	0.00	0.00	5 000.00	0.00	0.00	0.00	9 950.00	49 750.00	100	49 750.00	49 750.00	49 750.00
20 - APMVEAC	35 940.00	0.00	0.00	0.00	5 000.00	0.00	0.00	0.00	10 235.00	51 175.00	100	51 175.00	51 175.00	51 175.00
21 - ECMWF	234 450.00	0.00	0.00	0.00	10 000.00	0.00	0.00	0.00	61 112.50	305 562.50	100	305 562.50	305 562.00	305 562.00
22 - IMR	78 280.00	0.00	0.00	0.00	9 000.00	0.00	1 000.00	0.00	22 070.00	110 350.00	100	110 350.00	110 350.00	110 350.00
23 - AIN	372 378.20	0.00	53 621.80	0.00	22 000.00	0.00	6 000.00	0.00	113 500.00	567 500.00	70	397 250.00	397 250.00	397 250.00
24 - EF	276 000.00	0.00	0.00	0.00	14 000.00	0.00	5 000.00	0.00	73 750.00	368 750.00	100	368 750.00	368 750.00	368 750.00
25 - HSPH														
26 - RG														
27 - ACARES														
Σ consortium	4 358 600.20	0.00	53 621.80	0.00	298 000.00	20 000.00	346 500.00	0.00	1 269 180.50	6 345 902.50		5 999 552.50	5 999 552.00	5 999 552.00

[1] See Article 6 for the eligibility conditions. All amounts must be expressed in EUR (see Article 21 for the conversion rules).
[2] The consortium remains free to decide on a different internal distribution of the EU funding (via the consortium agreement; see Article 7).

[3] Indirect costs already covered by an operating grant (received under any EU funding programme) are ineligible (see Article 6.3). Therefore, a beneficiary/affiliated entity that receives an operating grant during the action duration cannot declare indirect costs for the year(s)/reporting period(s) covered by the operating grant, unless they can demonstrate that the operating grant does not cover any costs of the action. This requires specific accounting tools. Please immediately contact us via the EU Funding & Tenders Portal for details.

[4] See Data Sheet for the funding rate(s).

[5] This is the theoretical amount of the EU contribution to costs, if the reimbursement rate is applied to all the budgeted costs. This theoretical amount is then capped by the 'maximum grant amount'.

[6] The 'maximum grant amount' is the maximum grant amount decided by the EU. It normally corresponds to the requested grant, but may be lower.

[7] See Annex 2a 'Additional information on the estimated budget' for the details (units, cost per unit).

[8] See Data Sheet for the flat-rate.

ANNEX 2a

ADDITIONAL INFORMATION ON UNIT COSTS AND CONTRIBUTIONS

SME owners/natural person beneficiaries without salary (Decision C(2020) 7115[1])

Type: unit costs

Units: days spent working on the action (rounded up or down to the nearest half-day)

Amount per unit (daily rate): calculated according to the following formula:

{EUR 5 080 / 18 days = **282,22**}
multiplied by
{country-specific correction coefficient of the country where the beneficiary is established}

The country-specific correction coefficients used are those set out in the Horizon Europe Work Programme (section Marie Skłodowska-Curie actions) in force at the time of the call (see Portal Reference Documents).

HE and Euratom Research Infrastructure actions[2]

Type: unit costs

Units[3]: see (for each access provider and installation) the unit cost table in Annex 2b

Amount per unit*: see (for each access provider and installation) the unit cost table in Annex 2b

* Amount calculated as follows:

For trans-national access:

$$\frac{\text{average annual total trans-national access costs to the installation (over past two years[4])}}{\text{average annual total quantity of trans-national access to the installation (over past two years[5])}}$$

For virtual access:

$$\frac{\text{total virtual access costs to the installation (over the last year[6])}}{\text{total quantity of virtual access to the installation (over the last year[7])}}$$

Euratom staff mobility costs[8]

Monthly living allowance

Type: unit costs

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1 Commission Decision of 20 October 2020 authorising the use of unit costs for the personnel costs of the owners of small and medium-sized enterprises and beneficiaries that are natural persons not receiving a salary for the work carried out by themselves under an action or work programme (C(2020)7715).

2 Decision of 19 April 2021 authorising the use of unit costs for the costs of providing trans-national and virtual access in Research Infrastructure actions under the Horizon Europe Programme (2021-2027) and the Research and Training Programme of the European Atomic Energy Community (2021-2025).

3 Unit of access (e.g. beam hours, weeks of access, sample analysis) fixed by the access provider in proposal.

4 In exceptional and duly justified cases, the granting authority may agree to a different reference period.

5 In exceptional and duly justified cases, the granting authority may agree to a different reference period.

6 In exceptional and duly justified cases, the granting authority may agree to a different reference period.

7 In exceptional and duly justified cases, the granting authority may agree to a different reference period.

8 Decision of 15 March 2021 authorising the use of unit costs for mobility in co-fund actions under the Research and Training Programme of the European Atomic Energy Community (2021-2025).

Units: months spent by the seconded staff member(s) on research and training in fission and fusion activities (person-month)

Amount per unit*: see (for each beneficiary/affiliated entity and secondment) the unit cost table in Annex 2b

* Amount calculated as follows from 1 January 2021:
{**EUR 4 300** multiplied by
country-specific correction coefficient** of the country where the staff member is seconded}[9]

**Country-specific correction coefficients as from 1 January 2021[10]

EU-Member States[11]

Country / Place	Coefficient (%)
Bulgaria	59,1
Czech Rep.	85,2
Denmark	131,3
Germany Bonn Karlsruhe Munich	101,9 95,8 98 113,9
Estonia	82,3
Ireland	129
Greece	81,4
Spain	94,2
France	120,5
Croatia	75,8
Italy Varese	95 90,7
Cyprus	78,2
Latvia	77,5
Lithuania	76,6
Hungary	71,9
Malta	94,7
Netherlands	113,9
Austria	107,9
Poland	70,9
Portugal	91,1
Romania	66,6
Slovenia	86,1

[9] Unit costs for living allowances are calculated by using a method of calculation similar to that applied for the secondment to the European Commission of seconded national experts (SNEs).

[10] ⚠ For the financial statements, the amount must be adjusted according to the actual place of secondment.
The revised coefficients were adopted in the Decision authorising the use of unit costs for the Fusion Programme co-fund action under the Research and training Programme of the European Atomic Energy Community 2021-2025. They are based on the 2020 Annual update of the remuneration and pensions of the officials and other servants of the European Union and the correction coefficients applied thereto (OJ C 428, 11.12.2020) to ensure purchasing power parity. The revised coefficient are applied as from 1 January 2021 through an amendment to the grant agreement.

[11] No correction coefficient shall be applicable in Belgium and Luxembourg.

Slovakia	80,6
Finland	118,4
Sweden	124,3

Third countries

Country/place	Coefficient (%)
China	82,2
India	72,3
Japan	111,8
Russia	92,7
South Korea	92,3
Switzerland	129.2
Ukraine	82.3
United Kingdom	97.6
United States	101,4 (New-York) 90,5 (Washington)

Mobility allowance

Type: Unit costs

Units: months spent by the seconded staff member(s) on research and training in fission and fusion activities (person-month)

Amount per unit: **EUR 600** per person-month; see (for each beneficiary/affiliated entity and secondment) the unit cost table in Annex 2b

Family allowance

Type: unit costs

Units: months spent by the seconded staff member(s) on research and training in fission and fusion activities (person-month)

Amount per unit: **EUR 660** per person-month; see (for each beneficiary/affiliated entity and secondment) the unit cost table in Annex 2b

Education allowance

Type: Unit costs

Units: months spent by the seconded staff member(s) on research and training in fission and fusion activities (person-month)

Amount per unit*: see (for each beneficiary/affiliated entity and secondment) the unit cost table in Annex 2b

*Amount calculated as follows from 1 January 2021:
{EUR 283.82 x number of dependent children[12]**}**

[12] For the estimated budget (Annex 2): an average should be used. (⚠ For the financial statements, the number of children (and months) must be adjusted according to the actual family status at the moment the secondment starts.)

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

THE CYPRUS INSTITUTE (CyI), PIC 965934440, established in CONSTANTINOU KAVAFI 20, NICOSIA 2121, Cyprus,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

Vasileios TSAKALOS with ECAS id ntsavass signed in the Participant Portal on 10/05/2024 at 09:19:49 (transaction id SigId-19121-IyENYuJHczPlHUB9RNp41mn7PcynCLzrb3bKgG3d84gAtSE1m1RA8tzRFa9VlgEN9QS2KBKXCvaCqQmyJ8zOwSW-yntOf97TTHqGzTPAPycp26-l9oem6InR0yZPkHV2grOSfrALUTgdqfiGK6N3Df583dNMOOGGfuybG1C9QA7i0nsJGBKkfxNAmYzRrqOzNgd9d). Timestamp by third party at 2024.05.10 09:19:56 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

ORGANISMOS ASFALISIS YGEIAS (HIO), PIC 881192427, established in KLIMENTOS 17 19, NICOSIA 1061, Cyprus,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

EBOS TECHNOLOGIES LIMITED (EBOS), PIC 997848022, established in ARCH. MAKARIOU III AND MESAORIAS 1 OFFICE 101, NICOSIA 2322, Cyprus,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

Christofi STELIOS with ECAS id nstelich signed in the Participant Portal on 08/05/2024 at 07:24:46 (transaction id SigId-2475-ugWHo6KP0IZSJnu0X0a9Dh7czftgvBpQF80SzlOdI6YhQjSL68mWbgX1F9S6r0in6rzWzXEM291HabCNshvv0bS-yntOf97TTHqGzTPAPycp26-jcGzf7DZ9xJIJFzrczrYWVjqOhEfxvx8nawLykieY7AzV3GzZYrmPOe0qzznHuPip3fN1InabZPBdRgk1zqe3AIJ). Timestamp by third party at 2024.05.08 07:24:56 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

PANCYPRIAN FEDERATION OF LABOUR (EKYSY), PIC 940255630, established in ARCHERMOU ST 29, LEFKOSIA 1045, Cyprus,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

MARINA KOUKOU with ECAS id n006liqk signed in the Participant Portal on 10/05/2024 at 07:45:09 (transaction id SigId-18731-yiCL0eWzfzq2GBPdGTVfljbV3OZzbqFGHF99MDSzwUUxPS2XfNyVteFiL25m3ghP8gnyzvIkRdLaUthguWGXvso-yntOf97TTHqGzTPAPycp26-GIroLpHlMG1Fh9HciEpQ9EWFqDptwQDbEmS6Ra34TCnzy1eIzLZtSGrOvT9Kx7hV5CRcVRgP7zwu0MsGQA7gNAG). Timestamp by third party at 2024.05.10 07:45:21 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

PANEPISTIMIO THESSALIAS (UTH), PIC 986152150, established in ARGONAFTON FILELLINON, VOLOS 38221, Greece,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

Ioannis Stefanidis with ECAS id n00e7v2d signed in the Participant Portal on 01/05/2024 at 05:26:39 (transaction id SigId-27226-bkgVDNzdNWHyDHnqCpnBJDcZZnRNVyUE4faYMATqQ8Kde6sShnzMiZXF2Ccd7BOJ2cCcexjj1LehuyPVIzR0TSm-yntOf97TTHq8GZt5aBGF4O-k2nJiyrdA8sypZcPoVtvphNsIoCi1IBXVIHqOHuIpzhFuzxkc35quXSNk0lVDesbyZDsQ8zoeWwnm1OgE18rM9m). Timestamp by third party at 2024.05.01 05:26:44 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

ETHNIKO KAI KAPODISTRIAKO PANEPISTIMIO ATHINON (NKUA), PIC 999643007, established in 6 CHRISTOU LADA STR, ATHINA 10561, Greece,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

Christos G. KARAGIANNIS with ECAS id nsfiktho signed in the Participant Portal on 02/05/2024 at 08:20:44 (transaction id SigId-30112-2NCtQaJowxyQL0VytoJwfg1hzt7747SKe6XPnn6GHB0aZABh55EBY4fPxzpJzHsqLqlY0ZIxCD9f9w4kDvt8QOm-yntOf97TTHq8GZt5aBGF4O-dE8TQsyP9evjH2aE2ORzhm6IyUJkj1wJB5xJV3BzSm4fjaVeu2RsQnf7BxzOAgliCTwIfotCzmI0WNh2Yb9UazP). Timestamp by third party at 2024.05.02 08:20:52 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

DIMOS KORYDALLOS (KOR), PIC 917517763, established in GRIGORIOU LAMBRAKI 240, KORYDALLOS 18120, Greece,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

Nikolaos Choursalas with ECAS id n00exo0c signed in the Participant Portal on 01/05/2024 at 10:04:58 (transaction id SigId-27747-EO8ute kTZLG1cDXj3volHtYgDzxzowI66C6LBkhyQeFCnrGXtiyapMWdqMxwX nNAqH6ZUaH9znh6JmpsPx0ui5W-yntOf97TTHq8GZt5aBGF4O-xiXb4 QParo4oKVlQzmuqBVVJiT09NNH9mwSHK4koE4xUE3AcXWa7v3VmV m71B9TzXVcdupPSTF4Kwb5WghZsHO). Timestamp by third party at 2024.05.01 10:05:05 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

MINISTRY OF LABOUR AND SOCIAL AFFAIRS (MLSA), PIC 916252204, established in STADIOU 29, ATHENS 10437, Greece,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

konstantinos Agrapidas with ECAS id n0088qfl signed in the Participant Portal on 01/05/2024 at 14:38:36 (transaction id SigId-28455-XG91ob6NPaUoRpJOBgV850L3bNXmud6jKVm1KTVcQclxOMIHhdnntmNvPv7f0CHGqiLK4JO9hhNa2zMzMb5iP8-yntOf97TTHq8GZt5aBGF4O-ZIzLxezflPIks4ITCfigQH5rniTsa2WezsVE1w1KXgg45V9mzWXjnYazPDzxQgfJKX8Cjh2oFAdzinNK0tnvU74C). Timestamp by third party at 2024.05.01 14:38:42 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

ANAPTYXIAKI ETAIREIA DIMOU TRIKKAION ANAPTYXIAKI ANONYMI ETAIREIA OTA (TRIKALA), PIC 991940043, established in VALKANOY 6, TRIKALA 421 00, Greece,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

Odisseas RAPTIS with ECAS id nraptiod signed in the Participant Portal on 09/05/2024 at 14:53:10 (transaction id SigId-17794-QCVzf VaOE891o8iWkBy22AC5EqMAcNvtTEtXfmRujA3TqTvl56HJu6nOMD1 BRD4zcqLqKzJZH4qCpAwoDBtKnbW-yntOf97TTHqGzTPAPycp26-5zj SKSHOe19njxlgU6UIkycSE4lzvIzdLic3CeaNUPmyVUPq6KcjO9KzJyCv RMOvtCKboCaKnm6r7rXdcduW1hK). Timestamp by third party at 2024.05.09 15:53:16 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNIVERSITA DEGLI STUDI DI CATANIA (UNICT), PIC 999874061, established in PIAZZA UNIVERSITA 2, CATANIA 95131, Italy,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

Salvatore BAGLIO with ECAS id nbaglisa signed in the Participant Portal on 02/05/2024 at 14:20:02 (transaction id SigId-36944-yttk7m4GzpBtU7rbOWiCqW5LwRmZzlSeKT0oTtj0c3xxqIbnlqerujnXYMR8Dx8cBWTPM8YsUtYfnsmYZY3HV4-yntOf97TTHq8GZt5aBGF4O-eRWHUZPTCvLdNYICkhVTk7UoZiofebJ1S4EC4ySrtJxLOBGaKZXIVkKJINnoQglZ8WSfkheaZzygKygxNZNzeZ). Timestamp by third party at 2024.05.02 14:20:07 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

AZIENDA OSPEDALIERA DI RILIEVO NAZIONALE GARIBALDI CATANIA (ARNAS), PIC 888631163, established in PIAZZA SANTA MARIA DI GESU 5, CATANIA 95124, Italy,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

Giuseppe Ettore with ECAS id n00f6vje signed in the Participant Portal on 09/05/2024 at 14:53:07 (transaction id SigId-17793-V5tn3rcnHbRwHvkA7V6teh2aWOxknV4zYFmzQXTt0Y59bPS144rM0AaiD233Y7rGhLzGJ3AwvSLBiQjRzwbohH4-yntOf97TTHqGzTPAPycp26-1bkKVXu4WLdiZRNILzmKMoZunaVeAhXZIMUbjdNLlT750Ra9ykzYZzKazzgD7qqrH6EVMzaV0XzijNHzUhzKLczPS). Timestamp by third party at 2024.05.09 14:53:12 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

AZIENDA SANITARIA LOCALE ROMA 1 (DEASL), PIC 912924134, established in BORGO SANTO SPIRITO 3, ROMA 00198, Italy,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

Marina DAVOLI with ECAS id ndavolim signed in the Participant Portal on 30/04/2024 at 10:42:10 (transaction id SigId-34871-VwRPe6B7rfy3quc5EBW088RZH7veUGX0goDzMLptekM20DjyIQIuHl4ahE7uYxFLl6icb7zrQMpHB7dJQezWbIW-jpJZscgsw0KZrf8dzSGvgE-BH6qBZFPWpKJ0XVj7eeHZNLbDhtLexrUQAk8UYPlXYIu9TzZpy5wezUn61kzr5x0JBsRApyO353WVhK5Tbd9zT0). Timestamp by third party at 2024.04.30 10:42:16 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNIVERSIDAD DE LEON (ULE), PIC 999453372, established in AVENIDA FACULTAD 25, LEON 24004, Spain,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

Carlos Gaspar POLANCO DE LA PUENTE with ECAS id n002f5op
signed in the Participant Portal on 29/04/2024 at 18:11:13
(transaction id SigId-30508-x8RpGY20mHc7HTeeUGEpcGcP6ogFkBHI
HkHTX62vkjXhJ5N5Qk5e34CDzXRTwBFJi3ErsEzT30zW6MMWhjfLBTm-
jpJZscgsw0KZrf8dzSGvgE-r6xrPQSZKmculWgZkhzNFK0zNzXvMODQka
OXGFDEWn41d9LWnxyzpzdIpO17nn7Ub7kflrqzzmksC4uxCoFDy0oO).
Timestamp by third party at
2024.04.29 18:11:18 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

FUNDACIO HOSPITAL UNIVERSITARI VALL D'HEBRON - INSTITUT DE RECERCA (VHIR), PIC 999541642, established in PASSEIG VALL D HEBRON 119-129 EDIFICIO DE RECERCA, BARCELONA 08035, Spain,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

Begoña Benito with ECAS id n00cqmz0 signed in the Participant Portal on 07/05/2024 at 16:50:15 (transaction id SigId-13724-AHk1q2jIRLowSzaGH6evoNjWCCDZ9S4zwFOlxibJX4PzioomtxPCRy7bhnt3Rn9zwzOzIeAxWYsNPq0hoEE8G0Q0-jpJZscgsw0KgVIkiVgvsPm-n2PR1ZpkV653zL6f9CDMur27yj3mAkuDy87mGizVxYelpZdYTQx3zIvwG2LDhjGbSjxdVwC52gFBeJqzoiugAJK). Timestamp by third party at 2024.05.07 16:50:19 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

AGENCIA ESTATAL CONSEJO SUPERIOR DE INVESTIGACIONES CIENTIFICAS (CSIC), PIC 999991722, established in CALLE SERRANO 117, MADRID 28006, Spain,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNIVERSIDADE NOVA DE LISBOA (UNL), PIC 960782479, established in CAMPUS DE CAMPOLIDE, LISBOA 1099 085, Portugal,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

Filomeno Fortes with ECAS id n005l2rl signed in the Participant Portal on 06/05/2024 at 11:46:24 (transaction id SigId-61614-GrzkdtY0xxZt3daXMBDakCPiOCzh3GWeBlzjUQzvlS3HzwF1qlqYgVU5P1LFOK1Kza2LBYnZL4mvua5xzeAtzIAL-yntOf97TTHq8GZt5aBGF4O-JodF6EcDZan1cFnQiGigJo5AxdzsNMalzczeaS91KZtsahsaVZqxPwyQzsgAIUay92zgQMDSpZOhERjl5HMDlVc). Timestamp by third party at 2024.05.06 11:46:31 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

UNIVERSIDADE DE AVEIRO (UA), PIC 999865331, established in CAMPUS UNIVERSITÁRIO DE SANTIAGO, AVEIRO 3810-193, Portugal,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

artur SILVA with ECAS id nsilvaau signed in the Participant Portal on 30/04/2024 at 16:07:28 (transaction id SigId-43207-p9d2UNTMGJIsHEzvt5zgPTXCKw0q4B1TRidOuUNeMkzkEzwRqUcRd8ELbrEk71dxA3za8B7ktSkxBHvYXPYUCKu-jpJZscgsw0KZrf8dzSGvgE-s93O8ZGqGSnuwFDk0jwP4QTI4Ao2cAL7MBu6xrN0Ca5GnhxhcLIw1MSgfsshIqFFQck8gmE92qITv2gTbyztWm). Timestamp by third party at 2024.04.30 16:08:04 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

MUNICIPIO DE AGUEDA (AGUEDA), PIC 998359891, established in PRACA DO MUNICIPO, AGUEDA 3754 500, Portugal,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

Carlos RODRIGUES with ECAS id nrodrcss signed in the Participant Portal on 03/05/2024 at 16:20:02 (transaction id SigId-53603-Qm7C7Jsc9J0nXzoU3sPeSGc16UgzRjjzXzojXf0n6Ph8GFvY0kuL2zVyxr9qjkZFgwWg9qQEgx4bOTn9gmynV8p-yntOf97TTHq8GZt5aBGF4O-UWzSqd4m7CBgzd21ww3tlHxwMzmp5fotoSrzOMVV7G95koGRp7Lg7gqoqwoL7LRVGh2HVZBNSbUmEzL3HQNb1xZ). Timestamp by third party at 2024.05.03 16:20:07 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

ASSOCIACAO PORTUGUESA DE MEDICOS VETERINARIOS ESPECIALISTAS EM ANIMAIS DE COMPANHIA (APMVEAC), PIC 882219851, established in RUA AMERICO DURAO 18D, LISBOA 1900-064, Portugal,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

EUROPEAN CENTRE FOR MEDIUM-RANGE WEATHER FORECASTS (ECMWF), PIC 999916741, established in SHINFIELD PARK, READING RG2 9AX, United Kingdom,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

Florian PAPPENBERGER with ECAS id npappefl signed in the Participant Portal on 29/04/2024 at 17:56:06 (transaction id SigId-30345-hzbUoPs4yoUYp8GjI3lARGDNoEU0BrzYsCBzHdULwOCclbTdlXhM2s185HuIWNUKXi4BWPONdzU8tVdNODJjnoq-jpJZscgsw0KZrf8dzSGvgE-gj0Y2DSbmqSKxYdK5yLnzkzqngqVDrKUPZ8USXsVvzVezecShDCFvPWRq3fiKsEdycBsbjYC7S152uw4Z4lqk44). Timestamp by third party at 2024.04.29 17:56:11 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

INSTITUT ZA MEDICINSKA ISTRA IVANJA (IMR), PIC 997623176, established in DR SUBOTICA 4 PRIZEMLJE, BELGRADE 11129, Serbia,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

Sasa RADOVANOVIC with ECAS id nradsasa signed in the Participant Portal on 29/04/2024 at 16:50:12 (transaction id SigId-29308-zksnzzXIjNgbezT3hCD0zsBFqUzvdipQpV5kWu8DKzq5c6vq8JEqMLuR24iWGOxS4h5m5tcpQ0yUlZKkgBG9DtQu-jpJZscgsw0KZrf8dzSGvgE-NoPx2pRuWmRG0xt28H5kCzuhVFzoriAHwHCCXr2idEyzX0UakcCASL5Qikzunui B0jLrs8c5BYpjCpOEmOsriTm). Timestamp by third party at 2024.04.29 16:50:17 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

AINIGMA TECHNOLOGIES (AIN), PIC 892135579, established in KAPELDREEF 60, LEUVEN 3001, Belgium,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

Athanasios Kakasis with ECAS id n005n1gp signed in the Participant Portal on 30/04/2024 at 10:12:43 (transaction id SigId-34076-cNB7C06GjyXm4JrmE2SBkAeFSezzPMY0OwIQ6e8CNWEkbEKoOjCzmljrzMHFkujxNMpqkU2AYaQFYQQWq9yfU2e-jpJZscgsw0KZrf8dzSGvgE-qprTMziO22icLUifoCsSkBZdX3KBtMxUnhroOBQ13N6DGyNltZDXlGmPBEMvhETtGVzizePLBF0AlLbQp3LtJ20). Timestamp by third party at 2024.04.30 10:12:52 CEST

ANNEX 3

ACCESSION FORM FOR BENEFICIARIES

EDENTIFY FOUNDATION MTU (EF), PIC 881410095, established in NARVA MNT 7, TALLINN 10117, Estonia,

hereby agrees

to become beneficiary

in Agreement No 101156653 — ISMED-CLIM ('the Agreement')

between UNIVERSITY OF CYPRUS (UCY) **and** the **European Climate, Infrastructure and Environment Executive Agency (CINEA)** ('EU executive agency' or 'granting authority'), under the powers delegated by the European Commission ('European Commission'),

and mandates

the coordinator to submit and sign in its name and on its behalf any **amendments** to the Agreement, in accordance with Article 39.

By signing this accession form, the beneficiary accepts the grant and agrees to implement it in accordance with the Agreement, with all the obligations and terms and conditions it sets out.

SIGNATURE

For the beneficiary

Danijela Paunkovic with ECAS id n00d9t03 signed in the Participant Portal on 30/04/2024 at 08:11:01 (transaction id SigId-32155-iPEJH AERg9zqp4OCbxzIGlaezbnOV03gKVq4JTbNHvyexVBnFmax7d9uc0 pGPwzS6UrCYQulsLonIUQb25CMzzHW-jpJZscgsw0KZrf8dzSGvgE-A XzXBsL1SnUnsohRL6YQKzklXR0Le3k4fJeDttG2yq6xiJDazh6s6ZMnXf Tv4lXTaZF313yZ0ER4F8dUwiBzuUW). Timestamp by third party at 2024.04.30 08:11:09 CEST

FINANCIAL STATEMENT FOR [PARTICIPANT NAME] FOR REPORTING PERIOD [NUMBER]

	Eligible[1] costs (per budget category)																	EU contribution[2]				Revenues
	Direct costs															Indirect costs	Total costs	EU contribution to eligible costs			Total requested EU contribution	Income generated by the action
	A. Personnel costs			B. Subcontracting costs	C. Purchase costs			D. Other cost categories								E. Indirect costs[2]		Funding rate %[3]	Maximum EU contribution[4]	Requested EU contribution		
	A.1 Employees (or equivalent) A.2 Natural persons under direct contract A.3 Seconded persons		A.4 SME owners and natural person beneficiaries	B. Subcontracting	C.1 Travel and subsistence	C.2 Equipment	C.3 Other goods, works and services	[D.1 Financial support to third parties]	D.2 Internally invoiced goods and services	[D.3 Transnational access to research infrastructure unit costs]	[D.4 Virtual access to research infrastructure unit costs]	*[OPTION for HE PCP/PPI:* D.5 PCP/PPI procurement costs*]*	*[OPTION for Euratom Programme Cofund Actions:* D.6 Euratom Cofund staff mobility costs*]*	*[OPTION for HE ERC Grants:* D.7 ERC additional funding*]*	*[OPTION for HE ERC Grants:* D.8 ERC additional funding (subcontracting, FSTP and internally invoiced goods and services)*]*	E. Indirect costs						
Forms of funding	Actual costs	Unit costs (usual accounting practices)	Unit costs[5]	Actual costs	Actual costs	Actual costs	Actual costs	[Actual costs]	Unit costs (usual accounting practices)	[Unit costs[5]]	[Unit costs[5]]	[Actual costs]	[Unit costs[5]]	[Actual costs]	[Actual costs]	Flat-rate costs[6]						
	a1	a2	a3	b	c1	c2	c3	[d1a]	d2	[d3]	[d4]	[d5]	[d6]	[d7]	[d8]	e = 0,25 * (a1 + a2 + a3 ~~+b+~~ c1 +c2 + c3 ~~+d1a + d2 + d3 + d4 [+ d5][+ d6]~~ [+d7] ~~[+ d8]~~)	f = a+b+c+d+e	U	g = f*U%	h	m	n
XX – [short name beneficiary/affiliated entity]																						

The beneficiary/affiliated entity hereby confirms that:

The information provided is complete, reliable and true.

The costs and contributions declared are eligible (see Article 6).

The costs and contributions can be substantiated by adequate records and supporting documentation that will be produced upon request or in the context of checks, reviews, audits and investigations (see Articles 19, 20 and 25).

For the last reporting period: that all the revenues have been declared (see Article 22).

① Please declare all eligible costs and contributions, even if they exceed the amounts indicated in the estimated budget (see Annex 2). Only amounts that were declared in your individual financial statements can be taken into account lateron, in order to replace costs/contributions that are found to be ineligible.

[1] See Article 6 for the eligibility conditions. All amounts must be expressed in EUR (see Article 21 for the conversion rules).

[2] If you have also received an EU operating grant during this reporting period, you cannot claim indirect costs - unless you can demonstrate that the operating grant does not cover any costs of the action. This requires specific accounting tools. Please contact us immediately via the Funding & Tenders Portal for details.

[3] See Data Sheet for the reimbursement rate(s).

[4] This is the *theoretical* amount of EU contribution to costs that the system calculates automatically (by multiplying the reimbursement rates by the costs declared). The amount you request (in the column 'requested EU contribution') may be less.

[5] See Annex 2a 'Additional information on the estimated budget' for the details (units, cost per unit).

[6] See Data Sheet for the flat-rate.

ANNEX 5

SPECIFIC RULES

CONFIDENTIALITY AND SECURITY (— ARTICLE 13)

Sensitive information with security recommendation

Sensitive information with a security recommendation must comply with the additional requirements imposed by the granting authority.

Before starting the action tasks concerned, the beneficiaries must have obtained all approvals or other mandatory documents needed for implementing the task. The documents must be kept on file and be submitted upon request by the coordinator to the granting authority. If they are not in English, they must be submitted together with an English summary.

For requirements restricting disclosure or dissemination, the information must be handled in accordance with the recommendation and may be disclosed or disseminated only after written approval from the granting authority.

EU classified information

If EU classified information is used or generated by the action, it must be treated in accordance with the security classification guide (SCG) and security aspect letter (SAL) set out in Annex 1 and Decision 2015/444[1] and its implementing rules — until it is declassified.

Deliverables which contain EU classified information must be submitted according to special procedures agreed with the granting authority.

Action tasks involving EU classified information may be subcontracted only with prior explicit written approval from the granting authority and only to entities established in an EU Member State or in a non-EU country with a security of information agreement with the EU (or an administrative arrangement with the Commission).

EU classified information may not be disclosed to any third party (including participants involved in the action implementation) without prior explicit written approval from the granting authority.

ETHICS (— ARTICLE 14)

Ethics and research integrity

The beneficiaries must carry out the action in compliance with:

- ethical principles (including the highest standards of research integrity)

[1] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

and

- applicable EU, international and national law, including the EU Charter of Fundamental Rights and the European Convention for the Protection of Human Rights and Fundamental Freedoms and its Supplementary Protocols.

No funding can be granted, within or outside the EU, for activities that are prohibited in all Member States. No funding can be granted in a Member State for an activity which is forbidden in that Member State.

The beneficiaries must pay particular attention to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of persons, the right to non-discrimination, the need to ensure protection of the environment and high levels of human health protection.

The beneficiaries must ensure that the activities under the action have an exclusive focus on civil applications.

The beneficiaries must ensure that the activities under the action do not:

- aim at human cloning for reproductive purposes
- intend to modify the genetic heritage of human beings which could make such modifications heritable (with the exception of research relating to cancer treatment of the gonads, which may be financed)
- intend to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer, or
- lead to the destruction of human embryos (for example, for obtaining stem cells).

Activities involving research on human embryos or human embryonic stem cells may be carried out only if:

- they are set out in Annex 1 or
- the coordinator has obtained explicit approval (in writing) from the granting authority.

In addition, the beneficiaries must respect the fundamental principle of research integrity — as set out in the European Code of Conduct for Research Integrity[2].

This implies compliance with the following principles:

- reliability in ensuring the quality of research reflected in the design, the methodology, the analysis and the use of resources
- honesty in developing, undertaking, reviewing, reporting and communicating research in a transparent, fair and unbiased way

[2] European Code of Conduct for Research Integrity of ALLEA (All European Academies).

- respect for colleagues, research participants, society, ecosystems, cultural heritage and the environment

- accountability for the research from idea to publication, for its management and organisation, for training, supervision and mentoring, and for its wider impacts

and means that beneficiaries must ensure that persons carrying out research tasks follow the good research practices including ensuring, where possible, openness, reproducibility and traceability and refrain from the research integrity violations described in the Code.

Activities raising ethical issues must comply with the additional requirements formulated by the ethics panels (including after checks, reviews or audits; see Article 25).

Before starting an action task raising ethical issues, the beneficiaries must have obtained all approvals or other mandatory documents needed for implementing the task, notably from any (national or local) ethics committee or other bodies such as data protection authorities.

The documents must be kept on file and be submitted upon request by the coordinator to the granting authority. If they are not in English, they must be submitted together with an English summary, which shows that the documents cover the action tasks in question and includes the conclusions of the committee or authority concerned (if any).

VALUES (— ARTICLE 14)

Gender mainstreaming

The beneficiaries must take all measures to promote equal opportunities between men and women in the implementation of the action and, where applicable, in line with the gender equality plan. They must aim, to the extent possible, for a gender balance at all levels of personnel assigned to the action, including at supervisory and managerial level.

INTELLECTUAL PROPERTY RIGHTS (IPR) — BACKGROUND AND RESULTS — ACCESS RIGHTS AND RIGHTS OF USE (— ARTICLE 16)

Definitions

Access rights — Rights to use results or background.

Dissemination — The public disclosure of the results by appropriate means, other than resulting from protecting or exploiting the results, including by scientific publications in any medium.

Exploit(ation) — The use of results in further research and innovation activities other than those covered by the action concerned, including among other things, commercial exploitation such as developing, creating, manufacturing and marketing a product or process, creating and providing a service, or in standardisation activities.

Fair and reasonable conditions — Appropriate conditions, including possible financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access, for example the actual or potential value of the results or background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged.

FAIR principles — ‘findability’, ‘accessibility’, ‘interoperability’ and ‘reusability’.

Open access — Online access to research outputs provided free of charge to the end-user.

Open science — An approach to the scientific process based on open cooperative work, tools and diffusing knowledge.

Research data management — The process within the research lifecycle that includes the organisation, storage, preservation, security, quality assurance, allocation of persistent identifiers (PIDs) and rules and procedures for sharing of data including licensing.

Research outputs — Results to which access can be given in the form of scientific publications, data or other engineered results and processes such as software, algorithms, protocols, models, workflows and electronic notebooks.

Scope of the obligations

For this section, references to ‘beneficiary’ or ‘beneficiaries’ do not include affiliated entities (if any).

Agreement on background

The beneficiaries must identify in a written agreement the background as needed for implementing the action or for exploiting its results.

Where the call conditions restrict control due to strategic interests reasons, background that is subject to control or other restrictions by a country (or entity from a country) which is not one of the eligible countries or target countries set out in the call conditions and that impact the exploitation of the results (i.e. would make the exploitation of the results subject to control or restrictions) must not be used and must be explicitly excluded from it in the agreement on background — unless otherwise agreed with the granting authority.

Ownership of results

Results are owned by the beneficiaries that generate them.

However, two or more beneficiaries own results jointly if:

- they have jointly generated them and
- it is not possible to:
  - establish the respective contribution of each beneficiary, or
  - separate them for the purpose of applying for, obtaining or maintaining their protection.

The joint owners must agree — in writing — on the allocation and terms of exercise of their joint ownership (‘**joint ownership agreement**’), to ensure compliance with their obligations under this Agreement.

Unless otherwise agreed in the joint ownership agreement or consortium agreement, each joint owner may grant non-exclusive licences to third parties to exploit the jointly-owned results (without any right to sub-license), if the other joint owners are given:

- at least 45 days advance notice and
- fair and reasonable compensation.

The joint owners may agree — in writing — to apply another regime than joint ownership.

If third parties (including employees and other personnel) may claim rights to the results, the beneficiary concerned must ensure that those rights can be exercised in a manner compatible with its obligations under the Agreement.

The beneficiaries must indicate the owner(s) of the results (results ownership list) in the final periodic report.

Protection of results

Beneficiaries which have received funding under the grant must adequately protect their results — for an appropriate period and with appropriate territorial coverage — if protection is possible and justified, taking into account all relevant considerations, including the prospects for commercial exploitation, the legitimate interests of the other beneficiaries and any other legitimate interests.

Exploitation of results

Beneficiaries which have received funding under the grant must — up to four years after the end of the action (see Data Sheet, Point 1) — use their best efforts to exploit their results directly or to have them exploited indirectly by another entity, in particular through transfer or licensing.

If, despite a beneficiary's best efforts, the results are not exploited within one year after the end of the action, the beneficiaries must (unless otherwise agreed in writing with the granting authority) use the Horizon Results Platform to find interested parties to exploit the results.

If results are incorporated in a standard, the beneficiaries must (unless otherwise agreed with the granting authority or unless it is impossible) ask the standardisation body to include the funding statement (see Article 17) in (information related to) the standard.

Additional exploitation obligations

Where the call conditions impose additional exploitation obligations (including obligations linked to the restriction of participation or control due to strategic assets, interests, autonomy or security reasons), the beneficiaries must comply with them — up to four years after the end of the action (see Data Sheet, Point 1).

Where the call conditions impose additional exploitation obligations in case of a public emergency, the beneficiaries must (if requested by the granting authority) grant for a limited period of time specified in the request, non-exclusive licences — under fair and reasonable conditions — to their results to legal entities that need the results to address the public emergency and commit to rapidly and broadly exploit the resulting products and services at fair and reasonable conditions. This provision applies up to four years after the end of the action (see Data Sheet, Point 1).

Additional information obligation relating to standards

Where the call conditions impose additional information obligations relating to possible standardisation, the beneficiaries must — up to four years after the end of the action (see Data Sheet, Point 1) — inform the granting authority, if the results could reasonably be expected to contribute to European or international standards.

Transfer and licensing of results

Transfer of ownership

The beneficiaries may transfer ownership of their results, provided this does not affect compliance with their obligations under the Agreement.

The beneficiaries must ensure that their obligations under the Agreement regarding their results are passed on to the new owner and that this new owner has the obligation to pass them on in any subsequent transfer.

Moreover, they must inform the other beneficiaries with access rights of the transfer at least 45 days in advance (or less if agreed in writing), unless agreed otherwise in writing for specifically identified third parties including affiliated entities or unless impossible under the applicable law. This notification must include sufficient information on the new owner to enable the beneficiaries concerned to assess the effects on their access rights. The beneficiaries may object within 30 days of receiving notification (or less if agreed in writing), if they can show that the transfer would adversely affect their access rights. In this case, the transfer may not take place until agreement has been reached between the beneficiaries concerned.

Granting licences

The beneficiaries may grant licences to their results (or otherwise give the right to exploit them), including on an exclusive basis, provided this does not affect compliance with their obligations.

Exclusive licences for results may be granted only if all the other beneficiaries concerned have waived their access rights.

Granting authority right to object to transfers or licensing — Horizon Europe actions

Where the call conditions in Horizon Europe actions provide for the right to object to transfers or licensing, the granting authority may — up to four years after the end of the action (see Data Sheet, Point 1) — object to a transfer of ownership or the exclusive licensing of results, if:

- the beneficiaries which generated the results have received funding under the grant
- it is to a legal entity established in a non-EU country not associated with Horizon Europe, and
- the granting authority considers that the transfer or licence is not in line with EU interests.

Beneficiaries that intend to transfer ownership or grant an exclusive licence must formally notify the granting authority before the intended transfer or licensing takes place and:

- identify the specific results concerned
- describe in detail the new owner or licensee and the planned or potential exploitation of the results, and
- include a reasoned assessment of the likely impact of the transfer or licence on EU interests, in particular regarding competitiveness as well as consistency with ethical principles and security considerations.

The granting authority may request additional information.

If the granting authority decides to object to a transfer or exclusive licence, it must formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information it has requested).

No transfer or licensing may take place in the following cases:

- pending the granting authority decision, within the period set out above
- if the granting authority objects
- until the conditions are complied with, if the granting authority objection comes with conditions.

A beneficiary may formally notify a request to waive the right to object regarding intended transfers or grants to a specifically identified third party, if measures safeguarding EU interests are in place. If the granting authority agrees, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

Granting authority right to object to transfers or licensing — Euratom actions

Where the call conditions in Euratom actions provide for the right to object to transfers or licensing, the granting authority may — up to four years after the end of the action (see Data Sheet, Point 1) — object to a transfer of ownership or the exclusive or non-exclusive licensing of results, if:

- the beneficiaries which generated the results have received funding under the grant
- it is to a legal entity established in a non-EU country not associated to the Euratom Research and Training Programme 2021-2025 and
- the granting authority considers that the transfer or licence is not in line with the EU interests.

Beneficiaries that intend to transfer ownership or grant a licence must formally notify the granting authority before the intended transfer or licensing takes place and:

- identify the specific results concerned
- describe in detail the results, the new owner or licensee and the planned or potential exploitation of the results, and
- include a reasoned assessment of the likely impact of the transfer or licence on EU interests, in particular regarding competitiveness as well as consistency with

ethical principles and security considerations (including the defence interests of the EU Member States under Article 24 of the Euratom Treaty).

The granting authority may request additional information.

If the granting authority decides to object to a transfer or licence, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

No transfer or licensing may take place in the following cases:

- pending the granting authority decision, within the period set out above
- if the granting authority objects
- until the conditions are complied with, if the granting authority objection comes with conditions.

A beneficiary may formally notify a request to waive the right to object regarding intended transfers or grants to a specifically identified third party, if measures safeguarding EU interests are in place. If the granting authority agrees, it will formally notify the beneficiary concerned within 60 days of receiving notification (or any additional information requested).

Limitations to transfers and licensing due to strategic assets, interests, autonomy or security reasons of the EU and its Member States

Where the call conditions restrict participation or control due to strategic assets, interests, autonomy or security reasons, the beneficiaries may not transfer ownership of their results or grant licences to third parties which are established in countries which are not eligible countries or target countries set out in the call conditions (or, if applicable, are controlled by such countries or entities from such countries) — unless they have requested and received prior approval by the granting authority.

The request must:

- identify the specific results concerned
- describe in detail the new owner and the planned or potential exploitation of the results, and
- include a reasoned assessment of the likely impact of the transfer or license on the strategic assets, interests, autonomy or security of the EU and its Member States.

The granting authority may request additional information.

Access rights to results and background

Exercise of access rights — Waiving of access rights — No sub-licensing

Requests to exercise access rights and the waiver of access rights must be in writing.

Unless agreed otherwise in writing with the beneficiary granting access, access rights do not include the right to sub-license.

If a beneficiary is no longer involved in the action, this does not affect its obligations to grant access.

If a beneficiary defaults on its obligations, the beneficiaries may agree that that beneficiary no longer has access rights.

Access rights for implementing the action

The beneficiaries must grant each other access — on a royalty-free basis — to background needed to implement their own tasks under the action, unless the beneficiary that holds the background has — before acceding to the Agreement —:

- informed the other beneficiaries that access to its background is subject to restrictions, or

- agreed with the other beneficiaries that access would not be on a royalty-free basis.

The beneficiaries must grant each other access — on a royalty-free basis — to results needed for implementing their own tasks under the action.

Access rights for exploiting the results

The beneficiaries must grant each other access — under fair and reasonable conditions — to results needed for exploiting their results.

The beneficiaries must grant each other access — under fair and reasonable conditions — to background needed for exploiting their results, unless the beneficiary that holds the background has — before acceding to the Agreement — informed the other beneficiaries that access to its background is subject to restrictions.

Requests for access must be made — unless agreed otherwise in writing — up to one year after the end of the action (see Data Sheet, Point 1).

Access rights for entities under the same control

Unless agreed otherwise in writing by the beneficiaries, access to results and, subject to the restrictions referred to above (if any), background must also be granted — under fair and reasonable conditions — to entities that:

- are established in an EU Member State or Horizon Europe associated country

- are under the direct or indirect control of another beneficiary, or under the same direct or indirect control as that beneficiary, or directly or indirectly controlling that beneficiary and

- need the access to exploit the results of that beneficiary.

Unless agreed otherwise in writing, such requests for access must be made by the entity directly to the beneficiary concerned.

Requests for access must be made — unless agreed otherwise in writing — up to one year after the end of the action (see Data Sheet, Point 1).

Access rights for the granting authority, EU institutions, bodies, offices or agencies and national authorities to results for policy purposes — Horizon Europe actions

In Horizon Europe actions, the beneficiaries which have received funding under the grant must grant access to their results — on a royalty-free basis — to the granting authority, EU institutions, bodies, offices or agencies for developing, implementing and monitoring EU policies or programmes. Such access rights do not extend to beneficiaries' background.

Such access rights are limited to non-commercial and non-competitive use.

For actions under the cluster 'Civil Security for Society', such access rights also extend to national authorities of EU Member States for developing, implementing and monitoring their policies or programmes in this area. In this case, access is subject to a bilateral agreement to define specific conditions ensuring that:

- the access rights will be used only for the intended purpose and
- appropriate confidentiality obligations are in place.

Moreover, the requesting national authority or EU institution, body, office or agency (including the granting authority) must inform all other national authorities of such a request.

Access rights for the granting authority, Euratom institutions, funding bodies or the Joint Undertaking Fusion for Energy — Euratom actions

In Euratom actions, the beneficiaries which have received funding under the grant must grant access to their results — on a royalty-free basis — to the granting authority, Euratom institutions, funding bodies or the Joint Undertaking Fusion for Energy for developing, implementing and monitoring Euratom policies and programmes or for compliance with obligations assumed through international cooperation with non-EU countries and international organisations.

Such access rights include the right to authorise third parties to use the results in public procurement and the right to sub-license and are limited to non-commercial and non-competitive use.

Additional access rights

Where the call conditions impose additional access rights, the beneficiaries must comply with them.

COMMUNICATION, DISSEMINATION, OPEN SCIENCE AND VISIBILITY (— ARTICLE 17)

Dissemination

Dissemination of results

The beneficiaries must disseminate their results as soon as feasible, in a publicly available format, subject to any restrictions due to the protection of intellectual property, security rules or legitimate interests.

A beneficiary that intends to disseminate its results must give at least 15 days advance notice to the other beneficiaries (unless agreed otherwise), together with sufficient information on the results it will disseminate.

Any other beneficiary may object within (unless agreed otherwise) 15 days of receiving notification, if it can show that its legitimate interests in relation to the results or background would be significantly harmed. In such cases, the results may not be disseminated unless appropriate steps are taken to safeguard those interests.

Additional dissemination obligations

Where the call conditions impose additional dissemination obligations, the beneficiaries must also comply with those.

Open Science

Open science: open access to scientific publications

The beneficiaries must ensure open access to peer-reviewed scientific publications relating to their results. In particular, they must ensure that:

- at the latest at the time of publication, a machine-readable electronic copy of the published version or the final peer-reviewed manuscript accepted for publication, is deposited in a trusted repository for scientific publications

- immediate open access is provided to the deposited publication via the repository, under the latest available version of the Creative Commons Attribution International Public Licence (CC BY) or a licence with equivalent rights; for monographs and other long-text formats, the licence may exclude commercial uses and derivative works (e.g. CC BY-NC, CC BY-ND) and

- information is given via the repository about any research output or any other tools and instruments needed to validate the conclusions of the scientific publication.

Beneficiaries (or authors) must retain sufficient intellectual property rights to comply with the open access requirements.

Metadata of deposited publications must be open under a Creative Common Public Domain Dedication (CC 0) or equivalent, in line with the FAIR principles (in particular machine-actionable) and provide information at least about the following: publication (author(s), title, date of publication, publication venue); Horizon Europe or Euratom funding; grant project name, acronym and number; licensing terms; persistent identifiers for the publication, the authors involved in the action and, if possible, for their organisations and the grant. Where applicable, the metadata must include persistent identifiers for any research output or any other tools and instruments needed to validate the conclusions of the publication.

Only publication fees in full open access venues for peer-reviewed scientific publications are eligible for reimbursement.

Open science: research data management

The beneficiaries must manage the digital research data generated in the action (‘data’) responsibly, in line with the FAIR principles and by taking all of the following actions:

- establish a data management plan (‘DMP’) (and regularly update it)

- as soon as possible and within the deadlines set out in the DMP, deposit the data in a trusted repository; if required in the call conditions, this repository must be federated in the EOSC in compliance with EOSC requirements

- as soon as possible and within the deadlines set out in the DMP, ensure open access — via the repository — to the deposited data, under the latest available version of the Creative Commons Attribution International Public License (CC BY) or Creative Commons Public Domain Dedication (CC 0) or a licence with equivalent rights, following the principle 'as open as possible as closed as necessary', unless providing open access would in particular:

    - be against the beneficiary's legitimate interests, including regarding commercial exploitation, or

    - be contrary to any other constraints, in particular the EU competitive interests or the beneficiary's obligations under this Agreement; if open access is not provided (to some or all data), this must be justified in the DMP

- provide information via the repository about any research output or any other tools and instruments needed to re-use or validate the data.

Metadata of deposited data must be open under a Creative Common Public Domain Dedication (CC 0) or equivalent (to the extent legitimate interests or constraints are safeguarded), in line with the FAIR principles (in particular machine-actionable) and provide information at least about the following: datasets (description, date of deposit, author(s), venue and embargo); Horizon Europe or Euratom funding; grant project name, acronym and number; licensing terms; persistent identifiers for the dataset, the authors involved in the action, and, if possible, for their organisations and the grant. Where applicable, the metadata must include persistent identifiers for related publications and other research outputs.

Open science: additional practices

Where the call conditions impose additional obligations regarding open science practices, the beneficiaries must also comply with those.

Where the call conditions impose additional obligations regarding the validation of scientific publications, the beneficiaries must provide (digital or physical) access to data or other results needed for validation of the conclusions of scientific publications, to the extent that their legitimate interests or constraints are safeguarded (and unless they already provided the (open) access at publication).

Where the call conditions impose additional open science obligations in case of a public emergency, the beneficiaries must (if requested by the granting authority) immediately deposit any research output in a repository and provide open access to it under a CC BY licence, a Public Domain Dedication (CC 0) or equivalent. As an exception, if the access would be against the beneficiaries' legitimate interests, the beneficiaries must grant non-exclusive licenses — under fair and reasonable conditions — to legal entities that need the research output to address the public emergency and commit to rapidly and broadly exploit the resulting products and services at fair and reasonable conditions. This provision applies up to four years after the end of the action (see Data Sheet, Point 1).

Plan for the exploitation and dissemination of results including communication activities

Unless excluded by the call conditions, the beneficiaries must provide and regularly update a plan for the exploitation and dissemination of results including communication activities.

SPECIFIC RULES FOR CARRYING OUT THE ACTION (— ARTICLE 18)

Implementation in case of restrictions due to strategic assets, interests, autonomy or security of the EU and its Member States

Where the call conditions restrict participation or control due to strategic assets, interests, autonomy or security, the beneficiaries must ensure that none of the entities that participate as affiliated entities, associated partners, subcontractors or recipients of financial support to third parties are established in countries which are not eligible countries or target countries set out in the call conditions (or, if applicable, are controlled by such countries or entities from such countries) — unless otherwise agreed with the granting authority.

The beneficiaries must moreover ensure that any cooperation with entities established in countries which are not eligible countries or target countries set out in the call conditions (or, if applicable, are controlled by such countries or entities from such countries) does not affect the strategic assets, interests, autonomy or security of the EU and its Member States.

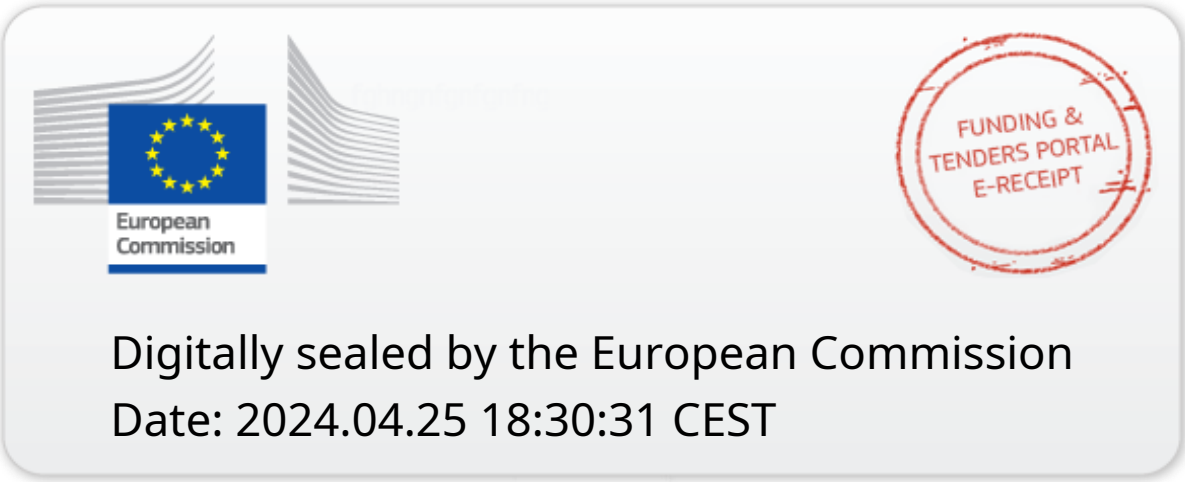
Recruitment and working conditions for researchers

The beneficiaries must take all measures to implement the principles set out in the Commission Recommendation on the European Charter for Researchers and the Code of Conduct for the Recruitment of Researchers[3], in particular regarding:

- working conditions
- transparent recruitment processes based on merit, and
- career development.

The beneficiaries must ensure that researchers and all participants involved in the action are aware of them.

[3] Commission Recommendation 2005/251/EC of 11 March 2005 on the European Charter for Researchers and on a Code of Conduct for the Recruitment of Researchers (OJ L 75, 22.3.2005, p. 67).



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