



ELISAH

*European Linkage of Initiative
from Science to Action in Health*

DELIVERABLE 1.1

Co-funded by
the European Union

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Istituto Nazionale dei Tumori

Sistema Socio Sanitario
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VERSION CONTROL SHEET

- PROJECT SUMMARY

Project acronym	ELISAH
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- DOCUMENT CONTROL

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DISCLAIMER

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EXECUTIVE SUMMARY

As detailed in Article 7 of the ELISAH Grant Agreement, the beneficiaries must have internal arrangements regarding their operation and co-ordination, to ensure that the action is implemented properly. 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 (as per Article 16 of the Grant Agreement)
- settlement of internal disputes
- liability, indemnification and confidentiality arrangements between the beneficiaries.

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

ANNEXES

Annex 1 - ELISAH Consortium Agreement, signed by all beneficiaries.

Consortium Agreement

ELISAH

European Linkage of Initiative from Science to Action in Health

EU4H-2022-PJ-12

Grant Agreement number: 101128640

Version 1 – 20240118

(Based on DESCA – Model Consortium Agreement for Horizon Europe, version 1.1, November 2022)

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Change Records

Version	Date	Changes
Version 0	20/09/2023	Initial draft
Version 1	18/01/2024	final draft

CONSORTIUM AGREEMENT

THIS CONSORTIUM AGREEMENT is based upon Regulation (EU) No 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation (2021-2027), laying down its rules for participation and dissemination (hereinafter referred to as “Horizon Europe Regulation”), and on the European Commission’s General Model Grant Agreement and its Annexes, and is made on 1 January 2024, hereinafter referred to as the “Effective Date”

BETWEEN:

FONDAZIONE IRCCS ISTITUTO NAZIONALE DEI TUMORI (INT), with legal address Via Venezian 1, 20133, Milan, Italy, the Coordinator;

INSTITUT CATALA D’ONCOLOGIA (ICO), PIC 998420031, established in Avinguda de la Granvia de l’Hospitalet, 199-203; 08908- L’Hospitalet del Llobregat, Spain;

ETHNIKO KAI KAPODISTRIAKO PANEPISTIMIO ATHINON (NKUA), PIC 999643007, established in Athina (Greece) at 6 CHRISTOU LADA STR 10561 with VAT number EL090145420;

UTILITY NON –PROFIT ENTERPRISE “CENTRAL CITY CLINICAL HOSPITAL OF IVANO-FRANKIVSK COUNCIL”, PIC 888304176 with legal address 114, Hetman Mazepy, 76025, Ivano-Frankivsk, Ukraine;

FUNDACIO INSTITUT D’INVESTIGACIO SANITARIA PERE VIRGILI (IISPV) which has its registered office at Escorxador Street, S/N, post code, 43003, Tarragona, with VAT number is ESG43814045

AZIENDA OSPEDALIERA UNIVERSITARIA POLICLINICO PAOLO GIACCONE DI PALERMO (AOUPPA), PIC 947085592, with legal address Via del Vespro 129, 90127, Palermo, Italy;

SALUTE DONNA ODV, PIC 883486865, established in Milan, Italy, Via Venezian, 1 – 20133;

CITTADINI PER L’ARIA ONLUS, PIC 906257033, established in Milan, Italy, Via Lentasio 9, 20122;

CARPATHIAN INSTITUTE OF ANALYTICS, PIC 883590946, established in 57 Shevchenka Str., 76018, Ivano-Frankivsk, Ukraine

UNIVERSITA’ DEGLI STUDI DI BRESCIA with legal address in Piazza del Mercato, 15 25121 Brescia Italy;

UNIVERSITA’ DEGLI STUDI DI PERUGIA with legal address in Piazza Università 1, 06123, Perugia, Italy;

hereinafter, jointly or individually, referred to as “Parties” or “Party”

relating to the Action entitled

European Linkage of Initiative from Science to Action in Health

In short,

ELISAH

hereinafter referred to as “Project”

WHEREAS:

The Parties, having considerable experience in the field concerned, have submitted a proposal for the Project to the Granting Authority as part of Horizon Europe – the Framework Programme for Research and Innovation (2021-2027).

To ensure that the action is implemented properly, the Parties wish to specify or supplement binding commitments among themselves in addition to the provisions of the specific Grant Agreement n. 101128640, to be signed by the Beneficiaries and the Granting Authority (hereinafter “Grant Agreement”).

The Parties are aware that this Consortium Agreement is based upon the [DESCA model consortium agreement](#).

NOW, THEREFORE, IT IS HEREBY AGREED AS FOLLOWS:

1 Definitions

1.1 Definitions

Words beginning with a capital letter shall have the meaning defined either herein or in the Horizon Europe Regulation or in the Grant Agreement, including its Annexes.

1.2 Additional Definitions

“Consortium Body”

Consortium Body means any management body described in Section 6 (Governance Structure) of this Consortium Agreement.

“Project Plan”

Project Plan means the description of the Action and the related agreed budget as first defined in the Grant Agreement and which may be updated by the Steering Committee.

“Granting Authority”

means the body awarding the grant for the Project.

“Defaulting Party”

Defaulting Party means a Party which the Steering Committee has identified to be in breach of this Consortium Agreement and/or the Grant Agreement as specified in Section 4.2 of this Consortium Agreement.

“Needed”

means:

For the implementation of the Project:

Access Rights are Needed if, without the grant of such Access Rights, carrying out the tasks assigned to the recipient Party would be technically or legally impossible, significantly delayed, or require significant additional financial or human resources.

For Exploitation of own Results:

Access Rights are Needed if, without the grant of such Access Rights, the Exploitation of own Results would be technically or legally impossible.

“Software”

Software means sequences of instructions to carry out a process in, or convertible into, a form executable by a computer and fixed in any tangible medium of expression.

“Third Party”

Third party means each entity who is not defined as a “Party” to this Consortium Agreement.

“Force Majeure”

Force Majeure means any situation or event that (a) prevents a Party from fulfilling its obligations under this Consortium Agreement, (b) was an unforeseeable, exceptional situation and beyond that Party’s control, (c) was not due to error or negligence on the part of the Party (or on the part of other Participants involved in the Action), and (d) proves to be inevitable in spite of exercising all due diligence.

2 Purpose

The purpose of this Consortium Agreement is to specify with respect to the Project the relationship among the Parties in particular concerning the organisation of the work between the Parties, the management of the Project and the rights and obligations of the Parties concerning *inter alia* liability, Access Rights and dispute resolution.

3 Entry into force, duration and termination

3.1 Entry into force

An entity becomes a Party to this Consortium Agreement upon signature of this Consortium Agreement by a duly authorised representative.

This Consortium Agreement shall have effect from the “Effective Date” identified at the beginning of this Consortium Agreement.

An entity becomes a new Party to the Consortium Agreement upon signature of the accession document (attachment 2) by the new Party and the Coordinator. Such accession shall have effect from the date identified in the accession document.

3.2 Duration and termination

This Consortium Agreement shall continue in full force and effect until complete fulfilment of all obligations undertaken by the Parties under the Grant Agreement and under this Consortium Agreement.

However, this Consortium Agreement or the participation of one or more Parties to it may be terminated in accordance with the terms of this Consortium Agreement.

If

- the Grant Agreement is not signed by the Granting Authority or a Party, or
- the Grant Agreement is terminated, or
- a Party's participation in the Grant Agreement is terminated,

this Consortium Agreement shall automatically terminate in respect of the affected Party/ies, subject to the provisions surviving the expiration or termination under Section 3.3 of this Consortium Agreement.

3.3 Survival of rights and obligations

The provisions relating to Access Rights, Dissemination and confidentiality, for the time period mentioned therein, as well as for liability, applicable law and settlement of disputes shall survive the expiration or termination of this Consortium Agreement.

Termination shall not affect any rights or obligations of a Party leaving the Project incurred prior to the date of termination, unless otherwise agreed between the Steering Committee and the leaving Party. This includes the obligation to provide all necessary input, deliverables and documents for the period of its participation.

4 Responsibilities of Parties

4.1 General principles

Each Party undertakes to take part in the efficient implementation of the Project, and to cooperate, perform and fulfil, promptly and on time, all of its obligations under the Grant Agreement and this Consortium Agreement as may be reasonably required from it and in a manner of good faith as prescribed by Belgian law.

Each Party undertakes to notify promptly to the Granting Authority and the other Parties, in accordance with the governance structure of the Project, of any significant information, fact, problem or delay likely to affect the Project.

Each Party shall promptly provide all information reasonably required by a Consortium Body or by the Coordinator to carry out its tasks and shall responsibly manage the access of its employees and other natural persons who act on its behalf to the EU Funding & Tenders Portal.

Each Party shall take reasonable measures to ensure the accuracy of any information or materials it supplies to the other Parties.

Each Party shall submit its contributions to the periodic reports in time and shall make sure that financial statements are completed and electronically signed by the deadline communicated in advance by the Coordinator.

4.2 Breach

In the event that the Steering Committee identifies a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement (e.g. improper implementation of the Project), the Coordinator or, if the Coordinator is in breach of its obligations, the Party appointed by the

Steering Committee, will give formal notice to such Party requiring that such breach will be remedied within 30 calendar days from the date of receipt of the written notice by the Party.

If such breach is substantial and is not remedied within that period or is not capable of remedy, the Steering Committee may decide to declare the Party to be a Defaulting Party and to decide on the consequences thereof which may include termination of its participation.

4.3 Involvement of Third Parties

A Party that enters into a subcontract or otherwise involves Third Parties in the Project remains responsible for carrying out its relevant part of the Project and for such Third Party's compliance with the provisions of this Consortium Agreement and of the Grant Agreement.

Such Party has to ensure that the involvement of third parties does not affect the rights and obligations of the other Parties under this Consortium Agreement and the Grant Agreement.

4.4 Specific responsibilities regarding data protection

Where necessary, the Parties shall cooperate in order to enable one another to fulfil legal obligations arising under applicable data protection laws (the *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 relevant national data protection law applicable to said Party) within the scope of the performance and administration of the Project and of this Consortium Agreement.

In particular, if it will be necessary for the fulfilment of legal obligations arising under the Regulation (EU) 2016/679 or the Parties shall undertake to conclude separate agreements, between the required Parties, aim to set out their roles and to regulate their liabilities, before any data processing or data sharing takes place. Such agreements will be drafted according to the provisions arising under the Regulation (EU) 2016/679.

5 Liability towards each other

5.1 No warranties

In respect of any information or materials (incl. Results and Background) supplied by one Party to another (or under the same control) under the Project, no warranty or representation of any kind is made, given or implied as to the sufficiency or fitness for purpose nor as to the absence of any infringement of any proprietary rights of third parties.

Therefore,

- the recipient Party shall in all cases be entirely and solely liable for the use to which it puts such information and materials, and
- no Party granting Access Rights shall be liable in case of infringement of proprietary rights of a third party resulting from any other Party (or its entities under the same control) exercising its Access Rights.

5.2 Limitations of contractual liability

No Party shall be responsible to any other Party for any indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts, except in case of breach of confidentiality.

A Party's aggregate liability towards the other Parties collectively shall be limited to once the Party's share of the total costs of the Project as identified in Annex 2 of the Grant Agreement.

A Party's liability shall not be limited under either of the two foregoing paragraphs to the extent such damage was caused by a willful act or gross negligence or to the extent that such limitation is not permitted by law.

5.3 Damage caused to third parties

Each Party shall be solely liable for any loss, damage or injury to Third Parties resulting from the performance of the said Party's obligations by it or on its behalf under this Consortium Agreement or from its use of Results or Background.

5.4 Force Majeure

No Party shall be considered to be in breach of this Consortium Agreement if it is prevented from fulfilling its obligations under the Consortium Agreement by Force Majeure.

Each Party will notify the Steering Committee of any Force Majeure without undue delay. If the consequences of Force Majeure for the Project are not overcome within 6 weeks after such notice, the termination of this Consortium Agreement towards the Party affected by Force Majeure and the transfer of tasks - if any - shall be decided by the Steering Committee.

5.5 Export Control

No Party shall be considered to be in breach of this Consortium Agreement if it is prevented from fulfilling its obligations under the Consortium Agreement due to a restriction resulting from import or export laws and regulations and/or any delay of the granting or extension of the import or export license or any other governmental authorization, provided that the Party has used its reasonable efforts to fulfil its tasks and to apply for any necessary license or authorization properly and in time.

Each Party will notify Steering Committee of any such restriction without undue delay. If the consequences of such restriction for the project are not overcome within 6 weeks after such notice, the transfer of tasks – if any – shall be decided by the Steering Committee.

6 Governance structure

6.1 General structure

The organisational structure of the consortium shall comprise the following Consortium Bodies:

1. Steering Committee (SC) is the decision making body of the Consortium and the highest level authority of the Project, with overall responsibility of management, including technical, financial and administrative aspect. Besides, it has the sole authority to decide

on issues that necessitate changes in the Grant Agreement or in this Consortium Agreement, such as major modifications of the Project plan, budget distribution possible additions or calls for new partners, as well as unresolved management issues;

2. The Coordinator is the legal entity acting as the intermediary between the parties and the Granting Authority and ensure the coordination among ELISAH Parties. In addition, the Coordinator shall perform the tasks assigned as described in the Grant Agreement and this Consortium Agreement.

In addition, to ensure the proper implementation of the ELISAH project, the organisational structure shall also comprise the following functions:

- The Work Package (WP) leaders are responsible for the proper implementation of the obligations of their respective WP, coordination and interaction within their respective WP, as well as across the WPs.

6.2 Members of the Steering Committee

The Steering Committee will be constituted by all the WP leaders and one co-PI for every WP and one representative for every Party not leading WPs Party (hereinafter referred to as "Member").

Each Member shall be deemed to be duly authorised to deliberate, negotiate and decide on all matters listed in section 6.3.7. of this Consortium Agreement. If necessary, each Party shall also be entitled to nominate a replacement Representative in the event that the original Representative is unable to attend any scheduled meetings of the Steering Committee.

The Steering Committee Coordinator (SC) will be dr. Paolo Contiero (INT) who will chair all meetings of the SC. An INT team will support the SC Coordinator to fulfil administrative tasks.

The Parties agree to abide by all the decisions issued by the Steering Committee.

This does not prevent the Parties from exercising their veto rights, according to Section 6.3.5, or from submitting a dispute for resolution in accordance with the provisions of settlement of disputes in Section 11.8 of this Consortium Agreement.

6.3 Operational procedures for the Steering Committee

6.3.1 Representation in meetings

Any Member:

- should be present or represented at any meeting;
- may appoint a substitute or a proxy to attend and vote at any meeting;
- and shall participate in a cooperative manner in the meetings.

6.3.2 Preparation and organisation of meetings

6.3.2.1 Convening meetings:

The Steering Committee meeting will be held by tele - or videoconference every six months to ensure transparent project evolution and governance.

If deemed necessary, extraordinary meetings can be arranged upon request of any Member.

	Ordinary meeting	Extraordinary meeting
Steering Committee	At least once every semester	At any time upon request of any member of the Steering Committee

6.3.2.2 Notice of a meeting

The SC Coordinator, supported by an INT team, shall give written notice of a meeting to each Member as soon as possible and no later than the minimum number of days preceding the meeting as indicated below

	Ordinary meeting	Extraordinary meeting
Steering Committee	14 calendar days	7 calendar days

6.3.2.3 Sending the agenda

The SC Coordinator, supported by an INT team, shall prepare and send an Agenda no later than 14 calendar days preceding the meeting, or 7 calendar days before an extraordinary meeting.

6.3.2.4 Adding agenda items

Any agenda item requiring a decision by the Members must be identified as such on the agenda.

Any Member may add an item to the original agenda by written notice to all of the other Members no later than 7 calendar days preceding the meeting and 2 days preceding an extraordinary meeting.

6.3.2.5 Adding agenda items during meetings

During a meeting the Members of the Steering Committee present or represented can unanimously agree to add a new item to the original agenda.

6.3.2.6 Compliance with the decisions of the Steering Committee

Decisions of the Steering Committee will only be binding once the relevant part of the minutes has been accepted according to section 6.3.6.2.

6.3.3 Decisions without a meeting

Any decision may also be taken without a meeting if

- a) the SC Coordinator circulates to all Members of the Steering Committee a suggested decision with a deadline for responses of at least 10 calendar days after receipt by a Party and
- b) the decision is agreed by the majority of two-thirds (2/3) of all Parties.

The SC Coordinator shall inform all the Parties of the outcome of the vote.

A veto according to Section 6.3.5. may be submitted up to 15 calendar days after receipt of this information.

The decision will be binding after the SC Coordinator, supported by an INT team, sends a notification to all Members. The SC Coordinator, supported by an INT team, will keep records of the votes and make them available to the Parties on request.

6.3.4 Voting rules and quorum

6.3.4.1 Quorum

The Steering Committee shall not deliberate and decide validly in meetings unless two-thirds (2/3) of its Members are present or represented (quorum).

If the quorum is not reached, the Coordinator shall convene another ordinary meeting within 15 calendar day. If in this meeting quorum is not reached once more, the Coordinator shall convene another extraordinary meeting which shall be entitled to deliberate, even if less than the quorum of Members are present or represented.

6.3.4.2 Votes for each Member

Each Member of the Steering Committee present or represented in the meeting shall have one vote.

6.3.4.3 Vote of a Defaulting Party

A Party which the Steering Committee has declared, according to Section 4.2, to be a Defaulting Party may not vote.

6.3.4.4 Majority

Voting Mechanism will only take place as a last chance when consensus cannot be reached. Each Member of the Steering Committee present or represented in a meeting shall have one vote. In case consensus between Steering Committee Members is not reached, Decision shall be taken on the majority of 2/3 of the votes cast.

6.3.5 Veto rights

6.3.5.1 Grounds for veto

A Party which can show and proof, with a high level of certainty, that its own work, time for performance, costs, liabilities, intellectual property rights or other legitimate interests would be severely affected by a decision of the Steering Committee may exercise a veto with respect to the corresponding decision or relevant part of the decision.

6.3.5.2 Decisions on the original agenda

When the decision is envisaged on the original agenda, a Party may only veto such a decision during the meeting.

6.3.5.3 Decisions on items added to the agenda

When a decision has been taken on a new item added to the agenda before or during the meeting, a Party may veto such decision during the meeting or within 15 calendar days after receipt of the draft minutes of the meeting.

6.3.5.4 Decisions without meetings

When a decision has been taken without a meeting, a Party may veto such decision within 15 calendar days after written notice by the Steering Committee Coordinator or the INT team of the outcome of the vote.

6.3.5.5 Obligations deriving from the exercise of veto

In case of exercise of veto, the Members of the Steering Committee shall make every effort to resolve the matter which occasioned the veto to the general satisfaction of all the Parties.

6.3.5.6 Decisions excluded from veto

A Party may neither veto decisions relating to its identification to be in breach of its obligations nor to its identification as a Defaulting Party. The Defaulting Party may not veto decisions relating to its participation and termination in the consortium or the consequences of them.

6.3.5.7 Leaving Party

A Party requesting to leave the consortium may not veto decisions relating thereto.

6.3.6 Minutes of meetings

6.3.6.1 Content and deadline for sending the drafts

The SC Coordinator, supported by an INT team, shall produce minutes of each meeting which shall be the formal record of all decisions taken. He/she shall send the draft minutes to all Members within 10 calendar days of the meeting.

6.3.6.2 Accepted minutes

The minutes shall be considered as accepted if, within 15 calendar days from receipt, no Member has sent an objection by written notice to the chairperson with respect to the accuracy of the draft minutes by written notice.

6.3.6.3 Accepted minutes: sending and copies

The SC Coordinator, supported by an INT team, shall send the accepted minutes to all the Parties and to the Coordinator, who shall retain copies of them.

6.3.7 Tasks and Decisions

6.3.7.1 Decisions

The Steering Committee shall be free to act on its own initiative to formulate proposals and take decisions in accordance with the procedures set out herein.

The following decisions shall be taken by the Steering Committee:

Content, finances and intellectual property rights:

- proposals for changes to Annexes 1 and 2 of the Grant Agreement to be agreed by the Granting Authority;
- changes to the Project Plan;
- modifications or withdrawal of Background in Attachment 1 (Background Included);
- additions to Attachment 3 (List of Third Parties for simplified transfer according to Section 8.3.2);
- additions to Attachment 4 (Identified entities under the same control).

Evolution of the consortium:

- entry of a new Party to the Project and approval of the settlement on the conditions of the accession of such a new Party;
- withdrawal of a Party from the Project and the approval of the settlement on the conditions of the withdrawal
- identification of a breach by a Party of its obligations under this Consortium Agreement or the Grant Agreement;
- declaration of a Party to be a Defaulting Party;
- remedies to be performed by a Defaulting Party;
- termination of a Defaulting Party's participation in the Project and measures relating thereto;
- proposal to the Granting Authority for a change of the Coordinator;
- proposal to the Granting Authority for suspension of all or part of the Project;
- proposal to the Granting Authority for termination of the Project and the Consortium Agreement.

The Steering Committee shall be responsible for the proper execution and implementation of its own decisions.

6.3.7.2 Tasks

The Steering Committee will be responsible for all strategic planning, ensuring that the timetable is maintained, that the milestone are met, and the corrective actions are taken if necessary.

The Steering Committee shall monitor the effective and efficient implementation of the Project.

Besides, The Steering Committee shall be responsible for:

- supporting the Coordinator in preparing meetings with the Granting Authority and in preparing related data and deliverables;
- revising and assessing Parties compliance to the agreed workplan;
- revising the workplan strategy if deemed necessary to meet Grant Agreement deadlines;

– preparing the content and timing of press releases and joint publications by the consortium or proposed by the Granting Authority in respect of the procedures of the Grant Agreement Article 17 and Annex 5 Section “Communication, Dissemination, Open Science and Visibility” and of Section 8 of this Consortium Agreement;

In addition, the Steering Committee, supported by an INT team, shall collect information at least every 6 months on the progress of the Project, examine that information to assess the compliance of the Project with the Project Plan and, if necessary, propose modifications of the Project Plan.

6.4 Coordinator

6.4.1 Role

The Coordinator is the legal entity acting as the intermediary between the parties and the Granting Authority and ensure the coordination among ELISAH Parties. The Coordinator shall, in addition to its responsibilities as a Party, perform the tasks assigned to it as described in the Grant Agreement and in this Consortium Agreement.

6.4.2 Tasks

In particular, the Coordinator shall be responsible for:

- monitoring compliance by the Parties with their obligations under this Consortium Agreement and the Grant Agreement;
- keeping the address list of Members and other contact persons updated and available;
- collecting, reviewing to verify consistency and submitting reports, other deliverables (including financial statements and related certifications) and specific requested documents to the Granting Authority;
- transmitting promptly documents and information connected with the Project to any other Parties concerned;
- administering the financial contribution of the Granting Authority and fulfilling the financial tasks described in Section 7.2;
- providing, upon request, the Parties with official copies or originals of documents that are in the sole possession of the Coordinator when such copies or originals are necessary for the Parties to present claims.

If one or more of the Parties is late in submission of any Project deliverable, the Coordinator may nevertheless submit the other 'Parties' Project deliverables and all other documents required by the Grant Agreement to the Granting Authority in time.

6.4.3 Coordinator's replacement

If the Coordinator fails in its coordination tasks, the Steering Committee may propose to the Granting Authority to change the Coordinator.

6.4.4 Prohibited declarations

The Coordinator shall not be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium, unless explicitly stated otherwise in the Grant Agreement or this Consortium Agreement.

6.4.5 Restrictive interpretation of tasks

The Coordinator shall not widen its role beyond the tasks specified in this Consortium Agreement and in the Grant Agreement

7 Financial provisions

7.1 General Principles

According to the provisions of the Grant Agreement, the principles and the provisions below apply to all the Parties signing this Consortium Agreement.

7.1.1 Distribution of Financial Contribution

The financial contribution of the Granting Authority to the Project shall be distributed by the Coordinator according to:

- the Project Plan,
- the approval of reports by the Granting Authority, and
- the provisions of payment in Section 7.2.

A Party shall be funded only for its tasks carried out in accordance with the Consortium Plan.

7.1.2 Justifying Costs

In accordance with its own usual accounting and management principles and practices, each Beneficiary shall be solely responsible for justifying its costs with respect to the Project towards the Granting Authority. Neither the Coordinator nor any of the other Beneficiary shall be in any way liable or responsible for such justification of costs towards the Granting Authority.

7.1.3 Funding Principles

A Party that spends less than its allocated share of the budget as set out in the Consortium Plan or – in case of reimbursement via unit costs - implements less units than foreseen in the Consortium Plan will be funded in accordance with its units/actual duly justified eligible costs only.

A Party that spends more than its allocated share of the budget as set out in the Consortium Plan will be funded only in respect of duly justified eligible costs up to an amount not exceeding that share.

7.1.4 Excess payments

A Party has received excess payment

- a) if the payment received from the Coordinator exceeds the amount declared or

- b) if a Party has received payments but, within the last year of the Project, its real Project costs fall significantly behind the costs it would be entitled to according to the Project Plan.

In case a Party has received excess payment, the Party has to inform the Coordinator and return the relevant amount to the Coordinator without undue delay. In case no refund takes place within 30 days upon request for return of excess payment from the Coordinator, the Party is in substantial breach of the Consortium Agreement.

Amounts which are not refunded by a breaching Party and which are not due to the Granting Authority, shall be apportioned by the Coordinator to the remaining Parties pro rata according to their share of total costs of the Project as identified in the Consortium Budget, until recovery from the breaching Party is possible. The Steering Committee decides on any legal actions to be taken against the breaching Party.

7.1.5 Revenue

In case a Party earns any revenue that is deductible from the total funding as set out in the Project Plan, the deduction is only directed toward the Party earning such revenue. The other Parties' financial share of the budget shall not be affected by one Party's revenue. In case the relevant revenue is more than the allocated share of the Party as set out in the Consortium Plan, the Party shall reimburse the funding reduction suffered by other Parties.

7.1.6 Financial Consequences of the termination of the participation of a Party

A Party leaving the consortium shall refund to the Coordinator any payments it has received except the amount of contribution accepted by the Granting Authority or another contributor.

In addition, a Defaulting Party shall, within the limits specified in Section 5.2 of this Consortium Agreement, bear any reasonable and justifiable additional costs occurring to the other Parties in order to perform the leaving Party's task and necessary additional efforts to fulfil them as a consequence of the Party leaving the consortium.

The Steering Committee should agree on a procedure regarding additional costs which are not covered by the Defaulting Party or the Mutual Insurance Mechanism.

7.2 Payments

7.2.1 Payments to Parties are the exclusive task of the Coordinator.

In particular, the Coordinator shall:

- notify the Parties concerned promptly of the date and composition of the amount transferred to its bank account, giving the relevant references;
- perform diligently its tasks in the proper administration of any funds and in maintaining financial accounts;

- undertake to keep the Granting Authority's financial contribution to the Project separated from its normal business accounts, its own assets and property, except if the Coordinator is a Public Body or is not entitled to do so due to statutory legislation.

With reference to Article 22 of the Grant Agreement, no Party shall before the end of the Project receive more than its allocated share of the maximum grant amount less the amounts retained by the Granting Authority for the Mutual Insurance Mechanism and for the final payment.

7.2.2 Payment schedule

The transfer of the initial pre-financing and interim payments to Beneficiaries will be handled in accordance with Articles 7 and 22.1 of the Grant Agreement following this payment schedule:

Funding of costs included in the Project Plan will be paid by the Coordinator to the Parties after receipt of payments from the Granting Authority without undue delay and in conformity with the provisions of the Grant Agreement. Costs accepted by the Granting Authority will be paid to the Party concerned.

The Coordinator is entitled to withhold any payments due to a Party identified by the Steering Committee to be in breach of its obligations under this Consortium Agreement or the Grant Agreement or to a Party which has not yet signed this Consortium Agreement.

The Coordinator is entitled to recover any payments already paid to a Defaulting Party except the costs already claimed by the Defaulting Party and accepted by the Granting Authority. The Coordinator is equally entitled to withhold payments to a Party when this is suggested by or agreed with the Granting Authority.

8 Results

In reference to the object of this section, each Party undertakes to conclude separate agreements aim to regulate all cases that are not set out in the Grant Agreement or in the Consortium Agreement.

8.1 Ownership of Results

Results are owned by the Party that generates them.

8.2 Joint ownership

Joint ownership is governed by Grant Agreement Article 16.4 and its annex 5, with the following additions:

Unless otherwise agreed:

- each of the joint owners shall be entitled to use their jointly owned Results for non-commercial research and teaching activities on a royalty-free basis, and without requiring the prior consent of the other joint owner(s);

- each of the joint owners shall be entitled to otherwise Exploit the jointly owned results and to grant non exclusive licenses to third parties (without any right to sub license), if the other joint owners are given:

- a) at least 45 calendar days advance notice; and
- b) fair and reasonable compensation.

The joint owners shall agree on all protection measures and the division of related cost in advance.

8.3 Transfer of Results

8.3.1 Transfer of ownership: procedures

Each Party may transfer ownership of its own Results, including its share in jointly owned Results, following the procedures of the Grant Agreement Article 16.4 and its Annex 5, Section Transfer and licensing of results, sub-section "Transfer of ownership".

8.3.2 Transfer of ownership: specific third parties

Each Party may identify specific third parties it intends to transfer the ownership of its Results to in Attachment (3) of this Consortium Agreement. The other Parties hereby waive their right to prior notice and their right to object to such a transfer to listed third parties according to the Grant Agreement Article 16.4 and its Annex 5, Section Transfer of licensing of results, sub-section "Transfer of ownership", 3rd paragraph.

8.3.3 Transferring Party's obligations

The transferring Party shall, however, at the time of the transfer, inform the other Parties of such transfer and shall ensure that the rights of the other Parties under the Consortium Agreement and the Grant Agreement will not be affected by such transfer. Any addition to Attachment (3) after signature of this Consortium Agreement requires a decision of the Steering Committee.

8.3.4 Mergers and acquisitions

The Parties recognise that in the framework of a merger or an acquisition of an important part of its assets, it may be impossible under applicable EU and national laws on mergers and acquisitions for a Party to give at least 45 calendar days prior notice for the transfer as foreseen in the Grant Agreement.

8.3.5 Link with Access Rights to Results

The obligations above apply only for as long as other Parties still have - or still may request - Access Rights to the Results.

8.4 Dissemination

8.4.1 Confidentiality

For the avoidance of doubt, the confidentiality obligations set out in Section 10 apply to all dissemination activities described in this Section 8.4 as far as Confidential Information is involved.

8.4.2 Dissemination of own (including jointly owned) Results

8.4.2.1 Procedures, prior notices and objections

During the Project and for a period of 1 year after the end of the Project, the dissemination of own Results by one or several Parties including but not restricted to publications and presentations, shall be governed by the procedure of Article 17.4 of the Grant Agreement and its Annex 5, Section "Communication, Dissemination and Visibility", subject to the following provisions.

Prior notice of any planned publication shall be given to the other Parties at least 45 calendar days before the publication. Any objection to the planned publication shall be made in accordance with the Grant Agreement by written notice to the Coordinator and to the Party or Parties proposing the dissemination within 30 calendar days after receipt of the notice. If no objection is made within the time limit stated above, the publication is permitted.

8.4.2.2 Grounds for objections

An objection is justified if

- a) the protection of the objecting Party's Results or Background would be adversely affected, or
- b) the objecting Party's legitimate interests in relation to its Results or Background would be significantly harmed, or
- c) the proposed publication includes Confidential Information of the objecting Party.

The objection has to include a precise request for necessary modifications.

8.4.2.3 Parties' obligations deriving from objections

If an objection has been raised, the involved Parties shall discuss how to overcome the justified grounds for the objection on a timely basis (for example by amendment to the planned publication and/or by protecting information before publication) and the objecting Party shall not unreasonably continue the opposition if appropriate measures are taken following the discussion.

8.4.2.4 Publication delay

The objecting Party can request a publication delay of not more than 90 calendar days from the time it raises such an objection. After 90 calendar days the publication is permitted, provided that the objections of the objecting Party have been addressed.

8.4.3 Dissemination of another Party's unpublished Results or Background

A Party shall not include in any dissemination activity another Party's Results or Background without obtaining the owning Party's prior written approval, unless they are already published.

8.4.4 Cooperation obligations

The Parties undertake to cooperate to allow the timely submission, examination, publication and defense of any dissertation or thesis for a degree that includes their Results or Background subject to the confidentiality and publication provisions agreed in this Consortium Agreement.

8.4.5 Use of names, logos or trademarks

Nothing in this Consortium Agreement shall be construed as conferring rights to use in advertising, publicity or otherwise the name of the Parties or any of their logos or trademarks without their prior written approval.

9 Access Rights

9.1 Background included

9.1.1 Reference to Attachment 1

In Attachment 1, the Parties have identified and agreed on the Background for the Project and have also, where relevant, informed each other that Access to specific Background is subject to legal restrictions or limits.

Anything not identified in Attachment 1 shall not be the object of Access Right obligations regarding Background.

9.1.2 Additional Background

Any Party may add additional Background to Attachment 1 during the Project provided they give written notice to the other Parties. However, approval of the General Assembly is needed should a Party wish to modify or withdraw its Background in Attachment 1.

9.2 General Principles

9.2.1 Parties' obligations

Each Party shall implement its tasks in accordance with the Project Plan and shall bear sole responsibility for ensuring that its acts within the Project do not knowingly infringe third party property rights.

9.2.2 Sublicense

Any Access Rights granted exclude any rights to sublicense unless expressly stated otherwise.

9.2.3 Costs

Access Rights shall be free of any administrative transfer costs.

9.2.4 Non exclusivity

Access Rights are granted on a non-exclusive basis.

9.2.5 Use of Results and Background

Results and Background shall be used only for the purposes for which Access Rights to it have been granted.

9.2.6 Form of requests for Access Rights and conditions for granting Access Rights

All requests for Access Rights shall be made in writing. The granting of Access Rights may be made conditional on the acceptance of specific conditions aimed at ensuring that these rights will be used only for the intended purpose and that appropriate confidentiality obligations are in place.

9.2.7 Evidence by the requesting Party

The requesting Party must show that the Access Rights are Needed.

9.3 Access Rights for implementation

Access Rights to Results and Background Needed for the performance of the own work of a Party under the Project shall be granted on a royalty-free basis, unless otherwise agreed for Background in Attachment 1.

9.4 Access Rights for Exploitation

9.4.1 Access Rights to Results

Access Rights to Results if Needed for Exploitation of a own Party's own Results shall be granted on a royalty-free basis.

9.4.2 Access rights to Background

Access Rights to Background if Needed for Exploitation of a Party's own Results, shall be granted on Fair and Reasonable conditions.

9.4.3 Timing of requests for Access Rights

A request for Access Rights may be made up to twelve months after the end of the Project or, in the case of Section 9.7.2.1.2, after the termination of the requesting Party's participation in the Project.

9.5 Access Rights for entities under the same control

Entities under the same control have Access Rights under the conditions of the Grant Agreement Article 16.4 and its Annex 5, Section "Access rights to results and background", sub-section "Access rights for entities under the same control".

Such Access Rights must be requested by the entity under the same control from the Party that holds the Background or Results. Alternatively, the Party granting the Access Rights may individually agree with the Party requesting the Access Rights to have the Access Rights include the right to sublicense to the latter's entity under the same control. Access Rights to an entity under the same control shall be granted on Fair and Reasonable conditions and upon written bilateral agreement.

Entities under the same control which obtain Access Rights in return fulfil all confidentiality obligations accepted by the Parties under the Grant Agreement or this Consortium Agreement as if such entities were Parties.

Access Rights may be refused to entities under the same control if such granting is contrary to the legitimate interests of the Party which owns the Background or the Results.

Access Rights granted to any entity under the same control are subject to the continuation of the Access Rights of the Party with whom it is under the same control, and shall automatically terminate upon termination of the Access Rights granted to such Party.

Upon cessation of the status as an entity under the same control, any Access Rights granted to such former entity under the same control shall lapse.

Further arrangements with entities under the same control may be negotiated in separate agreements.

9.6 Additional Access Rights

For the avoidance of doubt any grant of Access Rights not covered by the Grant Agreement or this Consortium Agreement shall be at the absolute discretion of the owning Party and subject to such terms and conditions as may be agreed between the owning and receiving Parties.

9.7 Access Rights for Parties entering or leaving the consortium

9.7.1 New Parties entering the consortium

As regards Results developed before the accession of the new Party, the new Party will be granted Access Rights on the conditions applying for Access Rights to Background.

9.7.2 Parties leaving the consortium

9.7.2.1 Access Rights granted to a leaving Party

9.7.2.1.1 Defaulting Party

Access Rights granted to a Defaulting Party and such Party's right to request Access Rights shall cease immediately upon receipt by the Defaulting Party of the formal notice of the decision of the Steering Committee to terminate its participation in the consortium.

9.7.2.1.2 Non-defaulting Party

A non-defaulting Party leaving voluntarily and with the other Parties' consent shall have Access Rights to the Results developed until the date of the termination of its participation.

It may request Access Rights within the period of time specified in Section 9.4.3

9.7.2.2 Access Rights to be granted by any leaving Party

Any Party leaving the Project shall continue to grant Access Rights pursuant to the Grant Agreement and this Consortium Agreement as if it had remained a Party for the whole duration of the Project.

9.8 Specific Provisions for Access Rights to Software

For the avoidance of doubt, the general provisions for Access Rights provided for in this Section 9 are applicable also to Software.

Parties' Access Rights to Software do not include any right to receive source code or object code ported to a certain hardware platform or any right to receive respective Software documentation in any particular form or detail, but only as available from the Party granting the Access Rights.

10 Non-disclosure of information

10.1 Definition of Confidential Information

All information in whatever form or mode of communication, which is disclosed by a Party (the "Disclosing Party") to any other Party (the "Recipient") in connection with the Project during its implementation whether it has been explicitly marked as "confidential" at the time of disclosure or not, is "Confidential Information" or when disclosed orally has been identified as confidential at the time of disclosure and has been confirmed and designated in writing within 15 calendar days from oral disclosure at the latest as confidential information by the Disclosing Party, is "Confidential Information".

10.2 Recipients' obligations after the end of the Project

The Recipients hereby undertake in addition and without prejudice to any commitment on non-disclosure under the Grant Agreement, for a period of 5 years after the final payment by the Granting Authority:

- not to use Confidential Information otherwise than for the purpose for which it was disclosed;
- not to disclose Confidential Information without the prior written consent by the Disclosing Party;
- to ensure that internal distribution of Confidential Information by a Recipient shall take place on a strict need-to-know basis; and
- to return to the Disclosing Party, or destroy, on request all Confidential Information that has been disclosed to the Recipients including all copies thereof and to delete all information stored in a machine-readable form to the extent practically possible. The Recipients may keep a copy to the extent it is required to keep, archive or store such Confidential Information because of compliance with applicable laws and regulations or for the proof of on-going obligations provided that the Recipient complies with the confidentiality obligations herein contained with respect to such copy.

10.3 Recipients' employees and third parties

The Recipients shall be responsible for the fulfilment of the above obligations on the part of their employees or third parties involved in the Project and shall ensure that they remain so obliged, as far as legally possible, during and after the end of the Project and/or after the termination of the contractual relationship with the employee or third party.

10.4 Exclusions

The above shall not apply for disclosure or use of Confidential Information, if and in so far as the Recipient can show that:

- the Confidential Information has become or becomes publicly available by means other than a breach of the Recipient's confidentiality obligations;
- the Disclosing Party subsequently informs the Recipient that the Confidential Information is no longer confidential;
- the Confidential Information is communicated to the Recipient without any obligation of confidentiality by a third party who is to the best knowledge of the Recipient in lawful possession thereof and under no obligation of confidentiality to the Disclosing Party;
- the disclosure or communication of the Confidential Information is foreseen by provisions of the Grant Agreement;
- the Confidential Information, at any time, was developed by the Recipient completely independently of any such disclosure by the Disclosing Party;
- the Confidential Information was already known to the Recipient prior to disclosure, or
- the Recipient is required to disclose the Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, subject to the provision Section 10.7 hereunder.

10.5 Recipient's due diligence

The Recipient shall apply the same degree of care with regard to the Confidential Information disclosed within the scope of the Project as with its own confidential and/or proprietary information, but in no case less than reasonable care.

10.6 Communications about breaches of confidentiality

Each Recipient shall promptly inform the relevant Disclosing Party by written notice of any unauthorised disclosure, misappropriation or misuse of Confidential Information after it becomes aware of such unauthorised disclosure, misappropriation or misuse.

10.7 Disclosure in compliance with laws, regulations or court administrative orders

If any Recipient becomes aware that it will be required, or is likely to be required, to disclose Confidential Information in order to comply with applicable laws or regulations or with a court or administrative order, it shall, to the extent it is lawfully able to do so, prior to any such disclosure

- notify the Disclosing Party, and
- comply with the Disclosing Party's reasonable instructions to protect the confidentiality of the information.

11 Miscellaneous

11.1 Attachments, inconsistencies and severability

This Consortium Agreement consists of this core text and:

- Attachment 1 (Background included);
- Attachment 2 (Accession document);
- Attachment 3 (List of third parties for simplified transfer according to Section 8.3.2);
- Attachment 4 (Identified entities under the same control);

In case the terms of this Consortium Agreement are in conflict with the terms of the Grant Agreement, the terms of the latter shall prevail. In case of conflicts between the attachments and the core text of this Consortium Agreement, the latter shall prevail.

Should any provision of this Consortium Agreement become invalid, illegal or unenforceable, it shall not affect the validity of the remaining provisions of this Consortium Agreement. In such a case, the Parties concerned shall be entitled to request that a valid and practicable provision be negotiated that fulfils the purpose of the original provision.

11.2 No representation, partnership or agency

Except as otherwise provided in Section 6.4.4, no Party shall be entitled to act or to make legally binding declarations on behalf of any other Party or of the consortium. Nothing in this Consortium Agreement shall be deemed to constitute a joint venture, agency, partnership, interest grouping or any other kind of formal business grouping or entity between the Parties.

11.3 Formal and written notices

Any notice to be given under this Consortium Agreement shall be addressed to the recipients as listed in the most current address list kept by the Coordinator.

Any change of persons or contact details shall be immediately communicated to the Coordinator by written notice. The address list shall be accessible to all Parties.

Formal notices:

If it is required in this Consortium Agreement (Sections 4.2, 9.7.2.1.1, and 11.4) that a formal notice, consent or approval shall be given, such notice shall be signed by an authorised representative of a Party and shall either be served personally or sent by mail with recorded delivery with acknowledgement of receipt.

Written notice:

where written notice is required by this Consortium Agreement, this is fulfilled also by other means of communication such as e-mail with acknowledgement of receipt.

11.4 Assignment and amendments

Except as set out in Section 8.3, no rights or obligations of the Parties arising from this Consortium Agreement may be assigned or transferred, in whole or in part, to any third party without the other Parties' prior formal approval.

Amendments and modifications to the text of this Consortium Agreement not explicitly listed in Section 6.3.1.2. require a separate written agreement to be signed between all Parties.

11.5 Mandatory national law

Nothing in this Consortium Agreement shall be deemed to require a Party to breach any mandatory statutory law under which the Party is operating.

11.6 Language

This Consortium Agreement is drawn up in English, which language shall govern all documents, notices, meetings, arbitral proceedings and processes relative thereto.

11.7 Applicable law

This Consortium Agreement shall be construed in accordance with and governed by the laws of Belgium excluding its conflict of law provisions.

11.8 Settlement of disputes


The Parties shall endeavour to settle their disputes amicably.

All disputes arising out of or in connection with this Consortium Agreement, which cannot be solved amicably, shall be finally settled by the courts of Brussels.

12 Signatures

The Parties have caused this Consortium Agreement to be duly signed by the undersign authorized representative in separate signature pages the day and the year first above written.

FONDAZIONE IRCCS ISTITUTO NAZIONALE DEI TUMORI,

Signature  DocuSigned by:
Name Carlo Nicora B7E7978B579546C...

Title General Manager

Date 10-apr-2024

INSTITUT CATALA D'ONCOLOGIA

Signature  DocuSigned by:
Margarita Garcia Martin

Name Margarita García Martín,

Title Deputy General Director

Date 22-Mar-2024

ETHNIKO KAI KAPODISTRIAKO PANEPISTIMIO ATHINON

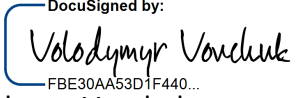
Signature  DocuSigned by:
FAD158A2AF6448C...

Name Christos G. Karagiannis

Title Vice-Rector for Research, Innovation, and Lifelong Learning

Date 15-Apr-2024

**UTILITY NON –PROFIT ENTERPRISE “CENTRAL CITY CLINICAL HOSPITAL OF IVANO-FRANKIVSK
COUNCIL**

Signature  DocuSigned by:
FBE30AA53D1F440...

Name Volodymyr Vovchuk

Title Acting Director

Date 26-Бер-2024

FUNDACIO INSTITUT D'INVESTIGACIO SANITARIA PERE VIRGILI (IISPV)

Signature  DocuSigned by:

Name Joan Vendrell Ortega 716E4E3F8790475...

Title Director

Date 22-mar.-2024

AZIENDA OSPEDALIERA UNIVERSITARIA POLICLINICO PAOLO GIACCONE DI PALERMO (AOUPPA)

Signature

Name Maria Grazia Furnari

Title General Manager

Date

Firmato digitalmente da: Maria
Grazia Furnari
Data: 27/05/2024 15:30:32

SALUTE DONNA ONLUS

Signature DocuSigned by:
Anna Maria Mancuso

Name Anna Maria Mancuso
2A4B999A1B8B4EB

Title President

Date 08-apr-2024

CITTADINI PER L'ARIA ONLUS

Signature 
DocuSigned by:

Name Anna Gerometta
CF3561F8E7B6444...

Title President

Date 27-mar-2024

CARPATHIAN INSTITUTE OF ANALYTICS

Signature  DocuSigned by:
6C3934E0387940A...

Name Olga Maksymovych

Title Chief Executive Officer (CEO)

Date

UNIVERSITA' DEGLI STUDI DI BRESCIA

Signature 
DocuSigned by:

Name Francesco Castelli
741E2B6A80124A1...

Title Rector

Date 22-mar-2024

UNIVERSITA' DEGLI STUDI DI PERUGIA

Signature DocuSigned by:
Prof. Vincenzo Nicola Talesa

Name Vincenzo Nicola Talesa
F0B4D642DCEA42C1

Title Director of Department of Medicine and Surgery

Date 15-apr-2024

Attachment 1: Background included

According to the Grant Agreement (Article 16.1) Background is defined as “data, know-how or information (...) that is (...) needed to implement the Action or exploit the results”. Because of this need, Access Rights have to be granted in principle, but Parties must identify and agree amongst them on the Background for the Project. This is the purpose of this attachment.

PARTY 1

As to **FONDAZIONE IRCCS ISTITUTO NAZIONALE DEI TUMORI**, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific restrictions and/or conditions for implementation (Article 16.4 Grant Agreement and its Annex 5, Section “Access rights to results and background”, sub-section “Access rights to background and results for implementing the Action”)	Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section “Access rights to results and background”, sub-section “Access rights for exploiting the results”)
INT make it available:		
- Expertise, methods and R-programs to compute breast cancer rates and their geographic distribution		
- Expertise, methods and R-programs to analyze cause-specific mortality in cancer patient cohorts	None	None
- The Open Registry System, an information system to develop population-based Cancer Registries and manage cohort data. Expertise to develop Cancer Registries		
- The Epilink record linkage system developed and tested to link electronic information sources. Expertise to record linkage		
- Expertise, methods and program to manage data from the COPERNICUS atmospheric pollutant EU database		
- Expertise, methods and program to manage data		

from the WATERBASE the
EEA's databases on the status
and quality of Europe's rivers,
lakes, groundwater bodies
pollutant EU database

- A Linux server and an
Oracle database to host
ELISAH common data

This represents the status at the time of signature of this Consortium Agreement.

PARTY 2

As to **INSTITUT CATALA D'ONCOLOGIA**, it is agreed between the Parties that, to the best of their knowledge, No data, know-how or information of **INSTITUT CATALA D'ONCOLOGIA** is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the action") or Exploitation of that other Party's Results (Article 16.1 and its Annex 5 Grant Agreement, Section "Access rights to results and background", sub-section "Access rights for exploiting the results").

This represents the status at the time of signature of this Consortium Agreement.

PARTY 3

As to **ETHNIKO KAI KAPODISTRIAKO PANEPISTIMIO ATHINON**, it is agreed between the Parties that, to the best of their knowledge, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background

The Medical School of NKUA includes a total of 86 University Medical Departments and Laboratories located in the campus at Goudi, in University Hospitals (Attikon, Laiko, Aretaieio, Aiginiteio) and in NHS Hospitals (Ippokrateio, Sotiria, vangelistimos, Alexandra, Agia Sophia, Aglaia Kyriakou, Genimatas, Sismanogleio, A. Syngros, KAT, Agia Olga), that provide daily, high-quality health services in the Athens metropolitan area.

The NKUA will provide:

- Various medical imaging equipment (MRI, CT, X-ray, US, Mammography system)
- A large variety of clinical evaluation tools and an extensive experience in clinical evaluation of patients. There is a large database of patient records and archive of a great number of laboratory and imaging examinations.
- Experience in Patient management for

Specific restrictions and/or conditions for implementation (Article 16.4 Grant Agreement and its Annex 5, Section “Access rights to results and background”, sub-section “Access rights to background and results for implementing the Action”)

None

Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section “Access rights to results and background”, sub-section “Access rights for exploiting the results”)

None

women in follow-up regarding regular breast cancer screening, blood testes etc. Encourage supported self-management follow-up for woman with breast cancer depending on the type of breast cancer and the treatment they have received.

- Advanced Research Information System (ARIS).
- Advanced cloud computing system for demanding and heavy load computational needs by National Infrastructures for Research and Technology (GRNET).
- Harmoni – High-performance Archiving and Retrieval of Medical On-line Imaging Service of long-term archiving and retrieval of imaging data in a cloud environment. Efficient and flexible management of large volumes of imaging data.
- Availability of the data of the Breast Cancer Registry of Greece.
- The Medical School of NKUA has significant

experience in Horizon and R&D projects and is directly engaged in startups and in the development of innovative business models for healthcare.

Cooperation bonds with the “NGO Union of Greek-Ukrainians at Greece” to provide assistance to educational intervention to young women and breast cancer patients targeting on the sensitive group of Ukrainian civilians and/or refugees.

This represents the status at the time of signature of this Consortium Agreement.

PARTY 4

As to **UTILITY NON –PROFIT ENTERPRISE “CENTRAL CITY CLINICAL HOSPITAL OF IVANO-FRANKIVSK COUNCIL**, it is agreed between the Parties that, to the best of their knowledge, [insert the relevant option here].

[Option 1 start]

the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific restrictions and/or conditions for implementation (Article 16.4 Grant Agreement and its Annex 5, Section “Access rights to results and background”, sub-section “Access rights to background and results for implementing the Action”)	Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section “Access rights to results and background”, sub-section “Access rights for exploiting the results”)
Expertise in the implementation of multicenter projects such as the two cross-border projects regarding healthcare issues and the clinical trials		
Expertise in the analysis of data	None	None
Expertise in the communication and engagement of population (awareness raising)	None	None
We will made available the data of the population-based Cancer Registry of Ukraine that will be completely anonymised before sending to the project coordinator (INT	None	None

This represents the status at the time of signature of this Consortium Agreement.

As to **FUNDACIO INSTITUT D'INVESTIGACIO SANITARIA PERE VIRGILI (IISPV)**, it is agreed between the Parties that, to the best of their knowledge, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific restrictions and/or conditions for implementation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the Action")	Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights for exploiting the results")
Expertise, methods and program for selecting and sharing anonymized cancer patient cohort with INT	None	None

This represents the status at the time of signature of this Consortium Agreement.

As to **AZIENDA OSPEDALIERA UNIVERSITARIA POLICLINICO PAOLO GIACCONE DI PALERMO (AOUPPA)**, it is agreed between the Parties that, to the best of their knowledge, [insert the relevant option here].

[Option 1 start]

the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific restrictions and/or conditions for implementation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the Action")	Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights for exploiting the results")
- Epidemiologic competencies on cancer		
- Specific competencies on breast cancer (specialised breast cancer registry)		
- Expertise in BIA-ALCL and limphomas associated to prostheses	None	None
- Expertise in record linkage and interoperability between different data flows		
- Expertise, methods and scripting, in R-language to export breast cancer, BIA-ALCL and limphomas data of the population based Cancer Registry of Palermo and Province, that will made available completely anonymised before sending to the project coordinator (INT)c		
- Expertise in management of Palermo and Province cancer registry data since 2006		
- Reasearch expertise in partecipation to national and international multicentric studies, including high-resolution studies, dealing about carcer epidemiology		

and evaluation of related risk factors or pathways of care (including prevention programs).

- A Windows SQLServer is in place at the Datacenter of AOUPPA to host cancer data population based of the Palermo and Province Cancer Registry. Each operator of Cancer Registry has access to data through a proprietary software (Cancer Registry Tool - CRTool), through a two-step login using user/password and verification SMS. Every password and access grants are changed every 6 and 12 months, respectively. The data exporting procedure, according to the Data Protection Officer and the Privacy Specialists Group and in compliance with GDPR, allow the extraction of the following variables: sex, month and year of birth, age at diagnosis, place of residence at diagnosis (included exclusively when a geographical analysis is required by the protocol study). In addition, when the information on the place of residence is required, this variable is not provided for cities with less of 1000 inhabitants.

This represents the status at the time of signature of this Consortium Agreement.

As to **SALUTE DONNA ONLUS**, it is agreed between the Parties that, to the best of their knowledge, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific restrictions and/or conditions for implementation	Specific restrictions and/or conditions for Exploitation
- Promotion of health education and the prevention of oncological diseases	(Article 16.4 Grant Agreement and its Annex 5, Section “Access rights to results and background”,	(Article 16.4 Grant Agreement and its Annex 5, Section “Access rights to results and background”,
- Information on the importance of the principles which are the basis of correct lifestyles	“Access rights to background and results for implementing the Action”)	sub-section “Access rights for exploiting the results”)
- Support of cancer patients in the treatment process	None	None
- Support of scientific research and the protection of patients' rights.		
- Territorial link with breast cancer patients		

This represents the status at the time of signature of this Consortium Agreement.

As to **CITTADINI PER L'ARIA ONLUS**, it is agreed between the Parties that, to the best of their knowledge, the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific restrictions and/or conditions for implementation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the Action")	Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights for exploiting the results")
- Citizen-Science for an improvement in air quality and health	None	None
- Support of legislative processes at local, national and European level into the framework of air pollution and climate change		
- proposal of effective strategies and solutions for the implementation of air quality improvements		
- dissemination of scientific results of studies on the environmental and health impact		

This represents the status at the time of signature of this Consortium Agreement.

As to **CARPATHIAN INSTITUTE OF ANALYTICS**, it is agreed between the Parties that, to the best of their knowledge, No data, know-how or information of **CARPATHIAN INSTITUTE OF ANALYTICS** is Needed by another Party for implementation of the Project (Article 16.1 and its Annex 5 Grant Agreement, Section “Access rights to results and background”, sub-section “Access rights to background and results for implementing the action”) or Exploitation of that other Party’s Results (Article 16.1 and its Annex 5 Grant Agreement, Section “Access rights to results and background”, sub-section “Access rights for exploiting the results”).

This represents the status at the time of signature of this Consortium Agreement.

As to **UNIVERSITA' DEGLI STUDI DI BRESCIA**, it is agreed between the Parties that, to the best of their knowledge, [insert the relevant option here].

[Option 1 start]

the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific restrictions and/or conditions for implementation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the Action")	Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights for exploiting the results")
Expertise, methods and models to assess population exposure to air pollution		
- Expertise, methods and models to manage and analyse data from the COPERNICUS EU databases	None	None

This represents the status at the time of signature of this Consortium Agreement.

As to **UNIVERSITA' DEGLI STUDI DI PERUGIA**, it is agreed between the Parties that, to the best of their knowledge, [insert the relevant option here].

[Option 1 start]

the following Background is hereby identified and agreed upon for the Project. Specific limitations and/or conditions, shall be as mentioned hereunder:

Describe Background	Specific restrictions and/or conditions for implementation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights to background and results for implementing the Action")	Specific restrictions and/or conditions for Exploitation (Article 16.4 Grant Agreement and its Annex 5, Section "Access rights to results and background", sub-section "Access rights for exploiting the results")
- Expertise, methods and programs to compute breast cancer rates and their geographic distribution, including analysis of geolocalized data;		None
- Expertise, methods and programs to analyze cause-specific mortality in cancer patient cohorts;	None	
- The Open Registry System , an information system to develop population-based Cancer Registries and manage cohort data. Expertise to develop Cancer Registries;		
- Expertise, methods and programs developed and tested to link electronic information sources. Expertise to record linkage, including probabilistic record linkage		

This represents the status at the time of signature of this Consortium Agreement.

Attachment 2: Accession document

ACCESSION

of a new Party to

ELISAH Consortium Agreement,

[OFFICIAL NAME OF THE NEW PARTY AS IDENTIFIED IN THE GRANT AGREEMENT]

hereby consents to become a Party to the Consortium Agreement identified above and accepts all the rights and obligations of a Party starting [date].

FONDAZIONE IRCCS ISTITUTO NAZIONALE DEI TUMORI, in its quality as Coordinator, hereby certifies that the consortium has accepted in the meeting held on [date] the accession of [the name of the new Party] to the consortium starting [date].

This Accession document has been done in 2 originals to be duly signed by the undersigned authorised representatives.

[Date and Place]

[INSERT NAME OF THE NEW PARTY]

Signature(s)

Name(s)

Title(s)

[Date and Place]

FONDAZIONE IRCCS ISTITUTO NAZIONALE DEI TUMORI

Signature(s)

Name(s)

Title(s)

Attachment 3: List of third parties for simplified transfer according to Section 8.3.2.

Attachment 4: Identified entities under the same control according to Section 9.5