Pre-Commercial Procurement (PCP)

Tender Document 4 (TD4)

Framework Agreement

Deadline to submit an offer:

15th September 2021, at 12:00 midday (CET)

Important notice: This Request for Tenders is composed by a set of documents listed hereafter:

- TD1 – Request for Tenders
- TD2 – Challenge Brief
- TD3 – Tender forms
- TD4 – Framework Agreement
- TD5 – Specific contract template for phase 1
- TD6 – Annexes

All documents available on *https://ecare-pcp.eu/* website.

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1 PREAMBLE

This is a framework agreement ("**Agreement**" or "**Framework Agreement**") between the following parties:

1. on the one part,

the "**Lead Procurer**", **AZIENDA SANITARIA LOCALE BENEVENTO** (ASLBN), addressed at Via Oderisio no. 1., Benevento, postcode 82100 in Italy and national registration number: IT01009680628, acting in the name and on behalf of the procurers in the buyers group (together with the Lead Procurer: "**Procurers or Buyers Group**"):

1. **CONSORCI SANITARI INTEGRAL** (CSI), addressed at Avinguda Josep Molins nos. 29-41, L'Hospitalet de Llobregat, postcode 08906, in Spain, and national registration number: ESQ5856254G.

2. **UNIKLINIKUM AACHEN** (UKA), addressed at Pauwels straße 30, postcode 52074 Aachen, Germany and national registration number: DE813100566.

3. **AYUNTAMIENTO DE SANTANDER** (SDR), addressed at Plaza del Ayuntamiento, s/n, Santander, postcode 39002, in Spain, and national registration number: ESP3907500G.

and on the other hand, the "Contractor", [insert details of the contractor],

[*OPTION for joint tenders:* acting in the name and on behalf of the other members of group of tenderers:

1. [insert the details of the members of the group of tenderers]

2.

The members of the group of tenderers are hereafter collectively referred to as "the Contractor" and will be jointly and severally liable vis-à-vis the Lead Procurer for the performance of this Framework Agreement and the Specific Contracts.***]***

The Lead Procurer, Buyers Group and the Contractor(s) shall be referred to together as "**Parties**", unless otherwise specified.

By signing this Agreement, the parties agree to implement the pre-commercial procurement in accordance with the Agreement and all the obligations it sets out.

The Agreement is composed of:

- Preamble
- Terms and Conditions
- Annex 1: TD1 – Request for Tenders
- Annex 2: TD2 –Challenge Brief
- Annex 3: Contractor offer, including technical and financial offer
- Annex 4: TD5 – Specific phase contract for phase 1 (signed)

2 TERMS AND CONDITIONS

2.1 Article 1— Definitions

"**Award criteria**" means, for each Phase, the criteria used to identify the most advantageous tender as detailed in the PCP request for tender.

"**Background IPR or Background**" means any data, know-how or information — whatever its form or nature (tangible or intangible), including any attached rights such as intellectual property rights ('background IPR') — that is held prior to the signing of the Framework Agreement, and identified by the parties involved in the PCP as background and is needed to implement the PCP or exploit the results of the PCP.

"Call back provisions" are incentives to pursue commercialization of the new solutions developed during the PCP process. IPR call-back provision provides that if an R&D provider that participated in the PCP abuses the IPR that it generated in the PCP (Foreground IPR) against the public interest or fails to commercialize the R&D results that it generated in the PCP within a certain timeframe defined in the PCP contract, the ownership of Foreground IPR shall revert to the public procurer.

"Call-off" means the procedure organized by the Lead Procurer to select the successful Contractor(s) who will participate in the next Phase of the Project under the Framework Agreement.

"Challenge brief" means the part of the Annex to the request for tender, explaining the background to the underlying need behind, and the aim and scope of the Project including Phase 1, and the corresponding subsequently issued documents for Phase 2 and Phase 3.

"Commencement Date" upon signature of the last party (Lead Procurer)

"Completion Date" means the date for the completion of an individual Phase or for the Project as a whole set out in Article.

"Contractor" means the person, firm, entity or company with whom the Lead Procurer enters into this Framework Agreement or a Work Order as designated on the first page of this Framework Agreement.

"Contractor's Representative" means a person legally authorized to represent the Contractor in respect of this Framework Agreement and who shall have the authority contractually to bind the Contractor in respect of all matters relating to the Project.

"Confidential information" means information that falls within the types of information which has been designated as confidential or an equivalent designation (e.g. classified, restricted, secret) by either Party or that ought to be considered as confidential by a reasonable business person, regardless of whether or not itis designated as confidential, however it is conveyed or on whatever media it is stored, including information which relates to the business affairs, properties, assets, trading practices, goods, services, developments, trade secrets, Intellectual Property rights, know-how, personnel, customers and suppliers of either Party, all personal data and sensitive personal data within the meaning of the Data Protection regulation , and other commercially sensitive information.

"Days" means calendar days save where the context otherwise requires.

"Data" means information generated by the Project and collected and/or used for the purposes of the Research, which can be processed manually, electronically or by other means.

"Default" means any breach by a Party to this Framework Agreement of its obligations under this Framework Agreement (including, without limitation, a fundamental breach or breach of a fundamental term).

"Deliverable(s)" means any document, product or element of any kind that are provided by the Contractor as part of its obligations within this Framework Agreement and identified in the "TD1 – Request for Tenders" document joined to this Agreement.

"End of Phase Report" means a report in written form to be submitted by the Contractor awarded a Work Order for that particular Phase to the Group of Procurers after each completed Phase of the Project, containing all information that is required in the End of Phase Report Form.

"Failure to commercially exploit results" means not marketing a commercial application of the results (directly or indirectly, through a subcontractor or licensee).

"Fair and reasonable condition" means appropriate conditions, including possible financial terms or royalty free conditions, taking into account the specific circumstances of the request for access, including in particular 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.

"Framework Agreement or Agreement" means this agreement containing the terms and conditions with respect to the execution of the eCare PCP covering all three Phases and all schedules and articles to those articles, as well as any documents referenced in or annexed to each of those Articles or Schedules, and in any event, including the Tender Documents.

"Fraud" means any offence under Laws creating offences in respect of fraudulent acts, fraudulent misrepresentation, and any other intentional deception, whether or not creating injury to the other Party, including deception deliberately practiced in order to secure unfair or unlawful gain.

"Foreground IPR or Foreground" or **"Results"** means any tangible or intangible output, such as data, knowledge or information, that is generated in the PCP, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights ('attached IPRs' or' IPRs attached to the results').

"Functional specifications" means the specifications set out in the Functional Specifications section in the eCare Challenge brief document (TD2) defining the required characteristics and set of functions of the outcome of the Project.

"Generated in the PCP" means in activities described in the PCP Framework Agreement and specific contracts.

"Intellectual property rights (IPR)" means Intellectual Property Rights refers to any and all patent rights (including but not limited to divisionals, extensions, improvement patents, supplementary protection certificates), inventions (whether or not patentable or capable of registration), trademarks, copyrights(including moral rights), topography rights, design rights, rights in and to databases (including the right to prevent the extraction or reutilisation of information from a database), trade secrets and rights of confidence, know-how, trade or business names, domain names, whether or not any of them are registered or registerable and including applications for registration, renewal or extension of any of them, and another rights or forms of protection of a similar nature which have an equivalent or similar effect to any of them which may now or in the future exist anywhere in the world.

"License" refers to a right given by an IPR owner to another person to use such rights (**"Licensee"**) in exchange for an agreed payment (fee or royalty). License can be exclusive or non-exclusive.

An **"Exclusive License"** means that no person or company other than the named Licensee can exploit the relevant intellectual property rights. A **"Non-Exclusive License"** grants to the Licensee

the right to use the intellectual property but means that the licensor remains free to exploit the same intellectual property and to allow any number of other Licensees to also exploit the same intellectual property.

"Month" means calendar month.

"Not generated in the PCP" means not generated in activities described in the PCP Framework Agreement or specific contracts.

"Phase" means an individual and separate part of the Project, where Phase 1 comprises feasibility study, Phase 2 comprises prototyping, and Phase 3 comprises original development of a limited volume of first products or Services to be piloted in procurers' sites in the form of a test series for field-testing purposes.

"PCP" means Pre-Commercial Procurement as defined by the European Commission Communication COM (2007) 799 final, 14.12.2007.

"Preferred Partner" means entities that are neither Lead Procurer, nor members of the Buyers Group, nor third parties providing in-kind contributions to the PCP, but that have a special interest in closely following the PCP. They may be beneficiaries/linked third parties involved in the EU grant (e.g. those involved in related additional networking activities') or they may be other entities that are not involved in the EU grant (e.g. other procurers on the market that are potential buyers for the solutions and have expressed an interest in closely following the PCP).

The preferred partners will be informed of all aspects of the eCare PCP and will be afforded access to all information concerning the PCP as they will take part of the different evaluation and monitoring committees. However, they will not assume to results or IPRs.

"Personal data" has the meaning given to it in the Data Protection Regulation.

"Price" means the total Price (excluding VAT) agreed between the Parties for each Phase of the Project, to be paid by the Lead Procurer to the Tenderer for each such Phase, subject to the terms and conditions of this Agreement.

"Research" means the scope of work (Research and development Services) specified in Article 4.

"Results (i.e. Foreground)" means any tangible or intangible output, such as data, knowledge or information, that is generated in the PCP, whatever its form or nature, whether or not it can be protected, as well as any rights attached to it, including intellectual property rights ('attached IPRs' or 'IPRs attached to the results').

"Pre-existing rights (i.e. Background IPR or Background)" means any data, know-how or information — whatever its form or nature (tangible or intangible), including any attached rights such as intellectual property rights ('Background IPR') — that is held prior to the signing of the Framework Agreement, and identified by the parties involved in the PCP as background and is needed to implement the PCP or exploit the results of the PCP.

"Royalties" are regular payments to the licensor, which reflect the use of the technology by the Licensee.

"Services" mean the Services being provided by the Tenderer in fulfilment of this Framework Agreement and any work order issued through it.

"Sideground IPR or Sideground" means any data, know-how or information — whatever its form or nature (tangible or intangible), including any attached rights such as intellectual property rights ('Sideground IPR') — that is generated during the timespan of the PCP but not in the PCP and is needed to implement the PCP or to exploit the results of the PCP.

"Specific phase contract" means the specific contract for each Phase of the R&D Services under the Framework Agreement, to be concluded between the Lead Procurer and the Contractor in addition to the Framework Agreement.

"Sub-contract" any contract or agreement between the tenderer and any Third Party whereby that Third Party agrees to provide Services to the Tenderer to enable or assist the Tenderer to provide the Services or any part thereof to the Buyers Group.

"Sub License" refers to rights to use the License that is given to a Third Party. The term "Third Party" is used to describe a legal entity which does not participate to the project that results are granted under a License.

"Tender document" means all documents issued or published by the Lead Procurer as part of the PCP process and made available on the eCare website, including without limitation - the TED (Tenders Electronic Daily) Notice, the Challenge brief as the document containing the Functional Specification, the Framework Agreement, any schedules, annexes or attachments there to.

"Tenderer" means the person, firm or company with whom the Lead Procurer enters into this Framework Agreement or a work order.

"Third Party" means entities that are neither the Lead Procurer nor members of the Buyers Group, nor preferred partners but that participate in the EU grant as third parties giving in-kind contributions to the PCP.

"VAT" means value added taxes.

"Work Order" means the contract documents to be issued to the Contractor that successfully tenders to carry out the work comprised in Phases 1, 2 and 3. The Work Order for Phase 1, 2 and 3 will be issued by the Group of Procurers separately.

"Sub License" refers to rights to use the License that is given to a Third Party. The term "Third Party" is used to describe a legal entity which does not participate to the project that results are granted under a License.

2.2 Article 2— Subject of the agreement

This Framework Agreement defines the general terms and conditions for the implementation of the PCP procurement of R&D services set out in Article 4 and for the Specific Contracts that will be awarded for each of the 3 PCP phases.

2.3 Article 3— Duration

The framework agreement starts with the signature of the last party and ends with acceptance of all Deliverables, until terminated in accordance with Article 21 or after complete discharge of all obligations both under this agreement and under any Specific phase contract tendered for by the Contractor.

The period of execution of the tasks may be extended only with the express written agreement of the parties before the expiration of the period for execution of the tasks.

2.4 Article 4— R&D services to be provided

The Contractor shall provide the R&D services (tasks, deliverables and milestones) to develop solutions to tackle the challenge set out in the tender and the Specific Contracts.

2.5 Article 5— Pricing, payment and accounting

5.1 The price for the R&D services to be implemented for each PCP phase will be set out in the specific contracts.

The prices shall be based on the binding unit prices in the tender and the following price conditions:

- The new units/unit prices are added to phase 2 or 3 offers, they shall become binding for the remaining phases
- The total amount to be paid by the Lead Procurer shall not exceed the relevant amount detailed in the Phase Contracts Phase by Phase by phase.

5.2 The payment and invoicing conditions are specified in section 5.5 'Contract implementation of the 'TD1 Request for Tender' document.

5.3 Payment is made by the Lead Procurer per phase following the award of the Phase contract and according to the payment stages defined in the PCP call for tender request schedule. Invoices are to be submitted in Euros and payments are made in Euros. The Contractor state the Price with and without VAT. The Price at the prevailing VAT rate as applicable in Italy (currently is 22%). Any other (including sales, service, use, lease, personal property, consumption, excise, withholding, or property) taxes, levies, tariffs and duties associated with the Contractor's performance of the Framework Agreement or which may be levied on the Price shall be the Contractor's responsibility. Payment to third parties employed or hired by the Contractor if any shall remain in the responsibility of the Contractor who shall ensure that such payment is made promptly.

5.4 The Lead Procurer may request at any time evidence as may reasonably be required that the Contractor has used the amounts paid in accordance with the Framework Agreement provisions. The Contractor shall maintain proper financial records relating to the Project at all times during the Project Period and for a period of six years after the end of the Project Period.

2.6 Article 6— Participation of preferred partners ant third parties providing in-kind contributions

The Preferred Partners are entities that are neither the Lead Procurer, nor members of the Buyers Group, nor Third parties providing in-kind contributions to the PCP, but that have a special interest in closely following the PCP. They may be beneficiaries/linked third parties involved in the EU grant (e.g. those involved in 'related additional networking activities') or they may be other entities that are not involved in the EU grant (e.g. other procurers on the market that are potential buyers for the solutions and have expressed an interest in closely following the PCP).

The preferred partners will be informed of all aspects of the eCare PCP and will be afforded access to all information concerning the PCP as they will take part of the different evaluation and monitoring committees. However, they will not assume to results or IPRs.

The table below contains the preferred partners and their involvement:

Preferred partner/third parties	PCP involvement
SCIENCE & INNOVATION LINK OFFICE (SILO), c/Claudio Coello, 52, 1ª planta, 28001 Madrid, Spain, www.silocompany.com	PCP consultants

SANTA CASA DA MISERICORDIA DA AMADORA (SCMA) Estrada da Portela, 2610-143 Amadora, Portugal, www.misericordia-amadora.pt	PCP Scientific and Technical Coordinators
TICBIOMED Edificio CEEIM. Campus de Espinardo, 7 30100 Murcia, Spain https://ticbiomed.org/	PCP consultant
JAGGAER España Avenida de Manoteras 20, Edificio Tokyo, 1ª planta, 28050 Madrid, Spain www.jaggaer.com	PCP platform

2.7 Article 7— Ownership of the results (Foreground), pre-existing rights (Background) and Sideground (including intellectual and industrial property rights)

7.1 Pre-existing rights (Background) and Sideground (including intellectual and industrial property rights).

The ownership of pre-existing rights will remain unchanged. The ownership of Sideground IPR remains the property of the party who generated it.

The Parties grant each other to each other's pre-existing rights and Sideground for carrying out the tasks assigned to them in the PCP, for exploitation of results generated in the PCP and for using the results for their own purposes.

Parties must inform each other about the generation of changes in Pre-existing rights and Sideground within **fifteen (15) Days** from the generation of the change and whether they rely on Pre-existing rights for each phases of the PCP.

The Contractors introducing Background must within **fifteen (15) Days** of the signing of the PCP Framework Agreement provide the Lead Procurer with a list of the pre-existing rights it holds and/or has access.

In order to be able to distinguish clearly between results and Pre-existing rights and to establish which Pre-existing rights are held by whom:

- tenderers are requested to list the Pre-existing rights for their proposed solution in their offers
- Procurers and Contractors will establish a list of respective pre-existing rights to be used — before the start of the contract.

The Parties grant each other to each other's pre-existing rights and Sideground for carrying out the tasks assigned to them in the PCP, for exploitation of results generated in the PCP and for using the results for their own purposes.

The Contractors are required to give a declaration of Background IPR in the technical offer.

The Lead Procurer and other members of the Buyers Group, Preferred partners and Third parties and providing in-kind contributions to the PCP do not hold any Pre-existing rights relevant to the PCP contracts.

7.2 Right and obligations related to the results (Foreground)

Each Contractor that generates results owns the attached IPRs and will own results that are not IPRs.

Each Contractor is responsible for the management and protection of its IPRs and bears the costs associated with this.

The Lead Procurer and the Buyers Group have the right to monitor the management of the IPRs.

The Contractors must inform the Buyers Group (via the Lead Procurer) of results that can be exploited, regardless of whether they can be protected or not, within **ninety (90) Days** from when they are generated. The information submitted to the Lead Procurer must include information about the contents of the results, the confirmation by the Contractor to protect them and the planned timing for protection.

If a Contractor does not seek protection for results that should be protected, the Buyers Group has the right to request that the results are transferred to them.

The Contractors grant to the members of the Procurers irrevocable, royalty-free, non-exclusive, worldwide access rights to use the results, for their own purposes until their expiry date.

For results that are an implementation of design specifications into simulations, prototypes, demonstrators or first products /services, those access rights are limited to duration of **five (5) years** and to the following purposes for fulfilling the R&D objectives of the PCP: develop and test disruptive digital solutions for the prevention and comprehensive management of frailty of older adults.

The ownership of the IPRs will be subject to the following:

- The members of the Buyers Group have the right to:
  - Access results, on a royalty-free basis, for their own use.
  - Grant (or to require the Contractors to grant) non-exclusive licenses to third parties to exploit the results under fair and reasonable conditions (without the right to sub-license).
- The Contractors may grant non-exclusive licenses to Third parties allowing them to exploit the results (or otherwise give the right to exploit them) — unless this impedes the access rights of the Procurers.
- The Contractors will have to transfer ownership of the IPRs to the members of the Procurers if they fail to comply with their obligation to commercially exploit the results or use the results to the detriment of the public interest, including security interests in the conditions of Article 14.
- The Contractors may transfer ownership of their Results — unless this is prohibited (or restricted) by the security obligations and provided that they ensure that their obligations (in respect of the results) apply to the new owner and that this new owner is obliged to pass them on in any subsequent transfer.

  In that situation, the Contractor must give them at least **ninety (90) Days** advance notice of its intention to transfer ownership of the results and that this notification must include sufficient information on the new owner to enable the members of the Buyers Group to assess the effects on their access rights. Any member of the Buyers Group may object within **forty-five (45) Days** of receiving notification, if it can show that the transfer would adversely affect its access rights. Should an objection be raised, the transfer may not take place until agreement has been reached between the parties concerned.

The Tenderers and the Contractors are required to set both price with the acquisition of IPR and price without the acquisition of IPR.

To ensure that a fair market price is offered, Tenderers must state two prices:

- The hypothetical price that they would have quoted if all IPR, including the ownership of Results under the PCP, would have been fully retained by the Buyers Group and Tenderers would not have the possibility to exploit the Results (the "**Virtual Price**") or
- the price that takes into account the fact that they keep ownership of the IPR attached to the Results under PCP, in accordance with the provisions of the contracts, and that they can exploit these Results (the "**Actual Price**").

7.3 Third Parties Rights and Obligations

Ownership of the pre-existing IPR remains with the Third Party that provides it. Ownership of Sideground IPR remains the property of the Party who generated it. The Contractors must ensure that their Subcontractors comply with their obligations under the Framework Agreement and Specific Contracts if they use Subcontractors. The Contractor shall obtain all necessary rights (transfer, licenses or other) from Subcontractors. If the right of use is subject to rights of a Third Party, the Contractor shall ensure that it obtains the necessary approval from the Third parties concerned). The Parties expressly acknowledge that Third Parties to the Buyers Group shall have certain rights on the Intellectual Property Rights and on the Results as a Third Party in accordance with the terms and conditions of this article.

7.4 Call back IPR rights

If the Contractor make a Failure to commercially exploit the results as described in Article 11— Commercial exploitation of results (or uses the results to the detriment of the public interest, *including security interests*), the Buyer's Group has the right to require that ownership of the results be transferred to them.

In this case, the Contractor shall be required to give the source code and designs to the Buyers Group with all its documentation.

2.8 Article 8— Staff appointment provision

All staff providing Services in connection with this Framework Agreement shall be bound by the same terms and conditions of service which are normally applicable to the Contractor's staff, as well as those applicable to the Contractor's Staff hereunder.

The Lead Procurer has a commitment to equal opportunities which the Contractor must adhere to. The Contractor must not discriminate on the grounds of gender, race, disability, sexuality, age, religion or otherwise or otherwise allow any applicable employment Law to be breached.

The Contractor will ensure that the terms and conditions of staff employed or hired to provide services in connection with this Framework Agreement contain provisions in respect of the protection of Intellectual Property compatible with the terms of this Framework Agreement, as well as such other terms and conditions applicable to Contractor's staff hereunder.

The Contractor shall ensure that any individuals employed by or having a contract for services with the Contractor relating to this Framework Agreement comply with any of the Lead Procurer's rules and regulations applicable to such services provision and Contractor's staff.

2.9 Article 9— Confidentiality

9.1 The parties shall keep confidential any data, documents or other material (in any form) that is identified as confidential at the time it is disclosed. This applies during the implementation of the Framework Agreement and Specific phase contracts and up to **five (5) years** after the end of the

Framework Agreement. An extension of the confidentiality will be made via an amendment if the H2020 Grant Agreement that binds the Procurers with the European Commission is extended.

If information has been identified as confidential only orally, it shall be considered to be confidential only if this is confirmed in writing within **fifteen (15) Days** of the oral disclosure.

9.2 The parties may disclose confidential information to their staff or to third parties involved in the PCP implementation only if:

(a) they need to be aware of this information in order to implement the PCP activities under the Framework Agreement and Specific Contracts; and

(b) they are bound by an obligation of confidentiality.

9.3 The confidentiality obligations cease to apply if:

(a) the disclosing party agrees to release the other party from the obligation;

(b) the information was already known by the recipient or is given to him without obligation of confidentiality by a third party that was not bound by any obligation of confidentiality;

(c) the recipient proves that the information was produced without the use of confidential information;

(d) the information becomes generally and publicly available, without breaching any confidentiality obligation; or

(e) the disclosure of the information is required by EU or national law.

This does not change the security obligations, which still apply. Stricter confidentiality obligations apply for information that is EU-classified or subject to a security recommendation.

2.10 Article 10— Promotion, publicity and communication

10.1 The Contractor shall undertake communication activities to create publicity about its participation to the procurement, and to promote the objectives and the results of the R&D carried out under the PCP.

All communication activities shall comply with the applicable confidentiality and security restrictions.

During the implementation of the contract and for a period of **three (3) years** after the end of the contract, the Contractor shall inform the Lead Procurer **thirty (30) Days** in advance of any (written or oral) publication or any other type of communication (in any media or form) relating to the services or results. Information on communication activities expected to have a major media impact shall be provided sufficiently in advance to allow the Lead Procurer to inform the EU.

All communication activities *(including in electronic form and via social media)* and infrastructure, equipment and major results financed by the PCP shall display the EU emblem and include the following text:

- for communication activities: 'This is part of the 856960-eCare PCP project that has received funding from the European Union's Horizon 2020 Research and Innovation Programme';
- for infrastructure, equipment and major results: 'This digital solution for frailty is part of the 856960-eCare PCP project that has received funding from the European Union's Horizon 2020 Research and Innovation Programme'

When displayed together with another logo, the EU emblem shall have appropriate prominence. The Contractor may use the EU emblem without first obtaining approval from the EU. This does not, however, give the Contractor the right to exclusive use. Moreover, the Contractor may not appropriate the EU emblem or any similar trademark or logo, either by registration or by any other means.

All communication activities shall indicate that they reflect only the author's views.

10.2 Procurers may use, for the purposes of communication and publicity, all information relating to the PCP, documents *(notably summaries)* and Deliverables, and any other material *(such as pictures or audio-visual material)* from the Contractor *(including in electronic form)*.

The Procurers may, in particular, publish the names of the participating Contractor and its project abstracts, the summaries of the main results from the R&D and the lessons learnt during the PCP *(e.g. relating to the feasibility of the different approaches to meeting the procurers' requirements that were explored, and the lessons learnt for potential future use of the solutions proposed)*.

This does not change the confidentiality obligations under Article 9.

Moreover, before publishing this information, the Procurers shall consult the Contractor, in order to avoid harm to legitimate business interests *(e.g. regarding aspects of the solutions that could be IPR-protected)* or distortion of competition.

10.3 The EU may use, for the purposes of communication and publicity, information relating to the PCP, documents *(notably summaries)* and Deliverables, and any other material *(such as pictures or audiovisual material)* from the Contractor *(including in electronic form)*.

If the EU's use of these materials, documents or information would risk compromising legitimate interests, the Contractor may, however, ask the Lead Procurer to request the EU not to use it.

The right to use the Contractor's materials, documents and information includes:

(a) use for its own purposes *(in particular, making them available to staff working for the EU (including for the European Commission, EU executive agencies, other EU institutions, bodies, offices or agencies) or for EU Member State institutions or bodies; and copying or reproducing them in whole or in part, in unlimited numbers)*;

(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 for the purposes of communication and publicity *(including shortening, summarising, inserting other elements (such as meta-data, legends, other graphic, visual, audio or text elements), extracting parts (e.g. audio or video files), dividing into parts or using in a compilation)*;

(d) translation;

(e) giving access in response to individual requests made under EU Regulation No 1049/2001[1], without the right to reproduce or exploit;

(f) storage in paper, electronic or other form;

(g) archiving, in line with applicable rules on document management, and

(h) authorising third parties to act on its behalf or sub-licensing the modes of use set out in points (b), (c), (d) and (f) to third parties if needed for the purposes of communication and publicity.

If the right of use is subject to rights of a third party *(including the Contractor's staff)*, the Contractor shall ensure that it obtains the necessary approval from the third parties concerned.

2.11 Article 11— Commercial exploitation of results

The Contractor shall, for at least **four (4) years** after the end of the Framework Agreement and the Specific Contracts, take measures to ensure that its results are exploited commercially (directly or indirectly, in particular through transfer or licensing).

2.12 Article 12— Conflicts of interest

12.1 The Contractor shall take all measures necessary to prevent a situation arising where the impartial and objective implementation of the Framework Agreement or a Specific Contract is compromised for reasons involving economic interests, political or national affinity, family, personal life or any other shared interest.

[1] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43.

The Contractor shall also take all measures necessary to prevent a situation in which its (previous or ongoing) professional activities affect the impartial and objective implementation of the Framework Agreement or a Specific Contract.

12.2 The Contractor shall notify the Lead Procurer without delay of any situation constituting or likely to lead to a conflict of interest *(including changes of ownership)* and shall immediately take all steps necessary to rectify this situation.

12.3 The Lead Procurer may instruct the Contractor to take specific measures to remedy the situation.

2.13 Article 13— Ethics and research integrity

13.1 The Contractor shall carry out the tasks assigned to it in the Framework Agreement and Specific Contracts in compliance with:

(a) ethical principles *(including the highest standards of research integrity)* and

(b) applicable international, EU and national law.

The Contractor may not:

- carry out activities in a country outside the EU, if they are prohibited in all EU Member States or
- destroy human embryos.

The Contractor may not carry out activities whose aim is to:

(a) carry out human cloning for reproductive purposes;

(b) modify the genetic heritage of human beings in such a way as could make such changes heritable (with the exception of research relating to cancer treatment of the gonads) or

(c) 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*.

The Contractor may not carry out activities that do not focus exclusively on civil applications.

The Contractor shall 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 essential 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;
- **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

This means that beneficiaries must ensure that persons carrying out research tasks follow the good research practices and refrain from the research integrity violations described in this Code.

13.2 Before starting any activity that raises an ethical issue, the Contractor shall submit to the Lead Procurer a copy of:

(a) any ethics committee opinion required under national law and

[2] The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011. http://www.esf.org/fileadmin/Public_documents/Publications/Code_Conduct_ResearchIntegrity.pdf

(b) any notification or authorisation for activities raising ethical issues required under national law.

2.14 Article 14— Security-related obligations

Non-applicable.

2.15 Article 15— Processing of personal data

The processing of personal data connected to the management and the execution of contracts, relating to the eCare Project, is guaranteed pursuant to EU Regulation 2016/679.

The Personal Data Controllers, for the purposes of the General Data Protection Regulation (GDPR) are the Procurers.

The Contractor is the Data Processors which process personal data on behalf of the Controllers, respects data subjects right to privacy and is committed to protecting the privacy of users.

The Contractor shall process personal data in compliance with the applicable EU and national law on data protection *(including as relates to authorisations and notification requirements)*.

The Contractor is committed to protect personal data and to respect data subject's privacy.

The Contractor must stipulate a Data Protection Agreement that is binding with regard to the Controllers and that sets out the subject-matter and duration of the processing, the nature and purpose of the processing, the type of personal data and categories of data subjects and the adequate technical and organizational measures so that the processing meets the requirements of EU Regulation 2016/679.

Specifically, pursuant to article 28 of EU Regulation 2016/679, the Contractor must declare that the processor:

- processes the personal data only on documented instructions from the controller,

- comply with the indications and provisions of EU Regulation 2016/679, in particular in relation to data protection by default and by design;

- adopt the appropriate technical and organizational measures to guarantee the right of access, rectification, cancellation and portability of the personal data processed;

- process data lawfully, fairly and in full compliance with current legislation (national and European) on data protection;

- ensures that persons authorised to process the personal data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality;

- adopt, according to its internal organization, technical and organizational measures suitable to guarantee a level of safety adequate to the risk, within the terms referred to in Article 32 of EU Regulation 2016/679, the measures adopted must be communicated and shared with the Lead Procurer;

- makes available to the controller all information necessary to demonstrate compliance with the obligations laid down in this Article and allow for and contribute to audits, including inspections, conducted by the controller.

2.16 Article 16— Obligation to provide information and keep records

16.1 The Contractor must, at any time during the implementation of the Framework Agreement and Specific Contracts or afterwards, provide any information requested by the procurers in relation to the Agreement or Contracts.

16.2 The Contractor must keep, for a period of up to **five (5) years** after the end of the Framework Agreement and Specific Contracts, records and other supporting documentation relating to their implementation.

This obligation includes records and other supporting documentation on scientific and technical implementation (in line with the accepted standards in the field) and on the price charged and the costs incurred by the Contractor.

The Contractor must keep the original documents. Digital and digitalised documents are considered originals if they are authorised under national law.

Should there be ongoing checks, reviews, audits, investigations, litigation or other pursuits of claims *(including claims by a third party against the procurers)*, the Contractor must keep all records and other supporting documentation until the end of these procedures.

2.17 Article 17— EU checks, reviews, audits and investigations

Should the EU *(including the European Court of Auditors or the European Anti-Fraud Office (OLAF))* decide to carry out a check, review, audit or investigation, the Contractor must make available all information, records and other supporting documents relating to the implementation of the Framework Agreement and Specific Contracts.

Should there be an on-the-spot visit, the Contractor must allow access to its premises and must ensure that the information requested is readily available.

2.18 Article 18— EU impact evaluation

Should the EU carry out an impact evaluation (of its grant to the procurers), the Contractor must make available all information, records and other supporting documents relating to the implementation of the Framework Agreement and Specific Contracts.

2.19 Article 19— Monitoring and reporting

19.1 During each Phase, the implementation by the Contractor of the R&D Services will be monitored periodically and reviewed against the expected Deliverables for that Phase.

19.2 The Lead Procurer may request that it or any party designated by it witnesses any tests or measurements to be performed by the Contractor or his subcontractor(s), and the Contractor shall give the Lead Procurer reasonable prior notice in writing of the date(s) and place(s) of such tests and measurements. In the event of failure by the Contractor to give such notice, the Lead Procurer shall be entitled to demand at any time that such tests and measurements be repeated at the expense of the Contractor, who shall be liable for any delay resulting therefrom.

19.3 The monitoring team will provide regular feedback to the Contractor after meetings or visits.

2.20 Article 20— Breach of contract

20.1 The Contractor must compensate the Lead Procurer and the Procurers if they are held liable by the EU for damage it sustained as a result of the implementation of the Framework Agreement or a specific contract or because it was not implemented properly.

20.2 The EU cannot be held liable for any damage caused to the Contractor or caused by the Contractor in connection with the implementation of the Framework Agreement or a Specific contract.

20.3 The Contractor shall indemnify and hold the Lead Procurer and the other Procurers free and harmless against loss and damage, including personal injury and death and related legal costs, arising from or in connection with its acts or omissions in relation to the Framework Agreement.

20.4 The Contractor's indemnity obligations under Article 20.3 shall be without prejudice to any other rights and remedies available to the Lead Procurer, including the right to terminate the Framework Agreement or any Specific Contract.

20.5 If the Contractor fails to deliver Results or other Deliverables compliant with the Framework Agreement, to the Lead Procurer shall give the Contractor the opportunity to amend, within an appropriate period. If to the Lead Procurer is still not satisfied after the expiry of such cure period it may (at its discretion): a) Withhold payments until satisfactory delivery; b) Cancel payments; c) Exclude the Contractor from the any subsequent Phases on the basis that the Contractor has not successfully completed the present Phase; and/or d) Terminate the Framework Agreement and/or any Specific Contract (see hereunder).

20.6 Acceptance by The Lead Procurer of any Deliverable or Result shall not limit the Contractor from liability in respect of such Deliverable or Result subsequently being discovered to be non-compliant with the requirements of the Framework Agreement, nor for any loss or damage which may arise as a result.

20.7 Except in case of infringement of Applicable Laws, gross negligence or wilful misconduct on its part, a Party shall not be liable to the other for loss of the Framework Agreement, loss of income or revenue, loss of customers or reputation or any other indirect or consequential loss or damage.

20.8 Except in case of liability pursuant to Article 7 (IPR), infringement of Applicable Laws, gross negligence or wilful misconduct on its part, each Party's total liability in relation to the Framework Agreement shall be limited to the total value of the Specific Contract under the application of which the act or omission giving rise to the liability took place.

20.9 The Contractor shall take out insurance to cover its liability under the Framework Agreement and shall provide evidence of his insurance cover if so required by the Lead Procurer. The Contractor shall ensure that the same applies to its subcontractors involved in activities under the Framework Agreement. Any such insurance shall be maintained for the duration of the Framework Agreement and for a minimum of **four (4) years** thereafter.

2.21 Article 21— Termination clauses and consequences of termination

21.1 The Lead Procurer shall be entitled to terminate this agreement at any time, including during the course of the Project, by notice in writing to the Contractor if:

a) the Contractor is in breach of any of its confidentiality obligations
b) the Contractor is in breach of any of its conflicts of interest obligations
c) the Contractor is in breach of any of its ethics and research integrity obligations
d) the Contractor is in breach of any of its data protection obligations
e) the Contractor undergoes any change in legal or beneficial ownership or control;
f) the Lead Procurer does not consent to the replacement of a Contractor Group member
g) the Contractor does not comply with any requirement set out in the Request for Tenders;
h) any approvals, consents or licenses required under this agreement or to enable the Services to be carried out lawfully are not granted, or lapse, terminate or otherwise cease to be of effect during the term of this agreement;
i) the Contractor fails to meet any Expected Outcome within **ten (10) Days** of the date by which the relevant Expected Outcome was to be achieved, or repeatedly fails over a period of **three (3) consecutive months** to achieve Expected Outcomes by the date(s) on which those Expected Outcomes were to have been achieved.

The assignments and/or licenses granted under the Framework Agreement by the Contractor to the Authority, any Buyers Group member or any other Third Party shall continue notwithstanding any expiry or termination of this agreement.

21.2 Unless expressly stated to the contrary, the service of a notice to terminate this agreement shall operate as a notice to terminate any Specific Contract then in force.

Within **thirty (30) Days** of the date of termination or expiry of this agreement, the Contractor shall return or destroy at the request of the Authority any Personal Data received from or on behalf of the Lead Procurer and/or the Buyers Group, or Confidential Information belonging to the Lead Procurer and/or the Buyers Group, either in its then current format or in a format nominated by the Lead Procurer.

Termination or expiry of this agreement shall be without prejudice to any rights, remedies or obligations of either Party accrued under this agreement before termination or expiry.

2.22 Article 22— Amendments

The Lead Procurer and the Contractor may agree to amend the Framework Agreement provided that:

All Amendment to the Framework Agreement shall be in writing. No Amendment shall have the purpose or the effect of making changes to the contracts which might call into question the decision awarding the contracts or result in unequal treatment of tenderers.

If at any time it appears likely that any provision of this Framework Agreement, in particular the PCP, needs to be amended, the Contractor shall immediately inform the Lead Procurer in writing requesting an Amendment to this Framework Agreement, giving full details of the justification for the request and giving proposals for the Amendment to this Framework Agreement at no additional cost to the Lead Procurer. Upon receipt of such a request, the Lead Procurer may:

- agree to vary the Framework Agreement;
- vary the Project in a manner which the Contractor agrees it can be carried out within the Project Period and the Price with regard to the relevant Phases;
- refuse the request and require the continuation of the Project in accordance with the Framework Agreement; or
- give notice of termination in accordance with Article 21 about termination. Any Amendment to this Framework Agreement shall reach agreement between the Parties.

2.23 Article 23— Interpretation

The interpretation and construction of this Framework Agreement shall be subject to the following provisions:

- The Framework Agreement terms have precedent over those in annexes;
- the terms set out in the request for tender have precedent over the Contractor's tender;
- a reference to any Act, Law, statute, enactment, order, regulation or other similar instrument shall be construed as a reference to the Act, Law, statute, enactment, order, regulation or instrument as subsequently amended or re-enacted (regardless of whether or not expressly so stipulated);
- the headings in this Framework Agreement are for ease of reference only and shall not affect its interpretation or construction;
- references to conditions are references to conditions in the Article of this Framework Agreement in which they appear, unless otherwise stated;
- where the context allows, references to any gender include the other gender and the neuter, and the singular includes the plural and vice versa;
- "including" means "including without limitation" (with related words being construed accordingly), in particular means "in particular but without limitation" and other general words shall not be given a restrictive interpretation by reason of their being.

2.24 Article 24— Applicable law and dispute settlement

24.1 Any legal claim, petition or application for judicial review, with regard to the eCare PCP Procedure, whether before civil law courts or administrative courts, shall be made before the Italian jurisdiction. By submitting a Bid, the Bidder accepts the exclusive jurisdiction of Italian courts.

Decisions taken with regard to the selection of bidders, awarding them with Phases 1, 2 or 3 or excluding them from the eCare PCP Procedure should be challenged by means of an administrative remedy before the Benevento administrative Court.

Any dispute or claim arising out of or in connection with the execution of the Framework Agreement or of the Phases contracts entered into between the Buyers Group and the Contractor, shall be heard by Benevento administrative Court.

24.2 This Framework Agreement shall be considered as a contract made in Italy and be construed in accordance with and governed by Italian Law, and no effect shall be given to any other choice-of-law or conflicts-of-laws rules or provisions.

24.3 Any dispute between the Parties arising out of or in connection with this Framework Agreement shall in the first instance be referred to the Contractor's Representative and the Lead Procurer's Representative for resolution. The Parties agree to work together in good faith to reach an agreed settlement of any such dispute. If within **fourteen (14) Days** of being referred to both the above Representatives, the dispute has not been resolved, and if the mediation attempt fails, all disputes - included those of not contractual nature shall be settled by the Benevento administrative Court that will have exclusive jurisdiction to deal with any dispute which has arisen or may arise out of or in connection with this Framework Agreement.

2.25 Article 25— Severalty

If any provision of this Framework Agreement is held invalid, illegal or unenforceable for any reason by any court of competent jurisdiction, such provision shall be severed and the remainder of the provisions here shall continue in full force and effect as if this Framework Agreement had been executed with the invalid provisions eliminated.

In the event of a holding of invalidity so fundamental as to prevent the accomplishment of the purpose of this Framework Agreement, the Parties shall immediately commence good faith negotiations to remedy such invalidity.

2.26 Article 26— Waiver

The waiver by the Lead Procurer (or any member of the Group of Procurers) of any right or remedy in respect of any breach of any term or condition or requirement of this Framework Agreement (including a Default) shall not prevent the subsequent enforcement thereof and shall not be deemed to be a waiver of any right or remedy in respect of any subsequent breach (including a Default). The Lead Procurer's (or any member of the Group of Procurers) delay in exercising, or failure to exercise, any right or remedy in connection with this Framework Agreement shall not operate as a waiver of that right or remedy. No waiver by the Lead Procurer or any member of the Group of Procurers in connection with this Framework Agreement shall be effective unless it is in writing and is duly signed by or on behalf of the Lead Procurer.

2.27 Article 25— Entry into force

The Framework Agreement becomes effective upon signing by both parties and shall remain in effect (unless terminated in accordance with Article 21) until the Completion Date of Phase 1 or of a later Phase that has been awarded the Contractor. However, confidentiality shall be remained for **four**

(4) years in accordance with confidentiality Article. Contractors who are awarded for the Phases 2 and 3 shall sign a formal assignment for that particular phase.

3 SIGNATURES

Both parties sign the Agreement using electronic signature certificate

Signed by the duly authorized signatory of the Lead Procurer:	**Signed by the duly authorized signatory of the Contractor/Lead Contractor:**
Full name:	**Full name:**
Position held:	**Position held:**
Date and stamp:	**Date and stamp:**