



CRANE

TD8 PCP Framework Agreement



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This is a framework agreement (“agreement”) between the following parties: on the one part, the Lead Procurer, REGION VÄSTERBOTTEN [RVB, Sweden], acting in the name and on behalf of the other members of the Buyers Group:

- KRISTIANSAND KOMMUNE (KSK)
- VICEPRESIDENCIA SEGUNDA Y CONSEJERIA DE SANIDAD Y SERVICIOS SOCIALES - JUNTA DE EXTREMADURA (EXT)

and

the Contractor, [insert details of the contractor],

[OPTION for joint tenders: acting in the name and on behalf of the other members of a 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, the Buyers Group and the Contractor(s) shall be referred to together as the Parties.

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

The agreement is composed of:

Preamble

Terms and Conditions

Annex 1 Grant Agreement Contributors

Annex 2 Ethical requirements for Field Testing Annex 3 Request for Tenders

Annex 4 Contractor's tender

Annex 5 Grant Agreement (Chapter 4)

1 TERMS AND CONDITIONS

Article 0 — Definitions

1. Status of definitions

Without prejudice to Article 19, the definition in this Article of words and phrases with capital first letters shall have precedence over definitions of the same words or phrases in Annexes to this agreement and over definitions in an offer for a Specific Contract.

2. List of definitions

Results or 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').

Generated in the PCP means activities described in this agreement and in the Specific Contracts.

Pre-existing rights 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 IPRs') — that is held prior to the signing of this agreement and is needed for the implementation of the PCP, or needed to exploit the Results, or needed, by any member of the Buyers Group, to use the Results.

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 IPRs') — that is generated during the timespan of the PCP but is not Generated in the PCP and is needed for the implementation of the PCP, or needed to exploit the Results, or needed, by any member of the Buyers Group, to use the Results.

Third Party means any legal entity which is not a member of the Buyers Group not the Contractor and not member of the Group of Tenderers.

Specific Contract means a contract, of which this agreement forms an integral part, for supply of R&D services by the Contractor offered for one of the three phases of PCP implementation.

Fair and Reasonable Conditions means appropriate conditions, including financial terms or royalty-free conditions, considering the specific circumstances of the request for access (for example, the actual or potential value of the Results or Background to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged).

Force Majeure means any unforeseeable and insuperable event affecting a Party fulfilling its obligations hereunder.

Article 1 — Subject of the agreement

This agreement defines the general terms and conditions for the implementation of the PCP of R&D services and for any Specific Contracts awarded for one or more PCP phase(s).

Award of Specific Contracts will take place according to the Contracting Approach documented in the Request for Tender. The Expected Outcomes to be achieved in Specific Contracts are documented in the Request for Tender.

Article 2 — Entry into force and duration

The Framework Agreement becomes effective upon signing by both parties and shall remain in effect (unless terminated in accordance with article 17) after complete discharge of all obligations both under this agreement and under any Specific Contract tendered for by the Contractor until the Completion Date of Phase 1 that has been awarded to the Contractor. Should the Contractor be awarded Phase II and/or Phase III, the Contractor shall sign a Specific Contract for each phase awarded.

The provisions of Articles 5, 6, 8, 12 and 20 shall survive the expiration or termination of this agreement to the extent needed to enable the Parties to pursue the remedies and benefits provided for in those Articles.

Article 3 — 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 Request for Tender and as detailed in any Specific Contracts.

Article 4 — Pricing, payment, and accounting

The total price offered for the R&D services to be implemented for each PCP phase shall be set out in any Specific Contract which may be awarded to the Contractor.

Prices shall take account of the requirements specified in chapter 2.5 and chapter 4.4 of the Request for Tender.

The payment and invoicing conditions shall be as specified in chapter 5.5 of the Request for Tender.

Article 5 — Ownership of the results (foreground), pre-existing rights (background) and sideground (including intellectual and industrial property rights)

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 access 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 phase 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 Contractors are required to give a declaration of Background IPR in the technical offer (TD6_Tender Application Template). The Lead Procurer and other members of the Buyers Group, do not hold any Pre-existing rights relevant to the PCP contracts.

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.

The Contractors grant to the members of the Procurers irrevocable, royalty-free, nonexclusive, 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 from the end of the present Framework Agreement and to the following purposes for fulfilling the R&D objectives of the PCP: to develop and test remote rehabilitation services for isolated areas.

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 licences to third parties to exploit the results under fair and reasonable conditions (without the right to sub-license).

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”).

Call back IPR rights

If the Contractor makes a Failure to commercially exploit the results as described in Article 10— 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.

If the event that the Buyers Group exercises the right to require transfer of ownership, the Contractor shall grant the Buyers Group access, at the prices specified in the Tender or, should no specification be made and no written agreement reach, at no charge, to all Background and Sideground necessary to exploit the Results (including the source code and designs with all its documentation).

Third Party rights and obligations

The Contractor must ensure that any subcontractor complies with the Framework Agreement and Specific Contracts.

The Contractor shall obtain all rights to any Foreground owned by a subcontractor, and sufficient rights to Background or Sideground to allow the Contractor to comply fully with its obligations under this agreement and under Specific Contracts.

The requirements specified in the Request for Tender in respect of subcontracting shall be complied with.

Article 6 — Confidentiality

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 this agreement and indefinitely after the end of this agreement.

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

The Parties may disclose confidential information to their staff or to staff of the Grant Agreement Contributors listed in Annex 4 or to staff of the Buyers Group only if:

- a) they need this information in order to implement the Grant Agreement, this agreement or a Specific Contract; and
- b) they are bound by an obligation of confidentiality.

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 was received from a Third Party without 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 the recipient having breached 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.

Article 7 — Promotion, publicity, and communication

- The Contractor shall undertake communication activities to create publicity about its participation in the procurement, and to promote the objectives and the results of the R&D carried out under the PCP (in particular, to other potential customers beyond the Buyers Group with the objective to achieve commercial exploitation of the Results (see Article 8 – Commercial exploitation of results)).
 - All communication activities shall comply with the applicable confidentiality and security restrictions.
 - During the implementation of the agreement and for a period of 4 additional years, the contractor shall inform the Lead Procurer 15 days in advance of any (written or oral) publication or any other type of communication (in any media or form) relating to the implementation 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 CRANE project that has received funding from the European Union’s Horizon 2020 Research and Innovation Programme (Grant 965277);
 - for infrastructure, equipment, and major results: ‘This service solution is part of the CRANE project that has received funding from the European Union’s Horizon 2020 Research and Innovation Programme’ (Grant 965277).
 - 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.
- The Lead Procurer and the Buyers Group 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 Lead Procurer and the Buyers Group may, in particular, publish the names of the Contractor and, in the case of a joint tender, the members of the group of tenderers, and the project abstract, summaries of the main results from the R&D and 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 6.
 - Moreover, before publishing this information, the lead procurer and the Buyers Group 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.
- 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 audio-visual 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 Regulation EC No 1049/2001, 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).

Article 8 — Commercial exploitation of results

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

If the contractor fails to commercially exploit the results within this period (or uses the results to the detriment of the public interest, including security interests), the Buyers Group has the right to require that ownership of the Results be transferred to them.

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

In the event that the Buyers Group exercises the right to require transfer of ownership, the Contractor shall grant the Buyers Group access, at the prices specified in the Tender or, should no specification be made and no written agreement reached, at no charge, to all Background and Sideground necessary to exploit the Results.

Article 9 — Conflicts of interest

- 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.
- 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.
- The lead procurer may instruct the Contractor to take specific measures to remedy the situation.

Article 10 — Ethics and research integrity

The Contractor shall carry out the tasks assigned to it in the Framework Agreement and in the 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, during the duration of the CRANE PCP contract, may not carry out activities that are prohibited in all EU Member States in a country outside the EU (where those activities are allowed).

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 highest standards of research integrity — as set out, for instance, in the European Code of Conduct for Research Integrity¹.

This implies notably compliance with the following essential principles:

- honesty;
- reliability;

¹ The [European Code of Conduct for Research Integrity](#) of ALLEA (All European Academies) of March 2017

- objectivity;
- impartiality;
- open communication;
- duty of care;
- fairness and
- responsibility for future science generations.

This means that contractor must ensure that persons carrying out research tasks:

- present their research goals and intentions in an honest and transparent manner;
- design their research carefully and conduct it in a reliable fashion, taking its impact on society into account;
- use techniques and methodologies (including for data collection and management) that are appropriate for the field(s) concerned;
- exercise due care for the subjects of research — be they human beings, animals, the environment or cultural objects;
- ensure objectivity, accuracy and impartiality when disseminating the results;
- allow — as much as possible and taking into account the legitimate interest of the contractor — access to research data, in order to enable research to be reproduced;
- make the necessary references to their work and that of other researchers;
- refrain from practicing any form of plagiarism, data falsification or fabrication;
- avoid conflicts of interest and misrepresentation of credentials or other research misconduct.

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 laws and
- b) any notification or authorisation for activities raising ethical issues required under national laws.

In addition, the contractor shall comply with the following ethics requirements:

- following ethical principles (including the highest standards of research integrity, notably as set out in the European Code of Conduct for Research Integrity, and, in particular, avoiding fabrication, falsification, plagiarism and other research misconduct)
- adhering to applicable international, EU and national law
- complying to ethical requirements for field testing, specified in Annex 2.

Article 11 — Processing of personal data

The Lead Procurer and the Buyers Group shall process personal data in compliance with the applicable EU and national law on data protection.

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 may grant its staff access to data only in so far as is strictly necessary for implementing, managing and monitoring the framework agreement and specific contracts.

The Contractor must inform the staff whose personal data are collected and processed by the Lead Procurer, the Buyers Group and/or the EU. For this purpose, the Contractor must provide them with the privacy statements of the Lead Procurer, the Buyers Group and the EU, before transmitting their

data. If explicit prior consent from the subjects of the data is needed, the Contractor must obtain such consent.

Article 12 — Obligation to provide information and keep records

The contractor must, at any time during the implementation of the Framework Agreement and Specific Contracts or afterwards, provide any information requested by the Lead Procurer or other member of the Buyers Group in relation to the agreement or contracts.

The contractor must keep, for a period of up to 5 years after the end of the Framework Agreement, records and other supporting documentation relating to its implementation or the implementation of the Specific Contracts.

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 against the Lead Procurer or Buyers Group), the Contractor must keep the records and other supporting documentation relating to the implementation of the Framework Agreement and Specific Contracts until the end of these procedures.

Article 13 — EU checks, reviews, audits, and investigations

Should the EU (including as represented by 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.

Article 14 — EU impact evaluation

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

Article 15 — Monitoring and reporting

During performance of any Specific Contract, the implementation by the Contractor of the R&D Services will be monitored periodically and reviewed against the deliverables agreed in the Specific Contract.

In good time before signing of a Specific Contract, a checklist will be prepared to consistently evaluate deliverables in respect of their being satisfactory.

Each procurer will comment on the checklist and a unified checklist will be used by each procurer independently. Any difference in interpretation will be discussed and resolved by a majority vote. The Lead Procurer shall apply the result in accepting the deliverable concerned.

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.

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

Article 16 — Breach of contract

1. The Contractor must compensate the Lead procurer and the Buyers group 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.
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.
3. The Contractor shall indemnify and hold the Lead Procurer and the other Buyers Group members 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.
4. The Contractor's indemnity obligations under Clause 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.
5. If the Contractor fails to deliver Results or other deliverables compliant with the Framework Agreement, the Lead Procurer shall give the Contractor the opportunity to amend, within an appropriate period. If satisfactory completion has not been achieved after the expiry of such cure period, the Lead Procurer may (at its discretion):
 - Withhold payments until satisfactory delivery;
 - Deduct payments in case of no satisfactory delivery; (The ratio of the deduction will be determined by the Buyers' Group. The impact and importance of the deliverable(s) and result(s) which have not been delivered or completed satisfactorily will be taken into account when determining the ratio of the deduction.)
 - Cancel payments;
 - Exclude the Contractor from the any subsequent Phases on the basis that the Contractor has not successfully completed the present Phase; and/or
 - Terminate the Framework Agreement and/or any Specific Contract (see hereunder).
6. Acceptance by the Lead Procurer of any deliverable or Result shall not release 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.
7. Except in case of infringement of applicable laws, gross negligence or willful 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.
8. Except in case of liability pursuant to clause 7 (IPR), infringement of applicable laws, gross negligence or willful 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.

9. The Contractor shall take out insurance to cover its liability under the Framework Agreement and shall provide evidence of this 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. The sum insured shall equal or exceed the total price of the latest Specific Contract signed.

Article 17 — Termination clauses and consequences of termination

1. The Lead Procurer shall be entitled to terminate this agreement at any time, including during performance of a Specific Contract, 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 or a member of the Group of Tenderers undergoes any change in legal or beneficial ownership or control;
 - f) the Contractor admits a new party to the Group of Tenderers without authorisation of the Buyers Group;
 - g) the Contractor is in breach of an obligation 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 deliver an Expected Outcome covered by a Specific Contract 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 consecutive months to achieve Expected Outcomes by the date(s) on which those Expected Outcomes were to have been achieved.
2. The assignments and/or licenses granted under the Framework Agreement by the Contractor to the Lead Procurer, any Buyers Group member, or any Third Party shall continue notwithstanding any expiry or termination of this agreement.
3. 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.
4. Within thirty (30) days of the date of termination or expiry of this agreement, the Contractor shall return or destroy any personal data received from another Party and any Confidential Information belonging to another Party, either in its then current format or in a format nominated by the Lead Procurer.
5. 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.

Article 18 — Amendments

The Parties may amend this agreement only in writing and only provided that the amendment does not have the purpose or the effect of making changes which might call into question the decision awarding Framework Agreements or Specific Contracts or otherwise result in unequal treatment of tenderers.

A Party desiring an amendment to this agreement shall notify the other Parties providing a duly justified request and a full new version of this agreement clearly showing all the proposed changes. Without prejudice to the right to terminate in accordance with Article 17, the Buyers Group may notify the Party desiring the amendment of their rejection or agree with the other Parties that an amendment be executed.

Should the duration of the Grant Agreement be extended, the Lead Procurer may propose this agreement and any Specific Contract not completed be amended in respect of durations and deadlines. In such cases no Party shall not withhold agreement unless that Party can show that the proposed amendment would significantly and disproportionately harm that Party's interests. Should agreement be withheld, the Lead Procurer may invoke dispute resolution.

Article 19 — Interpretation

The interpretation and construction of this Framework Agreement and of any Specific Contract concluded under it shall be subject to the following provisions:

- a) Terms defined in the Framework Agreement have precedence over those in annexes;
- b) Terms set out in the Request for Tender have precedence over those in the Contractor's tender;
- c) 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);
- d) Headings in this Framework Agreement are for ease of reference only and shall not affect its interpretation or construction;
- e) References to conditions are references to conditions in the Article of this Framework Agreement in which they appear, unless otherwise stated;
- f) Where the context allows, references to any gender include the other gender and the neuter, and the singular includes the plural and vice versa;
- g) "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;
- h) Further definitions are given in Article 0.

Article 20 — Applicable law and dispute settlement

Any legal claim, petition, or application for judicial review with regard to the performance of this agreement on the implementation of the CRANE PCP, whether before civil, criminal or administrative courts, shall be made only before the Swedish courts. In signing this agreement, the Contractor accepts the exclusive jurisdiction of Swedish courts.

This agreement shall be considered as a contract made in Sweden and be construed in accordance with and governed by Swedish Law, and no effect shall be given to any other choice-of-law or conflicts-of-laws rules or provisions. This agreement is outside the scope of Swedish procurement legislation.

Any dispute or claim arising out of or in connection with the execution of this agreement or of a Specific Contract shall be heard by the District Court in The local district court. Umeå, Skellefteå or Lycksele tingsrätt Sweden. Choose the one that suits your wish.

Article 21 — Force Majeure

A failure in the performance of this agreement cannot be imputed or assumed to a Party to the extent it is due to Force Majeure.

Each Party will immediately notify the other Parties in writing of any Force Majeure, stating the nature of the circumstances, their likely duration, and foreseeable effects.

If the Contractor is unable to fulfil its obligations owing to Force Majeure, it has the right to remuneration only for the services actually provided.

The Parties must take all necessary measures to limit any damage due to Force Majeure.

Article 22 — Notices

Notices to the Buyers Group shall be sent to the Lead Procurer Representative:

Name:

Address:

The Lead Procurer may change representative by written notification to all Parties.

Notices to the Contractor shall be sent to the Contractor Representative:

Name:

Address:

The Contractor may change representative by written notification to all Parties.

Annex 1 – Parties participating in the PCP

Beneficiaries of the Grant Agreement are:

- REGION VASTERBOTTEN (RVB)
- VICEPRESIDENCIA SEGUNDA Y CONSEJERIA DE SANIDAD Y SERVICIOS SOCIALES - JUNTA DE EXTREMADURA (EXT)
- KRISTIANSAND KOMMUNE (KSK)
- EL SITIO DE VALDELATARRA SL (VLD)
- EUROB CREATIVE SLNE (EUROB)
- OSLO UNIVERSITETSSYKEHUS HF (OUS)
- PPCN.XYZ APS (PPCN)

Linked Thirds parties in the Grant Agreement are:

- FUNDACION PARA LA FORMACION E INVESTIGACION DE LOS PROFESIONALES DE LASALUD DE EXTREMADURA FUNDESALUD (FS), affiliated or linked to EXT

Annex 2 – Ethical requirements for Field Testing

The requirements for field testing are described further below:

- Requirements related to recruitment: research participants will be recruited by the Buyers Group via medical professionals who ask their individual patients to consider voluntary enrolment. Only certain people who have the target condition will be eligible to take part in the field test. Details on the procedures and criteria that will be used to identify/recruit research participants will be provided. During the PCP's Phase III, the solutions awarded will be verified and compared against jointly defined criteria by the Buyers Group and other concerned final end-users in real-life operational conditions to verify fitness for purpose in view of potential conversion into permanent service of the solutions. Expected output from participating companies includes firstly field testing, secondly field test specification, thirdly specification of the final solution and other related technical documentation, and finally an updated cost/benefit evaluation.
- Field testing during validation stage will be undertaken at six sites by the procurers, three EU countries and one non-EU country. No transfer of personal data is planned to exchange or transfer with non-EU countries. Previously collected data will NOT be used in the field tests. All Parties shall rigorously apply the ethical standards and guidelines of Horizon 2020, regardless of the country in which the research is carried out. Furthermore, copies of the relevant ethics approvals from the host EU country and non-EU country will be submitted to the Commission. The Contractor must be aware of this procedure and respect it.
- Informed consent procedures: Copies of templates of Informed Consent Forms and Information Sheets will be provided by the Buyers Group to the Commission. These will be drafted in a language and terms understandable to the participants. They will follow the Directive 2001/20/EC relating to the implementation of good field test practices. Hospitals involved in the field testing will implement these procedures. The contractor must be aware of this procedure in each hospital and respect it.
- Vulnerable individuals/groups will not be involved in the field tests: Details must be provided about the measures taken to avoid that vulnerable individuals/groups participate in the field-testing. The Contractor must ensure that this requirement is maintained.

- Details on incidental findings policy must be provided: Incidental findings are not expected as a result of the proper nature of the chronic diseases. CRANE will NOT use invasive testing techniques but monitor the functionalities of CRANE solutions (such as treatment adherence, symptoms, blood pressure, etc.). The Contractor will inform the Lead procurer in case of incidental findings identified.
- Copies of ethical approvals for the collection of personal data by the competent University Data Protection Officer / National Data Protection authority must be submitted. In principle, ethical review is not required for our proof-of-concept study as:
 - assignment of patients is not decided in advance by a protocol but falls within current clinical practice.
 - the decision to use the product is clearly separated from the decision to include the patient in the study;
 - no diagnostic or monitoring procedures will be undertaken other than those ordinarily applied in clinical practice. Even so, considering that during the life of the Project new EU regulations should be applicable, contractors will be required to implement them with CRANE's Project Supervision guidance and support.
- However, during the implementation of the PCP, this procedure will be again reviewed and if necessary the procedure to obtain ethical approvals will be implemented. Each hospital will initiate the procedure according to its own protocols and timings. The Contractor must be aware of the procedure and work together with the hospital if further information should be required.
- Justification must be given in case of collection and/or processing of personal sensitive data: no personal sensitive data will be collected (i.e.: racial or ethnic origin of the data, political options, religious beliefs, membership of trade unions, sexual life, offences commission, sentences of any course for such offences, mental health condition). The Contractor must ensure that this requirement is respected in their solutions.
- Detailed information must be provided on the procedures that will be implemented for data collection, storage, protection, retention and destruction and confirmation that they comply with national and EU legislation: Data collection/storage/protection/retention/destruction and confirmation will follow the EU Directives: Directive 95/46/EC (Data Protection Directive) harmonizing a common standard set of data protection among the member states. Article 17 of the Directive 95/46/EC establishes the rules to ensure that the data controller implements appropriate technical and organisational measures to protect personal data from destruction, loss, unauthorised alteration, unauthorised disclosure or access, whether by accident or by unlawful action. Directive 2002/58/EC (Directive on privacy and electronic communications) for data in the communication sector, and Directive 2006/24/EC (Data Retention Directive) regulating data management in the context of public services delivered electronically. The European Commission plans to unify data protection within the European Union (EU) with a single law, the General Data Protection Regulation (GDPR). According to the above explanation, the Contractor must clearly explain how he will meet this requirement by answering the compliance criteria D and E in the tender documents.



SIGNATURES

Authorised to sign for the Buyers Group

(Full Name, Date, Place, Signature)

Authorised to sign for the Contractor

(Full Name, Date, Place, Signature)



CRANE

Comprehensive treatment of chronic patients in rural areas

