

Annex 1: concept Framework Agreement

PCP Framework Agreement



Connecting Patients and Carers using wearable sensor technology

Acronym: **NIGHTINGALE**

Project Number:727534

PCP Framework Agreement



PCP Framework Agreement

PREAMBLE

This is a Framework Agreement between the following parties:

on the one part,

- 1 the “lead procurer”, **University Medical Center Utrecht**, a public law entity founded by the Act on the Higher Education and Scientific Research, whose registered office is at the (3584CX) Heidelberglaan 100, Utrecht, The Netherlands (hereinafter: **UMC Utrecht or Procuring Entity**),
acting in the name and on behalf of the other members of the buyers group:

AND

- 2 **Karolinska Universitetssjukhuset, Stockholms Laens Landsting, Stockholm, Sweden**

AND

- 3 **University College London Hospitals NHS Foundation Trust, United Kingdom**

AND

- 4 **Katholieke Universiteit Leuven, Belgium**,
for the purposes of this agreement represented by **KU Leuven Research & Development**

- 5 **Universitätsklinikum Aachen, Germany**

hereinafter individually referred to as “Nightingale consortium members” and collectively referred to as “Nightingale consortium”,

and on the other hand, [insert details of the contractor], hereinafter referred to as the “contractor”,

For economic operators that jointly submit a tender: The members of a consortium of suppliers are hereinafter collectively referred to as the “Contractor” and will be jointly and severally liable vis-à-vis the Procuring Entity for the performance of this Framework Agreement and the specific contracts.

The Procuring Entity, buyers group and the contractor(s) shall be collectively referred to as the “parties” and individually as “party”, unless otherwise specified.

WHEREAS

- The Nightingale consortium members have entered into the Nightingale Grant Agreement with the European Union, no. 727534, H2020-SC1-2016-CNECT (“Grant Agreement”) whereby the European Union has awarded the Nightingale consortium members the grant for the action entitled ‘Connecting Patients and Carers using wearable sensor technology — NIGHTINGALE’, as set out in annex 1 to the Grant Agreement.

- The Procuring Entity nominated by the Nightingale consortium, in accordance with the public procurement principles governing the selection of the Contractor, proceeded with the selection of Contractors through a European Joint Pre Commercial Procurement procedure, initiated

on 01-11-2017 by the publication of the Contract Notice for the implementation of the action aforementioned – **Tender Number [...]**”;

- The Contractor has submitted an offer for the implementation of the Nightingale PCP Project on the development of a solution aimed at prediction and detection of physiological instability to prevent death and disability, by wearable smart monitoring leading to safer care (Nightingale objective), and has subsequently qualified for the awarding of a contract for Phase 1 (one) of the above mentioned procedure and consequently, has expressly manifested his/her will to undertake to provide the subject matter of this Framework Agreement, at terms and conditions set forth below;

- The Procuring Entity will make use of the Contractor’s specialist expertise, which will use professional resources with the knowledge and experience necessary to implement the activities set forth in this Framework Agreement;

- The Contractor declares that the “Contract Notice for the realization of a Research & Development Project (Pre-Commercial Procurement) on Nightingale, the “Tender Regulation”, all the declarations submitted in accordance with the templates provided by Annexes 4,5 & 6 to the Tender Regulation, the “Framework Agreement”, the “Common Challenge & Functional Specifications”, the “Tender Form” contents and the specific annexes and/or additional documentation, define adequately and completely the object of the R&D Services to be provided. Moreover, the Contractor declares that, in any case, was able to understand all elements of the documents mentioned here, for a suitable technical and economic evaluation of them and for the formulation of an offer;

- The Joint Pre-Commercial Procurement is divided into three R&D Phases, consisting respectively, in the following order, in:

- o **Phase I:** Solution exploration and design;
- o **Phase II:** Prototype development;
- o **Phase III:** Original development of a limited volume of first products or services in the form of a test series.

- This preamble, the deeds and documents mentioned in the same preamble and in the remainder of this Framework Agreement, including the “Contract Notice for the implementation of a Research and Development Project (Pre-Commercial Procurement) on *Nightingale*, the "PCP Request for Proposals", the "Common Challenge & Functional Specifications", and the documents attached to the same or complementary, although not physically annexed to this Agreement, are integral and essential part of the Framework Agreement. It also constitutes integral and substantial part of this Framework Agreement the document "Tender Form", submitted by the Contractor.

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

Now therefore, between the Parties, as above represented,

IT IS AGREED AS FOLLOWS:

TERMS AND CONDITIONS

As used in this Agreement the following capitalized terms and expressions shall have the meaning ascribed to them below:

“Assessment”	means the process of analysis to determine whether the specific requirements relating to a process, system, product, person or body are fulfilled;
“Award Criteria”	means, for each Phase, the criteria used to identify the most economically advantageous tender;
“Common Challenge”	means the accompanying document to the PCP Request for Tender Document, explaining the background to, the underlying need behind, and the aim and scope of the Project, and the corresponding subsequently issued documents for the following Phases 2 and 3;
“Completion Date”	means the date for the completion of an individual Phase or for the Project as whole;
“Confidential Information”	means information that falls within the types of information which has been designated as confidential by either party or that ought to be considered as confidential by a reasonable business person (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 Directive (officially Directive 95/46/EC) and its successor the Data Protection Regulation (EU) 2016/679 and the Project, including its deliverables and other commercially sensitive information;
“Days”	shall mean 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;

<p>“Default”</p>	<p>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);</p>
<p>“Evaluation committee”</p>	<p>means a committee of experts in the field of the Project, and/or technical experts, and/or general business experts, appointed by the Procuring Entity in its sole discretion;</p>
<p>“End of Phase Report”</p>	<p>means a report in written form to be submitted by the Contractor awarded a work order for that particular Phase to the Procuring Entity after each completed Phase of the Project, containing all information that is required in the End of Phase Report Form (see Nightingale Tender Form, Appendix X);</p>
<p>“Fair and reasonable market conditions”</p>	<p>means appropriate conditions, including financial terms or royalty-free conditions, taking into account the specific circumstances of the request for access (for example, the actual or potential value of the Results or Pre-existing rights to which access is requested and/or the scope, duration or other characteristics of the exploitation envisaged).</p>
<p>“Formal Assignment”</p>	<p>means the discrete contract documents to be issued to the contractor that successfully tenders to carry out the work comprised in Phases 1, 2 and 3. The Formal Assignment for Phase 1, 2 and 3 for each Phase will be issued by the Procuring Entity separately.</p>
<p>“Framework Agreement”</p>	<p>means this Agreement;</p>
<p>“Fraud”</p>	<p>means any offence under laws creating offences in respect of Fraudulent acts or at common law in respect of Fraudulent acts in relation to this Framework Agreement or defrauding or attempting to defraud or conspiring to defraud;</p>
<p>“Functional Specifications”</p>	<p>means the specifications set out in the Nightingale PCP Request for Tenders document defining the required characteristics and set of functions of the outcome of the Project;</p>
<p>“Generated in the PCP”</p>	<p>means in activities described in the PCP Framework Agreement and specific contracts.</p>
<p>“H2020”</p>	<p>means the Horizon 2020 Programme of the European Union;</p>

<p>“Insolvency Event”</p>	<p>means where the Contractor passes a resolution or the court makes an order that:</p> <ol style="list-style-type: none"> 1. the Contractor be wound up (otherwise than for the purpose of a bona fide and solvent reconstruction or amalgamation);or 2. a receiver, manager or administrator on behalf of a creditor is appointed in respect of all or part of the business of the Contractor; or 3. circumstances arise which entitle a court or creditor to appoint a receiver, manager or administrator or which entitle the court (otherwise than for the purpose of a solvent and bona fide reconstruction or amalgamation) to make a winding up order; or 4. the Contractor ceases to trade or is unable to pay its debts;
<p>“Intellectual Property Rights”</p>	<p>means patents, inventions (whether or not patentable or capable of registration), trademarks, service marks, copyrights, topography rights, design rights and Database rights, (whether or not any of them are registered or registerable and including applications for registration, renewal or extension of any of them), trade secrets and rights of confidence, trade or business names and domain names and all rights or forms of protection of a similar nature which have an equivalent effect to any of them which may now or in the future exist anywhere in the world;</p>
<p>“Internal use”</p>	<p>means usage of data, software or other products produced/developed during the Project - within the hospitals of Nightingale consortium members – for evaluation and research purposes.</p>
<p>“Language”</p>	<p>means the English Language unless otherwise agreed;</p>
<p>“Material”</p>	<p>means any report, executive summary, paper, abstract or other document or media provided by the Contractor;</p>
<p>“Month”</p>	<p>means calendar Month;</p>
<p>“PCP”</p>	<p>Pre-Commercial Procurement as defined by the European Commission Communication COM (2007) 799 final, 14.12.2007;</p>
<p>“Performance Conditions”</p>	<p>means the Contractual obligations of the Contractor as set out in the Framework Agreement;</p>

"Personal Data"	has the meaning given to it in section 1 of the Data Protection Directive (officially Directive 95/46/EC) and its successor the Data Protection Regulation (EU) 2016/679
"Phase"	means an individual and separate part of the Project, where Phase 1 comprises solution exploration, Phase 2 comprises prototyping, and Phase 3 comprises original development of a limited volume of first products or Services in the form of a test series;
"Phase 0"	means the first stage of the Project as described in this Agreement;
"Pre-existing rights"	means any data, know-how or information — whatever its form or nature (tangible or intangible), including any attached rights such as Intellectual Property Rights — 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.
"Price"	means the total Price (excluding VAT) agreed between the parties for each Phase of the Project, to be paid by the Procuring Entity (UMC Utrecht) to the Contractor for each such Phase, subject to the terms and conditions of this Agreement;
"Procuring Entity"	means a state organ, organization, institution or some other legal person ascertained by law, in this case the UMC Utrecht, Heidelberglaan 100, 3584 CX Utrecht, acting through its procurement department in the name and on behalf of the Nightingale consortium;
"Project"	means the Research and development Services as well as deliver a highly interoperable software solution that are required by Contractors to complete Phases 1, 2 and 3 and to generate the Results;
"Project Intellectual Property Rights"	means new Intellectual Property Rights arising from the Services and/or the Results and excluding Sideground and Pre-existing rights;
"Project Period"	means the period commencing on the Date of the signature page and ending on the Completion Date (Phase by Phase) or such later date as may be agreed between the parties for the completion of a particular Phase or the Project;

“PCP Request for Tender document”	means the invitation documents on which the tenders for the award of the work order for Phase 1 were submitted;
“Research”	means the scope of work (Research and development Services) specified in this Agreement;
“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.
“Services” and also “R&D Services”	means the Services being provided by the Contractor in fulfilment of this Framework Agreement and any work order issued through it;
“Sideground”	means any data, know-how or information — whatever its form or nature (tangible or intangible), including any attached rights such as Intellectual Property — 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. ‘Not generated in the PCP’ means not generated in activities described in the PCP Framework Agreement or specific contracts.
“Sub-Contract”	any contract or agreement between the Contractor and any third party whereby that third party agrees to provide Services to the Contractor to enable or assist the Contractor to provide the Services or any part thereof to the Procuring Entity;
“Tender Documents”	means all documents issued or published by the Procuring Entity as part of the PCP-process and made available on the TED website, including - without limitation - the TED Notice, the Functional Specification document, the Framework Agreement, any schedules, annexes or attachments there to;
“Tender Notice”	means the Nightingale PCP Tender Notice date, which will be made available on TED (Tenders Electronic Daily) at http://ted.europa.eu/TED/main/HomePage.do
“Contractor”	means the person, firm or company with whom the Procuring Entity enters into this Framework Agreement or a work order;

“Contractor’s Representative”	means a person authorized to represent the Contractor in respect of this Framework Agreement;
“Contractor’s Staff”	means the Contractor’s Representative and all employees, consultants, agents, and sub-Contractors (including their staff) which the Contractor engages in relation to a Phase;
“Variation”	means an amendment to this Framework Agreement executed through the completion of a Variation to Agreement form signed by the parties in accordance with Article 25;

Article 1 — Subject of the Framework 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 3 & 4 and for the specific contracts that will be awarded for each of the 3 PCP phases.

Article 2 — Duration

The Project is divided into the following phases:

- o Phase 0: Tender submission and admission based on all selection criteria and participation requirements, which are governed in particular by the PCP Request for Tenders and the Tender Notice;
- o Phases I - III: the implementation of the tender which is divided in three separate Phases comprising, respectively and in that order (the “Phases” and each a “Phase”):
 1. “Phase I”: Solution design and feasibility study
 2. “Phase II”: Prototype development
 3. “Phase III”: Development of a limited volume of first products or Services in the form of a test series.

The Framework Agreement becomes effective upon signing by both parties and shall remain in effect (unless terminated in accordance with Article 24) until the Completion Date (as defined below) of Phase I or of a later Phase that has been awarded to the Contractor. However, confidentiality obligations and provisions shall remain applicable for 5 years after the end of the Framework Agreement in accordance to Article 13. Please note that Contractors who are awarded contracts for the Phases II and III shall sign a formal assignment for that particular phase.

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.

Article 3 — R&D Services to be provided

The contractor shall provide the R&D Services required in each individual Phase as further described below (tasks, deliverables and milestones) to develop solutions to tackle the challenge set out in the tender, the challenge brief and the specific contracts.

Article 4 - Succession of Phase I, Phase II and Phase III of the Project

By the signing of the Framework Agreement, the Procuring Entity and the Contractor accept the general conditions set by this Framework Agreement. In case the Contractor gets awarded specific formal assignments per Phase, these have to be signed by the Procuring Entity and the Contractor. This assigns to the Contractor the task of performing the Services within the scope of respective Phase I, Phase II and Phase III of the Project. The Contractor acknowledges that the Procuring Entity will simultaneously enter into a similar contractual arrangements for the Project with other Contractors.

4.1 Assessment of Phase I and award of Phase II

On the Completion Date of Phase I, the Contractor shall submit to the Procuring Entity an “End of Phase Report” regarding such Phase together with the deliverables belonging to Phase I, which shall thereupon be reviewed and assessed by the Evaluation committee in order to determine whether the Contractor has complied with the Common Challenge and the Functional Specifications. Such assessment shall be performed at any time between the Completion Date of Phase I and the starting date of the next Phase, but in any case prior to the latter.

The Evaluation committee shall issue its decision regarding the satisfactory or successful completion of Phase I, not earlier than two (2) weeks and not later than four (4) weeks after the Completion Date of Phase I. In case the volume of Contractors leads to a longer evaluation process the Contractors will be informed.

- In case of contractors that have not satisfactorily completed Phase I, the Contractor needs to repay the reimbursement of the pre-payment to the Procuring Entity, the Contractor will not receive the payment for the work carried out in Phase I, and the Contractor will be excluded for awarding to Phase II.
- In case of contractors that have satisfactorily, but not successfully completed Phase I, the Contractor will be entitled to the payment for the work carried out in Phase I, but will be excluded for awarding to Phase II.
- In case of contractors that have successfully completed Phase I, the Contractor will be entitled to the payment for the work carried out in Phase I and his proposal for Phase II will be evaluated an a decision reached as to its advancement to Phase II.

If the Contractor is selected for Phase II, this Agreement shall continue in effect for the duration of the following Phases. The Contractor shall thereupon sign a formal assignment relevant to that phase. In addition, if the Contractor is not selected for Phase II, this Agreement shall, without prejudice to any surviving clauses, cease to have any effect upon the date announced by the Procuring Entity for final award of Phase II.

4.2 Assessment of Phase II and award of Phase III

On the Completion Date of Phase II, the Contractor shall submit to the Procuring Entity an End of Phase Report regarding such Phase together with the deliverables belonging to Phase II, which shall be reviewed and assessed by the Evaluation committee in order to determine whether the Contractor has complied with the Performance Conditions and the Functional Specifications. Such assessment shall be performed at any time between the Completion Date of Phase II and the starting date of the next Phase, but in any case prior to the latter.

The Evaluation committee shall issue its decision as to the award of the Phase III acceptance, after evaluation of the prototypes (approximately two months) after the Completion Date of Phase II.

- In case of contractors that have not satisfactorily completed Phase II, the Contractor needs to repay the reimbursement of the pre-payment to the Procuring Entity, the Contractor will not receive the payment for the work carried out in Phase II, and the Contractor will be excluded for awarding to Phase III.
- In case of contractors that have satisfactorily, but not successfully completed Phase II, the Contractor will be entitled to the payment for the work carried out in Phase I, but will be excluded for awarding to Phase III.
- In case of contractors that have successfully completed Phase II, the Contractor will be entitled to the payment for the work carried out in Phase II and his proposal for Phase III will be evaluated an a decision reached as to its advancement to Phase III.

If the Contractor is selected for Phase III, this Agreement shall continue in effect for the duration of that Phase. The Contractor shall thereupon sign a formal assignment relevant to that phase. In addition, if the Contractor is not selected for Phase III, this Agreement shall, without prejudice to any surviving clauses, cease to have any effect upon the date announced by the Procuring Entity for final award of Phase III.

4.3 In this Agreement, "successful completion" of a Phase shall be assessed in terms of overall compliance with the Functional Specifications. Successful completion of Phase 1 is a prerequisite to receiving an invitation for Phase 2. Successful completion of Phase 2 is a prerequisite to receiving an invitation for Phase 3.

4.4 Any award for Phases II and III will be communicated in writing by the Procuring Entity to the Contractor.

4.5 Any reference in this Framework Agreement to the Project refers also to any of the Phases awarded to the Contractor.

4.6 In each Phase at least 51% of the Services shall be performed within the EU Member States, or a country that is associated to H2020.

4.7 The Procuring Entity reserves the right not to award contracts for Phases for which it has not received any favourable or suitable or acceptable offer in relation to the Project; to stop, cancel, revoke, re-issue the PCP or not to award any Phase Contract for objective reasons. The Procuring Entity assumes no obligation whatsoever to compensate or indemnify the Contractors or Contractors for any expense or loss that may occur in the preparation of their tenders.

Article 5 - Administration and Direction of the Project

5.1 The Contractor shall ensure that each member of the Contractor's Staff engaged on the Project observes the terms and conditions of this Agreement and any Variation entered into between the parties hereto, and that the Contractor's Staff are advised of any changes in the scope of the Agreement or the Project.

5.2 In particular, as medical sensing, wearables and IT are dynamic and rapidly evolving fields, considering up to date R&D, modifications to Functional Specifications shall be made possible. These specifications will be added as an amendment to the existing functional specifications.

5.3 Notwithstanding the provisions of Article 24, the Procuring Entity may terminate this Framework Agreement with a Contractor if any of the Contractor's Key Staff are not available for the entire period needed to fulfil their duties in the Project, subject to prior discussion having first been held with the Contractor to attempt to identify and agree a mutually acceptable replacement and where the lack of availability of one or more of the Key Staff causes a Material risk to the fulfilment of the delivery objective of the Project.

5.4 The objectives and requirements of the Project are set out in the Common Challenge and the Functional Specifications document. Within the limits of such objectives and requirements, the details of the exact program to be followed and the day-to-day responsibility for carrying out this program will be under the control of the Contractor, in consultation, where appropriate, with the Procuring Entity's representative.

5.5 The Contractor shall inform the Procuring Entity on a regular basis and, in any case, promptly upon the Procuring Entity's first request, of the progress of the Project. In particular, but without prejudice to Article 8.7 and 25 below, the Contractor shall notify the Procuring Entity of any proposed deviation from the agreed scope of work or if significant developments occur as the Research and development work progresses as soon as possible after the Contractor becomes aware of the necessity or usefulness of such deviation.

5.6 The Contractor shall ensure full communication takes place between the parties and such others as may be notified to the Contractor by the Procuring Entity and shall advise as required on the Project.

5.7 Notwithstanding the provisions of Article 24, the Procuring Entity may terminate this Framework Agreement forthwith should the Contractor be unwilling or unable for any reason to continue with the Project or if, in the reasonable opinion of the Procuring Entity, the Contractor is consistently failing to achieve an acceptable standard in relation to the Project. If this occurs, the Procuring Entity shall not be obliged to make any further financial payment to the Contractor.

Article 6 - End of Phase Report and Evaluation

6.1 The Contractor shall provide an End of Phase Report on each relevant Phase of the Project, in the approved Language, within 14 Days as of the Completion Date. The End of Phase Report shall be in the form as provided by the Procuring Entity, and shall further be in compliance with the guidance notes issued by the Procuring Entity or Nightingale consortium representative as amended from time to time or as otherwise required by the Procuring Entity or the Nightingale consortium representative, and shall include the Data, methods, Results and final conclusions together with management information and any other information relating to the Project up to the Completion Date. Ownership of necessary Reports of all Phases will be transferred to the Procuring entity and Consortium Partners.

6.2 Notwithstanding the provisions of Article 6.1, the Procuring Entity or the Nightingale consortium representative is entitled to carry out a visit to the Contractor's premises at any time for the purpose of due diligence and evaluation in respect of the Project.

Article 7 - Obligations of the Contractor and the Procuring Entity

7.1 The Contractor shall manage and complete the Project in accordance with the Agreement, in particular the tender documents and shall in each Phase of the Project allocate sufficient resources to such Phase to enable it to comply with its obligations in such Phase.

7.2 The Contractor shall meet, with time being of the essence, delivery in any performance dates, including but not limited to End of Phase Reports and related deliverables. If the Contractor fails to do

so, the Procuring Entity may, after giving the Contractor not less than 14 Days' notice of its intention (without prejudice to any other rights it may have):

7.2.1 terminate this Agreement in whole or in part without liability to the Contractor;

7.2.2 refuse to accept any subsequent performance of the Project which the Contractor attempts to make;

7.2.3 hold the Contractor accountable for any loss and additional costs incurred; and

7.2.4 have all sums previously paid by the Procuring Entity to the Contractor under the Phase which is then running, refunded by the Contractor.

7.3 The Contractor shall:

7.3.1 co-operate with the Procuring Entity in all matters relating to the Project;

7.3.2 subject to the prior written approval of the Procuring Entity, appoint or, at the written request of the Procuring Entity, replace without delay:

7.3.2.1 the Contractor's Representative; and

7.3.2.2 Key Staff or any member of the Contractor's team, who shall be suitably skilled, experienced and qualified to carry out the Project.

7.3.3 subject to Article 7.3.2, ensure that the same person acts as the Contractor's Representative throughout the term of this Project;

7.3.4 procure the availability of the Contractor's Representative and Key Staff for the purposes of the Project;

7.3.5 promptly inform the Procuring Entity of the absence of the Contractor's Representative and/or Key Staff. If the Procuring Entity so requires, the Contractor shall provide a suitably qualified replacement;

7.3.6 not make any changes to the Contractor representative, Sub-Contractors or the Key Staff without the prior written approval of the Procuring Entity, such approval not to be unreasonably withheld or delayed; and

7.3.7 ensure that the Contractor's team uses reasonable skill and care during the Project.

7.4 be responsible for the accuracy of all drawings, documentation and information supplied to the Procuring Entity in connection with delivery of this Framework Agreement. The Contractor shall:

7.4.1 observe, and ensure that the Contractor's team observes, all rules and regulations and any other reasonable requirements of the Procuring Entity;

7.4.2 acknowledge and adjust to any modification with respect to the Functional Specifications by the Procuring Entity as mentioned in Article 5.1 of this Framework Agreement;

7.4.3 notify the Procuring Entity as soon as it becomes aware of any issues which arise in relation to the Project; and

7.4.4 before the commencement date, obtain, and at all times maintain all necessary licenses and consents and comply with all relevant legislation in relation to the Project, except for those licenses and consents that are related to the outcome of a specific Phase.

7.5 The Contractor acknowledges and agrees that the Contractor is entering into this Framework Agreement on the basis that the details of the Project are accurate and complete in all Material respects, and are not misleading.

7.6 The Procuring Entity shall:

7.6.1 co-operate with the Contractor in all matters relating to the Project and appoint (and replace, if appropriate) the Procuring Entity representative;

7.6.2 provide such access to the Procuring Entity's premises and sensitive data, if it is in accordance to data-protection officials, and such office accommodation and other facilities as may reasonably be requested by the Contractor and agreed rules and regulations with the Contractor in writing in advance, for the purposes of the Project;

7.6.3 provide such information as the Contractor may reasonably request and the Contractor considers reasonably necessary, in order to carry out the Project, in a timely manner, and ensure that it is accurate in all Material respects; and

7.6.4 inform the supplier of all health and safety and any other reasonable security requirements that apply at any of the Procuring Entity's premises.

Article 8 — Pricing, payment and accounting

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:

- if new units/unit prices are added to phase 2 or 3 offers, they shall become binding for the remaining phases
- if offered unit prices from phase 1 are changed in phase 2 and / or phase 3 offers, this should be duly notified and explained by Contractor.

The next payment conditions will apply:

8.1 The total amount to be paid by the procurement entity to the Contractor shall not exceed the relevant amounts detailed in Article 1.4.1 of the PCP Request for Tenders document. Subject to these limits the Contractor is free to administer received payments within the terms of this Framework Agreement without further reference to the Procuring Entity.

8.2 Payment for the Contractor's Services for each Phase will be made according to the following provisions:

8.2.1 PHASE I: payment of the Price for Phase I shall be made in two parts. The Contractor shall be paid a first payment of 50% of the Price for Phase I within 30 calendar days from the date of the decision of the Evaluation committee to award the Contractor to Phase 1 (one). The second payment of 50% shall be paid within 30 calendar Days from the date of the decision of the Evaluation committee confirming that the Contractor has complied with the Performance Conditions (see PCP Request for Tenders document) and the Functional Specifications applicable to such Phase and is thus considered to have completed a Phase *satisfactorily*. In case of Default, any payment already made

may be reclaimed, including for the case in which the Evaluation Committee comes to the conclusion that Phase I was not even *satisfactorily* completed.

8.2.2 PHASE II: payment of the Price for Phase II shall be made in three parts. The Contractor shall be paid a first payment of 20% of the Price for Phase II within 30 calendar Days from the date of the decision of the Evaluation committee to award the Contractor to Phase 2 (two). The second payment of 45% shall be paid within 30 calendar Days from the date of installation of the prototypes in the first testing environment and begin of the testing phase. The third payment of 35% shall be paid within 30 calendar Days from the date of the inspection and by the Evaluation committee confirming that the Contractor has complied with the Performance Conditions and the Functional Specifications applicable to such Phase. In case of Default, any payment already made may be reclaimed.

8.2.3 PHASE III: payment of the Price for Phase III shall be made in three parts. The Contractors shall be paid a first payment of 20% of the Price for Phase III within 30 calendar Days from the date of the decision of the Evaluation committee to award the Contractor to Phase 3 (three). The second payment of 45% shall be paid within 30 calendar Days from the date of installation of test series products in the first testing environment and begin of the testing phase and from the date of the decision of the Evaluation committee confirming that the Contractor has complied with the Performance Conditions and the technical requirements. The third payment of 35% shall be paid within 30 calendar Days from the date of the inspection of the Evaluation committee confirming that the Contractor has complied with the Performance Conditions and the Functional Specifications and is thus considered to have completed a Phase *satisfactorily*. In case of Default, any payment already made may be reclaimed, including for the case in which the Evaluation Committee comes to the conclusion that Phase I was not even *satisfactorily* completed.

8.3 The Contractor accepts, upon first request from the Procuring Entity, to provide the Procuring Entity with complete, relevant and clear information as well as documentary evidence about the allocation of monies paid by the Procuring Entity.

8.4 Payments to third parties employed or hired by the Contractor, if any, shall remain the responsibility of the Contractor who shall ensure that such payments are made promptly and shall hold the Procuring Entity harmless against any claim of such third parties.

8.5 During the Project Period, payments will be made by the Procuring Entity pursuant to invoices issued to the Procuring Entity; the Procuring Entity may suspend this payment at any time if, in the view of the Procuring Entity, acting reasonably, satisfactory progress on the Project has not been maintained, or reports have not been submitted as required under Article 6.

8.6 Without prejudice to Article 25 below, the parties expressly agree that the Contractor shall not make any changes to the work, or to the total amount payable under the Agreement, without the prior written approval of the Procuring Entity.

8.7 Subject to the confidentiality obligations set forth in Article 13, the Contractor grants to the Procuring Entity, acting, as the case may be, through agents authorized for that purpose, and to any statutory or regulatory auditors of the Procuring Entity, a right to access (and, if necessary to copy) the relevant financial records during normal business hours.

8.8 The Contractor shall provide all reasonable assistance at all times during the term of the

Agreement and during a period of ten years after termination or expiry of this Agreement for any reason whatsoever, for the purposes of allowing the Procuring Entity to obtain such information as is necessary to fulfil the Procuring Entity's obligations to supply information for national or supra-national parliamentary, governmental, judicial or other administrative purposes and/or to carry out an audit of the Contractor's compliance with this Agreement including all activities, performance, security and integrity in connection therewith.

8.9 If at any time an overpayment has been made to the Contractor for any reason whatsoever, the amount of such overpayment shall be taken into account in the assessing of any further payments, or shall be recoverable from the Contractor at the Procuring Entity's discretion.

8.10 The Contractor shall keep and maintain, up until at least ten years after this Agreement has been completed, full and accurate records of the Project including:

8.10.1 all aspects of the Project;

8.10.2 all expenditure paid by the Procuring Entity; and

8.10.3 all payments made by the Procuring Entity, and the Contractor shall on request allow the Procuring Entity or the Procuring Entity's representatives such access to those records as may be required in connection with the Agreement.

8.11 Where the Contractor enters into a Sub-Contract with a supplier or Contractor for the purpose of performing the Contract, it shall cause a term to be included in such a Sub-Contract that requires payment to be made of undisputed sums by the Contractor to the Sub-Contractor within a specified period not exceeding 30 calendar Days from the receipt of a valid invoice, as defined by the Sub-Contract requirements.

8.12 Wherever, under the Contract, any sum of money is recoverable from or payable by the Contractor (including any sum that the Contractor is liable to pay to the Procuring Entity in respect of any breach of the Contract), the Procuring Entity may unilaterally deduct that sum from any sum then due, or which at any later time may become due to the Contractor under the Contract or under any other agreement with the Procuring Entity.

8.13 The Contractor shall make any payments due to the Procuring Entity without any deduction whether by way of set-off, counterclaim, discount, abatement or otherwise, unless the Contractor has a final and enforceable court order requiring an amount equal to such deduction to be paid by the Procuring Entity to the Contractor.

8.14 The Procuring Entity presume that the intention is to prevent abnormal price offers, price estimation for research prices, and calculations of future market price of solutions. In case of suspicion of abnormal price offers the robustness of calculation has to be declared to the Nightingale core consortium or advisory board.

Article 9 - Intellectual Property Rights

9.1 All Pre-existing rights remain the property of the party introducing the same (or any third party supplier that owns it) and nothing contained in this Framework Agreement or any license contract pertaining or pursuant to the Project shall affect the ownership rights of either party (or any third party) in its Pre-existing rights.

9.2 The Contractor will provide each of the Nightingale consortium members an irrevocable, indefinite, worldwide, royalty-free and non-exclusive license to use all Results, including Project Intellectual Property Rights and the Pre-existing rights that are needed to perform the Project for the purpose of executing the Project as well as for non-commercial research purposes, including clinical trials set up to test the validity of the Results. In case of Results that constitute software, the non-commercial research license will extend to all updates and upgrades thereof during the clinical trials set up to test the validity of the Results.

9.3 If the Contractor (or any of its sub-Contractor) generates Project Intellectual Property Rights, whether the Contractor (or sub-Contractor) intends to file for protection of it or not, the Contractor shall within one Month from such generation inform the Procuring Entity about the contents of such Project Intellectual Property Rights.

9.4 Subject to Article 11, the Project Intellectual Property Rights shall remain vested within the Contractor. Subject to Article 11, the Procuring Entity shall enjoy the right to require the Contractor to grant non-exclusive licenses to third parties to exploit the Results, including Project Intellectual Property Rights and the Pre-existing rights that are needed to perform the Project under fair and reasonable market conditions without any right to sublicense. The Contractor and these third parties are responsible for establishing the fair market conditions.

Article 10 - Exploitation of Intellectual Property Rights

10.1 The Contractor shall inform the Procuring Entity of any Results which are capable of commercial exploitation, whether patentable or not.

10.2 Unless otherwise provided in the Agreement and subject to Article 11, the Contractor shall take all appropriate and necessary measures to ensure the proper management of the Project Intellectual Property Rights.

10.2.1 The Contractor shall at its own costs be responsible for the application, examination, grant, maintenance, management and defense of the Project Intellectual Property Rights in the Results and in particular, but without limitation, it shall ensure that:

10.2.1.1 the Results of the Project are identified, recorded and carefully distinguished from the outputs of other Research and development activities not covered by the Project;

10.2.1.2 prior to any publication on the Project, patentable inventions arising from the Results are identified, duly considered for patentability and, where it is reasonable so to do, patent applications in respect thereof are filed at the relevant Member State or European Patent Office; and

10.2.1.3 all such patent applications are diligently executed and prosecuted having regard to all relevant circumstances.

10.2.2 If the Contractor becomes aware of any product or activity of any third party that involves or may involve infringement or other violation of the Project Intellectual Property Rights, or any other proprietary right on the Results, the Contractor shall promptly notify the Procuring Entity of the infringement or violation.

10.2.3 Unless otherwise provided in this Agreement or unless the Project Intellectual Property Rights are assigned to the Procuring Entity and the Nightingale Members pursuant to Article 11, the Contractor shall take all appropriate measures to protect or defend said Project Intellectual Property Rights, or any

other proprietary right on the Results. The Contractor shall have the conduct and bear the costs of such proceedings. The Procuring Entity shall however:

10.2.3.1 have a monitoring/audit right on the conduct of the proceedings and the Contractor agrees to take the Procuring Entity's comments on the conduct of the proceedings in due consideration, and

10.2.3.2 provide reasonable assistance to the Contractor with respect to bringing any action.

10.3 The Contractor shall permit the Procuring Entity to monitor the operation and effectiveness of the Contractor's procedures for the management of Project Intellectual Property Rights in such a way as the Procuring Entity considers reasonably necessary.

10.4 The Contractor shall ensure the good management of Project Intellectual Property Rights consistent with the terms and conditions of the present Agreement;

10.4.1 the Contractor shall promote the dissemination of the Results of the Project; and

10.4.2 where they are capable of exploitation, exploit commercially the Project Intellectual Property Rights as well as the other Results (even if they cannot be protected by Intellectual Property Rights) to generate revenue by marketing commercial applications thereof;

10.4.3 and the Contractor shall refer to its participation to the project, the means of PCP related to the project and the H2020 grant of the European Commission.

Article 11 — Commercial exploitation of results

The Contractor shall, within five (5) years after the end of the Framework Agreement, take measures to ensure that the Project Results are exploited commercially (directly or indirectly, in particular through licensing). Contractor will report on request of the Procuring Entity about the progress on the commercial exploitation of the results during the 5-year period aforementioned (max. twice per year).

If the Contractor fails to commercially exploit the Results within this period, or uses the Results to the detriment of the public interest, the Contractor shall, according to the provisions of Article 9.3, at Procuring Entity's request, transfer the ownership of the Results to the Procuring Entity free of costs or sub-licenses IPRs to third parties indicated by the Procuring Entity.

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

Article 12 - Ownership of the Results and access rights to Results

12.1 Subject to the terms and conditions of the present Section 12 of the Agreement, the Material shall be the sole property of the Contractor and shall be subject to the Contractor's use, commercial or otherwise, including use in publications, communications or in submissions to any governmental agency.

12.2 Delivery of hardware, software, and reports

Delivery of the system is, where applicable, used in the sense of delivery of developed software and hardware in and for Nightingale, and installation comprising all necessary components, enabling an evaluation of a working prototype and pre-series model. Technical support and adequate instruction by the manufacturer are also mandatory.

Phase 0 and phase 1:

In these phases a delivery of hardware and/or software is not applicable. However, a feasibility study and an end of Phase report are necessary.

Phase 2:

The above described delivery is applicable. A sufficient number of prototype solutions have to be delivered by the Contractor to be able to test on at least 20 (healthy) volunteers and will be tested at two locations.

Respecting the very nature of PCP as R&D Service, please note that supply costs are not allowed to exceed a proportion of 50% of the total PCP contract value.

Phase 3:

The above described delivery is applicable. A sufficient number of pre-series models have to be delivered by the Contractor to the testing locations (Utrecht, Leuven, London, Stockholm and Aachen) to perform feasibility testing within actual patients at all testing locations simultaneously. The total number of pre-series models / patients per hospital are to be determined.

Testing will be performed by the Procuring Entities.

Respecting the very nature of PCP as R&D Service, please note that supply costs are not allowed to exceed a proportion of 50% of the total PCP contract.

12.3 The Project Intellectual Property Rights on the aforementioned prototypes or pilot systems shall be vested in the Contractor, who shall license them to the Procuring Entity and the other Nightingale members in accordance with Article 9.1.

Ownership of the Results and access rights to Results after Phase 3:

12.4 The Procuring Entity intends to set up a multicenter clinical trial as a separate project, outside the scope of this PCP Project after the completion of the PCP project, to test the validity of the Results and to allow the Contractor to obtain the needed certificates, such as the necessary CE-marks. The Procuring Entity intends to facilitate a large multicenter clinical trial to allow the Contractor to develop a feasible business plan to commercially exploit the Results. For the avoidance of any doubt, if during such clinical trial, the Procuring Entity subsequently purchases products from the Contractor which include Project Intellectual Property Rights, the Contractor may not charge the Procuring Entity for the license to these Project Intellectual Property Rights and the needed pre-existing rights as they have already been licensed for free to the Procuring Entity in the PCP.

Article 13 — 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 (including all the original materials, or any other materials, prepared in connection herewith). This applies during the implementation of the Framework Agreement and up to 5 years after the end of the Framework 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 third parties involved in the PCP implementation only if:

- they need to be aware of this information in order to implement the PCP activities under the Framework Agreement and specific contracts; and
- they are bound by an obligation of confidentiality.

The confidentiality obligations cease to apply if:

- the disclosing party agrees to release the other party from the obligation;
- 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;
- the recipient proves that the information was produced without the use of confidential information;
- the information becomes generally and publicly available, without breaching any confidentiality obligation; or
- 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.

The Contractor is fully responsible and liable for the effective performance, by his employees, consultants and collaborators, of the confidentiality obligations herein and undertakes to impose this confidentiality obligation on all those persons who, as a result of their position, become acquainted – directly or indirectly – with any confidential information.

In the event of the Contractor's failure to comply with the confidentiality obligations herein, the Procuring Entity shall be entitled to terminate this Agreement forthwith, subject to prior notice of termination sent by registered letter with acknowledgement of receipt, without prejudice to claim further damages.

Article 14 — Promotion, publicity and communication

14.1 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 (in particular, to other potential customers beyond the lead procurer and buyers group with the objective to achieve commercial exploitation of the results (see Article 11 – Commercial exploitation of results)).

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

During the implementation of the contract and for a period of 5 years after the end of the contract, the contractor shall inform the Procuring Entity 28 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 Procuring Entity 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 Nightingale project that has received funding from the European Union's Horizon 2020 Research and Innovation Programme';
- for infrastructure, equipment and major results: 'This [infrastructure][equipment][insert type of result] is part of the Nightingale 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.

14.2 The Procuring Entity 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 audiovisual material) from the contractor (including in electronic form).

The Procuring Entity and the buyers group may, in particular, publish the names of the participating contractors and their 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 13.

Moreover, before publishing this information, the Procuring Entity 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.

14.3 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 Procuring Entity to request the EU not to use it.

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

- 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);

- 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);
- editing or redrafting for the purposes of communication and publicity (including shortening, summarizing, 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);
- translation;
- giving access in response to individual requests made under Regulation EC No 1049/2001, without the right to reproduce or exploit;
- storage in paper, electronic or other form;
- archiving, in line with applicable rules on document management, and
- authorizing 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 15 — Conflicts of interest

15.1 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.

15.2 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.

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

Article 16 — Ethics and research integrity

16.1 The contractor shall carry out the tasks assigned to it in the Framework Agreement and in the specific contracts in compliance with:

- ethical principles (including the highest standards of research integrity) and
- applicable international, EU and national law.

The contractor 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 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:

- (a) honesty;
- (b) reliability;
- (c) objectivity;
- (d) impartiality;
- (e) open communication;
- (f) duty of care;
- (g) fairness and
- (h) 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.

16.2 Before starting any activity that raises an ethical issue, the contractor shall submit to the lead procurer a copy of:

- any ethics committee opinion required under national law and
- any notification or authorisation for activities raising ethical issues required under national law.

¹ 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

Article 17 — Processing of personal data

17.1 The lead procurer and the buyers group shall process personal data in compliance with the applicable EU and national law on data protection.

17.2 The contractor shall process personal data in compliance with the applicable EU and national law on data protection (including as relates to authorizations 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 18 –Data Protection

For the purposes of this Article 18, the terms “Controller”, “Data Subject”, “Personal Data”, “Process” and “Processing” shall have the meaning prescribed under the Data Protection Directive (officially Directive 95/46/EC) and its successor the Data Protection Regulation (EU) 2016/679.

The Contractor shall (and shall ensure that all of its staff) comply with any notification requirements under the Data Protection Directive (officially Directive 95/46/EC) and its successor the Data Protection Regulation (EU) 2016/679 and all applicable national data protection laws and both parties will duly observe all their obligations under such EU and national data protection laws which arise in connection with this Framework Agreement.

Notwithstanding the general obligation in Article 17, where the Contractor is processing Personal Data for the Procuring Entity and Nightingale consortium members the Contractor shall:

1. Process the Personal Data only in accordance with instructions from the Procuring Entity (which may be specific instructions or instructions of a general nature) as set out in this Framework Agreement or as otherwise notified by the Procuring Entity;
2. Comply with all applicable laws;
3. Process the Personal Data only to the extent; and in such manner as is necessary for the provision of the provider's obligations under this Framework Agreement or as is required by law or any regulatory body;
4. Implement appropriate functional and organizational specifications to protect the Personal Data against unauthorized or unlawful processing and against accidental loss, destruction, damage, alteration or disclosure. These specifications shall be appropriate to the harm which might result from any unauthorized or unlawful processing, accidental loss, destruction or damage to the Personal Data and having regard to the nature of the Personal Data which is to be protected;
5. Take reasonable steps to ensure the reliability of its staff and agents who may have access to the Personal Data;

6. Obtain prior written consent from the Procuring Entity in order to transfer the Personal Data to any Sub-Contractor for the provision of the Services;
7. Not cause or permit the Personal Data to be transferred, stored, accessed, viewed or processed outside countries participating in Nightingale where the project activities are primarily performed without the prior written consent of the Procuring Entity;
8. Ensure that all staff and agents required to access the Personal Data are informed of the confidential nature of the Personal Data and comply with the obligations set out in this Article 18;
9. Ensure that none of the staff and agents publish disclose or divulge any of the Personal Data to any third parties unless directed in writing to do so by the Procuring Entity not disclose Personal Data to any third parties in any circumstances other than with the written consent of the Procuring Entity or in compliance with a legal obligation imposed upon the Procuring Entity; and notify the Procuring Entity (within five Working Days) if it receives:
 1. a request from a Personal Data subject to have access to that person's Personal Data; or
 2. a complaint or request relating to the Procuring Entity's obligations under the EU and/or national data protection laws;

The provision of this Article 18 shall apply during the Agreement period and for as long as Contractor processes or holds Personal Data for a Nightingale consortium member.

Article 19 - Anonymization of Personal Data

19.1 The Procuring Entity shall not be entitled to inspect, take or be supplied with copies of any specific basic factual (or "raw") Personal Data obtained in connection with the Project other than in an anonymized form. The Contractor shall ensure that all Personal Data is anonymized immediately when obtained and that the key to personal identities of all persons to whom the Personal Data relates is kept in a separate and secure place.

19.2 Contractor shall ensure that the Services are in line with and support the privacy design of the Research as set out in paragraph 5.1.2 of the Description of the Action attached as Annex 1 to the Grant Agreement. Specifically, the Contractor will ensure that devices/sensors will allow for Personal Data to be securely transmitted and encrypted while in wireless transit to allow all Personal Data to be stored on secure servers within the Nightingale consortium member's premises, or on secure servers from a certified Trusted Third Party (TTP) linked to the Nightingale consortium member's Electronic Medical Record system. Also, the Contractor will ensure that after the Personal Data is so stored and linked to the other pertinent clinical patient information, Personal Data and all other patient related Data will be removed from the device/sensor.

Article 20 — Obligation to provide information and keep records

20.1 The contractor must, at any time during the implementation of the Framework Agreement and specific contracts or afterwards, provide any information requested by the lead procurer or the buyers group in relation to the Framework Agreement or related contracts concerning the commercialization of the Results.

20.2 The contractor must keep, for a period of up to 10 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 digitalized documents are considered originals if they are authorized 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 22 — 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 23 — EU impact evaluation

Should the EU carry out an impact evaluation (of its grant to the lead procurer and 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 24 — Termination

24.1 Without prejudice to any other provision of this Framework Agreement, this Framework Agreement may be terminated by either party giving three months' notice in writing to the other, unless the time remaining to the end of the relevant Phase is less than three Months, in which case the notification time shall be all remaining time to the end of that Phase. Should the option to terminate be exercised by the Procuring Entity, it shall indemnify the Contractor from and against all and any actual loss unavoidably incurred by reason or in consequence of the termination provided that the Contractor takes all immediate and reasonable steps to minimize the loss.

24.2 With regards to Article 24.1 the Procuring Entity will not pay any sum which, when taken together with any sums paid or due or becoming due to the Contractor under this Framework Agreement, will exceed such total sums as would have been payable under this Framework Agreement if the Contractor had fulfilled its obligations under this Framework Agreement.

24.3 The Procuring Entity may at any time and from time to time by notice in writing terminate this Framework Agreement without liability for any damage, loss or expenses arising as a result of or in connection with such termination if there is a change of control in the Contractor which the Procuring Entity can reasonably demonstrate is prejudicial. The Procuring Entity shall only be permitted to exercise its rights pursuant to this clause for 6 (six) Months after any such change of control and shall

not be permitted to exercise such rights where the Procuring Entity has agreed in advance in writing to the particular change of control and such change of control takes place as proposed. The Contractor shall notify the Procuring Entity within 2 (two) weeks of any change of control taking place.

24.4 The Procuring Entity may at any time and from time to time by notice in writing terminate this Framework Agreement without liability for any damage, loss or expenses arising as a result of or in connection with such termination if:

24.4.1 any approvals consent or licenses required under this Framework Agreement are not given unconditionally within 6 (six) Months of the commencement of the Project Period;

24.4.2 the Contractor is subject to an Insolvency Event;

24.4.3 the Contractor is in Default under this Framework Agreement and if:

24.4.3.1 the Default is capable of remedy and the Contractor shall have failed to remedy the Default within 30 (thirty) Days of written notice being sent to the Contractor specifying the Default and requiring its remedy; or

24.4.3.2 the Default is not capable of remedy;

24.4.4 any provision of this Framework Agreement (other than as previously specified in the preceding provisions of this Article 24) expressly entitles the Procuring Entity to terminate this Framework Agreement;

24.4.5 the Contractor, or any sub-Contractor on whose resources he has relied in the procurement that has preceded this Framework Agreement, becomes subject to any exclusion criteria listed in the PCP Request for Tender document;

24.4.6 the Services are not in compliance with requirements on Research and development Services as defined in the most recent version of the Frascati Manual (Proposed Standard Practice for Surveys on Research and Experimental Development OECD, 6th Edition, 2002, ISBN 978-92-64- 19903-9, pp 29-50) and, where applicable its latest annexes or in case of non-compliance with any other requirement mentioned in the PCP Request for Tender document and declared in the signed declaration that is part of the tender.

24.5 Termination of this Framework Agreement by the Procuring Entity under the preceding provisions of this Article 24 shall (at the option of the Procuring Entity) terminate this Framework Agreement with immediate effect as from the date of service of the notice of that termination or from the expiry of a period (not exceeding 6 (six) Months) specified in that notice.

24.6 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.

24.7 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.

Article 25 — Amendments

25.1 If at any time, it appears likely that any provision of the Agreement or the Project, needs to be amended, the Contractor shall immediately inform the Procuring Entity in writing requesting a Variation to the Agreement, giving full details of the justification for the request and giving proposals for the Variation to the Agreement. Upon receipt of such a request the Procuring Entity may:

25.1.1 agree to amend the Agreement provided such Variation is non-discriminatory and does not amount to a substantial change of the Agreement, the scope of the service or the scope of the Results, as allowed under the then prevailing case law of the European Court of Justice;

25.1.2 amend the Project in a manner which the Contractor agrees can be carried out within the Project Period and within the Price with regard to the relevant Phases;

25.1.3 refuse the request and require the continuation of the Project in accordance with the Framework Agreement; or

25.1.4 give notice of termination in accordance with Article 24.

Article 26 — Subcontracting, Transfer, Assignment & Interpretation

26.1 The Contractor will allow the Commission, the European Court of Auditors (ECA) and the European Anti-fraud Office (OLAF) to exercise their rights under Articles 22 and 23 Grant Agreement (*mutatis mutandis*) and will comply with Articles 17.1, 18, 34, 35, 37, 36, 38, 39 and 46 Grant Agreement (*mutatis mutandis*).

26.2 The Contractor will ensure that in all Sub-Contracts the conditions from the Grant Agreement set out in clause 26.1 above are imposed upon the subcontractor.

26.3 A third party may replace a Contractor or a member of the Contractor in case of a consortium as a result of universal succession in the position of the Contractor following corporate restructuring, including takeover, merger, acquisition or in an Insolvency Event, provided that said third party meets all exclusion, selection, compliance and minimal technical criteria and the succession does not entail a substantial modification.

26.4 The Contractor is allowed to replace a subcontractor, provided that the new subcontractor meets all exclusion, selection, compliance minimal technical criteria and the replacement does not entail a substantial modification.

26.5 The Framework Agreement constitutes the entire agreement between the parties relating to its subject matter. Each party acknowledges that it has not entered into this Framework Agreement on the basis of any warranty, representation, statement, agreement or undertaking except those expressly set out in this Framework Agreement. Each party waives any claim for breach of this Framework Agreement, or any right to rescind this Framework Agreement in respect of, any representation which is not an express provision of this Framework Agreement. However, this Article does not exclude any liability which either party may have to the other (or any right which either party may have to rescind this Framework Agreement) in respect of any fraudulent misrepresentation or fraudulent concealment prior to the execution of this Framework Agreement. In case of discrepancy between the Framework Agreement, on the one hand, and the PCP Request for Tender Document, on the other hand, the documents shall prevail in the following order:

- Framework Agreement;
- PCP Request for Tender Document;
- Other Tender Documents; and
- Contractor's Tender in the Tendering Stage.

Article 27 — Applicable law and dispute settlement

This Framework Agreement shall be considered as an agreement made in the Netherlands and be construed in accordance with the law of The Netherlands. The place of jurisdiction shall be the court competent for UMC Utrecht in Utrecht, the Netherlands. Any legal claim, petition or application for judicial review, with regard to the present procurement procedure, shall be made in the Netherlands. By submitting a tender, the Contractor accepts the exclusive jurisdiction of the courts of The Netherlands.

Article 28 — Entry into force

This Framework Agreement shall enter into force between Parties on the day on which UMC Utrecht has received a signed duplicate of this Agreement of the authorized representative of each of the Parties.

SIGNATURES

The lead procurer signs for the buyers group and — in case of joint tenders — the lead contractor for the group of contractors (see also section 4.1 of the request for tenders).