



THALEA PCP

FRAMEWORK AGREEMENT



Ministerium für Innovation,
Wissenschaft und Forschung
des Landes Nordrhein-Westfalen



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Agència de Qualitat i
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THALEA PCP – FRAMEWORK AGREEMENT

FRAMEWORK AGREEMENT

BETWEEN

THE UNIVERSITY HOSPITAL AACHEN (UKA) (1)

(Acting through its procurement department in the name and on behalf of the THALEA consortium)

- AND -

TENDERER (2)

Example "THALEA"

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SECTION 1: FORM OF AGREEMENT

This Framework Agreement is made between

- (1) The University Hospital Aachen, Pauwelsstraße 30, 52074 Aachen (acting through its procurement department in the name and on behalf of the THALEA consortium) and
- (2) [Name] [registered number] of [registered office address] (“the Tenderer”)

The Procuring Entity and the Tenderer, together called “the parties” and individually “a party”.

IT IS AGREED as follows:

1. UKA enters into this Framework Agreement in the name and on behalf of the consortium of THALEA Contracting authorities: (i) University Hospital Aachen, Germany, (ii) University Hospital Maastricht, Netherlands, (iii) Parc Tauli Sabadell University Hospital, Spain, (iv) Hospital East Limburg, Belgium and (v) Northern Ostrobothnia Hospital District, Finland, each of which jointly participate and assume rights and obligations hereunder in accordance with the terms and conditions of Section 2 below.

2. The Tenderer will provide Research and development Services as well as deliver a highly interoperable software solution to UKA and THALEA consortium within a Project entitled "Telemonitoring and Telemedicine for Hospitals Assisted by ICT for Life saving co-morbid patients in Europe As part of a Patient personalized care program of the EU" in accordance with the Challenge Brief as provided in the tender documents.

The Project is divided into the following phases:

- Phase 0: Tender submission and admission based on all selection criteria and participation requirements, which are governed in particular by the Tender Regulations, the Functional Specification document and the Tender Notice;
- 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”):
 - “Phase I”: Solution design and feasibility study
 - “Phase II”: Prototype development
 - “Phase III”: Development of a limited volume of first products or Services in the form of a test series.

3. UKA will pay the Tenderer, as set out in clause five (5) of this Framework Agreement. UKA will also, where applicable, pay the Price for Phase II and the Price for Phase III to whichever Tenderer(s) are awarded for one or both of those Phases. Such payment will include all sums from UKA to the Tenderer for undertaking the Project.

4. This form of agreement (Section 1) together with the attached Section 2 are the documents which

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collectively form “the Framework Agreement”. If there is any inconsistency between this Section 1 and the terms and conditions set out in Section 2, the order of priority shall be: (1) Section 1 and (2) Section 2. The Framework Agreement shall cover all three Phases.

In case of inconsistency between the Tender Regulations and Tender Documents the order of priority shall be: 1) Framework Agreement, 2) General Conditions, 3) Challenge Brief.

The following shall hereafter collectively form the “**Framework Agreement**”:

- the General Framework (Section 1),
- the terms and conditions (section 2)

5. The Framework Agreement effected by the signing of this form of agreement constitutes the whole agreement between the parties and supersedes all prior negotiations, agreements, representations or understandings between them relating to the subject matter of this Framework agreement. Furthermore, it does not involve Agreement renegotiations on rights and obligations taking place after signature of the Framework Agreement (in accordance with Work program 2013 ICT- Information and communication technologies [European Commission C (2012)4536 of 09 July 2012], Appendix 6).

6. Each party acknowledges that, in entering into the Framework Agreement, it does not rely on any statement, representation, assurance or warranty of any person (whether a party to this Framework Agreement or not) other than as expressly set out in the Framework Agreement. Each party agrees that the only remedies available to it arising out of or in connection with any statement, representation, assurance or warranty shall be for breach of Agreement.

7. Nothing in this Framework Agreement shall limit or exclude any liability for Fraud or Fraudulent misrepresentation. Furthermore, THALEA has to fulfill quality standards of the GCP (Good clinical practice) and national requirements in terms of safety, ethics and healthcare.

8. The Framework Agreement becomes effective upon signing by both parties and shall remain in effect (unless terminated in accordance with clause 18) until the Completion Date (as defined below) of Phase I or of a later Phase that has been awarded the Tenderer. However, confidentiality shall be remained for 36 months in accordance to Section 2 clause 9. Please note that tenderers who are awarded for the Phases II and III shall sign a formal assignment for that particular phase (see THALEA General Conditions, appendix 10).

9. The parties expressly acknowledge that the Procuring Entity and the THALEA consortium members individually, shall have certain rights on the Intellectual Property Rights and on the Results as a third party beneficiary in accordance with the terms and conditions of Section 2 (Terms and Conditions) below.

[SIGNATURE PAGE FOLLOWS]

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Signed in original copies [one for each Party],

by the duly authorised signatory of the Procuring Entity UKA (Acting through its procurement department in the name and on behalf of the THALEA consortium):

.....
... Signature

.....
... Full Name

.....
... Position Held

.....
Date

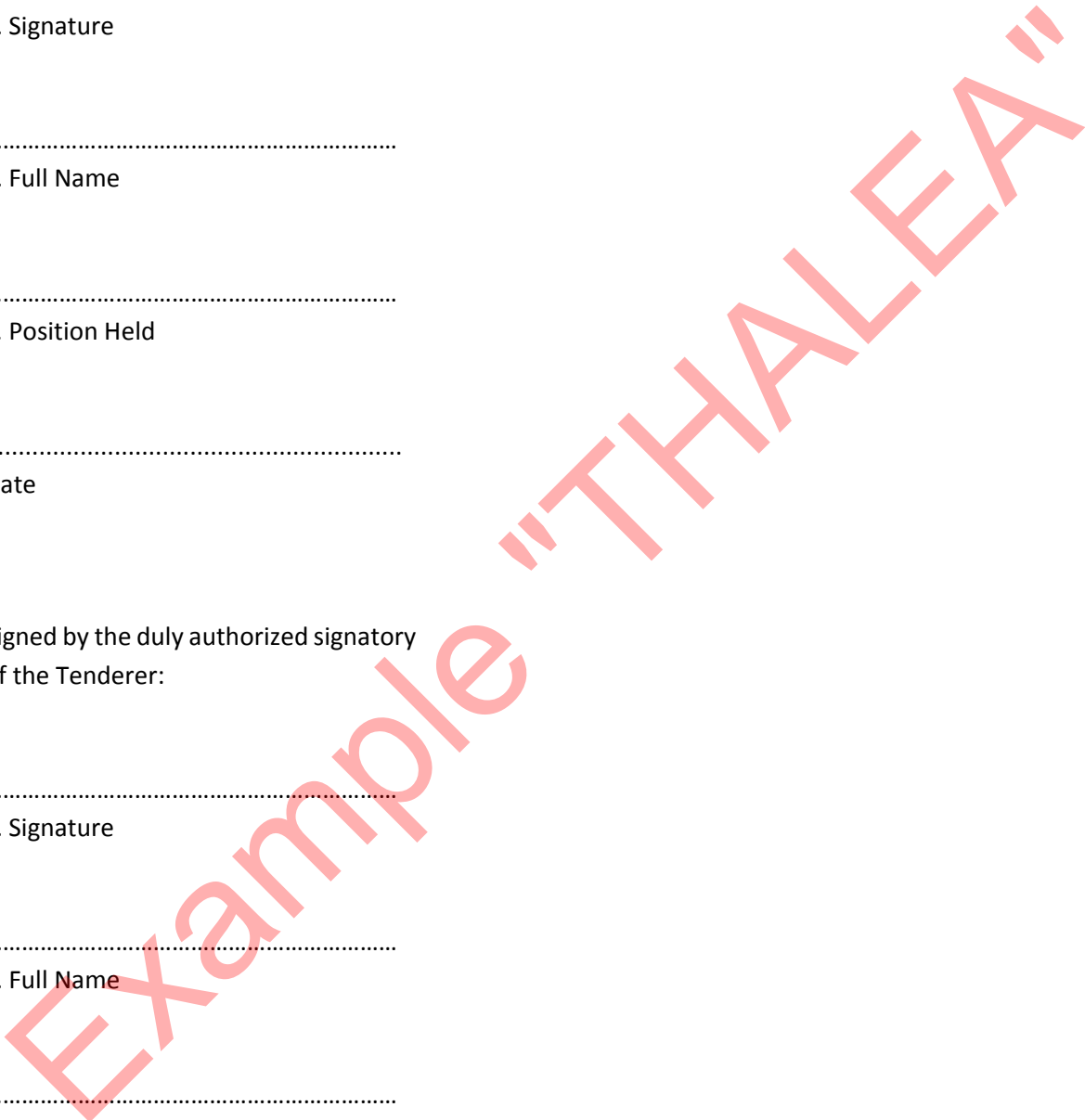
Signed by the duly authorized signatory
of the Tenderer:

.....
... Signature

.....
... Full Name

.....
... Position Held

.....
Date



SECTION 2: TERMS AND CONDITIONS**1 Glossary**

1.1 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;
“Assessment Committee”	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;
“Award Criteria”	means, for each Phase, the criteria used to identify the most advantageous tender;
“Background”	means information, technology or Intellectual Property Rights relating to such information or technology owned, developed or controlled by either of the parties prior to the date of this Agreement or which shall at any time thereafter become so owned, developed or controlled otherwise than as a result of the Project or under this Agreement, excluding, for the avoidance of doubt in any later Phases, Project Intellectual Property rights developed in an earlier Phase;
“Challenge Brief”	means the accompanying document to the General Conditions, 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 the German Federal Data Protection Act (BDSG) and the Project, including its deliverables and other commercially sensitive information;

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“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;
“Default”	means any breach by a party to this Framework Agreement of its obligations under this Framework Agreement (including, without limitation, a fundamental breach or breach of a fundamental term);
“End of Phase Report”	means a report in written form to be submitted by the Tenderer 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 THALEA Tender Form, Appendix 2);
“Foreground Intellectual Property”	means any Intellectual Property created by either party as a result of their involvement in this Framework Agreement of the THALEA project;
“Formal Assignment”	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.
“FP7”	means Seventh Framework Programme;
“Framework Agreement”	means this Agreement comprising Sections 1 and 2;
“Fraud”	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;
“Functional Specifications”	means the specifications set out in the THALEA Functional Specifications document defining the required characteristics and set of functions of the outcome of the Project;
“General Conditions”	means the invitation documents on which the tenders for the award of the work order for Phase 1 were submitted;

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<p>“Insolvency Event”</p>	<p>means where the Tenderer passes a resolution or the court makes an order that: (i) the Tenderer be wound up (otherwise than for the purpose of a bona fide and solvent reconstruction or amalgamation); or (ii) a receiver, manager or administrator on behalf of a creditor is appointed in respect of all or part of the business of the Tenderer; or (iii) 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 (iv) the Tenderer ceases to trade or is unable to pay its debts within the meaning of Insolvency Statute of 5 October 1994 (Bundesgesetzblatt (BGBl I S. 3044), Federal Law Gazette I page 2866), as last amended by Article 19 of the Act of 20 December 2011 (Federal Law Gazette I page 2854) or any similar event occurs under the law of any other jurisdiction;</p>
<p>“Intellectual Property”</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 THALEA consortium members - for evaluation and research purposes.</p>
<p>“Key Staff”</p>	<p>means the persons named in Section 2;</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 Tenderer under clauses 13 and 14;</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 Tenderer as set out in the Framework Agreement;</p>

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“Personal Data”	has the meaning given to it in section 1 of the Data Protection Directive (officially Directive 95/46/EC) and the German Federal Data Protection Act (BDSG)
“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 Section 1;
“Price”	means the total Price (excluding VAT) agreed between the parties for each Phase of the Project, to be paid by the Procuring Entity (UKA) to the Tenderer 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 University Hospital Aachen, Pauwelsstraße 30, 52074 Aachen, acting through its procurement department in the name and on behalf of the THALEA consortium;
“Project”	means the Research and development Services as well as deliver a highly interoperable software solution that are required by Tenderers to complete Phases 1, 2 and 3 and to generate the Results;
“Project Intellectual Property Rights”	means new Intellectual Property rights arising from or relating to the Services and the Results;
“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;
“Research”	means the scope of work (Research and development Services) specified in Section 2;
“Results”	means any Data, or information, or deliverables, or other Material generated by the Project;
“Services”	means the Services being provided by the Tenderer in fulfilment of this Framework Agreement and any work order issued through it;
“Sub-Contract”	any contract or agreement between the Tenderer and any third party whereby that third party agrees to provide Services to the Tenderer to enable or assist the Tenderer to provide the Services or any part thereof to the Procuring Entity;

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“Tender Documents”	means all documents issued or published by the Procuring Entity as part of the PCP-process and made available on the www.vergabe.nrw.de 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 THALEA PCP Tender Notice date, which will be made available on TED (Tenders Electronic Daily) at http://ted.europa.eu/TED/main/HomePage ;
“Tenderer”	means the person, firm or company with whom the Procuring Entity enters into this Framework Agreement or a work order;
“Tenderer’s Representative”	means a person authorized to represent the Tenderer in respect of this Framework Agreement;
“Tenderer’s Staff”	means the Tenderer’s Representative and all employees, consultants, agents, and sub-Tenderers (including their staff) which the Tenderer 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 clause 6;

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

- 1.2.1 a reference to any statute, enactment, order, regulation or other similar instrument shall be construed as a reference to the statute, enactment, order, regulation or instrument as subsequently amended or re-enacted;
- 1.2.2 the headings in this Framework Agreement are for ease of reference only and shall not affect its interpretation or construction;
- 1.2.3 references to conditions are references to conditions in the section of this framework Agreement in which they appear, unless otherwise stated;
- 1.2.4 where the context allows, references to male gender include the female gender and the neuter, and the singular includes the plural and vice versa.

2 Succession of Phase I, Phase II and Phase III of the Project

2.1 By the signing of the Framework Agreement, the Procuring Entity and the tenderer accept the general conditions set by this framework agreement. In case the tenderer gets awarded, specific Formal assignments per Phase have to be signed by the Procuring Entity and tenderer. This assigns to the Tenderer the task of performing the Services within the scope of respective Phase I, Phase II and Phase III of the Project. The Tenderer acknowledges that the Procuring Entity will simultaneously enter into a similar Contractual arrangement for the Project with other Tenderers Assessment of Phase I and award of Phase II

2.1.1 On the Completion Date of Phase I, the Tenderer 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 Assessment Committee in order to determine whether the Tenderer has complied with 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 Assessment Committee shall issue its decision as to the award of the Phase II acceptance, not earlier than four (4) weeks and not later than eight (8) weeks after the Completion Date of Phase I. In case volume of tenderers leads to a longer evaluation process Tenderers will be informed. The consent to Phase II shall only be awarded if the Assessment Committee has determined that Phase I has been "successfully completed". For phase 2 a *minimum* of 3 contracts is expected to be awarded. Before each phase, submitted offers for that phase are assessed and the best tenders are given a contract within the available budget for that phase. For each phase contracts are awarded until the remaining budget for that phase is insufficient to fund the next best tender. Any remaining budget after doing so is carried over to the total budget for the next phase. Such a budget carry-over may thus result in a small update of the maximum price per project for phase 3, which will be calculated as the updated maximum total budget for that phase after budget carry-over from the previous phase divided by the minimum number of contractors for that phase. Any such update will be communicated to tenderers after the relevant phase.

2.1.2 If the Tenderer is selected for Phase II, this Agreement shall continue in effect for the duration of the following Phases. The Tenderer shall thereupon sign a formal assignment relevant to that phase. In addition, if the Tenderer 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.

2.2 Assessment of Phase II and award of Phase III

2.2.1 On the Completion Date of Phase II, the Tenderer 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 Assessment Committee in order to determine whether the Tenderer 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.

2.2.2 The Assessment Committee shall issue its decision as to the award of the Phase III acceptance, after clinical evaluation of the prototypes (approximately two months) after the Completion Date of Phase II. The consent to Phase III shall only be awarded if the Assessment Committee has determined that Phase II has been "successfully completed". For phase 3 a *minimum* of 2 contracts is expected to be awarded. Before each phase, submitted offers for that phase are assessed and the best tenders are given a contract within the available budget for that phase. For each phase contracts are awarded until the remaining budget for that phase is insufficient to fund the next best tender.

2.2.3 If the Tenderer is selected for Phase III, this Agreement shall continue in effect for the duration of that Phase. The Tenderer shall thereupon sign a formal assignment relevant to that phase. In addition, if the Tenderer 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.

- 2.3 In this Agreement, "successful completion" of a Phase shall be assessed in terms of overall compliance with the Functional Specifications. Satisfactory completion of Phase 1 is a prerequisite to receiving an invitation for Phase 2. Satisfactory completion of Phase 2 is a prerequisite to receiving an invitation for Phase 3.
- 2.4 Any award for Phases II and III will be communicated in writing by the Procuring Entity to the Tenderer in accordance with clause 29 (notices) below.
- 2.5 Any reference in this Framework Agreement to the Project refers also to any of the Phases awarded to the Tenderer.
- 2.6 In each Phase at least 60 % of the Services shall be performed within the EU Member States or a country that is associated to FP7.
- 2.7 The Procuring Entity reserves the right not to award contracts for Phases for which it has not received any favorable 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 Tenderers or Contractors for any expense or loss that may occur in the preparation of their tenders.

3 Administration and Direction of the Project

- 3.1 The Tenderer shall ensure that each member of the Tenderer's Staff engaged on the Project observes the terms and conditions of this Agreement and any Variation entered into between the parties here to and that the Tenderer's Staff are advised of any changes in the scope of the Agreement or the Project.
 - 3.1.1 In particular, as Tele-intensive medicine 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.
- 3.2 Notwithstanding the provisions of clause 18, the Procuring Entity may terminate this Framework Agreement if any of the Tenderer'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 Tenderer 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.
- 3.3 The objectives and requirements of the Project are set out in 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 Tenderer, in consultation, where appropriate, with the Procuring Entity's representative.
- 3.4 The Tenderer 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 Clauses 5.7 and 6 below, the Tenderer 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 Tenderer becomes aware of the necessity or usefulness of such deviation.

- 3.5 The Tenderer shall ensure full communication takes place between the parties and such others as may be notified to the Tenderer by the Procuring Entity and shall advise as required on the Project.
- 3.6 Notwithstanding the provisions of clause 18, the Procuring Entity may terminate this Framework Agreement forthwith should the Tenderer be unwilling or unable for any reason to continue with the Project or if, in the reasonable opinion of the Procuring Entity, the Tenderer 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 Tenderer.

4 Obligations of the Tenderer and the Procuring Entity

- 4.1 The Tenderer 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.
- 4.2 The Tenderer shall meet, with time being of the essence, delivery any performance dates, including but not limited to End of Phase Reports and related deliverables. If the Tenderer fails to do so, the Procuring Entity may, after giving the Tenderer not less than 14 Days' notice of its intention (without prejudice to any other rights it may have):
- 4.2.1 terminate this Agreement in whole or in part without liability to the Tenderer;
 - 4.2.2 refuse to accept any subsequent performance of the Project which the Tenderer attempts to make;
 - 4.2.3 hold the Tenderer accountable for any loss and additional costs incurred; and
 - 4.2.4 have all sums previously paid by the Procuring Entity to the Tenderer under the Phase which is then running, refunded by the Tenderer.
- 4.3 The Tenderer shall:
- 4.3.1 co-operate with the Procuring Entity in all matters relating to the Project;
 - 4.3.2 subject to the prior written approval of the Procuring Entity, appoint or, at the written request of the Procuring Entity, replace without delay:
 - 4.3.2.1 the Tenderer's Representative; and
 - 4.3.2.2 Key Staff or any member of the Tenderer's team, who shall be suitably skilled, experienced and qualified to carry out the Project.
 - 4.3.3 subject to clause 4.3.2, ensure that the same person acts as the Tenderer's Representative throughout the term of this Project;
 - 4.3.4 procure the availability of the Tenderer's Representative and Key Staff for the purposes of the

Project;

- 4.3.5 promptly inform the Procuring Entity of the absence of the Tenderer's Representative and/or Key Staff. If the Procuring Entity so requires, the Tenderer shall provide a suitably qualified replacement;
- 4.3.6 not make any changes to the Tenderer representative, Sub-Tenderers or the Key Staff without the prior written approval of the Procuring Entity, such approval not to be unreasonably withheld or delayed; and
- 4.3.7 ensure that the Tenderer's team uses reasonable skill and care during the Project.
- 4.4 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 Tenderer shall:
 - 4.4.1 observe, and ensure that the Tenderer's team observe, all rules and regulations and any other reasonable requirements of the Procuring Entity;
 - 4.4.2 The Tenderer shall acknowledge and adjust to any modification with respect to the Functional Specifications by the Procuring Entity as mentioned in clause 3.1.1 of this Framework Agreement;
 - 4.4.3 notify the Procuring Entity as soon as it becomes aware of any issues which arise in relation to the Project; and
 - 4.4.4 before the commencement date, obtain, and at all times maintain all necessary licences and consents and comply with all relevant legislation in relation to the Project.
- 4.5 The Tenderer acknowledges and agrees that the Tenderer 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.
- 4.6 The Procuring Entity shall:
 - 4.6.1 co-operate with the Tenderer in all matters relating to the Project and appoint (and replace, if appropriate) the Procuring Entity representative;
 - 4.6.2 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 Tenderer and agreed rules and regulations with the Tenderer in writing in advance, for the purposes of the Project;
 - 4.6.3 provide such information as the Tenderer may reasonably request and the Tenderer 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
 - 4.6.4 inform the supplier of all health and safety and any other reasonable security requirements that apply at any of the Procuring Entity's premises.

5 Accounting and Payments

- 5.1 The total amount to be paid by the procurement entity to the Tenderer shall not exceed the relevant amounts detailed in clause two (2) of the General Conditions and clause 5.2 of this Framework Agreement. Subject to these limits the Tenderer is free to administer received payments within the terms of this Framework Agreement without further reference to the Procuring Entity.
- 5.2 Payment for the Tenderer's Services for each Phase will be made according to the following provisions:
- 5.2.1 PHASE I: payment of the Price for Phase I shall be made in two parts. The Tenderer 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 Assessment Committee to award the Tenderer to Phase 1 (one). The second payment of 50% shall be paid within 30 calendar Days from the date of the decision of the Assessment Committee confirming that the Tenderer has complied with the Performance Conditions (see General Conditions, clause 2.5) and the Functional Specifications applicable to such Phase. In case of Default, any payment already made may be reclaimed.
- 5.2.2 PHASE II: payment of the Price for Phase II shall be made in three parts. The Tenderer 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 Assessment Committee to award the Tenderer 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 Assessment Committee confirming that the Tenderer 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.
- 5.2.3 PHASE III: payment of the Price for Phase III shall be made in three parts. The Tenderers 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 Assessment Committee to award the Tenderer 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 Assessment Committee confirming that the Tenderer 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 Assessment Committee confirming that the Tenderer has complied with the Performance Conditions and the Functional Specifications. In case of Default, any payment already made may be reclaimed.
- 5.3 The Tenderer 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.
- 5.4 Payments to third parties employed or hired by the Tenderer, if any, shall remain the responsibility of the Tenderer who shall ensure that such payments are made promptly and shall hold the Procuring Entity harmless against any claim of such third parties.
- 5.5 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 clauses 13 and 14.

- 5.6 Without prejudice to clause 6 below, the parties expressly agree that the Tenderer 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.
- 5.7 Subject to the confidentiality obligations set forth in clause 9, the Tenderer 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.
- 5.8 The Tenderer 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 Tenderer's compliance with this Agreement including all activities, performance, security and integrity in connection therewith.
- 5.9 If at any time an overpayment has been made to the Tenderer 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 Tenderer at the Procuring Entity's discretion.
- 5.10 The Tenderer shall keep and maintain, up until at least ten years after this Agreement has been completed, full and accurate records of the Project including:
- 5.10.1 all aspects of the Project;
- 5.10.2 all expenditure paid by the Procuring Entity; and
- 5.10.3 all payments made by the Procuring Entity, and the Tenderer shall on request afford the Procuring Entity or the Procuring Entity's representatives such access to those records as may be required in connection with the Agreement.
- 5.11 Where the Tenderer enters into a Sub-Contract with a supplier or Tenderer 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 Tenderer to the Sub-Tenderer within a specified period not exceeding 30 calendar Days from the receipt of a valid invoice, as defined by the Sub-Contract requirements.
- 5.12 Wherever, under the Contract, any sum of money is recoverable from or payable by the Tenderer (including any sum that the Tenderer 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 Tenderer under the Contract or under any other agreement with the Procuring Entity.
- 5.13 The Tenderer 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 Tenderer has a final and enforceable court order requiring an amount equal to such deduction to be paid by the

Procuring Entity to the Tenderer.

- 5.14 The Procuring Entity presumes that 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 THALEA core consortium or advisory board. Tenders with a price that excludes wide commercialisation will not be eligible for funding. Price ceiling will be a price > 2 SD above average of all tenders and or purchase price > 700.000 € and/or a total cost of ownership on basis of a 5 year use time 1.200.000€.

6 Variation

- 6.1 If at any time it appears likely that any provision of the Agreement or the Project, needs to be amended, the Tenderer shall immediately inform the Procuring Entity in writing requesting a Variation to the Agreement (see THALEA_03_TENDER_FORM, Appendix 2, schedule E), 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:
- 6.1.1 agree to vary 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;
 - 6.1.2 vary the Project in a manner which the Tenderer agrees can be carried out within the Project Period and within the Price with regard to the relevant Phases;
 - 6.1.3 refuse the request and require the continuation of the Project in accordance with the Framework Agreement; or
 - 6.1.4 give notice of termination in accordance with clause 18.

7 Staff appointment

- 7.1 All staff providing Services in connection with this Framework Agreement shall be bound by the same terms and conditions of service which are normally applicable to the Tenderer's staff.
- 7.2 The Procuring Entity has a commitment to equal opportunities which the Tenderer must adhere to. The Tenderer shall not discriminate on the grounds of gender, race, disability, sexuality, age or religion or otherwise allow any applicable employment legislation to be breached.
- 7.3 The Tenderer will ensure that the terms and conditions of staff employed or hired to provide Services in connection with this Framework Agreement contain provisions in respect of the protection of Intellectual Property compatible with the terms of this Framework Agreement.
- 7.4 The Tenderer shall ensure that any individuals employed by or having a Contract for Services with the Tenderer relating to this Agreement comply with any of the Procuring Entity's rules and regulations in this respect.

8 Publicity

- 8.1 1 During any Project Period and prior to the publication of the Results in accordance with clause 17,

the Tenderer shall not, without the prior written consent of the Procuring Entity, which shall not be unreasonably withheld, release, or otherwise make available to third parties, any promotional information relating to the Agreement or the Project by means of any public statement in particular any press announcement or displays, oral presentations to meetings, publicity Material or communication on the Internet.

8.2 In the event that the Tenderer fails to comply with clause 8.1, the Procuring Entity is entitled to terminate the Agreement for Default by notice in writing in accordance with clause 18.4.3.

9 Confidentiality

9.1 In respect of any Confidential Information that may be received from the other party and subject to the remainder of this clause 9, the receiving party undertakes to keep secret and strictly confidential and shall not disclose any such Confidential Information to any third party, without the disclosing party's prior written consent provided that:

9.1.1 The receiving party shall not be prevented from using any general knowledge, experience or skills which were in its possession prior to the commencement of the Agreement concerned; and

9.1.2 Nothing herein shall be so construed as to prevent either party from using Data processing techniques, ideas, know-how and the like gained during the performance of the Agreement concerned in the furtherance of its normal business, to the extent that this does not result in a disclosure of Confidential Information or infringement of any valid Intellectual Property.

9.2 Clause 9.1 shall not apply to any Confidential Information received by one party from the other:

9.2.1 which is or becomes public knowledge (otherwise than by breach of this clause);

9.2.2 which was in the possession of the receiving party, without restriction as to its disclosure, before receiving it from the disclosing party;

9.2.3 which is received from a third party who lawfully acquired it and who is under no obligation restricting its disclosure;

9.2.4 is independently developed without access to the Confidential Information as evidenced by receiving party's written notes; or

9.2.5 which must be disclosed pursuant to a statutory, legal or parliamentary obligation placed upon the party making the disclosure.

9.3 The obligations of each of the parties contained in clause 9.1 above shall continue for a period of 36 Months following termination of this Framework Agreement.

9.4 Nothing in this clause 9 shall be deemed to prevent the Procuring Entity from disclosing, publishing or otherwise make use of the Material, Results, Data, lessons learnt, experiences, or other key Results of the Project.

10 Ownership of the Results and access rights to Results

10.1 Subject to the terms and conditions of the present Section 2 of the Agreement, the Data and Material

shall be the sole property of the Tenderer and shall be subject to the Tenderer's use, commercial or otherwise, including use in publications, communications or in submissions to any governmental agency.

10.2 Delivery of hardware, software, and reports

Delivery of the system is, where applicable, used in the sense of delivery of developed software in and for THALEA, necessary hardware needed for evaluation 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 or software is not applicable. However, a feasibility study and an End of Phase Report (see THALEA Tender Form, Appendix 2 Administrative Forms and Schedule B) are necessary.

Phase 2:

The above described delivery is applicable. At least three different types of prototype models have to be installed in the testing locations (hospitals of the Consortium). After an evaluation, the prototypes will be transferred to another testing hospital in order to evaluate the interoperability¹, as well as the efforts for installation and local adaptations in an alternative ICU-setting within the consortium. This will, as a consequence lead to a rotating test scheme, allowing conclusions about practical application in different environments.

Respecting the very nature of PCP as R&D Service, supply costs are not allowed to exceed a proportion of 50% of the total PCP contract value. We recommended to use hardware for lease or rent or already existing hardware available in the relevant testing environment.

Testing Scheme phase 2

ICU/ Prototype	UKA	AZM	FPT	ZOL	NOHD
A	A1	A2	A3	A4	A5
B	B5	B1	B2	B3	B4
C	C4	C5	C1	C2	C3
...
X	X3	X4	X5	X1	X2
<i>Explanation: A1 is the first evaluation of prototype A; B3 the third of prototype B; etc. In total 5 evaluation rounds are planned.</i>					

Prototype models will be returned to the tenderers after completed evaluation.

Phase 3:

The above described delivery is applicable. At least two different types of pre-series models have to be installed in the testing locations (hospitals of the Consortium). After an evaluation, the pre-series models will be transferred to another testing hospital in order to evaluate the interoperability as well as the efforts for installation and local adaptations in an alternative ICU-setting within the Consortium.

¹ Interoperability is essential and one of the most, if not the most important criterion of THALEA software. A license for interfacing and compliance with software standards has to be present.

This will, as a consequence lead to a rotating test scheme, allowing conclusions about practical application in different environments.

Respecting the very nature of PCP as R&D Service supply costs are not allowed to exceed a proportion of 50% of the total PCP contract. We recommended to use hardware for lease or rent or already existing hardware available in the relevant testing environment.

Testing Scheme phase 3

ICU/ Pre-series	UKA	AZM	FPT	ZOL	N O
A	A1	A2	A3	A4	A5
B	B4	B5	B1	B2	B3
...
X	X3	X4	X5	X1	X2

Explanation: A1 is the first evaluation of pre-series model A; B3 the third of pre-series model B; etc. In total 5 evaluation rounds are planned.

Use after project closure:

After phase three, any pilot systems developed in the Project shall be the property of the Procuring Entity and every single THALEA consortium member and shall remain within consortium during the two year period of internal use. According to the right assigned to the consortium to use the pre-series models for internal purposes (defined elsewhere) the software of the two final pre-series models shall be installed on hardware on premise of the Consortium members. All hospitals/ICUs shall be equipped with the software of the THALEA solution. This includes a training on premise for the users, e.g. personal of a telemedicine center and technicians of the developed software. Depending on the price of hardware and respecting PCP as a service contract, for lease or rent for a two year period resulting.

After the two-year period of internal use the software should be returned to the tenderer.

- 10.3 The Project Intellectual Property rights on the aforementioned prototypes or pilot systems shall nevertheless be vested in the Tenderer, who shall license them to the Procuring Entity and the other THALEA members in accordance with clause 15.1 below.
- 10.4 The Procuring Entity reserves the right to have access to the Results and to use them in accordance with the terms of clauses 15, 16 and 17.

11 Federal Data Protection Act

- 11.1 For the purposes of this clause 11, the terms “Controller”, “Data Subject”, “Personal Data”, “Process” and “Processing” shall have the meaning prescribed under the Federal Data Protection Act (“BDSG”).
- 11.2 The Tenderer shall (and shall ensure that all of its staff) comply with any notification requirements under the BDSG and both parties will duly observe all their obligations under the BDSG which arise in connection with this Framework Agreement.
- 11.3 Notwithstanding the general obligation in clause 11.2, where the Tenderer is processing Personal Data for the Procuring Entity and THALEA consortium members the Tenderer shall:
 - (a) 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;
- (b) comply with all applicable laws;
 - (c) 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;
 - (d) 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;
 - (e) take reasonable steps to ensure the reliability of its staff and agents who may have access to the Personal Data;
 - (f) obtain prior written consent from the Procuring Entity in order to transfer the Personal Data to any Sub-Tenderer for the provision of the Services;
 - (g) not cause or permit the Personal Data to be transferred, stored, accessed, viewed or processed outside countries participating in THALEA (GER, NL, FIN, ES, BEL) where the project activities are primarily performed without the prior written consent of the Procuring Entity;
 - (h) 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 clause 11;
 - (i) 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 personnel 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

11.4 notify the Procuring Entity (within five Working Days) if it receives:

- (a) a request from a Data subject to have access to that person's Personal Data; or
 - (b) a complaint or request relating to the Procuring Entity's obligations under the BDSG;
- The provision of this clause 11 shall apply during the Agreement period and for a period of 24 Months after its expiry.

12 Anonymisation of Personal Data

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 anonymised form. The Tenderer shall ensure that all Personal Data is anonymised 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.

13 Monitoring and Reporting

13.1 Progress of the Project will be reviewed periodically against the specifications and deliverables for each of the Phases. The Procuring Entity will put in place a monitoring team to that effect. If

necessary, monitoring meetings could be applicable and are mandatory for participating Tenderers. During these meetings, the Tenderer will present to the monitoring team the Results achieved during the previous period and, if necessary, provide an update to the work plan. A report of the meeting will be written by the monitoring team within two (2) weeks after the meeting and provided to the Tenderer for comments within one (1) week. These meetings will not change in any way the Contractual obligations of the Tenderer. However, based on the information gathered in this context and the Tenderer's comments, the Procuring Entity may conclude that the conditions enabling it to terminate the Agreement apply.

- 13.2 The Tenderer shall provide an interim report when reasonably required to do so by the Procuring Entity. Such interim report shall be in a form and otherwise in compliance with the guidance notes issued by the Procuring Entity representative as amended from time to time and shall detail all Data, methods, Results and provisional conclusions together with management information and any other information relating to the Project.
- 13.3 During the Project Period the Tenderer shall provide verbal or written reports as reasonably required by the Procuring Entity on any aspect of the Project.
- 13.4 The Tenderer will allow its facilities, procedures and documentation to be submitted for scrutiny by the Procuring Entity or its auditors in order to ascertain compliance with the relevant applicable laws and the terms of this Agreement.
- 13.5 The Tenderer shall retain and maintain all assets necessary to ensure continued compliance with legislation that may apply from time to time.

14 End of Phase Report and Evaluation

- 14.1 The Tenderer shall provide an End of Phase Report on each relevant Phase of the Project, in the approved Language, within 14 Days of the Completion Date. The End of Phase Report shall be in the form as set out in the Tender Form, Appendix 2, Schedule A, and shall further be in compliance with the guidance notes issued by the Procuring Entity or THALEA consortium representative as amended from time to time or as otherwise required by Procuring Entity or THALEA 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.
- 14.2 Notwithstanding the provisions of clauses 13 and 14.1, the Procuring Entity or THALEA consortium representative is entitled to carry out a visit to the Tenderer's premises at any time for the purpose of due diligence and evaluation in respect of the Project.

15 Intellectual Property Rights

- 15.1 The UKA, AZM, FPT, ZOL and NOHD will be assigned an irrevocable, worldwide, free and non-exclusive license to use all project Results, including foreground IPR and the limited degree of background information that is contained in documents produced during the contract for INTERNAL USE for 2 years. All Background Intellectual Property used or supplied for the purposes of this Framework Agreement in connection with the Project shall 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 rights of either party (or any third party) in its Background Intellectual Property.

- 15.2 The Tenderer shall within two weeks of the signing of this Framework Agreement provide the Procuring Entity or THALEA consortium with full information in writing about what Background Intellectual Property it (or any of its sub-Tenderers) holds or is using at the date of this Framework Agreement that pertains or may pertain to the Project or any part thereof.
- 15.3 If the Tenderer (or any of its sub-Tenderers) generates Foreground Intellectual Property, whether the Tenderer (or sub-Tenderer) intends to file for protection of it or not, the Tenderer shall within one Month from such generation inform the Procuring Entity about the contents of such Foreground Intellectual Property.
- 15.4 Subject to clauses 16.5, the Intellectual Property rights, generated by the Tenderer or any of its sub-Tenderers, arising out of Foreground Intellectual Property shall, in relation to the Procuring Entity, belong to the Tenderer.
The Procurers shall also enjoy the right to require participating R&D Providers to grant non-exclusive licenses to third parties to exploit the results under fair and reasonable market conditions without any right to sublicense.

16 Exploitation of Intellectual Property

- 16.1 The Tenderer shall inform the Procuring Entity of any Results which are capable of Commercial exploitation, whether patentable or not.
- 16.2 Unless otherwise provided in the Agreement and subject to clause 16.5, the Tenderer shall take all appropriate and necessary measures to ensure the proper management of the Project Intellectual Property Rights.
- 16.2.1 It shall at its own costs be responsible for the application, examination, grant, maintenance, management and defence of the Project Intellectual Property Rights in the Results and in particular, but without limitation, it shall ensure that:
- 16.2.1.1 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;
- 16.2.1.2 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
- 16.2.1.3 all such patent applications are diligently executed and prosecuted having regard to all relevant circumstances.
- 16.2.2 If the Tenderer 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 Tenderer shall promptly notify the Procuring Entity of the infringement or violation.

- 16.2.3 Unless otherwise provided in this Agreement or unless the Project Intellectual Property Rights are assigned to the Procuring Entity and the THALEA Members pursuant to clause 15.1, the Tenderer shall take all appropriate measures to protect or defend said Project Intellectual Property Rights, or any other proprietary right on the Results. The Tenderer shall have the conduct and bear the costs of such proceedings. The Procuring Entity shall however:
- 16.2.3.1 have a monitoring/audit right on the conduct of the proceedings and the Tenderer agrees to take the Procuring Entity's comments on the conduct of the proceedings in due consideration, and
- 16.2.3.2 provide reasonable assistance to the Tenderer with respect to bringing any action.
- 16.3 The Tenderer shall permit the Procuring Entity to monitor the operation and effectiveness of the Tenderer's procedures for the management of Project Intellectual Property in such a way as the Procuring Entity considers reasonably necessary.
- 16.4 The Tenderer shall be consistent with the good management of Project Intellectual Property and the terms of conditions of the present Section 2 of the Agreement;
- 16.4.1 the Tenderer shall promote the dissemination of the Results of the Project; and
- 16.4.2 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;
- 16.4.3 and the Tenderer shall refer to its participation to the project, the means of PCP related to the project and the FP7 grant of the European Commission.
- 16.5 If, within five (5) years of the end of the last awarded Phase in the Project, the Tenderer has not commercially exploited a Project Intellectual Property Right by marketing a commercial application of said Project Intellectual Property Right (directly or by any potential sub-Tenderers or licensee), and that the circumstances of the case show that the Tenderer has not even used its best endeavours to do so, or if the Tenderer (and/or any potential sub-Tenderer or licensee) is using the Project Intellectual Property to the detriment of the public interest, the Tenderer shall upon request of the Procuring Entity assign all non-exploited Project Intellectual Property Rights to the Procuring Entity and the individual THALEA Members without any costs, except transfer cost of patent offices or other administrative costs arising from the transfer.

17 Publication

- 17.1 During any Project Period and for a period of five (5) years after the expiry of the last Project Period (for Phase I, II or III as appropriate), any and all written or oral publication and/or communication or any other type of disclosure whatever the media or form relating to the Services or Results ("publication") by the Tenderer shall have to be notified to the Procuring Entity representative. A draft copy of any Project of publication by the Tenderer shall be submitted to the Procuring Entity's representative:
- for a written publication, at the same time as the submission to the editor for publication or at least twenty-eight (28) calendar Days before the date intended for publication whichever is

earlier. Moreover, the publication has co-authorship from members of the THALEA Consortium.

- for an oral communication or any other type of disclosure, and twenty (20) calendar Days before the forecasted date of submission to the organizer of a scientific meeting or of said other type of disclosure.

The Tenderer shall, on request of the Procuring Entity, remove any Confidential Information before the disclosure, except for Services or result related information necessary to the appropriate scientific presentation or understanding of the Project. In the event that the Tenderer fails to comply with clause 17.1, the Procuring Entity is entitled to terminate the Agreement by notice in writing with immediate effect.

17.2 Subject to the provisions of clause 8, the THALEA Members may at any time freely disclose, publish or otherwise share with the public the Results and any lessons learned of the Project, subject to prior written notification to the Tenderer of the intent to publish or share with the public at the latest three

(3) Months prior to publication in order to allow Tenderer to comply with its obligations under clauses 13 and 14 and, as the case may be, seek protection of any Project Intellectual Property Rights.

17.3 Any publication resulting from work carried out under this Agreement shall acknowledge the THALEA Members financial support and carry a disclaimer as the Procuring Entity may require or in the absence of direction from the Procuring Entity a notice as follows: “This report is work commissioned by the Department of Intensive Care and Intermediate Care, RWTH Aachen University

from the acting on its own behalf and on behalf of University Hospital Aachen, Germany - Ministry of innovation, science, and Research of North Rhine-Westphalia, University Hospital Maastricht, Netherlands, Ministry of Economic Affairs, Netherlands, Parc Tauli Sabadell University Hospital, Spain, Catalan Agency for Health Information, Assessment and Quality, Spain, (vii) Hospital East Limburg, Belgium and (viii) Northern Ostrobothnia Hospital District, Finland. The views expressed in this publication are those of the author(s) and not necessarily those of the aforementioned entities”.

18 Termination

18.1 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 Tenderer from and against all and any actual loss unavoidably incurred by reason or in consequence of the termination provided that the Tenderer takes all immediate and reasonable steps to minimize the loss.

18.2 With regards to clause 18.1, the Procuring Entity will not pay any sum which, when taken together with any sums paid or due or becoming due to the Tenderer under this Framework Agreement, will exceed such total sums as would have been payable under this Framework Agreement if the Tenderer had fulfilled its obligations under this Framework Agreement.

18.3 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 Tenderer 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 Tenderer shall notify the Procuring Entity within 2 (two) weeks of any change of control taking place.

- 18.4 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:
- 18.4.1 any approvals consent or licences required under this Framework Agreement are not given unconditionally within 6 (six) Months of the commencement of the Project Period;
 - 18.4.2 the Tenderer is subject to an Insolvency Event;
 - 18.4.3 the Tenderer is in Default under this Framework Agreement and if:
 - 18.4.3.1 the Default is capable of remedy and the Tenderer shall have failed to remedy the Default within 30 (thirty) Days of written notice being sent to the Tenderer specifying the Default and requiring its remedy; or
 - 18.4.3.2 the Default is not capable of remedy;
 - 18.4.4 any provision of this Framework Agreement (other than as previously specified in the preceding provisions of this clause 18) expressly entitles the Procuring Entity to terminate this Framework Agreement;
 - 18.4.5 the Tenderer, or any sub-Tenderer on whose resources he has relied in the procurement that has preceded this Framework Agreement, becomes subject to any exclusion criteria listed in the General Conditions;
 - 18.4.6 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 General Conditions and declared in the signed declaration that is part of the tender.
- 18.5 Termination of this Framework Agreement by the Procuring Entity under the preceding provisions of this clause 18 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.

19 Consequence of termination

- 19.1 Termination of this Framework Agreement, however caused, shall not:

- 19.1.1 release the Tenderer from any duty or obligation of confidence which falls on it, its servants, agents, employees or former employees under this Framework Agreement or under “The Act Against Unfair Competition (UWG)” chapter 4, §17.
- 19.1.2 prejudice or affect any rights, action or remedy which shall have accrued before termination or shall accrue thereafter to any Party.
- 19.2 To the largest extent permitted by law, the clauses 8, 9, 10, 15, 16, 17 shall survive the termination, howsoever caused, of the Agreement.

20 Equipment

The Tenderer shall take all practical steps to purchase all Materials, equipment, and Services necessary for the performance of the Services at a fair and reasonable Price (see also clause 10.2 of this Framework Agreement).

21 Warranties and Indemnities

- 21.1 The Tenderer warrants and represents that:
 - 21.1.1 the Tenderer has full capacity and Procuring Entity and all necessary licences, permits and consents to enter into and perform this Agreement;
 - 21.1.2 this Agreement is executed by a duly authorized representative of the Tenderer;
 - 21.1.3 there are no actions, suits or proceedings pending or, to the Tenderer’s knowledge, threatened against or affecting the Tenderer before any court or administrative body or tribunal that might affect the ability of the Tenderer to meet and carry out its obligations under this Agreement;
 - 21.1.4 the Project will be carried out by appropriately experienced, qualified and trained personnel with all due skill, care and diligence;
 - 21.1.5 the Tenderer will discharge its obligations hereunder with all due skill, care and diligence including, but not limited to, good industry practice and (without limiting the generality of the foregoing) in accordance with its own established internal procedures;
 - 21.1.6 the Tenderer will attribute (for each Phase for which he is awarded a Contract) the monies to the Services;
 - 21.1.7 the Services, the Results and the related Project Intellectual Property Rights and the Procuring Entity’s use of the Results and the related Project Intellectual Property Rights or of the Tenderer's Background in accordance with clause 15.1 shall not infringe any Intellectual Property Rights of any third party.

22 Indemnity, Insurance and limitation of the Procuring Entity and liability of THALEA Consortium

- 22.1 The Tenderer shall indemnify the Procuring Entity, its employees, officers, directors and agents fully against any and all liabilities, claims, actions, suits or proceedings whatsoever in respect of:

- 22.1.1 any damage to property, real or personal, including any infringement of third party Intellectual Property rights whether patents, copyright, registered designs or otherwise;
- 22.1.2 any injury to persons, including injury resulting in death; and
- 22.1.3 resulting from or in the course of, or in connection with the performance of the Services, except in so far as such damages or injury shall be due to any act or negligence of the Procuring Entity.
- 22.1.4 Fraud; or
- 22.1.5 Fraudulent misrepresentation.
- 22.2 The Tenderer shall promptly notify the Procuring Entity if any claim or demand is made or action brought against the Tenderer for infringement or alleged infringement of Intellectual Property which might affect the Project.
- 22.3 The Tenderer shall effect and maintain with a reputable insurance company a policy or policies of insurance providing an adequate level of cover in respect of all risks which may be incurred by the Tenderer, arising out of the Tenderer's performance of this Framework Agreement. Such policies shall include cover in respect of any financial loss arising from any advice given or omitted to be given by the Tenderer. Such insurance shall be maintained for the duration of the Agreement period.
- 22.4 The Tenderer shall hold employer's liability insurance in respect of staff in accordance with any legal requirement for the time being in force.
- 22.5 The Tenderer shall produce to the Procuring Entity's representative, on request, copies of all insurance policies referred to in this clause or other evidence confirming the existence and extent of the cover given by those policies, together with receipts or other evidence of payment of the latest premiums due under those policies.
- 22.6 Subject always to clause 22.1, the liability of either party for Defaults shall be subject to the following financial limits:
- (a) the annual aggregate liability of either party for Default resulting in direct loss of or damage to the property of the other under or in connection with this Framework Agreement shall in no event exceed one million Euros (€1.000.000,-) or twice the value (whichever is higher) of the Contract concerned unless otherwise agreed; and
 - (b) the annual aggregate liability under this Framework Agreement of either party for Default (other than a Default governed by clauses 15 (Intellectual Property Rights) or 22.6(a) shall in no event exceed one Million Euros (€1.000.000,-), or twice the value (whichever is higher) of the Contract concerned unless otherwise agreed; and
 - (c) the Tenderer shall effect and maintain appropriate professional indemnity insurance cover during the Contract period and shall ensure that all agents, professional consultants and Sub-Tenderers involved in the supply of the Services do the same. To comply with its obligations under this clause and as a minimum, the Tenderer shall ensure professional indemnity insurance held by the Tenderer and by any agent, Sub-Tenderer or consultant involved in the supply of the Services has a limit of indemnity of not less than one and a half Million Euros (€1.500.000,-) for each individual claim.

- 22.7 If, for whatever reason, the Tenderer fails to give effect to and maintain the insurances required by the provisions of this Framework Agreement the Procuring Entity may make alternative arrangements to protect its interests and may recover the costs of such arrangements from the Tenderer.
- 22.8 The provisions of any insurance or the amount of cover shall not relieve the Tenderer of any liabilities under this Framework Agreement. It shall be the responsibility of the Tenderer to determine the amount of insurance cover that will be adequate to enable the Tenderer to satisfy any liability referred to in clause 22.1.
- 22.9 Save as expressly stated elsewhere in this framework neither party shall be liable to the other for consequential loss or damage.

23 Assignability and “piggy-backing”

- 23.1 The Tenderer shall not Sub-Contract, transfer or assign the whole or any part of this Framework Agreement without the prior written consent of the Procuring Entity whose consent may be subject to such terms and conditions as the Procuring Entity may see fit to impose. Such consent will only be given if the acquiring party, who is to assume all corresponding obligations of the Tenderer under this Framework Agreement, can prove to the full satisfaction of the Procuring Entity that the acquiring party fulfils all minimum requirements and selection criteria of the procurement that has preceded this Framework Agreement.
- 23.2 The Tenderer shall be responsible for the acts and omissions of his Sub-Tenderers as though they were his own.
- 23.3 The organisations mentioned in clause 3.1 and 3.2 of the THALEA-PCP General Conditions are preferred partners. The preferred partners will get access rights to read the documentation of the THALEA deliverables and the right to attend prototype/final solution demonstrations.
- 23.4 Should the Procuring Entity (or any New Procuring Entity) become subject to a merger, split or other restructuring measure, its rights and obligations shall automatically – without any consent from the Tenderer being required – transfer to the new (where this is the case) legal entity that is to continue the activities encompassed by this Framework Agreement. In no case shall the rights and obligations of the parties hereunder be affected by any changes in the ownership of the procurement entity (or any new procurement entity).

24 Severability

- 24.1 If any provision of this Framework Agreement is held invalid, illegal or unenforceable for any reason by any court of competent jurisdiction, such provision shall be severed and the remainder of the provisions hereof shall continue in full force and effect as if this Framework Agreement had been executed with the invalid provisions eliminated and be replaced in consultation with the Procuring Entity and its Network of Procurers.
- 24.2 In the event of a holding of invalidity so fundamental as to prevent the accomplishment of the purpose of this Framework Agreement, the parties shall immediately commence good faith negotiations to remedy such invalidity.

25 Waiver

The waiver by the Procuring Entity of any right or remedy in respect of any breach of any term or condition or requirement of this Framework Agreement shall not prevent the subsequent enforcement thereof and shall not be deemed to be a waiver of any right or remedy in respect of any subsequent breach.

26 Prevention of Corruption

26.1 The Tenderer shall not:

26.1.1 offer or give, or agree to give, to any employee or representative of the Procuring Entity any gift or consideration of any kind as an inducement or reward for doing, or refraining from doing or having done or refrained from doing, any act in relation to the obtaining or execution of this or any other Agreement with the Procuring Entity or for showing or refraining from showing favour or disfavour to any person in relation to this or any such Agreement;

26.1.2 enter into this or any other Agreement with the Procuring Entity in connection with which commission has been paid by him or on his behalf, or with his knowledge, unless before the Agreement is made, particulars of any such commission and the terms and conditions of any Agreement for the payment thereof have been disclosed in writing to the Procuring Entity.

26.2 Any breach of this condition, by the Tenderer or by anyone acting on his behalf or employed by him, whether with or without his knowledge, or the commission of any offence by the Tenderer or by anyone acting for him or employed by him under applicable legislation on bribery and corruption (see General Conditions, Anti-bribery and Anti-Fraud Code of Conduct) in relation to this or any other Agreement shall entitle the Procuring Entity to terminate the Agreement and recover from the Tenderer the amount of any loss resulting from such a termination and/or recover from the Tenderer the amount or value of such gift, consideration or commission.

27 Traceability of payments

27.1 All payments to be made under this Agreement will be made in compliance with the traceability of financial flows obligations according to the guidelines of the German Money Laundering Act and the Tax Code.

27.2 The Tenderer hereby declares to be fully aware that lack of usage of bank transfer or postal transfer or of other collection and payment instruments suitable to grant the full traceability of financial flows is a cause of Agreement termination.

27.3 The Tenderer agrees to give immediate notice to the Procuring Entity and to the competent regulatory authority of noncompliance of sub-Tenderers with the guidelines of the German Money Laundering Act and the Tax Code.

28 Dispute Resolution

28.1 Any dispute between the parties arising out of or in connection with this Framework Agreement

(other than in relation to the payment of any money) shall in the first instance be referred to the Tenderer's Representative and the Procuring Entity representative for resolution. The parties agree to work together in good faith to reach an agreed settlement of any such dispute.

- 28.2 If within fourteen (14) Days of the meeting of the Tenderer's Project Manager and the Procuring Entity Contract Manager the dispute has not been resolved, the Parties agree to submit the dispute to a Director of the Tenderer and the appropriate Officer of the Procuring Entity or such other person as the Procuring Entity sees fit and who shall have responsibility to settle such dispute on behalf of the Procuring Entity. The Parties shall meet within seven (7) Days of the reference to them of any dispute and shall work together in good faith to resolve the dispute.
- 28.3 If within fourteen (14) Days if the dispute has not been resolved, the dispute may be referred, by either Party, to mediation by a mediator to be agreed between the Parties. The fee for the appointed mediator shall be shared equally between the Parties.
- 28.4 Nothing in Clauses 28.1, 28.2 or 28.3 shall preclude either Party from commencing an action in a court of law competent for UKA in Aachen, Germany / in a court according to paragraph 39 for a legal remedy where time is of the essence and the remedy sought is only available in a court of law. In all other circumstances the Parties shall attempt to resolve a dispute in accordance with Clause 28.2 before embarking on litigation.

29 Notices

All notices to be given hereunder shall be in writing via the official procurement Platform www.vergabe.nrw.de.

30 Relationships

This Agreement does not make any party the employee, agent, partner or legal representative of the other party for any purpose whatsoever. No party is granted any right or Procuring Entity to assume or create any obligation or responsibility, expressed or implied, on behalf of or in the name of the other party. In fulfilling obligations pursuant to this Agreement the Tenderer shall be acting as an independent Tenderer.

31 Prevention of Discrimination

- 31.1 The Tenderer shall not unlawfully discriminate within the meaning and scope of any law, enactment, order, or regulation relating to discrimination (whether in age, race, gender, religion, disability, sexual orientation or otherwise) in employment.
- 31.2 The Tenderer shall take all reasonable steps to secure the observance of clause 31.1 by all servants, employees or agents of the Tenderer and all suppliers and Sub-Tenderers employed in performance of this Framework Agreement.
- 31.3 The Tenderer shall notify the Procuring Entity immediately of any investigation of or proceedings against the Tenderer and shall cooperate fully and promptly with any requests of the person or body conducting such investigation or proceedings, including allowing access to any documents or Data required, attending any meetings and providing any information requested.

- 31.4 The Tenderer shall indemnify the Procuring Entity against all costs, claims, charges, demands, liabilities, damages, losses and expenses incurred or suffered by the Procuring Entity arising out of or in connection with any investigation conducted or any proceedings brought under any primary legislation on unlawful discrimination or human rights due directly or indirectly to any act or omission by the Tenderer, its agents, employees or Sub-Tenderers.
- 31.5 In addition to its obligations under clauses 31.1 to 31.4 above, the Tenderer shall ensure that it complies with all current employment legislation or any other relevant legislation relating to discrimination in the employment of employees for the purpose of providing the Project. The Tenderer shall take all reasonable steps (at its own expense) to ensure that any employee employed in the provision of the Project does not unlawfully discriminate within the meaning of this clause 31.5 and shall impose on any Sub-Tenderer obligations substantially similar to those imposed on the Tenderer by this clause 31.5.
- 31.6 The Tenderer shall undertake, or refrain from undertaking, such acts as the Procuring Entity requests so as to enable the Procuring Entity to comply with its obligations under any primary legislation on unlawful discrimination or human rights.
- 31.7 The Tenderer agrees to indemnify and keep indemnified the Procuring Entity against all loss, costs, proceedings or damages whatsoever arising out of or in connection with any breach by the Tenderer of its obligations under clause 31.

32 Conflicts of Interest

- 32.1 The Tenderer shall take appropriate steps to ensure that neither the Tenderer nor any staff is placed in a position where, in the reasonable opinion of the Procuring Entity, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Tenderer and the duties owed to the Procuring Entity under the provisions of this Framework Agreement. The Tenderer will disclose to the Procuring Entity full particulars of any such conflict of interest which may arise.
- 32.2 The Procuring Entity reserves the right to terminate this Framework Agreement immediately by notice in writing and/or to take such other steps it deems necessary where, in the reasonable opinion of the Procuring Entity, there is or may be an actual conflict, or a potential conflict, between the pecuniary or personal interests of the Tenderer and the duties owed to the Procuring Entity under the provisions of this Framework Agreement. The actions of the Procuring Entity pursuant to this clause shall not prejudice or affect any right of action or remedy which shall have accrued or shall thereafter accrue to the Procuring Entity.

33 Prevention of Fraud

- 33.1 The Tenderer shall take all reasonable steps to prevent Fraud by Staff and the Tenderer (including its shareholders, members, directors) in connection with the receipt of monies from the Procuring Entity.
- 33.2 The Tenderer shall notify the Procuring Entity immediately if it has reason to suspect that any Fraud has occurred or is occurring or is likely to occur.

33.3 If the Tenderer or its Staff commits Fraud in relation to this or any other Agreement with the Procuring Entity may:

- (a) terminate this Framework Agreement and recover from the Tenderer the amount of any loss suffered by the Procuring Entity resulting from the termination, including the cost reasonably incurred by the Procuring Entity of making other arrangements for the supply of the Services and any additional expenditure incurred by the Procuring Entity throughout the remainder of the Agreement Period; or
- (b) recover in full from the Tenderer any other loss sustained by the Procuring Entity in consequence of any breach of this clause.

34 Force Majeure

34.1 Neither Party shall be liable to the other Party for any delay in performing, or failure to perform, its obligations under this Framework Agreement (other than a payment of money) to the extent that such delay or failure is a result of Force Majeure. Notwithstanding the foregoing, each Party shall use all reasonable endeavours to continue to perform its obligations under this Framework Agreement for the duration of such Force Majeure. However, if such Force Majeure prevents either Party from performing its Material obligations under this Framework Agreement for a period in excess of 6 Months, either Party may terminate this Framework Agreement with immediate effect by notice in writing.

34.2 Any failure or delay by the Tenderer in performing its obligations under this Framework Agreement which results from any failure or delay by an agent, Sub-Tenderer or supplier shall be regarded as due to Force Majeure only if that agent, sub-Tenderer or supplier is itself impeded by Force Majeure from complying with an obligation to the Tenderer.

34.3 If either Party becomes aware of Force Majeure which gives rise to, or is likely to give rise to, any failure or delay on its part as described in clause 34.1 it shall immediately notify the other by the most expeditious method then available and shall inform the other of the period for which it is estimated that such failure or delay shall continue.

35 Performance Management

35.1 Payment is linked to satisfactory completion of a Phase. This will be based on the proposed end of phase reports (see Tender Form, Appendix 2) and the assessment of delivered prototypes and test series products.

35.2 When assessing if a Phase has been concluded to satisfaction the Procuring Entity checks:

- if the work proposed in the submitted tender has been carried out;
- if the funds have been allocated to the planned objectives;
- if a reasonable minimum quality has been delivered and
- if the reports have been submitted on time.

35.2.1 Reasonable minimum quality of a report means:

- The report can be read by somebody who is familiar with the topic, but not an expert;
- The report gives insight in the tasks performed in and the Results of the Project;
- The report is made using the End of Phase Report Form or (if applicable) the milestone report form

and the requirements of this form have been met.

35.2.2 Reasonable minimum quality of a demonstration (for Phase 2 or 3) means:

- The demonstration can be understood by somebody who is familiar with the topic, but not an expert. This could, for instance, be somebody with operational but not technical knowledge;
- The demonstration shows how the innovation works, how it can be used and (if applicable) how it is operated and maintained;
- The demonstration is accessible to parties appointed by the Procuring Entity, unless these are direct competitors of the Tenderer.

35.3 The quality of a final report is assessed by the Procuring Entity or persons chosen by it.

35.4 Successful completion of a Phase is a prerequisite to receive an award for the next Phase (as described in clause 2.2 and 2.3. Successful completion means:

- successful completion of all related milestones as described in the Contracted tender and
- the Results of the R&D are considered to be promising;
- the minimum requirements as formulated in the Challenge Brief and Functional Specifications document per challenge are met.

For Phase 1 „promising” means that the feasibility is convincing. For Phase 2 it means that the Procuring Entity is convinced of the feasibility, the applicability in an operational setting and the potential impact of the product.

36 Remedies for Poor Performance

If the Procuring Entity is not satisfied by the delivered Results or satisfactory completion of a milestone, it will first give the Tenderer the opportunity to amend the Results. For written reports this will have to be done within one week. For demonstrations (in Phase 2 or 3) a longer period may be given, but no more than 8 weeks maximum. If the Procuring Entity is still not satisfied with the Results after this period it may:

- withhold payment(s) until Results that meet the satisfaction of the Procuring Entity are produced;
- cancel payment;
- reclaim monies already paid;
- exclude the Tenderer from the next Phase;
- terminate this Framework Agreement in accordance with clause 18.

37 No Rights of Third Parties

A person who is not a Party to this Framework Agreement shall have no right to enforce any terms of it which confer a benefit on him.

38 Entire Agreement

The Agreement constitutes the entire agreement between the parties relating to its subject matter. Each party acknowledges that it has not entered into this Agreement on the basis of any warranty, representation, statement, agreement or undertaking except those expressly set out in this Agreement. Each party waives any claim for breach of this Agreement, or any right to rescind this Agreement in respect

of, any representation which is not an express provision of this Agreement.

However, this clause does not exclude any liability which either party may have to the other (or any right which either party may have to rescind this Agreement) in respect of any Fraudulent misrepresentation or Fraudulent concealment prior to the execution of this Agreement.

In case of discrepancy between the Framework Agreement, on the one hand, and the Functional Specifications document, on the other hand, the documents shall prevail in the following order:

1. Functional Specification Document;
2. Framework Agreement;
3. Other Tender Documents; and
4. The Tender in the Tendering Stage.

39 Law and Jurisdiction

39.1 This framework Agreement shall be considered as an Agreement made in Germany and be construed in accordance with German law. The place of jurisdiction shall be the court competent for UKA in Aachen, Germany. Any legal claim, petition or application for judicial review, with regard to the present procurement procedure, shall be made in Germany. By submitting a tender, the Tenderer accepts the exclusive jurisdiction of German Courts.

39.2 Ethical aspects have to be taken into account. Tenderers' and Procurers' ethical standards of production shall respect basic workers' rights, including the prohibition of forced labour and child labour, freedom of association and the right to organise and bargain collectively, equal remuneration for men and women for work of equal value, and non-discrimination in employment, fully implementing the conventions of the International Labour Organisation (ILO) (see COM (2001) 416 final).

Clinical studies, diagnostic and/or therapeutic interventions will be conducted according to the legal requirements (concerning approval ethics review board, and data protection laws) of the countries where testing will take place.

Conduct of clinical intervention studies is not foreseen, but prospectively planned evaluation of diagnostic performance of underlying algorithms of THALEA's software will be undertaken by clinicians bound to professional secrecy. Data transfer of medical data (sensitive data) outside the hospitals is not foreseen either. In case the latter should be necessary due to design of the solution, clearance by the data protection officer in writing and registration by local/federal authorities can be required.

Approval by local ethics review boards is necessary prior to anonymized analysis of routine data from PDMS or other source of clinically used primary documentation.