Executive Summary

This PCP Request for Tenders document should be read in conjunction with other documents associated with this Pre-Commercial Procurement (PCP). These documents are added as appendices (1 – 5) at the end of the PCP Request for Tenders document.

With this document, interested legal entities are invited to submit a tender for the provision of research and development (R&D) services and the further award of phase contracts in this PCP project, with the aim to develop new, beyond state-of-the-art solutions 'to obtain a much needed well-integrated patient safety system to alert caregivers across the continuum of care to impending deterioration in their patients and thus help prevent avoidable harm', as outlined in the Nightingale Common Challenge. The Common Challenge also contains details on background, challenges and expected outcome of the project.

The University Medical Center Utrecht, The Netherlands (UMCU) will be the Lead Procuring Entity acting in the name and on behalf of a consortium of five procuring partners who are (i) the UMCU, (ii) University Hospital of Leuven (UZ Leuven), Belgium, (iii) University College London Hospitals (UCLH), United Kingdom and (iv) Karolinska Universitetssjukhuset, Stockholms Laens Landsting, Sweden and University Hospital Aken (UKA), Germany.

Abbreviations

Abbreviation	Explanation
EMR	Electronic Medical Record
EU	European Union
FHIR standard	Fast Healthcare Interoperability Resources standard
GPA	Government Procurement Agreement
ICU	Intensive Care Unit
IPR	Intellectual Property Rights
LOS	Length of Stay
OMC	Open Market Consultation
PCP	Pre-Commercial Procurement
PPI	Public Procurement of Innovative Solutions
Q&A	Questions & Answers
R&D	Research & Development
SCG	Security Classification Guide
SME's	Small & Medium Enterprises
VAT	Value Added Taxes
WTO	World Trade Organization

Connecting Patients and Carers using wearable sensor technology

Acronym: **NIGHTINGALE**

Project Number:727534

PCP Request for Tenders

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1. General context

Patients die because signs of deterioration are missed. There is a huge unfulfilled need for better monitoring of vital signs and other data to identify high-risk patients who are on general hospital wards or at home. Patient deterioration is often overlooked or not detected at all. One of the reasons is the intensity in nursing and frequency of vital signs monitoring which decreases from the Intensive Care via ward towards home. Early detection of physiological instability is crucial to prevent death and disability.

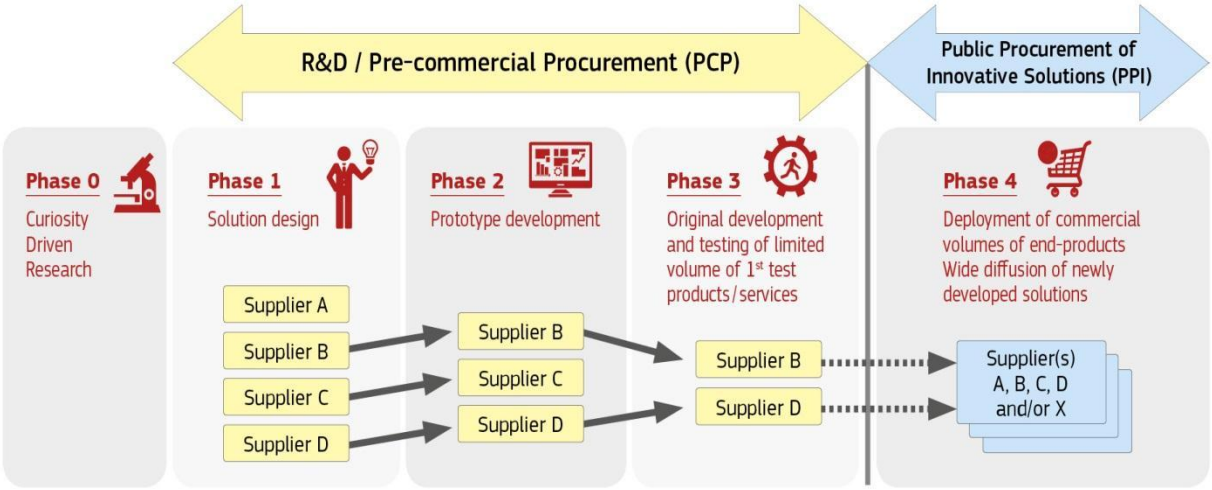
The consortium partners have performed an extensive search to discover possible solutions that can cover this challenge and are currently available on the market. We identified several 'wearable' devices that are designed to measure one or more vital signs and transmit these data wirelessly to another device such as a smartphone or network-attached 'bridge' (and from there to a server and the patient record). Currently the majority of wearable sensor devices appear to be geared towards lifestyle and sports. We identified only a handful of companies that produce a 'medical grade' wearable sensor that can measure and wirelessly transmit vital signs such as heart rate, respiratory rate and temperature. None of these companies currently has a user front end for the care giver that intelligently interprets the various signals to avoid repeated triggering of false alarms. Most systems that present data on a central terminal use traditional user-selectable alarm 'threshold' functionality. None of the currently available systems is sufficiently developed to allow remote monitoring of patients' vital signs in the home situation. Moreover, there is also a need to add in information from the medical record and from patient inputs as described above; i.e., demographic data, laboratory data, patient responses to questions or instructions.

The objective of Nightingale is: 'prediction and detection of physiological instability to prevent death and disability, by wearable smart monitoring leading to safer care'.
In the end, after successful (commercial) implementation in the healthcare market, Nightingale's long term performance can be described in the following 'performance indicators':

1. Safe reduction of Length of Stay (LOS) in the hospital
2. Reduced number of avoidable re-admissions to Intensive Care Unit (ICU)
3. Faster re-admission to ICU for patients who do need escalation of care
4. Reduction of mortality
5. Reduction of additional costs of care

1.1 Pre-commercial procurement (PCP)

Since there is no solution available that covers the above described challenge completely, the consortium partners decided to start this project as a '**Pre-commercial procurement**' **(PCP)**, to be able to develop these kind of innovative solutions together with industry. PCP means that public procurers challenge innovative players on the market, via an open, transparent and competitive process, to develop new solutions for a technologically demanding mid- to long-term challenge that is in the public interest and requires new R&D services.



**This is an example of the PCP process. In Nightingale PCP, we will select a minimum of 8 suppliers for phase 1, 4 suppliers for phase 2, and 2 suppliers for phase 3.*

PCP is characterized by the following four **features**:

1. Competitive development in phases to identify the solutions offering the best value for money

PCP targets situations that require radical innovation or R&D and for which there are typically no solutions on or close to the market yet. Different competing providers may have different ideas for solutions to the problem. As R&D is yet to take place, there is not yet any proof as to which of these potential alternative solutions would best meet customers' needs.

PCP therefore awards R&D contracts to a number of competing contractors at the same time, in order to compare different approaches to solving the problem. It thus offers innovators an opportunity to show how well their solution compares with others. It also allows a first customer test reference to be obtained from countries of the procurers that will test the solutions.

The R&D is split into three phases (solution design, prototyping, original development and testing of a limited set of 'first' products or services). Evaluations after each phase progressively identify the solutions that offer the best value for money and meet the customer's needs. This phased approach allows successful contractors to improve their offers for the next phase based on lessons learnt and feedback from procurers in the previous phase. Using a phased approach with gradually growing contract sizes per phase also makes it easier for smaller companies to participate in the PCP and enables SMEs to grow their business step-by-step with each phase.

Depending on the outcome of the PCP, procurers may or may not decide to follow-up the PCP with a public procurement to deploy the innovative solutions (PPI).

2. Public procurement of R&D services

PCP addresses mid- to long-term public procurement needs for which either no commercially stable solutions yet exist on the market, or existing solutions exhibit structural shortcomings that it requires further R&D to resolve. PCP is a way for procurers to trigger the market to develop new solutions that address these shortcomings. PCP focuses on specific identified needs and provides customer

feedback to businesses from the early stages of R&D. This improves the likelihood of commercial exploitation of the newly developed solutions.

PCP is explained in the PCP communication COM/2007/799 and the associated staff working document SEC/2007/1668. The R&D services can cover research and development activities ranging from solution exploration and design, to prototyping, right through to the original development of a limited set of 'first' products or services in the form of a test series. Original development of a first product or service may include limited production or supply in order to incorporate the results of field-testing and demonstrate that the product or service is suitable for production or supply in quantity to acceptable quality standards. R&D does not include quantity production or supply to establish the commercial viability or to recover R&D costs.[1] It also excludes commercial development activities such as incremental adaptations or routine or periodic changes to existing products, services, production lines, processes or other operations in progress, even if such changes may constitute improvements.

3. Open, transparent, non-discriminatory approach — No large-scale deployments

PCP is open to all operators on equal terms, regardless of the size, geographical location or governance structure. There is, however, a place of performance requirement that they must perform a predefined minimum percentage of the contracted R&D services in EU Member States or Horizon 2020 associated countries.

Any subsequent public procurement of innovative solutions (PPI), for the supply of commercial volumes of the solutions, will be carried out under a separate procurement procedure. Providers that did not take part in this PCP (or were not chosen to go through as far as the last phase) will thus still be able to compete on an equal basis in any subsequent procurement looking for contractors to provide a solution on a commercial scale.

4. Sharing of IPR-related risks and benefits under market conditions

PCP procures R&D services at market price, thus providing contractors with a transparent, competitive and reliable source of financing for the early stages of their research and development. Giving each contractor the ownership of the IPRs attached to the results it generates during the PCP means that they can widely exploit the newly developed solutions commercially. In return, the tendered price must contain a financial compensation for keeping the IPR ownership compared to the case where the IPRs would be transferred to the procurers (the tendered price must be the 'non-exclusive development price'; see section 4.5.4). Moreover, the procurers must receive rights to use the R&D results for internal use and licensing rights subject to certain conditions.

For more information, see PCP on the Europa website.

[1] See also Article XV(1)(e) WTO GPA 1994 and the Article XIII(1)(f) of the revised WTO GPA 2014.

1.2 Exemption from EU procurement directives, the WTO Government Procurement Agreement (GPA) and EU state aid rules

This procurement procedure is exempted from the **EU public procurement directives** because procurers do not retain all the benefits of the R&D (the IPR ownership stays with the contractors).[2]

It is also exempted from the **WTO Government Procurement Agreement (GPA)** because this Agreement does not cover R&D services[3] (the PCP being limited to such services — and any subsequent PPI procurements relating to commercial-scale supply of such solutions not being part of the PCP procurement).

The procurement does not constitute state aid under the **EU state aid rules**[4] because it follows an open, transparent, competitive procedure with risk- and benefit-sharing at market price. The division of all rights and obligations (including IPRs) and all selection and award criteria for all phases are published at the outset; the PCP is limited to R&D services and clearly separated from any potential follow-up PPI procurements; PCP contractors are not given any preferential treatment in a subsequent procurement for provision of the final products or services on a commercial scale.

The start of this PCP procurement was preceded by an open market consultation *(see summary and Q&A on https://www.nightingale-h2020.eu/sites/default/files/inline-files/QandAs%20from%20Nightingale%20open%20market%20consultation%20meetings_2.pdf .)*

1.3 EU funding

This PCP procurement is part of a project that is funded by the European Union's Horizon 2020 Research and Innovation Programme, under grant agreement No 727534 — Nightingale (see www.nightingale-h2020.eu).

The procurement must therefore comply with the rules imposed by the EU Horizon 2020 grant agreement.

For more information, see 'innovation procurement' and 'links to regional policy' in the Participant Portal Online Manual.

⚠ **Attention:** The EU is not participating as a contracting authority in this procurement.

1.4 Overview: contracting, budget and schedule

1.4.1 Total budget and budget distribution (per phase)

For the challenge a total budget of € 3,750,000 is available to fund PCP contracts (including VAT). All prices and payments will be in Euro. The expected duration is until the 1st November 2020,

2 See Article 16(f) of Directive 2004/18/EC (Article 14 of Directive 2014/24/EU), Article 24(e) of Directive 2004/17/EC (Article 32 of Directive 2014/25/EU) and Article 13(f)(j) of Directive 2009/81/EC.

3 See the EU's Annex IV of Appendix I to the WTO GPA.

4 See Point 33 of the Commission Communication on a framework for state aid for research and development and innovation (C(2014) 3282).

starting upon signing of the Framework Agreement.

This PCP will result in a Framework Agreement with three phases: Phase 1 Solution design and feasibility study; Phase 2 Prototyping; and Phase 3 Test Series. For Phase 1 a maximum budget of 200.000 EUR (incl. VAT) is available, for Phase 2 a maximum budget of 2,000,000 EUR is available, and for Phase 3 a maximum budget of 1,550,000 EUR is available.

Funding example

Possible Budget including VAT for R&D is as follows:

Effort	Phase 1 3 months	Phase 2 12 months	Phase 3 8 months	Budget
8 Tenderers	25,000			200,000 EUR
4 Tenderers		500,000		2,000,000 EUR
2 Tenderers			775,000	1,550,000 EUR
Total	-	-	-	3,750,000 EUR

For phases 1 and 2, contracts are funded until the remaining budget is insufficient to fund the next best tender. The exact number of contracts finally awarded will thus depend on the prices offered and the number of tenders passing the evaluation. As leftover budget from the previous phase will be transferred to the next phase, the total budget available for phases 2 and 3 may eventually be higher than stated here (but the maximum budget per contractor for phases 2 and 3 will remain the same). The lower the average price of tenders, the more contracts can be awarded. The total value of the contracts awarded can also be lower than initially expected if there are fewer tenders than expected that meet the minimum evaluation criteria. This PCP intends to accept a minimum number of 8 suppliers in Phase 1, a minimum number of 4 suppliers in Phase 2 and a minimum number of 2 suppliers in Phase 3.

Timeline of funding:

	Start of phase	After installation of prototype / test products	After completion of the phase	Total
Phase 1 3 months	50%	-	50%	100%
Phase 2 12 months	20%	45%	35%	100%
Phase 3 8 months	20%	45%	35%	100%

The Phases

Descriptions and phases are as follows:

- **Phase 1** is intended to demonstrate the feasibility of proposed concepts for new solutions. Phase 1 will be for the duration of 3 months and a maximum price of 25,000 Euros (including VAT) per Tenderer. For phase 1 a minimum of 8 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. Budgets will be paid to Tenderers if the phase is satisfactory completed. In section 6.2 & 6.3 this definition and process will be further explained. 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 2 and 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.

- **Phase 2** is intended to develop and evaluate prototypes or demonstrators from the more promising concepts in Phase 1. Phase 2 is dependent upon successful completion of Phase 1. For phase 2 a minimum of 4 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. The procuring entities will test the solutions coming from the pilots. In Phase 2 this will likely to be done in two hospitals. More information on the testing location(s) will be made available during Phase 1. Phase 2 will be for the duration of 12 months.

- **Phase 3** is intended for the original development of a limited volume of first products/services (test series). Phase 3 is dependent upon successful completion of Phase 2. 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. In Phase 3, testing will be done in a real environment. The procuring entities will test the solutions coming from the pilots in all procuring hospitals. In this way the Nightingale consortium can ensure that any locally required differences (e.g. different languages or different local health care regulations) can be covered whilst not burdening the pilots early on by having to cope with multiple testing centers. The final decision on which procurer will take responsibility for testing which project at which time will be taken before Phase 3 commences. In this way it will be easier to match the needs of the pilot projects to the testing capabilities / facilities of the procurers. Phase 3 will be for the duration of 8 months.

For more information on how R&D suppliers move from one phase to the next one, see sections 1.4.2, 6.2 and 6.3 below.

1.4.2 Contracting approach

The PCP is implemented by means of a framework agreement covering all three phases, with specific individual phase contracts for each of the R&D phases respectively (altogether 'contracts').

Following the tendering stage, a framework agreement and a specific contract for phase 1 are expected to be awarded to a minimum of 8 contractors.

A call-off will be organized for phase 2, with the aim of awarding a minimum of 4 'phase 2' contracts. Only offers from contractors that successfully completed phase 1 will be eligible for phase 2 (please see section 6.3 for the definition of 'successful' completion of a phase). The procurers will validate the phase 2 prototypes. At the end of phase 2, the Contractor has to deliver enough prototypes per solution to fulfil successful testing within at least 20 persons. The prototypes will be tested on former patients in two different procurers' hospitals.

A second call-off will be organized for phase 3, with the aim of awarding a minimum of 2 'phase 3' contracts. Only offers from contractors that successfully completed phase 2 will be eligible for phase 3. At the end of phase 3, the Contractor has to deliver enough products to allow testing of at least five patients simultaneously at the five different consortium sites. The field-testing at the end of Phase 3 is expected to take place in Utrecht, Stockholm, London, Leuven and Aachen, on actual high-risk patients.

The framework agreement sets all the framework conditions for the entire duration of the PCP (covering all the phases). There will be no renegotiation. The framework agreement remains binding for the duration of all phases for which contractors remain in the PCP. Tenderers that are awarded a framework agreement will also be awarded a specific contract for phase 1 (evaluation of tenders for the framework agreement and phase 1 are combined). Tenderers are therefore asked not only to submit their detailed offer for phase 1 in their tender, but also to state their goals, and to outline their plans (including price conditions) for phases 2 and 3, thus giving specific details of the steps that would lead to commercial exploitation of the R&D results.

Brief overview of the overall timing of the PCP (including the expected start and finish dates) and of the individual phases:

Phase 0 (publication of tender / submit proposals / signing agreements): **01-11-2017 – 15-02-2018**
Phase 1 developing solution design by tenderers: **15-02-2018 – 01-05-2018**
Phase 1 evaluation and signing phase 2 contracts: **01-05-2018 – 01-06-2018**
Phase 2 developing prototypes by tenderers: **01-06-2018 – 01-02-2019**
Phase 2 evaluation and signing phase 3 contracts: **01-02-2019 – 01-05-2019**
Phase 3 developing test products by tenderers: **01-05-2019 – 01-02-2020**
Phase 3 evaluation and testing: **01-02-2020 – 01-07-2020**

The offers for the next phase will be requested together with the end-of phase deliverables for the previous phase, as indicated in the Time schedule below. All contractors of the previous phase will be

invited to make offers for the next phase, successful completion of the previous phase is evaluated before evaluating the offers for the next phase, to determine which offers are eligible to proceed to the evaluation of offers for the next phase. For more information on how contractors will move from one phase to the other, please see sections 6.2 and 6.3 below.

1.4.3 Time schedule

The time schedule of the Nightingale PCP process is shown below. This schedule is subject to potential changes which will be duly published in advance, to allow proper and timely information of all interested parties:

Planned time schedule	
Date	**Activity**
	First tender procedure (framework agreement and phase 1 contracts)
01-11-2017	Publication of contract notice on TED
15-12-2017	Deadline for submitting questions about tender documents
22-12-2017	Deadline for lead procurer to publish replies to questions (Q&A on website)
12-01-2018	Deadline for submission of tenders for the framework agreement and phase 1
15-01-2018	Opening and evaluation of tenders
22-01-2018	Invitation to tenders that meet min. requirements to give an oral presentation
29-01-2018 & 30-01-2018	Oral presentation / answering questions by tenders that meet min. requirements
05-02-2018	Tenderers notified of decision on awarding contracts
05-02-2018	Standstill period of 10 days
15-02-2018	Signing of framework agreements and phase 1 specific contracts
15-02-2018	Publication of contract award notice in TED
	Implementation of phase 1 and call-off for phase 2
15-02-2018	Start of phase 1
	Names of winning phase 1 contractors and their project abstracts sent to EU and published on Nightingale PCP project website
15-03-2018	Short reporting by contractors to the Procuring Entity about progress and issues.
	Launch call-off for phase 2 (only offers from contractors that successfully complete phase 1 will be eligible and evaluated)
	Deadline for submitting questions on phase 2 call-off documents
	Deadline for lead procurer to circulate replies to questions to phase 2 bidders
01-05-2018	Deadline for submitting phase 2 offers

01-05-2018	Deadline for phase 1 final milestone(s)/final report/deliverable(s)
	Assessment of phase 1 final milestone(s)/final report/deliverable(s)
	Phase 1 contractors notified as to whether they have completed this phase satisfactorily and successfully
	End of phase 1
	Payment of balance for phase 1 to contractors that completed this phase satisfactorily
	Opening and evaluation of phase 2 offers
	Contractors notified of decision on awarding phase 2 contracts
	Standstill period of 10 days
	Signing of phase 2 specific contracts
	Implementation phase 2
01-06-2018	Start of phase 2
	Names of winning phase 2 contractors and their project abstracts published on Nightingale PCP project website and sent to EU
	Visit of phase 2 contractors to the premises(s) of the procurer(s), where applicable
	Visit(s) of the phase 2 supervisor/monitoring team to the contractor's premises to check progress in milestone(s)/deliverable(s)
	Feedback from phase 2 supervisor/monitoring team on phase 2 interim milestone(s)/deliverable(s)
	Interim payments
	Lab testing of the prototype developed during phase 2
	Feedback from phase 2 supervisor/monitoring team on lab testing of the prototype
	Launch call-off for phase 3 (only offers from contractors that successfully complete phase 2 will be eligible and evaluated)
	Deadline for submitting questions about phase 3 call-off documents
	Deadline for lead procurer to circulate replies to questions to phase 3 bidders
01-01-2019	Deadline for submitting phase 3 offers
01-01-2019	Deadline for submission of phase 2 final milestone(s)/final report /deliverable(s)
	Demonstration of prototype for the EU technical review of phase 2
	Assessment of phase 2 final milestone(s)/final report/deliverable(s)
	Phase 2 contractors notified as to whether they have completed this phase satisfactorily and successfully

	End of phase 2
	Payment of balance for phase 2 to contractors that completed this phase satisfactorily
	Opening and evaluation of phase 3 offers
	Contractors notified of decision to award phase 3 contracts
	Standstill period of 10 days
	Signing of phase 3 specific contracts
	Implementation phase 3
01-05-2019	Start of phase 3
	Names of winning phase 3 contractors and their project abstracts published on Nightingale PCP project website and sent to EU
	Visit of phase 3 contractors to premises(s) of procurer(s), where applicable
	Deadline for phase 3 interim milestone(s)/deliverable(s)
	Visit(s) of the phase 3 /monitoring team to the contractor's premises to check completion of phase 3 interim milestone(s)/deliverable(s)
	Feedback from phase 3 monitoring supervisor/monitoring team on phase 3 interim milestone(s)/deliverable(s)
	Interim payments
	Field-testing of products/services developed during phase 3
	Feedback from phase 3 supervisor/monitoring team on field-testing of the products/services
01-01-2020	Deadline for submission of phase 3 final milestone(s)/final report/ deliverable(s)
	Final demonstration of products/services developed during phase 3 (including to EU representatives)
	Assessment of phase 3 final milestone(s)/final report/deliverable(s)
	Phase 3 contractors notified as to whether they have completed this phase satisfactorily and successfully
	End of phase 3
	Summary of the lessons learnt and the results achieved by each contractor during the PCP sent to EU for publication purposes.
	Payment of balance for phase 3 to contractors that completed this phase satisfactorily

2. Procurers

This procurement relates to a joint PCP that will be carried out by the following **lead procurer**: University Medical Centre Utrecht (UMCU), Utrecht, The Netherlands.

The lead procurer is appointed to coordinate and lead the joint PCP, and to sign and award the framework agreement and the specific contracts for all phases of the PCP, in the name and on behalf of the following members of the **buyers group**:

- Katholieke Universiteit Leuven (KUL), represented by KU Leuven Research & Development, Leuven, Belgium
- University College London Hospitals NHS Foundation Trust (UCLH), London, United Kingdom
- Karolinska University Hospital (KUH), Stockholms Laens Landsting, Stockholm, Sweden
- University Hospital Aachen, Aken, Germany

The lead procurer is part of the buyers group.

The procurers in the buyers group have the following background/profile:

University Medical Center Utrecht

University Medical Center Utrecht (UMC Utrecht) belongs to the largest public healthcare institutions in the Netherlands and is an internationally leading healthcare provider, medical school and research institute that is exciting for its people, attractive to talent and embodies a culture of teamwork, innovation, sustainability and a competitive spirit. As a patient-centered organization, its 11,000 employees are dedicated to prevent disease, improve healthcare, develop new treatment methods and refine existing ones, with quality and patient safety as cornerstones. For more information visit www.umcutrecht.nl.

University College London Hospitals NHS Foundation Trust

University College London Hospitals NHS Foundation Trust (UCLH) is one of the largest NHS trusts in the UK and provides first-class acute and specialist services. The state-of-the-art University College Hospital which opened in 2005, is the focal point of UCLH alongside four cutting-edge specialist hospitals. UCLH is committed to research and development and forms part of UCL Partners which in March 2009 was officially designated as one of the UK's first academic health science centres by the Department of Health. UCLH works closely with UCL, translating research into treatments for patients. For more information visit www.uclh.nhs.uk.

Universitaire ziekenhuizen Leuven

Universitaire ziekenhuizen Leuven (UZ Leuven) is Belgium's largest university and a leading European research university and co-founder of the League of European Research Universities. UZ Leuven Leuven offers a wide variety of international Master's programmes, all supported by high-quality, innovative, interdisciplinary research. For more information visit www.kuleuven.be.

Karolinska Universitetssjukhuset

Karolinska Universitetssjukhuset (Karolinska University Hospital) is one of Europe's largest university hospitals and together with the Karolinska Institutet, works to strengthen the integration of care,

research and education with the patient's best interest in focus. For more information visit www.karolinska.se.

University Hospital Aachen

University Hospital Aachen (UKA) offers first-class medicine as a maximum-care teaching hospital based in the city of Aachen, Germany. With patient care, research and teaching under one roof UKA facilitates an intensive interdisciplinary dialogue and a dense clinical and scientific network. For more information visit www.ukaachen.de

3. Description of services to be procured

3.1 Motivation for the PCP

The Consortium's procurement methodology uses PCP in a complementary way for the Nightingale project. This strategy is aimed at achieving quality and efficiency improvements in the development of eHealth innovative solutions for patient monitoring aimed, in the end, at empowering the patients. The Nightingale consortium will use PCP procurement because:

Currently existing patient monitoring tools on the market fail to meet patient's and care providers' needs and exhibit immense technical shortcomings (e.g., lack of interoperability). Based on our prior art analysis and preliminary patent search, the Consortium concluded that the shortcomings of the currently available technology can only be solved by the development of a new ground-breaking technological solution. To achieve this result, new R&D is required. Two Open Market Consultation sessions were organized by the Nightingale consortium and confirmed the earlier conclusions. Therefore, Pre-Commercial Procurement (PCP) seemed to best meet the objectives of the Consortium in the Nightingale project, as this innovative competitive procurement methodology allows for the necessary R&D for a truly novel patient monitoring solution to be procured in the most efficient way and with the least amount of fragmentation.

PCP is a competition-like procurement model for the procurement of R&D services. PCP has been designed as a demand-side instrument which enables the public sector to engage with innovative businesses to deliver cutting-edge, innovative solutions that address specific public sector challenges and needs for which no solution exists yet on the market. Pre-Commercial Procurement is the procurement of R&D services involving risk-benefit sharing under market conditions, and competitive development in phases, where there is a clear separation between the procurement of the R&D services procured from the deployment of commercial volumes of end-products (PPI).

In the innovation cycle designing the transformation of an idea into a marketable product or service, PCP entails the use of competitive development in phases, which refers to the competitive approach used in PCP by procurers to buy R&D from several competing R&D providers in parallel to compare and identify the best value for money solutions on the market to address the PCP challenge.

3.2 Preparation for the PCP

As preparation for this PCP, a prior information notice (PIN) was published and an open market consultation was organized. The Nightingale project organized two (2) Open Market Consultation events on 31.3.2017 and 6.4.2017, with the purpose to inform the market on the upcoming planned PCP to develop innovative wireless and wearable technology that can be integrated into a clinical decision support system, to convey the Nightingale vision for these systems and to receive feedback on the goals of the project, the feasibility and the current technological status regarding the identified common challenge.
Before these events, a survey was organized with all possible participants and interested parties to gather information to structure the OMC events.
During the OMC, the Nightingale consortium initiated an open dialogue with the participants (which included the following categories: patient representatives, potential suppliers, technology

vendors/developers and health industry stakeholders), during which the market was provided with information regarding our envisaged project and given the possibility to give feedback regarding the feasibility and other aspects (as gathered through the questionnaire) of the proposed project.
A total number of 87 companies participated in the OMC.
The general feedback from the market could be summarized as follows:

- The common challenge, as presented, was judged innovative and relevant by both providers and patient representatives
- The proposed level for the solution was deemed a major challenge and the combination of an in-hospital and at-home solution was deemed difficult to achieve
- Many attendees indicated that they only could provide part of the requested solution and therefore wanted to partner with complementary groups and requested help from the consortium to facilitate this
- The attendees emphasized the need for a close and continuous interaction between the bidders and the consortium members to obtain the best results

For more information regarding the performed OMC and the results thereof, please check the Nightingale website.

3.3 PCP challenge

This procurement is for **R&D services** to develop **solutions** to tackle the following **common challenge**:
There is a clearly defined need to ensure monitoring of patient's vital signs continuously, both in normal hospital wards and after discharge home. When combined with intelligent adaptive algorithms, the potential of such systems to improve healthcare by reducing morbidity and mortality is enormous. The PCP instrument will allow us to align the efforts of European industry and deliver a ground-breaking, beyond state-of-the-art solution.
The Nightingale common challenge is focusing on:
'obtaining, through R&D, a much-needed well-integrated patient safety system to alert caregivers across the continuum of care to impending deterioration in their patients and thus help prevent avoidable harm'. This need is pressing in each of the participating hospitals, and it most likely reflects a common need throughout European healthcare. To maximize the benefits of the trend towards shorter hospitalization, we must not only improve detection of acute deterioration within the hospital, but also extend the safety net to the time period immediately after hospital discharge. The system that we envision includes both challenges to the manufacturers of wireless monitoring technology (robust sensing, artefact reduction, long battery life, patient acceptability) as well as challenges to software developers (adaptive machine-learning algorithms to create targeted alerts to caregivers and informal carers with an extremely low false positive alarm rate). Integration with existing EMRs via open standards should be flawless and intuitive. These changes and challenges will have the largest impact on the growing population of elderly Europeans, who have the highest likelihood for experiencing acute vital instability. Such solutions for advanced monitoring have the potential to transform healthcare, but are currently unavailable across the care continuum.

Objective and Key Performance Indicators of the Nightingale solution:
The objective of Nightingale is: 'predicting and detection of vital instability to prevent death and disability, by wearable smart monitoring leading to safer care'.

In the end, after successful (commercial) implementation in the healthcare market, Nightingale's long-term performance can be described in the following 'performance indicators':

- Safe reduction of Length of Stay (LOS) in the hospital
- Reduced number of avoidable re-admissions to Intensive Care Unit (ICU)
- Faster re-admission to ICU for patients who do need escalation of care
- Reduction of mortality
- Reduction of additional costs of care

In the short term, during the research & development phase of Nightingale, system performance can be described in the following 'performance indicators':

- Ease of use and acceptance by the users; both the patient as the nurses
- Technical validity of both hardware and software components

Scope

The Nightingale solutions should be supportive both in the hospital situation as in the home situation. For in-hospital use we are currently focusing on high risk surgical patients and high risk medical patients. For the home setting, we expect Nightingale solutions to be of added value for post-surgical patients and patients sent home after emergency room visits for acute medical conditions (who would otherwise need to be admitted 'for observation').

This is a common challenge shared by all procurers in the buyers group.
Please find a detailed description of the Nightingale common challenge including use cases in annex 3. Also, the functional specifications of the Nightingale challenge are provided in annex 3.

3.4 Expected outcomes (per phase) – end of phase deliverables

In the next overview, the objectives and their expected associated output, results and tasks to be carried out (milestones and end of phase deliverables) for each of the three phases are described:

Expected outcomes			
Phase 1			
	Objective:	Perform research to: 1. elaborate the solution design and determine the approach to be taken to develop the new solutions and 2. demonstrate the technical, financial and commercial feasibility of the proposed concepts and approach to meet the procurement need	
	Output and results:	A clear and feasible plan from a technical and commercial point of view how to develop and commercialize the solution successfully.	
	Milestones and deliverables		**By when?**
	Milestones:	M1.1) Having all deliverables submitted on time, meeting all minimum requirements.	1-5-2018, 12:00 CET
	Deliverables:	D1.1) Project abstract	28-2-2018
		D1.2) Technology design specification	1-5-2018

		D1.3) System architecture	1-5-2018
		D1.4) Market analysis & commercial plan	1-5-2018
		D1.5) Price & service fee estimation for the Nightingale solution	1-5-2018
		D1.6) Exploitation of results	1-5-2018
		D1.7) End of phase report	1-5-2018
Phase 2			
	Objective:	Develop, demonstrate and validate prototype systems in lab conditions	
	Output and results:	Passed all bench tests, safety tests and successful tests in human volunteers (former patients)	
	Milestones and deliverables		**By when?**
	Milestones:	M2.1) Having a developed prototype of the Nightingale solution ready for testing.	1-1-2019
		M2.2) The developed prototype of the Nightingale solution passed on minimum requirements in all tests.	1-4-2019
	Deliverables:	D2.1) Project abstract	15-6-2018
		D2.2) Documentation of R&D work and prototypes	1-1-2019
		D2.3) Detailed architecture specification	1-1-2019
		D2.4) Installed and operational prototype Nightingale solution	1-1-2019
		D2.5) Performance data, implementation and migration plan, estimation of implementation efforts	1-1-2019
		D2.6) Updated market analysis	1-1-2019
		D2.7) End of phase report	1-1-2019
Phase 3			
	Objective:	Original development and field-testing of a limited set of first products and/or services (the test series)	
	Output and results:	Well-functioning wireless wearable monitoring – as determined in a limited number of real patients - , successful integration with hospital EMR, properly functioning deterioration notification based on high-level decision support; low false alarm rate	
	Milestones and deliverables		**By when?**
	Milestones:	M3.1) Having a limited set of first products of the Nightingale solution ready for testing.	1-1-2020
		M3.2) The limited set of firsts products of the Nightingale solution passed on minimum requirements in all tests.	1-5-2020
	Deliverables:	D3.1) Project abstract	1-5-2019

		D3.2) Documentation of results	1-1-2020
		D3.3) Installed and operational test-series Nightingale solution	1-1-2020
		D3.4) Performance results	1-1-2020
		D3.5) Updated performance, migration and adaptability tests	1-1-2020
		D3.6) Final market analysis	1-1-2020
		D3.7) End of phase report	1-1-2020

The tasks and expected outcomes of each deliverable are specified in more detail below:

Phase 1:

M1.1) Having all deliverables submitted on time, meeting all minimum requirements.

D1.1) Project abstract (EU template)
D1.2) Technology design specification The technology design specification must comprise a comprehensive specification of the technologies that the contractor has developed and for which readiness will be demonstrated by integration into the pilot system. For the components developed within this PCP a comparison with an appropriate reference standard should be performed and technical details must be provided.
D1.3) System architecture specification System architecture specification is a document providing an overview on the architecture. The system architecture specification should explain how it extracts and transforms data of different source systems and maps these data to a common semantic basis, uniform terminology or coding concept in Nightingale. The basic concept of graphical display, detection algorithms and customization as well as the adaptation concept to different (sub)systems has to be drafted.
D1.4) Market analysis and commercial plan The market for the technologies developed within the Nightingale PCP must be analyzed. Reasons should be provided that there will be a sustainable market for these technologies. The document must comprise a description of the potential markets, analyze their size as well as trends, and provide an analysis of market profitability. Also the commercial and financial plan needs to be further developed.
D1.5) Price and service fee estimation for Nightingale solution The cost and service fee for the Nightingale solution should be estimated by means of a calculation in order to arrive at a reasonably accurate price setting, so that the buyers group may project the future budget impact of the solution.
D1.6) Exploitation of results Please indicate the potential exploitation of results of the Nightingale solution. Please specify also the potential for derivatives, such as 'downsized' solutions to monitor vital signs trends in chronic conditions, telemonitoring solutions such as remote patient monitoring as a service (medical call center), hospital-wide patient monitoring via a central 'control room', servicing one or more hospitals.
D1.7) End of phase report
In this report, a summary of the main results achieved in this phase should be presented, including a section that explains the IPR measures taken by the contractor to protect these results. Also, conclusions from this phase should be part of this report.

Phase 2:

M2.1) Having a developed prototype of the Nightingale solution ready for testing.

M2.2) The developed prototype of the Nightingale solution passed on minimum requirements in all tests.

D2.1) Project abstract (EU template)
D2.2) Documentation of R&D work and prototypes Report containing details about the technologies developed within the PCP documenting the progress of R&D work. Furthermore, testing of prototypes, which should be available for all critical new components and algorithms of the design, must also be documented.
D2.3) Architecture design documents specification Design efforts and experience of implementation process during Phase II should result in design documents which are the basis for the implementation in the next PCP-phase. The design documents must contain information on how the architecture and the pilot system will conform to performance targets. Also, an analysis of the architecture's availability level assumptions must be included.
D2.4) Installed and operational prototype of the Nightingale solution - The Phase 2 Nightingale solutions will be installed and tested in two test sites of the Consortium. This will indicate to the Consortium what efforts are required to interface solutions with current generation EMRs and will facilitate the initial performance tests.
D2.5) Performance and migration tests The prototypes of the Nightingale solution should allow assessing the performance of the sensor, the users' perceptions on usability as well as the quality of data transmission in human volunteers. We will evaluate the clinical decision support algorithms using databases containing historical real patient data. A discussion of the assumptions and limitations of the prototype models should be provided. Furthermore, a comparison with the reference execution times and energy efficiencies should be performed. The report must comprise an analysis of how close the architecture is to linear scaling performance with increasing numbers of patients.
D2.6) Updated market analysis and commercial plan. The market analysis and commercial plan for the technologies developed within the Nightingale PCP provided at the end of Phase I must be updated. It should be discussed how and why market prospects of the Nightingale solution and its derivatives changed.
D2.7) End of phase report
In this report, a summary of the main results achieved in this phase should be presented, including a section that explains the IPR measures taken by the contractor to protect these results. Also, conclusions from this phase should be part of this report.

Phase 3:

M3.1) Having a limited set of first products of the Nightingale solution ready for testing.

M3.2) The limited set of first products of the Nightingale solution passed on minimum requirements in all tests.

D3.1) Project abstract (EU template)
D3.2) Documentation of results Report which comprises a description of the technologies that have been developed, a documentation of the test system and a summary of the work that has been performed. The report should discuss progress beyond state-of-the-art due to the research and development work within this project and readiness of the technology for use in future products.
D3.3) Installed and operational pre-series Nightingale solution Report on the operational status of the test-series including the required software stack. It should document the execution of all provided Nightingale applications.
D3.4) Performance results Report containing results on data extraction, integration from source (EMR) to target system (Nightingale). Containing performance of extraction (reliability)of relevant information, transfer and mapping. Report on execution times for all provided scores and alerts in Nightingale applications and/or subsystems.
D3.5) Updated performance, migration and adaptability tests Updated versions of the performance of data acquisition from source systems, underlying algorithms and adaptability to different source systems should be provided.
D3.6) Final market analysis and commercial plan
The market analysis and business plan for the technologies developed within the PCP provided at the end of Phase II must be finalized. It should be discussed how and why market prospects changed.
D3.7) End of phase report
In this report, a summary of the main results achieved in this phase should be presented, including a section that explains the IPR measures taken by the contractor to protect these results. Also, conclusions from this phase should be part of this report.

3.5 IPR — Commercial exploitation of the results

Ownership of results (foreground)

Each contractor keeps ownership of the IPRs attached to the results it generates during the PCP implementation. The tendered price is expected to take this into account (see section 4.5.4).

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

- the members of the buyers group have the right to:
    - access results, on a royalty-free basis, for their own use, non-commercially and at no additional cost. This includes all Project Intellectual Property Rights of what has been achieved with regard to the implementation of the solution design (phase one) and the prototype development (phase two) and the original development of a limited volume of first products (phase three), and the pre-existing rights that are needed to perform the Project for the purpose of executing the Project as well as for non-commercial research purposes
    - grant (or to require the contractors to grant) non-exclusive licenses to third parties to exploit the results under fair and reasonable conditions (without the right to sub-

license), if the Contractor fails to commercially exploit the results of the R&D within five years after the end of the framework agreement

- the contractors will have to transfer ownership of the IPRs to the members of the buyers group if they fail to comply with their obligation to commercially exploit the results within a specific time limit (see below) or in case they use the results to the detriment of the public interest, including security interests.

Commercial exploitation of results

The contractors are expected to commercially exploit the results of the R&D undertaken in the PCP within a period of five years after the end of the framework agreement. Within this period, after phase 3 of the PCP process and the end of the framework agreement, contractors are required to arrange certification of the solution. The consortium intends to design and seek funding for a large scale European 'impact' study immediately following the completion of the PCP. The data from such a large scale clinical trial will facilitate the industry to acquire certification. However, contractors are required to develop a feasible business plan to commercially exploit the R&D results, therefore the feasibility of the business plan to commercially exploit the R&D results will be assessed as part of the award criteria (see section 4.7.3).

Pre-existing rights (background)

The ownership of pre-existing rights remains unchanged by the PCP.

The framework agreement contains a provision that describes in more detail the rights and obligations of the different parties regarding the pre-existing rights and results.

4. Conditions of tender

4.1 Eligible tenderers, joint tenders and subcontracting

Participation in the tendering procedure is **open** on equal terms to **all types of operators from any country,** regardless of their geographic location, size or governance structure.

Tenders may be submitted by a **single entity** or in collaboration with others. The latter can involve either submitting a **joint tender** or subcontracting, or a combination of the two approaches.

<u>For joint tenders:</u>
One Tenderer, consisting of a combination of companies (Consortium). Such a combination can in addition make use of Third Parties (Sub-contractors). Combinations of companies (Consortia) may participate in this PCP tender procedure, provided that their participation is in accordance with the principles of EU and applicable national competition law. The following requirements apply for joint tenders:

- The members of a Consortium must jointly appoint a lead contractor and a party authorized to act in the name and on their behalf;
- All members of the Consortium are individually tested against the Exclusion Criteria.
- The members of the Consortium must jointly meet the Selection Criteria.
- All members of the Consortium must accept joint and several liability by completing and adding '**Annex 5 - Statement of Consortium**';
- Each member of the Consortium must be listed in the professional register or trade register or a foreign equivalent in accordance with the legislation in force in the country where it is established;

For sub-contracting:
In the section 'Resources' of the Tender Form it shall be stated by the tenderer which part of the Nightingale PCP challenge, if any, is intended to be subcontracted to other suppliers or Tenderers. However, a minimum of 70% of the amount of R&D during the performance phase should be done by the tenderer itself.
At least 70% of the overall R&D services in each phase have to be performed by the Tenderer or the Contractor or at least by full-subsidiary companies to the Tenderer or the Contractor. The Assignment of tasks to sub-tenderers or sub-contractors has to be declared in advance to the procuring entity and needs the approval of the procuring entity. The execution of tasks assigned to a sub-contractor may not be the subject of further subcontracting.

A tenderer or contractor that wishes to rely on the resources of any Sub-Tenderer or Sub- contractor for the fulfilment of the requirements for participation in the PCP (and, where, applicable, an awarded contract), should demonstrate that these resources will be available to him. One way of demonstrating this is to submit a written commitment, a template to be signed by the subcontracting party, showing that the resources required of the Sub-Tenderer or Sub-contractor will be at the tenderers disposal for the full duration of the contract.

If the tenderer or contractor needs to change Sub-Tenderers or Sub-contractors, these new partners will have to prove that they have at least the same competences as the Sub- Tenderers or Sub-contractors or partners they will replace and that they comply with all the other contractual conditions, rights and obligations that are in the Framework Agreement and specific contracts: e.g. complying with the place of performance conditions, respecting the same IPR conditions, and respecting the ILO labour standards.

Participation in the open market consultation is not a condition for submitting a tender.

⚠ **Attention:**

There will, however, be a requirement relating to the place of performance of the R&D services (see below, 4.4 compliance criteria).

For phases 2 and 3, participation is limited to tenderers that successfully completed the preceding phase.

4.2 Exclusion criteria

The exclusion criteria are as follows:

Exclusion criteria	Evidence
A) Conflict of Interest	A) signing the Declaration (absence of conflict of interest) as part of annex 4, tender form
B) Bankruptcy	B) signing the declaration (absence of bankruptcy) as part of annex 4, tender form
C) Criminal offences	C) signing the declaration (absence of criminal offences) as part of annex 4, tender form

⚠ Tenderers that are subject to any of these criteria will be excluded.

A) Conflict of interest

Tenderers that are subject to a conflict of interest may be excluded. If there is a potential conflict of interest, tenderers must immediately notify the lead procurer in writing.

A conflict of interest is any situation where the impartial and objective implementation of the evaluation of tenders and/or implementation of the contract is compromised for reasons relating to economic interests, political or national affinity, family, personal life *(e.g., family or emotional ties)* or any other shared interest.

Tenderers must confirm by signing the Declaration in Annex 4, the Tender Form, that they are not subject to a conflict of interest in this Tender.

⚠ **Attention:** If an actual or potential conflict of interest arises at a later stage (i.e. during the implementation of the contract), the contractor must contact the lead procurer, who is required to notify the EU and to take steps to rectify the situation. The EU may verify the measures taken and require additional information to be provided and/or further measures to be taken.

B) Bankruptcy

A tenderer or contractor can be excluded from further participation in the PCP if it or any Sub-Tenderer on whose resources it relies upon in this procurement:

- Is bankrupt or is being wound up, is under compulsory administration or is the subject of a composition or has indefinitely stopped its payments or is subject to a prohibition on conducting business.
- Is the subject of proceedings for a declaration of bankruptcy, for an order for compulsory winding up or administration by the court or composition or any other similar proceedings.

- Has been convicted by a judgment which has the force of res judicata for an offence relating to professional practice. Has been guilty of grave professional misconduct and the procuring agencies can prove this.
- Has not fulfilled its obligations relating to social insurance charges or tax in its own country.
- In some material respect has failed to provide information requested or provided incorrect information required pursuant to this Request for Tenders document.

Tenderers must confirm by signing the Declaration in Annex 4, the Tender Form, that they are not subject to one of the above mentioned situations.

⚠ **Attention:** Should there be any doubt as to any of these criteria, tenderers may be requested to provide additional information such as an extract of the local chamber of commerce.

C) Criminal offences

If the Procuring Entity becomes aware that a tenderer, or a representative of the tenderer, or Sub-Tenderer, under a judgment that has entered into final legal force has been sentenced for a criminal offence listed below, such tenderer can be excluded from the PCP. Tenderers must confirm by signing the Declaration in Annex 4, Tender Form, that they are not subject to any of the criminal offences indicated below:

Participation in a criminal organization; this includes the following conduct:

Conduct by any person who, with intent and with knowledge of either the aim and general criminal activity of the organization or the intention of the organization to commit the offences in question, actively takes part in:

- Activities of a criminal organization, which shall be taken to mean a structured association, established over a period of time, of more than two persons, acting in concert with a view to committing offences which are punishable by deprivation of liberty or a detention order of a maximum of at least four years or by a more serious penalty, whether such offences are an end in themselves or a means of obtaining material benefits and, where appropriate, of improperly influencing the operation of public authorities, even where that person does not take part in the actual execution of the offences concerned and, subject to the general principles of the criminal law of the Member State concerned, even where the offences concerned are not actually committed;
- The organization's other activities in the further knowledge that its participation will contribute to the achievement of the above-mentioned criminal activities of the organization;
- Conduct by any person consisting in an agreement with one or more persons that an activity should be pursued which, if carried out, would amount to the commission of an offence as mentioned above, even if that person does not take part in the actual execution of the activity;
- Corruption; corruption shall be taken to mean deliberately promising or giving, directly or through an intermediary, an advantage of any kind whatsoever to an official, for himself or

for a third party for him to act or refrain from acting in accordance with his duty or in the exercise of his functions in breach of his official duties; or in the private sector, directly or through an intermediary, deliberately promising, offering or giving an undue advantage of any kind whatsoever, for himself or for a third party, in the course of business activities of that person in order that the person should perform or refrain from performing an act, in breach of his duties;

- Fraud; fraud meaning both expenditure fraud and revenue fraud. This means any act or deliberate omission involving the use or presentation of false, incorrect or incomplete statements or documents which has as its effect the misappropriation or wrongful retention of funds from, or the illegal diminution of the resources of the general budget of the European Communities or budgets managed by, or on behalf of, the European Communities, non-disclosure of information in violation of a specific obligation, with the same effect, the misapplication if such funds for the purpose other than those for which they were originally granted or the misapplication of a legally obtained benefit with the same effect;
- Money laundering, which shall be taken to mean:
  - The conversion or transfer of property, knowing that such property is derived from criminal activity or from an act of participation in such activity, for the purpose of concealing or disguising the illicit origin of the property or of assisting any person who is involved in the commission of such activity to evade the legal consequences of his actions;
  - The concealment or disguise of the true nature, source, location, disposition, movement, rights with respect to, or ownership of property, knowing that such property is derived from criminal activity or from an act of participation in such activity;
  - The acquisition, possession or use of property, knowing, at the time of receipt, that such property was derived from criminal activity or from an act of participation in such activity;
  - Participation in, association to commit, attempts to commit and aiding, abetting, facilitating and counselling the commission of any of the actions mentioned in the foregoing three paragraphs;

The exclusion criteria will remain unchanged for the entire duration of the PCP, thus applying also for the call-offs for the Phases 2 and 3.

4.3 Selection criteria

The selection criteria are as follows:

Selection criteria	Evidence
A) Ability to perform R&D up to original development of the first products or services and to commercially exploit the results of the PCP, including intangible results in particular IPRs	Description of the capacity, materials and equipment that are available to the tenderer for research, prototyping and limited production and supply of the first set of products or services. Description of the financial and organizational

	structures that are available to the tenderer for management, exploitation and transfer of IPRs and for generating revenue by marketing commercial applications of the results. Both part of the offer, to be added in section 'Resources' as part of annex 4, the Tender Form.

⚠ Tenderers that do not comply with this criterion will be excluded.

A) Ability to perform R&D up to original development of the first products or services and to commercially exploit the results of the PCP, including intangible results in particular IPRs

Tenderers must have:

1. the capacity (e.g., human resources), tools, material and equipment to:
    1. carry out research and lab prototyping
    2. produce and supply a limited set of first products or services and demonstrate that these products or services are suitable for production or supply in quantity and to quality standards defined by the procurers
2. the financial and organizational structures to
    1. manage, exploit and transfer or sell the results of the PCP (including tangible and intangible results, such as new product designs and IPRs)
    2. generate revenue by marketing commercial applications of the results (directly or through subcontractors or licensees).

⚠ **Attention:** Should there be any doubt as to this criterion, tenderers may be requested to provide additional information.

The selection criteria will remain unchanged for the entire duration of the PCP, thus applying also for the call-offs for the Phases 2 and 3.

4.4 Compliance criteria

Tenders must comply with the following compliance criteria:

Compliance criteria	Evidence
A) Compliance with the definition of R&D services	Financial part of the offer (annex 4, Tender Form)

B) Compatibility with other public financing	Declaration (absence of other incompatible public financing) as part of annex 4, tender form
C) Compliance with the requirements regarding the place of performance of the contract	Declaration (compliant with performing at least 51% of the R&D activities in EU member states or H2020 associated countries) as part of annex 4, tender form
D) Compliance with ethics requirements	*If the tender involves activities that raise ethical issues, the tenderer must submit an ethics self-assessment. To be added in annex 4, the tender form if applicable.*
E) Compliance with security requirements	*If the output of activities or results proposed in the tender raise security issues or uses EU-classified information, the tenderer must show that these issues are being handled correctly. To be added in annex 4, the tender form, if applicable.*

Offers for each phase will be evaluated against the above mentioned compliance criteria A to E.

⚠ Tenders that do not comply with these criteria will be excluded.

A) Compliance with the definition of R&D services

Tenders that go beyond the provision of R&D services will be excluded. The R&D services need to be 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).

R&D covers fundamental research, industrial research and experimental development, as per the definition given in the EU R&D&I state aid framework[5]. It may include exploration and design of solutions and prototyping up to the original development of a limited volume of first products or services in the form of a test series. Original development of a first product or service may include limited production or supply in order to incorporate the results of field-testing and to demonstrate that the product or service is suitable for production or supply in quantity to acceptable quality standards.[6] R&D does not include quantity production or supply to establish commercial viability or to recover R&D costs. It also excludes commercial development activities such as incremental adaptations or routine or periodic changes to existing products, services, production lines, processes or other operations in progress, even if such changes may constitute improvements. The purchase of commercial volumes of products or services is not part of the PCP and is therefore not permitted. This could be the scope of a follow-up PPI.

5 See Point 15 of the Commission Communication on a framework for state aid for research and development and innovation (C(2014) 3282).

6 See Article XV(1)(e) WTO GPA 1994 and the Article XIII(1)(f) of the revised WTO GPA 2014.

The definition of R&D services entails that the value of any products covered by the contract must be less than 50 % of the total value of the PCP framework agreement.

The following evidence is required:

- the financial part of the offer for the framework agreement must provide binding unit prices for all foreseeable items for the duration of the whole framework agreement
- the financial part of the offer for each phase must give a breakdown of the price for that phase in terms of units and unit prices for every type of item in the contract, distinguishing clearly the units and unit prices for items that concern products
- the offers for all three phases may include only items needed to address the challenge in question and to deliver the R&D services described in the request for tenders
- the offers for all three phases must offer services matching the R&D definition above
- the total sum of the value of products offered in each phase and all previous phases must be less than 50 % of the total value of the framework agreement

B) Compatibility with other public financing

Tenders that receive public funding from other sources will be excluded if this leads to double public financing or an accumulation of different types of public financing that is not permitted by EU legislation, including EU state aid rules.

The following evidence is required:

- Signing the Declaration in Annex 4, the Tender Form, for absence of other incompatible public financing

C) Compliance with requirements relating to the place of performance of the contract

Tenders will be excluded if they do not meet the following requirements relating to the place of performance of the contract:

1. At least 51% of the total value of activities covered by the framework agreement must be performed in the EU Member States or H2020 associated countries. The principal R&D staff working on the PCP must be located in the EU Member States or H2020 associated countries.

2. At least 51% of the total value of activities covered by each specific contract for each PCP phase must be performed in the EU Member States or in H2020 associated countries. The principal R&D staff working on each specific contract must be located in the EU Member States or H2020 associated countries.

The percentage is calculated as the part of the total monetary value of the contract that is allocated to activities performed in the EU Member States or in other countries associated to Horizon 2020. All activities covered by the contract are included in the calculation, i.e. all R&D and operational activities that are needed to perform the R&D services *(e.g. research, development and testing)*. This includes all activities performed under the contract by contractors and, if applicable, their subcontractors.

The principal R&D staff are the main researchers, developers and testers responsible for leading the R&D activities covered by the contract.

The countries associated to Horizon 2020 are those listed as associated countries in the Participant Portal Online Manual[7].

The following evidence is required:

- the financial part of the offer must provide binding unit prices for all foreseeable items for the duration of the whole framework agreement and give a breakdown of the price for the current phase in terms of units and unit prices (hours and unit price per hour), for every type of item in the contract *(e.g. junior and senior researchers)*
- a list of staff working on the specific contract (including for subcontractors), indicating clearly their role in performing the contract (i.e. whether they are principal R&D staff or not) and the location (country) where they will carry out their tasks under the contract
- a confirmation (by signing the Declaration, Annex 4 Tender Form) that, where certain activities forming part of the contract are subcontracted, subcontractors will be required to comply with the place of performance obligation to ensure that the minimum percentage of the total amount of activities that has to be performed in the EU Member States or in countries participating in Horizon 2020 is respected

D) Ethics and research integrity

Tenders will be excluded if they:

5 do not comply with the following rules:

  - ethical principles (including the highest standards of research integrity, notably as set out in the European Code of Conduct for Research Integrity[8], and, in particular, avoiding fabrication, falsification, plagiarism and other research misconduct)
  - applicable international, EU and national law

- include plans to carry out activities that are prohibited in all Member States or in a country outside the EU (where those activities are allowed)

- include activities whose aim is to:

  - carry out human cloning for reproductive purposes
  - modify the genetic heritage of human beings in such a way as could make such changes heritable (with the exception of research relating to cancer treatment of the gonads)
  - create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer

7 List of H2020 associated countries.

8 The European Code of Conduct for Research Integrity of ALLEA (All European Academies) and ESF (European Science Foundation) of March 2011.

- include activities that do not focus exclusively on civil applications

If the tender involves activities that raise ethical issues, the tenderer must submit an ethics self-assessment that:

- describes how the tender meets the legal and ethical requirements of the country or countries where the tasks raising ethical issues are to be carried out
- explains in detail how the tenderer intends to address the ethical issues identified, in particular as regards:
    - objectives *(e.g. dealing with vulnerable populations and dual-use goods[9])*
    - methodology *(e.g. involvement of children and related consent procedure and protection of data collected)*
    - the potential impact *(e.g. issues relating to the dual use of goods, environmental damage, stigmatisation of particular social groups, political or financial retaliation, benefit-sharing and malevolent use of results)*.

For information on ethics issues, see the guidance for EU grant beneficiaries How to complete your ethics self-assessment.

⚠ **Attention:**

Call-offs for phases 2 and 3 may request that this information be updated in the offers submitted for these phases.

Before starting the particular task that raises ethical issues, contractors must provide a copy of:

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

The framework agreement contains a provision on ethics.

E) Security

Tenders will be excluded if they do not:

(a) comply with EU, national and international law on dual-use goods or dangerous materials and substances

(b) comply with data protection requirements as provided under the new GDPR.

Tenders themselves must not contain any classified information.

[9] See Article 2(1) EU export control Regulation No 428/2009.

If the output of activities or results proposed in the tender raise security issues or uses EU-classified information, the tenderer must show that these issues are being handled correctly. In such a case, tenderers are required to ensure and to provide evidence of the adequate clearance of all relevant facilities. They must examine any issues (*such as those relating to access to classified information or export or transfer control*) with the national authorities before submitting their offer. Tenders must include a draft security classification guide (SCG), indicating the expected levels of security classification.

⚠ **Attention:**

If necessary for the tender procedure or for performing the contract itself, contractors will be requested to ensure appropriate security clearance for third parties *(e.g. for external experts needed to evaluate the proposal)*.

Call-offs for phases 2 and 3 may request that this security information be updated in the offers submitted for that phase.

Before starting the particular task that raises security issues, contractors must provide a copy of any export or transfer licenses required under EU, national or international law.

The framework agreement and/or the specific contracts contain a provision on security.

⚠ **Attention:** Should there be any doubt as to any of these criteria, tenderers may be requested to provide additional information.

The compliance criteria will remain unchanged for the entire duration of the PCP, thus applying also for the call-offs for the Phases 2 and 3.

4.5 Minimum technical criteria

The tenders / proposals will be assessed to see if the final solution will meet the following minimum technical criteria. The minimum requirements (knock out criteria) are shown below:

⚠ Tenders (proposed solutions) that do not meet these minimum requirements will be excluded.

Nightingale system
Final solution must be at least a sophistication level 3 system (Details in common challenge document)
Final solution must be compliant with all applicable law & standards of the participating buyer hospitals for use in a clinical environment
Final solution must correspond to at least Technology Readiness Level[10] 7 at the end of Phase 3
Sensing system
The final sensor(s) must be able to perform continuous monitoring for at least 5 days

[10] https://en.wikipedia.org/wiki/Technology_readiness_level

The final sensor(s) must measure at least the following parameters:
1. Heart rate
2. respiratory rate
3. temperature
4. motion and 3 axis position
Data Transmission
Data transmission of the final solution must be compliant with the HL7 standard
Data transmission of the final solution must be compliant with the Fast Healthcare Interoperability Resources (FHIR) standard
All sensors and integrated wireless signal transmission systems must be compliant with all applicable (National and European) safety regulations
(Wireless) data transmission must be encrypted

The minimum technical criteria will remain unchanged for the entire duration of the PCP, thus applying also for the call-offs for the Phases 2 and 3.

4.6 Award criteria

The tenders will be evaluated as set forth below, only if the tenderer is not subject to any of the exclusion criteria (section 4.2), and only if they fulfil the requirements in the selection criteria (section 4.3), the compliance criteria (section 4.4), the minimum technical criteria (section 4.5) and the administrative instructions (section 4.7).

Tenders that meet all the requirements, will be assessed to determine which tenders are the most promising and will be invited to participate in the next phase. This will be determined by assessing the offer based on the following award criteria as specified below. These criteria will guide assessors through evaluation of delivered results. It is to show tenderers what the main criteria are and how the results will be evaluated and scored. However, a detailed description of the Nightingale challenge and specifications can be found in the common challenge & functional specifications document (Annex 3). Please read carefully.

The evaluation of the received tenders will be based on technical, economic and organizational feasibility of the tenders. We will award the contract based on the best value for money award criteria. In addition to price, the award criteria would include impact on the challenge, quality of the bid and market potential/route-to-market potential.

⚠ **Attention:**

Additional sub-criteria may be added and will be further defined for the call-offs for phases 2 and 3, as a way of making the award criteria more precise, provided that they do not substantially change the existing criteria. For Phase 2 and Phase 3 evaluations, wherever possible, we will appropriately scale the results of measurements such as sensitivity, specificity, false alarm rate, robustness of data transmission (% data loss) and quantitatively award points (linked to the award criteria of course) based on measured performance and relative rank on scaled measurements.

Please find below an overview of the main award criteria that will apply during assessment for all phases. Secondly the specific assessment model for entry to phase 1, including sub criteria, is shown below.

MAIN AWARD CRITERIA – for assessment of all phases:

Criterion Total maximum points per Phase: 1000 points

		Phase 1 – assessment based on proposal (tender form)	Phase 2 – assessment based on solution design	Phase 3 – assessment based on prototype developing
Impact on the challenge		*Max. 600 points*	*450*	*350*
I.1	The extent of how well the proposed idea/ solution/ technology meets the challenge as detailed in the Common Challenge and Functional Specifications, and whether it will have the desired impact. Further categorized in the 5 building blocks: - sensing system - data transmission - artefact rejection - analysis system - usability	375 (Sensing system – 75 points Data transmission – 75 points Artefact rejection – 75 points Analysis system – 75 points Usability – 75 points)	200	100
I.2	The extent to which the approach demonstrates commercial feasibility, and whether it is a realistic commercialization plan / route to market and whether the right partners are committed to commercialize the product.	125	175	175
I.3	Potential of the proposal to address future/ wider challenges in the challenge area in an innovative way (e.g. by developing or employing novel concepts, approaches, methodologies, tools, or technologies).	100	50	25
Quality of the bid		*Max. 300 points*	*350*	*450*
Q.4	The extent of how realistic the technical development of the proposed idea/ solution / technology is. Further categorized in the 5 building	125 (Sensing system – 25 points Data transmission	250	350

	blocks: - sensing system - data transmission - artefact rejection - analysis system - usability	– 25 points Artefact rejection – 25 points Analysis system – 25 points Usability – 25 points)		
Q.5	Quality of the project team.	75	-	-
Q.6	The extent to which the bid shows a clear plan for the development of a working solution, and whether it is a reasonable plan to finish Phase 3 in time.	50	50	50
Q.7	The extent to which crucial risks (technical, commercial and other) to project success are identified, and how effectively these will be managed.	25	25	25
Q.8	The extent to which the tenderer and/or subcontractor shows or demonstrates to have dedicated the resources (e.g. human capital, equipment, etc.) necessary to perform the scope of the tender.	25	25	25
Price		*Max. 100 points*	*Max. 200 points*	*Max. 200 points*
P.9	The scoring will be calculated with the formula: Phase 1: max. price (25k) - your offered price / 250 = total points on price Phase 2: max. price (500k) – your offered price / 2500 = total points on price Phase 3: max. price (775k) – your offered price / 3875 = total points on price	(max price € 25k)	(max price €500k)	(max price €775k)
Total		Sum = 1000 points	Sum = 1000 points	Sum = 1000 points

All the above criteria are applicable for starting / admission to phase 1 and they are described more in detail on the next page.

PHASE 1 AWARD CRITERIA WITH SUB CRITERIA
(assessment model for starting / admission to phase 1)

Criterion	Sub criterion in phase 1	Information needed to assess criterion:	Possible score	Weight in phase 1	Max. points
Impact on the challenge				60%	600
I1.1	The extent of how well the proposed idea/ solution/ technology meets the challenge and whether it will have the desired impact - *The sensing system*	Proposal of the solution – building block 'Sensing system'	0-10	7,5%	75
I1.2	The extent of how well the proposed idea/ solution/ technology meets the challenge and whether it will have the desired impact - *Data transmission*	Proposal of the solution - building block 'Data transmission'	0-10	7,5%	75
I1.3	The extent of how well the proposed idea/ solution/ technology meets the challenge and whether it will have the desired impact - *Artefact rejection*	Proposal of the solution - building block 'Artefact rejection'	0-10	7,5%	75
I1.4	The extent of how well the proposed idea/ solution/ technology meets the challenge and whether it will have the desired impact - *The analysis system*	Proposal of the solution - building block 'Analysis system'	0-10	7,5%	75
I1.5	The extent of how well the proposed idea/ solution/ technology meets the challenge and whether it will have the desired impact - *Usability*	Proposal of the solution - building block 'Usability'	0-10	7,5%	75
I2.1	The extent to which the approach demonstrates commercial feasibility,	Provision of sustainable financing plan	0-10	5%	50

	and whether it is a realistic commercialization plan / route to market and whether the right partners are committed to commercialize the product.	(max. 1 A4) for the duration of the project, in order to demonstrate that companies are able to build up – gradually throughout the PCP process – sufficient financial capacity			
I2.2	The extent to which the approach demonstrates commercial feasibility, and whether it is a realistic commercialization plan / route to market and whether the right partners are committed to commercialize the product.	Provision of commercialization plan (max. 1 A4) for the duration of the project, in order to demonstrate that companies are able to commercialize the solution after phase 3. In this plan, also an overview of the estimated (future) TCO of the solution is required.	0-10	7,5%	75
I3	Potential of the proposal to address future/ wider challenges in the challenge area in an innovative way (e.g. by developing or employing novel concepts, approaches, methodologies, tools, or technologies)	Proposal of the solution.	0-10	10%	100
Criterion		Information needed to assess criterion:	Possible score	Weight	Max. points
Quality of the bid				30%	300
Q4.1	The extent of how realistic the technical	Technical plan / description of the	0-10	2,5%	25

	development of the proposed idea/ solution / technology is - *The sensing system*	technical approach - building block 'Sensing system'			
Q4.2	The extent of how realistic the technical development of the proposed idea/ solution / technology is - *Data transmission*	Technical plan / description of the technical approach - building block 'Data transmission'	0-10	2,5%	25
Q4.3	The extent of how realistic the technical development of the proposed idea/ solution / technology is - *Artefact rejection*	Technical plan / description of the technical approach - building block 'Artefact rejection'	0-10	2,5%	25
Q4.4	The extent of how realistic the technical development of the proposed idea/ solution / technology is - *The analysis system*	Technical plan / description of the technical approach - building block 'Analysis system'	0-10	2,5%	25
Q4.5	The extent of how realistic the technical development of the proposed idea/ solution / technology is - *Usability*	Technical plan / description of the technical approach - building block 'Usability'	0-10	2,5%	25
Q5.1	Quality of the project team: knowledge of the solution	Oral presentation & interview	0-10	2,5%	25
Q5.2	Quality of the project team: innovation power	CV of two key staff members for Nightingale, oral presentation & interview	0-10	2,5%	25
Q5.3	Quality of the project team: route to market	Oral presentation & interview	0-10	2,5%	25
Q6	The extent to which the bid shows a clear plan for the development of a working solution, and whether it is a reasonable plan to finish Phase 3 in time	Plan of action incl. milestones	0-10	5%	50
Q7	The extent to which crucial risks (technical,	Provision of a document with	0-10	2,5%	25

	commercial and other) to project success are identified, and how effectively these will be managed	risks and opportunities, including countermeasures (max. 2 A4)			
Q8	The extent to which the tenderer and/or subcontractor shows or demonstrates to have dedicated the resources (e.g. human capital, equipment, etc.) necessary to perform the scope of the tender	Plan of action incl. milestones, and description of the resources that will perform them	0-10	2,5%	25
Criterion		Information needed to assess criterion:	Possible points	Weight	Max. points
Price				10%	100
P9	The scoring in Phase 1 will be calculated with the formula: Maximum price (25k incl. VAT) - your offered price (incl. VAT) / 250 = total points on price (rounding up on whole numbers). For example, your offered price is € 15.000,- incl. VAT. Then you'll receive 40 points on this criterion: (25.000 – 15.000) / 250 = 40 Max price for phase 1 = € 25.000,- incl. VAT.	An offer for the services that will be delivered in Phase 1, with a clear overview of the costs of the resources that will be used and charged to the Nightingale consortium.	-	10%	100
Total				Sum = 100%	Sum = 1000 points

Every (sub)criterion will be assessed and the evaluation committee will give points per criterion based on the following table (except for criterion P9, price):

Assessment	Description
0 points	Insufficient (even basic criteria were incompletely met)
2 points	Poor (criteria were not adequately met)
4 points	Satisfactory (criteria were just met)
6 points	Good (criteria were met in essence)
8 points	Very good (corresponded fully to the defined criteria)
10 points	Excellent (criteria were met above expectations)

Every score per criterion will be multiplied with the determined weight percentage for the criterion.

For example, if a tender scores 8 points (Very good) for sub criterion I1.1, the extent of how well the sensing system as part of the proposed solution meets the challenge, this means this tender receives 8 points * 7,5 (%) = 60 points in total for this criterion out of a maximum of 75 points. Per criterion, this same methodology will be used. If a tender would score the maximum number of points for every criterion, a total maximum score of 1000 points can be given.

All the award criteria for phase 1 will be assessed on paper, based on the requested and delivered information by the tenderer in the Tender Form (Annex 4). Tenders that fulfil all requirements will be invited to give an oral presentation of their solution (max. 15 minutes) and asked to answer questions from the evaluation committee (max. 45 minutes). The presentation & interview will be used to assess award criterion Q5. Two key staff members of the Tenderer, that will have an important role during all the different phases of the Nightingale PCP process, will be asked to be present and send their CV to the Procuring Entity.

After assessment on paper and an oral presentation & interview by two key staff members of the tenderer, the evaluation committee needs to reach consensus per criterion, per tender. After the consensus meeting a ranking can be made.

Should there be any doubt as to any of these criteria, tenderers may be requested to provide additional information.

4.7 Submission content and format

4.7.1 Submission and format of tenders, tender closing time

The following requirements will apply on the submission and format of tenders. Tenderers or Contractors that do not comply with the formal requirements will be excluded from further participation in the PCP:

- Where a signature is requested, the relevant document must be validly signed by a duly authorized person(s). The signature must be from a staff member or staff members who according to the extract from the professional register or trade register is authorized to represent the Tenderer. If a document is signed by a person not listed in the professional register or trade register, an adequate proxy must be attached. Such a proxy must be signed by a person or persons who according to the extract from the trade register or the professional register or according to the articles of association are authorized to represent and bind the Company. The proxy must clearly state that the proxy holder is authorized to represent the company in connection with this tender.

- **The Tender must be completed and submitted by sending the Tender Form (annex 4) and the applicable appendices to the Nightingale email box: enquiries@nightingale-h2020.eu**

- The Tender must be submitted in English language.

- The Tender has the character of an irrevocable offer with a validity period of ninety (90) calendar days, counting from the closing date for submission of Tenders. If the Award Decision is objected to in preliminary relief proceedings, the validity period will be extended. The validity period will then be extended by ninety (90) calendar days, counting from the first day on which it ceased to be possible to appeal from the court judgment regarding the objection to the provisional award.

- Amounts must be stated in euros, excluding VAT, unless otherwise stated.

- All tenders must contain an administrative, technical and financial section (see tender form, annex 4).

- The contact person for this tender of the Nightingale consortium is Mr. G. Bekema and can be contacted via the following email address: enquiries@nightingale-h2020.eu. If he is out of office and you have an urgent question, you can contact Mr. J. Groenewegen as backup contact person at j.groenewegen@umcutrecht.nl.

- **The last date and hour for submission of a complete Tender is 12-01-2018 at 11:59 hr CET.**

- The Tenderer is responsible for timely digital submission of its Tender via email.

- **Tenders submitted by fax or post mail will not be accepted**.

More detailed information about the submission and layout requirements for the phase 2 and 3 offers will be provided in the call-off of that phase.

4.7.2 Administrative section of the tender

To ensure appropriate transparency in communication during the tender period for each Phase any communication will take place by the communication channel of the official Nightingale platform "www.nightingale-h2020.eu". Except where otherwise directed in these Instructions, Tenderers must not contact any person in relation to this competition other than those named in this Request for Tenderers document (or other supporting document), or if nominated, their designated deputy. The name of any designated deputy will be confirmed in writing.

All Tenders must be made using the Nightingale PCP Tender Form (see annex 4) which is part of the tender document pack - along with all of the other competition documentation - and which can be downloaded by following the instructions on the Nightingale web page. All Tenders must be submitted in accordance with the following rules:

1. Tenders and supporting documents must be written in English or a full English translation, provided at no cost to the Procuring Entity.
2. Tenders must not be qualified or accompanied by statements or a covering letter that might be construed as rendering the tender equivocal. Unauthorized alterations or additions must not be made to any component of the tender documents.

	Overview tender documents:	Action to be taken by tenderer:
0	Nightingale PCP Request for Tenderers (this document)	For your information. This document describes the Nightingale PCP process for the coming 3 Phases: how the selection & awarding process looks like, what Nightingale expects from tenderers, etc. By submission of a tender all regulations mentioned in this document will be accepted by the tenderer. Please note that tenderers who are awarded for the phases I, II and III shall sign the formal assignment for that particular phase.
1	Annex 1 - Nightingale PCP Framework Agreement	For your information (signature of contract needed only after awarding to phase 1).
2	Annex 2 - Model specific contract for phases 1/2/3	For your information (signature of contract needed only after awarding to phase 1, 2 and 3, respectively).
3	Annex 3 - Nightingale PCP Common Challenge, Use Cases and Functional Specifications	For your information. This info is the basis for the Tender and is related to the award criteria (note: the functional specifications are not knock out criteria).

4	**Annex 4 - Nightingale Tender Form**	**To be filled in and signed by tenderer.**
5	Annex 5 - Template for Statement of Consortium	To be filled in and signed by tenderer if applicable.

Tenders received after the closing date for the PCP (12-01-2018) will not be included in the evaluation process.

Tenderers must advise the Procuring Entity if:

- their ownership or the ownership of any member of their tendering consortium (or their parent company) changes, or
- any organization involved in the preparation of this contract is acquired by them or by any member of their consortium (or an associated company).

Tenders must not exceed the page limits set out in the Tender Form. The Tender will be considered up to the number of pages per section as designed and stated in the Tender Form; the excess pages will not be considered (for more information see: Tender Form, Annex 4).

If Tenderers consider that the page limit is insufficient to provide the information required by these instructions then a tender question should be raised (see section 5.2 below). No guarantee can be given that the page limit will be increased. However, if it will be increased after a formal tender question this adaptation will be applicable for all tenderers.

Tenders shall be received no later than the closing date for the PCP, **12:00 CET on 12th January 2018** (see section 1.4.3 for an indicative time schedule for the PCP).

More detailed information for the phase 2 and 3 offers will be provided later, in the call-offs for these phases.

4.7.3 Technical section of the tender

Tenders must include a **technical offer**, as part of the tender form (annex 4), containing:

(a) a plan that outlines: 1. the tenderer's idea for addressing all the requirements given in the PCP challenge description, relating both to functionality and performance; and 2. technical details of how this would be implemented

(b) a draft commercialization / route-to-market plan that explains the proposed approach to commercially exploit the results of the PCP, to bring a viable product or service onto the market and how to finance this during and after the PCP process

(c) a project plan and methodology, a risk assessment and risk mitigation strategy, and a description of the resources that the tenderer will use during the PCP process, to increase

the chance of reaching milestones and deadlines for deliverables during and after the PCP process

(d) a reply to the question "Does this tender involve **ethical issues**? (YES/NO)" and if YES, an ethics self-assessment, with explanations how the ethical issues will be addressed (see section 4.2)

(e) a reply to the question "Does this tender involve: activities or results that may raise **security issues** and/or **EU-classified information**[11] as background or results? (YES/NO)" and if YES information on how these issues will be addressed (see section 4.2)

The technical section of the tender should be drafted by using the Tender Form (annex 4). The information provided in the technical section of the tender will be used to evaluate the tenders, on the basis of the award criteria, minimum technical criteria and the compliance criteria A, D and E. More detailed information for the phase 2 and 3 offers (in particular on the technical implementation plan, updated business plan and list of IPRs) will be provided in the call-offs.

⚠ **Attention:**

Tenders failing to meet these requirements will be excluded.

The technical part must provide a *detailed* technical offer for phase 1 (including an explanation of the methodology, a work plan and details of deliverables and milestones), and must specify the plans for and objectives of the subsequent phases 2 and 3 and beyond (including a plan for commercial exploitation of the results).

4.7.4 Financial section of the tender

The tender must include a detailed **financial offer,** as part of the tender form (annex 4). Please use the tender form to specify:

(a) binding **unit prices** for all items needed for carrying out phase 1 and for items that are expected to be needed for phases 2 and 3 (given in euros, excluding VAT but including any other taxes and duties)

(b) a fixed **total price** for phase 1 and an estimated total price for phases 2 and 3, broken down to show unit prices and the number of each unit needed to carry out phase 1 (given in euros, excluding VAT but including any other taxes and duties).

In addition, the financial section must include:

(c) a **price breakdown** that shows the price for R&D services and the price for supplies of products (to demonstrate compliance with the definition of R&D in compliance criterion A)

[11] See Decision 2015/444/EC, Euratom on the provisions on security of EU-classified information.

(d) a **price breakdown** that shows the location or country in which the different categories of activities are to be carried out *(e.g. x hours of senior researchers in country L at y euro/hour; a hours of junior developers in country M at b euro/hour)* (to demonstrate compliance with the requirement relating to place of performance in compliance criterion C)

(e) the **financial compensation** valuing the allocation of ownership of the **IPRs** generated during the PCP to the tenderer, in order to ensure compliance with the EU R&D&I state aid framework: by giving an absolute value for the price reduction between the price offered in the tender compared to the exclusive development price (i.e. the price that would have been quoted were IPR ownership to be transferred to the procurers).

⚠ **Attention:** The unit prices quoted for each category of items *(e.g. hourly rates for junior and senior researchers, developers and testers)* remain binding for all phases (i.e. for the duration of the framework agreement). However, they can be indexed for phases 2 and 3 by max. 5%. If a tenderer wants to use this indexation, an explanation by tenderer in their offer is required.

All the information provided in the financial section of the tender will be used to evaluate the tenders on the basis of the price award criteria and the compliance criteria B and C.

More detailed information for the phase 2 and 3 offers will be provided in the call-off. The price for phase 2 and 3 offers must be based on the binding unit prices in the tender and the price conditions set out in the framework agreement. Where new units/unit prices (e.g. for new tasks or equipment) are subsequently added to the phase 2 or 3 offers, they will become binding for the remaining phases. Similar price breakdowns will be requested for the call-offs for phase 2 and 3.

Since the lead procurer, UMC Utrecht, will facilitate the payments to tenderers, the VAT regime of the Netherlands will apply.

4.8 Other tender conditions

4.8.1 Signed tenders

A signed tender will be considered to constitute a firm, irrevocable, unchangeable and binding offer from the tenderer.

The signature of an authorised representative will be considered as the signature of the tender (and will be binding on the tenderer or, for joint tenders, the group of tenderers).

4.8.2 Confidentiality

Tenderers must keep confidential any information obtained in the context of the tender procedure (including EU-classified information[12]).

[12] Commission Decision 2015/444/EC, Euratom of 13 March 2015 on the security rules for protecting EU-classified information.

4.8.3. Language

Tenders for phase 1, as well as offers for phase 2 and 3 call-offs must be submitted in English.

Deliverables must be submitted in English.

Communication (relating to either the tender procedure or the implementation of the contract) must be carried out in English.

4.8.4 Cancellation of the tender procedure

The procurers may, at any moment, cease to proceed with the tender procedure and cancel it.

The procurers reserve the right not to award any contracts at the end of the tender procedure.

The procurers are not liable for any expense or loss the tenderers may have incurred in preparing their offer.

5. Process rules and information

5.1 Opening and evaluation of tenders

The tenders will be opened on 15th of January 2018, 12:00 CET. Tenders will be initially opened and reviewed by a selected panel of experts: the evaluation committee. The evaluation committee consists of 5 expert teams: 1 expert team per procurer of the consortium. Each tender will, in principle, be assessed by all 5 expert teams.
The Procuring Entity will take care that each expert team contains at least the following expertise:

1. **1 clinician**
2. **1 medical technician**
3. **1 business expert,** with experience in R&D
4. **1 patient**

Due to constraints with regard to time and resources before Phase 1 (since the Procuring Entity does not know how many tenders need to be assessed), all tenders may not be assessed by all (5) expert teams. Depending on the number of proposals The Procuring Entity will receive, the following applies:

If the Procuring Entity receives 10 or less proposals, all 5 expert teams will assess every proposal.
If the Procuring Entity receives between 11 and 15 proposals, every proposal will be assessed by at least 4 expert teams (randomly defined).
If the Procuring Entity receives more than 15 proposals, every proposal will be assessed by at least 3 expert teams (randomly defined).

The evaluation committee will open & evaluate the tenders, carrying out the following four steps:

- **Step 1** — Checking whether the tenderer is not in one of the situations covered by the **exclusion criteria**
- **Step 2** — For tenderers passing Step 1, assessing whether the tenderer has the capacities necessary to perform the contract, on the basis of the **selection criteria**
- **Step 3** — For tenderers passing Step 2, evaluating the tender based on the **compliance criteria**
- **Step 4** — For tenders passing Step 3, evaluating the tender based on the **minimum technical criteria**
- **Step 5** — For tenders passing Step 4, evaluating the tender based on the **award criteria**

When reaching step 5, the evaluation committee will first evaluate the tenders on paper individually. After step 4, tenders that fulfil the requirements will be invited to give an oral presentation to the evaluation committee and to answer questions about their offered solution, to be able to assess award criterion Q5.

After assessment on paper and assessment of the presentation & interview, the evaluation committee will come together physically and compare their evaluation per tender. Per tender, per criterion, the experts that evaluated need to reach consensus (100% unanimity) since there are 5

scores per tender given (1 per expert team). After reaching consensus for the scores of all criteria and for all tenders, a ranking of the tenders can be made.

The criteria and the method for evaluating the bids for Phase 2 and 3 will essentially be based on the criteria and the method used in evaluating the original tenders as set out below, but may be elaborated or developed in further detail within those frames. The evaluation committee and this procedure will be the same for the evaluation of bids for Phase 2 & 3.

Tenders that do not comply with the formal requirements will be excluded from the tender evaluation.

5.2 Communication — Q&A

The Q&A from the open market consultation can be found on www.nightingale-h2020.eu.

For further questions, you may contact Mr. G. Bekema via enquiries@nightingale-h2020.eu in English. **Questions may be asked until the 15th of December 2017, 12.00 CET**.

A summary of all new questions and answers will be presented in an **anonymised** Q&A document that will be published on www.nightingale-h2020.eu and will be refreshed twice until the final version will be uploaded, planned for 22-12-2017.

Questions that were received until 15-11-2017 will be published with answers ultimately on 22-11-2017, questions that were received from 15-11-2017 until 1-12-2017 will be published with answers ultimately on 8-12-2017, and the last questions that were received from 1-12-2017 until 15-12-2017 (12.00 CET) will be published with answers as final version of the Q&A document on 22-12-2017.

For phases 2 and 3, the answers will not be published, but distributed to all contractors that successfully completed the previous phase.

Unless otherwise instructed, please do not use any other contact addresses or contact any other persons in connection with this procurement.

5.3 Procedures for appeal

The PCP tender procedure, the award, the Framework Agreement and any disputes relating thereto are governed exclusively by Dutch law. Disputes between parties involved in the tender that arise from this tender, must be submitted to the competent court in the district Midden-Nederland, location Utrecht. If a tenderer wishes to commence a proceedings following the award of contracts decision, the tenderer should commence the proceedings within the standstill period set out in the planning at the risk of forfeiting the right to commence a proceedings.

As lead procurer of the Nightingale consortium, UMC Utrecht has set up a complaints reporting desk where interested parties can report their complaints regarding the PCP tender procedure. The interested party can submit its complaint by writing to the complaints reporting desk, by sending an e-mail to Mr. L. Van Wijck: l.g.j.vanwijck@umcutrecht.nl .

A complaint is a written report from a party with an interest in the PCP tender procedure of the Nightingale consortium, in which the interested party explains in which respect it does not agree to the tender procedure or any part thereof. In order to ensure the independence and objectivity of the complaints reporting desk, complaints will be handled by a staff member of UMC Utrecht who is not directly involved in the tender.

Filing a complaint does not stop the tender procedure. UMC Utrecht is free to decide whether or not to suspend the tender procedure. If the complaining interested party has also instituted preliminary relief proceedings regarding the complaint, the handling of the complaint by the complaints reporting desk will be suspended until after the court judgment.

Interested companies are requested to submit any complaints regarding the tender procedure in the first instance through the Q&A module on the Nightingale website (and await the response), before they apply to the complaints reporting desk.

6. Conditions of the contracts

After the assessment of the tenders submitted in response to the PCP call, successful bidders will be requested to sign the Framework Agreement and the Phase 1 contract (see the templates given in Annexes 1 and 2). To further advance to Phase 2 and, respectively, to Phase 3, call-offs for each phase will be organized.

6.1. Monitoring

During each phase, contract implementation will be monitored periodically and reviewed against the expected outcomes (milestones, deliverables and output or results) for the phase. The intensity of monitoring and communication between the Consortium and the R&D providers will increase from Phase 1 to Phase 3. In Phase 1, contractors will be asked once to shortly report their status and the issues that they are facing in the development of their solution design (milestones, deliverables and output) on paper.

At the beginning of Phase 2, each contractor will be assigned a main contact person (their supervisor) from the monitoring team appointed by the procurers.

In Phase 2 & 3, where solutions need to be developed, there will be regular monitoring meetings between the contractor and the supervisor/monitoring team (so called 'sprint demos'). The monitoring team will provide regular feedback to contractors after meetings or visits. 2 meetings in Phase 2 and 3 meetings in Phase 3 per supplier (individual meetings with each supplier) will be planned to monitor and ensure progress as planned and maximize learnings throughout the whole PCP process. More details will be given in the call-offs for Phase 2 and 3.

The Nightingale consortium has planned the following (preliminary) intermediate sessions in Phase 2 & 3:

Monitoring	Method	Responsible	Frequency
Reviews and feedback of prototypes and original solution development during all R&D phases	Sprint Demo	Project manager / Project team lead (to be decided)	2 in Phase 2, 3 in Phase 3
Opportunity to test sensor (solution) against reference standard in healthy volunteers at one hospital site	Methods comparisons study (Part 1 study design Phase 2)	Project manager / Clinical validation lead (to be decided)	Continuous add the end of phase 2

Continuous status reporting during R&D phases regarding the tasks and activities that the consortium is responsible for (e.g. providing access to test sites, individuals, etc.)	E-mail / R&D supplier specific web forum / meeting --> to be decided!	Project manager (to be decided)	During all phases: once in Phase 1, to be decided for the other Phases

6.2. Payments based on satisfactory completion of milestones and deliverables of the phase

Payments corresponding to each PCP phase will be subject to the *satisfactory* completion of the deliverables and milestones for that phase.

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 Evaluation committee (composed of at least 1 clinician, 1 medical technician, 1 business expert and 1 patient per procurer of the consortium), in order to determine whether the Tenderer has complied with the Common Challenge and the Functional Specifications. Such assessment shall be performed at any time between the Completion Date of Phase I and the starting date of the next Phase, but in any case prior to the latter.

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

Satisfactory completion will be assessed according to the following requirements:

1. if the work corresponding to that milestone / deliverable has been carried out
2. if a reasonable minimum quality has been delivered
3. if the reports have been submitted on time
4. if the monies have been allocated to the planned objectives
5. if the monies have been allocated and the work has been carried out according to the compliance criteria (place of performance, public funding and R&D definition criteria)

and

6. if the work has been carried out in compliance with the provisions of the contract (including in particular verification if the contractor has duly protected and managed IPRs generated in the respective phase)

'Reasonable minimum quality' of a report means that:

7. the report can be read by somebody who is familiar with the topic, but not an expert
8. the report gives insight in the tasks performed in and the results
9. 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

'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 (for instance, 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 procurers, unless these are direct competitors of the contractor

Satisfactory completion in each of the phases does not mean successful completion.

The assessment will also consider the efforts made by contractors to take into account the feedback from the supervisor or the monitoring team.

Invoices must be submitted to the lead procurer.

Contractors' invoices must provide:

(f) a **price breakdown** showing the price for R&D services and the price for supplies of products (in order to demonstrate compliance with the definition of R&D in compliance criterion A)

(g) a **price breakdown** showing the location or country in which the different categories of activities were performed *(e.g. x hours of senior researchers in country L at y euro/hour, a hours of junior developers in country M at b euro/hour)* (in order to demonstrate compliance with the requirement relating to the place of performance in compliance criterion C).

Payment schedule for Phase 1 will be:

- 50% at the beginning of Phase 1.
- 50% after completion of the solution design and feasibility studies (Phase 1).

Payment for Phase 2 will be split in three parts: 20% at the assignment to Phase 2, 45% after installation of prototypes in first testing environment, and 35% after inspection and testing of prototypes developed during Phase 2.

Payment for Phase 3 will be split in three parts: 20% at the assignment to Phase 3, 45% after installation of test series products in first testing environment, and 35% after inspection and testing of test series products developed during Phase 3.

6.3. Eligibility for the next phase based on successful completion of the phase

Eligibility for participation in the next phase will be subject to *successful* completion of the current phase.

Successful completion of a phase will be assessed by the evaluation committee against the following requirements:

- if all milestones have been successfully completed
- if the R&D results meet the minimum functionality/performance requirements of the challenge description (i.e. the minimum quality/efficiency improvements which the procurers set forward for the innovative solutions to achieve)
- if the results of the R&D are considered to be promising

'Promising' means:

- for phase 1, that the feasibility is convincing
- for phase 2, that the feasibility, the applicability in an operational setting and the potential impact of the product is convincing

Please note that there is a difference between satisfactory completion and successful completion: a satisfactory completion is a requirement to receive the payment for that phase. Satisfactory completion includes completion of all the deliverables & milestones in the specific phase, and meeting minimum requirements set for that phase.

A successful completion is a prerequisite for passing from one phase to the next and includes the same aspects as satisfactory completion, but will also depend on the assessment of how promising the R&D is.

6.4. Finalization of phase 3: link with possible follow-up PPI procurement

The Nightingale consortium intends to launch a new call for tenders for any follow-up public procurement of innovative solutions (PPI) to deploy a commercial volume of innovative solutions and to start a multicenter study to be able to receive needed certificates (CE-mark etc.).