Nightingale
Smart monitoring, safer care

Below you will find the questions and answers of round 1, 2 and round 3 combined.

Round 1

Question 1

Question to figure 3 page 9 in common challenge functional specification document:

- The drawing in figure 3 gives the impression that the patient isn't an active user of the Nightingale Monitoring System
- In light of the motto "connecting patients and carers" we assume that it is the intention activating the patient as a direct Nightingale Monitoring System user as well (e.g., with entering observations, receiving questions, notifications, etc.). Is our assumption correct?

Answer:

YES, the Nightingale consortium wishes the solution to be much more than a simple one-way wireless monitoring setup. In order to capture highly relevant context information, it must be possible to contact the patient, and allow the patient to enter data and answer questions. Also, it must be possible for the patient or informal carer to initiate such contact. Critical illness often is accompanied by changes in mentation (somnolence, restlessness, etc.). Two-way communication with patients and informal carers could become an important means of capturing critical information about mentation/altered mentation - probably one of the most valuable vital signs.

We leave it to the suppliers to decide whether they propose using "of the shelf" technology (e.g., a smartphone app) to achieve this functionality or to implement similar functionality directly into their monitoring solution. In addition, if the decision support components of the solution involve machine learning and AI, part of the solution´s "intelligence system" might also initiate various types of patient interaction (for example, a push message: "are you OK"? "Would you like to speak to a nurse?"). Patient input is critical to design systems in such a way that they will be acceptable to patients and carers.

Nightingale
Smart monitoring, safer care

Question 2

- **Question to figure 3 page 9 in common challenge functional specification document:**
    - As per the scenarios and per the common Nightingale challenge description, the “Nightingale Monitoring System” seems to be triggered (or prescribed) ALWAYS by hospital staff and for patients that are treated initially in the hospital.
    - Is this correct?
    - If not, what other scenario’s do you see in triggering (or prescribing) a “Nightingale Monitoring System” for patients at risk? Please elaborate.

Answer:
NO, we do not see the Nightingale solution as an exclusive “hospital only” system. We already envision future uses of the Nightingale solution beyond hospital care or post-hospital discharge care. However, from a feasibility point of view within execution of this PCP, our *initial focus* for development and testing is indeed centered around the hospitalized patient and the early days after discharge from the hospital. The main reason is that this allows for much more comprehensive initial testing. We will explore the potential uses of the system as a safety monitor for patients who have visited an Emergency Department, and in whom a decision is made not to admit them to hospital. If this type of remote monitoring after initial ED diagnosis and treatment turns out to be feasible, it would allow hospitals to safely observe and monitor acute care patients in their own home setting, who would otherwise need to be admitted “for observation”. Obviously, this could be a huge benefit to patients and society.

We also envision several scenarios in which the Nightingale solution would be used in other health care settings, e.g., primary care, chronic conditions, geriatrics, nursing homes and hospices. For such applications, the hardware solution within Nightingale could probably be used with few modifications. However, the battery requirements, intermittent nature of data capture and transmission, the algorithms required for data capture, artefact rejection and interpretation will (probably) need to be different. Also, the type of captured

vital signs, data and interactions with patients and carers will have to be adapted to the specific chronic pathology, and this is out of scope for the current PCP. In addition, for such applications there is a need to design and organize a structure required for responding to the analyzed vital signs. We can envision the emergence of new medical services, e.g., medical call centers that observe the data, communicate initially with the patient and/or informal carer to exclude artefacts or trivial causes of abnormal vital signs. They would then contact the responsible nurse and/or doctor only when there is a valid suspicion of true deterioration.

Question 3

Question to figure 2 (page 5), figure 3 (page 9) and pages 21 & 32 in common challenge functional specification document:

- You use the term "Hospital Medical Record System" as clinical data provider for monitoring patients at risk in the home environment.
  - Can you please elaborate on what you exactly mean there?
  - Would you see other clinical data providers being in scope for this project?
  - These could be non-hospital Medical Record Systems, which capture relevant data during the out-of-hospital care process.
  - How to deal with this?

Answer:

Please also see our answer to Question 2. The initial development, testing and application of the prototype Nightingale solutions will be in hospitalized patients and patients early after discharge from the hospital. This means that the hospital Electronic Medical Record system (EMR) is the primary data source and data repository for the initial target population of Nightingale; for future uses of the system in patients with chronic pathologies this can and should be expanded to a much broader source of information and data, but this requires a completely different setup which is again out of scope for this PCP.

Many European hospitals do not allow export of privacy-sensitive medical data outside their (firewall) protected environments. This precludes the export of

medical context data to servers outside the hospital maintained by the solution provider. While this may or may not change in the future (we can envision certified "trusted third parties" who are compliant with all national and EU data protection regulation), for the time being, and in order to allow clinical testing within the five participating academic hospitals in the Netherlands, Belgium, UK, Sweden and Germany, patient data need to stay within the protected hospital IT environment. Tenderers are encouraged to elaborate on how their solution would align with a possible future acceptance among the care providers for cloud services, and assumed related handling of patient data externally.

Sensor data and the results of data entry by the patient and informal carer will therefore need to be brought into the secure hospital environment. Along these lines, it will also be necessary to install the clinical decision support logic on servers within the hospital environment.

Question 4

Are sensors that use inductive, resonance or radio charging allowed ?
Some experts say that this can react with some pacemakers and others are telling us that it is safe ?

Answer:

Yes, but every sensor must pass strict tests for RF interference. In patients wearing an implantable pacemaker or ICD, the charging process must not interfere with normal PM/ICD function, or else the sensor will be contraindicated in patients with such devices. If you propose to implement such a wireless charging method, we suggest to seek contact with manufacturers of the leading PM and ICD models.

The solution should be compliant with the norm Medical Design Standards for Power Supplies including the norm about EMC (IEC 60601-1 & IEC 60601-1-2). For the battery you should take into account the Global battery safety regulations (IEC 62133).

Nightingale
Smart monitoring, safer care

Round 2

Question 5

We have particularly questions on the interpretation of article 11 : *"If the Contractor fails to commercially exploit the Results within this period, or uses the Results to the detriment of the public interest, the Contractor shall, according to the provisions of Article 9.3, at Procuring Entity's request, transfer the ownership of the Results to the Procuring Entity free of costs or sub-licenses IPRs to third parties indicated by the Procuring Entity"*

We interpret this as if a certain feature e.g. a smart algorithm to predict patient deterioration in our system has been developed with partial or whole funding from Nightingale, but due to business reasons we decide in 2020 to commercialize a slightly other prediction algorithm that does not meet your expectations, or if formal FDA / CE approval become too expensive due to complex long lasting clinical trials we do not commercialize it at all within the 5 years, that all IP rights will flow to the 5 hospitals.
That obviously cannot have been your intention. All parties in our consortium see this as a roadblock.

Answer:
Note that Procuring Entity may only invoke article 11 of the concept Framework Agreement after the defined period expires and that Contractors are obliged to transfer ownership or provide a sub-license to a third party only "at Procuring Entity's request" and only in case Contractor "fails to commercially exploit the Results within this period, or uses the Results to the detriment of the public interest". Thus, Procuring Entity will only invoke this article when necessary to ensure that the solution developed in the PCP will be commercialised and the Contractor is refusing to do so, or when the Contractor is abusing the solution/IPRs developed during the PCP against the public interest. Consequently, if it becomes clear after the time period expires that for example an algorithm developed during a PCP does not fully meet the needs of the Contractor (or does not perform as expected in clinical trials) and some modifications to the algorithm are needed to meet the Contractors need, provided the Contractor is not blocking the commercialisation of the solution

or abusing the solution against the public interest, then the Procuring Entity will not use its right to invoke acticle 11.

Question 6

We have the following question regarding the minimum requirements of the sensor:

- What's meant by temperature? Skin temperature or core temperature?

Answer:

We realize that a wearable device that is in contact with the skin (garment), attached to the skin (patch) or worn at the wrist can only measure skin temperature at that location. Skin temperature, in turn, is likely to be influenced by ambient temperature under some conditions (e.g., outside in cold weather). True core temperature (nasopharyngeal, oesophageal, tympanic membrane, rectal temperature) can only be obtained continuously with invasive sensors, ingested sensors, or subcutaneously implanted sensors. Such solutions are are not patient-friendly, and beyond the scope of Nightingale wearable sensors.

Question 7

We have the following questions regarding the framework agreement:

- Can you clarify under which circumstances a Contractor would be forced to license Pre-existing rights to third parties?
- Related to this:
    - Can you clarify article 9.4?
    - What's exactly meant by "Subject to Article11"?
    - What's exactly meant by "needed to perform the Project"? Phase 1, 2, 3 or also after completion of phase 1, 2, 3 for exploitation?

Answer:

The Project Intellectual Property Rights shall remain vested within the Contractor with only one exception as set out in article 11. In addition and under the same conditions as set out in article 11 (in short, the expiration of the defined period and Contractor failing to commercially exploit the Results

within this period, or using the Results to the detriment of the public interest), Procuring Entity may grant non-exclusive licenses to third parties to exploit the Results under under fair and reasonable market conditions without any right to sublicense.

Needed to perform the Project only refers to the Project and the Project is limited to Phases 1, 2 and 3.

Question 8

Article 11 of the framework agreement:

- It refers now to Article 9.3. Is this correct? Or should it refer to Article 9.4?
- It says "transfer the ownership of the Results to the Procuring Entity free of costs or sub-licenses IPRs to third parties indicated by the Procuring Entity".
  Is it up to the Contractor to decide or does the Procuring Entity decides this?

Answer:

- The reference to 9.4 shall be updated.
- It is up to the Procuring Entity, see also other answers.

Question 9

One related question to Annex 2 – contract template:
Can you clarify the meaning of "apply mutatis mutandis" in Article 4?

Answer:
The Framework Agreement applies to the Project as a whole and the template contract in Annex 2 only applies to a specific phase of the Project. Thus, where the template contract in Annex 2 would refer to the 'Project' or to 'Results', the scope will be limited to the relevant phase at hand. That is an example of a difference which the phrase 'mutatis mutandis' is intended to capture.

Question 10

Nightingale
Smart monitoring, safer care

The issue that we have is that we are discussing with a few biosensor companies on linking their solutions with our intelligent backend data processing software, but that all our efforts to team up with a system integrator (i.e., a party that can provide functionality to read and write data from electronic health records, preferably using HL7 FHIR) seems to be troublesome. Typically these (monolithic) parties are not interested in teaming up with (smaller) niche market technology providers.

Our question: is it a feasible approach to propose a partial solution and require the Nightingale consortium to propose after submission a proposed consortium?
And what is the name of the company from Belgium that provides standardised access to health record data? Is it BeHealth?

Answer:
There are several companies specializing in such systems integration, for example one large EMR company markets a 'device connectivity' platform, independent from their EMR suite, while others offer their solutions independently from EMR vendors. We intend to organize an invitational conference early 2018 to introduce the Nightingale project to EMR vendors and discuss possibilities to solve the interoperability issues. Unfortunately, we cannot accept partial Nightingale solutions, but realize that it may be hard for smaller companies and consortia - at this stage - to guarantee interoperability with EMR systems from various vendors.

Question 11
We noticed that some provisions of the Framework Agreement are not fully clear and would require clarifications/modifications to the wordings. What is the preferred method for Tenderers to provide such wording proposals for modifications of the Framework Agreement?

Answer:
The preferred method is that the Tenders send in, article by article, the proposed phrasing of the articles to the Nightingale email address for questions with a short reasoning as to why a modification of the current

provision is necessary in the eyes of the Tenderer. The Nightingale Consortium shall respond in accordance with the procedure described in the Tender Documents.

Question 12

Framework Agreement.

Defined terms “Results”; “Services” ; “R&D Services” and “Material” would need to be more narrowly focused to avoid conflict with legacy projects that some of our consortium members have made commitments for. For some of these projects also local governmental funding has been received. Please consider narrowing the definition of these deliverables to the Results defined separately for each of the partners in the consortium in an appendix in line with the tender response.

Answer:

The definitions of “Services”, “R&D Services” and “Results” only refer to the scope of the Project, the PCP and this concept Framework Agreement. However, please feel free to suggest an alternative. See also our answer to question 11.

Quenstion 13

Framework Agreement.

Article 9.4: the second full sentence of this Article requires the parties to license Project Intellectual Property Rights and Pre-existing rights that may give rise to a conflict. As explained above, we are committed in other consortiums and some other commitments would probably conflict with such licenses, even non-exclusives. This does not mean we do not want to participate to the Nightingale tender, just that we cannot agree to anything that may conflict with a pre-existing commitment. Accordingly we would ask that the second and third sentences of this Article 9.4 be stricken.

Answer:

Article 9.4 follows from Pre Commercial Procurement law and regulations and hence, the Nightingale Consortium cannot deviate from it. The reasoning of

article 9.4 (read in junction with article 11) is that the Tenderer is incentivized to commercialize Results within a defined time period. The provisions in question are a last resort to ensure that the Result will be commercialized and to avoid an abuse of the solution against the public interest.

Question 14
Framework Agreement
Article 10.2.1.1: the Results of the Project are distinguished from the outputs of other Research activities. We could try our best here but we can't take a firm obligations as this will not be always possible. Outputs of each project are not always fully distinguishable.

Answer:
We advise you to take measures to make this possible as the distinction is relevant to determine all the obligations of the Tenderer following from the Framework Agreement and other documents (i.e. protection of Results, licensing of Project IP). If such a distinction cannot be made, the Nightingale Consortium stresses that it must have access to all Results.

Question 15
Framework Agreement
Article 10.2.3: the Contractor shall take all appropriate measures to protect or defend said Project IP Rights. We can't let anybody decide for us which results should be protected or defended. This is a business related decision, depending on the results and their capacity to be commercialized. The same reasoning applies for Section 10.3. We need to decide alone how we manage our IP.

Answer:
The obligation to arrange for adequate IP protection is a standard requirement for any EU funded project. Please note that Procuring Entity will not control IP protection, considering that it is the obligation of Contractor to ensure that all appropriate measures are taken and that Contractor must give due consideration to the comments of Procuring Entity on the conduct of proceedings.

Nightingale
Smart monitoring, safer care

Question 16
Framework Agreement.
Article 10.4.2: the Contractor shall exploit commercially the Project IP Rights. Once again, this decision is business decision and we will not be able to accept this at this stage of the collaboration.

Answer:
The commercialization of the Project IP Rights is a general requirement of the provision of EU funding. The funding is intended to result in new solutions being available on the market.

Question 17
Framework Agreement
Article 11: this article requires a commitment to commercially exploit Project Results, and obligates the parties to transfer ownership of such results for failure to comply. We would ask that each party commits to providing reasonable efforts to commercially exploit the Project Results, but not guarantees an outcome that may be beyond our control. Furthermore, for the reasons specified above with reference to Article 9.4, ownership of the Result must be retained by each party and cannot be transferred.

Answer:
The article is required by PCP law and regulations and therefore, the Nightingale Consortium cannot deviate from it. Please also see our answer to question 5.

Question 18
Framework Agreement
Articles 9.2, 12.3, 12.4 (last sentence), etc: we cannot commit to licensing Project Intellectual Property Rights or Results without risk of a conflict for the reasons specified above with reference to Article 9.4. Accordingly we would ask any such licensing obligations be stricken.

Answer:
The license in articles 9.2, 12.3 and 12.4 all concern a license for non-commercial research purposes. Such licenses are needed for the Nightingale consortium members to perform the Project.

Question 19
Framework Agreement
Article 9.4 vs Article 11: Could you please confirm that Article 9.4 only applies (i) in case the Contractor has failed to commercially exploit the Results within five years after the end of the Project, and (ii) only to the successful Tenderers for Phase 3?

Answer:
Confirmed

Question 20
Framework Agreement
Article 9.2., para 2: Could you please elaborate what is the intended meaning of “to the detriment of public interest” in this context?”

Answer:
The Nightingale Consortium assumes that article 11 is meant in the question. To detriment of public interest in this context means that the Results are not used against the welfare or well-being of the general public. Please also see our answer to question 5.

Question 21
If we are selected, who will receive the funding? The sole lead contractor who then redistributes the money within the consortium, or to each consortium members their account entitled to receive a part of the funding as to be further detailed for each phase in the tender response?

Answer:

The sole lead contractor.

Question 22

The Framework agreement refers to the Grant Agreement signed between the Nightingale consortium members and the European Union. By signing the Framework agreement, we agree to *"implement the pre-commercial procurement in accordance with the Grant Agreement"*. Could you please communicate with us such Grant Agreement?

Answer:

You can download the Model Grant Agreement via the following link: http://ec.europa.eu/research/participants/data/ref/h2020/mga/pcp_ppi/h2020-mga-pcp-ppi-cofund-multi_en.pdf

Question 23

The Tender documents are instructed to be submitted by email. How are the required signatures to be provided?

Answer:

You place the signature in the signature box and scan the document. Please also see Question & Answer Nr 26.

Question 24

How does the breakdown of costs (Annex 4) affect the evaluation? It seems that the total offered price is used as the award criterium (P9), but the breakdown of costs is not explicitly mentioned as an award criterium.

Answer:

This is for the Nightingale project team to give them a better understanding concerning the costs. The team requires a clear overview of the costs, since this project is funded by the EU.

Nightingale
Smart monitoring, safer care

Question 25

In the case of a joint tender by a consortium, what should be inserted in the breakdown of costs in Annex 4? Should the breakdown be calculated based on the average costs among the consortium partners or should the individual costs of each partner be visible?

Answer:

Please provide the information of each partner. It is needed for further accountability and transparency reasons regarding the project funding. However, please make sure you have one total price as a consortium.

Question 26

The Annex 4 is requested to be saved as Microsoft Word document (.doc or .docx). Since the Annex 4 is provided as a pdf document, it has to be converted by a specific software not included in standard office tools. Would it be possible to provide Annex 4 as a Microsoft Word document to simplify the process?

Answer:

You have to use these PDF files and send it in as PDF.

Question 27

Would the Nightingale project consider an submission from a university? We are developing a series of low cost disposable sensors that are focused on monitoring patient vital signs in an acute ward setting to detect a patients deterioration. Would the only possible way to participate would be to form a partnership with other companies?

Answer:

Yes, as long as you comply with all obligations and requirements.

Question 28

What are the durability/cleaning requirements for the patient sensor?

Nightingale
Smart monitoring, safer care

Answer:
We expect a single-use disposable sensor to last at least 5 days, preferably one week or more. Non-disposable sensors might have a disposable battery and/or disposable electrodes. Alternatively, for sensors with a non-disposable electronics/transceiver module it may be possible to design rechargeable versions, that could either be recharged in a charger (in that case, a patient would need two such devices, one currently worn by the patient and one currently charging). Finally, we can conceive of solutions that make use of wireless recharging (see also the answer to question #4).

Durability/cleaning of non-disposable sensors: we expect such modules to be water-resistant and cleanable with an antiseptic water-based disinfectant cloth. In case of a severely contaminated patient (MRSA or VRE), a nondisposable sensor may need to be able to withstand cleaning with more aggressive soultions, such as alcohol/chlorhexidine, or sodium hypochlorite. If not, it may need to be discarded after use in such highly infectious patients.

For all types of sensors it is highly desirable that they are able to withstand a daily shower.

Question 29
Does the theory for notification generation in level 3 alerting algorithms need to be developed or are desired alerting combinations defined?

Answer:
Alarms in a level 3 system can be viewed as an 'extended' Early Warning Score crossing a predefined notification threshold. Such a decision support system also needs to take into account changes in relevant laboratory values (e.g. hemoglobin, potassium, glucose, creatinine, blood gases), input from nurses ('nurse worry') and input from patients/informal carers. There are some published multivariable prediction scores for the deteriorating patient, for example the (proprietary) Rothman score[1], and eCART, a new AI-based decision tool from Dr. Dana Edelson's group at the University of Chicago. However, such extended functionality is relatively new and it will need to be externally validated and further refined.

1. Finlay GD et al. Measuring the modified early warning score and the Rothman Index: Advantages of utilizing the electronic medical record in an early warning system. **J Hosp Med. 2014 Feb; 9(2): 116–119..** doi: 10.1002/jhm.2132

2. Kang MA et al.: Real-Time Risk Prediction on the Wards: A Feasibility Study. **Crit Care Med. 2016 Aug; 44(8): 1468–1473**. doi: 10.1097/CCM.0000000000001716

Question 30

When unit price is provided is this the expected product Cost of Goods or the expected market price?

Answer:

'Unit price' is a term used by the EC concerning H2020 funding and means costs per unit, like hourly rates per category personnel or person. It has no relation with the product costs.In the Nightingale tender form in the paragraph about 'Commercial Feasibility' we ask for an overview of an estimation of the (future) total cost of ownership of the solution and an estimation of future market price of the developed solution.

Question 31

Is the 'Temperature' required skin temp or core temp equivalent? There are solutions available that talk about skin temperature, but the values in the minimum accuracy requirements suggests core temp. However the comments state "Cut-offs for hypothermia, normal, fever, (or hyperyrexia) could be used as well?"

Answer:

Please see the answer to question 6.

Question 32

Can the alerting algorithms for the hospital and home use be different? The tender seems to suggest that they recognize that the system will encounter different situations at home than at the hospital.

Nightingale
Smart monitoring, safer care

Answer:
YES, one of the main reasons for accepting a lower alert threshold in the home setting is that we expect the signals arriving from the patient at home to contain more artefact. It will also be harder to determine the source of the artefact. For example, a patient at home develops a sudden tachycardia and high respiratory rate; this cannot be immediately explained without a burdensome call to the the patient or informal carer. It could be harmless and caused strenuous activity (say, digging in the garden) or herald deterioration. We accept therefore that in the home setting the system may need to observe for a longer time period (perhaps up to 15 min) before generating alerts. Clearly, using information from motion sensors could help the system to distinguish between transient activity-induced high heart rate or deterioration caused by illness.

Question 33
How much of the information given by our company will be available to the others? and whom would they be? How is this guaranteed?

Answer:
During the selection no information is given to other companies. When the winning proposals are selected, we will ask these selected companies for the next round to write a summary (in concept) of their proposal, which will be distributed to the other companies.

Question 34
For "Project Risks - for assessment of criterion Q7", is this section looking for Project risks (i.e. resources, etc....) or Product risks (i.e. technical risks) ?

Answer:
This concerns all types of risks that can affect the success of the project and the way in which it is mitigated.

Nightingale
Smart monitoring, safer care

Round 3

Question 35

How to fill in the application form? - it is in pdf. Should we just simply convert pdf to WORD file using free applicatons e.g. http://www.pdfonline.com/pdf-to-word-converter/?

Answer:
You have to use these PDF files and send it in as PDF.

Question 36

What kind of technologies exactly is the procurer looking for?

Answer:
We do not wish to prescribe specific technologies, but the Nightingale solution will likely require advanced hardware- and software technology. It will need wearable multi-parameter vital signs sensors that can reliably transmit their data wirelessly. The sensor should be well accepted by patients. The system will need intelligent artefact rejection algorithms, as well as a clinical decision support system that is highly integrated with the hospital's Electronic Medical Record system.
Please see the 'Common Challenge' document in the Tender package for details.

Question 37

Who is the owner of the product that will be elaborated?

Answer:
See also the answer to question 56.

Question 38

Is the result of the project only the demonstrator?

Nightingale
Smart monitoring, safer care

Answer:
Via the PCP procedure, the Nightingale Consortium procures R&D services. A part of the PCP procedure will be a tested prototype. See paragraph 3.4 of the PCP Request for Tenders document for more detail.

Question 39
Where will the final products be installed?

Answer:
The `Phase 3' prototypes will be installed and evaluated in the 5 hospitals of the Nightingale consortium partners (Aachen, Leuven, London, Stockholm and Utrecht). The consortium partners intend to design a larger European IMPACT study to evaluate the effects of the Nightingale system on important patient outcomes such as mortality, disability-free survival, length of hospital stay, and readmissions. A formal Health Technology Assessment will be part of that study.

Question 40
Are the proposals (offers) confidential or they can be seen by somebody?

Answer:
The evaluation committee of the Nightingale Consortium will see the proposals. During the selection no information is given to other companies. When the winning proposals are selected, we will ask these selected companies for the next round to write a summary (in concept) of their proposal, which will be distributed to the other companies. Please note that, due to the PCP procedure, the Procuring Entity has to motivate the award decision compliant with regular procurement law.

Question 41
The last date and hour for submission of a complete Tender is 12-01-2018 at 11:59 hr CET. In this case, does it mean 11:59 am or 23:59 (pm)?

Answer:
The last date and hour for submission of a complete Tender is 12 January 2018 at 11:59 hr CET. This means 11:59hr AM

Nightingale
Smart monitoring, safer care

Question 42
The answer to Question #19 in the first round of questions indicates that Article 9.4 only applies to Tenderers selected for Phase 3. Article 12.3, however, appears to apply to Project Intellectual Property Rights for all phases (see also, Question #18). Could you please confirm that Article 12.3 only relates to licenses for non-commercial research purposes? Could you also confirm that Article 12.3 should reference Article 9.2 and not Article 9.1?

Answer:
Confirmed and Article 12.3 should indeed refer to Article 9.2.

Question 43
Could you please confirm that "Sideground" can include information and IP "generated during the timespan of the PCP, but not in the PCP and is needed to implement the PCP", but that neither the Procuring Entity nor the Nightingale consortium members will have access to Sideground IP?

Answer:
Confirmed.

Question 44
Where a contractor has Pre-existing rights (e.g., IP), and plans to further develop their technology related to such Pre-existing rights during the timespan of the PCP, without using resources provided during the PCP, what are best practices that a Contractor can use to ensure such technology will not fall under any of the IP obligations included in the Framework Agreement? Question #14 seems to address this issue, but the answer only references "tak[ing] measures" to follow the "distinction[s]" related to IP obligations. More objective guidance on this issue would help to avoid disputes in the future.

Answer
The format and the content of the deliverables will be elaborated per phase.

Nightingale
Smart monitoring, safer care

Question 45
With respect to Question #33, the answer appears to identify what sort of information will be made available to "other companies" through Phase 1. What information will be made available to other companies through Phases 2 and 3?

Answer:
The way of working will be the same so that no sensitive information is given to the parties that do not continue in the next phase. See also answer to question 40.

Question 46
Some of the answers provided in the first round appear to refine or provide additional detail regarding the Framework Agreement. Will the published questions and answers be made a part of the Framework agreement in some way (e.g., as an addendum to the Framework Agreement)?

Answer:
The articles of the Framework Agreement will be (legally) interpreted in light of these answers given. The Procuring Entity will make a definitive version of the Framework Agreement after the award decision. See also answer to question 48.

Question 47
Can any guidance be provided to help understand how "fair and reasonable" licensing terms will be determined under the Framework Agreement (e.g., see Article 9.4)?

Answer:
It is the responsibility of the Contractor and the third party to establish the fair and reasonable market conditions.

For some guidance on the European Commission's view on FRAND terms, you could find some guidance by the 2015 JCR Science and Policy Report entitled: "Fair, Reasonable and Non-Discriminatory (FRAND) Licensing Terms. Research

Nightingale
Smart monitoring, safer care

Analysis of a Controversial Concept", with authors MÉNIÉRE Yann and THUMM Nikolaus (file: jrc96258.pdf, ISBN 978-92-79-49280-8)

Question 48

On the first page of the tender form it is written ,,The document must be saved as Microsoft Word document (.doc or .docx)". The tender form is available in pdf. Taking it into account, how technically is it possible to save it as WORD? My question is related to the answer to question no 26 in FAQ (compiled version) which is contradictory to the sentence on the first page of the tender. So, finally should the tender be saved and submitted as WORD or pdf file?

Answer:

You have to use these PDF files and send it in as PDF.
The answers in the Q & A prevail over the text in the tender document. In addition; Q&A round 3 prevails over Q&A round 2 and Q&A round 2 prevails over round 1.

Question 49

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. How should we understand it?

Answer:

This is to prevent tenderers from offering proposals with already existing products that are more or less commercially available. The purpose of the PCP is to develop something new.

Question 50

Can the offer be partial, i.e. can it be submitted only for one or two components (chosen by a tenderer) out of 3 components, i.e. the nightingale system or only for sensing system or only for data transission?

Answer:

No, we will require the tenderer to submit an offer for a complete system that can be installed in each of our hospitals. Where a company's expertise is

limited to a single component of the solution, we encourage the formation of consortia that are able to collectively develop and build a full solution. One exception could be the notification device, which may be a hospital-wide purchasing decision that is entirely separate from Nightingale. In such cases we expect the Nightingale system to send alerts and other message types to the notification device using standard communication protocols.

Question 51
What annexes to the tender are required form the tenderer?

Answer:
The documents from annex 4 and 5.

Question 52
What is deadline for submitting offers on 12 January 2017 - does 11:59 CET mean 23:59 CET?

Answer:
The last date and hour for submission of a complete Tender is 12 January 2018 at 11:59 hr CET. This means 11:59hr AM.

Question 53
Budget and planning questions:
Can we buy in-house produced devices for signal capturing and for signal transmission at cost as part of the project?

Answer:
Yes, components that are ready to buy may be integrated in the total solution in this R&D project.

Question 54
Who covers the cost for the hardware/software needed for the "testing environment"? Should it be included in the budget? See page 56, file PCP Request for Tenders final.pdf

Nightingale
Smart monitoring, safer care

Answer:
This must be a part of your budget. The program does not have other monetary sources than what is funded by the EU. This means that the hospitals cannot provide extra funding during the test.

Question 55
Regarding maintenance and support of the Nightingale solution in the testing parts of the phases – who is responsible financially and physically, the supplier or the procurer? Are individual procurers' IT teams responsible for the maintenance, or should maintenance be planned within the budget?

Answer:
The tenderer is responsible for his solution. It is (also) in his interest that the solution works 100% when it is tested at the different hospitals. The maintenance must be part of the budget.

Question 56
What happens to the prototype – server, software, and monitoring devices – after Phase 3? Are they kept by the procurers or are they returned to the supplier?

Answer:
These items will be returned to the supplier.

Question 57
How many physicians will be available for consultation and mapping of the systems/EHR of each individual hospital? Who is going to cover these costs?

Answer:
Each hospital will provide one primary physician contact who will coordinate with colleagues and nurses from different departments and their associated patient wards where testing will take place.

Question 58
Are costs (e.g. maintenance, labor) covered during the so-called evaluation and testing parts/periods of each phase?

Nightingale
Smart monitoring, safer care

Answer:
These costs must be part of your budget.

Question 59
AI and decision support system development:
Are certain technologies/software preferred (open source e.g. R/Python/Scala/MySQL/Hadoop vs commercial e.g. Matlab/Oracle)?

Answer:
We are agnostic as to specific software platforms. However, if the solution requires the hospital to purchase licences for a specific platform, these costs must be pre-specified and will be weighed in the evaluation.

Question 60
If we buy commercial software, do we keep the license for ourselves after the project?

Answer:
The Framework Agreement does not affect ownership rights of the Contractors, except the anti-shelving clause in article 11 of the Framework Agreement. Thus, only in case the mentioned Commercial Software is part of the Results and the other conditions of article 11 of the Framework Agreement are also met, can the ownership rights to Commercial Software be affected.

Question 61
Could you clarify the contents of the dataset with historical patient data that will be used for evaluation at the end of Phase 2? Will sample/training set be provided to the suppliers?

Answer:
Because wireless vital signs monitoring is not yet frequently used in clinical practice, there are very few annotated datasets available with continuous vital signs data recorded from patients in low-care ward settings. None of the 5 academic hospitals within the Nightingale consortium possesses such databases. In the absence of real 'low-care patient ward' data, we may decide

to use data from patients recovering from anesthesia and surgery during the first day and night in a so-called 'postanesthesia care unit' (PACU). This situation resembles very much the ward setting, but here vital signs are continuously monitored. UMC Utrecht has a database with approximately 10,000 cases, which we intend to convert for use as a derivation and validation set. Provided we can obtain approval by the ethical committee, we intend to provide a fully anonymized training set of such data.

Question 62

What happens to algorithms that require input data, which is not present in the dataset with historical patient data (e.g. missing streaming/EHR/lab-test data)?

Answer: See also our answer question 61: when a sufficiently large number of relevant input data is unavailable, the algorithms can only be partly trained. Full functionality of the algorithms cannot be expected until a sufficiently large database has been built with all the required input data collected in the relevant domain (hospital wards and home setting). This will require clinical implementation of at least the sensing system, i.e. a level 1 or 2 monitoring approach. Witch respect to the proposed database of 'Day 1' postoperative data, this database also contains laboratory values, nurse observations and pain scores, etc.

Question 63

Can we use data from procurers (including follow up) to develop and improve detection/prediction algorithms?

Answer:
Yes, but please realise that our currently available data sets are very limited (either vital signs data recorded manually by nurses three times daily, or continuous vital signs recorded in 'intermediate' care settings (PACU, Medium Care). See also our answers to the previous questions 61 and 62.

Nightingale
Smart monitoring, safer care

Question 64

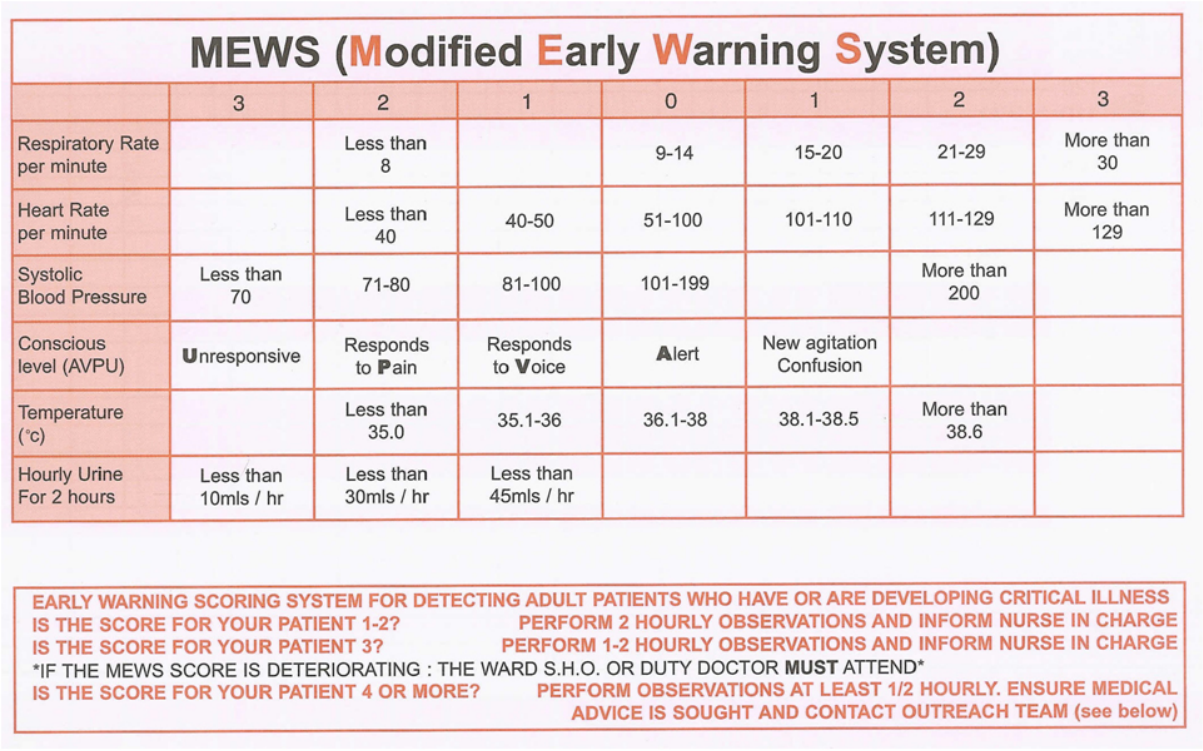
Regarding prediction algorithms – can we have a quantitative measurement of the endpoint variable "physiological instability"? Can you please quantify the prediction period (for both home and hospital setting)?

Answer:

Clinically 'physiological instability' either refers to one or more vital signs exceeding certain thresholds (please refer to the various Early Warning Score cards), or further deterioration in sick patients with one or more vital signs already within an abnormal zone. There are no 'hard' limits or boundaries for physiological instability. In many cases, the user will need to be able to adapt the boundaries for physiological instability, particularly in patients who are already ill. For elective admissions and surgical procedures, the system may be applied one or two days before the procedure and first 'learn' the normal patterns of the patient's vital signs over the day. These patterns can then serve as a baseline from which deviation/vital instability can occur. Please note also that not only the current values determine whether there is 'vital instability', the trends are equally important. For example, if heart rate and respiratory rate are both slightly elevated (HR 95/min, RR 25/min), but progress to tachycardia and tachpnea (RR 125/min, RR 32/min), there clearly is vital instability.

Nightingale

Smart monitoring, safer care



MEWS (Modified Early Warning System)							
	3	2	1	0	1	2	3
Respiratory Rate per minute		Less than 8		9-14	15-20	21-29	More than 30
Heart Rate per minute		Less than 40	40-50	51-100	101-110	111-129	More than 129
Systolic Blood Pressure	Less than 70	71-80	81-100	101-199		More than 200	
Conscious level (AVPU)	**U**nresponsive	Responds to **P**ain	Responds to **V**oice	**A**lert	New agitation Confusion		
Temperature (°c)		Less than 35.0	35.1-36	36.1-38	38.1-38.5	More than 38.6	
Hourly Urine For 2 hours	Less than 10mls / hr	Less than 30mls / hr	Less than 45mls / hr				

EARLY WARNING SCORING SYSTEM FOR DETECTING ADULT PATIENTS WHO HAVE OR ARE DEVELOPING CRITICAL ILLNESS

IS THE SCORE FOR YOUR PATIENT 1-2? PERFORM 2 HOURLY OBSERVATIONS AND INFORM NURSE IN CHARGE

IS THE SCORE FOR YOUR PATIENT 3? PERFORM 1-2 HOURLY OBSERVATIONS AND INFORM NURSE IN CHARGE

*IF THE MEWS SCORE IS DETERIORATING : THE WARD S.H.O. OR DUTY DOCTOR **MUST** ATTEND*

IS THE SCORE FOR YOUR PATIENT 4 OR MORE? PERFORM OBSERVATIONS AT LEAST 1/2 HOURLY. ENSURE MEDICAL ADVICE IS SOUGHT AND CONTACT OUTREACH TEAM (see below)

Question 65

We plan to collect data from patients (historical and prospective) in order to build and refine our prediction and detection models. The patients will provide consent for our research. Are we required to share these data with Nightingale procurers?

Answer:

No. If you are able to build your own prospective and historical datasets, you can use these to develop and refine your predictive algorithms. We will not require you to share these with us.

Question 66

Please clarify what “low false alarm rate” means. What is the reference value for “low”?

Nightingale
Smart monitoring, safer care

Answer:
A 'low' false alarm rate means that nurses are not hindered in their work by having to respond to frequent false alarms, thus taking away valuable nursing time from patients who are most in need of nurse attention. In the home setting, it means that a patient will not be paged or phoned every hour from a medical call centre to clarify her/his current situation. The acceptability of a certain number of false positive alarms is dependent on the severity of the patient's illness, the dangers of unrecognized deterioration, current case load and levels of nurse staffing. We intend to use focus group interviews as well as individual interviews to obtain more information on the acceptability of false alarms. For the designers of a Nightingale system, it means aiming at very high accuracy in artefact recognition and developing 'smart' algorithms that can take into account the interrelatedness of signals. For example, if the ECG signal appears to shows ventricular fibrillation but a pulse sensor detects a regular steady pulse, the ECG is probably corrupted.

Question 67
"Updated versions of the performance of data acquisition from source systems" ("PCP Request for Tenders final.pdf", p.24) – who will do the acquisition from source systems? We expect this to be done by the local IT teams. We can provide a "data request form" with data needed for the algorithms. Is that how you see it, or shall we really have access to EHR sources systems?

Answer:
Yes. Indeed we expect Nightingale systems to use standard HL7 interfaces to request data from EHR source systems.

Question 68
We have a fully operational system for 24/7 remote monitoring of vital signs of patients, and we plan to publish our findings, comparative studies (monitoring vs no-monitoring), cost-benefit analysis, algorithms, and case studies in journals. Will the Nightingale procurers desire to include their data and Nightingale patients so as to be co-authors of such papers?

Answer:
No, this not a requirement. If you already have a fully functional remote monitoring system and collaboration with particular hospitals, planned or ongoing comparative trials, etc., please use that support system to refine your current system and develop it into a Nightingale solution.

Question 69
Is it desirable to use machine learning algorithms, which have several local minima – and thus produce slightly different risk scores/alarms – such as neural Network/Deep Learning algorithms?

Answer:
We have no preference for any specific methodology, although we expect that a 'level 5' system will require some form of machine learning if it is to automatically update its algorithms.

Question 70
We aim to propose a level 5 analysis system. During the process of self-learning, such a system will autonomously and continuously update its model(s) for prediction of risk/alarm scores. It is possible that in different hospitals, the self-learning systems to evolve in different way, as the data provided to the analysis system will be different. Thus, the predicted risk/alarm score for two patients with the same characteristics treated at two hospitals will be different. Do you, therefore, envisage in the future the Nightingale solution to operate in a distributed-learning ecosystem (e.g. the EuroCAT oncology network, of which RWTH is a part)?

Answer:
This is an interesting issue. We realize that a 'Level 5' self-learning system is likely to evolve differently in various settings. A distributed learning system might both accelerate learning and produce more robust results. We can certainly envisage that hospitals pioneering advanced clinical decision support tools team up and collaborate in consortia such as EuroCAT.

Nightingale
Smart monitoring, safer care

Question 71

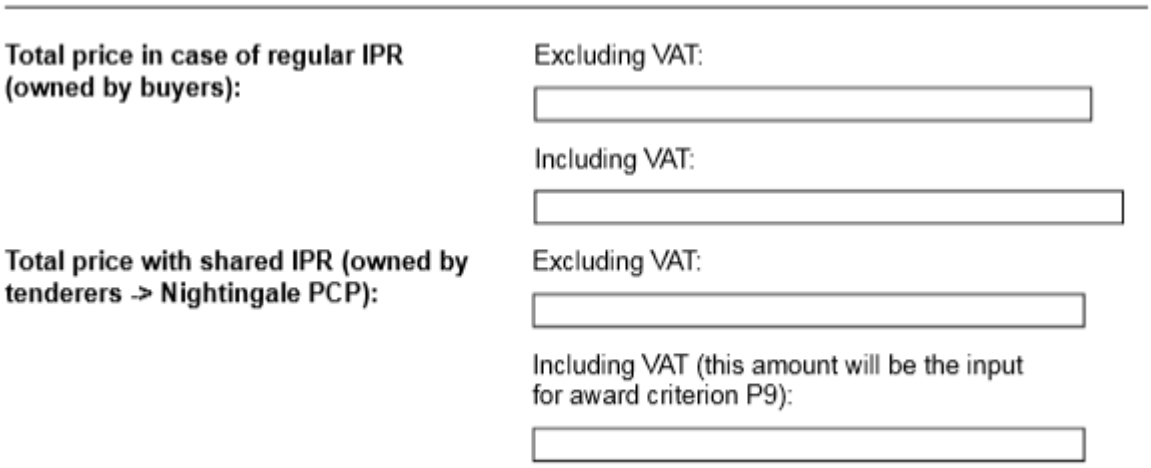
In project plan and Methodology: are there only milestones for phase 1 and written description for Phases 2 and 3 or are milestones for the overall project requested. This is with regards to template given.

Answer:

For the tender for Phase 2 and 3, the Tenderer is requested to describe the milestones for said Phase. Please see page 20 + 21 of the Request for Tenders regarding this topic.

Question 72

For the image below which is at the bottom of all the Price -Cost forms for each phase, please define each block on the right and what it represents and for the two sentences on the left what you are specifically looking for.



Answer:

Tenderers are asked to provide the price when the IPR is owned by the buyers and provide a price when the IPR is shared. This way it is visible what is the value of the IPR within this PCP Nightingale program.
We require the prices including and excluding VAT.

Question 73

Framework agreement, page 2, chapter 'Preamble', section 'whereas'.

In the first paragraph the Nightingale Grant Agreement is mentioned. As the consortium is granted to this action the agreement is mentioned in the contract it is of interest to know the content of this Grant Agreement. Could the consortium please provide this agreement

Answer:
You can download the Model Grant Agreement via the following link:
http://ec.europa.eu/research/participants/data/ref/h2020/mga/pcp_ppi/h2020-mga-pcp-ppi-cofund-multi_en.pdf

Question 74
Framework agreement, article 7.2.3
This article describes a unlimited liability to the contractor, which is very uncommon. We would suggest to limit this liability to 100% of contract value of the specific phase.

Answer:
Partially agreed. A cap on article 7.2.3 is acceptable for the amount to be received by the under the Framework Agreement, except for liability as result of a breach of data protection regulations.

Question 75
Framework agreement, article 20.1
This article describes unlimited access to all information in related to this framework agreement and concerning the commercialization of the results including financial and pricing information. There is no ending to this obligation. This gives a couple of problem. Listed companies are restricted in delivering this kind of commercial and financial information. So we suggest to limit this article in scope (information related to the framework agreement and limited commercial information (excluding pricing and financials) and also limit in time (ea. 5 years).

Answer:
Regarding the limitation of the obligation over time, the Nightingale Consortium shall limit the time period for a period of 10 years after the end of the Framework Agreement (see for this also Article 20.2).

Question 76
Framework agreement, article 20.2
This article describes the period the contractor needs to keep records and supporting documentation to its implementations or the implementation of the specific contracts. Which contract are meant by 'specific contracts'. The framework agreement and the contract of the 3 project phases? Or all the future contracts regarding this solution?

Answer:
The Framework agreement and the contract of the three project phases.

Question 77
Framework agreement, article 24.4.6
In this article the Frascati Manual is mentioned. Is it possible to explain/summarize what is mentioned with this manual ?

Answer:
The Frascati Manual sets out guidelines for the proper execution of scientific data research, R&D research and policy impact evaluation. You can read the latest version of the on the website of the OECD (http://www.oecd.org/sti/inno/frascati-manual.htm).

Question 78
(annex 3 page 6)
In the business case is mentioned that the potential savings in healthcare are calculated at €7,3 million per year per hospital with a capacity of 30.000 patients per year, based on the mentioned assumptions. We assume that the 30.000 patients also include minor treatments. Will all patients, even those who will leave the hospital directly after their treatment, need to be monitored? Changes in the amount of monitored patients will directly affect the business case.

Answer:
No, it is the hospital's decision if they want to monitor all patients (low, intermediate and high risk) or only intermediate and high risk patients. Clearly baseline risk changes the assumptions for the business case. For example, a Nightingale monitoring solution might be prescribed for intermediate risk patients who are operated in day-case surgery, but not for healthy patients undergoing minor outpatient procedures. We have developed a simple model (in Excel) where one can adjust each of these assumptions to see how they affect the hospital's bottom line. Please note that society bears the costs for a patient's death and long-term complications (permanent disability) and that these costs are often not visible on a 'hospital only' balance sheet. Furthermore, the healthcare system's financial structure also determines the apparent cost-effectiveness: in National Health Services it will be easier to uncover the economic benefits of the Nightingale solution, than in fragmented health care systems, with multiple, independently billing, providers.

Question 79
(annex 3 page 14)
This question is related with the question above. In the text is noted the following: "many artefacts in vital signs monitoring are caused by motion artefact. In contrast to anaesthetised patients and patients on intensive care units, most patients in the targeted groups are mobile and may be actively exercising several times a day".
We are interested which patients are going to be monitored and how fit these monitored patients are. Are the patients fit enough to leave their houses for example or are these patients mainly confined to bed?

Answer:
We definitely expect the Nightingale solution to be able to monitor freely moving patients. The fitness of an individual patient will vary from relatively fit before a planned operation, to very sick in the first days after surgery and then progressively fitter as mobilization and recovery occur. We have noticed that early mobilization is physically demanding for the patient and may often trigger a changes in vital signs (e.g., atrial fibrillation). This precludes a 'bed-

based only' wireless monitoring system. We can envisage a system that combines bed-based monitoring with wearable monitoring to obtain a 'best of both worlds' solution, however.

Question 80
(PCP Request for Tenders final page 22)
In the document is written the following text: 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. We are wondering how it could be possible to monitor more hospitals if the information can not leave the hospital?

Answer:
In the future we expect that a patient gives explicit consent that data may be shared among his/her providers in the entire care chain (primary care, hospital, rehabilitation). In such cases, a dedicated monitor centre maybe tasked with providing 24/7 surveillance of the wireless sensor data and initiate communication with the patient and/or informal carer, in case of suspected abnormalities. Only when there is true deterioration will the call centre nurse call a professional carer to see the patient.

Question 81
(PCP Request for Tenders final page 8)
In the document is written "the tendered price must be the 'non-exclusive development price'; see section 4.5.4)." Could you let us know where we can find Section 4.5.4, because we can't find it in the PCP Request for Tenders?

Answer:
The correct reference is Section 4.7.4.

Question 82
(PCP Request for Tenders final chapter 4)

The Main contractor need to sign Annex 4. How can we prove the compliancy of a sub-contractor? Is it also needed to provide sub-contractors compliancy evidence, in this first Phase? If so, could you please specify for what and in what form we need to submit the sub-contractor evidence?

Answer:
Subcontractors must also sign the declaration of Annex 4 and fill in the chapter on Professional secrecy, Ethical Issues, Security Issues.

Question 83
(Frameworkagreement art 5.7)
“Notwithstanding the provisions of Article 24, the Procuring Entity may terminate this Framework Agreement forthwith should the Contractor be unwilling or unable for any reason to continue with the Project or if, in the reasonable opinion of the Procuring Entity, the Contractor is consistently failing to achieve an acceptable standard in relation to the Project. If this occurs, the Procuring Entity shall not be obliged to make any further financial payment to the Contractor”.
'reasonable opinion of the Procuring Entity' is a broad understanding. Could you agree with a modification of this article into: “Notwithstanding the provisions of Article 24, the Procuring Entity may terminate this Framework Agreement forthwith should the Contractor be unwilling or unable for any reason to continue with the Project or if, the Contractor is consistently failing to achieve an acceptable standard in relation to the Project. If this occurs, the Procuring Entity shall not be obliged to make any further financial payment to the Contractor” ?

Answer:
Confirmed.

Question 84
(Frameworkagreement art 6.2)
"Notwithstanding the provisions of Article 6.1, the Procuring Entity or the Nightingale consortium representative is entitled to carry out a visit to the Contractor’s premises at any time for the purpose of due diligence and

evaluation in respect of the Project."
In addition we would add; ...with a maximum 1 visit/year, and it is subject to priori notice (at least 1 month), could you agree?

Answer:
Partially agreed. The Procuring Entity shall inform the Contractor of its visit a priori. To evaluate the Project, the Procuring Entity may want more visits than once a year.

Question 85
(Framework agreement art 7.3.5)
"promptly inform the Procuring Entity of the absence of the Contractor's Representative and/or Key Staff. If the Procuring Entity so requires, the Contractor shall provide a suitably qualified replacement"
Could you add which situations are really aimed here? Do we need to inform the client every time one of the Key Staff is out (for vacation for instance)

Answer:
The procuring entity whishes to have a single point of contact at the Contractor's. The Contractor is responsible to organise such. If during the PCP, Key Staff is replaced, the Procuring Entity must be informed. During vacation, it is up to the Contractor to arrange proper replacement and to communicate such to the Procuring Entity if necessary.

Question 86
(Framework agreement 10.3)
The Contractor shall permit the Procuring Entity to monitor the operation and effectiveness of the Contractor's procedures for the management of Project Intellectual Property Rights in such a way as the Procuring Entity considers reasonably necessary."
We have and are managing a lot of IPR's for many years,due to our procedures and policies we would ask the Procuring Entity to delete this article, could you agree with this?

Answer:
Not agreed. Since the PCP concerns the procurement of R&D services, development and protection of IPR's is a key element. Procuring Entity has a legitimate interest in the management of the Project Intellectual Property Rights, first considering the time and effort spent by Procuring Entity on providing input to Contractor, and second considering the protection and defence of the Project Intellectual Property Rights will affect Contractors ability to adequately commercialise said rights.

Question 87
In the quality section about the "Project Plan and Methodology" (page 13), in order to complete the table we have some doubts:
A) About resources, could you specify which type of resources are you interested in? Human resources, time resources, economic resources…?
B) Finally, we don't really understand the concept of success criteria. Could you provide us an example of a success criteria?

Answer:
A) Your Question relates to Q.6 (page 39). The hospitals cannot oversee which resources (people, knowledge, products, etc) you will be needing for your project. This will be different for each Tenderer.
B) Success criteria are measurable conditions for what needs to be done to make the project a success.

Question 88
About the "Price - Cost Breakdown" (page 18):
A) In the personnel column: do you expect us to indicate the amount of personnel separated by their role (junior/senior researchers) or do we have to separate the personnel according to their category (technician, researcher, etc…)?
B) Also, if our consortium is conformed by different companies, in the personnel column do we have to include the personnel of all the companies conforming the consortium or just the leading one?
C) In the second case, do we have to include the other companies of the consortium in the sub-contracting column? There is very little space for us if we have to indicate the companies and their countries.

Answer:
A) Please mention each category of R&D personnel and their role
B) If the coststs of the subcontractor have to be paid by the project, these costs have to be included.
C) please see answer to Question 89

Question 89
As we mentioned before, there are some sections of the Tender Form with very little space such as the table in “Price - Cost Breakdown” (page 18) or the one in “Project Plan and Methodology” (page 13).
According to page 49 of the document “PCP Request for Tenders” and example for the price breakdown would be: x hours of senior researchers in country L at y euro/hour; a hours of junior developers in country M at b euro/hour. But when introducing this example in the available space in the “Annex 4 Tender Form” (page 18) not all the text is contained within the boundaries of these areas and, therefore, not all the content is visible.
So, our question is: are we supposed to fill our Tender proposal in the “Annex 4 – Tender Form” or are we supposed to use it as a template?

Answer:
If you do not have enough space on the page, please use one or more extra pages.

Question 90
In line with the previous section… Would it be possible to attach as an Annex to this document some schemas, tables, diagrams in order to clarify some of the sections?

- For example, for the section “Project Plan and Methodology” (page 13) we would like to add the different Work Packages in form of a table but with the space provided that is not possible. So, could we send them as an Annex for this part?

Nightingale
Smart monitoring, safer care

Answer:
we do not want additional pages in free form. If we accept free form proposals including tables etc it will be more difficult for the people to evaluate the proposals.

Question 91
Finally, about the last date and hour for submission of the complete Tender, in the documents it says that the deadline is is 12-01-2018 at 11:59 hr CET. Could you specify if is it am or pm?

Answer:
The last date and hour for submission of a complete Tender is 12 January 2018 at 11:59 hr CET. This means 11:59hr AM.

Question 92
The solutions, during the project, has to meet the legislation of 5 countries. Some legislation is EU-wide like the GDPR and CE-certification. Are you aware of any local legislation that directly has impact on this project and which we have to take into account.

Answer:
No, at this time we are not aware of any national legislation that supersedes GDPR and CE. An important data safety aspect here is that we will bring the vital signs data into the protected hospital IT environment.

Question 93 (answer updated)
Framework agreement, article 11: This article goes about commercial exploitation and says failure of commercial exploitation is means not marketing the Results. This is a general term. What do you exactly mean by marketing. Does it mean we are willing to sell or are there additional requirements like maintaining the Results to meet new developments or improve the market readiness.

Answer:
Please refer to our answer to Question 99.

Nightingale
Smart monitoring, safer care

Question 94

Can we add to / evolve the consortium members or add subcontractors over time as we may uncover missing pieces when running through a joint learning from phase 1, 2 and 3?
What is the process for this?

Answer:

Since this is a procurement procedure, the Contractor may not add or replace consortium members or subcontractors during the PCP, unless such is permitted by, and under the mandatory conditions of, the Framework Agreement and/or procurement law. See also p. 26 of the Framework Agreement on the matter.

Question 95

Article 9.4: We would ask that the language of this Article be removed entirely. Given the very broad scope and expectations of the Nightingale initiative we cannot commit to extending rights to any of our background material. These expectations will necessarily require major investments and background IP from submitting companies well beyond the project specific funding. The magnitude of these legacy investments and vast amount of background IP in related technology areas, much of which has been developed collaboratively under restrictive terms and conditions, preclude us from making broad licensing commitments to our background IP. The commitments we can make will be included in Articles 9.2 and 11 such that Article 9.4 becomes altogether unnecessary.

Answer:

Please note that 9.4 only requires a non-exclusive license to Pre-existing rights that are **needed** to perform the Project. The best manner to solve this issue it to ensure that the solution developed by the Contractor is technology independent. Suppose a specific Contractor were to develop a solution based upon already existing hardware (and the Contractor controls the Pre-existing rights thereto), the Contractor could strive to develop the solution in such a manner that it would also be compatible with other types of hardware. In that case, the Pre-existing rights would not be **needed** to perform the Project.

Question 96 (answer updated)

Article 10.2.1.1: We would ask to modify the language to state that "the Contractor will take reasonable efforts to ensure the Results of the Project are identified, recorded and carefully distinguished from the outputs of other Research and development activities not covered by the Project." We could try our best here but we can't take a firm obligations as this will not be always possible given the broad scope and expectations of the Nightingale initiative.

Answer:

In order to protect your IP it is essential to document your results and all IP pertaining thereto that will be brought into the Nightingale solution.
Thus, we cannot agree to 'reasonable efforts' to identify and record the outputs of the Research. Each Contractor has the obligation to identify and record the activities within the Project. However, if certain technological developments can have use in another field than Nightingale (wireless monitoring integrated in a clinical decision support system), Contractor and Procuring Entity can agree that it is acceptable that the same work is covered by different research and development activities.

Question 97

Article 10.2.3: We would ask that the language of this Article be removed entirely. We will take measures viewed internally as appropriate to protect or defend Project Intellectual Property Rights, but any determination must be at our sole discretion. There cannot be any ambiguity regarding what is "appropriate" that would, for example, compel a company to make complex, strategic and potentially very expensive decisions regarding how to defend their intellectual property.

Answer:

Please see our answer to question 86.

Question 98

Article 10.4.2: We would ask that the language of this Article be replaced with something similar to that from Article 28.1 of the Grant Agreement. We would propose the following: "the Contractor will take measures aiming to ensure

exploitation of the Results, either directly or indirectly, in particular by:(a) using them in further research activities (outside the action); (b) developing, creating or marketing a product or process; (c) creating and providing a service, or (d) using them in standardisation activities". We are certainly motivated to exploit and commercialize results, but cannot provide a guarantee for actions that may be outside our control and which could subject our company to broad damages claims.

Answer:
The main goal for any PCP is to develop breakthrough innovative solutions for the societal challenges of the future and thus article 10.4.2 is a key article which cannot be further limited in scope. However, commercialization can take different forms, including providing services, as long as the results are available on the market to enable the public to benefit from the innovation. Also, article 10.4.2 provides room for some assessment, as it only concerns those Project Intellectual Property Rights and Results that are 'capable of exploitation'.

Question 99 (answer updated)
Article 11: We would ask to modify the language of the second full paragraph to state "If the Contractor fails to commercially exploit the Results within this period, or uses the Results to the detriment of the public interest, the Contractor shall, at Procuring Entity's request, grant the Procuring Entity a non-exclusive, royalty free license to the Project Intellectual Property Rights. For the avoidance of doubt the licensing obligation of this Article 11 shall not extend to any Pre-existing rights." We would hope that our proposal which essentially replaces the commitment to "transfer ownership" with a non-exclusive license will meet the core anti-shelving objective. Please also understand that this request is important given the very broad scope and expectations of the Nightingale initiative, and numerous related ongoing efforts within some parties answering the tender.

Answer:
First, for sake of clarity and completeness, please note that article 11 of the Framework Agreement only concerns the Results and does not include any right to transfer ownership of the Pre-existing rights to the Procuring Entity.

Second, article 11 of the Framework Agreement only applies in case Contractor fails to commercially exploit the Results within a period of five (5) years after the end of the Framework Agreement. Commercially exploiting the Results in this context means bringing the product to market and realizing sales. This also concerns separate commercialization of the different parts of the Results, even if these are commercialized in fields outside Nightingale.

If no such commercialisation is possible within the period set out in the Framework Agreement due to external circumstances, which the Contractor could not reasonably foresee, the Nightingale Consortium wishes to see a plan to bring the solution to market within the shortest period possible with corresponding milestones. If such a plan is inadequate to bring the solution to market in the reasonable opinion of the Nightingale Consortium, the Nightingale Consortium may invoke its rights under article 11 and article 9.

Question 100

Article 12.4: We would ask that the last sentence of this Article be removed. This language includes an obligation license background or pre-existing rights and should be removed for the same reasons articulated with reference to Article 9.4.

Answer:

This license is not the same as the license set out in article 9.4 Framework Agreement but rather concerns the non-commercial license needed for the clinical trials set up to test the validity of the Results which is set out in article 9.2 Framework Agreement.

Question 101

For each submitted question hereinabove it appears that the Grant Agreements dictated by the EU commission provide more flexibility in each of these issues than the currently proposed Framework agreement. Where this is true please consider adopting such concessions, and if in any instance the

Grant Agreement itself is the limiting factor consider how we may individually or collectively engage the EU commission so seek necessary relief.

Additionally, we understood that the liability is currently unlimited. It is important that our work will only be performed in a test environment (so that our risk is limited in terms of patient safety etc.) and that the work result is only used for the purpose of verification and validation testing in a non-production and non-revenue generating environment. Further, if the work performed by the consortium requires for the equipment to be shut down, the Nightingale partner will be responsible to take the necessary provisional compensation measures ensuring its information and alarm processes. The our consortium will not be held liable if, e.g. an alarm is not forwarded during such system interruption. We suggest to implement the above wording in the rubrum of article 4.

Answer:
Please note that the Framework Agreement is brought in line with the obligations imposed on the Consortium partners to all contracts with subcontractors as set out in article 13.1 of the Grant Agreement. The more detailed articles of the Grant Agreement such as those that concern beneficiaries' access rights to background IP only concern the relations between the Nightingale Consortium members.

Your description of the verification and validation testing matches the manner in which the Description of Work is set up. Concerning liability, please see our the answer to question 74.

Question 102
Can the offer be submitted only for software part of the subject of tender or is it necessary to submit it both for hardware and software part?

Answer:
No, we will require the tenderer to submit an offer for a complete system that can be installed in each of our hospitals. Where a company's expertise is limited to a single component of the solution, we encourage the formation of

consortia that are able to collectively develop and build a full solution. One exception could be the notification device, which may be a hospital-wide purchasing decision that is entirely separate from Nightingale. In such cases we expect the Nightingale system to send alerts and other message types to the notification device using standard communication protocols.

Question 103 (new)

I understand we are out of questions period but this issue is really critical. See attached a summary of what we find in the Tender documents which generates incongruity in phases duration. On the table states phase 2 lasts 12 months and phase 3 lasts 8 months but on the text appears different timings (phase 2, 11 months and phase 3, 14 months). We checked it with our legal department and they request a formal clarification.
Could you please provide this to us?

Answer:
The time schedule shown in paragraph 1.4.3 (pages 13-14-15 of the PCP Request for Tenders document) and the time period between these mentioned dates will be leading. Please use this schedule for your proposal.
This answer will also be published as formal clarification on the Nightingale website and by email to all interested parties.

The new deadline for submission of your proposal is Tuesday the 16th of January, 12:00 (AM) CET.

=== END ====