HSMonitor FAQ

Last update: 05.11.2020 09:23 CET

This document contains Frequently Asked Questions collected during the HSMonitor Open Market Consultation (OMC) events in March-May 2020, as well as questions submitted to suppliers@hsmonitor-pcp(dot)eu or the contact form on the website. The answers provided represent the joint position of the five HSMonitor procurers to their best knowledge at this point in time. In some cases, questions may have been merged and generalised to avoid duplication.

1.1 Specifically for Turkey: Can we receive patient data in accordance with KVKK (Turkish counterpart of GDPR)?

The data of the patients are shared with the suppliers who conduct the pilots on 2 main conditions: 1) the patient's open consent, 2) after the signature of necessary agreements between MOH and the supplier.

1.2 Can we receive this presentation?

Please check the project website. If you cannot find it, please send an email to suppliers@hsmonitor-pcp.eu

1.3 For phase 1, should we consider all procurers' health systems in our offers?

All procurers' health systems and health information systems should be considered in all phase offers.

1.4 Is there a platform for the interested suppliers to find and meet other interested suppliers from other countries? How can we communicate with other suppliers?

Not a "platform" but this questionnaire serves the same purpose. The profiles of suppliers seeking partnerships are posted here.

1.5 Are prototype studies going to be conducted in all procurer regions?

All phases of prototypes, demos, and trials will be conducted in all procurer regions.

1.6 Can existing solutions be used? Or do we have to develop all from scratch?

To the knowledge of HSMonitor Buyers Group, no solution that covers 100% of HSMonitor challenge exists. Existing solutions can be part of the sought-for HSMonitor systems. It should be well justified that even though these solutions/modules/functionalities have existed before, they will be customized to meet HSMonitor requirements.

1.7 Is there any additional material currently available related to the project?

This questionnaire contains a slide deck for suppliers and a draft file of use cases. Please also check project website regularly, subscribe to the newsletter (stay tuned), and follow us on social media.

1.8 When will you launch the request for tenders?

The project calendar sets the launch of request for tenders as August 2020. It remains to be seen whether this date will be achieved or will have to be postponed due to the COVID-19 outbreak. Please check project website regularly, subscribe to the newsletter (stay tuned), and follow us on social media.

1.9 Will the pilot studies be conducted in each partner's health ministries?

The pilot trials will be conducted in the regions of 5 procurers of the project. Not all these 5 procurers are health ministries. Please check project website for detailed information about the procurers.

1.10 What are the selection and award criteria for each phase? How does the EC participate in the evaluations? What is the evaluation board's structure like?

For the exclusion, selection, compliance, and award criteria, please refer to the request for tender documents when they are published. The EC does not participate in the evaluations. The evaluations will be conducted in each procurer region, mainly by 3 aspects: clinical, technical, work plan. These aspects are tentative. The evaluations of all procurers will then be consolidated. The scorecard which will be used in the evaluation of the technical sections of the offers, as well as more information about the evaluation of the offers, will be available in the request for tender documents.

1.11 Will you share the video record of this event?

Please check project website.

1.12 Do the number and quality of suppliers in a consortium of suppliers play an important role in the evaluations?

The call for tenders is open to any type of operators whether they are small, medium-sized, or large, and to any operator from any country, as long as at least 50% of the work will take place in EU member states or Horizon 2020 associated countries. The quality of the suppliers may be a good advantage, but it is not a direct advantage if the offer is poor in terms of clinical support, technical plan, work plan, etc. Geographical coverage of a tender, i.e. the tenderer's ability to cover all procurer areas in terms of product development and pilot execution, may be considered more important than the number of suppliers in a supplier consortium.

1.13 If we already have part of the solution in the market (some part to be developed), can we still apply in the tender?

Please check 1.6 above.

1.14 Will we have to provide medical devices? If yes, can we use devices from Korea, Israel, China or other manufacturers outside Europe?

Medical devices may be offered by a tenderer. All medical devices, regardless of their manufacturing country or region, should have CE certification. Please also check Request for Tender documents for more information when they are published.

1.15 Will you take precautions concerning import-export rules since Turkey is outside the EU market?

It is solely the tenderer's responsibility to take such precautions. Besides, for Turkey, offering to use devices which are not registered at the national authorities (e.g. medical devices not registered at Turkish Medicines and Medical Devices Agency or mobile phones not registered at Information Technology and Communication Authority) may be considered a flaw.

1.16 Are any needs to certify the solution under the medical devices' regulation?

- For **Turkey** the software (applications, etc.) developed for HSMonitor does not need to be certified under the medical devices regulation, as these applications will be used by a small number of users for piloting and testing purposes. Certification as medical device is necessary for large scale or commercial use, which is out of the scope of HSMonitor project.
- According to the **Croatian** national regulator, solution needs to be checked with this regulation https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en if the solution that will be tested is going to be classified as a medical device. Also, it is important to check if the piloting of the solution is classified as "clinical trial" or not and also to check if it needs ethical or not. This check can be made together with the suppliers in the early stages of the PCP (Phase I)
- In **Campania** applies the Italian Regulation on Medical devices, the same all over the Italian National Territory, though it is very likely that both medical devices and leisure devices will be used to monitor patient's clinical and non-clinical parameters. As for the Ethical committee, approval is required when a drug or a medical device is used for purposes that are not meant in the approval from the AIFA, or when collecting data for a repository or an observational study, to gather information on outcomes. On the other hand, the GDPR states that hospitals are already authorised to use clinical data collected for the everyday practice when they are used to ameliorate the service. Using a digital platform to support the delivery of usual care does not require therefore an ethical committee approval.
- In **Lombardy**, medical devices used to monitor the patient's status should be certified according to the Class they belong to. Therefore, decision Support software should be assessed to see if it falls under Class IIa or IIb, according to the Medical Device Regulation. I suggest this assessment will be performed in Phase 2, when technical specifications will be consolidated.
- In **Sweden,** non-certified solutions may be tested within a trial. However, ethical approval is necessary where you describe the test (what and how) in the application.

1.17 What countries will pilot the solutions?

Please check 1.5 above.

1.18 What are the consortium requirements for participation? Minimum and maximum number of partners, how many countries, etc?

Please check 1.12 above.

1.19 How many languages / countries should the prototypes be able to address?

The prototypes and solutions should be delivered in the procurers' languages (Croatian, Italian, Swedish, and Turkish) and English

In addition to the required languages, the suppliers could also deliver the solutions in additional languages for dissemination or marketing purposes, but this may not necessarily be considered as a superior work is accomplished.

Please also check Request for Tender documents for more information when they are published. Please also check 1.5 above.

1.20 Will the Hypertension protocols vary by county or will it be standard for the EU?

There is no unified pan-European hypertension guideline for hypertension (or any other diseases). The deviation between different national guidelines though are minor and the European Hypertension Society guidelines, or similar international guidelines, could most likely be used. A clinical comparison of the different national guidelines and the international guideline chosen is recommended. Procurers have to check for possible updates in the guidelines before deployment.

However, there may be some differences in the clinical workflows of each procurer the details of which will be shared with the suppliers of Phase 2 during the site visits and v1 and v2 demonstrations. Co-design plays its role in the customization of applications.

1.21 About consortia, if in Phase II for example, we realize that we need another partner in consortium, can we add another partner to our consortium? Or do we have to finish with partners who we made the consortium with in the beginning?

Inclusion of new partners to a supplier consortium is not allowed. However, inclusion of subcontractors is possible within limited capacity. Please check Request for Tender documents for more information when they are published

1.22 Is there any restriction regarding the size of a consortium applying to this PCP?

Please check 1.12 above.

1.23 For integration with procurers' EHR software and other systems, will there be specifications?

The Request for Tender documents will provide information about the existing systems of the procurers that new solutions need to integrate into. The information will include, for example,

the organisation owning/maintaining the system, any publicly available description, APIs, etc. where available.

1.24 How is expected that the cocreation process with the different health organizations will be conducted (e.g. regular meetings, workshops)?

In Phases II and III the contractors are expected to work closely with the procurers, and appropriate means (online meetings, face-to-face meetings and workshops) need to be planned in the offer.

1.25 What's the TRL suggested at the end of the third phase?

PCP projects focus on the exploration and design of technological solutions (Technology Readiness Levels-TRL 6-8). The aim is to bring innovative ideas and solutions of first products or services to initial development, on a small scale.

1.26 Is there any limitation on adding partners that might be introduced to a joint tender?

Please check 1.12 above first. In case of joint tenders, the participants must be identified clearly in the tender. There may be no change in the composition of a group that tendered at the beginning of the PCP procedure. Addition of subcontractors may be possible in some circumstances, which will be detailed in the Request for Tenders.

1.27 Is participation possible using the results of previous Horizon2020 funding?

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. An on/off award criterion related to this point will be part of the Request for Tenders.

1.28 How many test subjects do you intend to have in any trials?

Please refer to p. 11 and 13 of TD1 Request for tenders.

1.29 If a device or remote monitoring solution is proposed, how many devices will be required?

If a device or remote monitoring solution is proposed, a set of devices for each patient should be provided. The healthcare professionals' need for devices should also be considered, as well as the devices that may be used in the training sessions at the pilot locations.

1.30 Who will supply the test subjects?

The procurers will recruit the patients into the study. Training of the patients and enrolling them into the system is expected from the suppliers.

1.31 Regarding regulatory approval for the trials, will the procurers help the tenderers obtain regulatory approval for trials in the countries where the trials are run?

If a regulatory approval, other than ethical approval, should be considered needed for the trial, procurers can assist tenders. The need for such an approval is seen as unlikely.

1.32 What is the position with ethical approval from the tenderer hospitals?

An ethical approval is a task for procurer organisations with input from tenders regarding solutions to be tested.

1.33 Who will supply the test protocols?

Procurers.

1.34 What risk stratification algorithms can be used / are preferred for the proposed HSMonitor solution

SCORE risk charts or its interactive electronic version HeartScore (https://www.heartscore.org/en_GB/access) are widely used in a primary prevention and could thus be a good choice. N.B. that there is a differentiation in risk stratification based on whether the patient is from a low, medium, or high risk country. SCORE/HeartScore is not sufficient if you have target organ damage or diabetes were e.g. 2018 Practice Guidelines for the management of arterial hypertension of the European Society of Cardiology and the European Society of Hypertension (https://journals.lww.com/jhypertension/Fulltext/2018/12000/2018_Practice_Guidelines_for_the_management_of.2.aspx) adds information. In patients with type 2 diabetes various risk calculators exist and here e.g. the UKPDS risk engine (https://www.dtu.ox.ac.uk/riskengine/) is well validated. When choosing risk stratification algorithms you have to balance a wish for exactness and the information (blood sampling information etc.) this exactness requires.

1.35 What 'issues' are being referred to in the HSMonitor Challenge Brief in the functional requirements section - R8.7 and R8.8 on page 18

Issues are any incidences that do not go according to the treatment plan of the patient such as undesired behaviour or daily routine, out-of-range blood pressure, not adhering to the treatment plan, etc.

1.36 Can, in the case of subcontracting, a university / research institution be a subcontractor

Yes. Not-for-profit organizations such as academic institutions and research centres can also be subcontractors.

1.37 Currently, we are building our consortium. We are also planning to build an advisory board, which will be composed of the medical doctors/practitioners. Can we meet the board's labour from the subcontracting costs?

Yes. Please see Section 3.1.2 Subcontracting of TD1 Request for tenders, and please describe your approach to this type of subcontracting in your tender.

1.38 Can you please tell me how many citizens form part of the procurer region Federico II University Hospital in Naples, Italy. Do they cater for the whole of Naples or for a smaller region in Naples?

The Federico University Hospital is located within the city of Naples (the whole metropolitan area including nearby cities sums app to 1,3 Million people). The hospital also includes some reference centres for the whole Campania Region (6M people). The outpatient clinic for Hypertension enrols >25000 patients, mostly form Naples, but coming from all over Campania.

1.39 On the page of 74, under the Interface and Interoperability heading, it is mentioned that "the citizen should be able to register with an account to be able to perform further actions and store the data.

1.39.1 When we look at Enrolling users into the HSMonitor service part on pages 76 and 77, there is no information on how the HSMonitor portal works to enrol new users who want to register to realize further actions.

1.39.2 Accordingly, should we freely create the algorithm for how and under what conditions the application for registration to HSMonitor from outside to the doctor or the system administrator?

The solution should be considered divided in two parts. The first part, that is dedicated to the general population, should include a light registration, aimed to allow the free navigation of the website content for the general public. The second part regards registration into a clinic, and therefore should include a more comprehensive registration and the identification of the patient through means of the unique social security number. Differences might occur in the procedures in the different regions of the procurers.

1.40 In the Challenge Brief (p. 12) it is stated that "In any case, the HSMonitor solution shall offer no more than two different devices per patient. The device(s) shall be as unobtrusive and compact as possible." Our question is: is the patient's smartphone considered/counted as one device for this requirement? In other terms: do you mean that we can have max. 1 smartphone + 1 other device or max. 1 smartphone + 2 other devices?

The patient' smartphones are not considered to be one of these devices. It is generally accepted by the Buyers Group that the majority of the patients will already be smartphone users. Still, the tenderers may include smartphones in their offers, and 2 other devices. If smartphones are included in the offer, operational costs such as GSM data costs should also be considered.

Please also see 1.45 below.

1.41 On the front page of the "HSMonitor_RfT_TD3b Declaration of Honour - On/Off Award Criteria" it is said that the form has to be provided only by Lead Contractor but on page of the " HSMonitor_RfT_TD5 Tender Application Template - Administrative" it is indicated that it has to be provided by all Co-contractors/Partners. Which one is correct?

The information in "HSMonitor_RfT_TD3b Declaration of Honour - On/Off Award Criteria" is correct. The table in "HSMonitor_RfT_TD5 Tender Application Template - Administrative" has been adjusted accordingly.

1.42 The title of Section 7 of the "HSMonitor_RfT_TD3a Declaration of Honour - Exclusion Criteria" recites "Evidence upon request" but it is unclear to us if any document has to be provided at the time of submission because further down in the same section , it says "The person is not required to submit the evidence if it has already been submitted for another procurement procedure". Is there any evidence to be provided at the time of submission?

The tenderer may provide evidence in this section when submitting the tender, but that is not mandatory. The tender should be prepared to provide evidence if requested by the HSMonitor Evaluation Committee during the tender evaluation process.

1.43 Concerning the Financial Part, there is no mention of any server to be supplied for Phase 3. Can we assume that the central applications will be run on servers provided by the procurers? Should we host them in a cloud?

R6.2 clearly states that “The HSMonitor solution shall be hosted on the servers which are physically located in the geographical/juridical areas of the five procurers.” Therefore, cloud storage is not allowed.

Please find below the preferences of each Procurer regarding the location of the pilot servers:

Ministry of Health of TURKEY: Will host the solutions in its own servers. The access to the suppliers will be given with VPN accounts after signing the necessary agreements. This will take place in Phase 3 and may take place in Phase 2 if the suppliers would like to run tests.

DZZC: The developer should provide servers which are physically located in the geographical/juridical area of Zagreb, Croatia.

FOUND: The solutions will be hosted in the hospital servers. Access will be granted to the identified suppliers, provided that all the necessary security procedures are put in place. It may involve special agreements to be signed by the suppliers.

LOM: HSMonitor Platform might be either installed in the pre-existing ARIA Server Farm (on-site or in the cloud), or on an Auxologico Hospital Server, or on a server provided by the supplier. The decision is conditioned by the specific characteristics of the selected solution. In Phase 1 Proposal, it is suggested to include the Server. This requirement will be refined in Phase 2, according to the aforementioned functional, technical and security characteristics of the selected solution

RJH: Servers need to be on premise and should be provided by the supplier.

1.44 Just for your information, in the Challenge Brief, the number of pilot locations indicated is sometimes 4, sometimes 5. We assume that the correct number is 5.

Yes, the correct number is 5. This will be adjusted consistently in the Challenge Brief.

1.45 It is not very clear to us if "two different devices" are meant to be the absolute total number of devices that it is possible to use at patient premises or whether it is possible to assign more than two devices to patients, with only two maximum to be used by the patient at the same time of the day. E.g. Can a wearable heart monitor, a sphygmomanometer and a weight balance be used by the patient, with the first worn eight hours a day, the second used three times a day and the third used once a week?

R4.3 Parameters - device numbers and use states that "In any case, the HSMonitor solution shall offer no more than two different devices per patient. The device(s) shall be as unobtrusive and compact as possible."

However, please remember that it should be possible to wirelessly connect as many devices to the solution as possible.

In order words, and going from your example, you may offer 2 devices (and a smart phone) with your system. But the patients may already have other devices which they would like to pair with your solution. Your solution should allow this.

Please also see 1.401.40 above.

1.46 "The HSMonitor solution shall be hosted on servers physically located within the geographic regions of the five pilots.". We were wondering what you exactly mean for regions. If region is intended as European Union, will a Cloud Service based in Europe be admitted, with the sole Turkey served by local servers or country-local Cloud services? Or should we intend regions as sub territories in a Country? E.g. Italy participates to the PCP with Campania Region and Lombardy Region. So, shall the servers have to be physically located within Campania and Lombardy territories?

Please check 1.43 above.

1.47 The Request for Tenders document at page 38, paragraph 4.1. reads that "All offers must indicate their minimum validity period from submission (at least six months)". In which part of the offer or in which exact document or documents composing the official documentation to be submitted do we have to indicate the minimum validity period as required?

In the "Executive Summary" of "TD6 Tender Application Template - Technical".

1.48 Document TD3a of the Administrative documentation, at points 7 and 8, reads that "upon requests Upon request and within the time limit set by the contracting authority the person must provide information on the persons that are members of the administrative, management or supervisory body" and a list of documents are then described. However, if we properly understood, we don't have to submit any of this documentation at the moment, but in case, it will be requested directly by the procuring authority?

True.

1.49 (Early detection and prevention – R1): Is there a specific risk prediction algorithm that is expected to be implemented, or are the tender applicants free to choose among the existing risk prediction algorithms available in the literature?

See 1.341.34 above. The solution should take into consideration available risk stratificators.

1.50 (Early detection and prevention – R1): Are tender applicants expected to propose novel risk prediction algorithms within the scope of the project?

See 1.34 above. Novel prediction algorithms are not expected. All caregivers want to work in accordance with what is validated, or at least best practice. A new and improved prediction algorithm could potentially though be a future result of HSMonitor.

1.51 (Optimising drug therapy and improving treatment adherence – R3): Related with drug-drug/drug-food/drug-metabolism interactions, can we assume that the scope is restricted with hypertensive drugs covered in evidence based guidelines (European Society of Hypertension and American Society of Hypertension)?

The drug/drug interaction should also consider the use of compounds that increase blood pressure as a side effect.

1.52 (Devices and remote monitoring – R4): Can we assume that we will be able to retrieve recent lab results of interest (such as Glucose (fasting, 2h, and random separately), HbA1c, ECG, Waist circumference, Total Cholesterol, HDL, Cholesterol, eGFR, creatinine) from local systems at pilot sites via our integrations? Will it be also possible for healthy population (for carrying out risk prediction functionality for citizens via mobile apps)

For patients yes if such data are recorded in the EHR, for the healthy population the input of validated such data is not likely. Self-reported data could be an option.

Please also consider legal and ethical aspects here including GDPR and KVKK, and if any, other laws and regulations.

1.53 (Devices and remote monitoring – R4): Will it be adequate to use CE Marked medical devices, or are we expected check approval of local FDA departments of all pilot sites?

Use of CE approved devices are OK requires no other approval than a potential ethical approval, see also 1.16 above, 1.31 and 1.32 above.

1.54 (Devices and remote monitoring – R4): Do the devices we choose need to be natively compliant with Continua Health Alliance Interfaces and IEEE 11073 standards? Would it be adequate if we develop the necessary adapters to make them Continua Health Alliance and IEEE 11073 compliant?

The devices need to be compliant with Continua HA interfaces and with IEEE standards.

1.55 (Quality and outcome reporting – R7): R7.3 says 'Daily analysis and summaries of care provided and its outcomes: The HSMonitor solution shall provide daily analysis and summaries of the care provided and its outcomes per patient. The analysis can be viewed by the healthcare professional on request (pull). The analysis shall include medical (e.g. blood pressure values) and organisational (e.g. waiting times to appointment, reaction to messages sent) quality parameters': The organisational outcome parameter 'waiting times for appointment' is confusing. Can we assume that the outcomes will be relevant with the Hypertension management solution we will employ, rather than regular organisational procedures of local health systems?

It is the preference of the healthcare professionals to have access to both clinical and organizational quality parameters, as both of these indicators assist the healthcare professionals in their care-giving and decision-making process.

1.56 (Patient-professional collaboration and co-ordination – R8): R8.17 says 'The HSMonitor solution shall give the patients enrolled in HSMonitor the ability to see the availability of their physician in order request and schedule visitation'. Here, are we expected to be integrated with local appointment systems at pilot sites?

If local appointment systems exist in the procurer regions, this type of integration will be expected.

1.57 (Non-functional requirements): R10.19 says 'The HSMonitor solution shall work well when there is no internet connection; e.g. caching of changes.'. Can we assume that this will include a limited subset of functionality, for example excluding online features such as synchronous messaging?

Yes. Please explain in your offer what functionalities your solution will support offline and what functionalities it will not.

1.58 (Training and education – R9): R9.1 says "additional languages can be easily added." Could one of the new languages to be added be Arabic?

It could be any language if a supplier believes the addition of that language is an added value in terms of commercialization of their solution.

1.59 (Non-functional requirements): R10.17 says "The HSMonitor solution shall be usable with delay no greater than 0.5 ms."We assume that the integration of third party applications and devices (BP measurement, wearable devices, ..) is not included in this period. Is it correct?

It is correct. However, please keep in mind that devices that work with long response time are not favoured by the Buyers Group.

1.60 (Non-functional requirements): R10.19 says" The systems shall be accessible from and fully compatible with all major browsers including Google Chrome, Mozilla Firefox, Opera, Microsoft Edge, Microsoft Internet Explorer, and Apple Safari". We kindly require you to extract Microsoft Internet Explorer at this list, as it will no longer be supported by Microsoft later on 2021.

Microsoft will stop supporting IE11 in August 2021. Compatibility with Microsoft Internet Explorer will not be required.

If you think any other browser listed here cannot or should not be included in HSMonitor systems, please explain it in your offer and justify.

1.61 In the "Declaration of Honour On/Off Award Criteria" document, clause "1.1.5 Compliance with Security Requirements" refers to the evidences in Section 4.4.5. however, 4.4.5 couldn't be found in related documents. Could you please clarify.

"1.1.5 Compliance with Security Requirements" should refer to section 3.4.1 of the Call for Tenders.

1.62 It is mentioned that paper copy should delivered by registered mail by the submission deadline. Can it be delivered by hand to the address of Ministry of Health in Ankara/Turkey?

It is not mentioned that one originally signed complete paper copy of the administrative, technical and financial sections of the tender must be DELIVERED by registered mail by the deadline. It is mentioned that one originally signed complete paper copy of the administrative, technical and financial sections of the tender must be SENT by registered mail by the deadline. Hand-delivery is not accepted. All deliveries should be made via registered post.

1.63 Documentation – the documents listed in the tender documentation is not the documents officially listed on www.cezih.hr. EHR document in the tender document is in a collision with officially uploaded CEZIH documentation. Also, its content is not the same as EHR currently in production in Croatia. Can you confirm you put a link to the correct document describing EHR?

At the time of the tender preparation we used the officially listed documents available to us. If you find the information provided is outdated please use the version which is currently listed on the official website of CEZIH or on the websites the legal entities maintaining it- Croatian Ministry of Health (CEZIH owner) and Croatian Health Insurance Fund (CEZIH operator) to see if there are any more up to date information available.

1.64 The document "G1_User_Interface_Implementation_Guidelines.doc" was created in 2005., and it is also not on an official list of the CEZIH documentation. Is it possible that after CEZIH migration to another platform (in 2014) this document is no longer valid? Can you confirm all the interfaces described in it are still available?

The document is located here: http://www.cezih.hr/pzz/dokumenti_pzz/G1_IMPL_GUIDELINES.zip At the time of the tender preparation we used the officially listed documents available to us. If you find the information provided is outdated please use the version which is currently listed on the official website of CEZIH or on the websites the legal entities maintaining it- Croatian Ministry of Health (CEZIH owner) and Croatian Health Insurance Fund (CEZIH operator) to see if there are any more up to date information available.

1.65 Architecture – official CEZIH web site does not provide any documentation describing the web service interface for CEZIH EHR.

1.65.1 a) Is it possible to get patient medical data from CEZIH EHR via web services?

1.65.2 b) If yes, please provide us technical documentation describing web

1.65.3 c) If not, is it possible to get it in any other way for pilot purposes?

1.65.4 d) Are there any technical or legal obstacles to get EHR data for the pilot?

We advise you to contact Croatian Ministry of Health (CEZIH owner) and Croatian Health Insurance Fund (CEZIH operator). As a provider of healthcare services, DZZC has no control over the CEZIH system, so the issues should be handled by a developer and the aforementioned institutions. a) Yes but only for CEZIH certified applications and vendors. b) We refer you to the website www.cezih.hr, and the documentation about the certification procedure http://www.cezih.hr/dokumenti/Protokol_za_provodenje_certifikacije_2016_s_pojasnjenjima.pdf and http://www.cezih.hr/dokumenti/Izjava_o_prihvacanju_uvjeta_certifikacije_2017.doc To our knowledge, this documentation is only available in Croatian language. d) Yes, a CEZIH certified entity is authorised to develop applications that access the data stored on CEZIH, but the data itself is private and can be accessed by the patient and their GP and only the G1 category applications can access and write the complete EHR.

1.66 Architecture – on the official CEZIH website, a description of IK component is listed. Is that the only way to communicate with CEZIH services or communication via HL7v3 messages are allowed?

We are aware that the communication with CEZIH is possible through the IK component. We advise you to contact Croatian Ministry of Health (CEZIH owner) and Croatian Health Insurance Fund (CEZIH operator) for the information about possible other ways to communicate with CEZIH services. As a provider of healthcare services, DZZC has no control over the CEZIH system, so the issues should be handled by a developer and the aforementioned institutions.

1.67 Architecture – is it possible to get the patient's medical and personal data stored in DZZC locally, from MCS's application?

1.67.1 a) Are there any legal or technical obstacles?

1.67.2 b) Is there a web service providing EHR data available? If not, please describe possible solutions to get EHR data from MCS's application at regular intervals.

The MCS grupa d.o.o. application Medicus.net does not store data locally. As a provider of healthcare services, DZZC has no control over MCS grupa products, so the issues should be handled by a developer and the aforementioned institution.

1.68 Architecture – is it possible to get the patient's medical and personal data stored in DZZC locally, from MCS's application?

1.68.1 a) Are there any legal or technical obstacles?

1.68.2 b) Is there a web service providing EHR data available? If not, please describe possible solutions to get EHR data from MCS's application at regular intervals.

The MCS grupa d.o.o. application Medicus.net does not store data locally. As a provider of healthcare services, DZZC has no control over MCS grupa products, so the issues should be handled by a developer and the aforementioned institution.

1.69 Responsibilities – Who is the one responsible to ensure HSPilot application will get user ID (needed for communication with CEZIH) on time, who will issue needed certificates, set proper roles in CEZIH for HSpilot application, etc.?

1.69.1 a) Who is the one on the procurer site who will be handling these issues?

1.69.2 b) Is it DZZC or someone else?

1.69.3 c) Which institution will be the contact point?

Insuring interoperability with the existing EHR/PHR systems (in Croatia, CEZIH) is the requirement (R6.1) for HSMonitor solution, therefore it is the responsibility of a developer to meet all prerequisites needed to ensure compliance with the requirement. We advise you to contact Croatian Ministry of Health (CEZIH owner) and Croatian Health Insurance Fund (CEZIH operator). As a provider of healthcare services, DZZC has no control over the CEZIH system, so the issues should be handled by a developer and the aforementioned institutions.

1.70 Certification process – if HSPilot application needs to communicate with CEZIH services, is it obligated to go through the certification process like some vendors did (G2, G3, etc.)? If yes, is the certification done by each CEZIH service? Where is the process of certification and its prerequisites described?

We can only provide data that is publicly available on the CEZIH website. To our knowledge, all application developers should follow the certification procedure as described on the CEZIH website. If additional information is required, Croatian Ministry of Health (CEZIH owner) and Croatian Health Insurance Fund (CEZIH operator) should be contacted. The certification process is done for each new service and the process is described here: http://www.cezih.hr/dokumenti/Protokol_za_provodenje_certifikacije_2016_s_pojasnjenjima.pdf and http://www.cezih.hr/dokumenti/Izjava_o_prihvacanju_uvjeta_certifikacije_2017.doc.

1.71 Deployment site – Is it legally allowed to deploy HSPilot application in the cloud? If yes, is there a restriction on location? Is it possible to deploy it on CEZIH hardware and if it is, under what conditions?

R6.2 clearly states that “The HSMonitor solution shall be hosted on the servers which are physically located in the geographical/juridical areas of the five procurers.” Therefore, cloud storage is not allowed. DZZC has no control over the CEZIH system, so the issues should be handled by a developer and the Croatian Ministry of Health (CEZIH owner) and Croatian Health Insurance Fund (CEZIH operator). The server should be provided by the solution developer. The certification process is described here: http://www.cezih.hr/dokumenti/Protokol_za_provodenje_certifikacije_2016_s_pojasnjenjima.pdf and http://www.cezih.hr/dokumenti/Izjava_o_prihvacanju_uvjeta_certifikacije_2017.doc.

1.72 Documentation states that CDA XML objects, HL7 messages and openEHR archetypes are available as Information exchange standards. Will it be correct to assume that different services utilize different standards as opposed to assumption that each service is available in all listed standards?

It is correct that different services use different standards.

1.73 [Referring to the Croatian procurer] Which version of HL7 messages is in use, version 2 or version 3?

In Croatia the HL7 version 3 is in use.

1.74 openservices.cambio.se exposes APIs in openEHR format. Is it possible (or will it be possible) to use Archetype Query Language (AQL)?

No, Cambio open services (COS) does not support AQL

1.75 Is there mapping standard or matrix for mapping between OpenEHR and HL7 (v2, v3, CDA and FHIR)?

Please refer to the documentation for OpenEHR: https://specifications.openehr.org/releases/RM/Release-1.0.3/integration.html.

1.76 Which is the max length (max number of pages) for TD5_Application Template – Administrative?

As there is no limit on the consortium size and therefore the number of declarations and other documents (e.g. TD3a), there is no limit to the administrative section.

1.77 Can we include as appendix of TD5, TD3a and TD3b documents(PDF) or we need to report the content under Chapter 3 of TD5?

The declarations such as TD3a and TD3b which are part of the administrative section can be appended at the end of TD5.

1.78 In TD1_Request for tenders, 3.4.2 Weighted award criteria, includes specific weights for the awarding of each phase (from phase I to phase III) except for the "Tendering Phase", are there any specific weights for the evaluation of a tenderer (for accessing phase I)?

In the tendering phase, tenderes try get into phase I, hence for evaluation the weights under TD1 3.4.2 "Award criteria for phase I" are used; to get into phase II, "Award criteria for phase II" etc.

1.79 Templates used for the call for tenders will be used also in the subsequent phases? If yes, the level of detailed is higher as you pass in phases?

It is expected that some templates (e.g. the technical section) will be re-used and enriched.

1.80 How many languages / countries should the solution be able to address? If the solution will be provided in, ex. ITA and ENG languages, will it be considered sufficient?

The HSMonitor solution shall be available in the different languages covered by the HSMonitor procurers (Croatian, Italian, Swedish, Turkish and English). It shall furthermore be agnostic to language, used terminology shall be easily changeable and the solution shall be developed in a way so that additional languages can be easily added. See also non-functional requirements R10.7 - R10.11 and 1.19 above.