# EHR platform and tools, based on openEHR -Referral round #2

den 22 december 2020 08:42

This document is NOT an actual procurement, but instead a second referral round of the latest version of descriptive text and of requirements that may be used in the later actual procurement.

Please note

- the change of procurement areas from three separate to one unified , as described in section 3.2.1.
- that comments about specific sections/requirements shall be communicated via the supplied spreadsheet template
- that there is a separate spreadsheet with a suggested base price evaluation model that you may also look at and comment. That base price will then be added to depending on responses to other requirements. Details about price evaluation will be available in the actual later procurement

The deadline for comments is January 26, 2021 via the Region's Tendsign platform. The actual procurement will start no earlier than after those comments have been analysed.

## Project Description (for actual procurement later)

An Electronic Health Record (EHR) related combined procurement of: 1. An openEHR-based clinical data repository (CDR) platform and platform administration tools; 2. Tools for development and content maintenance, for example low/no-code editors to assist creation of openEHR template-based interfaces like input forms; 3. AQL query authoring tools and environments for presentation and visualisation of query responses.

A tenderer that combines parts from different suppliers must coordinate collaboration and make a bid on the entire procurement. The tenderer must take full responsibility of making sure the different parts in the bid work smoothly together and support common workflows, deployment and administration.

We are interested in two main areas of use: 1. Normal hospital EHR use cases; 2. Use cases such as patient registries, biobank information, and patient owned data.

See chapter 3 in the procurement document for details about usage and features.

# 2.1 Definitions

den 11 mars 2020 11:23

Terms and abbreviations used in this document are listed below.

General terms:

- Agreement = Procurement contract
- Buyer = The contracting authority supplier, in this procurement Region Östergötland
- Contractor = The tenderer that signs the framework agreement
- Subcontractor = A supplier that the tenderer intend to hire for a specific part of the contract
- Framework agreement = The form of agreement that is signed after the procurement
- Procurement document = The document basis of the procurement
- **RÖ** = Region Östergötland

EHR specific terms:

- AQL = Archetype Query Language
- **CDR** = Clinical Data Repository, an EHR platform component that can store and retrieve (in this case openEHR based) clinical data about individual patient and aggregated (population based) data
- **CDS** = Clinical Decision Support
- **EHR** = Electronic Health Record
- Form authoring environment = Either a single tool or a set of well integrated tools, programs and components that performs the desired functions. A supporting functionality of the openEHR platform, tool suite or a separate component that the Region's staff or contractors can use when developing client software. The form renderer supports rendering forms that were designed in a form builder tool or similar that is aware of openEHR-templates
- **Rendering functionality** = Refers to rendering forms in web applications targeted at end-users, forms created in the authoring environment
- **RM** = Reference Model
- **U1..U6** = The identities of the six user roles that RÖ has defined for the openEHR platform and tools. The user roles are described in the section "User roles and needs"

# 3.1 General (Common/introduction)

den 22 december 2020 10:56

# 3.1.1. Background

Region Östergötland (RÖ) is a Swedish healthcare region that serves approximately 500 000 inhabitants. In addition, RÖ provides other interregional and nationwide healthcare related services.

This is a procurement for an openEHR CDR platform, and for openEHR form and query tools.

The openEHR platform will be included as a component in RÖ's general digitalization platform (RÖD). RÖ is interested in two main categories of use and associated tools for development and maintenance:

- 1. Normal hospital EHR use cases
- 2. Use cases such as patient registries, biobank information, and patient owned data

The platform will also be used in attempts to tame "feral" systems, see: <u>https://youtu.be/3Wj2H4IYyjE</u>.

The platform might get used for all the above categories in interregional and national collaborations where RÖ is a partner and provides services. The most frequent partners are the neighbouring regions in "Sydöstra Sjukvårdsregionen" (RÖ + Jönköping and Kalmar regions).

Growing per EHR record licensing cost models may be an issue for some of the use cases, especially use case category 2 above. Biobanks and registries may for example contain information from a constantly growing number of living and dead people. Thus, combinations of openEHR solutions and platforms may be of interest, for example commercial and open source or other reasonably scaling licensing models.

In 2018 RÖ conducted an openEHR RFI and in 2019 RÖ tested an openEHR platform to see how it fits use cases, organization and workflows. Low-code/no-code generation and configuration tooling for dynamic forms based on openEHR templates has been an appreciated feature in RÖ. This includes form rendering functionality for inclusion in web/HTML5-applications. The availability of "simplified formats" (along the lines of <u>https://specifications.openehr.org/releases/ITS-</u> REST/latest/simplified data template.html) has also been appreciated for some use cases.

For more background see:

- <u>https://discourse.openehr.org/t/swedish-openehr-platform-procurement-q1-2020/247</u>
- <u>https://openehr.atlassian.net/wiki/spaces/resources/pages/416514052/Procurement+of+openEHR-related+systems+and+services</u> (including documents linked or available as downloads)
- Recorded pre-procurement presentation/demo playlist <u>https://www.youtube.com/playlist?</u> <u>list=PLhWi0RtmG26UIt0qtzmOLITbu10svShMK</u>

## 3.1.2. Project goals

- 1. RÖ wants to procure a permanent full scale openEHR solution including support for application development and maintenance.
- 2. Other Swedish regions have shown interest in similar openEHR-based capabilities, thus a goal is to make RÖ's procurement process as transparent as possible so that other regions can reuse parts of the process, documents and experiences. Thus if your response contains any confidential parts, then mark those parts as confidential. Please do NOT mark the entire response as confidential, only reasonably business sensitive parts.

## 3.1.3 Business impact goals

The main business impact goals of the introduction of the openEHR platform are the following:

- Faster adaption of IT systems to the constantly changing needs of the health care clinicians, including a more efficient system development process. This will be measured in terms of:
  - $\circ~$  Actual time from identified need to implemented solution
  - $\circ~$  Efficiency as experienced by the clinicians
- Increased control of stored health record data and increased reuse of information structures within and between applications. This will be measured in terms of:
  - Number of "tamed" so called feral systems (see link above)
  - To what extent development and maintenance staff within the IT organization experience increased control and efficiency
  - Increased quality in data analysis
- Increased freedom of action for both RÖ and its employees. This will be measured in terms of:
  - How much health care data that is owned by RÖ and accessible in open formats (and thus not "locked in" by external system suppliers)
  - That health care clinicians experience increased possibilities to adjust the IT systems according to their changing needs without being dependent on resources from the IT department

# 3.2 Intended use

den 22 december 2020 08:40

## 3.2.1 Market and procurement context

Region Östergötland (RÖ) wants to encourage a diversified market for openEHR-based tools and platforms. In a previous referral we tested the idea of splitting a procurement in several procurement areas that could be won separately by different tenderers. Such a split is no longer desired; instead we are asking tenderers to form collaborations or consortia that make a bid on the entire procurement, mainly for the following reasons:

- We want the bidding tenderer to take full responsibility of making sure the different parts in the bid (that still may come from several partners or subcontractors) work smoothly together and support common workflows, deployment and administration. We want to prevent potential situations where different suppliers disagree on whose responsibility it is to fix problems regarding compatibility between tools and platform etc.
- It radically simplifies the procurement evaluation.
- It simplifies contracts and potential contract renewals.

RÖ wants to encourage a diverse market also after completing this procurement, so please note that this procurement does not give the winner exclusivity regarding openEHR-related solutions for RÖ. RÖ reserves the right to, by itself or together with other actors, use and buy/procure other openEHR-related tools, platforms and services in parallel to the solutions contracted in the current procurement.

The current procurement covers mainly the following areas:

- An openEHR-based CDR platform and platform administration tools
- Tools for development and content maintenance, for example low/no-code editors to assist creation of openEHR template-based interfaces like input forms
- AQL authoring tools and environments for presentation and visualisation of AQL responses

In addition to this procurement, there will be a separate procurement for consultancy services concerning openEHR-related development, where both responses regarding archetype development and responses regarding openEHR-based software development are of interest. This will likely be done by including openEHR-related skills as a part of the services procured in a general IT-related consultancy procurement in RÖ that is already scheduled for the late fall of 2020.

#### 3.2.2 User roles and needs

To reach the business impact goals, it is essential that the procured solution meets the needs and expectations of the different target groups that will use the openEHR CDR platform and tools. Typical characteristics of the different users of the RÖ openEHR platform and tools are described below. Not all roles are equally central from a procurement perspective, some are assumed to be of more importance than others. The user roles also use different parts of the openEHR solution, where some are mostly involved with the platform, while others only use a form builder or are end-users of applications developed on openEHR.

How well the needs of these user roles are met, is part of the procurement evaluation criteria. The user roles are referred to as U1, U2, U3, U4, U5 and U6 throughout this document.

#### U1 - Platform Administrator/Technician

U1 works in the IT department, has a technical education and a few years working experience. It is his job to ensure that the platform and the development tools are sound and up and running.

U1 is an advanced user that needs powerful tools for administration of the openEHR platform. He wants to have full control and overview, and efficient configuration and error handling and system diagnostics tools. The openEHR platform is not his only responsibility at work; there are many other

systems as well, so he values extensive system documentation. Sometimes he needs support, and he is grateful that he gets it quickly.

#### U2 - Application and Content Developer/Administrator

U2 is an informatician, a software developer or a system/content manager.

She develops applications, builds integrations, does information modelling and form building, and designs queries for information retrieval. She is also responsible for maintenance of applications, information structures and content.

U2 gives technical support and help to other users of the openEHR tools. When functions that are more complicated are needed in an openEHR-based application, U2 takes care of it.

U2 is an advanced user with high demands on smart functions in the development tools.

#### U3 - Super user

U3 is a nurse, a physician or a researcher at a health care unit and is interested in how new technical solutions can be used to improve the patient care, working processes, and gaining new medical knowledge. U3 maintains existing forms and templates in the openEHR-based applications that the department uses. U3 really prefers to be able to solve problems himself if possible. But in rare cases it gets a bit too complicated, for instance when programming skills are necessary or when a new template is needed, and then U3 contacts U2 for help and they cooperate on the solution. U3 also generates reports from the health care systems that the care department needs; often it is standard reports that are generated repeatedly, but sometimes a special report is needed.

U3 does not use the openEHR tools on a daily basis, but is more of a "burst" user where intense use is combined with periods of little use or no use at all. This pattern of use means that he might not ever be fluent in how to use the tools.

Since U3 does not have deep technical knowledge it is important that the tools he uses to update forms and templates are easy to use. It is also important for U3 that it is easy to get an overview of which templates and forms that the clinic is using, that version handling is easy and straightforward, and that efficient search and filtering tools are available. U3 also needs a comprehensible report generation tool.

#### U4 - Newbie

U4 is a nurse or a physician at a hospital, but may also be an informatician or a software developer. U4 has a few years working experience but no or little knowledge of openEHR. Now is the first time U4 takes part in maintaining existing forms and templates or in developing a new openEHR-based solution.

It is important for U4 that the tools for developing forms are easy to learn and that the user documentation is pedagogical and covers all common use cases and functions. Some kind of introductory training to get started would help U4 a lot.

#### **U5** - External Actor

U5 is a company, a student, another health care region, or a researcher. U5 contributes to RÖ by delivering applications or content. U5 has no direct access to RÖ's systems and uses her own development tools.

It is important for U5 that a full range of REST APIs is available, and U5 values extensive system documentation. It could be convenient for her to use RÖ's openEHR tool licenses for a limited period when developing on behalf of RÖ.

#### U6 - Application End-User

U6 is a health care clinician or a citizen. U6 wants to enter and retrieve information from and to the health record system. U6 has no interest in the technical aspects of the applications they use; the important thing is that the applications support what they want to do in a smooth way. This may

include that the applications are always available, or that only information that is relevant in the particular context is shown. In some situations, it may be of interest for U6 to switch language in an application. Since U6 could be any citizen, it might be the case that he has some kind of disability, for instance impaired vision, and is in need of things like enlarged text or textual descriptions of images.

Thus, U6's needs concerns the results of using the openEHR platform and development tools; as long as the resulting applications are stable and good, U6 is happy.

# 3.3 Evaluation criteria

den 22 december 2020 10:57

# 3.3.1 Points

The following linear scale is used when rating requirements of type evaluation:

- 0 = Not approved, the solution is insufficient
- 1 = Approved, but the solution does not meet all expectations
- 2 = Approved, the solution meets the expectations
- 3 = Approved, the solution exceeds the expectations

## 3.3.2 Weighting

Some requirements are regarded extra important and are therefore weighted higher than others. The weights are stated in the requirements.

#### 3.3.3 Attached document responses

If not otherwise stated, the following applies to responses of type "attachment".

Each attached description must follow these restrictions:

- Maximum 10 000 characters in total, characters are counted without spaces. Responses with less than maximum number of characters are very welcome.
- Maximum 8 A4 pages (including text, images and illustrations).
- Minimum font size 10 pt.
- Images like screenshots and other illustrations are allowed (within the page limits above).
- Very short texts like numbers or labels may be added to images/screenshots, but other descriptive text should be kept in the text part of the document, not be added into the pictures.
- Tables are allowed and character content in tables counts toward the total character limit of the document.
- No movie clips are allowed.
- No links or references to external sources of information will be followed or evaluated. You may refer to your own responses in other parts of this procurement though.

## 3.3.4 Functional requirements

The functional evaluation criteria are usually described in conjunction with each functional requirement. For responses of type "attachment", please note the attachment length limitations described above if not stated otherwise.

## 3.3.5 Usability evaluation

The offered solution is evaluated in terms of how well it meets the needs of the 6 defined user roles (U1-U6).

The evaluations are based on the following two criteria from the HEART model (Google's UX metrics).

• Happiness

Where "happiness" is interpreted as how comprehensible and easy to use the offered solution is, and how satisfied the users feel

• Task success

Where "task success" is interpreted as how efficiently and effectively tasks can be completed and how robust the offered solution is

A linear scale 0-3 is used when rating each criterion. The interpretation of the scale is described above in the "Points" section.

The usability evaluations are performed in 2 steps:

- In step 1, the vendor provides textual descriptions of the offered solution that explains how the solution meets the needs of the targeted user roles
- In step 2, RÖ tests the offered solution by letting representatives of the user roles perform tasks using the solution

When doing the usability evaluations, focus is on functions and properties of the described solution that specifically fits the targeted user roles.

In evaluation step 2, the persons performing the tests have access to a ready-made openEHR template OPT file, medical data samples for a few test patients, and a predefined AQL query - similar but not identical to the data that was used in the pre-procurement earlier this year (<u>https://discourse.openehr.org/t/swedish-openehr-platform-procurement-q1-2020/247</u>). The exact tasks that are performed during the tests are not published in advance, but they are based on the requirements stated in other parts of the tender.

# 3.4 Requirements for CDR Platform and platform administration tools

den 22 december 2020 10:53

| Req  | Туре                     | Answer | Evaluation criteria  |
|--|--------------------------|--------|--|
| 3.4.1. Support for the Reference Model (RM), Terminology (TERM) and Process Model (PROC) specifications  |                          |        |  |
| <ul> <li>a. When processing, storing and retrieving data, the platform must support version 1.0.4 or higher of all of the following openEHR Reference Model (RM) Specification information model packages: <ul> <li>EHR</li> <li>Common</li> <li>Data Structures</li> <li>Data Types</li> <li>Support</li> <li>Integration</li> </ul> </li> </ul>  | Must                     | Yes/No |  |
| b. When processing, storing and retrieving data, the platform <b>must</b> support<br>the contents of version 2.1.0 or higher of the openEHR Terminology (TERM)<br>Specification.   | Must                     | Yes/No |  |
| c. When processing, storing and retrieving data, the platform should support version 1.0.4 or higher of the openEHR Reference Model (RM) Specification package named "Demographic".  | Should                   | Yes/No |  |
| d. The CDR should support a "Tags" feature for tagging stored items, retrieving items based on tags, and AQL querying selection criteria based on tags. See discussion at <u>https://openehr.atlassian.net/l/c/ZCetz6dB</u> .  | Should                   | Yes/No |  |
| e. The tenderer must describe which versions of the openEHR RM and TERM<br>Specifications the platform supports. If not up to date, the upgrade strategy<br>must be briefly described.   | Evaluation<br>Linear 0-3 | Text   | f. Not being up to date<br>and poor update<br>strategy reduce<br>points.                 |
| g. When processing, storing and retrieving data, the platform should support version 1.0.0 or higher of the openEHR Task Planning (TP) Specification.  | Should                   | Yes/No |  |
| <ul> <li>h. The tenderer must describe which version of the openEHR Task Planning<br/>Specification and any other specifications from the openEHR Process Model<br/>(PROC) Component that are currently supported. The planned upgrade<br/>strategy must also be outlined.</li> </ul>  | Evaluation<br>Linear 0-3 | Text   | <ul> <li>Not being up to date<br/>and poor update<br/>strategy reduce points.</li> </ul> |
| 3.4.2. Validation  |                          |        |  |
| a. When validating input data the platform <b>must</b> support using archetypes and templates (e.g. via operational templates) based on version 1.4 or higher of AOM/ADL/OPT.  | Must                     | Yes/No |  |
| b. When validating input data the platform should support using archetypes<br>and templates (e.g. via operational templates) based on version 2.0.6 or<br>higher of AOM/ADL/OPT.   | Should                   | Yes/No |  |
| 3.4 3 Triggering CDS Hooks and Cambio CDS  |                          |        |  |
| Info-text:<br>RÖ is a customer of Cambio and already has access to Cambio's CDS (Clinical<br>Decision Support) tools and CDS portal that can be used to execute (GDL2)<br>CDS rules and return responses. Even though a complete EHR procurement<br>often would request CDS functions, this procurement instead mainly requests<br>the possibility to trigger a CDS using HL7 FHIR CDS hooks and processing the<br>results. It is assumed that a CDS can write information back to the CDR using<br>the standard openEHR REST APIs as specified in other requirements. For<br>information about "CDS Hooks" mentioned below, including CDS Hooks<br>Responses like "CDS cards" see <u>https://cds-hooks.org/</u> and <u>https://cds-hooks.hl7.org/</u> Also note that supporting OAuth is usually necessary when |                          |        |  |

| calling such services.   |                          |            |   |
|--|--------------------------|------------|---|
| a. A When storing new or changed EHR content, the platform should support<br>triggering external CDS systems using HL7 CDS Hooks, version 1.0 or later,<br>based on what templates or archetypes the new content contains.   | Should                   | Yes/No     |   |
| b. When storing new or changed EHR cont and ent, the platform should<br>support triggering external CDS systems using HL7 CDS Hooks, version 1.0<br>or later, based on stored AQL queries; with the stored AQL queries acting as<br>filters determining if triggering should be done or not.   | Should                   | Yes/No     |   |
| <ul> <li>c. The tenderer must describe if and how external CDS platforms can be triggered through HL7 CDS Hooks, when storing new or changed EHR content in the CDR. Are other trigger conditions than AQL or archetypes/templates provided?</li> <li>Describe if, and if so how, any CDR platform input APIs can be called in ways that require a CDS call to validate content of the transaction before it is allowed to go on.</li> <li>Also describe if and how the offered tools, platform or utilities support the development of functions that send along the FHIR Hook "Context" information etc. when calling a CDS.</li> </ul>  | Evaluation<br>Linear 0-3 | Attachment | d. Clearly described<br>flexible and<br>convenient provided<br>options increase<br>points.  |
| <ul> <li>e. The tenderer must describe if and how the offered tools, platform and utilities support development of applications that can show resulting "CDS Cards" (CDS responses).</li> <li>Note: This requirement likely refers more to included form/application development tools in your offering than to the CDR backend, but it is presented here in order to keep CDS integration requirements in one place.</li> </ul>   | Evaluation<br>Linear 0-3 | Text       | f. Clearly described<br>flexible and<br>convenient provided<br>options increase<br>points.  |
| g. Describe what kind of integration tests (if any) you have done between your offering and Cambio CDS, and describe the results of those tests.   | Evaluation<br>Linear 0-3 | Text       | h. Credible,<br>comprehensive<br>transparent tests with<br>good results increase<br>points. |
| 3.4.4 Other CDS systems, rules and triggers  |                          |            |   |
| <ul> <li>a. Before permanently storing EHR content, some applications may want to<br/>run CDS rules, or call external CDS systems through CDS hooks or other<br/>means, and show responses to the user or trigger other processes. Example:<br/>EHR data recently entered in a GUI but not yet complete and sent to final<br/>storage.</li> <li>The tenderer must describe how the CDR platform or other application<br/>development or support functions provided with the procurement offering<br/>support execution of clinical decision support (CDS) rules also using clinical<br/>data that is not yet permanently stored in the platform as final EHR content.</li> </ul> |                          | Text       | b. Clearly described<br>flexible and<br>convenient provided<br>options increase<br>points.  |
| <ul> <li>c. The tenderer must describe available CDS functions, formalisms and versions included with the offering (if any) that are <i>not</i> based on CDS hooks. Openly specified or standardized formalisms are preferred.</li> <li>The tenderer must also describe if and how CDS rules (or equivalent advanced algorithms) can be used on already stored data for single and multiple patients.</li> </ul>   | Evaluation<br>Linear 0-3 | Text       | d. Providing useful open<br>functionality<br>increases points.                              |
| e. When storing new or changed EHR content, the CDR platform should<br>support triggering (other, not based on CDS hooks) internal and external<br>processes configured by the customer (for example message transmissions)<br>based on what templates or archetypes the new content contains.   | Should                   | Yes/No     |   |
| f. When storing new or changed EHR content, the CDR platform should<br>support triggering (other, not based on CDS hooks) internal and external<br>processes configured by the customer (for example message transmissions)<br>based on stored AQL queries; with the stored AQL queries acting as filters<br>determining if triggering should be done or not.  | Should                   | Yes/No     |   |
| g. When storing new or changed EHR content, the CDR platform should  | Should                   | Yes/No     |   |

| Task Plans (TP).   | lustion                  |        | · Oliverski Jasovihod  |
|--|--------------------------|--------|--|
| h. The tenderer must describe if and how external processes or APIs can be<br>triggered by CDS, AQL, and TP execution. Example: Using some message<br>broker/bus/queue, enterprise service bus, RPC, web hooks or similar. The<br>tenderer must also describe what can be used as triggers and how.  | Evaluation<br>Linear 0-3 | Text   | i. Clearly described<br>flexible and<br>convenient provided<br>options increase<br>points.           |
| 3.4.5 APIs and Formats   |                          |        |  |
| <ul> <li>a. The platform must support version 1.0.0 or higher of openEHR's standardized REST APIs, including at least the following APIs (using at least one of openEHRs canonical formats): <ul> <li>EHR</li> <li>Query</li> <li>Definitions</li> </ul> </li> </ul>   | Must                     | Yes/No |  |
| b. The REST API implementation should support openEHR Canonical JSON-<br>format.   | Must                     | Yes/No |  |
| c. The REST API implementation should support openEHR Canonical XML-<br>format.  | Should                   | Yes/No |  |
| d. The REST API implementation should support openEHR "Simplified Data<br>Template" ncSDT format or similar (see<br><u>https://specifications.openehr.org/releases/ITS-</u><br><u>REST/latest/simplified_data_template.html</u> ).   | Should                   | Yes/No |  |
| e. The REST API implementation should support openEHR "Simplified Data<br>Template" simSDT format or similar.  | Should                   | Yes/No |  |
| <ul> <li>f. If Simplified Data Template (SDT) or similar is supported, describe <ul> <li>what variants are supported and the degree of support,</li> <li>associated API &amp; tooling support, for example if template-specific example data instances can be generated via API in SDT or similar format and</li> <li>how you intend to adjust to ongoing openEHR standardisation of SDT formats.</li> </ul> </li> </ul> | Evaluation<br>Linear 0-3 | Text   | g. Poor API/Tooling of<br>not being up to dat<br>regarding<br>standardisation<br>efforts reduce poir |
| h. The platform or accompanying utilities should support data import and<br>export using Template Document Schema (TDS) and Template Data<br>Documents (TDDs) or similar XML-based simplified openEHR archetype-<br>based and template-based formats and transforms.   | Should                   | Yes/No |  |
| <ul> <li>i. If TDS/TDD or similar XML transform is supported, describe:</li> <li>what variants are supported and the degree of support and</li> <li>associated API &amp; tooling support (for example if template-specific example data instances can be generated via API in TDD or similar formats).</li> </ul>  | Evaluation<br>Linear 0-3 | Text   | j. Poor support or<br>limited tooling redu<br>points   |
| k. The platform, or tools/utilities included in the offer, should support creation<br>and scalable execution of HL7 FHIR-mappings/conversions to and from<br>openEHR formats, thus enabling data import and export using HL7 FHIR.   | Should                   | Yes/No |  |
| I. If HL7 FHIR is supported, describe what version and what kind of FHIR usage scenarios are supported and the degree of support. Also describe associated API and tooling support to create and update FHIR mappings.   | Evaluation<br>Linear 0-3 | Text   | m. Poor support or<br>limited tooling<br>reduce points   |
| 3.4.6 AQL & Terminology  |                          |        |  |
| a. When querying data, the platform <b>must</b> support responding to ad-hoc and to parametric stored queries using the openEHR Archetype Query Language (AQL) version 1.0.0 or higher.  | Must                     | Yes/No |  |
| b. When querying data the platform should, in addition to standard AQL, support free-text search.  | Should                   | Yes/No |  |
| c. When querying data the platform should support nested queries.  | Should                   | Yes/No |  |
|  | Should                   | Yes/No |  |

| published in a public openEHR release.   | Cha II                   | N//h1      |  |
|--|--------------------------|------------|--|
| f. When querying data the platform should support search criteria based on tags/annotations. See discussion at: <u>https://openehr.atlassian.net/l/c/ZCetz6dB</u> .  | Should                   | Yes/No     |  |
| g. When querying data the platform should support advanced terminology based search criteria, for example using terminology servers or terminology function to resolve hierarchical and other terminology-relations in queries.  | Should                   | Yes/No     |  |
| <ul> <li>h. A terminology server/service (or integrations to a recommended free<br/>terminology server product) should be included in the product offering.</li> </ul>   | Should                   | Yes/No     |  |
| i. The terminology server/service should support multilingual terminologies.   | Should                   | Yes/No     |  |
| j. The tenderer must describe and exemplify the way search can be done using<br>terminology service, free text, folders, directories, tags, nested/combined<br>queries etc. The tenderer must also describe planned adjustments to<br>ongoing openEHR standardisation of these things.   | Evaluation<br>Linear 0-3 | Attachment | k. Limited capacities and<br>poor update strategy<br>reduce points.  |
| 3.4.7 Logical separation and roles   |                          |            |  |
| a. The platform should support domains/namespaces/partitions or similar mechanisms to achieve a logical separation of patient data into different logical partitions isolated from each other in the same server/cluster installation.   | Should                   | Yes/No     |  |
| b. The system should support definition of user roles to restrict the access of data within particular domains/namespaces/partitions   | Should                   | Yes/No     |  |
| c. The system should support definition of user roles to restrict the access to<br>the results of specific stored parametric AQL queries or similar predefined<br>parametric views of data.  | Should                   | Yes/No     |  |
| d. The tenderer must describe the logical separation features and describe<br>how roles work in the platform (within and between<br>domains/namespaces/partitions). Explain if and how role information from<br>an Identity Provider (IDP) about an authenticated user can be used by the<br>platform to restrict or give access to data.  | Evaluation<br>Linear 0-3 | Text       | e. Weaknesses regarding<br>separation system,<br>role system, IDP- and<br>configuration<br>possibilities reduce<br>points.   |
| 3.4.8 Administrator functions  |                          |            |  |
| a. The platform should support efficient bulk import and export of<br>COMPOSITIONs, EHRs and other stored data from/to file system in open<br>well documented formats.   | Should                   | Yes/No     |  |
| <ul> <li>b. The platform must support the possibility to physically delete individual<br/>compositions.</li> </ul>   | Must                     | Yes/No     |  |
| c. The platform must support the possibility to physically delete an entire EHR.   | Must                     | Yes/No     |  |
| d. The platform should include tooling/UI for (logical) merging of EHRs (for<br>example after an unidentified person becomes identified).  | Should                   | Yes/No     |  |
| e. The platform should support tooling/UI for (logical) transfer of<br>COMPOSITIONs from one EHR to another EHR (for example if entered in<br>wrong patient's record).   | Should                   | Yes/No     |  |
| <ul> <li>f. The tenderer must briefly describe the following:</li> <li>1. if it is possible to export system configuration between different instances of the system (for example test and production) and how it is done,</li> <li>2. if and how soft launches of new versions of the system can be done and if different versions of system parts can run simultaneously within the same installation,</li> <li>3. typical downtime due to upgrades in a system sized for managing the EHRs for 500 000 inhabitants and how that downtime was measured.</li> </ul> | Evaluation<br>Linear 0-3 |            | g. Good configuration<br>export/import and<br>credible descriptions<br>of functions<br>supporting no or<br>minimal downtime<br>when upgrading<br>systems increase<br>points. |
| Details regarding upgrades and related administration can be further described in later sections about usability evaluation for administrators (U1) if you want to.  |                          |            |  |
|  |                          |            |  |

| current deployments   |                          |            |  |
|---|--------------------------|------------|--|
| a. Provide descriptions of and results from tests investigating correctness of<br>the platform's implementation of the openEHR specifications. If available,<br>independent validations or certifications of conformity can also be<br>attached.  | Evaluation<br>Linear 0-3 | Attachment | b. Credible, transparent<br>tests with correct<br>results increase<br>points.  |
| c. The tenderer must provide descriptions of and results from tests<br>investigating scalability and performance tests of the system and describe<br>the hardware-, OS- and database-setup used in such measurements. The<br>tenderer must also describe how the use of EHR/CDR storage disk space<br>scales with an increased amount of content. Statistics from clinically<br>deployed systems are also of interest, if available.  | Evaluation<br>Linear 0-3 | Attachment | d. Credible, transparen<br>tests and statistics<br>with good results<br>increase points.   |
| e. The tenderer must describe its or its business partners' experience (if any)<br>of deploying the platform to customers providing healthcare to 500 000<br><i>inhabitants</i> or more. The tenderer must also describe the top five largest<br>deployments, their number of active EHRs and the total number of<br>Compositions, if available.  | Evaluation<br>Linear 0-3 | Attachment | f. Proven track record increases points.   |
| g. How many current deployments contain 500 000 patient EHRs or more<br>(with clinical content) right now?  | Evaluation<br>Linear 0-3 | Number     | h. More deployments<br>increase points. Scal<br>0=0p, 1=1p, 2-4=2p,<br>+=3p  |
| The tenderer must describe any prebuilt products or EHR-modules, based on<br>the platform, that have been deployed in clinical use, for instance end user<br>applications for surgery, emergency wards, medications, primary care. (The<br>applications do not necessarily need to be included in the bid, the question<br>probes available application breadth and experience of using the platform<br>as a base for development.)   | Evaluation<br>Linear 0-3 | Text       | j. Proven development<br>track record increase<br>points.  |
| k. Are any products, tools or modules that you or your partners have<br>developed based on the CDR platform (or produced by using the authoring<br>tools) certified (CE labelled) according to EU Medical Device Directive<br>93/42/EEC (MDD) or the EU Medical Devices Regulation (MDR)? If yes, state<br>which products or modules that fulfil which regulation and what<br>classification each part or system has (class I, IIa, IIb or III).  | Evaluation<br>Linear 0-3 | Text       | I. Proven MDR and MD<br>experience increase<br>points.   |
| <ul> <li>m. Our aim is to use procured/provided applications for both administrative and clinical tasks. It is therefore important that relevant products, tools, components or modules that will be clinically used for a medical purpose are either CE-labelled according to EU Medical Device Directive 93/42/EEC (MDD) or the EU Medical Devices Regulation (MDR), at the time of purchase, or at a later stage when the need is identified in Region Östergötland. General CDR platform capabilities will also be used as components to create new and modified clinical applications that need to conform to MDD/MDR or equivalent requirements.</li> <li>To make this possible it is important that you or your partners have experience of such CE-labelling and quality control processes.</li> <li>Describe your experience, if any, of the process to CE label a software according to MDD/MDR. Also, describe if and how you can support RÖ in such processes when building applications based on your platform. Describe if and how you can be transparent regarding your internal quality and testing procedures, fault-detection mechanisms etc. that may be of importance when CE-labelling an application built partly using your platform. For example can you send relevant test protocols, results and procedures upon request when we want to certify a product built using</li> </ul> | Evaluation<br>Linear 0-3 | Attachment | n. Proven MDR and<br>MDD labelling<br>experience<br>increases points.<br>Offering good<br>information to help<br>RÖ and our partners<br>build CE-compliant<br>applications based of<br>the platform and<br>provided tools<br>increases points.<br>Promising requester<br>transparency<br>increases points. |
| your platform.<br>3.4.10 Licensing, included support, training and extras   |                          |            |  |
| Info text:  |                          |            |  |
| RÖ is interested in two different main categories of use cases and associated   |                          |            |  |

| <ul> <li>(for approximately 500 000 inhabitants).</li> <li>Use case category #2: Specific (often clinically narrow) use cases such as patient registries (including some nation-wide), biobank information, and patient owned data.</li> </ul>  |                          |        |  |
|---|--------------------------|--------|--|
| For use case category #2 the number of patients and associated EHRs may grow large (millions) over time, although not necessarily with very much data per patient.  |                          |        |  |
| <ul> <li>a. The tenderer must explain how your licensing model works, scales and impacts the cost of both use cases described above.</li> <li>If use case category #2 leads to zero cost or lower cost than use case category #1, then describe the conditions that need to be fulfilled in order to apply the lower (or zero) cost to applications of type #2.</li> </ul>  | Evaluation<br>Linear 0-3 |        | <ul> <li>b. Price models where<br/>the cost per patient i<br/>zero for category #2<br/>give maximum points<br/>If the per patient cos<br/>for category #2 is<br/>more than zero, then<br/>- a lower price for<br/>category #2 than for<br/>category #1, increase<br/>points.</li> <li>good transparent<br/>explanations of how<br/>the licensing model<br/>separates use cases of<br/>category #1 from<br/>category #2 increase<br/>points.</li> </ul> |
| c. Telephone or video conference support during workdays 9-16 (Swedish<br>time) for critical issues in production EHR systems, and email response<br>within 2 workdays for non-critical issues, <b>must</b> be supplied for use case<br>category #1 (clinical EHR use).   | Must                     | Yes/No |  |
| <ul> <li>d. The tenderer must describe the offered support for use case #1 (clinical EHR use):</li> <li>What are the opening hours (Swedish time) when you will offer telephone/videoconference support for critical issues in production EHR systems?</li> <li>What do you define as critical issues in production EHR systems (use case #1)?</li> <li>Is telephone/videoconference support during office hours also offered for non-critical issues, if so is free usage of it limited to a certain number of hours or per month/year etc.? How many? Should it he headed (scheduled in advance? How far in advance?</li> </ul> | Evaluation<br>Linear 0-3 | Text   | e. More and wider<br>included support<br>increases points.   |
| <ul> <li>it be booked/scheduled in advance? How far in advance?</li> <li>Do you provide support in Swedish?</li> <li>What are the maximum email response times for non-critical issues?</li> </ul> f. Email response within 1 workday for critical issues and 4 workdays for non-critical issues, must be supplied for use case category #2 (registries, biobank)   | Must                     | Yes/No |  |
| etc.).<br>g. The tenderer must describe the offered CDR platform support for use case<br>category #2 (registries, biobank etc.):  | Evaluation<br>Linear 0-3 | Text   | h. More and wider<br>included support  |
| <ul> <li>Do you provide same day telephone/videoconference support during<br/>business hours for critical issues in the platform? If so, what are the</li> </ul>  |                          |        | increases points.<br>For maximum points<br>the expectation is<br>telephone/videocor<br>rence workdays 9-10   |

| critical issues?   |                          |            | for non-critical issues.  |
|--|--------------------------|------------|---|
| i. The tenderer must describe the software developer training that you include<br>in the offer, if any.  | Evaluation<br>Linear 0-3 | Text       | j. Generous relevant<br>training offering<br>increases points.  |
| <ul> <li>k. Optionally, add information about additional openEHR platform related functions or tools included in the offering, that are not covered in the other requirements above. Of special interest are tools and functions supporting: <ol> <li>Integration with HL7 v2 messages</li> <li>Integration with PACS/imaging systems via DICOM etc.</li> <li>Statistics for follow-up and research</li> <li>Export to business intelligence platforms</li> <li>OHDSI collaboration (see <a href="https://ohdsi.org/">https://ohdsi.org/</a>)</li> </ol> </li> </ul>   | Evaluation<br>Linear 0-3 | Attachment | I. Included tools and<br>functions deemed of<br>value to Region<br>Östergötland increase<br>points, especially<br>within the listed<br>areas. |
| m. RÖ will have separate environments for development, tests and production use of the platform.   | Must                     | Yes/No     | -   |
| There must not be any extra cost incurred for running development and<br>test environments that will not be used for clinical purposes (but may<br>contain copies of production data or other test data).<br>Is use in test environment etc. free of extra costs?  |                          |            |   |
|  |                          |            |   |
| 3.4.11 Usability evaluation, part 1, from descriptions   |                          |            |   |
| <ul> <li>a. Attach a description of how the offered solution meets the needs of user role U1 (Platform Administrator/Techinician). Describe the functions and properties of the solution that are particularly beneficial for the user role in question, and also motivate why. Follow the attachment length limitations described in the Evaluation criteria chapter, section Attached document responses.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details regarding the evaluation are found in chapter 6 Evaluation criteria.</li> </ul>              | Evaluation<br>Linear 0-3 | Attachment | <ul> <li>b. RÖ evaluates and<br/>rewards 0-3 points<br/>per criterion<br/>Maximum total score:</li> <li>6</li> </ul>                          |
| <ul> <li>c. Attach a description of how the offered solution meets the needs of user role U2 (Application and Content Developer/Administrator). Describe the functions and properties of the solution that are particularly beneficial for the user role in question, and also motivate why. Follow the attachment length limitations described in the Evaluation criteria chapter, section Attached document responses.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details regarding the evaluation are found in chapter 6 Evaluation criteria.</li> </ul> | Evaluation<br>Linear 0-3 | Attachment | d. RÖ evaluates and<br>rewards 0-3 points<br>per criterion<br>Maximum total score:<br>6   |
| <ul> <li>e. Attach a description of how the offered solution meets the needs of user role U5 (External Actor). Describe the functions and properties of the solution that are particularly beneficial for the user role in question, and also motivate why. Follow the attachment length limitations described in the Evaluation criteria chapter, section Attached document responses.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details regarding the evaluation are found in chapter 6 Evaluation criteria.</li> </ul>                                  | Evaluation<br>Linear 0-3 | Attachment | f. RÖ evaluates and<br>rewards 0-3 points per<br>criterion<br>Maximum total score:<br>6   |
| 3.4.12 Usability evaluation and openEHR compliance, part 2,  |                          |            |   |
| by testing   |                          |            |   |
| a. The offered solution must be temporarily available so that RÖ can run tests   | Must                     | Attachment |   |

| b. User manuals must be available before the evaluation. Attach information about how to download or access the user manuals.  | Must                     | Attachment |  |
|--|--------------------------|------------|--|
| c. Training (attached video or similar) covering the basics of the system should<br>be provided before the evaluation. Maximum length of video is 40 minutes.<br>Attach information about how to download or access the training material.   | Should                   | Attachment |  |
| <ul> <li>d. Representatives for user role U1 will perform tests for the usability evaluation part 2.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details regarding the evaluation are found in chapter 6 Evaluation criteria.</li> </ul>         | Evaluation<br>Linear 0-3 |            | RÖ evaluates and rewards 0-3 points per criterion.   |
| <ul> <li>e. Representatives for user role U2 will perform tests for the usability evaluation part 2.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details regarding the evaluation are found in chapter 6 Evaluation criteria.</li> </ul>         | Evaluation<br>Linear 0-3 |            | RÖ evaluates and rewards 0-3 points per criterion.   |
| <ul> <li>f. Representatives for user role U5 will perform tests for the usability evaluation part 2.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details regarding the evaluation are found in chapter 6 Evaluation criteria.</li> </ul>         | Evaluation<br>Linear 0-3 |            | RÖ evaluates and rewards 0-3 points per criterion.   |
| <ul> <li>g. RÖ will perform tests of openEHR standard conformity through the openEHR REST APIs. The content of these tests will not be published ahead of test sessions.</li> <li>If not already provided in other documentation, attach instructions regarding how to call your API.</li> </ul> | Evaluation<br>Linear 0-3 | Attachment | Evaluation of text<br>results, as described in<br>question g)<br>Incorrect results reduce<br>points. |
| 3.4.13 General technical requirements relating to message<br>transfer to and from the system and the Region's API<br>Gateway and API management  |                          |            |  |
| Note: The general technical requirements (3.4.13 - 3.4.21) are repeated (somewhat modified depending on context) in other chapters.  |                          |            |  |
| a. The system must support REST calls over HTTPS for data transfer.<br>Yes/No. Yes is required   |                          |            |  |
| b. The API consumer should be able to use parameters to choose the format of the response data.<br>Yes/No. Yes is desired  |                          |            |  |
| c. Available REST API:s should be described using the OpenAPI specification.<br>Yes/No. Yes is desired   |                          |            |  |
| d. The system must support the OAuth 2.0 Code Flow for authorization and delegation when a user identity is needed.<br>Yes/No. Yes is required   |                          |            |  |
| e. The system should support the OAuth 2.0 Client Credential Flow for authorization and delegation.<br>Yes/No. Yes is desired  |                          |            |  |
| f. The system should support a signed JSON Web Token for authorization and delegation.<br>Yes/No. Yes is desired   |                          |            |  |
| <b>g.</b> The system must support mutual TLS for authorization and delegation. Yes/No. Yes is required   |                          |            |  |
| h. The system should support basic authentication for authorization and delegation.<br>Yes/No. Yes is desired  |                          |            |  |
| i. All things that can be administered with the system administration GUI must be possible to access through APIs.<br>Yes/No. Yes is required  |                          |            |  |
| I  |                          |            |  |

| j. The system API:s must be available to use without any extra cost or development.<br>Yes/No. Yes is required  |
|---|
| k. The system API:s must be documented, and the documentation must<br>be available without any extra cost.<br>Yes/No. Yes is required   |
| 3.4.14 Branding   |
| Applications facing the end user (U6) should be possible to configure<br>and brand with the Region Östergötland brand and styles.<br>Yes/No. Yes is desired                   |
| 3.4.15 Cloud Services   |
| The openEHR CDR platform must be possible to install on premise.<br>Yes/No. Yes is required   |
| 3.4.16 Infrastructure requirements for "on prem" products.<br>(Section not applicable for pure cloud services.)   |
| a. The servers must support virtualization with support for at least<br>Vmware vSphere.<br>Yes/No. Yes is required  |
| b. The servers must use DNS for name lookup, thus not rely on fixed IP-<br>addresses to external services.<br>Yes/No. Yes is required   |
| c. It should be possible to store data in the system externally from the server using Cifs or NFS.<br>Yes/No. Yes is desired  |
| d. The system should support monitoring using the Microsoft System<br>Center Operation Manager.<br>Yes/No. Yes is desired   |
| e. The system should support that antivirus software can scan server<br>and client operating system environments and file uploads and<br>downloads.<br>Yes/No. Yes is desired |
| f. The system should support antivirus software Symantec Endpoint<br>Protection.<br>Yes/No. Yes is desired  |
| g. The system should support the clock synchronization protocols NT5DS or NTP.<br>Yes/No. Yes is desired  |
| h. The system should support proxy usage when communicating with the internet.<br>Yes/No. Yes is desired  |
| i. The system should not use hardware protection locks.<br>Yes/No. Yes is desired   |
| j. The system should not use MAC address lock for software.<br>Yes/No. Yes is desired   |
| 3.4.17 Operating system requirements for "on prem" products. (Section not applicable for pure cloud services.)  |
| a. The system should support the latest version of Microsoft Windows<br>Server or Linux.<br>Yes/No. Yes is desired  |
| b. If the system supports Linux, the system must be able to run on an open source Linux distribution without licensing cost.<br>Yes/No. Yes is desired                        |
| c. System dependencies to the operating system must support the OS supplier's life cycle.<br>Yes/No. Yes is required  |
| 3.4.18 Confidentiality (Section not applicable for programs installed locally on end users computer.)   |
| a. The system should be able to create roles with different configurable  |

| permissions in the system.   |
|--|
| Yes/No. Yes is desired   |
| b. The system should not have any limitation regarding the number of roles that can be created.<br>Yes/No. Yes is desired                        |
| c. Access to functions in the system should be possible to control with permissions.<br>Yes/No. Yes is desired                                   |
| d. Access to the system logs and logging services should be controlled using permissions.<br>Yes/No. Yes is desired                              |
| e. The system should support federated authentication using the SAML 2.0 standard.<br>Yes/No. Yes is desired                                     |
| f. The system must support federated authentication using the Oauth 2.0 standard with identity layer OpenID Connect.<br>Yes/No. Yes is required  |
| g. The system should support authorization using the SAML 2.0 standard.<br>Yes/No. Yes is desired  |
| h. The system should support authorization using the Oauth 2.0 standard with identity layer OpenID Connect.<br>Yes/No. Yes is desired            |
| i. All communication to and form the system must preserve confidentiality, for example by using encrypted communication. Yes/No. Yes is required |
| j. User activity in the system must be logged.<br>Yes/No. Yes is required  |
| <b>k.</b> The id of the user performing an activity in the system must be logged.<br>Yes/No. Yes is required                                     |
| I. The time and date for when an activity is executed must be logged.<br>Yes/No. Yes is required   |
| m. The system should be able to log all logins.<br>Yes/No. Yes is desired  |
| n. The system should log all errors and deviations.<br>Yes/No. Yes is desired  |
| 3.4.19 Requirements for web based Client software (Section only applicable to web-based software)  |
| a. The user interface must be web-based.<br>Yes/No. Yes is required  |
| <b>b. The user interface should support Microsoft Edge.</b><br>Yes/No. Yes is desired  |
| c. The user interface must support Google Chrome.<br>Yes/No. Yes is required   |
| d. The user interface should support Mozilla Firefox.<br>Yes/No. Yes is desired  |
| e. The user interface should support Safari.<br>Yes/No. Yes is desired   |
| f. The user interface should not depend on plugins in the browser.<br>Yes/No. Yes is desired   |
| g. If plugins are needed in the browser, describe which plugins.<br>Text field   |
| h. All plugins for browsers must follow the life cycle of the browser and plugin suppliers.<br>Yes/No. Yes is required                           |
| i. The web application should be responsive to the end users' browser capabilities and screen size.<br>Yes/No. Yes is desired                    |

| The web application dependencies must follow the life cycle of the browser suppliers that you have responded to as supported above.                |  |
|--|--|
| 3.4.20 Network Protocol Requirements   |  |
| a. The system must be able to communicate with Region Östergötland's network via the TCP/IP, IPv4 network protocol. Yes/No. Yes is required        |  |
| b. The system should be able to communicate with Region<br>Östergötland's network via the TCP/IP, IPv6 network protocol.<br>Yes/No. Yes is desired |  |
| c. The tenderer must describe network ports and protocols used for<br>communication to and from the system.<br>Text field                          |  |
| 3.4.21 Documentation   |  |
| a. Course or online training material should be available for education of system administrators.<br>Yes/No. Yes is desired                        |  |
| b. Course or online training material should be available for education of system users.<br>Yes/No. Yes is desired                                 |  |
| c. System administration documentation for the system must be available and up to date.<br>Yes/No. Yes is required                                 |  |
| d. Technical documentation for the system must be available and up to date.<br>Yes/No. Yes is required   |  |
| e. User documentation for the system must be available and up to date.<br>Yes/No. Yes is required  |  |
|  |  |

# 3.5 Form authoring and rendering

den 22 december 2020 11:00

Notes:

- 1. The (form) "authoring environment" below can be understood as either a single tool or a set of well integrated tools, programs and components that performs the described desired functions.
- 2. The "renderer" functionality refers to rendering forms in end user (U6) targeted web-applications, forms created in the authoring environment. This can be done in different ways. Supplying a generic form-loading rendering module to be included in webapps is one way. Solving the task by compiling forms to webapp components or (sub)pages is an example of another way (of many possible ways).

| Req  | Туре                     | Answer | Evaluation criteria  |
|--|--------------------------|--------|--|
| 2.5.1 Versions of openEHR supported by form authoring  |                          |        |  |
| tools  |                          |        |  |
| <ul> <li>a. When authoring or displaying forms referring to or otherwise involving elements from the openEHR Reference Model (RM), the tools must support version 1.0.4 or higher of all of the following RM Specification information model packages: <ul> <li>EHR*</li> <li>Common</li> <li>Data Structures</li> <li>Data Types</li> </ul> </li> <li>* = The form authoring tool does not need to assist creating forms for the EHR_ACCESS and EHR_STATUS objects in the EHR package.</li> </ul> | Must                     | Yes/No |  |
| <ul> <li>b. When authoring or displaying forms referring to or otherwise involving elements from the openEHR Reference Model (RM), the tools should support version 1.0.4 or higher of all of the following RM Specification packages: <ul> <li>EHR</li> <li>Support (or provide equivalent way to assist with terminology content when authoring forms)</li> <li>Integration</li> </ul> </li> </ul>   | Should                   | Yes/No |  |
| c. When authoring or displaying forms referring to or otherwise involving<br>content from the openEHR Terminology (TERM) Specification, the tools<br><b>must</b> support version 2.1.0 or higher of the Terminology (TERM)<br>Specification.   | Must                     | Yes/No |  |
| d. The tenderer must describe which versions of the openEHR RM and TERM<br>Specifications the tools and components support. If not up to date, briefly<br>describe the upgrade strategy and timeline.  | Evaluation<br>Linear 0-3 | Text   | e. Not being up to<br>date and poor<br>update strategy<br>reduce points. |
| f. When authoring or displaying forms the tools should support version 1.0.0 or higher of the openEHR Task Planning (TP) Specification.  | Should                   | Yes/No |  |
| g. The tenderer must describe which version of the openEHR Task Planning<br>Specification and any other specifications from the openEHR Process<br>Model (PROC) Component that are currently supported. Also outline the<br>planned upgrade strategy and timeline.   | Evaluation<br>Linear 0-3 | Text   | h. Not being up to<br>date and poor<br>update strategy<br>reduce points. |
| 3.5.2 Authoring environment  |                          |        |  |
| a. The authoring environment must support automatic or semiautomatic generation of data entry forms from openEHR templates.  | Must                     | Yes/No | -  |
| b. Automatically or semi-automatically generated forms and form<br>parts/components must be possible to modify manually in the authoring<br>environment.   | Must                     | Yes/No | -  |
| c. The authoring environment should include possibilities to easily preview<br>forms, and during such preview support template based validation of<br>example EHR data based on the openEHR models.  | Should                   | Yes/No | -  |
| d. A form preview function in the authoring environment should be able to  | Should                   | Yes/No | -  |

| commit valid data into an openEHR repository via openEHR standard REST<br>APIs into an EHR selected by the user (U2-U5), for example the EHR of a<br>test patient.  |                          |            |   |
|---|--------------------------|------------|---|
| e. The authoring environment must support basic formatting possibilities like<br>headings, style, layout and also different widget types for multiple choice<br>fields, such as drop down menus, check boxes, radio buttons, single and<br>multiple choice lists.   | Must                     | Yes/No     | -   |
| f. The tenderer must describe the above mentioned (a-e) formatting<br>functions and widgets, plus which other than the mentioned basic ones<br>that the system supports. Also provide screenshots where suitable.   | Evaluation<br>Linear 0-3 | Attachment | g. Availability of<br>many relevant<br>functions and<br>widgets with good<br>usability increase<br>points   |
| <ul> <li>h. The authoring environment must support creation of conditional expressions changing which fields (or form sections) in the rendered end user (U6) interface to hide or show based on other end user input in the form.</li> <li>Example: In the "Pulse" archetype, if "Regularity" is set to "irregular" then show the "Irregular type" choices.</li> </ul>   | Must                     | Yes/No     | -   |
| <ul> <li>i. The tenderer must describe how conditional expressions that show/hide parts can be created. Is it for example done through coding by developers (U2) and/or via a low/no-code environment for non-programmers (e.g. U3 &amp; U4)</li> </ul>   | Evaluation<br>Linear 0-3 | Text       | j. Availability of both<br>good low/no-code<br>editing options<br>and the option of<br>powerful<br>coding/programmi<br>ng control is<br>needed for<br>maximum points. |
| k. The authoring environment and renderer must support scripting with<br>calculations (e.g. for risk scores like NEWS2) where the result can be<br>automatically entered e.g. in a summary field in the template.   | Must                     | Yes/No     | -   |
| a. The tenderer must describe how scripting with calculations can be done,<br>including form-internal formulae or external (e.g. GDL-based client or<br>server side) calculations.  | Evaluation<br>Linear 0-3 | Text       | m. Availability of<br>many relevant<br>possibilities with<br>good usability<br>increase points  |
| <ul> <li>n. The authoring environment and end user (U6) facing rendered forms must<br/>support terminology content browsing, lookup, filtering and selection.</li> </ul>  | Must                     | Yes/No     |   |
| a. The tenderer must describe the terminology content browsing, lookup,<br>filtering and selection functions available. Also describe included or<br>compatible terminology server/services.  | Evaluation<br>Linear 0-3 | Attachment | p. Powerful<br>functions with<br>good usability<br>increase points.   |
| q. Describe the dependency tracking and dependency management provided<br>by the authoring environment. For example available tracking of in what<br>forms a certain version of an archetype, template or terminology<br>item/code is used.   | Evaluation<br>Linear 0-3 |            | r. High coverage of<br>different kinds of<br>dependencies and<br>useful views<br>presenting them<br>increase points   |
| <ul> <li>s. It must be possible to enter a value once in a form in a user interface, and<br/>then automatically record that value in more than one place in the<br/>template(s) the form is based on.</li> <li>Example: Enter a value for "Inspired oxygen" in the form once, but record<br/>the value in both the "Respiration" and the "Pulse oximetry" observations<br/>(in e.g. a vital signs template) when stored.</li> </ul> | Must                     | Yes/No     | -   |
| <ul> <li>t. The tenderer must describe if and how the authoring environment and<br/>renderer supports the use of images and illustrations to enter structured<br/>information.</li> <li>Example: Point out the location of an injury on a body image when<br/>selecting "Body site" in the "Problem/Diagnosis" archetype.</li> </ul>  | Evaluation<br>Linear 0-3 | Attachment | u. Availability of<br>relevant<br>possibilities with<br>good usability<br>increase points   |

| v. The authoring environment and renderer should have multilingual support<br>so that it is possible to switch the template-based parts of an authored<br>GUI/form between all languages supported by the template.   | Should                   | Yes/No     |   |
|---|--------------------------|------------|---|
| w. The authoring environment and renderer should have multilingual<br>support so that it is possible to switch terminology languages in the<br>terminology support function.  | Should                   | Yes/No     |   |
| x. The authoring environment itself should have a multilingual GUI support<br>so that all can essential components/tools can be easily localized to<br>Swedish.   | Should                   | Yes/No     |   |
| <ul> <li>y. The authoring environment and renderer (or other included components)<br/>should support development of forms/components that at runtime can<br/>import data from an end users' (U6) sensors into forms.</li> <li>Example: Reading of a patient's pulse oximetry and blood pressure devices<br/>via Web Bluetooth API in browsers.</li> </ul>   | Should                   | Yes/No     |   |
| z. Describe if and to what extent the authoring environment and renderer<br>supports formatting in free text fields in forms, and describe available<br>formatting widgets like WYSIWYG editors etc. Briefly describe if and how<br>the rules and options described in<br><u>https://specifications.openehr.org/releases/RM/latest/data_types.html#_f</u><br><u>ormatting_and_hyperlinking</u> are enforced.                              | Evaluation<br>Linear 0-3 | Text       | aa. Availability of<br>relevant possibilities<br>with good usability<br>increase points.<br>Enforcement of the<br>markdown rules<br>from the<br>specification is<br>required for<br>maximum points. |
| ab. Describe if and how the authoring environment and renderer support<br>development of applications that let the end user (U6) upload and include<br>image/multimedia content in forms and submit as EHR content. Also<br>describe any possible support for storing such content in VNA/PACS with<br>links (and possibly thumbnails) in openEHR CDR/platforms.  | Evaluation<br>Linear 0-3 | Text       | ac. Availability of<br>relevant possibilities<br>with good usability<br>increase points.<br>Good integration<br>possibilities with<br>VNA/PACS is<br>required for<br>maximum points.                |
| ad. The authoring environment must support at least one OPT (operational template format) or other template format that can be exported from openEHR's online Archetype Designer at <a href="https://tools.openehr.org/">https://tools.openehr.org/</a> and at least one that can be exported from openEHR's Clinical Knowledge manager at <a href="https://ckm.openehr.org/">https://ckm.openehr.org/</a> and at                         | Must                     | Yes/No     |   |
| ae. The authoring environment (or other included utilities) should, without<br>additional cost, include a (or refer to an open) conversion service that makes<br>it possible to use both the OPT and OPT2 (operational template) formats.   | Should                   | Yes/No     |   |
| af. The authoring environment and renderer should internally support AOM2/ADL2 based formats like OPT2.   | Should                   | Yes/No     |   |
| ag.The authoring environment and renderer should support building applications using openEHR task planning.   | Should                   | Yes/No     |   |
| ah. Describe which version of the openEHR Task Planning Specification and<br>any other specifications from the openEHR Process Model (PROC)<br>Component that are currently supported. The planned upgrade strategy<br>and timeline must also be outlined.  | Evaluation<br>Linear 0-3 | Text       | ai. Not being up to<br>date and poor<br>update strategy<br>reduce points.   |
| aj. The authoring environment should support easy retrieval and storage of<br>assets (archetypes, templates, forms etc.) in some commonly used openly<br>specified version control systems (for example GIT-based ones) or asset<br>management systems.   | Should                   |            |   |
| ak. The tenderer must attach documentation specifying how to construct<br>and add customer created components and widgets. The authoring<br>environment and form renderer should support addition of customer<br>created widgets for certain parts of openEHR templates, based on for<br>example openEHR datatypes and template annotations. This should be done<br>in a way that treats customer created widgets in a way similar to the | Evaluation<br>Linear 0-3 | Attachment | Al. Availability of<br>well documented<br>relevant possibilities<br>with good usability<br>increase points. To<br>achieve maximum   |

| widgets originally provided by the authoring environment.  |        |        | points the<br>component<br>interface<br>specification should<br>be openly published<br>for free unrestricted<br>use by anybody,<br>and ideally based on<br>open standards like<br>JavaScript ES6<br>modules. |
|--|--------|--------|--|
| am. The authoring environment and renderer should support using AQL calls at runtime to pre-populate (author selectable) form fields.  | Should | Yes/No |  |
| an. The authoring environment and renderer should support using (author defined) JavaScript (or TypeScript) code at runtime to pre-populate (author selectable) form fields. Such code should be allowed to make external REST and GraphQL API calls to in order to fetch data from other sources.                                     | Should | Yes/No |  |
| 3.5.3. Rendering and usage of authored forms/components  |        |        |  |
| a. The publishing process and form handling must be semi-automated so<br>that forms updated or created in the form authoring environment can be<br>validated and tested and then published and launched also by non-<br>programmers (U1, U2, U3 and U5) so that they then are automatically<br>rendered in end-user (U6) applications. | Must   | Yes/No |  |
| b. The authoring environment or form renderer must support development<br>of and usage of openEHR template-based UI forms in other web based<br>(HTML5+JS+CSS) clients.  | Must   | Yes/No |  |
| <ul> <li>c. It should be possible to configure and call the web based renderer function/module(s) using standardised JavaScript (ES6) modules. (As described in for example <u>https://developer.mozilla.org/en-US/docs/Web/JavaScript/Guide/Modules</u>)</li> </ul>   | Should | Yes/No |  |
| d. The form authoring environment or utilities included in the offer should<br>support development of native Android client applications that can render<br>openEHR template-based UI forms (produced by the authoring<br>environment).  | Should | Yes/No |  |
| e. The form authoring environment or utilities included in the offer should<br>support development of native iOS client applications that can render<br>openEHR template-based UI forms (produced by the authoring<br>environment).  | Should | Yes/No |  |
| f. It must be possible to freely redistribute the (possibly compiled) parts of a client application that are based on the form renderer as Open Source in components, applications and associated open code repositories.  | Must   | Yes/No |  |
| g. When the end-user (U6) enters data, the form renderer (or well-<br>integrated supporting services and components) must validate the data<br>based on constraints in the corresponding openEHR templates.  | Must   | Yes/No |  |
| h. When the end-user (U6) enters data, it should be possible to validate a majority of the archetype-based and template-based data in client-side code without calling a server.   | Should | Yes/No |  |
| i. If a template supports multiple natural languages, the form renderer should support rendering the corresponding form in multiple natural languages too.   | Should | Yes/No |  |
| j. The form renderer should support the use of CSS and other relevant configuration options for customer branding purposes.  | Should | Yes/No |  |
| k. The rendered forms and supporting components, must admit submission<br>of data (entered by U6) to openEHR-compliant CDRs (back-end platforms)<br>through openEHRs standard REST interfaces.   | Must   | Yes/No | -  |
| I. The rendered forms and supporting components, should admit submission of data (entered by U6) to openEHR-compliant CDRs (back-end platforms)  | Should | Yes/No |  |

| successfully tested with at least two independent CDR platforms, commercially or openly available.  |                          |            |   |
|---|--------------------------|------------|---|
| m. The Tenderer must describe which openEHR-compliant CDR platforms the<br>authoring environment and renderer have been tested with. Also<br>describe how the tests were performed and the results.   | Evaluation<br>Linear 0-3 | Attachment | n. Credible,<br>transparent tests<br>with correct<br>results increase<br>points. Tests with<br>more CDR<br>products increase<br>points.   |
| <ul> <li>b. Our aim is to use applications built with the authoring environment and renderer for both administrative and clinical tasks. It is therefore important that relevant applications that will be clinically used for a medical purpose can be CE-labelled according to EU Medical Device Directive 93/42/EEC (MDD) or the EU Medical Devices Regulation (MDR)</li> <li>To make this possible it is important that you or your partners have experience of such CE-labelling and quality control processes.</li> <li>Describe your experience, if any, of the process to CE label a software according to MDD/MDR. Also, describe if and how you can support RÖ in such processes when building applications based on your platform. Describe if/how you can be transparent regarding your internal quality and testing procedures, fault-detection mechanisms etc. that may be of importance when CE-labelling an application built partly using your platform. (For example can you send relevant test protocols, results and procedures upon request when we want to certify a product built using your platform.)</li> </ul> | Evaluation<br>Linear 0-3 | Attachment | p. Proven MDR and<br>MDD experience<br>offered support<br>and transparence<br>increase points.  |
| <ul> <li>p. Describe the offered support for form authoring and rendering toold:</li> <li>Do you provide same day support during business hours for critical issues in the tools and renderer functions? To what extent is that covered in the offering?</li> <li>What do you define as critical issues?</li> <li>Do you provide support in Swedish?</li> <li>What are the regular response times for critical and for non-critical issues?</li> </ul>  | Evaluation<br>Linear 0-3 | Text       | r. More and wider<br>included support<br>increases points.<br>For maximum<br>points the<br>expectation is<br>workdays 9-16<br>(Swedish time) for<br>critical support<br>issues and<br>response within a<br>working days for<br>non-critical issue |
| 3.5.4 Usability evaluation of form authoring and rendering, part 1  |                          |            |   |
| <ul> <li>The tenderer must attach a description of how the offered solution meets<br/>the needs of user role U1 (Platform Administrator/Technician). Describe<br/>the functions and properties of the solution that are particularly beneficial<br/>for the user role in question, and also motivate why. Follow the<br/>attachment length limitations described in the Evaluation criteria chapter,<br/>section Attached document responses.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details regarding the evaluation are found in chapter Evaluation criteria.</li> </ul>   | Evaluation<br>Linear 0-6 | Attachment | b. RÖ evaluates ar<br>rewards 0-3<br>points per<br>criterion<br>Maximum total<br>score: 6   |
| The tenderer must attach a description of how the offered solution meets<br>the needs of user role U2 (Application and Content<br>Developer/Administrator). Describe the functions and properties of the<br>solution that are particularly beneficial for the user role in question, and<br>also motivate why. Follow the attachment length limitations described in<br>the Evaluation criteria chapter, section Attached document responses.   | Evaluation<br>Linear 0-6 | Attachment | d. RÖ evaluates ar<br>rewards 0-3<br>points per<br>criterion<br>Maximum total<br>score: 6   |

| Evaluation criteria:<br>• Happiness   |                          |            |  |
|---|--------------------------|------------|--|
| • Task success<br>Details regarding the evaluation are found in chapter Evaluation criteria.  |                          |            |  |
| <ul> <li>e. The tenderer must attach a description of how the offered solution meets the needs of user role U3 (Super User). Describe the functions and properties of the solution that are particularly beneficial for the user role in question, and also motivate why. Follow the attachment length limitations described in the Evaluation criteria chapter, section Attached document responses.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> </ul>   | Evaluation<br>Linear 0-6 | Attachment | f. RÖ evaluates and<br>rewards 0-3 points<br>per criterion<br>Maximum total<br>score: 6    |
| <ul> <li>g. The tenderer must attach a description of how the offered solution meets the needs of user role U4 (Newbie). Describe the functions and properties of the solution that are particularly beneficial for the user role in question, and also motivate why. Follow the attachment length limitations described in the Evaluation criteria chapter, section Attached document responses.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details regarding the evaluation are found in chapter Evaluation criteria.</li> </ul>               | Evaluation<br>Linear 0-6 | Attachment | h. RÖ evaluates and<br>rewards 0-3<br>points per<br>criterion<br>Maximum total<br>score: 6 |
| <ul> <li>i. The tenderer must attach a description of how the offered solution meets the needs of user role U5 (External Actor). Describe the functions and properties of the solution that are particularly beneficial for the user role in question, and also motivate why. Follow the attachment length limitations described in the Evaluation criteria chapter, section Attached document responses.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details regarding the evaluation are found in chapter Evaluation criteria.</li> </ul>       | Evaluation<br>Linear 0-6 | Attachment | j. RÖ evaluates and<br>rewards 0-3 points<br>per criterion<br>Maximum total<br>score: 6    |
| <ul> <li>k. The tenderer must attach a description of how the offered solution meets the needs of user role U6 (Application End-User). Describe the functions and properties of the solution that are particularly beneficial for the user role in question, and also motivate why. Follow the attachment length limitations described in the Evaluation criteria chapter, section Attached document responses.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details regarding the evaluation are found in chapter Evaluation criteria.</li> </ul> | Evaluation<br>Linear 0-6 | Attachment | I. RÖ evaluates and<br>rewards 0-3 points<br>per criterion<br>Maximum total<br>score: 6    |
| 3.5.5 Usability evaluation and openEHR compliance of form authoring and rendering, part 2, by testing   |                          |            |  |
| a. The offered solution needs to be temporarily available so that RÖ can run tests on it. Attach either information about how to download and install the authoring environment and renderer, or information about how to access a remote installation.   | Must                     | Attachment |  |
| b. User manuals must be available before the evaluation. Attach information about how to download or access the user manuals.   | Must                     | Attachment |  |
| c. Training (attached video or similar) covering the basics of the system<br>should be provided before the evaluation. Maximum length of video is 40<br>minutes. Attach information about how to download or access the training<br>material.   | Should                   | Attachment |  |
| <ul> <li>Representatives for user role U1 will perform tests for the usability<br/>evaluation part 2.</li> <li>Evaluation criteria:</li> </ul>  | Evaluation<br>Linear 0-6 |            | RÖ evaluates and rewards 0-3 points per criterion  |

| <ul> <li>Happiness</li> <li>Task success</li> <li>Details regarding the evaluation are found in chapter 6 Evaluation criteria.</li> </ul>  |                          |            | Maximum <del>total</del><br>score: 6   |
|--|--------------------------|------------|--|
| <ul> <li>e. Representatives for user role U2 will perform tests for the usability evaluation part 2.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details regarding the evaluation are found in chapter 6 Evaluation criteria.</li> </ul> | Evaluation<br>Linear 0-6 |            | RÖ evaluates and<br>rewards 0-3 points<br>per criterion<br>Maximum total<br>score: 6 |
| <ul> <li>f. Representatives for user role U3 will perform tests for the usability evaluation part 2.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details regarding the evaluation are found in chapter 6 Evaluation criteria.</li> </ul> | Evaluation<br>Linear 0-6 |            | RÖ evaluates and<br>rewards 0-3 points<br>per criterion<br>Maximum total<br>score: 6 |
| <ul> <li>g. Representatives for user role U4 will perform tests for the usability evaluation part 2.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details regarding the evaluation are found in chapter 6 Evaluation criteria.</li> </ul> | Evaluation<br>Linear 0-6 |            | RÖ evaluates and<br>rewards 0-3 points<br>per criterion<br>Maximum total<br>score: 6 |
| <ul> <li>h. Representatives for user role U5 will perform tests for the usability evaluation part 2.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details regarding the evaluation are found in chapter 6 Evaluation criteria.</li> </ul> | Evaluation<br>Linear 0-6 |            | RÖ evaluates and<br>rewards 0-3 points<br>per criterion<br>Maximum total<br>score: 6 |
| <ul> <li>i. Representatives for user role U6 will perform tests for the usability evaluation part 2.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details regarding the evaluation are found in chapter 6 Evaluation criteria.</li> </ul> | Evaluation<br>Linear 0-6 |            | RÖ evaluates and<br>rewards 0-3 points<br>per criterion<br>Maximum total<br>score: 6 |
| j. RÖ will perform tests of openEHR standard conformity of data entered in<br>forms and sent from the renderer through the openEHR REST APIs to a CDR<br>or CDR test-stub. The content of these tests will not be published ahead of<br>test sessions.                                   | Evaluation<br>Linear 0-3 | Attachment | Incorrect results reduce points.   |
| 3.5.6 General technical requirements relating to message transfer to and from the system and the Region's API Gateway and API management   |                          |            |  |
| Note: The general technical requirements (3.5.6 - 3.5.14) are repeated (somewhat modified depending on context) in other chapters.   |                          |            |  |
| The system must support REST calls over HTTPS for data transfer.<br>Yes/No. Yes is required  |                          |            |  |
| 3.5.7 Cloud Services   |                          |            |  |
| Form authoring tools may be delivered as cloud services or on premise solutions; describe the delivery model.<br>Text field  |                          |            |  |
| 3.5.8 Branding   |                          |            |  |
| Applications facing the end user (U6) should be possible to configure<br>and brand with the Region Östergötland brand and styles.<br>Yes/No. Yes is desired  |                          |            |  |
| 3.5.9 Infrastructure requirements for "on prem" products.<br>(Section not applicable for pure cloud services.)   |                          |            |  |
| a. The servers must support virtualization with support for at least<br>Vmware vSphere.  |                          |            |  |

| Yes/No. Yes is required   |
|---|
| b. The servers must use DNS for name lookup, thus not rely on fixed IP-<br>addresses to external services.<br>Yes/No. Yes is required   |
| c. It should be possible to store data in the system externally from the server using Cifs or NFS.<br>Yes/No. Yes is desired  |
| d. The system should support monitoring using the Microsoft System<br>Center Operation Manager.<br>Yes/No. Yes is desired   |
| e. The system should support that antivirus software can scan server<br>and client operating system environments and file uploads and<br>downloads.<br>Yes/No. Yes is desired |
| f. The system should support antivirus software Symantec Endpoint<br>Protection.<br>Yes/No. Yes is desired  |
| g. The system should support the clock synchronization protocols NT5DS or NTP.<br>Yes/No. Yes is desired  |
| h. The system should support proxy usage when communicating with the internet.<br>Yes/No. Yes is desired  |
| i. The system should not use hardware protection locks.<br>Yes/No. Yes is desired   |
| j. The system should not use MAC address lock for software.<br>Yes/No. Yes is desired   |
| 3.5.10 Operating system requirements for "on prem" products. (Section not applicable for pure cloud services.)  |
| a. The system should support the latest version of Microsoft Windows<br>Server or Linux.<br>Yes/No. Yes is desired  |
| b. If the system supports Linux, the system must be able to run on an open source Linux distribution without licensing cost.<br>Multiple choice. Yes, No, not applicable      |
| c. System dependencies to the operating system must support the OS supplier's life cycle.<br>Yes/No. Yes is required  |
| 3.5.11 Confidentiality (Section not applicable for programs installed locally on end users computer.)   |
| a. The system should be able to create roles with different configurable permissions in the system.<br>Yes/No. Yes is desired   |
| b. Access to functions in the system should be possible to control with permissions.<br>Yes/No. Yes is desired  |
| c. Access to the system logs and logging services should be controlled using permissions.<br>Yes/No. Yes is desired   |
| d. The system should support federated authentication using the SAML 2.0 standard.<br>Yes/No. Yes is desired  |
| e. The system should support authorization using the SAML 2.0 standard.<br>Yes/No. Yes is desired   |
| f. The system should support authorization using the Oauth 2.0<br>standard with identity layer OpenID Connect.<br>Yes/No. Yes is desired                                      |

| g. All communication to and form the system must preserve confidentiality, e.g. by encrypted communication. Yes/No. Yes is required  |
|--|
| h. User activity in the system must be logged.<br>Yes/No. Yes is required  |
| i. The id of the user performing an activity in the system must be<br>logged.<br>Yes/No. Yes is required   |
| j. The time and date for when an activity is executed must be logged.<br>Yes/No. Yes is required   |
| k. The system should be able to log all logins.<br>Yes/No. Yes is desired  |
| I. The system should log all errors and deviations.<br>Yes/No. Yes is desired  |
| 3.5.12 Requirements for web-based Client software (Section only applicable to web-based software)  |
| a. The user interface should be web-based. (If it is, respond to the rest<br>of this section.)<br>Yes/No. Yes is desired   |
| <b>b. The user interface should support Microsoft Edge.</b><br>Yes/No. Yes is desired  |
| c. The user interface must support Google Chrome.<br>Yes/No. Yes is required   |
| d. The user interface should support Mozilla Firefox.<br>Yes/No. Yes is desired  |
| e. The user interface should support Safari.<br>Yes/No. Yes is desired   |
| f. The user interface should not depend on plugins in the browser.<br>Yes/No. Yes is desired   |
| g. If plugins are needed in the browser, describe which plugins.<br>Text field   |
| h. All plugins for browsers must follow the life cycle of the browser and plugin suppliers.<br>Yes/No. Yes is required   |
| i. The web application should be responsive to the end users' bowser capabilities and screen size.<br>Yes/No. Yes is desired   |
| j. The web application dependencies must follow the life cycle of the browser suppliers that you have responded to as supported above. Yes/No. Yes is required                         |
| 3.5.13 Requirements for client software locally installed.<br>(Section not applicable for purely web based services)   |
| a. Windows-based software installation files should be delivered as MSI-, MSIX-packages or EXE-files with ability to run in silent mode during installation.<br>Yes/No. Yes is desired |
| b. The tenderer must describe the application's recommended distribution method.<br>Text field   |
| c. Does the system require frameworks or language runtime<br>systems/environments like .NET or Java?<br>Yes/No. Yes is desired   |
| d. If yes (applies on question c), what versions of .NET, Java or other frameworks and runtime systems are required?<br>Text field   |

e. All dependencies on required frameworks or language runtime

| systems/environments such as .NET or Java should follow the corresponding official version support life-cycles.<br>Yes/No. Yes is desired  |  |
|--|--|
| f. All dependencies on required frameworks or language runtime<br>systems/environments should be able to run on an open source<br>distribution without licensing cost.<br>Yes/No. Yes is desired |  |
| g. Client applications must be compatible with Windows 10 Enterprise (64-bit).<br>Yes/No. Yes is required  |  |
| h. Client applications must continuously support the releases of<br>Windows 10 that are in the "Semi-Annual Channel" during the period<br>they are supported.<br>Yes/No. Yes is required         |  |
| i. The tenderer must describe the client minimum hardware and performance requirements.<br>Text field  |  |
| j. The client software installation must avoid modifying exisiting system files of the operating system.<br>Yes/No. Yes is required  |  |
| k. The software should not require registration by end users or require hardware locks.<br>Yes/No. Yes is desired  |  |
| I. The system must support proxy when communicating with the internet.<br>Yes/No. Yes is required  |  |
| m. Client applications not already web-based, should have a development plan for web-based technology. Yes/No. Yes is desired  |  |
| n. The system must be able to communicate with Region Östergötland's network via the TCP/IP, IPv4 network protocol. Yes/No. Yes is required  |  |
| o. The system should be able to communicate with Region<br>Östergötland's network via the TCP/IP, IPv6 network protocol.<br>Yes/No. Yes is desired   |  |
| p. The tenderer must describe network ports and protocols used for communication to and from the system.<br>Text field   |  |
| 3.5.14 Documentation   |  |
| a. Course or online training material should be available for education of system administrators.<br>Yes/No. Yes is desired  |  |
| b. Course or online training material should be available for education of system users.<br>Yes/No. Yes is desired   |  |
| c. System administration documentation for the system must be<br>available and up to date.<br>Yes/No. Yes is required  |  |
| d. Technical documentation for the system must be available and up to date.<br>Yes/No. Yes is required   |  |
| e. User documentation for the system must be available and up to date.<br>Yes/No. Yes is required  |  |

# 3.6 AQL tools

den 22 december 2020 10:59

| Req  | Туре                     | Answer     | Evaluation criteria   |
|--|--------------------------|------------|---|
| 3.6.1 Versions of openEHR required for AQL tools   |                          |            |   |
| <ul> <li>a. When authoring queries, displaying queries and displaying query results referring to or otherwise involving elements from the openEHR Reference Model (RM), the tools <b>must</b> support version 1.0.4 or higher of all of the following RM Specification information model packages: <ul> <li>EHR</li> <li>Common</li> <li>Data Structures</li> <li>Data Types</li> <li>Integration</li> </ul> </li> </ul> | Must                     | Yes/No     |   |
| <ul> <li>b. When authoring queries, displaying queries and displaying query results<br/>referring to or otherwise involving content from the openEHR<br/>Terminology (TERM) Specification, the tools <b>must</b> support version 2.1.0<br/>or higher of the Terminology (TERM) Specification.</li> </ul>   | Must                     | Yes/No     |   |
| c. The tenderer must describe which versions of the openEHR RM and<br>TERM Specifications the tools and components support. If not up to<br>date, briefly describe the upgrade strategy and timeline.  | Evaluation<br>Linear 0-3 | Text       | d. Not being up to date and poor update strategy reduce points.   |
| <ul> <li>e. The tool should support a "Tag" feature, including authoring and sending<br/>AQL queries based on tags. See discussion<br/>at: <u>https://openehr.atlassian.net/l/c/ZCetz6dB</u></li> </ul>  | Should                   | Yes/No     |   |
| f. When authoring, displaying queries and query results the tools should<br>support version 1.0.0 or higher of the openEHR Task Planning (TP)<br>Specification.  | Should                   | Yes/No     |   |
| g. Describe which version of the openEHR Task Planning Specification and<br>any other specifications from the openEHR Process Model (PROC)<br>Component that are currently supported. Also outline the planned<br>upgrade strategy and timeline.   | Evaluation<br>Linear 0-3 | Text       | h. Not being up to date and<br>poor update strategy reduce<br>points.   |
| 3.6.2 AQL tool features  |                          |            |   |
| a. The tool must support authoring of AQL queries according to the openEHR "Archetype Query Language (AQL)" specification, release 1.0.0 or later.   | Must                     | Yes/No     |   |
| b. The tool should support sending AQL queries to a CDR and<br>processing/displaying responses of both ad-hoc and stored AQL queries,<br>through APIs according to the openEHR REST API specifications, release<br>1.0.0 or later.   | Should                   | Yes/No     |   |
| c. The tool should support storage and listing of stored queries via openEHRs REST "Definitions API" Specification.  | Should                   | Yes/No     |   |
| d. Describe which versions of the openEHR Archetype Query Language<br>(AQL) the tool can use and which versions of the openEHR REST "Query"<br>and "Definitions" API specifications the tool supports. If not up to date,<br>the planned upgrade strategy and timeline must also be outlined.  | Evaluation<br>Linear 0-3 | Text       | e. Not being up to date and<br>poor update strategy reduce<br>points.   |
| f. The tool user interface should support storage, reuse and modification of previously used queries.  | Should                   | Yes/No     |   |
| g. The query authoring tool should highlight or prevent syntax errors in AQL queries.  | Should                   | Yes/No     |   |
| <ul> <li>h. Describe available low-/no-code functionality (such as drag-and-drop<br/>GUI) to create queries from (query author selectable) openEHR<br/>archetypes, templates and reference model objects and attributes. Also<br/>provide screenshots where suitable.</li> </ul>   | Evaluation<br>Linear 0-3 | Attachment | i. Availability of relevant<br>functions and widgets with<br>good usability increase<br>points. To receive full score a |

|   |                          |            | template based query<br>authoring function must<br>support at least one OPT<br>(operational template<br>format) or other template<br>format that can be exported<br>from openEHR's online<br>Archetype Designer at<br><u>https://tools.openehr.org/</u><br>and at least one that can be<br>exported from openEHR's<br>Clinical Knowledge Manager<br>at <u>https://ckm.openehr.org/</u> |
|---|--------------------------|------------|--|
| <ul> <li>j. Describe features supporting authoring and execution of AQL queries using terminology systems in intelligent ways, for example queries using hierarchical or other structures in SNOMED CT. Also describe available integrations to terminology servers/services. Provide screenshots where suitable.</li> <li>Example use case, querying patient data using the hierarchical structure of SNOMED CT:</li> <li>First find patients and compositions where the "Body site" contains a descendant of "31156008  Structure of left half of body". Then instead find the descendants of "61685007   Lower limb structure (body structure)". Then the combination (intersection) of both constraints.</li> </ul> | Evaluation<br>Linear 0-3 | Attachment | k. Availability of relevant<br>functions with good usability<br>increase points  |
| I. The tenderer must describe any dependency tracking and dependency<br>management provided by the query tool and included supporting<br>components. For example, tracking of which stored queries that use a<br>certain version of an archetype, template or terminology item/code. Also<br>describe any features for naming stored queries, for sorting and<br>tagging/meta-information, and for grouping by user or role. Provide<br>screenshots where suitable.   | Evaluation<br>Linear 0-3 | Attachment | <ul> <li>High coverage of different<br/>kinds of dependencies and<br/>useful views presenting<br/>them increase points</li> </ul>  |
| n. The tenderer must describe available list- and reporting user interface<br>features showing results from executing openEHR queries. Also provide<br>screenshots where suitable. For example, features useful for data<br>exploration in clinical follow-up and research.   | Evaluation<br>Linear 0-3 | Attachment | o. Availability of relevant<br>functions and widgets with<br>good usability increase<br>points   |
| <ul> <li>p. The tenderer must describe the offered support for AQL Tools:</li> <li>Do you provide same day support during business hours for critical issues in the tools and renderer functions? To what extent is that covered in the offering?</li> <li>What do you define as critical issues?</li> <li>Do you provide support in Swedish?</li> <li>What are the regular response times for critical and for non-critical issues?</li> </ul>   | Evaluation<br>Linear 0-3 | Text       | <ul> <li>q. More and wider included<br/>support increases points.</li> <li>For maximum points the<br/>expectation is workdays</li> <li>9-16 (Swedish time) for<br/>critical support issues and<br/>response within 2 working<br/>days for non-critical issues.</li> </ul>  |
| 3.6.3 Usability evaluation of AQL tools, part 1   |                          |            |  |
| <ul> <li>a. The tenderer must attach a description of how the offered solution meets the needs of user role U1 (Platform Administrator/Technician). Describe the functions and properties of the solution that are particularly beneficial for the user role in question, and also motivate why. Follow the attachment length limitations described in the Evaluation criteria chapter, section Attached document responses. Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details and instructions about the evaluation are found in chapter Evaluation criteria.</li> </ul>  | EvaluationLi<br>near 0-3 | Attachment | b. RÖ evaluates and rewards<br>0-3 points per criterion<br>Maximum total score: 6  |
| c. The tenderer must attach a description of how the offered solution<br>meets the needs of user role U2 (Application and Content<br>Developer/Administrator). Describe the functions and properties of the<br>solution that are particularly beneficial for the user role in question, and   | EvaluationLi<br>near 0-3 | Attachment | d. RÖ evaluates and rewards<br>0-3 points per criterion<br>Maximum total score: 6  |

| <ul> <li>the Evaluation criteria chapter, section Attached document responses.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details and instructions about the evaluation are found in chapter</li> </ul>   |                          |            |   |
|--|--------------------------|------------|---|
| Evaluation criteria.   |                          |            |   |
| <ul> <li>e. The tenderer must attach a description of how the offered solution meets the needs of user role U3 (Super User). Describe the functions and properties of the solution that are particularly beneficial for the user role in question, and also motivate why. Follow the attachment length limitations described in the Evaluation criteria chapter, section Attached document responses.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details and instructions about the evaluation are found in chapter Evaluation criteria.</li> </ul> | EvaluationLi<br>near 0-3 | Attachment | f. RÖ evaluates and rewards<br>0-3 points per criterion<br>Maximum total score: 6 |
| <ul> <li>g. The tenderer must attach a description of how the offered solution meets the needs of user role U4 (Newbie). Describe the functions and properties of the solution that are particularly beneficial for the user role in question, and also motivate why. Follow the attachment length limitations described in the Evaluation criteria chapter, section Attached document responses.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details and instructions about the evaluation are found in chapter Evaluation criteria.</li> </ul>     | Evaluation<br>Linear 0-3 | Attachment | h. RÖ evaluates and rewards<br>0-3 points per criterion<br>Maximum total score: 6 |
| 3.6.4 Usability evaluation and openEHR compliance of AQL tools, part 2, by testing   |                          |            |   |
| a. The offered solution needs to be temporarily available so that RÖ can<br>run tests on it. Attach either information about how to download and<br>install the AQL authoring and execution tools, or information about how<br>to access a remote installation of them.  | Must                     | Attachment |   |
| b. User manuals must be available before the evaluation. Attach<br>information about how to download or access the user manuals.   | Must                     | Attachment |   |
| <ul> <li>c. Training (attached video or similar) covering the basics of the system<br/>should be provided before the evaluation. Maximum length of video is<br/>40 minutes. Attach information about how to download or access the<br/>training material.</li> </ul>   | Should                   | Attachment |   |
| <ul> <li>d. Representatives for user role U1 will perform tests for the usability evaluation part 2.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details regarding the evaluation are found in chapter 6 Evaluation criteria.</li> </ul>   | Evaluation<br>Linear 0-3 |            | RÖ evaluates and rewards 0-<br>points per criterion<br>Maximum total score: 6     |
| <ul> <li>e. Representatives for user role U2 will perform tests for the usability evaluation part 2.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details regarding the evaluation are found in chapter 6 Evaluation criteria.</li> </ul>   | Evaluation<br>Linear 0-6 |            | RÖ evaluates and rewards 0-<br>points per criterion<br>Maximum total score: 6     |
| <ul> <li>f. Representatives for user role U3 will perform tests for the usability evaluation part 2.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> </ul>   | Evaluation<br>Linear 0-6 |            | RÖ evaluates and rewards 0-<br>points per criterion<br>Maximum total score: 6     |

| Details regarding the evaluation are found in chapter 6 Evaluation criteria.   |                          |            |  |
|--|--------------------------|------------|--|
| <ul> <li>g. Representatives for user role U4 will perform tests for the usability evaluation part 2.</li> <li>Evaluation criteria: <ul> <li>Happiness</li> <li>Task success</li> </ul> </li> <li>Details regarding the evaluation are found in chapter 6 Evaluation criteria.</li> </ul> | Evaluation<br>Linear 0-6 |            | RÖ evaluates and rewards 0-3<br>points per criterion<br>Maximum total score: 6 |
| <ul> <li>h. RÖ will perform tests of openEHR standard conformity of queries<br/>authored in and stored/executed by the AQL tool through the openEHR<br/>REST APIs to a CDR or CDR test-stub. The content of these tests will not<br/>be published ahead of test sessions.</li> </ul>     | Evaluation<br>Linear 0-3 | Attachment | Incorrect results reduce points.   |
| Note: The general technical requirements (3.6.5 - 3.6.13) are repeated (somewhat modified depending on context) in other chapters.   |                          |            |  |