**Upphandlingsdokument**
2020-07-16

**Upphandlande organisation**

Region Östergötland
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**Upphandling**

External referral of EHR platform and tools, based on openEHR
ER-2020-08
Sista anbudsdag: 2020-08-16 23:59

**Symbolförklaring**

- Texten ingår i annonsen
- Texten ingår i kvalificeringen
- Texten kommer att ingå i avtalet
- Texten kommer att publiceras i avtalskatalogen
- Texten/frågan innehåller krav som måste uppfyllas
- ESPD Texten/frågan innehåller ESPD-krav
- Frågan är viktad och ingår i utvärderingen
- Frågan ställs endast upplysningsvis
- Frågan besvaras av upphandlaren
- Frågan är markerad för särskild uppföljning

# Innehåll

# 1. External referral EHR platform and tools, based on openEHR

## 1.1 External referral– ER-2020-08 of EHR platform and Tools, based on openEHR

### 1.1.1 Covering letter

Region Östergötland will soon annonuce a procurement in the area OpenEHR.

Before the procurement is announced, we would like to have views/comments on our work material. We believe that your views/comments are important for developing and securing our upcoming procurement documents.

After the referral period, Region Östergötland will analyze all the comments we received and the providers will not get any feedback. We will than design a final procurement document that will be published electronically.

Providers can write the comments directly in Tendsign under each question or use the Excel fil "External referral comments"

### 1.1.2 Symbol explanations

- The included response alternatives generated by the procurement system are partly in Swedish. Translations:

- Ja/Nej = Yes/No¨
- Fritext = Free-text reply
- Linjär skala. 0 - 3 Points = Linear Scale. 0 - 3 Points
- Bifogad fil = Attached file

## 1.2 Areas

· Area = The future procurement will likely be split in different parts (areas) that can be responded to separately.

· Area 1 = Platform and platform administration tools

· Area 2 = Development and content maintenance tools, with the subsections "Form authoring and rendering" plus "AQL authoring and execution Tools"

## 1.3 Definitions

In the document, several terms may refer to the same thing.

Must=Indicates that a question is mandatory and must be fulfilled; otherwise the tender response is

disqualified and will not be considered.

Should =Indicates that a question is desirable but not mandatory to fulfil. Fulfilling the requirement gives higher scores.

U1..U6 = The IDs of the six user roles that RÖ has defined for the openEHR platform and tools. Described in section "User roles"

Form authoring Environment = Is either a single tool or a set of well integrated tools, programs and components that performs the desired functions requested in section It is openEHR-template-aware and will support for example the Region's staff (U2) or contractors (U5) when configuring forms and developing parts of client software based on openEHR models.

Rendering functionality = Functions rendering forms in end user (U6) targeted web-applications, forms created in the (above described)authoring environment. This can be done in different ways, see section “Authoring environment” for details.

RM = The openEHR Reference Model

AQL = Archetype Query Language

## 1.4 General

### 1.4.1 Background

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

This is a external referral for an openEHR platform, for openEHR tools, and for related openEHR services.

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

- Normal hospital EHR use cases
- 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: https://youtu.be/3Wj2H4IYyjE

Growing per EHR record licensing cost models may be an issue for some of the use cases. 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, e.g. Commercial and open source or other reasonably scaling licensing models.

In 2018 Region Östergötland conducted an openEHR RFI and in 2019 Region Östergötland 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 Region Östergötland. This includes form renderer for inclusion in web/HTML5-applications. The availability of “simplified formats” (along the lines of https://specifications.openehr.org/releases/ITS-REST/latest/simplified_data_template.html) has also been appreciated for some use cases.

**For more background see:**

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

## 1.4.2 Project goals

Region Östergötland wants to procure a permanent full scale openEHR solution including support for application development and maintenance. 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.)

## 1.4.3 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:
  - Actual time from identified need to implemented solution
  - 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 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

### 1.4.4 User roles

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 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 developing an 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.

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.

| area | U1 | U2 | U3 | U4 | U5 | U6 |
|---|---|---|---|---|---|---|

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **2** | **Template and archetype builder** | X? | X | | X | | |
| **2** | **Form renderer** | | X | | | X | (X*) |
| **2** | **Form builder tools** | X? | X | X | X | X | X |
| **2** | **AQL authoring and execution tools** | X? | X | X | X | | |
| **1** | **Platform** | X | X | | | X | |

## 1.5 Evaluation criteria

### 1.5.1 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.

### 1.5.2 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.

### 1.5.3 Usability evaluation

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

**The evaluation criteria are based on 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.

In evaluation step 2, the persons performing the tests have access to a ready-made openER 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 (LINK). The exact tasks that are performed during the tests are not published in advance, but they are based on the requirements stated in tender area 1 and 2.

### 1.5.3.1 Instructions for evaluation part 1

Each attached description should describe the functions and properties of the solution that are particularly beneficial for the user role in question, and also motivate why. (Please note the attachment length limitations described above.)

### 1.5.3.2 Instructions for evaluation part 2

**Provide the following before the evaluation; you will be given 10 days of notice:**

- User manuals must be provided before the evaluation
- Training (attached video or similar) covering the basics of the system should be provided
    - Maximum length of video: 40 minutes

## 1.5.4 Points

**The following scale is used when rating the happiness and task success criteria:**

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

In case the evaluated solutions deviate from the expectations, a motivation will be provided by RÖ to clarify why they deviate.

## 1.6 Generel IT-requirements

### 1.6.1 Requirements relating to message transfer to and from the system and the Region's API Gateway and API management

**a. The system must support REST calls over HTTPS for data transfer.**
Ja/Nej

**b. Response data must be available in JSON format.**
Ja/Nej

**c. The system must support the OAuth 2.0 Code Flow for authorization and delegation when a user identity is needed.**
Ja/Nej

**d. The system must support mutual TLS for authorization and delegation.**
Ja/Nej

**e. The system API:s must be available to use without any extra cost or development.**
Ja/Nej

**f. The system API:s must be documented, and the documentation must be available without any extra cost.**
Ja/Nej

### 1.6.2 Confidentiality

**a. he system must support federated authentication using the Oauth 2.0 standard with identity layer OpenID Connect.**
Ja/Nej

**b. All communication to and form the system must preserve confidentiality, e.g. by encrypted communication.**
Ja/Nej

**c. All essential system activity must be logged.**
Ja/Nej

**d. The id of the user performing an activity in the system must be logged.**
Ja/Nej

**e. The time and date for when an activity is executed must be logged.**
Ja/Nej

### 1.6.3 Documentation

**a. System administration documentation for the system must be available and up to date.**
Ja/Nej

**b. Technical documentation for the system must be available and up to date.**
Ja/Nej

**c. User documentation for the system must be available and up to date.**
Ja/Nej

## 1.7 Area 1 EHR Platform and platform administration tools

### 1.7.1 Support for the Reference Model (RM), Terminology (TERM) and Process Model (PROC) specifications

**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 packages:**

*** EHR**

*** Common**

*** Data Structures**

*** Data Types**

*** Support**

*** Integration**

Ja/Nej

**b. When processing, storing and retrieving data, the platform must support the contents of version 2.1.0 or higher of the openEHR Terminology (TERM) Specification.**

Ja/Nej

**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 "Demographics".**

Ja/Nej

**d. 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 "Extract".**

Ja/Nej

**e. Describe which versions of the openEHR RM and TERM Specifications the platform supports. If not up to date, the upgrade strategy must be briefly described.**

Fritext

**f. Evaluation of question e)**
**Not being up to date and poor update strategy reduce points.**

Linjär skala. 0 - 3 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.**

Ja/Nej

**h. Describe which version of the openEHR Task Planning Specification and any other specifications from the openEHR Process Model (PROC)cComponent that are currently supported. The planned upgrade strategy must also be outlined.**

Fritext

**i. Evaluation of question h)**
**Not being up to date and poor update strategy reduce points.**

Linjär skala. 0 - 3 Points

### 1.7.2 Validation, rules and triggers

**a. When validating input data the platform must support using archetypes and templates (e.g. via operational templates) based on version 1.4 or higher of AOM/ADL/OPT.**

Ja/Nej

**b. When validating input data the platform should support using archetypes and templates (e.g. via operational templates) based on version 2.0.6 or higher of AOM/ADL/OPT.**

Ja/Nej

**c. When invoked via API the platform should support execution of openEHR-based clinical decision support (CDS) rules based on GDL, GDL2 or similar using clinical data already stored in the platform.**

Ja/Nej

**d. It should be possible to apply CDS rules both to an individual EHR and to all patients' stored EHRs (population based CDS).**

Ja/Nej

**e. When invoked via API the platform (or GUI support-functions provided with the platform offering) should support execution of openEHR-based clinical decision support (CDS) rules based on GDL, GDL2 or similar, using clinical data supplied via API data not yet permanently stored in the platform as final EHR content.**

**Example: EHR data recently entered in a GUI.**

Ja/Nej

**f. Describe available CDS formalisms and versions. Openly specified or standardized formalisms are preferred.**

Fritext

**g. Evaluation of question f)**

**Not providing suitable open CDS functionality reduces points.**

Linjär skala. 0 - 3 Points

**h. When storing new or changed EHR content, the platform should support triggering other internal and external processes (e.g. CDS apps or message transmissions) based on stored CDS rules.**

Ja/Nej

**i. When storing new or changed EHR content, the platform should support triggering other internal and external processes (e.g. CDS apps or message transmissions) based on stored AQL queries.**

Ja/Nej

**j. When storing new or changed EHR content, the platform should support triggering other internal and external processes (e.g. CDS apps or message transmissions) based on Task Plans (TP).**

Ja/Nej

**k. Describe if and how external processes or APIs can be triggered by CDS, AQL, and TP execution. (Example: Using some message broker/bus/queue, enterprise service bus, RPC, web hooks or similar.)**

Fritext

**I. Evaluation of question k)**

**Clearly described flexible and convenient provided options increase points.**

Linjär skala. 0 - 3 Points

## 1.7.3 APIs and Formats

**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):**

*** EHR**

*** Query**

*** Definitions**

Ja/Nej

**b. The REST API implementation should support openEHR Canonical JSON-format.**

Ja/Nej

**c. The REST API implementation should support openEHR Canonical XML-format.**

Ja/Nej

**d. The REST API implementation should support openEHR "Simplified Data Template" ncSDT format or similar (see https://specifications.openehr.org/releases/ITS-REST/latest/simplified_data_template.html).**

Ja/Nej

**e. The REST API implementation should support openEHR "Simplified Data Template" simSDT format or similar.**

Ja/Nej

**f. If Simplified Data Template (SDT) or similar is supported, describe**

*** what variants are supported and the degree of support,**

*** associated API & tooling support, for example if template-specific example data instances can be generated via API in SDT format and**

*** how you intend to adjust to ongoing openEHR standardisation of SDT formats.**

Ja/Nej

**g. Evaluation of question f)**

**Poor API/Tooling or not being up to date regarding standardisation efforts reduce points.**

Linjär skala. 0 - 3 Points

**h. The platform should support data import and export using Template Document Schema (TDS) and Template Data Documents (TDDs) or similar XML-based simplified openEHR archetype-based and template-based formats and transforms.**

Ja/Nej

**i. If TDS/TDD or similar is supported, describe:**

*** what variants are supported and the degree of support and**

*** associated API & tooling support (for example if template-specific example data instances can be generated via API in TDD or similar formats).**

Fritext

**j. Evaluation of question i)**

**Poor support or limited tooling reduce points.**

Linjär skala. 0 - 3 Points

**k. The platform, or tools/utilities included in the offer, should support creation and scalable execution of HL7 FHIR-mappings/conversions to and from openEHR formats, thus enabling data import and export using HL7 FHIR.**

Ja/Nej

**l. 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.**

Fritext

**n. Evaluation of question l)**

**Poor support or limited tooling reduce points.**

Linjär skala. 0 - 3 Points

### 1.7.4 AQL & Terminology

**a. When querying data the platform must support responding to ad-hoc and parametric stored queries using the openEHR Archetype Query Language (AQL) version 1.0.0 or higher.**

Ja/Nej

**b. When querying data the platform should, in addition to standard AQL, support free text search.**

Ja/Nej

**c. When querying data the platform should support nested and combined queries.**

Ja/Nej

**d. When querying data the platform should support search criteria based on FOLDER/directories.**

Ja/Nej

**e. When querying data the platform should support search criteria based on tags/annotations.**

Ja/Nej

**f. When querying data the platform should support advanced terminology based search criteria, e.g. using terminology servers or terminology function to resolve hierarchical and other terminology-relations in queries.**

Ja/Nej

**g. A terminology server/service (or integrations to a recommended free terminology server product) should be included in the product offering.**

Ja/Nej

**h. The terminology server/service should support multilingual terminologies**

Ja/Nej

**i. Describe and exemplify the way search can be done using terminology service, free text, folders, directories, tags, annotations, nested/combined queries etc. Also describe how you intend to adjust to ongoing openEHR standardisation of these things.**

Bifogad fil

**j. Evaluation of question i)**

**Limited capacities and poor update strategy reduce points.**

Linjär skala. 0 - 3 Points

## 1.7.5 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.**

Ja/Nej

**b. The system should support definition of user roles to restrict the access of data within particular domains/namespaces/partitions.**

Ja/Nej

**c. The system should support definition of user roles to restrict the access to the results of specific stored parametric AQL queries or similar predefined parametric views of data.**

Ja/Nej

**d. Describe the logical separation features and describe how roles work in the platform (within and between domains/namespaces/partitions). Explain if and how role information from an Identity Provider (IDP) about an authenticated user can be used by the platform to restrict or give access to data.**

Fritext

**e. Evaluation of question d)**

**Weaknesses regarding separation system, role system, IDPand configuration possibilities reduce points.**

Linjär skala. 0 - 3 points

### 1.7.6 Administrator functions

**a. The platform should support efficient bulk import and export of COMPOSITIONs, EHRs and other stored data from/to file system in open well documented formats.**

Ja/Nej

**b. The platform should support physical delete of individual compositions.**

Ja/Nej

**c. The platform should support physical delete of an entire EHR.**

Ja/Nej

**d. The platform should include tooling/UI for (logical) merging of EHRs (e.g. after an unidentified person becomes identified).**

Ja/Nej

**e. The platform should support tooling/UI for (logical) transfer of COMPOSITIONs from one EHR to another EHR (e.g. if entered in wrong patient´s record).**

Ja/Nej

**f. Describe briefly if it is possible to export system configuration between different instances of the system (for example test and production) and how it is done. Also briefly describe 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. Describe typical downtime due to upgrades in a system sized for managing the EHRs for 500 000 inhabitants and how that downtime was measured. (Details regarding upgrades and related administration can be further described in later sections about usability evaluation for administrators (U1) if you want to)**

Fritext

**g. Evaluation of question f)**

**Good configuration export/import and credible descriptions of functions supporting no or minimal downtime when upgrading systems increase points.**

Linjär skala. 0 - 3 Points

### 1.7.7 Tests, openEHR compliance, MDR/CE-experience & current deployments

**a. Provide descriptions of and results from tests investigating correctness of the platform's implementation of the openEHR specifications. If available, independent validations or certifications of conformity can also be attached.**

Bifogad fil

**b. Evaluation of question a)**

**Credible, transparent tests with correct results increase points.**

Linjär skala. 0 - 3 Points

**c. Provide descriptions of and results from tests investigating scalability and performance tests of the system.**

Bifogad fil

**d. Evaluation of question c)**

**Credible, transparent tests with good results increase points.**

Linjär skala. 0 - 3 Points

**e. Describe if you or your business partners have experience of deploying the platform to customers providing healthcare to 500 000 inhabitants or more? If so, how big are the largest deployments? How many current deployments are running for populations over 500 000 patients?**

Fritext

**f. Evaluation of question e)**

**Proven track record increases points.**

Linjär skala. 0 - 3 Points

**g. Describe any prebuilt products or EHR-modules based on the platform that have been deployed in clinical use, for instance end user applications for surgery, emergency wards, medications, primary care.**

Fritext

**h. Evaluation of question g)**

**Proven track record increases points.**

Linjär skala. 0 - 3 Points

**i. Are any of the offered products, tools or modules that you provide certified (CE labelled) according to EU Medical Device Directive 93/42/EEC (MDD) or the EU Medical Devices Regulation (MDR)? If yes, state which products or modules that fulfil which regulation and what classification each part/system has (class I, IIa, IIb or III)**

Fritext

**j. Evaluation of question i)**

**Proven MDR and MDD experience increases points.**

Linjär skala. 0 - 3 Points

**k. 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.**

**To make this possible it is important that you or your partners have experience of such CE-labelling and quality control processes.**

**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 your platform.**

Bifogad fil

**l. Evaluation of question k)**

**Proven MDR and MDD experience, offered support and transparency increase points.**

Linjär skala. 0 - 3 Points

## 1.7.8 Licensing, included support, training and extras

**a. Describe the offered support.**

**For example:**

*** Do you provide 24/7 support for critical issues in production EHR systems? To what extent is that covered in the offering?**

*** Do you provide support in Swedish?**

*** What is the regular response times for urgent and for non-urgent issues?**

Fritext

**b. Evaluation of question a)**

**More and wider included support increases points.**

Linjär skala. 0 - 3 Points

**c. Describe the installation support that you offer.**

Fritext

**d. Evaluation of question c)**

**Generous support offering increases points.**

Linjär skala. 0 - 3 Points

**e. Do you, or partners that can be contracted for development, provide any prebuilt products or EHR-modules based on the platform, for instance end user applications for surgery, emergency wards, medications, primary care or other areas.**

Fritext

**f. Evaluation of question e)**

**Proven platform based application development experience increases points.**

Linjär skala. 0 - 3 Points

**g. Describe any prebuilt products or EHR-modules based on the platform that are included in the offering.**

Bifogad fil

**h. Evaluation of question g)**

**Included products/modules deemed of value to Region Östergötland increase points.**

Linjär skala. 0 - 3 Points

**i. Optionally, add information about additional openEHR platform related functions or tools included in the offering, that are not covered in the other requirements above, for instance template, archetype and development tools.**

Fritext

**j. Evaluation of question i)**

**Included products/modules deemed of value to Region Östergötland increase points.**

Linjär skala. 0 - 3 Points

**k. Region Östergötlande will have separate environments for development, test(s) and production use of the platform. There must not be any extra cost incurred for running development and test environments that will not be used for clinical purposes (but may contain copies of production data or other test data).**

Ja/Nej

**l. Region Östergötland is interested in two (2) different main areas of use and associated tools for development and maintenance.**
**Use case #1: Normal hospital EHR use cases and (for approximately 500 000 inhabitants)**
**Use case #2: Specific (often clinically narrow) use cases such as patient registries (including some nation-wide), biobank information, and patient owned data.**

**For use case #2 (registries etc.) the number of patients and associated EHRs may grow large (millions) over time, although not necessarily with very much data per patient. Explain how your licensing model scales and impacts the cost of such use cases.**

Fritext

**n. Evaluation of question l)**

**Good transparent explanations of licensing models that indicate modest or no increase of cost for use cases of type #2 increase points.**

Linjär skala. 0 - 3 Points

## 1.7.9 Usability evaluation, part one (1), from descriptions

**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.**

**Evaluation criteria:**

*** Happiness**

*** Task success**

**Details regarding the evaluation are found in chapter "Evaluation criteria".**

Bifogad fil

**b. Evaluation of question a)**

**Region Östergötland evaluates and rewards 0-3 points per criterion Maximum total score: six (6)**

Linjär skala. 0 - 6 Points

**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.**

**Evaluation criteria:**

*** Happiness**

*** Task success**

**Details regarding the evaluation are found in chapter "Evaluation criteria".**

Bifogad fil

**d. Evaluation of question c)**

**Region Östergötland evaluates and rewards 0-3 points per criterion Maximum total score: six (6)**

Linjär skala. 0 - 6 Points

**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.**

**Evaluation criteria:**

*** Happiness**

*** Task success**

**Details regarding the evaluation are found in chapter "Evaluation criteria".**

Bifogad fil

**f. Evaluation of question e)**

**Region Östergötland evaluates and rewards 0-3 points per criterion Maximum total score: six (6)**

Linjär skala. 0 - 6 Points

## 1.7.10 Usability evaluation and openEHR compliance, part two (2), by testing

**a. The offered solution must be temporarily available so that RÖ can run tests on it. Attach either information about how to download and install the platform software, or information about how to access a remote installation of the platform.**

Bifogad fil

**b. User manuals must be available before the evaluation. Attach information about how to download or access the user manuals.**

Bifogad fil

**c. Training (attached video or similar) covering the basics of the system must be provided before the evaluation. Maximum length of video is 40 minutes. Attach information about how to download or access the training material.**

Bifogad fil

**d. Representatives for user roles U1, U2, and U5 will perform tests for the usability evaluation part 2.**
**Evaluation criteria:**
*** Happiness**
*** Task success**

**Details regarding the evaluation are found in chapter "Evaluation criteria".**
**Region Östergötland evaluates and rewards 0-3 points per criterion per user role.**
**Maximum total score: 18**

Linjär skala. 0 - 18 Points

**e. Region Östergötland 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.**

Bifogad fil

**g. Evaluation of question e)**

**Incorrect results reduce points.**

Linjär skala. 0 - 3 Points

## 1.7.11 General IT-Requirements for EHR platform and platform administration tools

### 1.7.11.1 Requirements relating to message transfer to and from the system and the Region's API Gateway and API management

**a. Response data should be available in XML format.**

Ja/Nej

**b. The API consumer should be able to use parameters to choose the format of the response data.**

Ja/Nej

**c. Available REST API:s should be described using the OpenAPI specification. Attach a zip-file containing API description files based on version 2.0 or higher of the OpenAPI specification https://github.com/OAI/OpenAPI-Specification).**

Ja/Nej

**d. The system should support the OAuth 2.0 Client Credential Flow for authorization and delegation.**
Ja/Nej

**e. The system should support a signed JSON Web Token for authorization and delegation.**
Ja/Nej

**f. The system should support basic authentication for authorization and delegation.**
Ja/Nej

**g. The system must provide API access to all essential functions and information objects.**
Ja/Nej

### 1.7.11.2 Usability & branding

**Applications facing the end user (U6) should be possible to configure and brand with the Region Östergötland brand and styles.**
Ja/Nej

### 1.7.11.3 Infrastructure requirements for "on prem" products. (Section not applicable for pure cloud services.)

**a. The servers must support virtualization with support for at least Vmware vSphere.**
Ja/Nej

**b. The servers must use DNS for name lookup, thus not rely on fixed IP-addresses to external services.**
Ja/Nej

**c. It should be possible to store data in the system externally from the server using Cifs or NFS.**
Ja/Nej

**d. The system should support monitoring using the Microsoft System Center Operation Manager.**
Ja/Nej

**e. The system should support that antivirus software can scan server and client operating system environments and file uploads and downloads.**
Ja/Nej

**f. The system should support antivirus software Symantec Endpoint Protection.**
Ja/Nej

**g. The system should support the clock synchronization protocols NT5DS or NTP.**
Ja/Nej

**h. The system should support proxy usage when communicating with the internet.**
Ja/Nej

**i. The system should not use hardware protection locks.**
Ja/Nej

**j. The system should not use MAC address lock for software.**
Ja/Nej

### 1.7.11.4 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 Server or Linux.**
Ja/Nej

**b. If Linux - the system should be able to run on an open source distribution without licensing cost.**
Ja/Nej

**c. System dependencies to the operating system must support the OS supplier's life cycle.**
Ja/Nej

### 1.7.11.5 Confidentiality

**a. The system should be able to create roles with different configurable permissions in the system.**
Ja/Nej

**b. The system should not have any limitation regarding the number of roles that can be created.**
Ja/Nej

**c. Access to essential functions in the system should be possible to control with permissions.**
Ja/Nej

**d. Access to the system logs and logging services should be controlled using permissions.**
Ja/Nej

**e. The system should support federated authentication using the SAML 2.0 standard.**
Ja/Nej

**f. The system should support authorization using the SAML 2.0 standard.**
Ja/Nej

**g. The system should support authorization using the Oauth 2.0 standard with identity layer OpenID Connect.**
Ja/Nej

**h. User interaction with essential system functions should be possible to track with non-repudiation methods.**
Ja/Nej

**i. The system should support using a SIEM system for logging.**
Ja/Nej

**j. The system should be able to log all logins.**
Ja/Nej

**k. The system should log all errors and deviations.**
Ja/Nej

### 1.7.11.6 Requirements for Web based Client software (Section only applicable to web based software)

**a. The user interface must be web-based.**
Ja/Nej

**b. The user interface must support Microsoft Edge.**
Ja/Nej

**c. The user interface must support Google Chrome.**
Ja/Nej

**d. The user interface should support Mozilla Firefox.**
Ja/Nej

**e. The user interface should support Safari.**
Ja/Nej

**f. The user interface should not depend on plugins in the browser.**
Ja/Nej

**g. If plugins are needed in the browser, describe which plugins.**
Fritext

**h. All plugins for browsers must follow the life cycle of the browser and plugin suppliers.**

Ja/Nej

**i. The web application should be responsive to the end users' bowser capabilities and screen size.**

Ja/Nej

**j. The web application dependencies must follow the life cycle of the browser suppliers that you have responded to as supported above.**

Ja/Nej

### 1.7.11.7 Requirements for client software locally installed. (Section not applicable for purely web based services)

**a. Client applications not already web based, should have a development plan for web-based technology.**

Ja/Nej

**b. If multicast is needed - describe the possibilities of configuring the addressing of multicast.**

Fritext

**c. The system must be able to communicate with Region Östergötland's network via the TCP / IP, IPv4 network protocol.**

Ja/Nej

**d. The system should be able to communicate with Region Östergötland's network via the TCP / IP, IPv6 network protocol.**

Ja/Nej

**e. Describe network ports and protocols used for communication to and from the system.**

Fritext

**f. Attach a system description showing parts and APIs and protocols used between network nodes.**

Bifogad fil

### 1.7.11.8 Documentation

**a. State whether course or online training material is available for education of system administrators, and describe the content of it.**

Fritext

**b. State whether course or online training material is available for education of system technicians, and describe the content of it.**

Fritext

**c. State whether course or online training material is available for education of system users, and describe the content of it.**

Fritext

**d. System administration documentation for the system must be available and up to date.**

Ja/Nej

**e. Technical documentation for the system must be available and up to date.**

Ja/Nej

**f. User documentation for the system must be available and up to date.**

Ja/Nej

## 1.8 Area 2, Development and content maintenance Tools

### 1.8.1 Versions of openEHR required for all form and AQL tools

**a. When authoring or displaying forms and queries 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 packages:**

*** EHR**

*** Common**

*** Data Structures**

*** Data Types**

*** Support**

*** Integration**

Ja/Nej

**b. When authoring or displaying forms and queries referring to or otherwise involving content from the openEHR Terminology (TERM) Specification, the tools must support version 2.1.0 or higher of the Terminology (TERM) Specification.**

Ja/Nej

**c. Describe which versions of the openEHR RM and TERM Specifications the tools and components support. If not up to date, briefly describe the upgrade strategy and timeline.**

Fritext

**d. Evaluation of question c)**

**Not being up to date and poor update strategy reduce points.**

Linjär skala. 0 - 3 Points

**e. When authoring or displaying forms and queries the tools should support version 1.0.0 or higher of the openEHR Task Planning (TP) Specification.**

Ja/Nej

**f. Describe which version of the openEHR Task Planning Specification and any other specifications from the openEHR Process Model (PROC) Component that are currently supported. Also outline the planned upgrade strategy and timeline.**

Fritext

**g. Evaluation of question f)**

**Not being up to date and poor update strategy reduce points.**

Linjär skala. 0 - 3 Points

## 1.8.2 Authoring environment

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).

**a. The authoring environment must support automatic or semiautomatic generation of data entry forms from openEHR templates.**

Ja/Nej

**b. Automatically or semi-automatically generated forms and form parts/components must be possible to modify manually in the authoring environment.**

Ja/Nej

**c. The authoring environment should include possibilities to easily preview forms, and during such preview support template based validation of example EHR data based on the openEHR models.**

Ja/Nej

**d. A form preview function in the authoring environment should be able to commit valid data into an openEHR repository via openEHR standard REST APIs into an EHR selected by the user (U2-U5), for example the EHR of a test patient.**

Ja/Nej

**e. The authoring environment must support basic formatting possibilities like headings, style, layout and also different widget types for multiple choice fields, such as drop down menus, check boxes, radio buttons, single and multiple choice lists.**

Ja/Nej

**f. Describe the above mentioned formatting functions and widgets, plus which other than the mentioned basic ones that the system supports. Also provide screenshots where suitable.**

Fritext

**g. Evaluation of question f)**

**Availability of many relevant functions and widgets with good usability increase points**

Linjär skala. 0 - 3 Points

**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.**
**Example: In the "Pulse" archetype, if "Regularity" is set to "irregular" then show the "Irregular type" choices.**

Ja/Nej

**i. 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 & U4)**

Fritext

**j. Evaluation of question i)**

**Availability of both good low/no-code editing options and the option of powerful coding/programming control is needed for maximum points.**

Linjär skala. 0 - 3 Points

**k. The authoring environment and renderer must support scripting with calculations (e.g. for risk scores like NEWS2) where the result can be automatically entered e.g. in a summary field in the template**

Ja/Nej

**l. Describe how scripting with calculations can be done, including form-internal formulae or external (e.g. GDL-based client or server side) calculations.**

Fritext

**m. Evaluation of question l)**

**Availability of many relevant possibilities with good usability increase points**

Linjär skala. 0 - 3 Points

**n. The authoring environment and end user (U6) facing rendered forms must support terminology content browsing, lookup, filtering and selection.**

Ja/Nej

**o. Describe the terminology content browsing, lookup, filtering and selection functions available. Also describe included or compatible terminology server/services.**

Fritext

**p. Evaluation of question o)**

**Powerful functions with good usability increase points.**

Linjär skala. 0 - 3 Points

**q. Describe the dependency tracking and dependency management provided by the authoring environment. For example available tracking of in what forms a certain version of an archetype, template or terminology item/code is used.**

Fritext

**r. Evaluation of question q)**

**High coverage of different kinds of dependencies and useful views presenting them increase points.**

Linjär skala. 0 - 3 Points

**s. It must be possible to enter a value once in a form in a user interface, and then automatically record that value in more than one place in the template(s) the form is based on.**

**Example: Enter a value for "Inspired oxygen" in the form once, but record the value in both the "Respiration" and the "Pulse oximetry" observations (in e.g. a vital signs template) when stored.**

Ja/Nej

**t. Describe if and how the authoring environment and renderer supports the use of images and illustrations to enter structured information.**

**Example: Point out the location of an injury on a body image when selecting "Body site" in the "Problem/Diagnosis" archetype.**

Fritext

**u. Evaluation of question t)**

**Availability of relevant possibilities with good usability increase points**

Linjär skala. 0 - 3 Points

**v. The authoring environment and renderer should have multilingual support so that it is possible to switch the template-based parts of an authored GUI/form between all languages supported by the template.**

Ja/Nej

**w. The authoring environment and renderer should have multilingual support so that it is possible to switch terminology languages in the terminology support function.**

Ja/Nej

**x. The authoring environment itself should have a multilingual GUI support so that all can essential components/tools can be easily localized to Swedish.**

Ja/Nej

**y. The authoring environment and renderer (or other included components) should support development of forms/components that at runtime can import data from an end users' (U6) sensors into forms.**

**Example: Reading of a patient's pulse oximetry and blood pressure devices via Web Bluetooth API in browsers**

Ja/Nej

**z. Describe if and to what extent the authoring environment and renderer supports formattin free text fields in forms, and describe available formatting widgets like WYSIWYG editors etc Briefly describe if and how the rules and options described in https://specifications.openehr.org/releases/RM/latest/data_types.html#_formatting_and_hyper are enforced.**

Fritext

**aa. Evaluation of question z)**

**Availability of relevant possibilities with good usability increase points. Enforcement of the markdown rules from the specification is required for maximum points.**

Linjär skala. 0 - 3 Points

**ab. Describe if and how the authoring environment and renderer support development of applications that let the end user (U6) upload and include image/multimedia content in forms and submit as EHR content. Also describe any possible support for storing such content in VNA/PACS with links (and possibly thumbnails) in openEHR CDR/platforms.**

Fritext

**ac. Evaluation of question ab)**

**Availability of relevant possibilities with good usability increase points. Good integration possibilities with VNA/PACS is required for maximum points.**

Linjär skala. 0 - 3 Points

**ad. The authoring environment must support both the OPT and OPT2 (operational template) formats or include (or refer to) a conversion service, without additional cost, that makes it possible to use both.**

Ja/Nej

**ae. The authoring environment and renderer should internally support AOM2/ADL2 based formats like OPT2.**

Ja/Nej

**af. The authoring environment and renderer should support building applications using openEHR task planning.**

Ja/Nej

**ag. Describe which version of the openEHR Task Planning Specification and any other specifications from the openEHR Process Model (PROC) Component that are currently supported. The planned upgrade strategy and timeline must also be outlined.**

Fritext

**ah. Evaluation of question ag)**

**Not being up to date and poor update strategy reduce points.**

Linjär skala. 0 - 3 Points

**ai. The authoring environment should support easy retrieval and storage of assets (archetypes, templates, forms etc.) in some commonly used openly specified version control systems (e.g. GIT-based ones) or asset management systems.**

Ja/Nej

**aj. Attach documentation specifying how to construct and add customer created components and widgets. The authoring environment and form renderer should support addition of customer created widgets for certain parts of openEHR templates, based on e.g. openEHR datatypes and template annotations. This should be done in a way that treats customer created widgets in a way similar to the widgets originally provided by the authoring environment.**

Bifogad fil

**ak. Evaluation of question aj)**

**Availability of well documented relevant possibilities with good usability increase points. To achieve maximum points the component interface specification should be openly published for free unrestricted use by anybody, and ideally based on open standards like JavaScript ES6 modules.**

Linjär skala. 0 - 3 Points

**al. The authoring environment and renderer should support using AQL calls at runtime to pre-populate (author selectable) form fields.**

Ja/Nej

**am. 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 in order to fetch data from other sources.**

Ja/Nej

### 1.8.3 Rendering and usage of authored forms/components

**a. The publishing process and form handling must be semi-automated so that forms updated or created in the form authoring environment can be validated and tested and then published and launched also by non-programmers (U1, U2, U3 and U5) so that they then are automatically rendered in end-user (U6) applications.**

Ja/Nej

**b. The authoring environment or form renderer must support development of and usage of openEHR template-based UI forms in other web based (HTML5+JS+CSS) clients.**

Ja/Nej

**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 https://developer.mozilla.org/en-US/docs/Web/JavaScript/Guide/Modules)**

Ja/Nej

**d. The form renderer should support development of and usage of openEHR template-based UI forms in Android based clients.**

Ja/Nej

**e. The form renderer should support development of and usage of openEHR template-based UI forms in iOS based clients.**

Ja/Nej

**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.**

Ja/Nej

**g. When the end-user (U6) enters data, the form renderer (or well-integrated supporting services and components) must validate the data based on constraints in the corresponding openEHR templates.**

Ja/Nej

**h. When the end-user (U6) enters data, it should be possible to validate a majority of the archetype-/template-based data in client-side code without calling a server.**

Ja/Nej

**i. If a template supports multiple natural languages, the form renderer should support rendering the corresponding form in multiple natural languages too.**

Ja/Nej

**j. The form renderer should support the use of CSS and other relevant configuration options for customer branding purposes.**

Ja/Nej

**k. State to what extent the form authoring and rendering tools support rendering of forms in a way that complies with the subset of the Web Content Accessibility Guidelines (WCAG) 2.1 that is specified in chapter 6 Evaluation criteria. If the specified subset or a part of it is not supported, the upgrade strategy must be described.**

Bifogad fil

**l. The rendered forms and supporting components, must admit submission of data (entered by U6) to openEHR-compliant CDRs (back-end platforms) through an openEHRs standard REST interfaces. This must have been successfully tested with at least two independent CDR products, commercially or openly available.**

Ja/Nej

**m. Describe which openEHR-compliant CDR products the authoring environment and renderer have been tested with. Also describe how the tests were performed and the results.**

Bifogad fil

**n. Evaluation of question m)**

**Credible, transparent tests with correct results increase points. Tests with more CDR products increase points.**

Linjär skala. 0 - 3 Points

**o. 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)**

**To make this possible it is important that you or your partners have experience of such CE-labelling and quality control processes.**

**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.)**

Bifogad fil

**p. Evaluation of question o))**

**Proven MDR and MDD experience, offered support and transparency increase points.**

Linjär skala. 0 - 3 Points

### 1.8.4 Usability evaluation of form authoring and rendering, part 1

**a. 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:**

*** Happiness**

*** Task success**

**Details regarding the evaluation are found in chapter Evaluation criteria.**

Bifogad fil

**b. Evaluation of question a)**

**Region Östergötland evaluates and rewards 0-3 points per criterion Maximum total score: six (6)**

Linjär skala. 0 - 6 Points

**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.**

**Evaluation criteria:**

*** Happiness**

*** Task success**

**Details regarding the evaluation are found in chapter Evaluation criteria.**

Bifogad fil

**d. Evaluation of question c)**

**Region Östergötland evaluates and rewards 0-3 points per criterion Maximum total score: six (6)**

Linjär skala. 0 - 6 Points

**e. 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.**

**Evaluation criteria:**

*** Happiness**

*** Task success**

**Details regarding the evaluation are found in chapter Evaluation criteria.**

Bifogad fil

**f. Evaluation of question e)**

**Region Östergötland evaluates and rewards 0-3 points per criterion Maximum total score: six (6)**

Linjär skala. 0 - 6 Points

**g. 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.**

**Evaluation criteria:**

*** Happiness**

*** Task success**

**Details regarding the evaluation are found in chapter Evaluation criteria.**

Bifogad fil

**h. Evaluation of question g)**

**Region Östergötland evaluates and rewards 0-3 points per criterion Maximum total score: six (6)**

Linjär skala. 0 - 6 Points

**i. 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.**

**Evaluation criteria:**

*** Happiness**

*** Task success**

**Details regarding the evaluation are found in chapter Evaluation criteria.**

Bifogad fil

**j. Evaluation of question i)**

**Region Östergötland evaluates and rewards 0-3 points per criterion Maximum total score: six (6)**

Linjär skala. 0 - 6 Points

**k. 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.**

**Evaluation criteria:**

*** Happiness**

*** Task success**

**Details regarding the evaluation are found in chapter Evaluation criteria.**

Bifogad fil

**l. Evaluation of question k)**

**Region Östergötland evaluates and rewards 0-3 points per criterion Maximum total score: six (6)**

Linjär skala. 0 - 6 Points

## 1.8.5 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.**

Bifogad fil

**b. User manuals must be available before the evaluation. Attach information about how to download or access the user manuals.**

Bifogad fil

**c. Training (attached video or similar) covering the basics of the system should be provided before the evaluation. Maximum length of video is 40 minutes. Attach information about how to download or access the training material.**

Bifogad fil

**d. Representatives for user roles U1, U2, U3, U4, U5, and U6 will perform tests for the usability evaluation part 2.**

**Evaluation criteria:**

*** Happiness**

*** Task success**

**Details regarding the evaluation are found in chapter 6 Evaluation criteria.**

Linjär skala. 0 - 36 Points

**e. Region Östergötland will perform tests of openEHR standard conformity of data entered in forms and sent from the renderer through the openEHR REST APIs to a CDR or CDR test-stub. The content of these tests will not be published ahead of test sessions.**

Bifogad fil

**g. Evaluation of question e)**

**Incorrect results reduce points.**

Linjär skala. 0 - 3 Points

### 1.8.6 AQL tools

**a. The tool must support authoring of AQL queries according to the openEHR "Archetype Query Language (AQL)" specification, release 1.0.0 or later.**

Ja/Nej

**b. The tool should support sending AQL queries to a CDR and processing/displaying responses of both ad-hoc and stored AQL queries, through APIs according to the openEHR REST API specifications, release 1.0.0 or later.**

Ja/Nej

**c. The tool should support storage and listing of stored queries via openEHRs REST "Definitions API" Specification.**

Ja/Nej

**d. Describe which versions of the openEHR Archetype Query Language (AQL), openEHR REST "Query" and "Definitions" API specifications the tool supports. If not up to date, the planned upgrade strategy and timeline must also be outlined.**

Fritext

**e. Evaluation of question d)**

**Not being up to date and poor update strategy reduce points.**

Linjär skala. 0 - 3 Points

**f. The tool user interface should support storage, reuse and modification of previously used queries.**

Ja/Nej

**g. The query authoring tool should highlight or prevent syntax errors in AQL queries.**

Ja/Nej

**h. Describe available low-/no-code functionality (such as drag-and-drop GUI) to create queries from (query author selectable) openEHR archetypes, templates and reference model objects and attributes. Also provide screenshots where suitable.**

Bifogad fil

**i. Evaluation of question h)**

**Availability of relevant functions and widgets with good usability increase point**

Linjär skala. 0 - 3 Points

**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.**

**Example use case: Query patient data using the hierarchical structure of SNOMED CT:**

**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.**

Bifogad fil

**k. Evaluation of question j)**

**Availability of relevant functions with good usability increase points.**

Linjär skala. 0 - 3 Points

**l. Describe any dependency tracking and dependency management provided by the query tool and included supporting components. For example, available tracking of in what stored queries a certain version of an archetype, template or terminology item/code is used. Also describe any features for naming stored queries, sorting and tagging/metainfo, grouping by user or role.**

Fritext

**m. Evaluation of question l)**

**High coverage of different kinds of dependencies and useful views presenting them increase points.**

Linjär skala. 0 - 3 Points

**n. Describe available list- and reporting user interface features showing results from executing openEHR queries. Also provide screenshots where suitable. For example, features useful for data exploration in clinical follow-up and research.**

Bifogad fil

**o. Evaluation of question n)**

**Availability of relevant functions and widgets with good usability increase points.**

Linjär skala. 0 - 3 Points

## 1.8.7 Usability evaluation of AQL tools, part 1

**a. 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 Attache document responses.**

**Evaluation criteria:**
*** Happiness**
*** Task success**

**Details and instructions about the evaluation are found in chapter "Evaluation criteria".**

Bifogad fil

**b. Evaluation of question a)**

**Region Östergötland evaluates and rewards 0-3 points per criterion Maximum total score: six (6)**

Linjär skala. 0 - 6 Points

**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.**

**Evaluation criteria:**

*** Happiness**

*** Task success**

**Details and instructions about the evaluation are found in chapter "Evaluation criteria".**

Bifogad fil

**d. Evaluation of question c)**

**Region Östergötland evaluates and rewards 0-3 points per criterion Maximum total score: six (6)**

Linjär skala. 0 - 6 Points

**e. 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.**

**Evaluation criteria:**

*** Happiness**

*** Task success**

**Details and instructions about the evaluation are found in chapter "Evaluation criteria".**

Bifogad fil

**f. Evaluation of question e)**

**Region Östergötland evaluates and rewards 0-3 points per criterion Maximum total score: six (6)**

Linjär skala. 0 - 6 Points

**g. 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.**

**Evaluation criteria:**

*** Happiness**

*** Task success**

**Details and instructions about the evaluation are found in chapter "Evaluation criteria".**

Bifogad fil

**h. Evaluation of question g)**

**Region Östergötland evaluates and rewards 0-3 points per criterion Maximum total score: six (6)**

Linjär skala. 0 - 6 Points

## 1.8.8 Usability evaluation and openEHR compliance of AQL tools , part two (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 AQL authoring and execution tools, or information about how to access a remote installation of them.**

Bifogad fil

**b. User manuals must be available before the evaluation. Attach information about how to download or access the user manuals.**

Bifogad fil

**c. Training (attached video or similar) covering the basics of the system should be provided before the evaluation. Maximum length of video is 40 minutes. Attach information about how to download or access the training material.**

Bifogad fil

**d. Representatives for user roles U1, U2, U3, and U4 will perform tests for the usability evaluation part 2.**
**Evaluation criteria:**

*** Happiness**

*** Task success**

**Details regarding the evaluation are found in chapter "Evaluation criteria".**

Linjär skala. 0 - 24 Points

**e. Region Östergötland will perform tests of openEHR standard conformity of queries authored in and stored/executed by the AQL tool through the openEHR REST APIs to a CDR or CDR test-stub. The content of these tests will not be published ahead of test sessions.**

Bifogad fil

**f. Evaluation of question e)**

**Incorrect results reduce points.**

Linjär skala. 0 - 3 Ponts

## 1.8.9 General IT-Requirements for Area 2 (Form authoring and rendering + AQL

**tools)**

### 1.8.9.1 Requirements relating to message transfer to and from the system and the Region's API Gateway and API management

**a. Available REST API:s should be described using the OpenAPI specification.**
Ja/Nej

**b. The system should support the OAuth 2.0 Client Credential Flow for authorization and delegation.**
Ja/Nej

**c. The system should support a signed JSON Web Token for authorization and delegation.**
Ja/Nej

**d. The system should support basic authentication for authorization and delegation.**
Ja/Nej

### 1.8.9.2 Usability & branding

**Applications facing the end user (U6) should be possible to configure and brand with the Region Östergötland brand and styles.**
Ja/Nej

### 1.8.9.3 Infrastructure requirements for "on prem" products. (Section not applicable for pure cloud services.)

**a. The servers must support virtualization with support for at least Vmware vSphere.**
Ja/Nej

**b. The servers must use DNS for name lookup, thus not rely on fixed IP-addresses to external services.**
Ja/Nej

**c. It should be possible to store data in the system externally from the server using Cifs or NFS.**
Ja/Nej

**d. The system should support monitoring using the Microsoft System Center Operation Manager.**
Ja/Nej

**e. The system should support that antivirus software can scan server and client operating system environments and file uploads and downloads.**
Ja/Nej

**f. The system should support antivirus software Symantec Endpoint Protection.**
Ja/Nej

**g. The system should support the clock synchronization protocols NT5DS or NTP.**
Ja/Nej

**h. The system should support proxy usage when communicating with the internet.**
Ja/Nej

**i. The system should not use hardware protection locks.**
Ja/Nej

**j. The system should not use MAC address lock for software.**
Ja/Nej

### 1.8.9.4 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 Server or Linux.**
Ja/Nej

**b. If Linux - the system should be able to run on an open source distribution without licensing cost.**
Ja/Nej

**c. System dependencies to the operating system must support the OS supplier's life cycle.**
Ja/Nej

### 1.8.9.5 Confidentiality

**a. The system should be able to create roles with different configurable permissions in the system.**
Ja/Nej

**b. The system should not have any limitation regarding the number of roles that can be created.**
Ja/Nej

**c. Access to essential functions in the system should be possible to control with permissions.**
Ja/Nej

**d. Access to the system logs and logging services should be controlled using permissions.**
Ja/Nej

**e. The system should support federated authentication using the SAML 2.0 standard.**
Ja/Nej

**f. The system should support authorization using the SAML 2.0 standard.**
Ja/Nej

**g. The system should support authorization using the Oauth 2.0 standard with identity layer OpenID Connect.**
Ja/Nej

**h. User interaction with essential system functions should be possible to track with non-repudiation methods.**
Ja/Nej

**i. The system should support using a SIEM system for logging.**
Ja/Nej

**j. The system should be able to log all logins.**
Ja/Nej

**k. The system should log all errors and deviations.**
Ja/Nej

### 1.8.9.6 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 rest of this section)**
Ja/Nej

**b. The user interface must support Microsoft Edge.**
Ja/Nej

**c. The user interface must support Google Chrome.**
Ja/Nej

**d. The user interface should support Mozilla Firefox.**
Ja/Nej

**e. The user interface should support Safari.**
Ja/Nej

**f. The user interface should not depend on plugins in the browser.**
Ja/Nej

**g. If plugins are needed in the browser, describe which plugins.**
Ja/Nej

**h. All plugins for browsers must follow the life cycle of the browser and plugin suppliers.**
Ja/Nej

**i. The web application should be responsive to the end users' bowser capabilities and screen size.**
Ja/Nej

**j. The web application dependencies must follow the life cycle of the browser suppliers that you have responded to as supported above.**
Ja/Nej

### 1.8.9.7 Requirements for client software locally installed. (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.**
Ja/Nej

**b. Describe the aplication's recomended distribution method.**
Fritext

**c. Does the system require frameworks or language runtime systems/environments like .NET or Java?**
Ja/Nej

**d. If yes what versions of .NET, Java or other frameworks and runtime systems?**
Fritext

**e. All dependencies on reqiured frameworks or language runtime systems/environments such as .NET or Java should follow corresponding official version support lifecycles.**

Ja/Nej

**f. All dependencies on reqiured frameworks or language runtime systems/environments should be able to run on an open source distribution without licensing cost.**

Ja/Nej

**g. Client applications must be compatible with Windows 10 Enterprise (64-bit).**

Ja/Nej

**h. Client applications must continously support the releases of Windows 10 that are in the "Semi-Annual Channel" during the period they are supported.**

Ja/Nej

**i. Describe the client minimum hardware and performance requirements.**

Fritext

**j. The client software installation must avoid modifying exisiting system files of the operating system.**

Ja/Nej

**k. The software should not require registration by end users or require hardware locks.**

Ja/Nej

**l. The system must support proxy when communicating with the internet.**

Ja/Nej

**m. Client applications not already web based, should have a development plan for web-based technology.**

Ja/Nej

**n. If multicast is needed - describe the possibilities of configuring the addressing of multicast.**

Fritext

**o. The system must be able to communicate with Region Östergötland's network via the TCP / IP, IPv4 network protocol.**

Ja/Nej

**p. The system should be able to communicate with Region Östergötland's network via the TCP / IP, IPv6 network protocol.**

Ja/Nej

**q. Describe network ports and protocols used for communication to and from the system.**

Fritext

**r. Attach a system description showing parts and APIs and protocols used between network nodes.**

Bifogad fil

### 1.8.9.8 Documentation

**a. State whether course or online training material is available for education of system administrators, and describe the content of it.**

Fritext

**b. State whether course or online training material is available for education of system technicians, and describe the content of it.**

Fritext

**c. State whether course or online training material is available for education of system users, and describe the content of it.**

Fritext

**d. System administration documentation for the system must be available and up to date.**

Ja/Nej

**e. Technical documentation for the system must be available and up to date.**

Ja/Nej

**f. User documentation for the system must be available and up to date.**

Ja/Nej