

Tender
5/9/2023

Procuring organization

Region Östergötland
Bernadett Brink

Procurement

RFI, Request for Information of openEHR
platforms and related tools
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Legend

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------|
|  The text is included in the advert |  The text is included in the qualification |
|  The text will be part of the contract |  The text will be published in the contract catalogue |
|  The text/question contains requirements to be met |  The text/question contains ESPD requirements |
|  The question is weighted and included in the evaluation |  The question is weighted and included in the evaluation |
|  The question is asked for information only |  The question is answered by the buyer |
|  The question is marked for special follow-up |  The answer does not meet the requirement in the question |
|  Updated section or question | |

Tenderers

Supplier	Tender	Corporate ID	Qual.
Dedalus Sweden AB	Dedalus responds to RFI of openEHR platforms and related tools	5592629629	

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1. Invitation to openEHR RFI and demo

1.1 Invitation to openEHR RFI and demo

Sydöstra sjukvårdsregionen (including Region Östergötland, Region Kalmar län and Region Jönköpings län), Västra Götalandsregionen, Region Uppsala, Region Stockholm, and Region Skåne hereby invites suppliers of openEHR platforms and related tools (in this document called “Solution”) to a request for information and a product demonstration.

1.1.1 RFI process

This RFI process is divided into two (2) parts:

- The first part is open for all suppliers of openEHR solutions and consists of questions to be answered in written format, plus an appendix for context.
- The second part consists of an online product demonstration and is subject to specific qualification criteria. See Part 2: Demonstration sessions for details.

1.1.2 Date and time for demonstration sessions

The following time slots are available:

Date	Time (CEST/UTC+2)			
May 31	8:00-10:00 AM	10:00-12:00 AM	1:00-3:00 PM	3:00-5:00 PM
June 1	8:00-10:00 AM	10:00-12:00 AM	1:00-3:00 PM	3:00-5:00 PM
June 2	8:00-10:00 AM	10:00-12:00 AM	1:00-3:00 PM	3:00-5:00 PM

June 5 is reserved as an extra date for back-up purposes.

State which is your company’s preferred demo time slot, and also state all other time slots being acceptable alternatives.



Text field

May 31st 10:00-12:00 AM or 1:00-3:00 PM, 3.00-5.00 could also be possible

1.1.3 Terms and definitions

Solution	The openEHR platform, related tools, and supporting applications that the RFI respondent can offer
RFI respondent	The part responding to the RFI
RFI document	This document

Application	A CDR external application integrated with the CDR, as part of - or not part of - the Solution.
CDR	Clinical Data Repository implementing the openEHR specifications
We	The group of county councils issuing the RFI document
Request Context	All request metadata on the incoming HTTP request such as methods, headers, access tokens etc
Personal Data	The term "personal data" is used throughout this document to describe every piece of information related to a specific patient kept by a healthcare organization.

1.1.4 No procurement

This is not a procurement. Please note that this does not constitute an RFP. Response to this invi

However, this is not bound to accept any of such information and/or expression of interest or to consider it further in any associated documents such as a RFP.

1.1.5 Confidentiality

During the RFI process, confidentiality prevails according to Chapter 19, Section 3 of the Public and Confidentiality Act (2009: 400).

Upon completion of the RFI, continued confidentiality may apply if there is reason to fear that a disclosure of information concerning the individual's business and operating conditions could cause harm to the individual. Furthermore, continued confidentiality may apply for the protection of the public interest.

When appealing decisions on confidentiality of information, RFI respondent shall assist the county councils and be responsible for their own costs arising from this.

In the event that the RFI respondent requests confidentiality, the RFI respondent must enclose documents describing the scope of the confidentiality and describe what damage the RFI respondent may suffer in the event of a publication. If the RFI respondent requests confidentiality, the RFI respondent must enclose a document specifying the parts of the RFI document for which the RFI respondent requests confidentiality and describe the damage the RFI respondent may suffer in the event of a publication.

a. Is privacy requested?

Yes/No



Answer

No

b. In those cases that the RFI respondent requests confidentiality, the RFI respondent must here attach what the privacy includes and describe which damage the bidder will suffer upon publication.

Attachment





1.1.6 Questions about the request for information

All questions regarding the RFI must be asked via the VISMA TendSign RFI system, www.tendsign.com.

The wishes to receive questions in such a way that, together with the county councils answer, they can be published without taking measures. The questions should therefore not contain information about the questioner's company, products or other information that can identify the questionnaire.

The county councils want the RFI respondent to ask questions one at a time with reference to the point in the RFI document to which the question relates.

The county councils answer the questions electronically in VISMA TendSign.

1.2 About this RFI

Region Östergötland, Västra Götalandsregionen, Region Uppsala, Region Stockholm, Region Skåne, and Region Kalmar (collectively referred to as "we" and "us" in this document) cover two thirds (⅔) of Sweden's population. The majority of the county councils manage university hospitals with an extensive share of research and advanced healthcare. This RFI initiates the way forward, towards better healthcare and documentation solutions in Sweden.

This RFI aims at reaching all suppliers of openEHR solutions with an interest in the European market, in order to get an update on the latest news within the field. Doing this as a joint activity ensures higher quality results and is also timesaving for all parties.

The RFI may result in one or several procurements, either by each county council separately or by two or more county councils together. No decisions regarding possible joint procurements are taken yet and more county councils and organizations than these 5 may initiate procurements based on this RFI. Also note that all suppliers are welcome to take part in later coming procurements. There is no obligation to participate in the RFI and demo sessions, and participation does not affect later evaluation.

1.2.1 Facts about the County councils

The table shows some facts in figures about the county councils.

	Inhabitants <small>(Total Swedish population is 10,5 million)</small>	Hospitals	Health clinics	Dental care clinics	National specialized medical care assignments <small>(46 different ones available)</small>	Current main EHR system
Region Stockholm	2 440 027	5 (N/A)	Appr 600 (appr 1900)	Appr 80 (N/A)	36	CGM TakeCare
Region Uppsala	400 682	2 (3)	36 (58)	25 (80)	14	Cambio Cosmic
Region Östergötland	471 912	3 (3)	33 (47)	33 (109)	6	Cambio Cosmic

Region Skåne	1 414 324	9 (10)	100 (182)	69 (69)	25	Cerner Millenium
Västra Götalandsregionen	1 758 656	18 ()	117 ()	167 ()	29	Cerner Millenium
Region Kalmar län	247 711	3 (3)	26 (37)	18 (31)	N/A	Cambio Cosmic
Region Jönköpings län	369 184	3 (3)	28 (40)	26 (86)	N/A	Cambio Cosmic
Sum	7 102 496					

Population 2022 according to <https://www.statistikdatabasen.scb.se/>

National specialized medical care according to <https://www.socialstyrelsen.se/en/clinical-practise-guidelines-and-regulations/regulations-and-guidelines/national-specialised-medical-care/>. Numbers within parenthesis () include collaborating private clinics etc.

1.2.2 Business impact goals

Three business impact goals of introducing openEHR-based healthcare systems are:

- Faster adaptation of IT systems to the constantly changing needs of the healthcare clinicians, including a more efficient system development process
- Increased control of stored health record data and increased reuse of information structures within and between applications, and between caregivers
- Increased freedom of action for the regions when the data is stored in a vendor neutral and open format

1.2.3 Purpose

The Swedish county councils are in the process of establishing an infrastructure for information management and information governance based on an information strategy and its target architecture. A key component of this infrastructure is to be able to store healthcare related information in a standardized and application neutral way.

The interoperability solution is an addition to existing healthcare information systems. A subset of the patients' medical records must be possible to handle in the CDR component both as master record as well as copies. We need a standardized reference model for how the information and data is structured and implemented in the CDR. Each application that renders information should have the ability to select, and customize its information stored in the CDR, in accordance with the reference model.

An example where this CDR capability would be relevant, is when an independent health app is used, but is not part of the main healthcare information system. In the long term, the CDR component will also be used for other applications of healthcare related information. Another early application will be remote/home monitoring.

Other secondary uses of interest are: patient created data, biobank data, healthcare business development, BI, AI, CDR, research, and quality registries.

2. Part 1: Questions

2.1 Questions

Answer the questions in this section in writing. Answer the questions that are relevant to your Solution. Not all questions in this RFI need to be answered, but the majority needs to be answered in order for you to be invited to the demonstration.

The supplier must enter all answers in the system.

The supplier may not attach documents.

2.1.1 General

a. What is the name and intended purpose of your Solution? Please name and (very briefly) describe the openEHR-related tools and platform components that you may be referring to in other parts of your RFI response.



Text field

We offer in partnership with Vita Group the HIP CDR, a comprehensive platform around the openEHR standard with a strong emphasis on vendor-neutrality and open source distributions. A vendor neutral open health platforms based on open source components in order to minimize dependency for the user from certain vendors of the CDR platform itself. The HIP CDR is fully based on an open source maintained distribution called EHRbase. EHRbase itself is supported and maintained from vitagroup and other supporters. This distribution is maintained and continuously developed under a GPL2 Apache license (open core license). HIP CDR is based on modern cloud-technologies and includes advanced scalability and multi-tenancy functionalities. Components include a data integration engine for (bidirectional) mappings to and from openEHR via HL7 FHIR, HL7 v2, graphical user interfaces for system administration, a demographics storage based on FHIR, an ATNA logging repository and comprehensive tools for software development.

b. In which country is your company located? Are there any sales partners or support partners in Sweden or Swedish speaking staff? Can your Solution or parts of it, e.g. additional services or license packs, be delivered via existing national Swedish framework agreements (see <https://www.avropa.se/topplankar/In-English/>).



Text field

Dedalus is an international company with office in Sweden with Swedish speaking staff. Our partner Vita Group is located in Germany. When so applicable/appropriate we can deliver via such framework agreements

c. Describe the overall architecture of your Solution.



Text field

HIP CDR is based on a service-oriented architecture leveraging containerization via Kubernetes and OpenShift. Services are securely connected through a messaging queue (based on RabbitMQ, optionally Kafka). Through the architecture, HIP CDR is easily extensible by introducing new services.

d. Describe if/how openEHR's Task Planning functionality (or other process support) is supported by your Solution now, and your future roadmap for such support.



Text field

HIP CDR currently does not support Task Planning. Though, we have experience in integrating with BPMN-based processes. As Task Planning is still in an early level of maturity and we are continuously observing and evaluating the market in this regard.

e. Describe if/how the Solution supports development and use of clinical decision support (CDS), for example using openEHR's GDL or GDL2 specifications now, and your future roadmap for such support.



Text field

The HIP CDR does not implement GDL (2) itself, but can be integrated with an external GDL service. GDL is currently not on the roadmap as recent developments around openEHR Expression Language (EL) might provide an alternative approach with broader field of application.

2.1.2 Delivery models

a. List the delivery/deployment models you support, such as local installation (OnPrem) or cloud installation (for instance SaaS)?



Text field

The HIP CDR can be deployed on premises or in a cloud environment (like Azure, AWS). Only precondition is the availability of a sufficiently sized Kubernetes/OpenShift Cluster.

b. Describe, in the case of SaaS deployments, your subcontractor structure used to deliver the service. List any hyperscaler public cloud services used and the jurisdiction they operate in with relation to the EU/GDPR and transfer of personal data.



Text field

Dedalus can deliver SaaS, both in Sweden and in Germany. In the case of delivery from Sweden, the service is operated by Dedalus Sweden AB. In Sweden the physical data centre is rented by Dedalus, DC-classification is III or IV. The operations concerning the software and hardware is operated by Swedish speaking personnel for Swedish DC. For Dedalus fully owned data centers located in Frankfurt, Germany the software and hardware is operated by English speaking personnel. Normal operation includes needed redundance covered in DC-classification III/IV. From a legal standpoint the EU/GDPR requirements are fulfilled.

c. If you are dependent on third-party suppliers in your solution proposal, how do you package this with an overall responsibility regarding usability, licenses and support?



Text field

Regarding the full scope i.e. which third-party suppliers that could be considered depends on what precise solution will be procured/tendered. For a big portion of the information herein, our partner Vita Group is a third-party supplier of our solutions proposal. In general we aim to provide a joint package for a seamless solution back to back with (when applicable) our sub-suppliers/partners. For large scaled infrastructures, the HIP CDR is provided on a highly scalable infrastructure that includes high performance capabilities/provider for horizontal scaling needs based on PostgreSQL databases. Industry standard SLAs are offered, levels are set in dialogue with client needs in focus.

d. Can applications based on output from your products be published as open source? If so, are there any restrictions on usage? This implies e.g. that generated code, forms, configuration information etc. and exported runtime components should be perpetually allowed to be included in open source based systems and in associated, possibly public, versioning systems (like GitHub).



Text field

For most artifacts, this is possible. The only exception are the CDR Forms which are provided by a third party (Cambio) and require the availability of a form rendering library which is not under an open license. If forms are created based on third party libraries like Medblocks UI, these can be published under an open source license.

e. Describe how your product can be installed using containers and container orchestration tools such as Kubernetes.



Text field

HIP CDR is built on Kubernetes and is fully described using HELM charts. As an alternative, OpenShift can be used as well. Monitoring and alerting within the runtime environment of the HIP CDR are realized via standard tools of the respective Kubernetes environment. For this purpose, HIP CDR relies on Prometheus and Grafana, among others, as free software solutions.

f. Describe your approach to scaling your Solution. Describe known limitations, for instance regarding performance.



Text field

HIP CDR is built on a service-oriented architecture on Kubernetes/OpenShift, it can leverage various scaling functionalities. The number of containers can be scaled up and down depending on the actual demand. It also provides effective load balancing capabilities to optimize the distribution of the workload among container instances. It also ensures appropriate allocation of resources to applications.

On the database level, HIP CDR supports Postgres (and optionally derivatives like AWS Aurora, Google AlloyDB, EnterpriseDB, Azure Cosmos DB, Crunchy Data). For scenarios where horizontal scaling is required, HIP CDR can be combined with YugabyteDB (or equivalent).

YugabyteDB (or equivalent) constitutes a distributed SQL database (sometimes referred to as "NewSQL") and will be providing the following features:

- A standard SQL API for accessing and manipulating data and objects
- Automatic data distribution across nodes in a cluster
- Automatic data replication in a strongly consistent manner
- Distributed query execution so clients need not know about the underlying distribution of data
- Support for distributed ACID transactions
- Serve both scale-out RDBMS and internet-scale OLTP workloads with low query latency.

A particular strength is the support of multi-document transactions across multiple shards with high performance and low latency, which is required to properly implement the semantics of openEHR contributions, which concurrently handle operations on multiple documents and objects within a single transaction.

As for YugabyteDB, it is fully open-source under Apache 2 license and provides enterprise options for deployments on-premises and managed services in the various cloud environments. This gives the flexibility to operate within an organization's own infrastructure or through various providers.

g. Briefly describe your three (3) largest or most interesting customer installations based on an openEHR CDR. Also describe how long it took to go from purchase to operational system with real patient data and actual use.



Text field

Vita Group's open source implementation EHRbase and the commercial offering HIP CDR is used in numerous projects globally. We consider the three listed projects, below, to be the most interesting interesting ones from the perspective of this RFI:

1) Network University Medicine Routine Data Platform (NUM RDP): Commissioned by the German government, NUM RDP provides a centralized IT platform based on openEHR to integration research data on COVID-19 from all 35 German university hospitals. The solution provides a portal to allow research to define and query for patient cohorts and provide access to raw data. NUM Codex was developed and deployed within 8 months.

2) Marienhausgruppe Hospitals: Marienhausgruppe is a German holding consisting of 11 hospitals across 15 locations. They commissioned HIP CDR to establish a shared clinical data repository to allow seamless exchange and use of data between the hospitals and to strategically enhance their capabilities to innovate on their data. Preparation of the installation has started in April.

3) Catalunya Data Platform: The government of Catalunya commissioned an openEHR-based data platform to serve the approximately 8 million inhabitants of the region. vitagroup were chosen to deliver OpenEHR solutions for the platform using HIP CDR and especially EHRbase as one of its main components in co-operation with partner. Installation will likely start around July 2023.

h. Describe what kind of infrastructure your Solution requires from a customer. Also describe your normal implementation/deployment process.



Text field

If hosting on premises is considered, a professionally managed Kubernetes/OpenShift environment is key.

i. Describe your software lifecycle strategy and release cadence.



Text field

While HIP CDR is based on continuously deployment methods, we typically provide customers with updates once a quarter.

j. Describe your future roadmap. What major features are planned and when are they planned to be released?



Text field

2023: Full support of Attribute Based Access Control (ABAC), Advanced AQL Query Editor
2024: Graphical User Interface for CDR Bridge, openEHR Expression Language

2.1.3 Legal and regulatory aspects

Please refer to background information in appendix “OpenEHR – an Implementors Guideline related to Swedish laws and regulations in healthcare”. It also reflects our level of ambition, and discusses some different possible openEHR-based solutions. Please feel free to be inspired by this document; we also look forward to receiving alternative solutions and discussions. We refer to COMPOSITIONs below to make the text more readable but we are actually interested in corresponding behavior regarding all relevant VERSIONED_OBJECTs (for example FOLDERS).

2.1.3.1 Multi-tenancy, Federation and Metadata

a. Describe how the Solution can be configured to support multi-tenancy where clinical data for hundreds of organizations (care providers/care units) can be managed efficiently.



Text field

HIP CDR provides multi-tenancy capabilities across all services. The implementation is based on a combination of row-level security (RLS) and OAuth2/openID. Especially in combination with YugabyteDB (or equivalent) for horizontal scaling, the system can handle greater numbers of tenants without loss of performance.

b. Describe how the Solution can be configured in a fine-grained multi-tenant model (see Appendix A) so that a COMPOSITION and/or parts of a COMPOSITION within an EHR record can be attributed organizational ownership. Also describe how and where this metadata can be persisted.



Text field

Given the approach described in Appendix A, the multi-tenancy of HIP CDR needs to be complemented by extended capabilities on the Attribute Based Access Control. HIP CDR implements ABAC using XACML and enforces the policies on the database level for sufficient performance and granularity. This solution is currently under development. For persistence, XACML rules could be combined either with specific elements inside compositions or tags.

c. Describe how metadata about organizational ownership/multi-tenancy, and about source (e.g. originating/feeder-system), can be verified/validated against the Request Context and/or external attribute sources to make sure that the proposed metadata is valid and that the user has sufficient permissions to write/modify data for this unit.



Text field

Authentication and authorization in HIP CDR require the assertion of a token, containing information about the requestor, including role and affiliations. This information can be used by the policy decision point along with data extracted from further request parameters (e.g. the provided metadata in the request body or request parameters). Authentication and authorization in HIP CDR require the assertion of a token, containing information about the requestor, including role and affiliations. This information can be used by the policy decision point along with data extracted from further request parameters (e.g. the provided metadata in the request body or request parameters), compositions/versioned_objects already received in the EHR (and potentially other external attributes) to evaluate the rules.

2.1.3.2 Querying and Multi-tenancy

a. Describe how (see Appendix A) the Solution can be configured to filter a response from the EHR API resource endpoints based on metadata from the Request Context, external attribute source and/or metadata on the COMPOSITION itself (such as validated metadata for organizational ownership).



Text field

see answer above

b. Describe how (see Appendix A) the Solution can be configured to block or filter out parts of a RESULT_SET from the Query Execute API resource endpoints based on metadata from the Request Context, external attribute source and/or metadata on the COMPOSITION itself, such as validated metadata for organizational ownership. (Example of possible solution: Incoming ad-hoc queries and/or stored queries may be temporarily modified to support the filtering.)



Text field

The policy enforcement point of EHRbase will likely work directly on the database level. Hence, manipulation of requests and result sets is possible. However, there is a question if data should be removed "silently" or there should be a notification to the client. There is a potential patient safety concern if data is removed from result sets without further notice (for example psychiatric medication).

c. Describe if and how (a possibly extended set of) the openEHR Reference Model can be used to block or filter out parts of a RESULT_SET from the Query Execute API resource endpoints based on metadata from the Request Context, and/or external attribute sources. Describe at least support for using the following classes for blocking/filtering data



i. FOLDERS

ii. TAGsF

iii. EEDER_AUDIT

Text field

i. FOLDERS: openEHR Folders are fully support in HIP CDR, however querying of folders is not yet defined in the openEHR specifications. Hence, while Folders can potentially be used for access control, the exacts specifications will have to added to the standard to ensure interoperability

ii. TAGsF: Tags are currently not supported by HIP CDR, but could potentially be used as input for the policy decision point as they will be queryable via AQL. Analogue to folders, there should be an alignment in the AQL specifications.

iii. EEDER_AUDIT: Feeder_Audit are fully accessible via AQL and can potentially be used as input for the policy decision point

d. Describe how the Solution can be configured to block and/or allow requests to resource endpoints from the ITS-REST specification based on metadata from the Request Context and/or external attribute sources.



Text field

For securing the external HIP-CDR APIs, RBAC functionalities integrated in Keycloak are used. Policies, Scopes and Permissions are defined within Keycloak as Policy Access Points and stored in the Keycloak database. User / Clients are authenticated against Keycloak and retrieving oAuth tokens as authentication result. Basing on service endpoint and available oAuth token information the Policy Enforcement Points of the services requested RPT tokens from Keycloak (respectively the PDP) containing a list of allowed scopes for the given parameters.

2.1.3.3 Bulk Operations

a. Describe any tooling and/or APIs available for managing bulk operations on COMPOSITIONs. Describe how the target set of COMPOSITIONs (bundle/batch) can be defined from a result of an AQL query.



Text field

There is no such functionality to define a target set of bulk operations using AQL.

b. Describe any tooling and/or APIs available for managing bulk import operations of COMPOSITIONs. Describe how metadata on COMPOSITIONs are validated/verified.



Text field

HIP CDR provides a bulk loader for compositions. In this case, data is validated outside HIP CDR (using the validation capabilities of the openEHR SDK) to ensure only validated data is loaded into the database.

2.1.3.4 Audit Logging

a. Describe the set of triggers (instrumentation) the Solution can use for audit logging. What is logged and when?



Text field

Triggers that can be used for logging: Application Activity (DCM 110100)
Order Record (DCM 110109)
Patient Record (DCM 110110)
Procedure Record (DCM 110111)
Security Alert (DCM 110113)
User Authentication (DCM 110114)

b. Describe how the Solution can be configured to export audit logs and/or integrated to external SIEM systems. Also describe and/or list the supported technical interfaces.



Text field

IHE ATNA-compliant recording of audit events according to the IHE IT Infrastructure Specification (ITI TF-2a, Chapter 3.20 - ITI-20) (https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol2a.pdf) are a key feature of HIP CDR. The endpoint that receives logs can be configured for redirections to external systems. System administrators can access the logs using Kibana. Access is restricted to authorized users through OAuth2 authentication and the restriction and user roles in Keycloak.

2.1.3.5 Certification of products, tools and modules

a. Are any of your openEHR products, tools or modules certified (CE labeled) according to EU Medical Device Directive 93/42/EEC or the EU Medical Devices Regulation (MDR)? If yes, please state which product or module that fulfills which regulation.



Text field

HIP CDR itself is not a medical device. However, specific solutions built on HIP CDR can be certified according to MDR and CE.

b. Describe your experience of the process to CE label a software as a medical device?



Text field

Dedalus and Vitagroup are certified as a medical device manufacturer and develops according to the quality requirements prescribed for the development of medical devices. Due to the medical device hardware developed by the companies there are many years of experience in this area.

2.1.3.6 Accessibility

Describe how the Solution supports (or helps creating) end user interfaces in accordance with the European accessibility directive European accessibility act - Employment, Social Affairs & Inclusion - European Commission (europa.eu).



Text field

As a data backend, the HIP CDR is use case agnostic. This means that the CDR does not necessarily provide user interfaces. With a central, interoperable database, applications from other manufacturers can be connected very easily and benefit from the CDR. These applications can then be designed according to the specifications of the European accessibility act. The interfaces such as Login Screen and Data Viewer that the HIP CDR comes with allow changing the displayed language as well as changing the color mode. Thus, language barriers are easily overcome and good readability is ensured via a good contrast. Since the front-end applications of the CDR are web applications, read-aloud functionalities can be used via the browser.

2.1.4 Platform and development

a. What parts of the Solution are open source and what parts are proprietary? Describe what open source license you use.



Text field

The data storages of HIP CDR are open source. Medical data is stored in EHRBase, demographic data is stored in HAPI FHIR. For authentication and authorization HIP CDR uses Keycloak. The supported databases are Postgres and YugabyteDB, which are both open source products. Proprietary parts include HELM charts, CDR Suite, CDR Bridge and enterprise plugins for EHRbase for transactional compensation according to the SAGA pattern, ATNA logging, Authorization and YugabyteDB integration.

b. Describe any prebuilt products or EHR-modules based on the platform that you can provide, for instance end-user applications for surgery, emergency wards, medications, or primary care. Also describe any provided "portal" functionality or similar that can easily be configured to different use cases where e.g. clinical end users can browse, read and enter openEHR-based data. Also briefly describe the pricing model for these.



Text field

The HIP CDR will provide a data viewer component for common (international) archetypes and a generic rendering of compositions (and FHIR resources). This allows clinical users to quickly gain an overview of data stored in the CDR for a particular patient.

c. Describe your integration support, tooling and experience, including but not limited to the list items i-vii below. Clearly indicate which list item the answer refers to.



i) Software development kits (SDK:s) for developing and integrating towards your API:s etc.

ii) Publish/subscribe patterns

iii) HL7 FHIR

iv) API standards (such as HL7 v2, IHE, ODBC, OpenAPI) and other interoperability and connectivity standards

v) Integrations with medical imaging standards such as DICOM

vi) OMOP and other standards used for research

vii) Existing EHR systems in Sweden (if so, please state which)

Text field

i) Software development kits (SDK:s) for developing and integrating towards your API:s etc: The HIP CDR provides a Java-based openEHR Software Development Kit ("openEHR SDK") under an open source license. Functions of the SDK include the following:

Composition Serializer

There are multiple serialization formats in openEHR (Canonical XML/JSON, FLAT, STRUCTURED) which serve distinct purposes. The Composition Serializer allows to transform compositions from any format to the other.

OPT to WebTemplate Transformation

The SDK can consume templates and transform these into the WebTemplate format.

Example Generator

This function allows to create test data from any openEHR Template. This is helpful to swiftly create some technical test data.

Java Class Generator

Based on openEHR Templates, the SDK can automatically create Java classes. These can be used to create and update compositions and to implement business logic in the application layer. Additionally, the models can be used to create custom APIs using framework like Spring Boot. Using a maven plugin, generation of classes can be made part of the software build process.

AQL Parser, Query Generator and Object Model

To create, manipulate, validate and serialize AQL statements, the SDK provides AQL parser and object model. These capabilities can be combined with the Java classes generated from templates to generate AQL statements from the openEHR clinical models.

openEHR REST Client

The SDK provides classes and functions to facilitate the use of the openEHR REST API. This includes the endpoints for Directory, Contributions, EHRs, Compositions and Queries.

Template-based Data Validation

The SDK provides functions to validate compositions against their corresponding Templates. This can be of use for offline validation of data before sending to an openEHR repository or as part of custom workflows.

OPT-Parser

OpenEHR Templates can be parsed, validated and transformed into an object representation.

ii) Publish/subscribe patterns: The HIP CDR provides a message queue based on AMQP and therefore offers well-established publishing and subscription mechanisms. These patterns are used by the Event Trigger mechanism in HIP CDR which allows to publish messages on selected topics based on incoming compositions. Payload of the messages can be the whole composition or the resultset of a locally executed AQL query. Services can subscribe to topics to receive

selected messages.

iii) HL7 FHIR: In the CDR, demographic data is stored in a FHIR database. In addition, the CDR provides a FHIR API gateway, where fhir speaking applications or systems can connect via REST. The transmitted medical FHIR data can be converted to the openEHR standard using the CDR Bridge. The same applies to retrieve structured data as FHIR resources. The provisioning and connection of the FHIR capable system is guided by integration specialists.

iv) API standards (such as HL7 v2, IHE, ODBC, OpenAPI) and other interoperability and connectivity standards: The HIP CDR supports most of the common standards. The CDR Bridge provides standard mappings, which can be extended by custom mappings based on a domain specific language if required. These mappings assign the message content (e.g. from HL7 V2) to the appropriate location in the highly structured HIP CDR data store. The connection between the external system and the CDR is established by an individual connector. Furthermore, the CDR also supports ODBC.

v) Integrations with medical imaging standards such as DICOM: Integration with DICOM has not been done, yet

vi) OMOP and other standards used for research: EHRbase as part of HIP CDR was used for the development of an openEHR to OMOP converter (EOS & OMOCL):

<https://github.com/SevKohler/Eos>

Hence, the component can be easily integrated to enable a conversion between the standards.

vii) Existing EHR systems in Sweden (if so, please state which): Dedalus has today an implementation of interoperability between Region Stockholm pre-hospital journal solution FRAPP and national solutions and to other systems used in Stockholm. The solution utilises the ability to exchange data between two different domains, acute- and pre-hospital care. The integration is complex and uses the Regional and National service platform, also giving access to the National Patient Overview (NPÖ).

d. Describe how an external terminology server can be connected to the Solution and used both for term selection in forms/GUI and for validation of incoming COMPOSITIONs via API. What terminology server standards or products have been successfully tested and used with the Solution?



Text field

The HIP CDR provides capabilities to integrated with FHIR terminology services to ensure semantic interoperability. Using terminology binding, incoming openEHR compositions can be automatically checked on compliance with defined value sets and terminologies. Additionally, AQL Queries can be enhanced by embedding external terminology service calls. Depending on the use-case, a configuration of EHRbase determines if compositions will be stored or rejected for the case that the external service (including caches) cannot be reached. GUIs of third party applications are integrated separately and individually.

e. Describe if/how the openEHR demographic model specification is supported by your Solution now, and your future roadmap for such support.



Text field

There is currently no support for the openEHR demographics models beyond the demographic information model which are part of the openEHR Reference Model. We consider support of the demographics IM, at minimum through a REST API, though there is still the question if FHIR demographics models might be practical and sufficient in most use-cases.

f. Describe query mechanisms in your Solution. Clearly indicate which list item the answer refers to.



i) Describe what version of the AQL specification the CDR supports and if something from the specification is not yet supported.

ii) What parts of the RM can be reached and used as selectors and filters in queries in addition to more “normal” COMPOSITION content? For example, how can FEEDER_AUDIT, LINK, FOLDER (including the FOLDER.details ITEM_STRUCTURE) and TAGs be used to select and filter content through AQL syntax (extensions) and/or via context information like API call parameters?

Text field

i) The HIP CDR supports the version 1.1.0 of the Archetype Query Language. The implementation supports the basic query structure SELECT, FROM, WHERE, ORDER BY and LIMIT, predicates, LIKE and matches operators, logical operators (AND, OR, NOT, EXISTS), and aggregation functions (COUNT, MIN, MAX, SUM, AVG). Currently, there is only limited support for string, numeric and time functions.

ii) Querying on Feeder_Audit and other RM objects as part of compositions is fully supported in HIP CDR. EHR Status is supported, too. There is currently no defined standard in the specification how to Folders should be queried as part of AQL queries. Folders will be added eventually once there is clarify about the standardization. Tags are not yet supported (as the feature itself is not yet implemented) but will also become available eventually.

g. Describe if and how you support use of openEHR’s TAG and FOLDER classes and mechanisms, including for what API endpoints (such as .../composition and .../query) they can be used to for example show/hide data based on if data belongs to certain FOLDERS (or it’s subfolders) or not, or based on the presence or absence of certain TAG keys and TAG values.



Text field

As stated, Tags are not yet implemented. Folders are implemented, though, as accessing folders is not defined in AQL, need to be queried using the folder endpoint to obtain a list of uids of versioned objects referenced in the retrieved folder. Once the specification has advanced on this topic, it will be added to HIP CDR.

2.1.5 Tools

a. Does the Solution provide integrated version control tool support (for example Git/Github integrations) for easy retrieval and storage of assets, such as archetypes, templates, forms, and queries? If yes, please describe it briefly.



Text field

There is currently no support of version control systems to manage assets in HIP CDR. However, the openEHR SDK provides functionalities to implement custom Template Providers which can be used to automatically populate the CDR.

b. Describe how/if your products include tool support, and how well they comply with specifications, for openEHR archetype/template lifecycle management and related form lifecycle management.



Text field

The HIP CDR itself provides basic support of lifecycle management. Referential integrity is enforced to ensure that openEHR compositions always refer to a template. Administrators can enforce the update of a template. Deprecation of the templates will be added soon, however, this should be aligned with the further development of openEHR specifications. Cambio Forms allow to manage multiple versions and switch between them forth and back.

c. Describe how your Solution supports multilingual openEHR models in data and end user interfaces. How do you provide workarounds for OPT 1.4 multilingual limitations? Describe if tool-interfaces are multilingual and can be translated and localized to Swedish.



Text field

In general, Templates are handled according to the standard which can handle multiple translations. We assume this limitation is the same as described here:
<https://discourse.openehr.org/t/limitation-preventing-multilingual-repeated-parts-in-the-opt-operational-template-export-format/2760>

As we have not encountered this situation in our projects, we will ensure that the workaround based on annotations will be implemented in EHRbase

d. To what extent do you support combining your Solution with components from other openEHR vendors? Describe successful tests you have done regarding this.



Text field

As HIP CDR aims to be highly conformant with the openEHR specifications, compatibility with components of other openEHR vendors is likely. Concrete examples of tools and components of other vendors have been demonstrated on Cambio Forms and Medblocks UI. During the development of the German COVID-19 data platform, it was possible to migrate a frontend application between Better Platform and EHRbase as part of HIP CDR.

e. Describe how/if your Solution includes tool support for (ad-hoc and stored) AQL management and use, and how well they comply with (and possibly extend) specifications, for instance the examples in the list items i-iv below. Clearly indicate which list item the answer refers to.



i) Nested and/or joined AQL queries

ii) Development and testing of variables in parametric queries

iii) AQL tools and environments for authoring queries, presentation, export and visualization of AQL responses

iv) Built in configurable/programmable pre- and/or post-processing of queries and results (server and/or client side)

Text field

- i) The HIP CDR has a tool called Cohort Explorer to define patient cohorts. This can be used to combine multiple AQL queries using set operators to count queries. Sub-Selects and JOINS are currently not supported as they are not defined in the AQL specification.
- ii) There are no dedicated tools to test parameters for queries. This can be done as part of REST requests
- iii) An advanced AQL editor is scheduled for 2023. There is basic AQL builder functionality in the Cohort Explorer tool which uses a visual approach to define queries, validate AQL syntax and store queries including parameters. Within the Cohort Explorer, there is UI-support to correctly fill query parameters.
- iv) There is currently no functionality provided by the platform for post- and preprocessing of queries in HIP CDR. HIP CDR's openEHR SDK provides a comprehensive set of functions including an AQL parser and AQL Object Model that can be used to parse and manipulate queries and result sets on the client-side. This way, manipulation of AQL can be done in very flexible ways.

f. Describe how/if your Solution includes tool support for templates, and how well it complies with specifications for the examples in the list items i-iii below. Clearly indicate which list item the answer refers to.



i) Support for nested/embedded templates

ii) What template tools that have been tested and found compatible with your Solution

iii) Support for templates based on ADL 2

Text field

i) The HIP CDR accepts templates in OPT format. Therefore, embedded templates need to be part of a composition-based template before it can be loaded into HIP CDR

ii) Archetype Designer, LinkEHR and Ocean Template Designer

iii) There is currently no support for Templates based on ADL 2.0. There is still discussions within the community how to conduct the change across the whole tool-chain including CKM, Archetype Designer and CDRs. Once the roadmap for this change ist clear, HIP CDR will also provide support for ADL 2.

g. Describe how/if your Solution includes tool support for the examples in the list items i-v below. Clearly indicate which list item the answer refers to.



i) Developing GUI:s

ii) Data management

iii) Import, export, and migration of data, metadata and system configuration, in open well documented formats.

iv) SMART on FHIR integration

v) Mapping and conversion support other standards such as HL7/FHIR

Text field

i) The HIP CDR integrates with Cambio Form Editor by providing functions to import, visualise, test and provide forms definitions.

ii) Dedalus propose a three-layer solution where the OpenEHR functionality is the core and with two supporting layers.

1. API-Gateway
2. DC4H Core
3. OpenEHR CDR

The outer layer is the API-gateway which governs incoming- and out-going request, searches, and controls access to the solution. The gateway can protect the solution from overload, excessive secondary use querying to maintain a normal consumption levels for direct patient relates tasks.

The middle layer is the DC4H Core which is the information switchboard that connects to consent, logging, and terminology functions. The DC4H transform, split, and join various data sources to make it easier to fulfil the requirements set by the OpenEHR information model. DC4H also have support for FHIR and other standards like IHE.

OpenEHR related tasks is handled within the CDR layer. The preservation of data for primary and secondary use is accordingly to the standard. Queries and results are sent from the CDR to above layer and finally to the requesting end user. Input to the CDR is trough the Gateway to control user access rights and consent. The DC4H is used for additional queries for example; Terminology, needed to fulfil the standard.

HIP CDR provides a data viewer for system administrators that provides a quick overview over data. Concurrently, an advanced clinical data viewer is under development that will also allow clinical users to view, annotate and update openEHR compositions for selected EHRs.

iii) System configurations are defined by HELM charts which allows easy copying of system configurations.

iv) At the moment SMART on FHIR is not supported by HIP CDR. However, it is possible to use it due to the authentication and authorization standards used (OAuth2, OIDC).

v) The CDR Bridge provides different connectors and is based on a generic path language. This allows to define further formats for conversion if required.

h. Describe how/if your Solution includes tool support for creation and use of entry forms based on openEHR templates. Clearly indicate which list item i-ii the answer refers to.



i) Which form rendering tools have been tested and found compatible with your CDR/platform?

ii) Do you supply a form builder and renderer? If yes, please briefly describe its features, for instance drag-n-drop, smart pictures (allowing annotations, term binding, graphs), low code/no code, conditional expressions.

Text field

i) Medblocks UI, Solid Clouds and Cambio Forms

ii) The HIP CDR does not supply its own form building tool but integrates Cambio Forms. Cambio Forms provides functions to create forms from one or more templates via drag & drop, allows to define layouts through placing of visual elements on a canvas, supports multi-language forms and has a simple scripting language to introduce some logic to a form.

i. Describe how/if your products include tool support, and how well they comply with any open specifications, for log management, such as alarms and access logs.



Text field

All read and write data accesses and user logins must be logged without gaps in HIP CDR. The Audit Trail and Node Authentication (ATNA) integration profile is used for this purpose. This describes the data structures and transactions for sending event logs to an audit record repository. Information is thus not deleted during an update, but supplemented by a new version. An ATNA Audit Trail Database component based on Elasticsearch, Logstash and Kibana (formerly known as ELK Stack, now Elastic Stack) is used to permanently store and provide event logs. Elasticsearch is a high-performance open source search engine based on Apache Lucene, which makes it possible to search event logs at high speed.

Logstash is an open source tool to accept and forward logs from various sources. In the ATNA Audit Trail Database component, Logstash implements the necessary endpoints to accept and store syslog files.

Kibana provides a dashboard for Elasticsearch. It can quickly display desired parameters using various visualization tools. It also allows to set alerts.

From the Elastic Stack perspective, ATNA logs are simply syslog messages. ATNA messages from the solution's various services (including the CDR Bridge) are sent directly to Logstash.

For system administrators, logs are accessed using Kibana. Access can be managed for authorized users through OAuth2 authentication and the ability to restrict rights for defined user roles in Keycloak. HIP CDR uses this approach also for authentication and authorization in all services and allows the implementation of a single sign-on (SSO).

2.1.6 IT and Information Security

a. Describe what kind of IT security features are implemented in your Solution, for instance support for securing API, data at rest, data in transport, data in operation, data removal, and logging and audit.



Text field

The HIP CDR offers the option of encryption at various levels for both data storage (data at rest) and data transfer (data in transit).

In order to ensure the security of data at rest, the system offers the option of encrypting disks on which sensitive information is stored in the data center at the storage level. In addition, the PostgreSQL database used offers native options for encryption at the database level, which can be activated in the system if required and used in addition to other measures. For securing data transfers, transport encryption via TLS is used for all incoming and outgoing communication via unsecured networks, as well as access control using appropriate authentication measures.

All transactions within its various components (and login attempts) are logged by HIP CDR according to ATNA standard and are stored in a dedicated logging repository based on Elastic Stack.

b. State if there are any relevant IT security certifications for your Solution, such as ISO27001, ISO27018.



Text field

Dedalus is a large software provide that only operates in the medical software field. The core is ISO-9001 certification for all production of software. For products falling under the EU MDR and EU IVDR regulation is Dedalus operating under the ISO-13485 standard. Dedalus also implements ISO-27001 as default for all products. Vitagroup is currently obtaining the ISO27001 certification. However, vitagroup already works according to these ISO standards. The whole development process is guided by the SAFe framework that allows medium term commitment on the agreed roadmap and at the same time allows maximum flexibility to react to certain market requirements and change of requirements. On top vitagroup holds in one of its entities the ISO13485 certification to develop software as a medical product if necessary and required.

c. Describe what kinds of authentication, authorization and access methods your Solution supports, for instance external IDP, role-based access control, privileged users control, just-in-time access.



Text field

External IDPs can be connected via Keycloak using OpenID Connect and SAML v2.0. In addition Keycloak can integrate external user databases/directories (LDAP, Active Directory) to perform User federation. Authentication is based on OAuth2/openID. User administration for the various applications is performed at the HIP CDR level by Keycloak. Users are assigned to roles with dedicated scope permissions to defined services or resources. This approach is currently being extended by an XACML-based Attribute Based Access Control (ABAC) approach to streamline authorization processes from securing endpoints to fine-granular access control on stored data level. During the ABAC policy decision process all available user attributes, request parameter and relevant data attributes are taken into account. In addition, HIP CDR can also implement additional 2-factor authentication. External IDPs can be connected via Keycloak using OpenID Connect and SAML v2.0. In addition Keycloak can integrate external user databases/directories (LDAP, Active Directory) to perform User federation. Authentication is based on OAuth2/openID. User administration for the various applications is performed at the HIP CDR level by Keycloak. Users are assigned to roles with dedicated scope permissions to defined services or resources. This approach is currently being extended by an XACML-based Attribute Based Access Control (ABAC) approach to streamline authorization processes from securing endpoints to fine-granular access control on stored data level. During the ABAC policy decision process all available user attributes, request parameter and relevant data attributes are taken into account. In addition, HIP CDR can also implement additional 2-factor authentication.

d. Do you use supply chain risk management strategies/tools, such as SBOM? Describe how you mitigate risks associated with development, maintenance, acquisitions and, sunseting of systems/components and/or services? How are risks and mitigating actions documented and what is your strategy for enforcing compliance?



Text field

Dedalus is a large software provider that only operates in the medical software field. The core is ISO-9001 certification for all production of software. For products falling under the EU MDR and EU IVDR regulation is Dedalus operating under the ISO-13485 standard. Dedalus also implements ISO-27001 as default for all products. HIP CDR provides automatic generation of SBOMs using OWASP Dependency Track. Audits/scans are conducted periodically to identity vulnerabilities and risks.

2.1.7 Training, documentation and consultant services

a. Describe the availability of course or on-line training for administrators, technicians, tool users, software developers, EHR end-users (if you provide modules/products for end-users).



Text field

We provide trainings for platform endusers (such as developers, health informaticians and system administrators) as well as "train the trainer" in-depth training to allow organizations to scale their educational program.

b. Describe which kind of product documentation you provide, for instance user manuals, installation guides, system administration guides.



Text field

HIP CDR comes with user manuals for installation and administration along with documentation for software developers and end users.

c. Do you offer consultant services for implementation, configuration and/or development?



Text field

Yes

3. Part 2: Demonstration

3.1 Demonstration sessions

The second part of this RFI consists of a demonstration session where selected respondents, that meet the qualification criteria described below, are invited to demo their Solution.

3.1.1 Qualification and prioritization criteria

To be qualified for a demo time you will need to demonstrate a Solution that is helpful when creating applications, capturing or storing clinical data based on openEHR standards, that is, not just general integration or CDR products. If there is competition for available presentation/demo slots, the written responses to above listed questions will be used as prioritization criteria.

A maximum of six (6) suppliers will get an invite to a demo session.

3.1.2 Purpose

The purpose of the demo is to show how your Solution meets the needs of the stated target groups and the user stories described below.

3.1.3 Dates

The demo sessions are held on May 31, June 1 and June 2. June 5 is reserved as an extra date for back-up purposes. Each demo is limited to two (2) hours.

3.1.4 Format

The demo is an online two (2) hour session via Zoom. The sessions are recorded and made public on Youtube when all suppliers have held their sessions. The purpose of publication is to help other organizations interested in openEHR systems.

A demo session is on the following format:

- Short introduction of company and Solution and what is going to be presented in the demo (maximum 2 minutes)
- Demo based on target group descriptions and user stories
- Discussion with questions and answers (minimum 30 minutes)
- Optionally and on request, the recording can be stopped for the last 15 minutes of the discussion, if there are parts that should not be made publicly available.

Additional county councils may later join the RFI and attend the demonstrations as listeners.

3.1.5 Instructions

To reach business impact goals and purposes, it is essential that a procured solution meets the needs and expectations of the different target groups that will use the openEHR Solution. A number of essential target groups are identified – Platform administrator/technician, Application and content developer/administrator, Super user, External actor, Application end-user, and Newbie.

Each target group has a description and some of them have one or several user stories that highlight aspects of the target group that we think would be interesting for a demo. Use these descriptions and user stories as a basis for your demo. You are not expected to demo everything.

During the demo session, please refer to which target groups/user stories you are demonstrating.

3.1.6 Application and Content Developer/Administrator

This is an informatician, a software developer or a system/content manager. She develops applications, builds integrations, does information modeling and form building, and designs queries for information retrieval. She is also responsible for maintenance of applications, information structures and content. She 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, the application and content developer/administrator takes care of it. She is an advanced user with high demands on smart functions in the development tools.

User stories based on Application and content developer/administrator:

1. As an informatician I want to connect an external terminology service to make sure that the terms within the data are consistent with appropriate terminology standards and valuesets/subsets.
2. As a healthcare system developer I want to integrate software to be able to store and retrieve medical data in an openEHR EHR system alongside other healthcare system vendors.
3. As a healthcare developer working on a SmartOnFhir application I want to be able to access part of the openEHR information as standard FHIR API.
4. As an administrator or developer I want to configure or be able to create solutions for collecting IoT device measurements from patients. This includes
 - a) data from medical devices that we as healthcare providers have provided, support and collect data from.
 - b) data from patients' privately purchased devices (smartwatches, blood pressure meters etc) that they may have connected to apps in their Android and iOS devices - this transfer may be initiated by the patient without being actively requested by healthcare (e.g. before a visit). Such data should when stored be possible to identify as patient reported so that it can be logically separated from other data.
 - c) where the data was created and by which person and device.
5. As an administrator or developer I want to configure or be able to create solutions for collecting data from patient-reported forms, photos, and videos.
6. As an administrator I want to be able to referens see Appendix A
 - a) create/define metadata attributes to personal data so the Solution can be configured to meet our needs.
 - b) add/update metadata for a specific piece of personal data.
 - c) add/update metadata to personal data as a bulk update, e.g. for all compositions created at a certain organizational unit.
 - d) use metadata to create functions managing what information a user has access to e.g. in an overview of an encounter of a patient who received specialist care.

3.1.7 Platform Administrator/Technician

This person 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. The platform administrator/technician 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.

User stories based on Platform administrator/technician:

1. As a server-admin, I want to use supporting functions so that I can carry out technical troubleshooting.
2. As a first line support tech, I want to view the system's operational status via web-UI so that I can at a glance check if there are any issues.
3. As an administrator I want to manage access-rights, e.g. configuring rules, roles and access control policies, so that I can restrict access to information based on user context and information attributes.

3.1.8 Super user

The super user is a nurse, a physician or a researcher at a healthcare unit and is interested in how new technical solutions can be used to improve the patient care, working processes, and gaining new medical knowledge. The super user maintains existing forms and templates in the openEHR-based applications that the department uses. The super user 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 the super user contacts application and content developer/administrator for help and they cooperate on the solution. The super user also generates reports from the healthcare systems that the care department needs; often it is standard reports that are generated repeatedly, but sometimes a special report is needed.

The super user 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 the super user 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 the super user 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. The super user also needs a comprehensible report generation tool.

User stories based on Super user:

1. As a clinician, I want to build and design a dynamic form, based on existing templates, with conditional form field display logic and automatic calculations, for structured documentation.
2. As a researcher, I want to create reusable methods to search, collect and present data, for example regarding a certain patient group/diagnosis and only for a specific gender at a certain age.
3. As a clinician, I want to design and generate ad hoc reports, from data collected through a form.
4. As a new employee (or occasional "burst" user) I need user friendly, and intuitive easy to use tools and graphical user interfaces.

3.1.9 Application End-User

Application end-user is a healthcare clinician or a citizen. He wants to enter and retrieve information from and to the health record system. The application end-user 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 the application end-user to switch language in an application. Since he 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, his needs concern the results of using the openEHR platform and development tools; as long as the resulting applications are stable

and good, he is happy.

User stories based on Application end-user:

1. As a clinician, I want to have a Clinical Decision Support and process support functionality, to improve the quality of care and reduce risks.

3.1.10 External Actor

External actor is a company, a student, another healthcare region, or a researcher. The external actor delivers applications or content. The external actor has no direct access to the internal systems and uses her own development tools. It is important for her that a full range of REST APIs is available, and she values extensive system documentation. It could be convenient for her to use openEHR tool licenses for a limited period when developing on behalf of a healthcare region.

3.1.11 Newbie

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