Procuring organization	**Procurement**
Region Östergötland Bernadett Brink	RFI, Request for Information of openEHR platforms and related tools RFI-2020-08:2 Version 2: published 4/18/2023 11:46 AM Tender closing date: 5/10/2023 11:59 PM

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	ESPD	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.
Eweave AB	eWeave Core	5567811491	

Contents

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

2/6 kl 13-15
2/6 kl 15-17
1/6 kl 13-15
1/6 kl 15-17

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 counsils 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

    📎 0 attached documents

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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 counsils 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 counsils 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 counsils 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 (Total Swedish population is 10,5 million)	Hospitals	Health clinics	Dental care clinics	National specialized medical care assignments (46 different ones available)	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

eWeave Core's demografiska plattform
För varje demografiskt objekt skapar systemet en egen EHR. Fullt skalbar lösning som kan fungera som en regional OpenEHR databas, som kan användas och anropas av andra kommande OpenEHR system. Fördelen med denna lösning i jämförelse med en standard demografisk databas är att man kan separerar demografi från journaluppgifter. Systemet skapar vid inloggning med SITHs kort, med hjälp av relationspekare, automatiskt en kopia av organisations hierarkin från den underliggande HSAid katalogen Man slipper då lägga in demografiska objekt i EHR delen, vilket är en säkerhetsmässigt sämre lösning för skydd mot intrång. Det är dessutom mycket svårt att konstruera dessa relationer och täcka in alla situationer vid datautbyte från andra yttre källor.
eWeave Core's EHR plattform
En patients alla journaldata som idag ligger utspritt på en mängd olika icke OpenEHR baserade system inom en region. Core skulle kunna samla ihop journaldata och skapa en journal för en patient.
Kan även vara en egen källa för strukturerad patientdata och kommunicera med en större regional plattform, kvalitetsregister mm.
Vi strävar efter att vara ett system där man kan testa och utvärdera arketyper, "archetype templates" och formulär direkt. Ett komplement till CKM hos openEHR.

eWeave Core är har verktyg och teknik för att inom en kort utvecklingstid, skapa ett journalsystem i produktion eller användas för utvecklingsarbete.
• Utvecklare och intresserad vårdpersonal kan importera arketyper och bygga ihop templates/Compositions/formulär i inom områden där det finns en nationell samsyn och rutiner. tex. Mödravård. Dessa templates kräver moduleringsarbete för att ge ett attraktivt och funktionellt gränssnitt sammankopplas till mallar och kan infogas i färdiga appar. Kan snabbt ge ett körbart system efter att verksamhetsansvariga specificerat de kliniska behoven. Lagring och uppläsning patientdata, hälsoöversikter av nyckeldata, utskrifter, rapporter mm. Datautbyte med tex. Smart on FHIR, tjänstekontrakt mm. Ex finns idag i form av Barnhälsovård i produktion sedan 2017.
• Andra möjliga projekt är att modulera och utveckla en generell läkemedelsmodul baserat på internationella arketyper. Kan sedan användas av andra leverantörer som bygger OpenEHR lösningar
• För personer inom organisationer och företag som vill lära sig mer om OpenEHR bygga formulär. spara data och se resultat, möjligheter och gränssnitt.
• Tekniska utvecklingsprojekt med samarbete mellan regioner och företag

eWeave kan sätta upp serversystem hos kund eller i form av molntjänster. Genom att definiera olika profiler kan användare och utvecklare presenteras för olika arbetsytor inom samma organisation
eWeave kan leverera utbildnings serier på distans, riktad mot användare med olika tekniska kunskapsnivåer inom OpenEHR.

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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

Sverige

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c. Describe the overall architecture of your Solution. ⓘ

Text field

OpenEHR baserad komplett informationsplattform, för lagring av strukturerad, terminologibunden data. Tekniskt även ett fungerande journalsystem. Serverstruktur uppbyggnad medför en ökad säkerhet, och är fullt skalbar.
• Webbservrar enligt lastbalansering
• Databasserver systemgrupp
• Databasserver demografiska objekt (användare, patienter, vårdenheter, grupper mm)
• Databasserver EHR
Där alla kan sättas upp som master-master databaser eller kluster

eWeave Core kan användas vid alla typer av hälso- och sjukvård. Specialiseringen sker med hjälp av interna verktyg som sätter samma templates. Mallar byggs samman och där det ingår diagnos och arbetsflöden.
All data finns lagrad i ett strukturerat informationslager. Delar av detta material är migrerat från andra system. Detta informationslager kan utökas på ett gränslöst sätt genom byggande av nya specialiserade arketyper. Information kan då både migreras från andra källor eller matas in direkt i systemet Kan fungera som ett gemensamt informationslager med tjänster mot andra system. Lösningens integrationsgränssnitt inklusive transportprotokoll, Web Services och standarder för meddelandeformat (semantisk interoperabilitet) ser ut på följande sätt:.
eWeave Core kan hämta data via:
• Tjänstekontrakt (SOAP)
• XML format
• JSON format
• Webbtjänster kan hanteras via SOAP, FHIR mm

Specifikationen SMART för åtkomst av FHIR-resurser och stöd för konsumtion av HL7 FHIR RESTful API:er sker genom att eWeave Growth kan konsumera data av HL7 FHIR version 4 enligt beskrivning på https://www.hl7.org/fhir/http.html
Vår implementering bygger i nuläget på dcarbone öppna källkod "Tools for consuming data from a FHIR server with PHP".

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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

Första utkastet till Task Plan kom samma år som vår applikation gick i produktion (2017). Försök har gjorts att bygga Task plans i Archetype Designer, som dock inte har implementerats. Har inte prövat Nedap Medical flow.
Vår processlösning grundas helt på att man använder en demografisk OpenEHR lösning där varje demografiskt objekt får sin egen EHR. Varje demografiskt objekt får då sin egna kalenderfunktion.
Genom att använda mallfunktionen ,kan man gruppera templates längs en patients kalendertidslinje i journalen. Här kan man då ha en övergripande workplan med flera taskplans. Tidpunkterna framåt kan skapas utifrån en patients ålder vid ett visst datum eller utgå från dagens datum och framåt.
Genom denna teknik fångar man de globala attributen Context, calender, timeline,event_wait_states
Genom att koppla mallarna hårt till planeringsåtgärder får man automatisk samband med demografisk metadata rörande taskparticipation mm.
I nuvarande BHV applikation finns en Task plan som kan rullas ut för barnets kalender mellan 0-5 år med några klick och med rätt preliminärbokat tidsintervall. Totalt 16 st förberedda kontaktpunkter för ett barn där vårdgivaren får stöd för olika obligatoriska observationer, tester och aktiviteter.På samma sätt kan man hantera olika vårdprogram och vårdplaner. Beskrivningar och verksamhetsstöd nås direkt genom inbyggda knapplänkar i formuläret. Detta innebär ett avsteg från OpenEHR modellen då vi inte bygger med Instruction-Activity, Action arketyper som motorer. Vi har dock gjort olika testmodeller för detta men som inte gett en övertygande funktionalitet då Task Planning specifikationen saknades vid moduleringsansatsen.

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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

Vi har utvecklat särskilda formulärfunktioner som GDL oss veterligen inte täcker idag. Vi har dock intresse att även implementera GDL

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

Cloud: Multi-tenant och Multi-instance lösning
Local: Webbläsare
Tänkt bild går inte att visa

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

Text field

All trafik är krypterad med PKI

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

Program och databastekniska frågor supporteras direkt av oss. Vi har licenser för support av Sencha, MariaDB,

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

Nej, I nuvarande form går det inte

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

Text field

Ja, men inte testat I produktion. Färdiga lösningar finns för hur det kan göras med MariaDB, som vi använder.

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

Text field

Vi använder en mängd minde cachade svarssegment vid databasfrågor. Systemet ställer små frågor som cachas för att snabba upp de totala svaren från databasen. Flera databasservrar som jobbar parallellt minskar svarstiderna.

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

Region Örebro läns barnhälsovård. Driftstart 2017. Idag finns 1774 unika användare och 79 vårdenheter registrerade. Totalt finns 76000 patienter i databasen. Ca 1 år tog det för att samla in vårdgivares önskemål och krav och därefter bygga specialiserade arketyper grundat på det nationella barnhälsovårdsprogrammet där även digitaliserade tillväxtkurvor och vaccinationsprogram ingår.

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

Text field

Installation av virtuella serversystem enligt ovan. Uppkoppling och anslutning till Befolkningsregistret, HSAid katalogen och mot tex SAML tjänst mot kundens gränssnitt. Färdiga arketypbaserade valbara appar för drift och loggning rapportering mm. En egen EHR finns för varje patient, vårdgivare och vårdenhet. Loggning och versionshantering på alla nivåer. Styrning genom behörighetskontrollerade appar som visas i gränssnittet.

i. Describe your software lifecycle strategy and release cadence.

Text field

Vid ny version av systemet uppdateras även serverprogramvara och dataserver till senaste testade version. En till två större versionsuppdateringar per år. Idag version 7.0.0

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

Text field

AQL har är inte installerat i Core vilket är ett avsteg från OpenEHR specifikationen. Skälen till detta är:
• Fungerande AQL frågor mot den demografiska OpenEHR delen fanns inte publicerat eller testat 2017 vid vår produktionsstart och saknas fortfarande. Detta förhållande krävde framtagning av egen lösning för att få en kodad interaktion mellan den demografiska servern och EHR servern. Är en förutsättning att få till en PDL godkänd dokumentationsrutin.
• Verkligheten ser fortfarande ut på likartat sätt som det gjorde när vår OpenEHR resa startade för 15 år sedan. Under en fortsatt överskådlig tid kommer en patients journaldata finnas utspritt i ett stort antal olika system av icke arketypbaserade modell, med oftast ostrukturerad datalagring, som inte kan hantera en AQL fråga/svar. Regionernas satsningar på centrala plattformar är fortfarande till 100 % , av icke OpenEHR typ.
• Konsekvensen av detta är AQL metoden bara kommer att fungera åt ett håll (datauttag ur OpenEHR baserat system) och att man alltid sedan hamnar i en mappningsförfarande av resultatet AQL är en utmärkt metod för att hantera arketyper, med kräver kunskaper att formulera en fråga och svaret kan vara problematiskt att felsöka.
• Vi har därför börjat försök med att se om det går att förenkla datauttaget på ett "OpenEHR sätt", och som kan komplettera det egenutvecklade indexsystem som vi har idag. Vi har därför lyft ut Item_ tag klassen (Tag package). Målsättningen är att lägga till en Tag märkningsfunktion på fältnivå i vår editor av en template. Om sedan "kravet" är att det Tag märkta fältet måste vara kodat (Snomed CT, andra officiella register), kan man få en fältmärkningsrutin som är gångbar mot andra system, mot en nationell plattform ,mot kvalitetsregister mm Detta stabila mappningsunderlag kan då lättare tas fram från en rapportgenerator utan AQL, och levereras som tex JSON kod. Denna metod skulle då fungera både mot den demografiska och EHR servern. Vi tror att det framtida kommunikationsformatet kommer att domineras av Smart on FHIR, och tror att det är klokt att försöka förhålla sig till dessa trender.
• Utökade formulärfunktioner för koppling och visualisering av demografisk information direkt i EHR formulären, som en information vid dokumentationen. Ingen lagring får dock ske på EHR sidan, av säkerhetsskäl, vilket följer OpenEHR's modell.

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

Genom att sätta upp regionala OpenEHR baserade demografiska databaser som bör användas av alla leverantörer som bygger OpenEHR lösningar , liksom för mappning av data från äldre typer av journalsystem.
Det skulle vända på dagens situation där en patients journaluppgifter ligger spritt i en mängd olika system. Istället lagras en patients data i samma EHR. Ger full kontroll av metadata när man utnyttjar de demografiska funktionerna -relationer och versioner. Ska dessa relationer hittas och fångas i efterhand, ökar svårighetsgraden dramatiskt.

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

Ägarskapet till en composition följer Open EHR modell genom att peka på poster i den demografiska databasen där alla organisationsuppgifter och relationer finns lagrat

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

Användarrättigheter är kontrollerade i kundens portal. När vårdgivaren loggar in i Core och har valt ett medarbetaruppdrag, görs ett uppslag mot HSAid katalogen. Finns vårdgivaren där tidigare så kontrolleras att alla uppgifter är uppdaterade. Är det första gången, skapas en ny vårdgivar EHR och en ny relation till vårdenhetens EHR per automatik. Vid val av patient sker en slagning mot befolkningsregistret och relationer skapas mot vårdgivaren och vårdgivarorganisationen. Från patientens aktivitetslista kan öppnas nästa förplanerade steg i vårdplanen tex 2,5 års besök. Mallen består då av en vårdkontaktregistrering som kompletteras vid behov med mer detaljer om tider och deltagare och hälsoärendebeteckning mm. Dokumentations behovet (formulär /compositions) för just detta besök finns tillgängliga under en serie flikar. Finns behov av ytterligare formulär så kan dessa väljas och öppnas i en plus flik i webbläsaren. All demografisk data lagras genom pekare gällande för den aktuella vårdkontakten.

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

Vi arbetar med FHIR lösningar för import och export

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

Vi arbetar med FHIR lösningar för import och export

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

Vi har ingen praktisk erfarenhet av detta

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

Vi har ingen praktisk erfarenhet av detta

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

Genom indexering av de efterfrågade datafälten i en Composition (inklusive demografisk metadata) kan data exporteras/importeras via API mot tex tjänstekontrakt, FHIR eller REST. Man kan därmed göra urval i en Composition eller ta alla intressanta datafält. Dessa hittas då oberoende av om arketypen är infogad i flera olika Compositions

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

Vi importerar många arketyper manuellt till vår databas. Dessa sätts sedan samman till större modeller(templates) och valideras. En arketyp kan infogas i många olika templates och därmed förekomma i flera formulär.

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

Vi lagrar I huvudsak allt enligt openEHR:s class audit_details. Vid alla händelser i systemet enligt openEHR, dvs vilket system, av vem, när och eventuell kommentar. OBS Det här används även I demografiska händelser t.ex. när man öppnar patient och sedan dess EHR via contribution

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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

Systemet sammanställer alla loggar som lagrats I systemets databaser. Dessa kan sedan exporteras ut som loggfiler I CSV-format och användas och tolkas i andra system.

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

CE märkning har tidigare skett till Läkemedelsverket och då med klassificering: Tillverkare av nationella medicinska informationssystem (NMI). Detta har då omfattat eWeave Core som är en OpenEHR baserad plattform och är den väsentligaste komponenten. eWeave Growth som är modulen med tillväxtkurvor ingår också.
eWeave Core (med Growth) omfattas idag av MDR kraven som Old devices eller direktivprodukt Någon separat registrering av eWeave Growth finns inte, men på begäran kommer CE-certifikat (MDD/AIMD/IVDD), CE-intyg (MDR/IVDR) eller försäkran
om överensstämmelse ((Declaration of conformity) för lägre riskklassprodukter) att inlämnas.

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

Text field

Besvarad enkät om NMI :s uppdateringsarbete 2021-06

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

Erfarenhet av detta arbete saknas

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

PHP, MariaDB och ArangoDB. För större system så finns licenser för MariaDB Javascript ramverk från Sencha.

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

BHV - barnhälsovård. Samma app kan användas för tex primärvård men då efter att formulär byts
Growth- digitaliserade tillväxtkurvor, pubertetsdata mm Kan även implementeras som stand alone
Provacc- vaccinationsmodul
Användarlicens/ mån

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) Sencha javascript framwork
ii)Dreamweaver, IntelliJ
iii)Webbapplikationen eWeave Growth kan kommunicera med underliggande FHIR servrar enligt SMART på FHIR enligt OAuth-standarden. Vi använder i botten PHP som skriptspråk i servern med en mängd PHP-anpassade moduler
iv)Vi använder mestadels de funktioner för kommunikation som finns inom PHP
v) Nej
vi) IntelliJ
vii) Region Örebro län Sverige

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

ⓘ

Vi har openEHR, ICD10, Snomed-CT, teminologi standarder internt inlagda i MariaDB. Befolkningsregister, HSAID-katalog, olika SOAP tjänster kan kopplas in.

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

Text field

ⓘ

Fullt implementerad demografisk openEHR server i drift.

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)Våra interna databasfrågor bygger på SQL. Vi testar TAG funktionen som del i AQL
ii)SQQL och REST används i systemet

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

ⓘ

Vi ser detta som en som en lovande utvecklingsväg för datauttag. Vg se mer i svar 2.1.2 J)

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

ⓘ

Nej

---

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

ⓘ

Arketypeditor: LinkEHR och Ocean Archetype Editor. Intern Core template editor

---

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

ⓘ

I konfigureringsmodulen kan ett förstahandsspråk och ett andrahandsspråk väljas. T.ex. svenska och engelska. Om systemet inte hittar dessa två olika språk används arketypens första språk.

---

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

ⓘ

Arketyper och templates som används i andra openEHR system kan importeras och implementeras som ADL filer. Arketyper kan hämtas från bibliotek på CKM OpenEHR. Några andra samarbeten har inte skett ännu.

---

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 dagsläget finns en välfungerande rapportgeneratorfunktion med exportfunktionalitet
Mappning mot tjänstekontrakt, FHIR resurser och TAG resurser (objekt)
i) Nej
ii) Via grafiskt gränssnitt så kan endast giltiga variabler användas som "parametric queries"
iii) Nej
iv) Nej

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

Intern template editor som fogar samman importerade validerade arketyper
i) ja
ii)Archetype Designer, LinkEHR
iii) Ja

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) ja
ii) Ja
iii) Exempel på överföringsteknik som kan användas för inläsning av data är tjänstekontrakt eller annan webbtjänst enligt SOAP, FHIR eller via filöverföring (CSV, XML eller JSON).
iv) Webbapplikationen eWeave Growth kan kommunicera med underliggande FHIR servrar enligt SMART på FHIR enligt OAuth-standarden.

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)Arketypeditor: LinkEHR och Ocean Archetype Editor
ii) Ja vi har en egen hantering för uppbyggnad av nya formulär. Alla ingående fält kan anpassas efter de regler som anges I openEHR vilket inkluderar termbindning mm. Kan även kompletteras med egenutvecklad funktionalitet t.ex. historiska (versioner) av tidigare fältvärden. Dessa utgår ifrån archetype templates. Formulären kan även förses med intelligens.

---

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

Enligt openEHR audit_details som ingår I en mängd funktioner I openEHR.

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

All kommunikation sker krypterat. Alla händelse I systemet loggas. Data kan tas bort permanent (enligt särskilt regelverk på begäran av patient) Data som skapas kan läggas I en sk papperskorg ,med möjlighet för senare återskapande.
Systemet övervakas i en särskild on-line app där aktiva användare kan följas, öppnade compositions, konflikter mm. Antal sparade, signerade ,kastade och utskrivna dokument kan tas fram under definierade tidsperioder och mycket mer kan följas
Logfiler för aktiviteter sparas och speglas på tre demografiska nivåer egna journaler-. Patient, användare och användarens organisationstillhörighet (via val av medarbetaruppdrag från HSA id katalogen).

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

Text field

Nej

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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

Autentisering kan ske via användarnamn/lösen som kan kompletteras med Multifaktorautentisering (MFA), SITHS, MS AD

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

Text field

Det system av mjukvaror som ingår i vår plattform finns i en särskild förteckning. Varje komponent uppdateras i takt med att validerade uppdateringar levereras

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

Serverinstallation och utbildning
Installation av virtuellt serversystem på kundens hårdvara. Access för eWeave support men i övrigt styr kunden behörigheten för fritt antal användare, grupperade i profiler utifrån roller och kunskapsnivåer. Skapar kunden ett gränssnitt mot Befolkningsregister (BF) och HSAid katalogen för användare och testpatienter, förbättras användarvänligheten och funktionaliteten. Anslutning kan även göras mot eWeave 's molntjänst där dock BF och HSAid kopplingar saknas

• All utbildning sker på distans samtidigt som deltagarna är uppkopplade mot sin Core installation profil. Max 5 deltagare per tillfälle. Kommunikation sker med Teams eller Zoom
• En grundläggande utbildningsserie består av fyra utbildningstillfällen på vardera 1,5 tim
Innehåll:
1. Lokal installation av Archetype editor. Genomgångar av Clinical knowledge manager- CKM. Nedladdning av valda arketyper till Core. Praktiska övningar och repetitioner.
2. Bygga ihop en templates av importerade arketyper. Påbörja fältmodulering
3. Fortsatt fältmodulering och skapande av formulär. Addera formulärfunktioner
4. Gruppera formulär i mallar motsvarande ett vårdprogram och tidsätta dessa med verktyg I en kalendertidslinje Översiktlig inkoppling in mallar i appar, skapa dynamiska knappar Öppna appar i en testpatientjournal spara och läsa upp data
• Specialanpassad teknikutbildning för mer avancerade användare och utvecklare
Support
• .Avtal om fast supportsidan/ vecka kan tecknas
• Timdebitering för supporttjänster
• Avtal för samarbete kring utvecklingsprojekt

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

Text field

Omfattande dokumentation finns som Hjälp (?) i systemet för alla sektioner

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

Text field

Ja

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.