

PRELIMINARY MARKET REQUEST FOR INFORMATION FOR THE TENDER OF A CLINICAL KNOWLEDGE REPOSITORY PLATFORM ACCORDING TO THE OPENEHR STANDARD

ANNEX 1: CONTEXT CATALAN HEALTH SYSTEM AND EHR VISION

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1 Background

Catalonia health system has embarked on a programme of modernisation of its IT systems, broadly based on establishing a *patient-centric health record* within a *knowledge-driven open platform environment*.

1.1 Goals

There are a number of goals for this project, of which the following are examples, but not exhaustive.

1.1.1 Healthcare Professional Goals

Goals relating to improving the work experience for our healthcare professionals, in all settings, and enabling them to deliver higher quality care. For instance:

- Reduce administrative workload;
- Reduce complexity of Health Information Technology solutions;
- Improve worker compliance to structured input quality data aims;
- Reduce time / difficulty of training;
- Reduce missed / delayed handovers;
- Enable care pathways and guidelines to be efficiently incorporated directly into the clinician workplace.

1.1.2 Healthcare Outcomes Goals

Goals relating to desired health and wellness outcomes across the Catalan population. For instance:

- Improve information availability for healthcare related decisions;
- Changes in physician behaviour, and ultimately patient outcomes, resulting from routine execution of risk assessment guidelines, e.g. for stroke risk, diabetes type 2.

1.1.3 Economic Goals

Goals relating to the overall economics of CatSalut's IT operations. For instance:

- Reduce development time, including time to delivery of applications; time to incorporate new data items to existing forms;
- Reduce Maintenance Costs;
- Reduce professional (user) training costs;
- Reduce Data Transformation / Validation Costs.

1.1.4 IT Procurement and Management Aims

The following aims relate to how we want procurement to function in the future.

- Incremental procurement based on component-level products and platform interface conformance;
- Minimise integration risks by minimising unvalidated connections, i.e. major integrations

(e.g. lab messaging) should have been established and implemented by vendors;

- Quickly establish internal skill with the platform such that in-house client components may be engineered;
- Ability to add new domain data elements, plans, rules etc. without reference to vendor, or incurring new contractual charges.

1.1.5 Technological Aims

The following aims relate to the type of technological environment we want to establish.

- Establishing a true patient-centric Electronic Health Record (EHR);
- Bring computable clinical practice guidelines (CPGs) and decision support to point of care;
- Interoperability as an automatic outcome;
- Enable smooth integration of emerging Al and machine learning services, e.g. for decision support, process mining etc;
- Being knowledge- and model-driven; converting implicit knowledge to explicit;
- Maximise independence of domain semantics (application logic, querying, reporting) from infrastructure technology (OS, DB, etc);
- Perform technology refresh, including to use modern responsive UI/UX frameworks;
- Single-source application deployment to all device types;
- Enable clinical safety evaluation and testing to be efficiently performed.

1.2 Architectural Principles

The key paradigms of the platform architectural approach we intend to implement are as follows:

- Component-based, with many components deployed as services;
- Knowledge-driven, such that the domain semantics of data-sets, business/clinical processes, decision support etc, are defined in models and terminology that are represented and maintained separately from the software and databases;
- Emerging technology-enabled, such that emerging AI and other intelligent technologies can be deployed to reduce work (e.g. image interpretation) and support more personalised and preventive healthcare.

Based on these paradigms, the **CatSalut Health Information Technology platform** (HITP) is defined as a living architecture according to which the CatSalut health computing environment will function over the coming years. Some of the fundamental components of the environment include:

- Patient-centric health record, implemented as a Catalan <u>clinical</u> data repository (CDR);
- Process automation, using emerging technologies for representing care pathway plans;
- **Guideline and decision support**, using emerging technologies for representing clinical logic, rules etc.

Additionally, the environment will enable other systemic needs to be implemented. For instance:



- Consent management based on a citizen privacy and legitimate relationship model;
- General Data Protection Regulation (GDPR).

Although the platform view is new, the approach to deployment is intended to be judicious and incremental, such that existing systems (generally non-platform-oriented) continue to be operationally available, while being modified and/or replaced over time so as to connect to the platform.

The development approach will also change over time, toward a platform-oriented process characterised by the following kinds of development:

- knowledge engineering, producing models of data, clinical guidelines etc undertaken by domain experts;
- low/no code application development option, based on models undertaken by business / application / usability experts;
- back-end and infrastructure development undertaken by professional IT staff.

This assumes the usual infrastructure-related activities, including continuous integration (CI), deployment (DevOps), DB management, security, etc, and similarly, project management.

1.3 Standards and Standardisation

The approach of CatSalut to standardisation prioritises *fitness for purpose* and overall *platform coherence*. Four kinds of health IT standards are distinguished, as follows:

- Semantic standards, e.g. ontologies, terminologies; e.g. ICDx, Snomed CT;
- **Architectural standards** for health information systems; e.g. openEHR, ISO 13606, certain IHE standards;
- Interoperability standards aimed at standardising specific communications between systems and also applications; e.g. HL7v2, HL7 CDA, H7 FHIR, IHE profiles of HL7, DICOM etc;
- Quality standards aimed at improving quality aspects of concrete artefacts developed for health IT; e.g. ISO/TR 14639-2:2014 (Health informatics — Capacity-based eHealth architecture roadmap)¹, ISO/TS 21564:2019 (Health Informatics — Terminology resource map quality measures (MapQual))².

The CatSalut HITP makes intends to use of the first two categories, which are 'model-based', in its platform architecture, particularly openEHR as the basis for the patient-centric health record, terminology standards, with other standards (e.g. IHE) adopted and/or adapted for various other major platform components (e.g. system logging, consent, access control).

1 See https://www.iso.org/standard/54903.html

2 See https://www.iso.org/standard/71088.html

2 The Catalan Health System

2.1 Overview

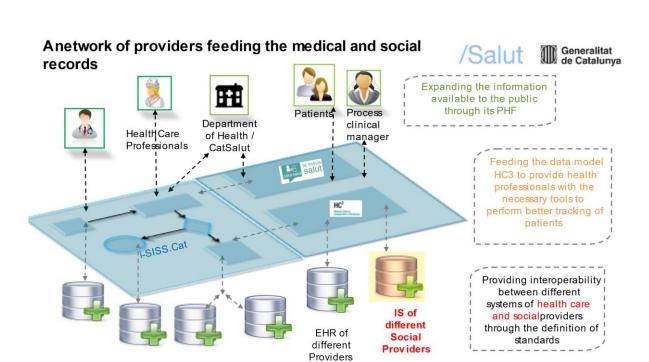
The Catalan health system

/Salut Generalitat de Catalunya

- Population7.550.830(2017)
- Life expectancy83 years(2016)
- Birth rate9,2 (2016)
- Infant mortalit 2.47 (2016).
- · 70 Hospitals
- 421 Primary Carecentres.
- 240 Mental Healthcentres.
- · 140 Social & Healthcentres.

Healthcare Model features

- Funded by taxes, coayment in pharmaceutical products
- · Universal coverage, free access
- Very wide range of publicly covered services
- Services provided mainly in public facilities
- Multi-provider mode(>160 providersi)ntegratedinto a single public network





3 Platform Target State

The current procurement is being undertaken with the aim to establish an open platform-based environment for Catalonia as a whole, based around a shared EHR for each citizen. A platform environment is best understood as a process, with no definitive end-state. Hence, we characterise the endeavour by our intended target state at a nominal point in time of 3 years ahead.

3.1 Healthcare IT Standards and Technologies

The CatSalut platform is designed as a coherent collection of components (mostly services), reflecting an appropriate separation of concerns, e.g. of EHR from terminology, lab integration etc. A number of key technologies and standards are implicated, as follows:

- openEHR core EHR, formalisms (meta-models) for Task Planning, guidelines, decision support;
- openEHR –knowledge-base of archetypes (data groups), templates (data sets), guidelines, rules and terminology subsets used to define the system semantics;
- IHE various APIs, e,g, ATNA system log, APPC advanced consent etc;
- HL7, DICOM various common interoperability standards (HL7v2, CDA, FHIR, CDS hooks) relating to lab results, imaging orders and results, and potentially other clinical and demographic data;
- ICD, SNOMED, LOINC etc terminology standards;
- ISO 13606 national summary record.

These standards will be adapted as necessary to ensure the coherence of the platform.

3.2 CatSalut EHR versus Institutional EMR

The CatSalut EHR is for use by primary care, social care, aged care, and citizen access. For hospital and other acute and/or episodic care, it is assumed that existing institutional Electronic Medical Record systems (EMRs) will continue in operation in the long term, based on the assumption that in-patient care generates large amount of information much of which is not required after discharge. This is expected to hold even if such EMRs are upgraded to use the same platform EHR technology as the CatSalut EHR. Nevertheless, health professionals within acute settings need to be able to view and update the CatSalut EHR. This may be achieved by various means, including provision of a patient EHR view within the EMR application environment, as well as various means of synchronising information in both directions, i.e. at admission and discharge, and during out-patient care. Medication list synchronisation is needed in both directions for example, as well as care plan, discharge summary and recent lab results. In the long term, the EMR environment is intended to work seamlessly with the regional EHR, and to share access to e.g. single-source-of-truth lists for medications, problems, allergies etc. which will be provided in the CatSalut EHR environment.

3.3 The CatSalut Health Information Technology Platform (HITP)

The platform is illustrated in Figure 1 below. For reasons of clarity, applications other than the

clinical workstation and generic openEHR apps are not shown on this diagram.

The main components of the CatSalut HITP are as follows.

3.3.1 Core Platform (based on openEHR)

The minimal set of core services and components required to support an openEHR health record.

- EHR: shared, patient-centric health record;
- **Demographics cache** (optional): for recording and maintaining healthcare professional and other (e.g. guardian) demographic information referenced locally by EHRs, *which is not maintained* in external patient and provider registries;
- Privacy and Consent: computable definitions of patient privacy and information use settings;
- Querying: responsible for processing patient and population queries against the main EHR repository;
- **EHR dump/load**: system level repository dump/load function suitable for transferring EHRs to a new product version or product;
- References to legacy patient record documents maintained in a Document Server
 long-term available references between new regional patient record, and legacy data for the same patient;
- Platform Knowledge services ('Definitions'): templates, archetypes, plans, guidelines, rule-sets:
- EHR Admin: system administration dashboard;
- REST APIs: Resource-oriented APIs for access via the HTTP-based REST protocol;
- **Native APIs**: APIs exposed in implementation native technology, e.g. Java, .Net etc; normally used for efficiency purposes by other externally visible services.

3.3.2 Extended Platform (based on openEHR)

An extended set of services and components required to support common facilities based around a shared EHR.

- Identity and Access Management: responsible for representing user identities, roles, capabilities etc;
- (optional) EHR / Subject Index: where the EHR is identified only by EHRid, this service
 provides a secure cross-reference between patient identifier
- EHR Archive: long term storage for EHRs for e.g. deceased patients, other patients no longer with care relationship (e.g. moved away);
- EHR Extract and Export: create extracts for provision to other non-directly connected systems, controlled by privacy and consent settings;
- Event-Condition-Action (ECA) rules and Notifications components for representing rules under which specific events (e.g. committing certain content such as positive Covid test result) and generating programmed notifications to external parties and systems.
- EHR/EMR gateway: synchronise content across shared EHR and institutional EMRs;

- Patient Data Importer: import and convert to openEHR form externally generated EHR content, including lab results, image reports;
- ETL: extract, transform and load facility capable of extracting EHR content into generic forms required by e.g. analytics, registries (vaccinations etc) and reporting systems.

3.3.3 Platform Related Services

The following components are essential services required for the EHR platform to function, and which may be provided by the vendor, or else for which integration is available from the vendor:

- **Terminology service**: provision of terminology for operational use, via an API such as the FHIR terminology service, OMG CTS2 or other published interface;
- System Log: secure log of specified interactions (e.g. CRUD operations) with the EHR and potentially other components;
- CatSalut **reference data** / knowledge services, e.g. drug dictionary etc.
- MPI: registries of patients, providers and facilities.

3.3.4 Other Integration Interfaces

The following components are used to effect common integrations with external systems:

- · Laboratory & imaging orders and results;
- Prescriptions and pharmacy;
- National ISO 13606 summary record;
- CatSalut public health, analytics, research etc.

3.3.5 Major Applications

The platform will support various applications, including the following:

- Clinical workstation the main clinical professional application for interacting with the regional EHR;
- **Professional Portal** a generic web portal mainly used for viewing the patient record, usually with some modification operations;
- Patient Portal a patient-oriented portal on the EHR;
- Decision support enabling computational representation and execution of decisionsupport guidelines, scores and rules to generate notifications to users and other systems;
- Task Planning enabling computational representation and execution of standard care pathways and care protocols.



3.4 Open platform development

The following components are used as part of application development and system testing and deployment:

- Low code development environment / SDK, including for mobile devices;
- Modelling tools for developing archetypes, templates, guidelines, rules etc;
- Sandbox instances/development and tests environment;
- Generic data and system inspection tools;
- System **instrumentation console** (performance monitor, load view etc).

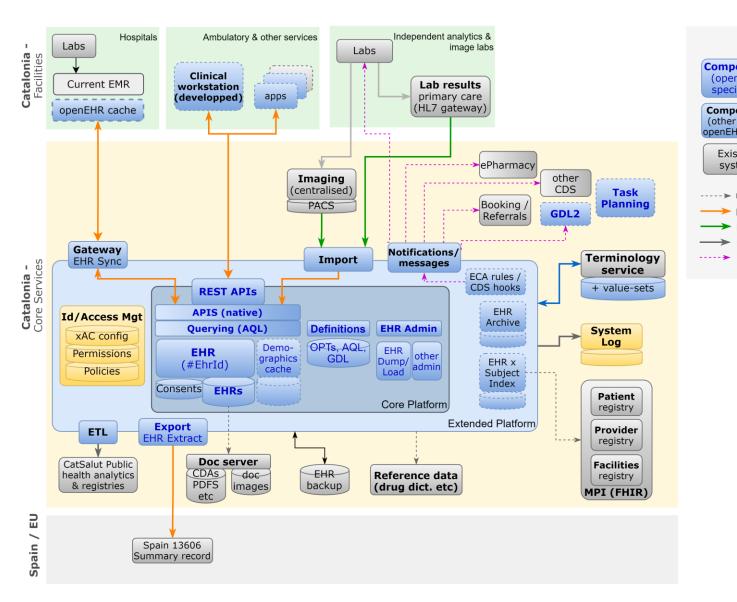


Figure 1 CatSalut Health IT Platform

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