

THE OPENEHR FOUNDATION - MOVING FORWARD

December 12th 2012

Introduction

The openEHR Foundation is evolving to become an operational organisation. A transitional Board established in 2011 has been formed to bring about a series of changes that are outlined in this document. These changes include a move to a Board elected by Qualified Members and Partners as soon as administrative arrangements are in place. Our aim is to support a thriving community of experts who participate in development of the specifications, tools and clinical models to support a standard shareable electronic health record and enable interoperability around the world. We believe this will enhance the efficiency of eHealth applications considerably and provide an important foundation for improving health care globally.

The openEHR Foundation has evolved through several phases, since its incorporation in 2002. In retrospect, these might be summarized as:

- Exploration: the first few years in which there was very loosely defined governance, development focused on specifications, and software was limited to artefact-authoring and validation tools, culminating with release 1.0 in 2006.
- Community building and trial use: basic governance was established for change management
 of specifications; initial versions of system components were created; culminating in Release
 1.0.2 of the specifications in 2008.
- Implementation: Release 1.0.2 is now used by many developers in industry, adcademia and
 government programs. Archetype management tools have been developed and deployed in
 a number of national eHealth programs. During this time, a number of change requests and
 unmet needs have been documented but not yet acted upon, pending decisions about future
 governance and process.

It is time to move to a new phase to meet the needs of industry and government programs and to further refine our specifications, clinical modeling process and supporting software tools. Quality, clinical relevance and documentation are the real focus as well as ensuring a smooth, backwardly compatible, development path. The aim is to guarantee that data and components can be *trusted* by end users and care-delivery organisations. The next phase will involve considerable consolidation and include changes in:

- Organisation: establish stronger and more open governance of the assets of the Foundation
- Engagement and advocacy: make it clearer how people and organisations can participate in the Foundation and what benefits will accrue
- *Licensing*: ensure that our licensing model is appropriate for widespread uptake without encumbrance, engendering government and industry confidence.

In September 2012, the Foundation convened a meeting of the openEHR Transitional Board and various stakeholders using openEHR, including vendors, academics and standards experts. The result of the meeting was a review of objectives, and a reformulation of the organisational structure, governance and business model needed to achieve them. This document now represents a consensus of key stakeholders.



MISSION

The mission of the Foundation remains the same:

- Making the interoperable, life-long electronic health record a reality
- Improving health care in the 'information society'.

It does this by:

- Developing open specifications
- Supporting development of open source software
- Supporting authoring of clinical content models as archetypes, templates and related terminology subsets
- Ensuring that all outputs can be used around the world.

The Foundation has reaffirmed that it will:

- Keep to key founding values of requirements focus, agility and coherence
- Grounded in implementation, implementation, implementation
- Focus on the essentials that everyone requires
- Raise the profile of the Foundation through improved engagement and accessibility
- Consolidate relationships to related standards, industry and professional bodies
- Maintain maximum transparency throughout.

KEY STRATEGIC ACTIVITIES

The key differentiator for openEHR is a relatively straightforward method to achieve functioning electronic health records and semantic interoperability.

PUBLICISING THE OPENEHR METHOD

The openEHR Method has arisen from a separation of information features which are required to be concrete and stable from clinical information definitions which are necessarily labile and constantly evolving. The former generally relate to provisions for accountability and audit trail as well as support for distributed computing. The openEHR specifications refer to this as the reference model (RM). The RM is a regular set of object-oriented classes which can be expressed in software and UML. This is the first level model.

The latter is clinical content, such as a report, a blood sugar measurement, a physical examination finding. While it is possible to write a schema for each of these clinical content specifications, the reality is that they evolve over time, sometimes rapidly. The openEHR method allows these volatile clinical models to be expressed in a language known as ADL¹, providing a second level of modeling capability. The tools aim to make it possible for clinicians and other domain experts to work at this level.

The openEHR Method includes:

• The innovative two level modeling approach with RM and ADL

¹ Archetype Definition Language from the openEHR Foundation.



- Clinical specification of the content (at the level of the archetype and template)
- Evolution of the clinical models over time with a formal update and publication process
- The ability to store, display and query structured data that may be unknown to any particular application
- Formal specialisation of second level clinical models (archetypes and templates) to meet local needs in a particular setting while remaining compatible with the shared health record.

STAKEHOLDER CONFIDENCE

The Foundation aims to build confidence in openEHR by focusing on stakeholders. The following stakeholders have been identified as key in the next three years:

- Clinical system suppliers
- National eHealth programs
- Health provider organisations
- Clinicians at the coal face
- Health professional organisations
- Health ministries
- Standards organisations (SDOs)
- Health payers
- Citizens and civil organisations
- Academics and researchers

The major focus is clinical system suppliers, recognizing that these are the organisations which are directly responsible for implementing openEHR. National eHealth programs remain a focus in many parts of the world, as suppliers often seek standards adopted by such programs. Providers and payers are important advocates, as are clinicians and their organisations. Although citizen groups appear further down the list, the Foundation recognises that empowering citizens is critical to improving health outcomes. Academics and researchers are also critical to the success, but the Board feels these groups are reasonably engaged already.

To gain the trust and increase uptake of openEHR internationally the following areas of activity and development are considered the most important over the next 3 years:

- Clinical models, the Clinical Knowledge Manager (CKM) web-based application and the attendant methodology for specifying EHR content
- Tooling to support the uptake of openEHR modeling and implementation
- Community expansion, including user groups
- Training/Educational Resources
- Case studies, success stories
 - Championing of key developers through announcements and website
- Development of applications and openEHR Servers
- High quality specifications & methodology
- A web site/wiki/Jira/Github/Mailing lists

Authoring, review and publication of openEHR archetypes is considered by far the most important activity over the next three years along with tools to support this activity. The importance of other activities is not underestimated; rather the benefits of all implementations are greatly enhanced



when there are shared archetypes (clinical content specifications) to use as the data models within the application.

Translation of key openEHR Foundation documents and development of the online in other languages, addressing local or language specific issues are important. This is primarily the responsibility of the Localisation Program.

ESTABLISH THE FUNDING MODEL

The openEHR Foundation will become a trading Non-Government Organisation (NGO) with a funding model based on:

- Organisational Partners with paid annual membership:
 - Industry Partners whose openEHR-based offerings have achieved the accepted level of conformance
 - o Academic Partners who have accredited education, research or R&D capability
 - National Partners who have committed to use openEHR as part of their eHealth program
- Sponsoring Partners of the Foundation to provide funds or in kind support in return for organisation Logo visibility on the openEHR website
- Payments to the Foundation to broker a particular work program which would be outsourced to suitable organisations
- Potentially:
 - Conference revenues
 - o Donations.

The key areas of fund raising in the short term will be:

- Sponsorship based on a seed grant to establish a sustainable organisation
- Partner membership fees (see Partners below)

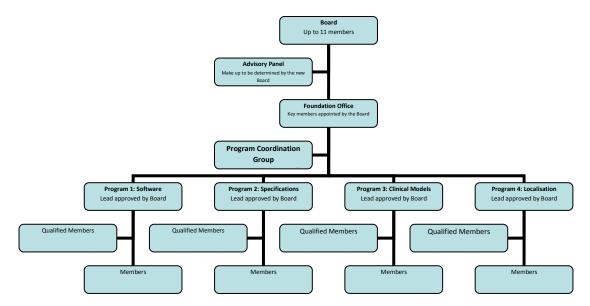
THE OPENEHR FOUNDATION STRUCTURE AND GOVERNANCE

It is proposed to alter the structure of the openEHR Foundation both in terms of membership and organisational structure.

Two categories of membership are defined: Organisational Membership or Partners (paying) and Individual Membership (free). Within the Individual category, various sub-categories are recognised, based on seniority and level of responsibility in a similar manner to open source organisations such as the Apache Foundation. Members with rights to make changes to Foundation Assets will be known as Qualified Members.

The work of openEHR will be divided into four 'Programs'. Three programs, namely Specifications, Software, and Clinical Models will concentrate on development, while a fourth Localisation program will focus on enabling local members and users around the world. This will be done by establishing a network of local Affiliate Organisations responsible for advocacy, education, translation, and local activities such as user groups.





FOUNDATION BOARD

The Foundation Board will be larger and more representative. Its responsibilities will be to develop strategy, appoint the CEO, approve key appointments (Program leads), and determine policy for financial and human resources delegation. The membership of the Board will consist of:

- 2 Directors nominated and elected by Qualified Individual Members
- Up to 7 appointed by Partners on the basis of the skills needed for the Board to function effectively
 - o 2 Directors by Industry Partners
 - o 1 Director by Academic Partners
 - Up to 5 Directors by National Partners -1 appointment per region
 - The Americas
 - Asia (Former Soviet States, China and India)
 - SE Asia and Pacific
 - Africa
 - Europe and Middle East
- One senior director (which may be an additional appointment) who may be appointed as the President of the openEHR Foundation as determined by the Board.

Differential terms of up to 2-4 years at the outset will provide a staged re-election process going forward. The Board will appoint a CEO when sufficient funds become available. Ongoing terms of appointment will be up to three years.

The Leader of each program group will be decided by the Qualified Members of that Program (by election if necessary) and approved by the Board. The initial Program Leads have been appointed by the Board during the establishment phase and are:

• Specifications: Thomas Beale

Software: Erik Sundvall

Clinical Models: Heather LeslieLocalisation: Koray Atalag



The Board may appoint an Advisory Panel with members determined by the Board who may seek nominations from Qualified Members and Partners.

INTERIM BOARD MEMBERS AND DECLARED INTERESTS

Director	Current roles and interests
Sam Heard, Chair person (Dr Med)	CEO of Ocean Informatics Pty Ltd Chair of NT General Practice Education Board Senior Visiting Research Fellow, UCL
David Ingram (PhD)	Emeritus Professor of Health Informatics, UCL Director of Charing Systems, UCL Business Director of a number of unrelated charities
lan McNicoll (Dr Med, M HI)	Contractor to Ocean Informatics, NHS Scotland, NHS England (Health Informatician) Executive of HandiHealth
Jussara Rotzsch (Dr Med)	Contractor with the Ministry of Health and other Brazilian agencies (Health Informatician)
Dipak Kalra (Dr Med, PhD)	Professor of Health Informatics, UCL President elect of EuroRec Contractor to various national eHealth Programs Editor of AMIA Standards Publication
Bill Aylward (Dr Med, PhD)	Director of Open Eyes Project Chairperson of Audit, Royal College of Ophthalmologists Chair of Expert Working Group in National Information Centre, NHS England

FOUNDATION OFFICE

The Foundation Office will manage the day-to-day operation of the Foundation and provide overarching management of the Foundation programs. Coordination of Program activities will be reviewed by a special group appointed by the Foundation Office and approved by the Board. This group will be known as the Program Coordination Group. The Foundation aims to have a small number of paid staff to support this work, including a Chief Executive Office, and provide support where needed by the Program Leads. All work is performed in 'projects', administered by the respective program groups.

Core activities include:

- Manage the finances of the Foundation
- Ensure effective working and coordination of the Programs
- Member communications and relationships
- Running an annual conference where the *open*EHR community meets face-to-face
- Liaise with industry, eHealth standards bodies and national eHealth programs.

THE PROGRAM COORDINATION GROUP

A group will be formed and supported by the Foundation Office that ensures coordination of the activities of the Foundation. This group will work with the Programs and Community to ensure:

- Requirements are gathered and documented
- Specifications address requirements in a timely manner
- Clinical models are generated in sufficient numbers to support health care



- Changes are managed to minimise disruption and burden on industry
- Tooling support is available
- People are sufficiently aware of the Foundation activities.

PARTICIPATION

Participation of individuals in the Foundation will be at different levels. The key participants will be Members who can participate in projects and, through that experience, become Qualified Members and able to commit changes to the core assets of the Foundation. Qualified Members are then able to go on to be members of a Program Group and perhaps lead a Project within that Program.

MEMBERSHIP

Members may:

- Join the Foundation by subscribing to the Mailing Lists
- Participate in the day-to-day Program and Project work of the Foundation
- Have access to all openEHR Foundation assets

QUALIFIED MEMBERSHIP

After gaining experience contributing to one or more Foundation Projects, individual Members may qualify (Apache style) for the right to commit work or take on other key roles, overseen by Program Leads and the Foundation Office. Qualified Members may:

- take on formal roles in the Programs or Projects
- nominate up to 2 Foundation Board directors and vote for directors if there are excess nominations.

Each Program will keep a register of Qualified Members which will be updated annually in December. The register will include the person's name, qualifications, country of residence, email address, employing organisation(s) and date of review. The people on this register at the announcement of an election to the Board will be eligible to nominate and vote for 2 board members. If less than 3 nominations are received by the nomination closing time, no election will be held.

PARTNERS

The openEHR Foundation will establish an organisational membership category known as Partners consisting of the following types:

- Industry Partners
 - o Software suppliers using openEHR
- Academic Partners
 - Universities and training organisations
- National Partners
 - Ministries of Health or national eHealth Programs
- Sponsoring Partners
- Large companies or organisations who want to provide resources to raise the profile of openEHR and their own organisation for mutual benefit.



Partners will be responsible to ensure that their membership information is up to date and includes the email address of the person who will nominate and vote on behalf of the organisation.

Partners will the gain the following benefits:

- Preferential access to and planning of conferences and educational events
- Option to establish formal bilateral relationships with the Foundation if appropriate
- Access to a workspace within the Clinical Knowledge Manager (CKM) either as a standalone instance (as part of a national eHealth Program) or as a subdomain of a national or international CKM instance
- The right to endorse particular assets of the Foundation

All Partners who are fully paid up Organisational Members at the announcement of a Board election will be able to nominate and vote for up to two vacant organisational member positions.

NATIONAL MEMBERS

National governments or government organisations will be able to take out national membership on the basis of a contribution to the running costs of the openEHR Foundation. National Members will be entitled to install and maintain a badged national instance of the openEHR Knowledge Manager as part of the negotiated arrangement.

National Members will be able to nominate and vote for a Board Member within their region. Arrangements to ensure participation by all National Members within a region may be instigated if deemed necessary.

NATIONAL AFFILIATES

The openEHR Foundation will work with other nationally focused not-for-profit organisations (including SDOs) under the Localisation Program. Any organisation taking on the lead in development and uptake of openEHR in a country can be recognised as an Affiliate. Affiliate status is decided by the Foundation Board and recognised with a formal bilateral MOU.

Affiliates of the openEHR Foundation must satisfy the following criteria:

- Non-for-profit or public organisation
- Demonstrable open membership
- Agree to engage with openEHR Foundation on a regular basis in order to facilitate planning
- Agree to requirements on use of openEHR trademarks, domain names, and other elements of branding.

Current Affiliates of the openEHR Foundation are:

- HL7 Australia
- HL7 New Zealand
- SBIS, Brazil



ASSET ENDORSEMENT

The openEHR Foundation will establish a means for Partners to endorse particular assets published by the Foundation or National Partner, providing the means to demonstrate that particular artefacts have the backing of these parties. An endorsement process will be developed for:

- Specifications
- Clinical Models
- Software.

The mechanism for endorsement will first be developed for the Clinical Models (archetypes, templates and terminology reference sets) and become part of the Clinical Knowledge Manager environment.

INTELLECTUAL PROPERTY AND LICENSING

The three areas of work that constitute the Foundation IP will be licensed in the following manner:

TABLE 1: LICENSES

Asset	Description	License
Specifications	Specifications for software and development processes	Copyright openEHR Foundation Creative Commons: CC-BY-ND
Software	Open source software supported by the Foundation	Apache II
Clinical Models	Archetypes, Templates and Terminology subsets developed by the openEHR community	Creative Commons: CC-BY (or equivalent) Choice of contributors to: Give copyright to openEHR Foundation Use CC-BY license and make available in a content management environment approved by the Foundation.

Some Members of the openEHR Foundation have expressed concern regarding the CC-BY-ND (free use, acknowledgement and no derivatives) for the specification as it will mean it is not possible to branch the specifications. The Interim Board has judged that the organisation is too early in its development to judge whether the potential chaos arising from multiple branches would be more damaging than the lack of commitment to allowing unfettered use of the specifications. This position is not seen as irrevocable and should be reviewed regularly.

Clearly the 'no derivatives' aspect of the specification license means that the Foundation needs to be responsive to all concerns, supportive of experimentation. The Board seeks to keep some singularity in approaches to enable interoperability.

PRINCIPLES OF LICENSING:

• openEHR Specifications, Software and Clinical Models (archetypes, templates and terminology subsets) made available to the public at no cost



- Specifications, open source software and Clinical Models can be used without restriction in commercial products
- That authoring of derivative models (archetypes, templates and terminology subsets) by one party does not in any way limit the rights of others to create those same models.
- Forms or other software artefacts using the models as inputs can be protected in the same way as any other work is protected commercially (regardless of openEHR Foundation licenses)
- Query languages using the models may be freely developed and protected commercially without restriction
- The IP of the logical model should be protected by the Foundation regardless of its physical expression (e.g. ADL, XML etc.)
- Require Contributors to declare if there are any current or future IP or patent claims in any content being contributed
- The openEHR Foundation will verify or obtain appropriate agreements where needed to use any external IP including:
 - o measurement scales (eg Glasgow Coma, Braden etc)
- Terminology codes, value sets and reference sets.

LOCALISATION AND ADVOCACY

A fundamental requirement for advance of eHealth is that technologies can be easily adapted and used across as large a range of settings as possible — across nations, regions and in different healthcare settings. Accordingly, the openEHR Foundation has established the Localisation Program to work specifically in this domain.

Supporting local uptake will require advocacy. While this will be a concern of the Board and operational group, it is likely that the best advocacy will come from those who are working in similar settings and with the same language to those seeking solutions. It will be very helpful if the advocates have already made progress.

The Localisation Program will assist with:

- Helping local groups to build a presence and effective organisation
- Support with understanding the Foundation's materials and processes
- Support collaborating academic centers and projects
- Provide materials and presentations that explain the potential and realised social benefit of openEHR
- Finding national organisations that can function as openEHR Affiliates
- Establishment of new openEHR Affiliates.

CLINICAL PIONEERS

The Foundation Board and Office, with the support of the openEHR community, will seek to raise the profile of openEHR clinical pioneers. These pioneers will be:



- In active clinical practice and involved in using health records to raise care to a new level through dynamic new approaches or marshalling colleagues to align around demonstrable outcome gains
- Using openEHR as the foundation technology for this work

TABLE 2: EXAMPLES OF OPENEHR PIONEERS

Pioneer	Location	Description
Tony Shannon	Leeds Teaching Hospitals, UK	Clinical Portal
Bill Aylward	Moorfields Eye Hospital, London UK	The Open Eyes project
Dolly Olesen	Centre for Healthcare Related Infection Surveillance and Prevention, Queensland Health, Australia	Infection Control System
Rong Chen	Stockholm, Sweden	Cambio software developments based on openEHR approaches

STRATEGIC APPROACH TO STANDARDISATION

IHTSDO

A relationship with IHTSDO is key to openEHR, since openEHR's own work relies heavily on quality terminology and related tooling. The openEHR Foundation will work with IHTSDO to:

- Agree on a clinical model/terminology interface
- Integrate openEHR and IHTSDO tools.

CLINICAL INFORMATION MODELING INITIATIVE (CIMI)

This quasi-standards forum has been formed to address global interest in clinical modeling and identify a modelling formalism and repository tooling for managing clinical models. CIMI decided in 2011 to use openEHR's Archetype formalisms as the native clinical modeling formalism, and as a basis for extending UML to provide the same capability. A key function of CIMI is in bringing together diverse agencies with interests in clinical content.

The openEHR Foundation will work with CIMI on new requirements for clinical modelling, and providing support for repository tooling and modelling methodology.

ISO TC 215

The openEHR Foundation will work with experts in the standards community on improving ISO e-Health standards in general, and specifically on the ISO 13606 revision started in 2012. openEHR will provide a snapshot of ADL/AOM 1.5 as a candidate for the revision of ISO 13606-2, and will work with the wider community on a revised version of ISO 13606-1 which fully harmonises the openEHR information models with the 13606 equivalent.



HL7

The openEHR Foundation will work with HL7 primarily on connecting content modelling technology and models with HL7 concrete formalisms, including CDA and FHIR.

OMG

The openEHR Foundation will work via its members on various OMG standards, including the recently proposed Archetype Modelling Language (AML) extension to UML.

SERVICE ORIENTED PLATFORM AND INTERFACES

The openEHR Foundation will work with a number of formal and informal bodies on developing harmonised service models and APIs for health applications working with archetype-enabled information. These include:

- SMArt (Harvard, US)
- HANDI mobile platform (UK)

THE OPENEHR WEBSITE - A CLEAR MESSAGE

The openEHR online presence will be implemented with the following technologies:

- Website
- Clinical Knowledge Manager with archetypes, templates and terminology subsets
- Discussion lists for Programmes and specific projects
- Wiki(s)
- Version control repositories including openEHR@GitHub and Subversion
- Issue trackers for all Programmes and projects
- openEHR YouTube channel
- openEHR presence on FaceBook, LinkedIn, and other social media
- openEHR entries on Wikipedia and other open knowledge portals.

The openEHR Website provides excellent visibility for a mostly technical audience. The Web site needs to give a much clearer message about the organization, who is using the outputs and how to participate. Key messages will be:

- An introduction for visitors about openEHR
 - o What is openEHR?
 - O Who is using it?
 - o How do I make use of it?
- What is available for Members & Qualified Members
- What is available for Partners: Industry, National, Academic, Sponsoring
- Success stories with openEHR
 - Marand
 - Ocean
 - o Cambio
- A link to accreditation processes and Industry Partners
- Information about use of openEHR in National eHealth Programs



- The four programs clearly represented and accessible
- An overview of the specifications with obvious links to related requirements and change management
- A software development repository ideally with Hosting (Jira, GitHub)
- Content repository and associated development/consultation/governance (CKM)
- Record of openEHR Foundation activities, operations and finances
- Open user community and membership with search by role and demographics developer etc
- Library of openEHR related publications
- Diary and events
- Support for accreditation of systems in future

The emphasis will be on clarity and efficiency of use.

