# THE *OPEN*EHR FOUNDATION - MOVING FORWARD

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## INTRODUCTION

The *open*EHR Foundation is about to change to become a working organisation. A new Transitional Board has been formed to bring about a series of changes that are outlined in this document. 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 logical electronic health record and enable interoperability. We believe this will enhance healthcare and the efficiency of eHealth applications considerably.

The *open*EHR 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.
- *Implementation*: Release 1.0.2 is now used by many developers, including in industry and government programmes; archetype management tools have been developed. During this time, a number of change requests and unmet needs have been documented but not yet acted upon, pending decisions about future governance.

It is time to move to a new phase to meet the needs of industry and government programmes and to further refine the *open*EHR specifications, clinical modeling process and supporting software tools. Quality 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:* make it clearer how people and organisations can participate in the Foundation
- *Licensing*: ensure that our licensing model is appropriate for widespread uptake without encumbrance and engenders government and industry confidence.

This document sets out a forward-looking manifesto for the Foundation, to deliver these outcomes.

## MISSION

- 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

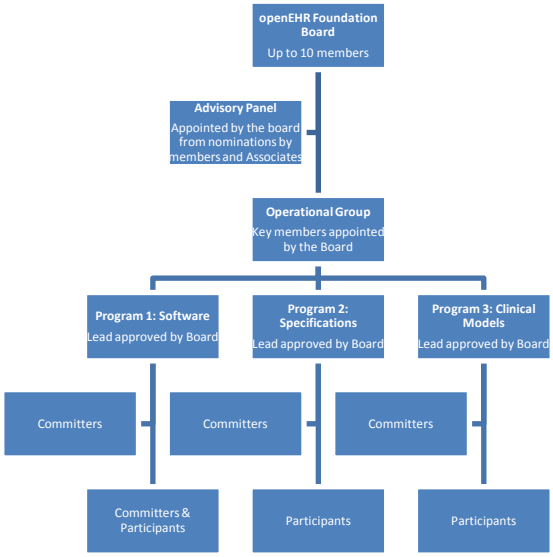
## ESTABLISH THE FUNDING MODEL

Move the Foundation to a trading Non-Government Organisation (NGO) with a funding model based on:

- Organisational Associate fees
- Project resourcing
- Possible
    - Fee for use of Trademark
    - Conference revenues
    - Donations

## *OPEN*EHR FOUNDATION STRUCTURE AND GOVERNANCE

It is proposed to alter the structure of the openEHR Foundation by dividing the activities into three Programs, namely 'specifications', 'software', and 'clinical models'. Work will be carried out in 'projects' within these Program areas by community members. An Operations Group will manage the Programs. The foundation board will be a larger group elected by the Associates, and an Advisory Panel added to provide external strategic input.




## FOUNDATION BOARD

The Foundation Board will be larger and more representative. Its responsibilities will be:

- Develop strategy and delegation of responsibilities
- 10 Board Members nominated and elected by Associates

- Initially:
    - UCL and Ocean to have one Board Member each for 5 years
    - Up to 4 other key organisations providing resources to be offered Board Membership for 5 years
- Appoint key members of the Operations Group
- Approve leaders of each Program Group whom are determined by the Members
- Appoint Advisory Panel from nominations by Members

## ADVISORY PANEL

This group will be established to enable broader input into the Board's formulation of strategy and review of effectiveness of the Foundation. The group will be:

- Nominated by Members
- Selected and Appointed by the Foundation Board (maximum 15 people)
- Drawn from a wide range of stakeholders e.g. government, industry, related NGOs, academia.

## OPERATIONS GROUP

The Operations Group manages the day-to-day operation of the Foundation and provides over-arching management of the three Foundation programmes. The Foundation will aim to have a number of paid staff to support this work including a Chief Executive Office and three Programme Leads. All work is performed in 'projects', administered by the respective program groups.

Core activities include:

- Manage requirements gathering and documentation
- Manage development of the *open*EHR specifications
- Manage authoring of archetypes and other knowledge artefacts
- Manage open source software projects
- Oversee organisational and professional development work – supporting education, uptake and evaluation
- 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 first appointment will be a business development person, then administrative support, before moving to a full operational structure.

## PARTICIPATION

Participation of individuals in the Foundation will be at different levels. The key participants will be Members who can become Contributors and, through that experience, become qualified to commit


changes to the core assets of the Foundation. These Committers are then able to go on to be members of a Program Team and perhaps lead a Project within that Program.

### MEMBERSHIP

The membership model is:

- Free individual membership
    - enables participation in the affairs of the Foundation and access to all assets
- After gaining experience contributing to different Foundation Programs, individual Members will qualify (Apache style) for the right to commit work or take on other key roles, overseen by Programme leads and the Operational Group
- Qualified Members will become leaders of the Programmes or Software Projects.

### ASSOCIATES

The *open*EHR Foundation will establish a group of fee-paying Organisational Associates. This group will:

- be open to industry, universities, governments, standards development organisations
- nominate Foundation Board directors and vote for directors if there are excess nominations
- have preferential access to and planning of conferences and educational events
- be able to establish bilateral relationships with the Foundation if appropriate.

## ENDORSEMENT PROGRAM

The openEHR Foundation will establish a means for organisations and members to endorse particular assets published by the organisation. This will provide a 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 main Foundation IP will be licensed in the following manner:

**TABLE 1: LICENSES**

| Asset | Description | License |
|---|---|---|
| **Specifications** | Specifications for software and processes | Copyright openEHR Foundation |
| **Software** | Software with IP rights ascribed to the *open*EHR Foundation | Apache II |
| **Clinical Models** | Archetypes, Templates and Terminology subsets developed by the community | Creative Commons for organisational and individual use. CC-BY-(SA) The Share Alike (SA) is specifically applied to derived archetypes and templates only. |

## PRINCIPLES OF LICENSING:

- *open*EHR Specifications, Software and Clinical Models (archetypes, templates and terminology subsets) available at no cost
- Specifications, open source software and Clinical Models can be used without restriction in commercial products
- Protection to ensure 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
- 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

- Have formal agreement to use any measurement scales (eg Glasgow Coma, Braden etc) if required
- Have a formal agreement to use any terminology codes, value sets and reference sets where required.

# Priority Activities

## Clinical Pioneers

The Foundation Board and Operational Group with the support of the Community will seek to raise the profile of between 5 and 10 openEHR clinical pioneers. These pioneers will be:

- In active clinical practice and involved in using health records to shift the level of 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 |

## Strategic Approach to Standardisation

### IHTSDO

- Work with IHTSDO on a clinical model/terminology interface
- Work with IHTSDO on tool integration

### Detailed Clinical Models

- Work with the international DCM group on developing a universally acceptable formalism for clinical modelling

### ISO 13606

- Develop a manifesto and community action which might include
    - A commitment to work towards harmonisation of openEHR as the implementation pathway of 13606
    - Alignment of 13606 as a pure subset of *open*EHR
- Special attention will be needed to deal with ISO/HL7 data types (?profile as for IMH)

### HL7

- Maximise formal tooling to move from archetypes to HL7 artefacts (e.g. Australia)
- Offer *open*EHR as a pathway for standardisation of structured data
- Continue to work towards simplification of data types that can be used in systems

### ASTM CCR

- Maintain alignment through templates (e.g. New Zealand)

## Service Oriented Platform and Interfaces

The *open*EHR specifications have been designed to support services in a service-oriented architecture (SOA). These services include the EHR and Demographics at present with means of accessing other key resources such as Terminology. The service layer includes a 'virtual EHR' for decision support.

Further development of the platform API to version 1.0 is necessary for many initiatives where service level specification is all that is being sought. The role of AQL (Archetype Query Language) in such a platform approach is powerful as are templates which deliver simple 'micro-formats' for key archetypes such as Allergy/adverse reactions, problem/diagnosis and medications.

Implementation of key IHE profiles will be actively pursued.

## Software Development

The focus of software development needs to be:

- open source workbench tooling that enables verification of software against specifications
- open source software that enables end-to-end demonstration of archetype/template life cycle
- prototype implementations that enable vendor and open source community engagement

### Application Bootstrap and Showcase

The clinical community finds it challenging to engage with the Foundation without experiencing the software based on archetypes and templates. For this reason the Foundation will:

- Nominate 2 – 3 applications which are open source and associated with Clinical Pioneers for high profile support by the community
- Develop a showcase on the website where people can see and use applications based on the openEHR Platform

Raising the profile of components and applications using openEHR is a priority.

### Access to the Reference *open*EHR ADL Compiler from Java

There are a number of initiatives to make the work of the Foundation more available to those using a diverse set of languages (Java, Python etc). These activities need support and a raised profile.

## ENGAGEMENT

Engagement of users and other stakeholders will be greatest through uptake of the results of the participation of employees and members. Most of the actions in this paper aim to address this issue. The catch phrase is: “Free to participate, free to use”.

However, both government and industry need to feel confident that the openEHR Foundation assets will be maintained and developed in a responsible manner. This will be achieved through suitable engagement that does not lead to unnecessary proliferation of representation.

The openEHR Foundation is seeking industry, government and academic support through fees that provide access to the governance process. One way to engage this support is to seek a Board Member from existing organisations that have considerable buy-in. Examples might include:

- IHTSDO for terminology
- Continua for devices and consumer entered data

Such positions would be linked to some financial support and the assurance that the interface with that domain would be managed by the openEHR Foundation Board. Licensing for national uptake of openEHR might be managed by such organisations where close coordination with existing work was critical.

Another way to proceed is to seek substantial support from a number of industry players and to enlist their support in a governance capacity by nominating a Board Member for a period of 5 years. This would be restricted to perhaps 3 Board positions over the next phase of the openEHR Foundation’s operations. The constitution would revert to nominations and voting by Associates after a suitable period.

The openEHR Foundation may itself nominate a Director to other organisations in the future.

## A CLEAR MESSAGE

The openEHR Web site 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 need to be:

- An introduction for visitors about openEHR (half a page)
- An overview of the specifications with obvious links to related requirements and change management
- A software development repository ideally with Hosting (Jira, GitHub)
- Software bootstrap and showcase (see above)
- 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

# APPENDIX A

Some very limited examples of how each Program might operate. The actual operations of the Programs will be determined by the Members participating in that program and be approved by the Operational Group. The Board may determine that some operational requirements are essential and make proposals to the Program Teams.

## SOFTWARE PROGRAMME

The Software Program will be run by the Software Team who will undertake design of the architecture for the openEHR software tools. The actual tool development will be run as Projects under this Program.

| What | Who | Description |
|---|---|---|
| **Propose a new Project** | Software Programme Team | Projects will be accepted as openEHR Projects by the Software Team. The source repository and commencement documentation will be agreed. |
| **Begin a new Project** | At least two qualified Members | At least two Members will be qualified by the Software Team to commit changes to the software source code. |
| **Commit a source code change** | A qualified Member (committer) | Members working on the project will have to submit code to a qualified Member to commit the changes. |
| **Tool approval** | Software Program Team | For a tool to be a recognised openEHR tool it will have to meet the standards required by the Software Program Team. |

## SPECIFICATIONS PROGRAMME

Members will qualify to edit changes to the specifications. All changes will be approved by the Specification Programme Team which consists of Qualified Members and may form a special subgroup for this purpose. A change to a specification may proceed as follows:

| What | Who | Description |
|---|---|---|
| **Propose a change to a specification** | A Member will propose a change. | The change will be entered in the Change Control Application which requests particular information. |
| | A Qualified Member on the Specification Team | A member of the Specification Team will review the proposal and either: a) ensure it is adequately documented; or b) explain to the proposer why the change is not warranted. This will result in a) passing the change request to the Specification Team or |

| | | |
|---|---|---|
| | | b) withdrawal of the change by the Member who proposed it. |
| **Review a proposed change to the specification** | The Specification Team | The team will: a) accept the change; b) put the change and one or more alternatives to the Members who subscribe to the Specification email list; c) reject the change and notify the list and the Member who proposed the change as to the reason. |
| **Change the specification** | A Qualified Member on the Specification Team | A member of the Specification Team qualified to edit a specification will author the changes. |
| **Release the draft changes** | The Specification Team | The Specification Team will review the changes and release them as draft if they are satisfactory. |
| **Update the change register** | A Qualified Member on the Specification Team | The member of the Specification Team will update the change request information to describe any changes and reasons for these changes, including information as to why a change was not undertaken. |

## Clinical Models Programme

The openEHR Clinical Models will be managed within a comprehensive asset management environment, such as CKM. Proposals for changes or new clinical models can be proposed by one or more Members. The Clinical Models Team will determine if there are sufficient personnel (volunteer or funded) to ensure the quality of the model proposed. Actual changes to published Clinical Models will be undertaken by one or more Qualified Members.

| What | Who | Description |
|---|---|---|
| **Propose a change to a clinical model** | A Member will propose a change. | A proposed change will be entered on the model discussion list or as a formal request to the Clinical Model Team. |
| | A Qualified Member on the Clinical Model Team | A member of the Clinical Model Team will review the proposal and either: a) ensure it is adequately documented; or b) explain to the proposer why the change is not warranted. This will result in a) passing the change request to the Clinical Model Team or b) withdrawal of the change by the Member who proposed it. |
| **Review a proposed change to** | A group of Qualified Members | The group will propose a new model that |

| | | |
|---|---|---|
| **the clinical model.** | governing the Clinical Model. | encompasses the change. |
| **Enlist Members to review the change** | Members or non-Members who subscribe to be notified of changes to that Clinical Model | Repeat the formal review process until there is general consensus that the Model meets the new requirement ensuring backward compatibility with existing data wherever possible. |
| **Release the new Clinical Model** | The Clinical Model Team | The Clinical Model Team will review the new model and ensure it is consistent with the repository of openEHR clinical models and uses terminology appropriately. The Clinical Model Team will then publish the new clinical model. |