Introducing *open*EHR

The *open*EHR foundation

is an independent, non-profit community, facilitating the creation and sharing of health records by consumers and clinicians via open-source, standards-based implementations.

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Overview of *open*EHR

The Foundation

The *open*EHR Foundation is a not-for-profit company, limited by guarantee. Its founding shareholders are University College London, UK and Ocean Informatics Pty Ltd, Australia. It is regulated under the UK Companies Acts 1985 and 1989. The aims and management of the Foundation, exercised through its Board of Directors, are described on the openEHR website. The Board is responsible for the governance of the Foundation, including strategic direction, financial management, legal regulation, and intellectual property (IP) management. The Board determines the roles, structures, and procedures of the Foundation and ensures that these function correctly. The major work of technical and clinical oversight and supervision of *open*EHR product developments is delegated to the Architectural Review Board (ARB) and Clinical Review Board (CRB).

Aims

The *open*EHR Foundation is dedicated to the development of an open, interoperable health computing platform, of which a major component is clinically effective and interoperable electronic health care records (EHRs). It does this by researching clinical requirements, and creating specifications and implementations. The specifications take the form of modular information models, service models and clinical information models. The platform supports the following requirements:

- ability to record any **clinical information**, including complex time-based lab results, imaging, diagnoses, care plans, evaluations, patient education material, and stateful, workflow-based instructions and intervention information;
- **archetype- and template-enabling** of all clinical systems, empowering clinical professionals to define the content, semantics and user interfaces of systems independently from the software;
- proper **integration with terminology** systems, incuding with: SNOMED-CT[1] so that reliable inferencing and decision support based on EHR data will be possible; LOINC[2], so that traceability and sharing of laboratory data is possible; and ICDx[3] and ICPC[4] classifications, enabling reliable reimbursement, management, and public health studies;
- ability to integrate *open*EHR with **messaging** systems, particularly HL7 version 2 and EDIFACT, via the use of "legacy archetypes" and systematic mapping definitions;
- ability to integrate with existing **hospital information systems** and other databases, also via the use of legacy archetypes;
- **integration with applications** via a published API;
- **distributed versioning** and merging of EHR, demographic and other information;
- to make the architecture **componentised, adaptive and future-proof**, so that it may be a reliable basis for managing 100 year+ health records.

The Foundation publishes the specifications for the architecture openly. It also publishes "implementation technology specification" expressions, such as XML and database schemas corresponding to

1. A major ontological terminology effort by the College of American Pathologists; see http://www.snomed.org
2. A code system for laboratory observations. See http://www.regenstrief.org/loinc/.
3. WHO International Classification of Diseases. See http://www.who.int/classifications/icd/en/.
4. Primary care classificatoin. See http://www.globalfamilydoctor.com/.

the models. From these artifacts it creates open source implementations which are validated in clinical environments, used for further research, and ultimately deployed in actual clinical environments.

The other major activity of the *open*EHR Foundation is the development of evidence-based clinical information and workflow models, known as *archetypes*. These are developed collaboratively by domain experts, and published openly in an online, intelligent repository, and are directly consumable by systems based on the *open*EHR archetype principle.

Modus Operandi

The *open*EHR Foundation works in an open manner, based on active relationships with domain experts and users, with national and international standards bodies, including ISO, CEN, and sHL7, with software and system developers, and with educational institutions and researchers. The technical work is carried out within a scientific framework i.e. the use of an experimental methodology to validate and refine hypotheses. It is performed in an engineering mode, i.e. with a dedicated team undertaking an iterative process of requirements capture, design, implementation and testing. All of its deliverables are version-controlled and formally change-managed.

Unlike closed commercial developments, *open*EHR conducts its development in the open, with direct community involvement in specification, software implementation and evaluation, so that users can see and trust the foundations and structures of the software they are using.

Membership

Membership of *open*EHR implies a commitment towards realising the vision of high quality, interoperable EHRs, and a willingness to share ideas and experience. Membership is free, and is available simply by registration on the *open*EHR.org website.

*open*EHR Activities

The *open*EHR Foundation works in two broad activity areas: the “technical” and the “clinical”. The technical area is where engineering work is done, including specifications, implementations, testing and conformance. The clinical area is where healthcare domain professionals and organisations engage with *open*EHR, including on the development and deployment of ontologies, archetypes, templates, guidelines, and clinical education and training. These two areas of activity in *open*EHR are visible in the “two-level modelling” approach of *open*EHR, through which a rigorous yet flexible development framework enables reliable sharing of clinical meaning in addition to guaranteed data interoperability.

Management

Within each of the two *open*EHR activity areas, work is performed by project groups (PGs) each comprising a team of developers responsible for the work done on a project. Change management on some of these projects is overseen by a review board. In the technical area, the Architectural Review Board (ARB) performs this function. Its membership comprises some eight members of *open*EHR, appointed by the Foundation Board, all with long-term experience in an area of health informatics. The current membership of the ARB is posted on the *open*EHR website ARB page. The role of the ARB is to review and make decisions on change requests (CRs) for *reference* projects (defined below). It operates using simple majority voting.

In the clinical area, the Clinical Review Board (CRB) performs a corresponding change management function. The CRB, likewise, comprises an international group of experienced clinical professional

members of *open*EHR. Issues affecting both areas are managed through consultation between the board.

The management structure of *open*EHR is illustrated in FIGURE 1. Projects whose change is managed by the ARB or CRB are shown joined to the relevant board of review; others are not..

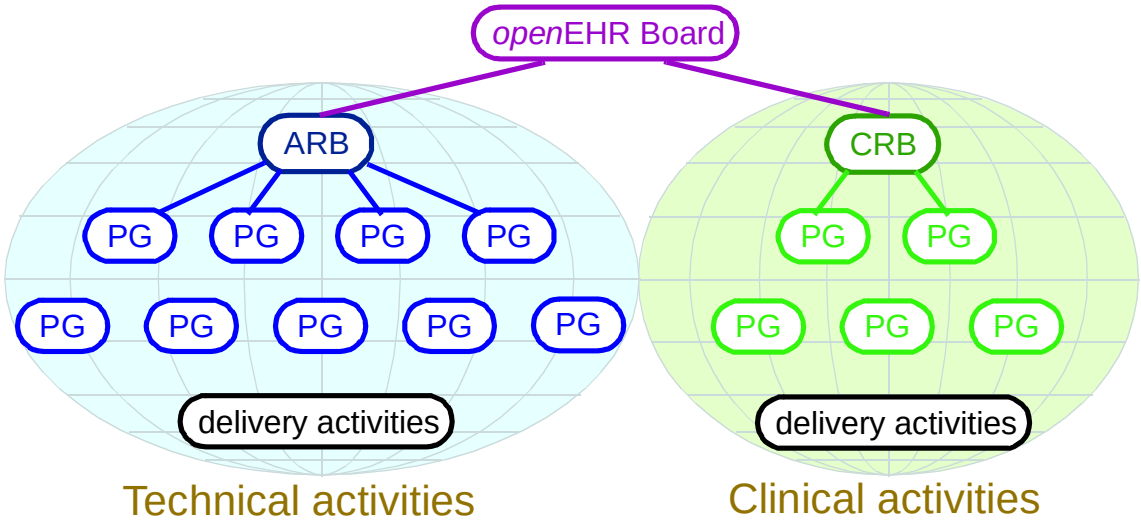

FIGURE 1 Management Structure of *open*EHR

What is an "*open*EHR Project"?

An *open*EHR project is defined as any project that:

- is based on *open*EHR in one of the following ways:
  - contributes to *open*EHR specifications or
  - aims to build something that satisfies *open*EHR conformance criteria of nominated *open*EHR specifications;
- agrees to use the relevant Technical or Clinical Change Management plan (CM Plan) and;
- agrees to the IP framework defined by *open*EHR for its products and services;
- is registered as an *open*EHR project with the *open*EHR Foundation.

Common aspects of *open*EHR change management in both activity areas include:

- the use of version and change management toolset/environment;
- the use of Problem Reports (PR) and Change Requests (CR), and the lifecycle and process for handling them;
- the use of defined operating procedures including for the distribution and publication of artefacts (also described in the CM plans).

Similarly, *open*EHR projects agree to respect the following intellectual property rights.

- All project documents must use the *open*EHR public licence (document form).
- Project source code must use the *open*EHR open source licence.
- The project must respect and preserve the structure of the **org.openehr** namespace, which is managed by the ARB.
- Irrevocability: organisations contributing to projects cannot retrospectively revoke the right of the *open*EHR Foundation and community to continue to use software or other artefacts

which they have developed within the *open*EHR environment (since this would contravene the terms of the license). They may of course use any such developed works as a basis for other developments. This condition ensures that neither the community (which may have come to rely on a component) nor the original developing organisation (which may have spent significant time and money on the development) lose access to the work; if the interests cease to coincide, the development is simply "forked", and only one line remains within the *open*EHR framework.

Copyright of donated IP may optionally be transferred to the *open*EHR Foundation, converted to joint copyright with the *open*EHR Foundation, or may remain with the originating organisation or author.

Projects agreeing to this framework can take advantage of the facilities provided by the *open*EHR Foundation, including version management, build servers and a distribution server. It particularly enables smaller projects to proceed where otherwise they might not have sufficient material resources.

This approach to development is offered as a collaboration environment by *open*EHR, and is not a requirement of developing *open*EHR-compliant products. Development organisations are welcome to develop *open*EHR-based products in any way they see fit. It is expected that many projects will be executed by companies, universities and others, according to their own needs and priorities, including fully commercial and closed source projects.

What is an "*open*EHR Product"?

Regardless of the manner in which its development proceeds, a component, executable, or other artefact (such as a information model schema) can only be represented or promoted as an "*open*EHR product", and can only use service marks containing terms such as "*open*EHR", "*open*EHR-compliant", "*open*EHR 1.x compliant" and so on, if it has been shown to be conformant to the appropriate *open*EHR specification(s), through a testing procedure defined and certified by the Foundation, against a specified set of test cases, test data or other appropriate test material. The name "*open*EHR" is registered internationally as a trademark, and its use with respect to products and services requires permission of the *open*EHR Foundation. In practical terms this means that users of *open*EHR-certified end products (particularly those for clinical information management) can rely on claims by the developer to be "*open*EHR compliant". It aims to prevent non-conformant (potentially faulty) software or other products being promoted under the banner of *open*EHR. The test cases and criteria are developed by the community and reviewed by the ARB and/or CRB.

The following figure illustrates the relationship among *open*EHR projects, products, and non-*open*EHR work.

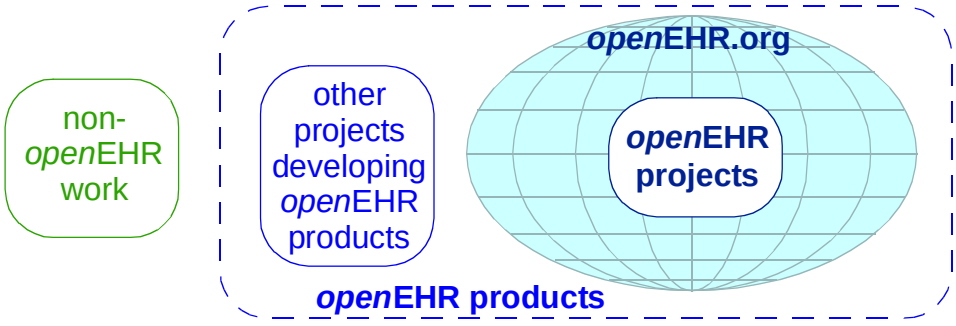

FIGURE 2 Relationship between Projects and Products

Intellectual Property

The *open*EHR Foundation has created a framework to enable the *open*EHR community to build a repository of intellectual property (IP), for common use. Since the IP includes specifications, software, knowledge bases (e.g. clinical vocabularies) and educational materials, which will find use in clinical and related environments, as well as use in research and education, some legal protection is also required. This is to ensure continuing quality and open access to the IP. The measures adopted by the *open*EHR Foundation are typical of those used by standards development organisations (due to the fact that *open*EHR publishes specification documents), and other open source development organisations: copyright, source code licensing, trade- and service-mark protection, and control of the *open*EHR namespace.

Copyright: Recognition of Authorship

*open*EHR copyright exists on four kinds of deliverables: documents, software source (including schemas, interfaces), executable software, and knowledge products, such as terminologies. Legally, copyright law guarantees that the original author of the original version of a given artefact is always recognised. However, it does not, on its own, offer much legal protection of such IP, due to the fact that such artefacts keep changing over time, unlike artistic works, which are generally published once only in their finished form (and for which copyright law was mainly developed). For this reason, the *open*EHR Foundation does not demand that the output of all *open*EHR projects be copyrighted to the Foundation - the copyright may be retained by the original developer, or a joint copyright may be adopted. However, all reference specifications, ITSs and reference implementation project deliverables must be solely or jointly copyrighted to the *open*EHR Foundation. Deliverables of non-reference implementation projects may retain the copyright of the original developing organisation.

Source Licenses: Protection for Developers

Because specification documents, software and related artefacts are by their nature constantly changing, the conditions of use, copying, modification and sale are specified explicitly in licenses, rather than relying on potentially unreliable copyright law (which in any case varies across jurisdictions). Two types of license are used - one for documents, and one for software and related materials. The *open*EHR licenses are available from the Foundation website `license page`. These licenses are designed to guarantee fair, open and continued availability of all *open*EHR products to the *open*EHR community. They provide the main protection for developers of materials that their work will not be taken out of circulation, or otherwise appropriated by private individuals or bodies.

Trademark & Service-marks: Protection for Users

Controlled use of the "*open*EHR" trademark and related service-marks is the main protection for users of *open*EHR products, ensuring that, for any product claiming to be compliant, conformant or otherwise based on *open*EHR, this is in fact the case, and that the exact meaning of the claimed conformance/compliance can be investigated (e.g. by accessing and inspecting the relevant test cases or other materials from the *open*EHR website). The "*open*EHR" trademark and any related service-mark may only be used with permission of the *open*EHR Foundation.

End-use Licenses: Rights of Users

End-use licenses govern the conditions of use of end products - artefacts that can be deployed in a runtime environment. The *open*EHR Foundation itself employs only a minimal end-use license for its reference implementations, which essentially says that the relevant artefact can not be modified while being presented as its original. This simply ensures that a published component is not altered at the binary level and passed off as the original (or at least that where this happens, it is clearly in violation

of the conditions of use). More complex end use licenses (often called “EULAs” - end use license agreements) may be used by commercial organisations to control the use of their products; such licenses are not the business of the *open*EHR Foundation.

The *open*EHR.org Domain and org.openehr Namespace

The *open*EHR Foundation owns the `openEHR.org` internet domain, all related variants and sub-domains, and by extension, the `org.openehr` namespace. Population of the namespace (for example with Java libraries and XML-schemas) is managed on behalf of the Foundation by the *open*EHR ARB, for the benefit of the community. The principal aim is to ensure that the namespace is clearly defined. Only *open*EHR reference deliverables may be defined in the `org.openehr` namespace.

Technical Activities

FIGURE 3 illustrates the areas technical activity of *open*EHR, including specification and implementation projects, and delivery/deployment activities.

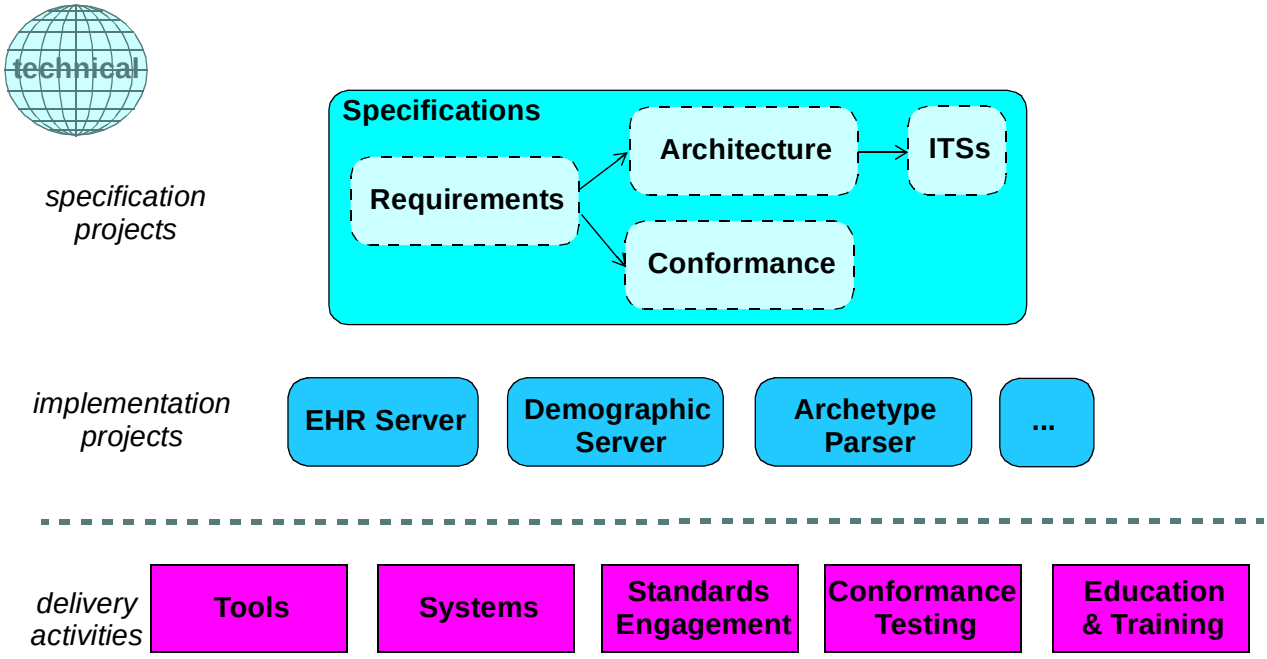

FIGURE 3 *open*EHR Technical Activities

Requirements Project

*open*EHR undertakes the collation of requirements for the design, implementation and deployment of interoperable EHRs a) to support the seamless sharing and continuity of health care and b) to enable EHR systems to interface with medical knowledge, evidence of best practice and other systems needed to deliver safe, secure and effective health services. Requirements developed by *open*EHR are contributed to relevant international standards initiatives.

Architecture Project

The *open*EHR Foundation publishes a number of formal model specifications, including: the *open*EHR Reference Model (RM), consisting of the primary information models (IMs), the archetype

model (AM) which includes the Archetype Definition Language (ADL) and Archetype Object Model (AOM), and the *open*EHR service model (SM), which defines interfaces to major software services in a health information environment.

Because these specifications are underpinned by explicit requirements and by the results of implementation and deployent of previous versions and thus constitute an evidence-based information architecture. As with requirements, *open*EHR architectural specifications are also contributed to relevant international standards initiatives.

Abstract information models are published as directly usable implementation technologies specifications (ITSs), such as OMG IDL, XML, programming languages, and database schemas.

Implementation Projects

The *open*EHR Foundation engages in the implementation of interoperable software components, including archetype and EHR tools and components, using rigorous design and development methodologies. These reference implementations enable the validation of the published specifications, ensuring they are not simply 'paper' exercises.

Standards Activities

The *open*EHR Foundation is committed to supporting relevant government-sponsored and industry-based standards bodies as a means of encouraging the widespread and effective adoption of interoperable EHRs. Members of *open*EHR work closely with standadisation bodies, including ISO TC215, CEN TC/251, HL7 and national standards bodies.

Educational Activities

In order to promote and assist understanding and acceptance of *open*EHR methodology and models by a wide audience, the *open*EHR Foundation develops educational materials, runs workshops, and provides consultancy services internationally. It also develops materials suitable for use in clinical, healthcare, and health informatics courses.

Clinical Activities

Activities in the *open*EHR clinical activity area are illustrated in FIGURE 4.

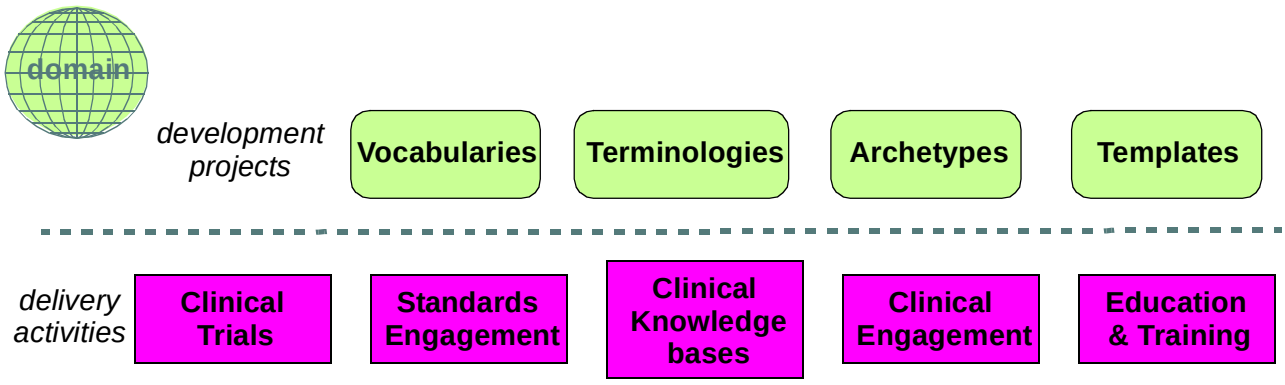

FIGURE 4 *open*EHR Clinical Activities

Vocabularies and Terminology

In the clinical activity area, *open*EHR is concerned with existing and emerging clinical ontologies and terminologies. It also develops specific *open*EHR terminologies of its own to facilitate the integration of software components and knowledge bases, through the use of archetypes and templates.

Archetypes and Templates

Archetypes are a key element of the *open*EHR methodology. They are reusable, structured models of clinical information concepts that appear in EHRs, such as 'test result' , 'physical examination' and 'medication order', and are expressed in terms of constraints on the reference model. All data in *open*EHR EHRs are instances of reference model entities, configured by archetypes. Archetypes also act as mediators between data and terminology. They are language- and terminology-neutral.

Templates are (usually) locally defined models of screen forms, and ring together a selection of archetypes, terminologies, language and other details relevant to the particular local use of archetypes. For example, concepts such as 'referral' and 'prescription' are modelled as templates, which in turn use archetypes for more fine-grained concepts.

Educational Activities

The *open*EHR Foundation develops methodologies and publishes methods and materials for the formulation and use of archetypes, templates, terminologies and clinical guidelines, including those developed by *open*EHR projects. In collaboration with academic colleagues, it also develops materials suitable for use in clinical, healthcare and post-graduate health informatics courses.

Standards Activities

The *open*EHR Foundation is .working with national and international standards bodies and professional organisations to establish standards for the representation, capture and sharing of clinical knowledge for use in health information environments.

The *open*EHR Methodology

The *open*EHR development methodology, designed to formally integrate technical and clinical work in a coherent manner is summarised by FIGURE 5. In the technical environment, modellers and software developers create small, generic models and specifications which are then implemented within systems. They also build tools to support users performing modelling the healthcare domain - the building of archetypes above terminologies and ontologies. At runtime, systems are driven by the definitions created by domain experts using the tools. The information processing capabilities of such systems can evolve smoothly, based mainly on ongoing tool-enabled development work of clinical experts, rather than by continual software maintenance and redeployment.

The key benefits of this approach are:

- direct, flexible and sustainable involvement of domain experts and users;
- significant reductions available in costs of development and deployment of health information systems, due to smaller, more stable software;
- the creation of a much more adaptable and durable health computing environment.

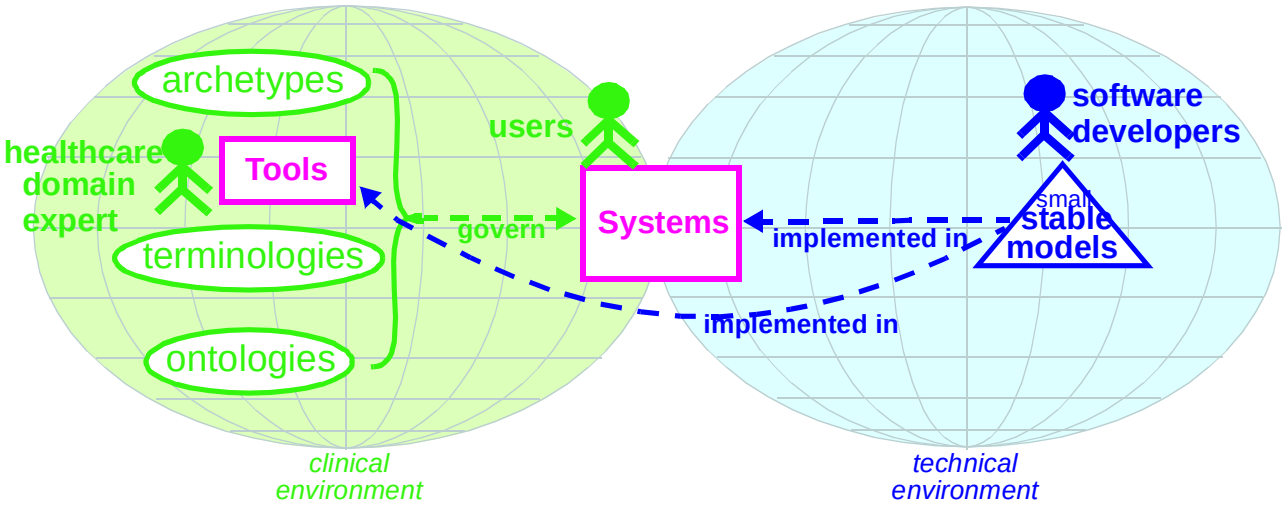

FIGURE 5 The *open*EHR Development Methodology

Participating in *open*EHR

A useful starting point for prospective participants is the openEHR primer.

Membership is free, and obtained via the membership page.

The Foundation maintains four discussion lists:

- *openehr-announce*: one way list for major announcements;
- *openehr-technical*: dedicated to *open*EHR technical architecture, archetype language, service models and so on; recommended for all ICT professionals working with *open*EHR, and healthcare professionals interested in technical issues;
- *openehr-clinical*: dedicated to clinical modelling, archetype development, terminologies, clinical use and demonstration of *open*EHR; recommended for health professionals and ICT people interested in the clinical world;
- *openehr-implementers*: dedicated to implementation issues. Recommended for actual and prospective implementers.

Developers are encouraged to visit the developer page. An equivalent starting point for health professionals is the clinicians' page.

Organisations interested in supporting or contributing to *open*EHR should contact Dr Dipak Kalra at d.kalra@chime.ucl.ac.uk or or info@openEHR.org.

Amendment Record

Issue	Details	Who	Completed
RELEASE 1.0			
1.1	Changes to Aims and Modus Operandi.	T Beale	02 Jan 2006
1.0	Final group review.	D Ingram, D Kalra, D Lloyd	15 Mar 2005
0.9.5	David Ingram review.	D Ingram	12 Mar 2005
0.9.1	Various comments from Dipak.	D Kalra	03 Mar 2005
0.9	Initial writing. Based on CM Plan and *open*EHR planning meetings.	T Beale S Heard D Ingram D Kalra D Lloyd	12 Feb 2005