openEHR

openEHR International

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openEHR
Clinical Program Board (CPB)

Terms of Reference

Amendment Record

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1.0.0	S Garde, PhD (Ocean, DE), P Miller MD (NHS Scotland), Vebjørn Arntzen MD (Oslo UH, NO), J Holslag MD (Nedap, NL), M Nyström PhD (Cambio, SE), S Ljosland Bakke RN (HelseWest, NO), R Dunscombe (Imperial, UK), I McNicoll MD (FreshEhr, UK), H Grain (GeHCo, AU), T Beale (openEHR, UK)	14-11-2022	Initial writing, based on openEHR ToR template, and Clinical Program RFC Sep 2022.

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1 Nomenclature

In this document, the following specific terms are used:

Term	Meaning
openEHR International Board	Refers to the top board of openEHR International, formally known as the openEHR CIC (Community Interest Company) Board
CR	Change Request. Usually created in response to one or more issue reports.
member of openEHR	A *member of openEHR* is any individual who is either: • a currently subscribed individual or professional member of openEHR OR • an employee of a currently subscribed Industry or Organisational Partner of openEHR OR • a member of an Associate Organisation of openEHR.

2 Introduction

This document constitutes the formal Terms of Reference for the **openEHR Clinical Program Board (CPB)**, as approved by the openEHR International Board.

The intention of these Terms of Reference is to provide a clear basis for:

a) openness to new participation;
b) representation of stakeholders;
c) a meritocratic membership model;
d) quality decision making;
e) transparency of deliverables and activity to the outside world;
f) a defined relationship with the openEHR International Board;
g) professional conduct.

This document does not seek to define all the working structures, plans or communications specific to the work of the Program – such details are generally described in other documents developed by the CPB.

3 Clinical Program

The openEHR Clinical Program develops archetypes, templates and terminology subsets, and related documentation, guidance etc, for clinical use in an international setting. These are freely available via the web. The following sections describe the structure and scope of the openEHR Clinical Program.

3.1 Structure

The **Clinical Program membership** consists of the following entities:

1. The **Clinical Program Board (CPB)**, the governing board of the openEHR Clinical Program, which is accountable to the openEHR International Board for its running;
2. The **Clinical Program Expert Panel (CPXP)** is an additional group of experts invited by the CPB, which enables a larger number of experts to participate in the work of the Clinical Program without all having to be formally responsible. The Expert Panel is considered part of the Clinical Program team, and accordingly has access to all internal communications, and to the CPB tool environment. However, it has no formal responsibilities or voting rights.

The above arrangement is primarily to limit the size of the group formally responsible for the work to a leadership team. These will be people who have the capacity and time to take responsibility (collectively) for the Program, vote on matters requiring it, and undertake planning and reporting.

The Expert Panel consists of people of the same kinds of qualifications as CPB members, but who will typically be able to devote less time, may be focussed only on specific areas corresponding to their expertise domain, and who are not formally responsible for votes, reporting etc.

The work of the Program is organised via **Work Groups (WGs)**, created by the CPB for long-running areas of activity. These could be focussed on a clinical sub-domain (e.g. obstetrics), a narrower clinical theme (e.g. PROMS) or related to some other theme, e.g. engagement, quality etc.

Each WG that engages in modelling work (i.e. creating and maintaining archetypes and other kinds of models) acts as the editorial group for any openEHR clinical models in the corresponding area.

3.2 Relationship with openEHR International Board

The CPB is organisationally subordinate to the openEHR International Board, which gives it authority for running the Clinical Program. The CPB is required to report to the openEHR International Board; the CPB must also obtain approval for proposed changes to these Terms of Reference. In matters of misconduct, the openEHR Board has final authority.

3.3 Aims

The primary aim is to establish the openEHR clinical models as an internationally available authoritative source of healthcare data semantics for users of any EHR architecture or interoperability standard, including openEHR.

Here, 'clinical' covers traditional clinics, hospital care, tertiary care, social and community healthcare, and related administrative functions.

3.4 Scope

The scope of activities of the Clinical Program intended to achieve these aims includes but is not limited to the following:

1. **Planning** - roadmap development;
2. **Engagement** - outreach to relevant organisations to enable scaling and sustainability of the modelling effort;
3. **Methodology** - development and maintenance of methods relating to model development and maintenance;
4. **Model development and maintenance** - primary authoring, adoption, translation and quality control of clinical models;
5. **Model dissemination** - publishing and dissemination of clinical models in the openEHR community and within relevant e-health environments;
6. **Infrastructure and tooling** - requirements specification of modelling, testing, verification and repository tools.

A more detailed description of scope may be found in the **Clinical Program roadmap**.

4 Clinical Program Board (CPB)

4.1 Definition

The Clinical Program is managed by the Clinical Program Board (CPB), with the aid of the CP Expert Panel. The CPB membership consists of community members who are qualified (see below) and who have an interest in achieving the aims of the Program.

The CPB membership is posted online at http://www.openehr.org/programs/clinical at an easily accessible location, known as the *CPB home page*.

4.2 Responsibilities

The responsibilities of the Clinical Program Board are as follows:

1. Maintenance of the Clinical Program Roadmap;
2. Determination of resource needs, including human resource and funding;
3. Management of all clinical models and related artefacts, including development, adoption, translation, processing of issues, change requests and reviews of clinical models and related artefacts;
4. Communication to the openEHR community of clinical model reviews, releases as well as changes to the roadmap, board composition and governance documents.
5. Publishing of the clinical models;
6. Risk management, including identification and management of risks related to planned work;
7. Reporting to the openEHR International Board on:
    a. routine progress;
    b. risks and remediation;
    c. resource requirements;
    d. fiscal position;
    e. all other matters of relevance to the delivery of the clinical program.

In addition, the openEHR International Board may advise of requirements for releases and prioritisation of work.

Particular members of the CPB may be assigned to handle major scope areas and/or specific responsibilities listed above.

4.3 Size

The CPB is intended to include sufficient members and knowledge to cover the Scope of activities (section 3.4 above) and to execute the formal responsibilities of the Program.

An absolute minimum of five (5) is required.

Maximum membership of the CPB is limited to 20, on the basis that any larger number becomes difficult to coordinate. Note that the size of the CP Expert Panel is effectively unlimited, but for practical reasons will need to be limited to numbers that may effectively be coordinated in meetings and decision-making.

4.4 Co-chairs

The Clinical Program Board has 1-3 elected co-chairs, who facilitate the work of the Board. The exact number is based on practical needs, and will normally increase with the size of the Board.

The responsibilities of the co-chairs are as follows:

a) to plan and run CPB meetings and perform appropriate follow-up of tasks;
b) to facilitate the execution of the work of the CPB, mainly by managing completion of modification of task deadlines;
c) to report progress and issues to the openEHR International board;
d) to arbitrate in case of disputes.

Administrative support for co-chairing will be required.

4.5 Length of membership

There is no limit on duration of membership of the CPB.

4.6 Establishment

An initial CPB of up to seven (7) members is established by the openEHR International Board as follows:

a) nominations are solicited openly within the openEHR community for candidates satisfying the CPB qualifications (defined below);
b) the nominated individuals will be asked to indicate acceptance (if not self-nominated) and to provide proof of qualification (via a form);
c) accepting candidates are assessed by the openEHR International Board according to the qualification criteria in order to form a final list of accepting qualified candidates;
d) the openEHR International Board will form the Clinical Program Board from the first seven (or fewer) candidates from the list, ranked according to qualifications and representativeness.

5 CPB Operation

5.1 Basis

The CPB operates in its steady state according to the meritocracy approach established by Apache Foundation and other large open source organisations. Accordingly, new members are added via acceptance by the existing CPB membership, according to the rules defined in this document.

5.2 New Members

Candidature for membership of the CPB is by nomination. New nominations may be made in the following situations:

a) The Clinical Program advertises within the community for a new member, e.g. due to a resignation, or need for more human resource;
b) Community members, typically representing a newly joined organisation may self-nominate at any time.

A new nomination must satisfy the CPB Member Qualifications described below.

5.3 Candidature

The candidate should supply a short CV and other qualifying information providing their:

a) statement of interest in working on the Clinical Program;
b) statement of commitment of time and availability;
c) statement of qualifications, according to Section 6;
d) statement of known conflicts of interest.

5.4 Election

The election process is as follows:

a) A new nomination is sent to the co-chairs of the Clinical Program Board, who will publish it internally.
b) A period of up to 28 days may follow to allow for assessment by the current membership. During this period:
    i. the candidate may be asked for more information;
    ii. the candidate may be asked to participate in an online or face to face interview;
    iii. the nomination may be rejected on formal grounds, such as lack of qualification.
c) If the nomination is not rejected, a formal vote is taken, in which the new member is accepted into the Program based on a super-majority vote of the existing members.

5.5 Resignation

An existing Program member may resign at any time from the CPB. In this case, the fact and effective date of resignation will be published, and the published Program membership updated accordingly.

If the resignation is of an CPB co-chair, nominations for a new co-chair are called for, and the CPB rules for co-chair election described below followed.

5.6 Termination

A CPB member will be asked to resign in the case of pertinent conflicts of interest.

An CPB member who has been referred to the openEHR International Board by the CPB for disruptive or other unprofessional behaviour, according to the openEHR Code of Conduct, may be removed by the openEHR International Board following attempts at arbitration.

Where termination leaves a vacancy, the same rules as for resignations are followed.

5.7 Co-chair Elections

Co-chair positions last 2 years. Elections of co-chair(s) by the Program Board are held every 2 years at a fixed date, as well as in the case of resignation of a co-chair. At election time, the positions of co-chairs who have spent 2 years in the position and/or who have resigned are considered vacant. A vacating co-chair may re-nominate or be nominated for a successive term.

The co-chair election process is as follows:

- Existing co-chairs formally indicate resignation to the CPB;
- During the period prior to new co-chairs being elected, a previous co-chair (or his/her nominee) volunteers to execute the election process;
- If the CPB wishes to agree a change in the number of co-chairs, it should do so and announce the intended number;
- Nominations for co-chairs are requested within the CPB;
- A period of up to 2 weeks, or less, by consensus, is allowed for gathering of nominations;
- The nominations are announced and posted clearly within the CPB;
- The number of open co-chair positions is the originally announced number or the number of nominees, whichever is lower;
- At the close of the nomination period, a vote is run either in a meeting or asynchronously; in the latter case, up to one week may be allowed for votes to be received;
- A separate vote is made by each CPB member for each open co-chair position, limited by the
- Votes are tallied for the nominees and the new co-chairs are declared as the nominees with the highest number of votes according to the required number of co-chairs;
- The new co-chairs are announced publicly and indicated on the CPB home page.

A system of alternating / rotating terms may be used to spread the workload and experience across the CPB membership, although this is not strictly required.

Election to co-chair position requires a super-majority CPB membership vote.

6 CPB Member Qualifications

A new candidate for election to the CPB must be **must be a member of openEHR** (as per Definitions section) and should demonstrate the following qualifications.

6.1 Skills and Knowledge

The Clinical Program Board operates as a meritocracy, following the Apache model. This means the starting team (who are considered creators of the effort, and thus 'competent') can establish what qualifications are required of new members. These may be any combination of formal qualifications and participatory experience.

The only formally required qualification for accession to the Clinical Program Board or Expert Panel is:

- An understanding and acceptance of the openEHR mission;

Otherwise, any of the following qualities are desirable:

- Clinical background (with some minimum understanding of information issues), including specific domains; public health, medical research;
- Healthcare management background including knowledge of administration, clinical workflow, etc
- Health informatics background: a demonstrable knowledge of key health informatics areas such as EHR, terminology, etc;
- openEHR experience: some period of active participation in the openEHR community (e.g. CKM review) and /use of openEHR systems or products;
- Experience in knowledge engineering and quality control;
- Experience in open source community building and engagement;
- Experience in tool usability / UX analysis.

6.2 Commitment

The following commitment is agreed to.

a) An expressed interest in actively working on the Program;
b) Agreement to work as an expert for the aims of the Program rather than commercial or other goals of their employer;
c) Availability to attend ideally 70% of calls / meetings over the year;
d) Availability to contribute sufficient time to perform the work, generally a few hours a month;
e) Maintenance of openEHR membership.

It is up to the CPB to agree the engagement mode of any particular member, which may be more or less asynchronous, depending on time-zone and other factors.

6.3 Conflicts of Interest

Any potential conflicts of interest must be declared by the candidate, and the candidate must agree to indicate any such conflict of interest in discussions and decision-making processes of the Program in which they are involved.

7 Clinical Program Expert Panel (CPXP)

7.1 Definition

The CP Expert Panel is an adjunct group of experts invited by the CPB to provide expert input and guidance.

7.2 Size

There is no formal size limit on the CP Expert Panel.

7.3 Qualifications

CPXP members **must be members of openEHR** (as per the definitions section), and have the same skills and experience requirement as CPB members.

The level of commitment to working on the activities of the Program is at the discretion of the CPB.

7.4 Nomination

Individuals are nominated to the CP Expert Panel by a CPB member on the basis of specifically recognised expertise relevant to the work of the CPB.

7.5 Candidature

A nominee becomes a candidate for invitation following a CPB discussion and general consensus, or a vote if needed. The candidate is asked to provide:

a) a CV or similar description of qualifications;
b) a declaration of any conflicts of interest;
c) a declaration that he or she is willing to participate on an ad hoc basis, including review of specific issues, models or other deliverables that are in the area of the candidate's expertise.

Following a positive vote, the candidate is invited to join the CP Expert Panel.

7.6 Resignation

A CP Expert Panel member may resign at any time.

7.7 Termination

A CP Expert Panel member will be asked to resign in the case of pertinent conflicts of interest.

A CP Expert Panel member who has been referred to the openEHR International Board by the CPB for disruptive or other unprofessional behaviour, according to the openEHR Code of Conduct, may be removed by the openEHR International Board following attempts at arbitration.

7.8 Length of Membership

There is no time limit on CP Expert Panel membership.

7.9 Rights

CP Expert Panel members have access to all the same materials and resources as the CPB, including any private discussion groups, private wiki pages and internal documents.

CP Expert Panel members do not participate in formal voting, other than at the Work Group level.

7.10 Responsibilities

The primary responsibility of members of the CP Expert Panel is to participate in particular CPB work items to which their expertise is relevant, including review and/or proposal of changes to deliverables, technical directions and so on.

8 Working Groups

The CPB may create Working Groups (WGs) at any time dedicated to a particular activity for a sustained period. Creation is performed via consensus or vote. Termination of a WG is undertaken the same way.

Membership of WGs may include CPB and/or CP Expert Panel members, and is on a volunteer basis, with a WG lead being established at the time of creation.

Email: comms@openEHR.org Web: http://www.openEHR.org

Informal groups or teams may be formed at any time to deal with short term needs, and are not subject to any special governance beyond that of the CPB as stated here.

9 Decision-making

Decisions are taken by the CPB on two categories of item: governance and routine work items (i.e. items relating to deliverables). Governance questions require a super-majority vote, while routine work items require a simple majority.

9.1 Voting Rules

A *simple majority* is defined as:

a) For an odd number of members, the integral number above the total x 0.5, e.g. 4 out of 7, 6 out of 11 etc;
b) For an even number of members, half the member count plus one, e.g. 4 out of 6, 6 out of 10 etc.

A *super-majority* is defined as:

a) The integral number above 2/3 x number of members.

For the purposes of this document, the term *majority* is always with respect to the total CPB membership, rather than the number of members present at a particular meeting or call. This may mean that although a meeting or call has quorum, it may not have a majority in attendance in situations where a vote is needed. In such cases, a vote may be run asynchronously (see Formal Vote Process below).

9.2 Quorum

For the purposes of formal voting on routine matters requiring simple majority, a regular meeting or call is regarded as quorate with a simple majority of CPB members present.

For meetings or calls whose objective is to undertake a vote requiring super-majority, 2/3 of the membership is required to constitute a quorum.

9.3 Consensus Process

Decisions on change and release management are primarily made by consensus, i.e. agreement of a quorum of members with no serious objections voiced. Where there are objections, the following process will be used:

a) the co-chairs will manage a more formal round of discussions which seek to expose the points of difference and disagreement;
b) If this fails to result in consensus, the co-chairs may initiate either a formal vote (see below) or an open community review of the issue with a fixed timeline, whichever appears most appropriate;
c) in the case of a community review, the results will be the basis of a further round of CPB discussion aimed at finding a consensus position;
d) in the case of a formal vote, the procedure in Section 9.4 is followed.

Where there is any remaining dispute, it can be referred by the CPB co-chairs to the openEHR International Board for resolution. This may require an extraordinary meeting / conference.

9.4 Formal Vote Process

Sometimes a formal vote will be required. This can only occur when there is a quorum of 2/3 of the CPB members available in a face to face meeting or live teleconference / webconference. The procedure is as follows:

a) a motion is tabled;
b) the motion is seconded;
c) votes are gathered;

d) vote by proxy is allowed, supported by a written confirmation (e.g. email) from the absent voter;
e) the motion is considered passed if a simple majority of the CPB membership is obtained.

Asynchronous voting may be used once a motion is tabled and seconded in a meeting. A period of at least a week and no more than 28 days is stated for the gathering of asynchronous votes.

10 Meetings

10.1 Venue

Most work of the CPB is performed via teleconferences, and asynchronously, via discussion groups, online issue trackers, CKM and other tools.

10.2 Frequency

Calls / meetings of the CPB should be held on average at least once a month. This may vary for reasons of holidays, external events etc.

10.3 Attendance

CPB members should attend CPB meetings at least 70% of the time.

CP Expert Panel members are encouraged to attend as often as possible, particularly when requested for meetings whose agenda relates to specific Expert Panel member knowledge areas.

Guests may be invited to meetings by consensus of the CPB.

10.4 Chairing

Calls and meetings are chaired by any available co-chair, by agreement among co-chairs. In the event of absence of all co-chairs, a proxy nominated from the CPB membership may chair a meeting.

10.5 Note-taking

Minutes or appropriate notes will be taken for each call and meeting, including agenda, main discussions, decisions and actions. These should be made visible on e.g. a dedicated area on the openEHR Confluence site or a similar location such as Discourse.

11 Reporting

A report of Program activity to the openEHR International Board is to be provided by the CPB co-chairs quarterly as well as on request. Other issues, including identified risks to progress and resourcing problems are to be reported to the openEHR International Board in a timely fashion.

12 Deliverables

12.1 Identification

All formal deliverables created by the Clinical Program must be uniquely and unambiguously identified. In the case of clinical models and related artefacts, the identification system, versioning rules etc must be published openly and supported in methodology and tools.

A ‘formal deliverable’ is any document or other artefact intended for open publication.

12.2 Change Management

The Clinical Program must undertake adequate change management measures, including version and release management of all its deliverables, including clinical models and documents. The detailed rules and mechanisms for doing so must be published openly.

12.3 Issue Reporting

It must be possible for issues with published materials to be reported via a publicly visible and advertised issue reporting system. All issues reported should be responded to in a timely fashion.

13 Remuneration and Expenses

Where the time of CPB or CPXP members is not covered by their primary employer, funding may be available within openEHR for remuneration. Requests may be made to the CPB, which will determine with the openEHR CIC what possibilities exist.

With respect to expenses likely to be incurred by any CPB or CPXP member in the execution of openEHR work, and not covered by their employer, requests must be made to the CPB *prior* to any expenditure. The CPB does not guarantee to cover expenses, but will consider requests.

14 Professional Conduct

CPB members are required to respect the openEHR Code of Conduct.

In order for the CPB development and decision-making processes to run efficiently, and to provide an enjoyable experience for participants, contributions should follow the following guidelines:

a) contributions to discussions and debates should be based on considerations (e.g. technical, clinical) relevant to the matter at hand;
b) debates (online and face to face) should be conducted in a professional and scientific manner, with a willingness to follow the governance principles stated here, and in cases of dispute, to accept consensus, votes, and the outcome of any arbitration.

In the event of a member's participation causing problems, the matter should be referred to in the first instance to the chair of the Clinical Program Board, and if necessary, an extraordinary meeting or meetings called for the purpose of arbitration. Arbitration will proceed with the Clinical Program Board. If an agreement cannot be reached this way, the matter will be referred to the openEHR International Board.

15 Evolution of these Terms of Reference

The governance structures and procedures described above will inevitably need to change over time. The process for proposing and executing changes is as follows:

a) A change can be proposed by anyone within the Clinical Program, or by the openEHR International board. This request should include a statement of the problem being experienced with the current governance.
b) Requests for change are welcome from the wider community, but need to be advocated for by an existing CPB member;
c) The CPB co-chairs undertake to refine the request into a specific change in the rules that addresses the problem.

d) This is then published within the CPB for review for a stated period, e.g. 28 days.
e) Further refinement may be carried out on the back of the review.
f) When no further modifications are proposed, the CPB holds a vote to accept the modified version of the governance document; this must pass by a super-majority;
g) A final detailed proposal is presented to the openEHR International board by the CPB co-chairs.
h) The openEHR International Board will notify its acceptance or otherwise within a period of 2 weeks;
i) If accepted, the change is publicly notified to take effect on a certain date, at which time the governance provisions in these Terms of Reference are modified accordingly;
j) If not accepted, an explanation is provided as a basis for further adjustments by the CPB, after which the new version may be re-submitted.

The openEHR International Board can unilaterally request a change to these Terms of Reference, usually in order to ensure alignment of governance provisions of the Program with the organisation as a whole. Such changes may be made and accepted without undertaking the review process described above.