



CML-CAB: CML Community Advisory Board Protocol and Terms of Reference

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Background

Patient advocates have an important role to play in ensuring that all patients have access to optimal support, treatment and care. They also have a key contribution to make to the drug development process and other aspects of disease-related research. For this reason, a number of CML advocates have started to build their research competencies and are now contributing to research discussions with different stakeholders. In the light of this, and adopting the model used by HIV/AIDS advocates, the CML Advocates Network (CMLAN) has decided to establish a CML Community Advisory Board (CML-CAB) which has the objective of providing researchers, academics, government, policy makers, authorities and the pharmaceutical industry with advice and input on different issues that impact on patients' lives. CML Advocates Network believes that the establishment of this accountable network of advocates, who speak from the unique perspective of CML patients or carer, will help improve research, facilitate community capacity building and help tackle the many challenges faced in ensuring access to optimal support, treatment and care.

Purpose

The CML Community Advisory Board (CML-CAB) is a working group of the CML Advocates Network (CMLAN). It is a global panel of leading patient advocates from all world regions (CML-CAB members) who all represent the unique perspective of a CML patient or relative. CML-CAB members work together to address issues of strategic importance to the community at large and advocate for the best possible research and equal access to the most innovative treatment & care for CML patients around the world. CML-CAB monitors pharmaceutical developments and research in CML through active and targeted interaction, long-term cooperation and continued dialogue with pharmaceutical partners, regulators, medical experts, and the scientific CML-community.

The common goal of the CML-CAB is:

- Providing researchers, academics, government, policy makers, authorities and the pharmaceutical industry with advice and input on different issues that impact on patients' lives
- Promoting best-in-class CML research as well as the harmonisation of good clinical practice, standard of care and access to best available CML therapies and diagnostic tools
- Ensuring patient needs are considered when setting research priorities
- Developing patient-friendly clinical trials and helping interested patients access these
- Addressing problems CML patients face in accessing optimal diagnosis, monitoring, treatment and care
- Improving the outcomes of CML patients
- Improving the quality of patient information and education
- Building CML advocacy community capacity

Participants of the CML-CAB meetings will have the opportunity of a two-way dialogue discussing key topics in CML between key leading advocates of the patient community and external stakeholders, and discussing potential follow-up actions.

The CML Advocates Network (CMLAN) publicly displays its objectives for the CML-CAB publishing information relating to the names of CML members as well as Executive Summaries (see minutes' section below) relating to previous meetings of the CML-CAB. The CML Advocates Network's Executive Director (CMLAN ED) supported by the CML-CAB Officer is accountable for making sure that this information is kept up to date.

Strategic priorities

The two main strategic pillars of the CML-CAB are "Research" and "Access"

Priority "Research"	Priority "Access"	CAB Strategies	
Participation in clinical trials in low & middle income countries	Improve access to treatment		Increase sharing of experience between CAB members
Increase of QoL of CML patients <small>(which may include side effect management, therapy-free remission)</small>	Improve access to monitoring		Level up knowledge of CAB members to become experts
Achieve cure		Involvement in design of all relevant clinical trials	

Topics

CML-CAB meetings are community-run advisory boards where the patient community decides on the topics of highest relevance and impact for the patient community. The CML-CAB meeting agenda is decided by the CML-CAB chair(s) with support from the CAB Officer and the CMLAN ED.

External stakeholders attending the CAB meeting can make suggestions for agenda points, but the final decision on the agenda rests with the CML-CAB chair(s) who decide(s) in the interest of the community.

Topics that may be discussed in the CML-CABs include but are not limited to:

- Research priorities in CML from the community perspective and patient engagement in R&D;
- Suggestions for trials that meet and initiate trials to reflect patient and community needs;
- Review of a proposed clinical trial design
- Update on ongoing trials with regard to adverse events, compliance, and interim results; interim results;
- Review of informed consent forms and patient information in terms of both content and language;
- Discussion on ethical and GCP issues associated with a trial;
- How to ensure a patient perspective within other entities such as investigator and advisory meetings;
- Fair, sustainable, and affordable pricing;
- Clinical trials access;
- Access to diagnostics, treatment and support;
- Cure for CML
- Patient reporting of adverse events
- Substandard medicines;
- Evolving CML patient journey;

- Best practices in co-creating tools, resources and materials that are targeted at meeting patient needs;
- Ways to support CML advocacy capacity building;
- Community expectations and experience of pharmaceutical companies.

Schedule

CML-CAB meets on a regular basis, at least once a year, but usually around 3 times a year. Additional ad hoc meetings as well as workgroup meetings are possible.

A face-to-face CML-CAB meeting usually lasts for 1-3 days and consists of a CAB-internal preparatory meeting, a CAB-internal training, the CML-CAB sessions with individual external parties (which usually last half day or a full day) and a CAB-internal debrief meeting following the aforementioned CML-CAB sessions. The CAB-internal preparatory meeting and the debrief meeting are mandatory before and after each CML-CAB. The training meeting, however, is optional.

CML-CAB meetings can also be virtual or in a hybrid format. In that case, the CML-CAB meeting can be held as 3 to max. 4 hours meeting (with short breaks in between) or spread over 2 days by split into a 2 days meeting, e.g. with 2 hours meeting time per day (+ preparatory meeting (mandatory) + training session (optional) + debrief meeting (mandatory)).

Membership

CML-CAB members come from patient-based, non-profit organisations that are members of the CML Advocates Network.

The CML Advocates Network Steering Committee (CMLAN SC) will guide & supervise the CML-CAB, led by the chair(s).

The number of CML-CAB members and members of the CML Advocates Network Steering Committee (CMLAN SC) invited to the CAB-meetings will be defined by the CML-CAB chair(s) according to the expertise and experience required for the particular meeting. In global CML-CAB meetings, the agreed minimum number is 8 participants (one representative of each region plus the two chairs).

Further expansion of CML-CAB membership will be discussed and decided by the CML-CAB chair(s), based on individual applications received, whereas the CML-CAB self-assessment survey will be utilized to open up nominations among the whole CML Advocates Network's membership. Interested individuals may apply for CML-CAB membership by completing the survey. The CML-CAB chair(s) will ultimately determine which applicants will be accepted to the CML-CAB members' pool. The CML-CAB chair(s) will take care to ensure as broad a geographical and knowledge coverage as possible. Once a new CML-CAB members' application has been approved by the chair(s), the candidate will need to sign a Confidentiality Agreement and a Declaration of Interest and undergo a pre-defined onboarding process which consists of trainings and materials for self-study. Guidance will be provided by the CML-CAB Officer and the CMLAN ED.

It is expected that CML-CAB members:

- Are actively involved in CML advocacy in their country/region
- Have a good command of English (understanding, verbal expression & written expression are measured in the CML-CAB self-assessment survey based on CEFR standard)

- Have a deep understanding about the challenges faced daily by CML patients in the region they represent;
- Have extensive knowledge in at least one of the following areas (measured in the CML-CAB self-assessment survey):
 - Clinical/research
 - Access
 - Collaboration
 - CML-specific drug expertise

CML-CAB members are appointed as individuals based on their individual qualifications and experience, and not as representatives of their own patient organisation.

CML-CAB member responsibilities are to:

- Participate actively in meetings of CML-CAB when invited;
- Respect confidentiality of CML-CAB's work;
- Respect group procedures/decisions and diverging opinions expressed by other members;
- Be available for tasks such as minute taking, company liaison, protocol reviews and being experts in specific thematic areas;
- Be visible and interact with the local community when possible;
- Be informed about local patient, clinical trial and treatment issues;
- Provide input to meeting agendas and ensure personal meeting preparation;
- Identify and propose new members suitable for CML-CAB;
- Sign the CML-CAB confidentiality agreement, declaration of interests and disclosure of financial contributions received from industry for performing personal activities, and renew if needed

CML-CAB membership can be terminated for any of the following reasons:

- Breaching confidentiality;
- Disrespect of group procedures and other members;
- Unexplained inactivity and lack of commitment;
- Not submitting / renewing their Confidentiality Agreement and/or Declaration of Interest;
- Not showing up at two meetings without serious reasons after registration has been confirmed;
- A request by a member to terminate his or her membership.

Financial compensation

CML-CAB members are entitled to an honorarium of 500 € per CAB meeting each.

The chair(s) is/are entitled to an honorarium of 1000 € per CAB meeting each.

Payment of the honorarium requires full participation in all sessions of the full CML-CAB meeting including training and preparatory sessions (no additional compensation for the latter two!).

Travel costs and other expenses can be reimbursed against a duly signed reimbursement form and original receipts (where required).

The CML-CAB officer will be liaising with the CML-CAB members on their honoraria and expenses and process the payments.

Governance and Decision Making

The CML-CAB is comprised of one to two chair(s) (acting in his/her/their role(s) as chair and co-chair), and CAB-members (currently, as per January 2021, 17 members) representing the following 6 world regions: Western Europe & Israel, Eastern Europe, North America, Latin America, Africa & Middle East, Asia-Pacific. Members of the CML Advocates Network Steering Committee may additionally join CML-CABs on the personal invitation of the chair(s). The CML-CAB's management is provided and led by the CML-CAB Officer and the CMLAN ED.

The distribution of work and responsibilities will be based on the CML-CAB "RACI" matrix ("Responsible, Accountable, Consulted, Informed") as per ANNEX 1. The matrix lists all CAB specific activities and defines who is involved in which activity and in which form.

The CML Advocates Network's Steering Committee (CMLAN SC) and the CMLAN ED cannot 'veto' the CML-CAB chair(s)' decision without firstly trying to reach consensus and secondly justifying their differing position. Likewise, the CML-CAB chairs must justify his or her / their viewpoint in such matters. The CML-CAB chair(s) must be present and heard in situations of disagreement.

The CML-CAB chair and a CML-CAB co-chair are elected by the CMLAN SC for a two-year period. The CMLAN SC may also decide by qualified majority about the termination of the chair(s)'s position and will appoint a replacement until the next meeting of the CMLAN SC.

Participation in CML-CAB meetings

The CML-CAB chair(s) will select participants from the CML-CAB member pool based on the skills identified in the CML-CAB self-assessment survey and the topics discussed in that specific CAB meeting. The CML-CAB chair(s)' choice shall reflect the expertise required for particular meeting as well as appropriate regional representation to the best possible extent. Other selection criteria include individual availability, workload, avoidance of overbooked meetings, financial capacity, room capacity (both virtual and physical), level of commitment, etc.

Confidentiality

It is of key importance that the CML-CAB discusses issues of highest relevance to both the patient community as well as the company or other stakeholder (researchers, regulators, etc.) in a two-way dialogue. The outcome of the discussions should have impact on the actions of both the company / other stakeholder and the community in terms of CML treatment and care.

It is important for patient advocates to have access to confidential information from research groups and the pharmaceutical industry. Therefore, CML-CAB asks companies to disclose information of scientific and commercial value during the meeting as it is available, and prior to publication.

As a result, CML-CAB operates under confidentiality, which is of paramount importance for the smooth and efficient functioning of CML-CAB. Therefore, a confidentiality agreement must be signed by all CML-CAB members and members of the CML Advocates Network Steering Committee that may additionally join CABs on the personal invitation of the chair(s), or that have access to the CML-CAB specific file server and its confidential files of previous CAB meetings.

All information disclosed by companies is considered non-confidential unless expressly stated otherwise. It is expected that e.g. corporate strategies, development pipelines, unpublished data and commercially sensitive information will be earmarked as confidential, while e.g. concepts of treatment

and care, advocacy strategies and patient information will be non-confidential. Positions and decisions taken by CML-CAB are public, while internal discussions and contents are strictly confidential to CML-CAB members.

There may be extremely serious exceptional cases when confidentiality may have to be compromised, e.g. if patients are at risk. In such cases, it is absolutely imperative to seek discuss the matter with the chair(s) before any action is taken.

In case of a breach of confidentiality of CML-CAB members, the following procedure will be followed:

- A hearing will be held with the chair(s) at which the member in question will have to explain why s/he breached confidentiality.
- If the explanation is not deemed satisfactory, the person's CML-CAB membership will be terminated.
- This CML-CAB decision will be communicated to all interested parties.

Preparatory calls and topics of the CML-CAB with companies

The topics of the CML-CAB meeting with companies will be discussed in preparatory conference calls and via e-mail between the CML-CAB chair(s), the facilitator and the company liaison. Among others, the following details are part of such discussions:

1. Review of CAB concept and ground rules
2. CML community's issues of interest for discussion at CAB
3. Company's issues of interest for potential discussion at CAB
4. Agree on the agenda of the CML-CAB
5. CAB timing and logistics
6. Any other business

Meeting minutes

CML-CAB meetings and decisions are recorded by the CML-CAB minute taker. The minute taker, appointed by the CML-CAB Officer, delivers a confidential set of minutes. Besides these, within a week after the meeting the CML-CAB Management team will compile a short Executive Summary (max. 2-3 pages). This document will be based on internal notes taken during the meeting and not directly on the confidential minutes developed by the minute writer. Both sets of minutes are provided to the company or other stakeholder, reviewed and approved by all parties involved.

The confidential set of minutes is made available only to the CML-CAB members who have signed the confidentiality agreement, as well as the respective company representatives that were part of that meeting and are stored on the internal file system.

The Executive Summary – besides being stored on the internal file system – will be published in the CML-CAB section on the CML Advocates Network's website (see <https://www.cmladvocates.net/cml-cab>) and used to actively promote CML-CAB initiatives e.g. via the CMLAN Social Media channels, CML-CAB's dedicated newsletter "CML-CAB News" and articles on the CML Advocates Network's website (www.cmladvocates.net) highlighting initiatives and overall meeting outcomes.

The minute taker is chosen by the CML-CAB chair(s), and all contractual arrangements with the minute taker (incl. negotiation of the minute taker's fee) fall within the responsibility of the CML-CAB officer in close cooperation with the CMLAN ED and in consideration of the project budget. Timelines for the delivery of the minutes are stipulated in the contract.

Evaluation

The CML-CAB chair(s) evaluate the progress made in CABs as well as work of members as well as the group as a whole. Evaluation is an ongoing process, but once a year, the chair(s) must update the CML Advocates Network's Steering Committee (CMLAN SC) in CMLAN SC Meetings about CML-CAB plans and progress. Those CML-CAB chairs that are not members of the CMLAN SC will be invited as observers to the full or part of the CMLAN SC meeting. The CML-CAB chairs should furthermore update the CMLAN membership about the activities going on at CML-CAB. This can either happen at the annual meeting (e.g. CML Horizons) or through online media (e.g. newsletter or online meetings for CMLAN membership).

Financing

Pharmaceutical companies contribute to the funding of the group's activities (e.g. meetings, travel and accommodation of the CML-CAB members, and expenses for the training sessions).

The CMLAN ED supported by the CML-CAB Officer is accountable for developing and maintaining a budget plan for the overall CML-CAB program and also on a per meeting basis as well as being accountable for the sending of funding requests and managing subsequent funding agreements on behalf of the CML-CAB.

Financial operations are the responsibility of the chair(s) of CML-CAB together with the CMLAN ED. The overall annual operating budget for the CML-CAB is approved by the CML Advocates Network Steering Committee. The CML-CAB chairs and CMLAN ED endeavour to remain within established budgets and financial reporting is assured through presentation of CML-CAB financial records to the CML Advocates Network Steering Committee at least once per year. For the purposes of fundraising all incoming funds are requested by the Leukemia Patient Advocates Foundation which is the legal entity representing CML Advocates Network and whose relationship with CML Advocates Network has been established through a formal agreement (October 2018).

Company participants

The company should send representatives who have the seniority, commitment and position to take follow-up action in the following four areas:

- Clinical Development Department (to discuss about e.g. future clinical trials, protocols)
- Medical Department (to discuss medical issues, e.g. side effects)
- Market Access (to discuss about e.g. expanded access programs, compassionate use, not HTA)
- Patient Relations (someone who is responsible for patient engagement and is the point of contact for patient groups)

And if each of these four roles is covered, the company can send 3 additional people from any role, totalling in a maximum 7 participants from the company for physical face-to-face meeting. In the case of virtual or hybrid meetings, the maximum no. of participants will be determined by the chair(s).

Company Liaison

Companies collaborating with CML-CABs need to appoint one company liaison. The company liaisons collaborate closely with the CMLAN ED, CML-CAB chair(s) and the CML-CAB Officer. The liaisons' responsibilities include:

- Update CML-CAB on company news and people.

- Responsible of CML-CAB communication with company and its departments, especially between meetings.
- Being informed on development pipeline, planned trial protocols.
- Being informed on safety issues.
- Review minutes last meeting, identify pending issues.
- Provide input to meeting agenda.
- Collaborate on pre-meeting preparation and execution.
- Identify relevant files for meeting preparations.
- Post meeting: Proactively pursue follow-up with company.

From the CML Advocates Network side the CMLAN ED will articulate any broader strategic relationship between the CML-CAB and the Company Liaison in term of potential future CAB topics to be addressed. In this context the CMLAN ED will act on behalf of the CML-CAB chair(s) and report back to or involve them when appropriate in relevant discussions with companies.

CML-CAB Follow-up

The CMLAN ED supported by the CML-CAB Officer is accountable and jointly responsible for making sure that agreed upon open actions are being followed up by those that committed to them, within timelines that are agreed or need to be defined. This is generally accomplished via a tracking table (“Actions Tracker”) which outlines the open actions, responsible individuals, deadlines and latest information relating to said actions

ANNEX 1:

CML-CAB "RACI" matrix						
R = Responsible – The person who performs the action/task.						
A = Accountable – The person who is held accountable that the action/task is completed.						
C = Consulted – The person(s) who is consulted before performing the action/task.						
I = Informed – The person(s) who is informed after performing the action/task.						
Category	Step	Action/Task	Responsible	Accountable	Consulted	Informed
Content	1	Development of CAB meeting agenda	CAB officer CMLAN ED	CAB chairs CMLAN ED	-	-
	2	Choice of companies for each CAB meeting	CAB officer CMLAN ED	CAB chairs CMLAN ED	-	CAB members
	3	Choice of training topic and implementation	CAB officer CMLAN ED	CAB chairs	-	CAB members
	4	Choice of participants per CAB meeting	CAB chairs	CAB chairs	CAB officer CMLAN ED	CAB members
	5	Make sure Executive Summary is signed off by chairs and stakeholder (e.g. pharmaceutical partners, regulators, medical experts, scientific CML-community, etc.) in final form 2 weeks after meeting	CAB officer	CMLAN ED	CAB chairs	-
	6	Make sure Confidential Minutes are signed off by chairs and stakeholder (e.g. pharmaceutical partners, regulators, medical experts, scientific CML-community, etc.) in final form 3 months after meeting	CAB officer	CMLAN ED	-	-
	7	Make sure agreed open actions are being followed up by those that committed to them, within timelines that are agreed or need to be defined	CAB officer CMLAN ED	CMLAN ED	CAB chairs	CAB members
	8	Coordinate CAB workgroups	CAB officer CMLAN ED	CMLAN ED	CAB chairs	CAB members
	9	Make sure confidential minutes of CAB meetings are stored on Nextcloud file system and shared with CAB-members (only those that have signed CA agreement) & participating stakeholder representatives.	CAB officer	CMLAN ED	-	CAB members
	10	Make sure Executive Summaries are stored on Nextcloud file system and publicly available on the website and shared via newsletter and social media channels.	CAB officer	CMLAN ED	-	CAB members
	11	Keep all CAB files for CAB members and chairs up to date; consistent document storage on NextCloud	CAB officer	CAB officer	-	-
	12	Update the public part of the CMLAN website about the CABs, why we do them, what we do, and what they concluded on, so everyone can see what we do	CAB officer	CMLAN ED	CMLAN ED	CAB members, CMLAN SC
Meeting logistics	13	Selection of date of CAB meetings	CAB officer CMLAN ED	CAB chairs	CAB members	-
	14	Prepare introductory presentations, Coordinate internal + external CML-CAB presentations	CAB officer	CAB chairs	CMLAN ED	-
	15	Selection of city and venue	CAB officer	CAB chairs	CAB chairs CMLAN ED	CAB members
	16	Coordinate minute taker and facilitator	CAB officer	CAB officer	CMLAN ED	CAB members
	17	Fix room, logistics and AV	CAB officer	CAB officer	CMLAN ED	CAB chairs CAB members
CAB Management	18	Travel bookings for CAB members	CAB officer	CAB officer	CAB members	-
	19	Create and maintain project plan with timelines	CAB officer	CAB chairs	CMLAN ED	-
	20	Create and maintain a budget plan and administer the budget - overall for CAB programme and per meeting	CAB officer	CMLAN ED	CAB chairs	-
	21	Manage grant agreements for CAB programme	CAB officer	CMLAN ED	CAB chairs	-
	22	Make sure all CAB members have provided valid/updated Confidentiality Agreements (CAs) and Declarations of Interest (DoIs)	CAB officer	CMLAN ED	-	CAB chairs
23	Keep CAB protocol / terms of reference up to date	CAB officer	CAB chairs	CMLAN ED	CMLAN SC	
Legend:						
CAB chairs	= CML-CAB chairs					
CAB officer	= CML-CAB officer					
CAB members	= CML-CAB members (currently 17, information as of January 2021)					
CMLAN SC	= CML Advocates Network's Steering Committee					
CMLAN ED	= CML Advocates Network's Executive Director					