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

[Version 1.13 / release date 7 February 2024]

**Background**

CML Community Advisory Board (CML-CAB) is a working group of the CML Advocates Network (CMLAN). It is a key strategic tool to have a dialogue of experienced advocates and CML stakeholder decision makers about the advocacy community´s priorities and concerns. CML-CAB is composed of a global panel of 25 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 and research 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.

**Purpose**

The common goal of the CML-CAB is:

- **Providing** CML stakeholders (researchers, academics, government, policy makers, authorities, and pharmaceutical industry) with advice and input on different issues that can ultimately impact 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.
- **Supporting in the development of** patient-friendly clinical trials and helping interested patients access these.
- **Addressing** problems CML patients face in accessing optimal diagnosis, monitoring, treatment, and care throughout their CML journey.
- **Contributing to improving** the CML patient outcomes.
- Improving patients´ quality of life (QoL) through these interactions with CML stakeholders
- **Improving** the quality of information and education.
- **Building** CML advocacy community capacity.

CML-CAB meetings provide the opportunity to establish a two-way dialogue between key leading advocates of the patient community and external CML stakeholders, discussing key topics in CML as well as potential follow-up actions.

CMLAN publicly displays its objectives for CML-CAB by publishing information relating to the names of CML members as well as Executive Summaries (see minutes' section below) related to previous CML-CAB meetings. CML Advocates Network´s Director (CMLAN Director) 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 (which may include side effect management, therapy-free remission) | 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 latter. The CML-CAB meeting agenda is decided by the CML-CAB chair(s) with support from the CML-CAB Management Team, composed of the CAB Officer, and the CMLAN Director.

External stakeholders attending the CML-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 patient community.

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

- Research priorities in CML from the community perspective and patient engagement in R&D.
- Suggestions for ongoing trials and initiation of trials that meet and reflect the patient community needs.
- Review of a proposed: clinical trial design, changes to regulatory or treatment standards.
- Update on ongoing trials with regard to adverse events, compliance, and 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.
- Access to Clinical trials.
- Access to diagnostics, treatment and support across geographical regions.
- Cure for CML
- Adequate and accurate patient reporting of adverse events
- Substandard medicines.
- Evolving CML patient journey.
- Best practices in co-creating tools, resources and materials targeted at meeting patient needs.
- Ways to support CML advocacy capacity building.
- Community expectations and experience of pharmaceutical companies.
- Ways of improving communications between the patient community and all CML stakeholders.

**Schedule**

Ideally, CML-CAB meets at least once 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 and may be done virtually. The training meeting, however, is optional and will be done if deemed useful or necessary. It can also be held virtually ahead of the official CML-CAB meeting.

CML-CAB meetings can also be virtual or in a hybrid format. In that case, the CML-CAB meeting can be held as a 3 to max. 4 hours meeting (with short breaks in between) or spread over 2 days by splitting it into a 2-day 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 CMLAN and are appointed as individuals based on their individual qualifications and experience, and not as representatives of their own patient organisation.

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

CML-CAB members are obliged to complete a Skills Self-Assessment questionnaire and renew / update the same on a bi-annual basis (once every two years). Based on CML-CAB members´ responses to the self-assessment questions, a skills matrix is created to map out the skills and competencies across the CML-CAB members´ pool.

The number of CML-CAB members and members of the 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. The assessment will be done on the basis of the skills matrix. In global CML-CAB meetings, the agreed minimum number is 8 participants (one representative of each geographical 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. To open nominations a formal “call for application” will be circulated to members of CMLAN. The “call for application” shall include the document “CML Community Advisory Board - Appointment to membership” (ANNEX 7) and the CML-CAB Application form incl. Skills Self-Assessment Survey. 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. 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 training and materials for self-study. Guidance will be provided by the CML-CAB Officer and the CMLAN Director.

On a bi-annual basis (once every two years), the CML-CAB chairs along with the CML-CAB Management team shall review the member’s pool makeup and recommend changes based upon the status of member participation and engagement needs for the following year, always making sure that the highest quality CML-CAB pool is maintained. The CML-CAB chair(s) will ensure as broad a geographical and knowledge coverage as possible.

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 two of the following areas:
    - Clinical/Research
    - Access
    - Collaboration
    - CML-specific drug expertise

CML-CAB member responsibilities are to:

- Participate actively in CML-CAB meetings 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.
- Complete the Skills Self-Assessment questionnaire and renew on a bi-annual basis.
- Have a profile on the research portal ORCID, keep it up to date, and share their ORCID ID to raise the profile of CML-CAB as a whole and of each CML-CAB participant individually.
- Have a profile on a relevant professional or advocacy related Social Media account, keep it up to date, and share their URL to raise the profile of CML-CAB as a whole and of each CML-CAB participant individually.
- Be informed about local patient-related, 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 and Data Processing Agreement" (ANNEX 2), "CML-CAB Declaration of Interests" incl. disclosure of financial contributions received from industry for performing personal activities (ANNEX 4). It should be renewed as needed annually, i.e. once every year, at a minimum).
- Review and sign the CML-CAB Photography Consent Form (ANNEX 3) if he/she agrees that photographs of him/her are taken at CML-CAB meetings.

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

- Breaching confidentiality.
- Disrespect of group procedures and other members.
- Not answering e-mails, etc. in a timely manner.
- Unexplained inactivity and lack of commitment.
- Not submitting / renewing their Confidentiality Agreement, Declaration of Interest, ORCID profile or skills self-assessment questionnaire, or not keeping these up to date.
- Not attending up to two meetings without serious reasons after registration has been confirmed.
- A request by another CML-CAB member to terminate his or her membership due to serious reasons.

The decision to dismiss CML-CAB members is taken by the CML-CAB chair(s) in close consultation with the CMLAN Director and the CML-CAB Officer.

**Financial compensation**

Depending on the nature of the meeting (e.g., if the meeting is externally funded or not), CML-CAB meetings can or not be remunerated. The chair(s) will designate which meetings are remunerated and which are not.

If remunerated, CML-CAB members are each entitled to an honorarium of 1000 € for a full face-to-face CAB meeting (8 hours). The chair(s) is/are each entitled to an honorarium of 1200 € for a full face-to-face CAB meeting.

For virtual CML-CAB meetings, a base hourly rate of 125 € is paid to CML-CAB members and 150 € are paid to CML-CAB chairs, based on the assumption that the 1000 € / 1200 € correspond to a daily rate (8-hours-day). At the discretion of the CAB Chairs, an engagement where very specialized talent is required and negotiated the CAB member reimbursement rate may be higher.

Sample calculation: 1000 / 8 = 125 € per hour for each CML-CAB member or 1200 / 8 = 150 € per hour for each CML-CAB chair). Prep and training meetings are reimbursed in the same manner and rate. Payment of the honorarium requires full participation in ALL sessions of the full CML-CAB meeting including training and preparatory sessions (no additional compensation is envisaged for the latter two in case of lump sum honorarium of 1000 € / 1200 €, respectively, for face-to-face CML-CAB meetings!).

Travel costs and other expenses can be reimbursed against a duly signed expense 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 if applicable.

**Governance and Decision Making**

The CML-CAB is composed of one to two chair(s), and a minimum of 6 CAB-members representing the following 6 world regions: Western Europe & Israel, Eastern Europe, North America, Latin America, Africa & Middle East, Asia-Pacific. Members of the CMLAN SC may additionally join CML-CAB meetings on personal invitation by the chair(s). The CML-CAB management team is provided by the CML-CAB staff: a CML-CAB Officer, a Scientific Project Manager and the CMLAN´s Director who work closely with the chair(s).

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 CMLAN SC and the CMLAN Director cannot ‘veto’ the CML-CAB chair(s)’ decision without first 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.

*CML-CAB chair(s) nomination process:*

The CML-CAB chair(s) is / are elected by the CMLAN SC for a two-year period. With a minimum of 3 months before the term of the present CML-CAB chair(s) comes to an end, the CML-CAB Management team will release a “Call for applications” by circulating the document “CML Community Advisory Board - Elections to CML-CAB chair position” (ANNEX 5) which includes the application form template. Interested candidates are then asked to submit their application by completing the official application form or, alternatively, submit a video application. The CMLAN SC decides on the final candidate(s) for

the position(s) of CML-CAB chair(s) by online vote or during a formal Steering Committee Meeting, shortly after which the final candidate(s) will formally be announced. Re-election is allowed.

*Eligibility criteria for the position of "CML-CAB chair":*

CML-CAB chair(s) need to be active CML-CAB members.

*Expectations / duties & responsibilities of the CML-CAB chair(s):*

CML-CAB chair(s) provide(s) overall guidance on all CML-CAB related matters and steering the dialogue with stakeholders around CML-CABs interests. The detailed responsibilities are set out in the CML-CAB "RACI" matrix that comes attached to this CML-CAB Protocol as ANNEX 1 as well as in the document "Job Description - Community Advisory Board Chairs (CML-CAB Chair)" ANNEX 6.

CML-CAB chair(s) is/are expected to participate in a monthly virtual meeting with the CML-CAB management team to provide input and discuss relevant topics. Besides attending CML-CAB meetings (virtual and face-to-face), the chair(s) is / are invited to attend CMLAN SC meetings in their specific role as CML-CAB chair(s) with no voting rights, and is / are further expected to review and reply to regular e-mail correspondence on CML-CAB related matters coming from the CML-CAB management team to fulfil the tasks listed in the CML-CAB "RACI" matrix.

*Termination of the CML-CAB chair(s)´s position:*

The CMLAN SC may decide by qualified majority about the termination of the chair(s)'s position and will appoint a replacement until the next Steering Committee meeting.

**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 mapped out in the skills matrix and the topics discussed in that specific CAB meeting. The CML-CAB chair(s)' choice shall reflect the expertise required for a 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, needed expertise, etc.

**Confidentiality**

It is of key importance that the CML-CAB discusses issues of high relevance to both the patient community as well as the company or other stakeholders (researchers, regulators, etc.) in a two-way dialogue. The outcome of the discussions should have an impact on the actions of both the company / other stakeholder and the patient 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 CML-CAB Confidentiality and Data Processing Agreement (ANNEX 2) must be signed by all CML-CAB members and members of the CMLAN SC that may additionally join CABs on personal invitation by 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 imperative to seek to 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 taker. 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 resources section on CMLAN´s website (see https://www.cmladvocates.net/cml-cab-resources/) 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 CMLAN´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 fee) falls within the responsibility of the CML-CAB officer in close cooperation with the CMLAN Director, 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 and the group as a whole. Evaluation is an ongoing process, but once a year, the chair(s) must update the CMLAN SC in Steering Committee Meetings about CML-CAB plans and progress. The CML-CAB chairs should furthermore update CMLAN´s members 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 Director supported by the CML-CAB Officer is accountable for developing and maintaining a budget plan for the overall CML-CAB program and on a per meeting basis as well as being accountable for sending funding requests and managing subsequent funding agreements on behalf of CML-CAB. Budgets are developed in close consultation with the Treasurer of the CMLAN SC. The CMLAN Director supported by the CML-CAB Officer is furthermore accountable for exploring other funding sources such as donations, European co-funding, etc. to make sure activities that are not typically funded by industry (such as Academic CML-CAB) are self-funded and do not put a strain on the CMLAN´s overall budget and reserves.

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

**Company participants**

The company should send representatives who have the seniority, commitment, and position to take follow-up actions 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).

If each of these four roles are covered, the company can send 3 additional people from any role, with a maximum of 7 participants for a face-to-face meeting. In the case of virtual or hybrid meetings, the maximum no. of participants shall 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 Director, CML-CAB chair(s) and the CML-CAB Officer. The liaisons' responsibilities include:

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

From the CMLAN side, the CMLAN Director will articulate any broader strategic relationship between the CML-CAB and the Company Liaison in terms of potential future CAB topics to be addressed. In this context the CMLAN Director 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 Director 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. However, other follow-up methods are equally acceptable and will be left at the discretion of the CML-CAB Management Team along with the CAB chair(s).

CML-CAB COMMUNITY ADVISORY BOARD

# 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 |
|---|---|---|---|---|---|---|
| Overall CAB Management & Operations | 1 | Create and maintain project plans with timelines | CAB officer | CMLAN Dir | CMLAN SPM<br>CMLAN Dir | CAB chairs |
| | 2 | Approve overall annual operating budget for CML-CAB | CMLAN SC | CMLAN Dir | CAB chairs<br>CAB officer<br>CMLAN SPM | CAB officer<br>CMLAN SPM |
| | 3 | Create and maintain a budget plan and administer the budget - overall for CAB programme and per meeting | CAB officer | CMLAN Dir | CMLAN Dir<br>CMLAN Treas | CAB chairs<br>CMLAN SC |
| | 4 | Manage grant agreements for CAB programme | CAB officer<br>CMLAN SPM | CMLAN Dir | CMLAN Dir<br>CAB chairs | CMLAN SC |
| | 5 | Decide on whether a specific CAB meeting will be remunerated or not. | CAB chairs | CAB chairs | CAB officer<br>CMLAN SPM<br>CMLAN Dir | CAB members<br>CMLAN SC |
| | 6 | Coordinate the replacement of CML-CAB chairs when their term is coming to an end (call for applications, handling nominations, voting by CMLAN SC, etc.) | CAB officer | CMLAN Dir | CAB members | CMLAN SC<br>CAB chairs |
| | 7 | Appoint new CML-CAB chair(s) when 2-years term of previous chair(s) is coming to an end | CMLAN SC | CMLAN SC | CMLAN Dir<br>CAB officer | CAB members<br>CMLAN Dir<br>CAB officer<br>CMLAN SPM<br>CAB chairs<br>CMLAN S&M |
| | 8 | Complete (new CML-CAB members) upon joining CML-CAB or review / update Skills Self-Assessment Survey on a bi-annual basis. | CAB members | CAB officer | CMLAN Dir<br>CMLAN SPM | CAB chairs |
| | 9 | Create and maintain an ORCID profile ORCID profile. | CAB members | CAB officer | CMLAN Dir<br>CMLAN SPM | CAB chairs |
| | 10 | Review CML-CAB pool makeup on a bi-annual basis (minimum) and recommend changes. | CML-CAB chairs<br>CAB officer<br>CMLAN SPM<br>CMLAN Dir | CAB chairs | CMLAN SC | - |
| | 11 | Coordinate the replacement of CML-CAB members and the addition of others. | CAB officer | CAB chairs | CMLAN Dir | CAB members<br>CMLAN SC<br>CMLAN S&M |
| | 12 | Map out existing skills in a skills matrix and keep the matrix up to date. | CAB officer | CAB chairs | CMLAN Dir | CAB chairs |
| | 13 | Make sure all CAB members and stakeholders (such as e.g. researchers in Academic CML-CAB meetings) have provided valid/updated Confidentiality Agreements (CAs) and Declarations of Interest (DoIs) | CAB officer<br>CMLAN SPM | CMLAN Dir | - | CAB chairs |
| | 14 | Coordinate CAB workgroups (meeting coordination, follow-up, payments) | CAB officer | CMLAN Dir | CMLAN SPM | WG members |
| | 15 | Keep all CAB files for CAB members and chairs up to date; consistent document storage on NextCloud | CAB officer | CAB officer | CAB chairs | CAB members,<br>CML-CAB chairs |
| | 16 | Update the CML-CAB section on the CMLAN website, why we do them, what we do, and what they concluded on, so everyone can see what we do | CAB officer | CMLAN Dir | CAB chairs | CAB members<br>CMLAN SC |
| | 17 | Keep CAB protocol / terms of reference up to date | CAB officer | CAB chairs | CMLAN SPM<br>CMLAN Dir<br>CMLAN chairs | CMLAN SC |

| | | | | | | |
|---|---|---|---|---|---|---|
| **CML-CAB Meeting Content & Participation** | 18 | Development of CAB meeting agenda | CAB officer<br>CMLAN SPM<br>CMLAN Dir | CAB chairs<br>CMLAN Dir | CAB chairs | CAB members |
| | 19 | Choice of companies or other stakholder representatives for each CAB meeting | CAB officer<br>CMLAN SPM<br>CMLAN Dir | CAB chairs<br>CMLAN Dir | CAB chairs | CAB members |
| | 20 | Choice of training topic and implementation | CAB officer<br>CMLAN SPM<br>CMLAN Dir | CAB chairs<br>CMLAN Dir | CAB chairs | CAB members |
| | 21 | Choice of participants per CAB meeting, incl. inviting CMLAN SC members if deemed suitable | CAB chairs | CAB chairs | CAB officer<br>CMLAN SPM<br>CMLAN Dir | CAB members<br>CMLAN SC |
| **Meeting logistics, incl. materials & outputs** | 22 | Selection of date of CAB meetings | CAB officer<br>CMLAN SPM<br>CMLAN Dir | CMLAN Dir | CAB chairs<br>CAB members | CAB members,<br>CMLAN SC<br>CML-CAB chairs |
| | 23 | Selection of city and venue | CAB officer<br>CMLAN SPM<br>CMLAN Dir | CMLAN Dir | CAB chairs | CAB members,<br>CMLAN SC<br>CML-CAB chairs |
| | 24 | Prepare introductory presentations,<br>Coordinate internal + external CML-CAB presentations | CAB officer<br>CMLAN SPM<br>CMLAN Dir | CMLAN Dir | CAB chairs<br>CMLAN SPM<br>CMLAN Dir | CAB chairs |
| | 25 | Coordinate minute taker and facilitator | CAB officer | CAB officer | CMLAN Dir<br>CMLAN SPM | CAB chairs |
| | 26 | Fix room, logistics and A/V | CAB officer | CAB officer | CMLAN Dir<br>CMLAN SPM | CAB chairs |
| | 27 | Travel bookings for CAB members | CAB officer | CAB officer | CAB members | CAB chairs |
| | 28 | 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 6 weeks after meeting | CAB officer<br>CMLAN SPM | CMLAN Dir | CMLAN chairs | - |
| | 29 | 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<br>CMLAN SPM | CMLAN Dir | CMLAN chairs | - |
| | 30 | 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) & participanting stakeholder representatives. | CAB officer<br>CMLAN SPM | CMLAN Dir | - | CAB members<br>CAB chairs |
| | 31 | 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 Dir | - | CAB members<br>CAB chairs<br>CMLAN SC |
| | 32 | 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<br>CMLAN SPM<br>CMLAN Dir | CMLAN Dir | CAB chairs | CAB members |
| **Others** | 33 | Invite CML-CAB chairs to CMLAN SC meetings | CMLAN Dir | CMLAN SC | - | CAB chairs |

* The Chair of the CMLAN Steering Committee and a LePAF representative must sign any binding agreements.

| **Legend:** | |
|---|---|
| CAB chairs | = CML-CAB chairs |
| CAB officer | = CML-CAB officer |
| CMLAN SPM | = CML Advocates Network´s Scientific Project Manager |
| CAB members | = CML-CAB members |
| CMLAN SC | = CML Advocates Network´s Steering Committee |
| CMLAN Treas | = CML Advocates Network´s Treasurer |
| CMLAN Dir | = CML Advocates Network´s Director |
| CMLAN S&M | = CML-CAB Advocates Network´s Staff and Members |

**Last updated: 7 February 2024**

# CML-CAB: CML Community Advisory Board Confidentiality and Data Processing Agreement

**ANNEX 2**

[Version 11.2023]

This Confidentiality and Data Processing Agreement - effective as of date of last signature and until terminated by either party or until replaced by a new agreement -

is between

_____

hereinafter referred to as the CML-CAB member, resident in

_____

and the Leukemia Patient Advocates Foundation, legal representative for CML Advocates Network and CML-CAB as one of its working groups, hereinafter referred to as “CML-CAB”.

This "Agreement" is to give consent on processing personal data/photos/video for CML-CAB meetings, and further dissemination processes. It shall further preserve confidentiality and impede that confidential information is disclosed to third parties.

CML-CAB is responsible for the processing of CML-CAB members´ personal data, thereby acting as the data “controller”. If you have any questions about the photography or the processing of your personal data, pls contact us at info@lepaf.org.

The above listed parties declare their intention and willingness to collaborate effectively during CML-CAB meetings (no matter whether attendance is virtual or in-person) and to discuss the respective meeting topics openly and fact-based.

Strictly no recordings (audio, video, screenshots, and photos) by participants are allowed during CML-CAB meetings. Meeting audios will be recorded solely for minute taking purposes. Recordings are for reporting purposes only and will be deleted after finalisation of the minutes. It will only be provided to the CML-CAB Management Team (responsible for compiling an Executive Summary for public distribution) and the minute taker (responsible for compiling the confidential minutes of the meeting, strictly confidential to CML-CAB Members and stakeholders invited to CML-CAB meetings).

All information disclosed at CML-CAB meetings by participating external stakeholders is considered non-confidential unless expressly stated otherwise. For example, information typically provided by pharmaceutical companies in a CML-CAB setting such as concepts of treatment and care, advocacy strategies and patient information initiatives are considered to be non-confidential.

However, in order to work effectively and to ensure that the community considerations are taken into account, it may be necessary for those stakeholders to provide CML-CAB with information of confidential, sensitive nature, relating e.g., to existing and future compounds, unpublished data, development roadmaps, etc., in whatever form disclosed by such meeting participants to CML-CAB and/or its members. All such confidential information will be earmarked as confidential and is hereafter referred to as “confidential information”.

External stakeholders participating in CML-CAB meetings (e.g., researchers, pharmaceutical companies) agree to disclose the confidential information to the CML-CAB member who agrees to receive the same on the following conditions:

- Confidential information will be used solely for the purpose set out above and for no other purpose whatsoever. No conclusions, results or other material created as a result of the direct participation in presentations will be used without prior written consent from CML-CAB through its legal representative, as well as from CML-CAB meeting participants / external stakeholders, if the confidential information was provided by such meeting participants / external stakeholders.
- All confidential information and results will be held in the strictest confidence at all times and will not be disclosed, as a whole, or in part thereof, to any non-member of the CML-CAB or third party, nor will any third party be allowed to have access to the same or any part thereof without prior written consent granted by any of the meeting participants / external stakeholders and the CML-CAB.
- The above-mentioned limitations refer to material that is specifically mentioned as confidential and is of commercial or academic value and shall not apply to any other part of information.

It is agreed that the limitations mentioned above shall not apply to any part of information that:

- Was already known to any CML-CAB member prior to its disclosure during CML-CAB meetings.
- Is public knowledge or subsequently becomes known to the public other than by breach of this agreement or of similar confidentiality obligation.
- Is approved for release by written authorization of a duly authorised representative of the CML-CAB meeting participant / external stakeholder.
- Is received without restriction from any third party that is entitled to disclose the information.

**Positions, Decisions and Meeting Minutes**

Positions and decisions taken by CML-CAB are public, while internal discussions and contents are strictly confidential to CML-CAB members.
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 two weeks after the meeting the CML-CAB Management team will compile a short Executive Summary. 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 approval process must be completed within 6 weeks following the meeting.

The confidential set of minutes is made available only to CML-CAB members who have signed the confidentiality agreement 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 table published under https://www.cmladvocates.net/cml-cab-resources) and used to actively promote CML-CAB initiatives e.g., via the CML Advocates Network´s 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.

**Data Processing**

1. What personal data will CML-CAB process?

CML-CAB will process the personal data necessary to adequately perform CML-CAB meetings and further communication activities related to the meetings, which includes your name, contact details, photos and videos.

2. For which purposes will CML-CAB use CML-CAB meetings participants´ / CML-CAB members´ personal data and why is this justified?

The data taken will be used solely for the purpose of performance and communication of the meetings, as per the following specific purposes:

- Communicate with CML-CAB meetings participants´ / CML-CAB members´ during the

preparation process, and further communication of the CML-CAB meetings.
- Sending CML-CAB meetings participants´ / CML-CAB members´ information regarding the meetings, and further activities that result from these.
- Photographs and videos may be used on the website of the CML Advocates Network, social media pages, internal newsletters, or any other communication material related to the meetings.
- Data may be used to prepare rolling slides for CML-CAB meetings.
- Data may be used to prepare who-is-who booklets of the CML-CAB meetings with information regarding all attendees.

CML-CAB will always process personal data for a specific purpose, and only process the personal data which is relevant to achieve that purpose. In addition to the specific purposes identified in the Agreement, personal data may also be used for the following general purposes:

- answer any questions or requests CML-CAB meeting participants / CML-CAB members may have.
- manage IT resources, including infrastructure management and operational continuity.
- archiving and record-keeping; and
- any other purposes imposed by law and authorities.

The legal basis for processing data is the CML-CAB meetings participants´ / CML-CAB members´ consent, as provided through this Agreement.

3. Who will have access to the personal data provided and to whom will they be transferred?

CML-CAB will not sell, share, or otherwise transfer personal data to third parties other than those attending CML-CAB meetings. In the course of our activities and for the same purposes as those outlined in this Agreement, participants´ / CML-CAB members´ personal data can be accessed by, or transferred to the following categories of recipients, on a need-to-know basis to achieve such purposes:

- Trustees of the Leukemia Patient Advocates Foundation.
- Steering Committee member and staff members of the CML Advocates Network of whom CML-CAB is a working group.
- Our suppliers and services providers that provide services and products to CML-CAB.
- IT systems providers, cloud service providers, database providers and consultants.
- Partners who offer products or services jointly with CML-CAB.
- Any third party to whom CML-CAB assigns or novates any of its rights or obligations; and

The above third parties are contractually obliged to protect the confidentiality and security of CML-CAB meetings participants´ / CML-CAB members´ personal data, in compliance with applicable law.

CML-CAB meetings participants´ / CML-CAB members´ personal data can also be accessed by or transferred to any national and/or international regulatory, enforcement, public body or court, where CML-CAB is required to do so by applicable law or regulation or at their request.

The personal data collected from CML-CAB meeting participants / CML-CAB members may also be processed, accessed or stored in a country outside the country where the CML Advocates Network is located, which may not offer the same level of protection of personal data. If personal data is transferred to external companies in other jurisdictions, CML-CAB will make sure to protect personal data by (i) applying the level of protection required under the local data protection/privacy laws applicable to CML-CAB, (ii) acting in accordance with internal policies and standards and, (iii) for entities located in the European Economic Area, unless otherwise specified, only transferring personal data on the basis of standard contractual clauses approved by the European Commission. CML-CAB meetings participants may request additional information in relation to international transfers of personal data and obtain a copy of the adequate safeguard put in place by exercising their rights as set out below.

4. How long does CML-CAB store CML-CAB meetings participants´ / CML-CAB members´ personal data?

CML-CAB will only retain CML-CAB meetings participants´ / CML-CAB members´ personal data for as long as necessary to fulfil the purpose(s) for which it was collected or to comply with legal or regulatory requirements. After that, CML-CAB will securely delete or anonymize them. The CML-CAB meetings participant / CML-CAB member has the right to withdraw consent of data processing and storage at any time.

5. What are CML-CAB meetings participants´ / CML-CAB members´ rights and how can they be exercised?

Under the General Data Protection Regulation (GDPR), CML-CAB meeting participants / CML-CAB members have the right to access, rectify, or erase their personal data. They also have the right to object to the processing of their data and the right to withdraw their consent at any time, or ask for it to be updated, restricted, deleted, or transferred to another organisation. They have a right to request a copy of the personal information CML-CAB holds about them.

If CML-CAB meeting participants / CML-CAB members choose to withdraw their consent after printed materials have been produced, it may not be possible to remove photographs from those materials. This may result in the continued use of your photograph in printed materials despite withdrawal of consent.

If you have a question or want to exercise the above rights, please contact us at info@lepaf.org.

**CML-CAB shared files, email distribution list, WhatsApp groups and Telegram group**

CML-CAB members have access to the CML-CAB specific file server (path: Nextcloud\CML-CAB Members (confidential)) where confidential files of previous CAB meetings and main CML-CAB documents (CML-CAB protocol, Confidentiality & Data Processing Agreement, Declarations of Interest, and others) are stored. All materials stored on the fileserver are strictly confidential and must not be shared.

All discussions and materials posted on email discussion lists or other internal communication channels (such as the groups´ distinct WhatsApp and Telegram chat groups) are of confidential nature. Reposting or forwarding to other lists or persons is not allowed. Reposting of information that is in the public domain by no breach of a confidentiality obligation, is allowed, but has to be copy/pasted in a new email, in order to protect the privacy of the original sender.

It is agreed that CML-CAB shall vest all copyright, and any other intellectual property rights in the information, whether or not the results are selected for use and/or publication.

| | |
|---|---|
| On behalf of the CML-CAB: | CML-CAB member: |
| Name: _____ | Name: _____ |
| Signature: _____ | Signature: _____ |
| Date: xx.xx.2023 | Date: xx.xx.2023 |

# CML-CAB: CML Community Advisory Board
# Consent for Photography

**ANNEX 3**

[Version 11.2023]

**Introduction:**
We would like to take photographs of participants at CML-CAB Meetings (virtual or face-to-face) for communication about these events. To do this, we need your consent. Please read the following information carefully before signing this consent form.

**Information about the data controller:**
The data controller for this photography activity is the Leukemia Patient Advocates Foundation, with address at Münzgraben 6, P.O.B. 453, CH-3000 Bern 7 Switzerland. If you have any questions about the photography or the processing of your personal data, you can contact us at info@lepaf.org.

**Information about the data processing:**
The photographs taken will be used solely for the purpose of communication about CML-CAB Meetings. The photographs may be used on the CML Advocates Network´s or Leukemia Patient Advocates Foundation´s website, social media pages, internal newsletters, or any other communication material related to the conference. The legal basis for processing your data is your consent, as provided by you through this consent form.

**Information about data retention:**
We will retain the photographs for as long as necessary to achieve the purpose for which they were collected. After that, we will securely delete or anonymize them.

**Information about your rights:**
Under the General Data Protection Regulation (GDPR), you have the right to access, rectify, or erase your personal data. You also have the right to object to the processing of your data and the right to withdraw your consent at any time.

Please note that if you choose to withdraw your consent after printed materials have been produced, it may not be possible to remove your photograph from those materials. This may result in the continued use of your photograph in printed materials despite your withdrawal of consent. The cost of reprinting or destroying printed materials may be quite cumbersome and costly.

**Consent:**
By signing this consent form, I consent to Leukemia Patient Advocates Foundation taking photographs of me at CML-CAB Meetings and using them for the purpose of communication about these meetings. I understand that I can withdraw my consent at any time by contacting info@lepaf.org. I also understand that I have the right to access, rectify, or erase my personal data by contacting info@lepaf.org.

Name: _____

Signature: _____

Date: _ _. _ _ ._ _ _ _

# CML-CAB: CML Community Advisory Board Declaration of Interest (DoI)

**ANNEX 4**

[Version 11.2023]

## Introduction and purpose

You have been invited by the Leukemia Patient Advocates Foundation to join the "CML Community Advisory Board" (CML-CAB) based on your experience and knowledge about different aspects of CML patient advocacy. This experience and knowledge come from long-term and in-depth involvement in cancer patient advocacy at both a national and international level. Because of your experience, it is inevitable that you will have several legitimate on-going interests with different public (both government and non-government) and private (e.g., pharmaceutical companies, medical device companies, healthcare providers etc.) organisations.

The purpose of Declarations of Interests is to protect you and the CML-CAB from any suggestion or perception of impropriety. Conflicts of interest may arise when a CML-CAB member's personal, business, occupational or professional interests' or affiliations may conflict with the discussions held or decisions made at the CML-CAB.

CML-CAB does not want to limit or influence in any way your involvement with other organisations – we just want to provide transparency and help participants of the CML-CAB to understand whether a potential conflict of interest exists.

In the light of the above we are asking all CML-CAB members to make a declaration of their interests. Please identify what these interests are by returning the form on the next pages. This will be provided to all CML-CAB members and external CML-CAB participants, but not made available publicly.

We kindly ask you to complete and return this Declaration of Interests form (DoI) to anastasia@cmladvocates.net.

### Definition of categories of interest

*Consultancy*
This is where you provide consultancy services to a public or private organisation regardless of contractual arrangements, format **(physical or virtual)** or any form of remuneration.

*Committee membership*
This is where you participate in a committee (e.g., steering committee, advisory board, data monitoring committee etc.) with the role of providing advice/expressing opinions to a public or private organisation, regardless of contractual arrangements, format **(physical or virtual)** or any form of remuneration.

*Other*
This is where some other interest exists that may be relevant to your role on the CML-CAB (e.g., close family member working for a relevant public or private organisation etc.).

**GDPR**

Under the General Data Protection Regulation (GDPR), you have the right to access, rectify, or erase your personal data. You also have the right to object to the processing of your data and the right to withdraw your consent at any time. We need your consent for processing the data provided above.

The data controller for your data is the Leukemia Patient Advocates Foundation, with address at (enter postal address). If you have any questions about the data or the processing of your personal data, you can contact us at info@lepaf.org.

Information about the data processing: The data taken will be used solely for the assessment of potential conflicts of interest. The data will only be provided to trustees of the Leukemia Patient Advocates Foundation as well as steering committee members and staff members of the CML Advocates Network, a committee of the Leukemia Patient Advocates Foundation. The data will not be published in the public domain.

The Leukemia Patient Advocates Foundation will retain the data for the time you are involved in the initiatives and activities of the CML Advocates Network but will make sure to delete them at maximum one year after you have ceased all activities.

# CML-CAB: CML Community Advisory Board
# Declaration of Interest (DoI)

[Version 11.2023]

**Your Name:** Click here to add text.

**Organisation(s):** Click here to add text.

**Country:** Click here to add text.

**E-Mail:** Click here to add text.

**Date:** Click here to add text.

Other than my involvement in the abovementioned organisation(s) I declare that, to the best of my knowledge, the only interests that are relevant to my role on the CML-CAB in companies and organisations are those listed below. **All current and/or past interests from the last 3 years should be declared.** In the case of previous employment in a pharmaceutical company, please declare all such past interests from your entire career. ***Please don't leave any fields blank! IF NOTHING TO DECLARE, PLEASE ADD "NOTHING TO DECLARE"***

## Employment

*Employment with a pharmaceutical company means any form of occupation, part-time or full-time, paid or unpaid, in the company. This includes also companies relating to medicinal products, e.g. contract research organisations (CROs), but not academic institutions.*

***List name(s) of company / companies or organisation(s) and your role within each below (1 line per company / organisation) or put NOTHING TO DECLARE!***

Click here to add text.

Click here to add text.

Click here to add text.

## Consultancy

*Consultancy means provision of advice to a pharma company, public institution or healthcare organisation, regardless of contractual arrangements, format (physical or virtual) or any form of remuneration or provision of pro-bono services.*

***List name(s) of company / companies or institution(s) or organisation(s) or put NOTHING TO DECLARE!***

Click here to add text.

**Strategic advice**

*Strategic advisory role means participation (with a right to vote on/influence the outputs) in an advisory board or steering committee with the role of providing advice, expressing opinions on the (future) strategy, direction or activities of a pharma company, public institution or healthcare organisation, regardless of contractual arrangements, format (physical or virtual) or any form of remuneration or provision of pro-bono services.*

***List name(s) of company / companies or institution(s) or organisation(s) (comma-separated) or put NOTHING TO DECLARE!***

Click here to add text.

**Financial interests**

*Current holding of stocks and shares, stock options, equities, bonds and or partnership interest in the capital of a pharmaceutical company with the exclusion of an investment fund, pension fund and/or similar arrangements.*

*Current intellectual property rights including patents, trademarks, know-how and/or copyrights relating to a medicinal products or healthcare service owned by you or of which you are directly a beneficiary.*

***List name(s) of company / companies or fund(s) (comma-separated) or put NOTHING TO DECLARE!***

Click here to add text.

**Grant, funding to organisation(s) and institution(s)**

*Current grants or other funding (other than compensation for services provided e.g. for consultancy) received from a pharmaceutical company, healthcare organisation or governmental institution by an organisation/institution to which you belong, or for which you perform any kind of activity, and which is used to support any of your activities whether or not they are related to your patient advocacy work. Clarification: If the organisation or institution to which you belong or are active for, currently receives any grants or funding from a pharmaceutical company, a healthcare organisation or a governmental institution, and you and your activities at your organisation or institution benefit directly from these grants or funding, then this needs to be described here. It does not matter if the grant is related to your patient advocacy work or not - the support needs to be declared.*

***List name(s) of company / companies or institution(s) or organisation(s) or put NOTHING TO DECLARE!***

Click here to add text.

**Any other interests or facts**

*Provide information on involvement additional organisations, institutions, initiatives or projects that may create a potential conflict of interest, e.g.:*

- *Academic and/or publicly funded research initiatives in healthcare*
- *Officer, director, trustee, employee, or consultant to any other professional society, research organisation, non-profit organisation or corporation in healthcare, which may be funded in full or in part from unrestricted grants from pharmaceutical companies or*

*governmental bodies, or may have potential conflicts of interest with the CML Advocates Network*

- *Membership of an Ethics Committee*
- *Employment, consultancy, strategic advisory role and financial interests of a first-line family member (i.e. spouse or partner, children and parents)*

***List name(s) of company / companies or institution(s) or organisation(s) or project(s) or put NOTHING TO DECLARE!***

Click here to add text.

Should there be any change to the above due to the fact that I acquire additional interests, I shall promptly notify the Leukemia Patient Advocates Foundation and submit an updated Declaration of Interests detailing the changes.

Signature:

_____

Date: Click here to add text.

# CML Community Advisory Board
# Elections to CML-CAB chair position

**ANNEX 5**

[Version 2.0 / release date 02 March 2023]

## Background

CML Community Advisory Board (CML-CAB) is a working group of the CML Advocates Network (CMLAN). It is a key strategic tool to have a dialogue of experienced advocates and CML stakeholder decision makers about the advocacy community´s priorities and concerns. CML-CAB is composed of a global panel of 25 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 and research 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 CML-CAB objectives are:**

- **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.
- **Supporting in the development of** patient-friendly clinical trials and helping interested patients access these.
- **Addressing** problems CML patients face in accessing optimal diagnosis, monitoring, treatment and care throughout their CML journey.
- **Contributing to improving** the CML patients' outcomes.
- **Improving** patients' quality of life (QoL) through these interactions with CML stakeholders
- **Improving** the quality of information and education
- **Building** CML advocacy community capacity.

CML-CAB meetings provide the opportunity to establish a two-way dialogue between key leading advocates of the patient community and external CML stakeholders, discussing key topics in CML as well as potential follow-up actions.

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

As per the CML-CAB Protocol, the CML-CAB is comprised of one to two chair(s) and a minimum of 6 CAB-members representing the following 6 world regions: Western Europe & Israel, Eastern Europe, North America, Latin America, Africa & Middle East, Asia-Pacific. Members of the CMLAN SC may additionally join CML-CAB meetings on personal invitation by the chair(s). The CML-CAB management team is provided by the CML-CAB staff: a CML-CAB Officer and the CMLAN´s Director who work closely with the chair(s).

The CML-CAB Protocol stipulates that the CML-CAB chair(s) is/are elected by the CML Advocates Network´s Steering Committee for a two-year period.

## Call for applications

Since the term of the current chairs is ending end of April 2025, CML-CAB is seeking expression of interest for one (or ideally again two) **volunteer CML-CAB chair(s)** that will be steering CML-CAB from **xxx up to xxx (add dates)**.

This is a unique chance to play a pivotal role in shaping the future of CML advocacy and driving meaningful impact for the global community. If you're passionate about advancing patient advocacy and eager to lead, we would love to hear from you!

## Eligibility

In order to be eligible to apply for the position of CML-CAB chair you **need to be an active CML-CAB member.**

## Expectations / duties & responsibilities

CML-CAB chair(s) provide(s) overall guidance on all CML-CAB related matters and steering the dialogue with stakeholders around CML-CABs interests. As per the CML-CAB "RACI" matrix (see Annex 1, CML-CAB Protocol), CML-CAB chair(s) is/are:

- Informed about the creation and maintenance of project plans with timelines.
- Consulted, along with the CAB Officer and CMLAN SPM on the overall annual operation budget for CML-CABs.
- Informed alongside the CMLAN SC on the creation and maintenance of a budget plan and budget administration-overall for CAB programme and per meeting.
- Consulted on grant agreements for CAB programme.
- Responsible and Accountable for whether a specific CAB meeting will be remunerated or not.
- Informed on the replacement and appointment of CML-CAB chairs once the term is coming to an end.
- Informed on the completion of new CML-CAB members upon joining CML-CAB or review/update Skills Self-Assessment Survey on a bi-annual basis.
- Informed on the creation and maintenance of ORCID profiles.
- Responsible and Accountable for reviewing the CML-CAB pool makeup on a bi-annual basis (minimum) and recommend changes.
- Accountable for coordinating the replacement of CML-CAB members and the addition of others.
- Accountable and Informed for mapping out the existing skills in a skills matric and keeping the matrix up to date.
- Informed about CAB members and stakeholders un to date/valid CA's and DOIs.
- Consulted and Informed on keeping all CAB files for CAB members and chairs and document storage on NextCloud up to date.
- Consulted on the updated CML-CAB section on the CMLAN website, why we do them, what we do, and what they concluded on, so everyone can see what we do.
- Accountable for keeping the CAB protocol/terms of reference up to date.
- Accountable and Consulted on the development of CAB meeting agenda.
- Accountable and Consulted on the choice of companies or other stakeholder representatives for each CAB meeting.
- Accountable and Consulted on the choice of training topic and implementation
- Responsible and Accountable for the choice of participants per CAB meeting, including inviting CMLAN SC members if deemed suitable
- Consulted and Informed on the selection of date for CAB meetings
- Consulted and Informed on the selection of city and venue for CML-CAB meetings
- Consulted and Informed on the introductory presentations and the coordination of internal+external CML-CAB presentations
- Informed on the coordination of the minute taker and facilitator
- Informed on the meeting logistics of CAB-CML meetings

- Informed on the travel bookings for CAB members
- Consulted on chairs and stakeholders signing off the Executive Summary in final form 6 weeks after meeting, and Confidential Minutes 3 months after meeting.
- Informed on the storage of Confidential Minutes of CAB meetings on NextCloud and shared with CAB-members (only those that signed CA agreements) & participating stakeholder representatives
- Informed on the storage of Executive Summaries on NextCloud and their availability on the website and shared via newsletter and social media channels
- Consulted that the agreed upon actions are being followed up by those that committed to them, within timelines that are agreed or need to be defined.
- Informed of their attendance to CMLAN SC meetings

## Time commitment

CML-CAB chair(s) is/are expected to participate in a monthly virtual meeting with the CML-CAB management team to provide input and discuss relevant topics.

The CML-CAB chairs(s) is/are further expected to review and reply to irregular e-mail correspondence on CML-CAB related matters coming from the CML-CAB staff, and is / are further expected to review and reply to regular e-mail correspondence on CML-CAB related matters coming from the CML-CAB management team to fulfil the tasks listed in the CML-CAB "RACI" matrix.

As per the CML-CAB protocol, CML-CAB meets at least once a year, with additional ad hoc meetings as well as workgroup meetings being possible.

- Meetings can be face-to-face, or virtual or in a hybrid format.
- Face-to-face meetings usually last 1-3 days and consist of a CAB-internal preparatory meeting (mandatory) + CAB-internal training (optional), + CML-CAB sessions with individual external parties (which usually last half day or a full day) + a CAB-internal debrief meeting (mandatory) following the aforementioned CML-CAB sessions.
- Virtual or hybrid meetings be held as a 3 to max. 4 hours meeting (with short breaks in between) or spread over 2 days by splitting it into a 2-day meeting, e.g., 2 hours meeting time per day + preparatory meeting (mandatory) + training session (optional) + debrief meeting (mandatory).

Besides attending CML-CAB meetings (virtual and face-to-face), the chair(s) is / are invited to attend CMLAN SC meetings in their specific role as CML-CAB chair(s) with no voting rights.

## Process

If you are interested in taking on the role of CML-CAB chair, please complete the **application form that comes attached to this letter** (see page 4) and submit to Anastasia at anastasia@cmladvocates.net **by xxx(add date)**. **Alternatively**, you can submit a **video application**.

The CMLAN Steering Committee will decide on the final candidate(s) for the position(s) of CML-CAB chair(s) by **online vote**. The final candidates will be announced by **xxx (add date)**

***Thank you for your interest and for submitting your written application or video application!***

**CML Community Advisory Board**
**Elections to CML-CAB chair and/or co-chair positions**

## APPLICATION FORM

**Please complete the form or submit your video application answering the question in rows 4 and 5 (optional) below.**

| | | |
|---|---|---|
| 1 | Name: | |
| 2 | Country: | |
| 3 | E-Mail-address: | |
| 4 | Please describe what your motivation is for applying to the position of CML-CAB chair and what you intend to contribute during the 2-year term (add dates: xxx to xxx) | |
| 5 | Comments / suggestions / wishes: | |

ANNEX 6

# JOB DESCRIPTION

# Community Advisory Board Chairs (CML-CAB Chair)

## *Background*

CML Community Advisory Board (CML-CAB) is a working group of the CML Advocates Network (CMLAN). It is a key strategic tool to have a dialogue of experienced advocates and decision makers about the advocacy community´s priorities and concerns. CML-CAB is composed of a global panel of 25 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 CML-CAB objectives are:**

- **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.

As per the CML-CAB Protocol, the CML-CAB is comprised of one to two chair(s), and a minimum of 6 CAB-members representing the following 6 world regions: Western Europe & Israel, Eastern Europe, North America, Latin America, Africa & Middle East, Asia-Pacific. Members of the CMLAN SC may additionally join CML-CAB meetings on personal invitation by the chair(s). The CML-CAB management team is provided by the CML-CAB staff: a CML-CAB Officer and the CMLAN´s Director who work closely with the chair(s).

The CML-CAB Protocol stipulates that the CML-CAB chair(s) is/are elected by the CMLAN Steering Committee (SC) for a two-year period. Re-election is allowed, though not explicitly mentioned in the CML-CAB Protocol. CML-CAB chair(s) is/are recruited from the CML-CAB membership. With that, CML-CAB chairs must be active CML-CAB members in order to be elected. In principle, CML-CAB chair(s) exercise(s) in a voluntary (unpaid) capacity.

## *Duties and Responsibilities*

CML-CAB chair(s) provide(s) strategic input and overall guidance and direction on all CML-CAB related matters and steer the dialogue with stakeholders around CML-CABs interests, ultimately ensuring CML-CAB´s effectiveness.

CML-CAB chair(s) is/are the direct interface between CML-CAB and the CMLAN SC, having to liaise with the chair of the CMLAN SC in all strategic, operational and financial aspects to ensure that the CML-CAB strategy is in line with CMLAN´s overall strategy and that there is full transparency in terms of the direction that CML-CAB is pursuing and the budgetary impact of CML-CAB.

As per the CML-CAB "RACI" matrix, CML-CAB chair(s) is/are:

- Informed about the creation and maintenance of project plans with timelines.
- Consulted, along with the CAB Officer and CMLAN SPM on the overall annual operation budget for CML-CABs.
- Informed alongside the CMLAN SC on the creation and maintenance of a budget plan and budget administration-overall for CAB programme and per meeting.
- Consulted on grant agreements for CAB programme.
- Responsible and Accountable for whether a specific CAB meeting will be remunerated or not.
- Informed on the replacement and appointment of CML-CAB chairs once the term is coming to an end.
- Informed on the completion of new CML-CAB members upon joining CML-CAB or review/update Skills Self-Assessment Survey on a bi-annual basis.
- Informed on the creation and maintenance of ORCID profiles.
- Responsible and Accountable for reviewing the CML-CAB pool makeup on a bi-annual basis (minimum) and recommend changes.
- Accountable for coordinating the replacement of CML-CAB members and the addition of others.
- Accountable and Informed for mapping out the existing skills in a skills matric and keeping the matrix up to date.
- Informed about CAB members and stakeholders un to date/valid CA's and DOIs.
- Consulted and Informed on keeping all CAB files for CAB members and chairs and document storage on NextCloud up to date.
- Consulted on the updated CML-CAB section on the CMLAN website, why we do them, what we do, and what they concluded on, so everyone can see what we do.
- Accountable for keeping the CAB protocol/terms of reference up to date.
- Accountable and Consulted on the development of CAB meeting agenda.
- Accountable and Consulted on the choice of companies or other stakeholder representatives for each CAB meeting.
- Accountable and Consulted on the choice of training topic and implementation
- Responsible and Accountable for the choice of participants per CAB meeting, including inviting CMLAN SC members if deemed suitable
- Consulted and Informed on the selection of date for CAB meetings
- Consulted and Informed on the selection of city and venue for CML-CAB meetings
- Consulted and Informed on the introductory presentations and the coordination of internal+external CML-CAB presentations
- Informed on the coordination of the minute taker and facilitator
- Informed on the meeting logistics of CAB-CML meetings
- Informed on the travel bookings for CAB members
- Consulted on chairs and stakeholders signing off the Executive Summary in final form 6 weeks after meeting, and Confidential Minutes 3 months after meeting.
- Informed on the storage of Confidential Minutes of CAB meetings on NextCloud and shared with CAB-members (only those that signed CA agreements) & participating stakeholder representatives
- Informed on the storage of Executive Summaries on NextCloud and their availability on the website and shared via newsletter and social media channels

- Consulted that the agreed upon actions are being followed up by those that committed to them, within timelines that are agreed or need to be defined.
- Informed of their attendance to CMLAN SC meetings

## *Time Commitment*

CML-CAB chair(s) is/are expected to participate in a monthly virtual meeting with the CML-CAB management team to provide input and discuss relevant topics.

The CML-CAB chairs(s) is/are further expected to review and reply to irregular e-mail correspondence on CML-CAB related matters coming from the CML-CAB staff and is / are further expected to review and reply to regular e-mail correspondence on CML-CAB related matters coming from the CML-CAB management team to fulfil the tasks listed in the CML-CAB “RACI” matrix.

As per the CML-CAB protocol, CML-CAB meets at least once a year. Additional ad hoc meetings as well as workgroup meetings are possible. Time commitment: 1-3 days per meeting for face-to-face meetings). The protocol stipulates that meetings can also be virtual or in a hybrid format (time commitment: 3-4 hours meeting time + preparatory meeting + training + debrief meeting).

Besides attending CML-CAB meetings (virtual and face-to-face), the chair(s) is / are invited to attend CMLAN SC meetings in their specific role as CML-CAB chair(s) with no voting rights.

# CML-CAB: CML Community Advisory Board Appointment to membership

**ANNEX 7**

[Version 11.2023]

**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 built their research competencies and are increasingly contributing to research discussions with different stakeholders. In the light of this, and adopting the model used by HIV/AIDS advocates, in 2016 the CML Advocates Network (CMLAN) established its CML Community Advisory Board (CML-CAB) with the main objective of providing CML stakeholders (e.g., researchers, academics, clinicians, government, policy makers, authorities, pharmaceutical industry, etc.) with advice and input on different issues that may impact 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 carers, helps improve research, facilitates community capacity building and tackles the many challenges faced in ensuring access to optimal support, treatment and care. Since 2021, CML-CAB naturally diversified to what is called Academic CML-CAB which aims at bringing together word-leading patient advocates, researchers and clinicians to jointly explore barriers and opportunities within the ongoing CML research as an integral part of CML-CAB.

**The CML-CAB objectives are:**

- **Providing** CML stakeholders (researchers, academics, government, policy makers, authorities and pharmaceutical industry) with advice and input on different issues that can ultimately impact 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.
- **Supporting in the development of** patient-friendly clinical trials
- **Addressing** problems CML patients face in accessing optimal diagnosis, monitoring, treatment and care throughout their CML journey.
- **Contributing to improving** the CML patient outcomes.
- Improving patients´ quality of life (QoL) through these interactions with CML stakeholders
- **Improving** the quality of information and education.
- **Building** CML advocacy community capacity.

As per the CML-CAB Protocol, CML-CAB is composed of one to two chair(s), and a minimum of 6 CAB-members representing the following 6 world regions: Western Europe & Israel, Eastern Europe, North America, Latin America, Africa & Middle East, Asia and Pacific. Members of the CMLAN SC may additionally join CML-CAB meetings on personal invitation by the chair(s). The CML-CAB management team is provided by the CML-CAB staff: a CML-CAB Officer and the CMLAN´s Director who work closely with the chair(s).

The CML-CAB Protocol stipulates that CML-CAB members come from patient-based, non-profit organisations that are members of CMLAN and are appointed as individuals based on their individual qualifications and experience, and not as representatives of their own patient organisation. The CML-CAB chairs are responsible for deciding – based on individual applications received – which applicants will be accepted to the CML-CAB members' pool. The CML-CAB chairs will take care to ensure as broad a geographical and knowledge coverage as possible.

**Call for applications**

CML-CAB would like to expand the CML-CAB membership and is therefore seeking for interested additional volunteer CML-CAB members willing to contribute to the work performed by the CML-CAB up **from xxx (add date) and reviewed on a bi-annual basis**.

**Eligibility**

To be eligible to apply for the position of **CML-CAB member** you need to be an active representative of a member organisation of the CML Advocates Network.

**Expectations / duties & responsibilities**

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 two of the following areas:
    - Clinical/Research
    - Access
    - Collaboration
    - CML-specific drug expertise

CML-CAB member responsibilities are to:

- Participate actively in CML-CAB meetings 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.
- Have a profile on the research portal ORCID, keep it up to date, and share their ORCID ID to raise the profile of CML-CAB as a whole and of each CML-CAB participant individually.
- Have a profile on a relevant professional or advocacy related Social Media account, keep it up to date, and share their URL to raise the profile of CML-CAB as a whole and of each CML-CAB participant individually.
- Be informed about local patient-related, 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 and Data Processing Agreement" (ANNEX 2), "CML-CAB Declaration of Interests" incl. disclosure of financial contributions received from industry for performing personal activities (ANNEX 4). It should be renewed as needed (annually at a minimum).
- Review and sign the CML-CAB Photography Consent Form (ANNEX 3) if he/she agrees that photographs of him/her are taken at CML-CAB meetings. This form needs to be renewed for each meeting.

**Time commitment**

CML-CAB members are expected to:

- Attend a 2-hours onboarding session (virtual)
- Undertake self-training by studying the materials from previous CML-CABs
- Attend CML-CAB meetings (1-3 days if face-to-face or 3-4 hours for a virtual meeting) if nominated by the chairs. Note: Not all CML-CAB members attend all CML-CAB meetings. The number of CML-CAB members and members of the 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 geographical region plus the two chairs).
- Attend the 2-hours preparatory meeting before and the 1-2 hours debrief meeting after each CML-CAB meeting.
- Study the pre-read materials circulated by the CML-CAB Management Team ahead of CML-CAB meetings to prepare for the meeting.
- Attend ad hoc virtual meetings called by the CML-CAB chairs or the CML-CAB Management Team if deemed required.
- Review and reply to regular e-mail correspondence on CML-CAB related matters coming from the CML-CAB management team to fulfil the tasks listed above (see section “Expectations / duties & responsibilities”).

**Process**

If you are interested in joining the CML-CAB membership, **please complete and submit the “Skills self-assessment survey and CML-CAB Application form” by xxx (add date)**. As the name suggests, the online form includes a Self-Assessment Survey where we are asking you to self-evaluate your knowledge and proficiency in different areas.

The CML-CAB Chairs will decide on the final candidate(s) and announce the selected members **by xxx (add date)**, with the term of successful candidates officially **starting on xxx (add date).**

***Thank you for your interest and for submitting your application!***