CML AdvocatesNetwork
Community Advisory Board

Community Advisory Boards in CML & Hematology

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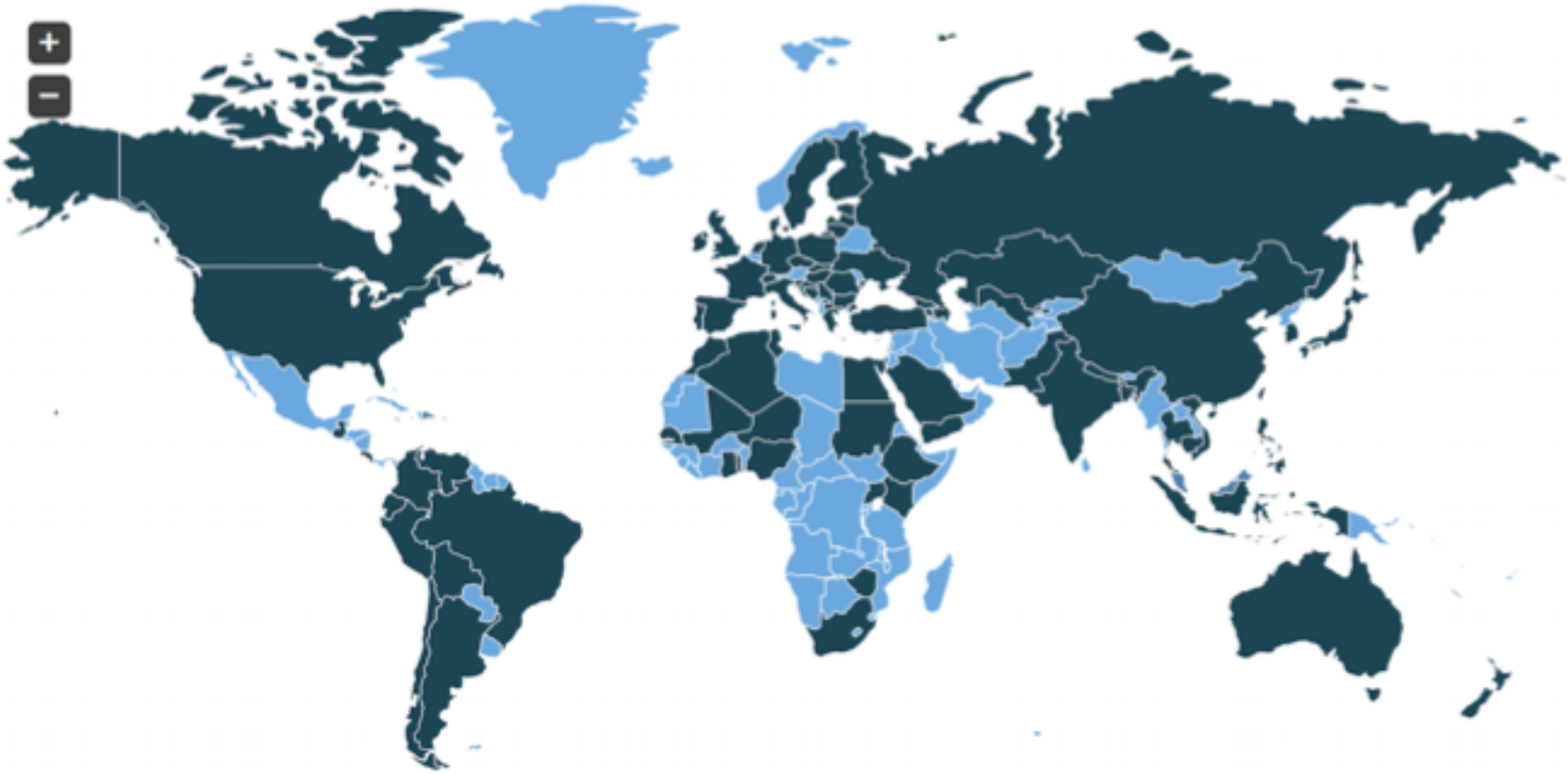
CML Advocates Network connecting 118 leukemia POs in 88 countries today



Countries with CML member organisations

Countries without CML member organisations

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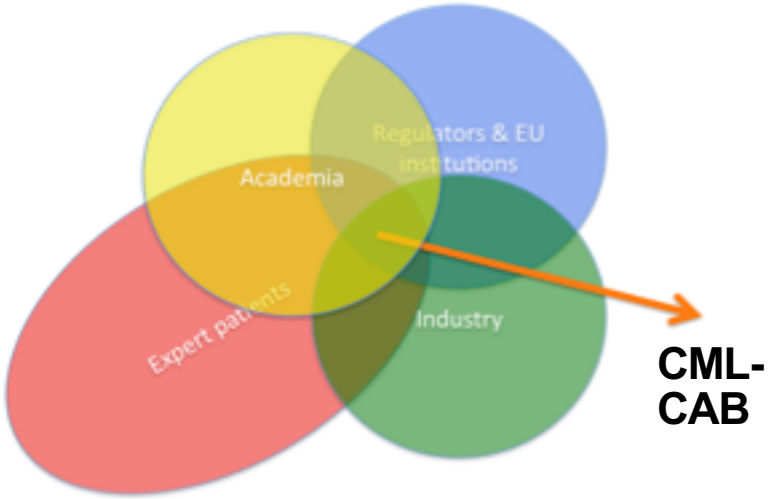
Why did we start to do CML Community Advisory Boards in 2016?

- **Research** is key towards better outcomes and CML cure, but often the trials are made without patient input
- **Care** (incl. monitoring) are often not reflecting true patients needs'
- **Access** to treatment and diagnostics is often suboptimal
- **Pharma's patient information** doesn't do what it should do
- **Many pharma ad boards** are relatively meaningless, little impact on their direction and action
- **We patients have a key role to play** in CML patients' access to optimal support, treatment and care
- **Patient centricity** is often just a glossy mission statement

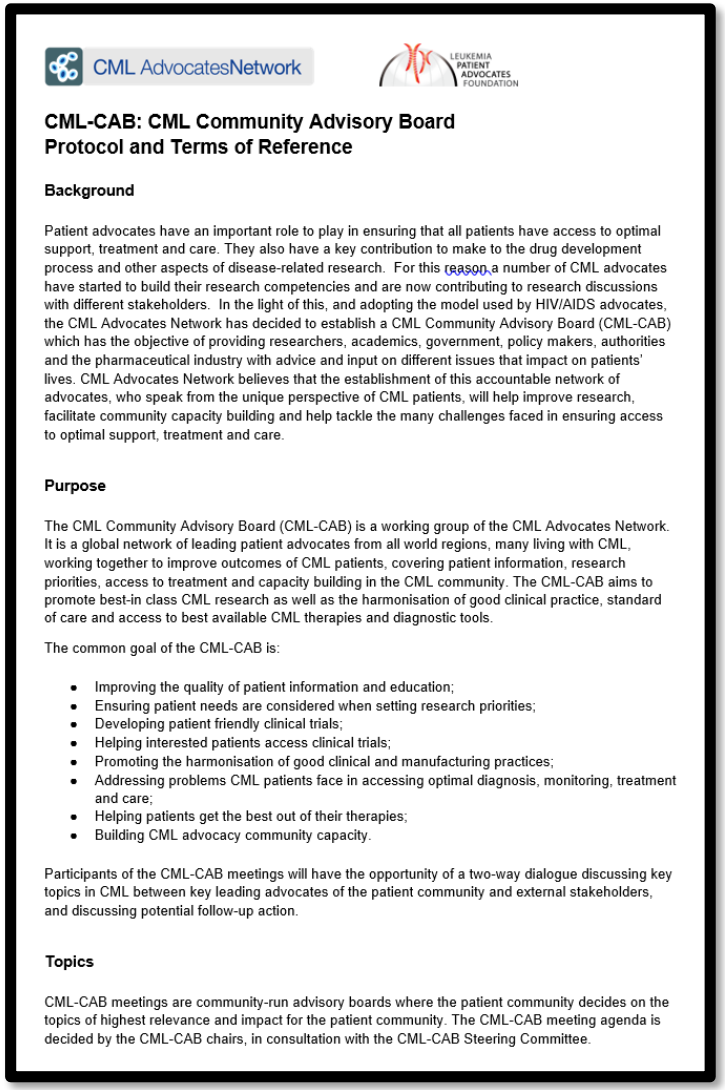
What are CML-CABs?

- **Patient-run community advisory boards** where patient organisations set the agenda and invite stakeholders
- **Two-way dialogue** with researchers, academics, authorities and pharmaceutical industry, to improve patients' well-being and outcomes
- **Platform** with needs & views of the patient community of different regions
- Address challenges that patients face in **accessing diagnosis, monitoring, treatment and care**
- Improve quality of **patient information** and education
- Develop **patient-focused trials**
- **Build capacity** and knowledge in our community



A proven, agreed ruleset: The CML-CAB Terms of Reference

- Based on EATG ECAB (1997)
- Re-used and adapted EATG ECAB protocols (rev. 11):
  - Purpose
  - Topics
  - Schedule
  - Membership
  - Governance
  - Participation and composition
  - Confidentiality
  - Meeting minutes (2 versions)
  - Evaluation
  - Financing
  - Company participants



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LEUKEMIA PATIENT ADVOCATES FOUNDATION

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

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 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, 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. It is a global network of leading patient advocates from all world regions, many living with CML, working together to improve outcomes of CML patients, covering patient information, research priorities, access to treatment and capacity building in the CML community. The CML-CAB aims to promote 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.

The common goal of the CML-CAB is:

- Improving the quality of patient information and education;
- Ensuring patient needs are considered when setting research priorities;
- Developing patient friendly clinical trials;
- Helping interested patients access clinical trials;
- Promoting the harmonisation of good clinical and manufacturing practices;
- Addressing problems CML patients face in accessing optimal diagnosis, monitoring, treatment and care;
- Helping patients get the best out of their therapies;
- 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 action.

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 chairs, in consultation with the CML-CAB Steering Committee.

Why confidentiality?

- We want to discuss **issues of highest relevance to both the patient community as well as the company**, which should lead to impact and action on both sides.
- Without confidentiality agreements, pharma would not provide **confidential information that is commercially sensitive and unpublished** – and must be "firewalled"

Confidential	Non-confidential / public
• Corporate strategies • Development pipelines • Unpublished data • Commercially sensitive information • Discussions and persons	• Concepts of treatment and care • Advocacy strategies • Patient information • Positions and decisions taken by the CAB

A typical set-up of a CML-CAB

A CAB is hard work:

- Mandatory training session – no participation without training
- Preparatory sessions with strategic alignment
- Confidential company sessions – each1x4 hours or 2x4 hours
- 2, 3 or 4 separate company sessions

Patient experts in the CML-CAB

- CABs need patient experts who are…
  - outspoken
  - technically well-trained, selected by expertise, not role
  - evidence-based
  - able to speak beyond their case and country
  - able not to dominate the meeting, and not to drift away
- Starting composition: 15 members
  - “Board” of the CML Advocates Network, with 3 permanent members and 1 elected leader of 6 world regions
  - Each regional representative to appoint 1 most knowledgeable advocate from their region
  - Additional specialist advocate on pediatric CML

5 CML-CABs held to date

5 CML-CABs to date:

- **May 2016** with 2 companies + training on drug development process and CML research
- **February 2017** with 3 companies + training on partnerships and CABs as an advocacy tool
- **May 2017** with 4 companies
- **November 2017** with 2 companies, + training on collaboration with industry
- **May 2018** with 3 companies, + training on PRO tools

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Outcomes of recent CML-CABs

- Discussed the **drug development pipeline** of the companies who are engaged in CML
  - Invitations to investigator meetings, impact on future trials
  - Input into our CML trial database
  - Background knowledge e.g. for regulatory discussions
  - Involvement of CML community in CML drug development
- Dialogue about **improving access to drugs**
  - Companies often not aware about inequalities and real-world access issues outside of their „big markets“
  - Advocates learned about corporate access programs, provided input
- **Discussed improving collaboration** of companies with CML community
- Influenced **patient services** developed by companies (PSPs, info)
- **Built capacity by training** CML-CAB members
  - Increased the number of advocates with technical knowledge about CML trials, interpreting science, access barriers, working with pharma

Don’t let anyone take control over your meeting – some may try…

- Trying to get unpleasant topics off the agenda
- “There is no new topic on the next CAB agenda”
  → because follow-up actions have not been ticked!
- Bring people that have nothing to say or decide – “we will get back to you on this”
- Bringing agency people to run the show
- Waste your collective time with presentations about things you already know in order not to get to the tacky issues

1st multi-company EU Hematology-CAB
18 June 2018

Outline:

- Leaders of 12 pan-European hematology PO umbrellas +
  7 elected representatives of EuroBloodNET ERN
- 3h prep session for „venting“, strategic alignment, distribution of questions
- 9 companies in one room, each company with 8 min elevator pitch presentation with position and suggestions to the patient community
- Group discussion with advocates
- Identified follow-up action

Topics (1.5h each):

- Effective patient engagement in industry R&D
- Evidence generation by POs to improve decision making in industry
- Overcoming compliance and legal hurdles in the collaboration between POs and industry

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Conclusions and lessons learned

- **The EATG ECAB model has been well established in Chronic Myeloid Leukemia and hematology** – probably the most effective collaboration tool between PO and industry
- **Multi-company Hem-CAB has worked well**, but multi-disease multi-company also has constraints
- Preparatory sessions and training are crucial; additional benefits for other advocacy activities (→ patient experts)
- **Agendas are usually too packed**. Min 1.5h/topic advisable
- **Don't let industry negotiate about the CAB terms,** legal contracts, confidentiality terms = nightmare
- **Build a secretariat** for the CAB!