



CML Advocates Network
Community Advisory Board

**Setting the agenda when engaging
with key stakeholders:**

CML Community Advisory Boards

**17 May 2019, CML Horizons 2019
Jan Geissler, Pat Garcia-Gonzalez**



The evolution of New Horizons and CML Advocates Network

Pat Garcia-Gonzalez - Jan Geißler - Maria Isabel Gomez - Jana Pelouchová - Giora Sharf - Anita Welborn

Why CML Community Advisory Boards?

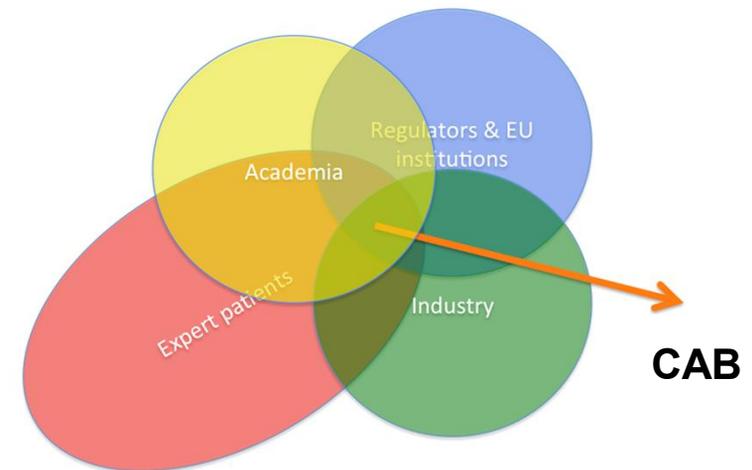
- **Research is key towards better outcomes**, but often the trials are done without patient input, do not deliver on unmet needs, do not deliver patient-relevant data (e.g. PRO, QoL), are run in the wrong countries, do not recruit
- **Care pathways** are often not reflecting true patients needs' and real-life situations
- **Access** to treatment and monitoring is often suboptimal or non-existent – focus on the “most attractive big markets”, not on hugest unmet need
- **Pharma's patient information** often doesn't answer our questions, is sometimes inappropriate (“smiling happy people riding a bike at the beach in the sunset”)
- **Pharma advisory boards** are often not meaningful, have little impact, provide no reports or follow-up

How do CABs work?

- **Building on the successful model of the HIV community:**
 - **A strategic committee/meeting to discuss research, access to treatment and care and collaboration**
 - **Key strategic tool** to influence companies on patients' needs (trials, access, care, information etc)
 - **A model of a united patient community**

This is how it works:

- **We invite participants** from the companies
- **A two-way dialogue where we set the agenda** and pick the topics that are most meaningful to us
- **We respect confidentiality** to have a trusted and open dialogue
- **We report to our members** through our regional representatives & with public minutes (but not confidential stuff!)
- **We ensure follow-up** through the CAB office, not one-off meetings
- **We grow leaders** by providing training to our CAB members



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
- 2-4 confidential company sessions – each 1x4 hours or 2x4 hours
- Based on a protocol that defines purpose, governance, membership, decision rules, confidentiality, minutes

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, pharma would not provide confidential information

Confidential	Non-confidential / public
<ul style="list-style-type: none">• Corporate strategies• Development pipelines• Unpublished data• Commercially sensitive information• Discussions and persons	<ul style="list-style-type: none">• Concepts of treatment and care• Advocacy strategies• Patient information• Positions and decisions taken by the CAB

8 CML-CABs in 18 sessions from 2016-2019



Date	Company CAB sessions	CAB Training sessions
5/2016	Novartis, Pfizer	Drug development process and CML research
2/2017	Novartis, Takeda, Ariad	Partnerships; CABs as an advocacy tool
5/2017	Novartis, BMS, Pfizer, Incyte	CML Horizons 2017
11/2017	Novartis, Incyte, Takeda	Collaboration with industry
5/2018	Novartis, Pfizer, Incyte	PRO & QoL instruments
11/2018	Novartis (+ CEO)	
3/2019	Pfizer, Incyte, Takeda	Strategic priority setting on CABs
5/2019	Novartis	CML Horizons 2019

CML-CAB Members (today)

Chairs:

- Pat Garcia-Gonzalez (USA)
- Jan Geissler (Germany)

Western Europe & Israel:

- Rita Christensen (Denmark)
- Cornelia Borowczak (Germany)
- Felice Bombaci (Italy)
- Zack Pemberton-Whiteley (UK)
- Giora Sharf (Israel)
- Yair Bar David (Israel)

Eastern Europe:

- Šarūnas Narbutas (Lithuania)
- Jelena Cugurovic (Serbia)
- Jana Pelouchova (Czech Republic)

Africa:

- Bahija Gouimi (Morocco)
- Eunice Oreka (Nigeria)

Asia:

- Rod Padua (Philippines)
- Yoke Choon Yong (Malaysia)
- Param Puthen (India)

Latin America:

- Mercedes Arteaga (Argentina)
- Silvia Castillo De Armas (Guatemala)

North America:

- Lisa Machado (Canada)
- Gail Sperling (USA)

What did we discuss with the companies in the CABs 2016-2019?

	Topic area	Novartis	Pfizer	BMS	Ariad, Takeda, Incyte
Clinical / Research	Development pipeline, clinical trials, path to cure	Dark Blue	Dark Blue	Light Blue	Dark Blue
	Therapy-free remission	Dark Blue	Dark Blue	Dark Blue	Light Blue
	Patient-reported outcomes / Quality of life	Dark Blue	Dark Blue	Light Blue	Dark Blue
	Pediatric use of the drug	Dark Blue	Dark Blue	Dark Blue	Light Blue
	Drug safety & side effect management	Dark Blue	Dark Blue	Dark Blue	Dark Blue
	Food effects (fasting)	Dark Blue	Light Blue	Light Blue	Light Blue
	Trials: Selection of countries and sites	Dark Blue	Light Blue	Light Blue	Light Blue
Access	Value proposition of the drug	Red	Red	Light Blue	Light Blue
	Access strategies in different regions	Red	Red	Light Blue	Red
Collabor. & other	Educational material	Orange	Orange	Light Blue	Orange
	Falsified drugs	Light Blue	Light Blue	Light Blue	Orange
	Collaboration barriers, compliance	Orange	Light Blue	Light Blue	Orange



Overall outcomes of the CML-CABs

- **Discussed drug development pipeline** of the companies
 - Invitations to investigator meetings
 - Some impact on trial design, some additional trial sites input into PRO/QoL tools, > feedback on challenges of drug administration, ...
- **Addressed access issues to drugs & monitoring**
 - Made inequalities, real-world access issues outside of „big markets“ more understandable. Provided input into corporate access programs
- **Addressed collaboration issues**
 - Compliance, financial support, local collaboration
- **Contributed to design of company-led patient services**
 - PSPs, patient information
- **Trained CML-CAB members**
 - Increased the number of advocates with technical knowledge about CML trials, interpreting science, access barriers, working with pharma



Strategic priorities for the CAB 2019

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

EU Hematology CAB (Hem-CAB)

- Organised by the EuroBloodNet ePAG representatives on 18 June 2018
- Leaders of 12 pan-European hematology PO umbrellas
- 8 companies in one room
- CML Advocates Network represented by Šarūnas and Jan
- Group discussion with advocates, identified follow-up action:
 - 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



Conclusions

- **The CML-CAB is our key strategic tool to influence companies in a two-way dialogue about our priorities**
(and potentially academic researchers in the future)
- **The CML community has pioneered this in cancer**, based on the HIV model. Hematology, Myeloma, Melanoma, Lymphoma coalitions are following.
- **Contact your regional member of the CML Steering Committee** about the CAB outcomes, and to provide input on agenda, topics, nominations of CAB candidates