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, to 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

<table>
<thead>
<tr>
<th>Confidential</th>
<th>Non-confidential / public</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Corporate strategies</td>
<td>• Concepts of treatment and care</td>
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<tr>
<td>• Development pipelines</td>
<td>• Advocacy strategies</td>
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<td>• Unpublished data</td>
<td>• Patient information</td>
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<tr>
<td>• Commercially sensitive information</td>
<td>• Positions and decisions taken by the CAB</td>
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<td>• Discussions and persons</td>
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# 8 CML-CABs in 18 sessions from 2016-2019

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

<table>
<thead>
<tr>
<th>Topic area</th>
<th>Novartis</th>
<th>Pfizer</th>
<th>BMS</th>
<th>Ariad, Takeda, Incyte</th>
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<tbody>
<tr>
<td>Development pipeline, clinical trials, path to cure</td>
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<td>Therapy-free remission</td>
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<td>Patient-reported outcomes / Quality of life</td>
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<td>Pediatric use of the drug</td>
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<td>Drug safety &amp; side effect management</td>
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<td>Food effects (fasting)</td>
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<td>Trials: Selection of countries and sites</td>
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<td>Value proposition of the drug</td>
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<td>Access strategies in different regions</td>
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<td>Educational material</td>
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<tr>
<td>Falsified drugs</td>
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<td>Collaboration barriers, compliance</td>
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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

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

https://www.cmladvocates.net/110-news/861
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