Meaningful engagement of patients in the design and conduct of clinical trials

François Houÿez, EURORDIS

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CAB exist since the 90s (Cancer, HIV,haemophilia…) Driven by patient networks

A group of 10-16 patients who offer their expertise to public or private sponsors of clinical research	Overall programme development A single clinical trial Safety, PROMs, compassionate use, pricing, access…
The same group of patients advises several sponsors in their field	Avoids selection of patients' representatives by the sponsor. Training programme and learning by doing
Agenda and secretariat driven by the patients. Guidelines, SOPs, templates, decision tracker etc.	Confidentiality arrangements except on Compassionate use
Companies engage with CABs to discuss unmet needs, the impact of the disease, how to measure efficacy etc.	

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Community Advisory Boards

Recommendations to Developers

CIOMS Report Working Group XI

Consider working with patient community advisory boards (CABs), which are organised and driven by patient advocates who decide on the agenda and the attendee list and create a professional space for stakeholders to come together

Recommendations to CABs

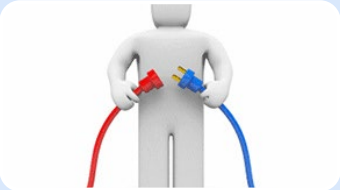
Conference on Community Advisory Boards, Bergen, 1996

- Independence
- Transparency, openness
- Operating procedures
- Members' recruitment, training
- Mechanisms for quality assessment and measurements of their impact
- Attitude of physicians
- ...

Support and mentoring from umbrella organisations

Identification of areas where CABs are needed

- Call to Members
- Feedback from experts, horizon scanning
- Webinars to patient networks, meetings, preparatory phase (6-9 months)



Matchmaking with industry

- Contact or help contacting developers /sponsors
- Receives direct requests from developers

Mentoring

- Help preparing and running CAB meetings
- Keeping guidelines up-to-date, developing policies
- Back-end office, “treatment advocate advice”

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Some existing CABs, alphabetical order

Angelman syndrome
Atypical Haemolytic Uremic Syndrome
Cystic Fibrosis
Cystinosis
Dravet syndrome
Duchenne Muscular Dystrophy
Hered. Haemorr. Telangiectasy
HIV/AIDS and other viral diseases
Huntington disease
Limb Girdle Muscular Dystrophy
Multiple Sclerosis
Myotonic Dystrophies
Neurofibromatosis
Oncology / Lymphomas / Multiple myeloma…
Psoriasis
Pulmonology
Systemic sclerosis
Thalassemia
Tuberous Sclerosis Complex

Session 4 – Panel and audience discussion

Moderator: Spiros Vamvakas

Hilde de Keyser

CFE CAB

Sally Hofmeister

WDO CAB

Panel discussion input:
Go to **www.sli.do**

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Question 1

Your respective CABs:

- Year you started
- Numbers of members
- Numbers of products you work on
- Average number of meetings per year

Question 2

Involvement of patients in the design and the conduct of clinical trials:

- Can you both describe how your CAB intervenes at the design phase of a clinical trial?
- And during the clinical trial, in terms of advising the sponsor and/or informing trial participants on unexpected side effect, substantial amendments, trial interruption or trial results?

Question 3

- Do you follow-up the changes you proposed to the clinical trial protocols ?

- How do you evaluate the impact your CAB has on the product R&D?

- Examples of “successes”, or changes you obtained in the design or practical aspects of a trial?

Question 4

- Benefits of CABs, as you are engaging with different developers / pharmaceutical companies and not just one?

Question 5

1. CABs and their independence vis-à-vis developers : how do you ensure independence?
2. Do you exchange views with regulators and/or HTA? How?
3. CAB members participate in meetings with companies, and this is considered as consulting under policy 44 Handling competing interests (EMA).

-How do you address this within your organisations? Are CABs aware of this and does it play a role in their decision on how many members from the same organisation to include in a CAB?

Question 6

How do you evaluate the importance of having trained CAB members?

Is training a pre-requisite to join a CAB, or do your members learn by doing?

Principles

- **Must have**
  - Open Call for volunteers (patient groups, social networks…)
  - Agendas and composition made public (members' names)
  - Work with different developers in the field (when applicable)
  - Memorandum of Understanding for each project
  - Minutes and follow-up of each meeting
  - Elected CAB chair
- **Important to have**
  - Scientific secretariat
- **Guidelines**
  - How to start, how to operate, Travel and accommodation, Compensation for time spent, Declaration of interests, Insider trading prevention, Code of Conduct for CAB members

Thank you