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Participation of Patient Advocates in Community Advisory Boards

What are Community Advisory Boards, and why do we bother?

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This presentation would not have been possible without these people

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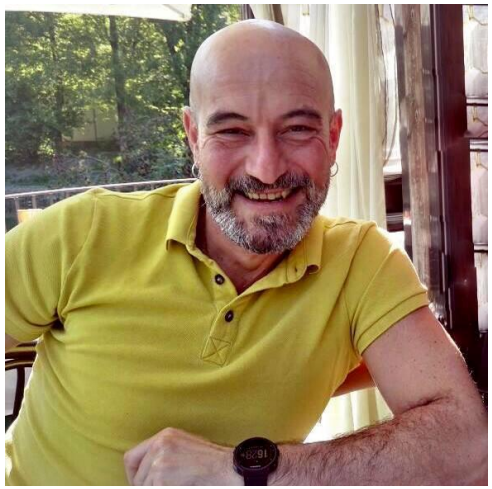
Jan Geißler



Giulio Maria Corbelli

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Why are we advocates?
We want impact for the good of patients

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- **Support patients** and their families affected by a challenging disease to make the right choices
- **Help clinicians** to give the best service possible to their patients, and prevent bad and outdated practice
- **Influence regulators and payors** to make sure they are basing their decisions on patient preferences and needs
- **Tell politicians to do policy *for* patients**, not just about patients

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Patient advocacy operates on three levels

Patient Support

- Inform, support, navigate

Health Policy

- Influence health policy, patient care

Research

- Contribute in partnership with clinicians, networks and industry

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It‘s not enough just to be on a mission and tell „patient knows best“: Know your stuff

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How do we waste our energy? The risk of advocacy failure.

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- **Barking up the wrong tree** – advocating at the wrong place (e.g. EU vs. national level)
- **Keeping chairs warm** – going to meetings that are "interesting" but don't make a difference
- **Being territorial** and wasting our energy with infighting and rivalry
- **Blaming others** that things are not happening instead of thinking about what I can do myself to change things
- **Disqualifying ourselves** by just being emotional, off-topic, and not well informed

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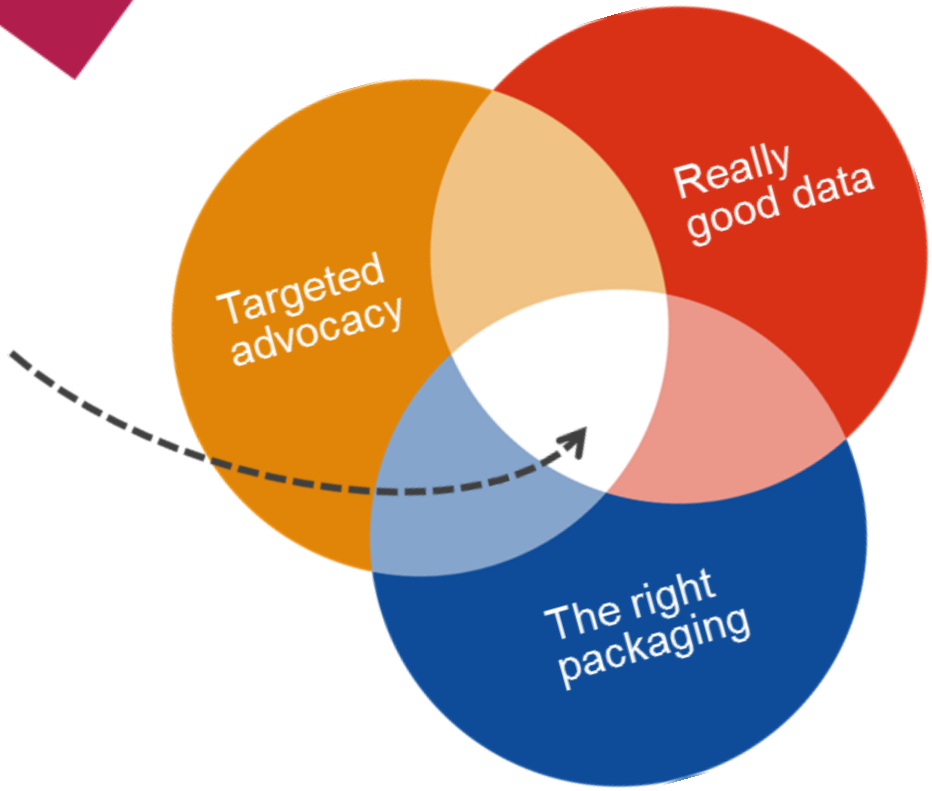
Evidence-based advocacy



Advocating in a targeted, evidence-based, well-educated and professional manner, and measure impact and outcomes of what we do

European AIDS Treatment Group

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Targeting your advocacy efforts

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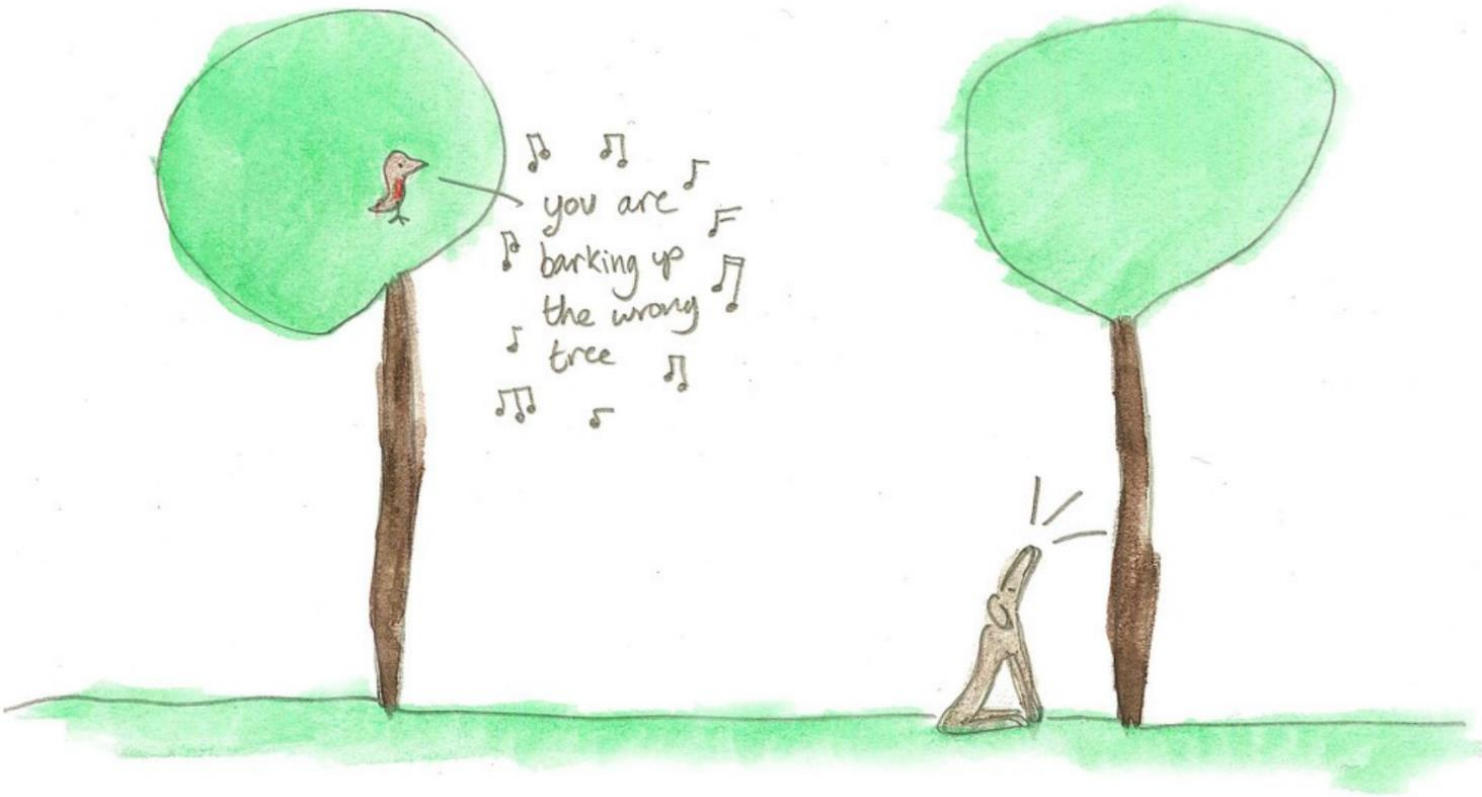

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Know your trees – and bark up the right one

Think about who you would like to influence:

- EU level vs. national level (e.g. EMA, HTA/reimbursement)
- Medical societies vs. study groups vs. individual clinicians
- Companies (→ drugs) vs. industry associations (→ systems)
- Disease-specific action (→ myeloma) vs. cross-disease joint action (→ healthcare system)
- Know what you can do, and what your umbrella organisations can do best, within the limits we all have

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Is “patient knows best” any better than “doctor knows best” ? Base it on data!

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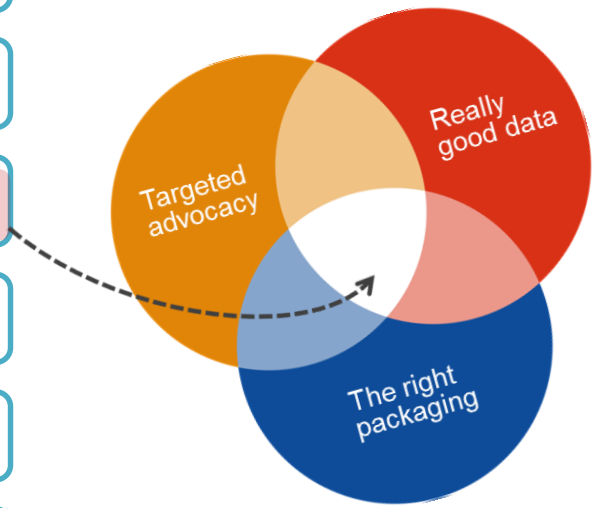
Negotiation tactics and building your case

1. Define the outcome and a possible a fall-back position (alternative outcome)
2. Consider the other party's position, possible resistance
3. Be clear with your reasoning, the benefits, the risks
4. Present evidence and proof to reassure
5. Make your delivery compelling
6. Explore barriers and resistance with empathy
7. Represent your case, ask for commitment



Source: Alison Dawkins, 360 Flexible Training Solutions @ ESO Masterclass (2018)

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Community Advisory Board: a definition

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In medicines development, a Community Advisory Board (CAB) is a group of patient representatives that serves as a link between a community and researchers.

Within clinical development a CAB may review clinical trial protocols and monitor clinical trials and help teach the community about them.

The CAB model has also been implemented in areas such as policy making and Health Technology Assessment (HTA).

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Types of Community Advisory Board

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'Community Advisory Board (CAB)' sometimes called 'Community Advisory Group (CAG)' can be long-term institutions or project-based, established for a single purpose such as:

- for research with a particular target group (e.g. adolescents)
- for specific studies (e.g. Tuberculosis vaccine studies)
- for disease-based research (e.g. HIV and co-infections European CAB)

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Definitions of "Community"

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A number of authors offer different definitions of community and who can speak for it.

The term community can mean[1]:

- a group of people who have a common set of interests, or a common set of characteristics (i.e. living with the same disease, or same age group, etc.)
- a group of people who live in a common area or location.

Another definition is[2]:

- A group of people with diverse characteristics who are linked by social ties, share common perspectives, and engage in joint action in geographical locations or settings.

[1] AVAC, Civil Society Engagement, http://www.avac.org/civil-society-engagement

[2] MacQueen M. et al, *What Is Community? An Evidence-Based Definition for Participatory Public Health*, Am J Public Health. 2001;91:1929–1938

Different CAB models

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CABs can be established according to different models:

- **Therapeutic area** specific: for example, HIV, Chronic myelogenous leukemia (CML), etc.
- **Research Institution** specific: for example, a network of researchers running different trials can set up an internal CAB to get advice on different research projects.
- **Single Trial** specific: this is usually needed when trial procedures are particularly risky or ethically challenging.
- **Industry** initiated: sometimes a pharmaceutical company may promote the establishment of a CAB to get advice on specific issues or on their whole medicines portfolio; in this case, specific procedures to ensure independence should be put in place.

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Defining “Community” for your CAB

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- It is important to make sure the CAB membership reflects the community itself.
- The selection of members to participate in CAB meetings should be based on the meetings objectives.
- It is also possible to invite non-members, such as minority groups, to best represent the community.

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What do CABs do in medicines R&D?

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CABs members are expected to provide advice on a range of topics involved in medicines R&D:

- **Ethics**: providing advice about the informed consent process and other ethical aspects of research protocols;
- **Research priorities**: discussing the unmet therapeutic need with researchers thus promoting a more focused and efficient scientific approach;
- **Study procedures**: enabling study participants to reduce the burden involved in clinical research (i.e. number of study visits, cumbersome procedures, etc.);
- **Information dissemination**: improving recruitment strategy, community knowledge about research, and efficient dissemination of the results.

The scope of some CABs work goes beyond medicine R&D and includes: access strategy, pricing issues, post-marketing surveillance, etc.

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General working model

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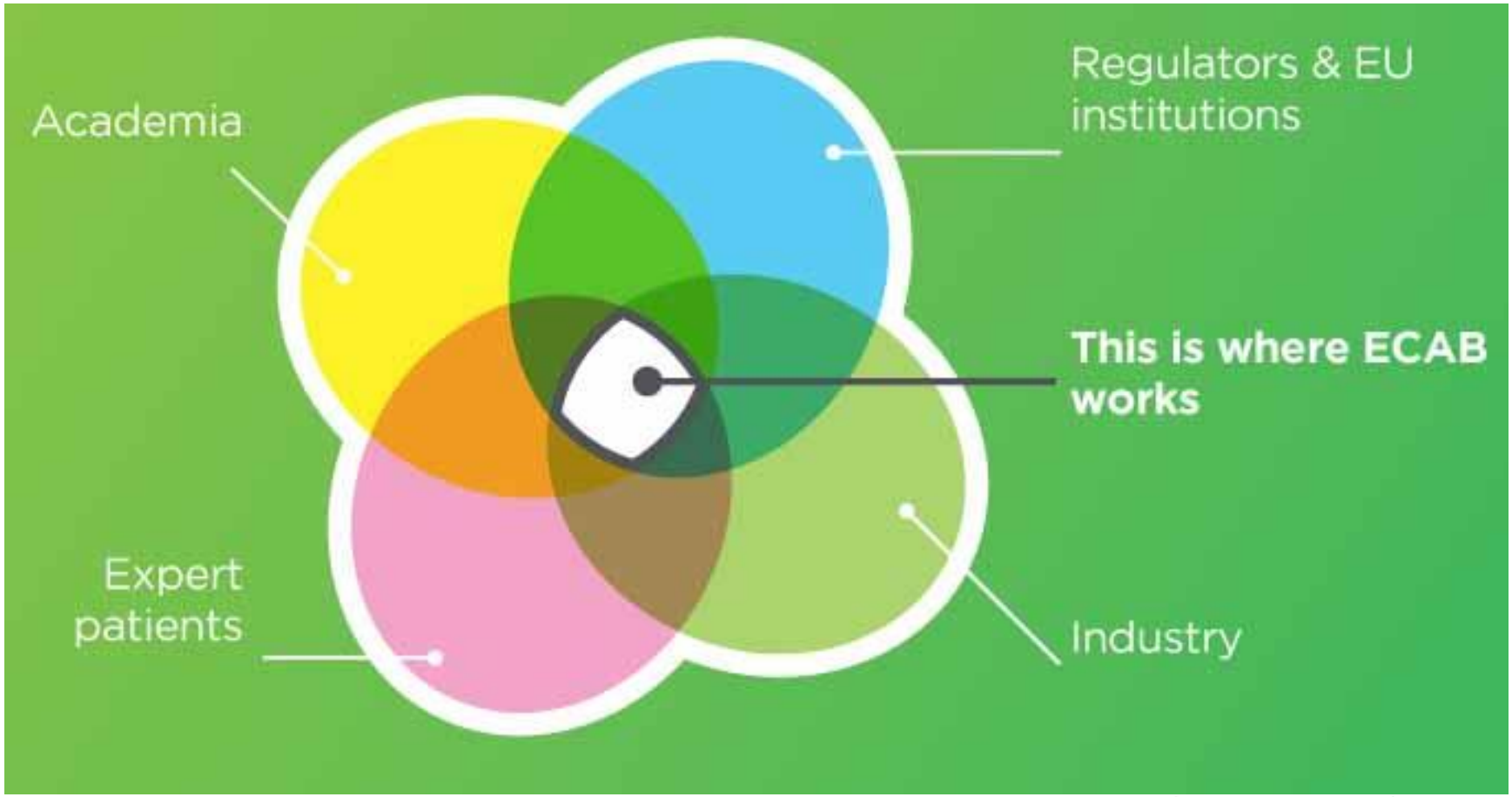

Arnold, M., Community Participation in Clinical Research, Hanover, 1997 and Derbyshire, J., *Patient groups - Do they have anything to say?*, in: European AIDS Treatment News, Spring 2011, 8-9

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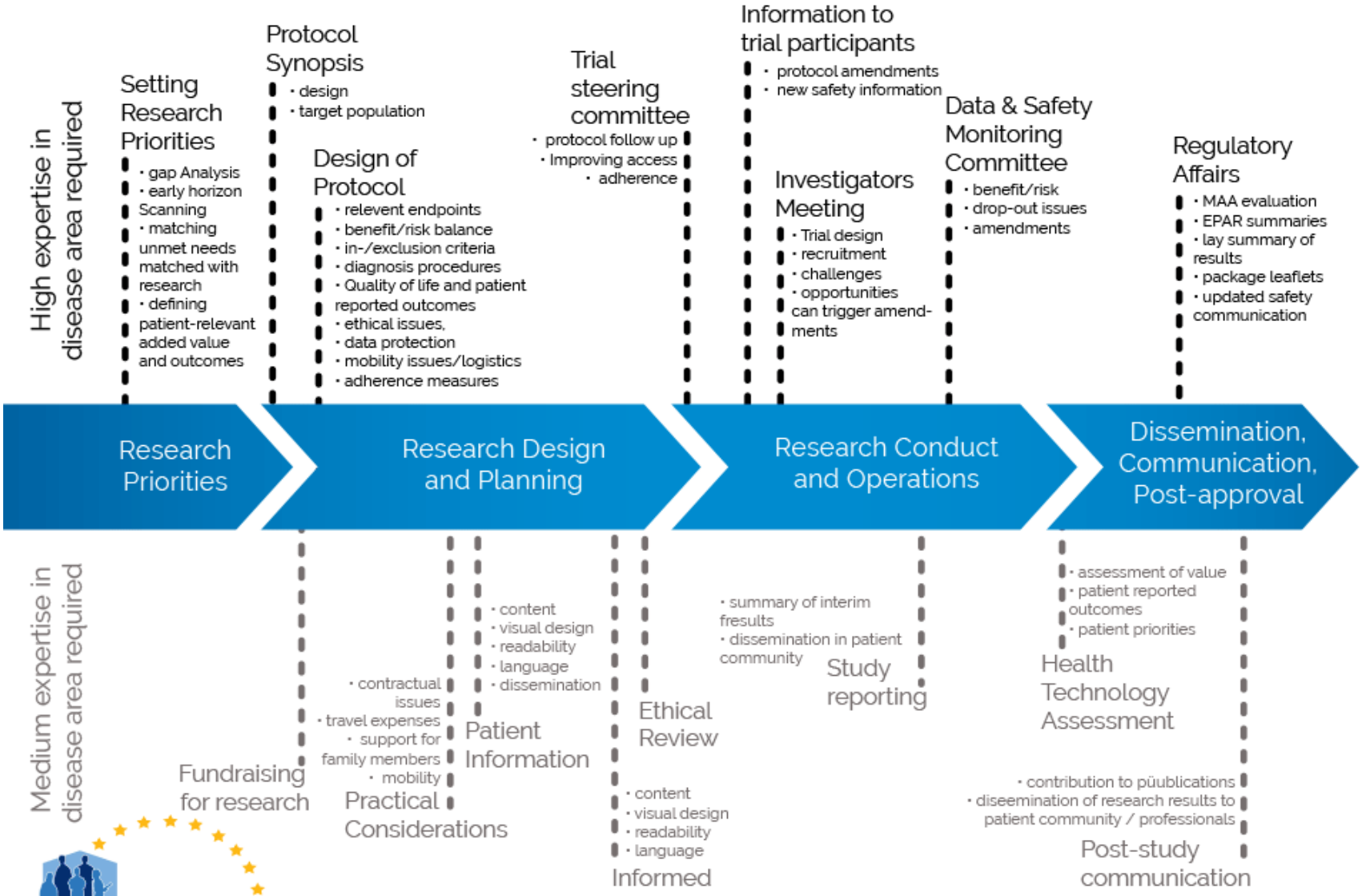
Patient involvement in medicines R&D



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www.eupati.eu

Geissler, Ryll, Leto, Uhlenhopp
EPALCO/EUPATI (2015, unpublished)

What do CABs do?

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CABs work can be beneficial at any step of patient involvement in medicine R&D.

CABs should be established and maintained in accordance with the EUPATI Guidance Documents:

- *Guidance for Patient Involvement in Industry-led Medicines R&D.*
- *Guidance for Patient Involvement in HTA.*
- *Guidance for Patient Involvement in Regulatory Processes.*
- *Guidance for Patient Involvement in Ethical Review of Clinical Trials.*

EUPATI, *Guidance for patient involvement in industry-led medicines R&D*, https://www.eupati.eu/patient-involvement/guidance-for-patient-involvement-in-industry-led-medicines-rd/

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Are CABs the only way?

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- CABs are the most common form of community engagement in community-based participatory research (CBPR)
- CBPR aims to understand communities' health priorities, to design research that addresses these priorities, and to involve communities throughout the research process (Israel et al., 1998).
- Other forms of community engagement may be:
  - hiring community members as project staff,
  - holding face to face public meetings in the community.
  - using digital media.

Kennedy C, Vogel A, Goldberg-Freeman C, Kass N, Farfel M. Faculty perspectives on community-based research: "I see this still as a journey." Journal of Empirical Research on Human Research Ethics. 2009;4(2):3–16. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3124219/

Challenges faced by CABs

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CABs' work can face different challenges:

1. Enabling an optimal representation of the community in the CAB
2. Managing internal conflicts whilst recognising different views
3. Establishing and maintaining independence
4. Ensuring funding and sustainability.

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An example of challenges faced by researchers

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In the course of their community-based research projects, CBPR researchers experienced four main types of challenges:

1. defining and representing the community,
2. sharing power in the community-academic partnership,
3. overcoming a history of institutional research in the local community that was not perceived to provide direct benefits to the community, and
4. balancing the competing demands of a career in academia, and working within incentive structures that may not always support community-engaged research.

Kennedy C, Vogel A, Goldberg-Freeman C, Kass N, Farfel M. Faculty perspectives on community-based research: "I see this still as a journey." Journal of Empirical Research on Human Research Ethics. 2009;4(2):3–16. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3124219/

ECAB work

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The work of ECAB is composed of several elements:

- regular meetings,
- substantial back-office work by the Scientific Officer and the thematic officers (e.g. hepatitis),
- interactive e-mail dialogue to keep the daily work of the organisation going.

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ECAB meetings

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- Most ECAB meetings are held over weekends; they are usually divided into five sessions, approximately 3.5 hours each, and companies and other presenters can reserve one or two sessions (which means either a half or a full day).
- Meetings with companies are conducted under strict confidentiality.
- Sunday morning meetings are reserved for the internal discussion of ECAB matters. Training sessions cover current or general scientific and policy related topics.
- As a full-time EATG staff member, the Scientific Officer supports the development and strengthening of EATG's activities in the key areas of science and research.

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ECAB meetings agenda

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- ECAB sets the agenda of the meetings. Taking the initiative is central to ECAB's work and success.
- Discussions during ECAB meetings vary from setting research priorities through clinical development to policy and access.
- Topics suggested by the companies are combined with the proposals and questions of the community, which are collected and collated by the company liaisons and the Scientific Officer.
- The designated ECAB company liaison will start working with the company representative(s) several weeks ahead of the meeting.
- Prior to meeting with the company, a pre-meeting between ECAB members and EATG staff takes place where new or inexperienced members are briefed.
- Questions are welcome (either prepared or spontaneous) during the meeting with the company.
- Minutes are taken during the meeting and shared with all participants for review and agreement.

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Organising a CAB

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Community Advisory Boards can be established in different settings and follow different procedures:

- CABs which are specific to a **research institution** or a **single trial** are usually organised by the researchers;
- **Industry initiated** CABs are often set up by the company itself, who can select members and organise the meetings; in this case ensuring CAB members independence is crucial;
- CABs working on a specific **therapeutic area** are usually set up by the organisation/s representing people living with that particular disease to discuss specific issues with pharmaceutical companies or researchers working on medicines R&D for that disease.

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Organising a CAB meeting

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Three phases can be identified in the process of organising a CAB meeting:

1. Before the meeting
    1. Clarifying purpose, functions, and rules
    2. Funding
    3. Defining the agenda
    4. Selecting participants
    5. Taking care of the logistics
2. During the meeting
    1. Chairing the session
3. After the meeting
    1. Follow up

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Examples for evidence-based advocacy

European AIDS Treatment Group

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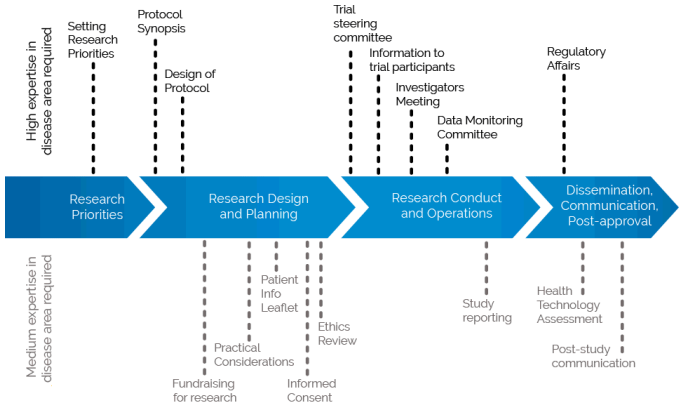
Burden of disease studies

- **Assessing the impact** of an illness on society, populations or countries, including the patient perspective regarding the burden on patients and carers – **Importance of Patient-Reported Outcome Measures (PROs)**.
- **Fine-grained** analysis of daily lived experience
- **Generate research questions** based on a different perspective from that of doctors and researchers
- **Early stages of involvement** is key for the success of patient inclusion



Anecdotal knowledge

Methodology

Evidence

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Observational, longitudinal studies / analyses

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- **Understanding the etiology and natural course/history of the illness.** Patients contribute their data in a systematic way
- **Greater and altruistic goals** that can ultimately lead to the definition of a research target and a treatment
- **Meaningful contribution of data is particularly important**
- **Pharmacovigilance studies post marketing** also count as non-interventional studies, and also rely on patient input
- **Early stages of involvement** are key for the success of patient inclusion

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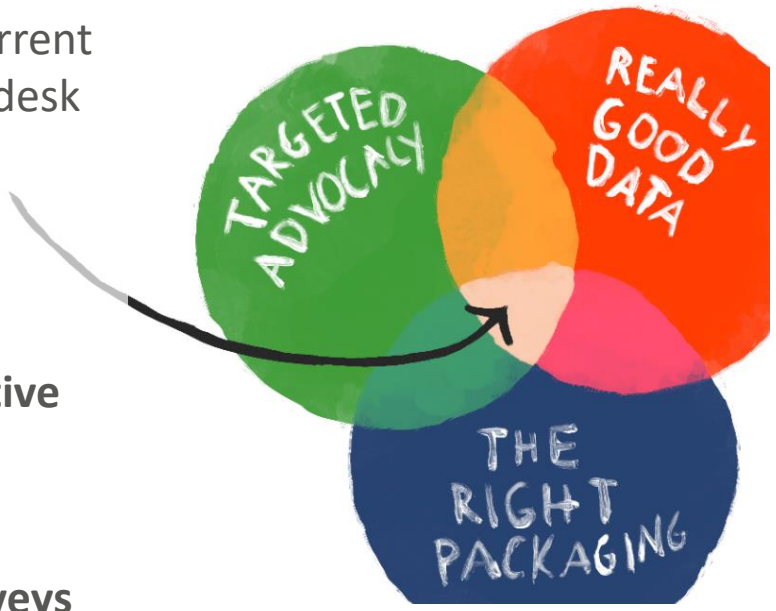
Meaningful data that patient groups can generate

- **Adherence** to therapies
- **Inequalities** in real-world access or current care patterns through interviews and desk research
- **Disease-related outcomes** through registries & biobanks
- Patient preferences through **quantitative surveys**
- Real-world PRO (e.g. QoL) through **investigator-initiated studies and surveys**



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CML Advocates Network Survey: Other than HCPs and industry expected, adherence to CML therapy is poor

Patient-led adherence research in CML:

- 12 languages, 2.546 patients from 63 countries recruited in 3 months
- Use of validated adherence instrument

Online

2151

Paper

395

Low adherence: 21%

Medium adherence: 46%

High adherence: 33%

www.cmladvocates.net/adherence

Factors influencing adherence in CML and ways to improvement: Results of a patient-driven survey of 2546 patients in 79 countries. Geissler et al, Journal of Cancer Research and Clinical Oncology (2017), DOI: 10.1007/s00432-017-2372-z

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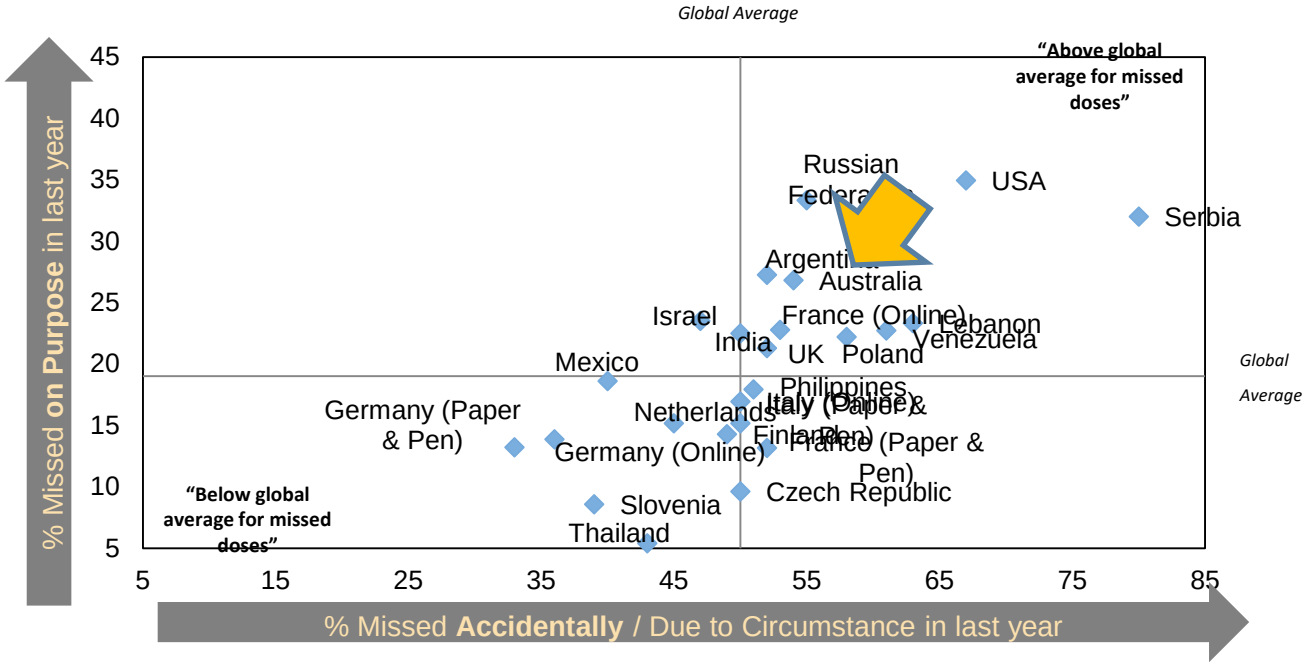
CML Adherence Survey: Rock-solid, multinational data to convince the “KOLs”



C2a / base=all respondents (n=2546) - Patients sometimes are not able to take their medication as prescribed. In the last month, have you missed a dose accidentally or due to circumstances that were outside of your control? C2c / base=all respondents (n=2546) – In the last year, have you missed a dose accidentally or due to circumstances that were outside of your control? C4a / base=all respondents (n=2546) - Patients sometimes make a conscious decision to miss a dose of medication. In the last month, have you decided to miss a dose? C4b / n=2258 - In the last year, have you decided to miss a dose?

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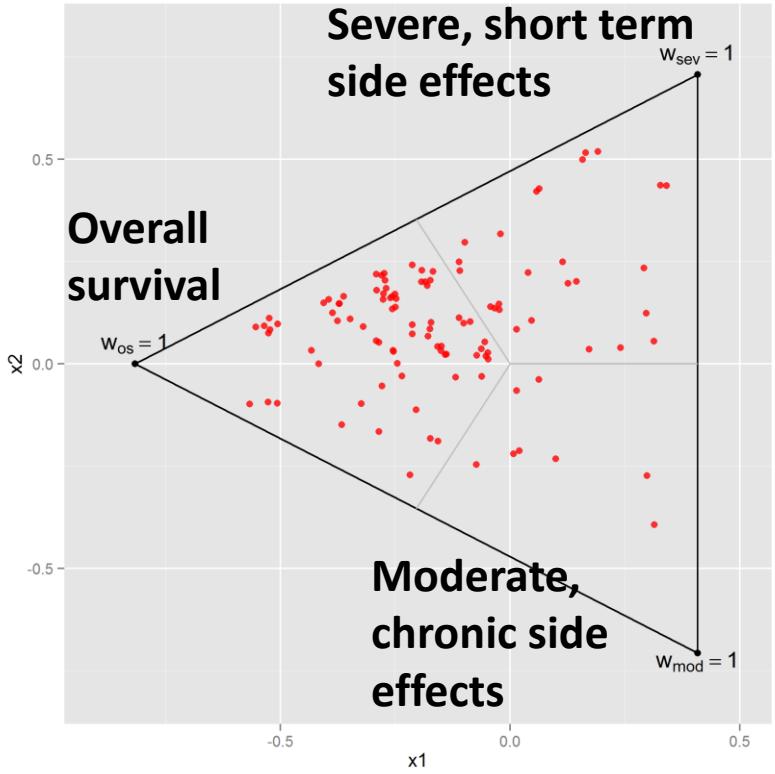
Patient values in benefit-risk assessment: EMA pilot

EMA in collaboration with MPE and MPNE co-created and tested a methodology to assess:

- How do individual patients value benefits and risks?
- Are there groups of patients with similar values in the population?
- Which type of evidence is useful for regulators?

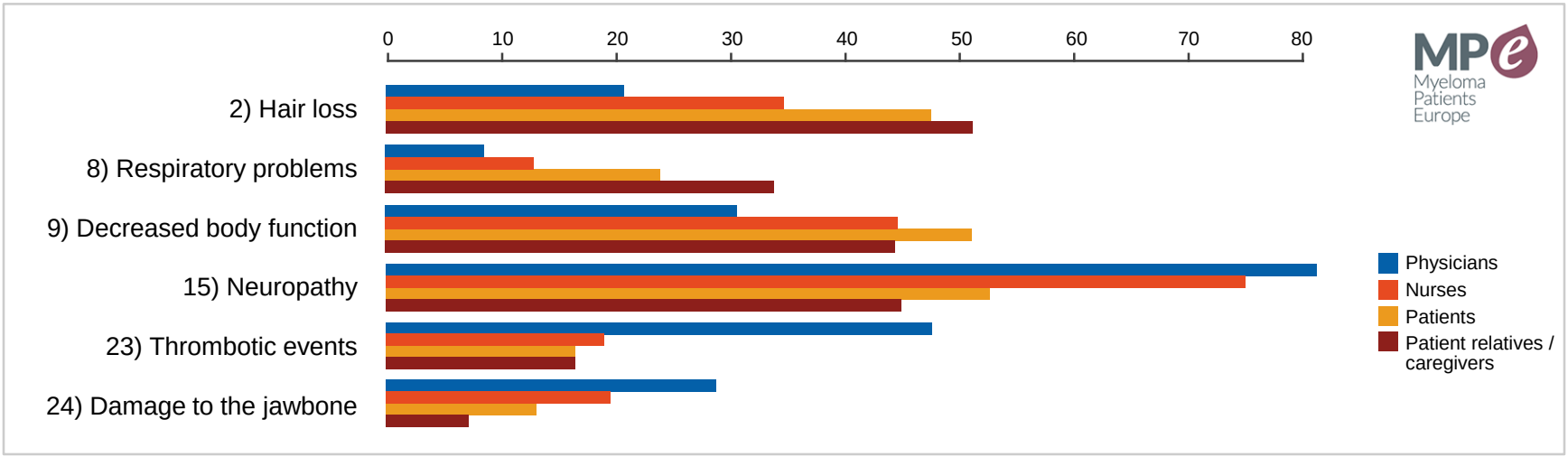


Postmus et al. *CPT*, 2015

Geißler, 2018

Don’t believe what your “KOLs” tell you – they may not see what patients really want

Treatment side-effects with the most negative impact on overall well-being (%)



Detecting Myeloma, ways to shortening an often painful and tedious patient odyssey: Results from an international survey. Myeloma Euronet (2009).
314 physicians & nurses, 260 patients & carers, 43 countries

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Evidence based advocacy in policy: Revision of EU Clinical Trials Directive

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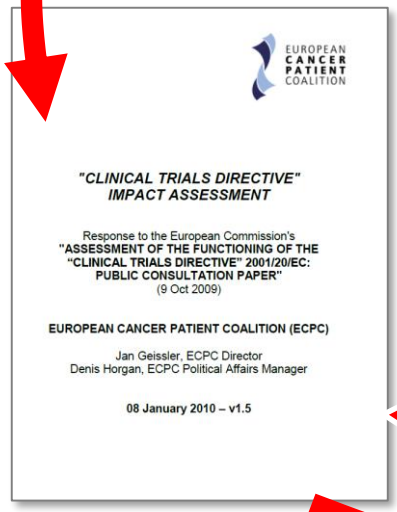
”[…] The **German Hodgkin Study group** was required to provide 100.000 copied pages of documents to Ethics reviews and authorities for a single study with 280 participating clinics and 65 ethics committees. Furthermore, the **GMALL study group** had to provide 35 folders and 12.000 pages for a study conducted in 13 centres. […]”


EUROPEAN CANCER PATIENT COALITION

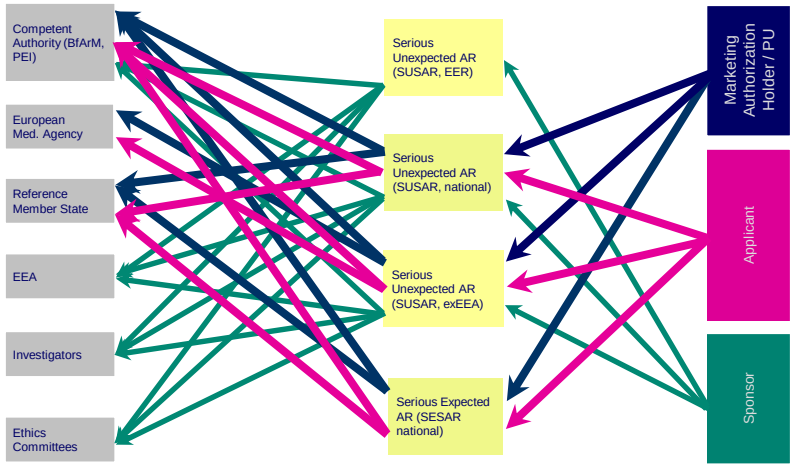
"CLINICAL TRIALS DIRECTIVE" IMPACT ASSESSMENT

Response to the European Commission's "ASSESSMENT OF THE FUNCTIONING OF THE "CLINICAL TRIALS DIRECTIVE" 2001/20/EC: PUBLIC CONSULTATION PAPER" (9 Oct 2009)

EUROPEAN CANCER PATIENT COALITION (ECPC)

Jan Geissler, ECPC Director
Denis Horgan, ECPC Political Affairs Manager

08 January 2010 – v1.5



Obligatory reporting of unexpected adverse events, based on German implementation of EU Clinical Trials Directive 2001/20/EC in medicines law (§63b AMG) and GCP act (§13 GCP)

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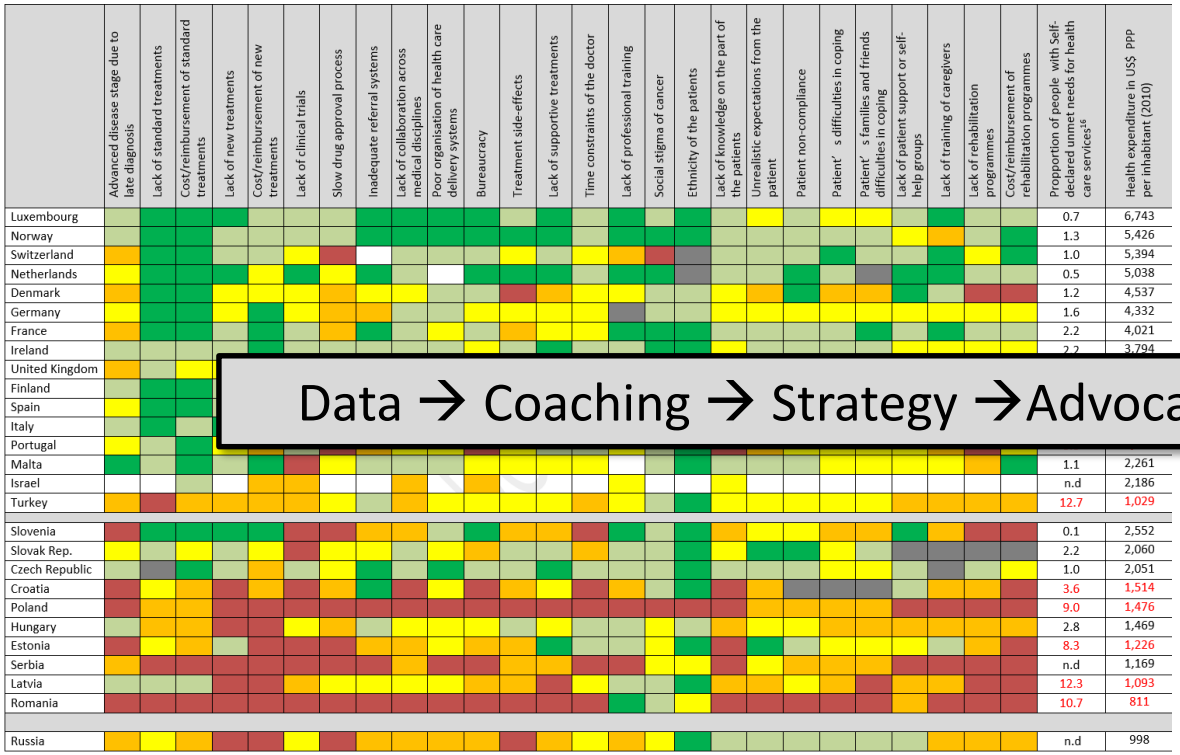
Evidence-based advocacy on access to therapies and

Myeloma Patients Europe



	Advanced disease stage due to late diagnosis	Lack of standard treatments	Cost/reimbursement of standard treatments	Lack of new treatments	Cost/reimbursement of new treatments	Lack of clinical trials	Slow drug approval process	Inadequate referral systems	Lack of collaboration across medical disciplines	Poor organisation of health care delivery systems	Bureaucracy	Treatment side-effects	Lack of supportive treatments	Time constraints of the doctor	Lack of professional training	Social stigma of cancer	Ethnicity of the patients	Lack of knowledge on the part of the patients	Unrealistic expectations from the patient	Patient non-compliance	Patient's difficulties in coping	Patient's families and friends difficulties in coping	Lack of patient support or self-help groups	Lack of training of caregivers	Lack of rehabilitation programmes	Cost/reimbursement of rehabilitation programmes	Proportion of people with Self-declared unmet needs for health care services[16]	Health expenditure in US$ PPP per inhabitant (2010)
Luxembourg																											0.7	6,743
Norway																											1.3	5,426
Switzerland																											1.0	5,394
Netherlands																											0.5	5,038
Denmark																											1.2	4,537
Germany																											1.6	4,332
France																											2.2	4,021
Ireland																											2.2	3,794
United Kingdom																												
Finland																												
Spain																												
Italy																												
Portugal																												
Malta																											1.1	2,261
Israel																											n.d	2,186
Turkey																											12.7	1,029
Slovenia																											0.1	2,552
Slovak Rep.																											2.2	2,060
Czech Republic																											1.0	2,051
Croatia																											3.6	1,514
Poland																											9.0	1,476
Hungary																											2.8	1,469
Estonia																											8.3	1,226
Serbia																											n.d	1,169
Latvia																											12.3	1,093
Romania																											10.7	811
Russia																											n.d	998

Data → Coaching → Strategy →Advocacy

Perceived barriers to access across countries in relation to self declared needs & health expenditure
Source: Myeloma Patients Europe "European Atlas of Access to Myeloma Treatment" (2016)

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Some learnings from my projects in evidence-based advocacy

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- **Quantitative data** (multiple choice, %) is much easier to analyze even for large number of patients and in multiple languages. Use this as much as possible.
- **Qualitative data** (comments, quotes, statements) is very powerful and reliable, but rather for small groups with limited numbers of patients – and may be hard to summarize.
- **Do a trial run** – pre-test your questionnaires with the target group
- **Get support by biostatisticians or market research experts** when developing your questionnaire. They can anticipate whether your questions will be valid and generate meaningful results.
- When self-made analysis is not enough, working with academic institutions might be optimal. However sometimes it is better to raise funds and **pay a professional to do the analytics/writing**!

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