	Totalresponde	CAB Members	Industry represents
To ensure products better meet patients' unmet medical needs	1	1	1
To make clinical trials more patient- oriented and reduce the burden of trial participation	2	4	3
To broaden access to products (in clinical trials and after market approval) and diminish access inequalities	3	2	5
To improve efficiency and speed of health product R&D	4	3	6
To enhance transparency and trust between the patient community and the pharmaceutical industry	5	5	2
To make patients more respected partners throughout the health product life cycle	6	6	4
To empower CAB members and the patient community through knowledge-sharing	7	7	7

Institutional context



Community contetx



## Impacts

Medicines development

Research relevance

Study ethics and inclusiveness

Study quality and efficiency

Quality of evidence and uptake of products

## **Stakeholders**

**Empowerment** 

Reputation and trust

Embedding of patient engagement

Patient
Engagement
Monitoring
and Evaluation
Framework



Expectations

Resources

Preparations

Representativeness of stakeholders



Learnings and changes

Learnings Changes



**Activities/process** 

Structure

Management
Interactions
Satisfaction

Policy context

Decision making context

Activities/process

CM consult network and investigate possibilities for trial sites in new areas/countries

**Assumption:** CM are diverse and well able to represent the patient community and its needs (I3). CM have large and diverse network within patient community.

During CAB meetings, CM recommend to IR to change inclusion and exclusion criteria and expand the number of clinical trial sites with specific sites and investigators from their network (A2, A3).

**Assumption:** CM and IR are satisfied with the setting, moderation and organization of the meeting. All CM were able to contribute to the discussion and felt heard. IR and CM felt an open and transparent atmosphere (A4). CM and IR build trust (A1).

CM share meeting minutes, requests and recommendations with IR, who disseminate outputs and insights within company (L5).

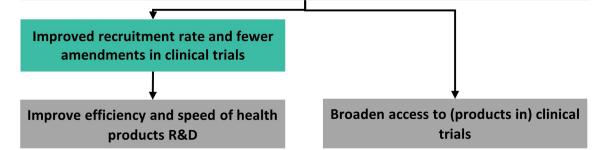
**Assumption:** IR and colleagues value different kinds of knowledge (both scientific and non-scientific) and appreciate CM expertise. Collaboration results in changes in attitude and beliefs about the value of the CAB.

Company increases number and locations of study sites and broadens inclusion and exclusion criteria for clinical trials (L5).

**Assumption:** Company has sufficient capacity and resources to implement recommendations. Company management and culture support patient engagement. CM recommendations are accepted by regulators and HTA bodies. Clinical trials sites are willing and able to engage.

Broader diversity of participants in clinical trials (e.g. age, nationality/geography, disease state)

**Assumption:** Patients are more likely to participate when trials are available/accessible.



## **Examples of context factors**

- Experience with patient engagement differs per CM and company.
- There is a large unmet need in rare diseases, putting pressure on health product R&D.
- In diseases that are less studied, research practices and networks are less established, raising the opportunity for the CAB to influence decision-making.

