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Patient Involvement in Clinical Research

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EUROPA DONNA The European Breast Cancer Coalition

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Tanja Spanic

Last DOI update: February 19, 2021

Financial Interests

Pfizer, Advisory Board, Personal, Member of Patient advisory board
Roche, Advisory Board, Personal, Member of Patient advisory board

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Principles of Successful Patient Involvement in Cancer Research

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Principles of Successful Patient Involvement in Cancer Research

I. **A shared vision**

II. **Strategy, level and timing of involvement**

III. **Communication, understanding and relationships**

IV. **Resources, knowledge and skills**

V. **Methods and approaches**

VI. **Ethical and legal aspects**

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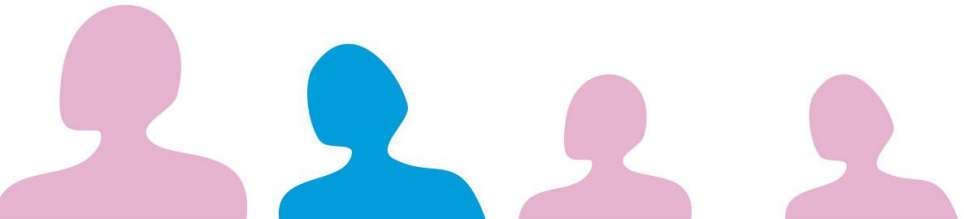
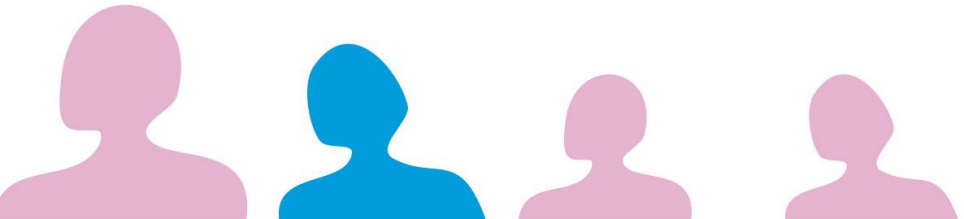


Principles of Successful Patient Involvement in Cancer Research

I. A shared vision

- **Involving patients, caregivers or patient advocates → cancer research more meaningful, relevant and valuable**
- **Focusing it on the actual needs and demands of the target group**
- **Involving patients and other stakeholders → inequality in European countries**



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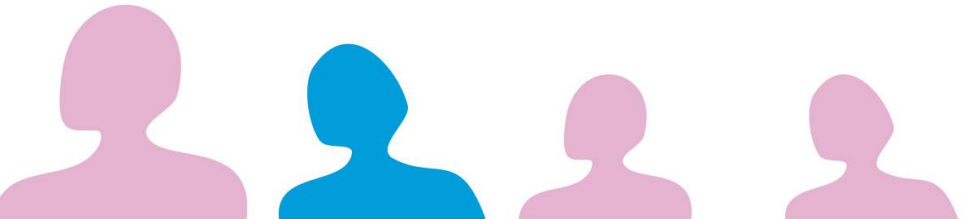

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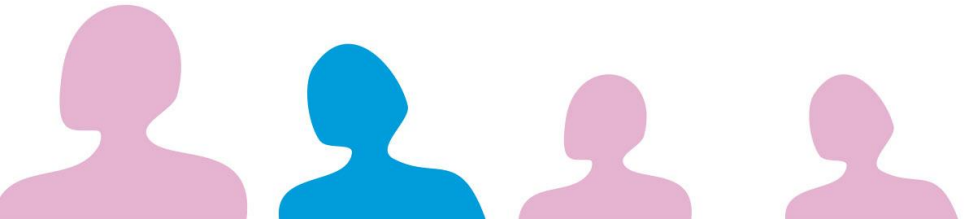
II. Strategy, level and timing of involvement

- **Patient involvement very early in the process**
- **Decision-making power on the side of the patients**
- **Match the right persons or entities to the right project**
- **The appropriate timing must be decided**
- **Involved across the whole research cycle**
- **Permanent patient panels or advisory boards**
- **Accessibility to and participation in international or multi- centric clinical studies should be offered to all countries in an equal manner**



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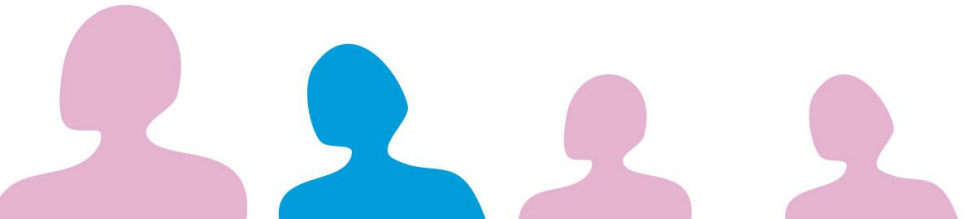

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III. Communication, understanding and relationships

- **accepting and respecting all stakeholder contributions**
- **building relationships based on mutual trust and empowerment of all those involved**
- **to understand and prioritize the motives, incentives and mutual expectations of all parties**
- **Thoughtfulness, openness, transparency, a team spirit and real teamwork**
- **Clear lines of communication and full transparency concerning goals, prerequisites, governance structures, codes of conduct, rules, decision-making processes and pathways of information**

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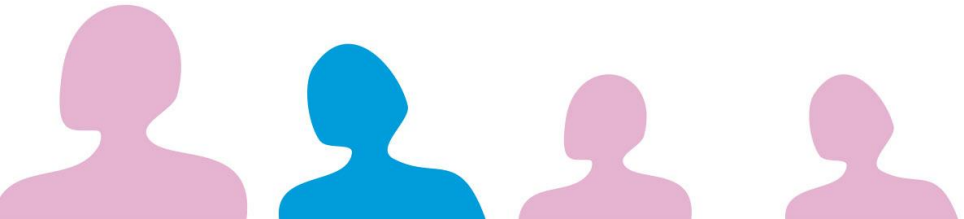
IV. Resources, knowledge and skills

- **the mind sets and dedication**
- **sufficient time, funding and flexibility**
- **all parties must have sufficient knowledge and skills**
- **Informed patient experts: experiential knowledge of living with their conditions and at least partial technical knowledge**
- **education programmes providing medical expertise, methodological expertise ,systems expertise; communication or negotiation skills**



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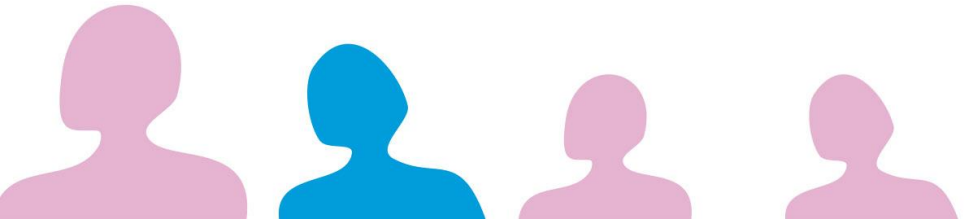

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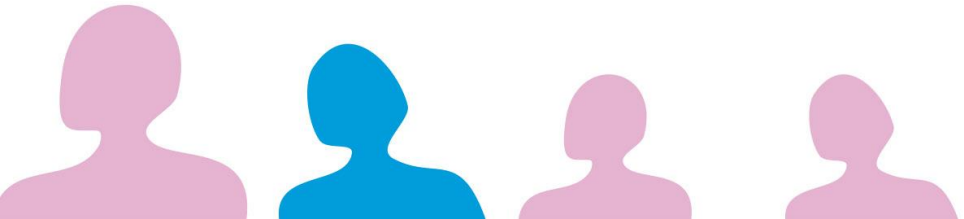
V. Methods and approaches

- **use existing, validated resources and reference points wherever possible**
- **Funding organizations → a vital role in addressing the deficits described.**
- **where to find potential individuals or organizations to involve?**
- **sufficient level of accessibility**
- **noticeable differences in implementation →reduce inequalities between European countries**



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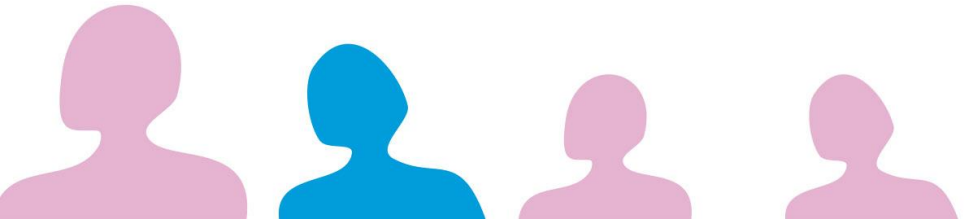
VI. Ethical and legal aspects

- **clearly specify, communicate and discuss underlying rules and legal issues**
- **rights and obligations need to be specific, reasonable, proportionate and comprehensible**
- **generating rules, schemes and template texts for patient sample use, data sharing/ data protection or obtaining informed consent for projects**
- **expose and discuss any ethical questions or dilemmas**
- **participating in discussions about ethical and legal aspects of projects and their research foci requires training for all project partners**



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Link:

https://www.gesundheitsforschung-bmbf.de/files/2021_06_01_Principles_Paper_bf.pdf