The Patient at the Centre of Clinical Research

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@eupatientsforum

“A STRONG PATIENTS’ VOICE TO DRIVE BETTER HEALTH IN EUROPE”

EPF European Patients Forum

Making research more patient-driven

From research *on/for* patients to research *with* patients

- Too many trials are on research questions – or measure outcomes – that are not the priority for patients
- Patients' preferences and priorities may be different from those of medical professionals, regulators, or industry
- Unmet needs are the driving force for patient groups to become active in medical research
  - Innovation that matters to patients → quality of life, the spectrum of patient-centred integrated care
  - Not only new therapies, but better therapies, better systems, social change…

Window of opportunity:

New kinds of partnerships between researchers, regulators, industry **and patients**

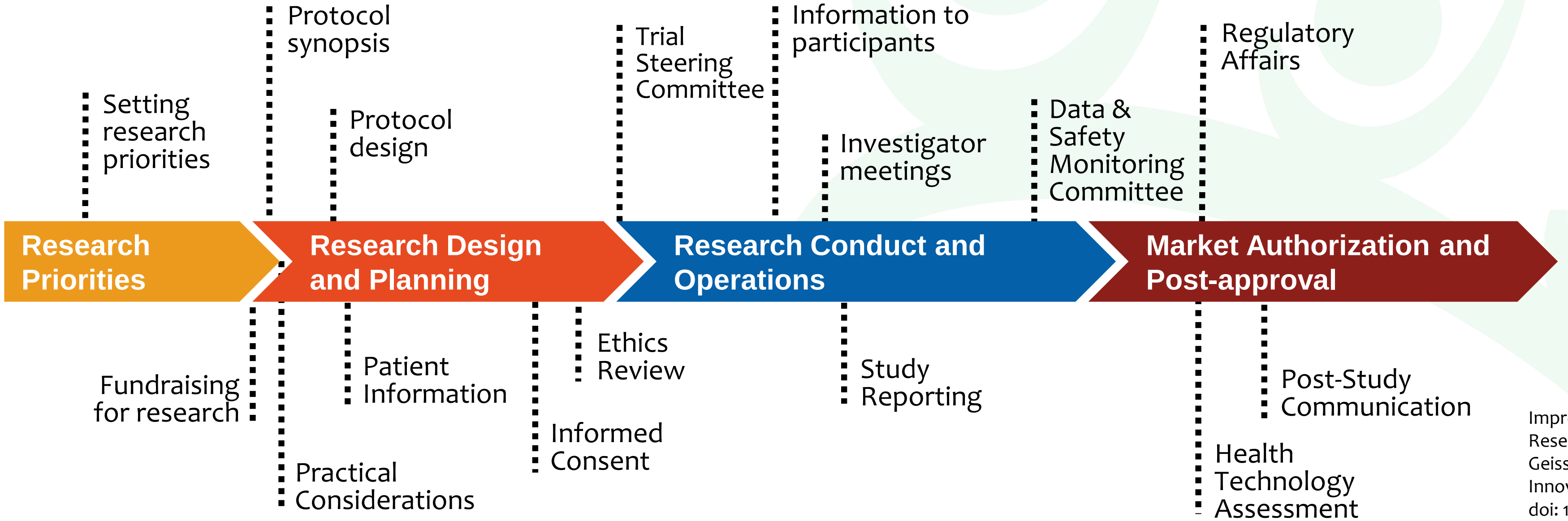
Why does patient involvement matter?

- Advances in medicine are only possible with the voluntary participation of patients
- Patients provide the data and take the risks, benefit from the results
- Legitimacy, transparency and accountability
- Involvement also leads to better, more relevant research results
  - Better alignment of innovation with real unmet needs
  - Improved design of trials, e.g. endpoints that are relevant to patients
  - Improved information material
  - Better recruitment, fewer drop-outs
  - Researchers’ assumptions are challenged: new insights, more context
  - Wider dissemination of findings
  - Potentially better regulatory outcomes

Patient involvement in research

To promote good practice requires engagement with all actors…

Impact of patient involvement is greater the earlier patients are involved – from priority setting stage to co-design & co-production of clinical research



Research Priorities

- Setting research priorities
- Fundraising for research

Research Design and Planning

- Protocol synopsis
- Protocol design
- Practical Considerations
- Patient Information
- Informed Consent
- Ethics Review

Research Conduct and Operations

- Trial Steering Committee
- Information to participants
- Investigator meetings
- Data & Safety Monitoring Committee
- Study Reporting

Market Authorization and Post-approval

- Regulatory Affairs
- Health Technology Assessment
- Post-Study Communication

Improving Patient Involvement in Medicines Research and Development: A Practical Roadmap. Geissler, Ryll, Leto, Uhlenhopp, Therapeutic Innovation & Regulatory Science (2017), doi: 10.1177/2168479017706405, and at www.eupati.eu

…But there is a need for a strong signal and guidance from regulators building on existing initiatives

Improving clinical trial diversity

- Clinical trials should better reflect the population that will ultimately use the medicine – a matter of **health equity**!
- Certain groups continue to be underrepresented which can undermine the quality of studies and hinder the full understanding of the benefit-risk profile
- Questions for reflection
  - Analyse countries' approaches and potential barriers at national level?
  - How to leverage new technologies and approaches to facilitate inclusivity? (digital technologies and social media, decentralised trials etc.)
  - Reviewing and broadening eligibility criteria?
  - Inclusive strategies for public outreach and information
  - The role of guidance, but also capacity-building and training of sponsors etc.

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