Patient involvement in medicines R&D

High expertise in disease area required

Setting Research Priorities
- gap analysis
- early horizon scanning
- matching unmet needs with research
- defining patient-relevant added value and outcomes

Protocol Synopsis
- design
- target population

Protocol Design
- relevant endpoints
- benefit/risk balance
- in-/exclusion criteria
- diagnosis procedures
- quality of life and patient reported outcomes
- ethical issues
- data protection
- mobility issues/logistics
- adherence measures

Trial steering committee
- protocol follow up
- improving access
- adherence

Information to trial participants
- protocol amendments
- new safety information

Investigators Meeting
- trial design
- recruitment
- challenges
- opportunities can trigger amendments

Data & Safety Monitoring Committee
- benefit/risk
- drop-out issues
- amendments

Regulatory Affairs
- MAA evaluation
- EPAR summaries
- lay summary of results
- package leaflets
- updated safety communication

Research Priorities | **Research Design and Planning** | **Research Conduct and Operations** | **Dissemination, Communication, Post-approval**

Medium expertise in disease area required

Fundraising for research

Practical Considerations
- contractual issues
- travel expenses
- support for family members
- mobility

Patient Information
- content
- visual design
- readability
- language
- dissemination

Ethical Review

Informed Consent
- content
- visual design
- readability
- language

Study reporting
- summary of interim results
- dissemination in patient community

Post-study communication
- contribution to publications
- dissemination of research results to patient community / professionals

Health Technology Assessment
- assessment of value
- patient-relevant outcomes
- patient priorities

EUPATI
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