Patient advocates involved in clinical development

Patient advocates can be involved in early clinical development through partnerships and working relationships with regulatory authorities, ethics committees, investigators, and industry.

Patient advocates can provide input into:

- Study design:
  - Studies should take into account the needs of the patients. This means the research priorities and research outcomes being measured should be important to and provide value for the users of the medicine.
- Study literature and informed consent:
  - Study literature and informed consent forms (and the informed consent process) should be clearly understandable to all study participants.
- Study logistics (such as travel, time spent):
  - The study should be planned so that it is convenient for study participants and takes their needs into account, especially those resulting from their indication/disease.
- Recruitment and retention:
  - Raising awareness of studies within the community of interested patients. Patient organisations should also be informed about relevant studies and be able to provide information to patients.
- Dissemination:
  - The results of research should be widely available.

Patient advocates can have roles as:

- Driving force:

        - Lobbying for the development of clinical trials for the condition(s) they/their organisations represent.
        - (Co-)financing a clinical trial.
        - Developing the clinical research protocol.
        - Getting a research team together for a clinical trial.
    - Co-research:
        - Leading a focus group or discussion session for research.
        - (Co-)writing a scientific article on the research results of the clinical trial.
    - Reviewer:
        - Review patient information that is to be used in a clinical trial.
    - Advisor:
        - Giving advice to, or being an advisory member of, a national or European regulatory authority committee, an ethics committee, or a clinical research programme committee.
    - Information provider:
        - Supplying disease, demographic, and/or other characteristic information on the members represented.
        - Supplying information to patients on the possibilities of taking part in a clinical trial.
    - Research participant:
        - As a participant in a clinical trial testing the effects of a new treatment or medicine.