SCHOOL OF PHARMACEUTICAL SCIENCES CSJM UNIVERSITY KANPUR

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Protocol

- A protocol is a document that states the reasoning behind and structure of a research project.
- Protocol also defined as a document that describes the background , rationale , objective , design, methodology, statistical consideration and organization of trial.
- The study protocol can be viewed as a written agreement between the investigator, the participants and the scientific community.

Background

- A clinical research protocol document must reflect both sound scientific rationale as well as local, national and, when applicable, international regulatory and human subject protections requirements.
- These requirements originate from a variety of sources, undergo frequent revision and are subject to interpretation.
- Tools to assist clinical investigators in the production of clinical protocols could facilitate navigating these requirements and ultimately increase the efficiency of clinical research.

Protocol Development

- Every clinical investigation begins with the development of a clinical protocol. The protocol is a document that describes how a clinical trial will be conducted (the objective(s), design, methodology, statistical considerations and organization of a clinical trial,) and ensures the safety of the trial subjects and integrity of the data collected.
- A research protocol is a document that describes the background, rationale, objectives, design, methodology, statistical considerations, and organization of a clinical research project. According to the ICH Good Clinical Practice guidelines, a protocol should include the following topics:
- Title Page (General Information)
- Background Information
- Objective/Purpose
- Study Design
- Selection and Exclusion of subject

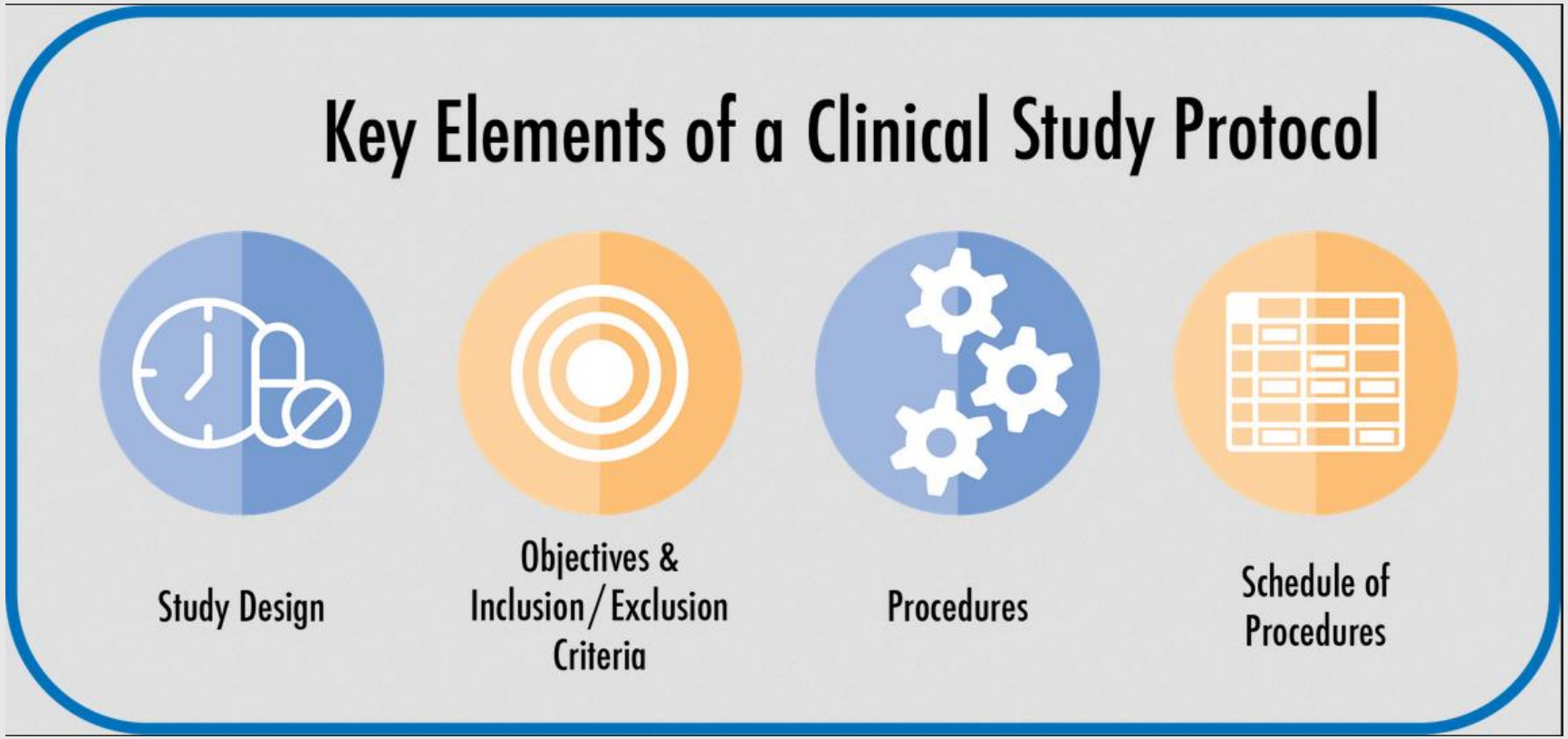
Continued

- Treatment of Subjects
- Assessment of Efficacy
- Assessment of Safety
- Adverse Events
- Discontinuation of the Study
- Statistics
- Quality Control and Assurance
- Ethics
- Data handling and Record keeping

Continued

- Publication Policy
- Project Timetable/Flowchart
- References
- Supplements/Appendices
  - The NIH provides many resources for protocol development to assist investigators in writing and developing clinical research protocols that are in compliance with regulatory/GCP requirements. Some NIH institutes have a mandatory requirement for using their protocol template.

Clinical Trial Protocol



Characteristics of clinical trials

Usually medical or clinical studies

Human subjects volunteer to participate

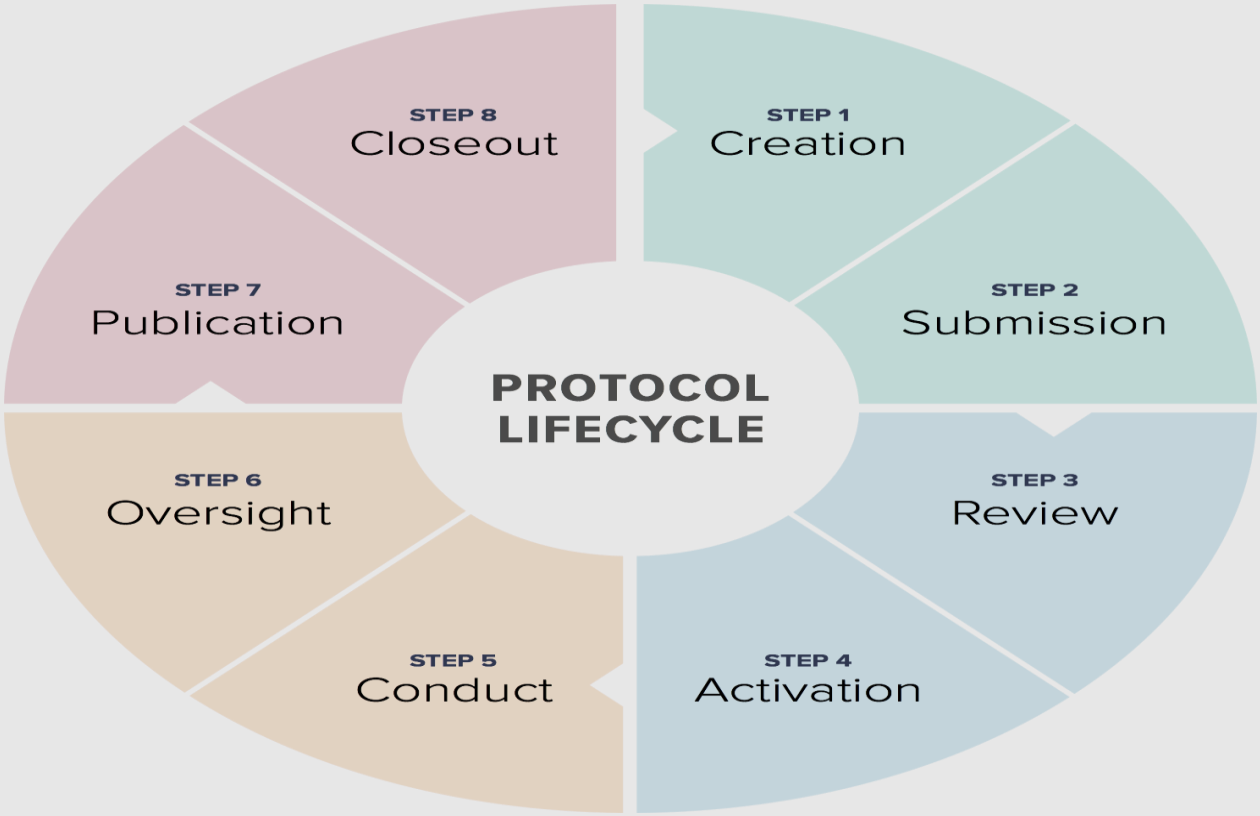
Constitute the last step of the research process*

Last for about 5-7 years

Investigations are carefully conducted following a pre-determined research protocol

Approval of relevant governing and ethical committees is essential

Steps in Protocol




Thank You!