Investigator Initiated Trials

Module 8 Topic 2

Investigator Initiated Trials Also Termed As

- Investigator Initiated Studies (IISs)
- Investigator Sponsored Trials (ISTs)
- Investigator Initiated Research (IIR)
- Non Sponsored Trials
- Non Registration Trials (NRTs)

Definition

- **Investigator initiated studies** (IIS) are clinical studies initiated and managed by a non-pharmaceutical company researcher (e.g. individual investigator, institution, collaborative study group, cooperative group) who, as the sponsor, is responsible for the conduct and management of the study as defined by all applicable laws and regulations

Definition (contd)

- Studies with scientific and medical merit developed and sponsored by an independent investigator or academic sponsor. An IIT may be a clinical or non-clinical study conducted without the participation of sponsor, for which the IIT applicant requests sponsor to provide either funding, drug product or both.

Are such trials truly initiated by investigators?

Are these trials initiated by industry?

Is there a need for such trials to complement industry initiated trials?

What is driving the need for IITs?

- Clinical trials are not, and cannot be, designed to determine all the potential uses for a medication
- IITs expand product knowledge, including safety
- Physician researchers often identify new ways of using existing treatments, thus improving the health of numerous other patients
- And there is always greater weight attached to non-industry sources of data

Important Caveats About IITs

The trial request must be initiated by the investigator and not by the company

- It has to be a spontaneous, unsolicited request
- The same needs to be directed to the medical department. The request, in the form of a concept note, is evaluated based on objective criteria such as
  - Credentials of the investigator (Curriculum Vitae showing s/he has designed and conducted original research; not black-listed)
  - Need for such a study (meets unmet medical need or fills a gap in medical literature)
  - Quality of design of the study,
  - Cost-effectiveness (needs to be reasonable enough to fit into the budget)

- Clinical investigators may wish to perform clinical trials with or without company drugs within or outside the approved product license or prior to marketing authorization

- Companies may consider requests to support such trials pre- and post-first marketing authorization

- The company may be willing to support these studies without taking the role of sponsor as defined by the International Conference on Harmonization (ICH)-Good Clinical Practice (GCP)

- Investigator must handle the responsibilities of both the sponsor and the investigator

- The investigator must conduct the trial in accordance with the protocol, meet all informed consent and IRB requirements and comply with record keeping and adverse experience reporting

EC Submission Requirements

EC Approval is a must for IITs

Following are the submission requirements:

- Proposed title of the study
- Name & contact information of the Principal Investigator and institution
- Brief scientific background & study rationale
- Study objectives
- Study design
- Curriculum vitae

Submission Requirements

Following will be required for the full proposal:

- Study procedures and timelines
- Study flowchart
- Statistical methods
- Data management plan
- Drug supply request
- Preliminary budget
- Associated/relevant and supportive literature citations
- Publication plan

Responsibility Of The Investigator In IITs

- Writing the protocol & developing case report forms
- Monitoring the study & reviewing the source documents
- Drug accountability
- Submitting safety reports to EC
- Complying with all applicable EC requirements.
- IND submission

Funds To IITs By

- Industry
- Government & Foundations
- Philanthropy
- Institution/ Cooperative Groups

Overarching Principles That Govern Evaluation Of IITS Include:

- The validity of the scientific question being addressed, ensuring that any data generated by an IIT complement the existing body of evidence and not simply be a repetition of a previous study/experiment
- The robust nature of the IIT experiment/investigation being conducted in terms of ethical and design elements
- A commitment by the investigator/sponsor to disseminate the findings in an appropriate, transparent, and timely manner