Role of the Sponsor

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Special Programme for Research & Training
in Tropical Diseases (TDR) sponsored by
UNICEF/UNDP/World Bank/WHO

Who or what is a Sponsor ?

An individual, company, institution or organisation which takes responsibility for the

- initiation
- management *and/or*
- financing

of a clinical trial.

Partnerships, Collaboration
Multiple Sponsors in one project

Who can be a Sponsor ?

- Pharmaceutical Companies
- Research Institutions/ Organizations
- International Health Organizations
- Funding Agencies

Framework

Manager ⇌ Clinical Coordinator

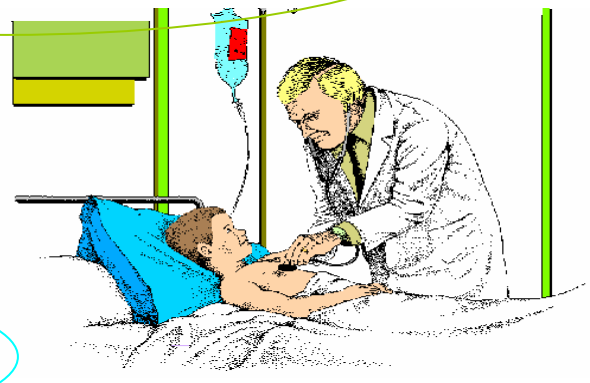
DATA management

DSMB

Clinical Monitor

Ethics Committee

Investigator



Sponsor Responsibilities

- Ensure scientific quality (expert review)
- Select qualified investigators
- Investigational product
- Ensure arrangements for the management and monitoring of the trial
- Data Management
- Safety information management and reporting
- Ensure compliance with protocol, GCP, regulatory requirements

SPONSOR – Qualified Personnel

For each stages of the process

Physicians, Clinical pharmacologist, Data Manager, Biostatistician, Medical writing…

- Trial design
- Trial management
- Data handling, verification, analyses
- Trial report

SPONSOR- Responsibilities

Development of the Protocol and associated documents (CRF)

Objective(s), design, methodology, statistical considerations, organization, ethics, data handling and record keeping financing and insurance, publication policy

Make available an Investigator's Brochure - including all subsequent updates

compilation of data on nonclinical and clinical data on the investigational product(s)

SPONSOR – Investigational Product

Manufacturing, Packaging, Labelling and Coding

- Product manufactured in accordance with GMP, coded and labelled to protect the blinding
- Determine storage conditions, times, and use
- Mechanism to permit rapid identification in case of blinded trial

SPONSOR -Investigational Product
Supplying and Handling

- Supply investigator
- Written instructions for storage and handling
- Written SOPs and maintain documents for delivery, receipt, handling, storage, dispensing, retrieval of unused product and return
- Maintain system and documentation for retrieving product and for the disposition of unused products
- Assure product stability over the period of use
- Maintain sufficient quantities of products used in the trials to reconfirm specifications

SPONSOR – Investigator's selection

- qualified, adequate resources, selection of the coordinating investigator
- provide the investigator with protocol, and up-to-date Investigator’s Brochure (IB) and sufficient time to review them
- obtain signed investigator's agreement: comply with GCP, applicable regulatory requirements, protocol, SOPs; permit monitoring, auditing and inspection

SPONSOR - Investigator

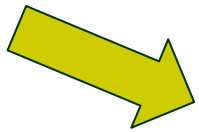
- Allocation of duties and functions: define, establish and allocate duties and functions
- Appropriate training for Investigator
- Record access
  - specified in the protocol : direct access to source document
  - verify that each subject has consented in writing

SPONSOR - Investigator

- Financing: documented and agreed
- Notification/Submission to Regulatory Authority: following local regulation
- Compensation to Subjects and Investigators:
  - provide insurance or indemnify the investigator
  - trial subjects compensation: following applicable regulatory requirements

Sponsor Data Management

- Assures that Data are
  - Complete
  - Reliable
  - Processed correctly
  - Data integrity preserved



Data Management system

- Collecting
- Handling
- Analysing
- Storing/archiving

SPONSOR – Safety Management and Reporting

- **Safety information and reporting**
  - responsible for the on-going safety evaluation
  - promptly notify all concerned investigators and regulatory authorities of findings that could affect adversely the subjects' safety
- **Adverse drug reaction reporting**
  - expedite the reporting to all investigators of all adverse drug reactions that are both serious and unexpected + regulatory requirements

Data Safety Monitoring Board

- Independent
- Advisory body
- Assessment of data during the conduct of the study
- Contributes to the scientific and ethical integrity of the study.

Responsibilities of the Sponsor

The sponsor is responsible for implementing and maintaining quality assurance and quality control systems with written SOPs to ensure that trials are conducted and data are generated, documented (recorded), and reported in compliance with the protocol, GCP, and the applicable regulatory requirement(s).

Quality Assurance (QA)

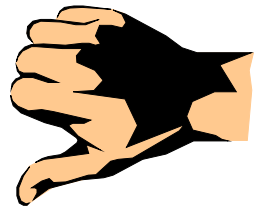
"All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented (recorded), and reported in compliance with GCP and the applicable regulatory requirement(s)."

(ICH GCP 1.46)

The First Law of GCP

What has not been planned,

will go wrong.



Corollary to the1st law of GCP

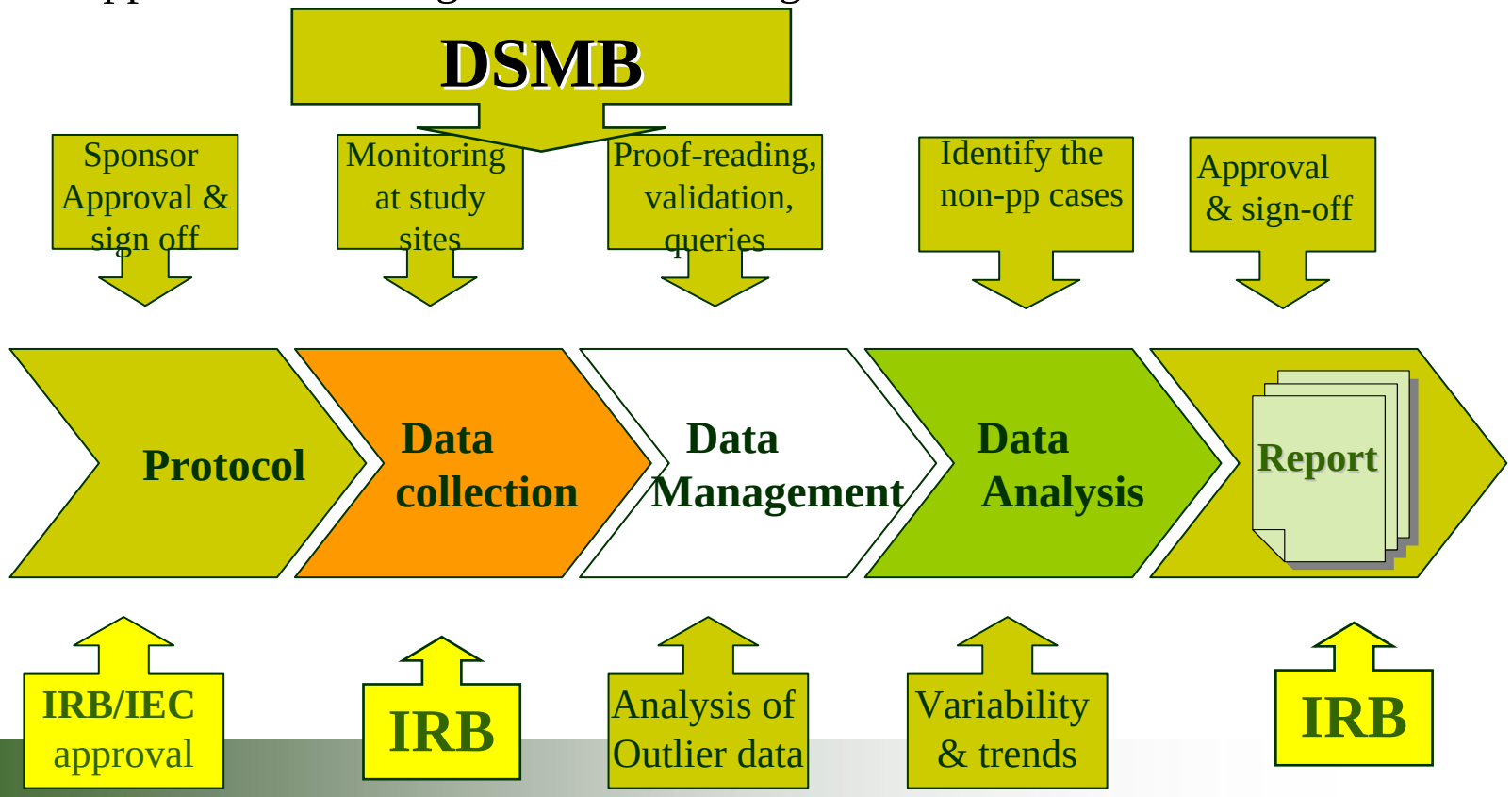
One can not plan every detail, but can minimize the ‘fall-out’ of an accident.

Quality Control (QC)

- Clinical Research: systematic checks on the compliance of the study process & reliability and credibility of data

-performed at every step of the clinical trial process

-applied to each stage of data handling.



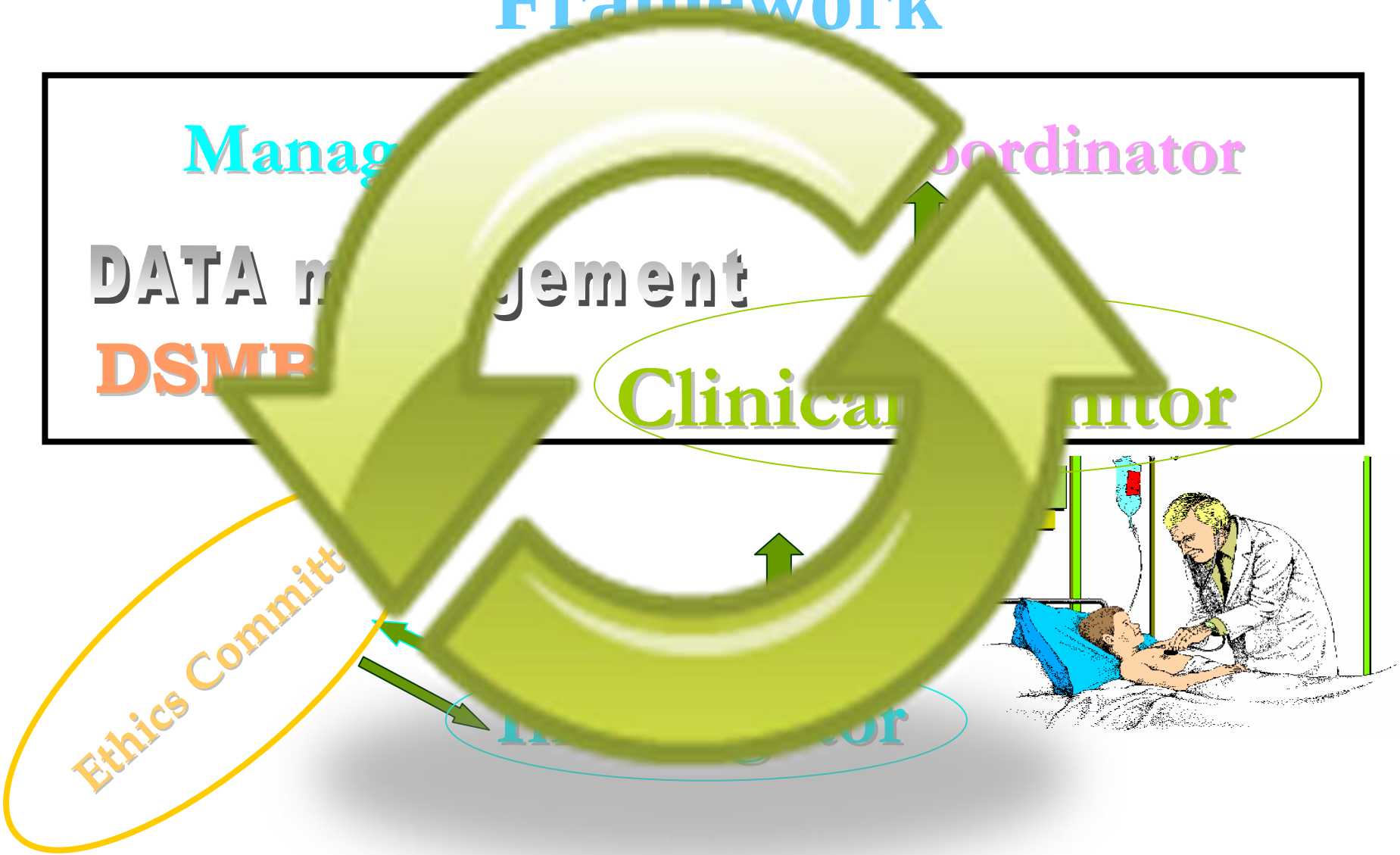
Sponsor Responsibilities - Monitoring

- Qualified monitors appointed by the Sponsor
- Determine appropriate extent and nature of monitoring

Sponsor <>Investigator Relationship

- Know the roles and responsibilities of all involved
- Know how these responsibilities are implemented

Framework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DATA m gement
DSMB
Clinica nitor
Ethics Committ
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