Chapter 3

Trial management

(Nova University Lisbon, Lisbon, Portugal)

Aim

The objective of this chapter is to provide students with a comprehensive overview of the principal aspects of developing, implementing and overseeing a clinical trial.

Summary

The development and conduction of a clinical trial involves complex planning and high investment of the participating stakeholders (regarding financial issues, time, and human resources). Implementation and participation in clinical trials requires continuous formation and specific training (including protocol, GCP, monitoring, data entry, data management and analysis, etc). Careful planning for the use of available resources needs to be taking into consideration in to order to optimize their use. To achieve a high level of success it is necessary to accurately plan before the trial starts, perform an adequate oversight and monitoring during the trial to ensure that subject rights and safety is maintained and to accurately report results and conclusions.

Trial management is the process of ensuring that a trial is run effectively and within budget and timelines. According to ICH GCP E6 (R2) Guidelines, the sponsor should utilize appropriately qualified individuals to:

- supervise the overall conduct of the trial;
- handle the data;
- verify the data;
- conduct the statistical analyses;
- prepare the trial reports.

The sponsor is responsible for implementing a robust system to manage quality throughout all stages of the trial process and should adopt a risk-adapted approach to identify the critical processes and data for the trial and how can any risks and/or vulnerabilities identified in these areas be mitigated. Although the sponsor can delegate trial management activities out to third parties, like Clinical Trial Units (CTUs) or Clinical Research Organizations (CROs), sponsor stays responsible for the implementation of procedures to ensure appropriate oversight of all delegated functions.

It is important that all phases of trial management are documented to define each step of the process. This ensures that all stakeholders of a clinical trial will have a clear plan of what, when and how trial activities will be carried out, but also enables auditors/inspectors to reconstruct the management of the clinical trial.

The planning phase includes the development of key trial documents such as Protocol, ICF, Investigator Brochure, CRF, TMF, ISF and documents that describe all the key processes of

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trial management activities (Monitoring and Data Management Plan and Standard Operating Procedures – SOPs).

Trial monitoring is key to overseeing the progress of the trial, ensuring that management strategies (described in a Trial Management Plan) are followed and compliant with the GCP, protocol and regulatory requirements The monitoring process should be performed in accordance with established in monitoring plan.

Trial management also includes data management, covering statistical data analysis plan to ensure data is accurate and robust, leading to credible results for Clinical Study Reports (CSR), dissemination and publications to the wider public.

Methods

E-learning materials (study materials, links to publications, videos, free templates), quiz questions, discussion boards.

Learning Outcomes

1. Identify and understand Trial Management key aspects
2. Identify sponsor role and responsibilities or sponsor´s representative
3. Trial management plan:
    - 3.1 Understand the objectives
    - 3.2 Describe how the trial managment procedures are defined
    - 3.3 Identify the study team organisation
    - 3.4 Develop a trial management plan with:
        - 3.4.1 Timeline
        - 3.4.2 Budget
        - 3.4.3 Communication plan
        - 3.4.4 Risk assessment
    - 3.5 Describe the essential documents for conducting a clinical trial according to EU clinical trial regulations and ICH GCP
    - 3.6 Explain the importance overseeing the progress of the trial and the quality management system
    - 3.7 Explain trial monitoring and the role of the monitor
        - 3.7.1 Understand the essential aspects of a monitoring plan
        - 3.7.2 Understand the different types of monitoring
        - 3.7.3 Identify the different types of monitoring visits and its purpose
        - 3.7.4 Understand the reports that result from monitoring visits and deviations from the protocol
    - 3.8 Understand the essential aspects of Clinical Study Reports (CSR)
    - 3.9 Explain the importance of trial´s result dissemination and publications to the wider public

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Complementarity to CONSCIOUS I Materials

While CONSCIOUS I is focused on introductory trial management aspects and discussed the basics of how to implement a clinical trial and the key players in clinical trials, as it was undergraduate level. In CONSCIOUS II we will discuss trial management aspects in more specific depth and advanced form addressing aspects not covered in CONSCIOUS I.

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2 Trial Management
- 2.1 Sponsor role and responsibilities or sponsor's representative
  - 2.1.1 Sponsor responsibilities
  - 2.1.2 Sponsor's representative in trial management
- 2.2 Trial management plan (goals, deliverables/procedures, and risk assessment and mitigation)
  - 2.2.1 Team Organization
  - 2.2.2 Management of the study
  - 2.2.3 Communication Plan
  - 2.2.4 Risk Assessment
- 2.3 Main essential documents for conducting a clinical trial
- 2.4 Overseeing the progress of the trial
- 2.5 Monitoring
  - 2.5.1 Selection and Qualification of Monitors
  - 2.5.2 Extent and nature of monitoring
  - 2.5.3 Monitoring plan
  - 2.5.4 Monitoring Visits
  - 2.5.5 Monitoring Reports
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  - 2.5.7 Management of deviations/breaches
- 2.6 Clinical Study Reports (CSR) and trial´s result dissemination and publications to the wider public

3 Conclusion

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