

## Chapter 6

### **Data management (FAIR data, CRF, database) and statistical analysis – standardizing, and analyzing generated data (statistical considerations for the clinical trial planning)**

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#### **Aim**

The primary objective is to comprehend the significance of Clinical Data Management in clinical research, as it contributes to the production of high-quality and dependable data from clinical trials, thereby enhancing its reliability for future sharing and reuse. Given that data management is an essential component of open research, CONSCIOUS II aims to emphasize this topic. We provide a comprehensive examination of the data flow process, starting from its source and concluding with a usable dataset for analysis at the Sponsor site. Additionally, we explore the benefits and drawbacks of utilizing paper CRF (pCRF) and electronic CRF (eCRF) for data capture.

#### **Summary**

Chapter 6 focuses on the core principles and standards of research data management, as outlined by the FAIR Principles and their global implementation. Data management (DM) encompasses a series of procedures involved in handling information during medical research. Its primary objective is to ensure the quality, integrity, and adherence to various protocols and regulations. Additionally, it assists key stakeholders, such as sponsors, research organizations, and clinical centers where data collection occurs, in staying on track. Effective data management plays a crucial role in guaranteeing the production of high-quality data, reports, validation, and a well-executed clinical trial. Effective data management means understanding where the data is, and the ability to get the data into some form where it can be appropriately managed.

#### **Methods**

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

#### **Learning Outcomes**

Students will be able to

1. Discuss the critical elements of good data management practices in clinical trials
2. Explain the principle of data management and its application to clinical trials
3. Discuss the principles of FAIR data and its application to clinical trials
4. Discuss the advantages and disadvantages of using pCRFs and eCRFs
5. Design a DMP and DCP for a clinical trial
6. List the information needed to calculate a sample size, explain what study power is and how to achieve it, and demonstrate the ability to calculate a sample size when provided with the necessary inputs

7. Explain the importance of allocation concealment for the integrity of a trial, and evaluate commonly used methods for achieving it
8. Data standards know-how
9. Understand the need of future data sharing and reuse

## **Complementarity to CONSCIOUS I Materials**

Original chapter – the issue has not been covered by the CONSCIOUS I project.

### **Content**

- 1 Introduction to the chapter
- 2 Introduction to data management
  - 2.1 Roles of data management
  - 2.2 Data quality
  - 2.3 Risk assessment
  - 2.4 Data management standards
  - 2.5 Tools for data management
- 3 FAIR Principles
  - 3.1 Findable
  - 3.2 Accessible
  - 3.3 Interoperable
  - 3.4 Reusable
  - 3.5 Role of data repositories and databases
  - 3.6 Methods of future reuse and data sharing
- 4 Therapeutic Area User Guide (TAUG) - Data Management Plan (DMP) - Data Clean Plan (DCP)
  - 4.1 DMP and DCP for clinical trials
  - 4.2 Paper case report forms (pCRF) vs Electronic Case Report Forms (eCRFs)
  - 4.3 International quality guidelines for clinical trials
- 5 Statistical considerations for the clinical trial planning
- 6 Conclusion