Chapter 4

Quality and regulatory affairs and sources of regulatory information

(Masaryk University, Brno, Czech Republic)

Aim

This chapter aims to provide a description of the European regulatory framework and guidelines for clinical trials, introduces existing freely accessible databases of regulatory information, and summarizes the obligations under the legislation for planning, conducting, and terminating clinical trials. The chapter further describes available clinical trials databases and introduces students to quality in the context of clinical research, including risk-based management and quality improvement.

Summary

Clinical trials must always be conducted in line with all applicable legislation – international and/or national. In addition, clinical research is covered by several guidelines (published by the European Medicine Agency, WHO, International Council of Harmonisation, etc.), which complement the legislation with practical aspects of how to implement legal requirements, comment on the legislation, and elaborate the legislative requirements in more detail. The legislation and guidelines together develop a complicated regulatory network that can be difficult at times to navigate. Therefore, it is crucial to get an overview of applicable legislation for specific investigational products that a postgraduate student or junior researcher may develop or evaluate. A different regulatory approach applies to the clinical evaluation of different investigational products (medicinal products, advanced therapies, other specific groups of medicines, medical devices) and types of the study (interventional trials, non-interventional studies).

In the EU, all clinical trials involving medicinal products performed on human beings must be listed in a publicly accessible EU database (EU CTR, CTIS). Other databases/registries allow the registration of clinical research of various focuses. These databases provide a free and accurate overview of trials conducted, planned, or completed.

To comply with the regulatory, ethical, and GCP standards for ensuring data accuracy and subject right and safety it is necessary to understand the terms quality or quality management system, that are not only applicable to the manufacture of the investigational product but also to the performance of clinical research.

Methods

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

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Learning Outcomes

Students will be able to

1. Identify and interpret the relevant regulatory information on clinical trials with medicinal products, advanced therapies, and medical devices
2. Identify and use sources of regulatory information
3. Describe the differences between EU regulations and EU directives, and extrapolate the practical implications
4. Outline the investigator's responsibilities resulting from regulatory requirements
5. Explain the differences between databases/registries of clinical trials, compulsory vs. voluntary registration
6. Explain the concept of quality in clinical research and its practical application to clinical trials
7. Apply the approach of risk-based management
8. Construct a Corrective and Preventive Action (CAPA) plan for a non-conformance

Complementarity to CONSCIOUS I Materials

The issue has not been covered by the CONSCIOUS I project.

Content

1 Introduction to the chapter

2 Regulatory framework
- 2.1 Regulatory authorities
- 2.2 European legislation, recommendations, and guidelines
- 2.3 Compliance with legislation: practical aspects for investigators
- 2.4 Databases of regulatory information

3 Databases of clinical trials
- 3.1 European databases
- 3.2 ICTRP, ClinicalTrials.gov, others
- 3.3 Trials registration vs. patient registries

4 Quality
- 4.1 Concept of quality in clinical research
- 4.2 Quality management system, risk-based management
- 4.3 International quality guidelines for clinical trials

5 Conclusion

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