Chapter 5

Pharmacovigilance and study medication

(University College Cork, Cork, Ireland, and Masaryk University, Brno, Czech Republic)

Aim

This chapter aims to give postgraduate students sufficient information to describe the importance of pharmacovigilance, why we need to monitor drug safety, and how it fits with the lifecycle of a medicinal product. The lesson will also describe the issues around investigational medicinal products and their handling, regulatory requirements, including responsibilities of team members. We will also focus on the broader perspective of using unauthorized products.

Summary

In order to prevent or reduce harm to patients and thus improve public health, mechanisms for evaluating and monitoring the safety of medicines from early development to clinical use are vital. In practice, this means having in place a well-organized pharmacovigilance system with a number of interconnected levels and pillars. But the safety of medicines starts long before they are actually administered to the patient. Well-established processes for monitoring the movement of the drug and the conditions in which it is kept are key to ensuring the quality of the drug, which of course, goes hand in hand with its safety and efficacy. Thus, the topic of pharmacovigilance will be taken together with the management of investigational medicinal products and other products.

In the context of a clinical trial, the World Health Organisation (WHO) defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects, all of which contribute to the protection of patients and public health and promote safe and effective use of medicinal products. Therefore, this lesson aims to provide the trialists of the future with adequate information to deeply understand and describe the importance of pharmacovigilance and its practical implementation in a clinical trial.

An investigational medicinal product acts as a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial. These include products already with marketing authorization but used or assembled (formulated or packaged) in a way different from the authorized ones or products with no approval. Study medication is a key component of most clinical trials, so it is not surprising that there is a plethora of regulations, strict mechanisms for monitoring the product flow, but also, for example, the conditions of its storage and use by the patient, and associated documentation. The chapter aims again to simplify the orientation of future trialists in this area. In addition, differences between an investigational medicinal product and an auxiliary medicinal product will be defined as well as information on the provision of the medication after the end of the clinical trial.

Co-funded by the
Erasmus+ Programme
of the European Union

Methods

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

Learning Outcomes

Students will be able to

1. Define the term pharmacovigilance and why it is needed
2. Explain principles of pharmacovigilance in clinical trials, specifics of unauthorized and authorized products
3. Define and understand the key drug safety definitions
4. Classify, grade and report adverse events, reactions, etc.
5. Describe and arrange the pharmacovigilance unit/teams in a clinical trial
6. Discuss the regulatory tools that best enable safe and effective monitoring throughout the lifecycle of a medicinal product
7. Describe what is meant by IMP, placebo, authorized/unauthorized medication
8. Design appropriate labeling for primary and secondary packaging
9. Describe the path of the IMP from the distributor through the patient to its destruction

Complementarity to CONSCIOUS I Materials

The theory of pharmacovigilance, including the drug safety definitions, MedDRA terminology and system of reporting is well described in the CONSCIOUS I project. This materials build on this theory and aims to provide the student with the practice-oriented guide on how to organize pharmacovigilance activities in a clinical trial. The issue of study medication has not been covered by the CONSCIOUS I project except for the placebo and its role.

Content

1 Introduction to the chapter

2 Practical aspects of pharmacovigilance in clinical trials
- 2.1 General introduction
- 2.2 Principles of setting of the pharmacovigilance unit/teams in a clinical trial
- 2.3 Reporting in clinical trials generally, including case reports
- 2.4 Specific procedures in pharmacovigilance, authorized and unauthorized products
- 2.5 Overview of phase IV clinical trials for post-marketing drug safety surveillance

3 Study medication
- 3.1 What all can be a study medication?
- 3.2 Regulatory framework of the study medication, responsibilities
- 3.3 Accompanying documentation and labelling
- 3.4 Pathway of the study medication to the patient (and back)
- 3.5 Compassionate use

4 Conclusion

Co-funded by the
Erasmus+ Programme
of the European Union