Chapter 9

Clinical evaluation and clinical investigations of medical devices

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Aim

When we speak of clinical trials, we mainly refer to clinical trials of medicines, so called investigational medical products. However, medical devices (MDs) play an equal important part in the treatment and care of patients. In Europe alone, there are more than 34,000 medical technology companies responsible for over 500 000 types of medical devices and in vitro diagnostics on the EU market.[1] The Regulation (EU) 2017/745 of European Parliament and of the Council ("MDR Regulation") that became applicable from 26 May 2021 made medical device developments more regulated and rigorous. Among many new regulatory requirements, a robust clinical evaluation is needed for medical devices and clinical investigations are mandatory in many cases.

The aim of this chapter is to provide a comprehensive picture on medical device developments: "From Idea to Realization" we will describe the MD development process with special focus on clinical investigations with practical examples. By the end of the chapter, students can understand the basic stakeholders, steps, and also difficulties of medical device developments.

Summary

In this chapter, we will start with references to earlier lesson in CONSCIOUS I, explaining students what was covered there and also the aim of this new lesson. Then we will study the steps of MD development process, next we focus on clinical evaluation and mostly clinical investigations. Beyond planning clinical evaluations, MD developers have important tasks that are different from the traditional IMP development: we will demonstrate these challenges with detailing registration requirements and vigilance of MDs. We will also show students some practical considerations when MDs are developed in an academic environment.

Methods

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

Learning outcomes

Students will be able to

1. Understand the MD development process and its stakeholders
2. Understand clinical evaluation and clinical investigation requirements
3. Identify the basic documentation requirements for application to authorities
4. Comprehend the process of clinical investigations according to MDR through case studies
5. Identify and use online systems (EUDAMED, UDI) connected to MD developments

[1] The European Medical Technology Industry in Figures 2022: https://www.medtecheurope.org/wp-content/uploads/2022/09/the-european-medical-technology-industry-in-figures-2022.pdf

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6. Understand and apply vigilance requirements

Complementarity to CONSCIOUS I Materials

Complementary chapter – The previous lesson in CONSCIOUS I mainly focused on some special aspects of MDR regulation (differences from MDD, classification of MDs, conformity assessment techniques). This new chapter is a more indepth training on the MD development process including stakeholders of the process, clinical investigations, registration requirements. The topics covered in CONSCIOUS I are not repeated in this chapter.

Content

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