Chapter 8
Clinical Research and Regulatory Affairs:
Skills and Tools in Pharmacy Education

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ABSTRACT

Clinical research is a large umbrella, and it mainly includes the implementation of clinical studies/trials. This field is crucial to assess the value of new developments in healthcare, be it new therapeutic interventions, medical devices, or systems of care. In order to protect human rights, the implementation of clinical trials is complex and extremely costly. In this context, medicines and medical devices are strongly regulated products before and after the market authorization. So during their training, pharmacists must develop skills in the area of regulatory affairs, design and methodology of clinical trials, and other clinical studies, as well as in the management of clinical projects to be prepared for the challenges of the clinical research and market access processes. With that purpose, knowledge and skills for clinical research should be developed in association with regulatory affairs.

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INTRODUCTION

Clinical research encompasses all investigations related to treatment, prevention, diagnosis, or prognosis of disease or improvement of health (Ioannidis, 2016). Clinical trial (CT) studies, designed to investigate the safety and the efficacy or effectiveness of a medicine, are considered one of the most appropriate methodologies that respond to such questions, consequently leading to a change in decision making (European Medicines Agency, n.d.; Ioannidis, 2016). In fact, randomized CTs (RCTs) are at the top of the pyramid of scientific evidence due to the robustness that can be achieved with this kind of study design.

To ensure both the highest standards of safety for participants and transparency of all information, CTs are strictly regulated by the European Medicines Agency (EMA) and Food and Drug Administration (FDA), respectively in Europe and the USA, and must obey specific requirements (European Medicines Agency, 2020b; Food and Drug Administration, 2020). Furthermore, the European regulation is also transposed into national law, in each country, making the process even more regulated in order to assure compliance with Good Clinical Practices (GCP).

During a CT, the changes in benefits, harms, cost, and other factors are considered before approving or not a new therapeutic intervention, medical device, or system of care. Moreover, even after the marketing authorization (MA), a clinical trial-resulting product must be constantly monitored and evaluated. The faster development and the increased complexity of regulated medicines and medical devices make the demand for ensuring the protection of both human and animal health by regulators a hard task. For this reason, the industry regulatory workforce is facing several difficulties to keep current knowledge concerning innovation and all the processes related to the regulatory science and new strategies, allowing regulators to stay in line with drugs in development, and patients to have faster access to innovative medicines (Altman et al., 2015; Philip A. Hines et al., 2019, 2020; Rasi, 2017).

These strategies must encompass the growing ecosystem of innovation in the development of human and veterinary medicines (Philip A. Hines et al., 2020).

To ensure the academic programs are following the market needs, and students are acquiring competencies derived from analysis of societal and patient needs, worldwide universities have adapted their programs by adding the regulatory science course (Moghissi et al., 2020).

The efficacy of an educational program is highly dependent on the perception of students' gaps and needs. It has been reported that pharmacy students have gaps in subjects such as communication, safety clinical research, and regulatory science (Warholak et al., 2011). Moreover, according to the literature, the process of learning includes five stages of skill acquisitions: (a) novice, (b) advanced beginner, (c) competence, (d) proficiency, and (e) expertise, during which the learner will