ABSTRACT

Objectives: To expose four-year pharmacy students to the unique learning environment of clinical research development. Through hands-on experience of their knowledge base of the drug development process and to gain interest in the field of clinical pharmacology. The second objective is to improve the understanding of the role of pharmacy schools in clinical research.

Background: Understanding the drug development process and how applied translational medicine and clinical research can impact pharmacy education to market in an efficient and cost-effective manner is an important aspect of a pharmacy student’s education. Pharmacy schools are typically limited and generalised regarding these topics.

ROTATION DESCRIPTION

A two-arm approach has been taken in designing the pharmacy clinical research rotation. The intent of this rotation is to provide an overview of the role of the pharmacy student in preclinical and clinical studies as well as their role in helping to ensure patient and staff safety. The pharmacy student also assists with drug information questions or related concerns that are raised by sponsors or staff during the rotation.

At the conclusion of this introductory period, the focus of the rotation shifts to putting the student in the role of the drug developer. The goal is to provide the student with a glimpse of some of the challenges and difficult decisions that must be made every day during a new clinical entity. The scope of projects was designed to be broad enough for students to get a glimpse of several challenges encountered during drug development. This involves the tasks associated with study design and associated risks in language that is clear for the general population.

First-in-Human (F1H) Study

The student is provided with an investigator’s brochure and asked to complete the human equivalent dose (HED) by identifying the nonobservable adverse effects (NOAEL) in the appropriate animal species and utilizing the correct conversion formula, as applicable, in accordance with FDA guidance for industry. They are then given the study protocol and evaluate whether the proposed starting dose is appropriate based upon their calculations. The student is to identify what risks may be anticipated with the new chemical entity and what can be done to mitigate these risks. The student is then given the safety data results for a dose level and provide justification for moving forward with the next dose level or alternatively stopping the study. The final discussion focuses on what the next step for development of this particular compound should be given the data obtained.

Thorough QT Study

The student is provided with an investigator’s brochure and asked to complete the human equivalent dose (HED) by identifying the nonobservable adverse effects (NOAEL) in the appropriate animal species and utilizing the correct conversion formula, as applicable, in accordance with FDA guidance for industry. They are then given the study protocol and evaluate whether the proposed starting dose is appropriate based upon their calculations. The student is to identify what risks may be anticipated with the new chemical entity and what can be done to mitigate these risks. The student is then given the safety data results for a dose level and provide justification for moving forward with the next dose level or alternatively stopping the study. The final discussion focuses on what the next step for development of this particular compound should be given the data obtained.

Bioavailability/ bioequivalence (BA/BE) Study

The student is asked to research the history and approval process for generic drugs. Then given basic pharmacokinetic information on a compound, they are asked to design a BA/BE study which complies with FDA regulations. This project gives students an awareness of the regulatory history and reasons behind performing these studies as well as introduces the student to basic concepts and principles of study design.

CONCLUSION

After completion of the Phase I Clinical Research Rotation, the pharmacy student will have been exposed to a variety of projects and experiences which are specific and unique to the clinical research environment. Students have the opportunity to see firsthand how pharmacists can apply clinical pharmacology skills learned during pharmacy school to contributing to pharmacology research. The rotation is designed to address the preconceived fears associated with working on a clinical study and spurring interest in participating in drug development and clinical research by removing some of the barriers that may dissuade students from considering these careers.

REFERENCES


