

## Module 5



### Aim:

The purpose of this module is to provide students with an understanding of the practical regulatory aspects of global clinical research, to enable them to provide effective advice on the regulatory issues likely to arise during clinical programmes.

## Regulatory Control of Clinical Research

### Learning outcomes

- Students will understand the principles of Good Clinical Practice and how it underpins research.
- Students will be able to describe the toxicity requirements to start and continue trials in different countries, and will understand the impact of ICH.
- Students will be able to identify the regulatory requirements for clinical research in global major markets, understand the importance of the EU Clinical Trial Directive and the pros and cons of using various countries in the clinical research programme.
- Students will be able to appreciate the global differences in medical culture when reviewing the impact of different guidelines on the clinical plan.
- Students will gain an insight into the complexities of pharmacovigilance in clinical research.
- Students will be able to understand the management of clinical trial supplies.
- Students will gain an appreciation of the legal aspects of clinical research, including insurance, indemnity and the role of the ethics committees.
- Students will gain an appreciation of the regulatory requirements for special population groups.

### The module will cover the following topics

- Good Clinical Practice
- Progression of clinical trials in relation to the toxicity programme
- Progression of clinical trials
- Regulatory requirements for clinical trials in the EU, US, Canada, Japan, Central and Eastern Europe and International Markets
- ADR reporting requirements for clinical trials
- Post marketing drug safety monitoring in the EU
- Clinical trial supplies management
- Legal aspects of clinical trials
- Regulatory requirements for special population groups

### Links with other modules

- Module 4 complements this module, covering the needs of global clinical development and effective advice on the suitability of clinical programmes from a regulatory perspective.



Validated  
by the  
University of Wales