

Qualified Personnel



- Clinical Manager
- CRA/ Monitor
- Medical Writer
- Medical Monitor
- Biostatistician
- Project Manager
- Auditor
- Physician

Define, establish, and allocate all trial-related duties and functions before initiating a trial

Utilize qualified individuals by education or training to assume responsibility for the proper conduct of the study.

Personnel will be thoroughly familiar with the appropriate use of that product as described in the study protocol

Be aware of and remain in compliance with applicable regulatory requirements

11/7/2018

Trial Management, Data Handling, and Recordkeeping



People

- Roles and Responsibilities
- Authorized Individuals

Electronic/Remote Systems

- Data Changes
- Data Security
- Data Blinding
- Data Ownership
- Data Integrity

Citation: ICH E6 (R2) Section 5.5

11

Trial Design



Primary and secondary endpoints

Measures to minimize bias, i.e. Randomization and Blinding

Eligibility criteria, stopping rules or discontinuation

Type/design of trial to be conducted, design schema, procedures and stages

IP Accountability procedures

Trial treatment(s) and the dosage and dosage regimen and duration

Citation: ICH E6 (R2) Section 5.4

11/7/2018 © MRCT Center 14

Online course Interpretation and application of ICH E6(R2) Good Clinical Practice

This online course is directed at educating and training government regulators (reviewers and inspectors) as well as other stakeholders on key concepts of International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) E6(R2). Using case studies and quizzes to reinforce understanding, this course can be taken in its entirety or as needed. Certificates will be given for full completion of the course.

Modules:

- What is ICH E6(R2) and how does it apply to regulators?
- The 13 Principles of ICH GCP
- IRB Responsibilities
- Investigator Qualifications and Responsibilities
- Sponsor Responsibilities
- Protocol and Investigator's Brochure
- Key Documents of ICH E6(R2)-Essential Documents
- GCP in Practice for Reviewers
- GCP in Practice for Inspectors