Introduction to Clinical Research
Good Clinical Practice

28 June 2019

Lebanese Order of Pharmacists

Phoenix
Clinical Research

Trainers

Christina Adel Habib

Quality Assurance Manager, Phoenix Clinical Research

- Christina has a Bachelor's degree from the Faculty of Pharmacy of Cairo University. Christina started her career 11 years ago in clinical research as a Clinical Trial Assistant and pursued her career by gaining experience to become a Clinical Research Associate, Sr. Clinical Research Associate, Clinical Project Lead and currently a Quality Assurance Manager at Phoenix Clinical Research.
- Her experience~~d~~ covered handling full monitoring responsibilities from feasibilities through site selection, site initiation, site monitoring for inpatients and outpatients studies to site closeout, preparing and conducting investigator meetings, delivering protocol training to study teams, preparing for audit/inspection visits, developing project plans, conducting internal audits, developing a Quality Management System (QMS) and leading to the ISO 9001:2015 certification.
- Christina's experience covered different therapeutic fields including Cardiology, Psychiatry, Multiple sclerosis, Oncology, Infectious disease and Gynecology.

Trainers

Maha Dakhloul

Clinical Operations Manager, Phoenix Clinical Research

- Maha has a Bachelor's degree from the Arab University of Beirut. Maha started her career 7 years ago in clinical research as a Clinical Research Coordinator and pursued her career by gaining experience to become a Clinical Research Associate, Regulatory Affairs Manager, Clinical Project Manager and currently Clinical Operations Manager at Phoenix Clinical Research.
- Her experience covered handling full monitoring responsibilities from feasibilities through site selection, site initiation, site monitoring for inpatients and outpatients studies to site closeout, preparing and conducting investigator meetings, delivering protocol training to study teams, managing a multidisciplinary team, preparing for audit/inspection visits, developing project plans, and participating in developing Quality Management System (QMS).
- Maha's experience covered different therapeutic fields including Autoimmune disease, Cardiology, Hematology, Infectious disease, Oncology and Rheumatology

Agenda

1. What is ICH-GCP
2. A Brief History of GCP
3. Why ICH-GCP ?
4. ICH-GCP Principles
5. Clinical Trial Terminology
6. Parties involved in a Clinical Trial
7. Investigator Responsibilities
8. Sponsor Responsibilities
9. Responsibilities of Regulatory Authorities
10. Independent Ethics Committee (IEC)/ Institutional Review Board (IRB)
11. Summary of changes in E6(R1) and E6(R2)