CITI Training Resources

Guidance and Resources for New Investigators - Courses & Descriptions

CITI Good Clinical Practice Modules are described below - http://www.citiprogram.org

- **CITI: FDA Regulated Research and ICH for Investigators** - Addresses responsibilities of investigators, IRBs, and sponsors when they participate in a study of an FDA-regulated product.
- **CITI: Conducting Investigator-Initiated Studies According to FDA Regulations and GCP** - Describes the role of sponsor-investigator, help determine whether an IND or IDE is required for your study, and indicate what documentation is required by the FDA.
- **CITI: Investigator Obligations in FDA-Regulated Clinical Research** - Describes the commitments and obligations that investigators assume when participating in clinical investigations; to subjects, IRB, sponsor organization, and the FDA
- **CITI: Managing Investigational Agents According to GCP Requirements** - Describes the responsibilities of investigators when using investigational products according to GCP standards.
- **CITI: Overview of U.S.FDA Regulations for Medical Devices** - Describes the differences of research regulatory requirements for various classes and categories of devices.
- **CITI: Reporting Serious Adverse Events** - Identify criteria for reporting serious adverse events (SAEs) to regulatory agencies and defines serious and unexpected events which require immediate reporting.
- **CITI: Audits and Inspections in Clinical Trials** - Identifies different entities that can inspect or audit a clinical trial investigator and factors that determine whether an investigator will be audited

Last updated: 26 Aug 2022

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