

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)

GOOD CLINICAL PRACTICE COURSE CURRICULUM COMPLETION REPORT

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EXPIRATION DATE 01/23/2015

GOOD CLINICAL PRACTICE COURSE (US FDA FOCUS) 2013

COURSE/STAGE: Stage 1/1
PASSED ON: 01/23/2014
REFERENCE ID: 12100067

REQUIRED MODULES	DATE COMPLETED	SCORE
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices	01/16/14	3/3 (100%)
Overview of New Drug Development	01/16/14	4/5 (80%)
Overview of ICH GCP	01/23/14	4/4 (100%)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations	01/23/14	4/4 (100%)
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP	01/23/14	3/3 (100%)
Investigator Obligations in FDA-Regulated Clinical Research	01/23/14	5/5 (100%)
Managing Investigational Agents According to GCP Requirements	01/23/14	5/5 (100%)
Overview of U.S. FDA Regulations for Medical Devices	01/23/14	3/3 (100%)
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices	01/23/14	4/4 (100%)
Detecting and Evaluating Adverse Events	01/23/14	4/4 (100%)
Reporting Serious Adverse Events	01/23/14	4/4 (100%)
Audits and Inspections of Clinical Trials	01/23/14	5/5 (100%)
Monitoring of Clinical Trials by Industry Sponsors	01/23/14	8/8 (100%)
Completing the CITI GCP Course	01/23/14	No Quiz

For this Completion Report to be valid, the learner listed above must be affiliated with a CITI Program participating institution or be a paid Independent Learner. Falsified information and unauthorized use of the CITI Program course site is unethical, and may be considered research misconduct by your institution.

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CITI Program Course Coordinator

Collaborative Institutional
Training Initiative
at the University of Miami