

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI)

GOOD CLINICAL PRACTICE (GCP) CURRICULUM COMPLETION REPORT

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EXPIRATION DATE 09/23/2017

GOOD CLINICAL PRACTICE (GCP)

COURSE/STAGE: Basic Course/1
PASSED ON: 09/24/2014
REFERENCE ID: 12737447

ELECTIVE MODULES	DATE COMPLETED
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices	09/24/14
Overview of New Drug Development	09/24/14
Overview of ICH GCP	09/24/14
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations	09/24/14
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP	09/24/14
Investigator Obligations in FDA-Regulated Clinical Research	09/24/14
Managing Investigational Agents According to GCP Requirements	09/24/14
Overview of U.S. FDA Regulations for Medical Devices	09/24/14
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices	09/24/14
Detecting and Evaluating Adverse Events	09/24/14
Reporting Serious Adverse Events	09/24/14
Audits and Inspections of Clinical Trials	09/24/14
Monitoring of Clinical Trials by Industry Sponsors	09/24/14
Completing the CITI GCP Course	09/24/14

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Collaborative Institutional
Training Initiative
at the University of Miami