COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Sarah Dzigiel (ID: 2614728)
- **Email:** sarah.dzigiel@rapidmedicalresearch.com
- **Institution Affiliation:** Quorum Review (ID: 620)
- **Institution Unit:** Clinical Study Coordinator
- **Phone:** 216-682-0320

- **Curriculum Group:** CITI Good Clinical Practice
- **Course Learner Group:** CITI Good Clinical Practice Course
- **Stage:** Stage 1 - GCP
- **Description:** **This ICH E6 GCP Investigator Site Training meets the Minimum Criteria for ICH GCP Investigator Site Personnel Training identified by TransCelerate BioPharma as necessary to enable mutual recognition of GCP training among trial sponsors.**

- **Report ID:** 17582240
- **Completion Date:** 01/08/2016
- **Expiration Date:** 01/07/2017
- **Minimum Passing:** 80
- **Reported Score*:** 94

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices (ID: 1350)	01/08/16	3/3 (100%)
Overview of New Drug Development (ID: 1351)	01/08/16	4/5 (80%)
Overview of ICH GCP (ID: 1352)	01/08/16	4/4 (100%)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID: 1354)	01/08/16	4/4 (100%)
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID: 1355)	01/08/16	3/3 (100%)
Investigator Obligations in FDA-Regulated Research (ID: 1356)	01/08/16	5/5 (100%)
Managing Investigational Agents According to GCP Requirements (ID: 1357)	01/08/16	4/5 (80%)
Overview of U.S. FDA Regulations for Medical Devices (ID: 1358)	01/08/16	3/3 (100%)
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices (ID: 1359)	01/08/16	3/4 (75%)
Detecting and Evaluating Adverse Events (ID: 1360)	01/08/16	4/4 (100%)
Reporting Serious Adverse Events (ID: 1361)	01/08/16	4/4 (100%)
Audits and Inspections of Clinical Trials (ID: 1363)	01/08/16	5/5 (100%)
Monitoring of Clinical Trials by Industry Sponsors (ID: 1362)	01/08/16	5/5 (100%)
Completing the CITI GCP Course (ID: 1364)	01/08/16	No Quiz
Quorum Review IRB (ID: 929)	01/08/16	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

CITI Program
Email: citisupport@miami.edu
Phone: 305-243-7970
Web: https://www.citiprogram.org

Collaborative Institutional Training Initiative at the University of Miami

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK TRANSCRIPT REPORT**

** NOTE: Scores on this Transcript Report reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. See list below for details. See separate Requirements Report for the reported scores at the time all requirements for the course were met.

- **Name:** Sarah Dzigiel (ID: 2614728)
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- **Report ID:** 17582240
- **Report Date:** 01/08/2016
- **Current Score**:** 94

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices (ID: 1350)	01/08/16	3/3 (100%)
Overview of New Drug Development (ID: 1351)	01/08/16	4/5 (80%)
Overview of ICH GCP (ID: 1352)	01/08/16	4/4 (100%)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID: 1354)	01/08/16	4/4 (100%)
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID: 1355)	01/08/16	3/3 (100%)
Investigator Obligations in FDA-Regulated Research (ID: 1356)	01/08/16	5/5 (100%)
Managing Investigational Agents According to GCP Requirements (ID: 1357)	01/08/16	4/5 (80%)
Overview of U.S. FDA Regulations for Medical Devices (ID: 1358)	01/08/16	3/3 (100%)
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices (ID: 1359)	01/08/16	3/4 (75%)
Detecting and Evaluating Adverse Events (ID: 1360)	01/08/16	4/4 (100%)
Reporting Serious Adverse Events (ID: 1361)	01/08/16	4/4 (100%)
Audits and Inspections of Clinical Trials (ID: 1363)	01/08/16	5/5 (100%)
Monitoring of Clinical Trials by Industry Sponsors (ID: 1362)	01/08/16	5/5 (100%)
Completing the CITI GCP Course (ID: 1364)	01/08/16	No Quiz
Quorum Review IRB (ID: 929)	01/08/16	No Quiz

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