COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

* 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:** Gita Gidwani (ID: 3662439)
- **Institution Affiliation:** Quorum Review (ID: 620)
- **Institution Email:** gita.gidwani@rapidmedicalresearch.com
- **Institution Unit:** investigator
- **Phone:** 2166820320

- **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.**

- **Record ID:** 22704328
- **Completion Date:** 02-Jun-2017
- **Expiration Date:** 02-Jun-2018
- **Minimum Passing:** 80
- **Reported Score*:** 98

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices (ID: 1350)	02-Jun-2017	3/3 (100%)
Overview of New Drug Development (ID: 1351)	02-Jun-2017	4/5 (80%)
Overview of ICH GCP (ID: 1352)	02-Jun-2017	4/4 (100%)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID: 1354)	02-Jun-2017	5/5 (100%)
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID: 1355)	02-Jun-2017	3/3 (100%)
Investigator Obligations in FDA-Regulated Research (ID: 1356)	02-Jun-2017	5/5 (100%)
Managing Investigational Agents According to GCP Requirements (ID: 1357)	02-Jun-2017	5/5 (100%)
Overview of U.S. FDA Regulations for Medical Devices (ID: 1358)	02-Jun-2017	3/3 (100%)
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices (ID: 1359)	02-Jun-2017	4/4 (100%)
Detecting and Evaluating Adverse Events (ID: 1360)	02-Jun-2017	4/4 (100%)
Reporting Serious Adverse Events (ID: 1361)	02-Jun-2017	4/4 (100%)
Audits and Inspections of Clinical Trials (ID: 1363)	02-Jun-2017	5/5 (100%)
Monitoring of Clinical Trials by Industry Sponsors (ID: 1362)	02-Jun-2017	5/5 (100%)
Completing the CITI GCP Course (ID: 1364)	02-Jun-2017	No Quiz
Quorum Review IRB (ID: 929)	02-Jun-2017	No Quiz

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Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

** 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.

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- **Record ID:** 22704328
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- **Current Score**:** 98

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices (ID: 1350)	02-Jun-2017	3/3 (100%)
Overview of New Drug Development (ID: 1351)	02-Jun-2017	4/5 (80%)
Overview of ICH GCP (ID: 1352)	02-Jun-2017	4/4 (100%)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID: 1354)	02-Jun-2017	5/5 (100%)
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID: 1355)	02-Jun-2017	3/3 (100%)
Investigator Obligations in FDA-Regulated Research (ID: 1356)	02-Jun-2017	5/5 (100%)
Managing Investigational Agents According to GCP Requirements (ID: 1357)	02-Jun-2017	5/5 (100%)
Overview of U.S. FDA Regulations for Medical Devices (ID: 1358)	02-Jun-2017	3/3 (100%)
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices (ID: 1359)	02-Jun-2017	4/4 (100%)
Detecting and Evaluating Adverse Events (ID: 1360)	02-Jun-2017	4/4 (100%)
Reporting Serious Adverse Events (ID: 1361)	02-Jun-2017	4/4 (100%)
Audits and Inspections of Clinical Trials (ID: 1363)	02-Jun-2017	5/5 (100%)
Monitoring of Clinical Trials by Industry Sponsors (ID: 1362)	02-Jun-2017	5/5 (100%)
Completing the CITI GCP Course (ID: 1364)	02-Jun-2017	No Quiz
Quorum Review IRB (ID: 929)	02-Jun-2017	No Quiz

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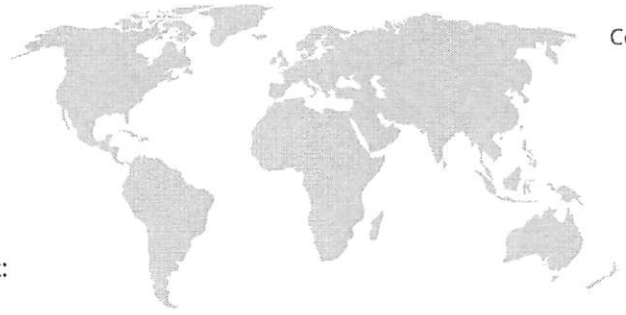
CITI PROGRAM



Completion Date 02-Jun-2017
Expiration Date 02-Jun-2018
Record ID 22704328

This is to certify that:

Gita Gidwani

Has completed the following CITI Program course:

CITI Good Clinical Practice	(Curriculum Group)
CITI Good Clinical Practice Course	(Course Learner Group)
1 - GCP	(Stage)

Under requirements set by:

Quorum Review

CITI

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2
COURSEWORK REQUIREMENTS*

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- **Curriculum Group:** CITI Health Information Privacy and Security (HIPS)
- **Course Learner Group:** CITI Health Information Privacy and Security (HIPS) for All Researchers
- **Stage:** Stage 1 - HIPS

- **Record ID:** 22704329
- **Completion Date:** 02-Jun-2017
- **Expiration Date:** 02-Jun-2018
- **Minimum Passing:** 80
- **Reported Score*:** 90

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Basics of Health Privacy (ID: 1417)	02-Jun-2017	16/16 (100%)
Health Privacy Issues for Researchers (ID: 1419)	02-Jun-2017	3/5 (60%)
Quorum Review IRB (ID: 929)	02-Jun-2017	No Quiz

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COMPLETION REPORT - PART 2 OF 2
COURSEWORK TRANSCRIPT**

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- **Curriculum Group:** CITI Health Information Privacy and Security (HIPS)
- **Course Learner Group:** CITI Health Information Privacy and Security (HIPS) for All Researchers
- **Stage:** Stage 1 - HIPS

- **Record ID:** 22704329
- **Report Date:** 02-Jun-2017
- **Current Score**:** 90

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
Basics of Health Privacy (ID: 1417)	02-Jun-2017	16/16 (100%)
Health Privacy Issues for Researchers (ID: 1419)	02-Jun-2017	3/5 (60%)
Quorum Review IRB (ID: 929)	02-Jun-2017	No Quiz

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- **Curriculum Group:** Basic/Refresher Course - Human Subjects Research
- **Course Learner Group:** Biomedical Research
- **Stage:** Stage 1 - Basic Course

- **Record ID:** 22704327
- **Completion Date:** 02-Jun-2017
- **Expiration Date:** 02-Jun-2019
- **Minimum Passing:** 80
- **Reported Score*:** 94

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Recognizing and Reporting Unanticipated Problems Involving Risks to Subjects or Others in Biomedical Research (ID: 14777)	02-Jun-2017	5/5 (100%)
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	02-Jun-2017	5/5 (100%)
Belmont Report and CITI Course Introduction (ID: 1127)	02-Jun-2017	3/3 (100%)
History and Ethics of Human Subjects Research (ID: 498)	02-Jun-2017	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	02-Jun-2017	5/5 (100%)
Informed Consent (ID: 3)	02-Jun-2017	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	02-Jun-2017	4/4 (100%)
Records-Based Research (ID: 5)	02-Jun-2017	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	02-Jun-2017	4/5 (80%)
Vulnerable Subjects - Research Involving Children (ID: 9)	02-Jun-2017	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	02-Jun-2017	3/3 (100%)
International Studies (ID: 971)	02-Jun-2017	3/3 (100%)
FDA-Regulated Research (ID: 12)	02-Jun-2017	5/5 (100%)
Research and HIPAA Privacy Protections (ID: 14)	02-Jun-2017	4/5 (80%)
Vulnerable Subjects - Research Involving Workers/Employees (ID: 483)	02-Jun-2017	4/4 (100%)
Hot Topics (ID: 487)	02-Jun-2017	No Quiz
Conflicts of Interest in Research Involving Human Subjects (ID: 488)	02-Jun-2017	3/5 (60%)
Quorum Review IRB (ID: 929)	02-Jun-2017	No Quiz

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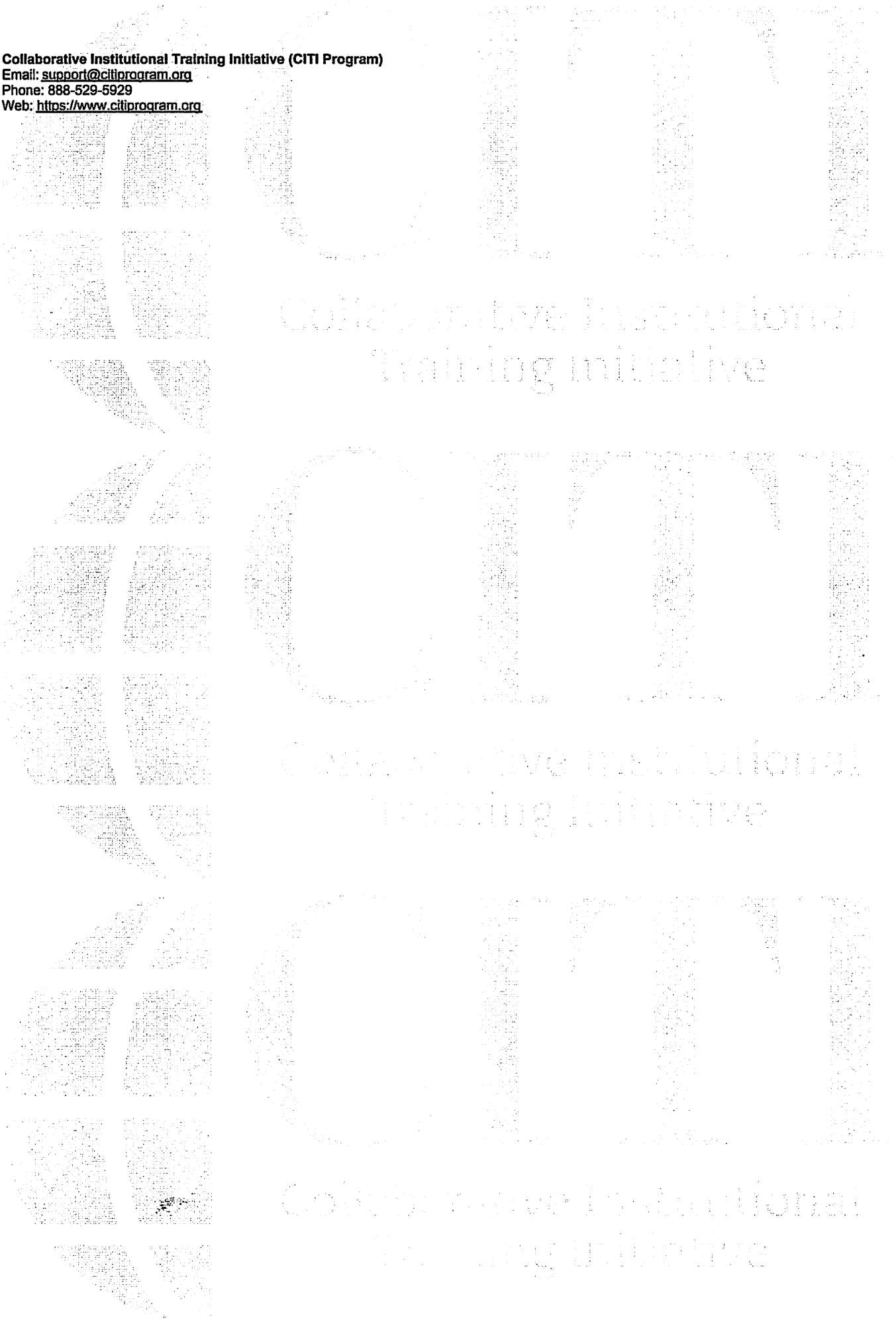

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- **Record ID:** 22704327
- **Report Date:** 02-Jun-2017
- **Current Score**:** 95

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
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Informed Consent (ID: 3)	02-Jun-2017	5/5 (100%)
Social and Behavioral Research (SBR) for Biomedical Researchers (ID: 4)	02-Jun-2017	4/4 (100%)
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Records-Based Research (ID: 5)	02-Jun-2017	3/3 (100%)
Genetic Research in Human Populations (ID: 6)	02-Jun-2017	4/5 (80%)
Vulnerable Subjects - Research Involving Prisoners (ID: 8)	16-Aug-2013	4/4 (100%)
Vulnerable Subjects - Research Involving Children (ID: 9)	02-Jun-2017	3/3 (100%)
Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates (ID: 10)	02-Jun-2017	3/3 (100%)
FDA-Regulated Research (ID: 12)	02-Jun-2017	5/5 (100%)
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