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:** ben marafino (ID: 6039088)
- **Email:** marafino@stanford.edu
- **Institution Affiliation:** Stanford University (ID: 389)
- **Institution Unit:** Biomedical Informatics
- **Phone:** 999-999-9999

- **Curriculum Group:** Human Subjects Research Protections
- **Course Learner Group:** Group 7: **IRB BioMed/GCP Research (All Medical Investigators and Staff)**
- **Stage:** Stage 1 - Basic Course
- **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:** 21881871
- **Completion Date:** 09-Jan-2017
- **Expiration Date:** 09-Jan-2020
- **Minimum Passing:** 80
- **Reported Score*:** 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	09-Jan-2017	5/5 (100%)
Belmont Report and CITI Course Introduction (ID: 1127)	09-Jan-2017	3/3 (100%)
History and Ethics of Human Subjects Research (ID: 498)	09-Jan-2017	7/7 (100%)
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	09-Jan-2017	5/5 (100%)
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices (ID: 1350)	09-Jan-2017	3/3 (100%)
Overview of New Drug Development (ID: 1351)	09-Jan-2017	5/5 (100%)
Overview of ICH GCP (ID: 1352)	09-Jan-2017	4/4 (100%)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID: 1354)	09-Jan-2017	4/4 (100%)
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID: 1355)	09-Jan-2017	3/3 (100%)
Investigator Obligations in FDA-Regulated Research (ID: 1356)	09-Jan-2017	5/5 (100%)
Managing Investigational Agents According to GCP Requirements (ID: 1357)	09-Jan-2017	5/5 (100%)
Overview of U.S. FDA Regulations for Medical Devices (ID: 1358)	09-Jan-2017	3/3 (100%)
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices (ID: 1359)	09-Jan-2017	4/4 (100%)
Detecting and Evaluating Adverse Events (ID: 1360)	09-Jan-2017	4/4 (100%)
Reporting Serious Adverse Events (ID: 1361)	09-Jan-2017	4/4 (100%)
Monitoring of Clinical Trials by Industry Sponsors (ID: 1362)	09-Jan-2017	5/5 (100%)
Audits and Inspections of Clinical Trials (ID: 1363)	09-Jan-2017	5/5 (100%)
Completing the CITI GCP Course (ID: 1364)	09-Jan-2017	No Quiz
Stanford University Module (ID: 750)	09-Jan-2017	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.

Verify at: www.citiprogram.org/verify/?k4b3f1750-d819-40bc-953f-e5d7977cb23f-21881871

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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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- **Report ID:** 21881871
- **Report Date:** 17-Jan-2017
- **Current Score**:** 100

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
History and Ethics of Human Subjects Research (ID: 498)	09-Jan-2017	7/7 (100%)
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices (ID: 1350)	09-Jan-2017	3/3 (100%)
Overview of New Drug Development (ID: 1351)	09-Jan-2017	5/5 (100%)
Belmont Report and CITI Course Introduction (ID: 1127)	09-Jan-2017	3/3 (100%)
Overview of ICH GCP (ID: 1352)	09-Jan-2017	4/4 (100%)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID: 1354)	09-Jan-2017	4/4 (100%)
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID: 1355)	09-Jan-2017	3/3 (100%)
Investigator Obligations in FDA-Regulated Research (ID: 1356)	09-Jan-2017	5/5 (100%)
Managing Investigational Agents According to GCP Requirements (ID: 1357)	09-Jan-2017	5/5 (100%)
Overview of U.S. FDA Regulations for Medical Devices (ID: 1358)	09-Jan-2017	3/3 (100%)
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices (ID: 1359)	09-Jan-2017	4/4 (100%)
Detecting and Evaluating Adverse Events (ID: 1360)	09-Jan-2017	4/4 (100%)
Reporting Serious Adverse Events (ID: 1361)	09-Jan-2017	4/4 (100%)
Audits and Inspections of Clinical Trials (ID: 1363)	09-Jan-2017	5/5 (100%)
Monitoring of Clinical Trials by Industry Sponsors (ID: 1362)	09-Jan-2017	5/5 (100%)
Completing the CITI GCP Course (ID: 1364)	09-Jan-2017	No Quiz
Basic Institutional Review Board (IRB) Regulations and Review Process (ID: 2)	09-Jan-2017	5/5 (100%)
Stanford University Module (ID: 750)	09-Jan-2017	No Quiz
Populations in Research Requiring Additional Considerations and/or Protections (ID: 16680)	09-Jan-2017	5/5 (100%)

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