## COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 1 OF 2 COURSEWORK REQUIREMENTS\*

\* Scores on this Requirements Report (Part 1) reflect quiz completions at the time all requirements for the course were met. The Transcript Report (Part 2) lists more recent quiz scores, including those on optional (supplemental) course elements.

• Name: Kritsanapong Titayanuwat (ID: 14248592)

• Institution Affiliation: Massachusetts Institute of Technology Affiliates (ID: 1912)

• Institution Email: poppop5566@outlook.com

• Institution Unit: Massachusetts Institute of Technology University

• **Phone**: 0955982188

• Curriculum Group: Good Clinical Practice (U.S. FDA Focus)

• Course Learner Group: GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)

• Stage: Stage 1 - GCP

• Record ID: 68564657
• Completion Date: 30-Mar-2025
• Expiration Date: 30-Mar-2028

Minimum Passing: 80Reported Score\*: 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices (ID: 1350)	25-Mar-2025	3/3 (100%)
Investigator Obligations in FDA-Regulated Research (ID: 1356)	25-Mar-2025	5/5 (100%)
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices (ID: 1359)	27-Mar-2025	4/4 (100%)
Overview of New Drug Development (ID: 1351)	27-Mar-2025	5/5 (100%)
Overview of ICH GCP (ID: 1352)	27-Mar-2025	4/4 (100%)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID: 1354)	29-Mar-2025	5/5 (100%)
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID: 1355)	30-Mar-2025	3/3 (100%)
Managing Investigational Agents According to GCP Requirements (ID: 1357)	30-Mar-2025	5/5 (100%)
Overview of U.S. FDA Regulations for Medical Devices (ID: 1358)	30-Mar-2025	3/3 (100%)
Detecting and Evaluating Adverse Events (ID: 1360)	30-Mar-2025	4/4 (100%)
Reporting Serious Adverse Events (ID: 1361)	30-Mar-2025	4/4 (100%)
Audits and Inspections of Clinical Trials (ID: 1363)	30-Mar-2025	5/5 (100%)
Monitoring of Clinical Trials by Industry Sponsors (ID: 1362)	30-Mar-2025	5/5 (100%)
Completing the CITI GCP Course (ID: 1364)	30-Mar-2025	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.

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Collaborative Institutional Training Initiative (CITI Program)

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Collaborative Institutional Training Initiative

## COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COMPLETION REPORT - PART 2 OF 2 COURSEWORK TRANSCRIPT\*\*

\*\* Scores on this <u>Transcript Report</u> (Part 2) reflect the most current quiz completions, including quizzes on optional (supplemental) elements of the course. The Requirements Report (Part 1) lists the reported scores at the time all requirements for the course were met.

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• **Phone**: 0955982188

• Curriculum Group: Good Clinical Practice (U.S. FDA Focus)

• Course Learner Group: GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)

• Stage: Stage 1 - GCP

• Description: This GCP training contains all of the attested CITI Program modules from the GCP for Clinical Trials with

Investigational Drugs and Medical Devices (U.S. FDA Focus) Version 2. 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: 68564657 • Current Score\*\*: 100

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices (ID: 1350)	25-Mar-2025	3/3 (100%)
Overview of New Drug Development (ID: 1351)	27-Mar-2025	5/5 (100%)
Overview of ICH GCP (ID: 1352)	27-Mar-2025	4/4 (100%)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID: 1354)	29-Mar-2025	5/5 (100%)
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID: 1355)	30-Mar-2025	3/3 (100%)
Investigator Obligations in FDA-Regulated Research (ID: 1356)	25-Mar-2025	5/5 (100%)
Managing Investigational Agents According to GCP Requirements (ID: 1357)	30-Mar-2025	5/5 (100%)
Overview of U.S. FDA Regulations for Medical Devices (ID: 1358)	30-Mar-2025	3/3 (100%)
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices (ID: 1359)	27-Mar-2025	4/4 (100%)
Detecting and Evaluating Adverse Events (ID: 1360)	30-Mar-2025	4/4 (100%)
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Monitoring of Clinical Trials by Industry Sponsors (ID: 1362)	30-Mar-2025	5/5 (100%)
Audits and Inspections of Clinical Trials (ID: 1363)	30-Mar-2025	5/5 (100%)
Completing the CITI GCP Course (ID: 1364)	30-Mar-2025	No Quiz

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