CERTIFICATE OF COMPLETION

CITI KOREA | Collaborative Institutional Training Initiative Program

The Collaborative Institutional Training Initiative(CITI) Program at the University of Miami

We present this certificate to

JIYEI SEO

Seoul National University Hospital

In recognition of successful completion of the requirements for

GCP for Clinical Trials with Drugs and Biologics

Completion Report No. : K-2020-34491500
Date Completed : January 6, 2020
Year of Birth : 1988

Paul G. Braunschweiger, Ph.D.
Professor
University of Miami
CITI Program Co-founder

B. I. Choe, M.B.A., LL.M., Ph.D.
Professor of Bioethics
The Catholic University of Korea
CITI-KOREA Program Director

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:** JIYEI SEO (ID: 7729310)
- **Email:** seojy@snuh.org
- **Institution Affiliation:** Seoul National University Hospital (ID: 2168)
- **Institution Unit:** clinical trial center
- **Phone:** 1067773830

- **Curriculum Group:** GCP for Clinical Trials with Drugs and Biologics
- **Course Learner Group:** Same as Curriculum Group
- **Stage:** Stage 1 - Stage 1

- **Report ID:** 34491500
- **Completion Date:** 01/06/2020
- **Expiration Date:** 01/05/2021
- **Minimum Passing:** 80
- **Reported Score*:** 100

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
CITI Program 교육 과정 준수사항 (ID: 15509)	01/05/20	No Quiz
CITI GCP 교육과정 개요 (ID: 16052)	01/05/20	3/3 (100%)
FDA 규정과 GCP가 제시하는 연구자 주도 임상시험의 수행 (ID: 16053)	01/05/20	3/3 (100%)
FDA 규제를 받는 연구에서의 시험자의 의무 (ID: 16054)	01/05/20	3/3 (100%)
GCP에 따른 임상시험용 의약품의 관리 (ID: 16055)	01/05/20	3/3 (100%)
의약품 임상시험에서의 대상자 동의 (ID: 16056)	01/05/20	3/3 (100%)
의약품 임상시험에 대한 의뢰자의 모니터링 (ID: 16057)	01/05/20	3/3 (100%)
임상시험에 대한 점검 및 실태조사 (ID: 16058)	01/05/20	3/3 (100%)
신약개발과정의 개요 (ID: 16059)	01/06/20	3/3 (100%)
ICH GCP의 개요 (ID: 16060)	01/06/20	3/3 (100%)
ICH - GCP E6와 FDA 규정간의 비교 (ID: 16061)	01/06/20	3/3 (100%)

이상반응의 발견과 평가 (ID: 16062)	01/06/20	3/3 (100%)
의약품 및 생물학적 제제 임상시험에서 중대한 이상반응의 보고 (ID: 16063)	01/06/20	3/3 (100%)
CITI GCP 교육과정 이수 (ID: 16064)	01/06/20	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: support@citiprogram.org
Phone: +1 305.907.3100
Web: https://www.citiprogram.org

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.**

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- **Stage:** Stage 1 - Stage 1

- **Report ID:** 34491500
- **Report Date:** 01/06/2020
- **Current Score**:** 100

REQUIRED, ELECTIVE, AND SUPPLEMENTAL MODULES	MOST RECENT	SCORE
CITI Program 교육 과정 준수사항 (ID: 15509)	01/05/20	No Quiz
CITI GCP 교육과정 개요 (ID: 16052)	01/05/20	3/3 (100%)
신약개발과정의 개요 (ID: 16059)	01/06/20	3/3 (100%)
ICH GCP의 개요 (ID: 16060)	01/06/20	3/3 (100%)
ICH - GCP E6와 FDA 규정간의 비교 (ID: 16061)	01/06/20	3/3 (100%)
FDA 규정과 GCP가 제시하는 연구자 주도 임상시험의 수행 (ID: 16053)	01/05/20	3/3 (100%)
FDA 규제를 받는 연구에서의 시험자의 의무 (ID: 16054)	01/05/20	3/3 (100%)
GCP에 따른 임상시험용 의약품의 관리 (ID: 16055)	01/05/20	3/3 (100%)
의약품 임상시험에서의 대상자 동의 (ID: 16056)	01/05/20	3/3 (100%)
의약품 임상시험에 대한 의뢰자의 모니터링 (ID: 16057)	01/05/20	3/3 (100%)
임상시험에 대한 점검 및 실태조사 (ID: 16058)	01/05/20	3/3 (100%)
이상반응의 발견과 평가 (ID: 16062)	01/06/20	3/3 (100%)
의약품 및 생물학적 제제 임상시험에서 중대한 이상반응의 보고 (ID: 16063)	01/06/20	3/3 (100%)

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