



CITI Program 기관회원 교육과정 개편 안내

(재)생명과학 연구윤리서재
 BICstudy

CITI Program 교육과정 개편 요약



CITI Program 교육과정은 관련 기준과 최신의 동향을 반영하여 수시로 콘텐츠를 개정하고 있습니다.
(재)생명과학연구윤리서재에서 제공하는 한국어 콘텐츠도 이를 반영하여 교육 과정명과 콘텐츠 내용을 아래와 같이 개편되었음을 안내 드립니다.

1. ICH GCP E6(R3) 기준을 반영한 GCP 교육과정

2. CITI Program 교육과정명과 동일한 영문제목 반영

3. GCP 보수과정 등 한국어 번역 콘텐츠 추가

4. 기관장(IO)/IRB 위원장/행정 등 선택 교육과정

5. 교육과정 세부 목차

1. ICH GCP E6(R3) 기준을 반영한 GCP 교육과정

국제약품규제조화위원회의 최신 가이드라인인 ICH E6(R3)가 CITI Program GCP 교육과정에 반영되었습니다.(2026년 01월 01일 기준)

✓ 최신 글로벌 규제 동향을 교육과정에 반영하여 글로벌 임상시험 환경에 대응

✓ 다국가 임상시험 참여 시 국제 표준을 준수하는 연구 역량 확보

✓ 향후 국내 관련 법령과 기준에 반영 가능성 대비

✓ ICH GCP E6(R3) 반영 교육과정

- 의약품 및 생물학적 제제 임상시험 (GCP-ICH 기준)[신규]
GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)
- 의약품 및 의료기기 임상시험(GCP-FDA 기준)[신규]
GCP for Clinical Trials with Investigational Drugs and Devices (U.S. FDA Focus)
- GCP SBR Advanced Refresher [심화/보수]
- GCP-ICH 기준 [심화/보수]
GCP ICH Refresher
- GCP-FDA 기준 [심화/보수]
GCP FDA Refresher

2. CITI Program GCP 교육과정명 변경

GCP 교육과정명을 미국 CITI Program GCP 교육과정명과 동일하게 변경됩니다.(2026년 3월 16일 기준)

✓ 다국가 임상시험 증가에 따라 교육과정명을 통일하여 국제적 통용성 강화

✓ ICH GCP E6(R3) 개정 사항 반영에 따라 교육과정명을 글로벌 표준에 맞추어 정비

변경 전

- 의약품 임상시험종사자들을 위한 임상시험관리기준 (기본)
GCP for Clinical Trials with Drugs and Biologics
- 의약품 및 의료기기 임상시험종사자들을 위한
임상시험관리기준(기본)
GCP for Clinical Trials with Drugs and Medical Devices
- 의료기기 임상시험종사자들을 위한
임상시험관리기준(기본)
GCP for Clinical Trials with Medical Devices

변경 후

- 의약품 및 생물학적 제제 임상시험 (GCP-ICH 기준)[신규]
GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)
- 의약품 및 의료기기 임상시험(GCP-FDA 기준)[신규]
GCP for Clinical Trials with Investigational Drugs and Devices (U.S. FDA Focus)
- 의료기기 임상시험 [신규]
GCP for Clinical Investigations of Devices

※ 변경된 교육과정명은 기존 이수자의 교육이수증에도 반영됩니다.

3. GCP 심화/보수 교육과정 개편

기존 GCP 교육 이수자를 대상으로 하는 GCP 보수 교육과정을 신설하였습니다.(2026년 3월 16일 기준)

✓ 정기적인 GCP 재교육을 통한 연구 역량 강화

✓ 기존 GCP 교육 이수자 대상 교육

✓ GCP 보수 교육과정 안내

GCP ICH Refresher

GCP-ICH 기준
[심화/보수]

GCP FDA Refresher

GCP-FDA 기준
[심화/보수]

GCP Device Refresher

의료기기 임상시험
[심화/보수]

GCP SBR Advanced

GCP SBR Advanced
Refresher [심화/보수]

4. 기관장(IO)/IRB 위원장/행정 등 선택 교육과정

CITI Program Human Subject Research

- Institutional/Signatory Official: Human Subjects Research
- IRB Chair
- IRB Administration Course
- IRB Administration: Advanced Course (2026년 4월 이후 서비스 예정)

※ 해당 교육과정의 추가 개설을 원하시는 기관은 02-749-7700 혹은 edu@bicstudy.org 로 별도 문의 바랍니다.

5. 교육과정 세부 목차(1)



의약품 및 생물학적 제제 임상시험 (GCP-ICH 기준)[신규] GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)

교육시간: 6H | 제공 언어 : 한국어/영어

- The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Biologics
- Overview of New Drug Development
- Overview of ICH GCP
- ICH – Comparison Between ICH GCP E6 and U.S. FDA Regulations
- Conducting Investigator-Initiated Studies According to FDA Regulations and GCP
- Investigator Obligations in FDA-Regulated Research
- Managing Investigational Agents According to GCP Requirements
- Informed Consent in Clinical Trials of Drugs and Biologics
- Monitoring Clinical Trials of Drugs by Industry Sponsors
- Audits and Inspections of Clinical Trials of Drugs and Biologics
- Detecting and Evaluating Adverse Events
- Reporting Serious Adverse Events in Investigations of Drugs and Biologics
- Completing the CITI GCP Course
- Korean GCP and Regulatory Requirement (한국의 임상시험관리기준 및 관련 규정)

5. 교육과정 세부 목차(2)



의약품 및 의료기기 임상시험(GCP-FDA 기준)[신규] GCP for Clinical Trials with Investigational Drugs and Devices (U.S. FDA Focus)

교육시간: 6H | 제공 언어 : 한국어/영어

- The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices
- Overview of New Drug Development
- Overview of ICH GCP
- ICH – Comparison Between ICH GCP E6 and U.S. FDA Regulations
- Conducting Investigator-Initiated Studies According to FDA Regulations and GCP
- Investigator Obligations in FDA-Regulated Clinical Research
- Managing Investigational Agents According to GCP Requirements
- Overview of U.S. FDA Regulations for Medical Devices
- Informed Consent in Clinical Trials of Drugs, Biologics, and Devices
- Detecting and Evaluating Adverse Events
- Reporting Serious Adverse Events
- Monitoring of Clinical Trials by Industry Sponsors
- Audits and Inspections of Clinical Trials
- Completing the CITI GCP Course
- Korean GCP and Regulatory Requirement (한국의 임상시험관리기준 및 관련 규정)

5. 교육과정 세부 목차(3)



의료기기 임상시험 [신규] GCP for Clinical Investigations of Devices

교육시간: 4H | 제공 언어 : 한국어/영어

- The CITI Good Clinical Practice Course for Clinical Investigations of Devices
- Overview of U.S. FDA Regulations for Investigational Devices
- Investigator Obligations in FDA-Regulated Clinical Investigations of Devices
- Conducting Investigator-Initiated Clinical Investigations of Devices
- Managing Investigational Devices According to GCP Requirements
- Informed Consent in Clinical Investigations of Devices
- Monitoring Clinical Investigations of Devices
- Audits and Inspections of Clinical Investigations of Devices
- Reporting Requirements for Clinical Investigations of Devices
- Completing the CITI Program's GCP Course for Clinical Investigations of Devices
- Korean GCP and Regulatory Requirement (한국의 임상시험관리기준 및 관련 규정)

5. 교육과정 세부 목차(4)



GCP-ICH 기준 [심화/보수] GCP ICH Refresher

교육시간: 4H | 제공 언어 : 한국어/영어

- GCP Refresher-International Council for Harmonisation (ICH): GCP Requirements
- GCP Refresher-Investigator's Responsibilities and GCP
- GCP Refresher-Informed Consent
- GCP Refresher-Safety Management
- GCP Refresher-Investigational Product (Drug) Management
- GCP Refresher-Audits, Inspection, and Monitoring of Research Studies
- GCP Refresher-Sponsor Responsibilities and GCP
- Korean GCP and Regulatory Requirement (한국의 임상시험관리기준 및 관련 규정)

5. 교육과정 세부 목차(5)



GCP-FDA 기준 [심화/보수] GCP FDA Refresher

교육시간: 4H | 제공 언어 : 한국어/영어

- International Council for Harmonisation (ICH): GCP Requirements
- Investigator's Responsibilities and GCP
- GCP Refresher – Informed Consent
- Safety Management
- Investigational Product (Drug) Management
- Audits, Inspection, and Monitoring of Research Studies
- Sponsor Responsibilities and GCP
- Conducting Clinical Investigations of Devices
- Review of U.S. FDA Regulations for Investigational Devices
- Additional GCP Standards for International Clinical Investigations of Devices
- Informed Consent and Exceptions to the Requirement for Clinical Investigations of Devices
- Oversight of Clinical Investigations of Devices
- Reporting Requirements for Clinical Investigations of Devices
- Korean GCP and Regulatory Requirement (한국의 임상시험관리기준 및 관련 규정)

5. 교육과정 세부 목차(6)



의료기기 임상시험 [심화/보수] GCP Device Refresher

교육시간: 4H | 제공 언어 : 한국어/영어

- Conducting Clinical Investigations of Devices
- Review of U.S. FDA Regulations for Investigational Devices
- Additional GCP Standards for International Clinical Investigations of Devices
- Informed Consent and Exceptions to the Requirement for Obtaining Consent for Clinical Investigations of Devices
- Oversight of Clinical Investigations of Devices
- Reporting Requirements for Clinical Investigations of Devices
- Korean GCP and Regulatory Requirement (한국의 임상시험관리기준 및 관련 규정)

5. 교육과정 세부 목차(7)



GCP SBR Advanced Refresher [심화/보수]

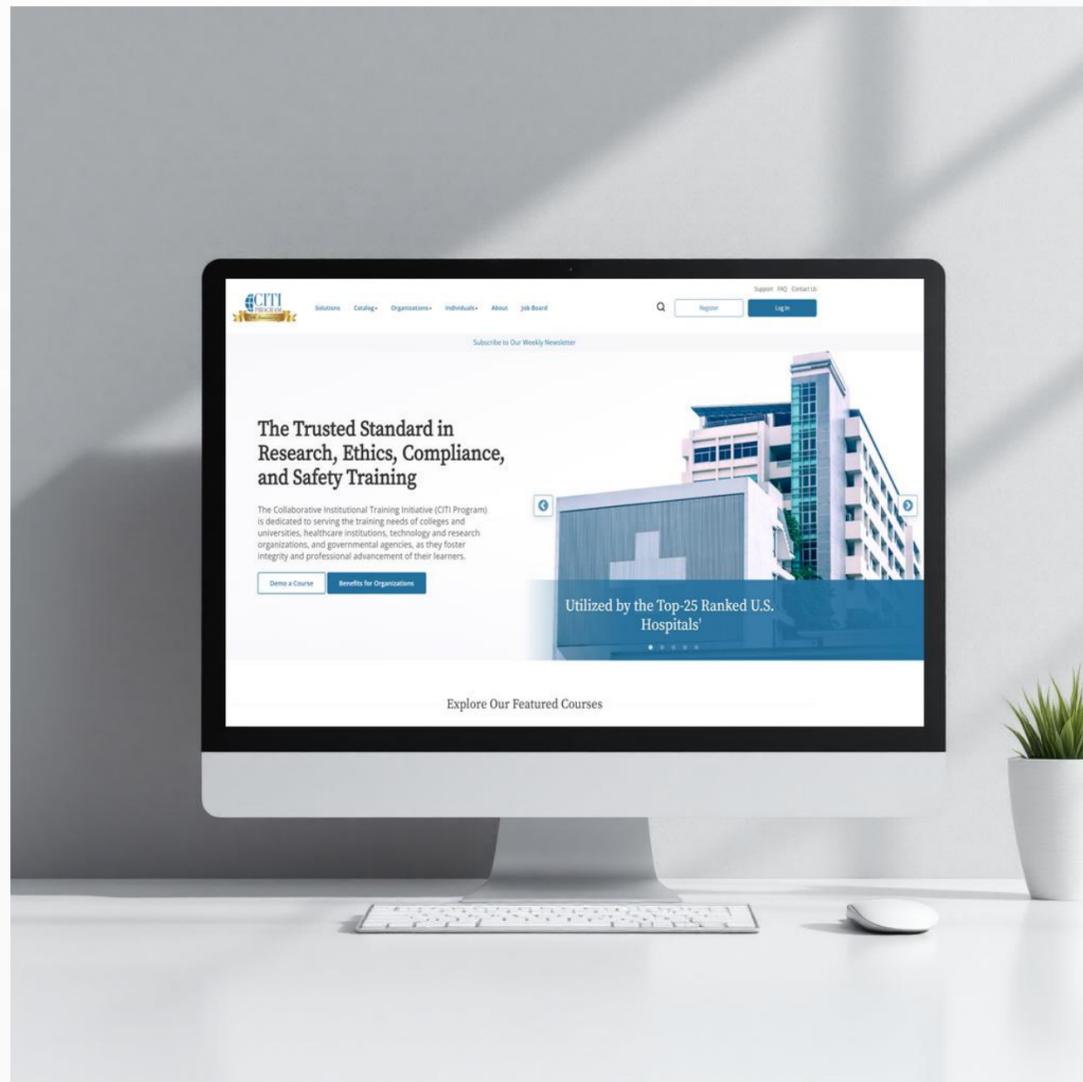
교육시간: 4H | 제공 언어 : 한국어/영어

- When a Social and Behavioral Research Study May be Considered a Clinical Trial
- Overview of ICH E6 GCP for Behavioral Interventions and Social Science Research
- Investigator's Role and Responsibilities in Behavioral Interventions and Social Science Research
- Informed Consent in Behavioral Interventions and Social Science Research
- Monitoring, Audits, Inspections, and Data and Safety Monitoring of SBR
- Korean GCP and Regulatory Requirement (한국의 임상시험관리기준 및 관련 규정)

[Additional Modules of Interset]

- Methods and Risks in Behavioral Interventions and Social Science Research
- Social Media in Behavioral Interventions and Social Science Research
- In-Depth Review of ICH E6 and TransCelerate Minimum Requirements

교육 과정 및 멤버십 문의



문의 시간 :
월~금(10시~ 17시)



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