GOOD CLINICAL PRACTICE (GCP)

Series Catalog

CITI Program's GCP series consists of three basic courses and three refresher courses.

The basic courses include:

- *GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)*
- *GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)*
- *GCP for Clinical Investigations of Devices*

The refresher courses include:

- *GCP FDA Refresher*
- *GCP ICH Refresher*
- *GCP Device Refresher*

This catalog provides a listing, description, and language availability for each module within the GCP series, as well as information on continuing education (CE) credits and how to access the series.

Subscription Information

The GCP series is available to subscribing organizations as part of the **base subscription fee**. Independent Learner registration is available for $110 USD/course. For more information on subscriptions, **click here**.

In order to meet the needs of subscribing organizations, the CITI Program can assist administrators in creating courses that best meet their organizational needs, including combining modules* from across the CITI Program. To discuss course recommendations that combine modules from different CITI Program offerings, please contact the CITI Program Help Desk at **support@citiprogram.org** or (888) 529-5929.

*Courses intended to present the principles of GCP must include all of the GCP modules within one of the CITI Program's GCP courses.

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TransCelerate Mutually Recognized GCP Training

For the following GCP courses, the 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. GCP courses are current with ICH E6 guideline, **ICH Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2**), adopted on 15 December 2016

Basic Courses

- **GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)**
- **GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)**

Refresher Courses

- **GCP FDA Refresher**
- **GCP ICH Refresher**

Translations

Spanish

- **Curso de Buenas Prácticas Clínicas (Enfocado en la FDA, Estados Unidos)**
- **Curso de Buenas Prácticas Clínicas para Ensayos Clínicos con Drogas (Enfocado en ICH**)

Portuguese

- **Curso de Boas Práticas Clínicas (Enfoque na Administração Federal Americana de Alimentos e Medicamentos)**

Basic Courses

For basic courses in the GCP series, it is highly recommended that organizations present all modules in a given course as required for a learner to earn a completion report. For more information, see the **Using CITI Program Content: Good Clinical Practice (GCP)** document.

GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)*

This course is intended for research personnel involved in drug, device, or biologic studies and who would benefit from FDA-focused training.

* 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. Organizations that wish to utilize this course in keeping with the minimum criteria must designate all available (FDA Focus) modules as "Required." GCP courses are current with ICH E6 guideline, **ICH Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2**), adopted on 15 December 2016

Continuing Education (CE) Credits and Units

View **CE credits, credit designation periods, and fees** for this course.

Module Title	Recommended Use	ID (Language)
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices	Required	1350 (English) 12149 (Spanish) 16359 (Portuguese) 16028 (Korean) 12751 (Chinese) 13440 (Thai) 13505 (French) 16558 (Vietnamese)
Overview of New Drug Development	Required	1351 (English) 12159 (Spanish) 16336 (Portuguese) 16029 (Korean) 12777 (Chinese) 13433 (Thai) 13514 (French) 16559 (Vietnamese)
Overview of ICH GCP	Required	1352 (English) 12720 (Spanish) 16337 (Portuguese) 16030 (Korean) 12779 (Chinese) 13438 (Thai) 13509 (French) 16560 (Vietnamese)

ICH – Comparison Between ICH GCP E6 and U.S. FDA Regulations	Required	1354 (English) 12153 (Spanish) 16369 (Portuguese) 16031 (Korean) 13988 (Chinese) 13442 (Thai) 13508 (French) 16259 (Khmer) 16115 (Vietnamese)
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP	Required	1355 (English) 12154 (Spanish) 16339 (Portuguese) 16032 (Korean) 12780 (Chinese) 13436 (Thai) 13507 (French) 16561 (Vietnamese)
Investigator Obligations in FDA-Regulated Clinical Research	Required	1356 (English) 12155 (Spanish) 16340 (Portuguese) 16033 (Korean) 12782 (Chinese) 13435 (Thai) 13513 (French) 16562 (Vietnamese)
Managing Investigational Agents According to GCP Requirements	Required	1357 (English) 12156 (Spanish) 16341 (Portuguese) 16034 (Korean) 13443 (Thai) 13512 (French) 16563 (Vietnamese)
Overview of U.S. FDA Regulations for Medical Devices	Required	1358 (English) 12151 (Spanish) 16342 (Portuguese) 16035 (Korean) 13925 (Chinese) 13439 (Thai) 13511 (French) 16564 (Vietnamese)
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices	Required	1359 (English) 12220 (Spanish) 16343 (Portuguese) 16036 (Korean) 13931 (Chinese) 13441 (Thai) 13510 (French) 16565 (Vietnamese)

Detecting and Evaluating Adverse Events	Required	1360 (English) 12152 (Spanish) 16367 (Portuguese) 16037 (Korean) 13930 (Chinese) 13432 (Thai) 13667 (French) 16566 (Vietnamese)
Reporting Serious Adverse Events	Required	1361 (English) 12158 (Spanish) 16345 (Portuguese) 16038 (Korean) 13934 (Chinese) 13434 (Thai) 13515 (French) 16567 (Vietnamese)
Monitoring of Clinical Trials by Industry Sponsors	Required	1362 (English) 12157 (Spanish) 16346 (Portuguese) 16039 (Korean) 12753 (Thai) 13517 (French) 16568 (Vietnamese)
Audits and Inspections of Clinical Trials	Required	1363 (English) 12150 (Spanish) 16347 (Portuguese) 16040 (Korean) 13917 (Chinese) 13444 (Thai) 13506 (French) 16569 (Vietnamese)
Completing the CITI GCP Course	Required	1364 (English) 12161 (Spanish) 16348 (Portuguese) 16041 (Korean) 13919 (Chinese) 13445 (Thai) 13548 (French) 16570 (Vietnamese)
Humanitarian Use Devices (HUDs)	Supplemental	16306 (English)
Phase I Research: Understanding Phase I Research	Supplemental	16873 (English)
Phase I Research: Protecting Phase I Subjects	Supplemental	16874 (English)

Overview of the Clinical Trial Agreement (CTA)	Supplemental	17356 (English)
Understanding the Terms of the Clinical Trial Agreement (CTA)	Supplemental	17357 (English)
Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA)	Supplemental	17358 (English)
Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites	Supplemental	17359 (English)

The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices

This module provides an overview of the GCP course along with links to the *Belmont Report*.

Overview of New Drug Development

This module describes the role of industry sponsors in the conduct of clinical trials under an investigational new drug (IND) application according to FDA regulations. It provides an overview of definitions, procedures, and timelines associated with the development of a new drug.

Overview of ICH GCP

The purpose of this module is to provide a basic understanding of the role of the ICH guidelines and the impact on conducting clinical research according to GCP. The purpose of the ICH and the basic requirements for compliance with ICH are described, including an overview of the ICH E6 GCP guidelines. This module concludes with a discussion of when the ICH GCP guidelines apply and an introduction to how these differ from the FDA regulations. GCP courses are current with ICH E6 guideline, ICH Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2), adopted on 15 December 2016

ICH – Comparison Between ICH GCP E6 and U.S. FDA Regulations

This module expands on the introduction presented in the *ICH Overview* module. The major differences between ICH guidelines and FDA regulations are presented, including critical areas such as confidentiality of medical records, signature of the person conducting the consent discussion, and impartial witnesses for illiterate subjects. This module also covers the differences between ICH GCP E6 and the FDA in terms of elements of consent.

Conducting Investigator-Initiated Studies According to FDA Regulations and GCP

This module discusses topics important to researchers who are also the sponsors of studies and thus are conducting investigator-initiated studies. Topics discussed include how to determine whether an investigational new drug (IND) application or an investigational device exemption (IDE) is required, the role of the sponsor-investigator, documentation required for INDs and IDEs, and reports that must be submitted to the FDA for active INDs/IDEs.

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Investigator Obligations in FDA-Regulated Clinical Research

This module describes the commitments and obligations assumed by investigators when they conduct industry-sponsored clinical investigations under investigational new drug (IND) requirements, including the requirements of the FDA Form 1572, Statement of Investigator. Required study records and reporting requirements continue the discussion. An overview of the investigator's relationship with the sponsor organization as well as the investigator's commitment to the subjects, the institutional review board/independent ethics committee (IRB/IEC), and the U.S. FDA are also included.

Managing Investigational Agents According to GCP Requirements

This module focuses on specific requirements associated with the management of investigational products by investigators. This includes requirements for shipping and storage of investigational agents, as well as recording the receipt, use, and final disposition of investigational agents. This module also reviews what constitutes investigational products and the management requirements for their use by study subjects.

Overview of U.S. FDA Regulations for Medical Devices

This module provides a review of the responsibilities of investigators conducting clinical research involving medical devices. It includes a discussion of the difference between significant risk and non-significant risk devices. The characteristics and marketing requirements for Class I, II, and III devices are reviewed. This module concludes with a review of investigator and institutional review board/independent ethics committee (IRB/IEC) responsibilities associated with clinical trials of medical devices and a discussion of the different options associated with early access to investigational devices in advance of FDA approval.

Informed Consent in Clinical Trials of Drugs, Biologics, and Devices

This module discusses informed consent guidelines, the required and optional elements of informed consent, and the process for obtaining informed consent. There is also a discussion of the differences between FDA and U.S. Department of Health and Human Services (HHS) regulations. Some of the challenges associated with informed consent and the concept of vulnerable subjects are also reviewed.

Detecting and Evaluating Adverse Events

This module reviews the definition of adverse events (AEs) and related clinical trial terminology. It describes the process for identifying AEs in clinical research, the issues to consider in assessing the severity and causality of AEs with examples to illustrate the evaluation process. This module also contains a discussion on determining severity and causality. Reporting of AEs to the institutional review board/independent ethics committee (IRB/IEC) completes the module.

Reporting Serious Adverse Events

This module discusses the criteria for reporting of serious adverse events (SAEs) to regulatory agencies, and sponsors. The discussion includes definitions for "serious" and "unexpected" adverse events and it reviews the requirements for the reporting of SAEs within time frames required by the FDA and the ICH. This module provides categories of relatedness to the investigational agent and how they affect reporting.

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Monitoring of Clinical Trials by Industry Sponsors

This module describes the obligation of industry research sponsors to monitor the progress of clinical trials under an investigational new drug (IND) or investigational device exemption (IDE) application in the U.S. The types of site visits conducted by industry sponsors are described, along with the basic requirements for each type of site visit. This module describes the role of the investigative site during interactions with industry sponsors as well as the requirements for recordkeeping in studies regulated by the FDA.

Audits and Inspections of Clinical Trials

This module provides a basic understanding of the monitoring, auditing, and inspecting of clinical trials conducted according to GCP standards. It describes the different entities that can inspect or audit a clinical trial, the factors that can determine whether an investigator will be audited, what the auditors and inspectors are looking for, and the results and consequences that can occur as a consequence of FDA inspection findings. Some FDA-regulated research may also involve federal funding, thereby requiring oversight by the Office for Human Research Protections (OHRP). As a result, this module includes information on OHRP compliance site visits and outcomes. The purpose of the FDA Bioresearch Monitoring Program is also discussed.

Completing the CITI GCP Course

This module summarizes the issues presented in the preceding modules.

Humanitarian Use Devices (HUDs)

This module provides a basic overview of the FDA regulations and responsibilities regarding HUDs. It describes the Humanitarian Use Device (HUD) program and Humanitarian Device Exemption (HDE) regulatory process, and explains the applicable requirements and differences between 1) a "clinical use" of a HUD to treat or diagnose patients or 2) a "HUD investigation." This module also categorizes the FDA regulations and IRB review requirements for HUD investigations within and outside of the HDE approved indications, and identifies additional federal rules or institutional requirements that may apply to the clinical use of a HUD or HUD investigations.

Phase I Research: Understanding Phase I Research

This module increases awareness of phase I research as it relates to regulatory requirements, Institutional Review Board (IRB) review, and safeguards for protecting human research subjects.

Phase I Research: Protecting Phase I Subjects

This module identifies ways in which researchers and staff involved in phase I research can apply the necessary safeguards to protect subjects involved in phase I research.

Overview of the Clinical Trial Agreement (CTA)

Discusses the general purpose of a CTA, roles and responsibilities of parties to the CTA, and how the CTA fits into the research enterprise. The module also compares and contrasts clinical trials involving drugs, biologics, and devices from a CTA perspective.

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Understanding the Terms of the Clinical Trial Agreement (CTA)

Provides an overview of the context behind certain CTA terms and sections, types of language used for CTA sections, and some key elements of each section. The module also outlines what should be addressed in the key sections of the CTA and the aim for each section.

Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA)

Discusses key roles of the researcher and site in managing the CTA, including initial assessment, review, and implementation. The module also describes how the CTA is linked to site policies, the protocol, and the informed consent form, and identifies key sections of the CTA that could present risk to the site.

Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites

Addresses strategies and preparation for CTA and study budget negotiations. The module also identifies terminology and alternative wording options to ensure a fair and balanced CTA.

GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)*

This course is intended for research personnel involved in drug and biologic studies and who would benefit from a more internationally focused training. It should be noted, however, that when appropriate, references to U.S. Food and Drug Administration (FDA) regulations and guidance are included.

* 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. Organizations that wish to utilize this course in keeping with the minimum criteria must designate all available (ICH Focus) modules as "Required." GCP courses are current with ICH E6 guideline, **ICH Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2**), adopted on 15 December 2016

Continuing Education (CE) Credits and Units

View **CE credits, credit designation periods, and fees** for this course.

Module Title	Recommended Use	ID (Language)
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Biologics	Required	14613 (English) 15273 (Spanish) 16359 (Portuguese) 16052 (Korean)
Overview of New Drug Development	Required	14621 (English) 15280 (Spanish) 16059 (Korean)
Overview of ICH GCP	Required	14622 (English) 15281 (Spanish) 16366 (Portuguese) 16060 (Korean)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations	Required	14625 (English) 15282 (Spanish) 16369 (Portuguese) 16061 (Korean)
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP	Required	14614 (English) 15274 (Spanish) 16360 (Portuguese) 16053 (Korean)
Investigator Obligations in FDA-Regulated Research	Required	14615 (English) 15275 (Spanish) 16361 (Portuguese) 16054 (Korean)
Managing Investigational Agents According to GCP Requirements	Required	14617 (English) 15276 (Spanish) 16362 (Portuguese) 16055 (Korean)

Informed Consent in Clinical Trials of Drugs and Biologics	Required	14618 (English) 15277 (Spanish) 16363 (Portuguese) 16056 (Korean)
Monitoring Clinical Trials of Drugs by Industry Sponsors	Required	14619 (English) 15278 (Spanish) 16364 (Portuguese) 16057 (Korean)
Audits and Inspections of Clinical Trials of Drugs and Biologics	Required	14620(English) 15279 (Spanish) 16365 (Portuguese) 16058 (Korean)
Detecting and Evaluating Adverse Events	Required	14623 (English) 15283 (Spanish) 16367 (Portuguese) 16062 (Korean)
Reporting Serious Adverse Events in Investigations of Drugs and Biologics	Required	14624 (English) 15284 (Spanish) 16368 (Portuguese) 16063 (Korean)
Completing the CITI GCP Course	Required	14626 (English) 15285 (Spanish) 16370 (Portuguese) 16064 (Korean)
Phase I Research: Understanding Phase I Research	Supplemental Note: This module does not hold CE credit designation.	16873 (English)
Phase I Research: Protecting Phase I Subjects	Supplemental Note: This module does not hold CE credit designation.	16874 (English)
Overview of the Clinical Trial Agreement (CTA)	Supplemental	17356 (English)
Understanding the Terms of the Clinical Trial Agreement (CTA)	Supplemental	17357 (English)
Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA)	Supplemental	17358 (English)
Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites	Supplemental	17359 (English)

The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Biologics

This module provides an overview of the GCP course along with links to the *Belmont Report*.

Overview of New Drug Development

This module describes the role of industry sponsors in the conduct of clinical trials under an investigational new drug (IND) application according to FDA regulations. It provides an overview of definitions, procedures, and timelines associated with the development of a new drug.

Overview of ICH GCP

The purpose of this module is to provide a basic understanding of the role of the ICH guidelines and the impact on conducting clinical research according to GCP. The purpose of the ICH and the basic requirements for compliance with ICH are described, including an overview of the ICH E6 GCP guidelines. This module concludes with a discussion of when the ICH GCP guidelines apply and an introduction to how these differ from the FDA regulations. GCP courses are current with ICH E6 guideline, ICH Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2), adopted on 15 December 2016

ICH – Comparison Between ICH GCP E6 and U.S. FDA Regulations

This module expands on the introduction presented in the *ICH Overview* module. The major differences between ICH guidelines and FDA regulations are presented, including a discussion of specific areas such as confidentiality of medical records, signature of person conducting the consent discussion, impartial witnesses for illiterate subjects, and the elements of informed consent.

Conducting Investigator-Initiated Studies According to FDA Regulations and GCP

Medical research is important and investigators strive to find novel therapies, new drugs, and modifications or new uses for existing drugs. This module introduces the requirements that must be met to conduct investigator-initiated trials of investigational drugs. This module provides an overview of when an investigational new drug (IND) application must be filed, the information that must be provided, and the requirements for monitoring of clinical trials. Given ICH E6 as a standard for the elements of clinical research including design, conduct, performance, monitoring, and auditing, this module provides a discussion as to the purposes of monitoring and summarizes its components.

Investigator Obligations in FDA-Regulated Research

When investigators participate in an industry-sponsored clinical investigation, they assume certain professional and legal obligations. Investigators, therefore, must understand the study and regulatory requirements to ensure the successful outcome of a clinical investigation. This module provides an overview of investigator commitments and obligations, and it summarizes the investigator's relationship with the industry-sponsor. Particular attention is focused on two aspects of the sponsor's site assessments covered by ICH guidelines: adequate resources and medical care of trial subjects. Reporting and record-retention are also included, with applicable references to both FDA and ICH requirements.

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Managing Investigational Agents According to GCP Requirements

GCP standards require specific management of investigational products by principal investigators. Definitions and information related to the requirements for the use of investigational products, as defined by the FDA and ICH, are presented as a basis for this module. ICH requirements associated with investigator control continues the discussion. This module concludes with sections on shipping, storage, dispensing, and final disposition of investigational agents.

Informed Consent in Clinical Trials of Drugs and Biologics

This module discusses the informed consent guidelines (as reflected in both FDA regulations and ICH guidelines), which set the required and additional elements of informed consent. This module also includes a discussion of the documentation of consent with specific discussion on the role of legally authorized representatives. Some of the challenges associated with informed consent and the concept of vulnerable subjects are also covered, including issues related to subjects who cannot consent and the exceptions to the informed consent requirements.

Monitoring Clinical Trials of Drugs by Industry Sponsors

U.S. federal regulations and ICH guidelines require that sponsors of clinical research monitor the studies of investigational drugs to ensure that they comply with standards for the protection of human research subjects. This module describes the obligation of industry sponsors to monitor the progress of clinical trials under an investigational new drug (IND) application as well as the requirements for site record-keeping in studies that are regulated by the U.S. FDA and in adherence to ICH E6. GCP courses are current with ICH E6 guideline, ICH Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2), adopted on 15 December 2016

Audits and Inspections of Clinical Trials of Drugs and Biologics

This module provides basic information on monitoring, audits, and inspections of clinical trials conducted according to standards for GCP. It describes the different entities that can inspect or audit a clinical trial, the factors that can determine whether an investigator will be audited, what the auditors and inspectors are looking for, and the results and consequences that can occur as a result of FDA inspection findings. Regulatory documents reviewed during inspections are presented and referenced to FDA and ICH GCP requirements.

Detecting and Evaluating Adverse Events

This module provides a review of the definition of adverse events (AEs) and related clinical trial terminology in accordance with ICH guidelines. It describes the process for identifying AEs in clinical research and identifies the factors to consider in assessing the severity and causality of AEs. Examples are provided to illustrate the evaluation process. This module also includes discussion on determining AE severity and causality, and the reporting of AEs to IRBs.

Reporting Serious Adverse Events in Investigations of Drugs and Biologics

This module discusses the criteria for reporting serious adverse events (SAEs) to regulatory agencies, and sponsors. The discussion, framed by both FDA regulations and ICH guidelines, includes definitions for "serious" and "unexpected" adverse events (AEs), and the time frames for the reporting of SAEs. This module provides categories of relatedness to the investigational agent and how they affect reporting.

(continued)

Completing the CITI GCP Course

This module summarizes the issues presented in the preceding modules.

Phase I Research: Understanding Phase I Research

This module increases awareness of phase I research as it relates to regulatory requirements, Institutional Review Board (IRB) review, and safeguards for protecting human research subjects.

Phase I Research: Protecting Phase I Subjects

This module identifies ways in which researchers and staff involved in phase I research can apply the necessary safeguards to protect subjects involved in phase I research.

Overview of the Clinical Trial Agreement (CTA)

Discusses the general purpose of a CTA, roles and responsibilities of parties to the CTA, and how the CTA fits into the research enterprise. The module also compares and contrasts clinical trials involving drugs, biologics, and devices from a CTA perspective.

Understanding the Terms of the Clinical Trial Agreement (CTA)

Provides an overview of the context behind certain CTA terms and sections, types of language used for CTA sections, and some key elements of each section. The module also outlines what should be addressed in the key sections of the CTA and the aim for each section.

Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA)

Discusses key roles of the researcher and site in managing the CTA, including initial assessment, review, and implementation. The module also describes how the CTA is linked to site policies, the protocol, and the informed consent form, and identifies key sections of the CTA that could present risk to the site.

Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites

Addresses strategies and preparation for CTA and study budget negotiations. The module also identifies terminology and alternative wording options to ensure a fair and balanced CTA.

GCP for Clinical Investigations of Devices

This course is intended for research personnel involved in drug and biologic studies and who would benefit from a more internationally focused training. It should be noted, however, that when appropriate, references to FDA regulations and guidance as well as International Organization for Standardization Guidelines ISO 14155:2011 are included.

Continuing Education (CE) Credits and Units

View **CE credits, credit designation periods, and fees** for this course.

Module Title	Recommended Use	ID (Language)
The CITI Good Clinical Practice Course for Clinical Investigations Involving Devices	Required	14633 (English) 15286 (Spanish) 16349 (Portuguese) 16042 (Korean)
Overview of U.S. FDA Regulations for Investigational Devices	Required	14637 (English) 15290 (Spanish) 16353 (Portuguese) 16046 (Korean)
Investigator Obligations in FDA-Regulated Clinical Investigations of Devices	Required	14635 (English) 15288 (Spanish) 16351 (Portuguese) 16044 (Korean)
Conducting Investigator-Initiated Clinical Investigations of Devices	Required	14634 (English) 15287 (Spanish) 16350 (Portuguese) 16043 (Korean)
Managing Investigational Devices According to GCP Requirements	Required	14636 (English) 15289 (Spanish) 16352 (Portuguese) 16045 (Korean)
Informed Consent in Clinical Investigations of Devices	Required	14638 (English) 15291 (Spanish) 16354 Portuguese) 16047 (Korean)
Monitoring Clinical Investigations of Devices	Required	14639 (English) 15292 (Spanish) 16355 (Portuguese) 16048 (Korean)
Audits and Inspections of Clinical Investigations of Devices	Required	14640 (English) 15293 (Spanish) 16356 (Portuguese) 16049 (Korean)
Reporting Requirements for Clinical Investigations of Devices	Required	14641 (English) 15294 (Spanish) 16357 (Portuguese) 16050 (Korean)

Completing the CITI Program's GCP Course for Clinical Investigations of Devices	Required	14642(English) 15295 (Spanish) 16358 (Portuguese) 16051 (Korean)
Humanitarian Use Devices (HUDs)	Supplemental Note: This module does not hold CE credit designation.	16306 (English)
Overview of the Clinical Trial Agreement (CTA)	Supplemental	17356 (English)
Understanding the Terms of the Clinical Trial Agreement (CTA)	Supplemental	17357 (English)
Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA)	Supplemental	17358 (English)
Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites	Supplemental	17359 (English)

The CITI Good Clinical Practice Course for Clinical Investigations Involving Devices

This module provides an overview of the GCP for Clinical Investigations Involving Devices course along with links to the *Belmont Report*.

Overview of U.S. FDA Regulations for Investigational Devices

This module reviews the responsibilities of investigators conducting clinical research involving medical devices. It includes a discussion of the difference between significant risk (SR) and non-significant risk (NSR) devices. The characteristics and marketing requirements for Class I, II, and III devices are reviewed. This module concludes with a review of investigator and institutional review board/independent ethics committee (IRB/IEC) responsibilities associated with clinical trials of medical devices and a discussion of the different options associated with early access to investigational devices in advance of FDA approval.

Investigator Obligations in FDA-Regulated Clinical Investigations of Devices

Investigators assume responsibilities when participating in clinical investigations sponsored by device companies under investigational device exemption (IDE) requirements. This module describes the commitments and obligations assumed by investigators. Required study records and reporting requirements continue the discussion. An overview of the investigator's relationship with the sponsor organization as well as the investigator's commitment to the subjects, the institutional review board/independent ethics committee (IRB/IEC), and the FDA is also included.

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Conducting Investigator-Initiated Clinical Investigations of Devices

This module discusses topics relevant to researchers who are also the sponsors of studies, i.e., investigator-initiated device studies. Topics discussed include significant risk (SR) and non-significant risk (NSR) device studies, sponsor-investigator investigational device exemptions (IDEs), and reporting requirements.

Managing Investigational Devices According to GCP Requirements

This module focuses on specific requirements associated with the management of investigational products by principal investigators, with a specific focus on GCP standards. This module includes a discussion of the regulation of studies involving investigational devices, including sponsor requirements for selecting investigators, investigator control of devices, packaging and shipping, and storage of devices.

Informed Consent in Clinical Investigations of Devices

This module discusses the informed consent guidelines, the required and optional elements of informed consent and the process for obtaining informed consent. There is also a discussion of the differences between FDA and U.S. Department of Health and Human Services (HHS) regulations. Challenges associated with informed consent and the concept of vulnerable subjects is also covered.

Monitoring Clinical Investigations of Devices

This module describes the obligation of industry research sponsors to monitor the progress of clinical trials under an investigational device exemption (IDE) in the U.S. The types of site visits conducted by industry sponsors are described along with the basic requirements for each type of site visit. The role of the investigative site during interactions with industry sponsors as well as the required documentation and a review of record keeping in studies regulated by the FDA are also covered.

Audits and Inspections of Clinical Investigations of Devices

This module provides a basic understanding of monitoring, audits, and inspections of clinical trials conducted according to standards for GCP. It describes the different entities that can inspect or audit a clinical trial, the factors that can determine whether an investigator will be audited, what the auditors and inspectors are looking for, and the results and consequences that can stem from FDA inspection findings. Because some FDA-regulated research may involve federal funds there may also be Office for Human Research Protections (OHRP) oversight. As a result, the module includes an overview of OHRP compliance site visits and outcomes. The purpose of the FDA Bioresearch Monitoring Program is also discussed.

Reporting Requirements for Clinical Investigations of Devices

The use of investigational devices can pose significant risks to subjects, and the FDA requires reporting of certain events to ensure that all entities are adequately informed when new risks appear. This module explains the reporting requirements of 21 CFR 812, the FDA regulations for the conduct of investigational device studies.

Completing the CITI Program's GCP Course for Clinical Investigations of Devices

This module summarizes the issues presented in its preceding modules.

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Humanitarian Use Devices (HUDs)

This module provides a basic overview of the FDA regulations and responsibilities regarding HUDs. It describes the Humanitarian Use Device (HUD) program and Humanitarian Device Exemption (HDE) regulatory process, and explains the applicable requirements and differences between 1) a "clinical use" of a HUD to treat or diagnose patients or 2) a "HUD investigation." This module also categorizes the FDA regulations and IRB review requirements for HUD investigations within and outside of the HDE approved indications, and identifies additional federal rules or institutional requirements that may apply to the clinical use of a HUD or HUD investigations.

Overview of the Clinical Trial Agreement (CTA)

Discusses the general purpose of a CTA, roles and responsibilities of parties to the CTA, and how the CTA fits into the research enterprise. The module also compares and contrasts clinical trials involving drugs, biologics, and devices from a CTA perspective.

Understanding the Terms of the Clinical Trial Agreement (CTA)

Provides an overview of the context behind certain CTA terms and sections, types of language used for CTA sections, and some key elements of each section. The module also outlines what should be addressed in the key sections of the CTA and the aim for each section.

Role of the Researcher and Site in Managing the Clinical Trial Agreement (CTA)

Discusses key roles of the researcher and site in managing the CTA, including initial assessment, review, and implementation. The module also describes how the CTA is linked to site policies, the protocol, and the informed consent form, and identifies key sections of the CTA that could present risk to the site.

Clinical Trial Agreement (CTA) Negotiation for Researchers and Sites

Addresses strategies and preparation for CTA and study budget negotiations. The module also identifies terminology and alternative wording options to ensure a fair and balanced CTA.

Refresher Courses

For the GCP refresher courses, it is highly recommended that organizations present all modules in a given course as required for a learner to earn a completion report. For more information, see the **Using CITI Program Content: Good Clinical Practice (GCP)** document.

GCP FDA Refresher*

This course is meant to reinforce the importance of concepts covered in the basic level *GCP for Clinical Trials with Investigational Drugs and Medical Devices (U.S. FDA Focus)* course.

* 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. Organizations that wish to utilize this course in keeping with the minimum criteria must designate all available (FDA Focus) modules as "Required." GCP courses are current with ICH E6 guideline, **ICH Integrated Addendum to ICH E6 (R1): Guideline for Good Clinical Practice E6 (R2**), adopted on 15 December 2016

Module Title	Recommended Use	ID (Language)
GCP Refresher - International Conference on Harmonisation (ICH): GCP Requirements	Required	16779 (English) 17371 (Spanish)
GCP Refresher - Investigator's Responsibilities and GCP	Required	16780 (English) 17372 (Spanish)
GCP Refresher - Informed Consent	Required	16781 (English) 17373 (Spanish)
GCP Refresher - Safety Management	Required	16782 (English) 17374 (Spanish)
GCP Refresher - Investigational Product (Drug) Management	Required	16783 (English) 17375 (Spanish)
GCP Refresher - Audits, Inspection, and Monitoring of Research Studies	Required	16784 (English) 17376 (Spanish)
GCP Refresher - Sponsor Responsibilities and GCP	Required	16785 (English) 17377 (Spanish)
GCP Refresher - Conducting Clinical Investigations of Devices	Required	17205 (English) 17362 (Spanish)
GCP Refresher - Review of U.S. FDA Regulations for Investigational Devices	Required	17206 (English) 17363 (Spanish)
GCP Refresher - Additional GCP Standards for International Clinical Investigations of Devices	Required	17207 (English) 17364 (Spanish)

GCP Refresher - Informed Consent and Exceptions to the Requirement for Obtaining Consent for Clinical Investigations of Devices	Required	17208 (English) 17365 (Spanish)
GCP Refresher - Oversight of Clinical Investigations of Devices	Required	17209 (English) 17366 (Spanish)
GCP Refresher - Reporting Requirements for Clinical Investigations of Devices	Required	17210 (English) 17367 (Spanish)

GCP Refresher - International Conference on Harmonisation (ICH): GCP Requirements

This module provides a basic understanding of the ICH's role and impact on conducting clinical research according to GCP. It describes the purpose of ICH and identifies the basic requirements for compliance with ICH GCP.

GCP Refresher - Investigator's Responsibilities and GCP

This module provides an overview of the investigator's role and responsibilities when conducting clinical research. It reviews regulatory requirements and GCP E6 guidelines for the investigator.

GCP Refresher - Informed Consent

This module provides an overview of informed consent in clinical research. It describes the requirements for complying with the informed consent regulations, the process for obtaining informed consent, and the regulations for waiving informed consent.

GCP Refresher - Safety Management

This module provides an overview of safety management in clinical research. It defines adverse events and related terminology, describes the process for identifying events, and describes the investigator's requirements regarding recording/documenting and reporting events.

GCP Refresher - Investigational Product (Drug) Management

This module describes an investigator's responsibilities when using investigational products according to GCP standards. It covers the management requirements for the use of investigational products and the requirements for storage and handling of drugs in clinical trials.

GCP Refresher - Audits, Inspection, and Monitoring of Research Studies

This module reviews auditing, inspections, and monitoring of drug studies in clinical research.

GCP Refresher - Sponsor Responsibilities and GCP

This module provides an overview of the sponsor's role and responsibilities in complying with GCP guidelines and applicable regulations. It reviews the similarities and differences between the roles of a sponsor and sponsor-investigator.

GCP Refresher - Conducting Clinical Investigations of Devices

This module identifies investigator responsibilities in clinical investigations, discusses federal regulatory requirements and international guidelines for investigational trials of devices. It also identifies what documents and reports are due to the U.S. and international regulatory authorities, and describes the role of a sponsor-investigator in a clinical investigation of a medical device.

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GCP Refresher - Review of U.S. FDA Regulations for Investigational Devices

This module describes the U.S. regulatory requirements for various classes and categories of medical devices and explain the differences between significant risk (SR), non-significant risk (NSR), humanitarian, and exempt medical devices.

GCP Refresher - Additional GCP Standards for International Clinical Investigations of Devices

This module discusses the international standards that address Good Clinical Practice (GCP) for the design, conduct, recording, and reporting of clinical investigations of devices involving human subjects to assess their safety and/or performance. Further, it describes the ISO 14155:2011 GCP standard and compares the ISO 14155:2011 GCP standard to the FDA regulations.

GCP Refresher - Informed Consent and Exceptions to the Requirement for Obtaining Consent for Clinical Investigations of Devices

This module describes the general requirements for obtaining and documenting informed consent, including orally without obtaining a signature on the consent form. It also describes the exception to the requirements for emergency use and emergency research and to the requirements for investigations of *in vitro* diagnostic assays.

GCP Refresher - Oversight of Clinical Investigations of Devices

This module describes the oversight of clinical investigations of medical devices in the U.S. and internationally.

GCP Refresher - Reporting Requirements for Clinical Investigations of Devices

This module explains the reporting requirements of 21 CFR 812 (Investigational Device Exemptions 2015) which is the FDA regulations for the conduct of clinical investigations of devices (21 CFR 812) and International Organization for Standardization (ISO) 14155:2011 - *Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice*, which is the international standard for the conduct of investigations of devices).

GCP ICH Refresher*

This course is meant to reinforce the importance of concepts covered in the basic level *GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)* course.

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Continuing Education (CE) Credits and Units

View **CE credits, credit designation periods, and fees** for this course.

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This module provides an overview of the sponsor's role and responsibilities in complying with GCP guidelines and applicable regulations. It reviews the similarities and differences between the roles of a sponsor and sponsor-investigator.

GCP Device Refresher

This course is meant to reinforce the importance of concepts covered in the basic level *GCP for Clinical Investigations of Devices* course. This course covers FDA regulation as well as International Organization for Standardization Guidelines ISO 14155:2011.

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