

FAQ – Updating GCP Training to ICH GCP E6 R3

FAQ Contents

1. How to update previously completed GCP training to ICH GCP E6 R3 on CITI
 - A. Completed CITI GCP (with Valid Expiry) Pg 1
 - B. Completed CITI GCP (Expired).....Pg 3
2. Alternative training method..... Pg 4
3. How to upload updated CITI completion report onto ECOS profile.. Pg 5

1. How to update previously completed GCP training to ICH GCP E6 R3

A. Completed CITI GCP (with Valid Expiry)

- 1) Login to CITI (<https://about.citiprogram.org/>)
- 2) Locate the GCP course or module that you need to review. This should be listed in the "My Courses" section of your account dashboard. (If you are affiliated with multiple organizations, please ensure you are selecting the proper "View Courses" button next to your desired affiliation).
- 3) Click on "Review Course" button next to the course title to see the module content, you can then select the "Review" button next to any module to begin retaking the quiz/exam.
If you have started the course but have not completed all required modules, you can navigate into the course as normal by selecting the "Continue Course" button - then select the "Review" button beside previously completed modules to retake the associated quiz/exam.

Completed Courses

[Learner Tools](#)


National Healthcare Group Pte Ltd.

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

Stage 1 - Independent Learner

[Post-Course Survey](#) ⓘ

Passed 03-Feb-2020

Not Earned 

[Review Course](#) [View - Print - Share Record](#)

- 4) Click on "Review" to retake the module.

Please review all the modules that have been updated with R3 updates and



are tagged with the “Updated” logo.

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

Course Content

- + 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
- + Managing Investigational Products 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

Updated modules

- Investigator Obligations (ID: 14615)
- Informed Consent in Clinical Trials of Drugs and Biologics (ID: 14618)
- Audits and Inspections of Clinical Trials of Drugs and Biologics (ID: 14620)
- Reporting Serious Adverse Events in Investigations of Drugs and Biologics (ID: 14624)

Ref: [GCP for Clinical Investigations of Drugs and Biologics \(ICH\)](#)

Please note that you will not be able to view the “Updated” logo within the actual course.

Required Modules

Complete all 13 required modules.

Modules	Completed	Score	
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Biologics (ID 14613)	Incomplete	-	Start
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID 14614)	Incomplete	-	Start
Investigator Obligations (ID 14615)	Incomplete	-	Start
Managing Investigational Agents According to GCP Requirements (ID 14617)	Incomplete	-	Start
Informed Consent in Clinical Trials of Drugs and Biologics (ID 14618)	Incomplete	-	Start
Monitoring Clinical Trials of Drugs by Industry Sponsors (ID 14619)	Incomplete	-	Start
Audits and Inspections of Clinical Trials of Drugs and Biologics (ID 14620)	Incomplete	-	Start
Overview of New Drug Development (ID 14621)	Incomplete	-	Start
Overview of ICH GCP (ID 14622)	Incomplete	-	Start
ICH—Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID 14625)	Incomplete	-	Start
Detecting and Evaluating Adverse Events (ID 14623)	Incomplete	-	Start
Reporting Serious Adverse Events in Investigations of Drugs and Biologics (ID 14624)	Incomplete	-	Start
Completing the CITI GCP Course (ID 14626)	Incomplete	-	Start


- 5) To download updated completion report, click on “View – Print Share Record” and “View/Print” under Completion report. Upload completion report on ECOS profile

Completed Courses

[Learner Tools](#)

National Healthcare Group Pte Ltd.
GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)
Stage 1 - Independent Learner
[Post-Course Survey](#) ⓘ

Passed 03-Feb-2020


Not Earned 

[Review Course](#) [View - Print - Share Record](#)

Completion Report

Completion Reports are transcripts of your course work, and include all quiz scores. Part 1 shows scores "frozen" at the time you completed and passed the course. Part 2 reflects scores for any subsequent quiz attempts.


View / Print


Copy Link 

Completion Certificate

Completion Certificates are "diplomas" that reflect course completion, but do not include quiz scores. Certificates are suitable for sharing with persons who do not need to see your quiz results, or posting online.

View / Print

Copy Link 

 Add to LinkedIn

B. Completed CITI GCP (Expired)

- 1) Locate the GCP course or module that you need to review. This should be listed in the "My Courses" section of your account dashboard. (If you are affiliated with multiple organizations, please ensure you are selecting the proper "View Courses" button next to your desired affiliation).
- 2) If the GCP certificate has expired, it would trigger the Refresher course. Please review all the modules that have been updated with R3 updates and are tagged with the "New" logo.

Course: GCP ICH Refresher

Course Content



GCP Refresher - International Conference on 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


Ref: [GCP ICH Refresher | CITI Program](#)

- 3) To download updated completion report, click on “View – Print Share Record” and “View/Print” under Completion report. Upload completion report on ECOS profile.

Completed Courses

[Learner Tools](#)

National Healthcare Group Pte Ltd.
GCP for Clinical Trials with Investigational Drugs and Biologics (ICH Focus)
Stage 1 - Independent Learner
[Post-Course Survey](#) ⓘ
Passed 03-Feb-2020

Not Earned 

[Review Course](#) [View - Print - Share Record](#)

Completion Report


Completion Reports are transcripts of your course work, and include all quiz scores. Part 1 shows scores “frozen” at the time you completed and passed the course. Part 2 reflects scores for any subsequent quiz attempts.

[View / Print](#) [Copy Link](#) ⓘ

Completion Certificate

Completion Certificates are “diplomas” that reflect course completion, but do not include quiz scores. Certificates are suitable for sharing with persons who do not need to see your quiz results, or posting online.

[View / Print](#) [Copy Link](#) ⓘ

 [Add to LinkedIn](#)

2. Alternative training method

Users are recommended to complete the updated CITI GCP R3 course.

Alternatives:

For those who had completed a GCP course which does not include ICH E6 (R3) Guideline:

(1) Self-read the ICH E6 (R3) GCP updates or view the [HSA Webinar recordings](#)), and

(2) Maintain a record of the ICH E6 (R3) GCP updates self-training, via documentation in a training log, to be filed in the Investigator File.












Example of self-training record (SAMPLE_ICH E6 (R3) GCP Training Record)

3. How to upload updated CITI completion report onto ECOS profile


- 1) Login to ECOS and click on user profile.
- 2) Scroll to Minimum Training Certificates section.

- 3) Click on the  icon to under the GCP training entry.

Minimum Training Certificates ⓘ
Note: Meet the minimum training requirement to conduct: ✓ Clinical Trials, Non-HBR, SBER + Add

Cluster	Name of Training Certification	File Name	Training Completion Date	Expiry Date	Validity Date	Action
National Healthcare Group	HBR Minimum Training	HBR ERC cert.pdf	02-Sep-2024	-	Permanent	 
National Healthcare Group	GCP	GCP - The Global Health Network.pdf	11-Jul-2021	-	Permanent	 
National Healthcare Group	CITI SBE	NHG Biomedical CITI.pdf	29-Jul-2022	-	Permanent	
National Healthcare Group	CITI FCOI	Test FCOI CITI.docx	01-Apr-2024	28-Apr-2026	Permanent	 
National Healthcare Group	CITI Biomed	NHG Biomedical CITI.pdf	01-Apr-2024	-	Permanent	 

- 4) Click on "Upload" to upload updated completion report and click on "Submit".

TTSH_User_ID02
Salutation: Dr 


No Record


Minimum Training Certificates ⓘ
Note: Meet the minimum training requirement to conduct: ✓ Clinical Trials, Non-HBR, SBER


Cluster	Name of Training Certification	File Name	Training Completion Date	Expiry Date
National Healthcare Group	HBR Minimum Training	HBR ERC cert.pdf	02-Sep-2024	-
National Healthcare Group	GCP	GCP - The Global Health Network.pdf	11-Jul-2021	-
National Healthcare Group	CITI SBE	NHG Biomedical CITI.pdf	29-Jul-2022	-
National Healthcare Group	CITI FCOI	Test FCOI CITI.docx	01-Apr-2024	28-Apr-2026
National Healthcare Group	CITI Biomed	NHG Biomedical CITI.pdf	01-Apr-2024	-


Certificate Detail X Close Save Submit

* Name of Training Certification
GCP

* File Name
[GCP - The Global Health Network.pdf](#) 

 Upload

* Training Completion Date
11-Jul-2021 

Expiry Date
Select date 

- 5) The completion report will be sent your institution's Minimum Training Secretariat for review. Please contact your institution for enquiries on training status.