

FAQ – Updating GCP Training to ICH GCP E6 R3

FAQ Contents

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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 CME/CEU logo.



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

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 in FDA-Regulated Research (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

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Not Earned 

Completion Report	Completion Certificate
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.	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	View / Print Copy Link
	in 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 CME/CEU logo.



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

Required Modules


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Completed Courses

[Learner Tools](#)

National Healthcare Group Pte Ltd.
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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](#)

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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.



SAMPLE_ICH E6 (R3)
GCP Training Record

Example of self-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 [✕](#) [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.