FAQ - Updating GCP Training to ICH GCP E6 R3

FAQ Contents

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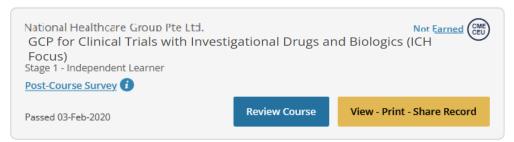
1. How to update previously completed GCP training to ICH GCP E6 R3

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





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 (New D
+ Overview of ICH GCP (CH)
+ ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations
+ Conducting Investigator-Initiated Studies According to FDA Regulations and GCP
+ Investigator Obligations (CAE) (CRI)
Managing Investigational Products According to GCP Requirements (CAR)
+ Informed Consent in Clinical Trials of Drugs and Biologics (31)
+ Monitoring Clinical Trials of Drugs by Industry Sponsors (CH)
+ Audits and Inspections of Clinical Trials of Drugs and Biologics (SE)
+ Detecting and Evaluating Adverse Events (SH)
+ Reporting Serious Adverse Events in Investigations of Drugs and Biologics (CAR)
Completing the CITI GCP Course

Updated modules

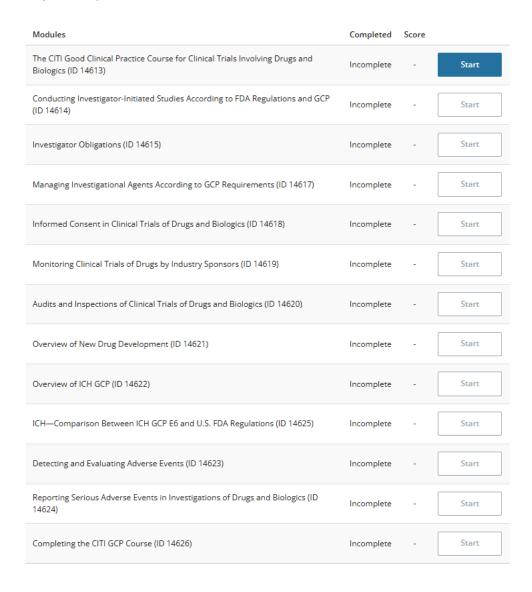
- Investigator Obligations (ID: 14615)
- Informed Consent in Clinical Trials of Drugs and Biologics (ID: 14618)
- Audits and Inspections of Clinical Trials of Drugs and Biologics (ID: 14620)
- Reporting Serious Adverse Events in Investigations of Drugs and Biologics (ID: 14624)

Ref: GCP for Clinical Investigations of Drugs and Biologics (ICH)

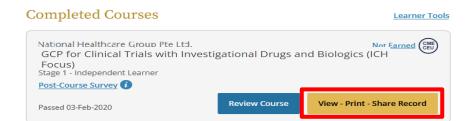
Please note that you will not be able to view the "Updated" logo within the actual course.

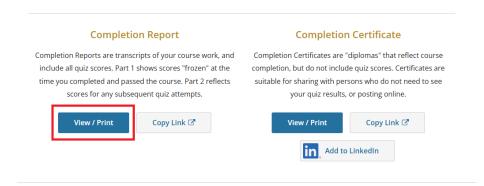
Required Modules

Complete all 13 required modules.



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

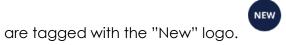




B. Completed CITI GCP (Expired)

- 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

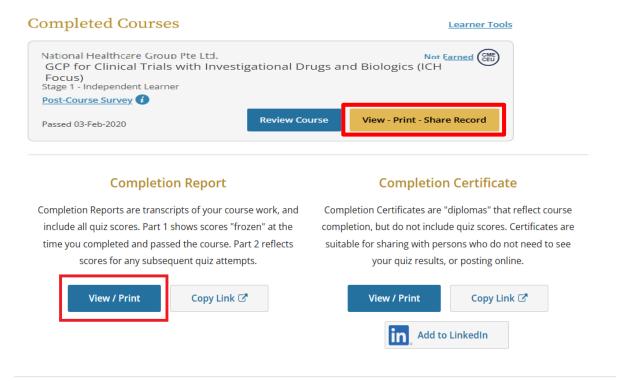


Course: GCP ICH Refresher



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.



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:

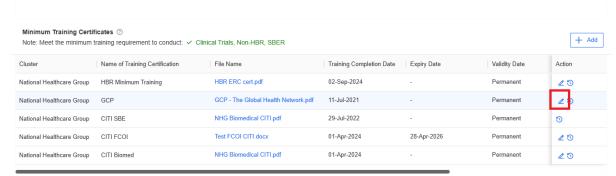
- (1) Self-read the ICH E6 (R3) GCP updates or view the <u>HSA Webinar</u> recordings), and
- (2) Maintain a record of the ICH E6 (R3) GCP updates self-training, via documentation in a training log, to be filed in the Investigator File.



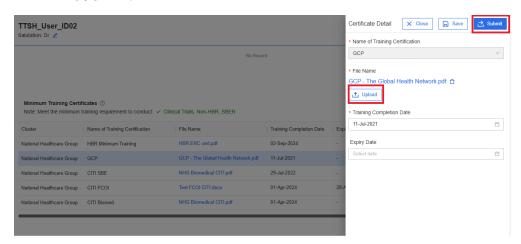
Example of self-training record (GCP Training Record)

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.



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



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