FAQ - Updating GCP Training to ICH GCP E6 R3

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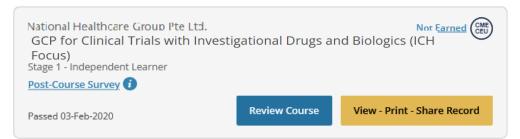
1. How to update previously completed GCP training to ICH GCP E6 R3

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

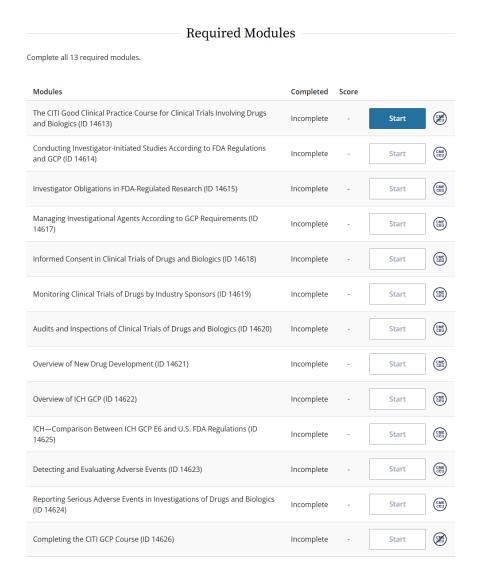
Learner Tools



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)



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)

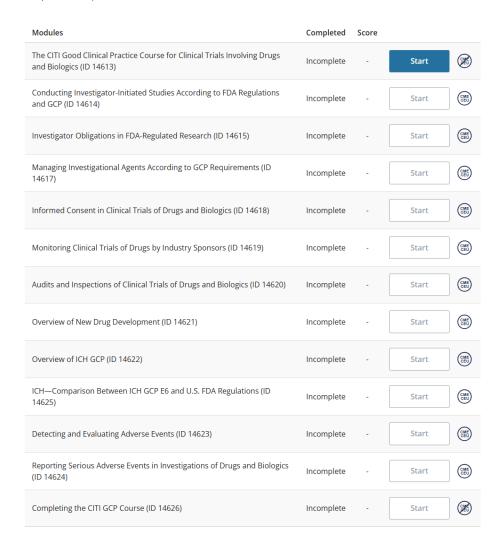
- 1) Locate the GCP course or module that you need to review. This should be listed in the "My Courses" section of your account dashboard. (If you are affiliated with multiple organizations, please ensure you are selecting the proper "View Courses" button next to your desired affiliation).
- 2) If the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



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





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 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.



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:

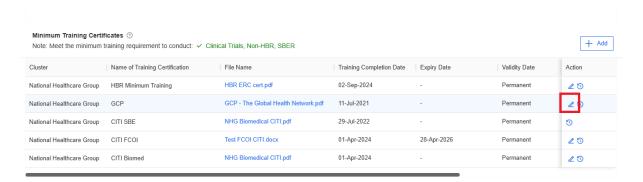
- (1) Self-read the ICH E6 (R3) GCP updates or view the <u>HSA Webinar</u> recordings), and
- (2) Maintain a record of the ICH E6 (R3) GCP updates self-training, via documentation in a training log, to be filed in the Investigator File.



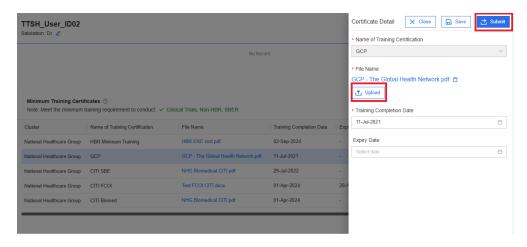
Example of self-training record (GCP Training Record)

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.