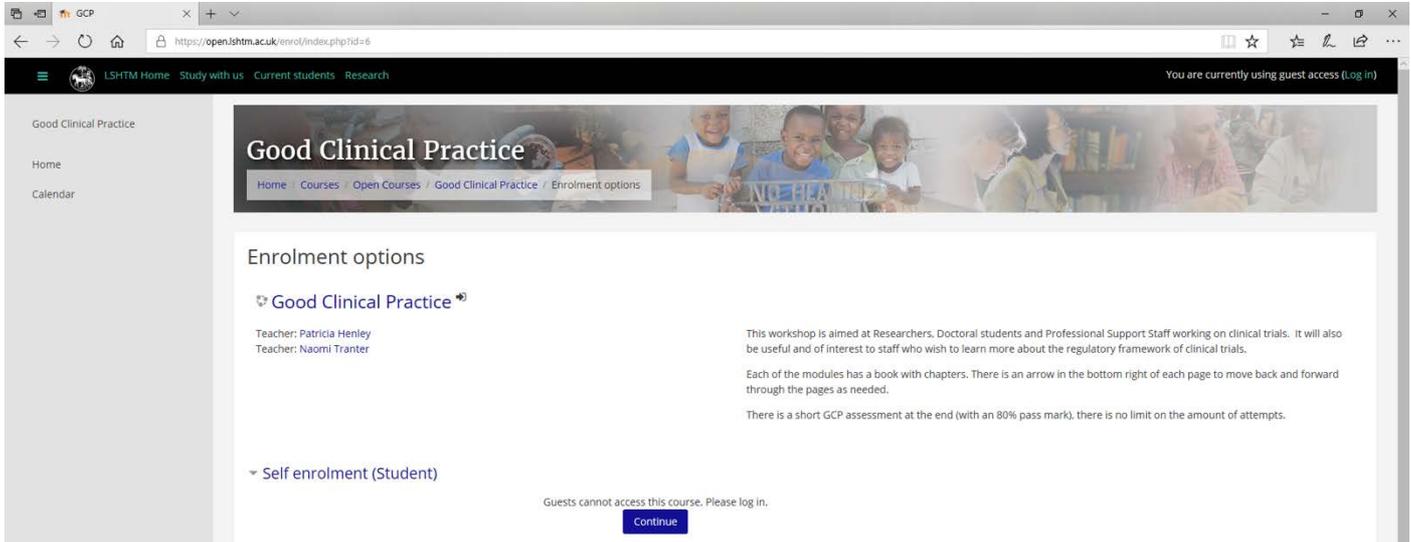


HOW TO ACCESS LSHTM GCP TRAINING

1. Go to <https://open.lshtm.ac.uk/enrol/index.php?id=6>

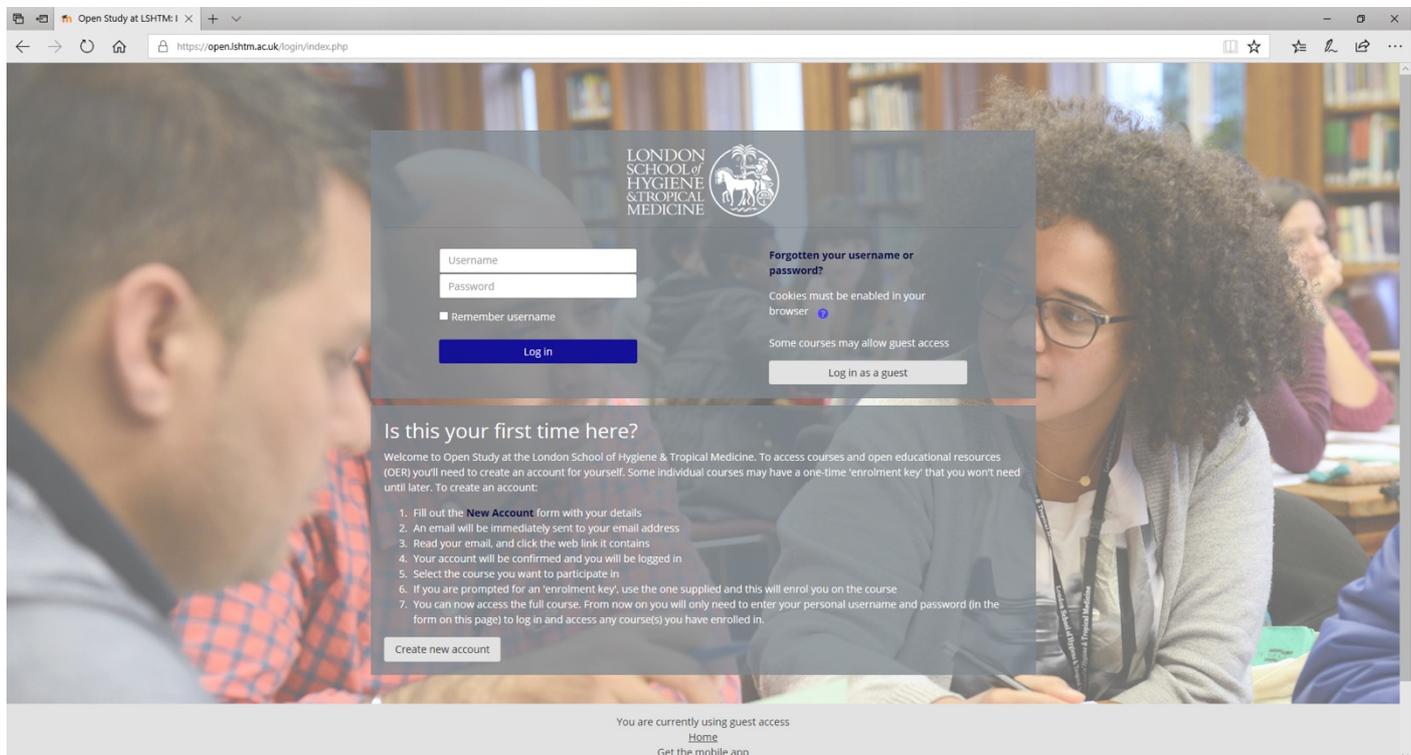
You will be taken to this screen:



The screenshot shows a web browser window displaying the LSHTM website. The URL in the address bar is <https://open.lshtm.ac.uk/enrol/index.php?id=6>. The page title is 'Good Clinical Practice' and the sub-page is 'Enrolment options'. The course is listed as 'Good Clinical Practice' with teachers Patricia Henley and Naomi Tranter. A 'Continue' button is visible at the bottom of the page.

2. Click continue

You will be taken to this screen:



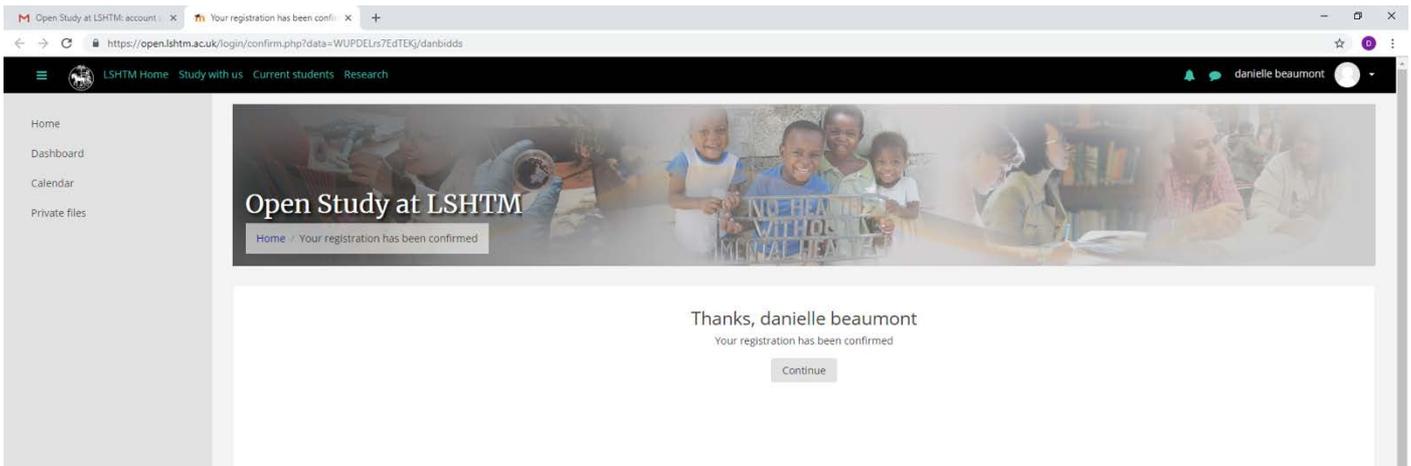
The screenshot shows the LSHTM login page. The URL is <https://open.lshtm.ac.uk/login/index.php>. The page features a login form with fields for 'Username' and 'Password', a 'Remember username' checkbox, and a 'Log in' button. There is also a 'Log in as a guest' button and a 'Create new account' button. The page includes the LSHTM logo and a list of steps for creating a new account.

3. **Already registered with LSHTM open study:** If you are already registered, please log in using your username and password. You will be taken to the GCP training homepage

4. First time user: If you are a first time user to LSHTM Open Study, you will need to create an account:

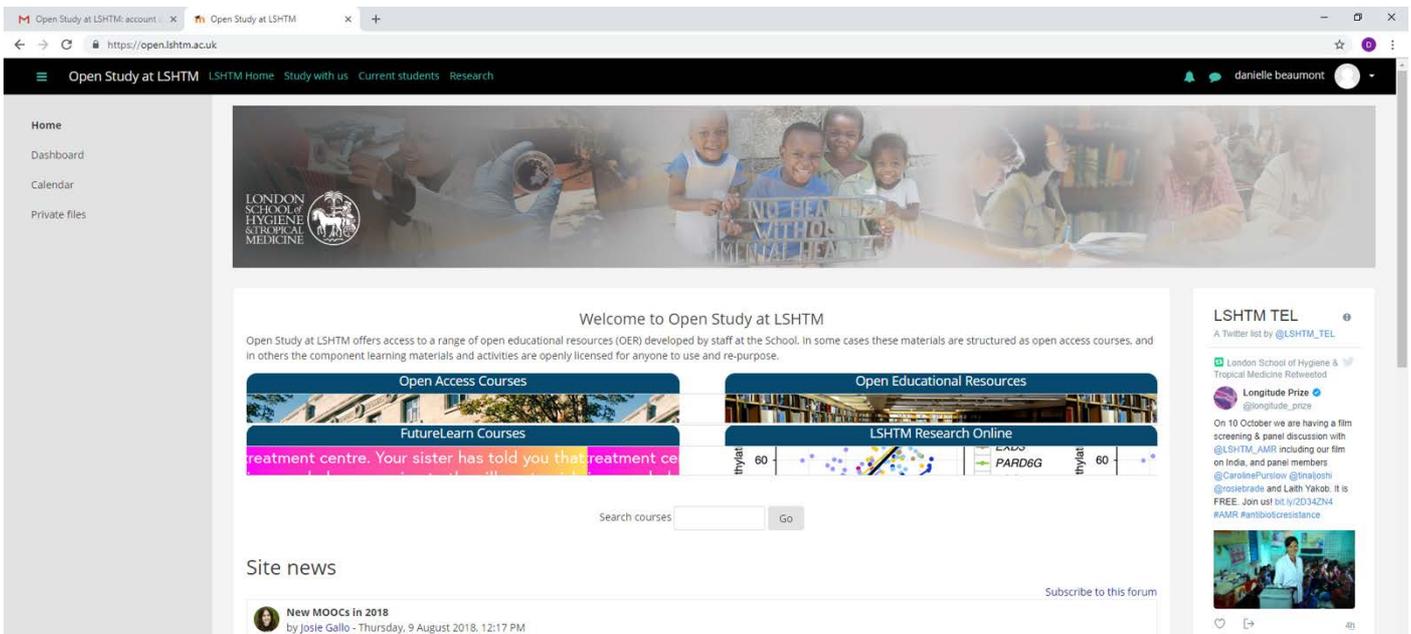
- i. Click **Create New Account**
- ii. Fill out the **New Account** form with your details
- iii. Note down your username and password as you will need this every time you log in.
- iv. An email will be immediately sent to your email address
- v. Read your email, and click the web link it contains to confirm your log in details
- vi. Your account will be confirmed and you will be logged in

5. When click web link in your email you will be taken to this screen:

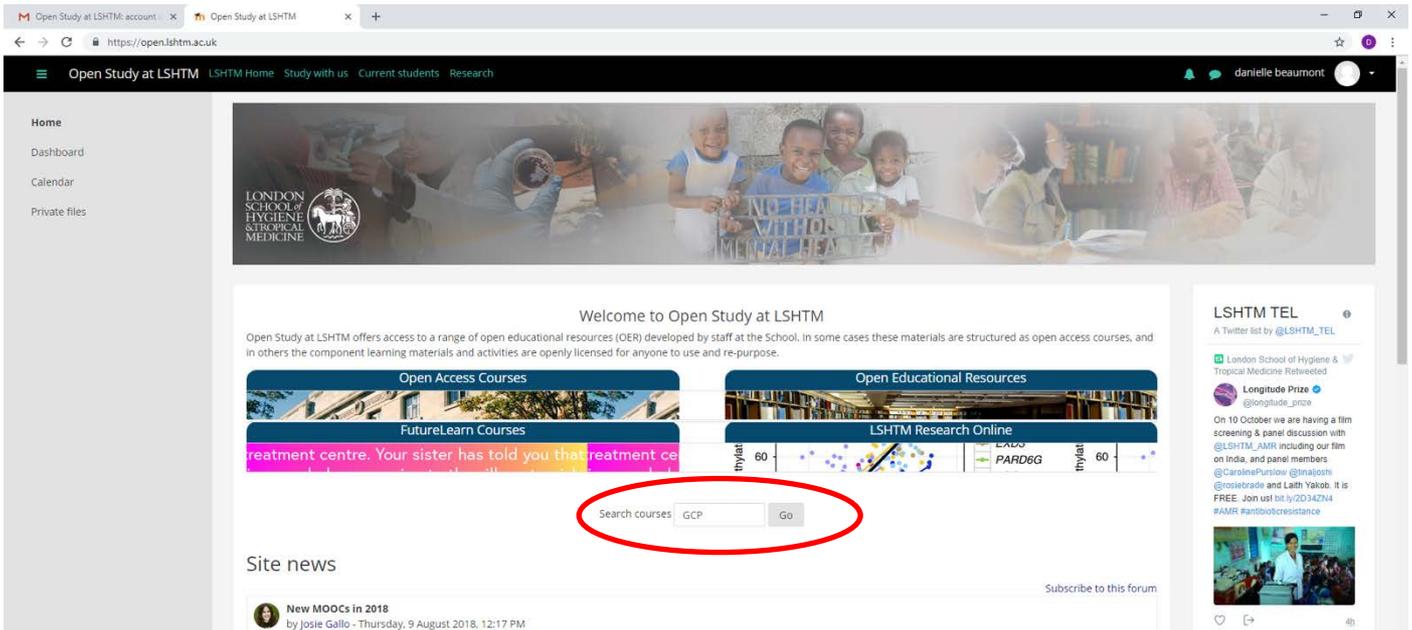


6. Click continue

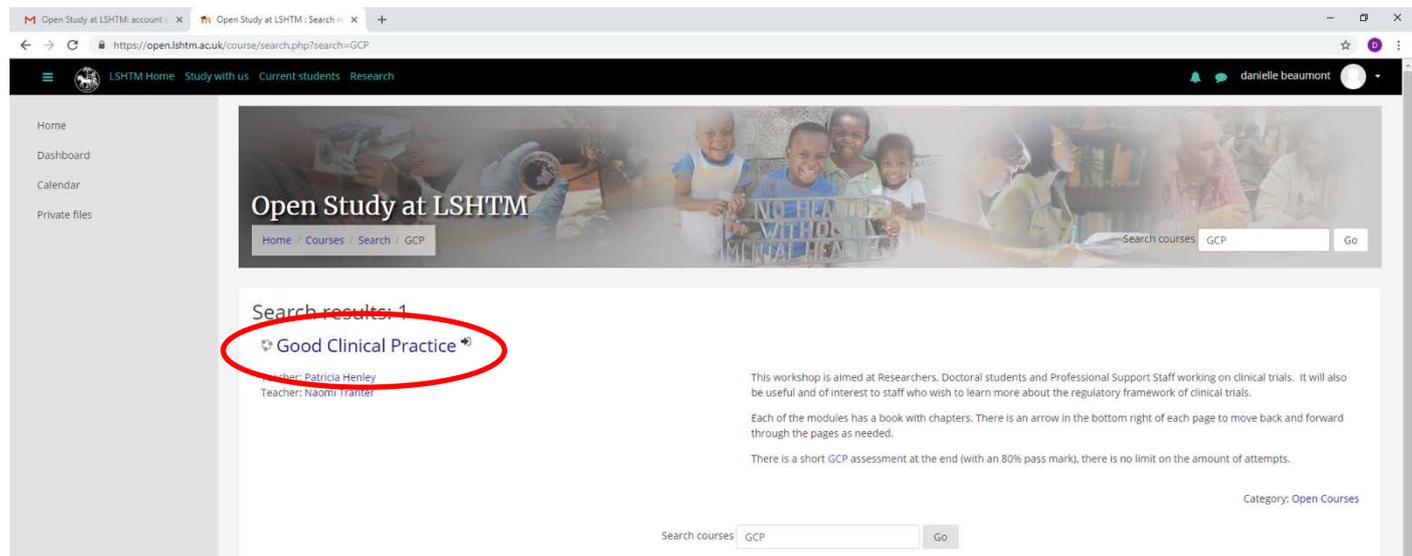
You will be taken to this screen:



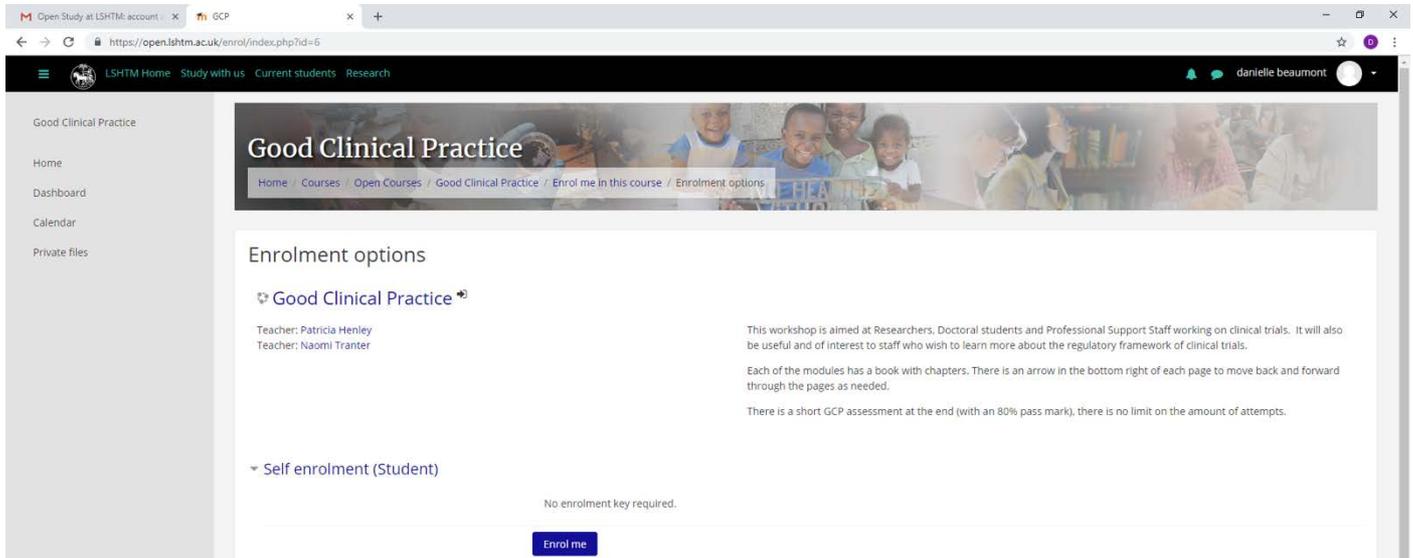
7. To select the GCP course type GCP in search courses as shown below (in the red circle). Click Go.



8. You will be taken to this screen. Click Good Clinical Practice hyperlink as shown below:



You will be taken to this screen:

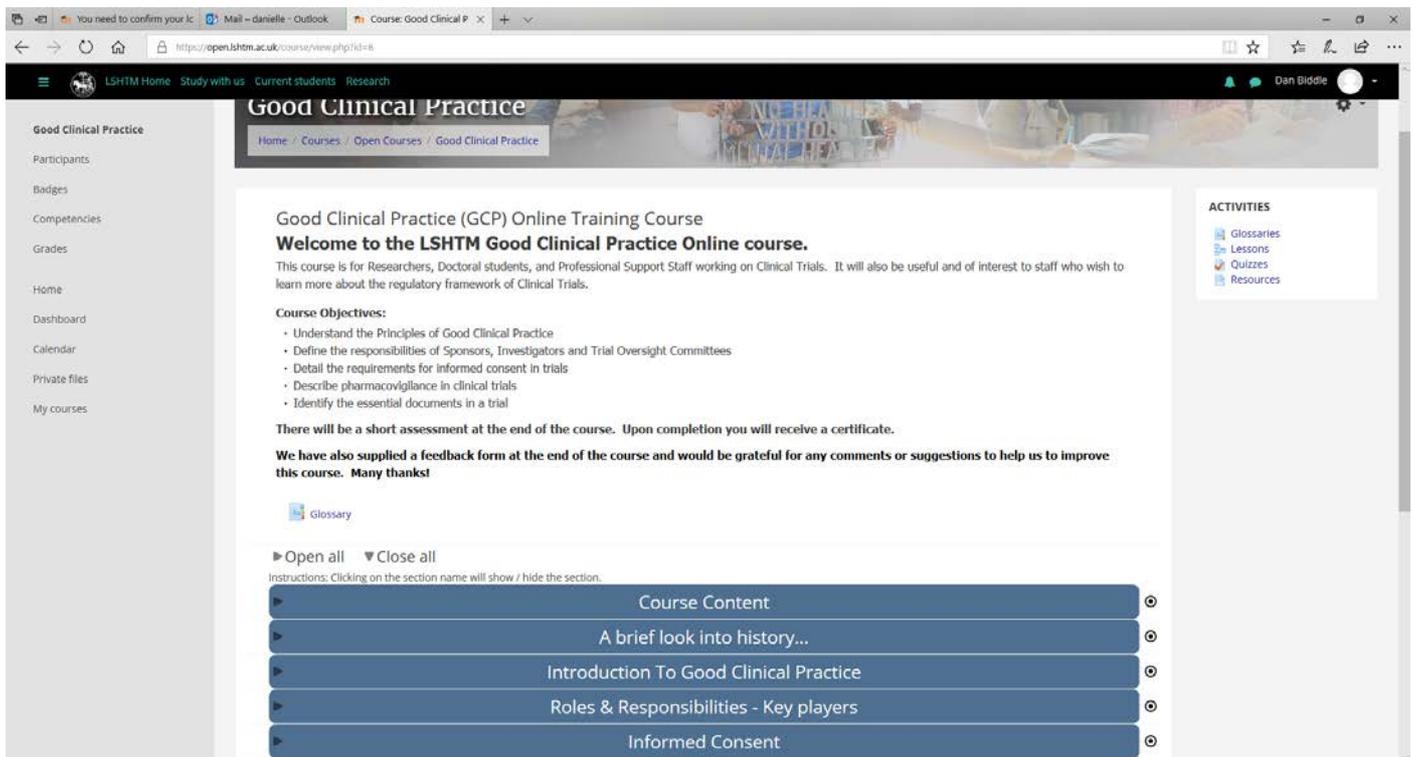


The screenshot shows a web browser window with the URL <https://open.lshtm.ac.uk/enrol/index.php?id=6>. The page title is "Good Clinical Practice" and the sub-page is "Enrolment options". The breadcrumb trail is: Home / Courses / Open Courses / Good Clinical Practice / Enrol me in this course / Enrolment options. The page content includes:

- Good Clinical Practice** (with a lock icon)
- Teacher: Patricia Henley
- Teacher: Naomi Tranter
- Description: "This workshop is aimed at Researchers, Doctoral students and Professional Support Staff working on clinical trials. It will also be useful and of interest to staff who wish to learn more about the regulatory framework of clinical trials. Each of the modules has a book with chapters. There is an arrow in the bottom right of each page to move back and forward through the pages as needed. There is a short GCP assessment at the end (with an 80% pass mark), there is no limit on the amount of attempts."
- Enrolment type: **Self enrolment (Student)**
- Message: "No enrolment key required."
- Enrol me** button

9. Click enrol me

You will be taken to this screen:



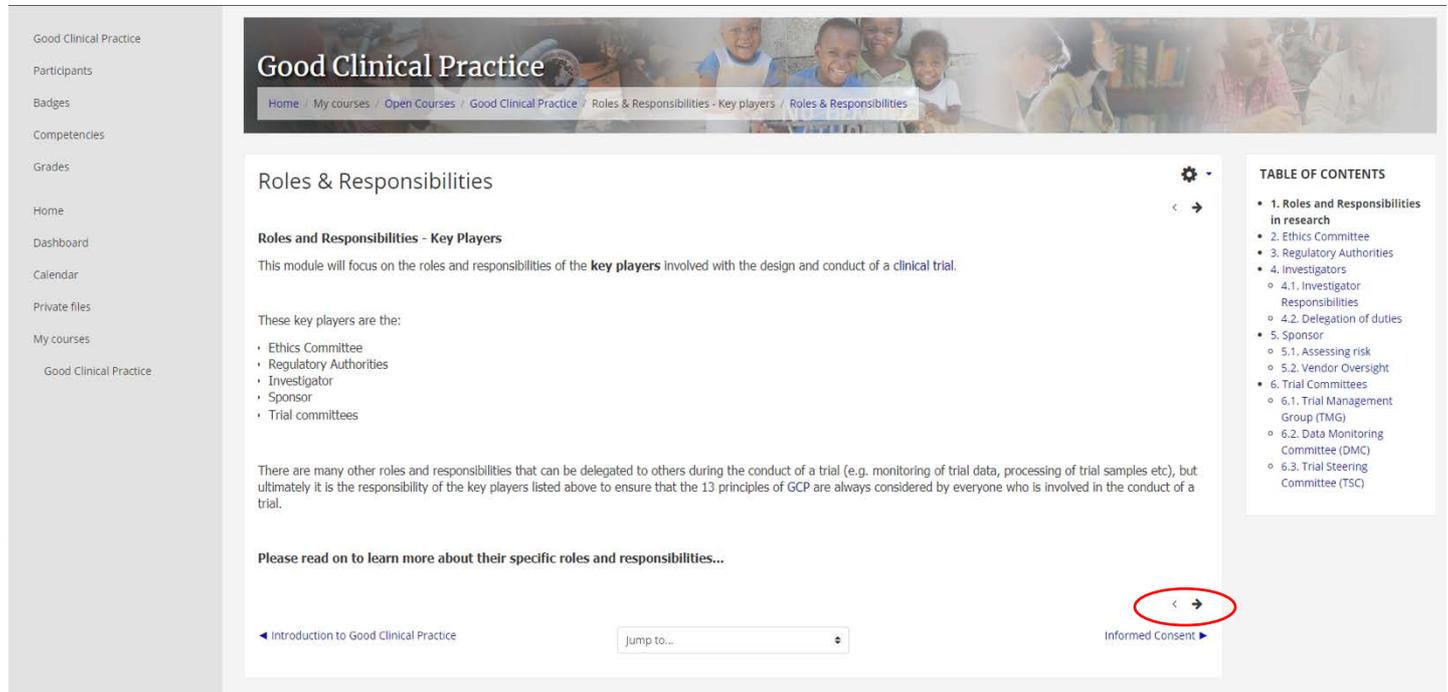
The screenshot shows a web browser window with the URL <https://open.lshtm.ac.uk/course/view.php?id=8>. The page title is "Good Clinical Practice" and the sub-page is "Good Clinical Practice (GCP) Online Training Course". The breadcrumb trail is: Home / Courses / Open Courses / Good Clinical Practice. The page content includes:

- Good Clinical Practice (GCP) Online Training Course**
- Welcome to the LSHTM Good Clinical Practice Online course.**
- Description: "This course is for Researchers, Doctoral students, and Professional Support Staff working on Clinical Trials. It will also be useful and of interest to staff who wish to learn more about the regulatory framework of Clinical Trials."
- Course Objectives:**
 - Understand the Principles of Good Clinical Practice
 - Define the responsibilities of Sponsors, Investigators and Trial Oversight Committees
 - Detail the requirements for informed consent in trials
 - Describe pharmacovigilance in clinical trials
 - Identify the essential documents in a trial
- Message: "There will be a short assessment at the end of the course. Upon completion you will receive a certificate. We have also supplied a feedback form at the end of the course and would be grateful for any comments or suggestions to help us to improve this course. Many thankst"
- Open all** / **Close all** (with a dropdown arrow)
- Instructions: "Clicking on the section name will show / hide the section."
- Course Content sections:
 - Course Content
 - A brief look into history...
 - Introduction To Good Clinical Practice
 - Roles & Responsibilities - Key players
 - Informed Consent
- ACTIVITIES** sidebar:
 - Glossaries
 - Lessons
 - Quizzes
 - Resources

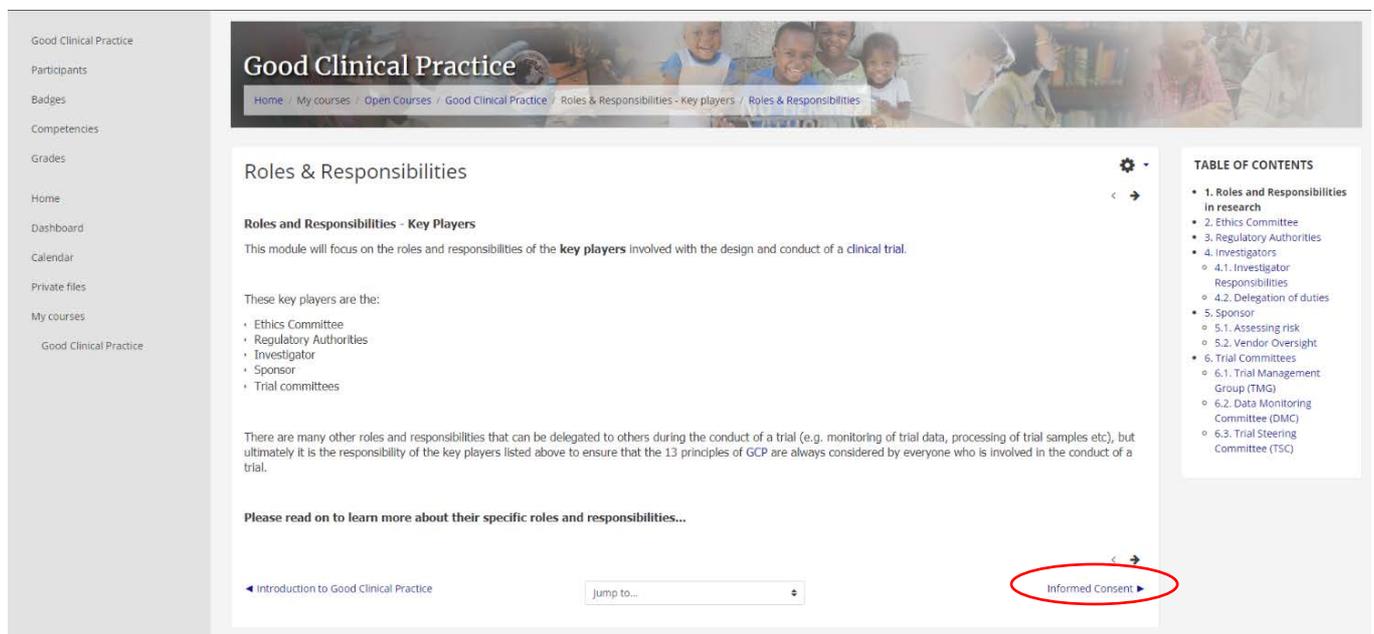
10. Welcome to the LSHTM GCP online course.

Please work your way through each of the course modules.

Use the grey arrows circled in red below to navigate through the information in each module.



To progress to the next module, click on the module name in blue, as shown in the screen below



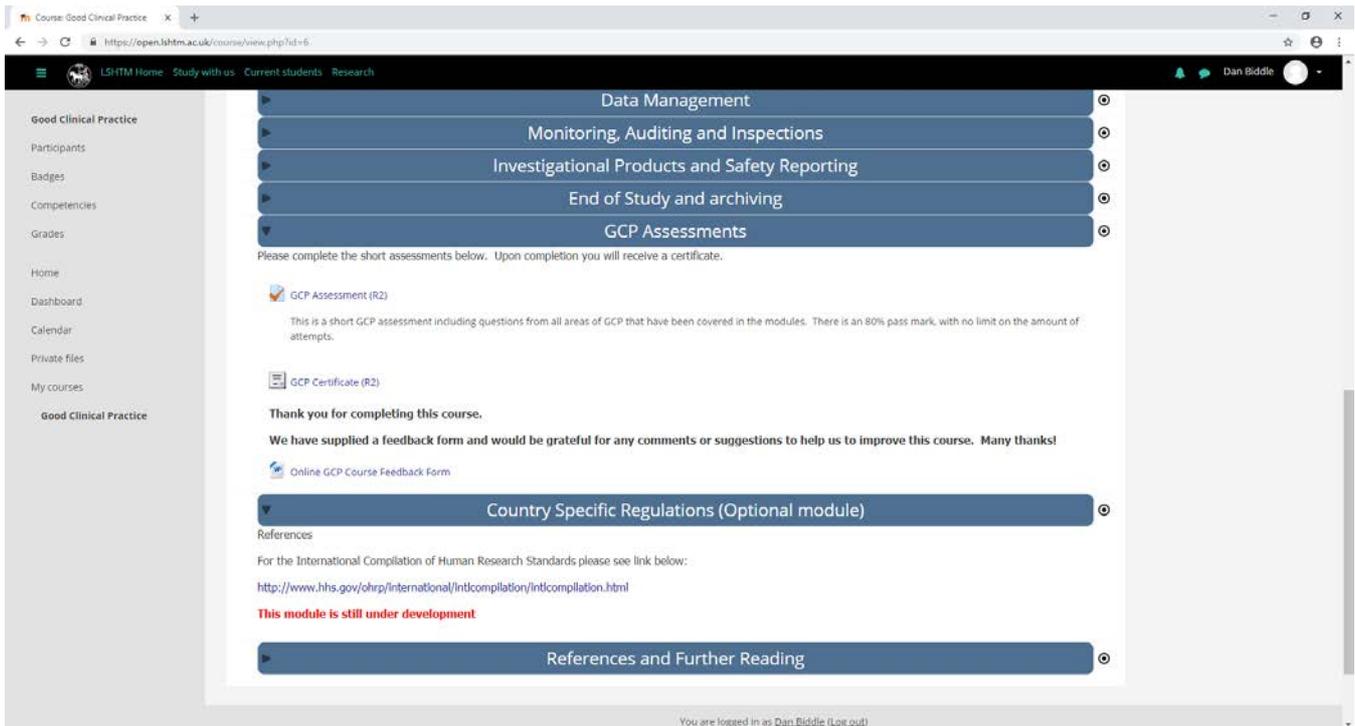
TAKING THE ASSESSMENT

Once you have read through the course modules, please complete the GCP Assessment. This is a short assessment which includes questions from all areas of GCP that have been covered in the modules.

There is an 80% pass mark, with no limit on the amount of attempts.

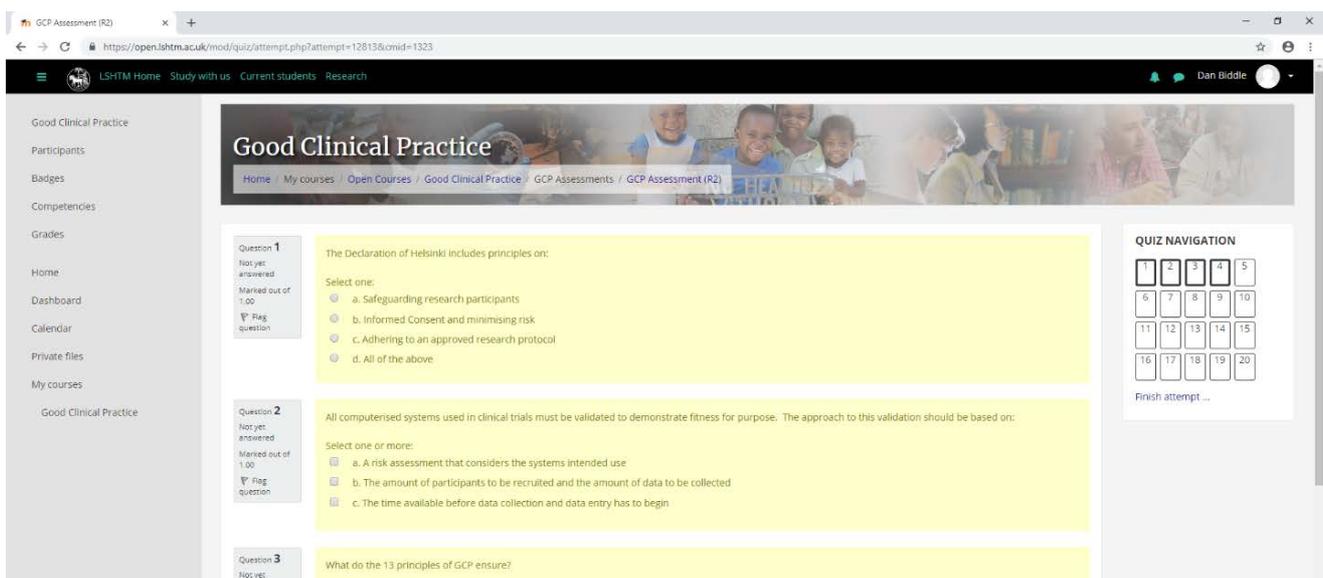
Instructions for taking the quiz follow below

1. Click GCP Assessment (R2)



The screenshot shows the LSHTM course interface for 'Good Clinical Practice'. The left sidebar contains navigation options like 'Participants', 'Badges', 'Competencies', 'Grades', 'Home', 'Dashboard', 'Calendar', 'Private files', and 'My courses'. The main content area lists several modules: 'Data Management', 'Monitoring, Auditing and Inspections', 'Investigational Products and Safety Reporting', 'End of Study and archiving', and 'GCP Assessments'. Below the 'GCP Assessments' module, there is a section for 'GCP Assessment (R2)' with a description: 'This is a short GCP assessment including questions from all areas of GCP that have been covered in the modules. There is an 80% pass mark, with no limit on the amount of attempts.' Below this, there is a 'Thank you for completing this course.' message and a link to an 'Online GCP Course Feedback Form'. At the bottom, there are sections for 'Country Specific Regulations (Optional module)' and 'References and Further Reading'.

2. Please work your way through the 20 questions, following the instructions

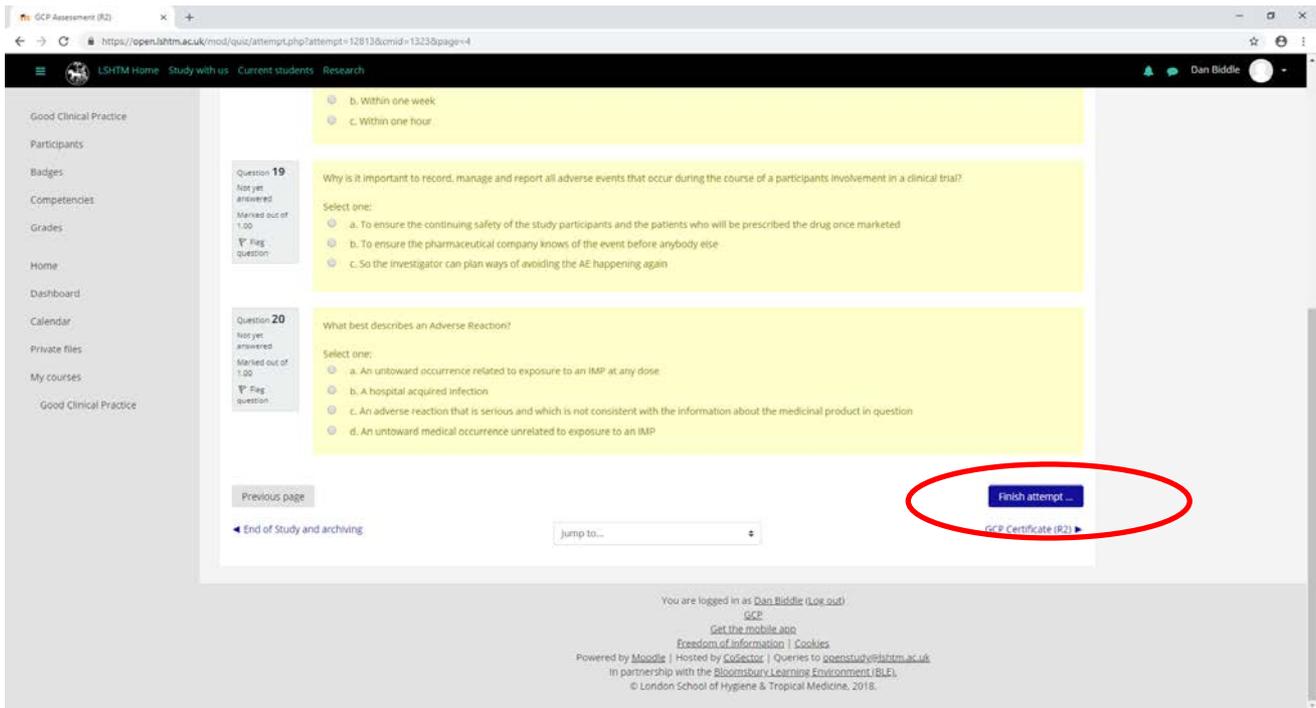


The screenshot shows the 'GCP Assessment (R2)' quiz interface. The top banner reads 'Good Clinical Practice' with a breadcrumb trail: 'Home / My courses / Open Courses / Good Clinical Practice / GCP Assessments / GCP Assessment (R2)'. The main content area displays three questions:

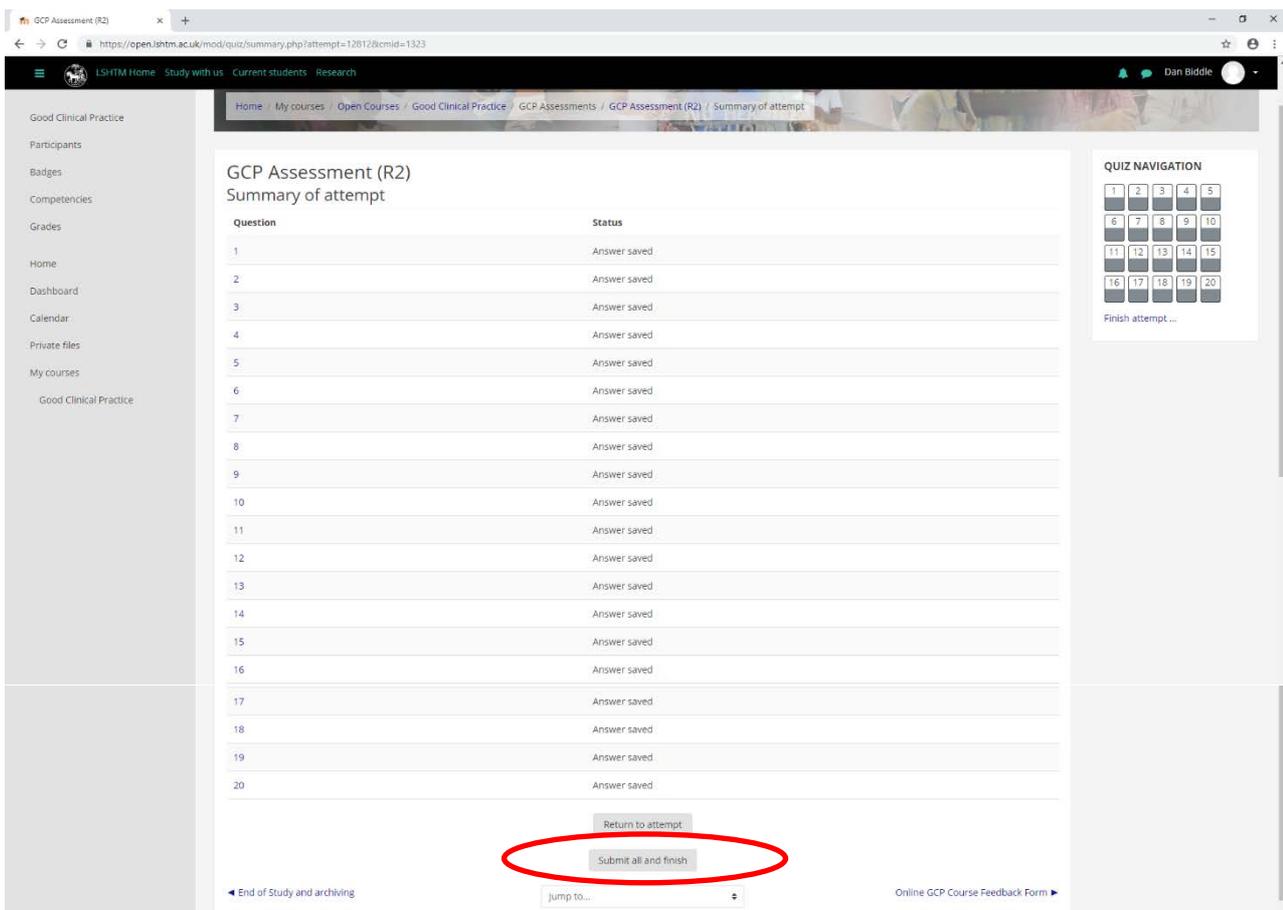
- Question 1:** The Declaration of Helsinki includes principles on:
 - Select one:
 - a. Safeguarding research participants
 - b. Informed Consent and minimising risk
 - c. Adhering to an approved research protocol
 - d. All of the above
- Question 2:** All computerised systems used in clinical trials must be validated to demonstrate fitness for purpose. The approach to this validation should be based on:
 - Select one (or more):
 - a. A risk assessment that considers the systems intended use
 - b. The amount of participants to be recruited and the amount of data to be collected
 - c. The time available before data collection and data entry has to begin
- Question 3:** What do the 13 principles of GCP ensure?

On the right side, there is a 'QUIZ NAVIGATION' section with a grid of question numbers (1-20) and a 'Finish attempt...' button.

3. When you have answered all 20 questions click Finish attempt



4. You will see a summary of questions you have answered. If any questions have been missed or not saved, please go back (click return to attempt) and answer the questions before you submit the quiz.

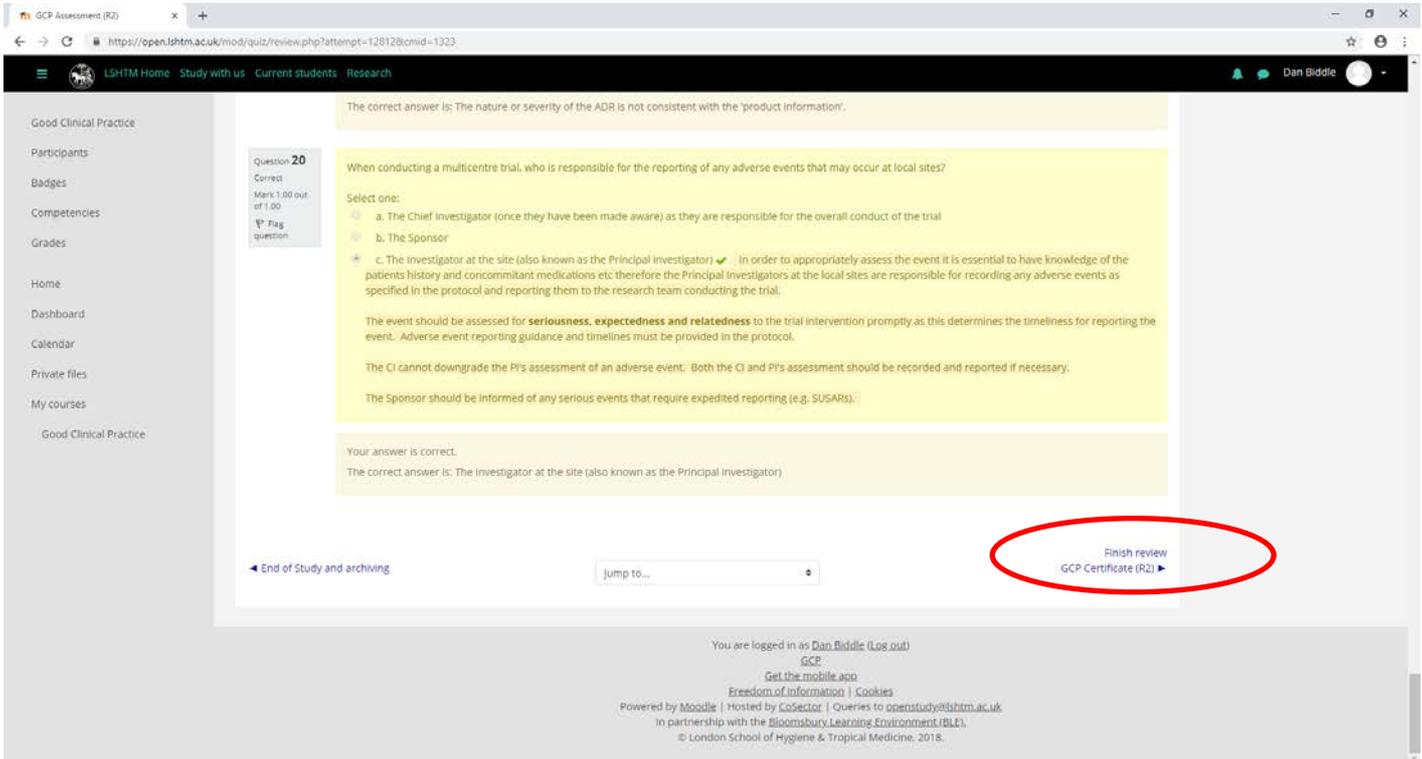


5. Click submit all and finish as shown above. Confirm you want to submit your quiz when prompted.

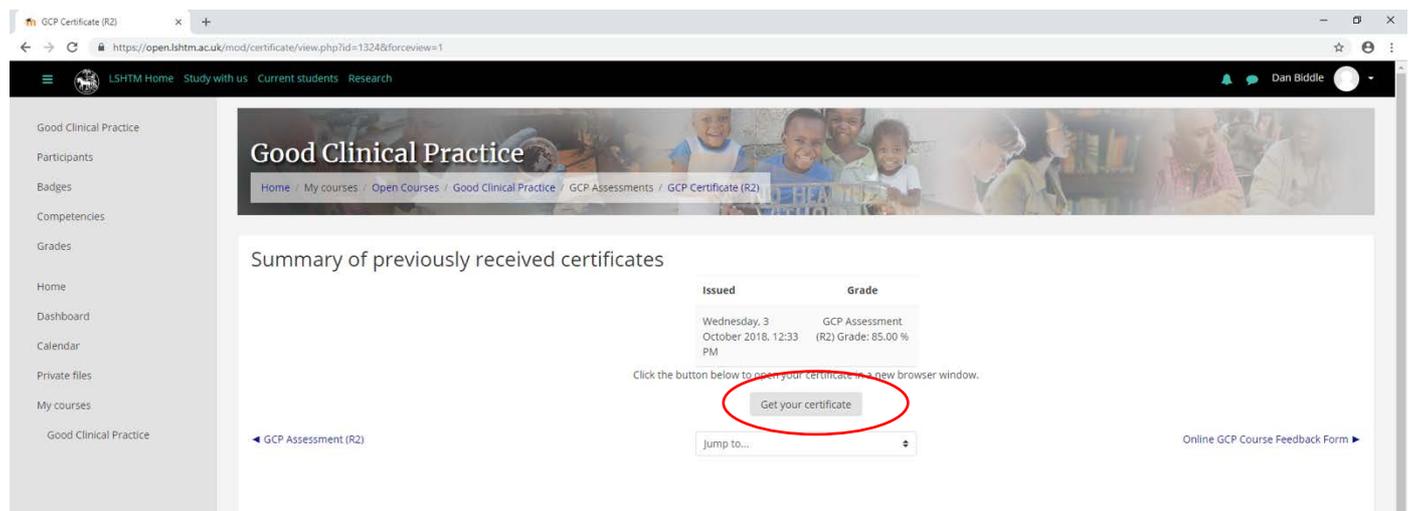
You will be provided with a summary of your answers, and how you scored on each question

6. If you have obtained a pass mark of 80% and above, at the bottom of the page you will see GCP Certificate (R2). Click this

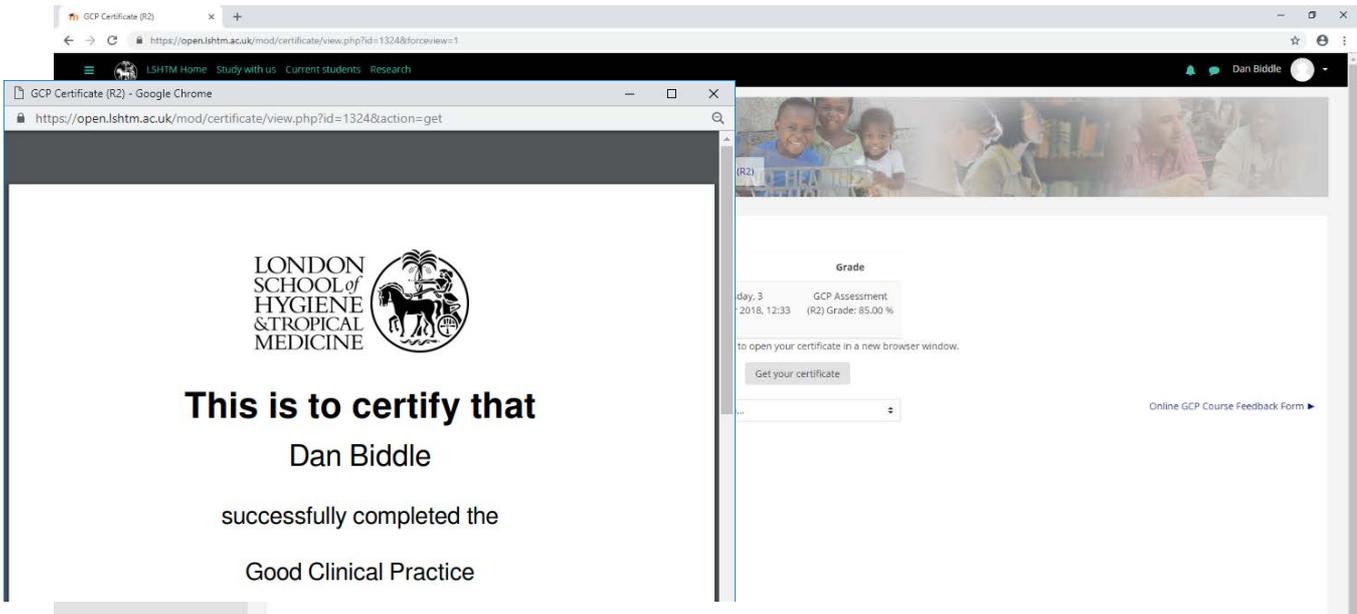
If you score less than 80%, please review the course modules and take the assessment again. Please jump to point 10 below to see how to do this.



You will be taken to this screen:

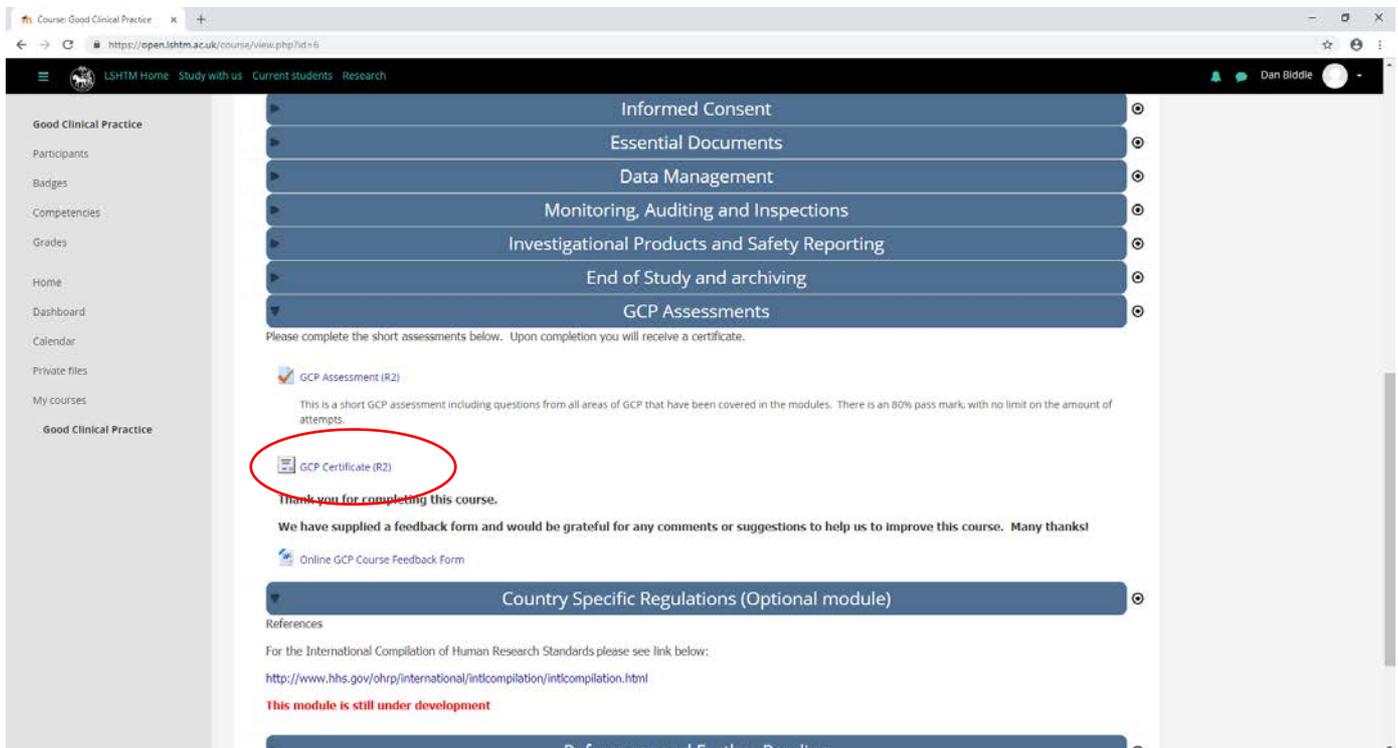


7. Click get your certificate. A pop up will appear with your certificate as shown below

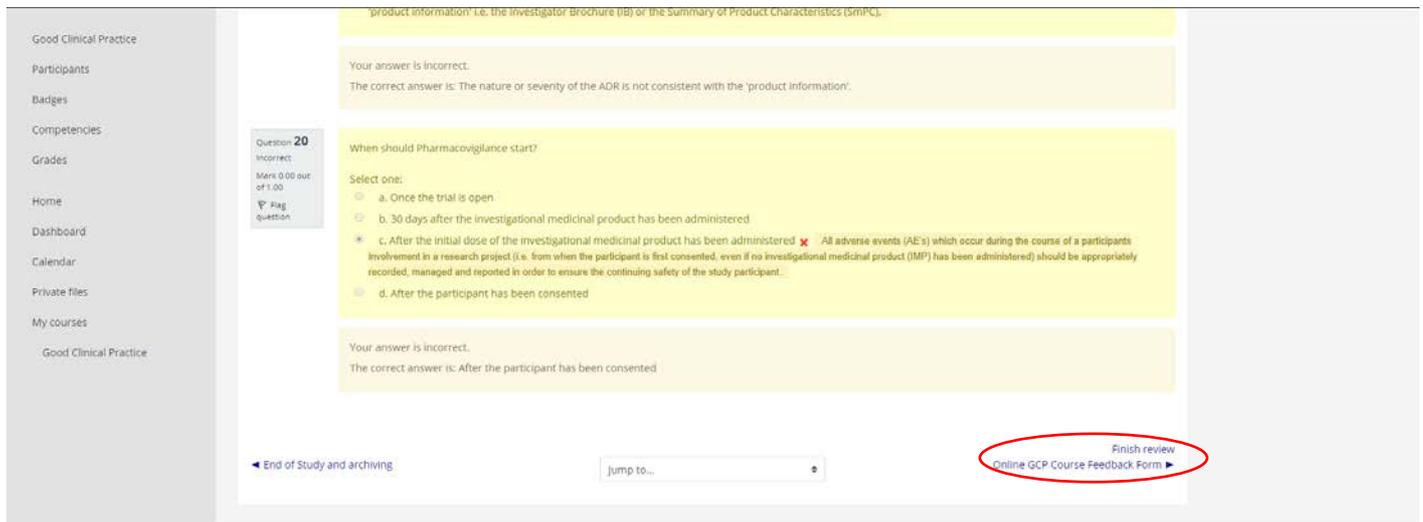


8. Please save a copy for your records send a copy to crash19@lshtm.ac.uk and upload a copy to your site's electronic ISF.

9. Your certificate will be saved in the GCP assessment section (as shown below)



10. If you do not pass with at least 80%, at the bottom of the summary of your answers please click 'Finish Review' circled in red



product information' i.e. the Investigator Brochure (IB) or the Summary of Product Characteristics (SmPC).

Your answer is incorrect.
The correct answer is: The nature or severity of the ADR is not consistent with the 'product information'.

Question 20
Incorrect
Mark 0.00 out of 1.00
Flag question

When should Pharmacovigilance start?

Select one:

- a. Once the trial is open
- b. 30 days after the investigational medicinal product has been administered
- c. After the initial dose of the investigational medicinal product has been administered. All adverse events (AE's) which occur during the course of a participants involvement in a research project (i.e. from when the participant is first consented, even if no investigational medicinal product (IMP) has been administered) should be appropriately recorded, managed and reported in order to ensure the continuing safety of the study participant.
- d. After the participant has been consented

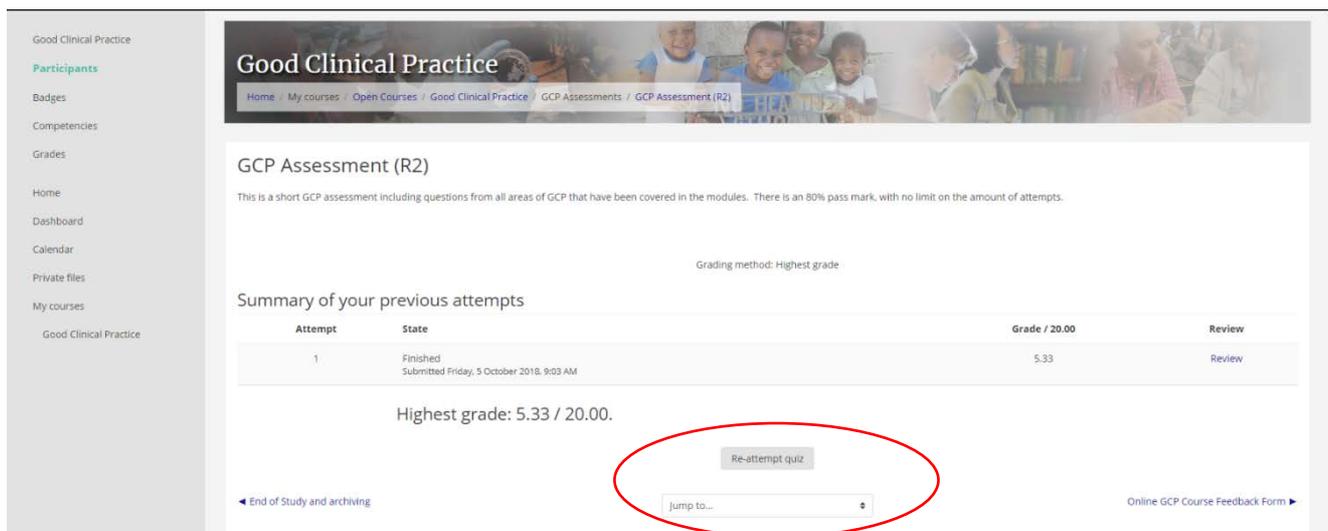
Your answer is incorrect.
The correct answer is: After the participant has been consented

◀ End of Study and archiving

Jump to...

Finish review
Online GCP Course Feedback Form ▶

11. You will be taken to this screen.



Good Clinical Practice

Home / My courses / Open Courses / Good Clinical Practice / GCP Assessments / GCP Assessment (R2)

GCP Assessment (R2)

This is a short GCP assessment including questions from all areas of GCP that have been covered in the modules. There is an 80% pass mark, with no limit on the amount of attempts.

Grading method: Highest grade

Summary of your previous attempts

Attempt	State	Grade / 20.00	Review
1	Finished Submitted Friday, 5 October 2018, 9:03 AM	5.33	Review

Highest grade: 5.33 / 20.00.

Re-attempt quiz

◀ End of Study and archiving

Jump to...

Online GCP Course Feedback Form ▶

If you wish to review the GCP materials again use the 'Jump to' to see the list of GCP modules

Alternatively, please click 'Re-attempt quiz' to take the assessment again. If you pass with 80% or above, please follow points 6 - 9 above and send a copy to crash19@lshtm.ac.uk.