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:

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Good Clinical Practice Home Calendar	Good Clinical Practice	CONTRACT AND ANY
	Enrolment options © Good Clinical Practice *	
	Teacher: Patricia Henley Teacher: Naomi Tranter	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.
	✓ Self enrolment (Student) Guests cannot access this o Continue	ourse. Please log in.

2. Click continue

You will be taken to this screen:



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

Protocol ID: NCT04343001

CRASH-19



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:

 M Open Study at LSHTM account x M W A Den Study at LSHTM account x C A Den Study at LSHTM Home LSHTM Home Dashboard Calendar Private files 	alor registration has been confirmed	
	Thanks, danielle beaumont Vour registration has been confirmed Continue	
6. Click continu	e	
You will be taken	to this screen:	
M Open Study at LSHTM: account x ↑ O ← → C ■ https://open.lshtm.ac.uk	pen Study at LSHTM x +	0 ×
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	Welcome to Open Study at LSHTM offers access to a range of open educational resources (OER) developed by staff at the School. In some cases these materials are structured as open access courses, and A Twitter list by @LSHTM_TEL	
	In others the component learning materials and activities are openly licensed for anyone to use and re-purpose.	
	Site news Subscribe to this forum	
	by Josle Gallo - Thursday, 9 August 2018, 12:17 PM	3



7. To select the GCP course type <u>GCP</u> 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:

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← → C ■ https://open.lshtm.ac.uk/course/search.php?search=GCP		* 🗿 :
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Home Dashboard Calendar Private files Open Study at LSH Home / Courses / Search / GCP	ТМ	Search courses GCP Go
Search results: 1 © Good Clinical Practice ® Nother: Esticla Henley Teacher: Naomi Tranter	This workshop is aimed at Researchers. Do be useful and of interest to staff who wish Each of the modules has a book with chap through the pages as needed. There is a short GCP assessment at the en	octoral students and Professional Support Staff working on clinical trials. It will also to learn more about the regulatory framework of clinical trials. ters. There is an arrow in the bottom right of each page to move back and forward d (with an 80% pass mark), there is no limit on the amount of attempts.
		Category: Open Courses
	Search courses GCP Go	
CRASH -19: How to access LSHTM GCP Training FINAL v1.0; 14/05/2020	Protocol ID: NCT04343001	Page 3 of 10

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Private files	Enrolment options		
	© Good Clinical Practice *		
	Teacher: Patricia Henley Teacher: Naomi Tranter	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.	
	* Self enrolment (Student)		
	No enrolment key required.		
	Enrol me		

9. Click enrol me

You will be taken to this screen:



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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.

Good Clinical Practice	Good Clinical Practice	
Badges	Home / My courses / Open Courses / Good Clinical Practice / Roles & Responsibilities - Key players / Roles & Responsibilities	
Competencies		and the second
Grades	Roles & Responsibilities	TABLE OF CONTENTS
Home Dashboard Calendar Private files My courses Good Clinical Practice	 Roles and Responsibilities - Key Players Roles and Responsibilities - Key Players This module will focus on the roles and responsibilities of the key players involved with the design and conduct of a clinical trial. These key players are the: Ethics Committee Regulatory Authorities Investigator Trace are many other roles and responsibilities that can be delegated to others during the conduct of a trial (e.g. monitoring of trial data, processing of trial samples etc.), but durinately it is the responsibility of the key players listed above to ensure that the 13 principles of GCP are always considered by everyone who is involved in the conduct of a trial. 	1. Roles and Responsibilities in research 2. Ethics Committee 3. Regulatory Authorities 4. Investigators 4. Investigators esponsibilities 5. Sponsor 5. 1. Assessing risk 5. 2. Vendor Oversight 6. Trial Committees 6.1. Trial Management Group (TMG) 6.3. Trial Management Group (TMG) 6.3. Trial Steering Committee (DMC) 6.3. Trial Steering Committee (TSC)
	Please read on to learn more about their specific roles and responsibilities	
	 ✓ Introduction to Good Clinical Practice Jump to ♦ Informed Consent ► 	

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)

	Data Management	0	
ood Clinical Practice	Monitoring, Auditing and Inspections	0	
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ashboard slendar	CLP Associations (ive) 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.		
vate files courses	To GCP Certificate (R2)		
Good Clinical Practice	Thank you for completing this course.		
	We have supplied a feedback form and would be grateful for any comments or suggestions to help us to improve this course. Many thanks!		
	🔄 Online GCP Course Feedback Form		
	Country Specific Regulations (Optional module)	0	
	References		
	For the International Compilation of Human Research Standards please see link below:		
	http://www.hhs.gov/ohrp/international/Inticompilation/inticompilation.html		
	This module is still under development		
	Peferonces and Eurthor Pearling		

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





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.

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	GCP Assessment (R2)			QUIZ NAVIGATION
tencies	Summary of attempt			
	Question	Status		
	1	Answer saved		11 12 13 14 15
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		Return to attempt		
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c submit a	all and finish as shown	above. Confirm you want to s	ubmit vour quiz when	prompted.
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معمد مطالة	vided with a summary	of your answers, and how you	scarad on each quasti	on



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 then 80%, please review the course modules and take the assessment again. Please jump to point 10 below to see how to do this.

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	h us Current student:	s Research	🌲 🐢 Dan Bio	dle 💽
and the second		The correct answer is: The nat	nature or severity of the ADR is not consistent with the 'product information'.	
Clinical Practice				
pants	Question 20	When conducting a multicent	entre trial, who is responsible for the reporting of any adverse events that may occur at local sites?	
5	Mark 1.00 out of 1.00	Select one:		
etencies	R. Mag	a. The Chief Investigator	stor (once they have been made aware) as they are responsible for the overall conduct of the trial	
5		 c. The Investigator at the 	the site (also known as the Principal investigator) 🖌 In order to appropriately assess the event it is essential to have knowledge of the	
		patients history and conco specified in the protocol a	ncommitant medications etc therefore the Principal Investigators at the local sites are responsible for recording any adverse events as of and reporting them to the research team conducting the trial.	
ward		The event should be asses	sessed for seriousness, expectedness and relatedness to the trial intervention promptly as this determines the timeliness for reporting the	
dar		event. Adverse event repo	eporting guidance and timelines must be provided in the protocol.	
e files		The CI cannot downgrade	de the PI's assessment of an adverse event. Both the CI and PI's assessment should be recorded and reported if necessary.	
urses		The Sponsor should be inf	informed of any serious events that require expedited reporting (e.g. SUSARs).	
d Clinical Practice				
		The correct answer is: The inv	Investigator at the site (also known as the Principal Investigator)	
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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 <u>crash19@lshtm.ac.uk</u> and upload a copy to your site's electronic ISF.
- 9. Your certificate will be saved in the GCP assessment section (as shown below)

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Participants	Essential Documents	۲	
Badges	 Data Management 	۲	
Competencies	 Monitoring, Auditing and Inspections 	•	
Grades	Investigational Products and Safety Reporting	•	
Home	End of Study and archiving	0	
Dashboard	GCP Assessments	•	
Calendar	Please complete the short assessments below. Upon completion you will receive a certificate.		
Private files	GCP Assessment (R2)		
My courses	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		
	Online GCP Course Feedback Form		
	Country Specific Regulations (Optional module)	0	
	For the International Compilation of Human Research Standards please see link below:		
	http://www.hhs.gov/ohrp/international/inticompilation/inticompilation.html		
	This module is still under development		
	References and Further Reading	0	



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).
Good Clinical Practice	
Participants	Your answer is incorrect.
Badges	The correct answer is: The nature or seventy of the ADR is not consistent with the 'product information'.
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and the second	Outsion 20 When should Pharmacovigilance start?
Grades	Mare 000 put Select one:
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Desinovard	 c. After the initial dose of the investigational medicinal product has been administered ¥. All advance events (AEs) which eccer during the owner of a participants involvement by the initial of the investigational medicinal product has been administered at the initial excert during the owner of a participants involvement by the initial dose of the investigational medicinal product has been administered to the investigation of the initial excert during the owner of the initial excert during the owner of the initial excert during the owner of the initial excert during the excert during the initial excert during the ex
Calendar	recorded, managed and reported in order to ensure the continuing safety of the study participant.
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My courses	
Good Clinical Practice	Your answer is incorrect.
	The correct answer is: After the participant has been consented
	Finish review
	End of Study and archiving Jump to Provide a contract of the study and archiving

11. You will be taken to this screen.

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		Highest grade: 5 33 / 20 00		

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 <u>crash19@lshtm.ac.uk</u>.