

# Guidance for completing GCP training and submitting the test



Tranexamic acid for the treatment of significant traumatic brain injury: an international randomised, double blind placebo controlled trial

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Go to [crash3.Lshtm.ac.uk](http://crash3.Lshtm.ac.uk)

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### CRASH 3 News

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- Join CRASH-3
- Patients randomised: 0
- Investigators Login

Click on 'Investigators Login'

### CRASH-3 Collaborators

Further information about CRASH-3 collaborators

### Related Organisations

### TCC GCP Training and Document Upload Login

Please enter your username and password, and click on one of the buttons below

Username\*

Password\*

GCP Training



Capacitación de BPC



Uploads

Username and password are available by emailing [Crash@Lshtm.ac.uk](mailto:Crash@Lshtm.ac.uk)

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## GOOD CLINICAL PRACTICE (GCP) TRAINING



The menu features the TCC logo (a blue oval with 'TCC' in white) and the text 'GCP TRAINING' below it. Below the logo are four blue buttons with white text: 'HOW TO USE THIS PROGRAMME', '1. TRAINING PACKAGE', '2. PEOPLE', and '3. PROCESS'. The '1. TRAINING PACKAGE' button is highlighted with a white border.

ICH E6  
GUIDELINE FOR  
GOOD CLINICAL  
PRACTICE

Start from the beginning...

# 1. INTRODUCTION

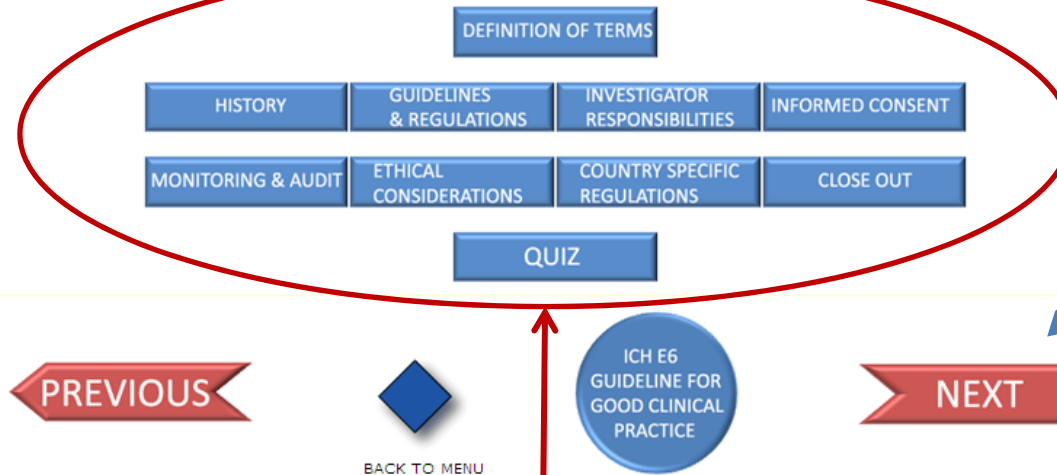
Good Clinical Practice (GCP) is an international ethical and scientific quality standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical trials that involve human participants. Compliance with GCP provides assurance that the data and reported results are credible and accurate, and that the rights, safety, confidentiality, and well-being of trial participants are protected.

GCP is not one set of safety standards, issued by one regulatory agency, or found in one document. Rather, the GCP standard has evolved over time, is recognised by regulatory agencies around the world, and includes the procedures by which drugs and devices are approved for human use.

This GCP and basic ethics training package for investigators contains 8 units. It is not necessary to take the Quiz if you have recently completed a GCP training course. However, we would recommend that you would browse the course to re-familiarise yourself with pertinent topics. Otherwise, to receive the training certificate, passing the GCP quiz with a score of 75% or higher is a mandatory requirement. Upon successful completion of the GCP quiz and submission of the 'Certification of Own Work', you will be provided with a 'Trial Coordinating Centre GCP training certificate' (Certificate of completion).

**THE FULL TRAINING PACKAGE WILL PROVIDE YOU WITH THE FOLLOWING** (follow the links on the buttons below):


- 1 Identify the reasons why Good Clinical Practice is required in clinical research
- 2 Identify the ethical principles which govern clinical research
- 3 Define the regulations and guidelines applicable to clinical research
- 4 Describe Investigator's responsibilities in conducting clinical research
- 5 Describe the informed consent process and documentation requirements; identify exceptions to the general rules and know the proper procedures in such exceptional situations
- 6 Prepare for successful monitoring visits and site audits by sponsors and regulatory bodies
- 7 Describe the ethical considerations in planning, designing, conducting and reporting clinical trials
- 8 Specify which organisation / regulatory agency is responsible for overseeing the conduct of clinical trials in the participant's own country.
- 9 Describe clinical trial close-out procedures and legal requirements



Following the arrows work through all the sections.

You can revisit any section at any time to refresh your knowledge

You are here: GCP training > Menu > Process > Publication plan



### 3.13 Publication BACK

**Clinical trials conducted by the TCC will require at least one of the following to report the results:**

(1) Those trials which require study reports to support marketing applications are required to meet the standards of the ICH Guidance for Structure and Content of Clinical Study Reports. Each Study Report for submission to the regulatory agencies for trials conducted by the TCC will follow a Statistical Analysis Plan which will be developed in line with the ICH Topic E3 Structure and Content of Clinical Study Reports.

Regulatory reports to be submitted at the end of a trial which do not have to support marketing authorisation will take the form of a publication to a peer review journal.

(2) All trials will submit publications to peer reviewed journals which will be done in accordance with:

- International Committee of Medical Journal Editors
- The CONSORT group
- Individual journal's publication policy

<a href="#">CONSORT statement</a>	<a href="#">COPE guidelines</a>
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DEFINITION OF TERMS			
HISTORY	GUIDELINES & REGULATIONS	INVESTIGATOR RESPONSIBILITIES	INFORMED CONSENT
MONITORING & AUDIT	ETHICAL CONSIDERATIONS	COUNTRY SPECIFIC REGULATIONS	CLOSE OUT
QUIZ			

You can access the QUIZ at the end of the last page or at the Introduction page.



## QUIZ



This quiz consists of 40 questions. Please answer each question by ticking one of the boxes. You will need to complete all the questions at the same time as there is no option to save and return. When you have finished, the programme will calculate your score. **You need to achieve at least 75% to pass.** If your score is lower you should re-visit some questions - the incorrect answers will be highlighted.

The quiz should take no more than half an hour to complete.

**1. What is the difference between an Adverse Event (AE) and an Adverse Drug Reaction (ADR):**

- Both terms mean the same
- An ADR has some recognized causal relationship with the medicinal product that an AE does not have
- An ADR is seen with a marketed product whereas an AE is seen with an experimental drug

**2. Good Clinical Practice is a standard providing assurance that:**

- The ethics committee will approved the study
- The results are of good quality and that the patient's rights are protected
- The experimental drug will obtain a marketing approval

**3. An Independent Ethics committee (IEC):**

- Must review the suitability of the protocol, investigators, facilities and the informed consent process
- Must have at least two lay members (non-scientific, non-medical members)
- Must meet at least every 6 weeks and return their opinion within 8 weeks of receipt of the documents

**4. An 'investigational product' is:**

- An active ingredient used in a clinical trial
- An active ingredient or a marketed product used in a clinical trial
- An active ingredient or a marketed product or a placebo used in a clinical trial

**5. For an Adverse Event or an Adverse Drug Reaction, 'Serious' includes:**

- Death, life threatening, hospitalisation, disability / incapacity, congenital anomaly / birth defect, but not cancer and overdose
- All of the above plus cancer and overdose
- Death and life threatening only



Tick one answer for each of the 40 questions.

<p>False</p>	
<p><b>34. Which of the following have the capacity to give legal valid Consent:</b></p> <ul style="list-style-type: none"> <li><input type="radio"/> Children (less than 16 years old)</li> <li><input type="radio"/> Elderly</li> <li><input type="radio"/> Patient with severe impairment in level of consciousness due to traumatic brain injury</li> </ul>	
<p><b>35. Which of the following is an advantage of double blind Randomised Controlled Trials (RCTs):</b></p> <ul style="list-style-type: none"> <li><input type="radio"/> The significance of the results does not have to be tested using statistical methods</li> <li><input type="radio"/> Blinding reduces bias on the part of both the investigator and the participant</li> <li><input type="radio"/> It does not help assure compliance with the principle of distributive justice, in that all participants have an equal chance of receiving the new therapy and likewise an equal chance of being exposed to the risks of that therapy</li> </ul>	
<p><b>36. A trial planned with an adequate sample size may be flawed by which of the following:</b></p> <ul style="list-style-type: none"> <li><input type="radio"/> A large number of participants lost to follow-up or by excessive missing data</li> <li><input type="radio"/> Using every means possible to reduce loss to follow-up</li> <li><input type="radio"/> Designing Case Record Forms to collect only the data required</li> </ul>	
<p><b>37. In measuring outcome, which of the following will not minimise measurement bias:</b></p> <ul style="list-style-type: none"> <li><input type="radio"/> Use of an objective outcome (e.g. death)</li> <li><input type="radio"/> Varying the assessment of outcome</li> <li><input type="radio"/> Investigators and patients are aware of the treatment allocation</li> </ul>	
<p><b>38. Which of the following best describes 'Statistical Power' of a trial:</b></p> <ul style="list-style-type: none"> <li><input type="radio"/> Probability you will detect a meaningful difference, or effect, if one were to occur</li> <li><input type="radio"/> Probability that a meaningful difference will be detected using a large sample</li> <li><input type="radio"/> Probability that you will eliminate a Type I error</li> </ul>	
<p><b>39. All clinical trial information should be:</b></p> <ul style="list-style-type: none"> <li><input type="radio"/> Kept with hospital records</li> <li><input type="radio"/> Stored in a locked room</li> <li><input type="radio"/> Accurately recorded, handled and stored</li> </ul>	
<p><b>40. Who is responsible for providing an up to date Investigator's Brochure to the responsible ethics committee:</b></p> <ul style="list-style-type: none"> <li><input type="radio"/> The sponsor</li> <li><input type="radio"/> The coordinating centre</li> <li><input type="radio"/> The PI</li> </ul>	
<p> <b>TOP</b></p>	<p><b>CALCULATE SCORE</b> </p>



Then calculate your score



You are here: [GCP training Menu](#) > [Introduction](#) > QUIZ



## QUIZ



This quiz consists of 40 questions. Please answer each question by ticking one of the boxes. You will need to complete all the questions at the same time as there is no option to save and return. When you have finished, the programme will calculate your score. **You need to achieve at least 75% to pass.** If your score is lower you should re-visit some questions - the incorrect answers will be highlighted.

The quiz should take no more than half an hour to complete.

**You achieved a score of 15 (38%). Unfortunately you have not passed. Please look at your incorrect answers below and try again.**

Attempt number: 2

**Incorrect**

1. What is the difference between an Adverse Event (AE) and an Adverse Drug Reaction (ADR):

- Both terms mean the same
- An ADR has some recognized causal relationship with the medicinal product that an AE does not have
- An ADR is seen with a marketed product whereas an AE is seen with an experimental drug

**Incorrect**

2. Good Clinical Practice is a standard providing assurance that:

- The ethics committee will approved the study



To pass, you need to answer at least 30 questions correctly. If you have not passed you will see this screen. The incorrect answers are highlighted.

## GCP TRAINING

# QUIZ



This quiz consists of 40 questions. Please answer each question by ticking one of the boxes. You will need to complete all the questions at the same time as there is no option to save and return. When you have finished, the programme will calculate your score. **You need to achieve at least 75% to pass.** If your score is lower you should re-visit some questions - the incorrect answers will be highlighted.

The quiz should take no more than half an hour to complete.

**Congratulations! You achieved a score of 36 (90%). Now enter your details below to inform the TCC of your success.**

Attempt number: 1

To assess your knowledge of local clinical trial regulations, please provide answers to the following:

1. In which country are you located?  required

2. Please give the name of organisation who has overall responsibility for the conduct of Clinical Trials in your country  required

Please give your details:

Surname:  required

Forename:  required

Title:  required

Appointment:  required

Role in trial:  required

Hospital:  required

email:  required

I certify that the GCP quiz was completed by me personally.  
required

SEND



If you have passed you will see this screen. Enter your details on the form, tick the 'own work' box, and click on SEND.



## Certificate of Completion

### **Good Clinical Practice training**

This is to certify that **Professor Albert Einstein** of **University Teaching Hospital, Antarctica**, has successfully completed GCP Training provided by the London School of Hygiene & Tropical Medicine on 31 February 2015.

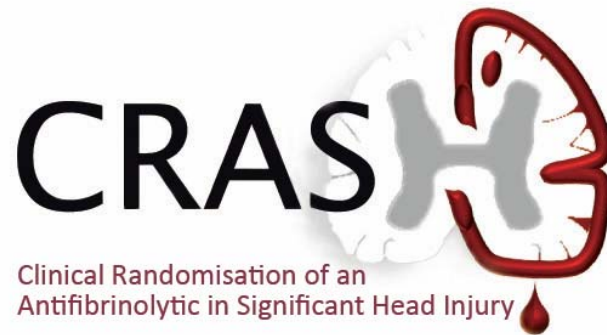
Ian Roberts  
Professor in Epidemiology

Haleema Shakur  
Senior Lecturer in Clinical Trials

#### THE FOLLOWING OBJECTIVES HAVE BEEN FULFILLED:

1. Reasons why GCP is required
2. Regulations and guidelines applicable to clinical research
3. Principal Investigator's responsibilities in conducting clinical research
4. Informed consent process and documentation requirements; exceptions to the general rules and the proper procedures in such exceptional situations
5. Preparation for successful monitoring visits and site audits by sponsors and regulatory bodies
6. Ethical considerations in planning, designing, conducting and reporting clinical trials
7. Knowledge of organisation / regulatory agency responsible for overseeing the conduct of clinical trials in the country of Principal Investigator.

- ❖ We will receive an automated email to tell us that you have passed.
- ❖ We will then send you a Certificate of Completion.
- ❖ A copy of the certificate should be filed in the Investigators' Study File Section 19 Site responsibilities.



Clinical Randomisation of an  
Antifibrinolytic in Significant Head Injury

### **Trial Coordinating Centre**

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