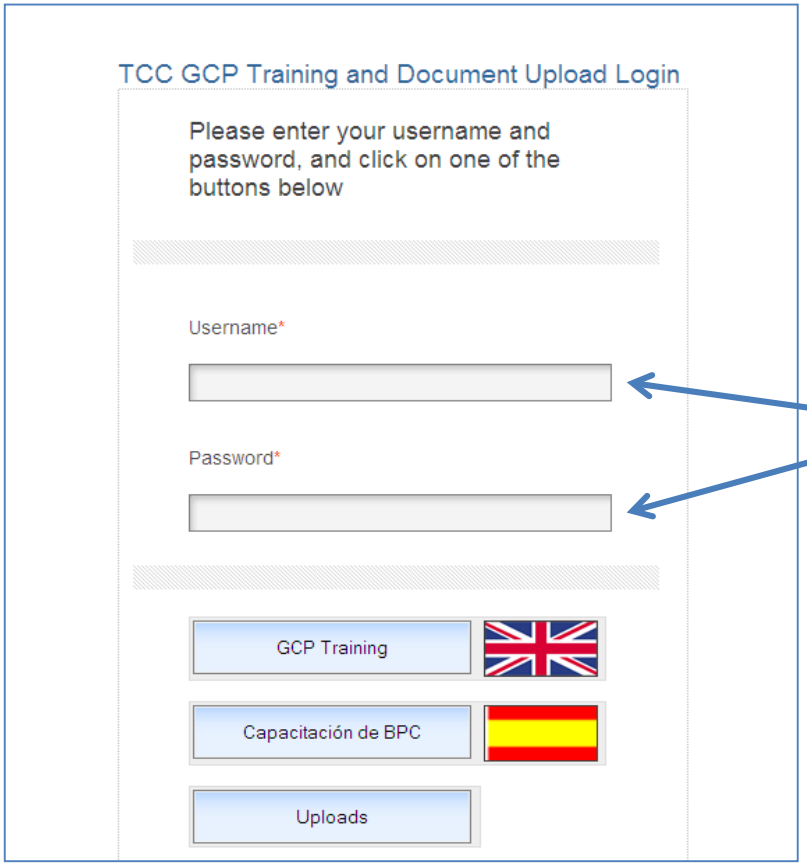
Haemorrhage alleviation with tranexamic acid - Intestinal system

GUIDANCE FOR COMPLETING GCP TRAINING AND SUBMITTING THE TEST

How can I access the GCP training?

- Please, email Haltit@Lshtm.ac.uk, we will provide:
  - Web-link to access the online training
  - Username and password



Username and password are available by emailing Haltit@Lshtm.ac.uk

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 county.

9 Describe clinical trial close-out procedures and legal requirements

DEFINITION OF TERMS

HISTORY | GUIDELINES & REGULATIONS | INVESTIGATOR RESPONSIBILITIES | INFORMED CONSENT

MONITORING & AUDIT | ETHICAL CONSIDERATIONS | COUNTRY SPECIFIC REGULATIONS | CLOSE OUT

QUIZ

PREVIOUS

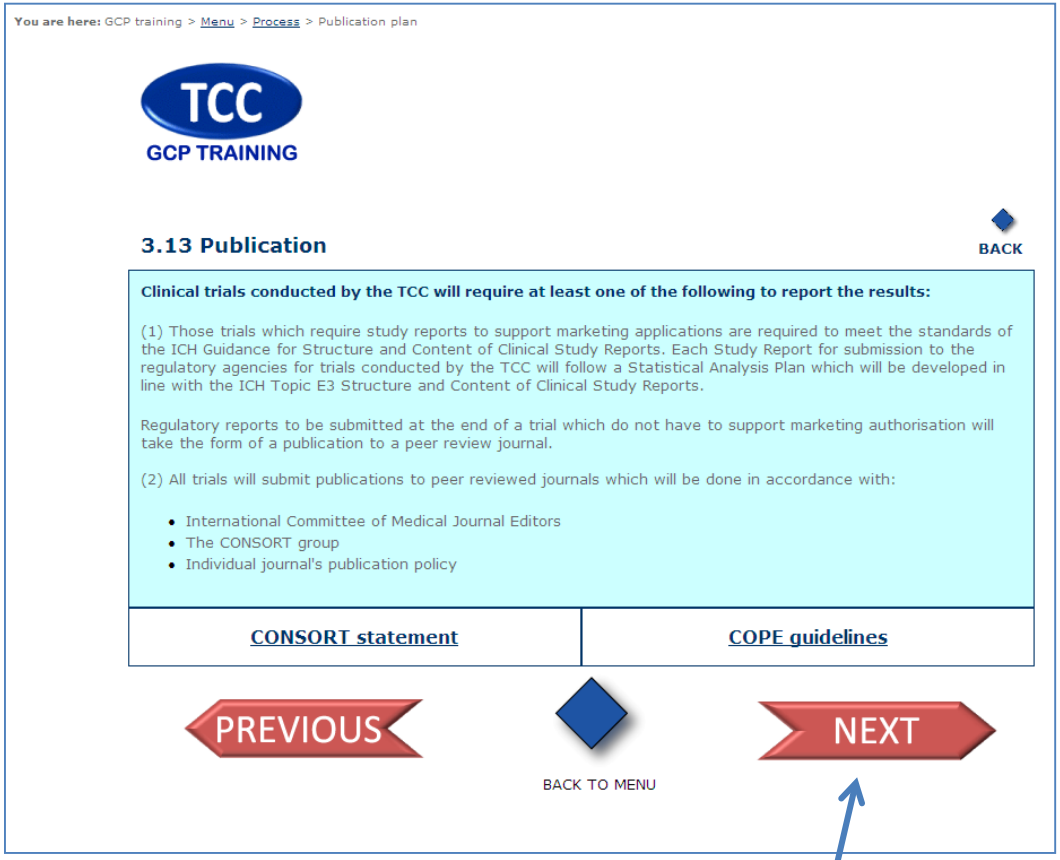
BACK TO MENU

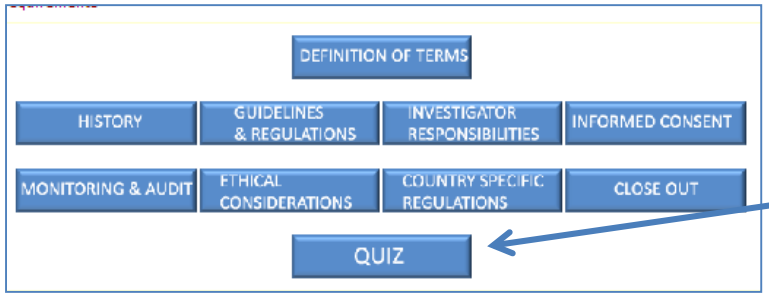
ICH E6 GUIDELINE FOR GOOD CLINICAL PRACTICE

NEXT

Following the arrows work through all the sections.

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





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

You are here: GCP training Menu > Introduction > QUIZ

TCC
GCP TRAINING

QUIZ

BACK

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.

34. Which of the following have the capacity to give legal valid Consent:

- Children (less than 16 years old)
- Elderly
- Patient with severe impairment in level of consciousness due to traumatic brain injury

35. Which of the following is an advantage of double blind Randomised Controlled Trials (RCTs):

- The significance of the results does not have to be tested using statistical methods
- Blinding reduces bias on the part of both the investigator and the participant
- 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

36. A trial planned with an adequate sample size may be flawed by which of the following:

- A large number of participants lost to follow-up or by excessive missing data
- Using every means possible to reduce loss to follow-up
- Designing Case Record Forms to collect only the data required

37. In measuring outcome, which of the following will not minimise measurement bias:

- Use of an objective outcome (e.g. death)
- Varying the assessment of outcome
- Investigators and patients are aware of the treatment allocation

38. Which of the following best describes 'Statistical Power' of a trial:

- Probability you will detect a meaningful difference, or effect, if one were to occur
- Probability that a meaningful difference will be detected using a large sample
- Probability that you will eliminate a Type I error

39. All clinical trial information should be:

- Kept with hospital records
- Stored in a locked room
- Accurately recorded, handled and stored

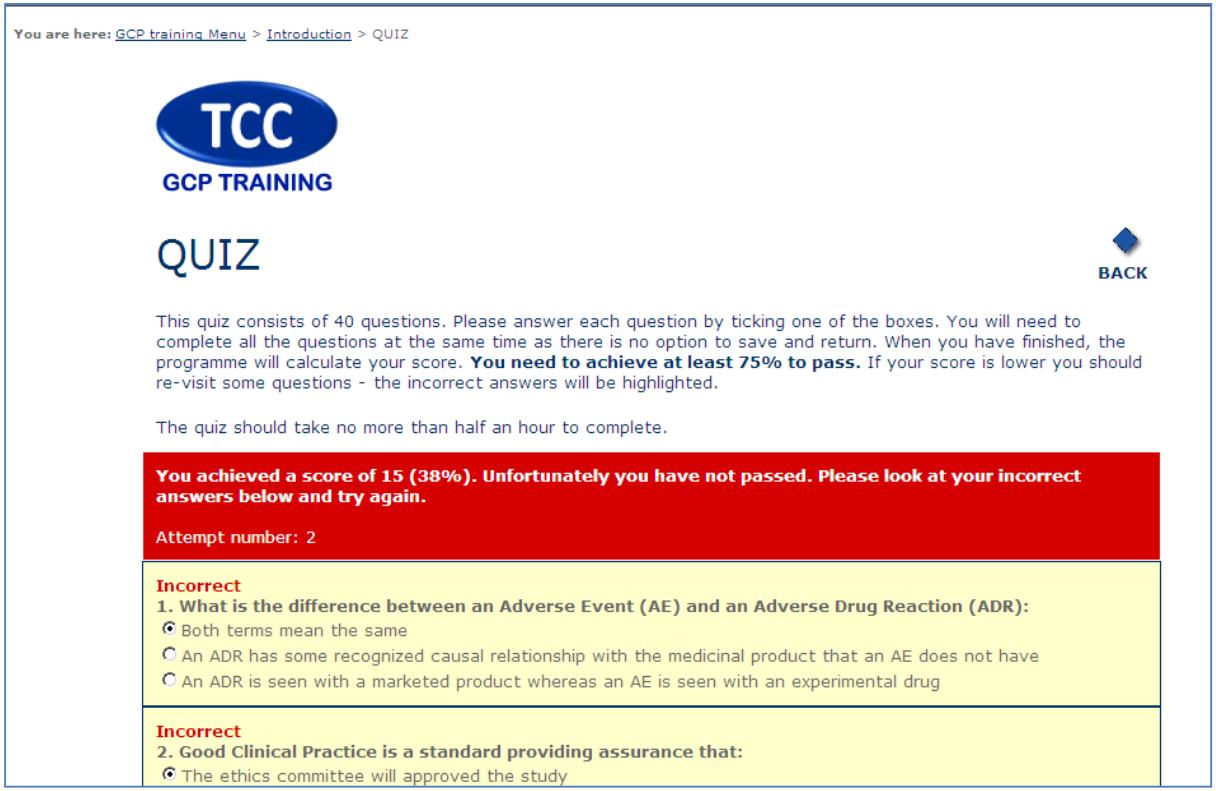
40. Who is responsible for providing an up to date Investigator's Brochure to the responsible ethics committee:

- The sponsor
- The coordinating centre
- The PI

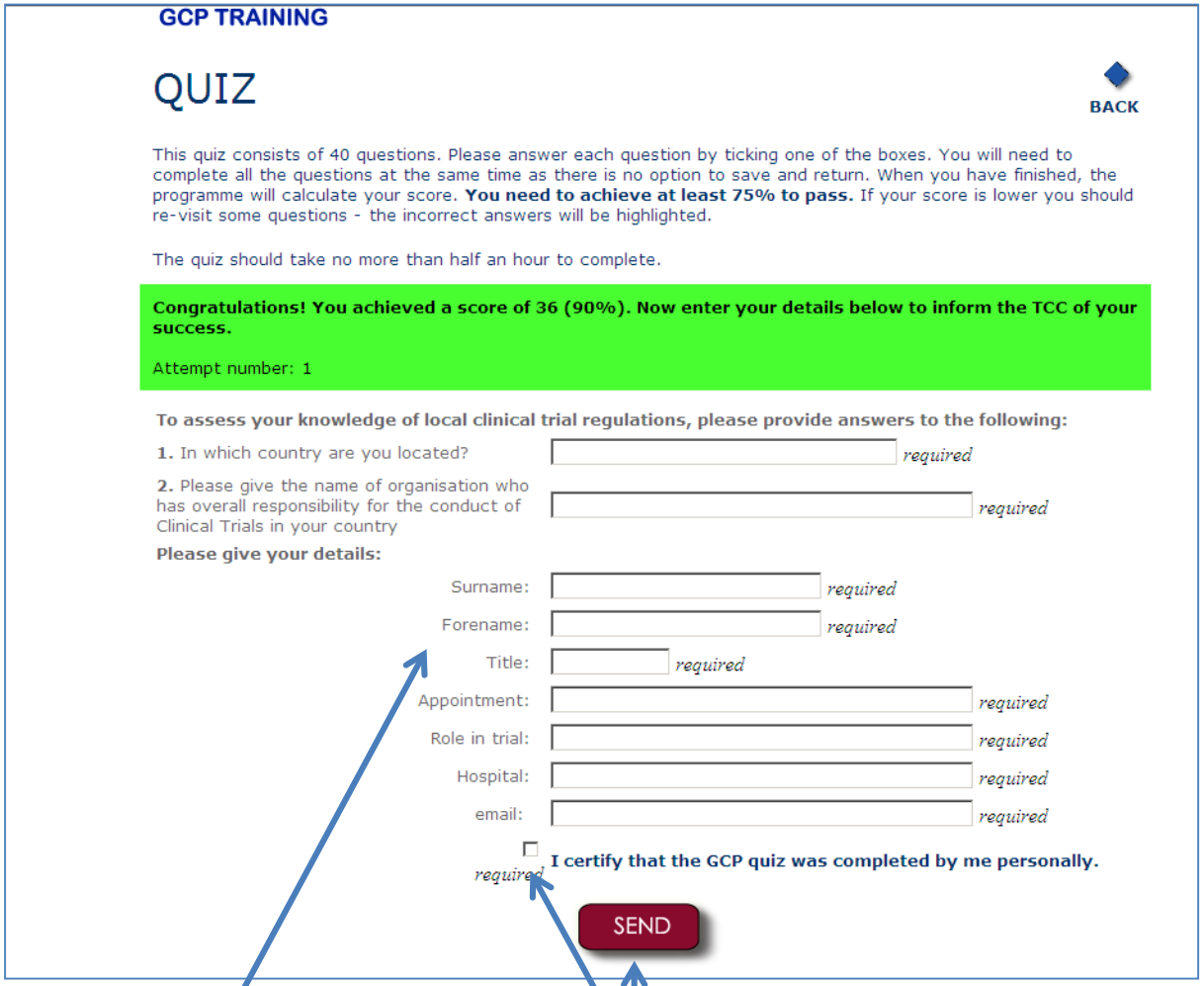
TOP

CALCULATE SCORE

Then calculate your score



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.



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

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contributing to health worldwide

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.

JOIN THE GLOBAL COLLABORATION

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UKCRC Registered Clinical Trials Units

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