




GOOD CLINICAL PRACTICE (ICH GCP)

PROFESSIONAL DEVELOPMENT COURSE

COURSE BOOKLET

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INVESTIGATOR AND SITE PERSONNEL GOOD CLINICAL PRACTICE (ICH GCP)

Introduction

Welcome to the Investigator and Site Personnel Good Clinical Practice (ICH GCP) online training program.

The ICH Good Clinical Practice (GCP) Guideline (ICH E6 R2) is a unified, globally recognised, ethical, scientific, and quality standard for conducting clinical trials. It sets the responsibilities and expectations of sponsors, investigators, and all other professionals involved in designing, conducting, monitoring, recording, and reporting of clinical trials. Complying with the guideline helps to ensure that the rights, safety, and well-being of participants are protected, and that the trial data and results are reliable.

The course satisfies the Minimum Criteria for Good Clinical Practice (GCP) training of investigators and site personnel (based upon ICH E6 R2) as defined by [TransCelerate](#). To satisfy these criteria, the course includes an overview of GCP, the principles of ICH GCP, and investigator responsibilities. Additionally, our course provides an overview of the Australian regulatory environment, and the roles and responsibilities of the sponsor, contract research organisation, and clinical trial monitor.

Course Overview

The Investigator and Site Personnel Good Clinical Practice (ICH GCP) online training program is an online, self-paced learning course consisting of two (2) lessons. Each lesson is organised into a series of topics, with 16 topics in total.

Each topic consists of one page of learning materials. Written content is accompanied by short videos, summary tables, and diagrams (including our own purpose-made infographics). References and recommended readings are listed at the end of each topic.

A GCP course assessment quiz will become accessible upon completion of the two lessons. A passing grade of at least 80% is required to pass the course and receive a certificate of completion.

The course and certificate are compliant with the [TransCelerate Site Qualification and Training \(SQT\) Initiative](#), reflecting professional recognition for ICH E6 Good Clinical Practice (GCP) Training targeted to investigator site personnel. The certificate is valid for a period of 3 years.

The course takes approximately 2 - 4 hours to complete.

Learning Objectives

There are a total of 16 course topics covering the following learning objectives:

- ◆ 1. Introduction to Clinical Trials
- ◆ 2. Good Clinical Practice – An Overview
- ◆ 3. The Australian Regulatory Environment
- ◆ 4. Roles and Responsibilities
- ◆ 5. Investigator Qualifications and Agreements
- ◆ 6. Resourcing
- ◆ 7. Medical Care of Trial Participants
- ◆ 8. Communication with HREC
- ◆ 9. Compliance with Protocol
- ◆ 10. Investigational Products
- ◆ 11. Randomization Procedures and Unblinding
- ◆ 12. Informed Consent of Trial Participants
- ◆ 13. Records and Reports
- ◆ 14. Progress Reporting and Final Reports
- ◆ 15. Safety Reporting
- ◆ 16. Premature Termination or Suspension of Trial

Pricing

We are currently offering our Good Clinical Practice (ICH GCP) Course for **A\$10 (inc. GST)**. This includes:

- Immediate course access
- A complete (71 page) downloadable study guide
- A personalised, compliant GCP training certificate.

This small fee allows us to cover the ongoing administrative costs of running this popular training course.

Bulk Purchasing

If you would like to purchase our Good Clinical Practice (ICH GCP) Training Course in bulk, please send an email to reception@genesishresearchservices.com with the subject "Bulk Course Purchase" or call us on +61 (0)2 4985 1860 to enquire. Please state the number of user enrolments you would like to purchase in bulk. Discounts are available for bulk purchases of 10 or more user enrolments.

Instructions

Please read the instructions below before starting the course. Following these instructions will ensure that your progress is updated correctly and that your certificate displays the correct information.

If you are experiencing any issues with the course, please refer to the [Frequently Asked Questions](#) before contacting us.

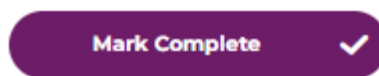
Course Content

The course consists of **2** lessons. Each lesson contains several **topics**. Each topic consists of one page of learning material. A list of References and Resources is provided for each unit.

Some topics contain embedded short **videos** that we recommend you take the time to watch.

Course Progression

At the end of each topic, you must click on the **“Mark Complete”** button to confirm your progress and move on to the next topic. This includes the GCP Course Assessment lesson page.



Once you have completed all topics within a lesson, you must click on **“Back to Lesson”** and then click on the **“Mark Complete”** button before moving on to the next lesson.

You can revisit topics at any time by clicking on the course title or the unit title above the progress bar located on the top of any course page.

Assessment Quiz

The final lesson contains the assessment quiz. The quiz consists of 20 randomised questions, including single choice (only 1 correct answer) and multiple choice (more than 1 correct answer possible) items. The type of question is indicated in parentheses ()'s underneath the question.

You will need to correctly answer at least **16 of the 20** questions (**a score of at least 80%**) to pass each unit.

There is no time limit. You may attempt the quiz as many times as you need to.

A results page will load upon finishing the quiz. To review your answers, click on the View Questions button. Correctly answered questions are highlighted green. Incorrectly answered questions are displayed with a red border, with the correct answers displayed in a green border.

Course Certificate



Once you have completed all lessons and topics and received a passing grade on the assessment quiz, a personalised course certificate will be generated.

NOTE: Before you can download your certificate, you must mark each course topic and lesson as complete.

To download your certificate, return to the main course (overview) page to find a certificate download button as shown.



You have successfully completed the course and earned a certificate!



Download
Certificate

You can also download your certificate from the [Student Account](#) page.

PLEASE NOTE: GCP course certificates will be **removed** from our website after 2 years. To avoid losing access, be sure to download your certificate and store it in a safe place. We recommend emailing yourself a copy for added security.

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