



RESEARCH FUNDAMENTALS

PROFESSIONAL DEVELOPMENT COURSE

COURSE BOOKLET

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Introduction

Genesis Research Services is dedicated to delivering accessible, contemporary training resources for clinical research professionals. Our goal is to support professional growth by providing tailored content that meets the needs of individuals across all backgrounds, roles, and experience levels in the research industry.

A successful career in clinical research requires a strong foundation in clinical trial concepts and an ongoing awareness of the industry's ever-evolving landscape. To support this, we developed the Research Fundamentals Training Course to offer a comprehensive introduction to key aspects of clinical trials, breaking down complex concepts often encountered in the world of clinical research.

The course is ideal for those new to clinical research, looking to enter the industry, or seeking to strengthen their understanding of essential trial concepts. The material is relevant to all professionals involved in the design, conduct, management, analysis, and reporting of clinical trials.

This course was developed by a team of experienced clinical research professionals, including site managers, medical researchers, and clinical trial coordinators.

Course Overview

The Research Fundamentals Training Course is an online, self-paced program consisting of four units that may be applied towards your yearly CPD portfolio.

Each unit includes a series of topics, supported by videos, recommended readings and external resources, summary tables, diagrams, and custom infographics. A comprehensive reference list of accessible peer-reviewed journal articles and reputable web resources is provided for further learning.

At the end of each unit, there is an assessment quiz, consisting of multiple choice and interactive questions. A certificate of completion is awarded upon completion of the course.

The units are designed to complement each other and expand your level of clinical trials knowledge. The units can be completed at your own pace, however, we recommend following the set order. Each unit, including readings and assessment quiz, is expected to take around two hours.

Learning Topics

◆ Unit 1: Introduction to Clinical Trials

- ◆ This unit provides a comprehensive introduction to clinical research. It covers the research roadmap and the four phases of clinical trials and discusses the differences between pharmaceutical and medical device trials.
- ◆ You will also learn about key aspects of research planning and trial development, including formulating a research question, hypotheses, and study objectives, outcome measures and endpoints, as well as protocol development and site selection. You will gain insights into participant recruitment strategies, enrolment processes, and study visits.

◆ Unit 2: Clinical Trial Regulation, Roles and Responsibilities

- ◆ This unit offers an overview of the regulatory landscape that governs human research, including Australian regulatory requirements and ethical review of clinical trials.
- ◆ This unit also outlines the roles and responsibilities of key stakeholders involved throughout the lifecycle of a clinical trial, including sponsors, contract research organisations, investigators, human research ethics committees, study coordinators, trial monitors, and other healthcare professionals.

◆ Unit 3: Clinical Research Study Design

- ◆ In this unit, you will learn about the fundamental elements of clinical research design, including randomisation, blinding, and controls. Common study designs, such as randomised controlled trials, crossover studies, and cohort studies, are discussed, including their unique purposes, strengths and weaknesses.
- ◆ This unit also covers how to mitigate bias and confounding factors through appropriate study design. Levels of evidence are also introduced.

◆ Unit 4: Understanding Clinical Trial Results

- ◆ This unit introduces fundamental statistical concepts necessary to interpret clinical trial data. You will learn about descriptive statistics, and inferential statistics, and the importance of hypothesis testing and determining statistical significance. Statistical methods to account for bias and confounders are discussed.
- ◆ This unit discusses the importance of correct interpretation and critical appraisal of trial results, assessing clinical relevance, and transparency in reporting trial outcomes.

Pricing

We are currently offering our Research Fundamentals Training Course for **AUD \$230 (inc. GST)**. This includes:

- ◆ Immediate course access
- ◆ Approximately 8 hours of learning
- ◆ Downloadable study guides for each unit
- ◆ Certificate of completion
- ◆ Free access to our [Good Clinical Practice \(ICH GCP\) Course](#).

Terms & Conditions

Use of any Genesis Research Services Course is subject to the [Online Education Terms and Conditions](#), which set out our **Refund Policy, Cancellation / Variation** details, **Disclaimers** and more. Please read these terms and conditions carefully prior to purchasing a course.

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 **4 units** (lessons). Each unit 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.

Recommended readings and other resources have been posted throughout the course. Click on the orange icon to access these. Whilst it is not necessary to read all of these to complete the course, we recommend saving and incorporating these into your own personal library. All external links should automatically open in a new tab.



Course Progression

At the end of each topic, you must click the **'Mark Complete'** button to confirm your progress and proceed to the next topic. This includes the References and Resources, as well as the Assessment Quiz pages.



Mark Complete ✓

Once all topics within a lesson are completed, click **'Back to Lesson'** and then click the **'Mark Complete'** button before proceeding 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

At the end of each unit is an assessment quiz. Each quiz consists of 10 randomised questions.

The quizzes consist of several types of standard and interactive questions:

- ◆ **Single choice** – only 1 correct answer.
- ◆ **Multiple choice** – more than 1 correct answer possible.
- ◆ **Ordering** – place the answers in the correct order.

- ◆ **Matching (sorting)** – match the sort elements to their associated items.
- ◆ **Fill in the blank** – type the correct answer in the empty space.

Instructions are provided in parentheses ()'s underneath each question.

You will need to correctly answer at least **8 of the 10** questions (**a score of at least 80%**) to pass each unit.

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

Course Certificate



Once you have completed all units and received a passing grade on all quizzes, a personalised course certificate will be generated.

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.

NOTE: You will not be able to download your certificate unless you have marked each topic and lesson as **complete**. This includes the quiz instructions pages. Please go back to each topic and lesson and mark them as complete. Your certificate download button should then appear.