




Research Fundamentals

Professional Development Course

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RESEARCH FUNDAMENTALS

Introduction

Genesis Research Services is dedicated to delivering contemporary and engaging 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 preparing to enter the clinical research field or new to the industry, and those seeking to expand or consolidate their knowledge of essential trial concepts. The material is relevant to all professionals involved in the design, conduct, management, analysis, and reporting of clinical trials.

Course Overview

The Research Fundamentals Training Course is an online, self-paced program consisting of four units. 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 several 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 course order. Each unit is expected to take around two hours to complete.

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.
- ◆ The roles and responsibilities of key stakeholders involved throughout the lifecycle of a clinical trial are outlined, including sponsors, contract research organisations, investigators, human research ethics committees, study coordinators, trial monitors, and other healthcare professionals.

◆ Unit 3: Clinical Research Study Design

- ◆ This unit provides an overview of 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 explained, including their unique purposes, strengths and weaknesses.
- ◆ This unit also discusses mitigation strategies for bias and how to control for confounding factors through appropriate study designs. 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 \(R3\)\) Online Training 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 to 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 **four units** (lessons). Each unit contains a series of **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 and Assessment Quiz pages.

Mark Complete ✓

Before progressing to the next unit, please make sure that **all unit topics, the unit quiz, and the unit page are marked as complete**. It is important that you do not skip these steps otherwise your course certificate will not display a completion date.

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 one correct answer.
- ◆ **Multiple choice** – more than one correct answer possible.
- ◆ **Ordering** – place the items 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 assessment quizzes, a personalised course certificate will be generated.

You may download your certificate from the following pages:

1. The main course (overview) page.
2. Your [Student Account](#) page.



You have successfully completed the course and earned a certificate!



Download
Certificate

NOTE: To ensure that your certificate displays a completion date, you must mark each topic and unit as **complete**. This includes the references and resources and quiz instructions pages.