genesis
researchservices

RESEARCH FUNDAMENTALS

PROFESSIONAL DEVELOPMENT COURSE

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Introduction

Genesis Research Services is committed to providing unique, accessible, and contemporary educational and training resources for clinical research professionals. Our aim is to champion professional and institutional development in clinical trials research by delivering real-world and readily usable content for professionals working in the research industry, regardless of background, role, or experience level.

Developing and expanding a successful career in research requires a contemporary understanding of clinical trial concepts and an ongoing awareness of the constantly evolving clinical trials landscape. To this end, we have developed the Research Fundamentals Training Course with the aim to provide a comprehensive introduction to key aspects of clinical trials in a step-by-step fashion and break down complex concepts often encountered in the world of clinical research.

The Research Fundamentals Training Course is intended for any clinical research professional, particularly those who are new to or looking to enter the industry, and those looking to expand or solidify their understanding of essential clinical trial concepts. The essential knowledge covered is relevant to all research professionals involved in the design, conduct, management, recording, analysis, and/or reporting of clinical trials.

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

Course Overview

The Research Fundamentals Training Course is an online, self-paced learning course that consists of four (4) lessons (units) that may be used towards your yearly CPD portfolio.

Each unit is organised into a series of topics. Written content is accompanied by videos, links to recommended readings (journal articles and other resources), summary tables, and diagrams (including our own purpose-made infographics). A comprehensive reference list of accessible peer-reviewed journal articles and reputable web resources is also provided to further support your learning.

Each unit includes a reflection of learning activities in the form of an assessment quiz, consisting of various multiple choice and interactive questions. A certificate of completion is issued upon the successful completion of the training 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, at a time that suits

you. We highly recommend completing the units in the set order. The expected duration of each unit, including the recommended readings and assessment quiz, is 2 hours.

Course Units

- **Unit 1: Introduction to Clinical Trials**
  - This unit provides a thorough introduction to clinical trials research. You will learn about the research roadmap, the different phases of research, developing a research question, hypothesis, and objectives, and what is involved in protocol development and site selection. This unit also provides an overview of what a typical clinical trial may involve, including participant recruitment, enrolment, and study visits.
- **Unit 2: Clinical Trial Regulation, Roles and Responsibilities**
  - This unit provides a brief introduction to the regulation of human research, the roles of the stakeholders involved, and the responsibilities that each stakeholder has in the lifecycle of clinical trials research.
- **Unit 3: Clinical Research Study Design**
  - This unit covers primary clinical trial design elements and commonly adopted structural study designs. You will learn about their purpose, unique functions, methodologies, and the advantages and disadvantages of each, as well as other important things to consider when designing a clinical trial, such as bias.
- **Unit 4: Understanding Clinical Trial Results**
  - This unit covers fundamental statistical concepts relevant to clinical trials, including key definitions and basic methods by which data generated can be summarised and analysed. You will learn about hypothesis testing and statistical significance, and the importance of correct interpretation and critical appraisal of trial results.

Pricing

We are currently offering our Research Fundamentals Training Course at an introductory price of **$180 (inc. GST)**.

This includes:

- Immediate course access
- Approximately 8 hours of learning
- Downloadable study guides for each unit
- Automatically generated certificate of completion
- Free access to our Good Clinical Practice (ICH GCP) Course.

Learning Topics

- Introduction to clinical trials research
  - The research roadmap, phases/stages of clinical trials, and differences between pharmaceutical and medical device trials.
- Clinical research planning
  - Defining the research question, hypothesis, and objectives.
- Clinical trial development and preparation
  - Choosing study outcomes and endpoints, protocol development, and site/investigator selection.
- Conduct processes of clinical trials
  - Participant recruitment, screening, consent and enrolment, study visits – treatment and follow-up.
- The regulations, ethics and standards that govern human research
  - Good clinical practice, regulatory authorities, Australian regulatory requirements and pathways, and ethical review of clinical trials.
- Different stakeholders involved in clinical trials research
  - The roles and responsibilities of sponsors, contract research organizations, investigators, trial coordinators, monitors, and other health professionals.
- Different types of clinical research and study designs
  - Observational and interventional study designs, levels of evidence.
- Bias in clinical trials
  - Different types and sources of bias and methods to minimise bias.
- Basic statistical concepts in clinical trials research
  - Data and variables, descriptive and inferential statistics, statistical significance and power, and statistical methods for bias and confounding variables.
- Interpretation of clinical trial results
  - Critical appraisal of published results, overview of systematic reviews, assessing true treatment effects, and reporting bias.

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 on the "**Mark Complete**" button to confirm your progress and move on to the next topic. This includes the References and Resources and Assessment Quiz pages.

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

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.

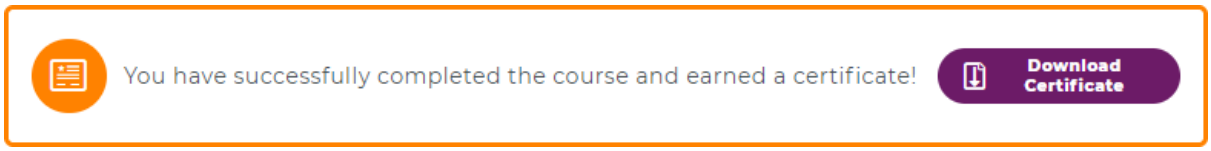
You will need to correctly answer at least **8 of the 10** questions (**a score of at least 80%**) to pass each unit.

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 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.