

OUR VISION

To be the Premier Educator for Service Excellence

OUR MISSION

To inspire Passion for Service and Contribution to Society through Excellence in Continuous Education

OUR VALUES

Responsibility, Integrity, Passion and Excellence (RIPE)

OUR CULTURE

An Open and Conducive Learning Environment, With Mutual Respect and Professionalism to Build A High Performance Organization

COURSE MODULES & SYNOPSIS

WSQ SPECIALIST DIPLOMA IN CLINICAL RESEARCH

Perform Data Management in Clinical Trials

In this module, you will formulate a search for writing a good monitoring report for a clinical research trial, conduct a search for writing a good monitoring report for a clinical research trial, evaluate the literature on writing a good monitoring report for a clinical research trial and document and apply this to practice.

Apply Primary Medical Knowledge and Medical Terminology in Clinical Trials & Describe the Emerging Technologies in Clinical Research

In this module, you will formulate a search for primary medical knowledge and medical terminology in clinical trials, conduct a search for primary medical knowledge and medical terminology in clinical trials and evaluate the literature on primary medical knowledge and medical terminology in clinical trials and document and apply this to emerging technologies.

Write a Good Monitoring Visit Report for a Clinical Research Trial

In this module, you will formulate a search for writing a good monitoring report for a clinical research trial, conduct a search for writing a good monitoring report for a clinical research trial and evaluate the literature on writing a good monitoring report for a clinical research trial and document and apply this to practice.

Manage Finances in Clinical Trials

In this module, you will formulate search for managing finances in clinical research trials, conduct search for managing finances in clinical research trials and evaluate the identified evidence related to managing finances in clinical research trials and document how these apply to the clinical research industry.

Adhere to Safety Requirements in Clinical Research

In this module, you will formulate a search for safety requirements in clinical research, conduct a search for safety requirements in clinical research and evaluate the literature on safety requirements in clinical research and document and apply this to practice.

Manage Trial Supplies in Clinical Trials

In this module, you will formulate a search for managing trial supplies in clinical trials, conduct a search for managing trial supplies in clinical trials and evaluate the literature on managing trial supplies in clinical trials and document and apply this to practice.

Manage Clinical Research Sites

In this module, you will formulate a search for managing clinical research sites, conduct a search for managing clinical research sites and evaluate the literature on managing clinical research sites and document and apply this to practice.

WSQ GRADUATE DIPLOMA IN CLINICAL RESEARCH

Apply Privacy Legislation and Data Protection in Clinical Trials

In this module, you will identify and appraise privacy provision in Singapore, appraise data privacy in clinical trials and identify and appraise commercial confidentiality in clinical trials.

Manage Insurance and Indemnification

In this module, you will identify and appraise Insurance in clinical trials, identify and appraise indemnification in clinical trials and evaluate the importance of insurance and indemnification in clinical trials.

Manage Pharmacovigilance Activities

In this module, you will identify and appraise pharmacovigilance process, monitor activities in relation to pharmacovigilance and describe roles and responsibilities in pharmacovigilance process.

Select Appropriate Research Design for Clinical Trials

In this module, you will formulate a search for appropriate research design for clinical trials, conduct a search for appropriate research design for clinical trials and evaluate the literature on appropriate research design for clinical trials and document and apply this to practice.

Formulate Research Problems into Empirically Testable Hypotheses

In this module, you will formulate search for formulating research problems into empirically testable hypotheses, conduct search for formulating research problems into empirically testable hypotheses and evaluate the evidence gathered on formulating research problems into empirically testable hypotheses and document how this evidence is applied to formulating research problems into empirically testable hypotheses.

Use Medical Statistics in Clinical Trial Management

In this module, you will formulate search for the use of medical statistics in clinical trial management, conduct search for the use of medical statistics in clinical trial management and evaluate the identified literature on the use of medical statistics in clinical trial management and document how these apply to the clinical research industry.

Evaluate Published Research Reports and Apply to Clinical Practice

In this module, you will formulate search for published research reports that apply to clinical practice, conduct search for published research reports that apply to clinical practice and evaluate the identified published research reports and document how these apply to clinical practice.



CSM ACADEMY
INTERNATIONAL



WSQ DIPLOMA / SPECIALIST DIPLOMA /
GRADUATE DIPLOMA IN:

**CLINICAL
RESEARCH**

**BEHIND EVERY
BREAKTHROUGH**

IS A TEAM OF SELFLESS INDIVIDUALS.

To apply: Visit us at <http://csmacademy.edu.sg/> or our office

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Cert No. : EDU-2-2105
Validity: 31-08-2017 to 30-08-2021
ERF Registration No. 200505735M
ERF Validity: 20/5/2018 - 19/5/2022

Awarded by:



SINGAPORE
WORKFORCE SKILLS
QUALIFICATIONS

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INTRODUCTION

Behind every cure for the various diseases that plagued a human body, is a team of scientists and their team of selfless clinical researchers.

Clinical research is a branch of healthcare science that studies the health and illnesses in human, and determines the effectiveness and safety of medications, devices, diagnostic products and treatment regimens intended for human use. It also considers the ethical issues that could arise from their implementation for prevention, treatment, diagnosis or for relieving symptoms of a disease.

The Clinical Research Programme – WSQ Diploma/ WSQ Specialist Diploma/ WSQ Graduate Diploma – is the first of its kind in the clinical research industry. Endorsed and validated by the industry, each diploma equips the students with practical knowledge and competency based skills to prepare them for a career in the field of Clinical Research.



COURSE DURATION

Part time:

WSQ Diploma in Clinical Research: 6 months;
 WSQ Specialist Diploma in Clinical Research: 4 months;
 WSQ Graduate Diploma in Clinical Research: 4 months.

COURSE COMMENCEMENT

January, March, July, October

- A minimum number of 15 students for the commencement of the class.
- Students will be informed 2 weeks before the commencement of the class.

COURSE DEVELOPER AND AWARDDING BODY

CSM Academy International, Singapore / Skillsfuture SG

ABOUT CSM ACADEMY

CSM Academy was established since 2005 as a Private Education Institute to deliver Service Management programmes with a major focus on healthcare services education. It delivers multi-level courses ranging from Certification and Diplomas to Bachelor's and Master's Degrees. Other than healthcare, CSM Academy also provides educational courses across a wide range of other disciplines including biomedical research, digital media, and hospitality & tourism.

CSM believes Life Skills is essential to meet the challenges of everyday life. To cope with the increasing pace and change of modern life, we offer healthcare courses which provides the necessary skills education not just workplace but home life.

LEARNING OBJECTIVES

- To provide trainees with skills and knowledge that will enable them to respond effectively in a rapidly changing health arena that is strongly influenced by healthcare trends and both local, and international legislations.
- To support and challenge trainees' the development of their skills and knowledge to enable them to either enter the industry and/or for those already in the industry, to upskill themselves in order to be able to perform in their professional practice more effectively.
- To encourage trainees to leverage on their acquired skills and knowledge to adapt to the ever-changing landscape in clinical research. To provide students with the opportunity to critically evaluate and explore the complexities of conducting clinical research in the current healthcare and legislative environment.

	WSQ Diploma in Clinical Research	WSQ Specialist Diploma in Clinical Research	WSQ Graduate Diploma in Clinical Research	Total Course Fees
Full Course Fees	\$12,000	\$12,000	\$12,000	\$36,000
Nett Fee after 50% subsidy	\$6,840	\$6,840	\$6,840	\$20,520
Nett Fee after 90% subsidy	\$2,040	\$2,040	\$2,040	\$6,120

COURSE MODULES & SYNOPSIS

WSQ DIPLOMA IN CLINICAL RESEARCH

Manage Documentation in Clinical Research

In this module, you will handle documents in the clinical trials settings, perform efficient filing in clinical trial management and ascertain that the document are being handled in accordance with regulatory guidelines.

Monitor Progress in Clinical Trials

In this module, you will learn to perform specific tasks in monitoring clinical trials, manage clinical trial site using monitoring tool, perform data monitoring in clinical trials, manage the electronic data capture (EDC) and interpret electronic source data in clinical trials.

Apply Principles of Pharmacology in Clinical Research

In this module, you will recognise the basic pharmacological principles in clinical trials, apply basic pharmacology in clinical trials and monitor the clinical research process to ensure that the correct pharmacological principles are used.

Manage Lab-related Matters in Clinical Research

In this module, you will identify the different laboratory related matters, interpret Laboratory results in clinical trials, apply principles of toxicity in clinical trials and calculate the correct drug dosage and IV flow rate using given formula.

Apply Ethical Theories to Trial Design

In this module, you will identify and appraise the key ethical theories that are employed within clinical research critically, determine the key ethical principles that should be adhered to within clinical trial design to assure the safety of patients, verify that the ethical principles are followed in clinical trials and document all non compliance in accordance to organisational procedure.

Use of Biostatistics in Clinical Research

In this module, you will identify and appraise the pertinent literature surrounding biostatistics in clinical trials, discuss the biostatistical approaches applied in the clinical research process, determine if the correct biostatistical approach is being use in clinical research process and document all non compliance in accordance to organizational procedure.

Interpret Clinical Development & Product Life Cycle in Clinical Research

In this module, you will identify the phases of the product life cycle, describe the relationship between clinical trials and product life cycle, identify the relationship between the product life cycle and the clinical trial and document how clinical trial industry audit the product life cycle.

Application of Clinical Trial in Drug Development Process

In this module, you will identify and appraise the phases of drug development in clinical trials, identify and appraise the phases of clinical development in clinical trials and describe the association between clinical development and drug development.

Apply Good Clinical Practices in Clinical Research

In this module, you will apply international principles of ethical conduct and subject protection, apply good clinical practices guidelines (International Conference on Harmonisation (ICH), Food and Drug Administration (FDA), Singapore Good Clinical Practice (SG GCP) and European Union (EU) Clinical trials directive), apply European Union – Good Manufacturing Practice (EU-GMP) in Clinical Trials and differentiate FDA Regulations from EU Regulations.

Manage Clinical Research Trials

In this module, you will manage Clinical Trials, manage data management issues, report adverse events, perform drug accountability and track corrective and preventative actions.

Initiate a Clinical Trial

In this module, you will learn to prepare a research proposal in clinical trial management manage contract negotiation for clinical trials and adhere to safety regulations during reporting in a clinical trial.

ENTRY REQUIREMENT

Language requirements:

At least a C6 at GCE O/A Level English or equivalent or Academic IELTS 6.0 or equivalent;no element lower than 5.5 or equivalent.

Academic requirements:

Bachelor or equivalent in Life Sciences of relevant fields.

FEES

Application Fee (Non-Refundable and non-transferrable)

For local students: S\$50.00 (before GST)
 (For Singaporeans / PRs / Foreigners with valid passes)
 For international students#: S\$600 (before GST)
 (For student pass holder)

Insurance Fees

Fee Protection Scheme***: Subject to prevailing market rate
 Medical Insurance Fee****: Subject to prevailing market rate

***The Fee Protection Scheme (FPS) serves to protect students' paid fees.

****It is compulsory for all local and international students to purchase medical insurance which is valid throughout their course of studies with the CSM Academy International. Local students (Singaporeans, PRs & Non-student's Pass holders) may opt-out for this scheme if they can provide the proof of adequate medical insurance coverage in Singapore.

Note: - Payment of fees is in Singapore Dollars
 - Payment method only by Cheque/ Nets/ Telegraphic Transfer

Miscellaneous Fees

Please ask for a copy from our Programme Executives

The programme is nationally accredited under the Clinical Research Workforce Skills Qualifications (WSQ) framework. Upon completion of the programme, students will be awarded WSQ Statement of Attainments (SOAs) and WSQ Qualifications under the Clinical Research WSQ framework.