CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS

# CERTIFIED EU CLINICAL TRIAL SAFETY AND PHARMACOVIGILANCE MANAGER™

## CTS™

**Fully Accredited By:**

Chartered Institute of Professional Certifications

CPD Certification Service






# PROGRAM OVERVIEW

Under **EU Clinical Trials Regulations**, sponsors must report fatal or life-threatening suspected unexpected serious adverse reactions (SUSARs) **within seven days** of awareness, and all other SUSARs **within 15 days. A single misclassified safety event, missed deadline, or lapse in oversight can place participants at risk, invite regulatory intervention, and derail clinical development**. These obligations demand accurate assessments, documented decisions, and unambiguous sponsor accountability

This certified program equips you with the expertise to manage **EU clinical trial safety, pharmacovigilance compliance, and regulatory reporting in accordance with Good Clinical Practice (GCP) and Good Pharmacovigilance Practices (GVP)**. You will learn to assess **serious adverse events**, identify **SUSARs**, determine expectedness using **Reference Safety Information (RSI)**, and manage expedited EudraVigilance submissions. The program also covers **ICSR management, E2B(R3), MedDRA coding, DSURs, CTIS** reporting obligations, urgent safety measures, and serious breach notifications.

## ACCREDITATIONS

CPD CERTIFIED
The CPD Certification Service

Trustpilot
4.8

CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS
4.6




# PROGRAM OVERVIEW

Beyond regulatory compliance, you will develop practical capabilities in **safety signal detection, risk mitigation, and pharmacovigilance governance**. You will strengthen **sponsor oversight**, manage **outsourced safety activities**, address emerging safety concerns, and establish effective **safety management processes** throughout clinical development.

Through practical case studies, you will learn to resolve **safety reporting failures, improve data reconciliation, investigate compliance gaps**, and implement effective corrective and preventive actions (CAPA). You will also gain the skills to strengthen **inspection readiness, reduce recurring errors, improve reporting timeliness, and measure safety performance** through meaningful compliance indicators.

Upon successful completion, you will earn the **Certified EU Clinical Trial Safety and Pharmacovigilance Manager (CTS™)** designation, validating your expertise in clinical safety oversight, pharmacovigilance compliance, and regulatory risk management. This certification elevates your professional credibility and accelerates your advancement into greater responsibilities in clinical safety, drug safety management, and pharmacovigilance leadership.

## ACCREDITATIONS

CPD CERTIFIED
The CPD Certification Service

Trustpilot
4.8

CHARTERED
INSTITUTE OF PROFESSIONAL CERTIFICATIONS
4.6

# KEY SKILLS YOU WILL GAIN

## From This Program



EU CTR 536/2014 REGULATORY COMPLIANCE
GOOD CLINICAL PRACTICE (GCP) COMPLIANCE
GOOD PHARMACOVIGILANCE PRACTICE (GVP) COMPLIANCE

CLINICAL TRIAL SAFETY GOVERNANCE
CLINICAL TRIAL SPONSOR SAFETY OVERSIGHT
ADVERSE EVENT (AE) ASSESSMENT
SERIOUS ADVERSE EVENT (SAE) MANAGEMENT

SUSAR IDENTIFICATION AND REPORTING
EXPEDITED SAFETY REPORTING COMPLIANCE
URGENT SAFETY MEASURES (USM) MANAGEMENT

EUDRAVIGILANCE SUSAR REPORTING
INDIVIDUAL CASE SAFETY REPORT (ICSR) MANAGEMENT
E2B(R3) ELECTRONIC SAFETY REPORTING
MEDDRA CODING AND TERMINOLOGY

REFERENCE SAFETY INFORMATION (RSI) ASSESSMENT

# YOUR FACULTY DIRECTOR




## Dr. Irene Michas

### Highly Distinguished Global Pharmacovigilance and Regulatory Compliance Expert

Dr. Irene Michas is a seasoned professional in the field of pharmacovigilance with more than twenty years of experience in the pharmaceutical industry. She served as **Regional Safety Manager-Senior Director for the Asia, Africa and Middle East region at Pfizer Research and Development UK** where she managed and implemented new business initiatives and updates to procedures and systems. She has led working groups for the development and global implementation of numerous initiatives to facilitate compliance with pharmacovigilance requirements.

Dr. Michas' expertise also extends to **the development of comprehensive training programs to support the global rollout of new pharmacovigilance systems (e.g., Argus, ARISg)**, and in leveraging advanced technology for the development of e-learning programs. Her **in-depth knowledge of international pharmaceutical product regulations and extensive experience in various aspects of drug development activities** make her an exceptionally qualified professional in the field of pharmacovigilance.

Dr. Irene Michas is a Phi Beta Kappa scholar with a Bachelor of Arts degree in the field of Biological Basis of Behaviour from the University of Pennsylvania, USA, as well as an MSc and PhD in Psychology (Developmental, Cognitive, Experimental) from Reading University, UK.

# OUR PARTICIPANTS

## Over 70% of FORTUNE 500 Companies Have Attended Our Accredited Programs Before

































# PROGRAM AGENDA

## MODULE 1 - INTRODUCTION TO EU CLINICAL TRIAL SAFETY & PHARMACOVIGILANCE

- Overview Of EU Clinical Trial Safety And Pharmacovigilance Across The Medicinal Product Lifecycle
- EU Clinical Trials Regulation (EU) No 536/2014 And The Clinical Trial Safety Framework
- Key EU Regulatory Bodies, Including EMA And National Competent Authorities, And Their Roles
- Clinical Trials Information System (CTIS), Eudravigilance And The Interaction Between Clinical-Trial And Post-Authorisation Safety Systems

## MODULE 2 - EU GCP, GOOD PHARMACOVIGILANCE PRACTICES & SAFETY COMPLIANCE

- Overview Of Good Clinical Practice (GCP) And Good Pharmacovigilance Practices (GVP)
- Relevant GVP Modules And Their Application To Clinical Development
- Interfaces Between Clinical Operations, Medical Safety, Pharmacovigilance And Regulatory Affairs
- Safety Governance, Procedures, Training And Compliance Monitoring

## MODULE 3 - CLINICAL TRIAL SAFETY GOVERNANCE & RESPONSIBILITIES

- Sponsor Responsibilities For Clinical Trial Safety Oversight
- Roles Of The Safety Manager, Medical Monitor, Pharmacovigilance, Clinical Operations And Regulatory Affairs
- Safety Governance Committees, Escalation Pathways And Decision-Making Processes
- Delegation, Oversight And Accountability For Internal Teams And External Service Providers

## MODULE 4 - ADVERSE EVENT ASSESSMENT & MEDICAL SAFETY MANAGEMENT

- Definitions And Classification Of AE, ADR, SAE And Suspected Adverse Reactions
- Assessment Of Seriousness, Severity, Causality And Expectedness
- Collection, Documentation And Follow-Up Of Safety Information
- Management Of Incomplete, Conflicting Or Medically Significant Safety Information




# PROGRAM AGENDA

## MODULE 5 - SAE, SUSAR & EXPEDITED SAFETY CASE MANAGEMENT

- End-To-End Management Of Serious Adverse Events (SAES)
- SUSAR Identification, Medical Review And Regulatory Reporting
- Expedited Reporting Requirements And Applicable Timelines
- Unblinding, Follow-Up Information And Reconciliation Of Safety Cases

## MODULE 6 - EXPEDITED REPORTING & URGENT SAFETY MEASURES

- EU Requirements For Expedited Safety Reporting
- Safety Reporting Through Appropriate Regulatory Systems And Processes
- Urgent Safety Measures (USMS), Immediate Risk-Control Actions And Escalation
- Safety-Related Protocol Changes, Temporary Halts And Communication With Authorities

## MODULE 7 - EUDRAVIGILANCE & INDIVIDUAL CASE SAFETY REPORT (ICSR) MANAGEMENT

- Role And Structure Of Eudravigilance Within The Eu Safety Framework
- ICSR Lifecycle: Intake, Triage, Validation, Processing, Medical Review, Follow-Up And Closure
- Duplicate Detection, Case Quality Control And Case Reconciliation
- Common ICSR Processing Errors And Data-Quality Challenges

## MODULE 8 - E2B(R3), MEDDRA CODING & SAFETY DATA STANDARDS

- E2B(R3) principles and electronic transmission of ICSRs
- Key E2B(R3) data elements and validation considerations
- MedDRA Hierarchy, Terminology And Coding Principles
- Data Quality, Coding Consistency And The Impact Of Structured Data On Safety Analysis

## MODULE 9 - REFERENCE SAFETY INFORMATION & DEVELOPMENT SAFETY UPDATE REPORTS

- Purpose And Regulatory Significance Of Reference Safety Information (RSI)
- Expectedness Assessment Against The Applicable Safety Reference Information




# PROGRAM AGENDA

- Investigator's Brochure Safety Information And Version Control
- Development Safety Update Reports (DSURS): Structure, Data Sources And Preparation

## MODULE 10 - SIGNAL DETECTION, EVALUATION & MANAGEMENT

- Principles And Methodologies For Pharmacovigilance Signal Detection
- Qualitative And Quantitative Approaches To Identifying Potential Signals
- Signal Validation, Confirmation, Prioritization And Evaluation
- Signal Management, Documentation, Escalation And Regulatory Communication

## MODULE 11 - BENEFIT-RISK ASSESSMENT & RISK MANAGEMENT PLANS

- Principles Of Benefit-Risk Assessment Throughout The Medicinal Product Lifecycle
- Integration Of Clinical Trial And Post-Authorisation Safety Information
- EU Risk Management Plans (RMPs), Safety Specifications And Identified/Potential Risks
- Risk-Minimization Measures, Monitoring And Updating The RMP

## MODULE 12 - QPPV RESPONSIBILITIES & PHARMACOVIGILANCE SYSTEM MASTER FILE

- Role, Responsibilities And Oversight Expectations Of The Qualified Person Responsible For Pharmacovigilance (QPPV)
- QPPV Oversight, Access To Safety Information And Escalation Responsibilities
- Pharmacovigilance System Master File (PSMF): Structure, Content And Maintenance
- PSMF Governance, System Documentation And Inspection Readiness

## MODULE 13 - SAFETY DATA RECONCILIATION, VENDOR OVERSIGHT & PV QUALITY SYSTEMS

- Reconciliation Between Clinical Databases, Safety Databases And External Safety Data Sources
- Safety Data Exchange Agreements (SDEAs) And Vendor Oversight
- Management Of CROS, Service Providers And Delegated Pharmacovigilance Activities
- PV Quality Systems, SOPs, Training, Metrics, Performance Monitoring And Quality Controls




# PROGRAM AGENDA

## MODULE 14 - CAPA, DEVIATIONS, AUDITS & REGULATORY INSPECTION READINESS

- Identification, Documentation And Investigation Of PV Deviations And Compliance Issues
- Root-Cause Analysis And Development Of Effective Corrective And Preventive Actions (CAPA)
- Pharmacovigilance Audits And Preparation For Regulatory Inspections
- Common Inspection Findings, Evidence Requirements And Effectiveness Checks

## MODULE 15 - INTEGRATED SAFETY MANAGEMENT ACROSS THE PRODUCT LIFECYCLE

- Integration Of Clinical Trial Safety, Pharmacovigilance, Signal Management And Risk Management
- End-To-End Management Of An Emerging Safety Issue From Initial Case Through Regulatory Action
- Cross-Functional Safety Communication, Governance And Decision-Making
- Practical Strategies For Maintaining Continuous PV Compliance And Inspection Readiness

## EXAMINATION

# YOUR CHARTER DESIGNATION




Chartered Institute of Professional Certifications' programs are unique as they provide you with professional charter designations and marks that can be used across your lifetime once you have completed our programs.

Upon successfully completing the program, you will earn the **Certified EU Clinical Trial Safety and Pharmacovigilance Manager (CTS™)** designation. This distinguished certification validates your professional mastery of EU clinical trial safety requirements, pharmacovigilance risk management, and regulatory compliance—demonstrating your proven ability to deliver effective safety reporting, stronger sponsor oversight, proactive risk mitigation, and inspection-ready clinical safety systems.

This program is developed by the **Chartered Institute of Professional Certifications**, and its content is certified by the **CPD Certification Service** as conforming to Continuing Professional Development principles—giving your credential independent, globally recognized standing.

# ABOUT US

**49,525** Business Leaders Have Attained Their Chartered Certifications Since 2009

**390** Certified and Fully Accredited Programs

**87%** Chartered Leaders Have Reported Career Promotions and Enhancements

## Chartered Institute of Professional Certifications

All of Chartered Institute of Professional Certifications programs are fully accredited programs. The professional charters and designations are trademarked credentials that can only be used by professionals who have completed and passed our accredited program. It is also independently accredited by CPD as adhering to the highest standards of continuing professional principles.



# OUR FACULTY DIRECTORS

## We Collaborate With Instructors From Renowned Institutions

HARVARD UNIVERSITY

Wharton University of Pennsylvania

Stanford University

UNIVERSITY OF MICHIGAN

LSE THE LONDON SCHOOL OF ECONOMICS AND POLITICAL SCIENCE

Columbia Business School

London Business School



# CONTACT US TODAY

We Thank You for Your Ongoing Support of Our Programs

## Singapore and Asia Pacific Enquiries

Email: advisor@charteredcertifications.com
Phone: +65 6716 9980
Address: Chartered Institute of Professional Certifications
1 Gateway Drive
#20-04 Westgate Tower
Singapore 608531

## Australia and New Zealand Enquiries

Email: advisor@charteredcertifications.com
Phone: +61 3 9909 7310
Address: Chartered Institute of Professional Certifications
530 Little Collins Street, Level 1
Melbourne VIC 3000, Australia

## UK, Europe and Middle East Enquiries

Email: advisor@charteredcertifications.com
Phone: +44 (020) 335 57898
Address: Chartered Institute of Professional Certifications
86-90 Paul Street
London, EC2A 4NE

## USA Enquiries

Email: advisor@charteredcertifications.com
Phone: +1 888 745 8875
Address: Chartered Institute of Professional Certifications
99 Wall Street #3936
New York, NY 10005