cliniminds™
Institute of Health Sciences Training & Management
AN ISO 9001:2015 Certified Academy

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ACCRE.
Assuring and Advancing Quality in
Clinical Research Education since1965

CERTIFICATE PROGRAM IN
SIGNAL DETECTION AND RISK MANAGEMENT

Program accredited by Accreditation Council for Clinical Research Education, USA

At the core of all PV activities, identifying and managing new/novel safety signals to establish safety profile of a product and ensure public health, is of utmost importance. With addition of new surveillance data sources and development of new methods of submitting spontaneous reports, such as web-based and mobile applications, Advanced and integrated safety data mining system supported by appropriately experienced personnel will be essential for better informed decision making and Signal management of product safety issues in real time

This training course will review approaches to the implementation of signal detection and data mining as part of your pharmacovigilance operations. The requirement for companies to perform signal detection is mandatory in Europe and highly recommended in the US. Many simple techniques can be applied to the generation and review of potential signals, which can also be augmented by the application of sophisticated data mining algorithms.

The Pharmacovigilance Signaling & Risk Management course covers key components of signal detection, including; definitions, objectives, examples, FDA risk management constituents, EU Signaling requirements and data mining principles. Each of these factors are crucial for a company to ensure that they match legislation – one of signaling and risk management's primary objectives is to understand and manage the risk profiles of drugs to help avoid hugely expensive and damaging drug withdrawals.

Pharmacovigilance Signaling & Risk management is a great addition to your knowledge in pharmacovigilance.

Cliniminds has been at the forefront of providing pharmacovigilance training and consulting solutions to the life sciences industry for the last several years. We have already trained over 8,000 professionals and successfully placed them in the industry. Cliniminds boasts of various programs, running for the last 13 years and over 100+ batches have passed and have been placed in the pharmaceutical companies, CROs, KPOs and other health science organizations. Our students have been placed with the leading companies

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Disclaimer –This course brochure is for the purpose of creating an awareness about the program and career options. The exact information on course structure would be given to you at the time of orientation, and may vary from this brochure.

Course Details

Signal Detection

1. Background to Signal Detection
2. Legalities
3. Signal Detection Objectives & Key Components
4. Signaling Analyses
5. Data Mining Examples
6. Information Component
7. Sources of Signals
8. Signal Management Databases
9. Signal Management Processes
10. Recommendation for Action
11. Communication
12. Summary and Quality Check

Risk Management

1. The new EU risk management plan
2. The Risk Evaluation and Mitigation Strategies Report

Who should take this course?

1. Drug safetyPhysicians, & Medical Reviewers
2. Drug Safety Associate
3. Aggregate report scientist
4. Experienced signal detection and risk management professionals
5. Investigators and clinical research coordinators
6. Medical Monitors
7. Investigator

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Advantages of Cliniminds Program

- Industry Accredited / Certified
- Completely Job Oriented.
- Accredited by the by Accreditation Council for Clinical Research Education, USA (ACCRE) &
  Certified by Pharmaceutical Society of India
- Training by the team of industry experts

Mode	Online E learning
Duration	04 Months
Methodology	Online Live Contact
Examination	Online Exams/ MCQs/ Project work
Certificate	Certificate would be awarded upon successful completion of the program. Programs Certified & Accredited by the **ACCRE, USA.**
Accreditation	Program is Certified & Accredited by **Accreditation Council for Clinical Research Education,US**
Payment	Through Debit/Credit cards using Paypal or wire payment through banks

Course Objectives

- To make you better equipped to understand the limitations and biases of the data, leading to better informed decisions regarding product safety

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