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

Think i

ACCRE
Assuring and Advancing Quality in
Clinical Research Education since1965

CERTIFICATE PROGRAM IN AGGREGATE REPORTING

Program accredited by Accreditation Council for Clinical Research Education, USA

Industry Accredited Program | Hands on Training | Since 2004

Over the course of the last two years, fundamental changes have been made to the format and structure of aggregate safety reports, triggered by the implementation of the Good Pharmacovigilance Practice measures in the European Union, together with the updated guidelines on PSURs and RMPs emanating from ICH.

These changes have increased both the complexity of the reports and the input required from non-safety departments, necessitating a new approach to the preparation of aggregate safety reports.

This training course focuses on the review and analysis of safety data in the PSUR, the PBRER and DSUR, and presents strategies to ensure effective planning for large PSURs, as well as processes to allow for consistency between safety documents.

Cliniminds has been at the forefront of providing clinical research and pharmacovigilance training and consulting solutions to the life sciences industry for the last several years. We have already trained over 7,500 professionals and successfully placed them in the industry. Cliniminds boasts of various programs, running for the last 12+ years and over 100 batches have passed and have been placed in the pharmaceutical companies, CROs, KPOs and other clinical research organizations. Our students have been placed with the leadingcompanies

Course Details

1. Aggregate Reports, Their significance and Types of Reports.
2. Preparation and distribution of Periodic Safety Update Reports (PSURs)
3. Preparation and distribution of Periodic Benefit- Risk Evaluation Reports (PBRERs)
4. Signal detection of Periodic Benefit- Risk Evaluation Reports (PBRERs).
5. Preparation and distribution of Periodic Adverse Drug Experience Reports (PADERs)
6. Preparation and distribution of Developmental Safety Update Report (DSURs)

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Who should take this course?

1. Beginners and experienced professional involved in aggregate report writing
2. Medical writers who also are involved in preparation of aggregate reports
3. Medical review physicians
4. Personnel involved in signal detection and risk management
5. All pharmacovigilance professional so that they can understand the important role played by aggregate reports in the field

Advantages of Cliniminds Program

- Industry Accredited / Certified
- Application of Clinical Research & Pharmacovigilance in real business like environment.
- Completely Job Oriented – Hands-on Training
- 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 – both full time and visiting senior faculty
- Small batch – 15 Seats

Mode	Online
Duration	03 Months
Methodology	Online/Webinar
Examination	Online Exams/ MCQs/ Project work
Certificate	Certificate would be awarded upon successful completion of the program. Program is Certified & Accredited by the ACCRE, USA
Accreditation	Program is Certified & Accredited by Accreditation Council for Clinical Research Education,US
International Payment	Through Debit/Credit cards using Paypal or wire payment through banks

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Delhi-NCR|Gurgaon|Guwahati|Bangalore|Bhopal|Kolkata|Pune|Mumbai|Trivandrum|Varanasi|Visakhapatnam International:Russia|SaudiArabia|US|UK

Course Objective

- To provide a comprehensive introduction to the Aggregate Reporting in pharmacovigilance.
- Candidate would be able to report all the relevant new information form appropriate sources.
- Become more familiar with roles/jobs as part of the studyteam.
- Will learn to summarize the medicine's approval status in different country and any significant variations related to safety.