



## **CERTIFICATE PROGRAM IN AGGREGATE REPORT WRITING**

**HANDS ON TRAINING | USA ACCRE ACCREDITED | SINCE 2004**

Over the course of the last 5 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.

Global clinical trials industry size is over US\$50 billion. Clinical research and allied sub sectors are rapidly growing industry globally with growth rate of over 12% per annum. As a result of this growth, sector requires highly specialized and skilled professional workforce in the areas of Clinical Research, Clinical Data Management and Pharmacovigilance. Over 10,000 fresher positions are created every year in the clinical trials and allied sectors in India alone. India's share in the clinical trials and related services outsourcing is approx. US\$3 billion. The sector employs over 50,000+ highly skilled professionals. Key global markets like China, South East Asia, Europe and America continue to grow in double digit.

India is now clearly positioned as the preferred outsourcing destination for clinical trials, clinical data management, pharmacovigilance and related services. India is attracting major Pharmaceutical, R&D organizations and CROs globally. India today offers excellent IT infrastructure, skilled manpower, and cost efficient solutions in this field, backed up by strong regulatory environment. Most global companies have now presence in India and several other companies are in the process of setting up business in India.

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 8,500+ professionals and successfully placed them in the industry. Cliniminds boasts of various programs, running for the last 18+ years with over 200+ batches have passed and have been placed in the pharmaceutical companies, CROs, KPOs & clinical research organizations.

Cliniminds has been awarded as the Best Clinical Research & Health Sciences Business Management Institute in India for the year 2011-2021 consecutively by various agencies like ASSOCHAM, Brands Academy and Economic Times.



### **Program Details – Modules**

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)
7. Reference Safety Information – Selection & Preparation

**Eligibility:** Drug Safety Physician, Medical Reviewer, Drug Safety Associates, Aggregate Report Writing Professionals, Experienced Signal Detection and Risk Management Professionals, All Professionals working in Pharmacovigilance / Drug Safety.

**Mode:** eLearning Live Sessions

**Duration:** 30 Hours Live Sessions – 14 Sessions

**Methodology:** Live eLearning Sessions, Related Software Training, eBooks, Audio Video Recordings and other content using Cliniminds Learning Management System.

**Examination:** Online MCQ Exam / Project

**Certificate:** Cliniminds Certification Accredited by Accreditation Council for Clinical Research & Education, United States of America

**Fee Payment:** NEFT / UPI / Card Payment / Cash / Cheque / International Payment using PayPal



### Cliniminds Head Office

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### TECHNOLOGY & KNOWLEDGE PARTNERS



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Making Safety Easy



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