

## **Drug Safety Internship Program**

### **Learning Objective:**

#### **Learn to process (preparation, analysis, and follow-up) of complex adverse event reports**

- Learn reporting to appropriate authorities and agencies worldwide. Work on stimulated cases to ensure all reporting paperwork is complete, following up on incomplete information, and recording the receipt of information.
- Will work on stimulated cases and adverse event to check if the event reports are complete.
- Learn to create a query, write a query and resolution.
- Check event code using MedRA code list (learn how to use the MedRA dictionary for event codes)
- Evaluate individual AE reports for
  - 1) Grading
  - 2) Relatedness
  - 3) Expectedness
- Learn to use CTCAE to grade an adverse event.
- Learn to write medical narrative using practical information.
- Work on stimulated cases- discuss individual case both serious and non-serious events.
- Learn to evaluate all information required of a case (product, reporter, event, and patient)
- Learn to identify duplicates and non-cases (Non reportable AEs).

**For more information and admission, please contact: [admissions@cliniminds.com](mailto:admissions@cliniminds.com)**

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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.