

## Certificate Program in Conducting & Managing Bioequivalence & Bioavailability Studies

BA/BE studies are required by regulations to ensure therapeutic equivalence between a pharmaceutically equivalent test product and a reference product. BE studies are done for Early and late clinical trial formulations, Formulations used in clinical trial and stability studies, if different Clinical trial formulations and to-be-marketed drug product. This program covers types of BA/BE studies, need of BE studies-NCEs & Generic Drugs, Analysis, Managing & Reporting of BE studies.

**Program Details** : The program would cover

- Introduction
- Basics of Pharmacokinetics
- The concept of Bioavailability and Bioequivalence-Regulatory Terminology
- Regulatory aspects of BE studies
- Need of Bioequivalence Studies- NCEs & Generic Drugs
- Intellectual Property Rights & TRIPs agreement
- Generic Drugs, ANDA approval, Reference List of Drugs & Orange book
- Approaches to Bioequivalence studies
- Types of BA/BE studies
- Design and Conduct of Bioequivalence Studies
- Study personnel required for conduct of BE studies and their role and responsibility
- Facilities for conducting BA/BE studies (CRO checklist)
- Departments - Clinical, Bio-Analytical and Quality Assurance
- Managing BE Studies
- Measurement Methodology
- Analysis of BE Studies
- Food effect BE studies
- Biowaivers

**Mode** : Online/Distance Learning

**Duration** : 6 Months

**Eligibility** : MD, MS, MBBS, BDS, BHMS, BAMS, BUMS, BPT, B.Pharms, Graduate/Post

Graduate Degree in Life Sciences, Mathematics, Pharmacology, Pharmacy, Medical Laboratory, Nursing, Biochemistry, Microbiology, Biotechnology and all professionals working with Pharmaceutical companies, CROs and Hospitals.

**Methodology** : Online Training Modules; Online learning System

**Examination** : Online MCQs

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.

[www.cliniminds.com](http://www.cliniminds.com)

Mobile: +91-9910068241; +91 9560665441; +91-9810068241; Email: [info@cliniminds.com](mailto:info@cliniminds.com)

India | Canada | US | UK | Saudi Arabia | Philippines |

- Certificate** : Certificate would be awarded upon successful completion of the program. Program is Certified & Accredited by the **Pharmaceutical Society of India**.
- Accreditation** : Accreditation would be awarded upon successful completion of the program. Program is Certified & Accredited by **Accreditation Council for Clinical Research Education, US**.
- Fee payment** : Fee Payable by Cash, Cheque/Bank draft in the name of “**TENET HEALTH EDUTECH PVT LTD.**” payable at Delhi. Fee can also be deposited in company bank account. We also accept Credit/Debit Cards.
- International Payments** : Through Debit/Credit cards using Paypal or wire payment through banks
- Course Objectives** :
- Distinguish between bioequivalence and bioavailability
  - Understanding the management and conduct of bioequivalence and bioavailability studies
  - Understand how factors related to the dosage form and patient variables affect drug stability, dissolution capacity, and absorption properties
  - Recognize problems that arise with bioequivalence and generic substitution
  - Learn which critical patient and disease factors require special consideration
  - Understand the process of approval of generic drugs in USA, Europe and India.

### Technology & Knowledge Partners



Cliniminds, Unit of Tenet Health Edutech Pvt. Ltd NOIDA ONE 602, Tower B  
Plot B8, Sector 62,NOIDA 201309,UP

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.

[www.cliniminds.com](http://www.cliniminds.com)

Mobile: +91-9910068241; +91 9560665441; +91-9810068241; Email: [info@cliniminds.com](mailto:info@cliniminds.com)

India | Canada | US | UK | Saudi Arabia | Philippines |