Current regulatory requirements for conducting clinical trials in India for investigational new drugs/new drug (Version 3.0)

Multi faculty

**TYPE OF COURSE**: Run | Elective | UG/PG

**COURSE DURATION**: 8 weeks (23 Aug' 21 - 15 Oct' 21)

**EXAM DATE**: 23 Oct 2021

**INTENDED AUDIENCE**: Undergraduate students

**COURSE OUTLINE**:
The course is developed by Clinical Development Services Agency (CDSA) in partnership with the Central Drugs Standard Control Organisation (CDSCO). The course is developed with NPTEL.

**ABOUT INSTRUCTOR**:
Prof. Braj Bhushan is a professor of psychology at IIT Kanpur. His research interest lies in Cognitive Neuropsychology, Cognitive Factors in Design, Trauma Psychology. He has been awarded with many laurels some being “Our Common Future Fellowship (2010), Volkswagen Stiftung, Germany”, “Abstract Award (2008), International Association for Suicide Prevention, 3rd Asia Pacific Regional Conference of IASP, Hong Kong”, “In Search of Excellence' Award (2004), IAAP and NAOP-I”, “Young Scientist Award (2002), Indian Science Congress Association”, “B.H.U. Merit and Prize Award (1991), Banaras Hindu University”.

**COURSE PLAN**:

**Week 1**: Lecture 0: Course overview | Lecture 1: Overview of Indian drug regulatory system | Lecture 2: Overview of drugs & cosmetics Act and Rules thereunder | Lecture 3: Overview of New Drug and Clinical Trials Rules Rules, 2019

**Week 2**: Lecture 4: Pre-clinical data requirements | Lecture 5: Rules governing clinical trials | Lecture 6A: Phases of clinical trial, forms, and fees | Lecture 6B: Regulatory pathway and data requirements for NDCT, 2019

**Week 3**: Lecture 7: BA/BE study and study centres: Legal provisions | Lecture 8: Guidelines to conduct BA/BE studies | Lecture 9: Ethics Committee registration and re-registration

**Week 4**: Lecture 10: Ethical considerations | Lecture 11: Good Clinical Practice | Lecture 12A: Requirements for import/manufacture of new drug/IND for conducting clinical trials in India | Lecture 12B: Requirements for import/manufacture of new drug/IND for sale/distribution and unapproved new drug for patients

**Week 5**: Lecture 13: Important issues | Lecture 14: Special concerns | Lecture 15: Clinical trial related guidelines (NDCT Rules)

**Week 6**: Lecture 16: Content of proposed clinical trial protocol | Lecture 17: Content of a clinical trial report | Lecture 18: Post marketing assessment and clinical trial compensation

**Week 7**: Lecture 19: Common observations during submission of CT/BA/BE protocol | Lecture 20: Common observations during CT/BA/BE centre inspections | Lecture 21: Drug development process: Overview