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

Multi faculty

INTENDED AUDIENCE : The course is suitable for individuals, both from industry (pharma, biotech, contract research organization) and academia who are involved or interested in Clinical trial and new drug development (R & D/manufacture/ import) in India. This includes investigators, regulatory affairs personnel, human ethics committee members, clinical trial team members/researchers.
PRE-REQUISITES : There is no pre-requisite to undertake this course. It is suitable for personnel with scientific/medical background (BSc/MSc/PhD/B Pharm/M Pharm/BAMS/BHMS/BDS/MDS/MBBS/MD/DM). Personnel working in the area of drug development/clinical trials/research may benefit from this course.
INDUSTRY SUPPORT:
Pharmaceutical companies, Research/Academic Institutions, Biomedical research organizations, Regulatory authorities, Medical colleges, Contract research organizations.

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.
Upon completion of this online course, the participants will understand:

- Current New Drugs and Clinical Trials Rules 2019 for conducting clinical trials of the new drug or investigational new drug (IND) to be manufactured or imported in India
- Essential documents required for the conduct and approval of clinical trials, new drug/IND
- Essence and purpose of important trial-related guidelines, such as Good Clinical Practice (GCP), national ethical guidelines for biomedical & health research for human participants (2017), etc

ABOUT INSTRUCTOR :

1) Prof. D. K. Sable, Assistant Drugs Controller (India), CDSCO HQ, New Delhi
2) Prof. Rubina Bose, Deputy Drugs Controller (India), CDSCO, West Zone, Mumbai
3) Prof. Y. K. Gupta, Principal Adviser (Projects), CDSA, THSTI, DBT
4) Prof. Nandini K. Kumar, Former Deputy Director General Sr. Grade, Indian Council of Medical Research (ICMR), Adjunct Faculty, CDSA, THSTI, DBT
5) Late Shri Arun Kumar B. Ramteke, Former Joint Drugs Controller (India), CDSCO; Consultant, Regulatory Affairs, CDSA, THSTI, DBT
6) Prof. Sucheta Banerjee Kurundkar, Director Training, CDSA, THSTI, DBT
7) Prof. M. Vishnu V. Rao, Scientist G & Director, ICMR – National Institute of Medical Statistics (NIMS); Administrator, Clinical Trial Registry - India (CTRI)

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
Week 8 : Lecture 22: Salient feature of NDCT 2019 (What's new in NDCT?) ; Lecture 23A: Online submission (SUGAM) ; Lecture 23B: Online submission (CTRI) ; Lecture 24: Tables given in NDCT 2019 and its content