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.

CDSA is an extramural unit of the Translational Health Science & Technology Institute (THSTI). THSTI is an autonomous institution under the Department of Biotechnology (DBT), Ministry of Science & Technology, Government of India. CDSA has a national mandate to enhance the capacity and capability of clinical development in India.

CDSCO is the National Regulatory Authority (NRA) of India. It is under the Directorate General of Health Services, Ministry of Health & Family Welfare, Government of India. CDSCO along with the state regulators are jointly responsible for grant of licenses of certain specialized categories of critical drugs such as blood and blood products, intravenous fluids, vaccines, and sera.

It is a pre-requisite for anyone carrying out a clinical trial or involved in new drug development or research for the purpose of seeking regulatory approval in India to know about the current regulatory requirements. This is even more pertinent given the many changes and amendments in the clinical trial and new drug approval rules and regulations in India in recent years.

Version 1 of this online course was launched in early 2019 with 12 lectures as a four-week course. It was attended by 1047 participants during Jan - Mar 2019. On March 19, 2019, the New Drugs and Clinical Trials (NDCT) Rules, 2019 were released. The current online course (Version 2) incorporates the changes and amendments that are part of these latest rules. A series of brainstorming sessions were conducted by CDSA with CDSCO for incorporating the new updates and the feedback received from version 1 participants. It also includes key issues that surfaced during the discussions at the six face-to-face programs (National workshop on regulatory compliance for accelerating innovations) that were conducted by CDSA (Dec 2018-July 2019) under the aegis of DBT, CDSCO, NITI Aayog, and BIRAC-NBM and inputs from the interactive session on NDCT Rules conducted by CDSA with CDSCO at THSTI (May 2019).

This course (version 2) has 24 lectures spread over a period of 8 weeks. This course also involves 8 weekly assignments and a final exit assessment. Only those wishing to undertake the certification exams (which requires payment of a fee) need to opt for the latter. This online course is free. The exam is optional for a fee.

COURSE OBJECTIVES AND EXPECTED LEARNING OUTCOME
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. Dr D. K. Sable, Assistant Drugs Controller (India), CDSCO HQ, New Delhi
2. Dr Rubina Bose, Deputy Drugs Controller (India), CDSCO, West Zone, Mumbai
3. Professor Y. K. Gupta, Principal Adviser (Projects), CDSA, THSTI, DBT
4. Dr 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. Dr Sucheta Banerjee Kurundkar, Director Training, CDSA, THSTI, DBT
7. Dr M. Vishnu V. Rao, Scientist G & Director, ICMR – National Institute of Medical Statistics (NIMS); Administrator, Clinical Trial Registry - India (CTRI)
8. Dr Atul Juneja, Scientist E, ICMR-NIMS; Coordinator, CTRI
9. Dr Tulsi Adhikari, Scientist E, ICMR-NIMS; Coordinator, CTRI
10. Dr Mohua Maulik, Consultant, ICMR-NIMS

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