

NPTEL Video Lecture Topic List - Created by LinuXpert Systems, Chennai

NPTEL Video Course - Multi Disciplinary - NOC:Current Regulatory Requirements for Conducting Clinical Trials

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Co-ordinating Institute - IIT - Madras

Sub-Titles - Available / Unavailable | MP3 Audio Lectures - Available / Unavailable

Lecture 1 - Courses Overview

Lecture 2 - Overview of Indian regulatory system

Lecture 3 - Overview of Drugs and Cosmetics Act and Rules thereunder

Lecture 4 - Overview of New Drugs and Clinical Trials Rules, 2019

Lecture 5 - Pre-Clinical Data Requirements

Lecture 6 - Rules Governing Clinical Trials

Lecture 7 - Phases of clinical trial, forms, and fees

Lecture 8 - Regulatory pathway and data requirements for NDCT, 2019

Lecture 9 - BA/BE study and study centers

Lecture 10 - Guidelines to conduct BA/BE studies

Lecture 11 - Ethics Committee registration and re-registration

Lecture 12 - Ethical Considerations

Lecture 13 - Good Clinical Practice

Lecture 14 - Requirements for import/manufacture of new drug/IND for conducting clinical trials in India

Lecture 15 - Requirements for import/manufacture of new drug/IND for sale/ distribution and unapproved new dr

Lecture 16 - Important issues

Lecture 17 - Special concern

Lecture 18 - Clinical trial related guidelines (NDCT Rules)

Lecture 19 - Content of Proposed Clinical Trial Protocol

Lecture 20 - Content of a Clinical Trial Report

Lecture 21 - Post Marketing Assessment and Clinical Trial Compensation

Lecture 22 - Common observations during submission of CT/BA/BE protocol

Lecture 23 - Common observations during CT/BA/BE centre inspections

Lecture 24 - Drug development process

Lecture 25 - Salient feature of NDCT 2019 - what's new in NDCT?

Lecture 26 - Online Submission 23A

Lecture 27 - Online Submission (CTRI)

Lecture 28 - Tables Given in NDCT 2019 and its Content

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