

Unit 3: Regulations Governing Clinical Trials

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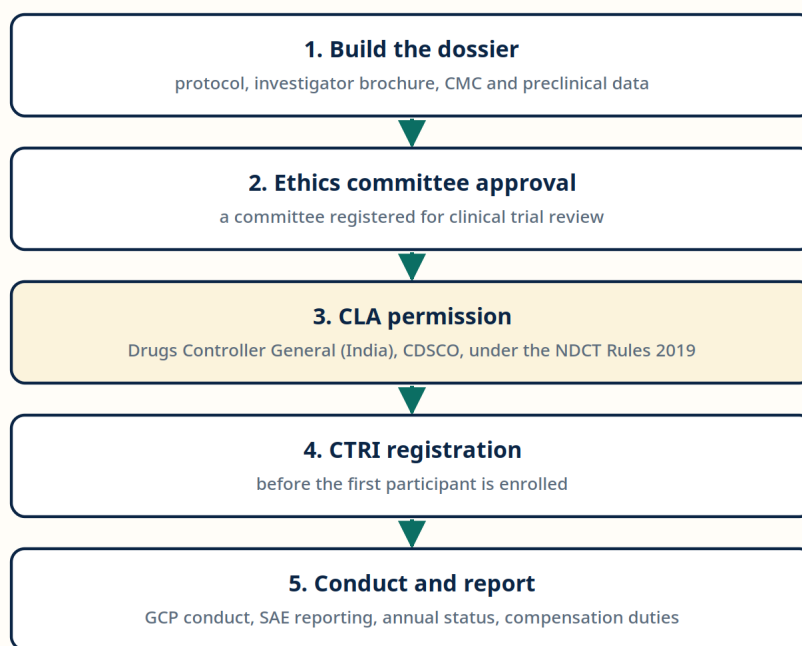
3.1 The Indian framework: from Schedule Y to the NDCT Rules 2019

India's clinical trial law grew inside the Drugs and Cosmetics Act 1940 and its Rules 1945, and the syllabus names its historical centre correctly: **Schedule Y**, the schedule to the Rules that for three decades prescribed the requirements and guidelines for permission to import or manufacture new drugs for sale and to conduct clinical trials. Schedule Y organised the application (the Form 44 era), the phases, the ethics committee approval, the informed consent expectations, the special population studies and the data to be submitted, and a generation of Indian regulatory practice was written in its vocabulary. Alongside it stood the CDSCO's medical device guidance of the pre 2017 period, when devices were regulated as drugs and only a notified subset attracted licensing. The position today, which this subject teaches alongside the syllabus text, is that the clinical trial provisions have been re founded: the **New Drugs and Clinical Trials Rules 2019**, made under the same Act and effective from March 2019, now govern clinical trials, bioavailability and bioequivalence studies, ethics committees and compensation in a single dedicated code, and the Medical Devices Rules 2017, effective from January 2018, do the same for devices. A regulatory professional must hold both layers at once: the syllabus's Schedule Y vocabulary, which older documents, examination papers and much industry speech still use, and the NDCT text, which is what a permission is actually granted under.

3.2 The NDCT Rules 2019: structure and substance

The syllabus itemises the Rules' coverage, and each item is a working territory. **Clinical trials** of new drugs and investigational new drugs require the prior permission of the **Central Licensing Authority**, the Drugs Controller General (India) at CDSCO (Unit 4), granted on an application with the protocol, investigator's brochure, ethics committee approval and the prescribed data, and the trial must be **registered with the Clinical Trials Registry of India (CTRI)** before the first participant is enrolled. **Bioavailability and bioequivalence studies** of new drugs and investigational new drugs are brought inside the same permission and ethics discipline, proportioned to their smaller scale. **General principles and practices** carry the GCP obligation, the responsibilities of sponsor and investigator, and the manufacture and labelling of the investigational product. The **conduct of clinical trials** chapters govern amendments, safety reporting of serious adverse events by investigator and sponsor on the Rules' clocks, the treatment and **compensation** of participants for trial related injury or death, which the Rules prescribe through a defined process of reporting, expert review and determination, and the grounds on which a permission may be suspended or cancelled. **Post market assessment** completes the arc of Unit 1's Phase IV: the authority may require post marketing surveillance and Phase IV studies as conditions, and act on their results. Two machinery points complete the picture: ethics committees for trials must be registered with the Central Licensing Authority (Unit 2), and the Rules build defined decision timelines and a deemed approval discipline into the permission chapters, an administrative reform whose periods differ by chapter and application type and are taught from the Rules' text rather than from any single number.

Starting a Clinical Trial in India: The Approval Pathway



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Figure: The Indian approval pathway: dossier, registered ethics committee approval, Central Licensing Authority permission and CTRI registration before enrolment (Unit 3, section 3.2).

3.3 The Medical Devices Rules 2017 and clinical investigation

For devices the parallel code is the **Medical Devices Rules 2017**, which created a risk based device regime (classes A to D, low to high risk) inside the same parent Act, with the Central Licensing Authority and State Licensing Authorities dividing licensing by class. On the clinical side the Rules require permission for the **clinical investigation** of an investigational medical device, supported by the clinical investigation plan, preclinical and risk data and ethics committee approval, conducted to good clinical practice expectations for devices (ISO 14155, Unit 5), with adverse events reported under the Rules' vigilance provisions; for IVDs the corresponding activity is performance evaluation at approved sites. The syllabus's pairing of the older "Medical Device guidance" with the 2017 Rules is the same two layer pattern as section 3.1: the guidance era explained the expectations, the Rules made them law.

3.4 The United States: FDA and the three statutory pathways

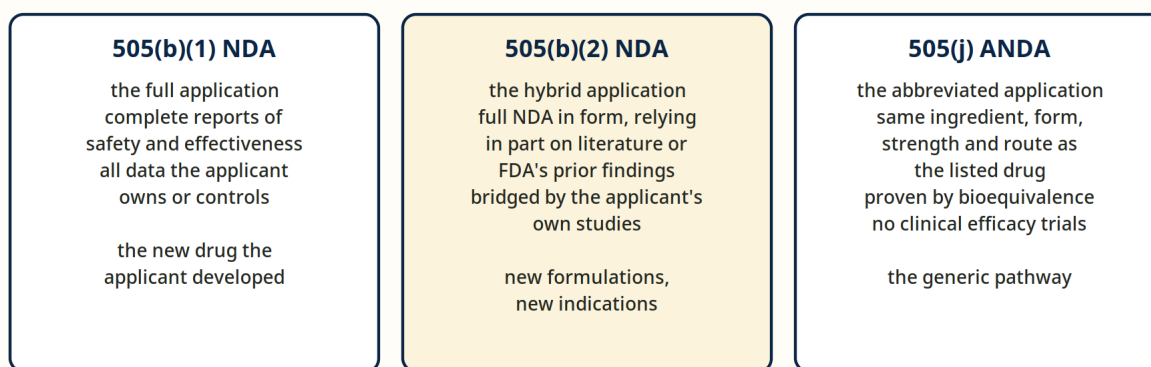
The American half of the unit opens with the agency and the statute. The **Food and Drug Administration** regulates trials through the investigational new drug framework of Unit 5; marketing approval flows from section 505 of the Federal Food, Drug, and Cosmetic Act, which provides the three application pathways the syllabus names verbatim, and a regulatory writer must never blur them:

Pathway	Statutory basis	What the applicant must show	Typical use
NDA, full application	Section 505(b)(1)	Complete reports of safety and effectiveness investigations, all data generated or owned by the applicant	A new drug developed by the applicant
NDA, hybrid application	Section 505(b)(2)	A full application in form, relying in part on investigations not conducted by or for the applicant and for which the applicant has no right of reference, such as published literature or FDA's prior findings	New formulations, new indications, changes that still need clinical bridging

Pathway	Statutory basis	What the applicant must show	Typical use
ANDA, abbreviated application	Section 505(j)	Sameness to a listed reference drug (active ingredient, dosage form, strength, route), plus bioequivalence; no independent clinical safety and efficacy trials	Generic drugs

The distinctions are of evidence and of rights: 505(b)(1) stands on the applicant's own data, 505(b)(2) builds a scientific bridge to data the applicant does not own, with the patent and exclusivity certifications that bridge demands, and 505(j) replaces clinical proof with pharmaceutical equivalence plus bioequivalence, which is why the BA/BE rules of Unit 5 (21 CFR Part 320) sit inside a clinical research subject. For the conduct of the trials themselves, the pathway is downstream: what matters upstream is that trials intended to support any of the three are run to the standards FDA will accept, which is the next two sections.

Section 505: The Three US Application Pathways



The difference is the evidence: own data, borrowed data bridged, or sameness proven

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Figure: The three section 505 pathways compared: the evidence each applicant must supply (Unit 3, section 3.4).

3.5 FDA acceptance of foreign clinical studies

A global programme is worthless if its data stop at the border, so the conditions on which FDA accepts studies it did not oversee are core syllabus. For studies **not conducted under an IND**, FDA accepts a foreign clinical study in support of an IND or a marketing application when, in the terms of 21 CFR 312.120: the study was conducted in accordance with GCP, including review and approval by an independent ethics committee; the design and conduct allow FDA to validate the data, through on site inspection if necessary; and the study population and conditions are applicable to the United States population and medical practice, the bridging judgement of Unit 1's multi ethnicity discussion. For marketing applications the parallel rule (21 CFR 314.106) adds that foreign data alone must be sufficient in themselves and from investigators of recognised competence. The doctrinal point is that acceptability is earned by conduct, not by geography: a study run to E6 standards with committee approval is portable.

3.6 FDA clinical trials guidance on Good Clinical Practice

FDA's own GCP position completes the American picture. FDA has adopted ICH E6 as guidance (the agency's clinical trials guidance document on good clinical practice that the syllabus names), while the binding obligations sit in the agency's regulations, the CFR parts of Unit 5: protection of human subjects (Part 50), institutional review boards (Part 56), financial disclosure (Part 54) and the IND rules (Part 312). The teaching point is the two storey structure of American compliance: follow the regulations because they

bind, and follow E6 because it is the standard they presuppose and the one the rest of the world shares.

3.7 The European Union: EMA and the clinical trials framework

The European system distributes the same work differently. Scientific standards and the centralised marketing authorisation sit with the **European Medicines Agency (EMA)**, but the authorisation of a clinical trial itself is granted by the **member states**, each pairing its competent authority with its ethics committees. The syllabus era framework was the Clinical Trials Directive 2001/20/EC, which first harmonised trial authorisation, GCP and safety reporting across the Union; the current framework, which the draft states as the present position, is the **Clinical Trials Regulation (EU) No 536/2014**, fully applicable since January 2025 after its transition period, under which a sponsor files one application through the single EU portal, the Clinical Trials Information System (CTIS), and receives a coordinated assessment with one decision per member state concerned. Trial data are publicly registered in the EU system as a transparency obligation. For the regulatory writer the comparison with sections 3.2 and 3.4 is the examinable whole: three systems, one scientific standard, three different doors by which a trial is allowed to begin.

One trial, three doors (the Unit 3 map)

India: CLA (DCGI, CDSCO) permission under the NDCT Rules 2019,
registered ethics committee approval, CTRI registration first
USA: IND in effect under 21 CFR Part 312 (filed with FDA, effective
unless placed on clinical hold), IRB approval under Part 56
EU: single application through CTIS under Regulation 536/2014,
coordinated assessment, one decision per member state concerned
Common floor in all three: ICH E6 GCP, valid informed consent,
safety reporting on prescribed clocks

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