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COMPARATIVE STUDY OF CLINICAL TRIAL APPROVAL TIMELINE IN INDIA AND USA

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ABSTRACT

Bringing a new medicine from laboratory discovery to patient access is a complex, expensive, and highly regulated journey lasting twelve to fifteen years. This review provides a detailed comparative analysis of clinical trial approval frameworks in India and the United States, examining regulatory authorities, legal provisions, approval timelines, ethical oversight, documentation requirements, and special mechanisms such as accelerated approval and orphan drug incentives. India's system, governed by the Central Drugs Standard Control Organisation under the Drugs and Cosmetics Act and the New Drugs and Clinical Trials Rules 2019, emphasizes participant protection through mandatory compensation, expedited safety reporting, and post-trial access. The United States, regulated by the Food and Drug Administration under the Federal Food, Drug and Cosmetic Act and 21 CFR, offers a more centralized and faster approval pathway with a 30-day Investigational New Drug review and no application fees. Key differences also exist in compensation policies, safety reporting timelines, ethics committee registration, and regulatory fees. Recent Indian reforms, including the SUGAM portal and the 2024 amendment regulating clinical research organisations, signal a move toward greater efficiency and transparency. The findings suggest

that while the US provides a speedier environment for clinical development, India demonstrates stronger ethical safeguards. Harmonisation efforts could benefit both systems and accelerate global access to safe and effective therapies.

KEYWORDS: Clinical trial approval, CDSCO, FDA, India, NDCTR 2019, Regulatory framework, United States.

INTRODUCTION

The process of transforming a lead compound identified during drug discovery into a marketable medicine is one of the most rigorously regulated activities in modern science. After finding a promising molecule, early tests (called preclinical) are performed on microorganisms or animals, followed by clinical trials on humans. To sell the drug, approval from government health agencies is mandatory. This procedure is very strict and complex, requiring assistance from research centres, pharmaceutical companies, and drug regulatory agencies such as the Central Drugs Standard Control Organisation (CDSCO) in India and the United States Food and Drug Administration (USFDA). It usually takes about 12 to 15 years to bring a new drug to the market.[1]

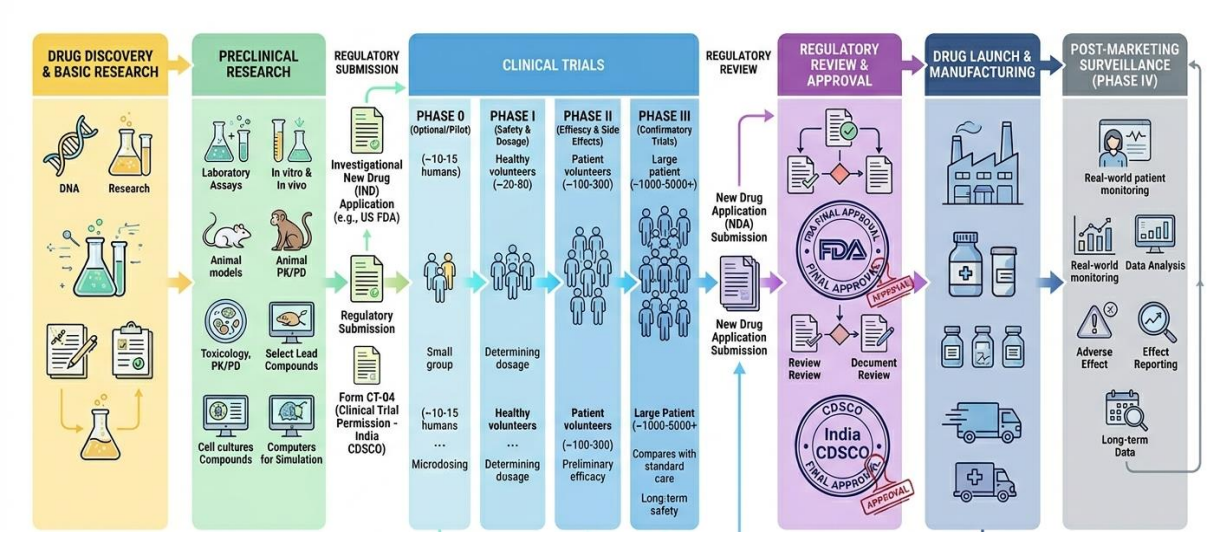

Figure 1: Overview of the drug Development Pipeline.

Understanding the nuances of clinical trial approval processes across different regulatory jurisdictions has become increasingly important in an era of globalisation, where multinational trials are common and pharmaceutical companies seek to launch products simultaneously in multiple regions. India and the United States represent two large but vastly different pharmaceutical markets. The US has a mature regulatory system that has evolved

over decades in response to public health crises and scientific advances. India, while having a long history of pharmaceutical manufacturing, has undergone substantial regulatory transformation in recent years, especially after the implementation of the New Drugs and Clinical Trials Rules (NDCTR) 2019.[2]

This review aims to provide a comprehensive comparative analysis of clinical trial approval processes in India and the United States. It examines regulatory frameworks, approval timelines, documentation requirements, ethical oversight mechanisms, special provisions for accelerated approval and orphan drugs, compensation policies, and safety reporting. By identifying key differences, similarities, and challenges, the review offers recommendations for improving efficiency and harmonisation.

Understanding Clinical Trials and Their Phases

Before comparing regulatory systems, it is essential to understand what clinical trials entail and the sequential phases through which investigational products must pass. A clinical trial is a methodical procedure designed to determine whether a medication or medical device is safe and effective in treating, preventing, or diagnosing a disease.[3]

Preclinical testing is performed in the laboratory using chemical and biochemical assays, cell-culture models, and animal models. It develops the pharmacological profile of the drug, determines acute toxicity in at least two animal species, and conducts short-term toxicity studies. The ultimate aim is to assess safety and biological activity before any human contact. This phase approximately takes about 4 years.[4]

Phase 0 clinical trial, also known as the exploratory investigational new drug study, is conducted on a limited number of human participants (about 10 patients). Researchers study pharmacodynamics and pharmacokinetics. This phase usually takes about one week and is conducted before Phase 1.[5]

Phase 1 clinical trial assesses a drug's safety profile. It is the initial stage of human testing and may last several months. Between 20 and 100 healthy volunteers are usually enrolled. The main goal is to evaluate the drug's absorption, distribution, metabolism, and excretion (ADME) characteristics, as well as dose-related adverse effects. About 70% of experimental products make it past this stage.[6]

Phase 2 clinical trial involves 50–300 participants and is the first inpatient study. It determines safety and efficacy, as well as the dose range and ceiling effect, in a controlled environment. Phase 2 is often conducted in a double-blind fashion. Drug toxicity and interactions are documented. The success rate is about 35%, and it takes six months to two years.[7]

Phase 3 clinical trial involves a large population (500–3000 participants) and is typically multicentric. It assesses safety on a broader scale and confirms the therapeutic efficacy noted in Phase 2. The primary goal is to calculate the benefit-to-risk ratio. About 25–30% of drugs pass this stage, which lasts one to four years.[8]

Phase 4 clinical trial is conducted after marketing approval. It may detect side effects not seen in earlier phases, such as idiosyncratic reactions. This stage lasts until the medication is available for purchase. The entire process from early lab research to post-marketing monitoring typically takes 12 to 18 years.[9]

Types of clinical trials include treatment trials (testing new treatments), prevention trials (finding ways to stop diseases), diagnostic trials (creating better diagnostic tools), screening trials (detecting diseases early), and quality-of-life trials (improving comfort for long-term illnesses). **Clinical trial methodologies** include randomised trials, open-label trials, single-blind trials, double-blind trials, and triple-blind trials.[10]

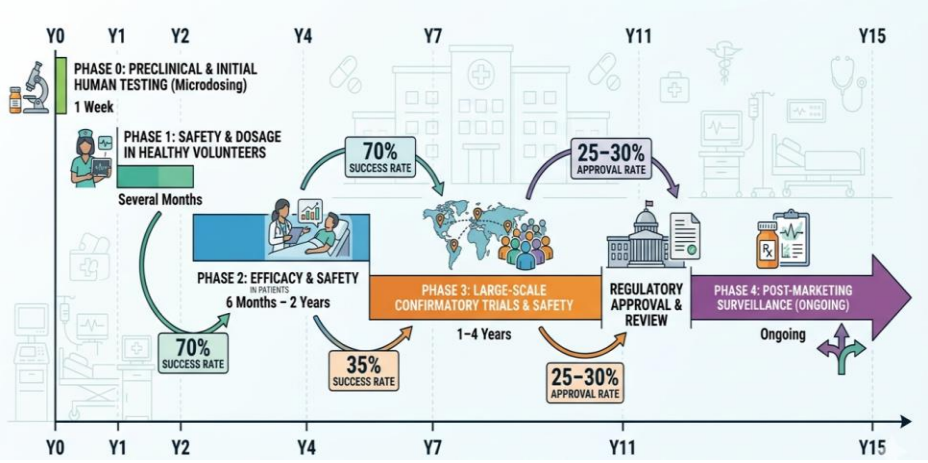

Figure 2: Clinical Trial Phases: A 15 Year Timeline & Success Rates.

Good Clinical Practice and ICH Guidelines

Good Clinical Practice (GCP) is a widely accepted international standard for the design, implementation, documentation, and reporting of clinical trials with human participants. GCP

primarily focuses on the protection of the rights, safety, integrity, and confidentiality of trial participants, as well as the accuracy and reliability of clinical trial data.[11] The International Council for Harmonisation (ICH) GCP guideline E6 was first released in 1996 as E6(R1) and updated in 2016 to E6(R2) to address increasing trial complexity and technological advances. However, with the rapid shift toward decentralised trials and digital health technologies, the limitations became evident. The ICH GCP E6(R3) guideline, adopted on January 6, 2025, modernises clinical trial conduct by introducing a flexible, risk-based, technology-driven framework.[12]

The core principles of ICH GCP include: clinical trials must be conducted according to ethical principles based on the Declaration of Helsinki; foreseeable risks must be weighed against potential benefits; the rights, safety, and well-being of subjects prevail over science and society; adequate non-clinical and clinical data must support the trial; trials must be scientifically sound with a clear protocol; each individual involved must be qualified; freely given informed consent is required; records must be handled to allow accurate reporting; confidentiality must be maintained; investigational products must meet Good Manufacturing Practice; and a quality system must be established.[13]

Figure 3: The 13 ICH GCP Principles.

Regulatory Framework in India

Regulatory Authority

The Central Drugs Standard Control Organisation (CDSCO) functions under the Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India, as

the National Regulatory Authority. Established under the Drugs and Cosmetics Act of 1940 and the Drugs and Cosmetics Rules of 1945, CDSCO ensures uniform enforcement of the provisions to promote and protect public health in India. Its responsibilities include approval of drugs, oversight of clinical trials, setting standards for drugs, and quality control of imported drugs. The Drug Controller General of India (DCGI) is the head of CDSCO and grants approval to new drugs after scrutinising clinical data.[14]

Legal Provisions Governing Clinical Trials

The Drugs and Cosmetics Act, 1940 and Rules, 1945 provide the legal framework for clinical trial regulation. The relevant rules are 122DA, 122DAA, 122DAB, 122DAC, 122DD, 122E, and Schedule Y. According to these regulations, conducting a clinical trial in India requires prior approval from DCGI, approval from a registered Ethics Committee, and mandatory registration with the Clinical Trials Registry-India (CTRI).[15]

Table 1: Regulatory requirements for conducting clinical trials (based on Drugs and Cosmetics Rules, 1945).

Rule	Description
Rule 122DA	Prescribes the process of seeking approval from the Licensing Authority (DCGI) for conducting a clinical trial on a new drug.
Rule 122DAA	Defines the term "clinical trial".
Rule 122DAB	Prescribes compensation and medical management in case of injury or death due to the clinical trial.
Rule 122DAC	Lists the requirements for seeking permission to conduct a clinical trial, including inspection, monitoring, and compliance.
Rule 122DD	Prescribes the registration and functioning requirements of Ethics Committees.
Rule 122E	Defines the term "new drug".
Schedule Y	Contains comprehensive guidelines for conducting clinical trials in India.

Transition from Schedule Y to New Drugs and Clinical Trials Rules 2019

Following malpractices that came to light in 2012, stricter regulations were introduced in 2013, including mandatory compensation and SAE reporting. To counter a slowdown in research, the New Drugs and Clinical Trials Rules (NDCTR) 2019 were introduced. These rules offer time-bound review of applications and greater flexibility. Their objectives include facilitating R&D in India, ensuring quicker availability of new drugs, introducing transparency, minimising costs, and ensuring participant safety and data integrity.[16] NDCTR 2019 contains thirteen chapters and eight schedules. Key schedules include Schedule I (general principles), Schedule II (requirements for permission), Schedule III (informed

consent, responsibilities of sponsor/investigator/EC, formats for SAE reporting), Schedule IV (BA/BE studies), Schedule V (post-market assessment), Schedule VI (fees), Schedule VII (compensation formula), and Schedule VIII (application forms).[17]

Indian Good Clinical Practice Guidelines

The first official GCP guidelines for India were formulated in 2001, consistent with WHO, USFDA, ICH-GCP, and EU GCP. The Indian GCP specifies ten ethical requirements: consent, community approval, protection from exploitation, privacy, risk minimisation, transparency, accountability, and essentiality. It also specifies the composition of the Independent Ethics Committee (IEC).[18]

ICMR Guidelines 2017

The ICMR guidelines (2017) cover all biomedical and health research involving human participants. Key provisions include risk classification (less than minimal, minimal, low, high), written and voluntary informed consent with detailed information, multidisciplinary Ethics Committee review, SAE reporting within 24 hours with causality assessment in 14 days, mandatory insurance or financial arrangements for research-related injuries, and post-trial access to investigational products subject to regulatory approval.[19]

Application Process: SUGAM Portal

The SUGAM portal is an integrated online system for submitting applications for clinical trials and BA/BE studies. Key forms include Form CT-04 (permission to conduct a clinical trial), Form CT-10 (permission to manufacture new drugs or INDs), Form CT-11 (permission to import), Form CT-05 (permission to conduct BA/BE study), and Form CT-08 (approval of BA/BE centre).[20]

Documentation Requirements

The documents required for a clinical trial application include: Form for clinical trial application, treasury challan, source of bulk drugs, details regarding chemicals and pharmaceutical drugs, animal pharmacology details, toxicology details, clinical pharmacology details, regulatory conditions in foreign countries, quality control protocol, clinical study protocol, investigator's brochure, case report form, patient data sheet and consent form, and list of investigators in India with addresses.[21]

Regulatory Timeline for Review and Approval

The DCGI may form one or more Expert Committees to review scientific aspects, with recommendations expected within 60 days. For drugs developed outside India, the DCGI reviews the application within 90 calendar days. For drugs discovered, researched, and developed in India, the timeline is 30 days. If the DCGI fails to respond within 30 days for Indian-developed drugs, the sponsor may consider the licence as deemed granted. The approval is valid for two years.[22]

The CDSCO review follows a three-tier system: (1) Subject Expert Committee (SEC) or IND Committee examines applications; (2) Technical Committee (TC) reviews SEC recommendations; (3) Apex Committee performs final examination, after which the DCGI issues final approval.[22]

Ethics Committee in India

The Ethics Committee (EC) is an autonomous body composed of medical, non-medical, scientific, and non-scientific members. Its functions include reviewing protocols, granting approval, monitoring adverse events, and assessing ethical standards. As per NDCTR 2019, ECs must register with the National Ethics Committee Registry for Biomedical and Health Research (NECRBHR). Provisional registration is valid for two years, final registration for five years. The EC approval timeline is 4 to 8 weeks, running semi-parallel with DCGI review.[23]

Clinical Trials Registry-India (CTRI)

CTRI (www.ctri.nic.in) is a free online registry launched on July 20, 2007, hosted by the ICMR-National Institute of Medical Statistics. It ensures prospective registration of all clinical trials undertaken in India before the first participant is recruited.[24]

Special Provisions in India

Accelerated approval is allowed for drugs intended for life-threatening or serious diseases, rare diseases, unmet medical needs, disasters, or defence situations. Approval can be based on surrogate endpoints, and local trials may be waived based on foreign data.[25]

Orphan drugs are defined as those targeting diseases affecting fewer than 500,000 people in India. Such drugs may get Phase III and IV trial waivers, easier review, and fee waiver.[26]

Post-trial access is mandatory under NDCTR if the investigator recommends it and the EC approves it, provided no alternative treatment is available. The sponsor is not responsible for post-trial adverse events.[27]

Regulatory Fee Structure

Table 2: Fee structure as per NDCTR 2019.

Sr. No.	Type of Application	Previous Fees (INR)	New Fees (INR)
1	Clinical Trial Application for Phase I	50,000	300,000
2	Clinical Trial Application for Phase II & III	25,000	200,000
3	Clinical Trial Application for Phase IV	No fee	200,000
4	Reconsideration of Clinical Trial Application	No fee	50,000
5	Application for conduct of BA/BE Study	25,000 (within 1 year) / 15,000 (1-4 years)	(not specified)
6	Reconsideration of BA/BE Study Application	No fee	50,000
7	Registration of BA/BE Study Centre	No fee	500,000
8	Reconsideration of BA/BE centre	No fee	500,000

Compensation for Trial-Related Injury

Schedule VII of NDCTR sets out a formula for calculating compensation. Serious Adverse Events must be reported within 24 hours. The EC must present recommendations within 60 days, including the compensation amount. The sponsor must pay the compensation within 30 days of the Central Licensing Authority's order.[28]

Recent Amendment (2024)

The amendment notified as G.S.R. 581(E) on September 19, 2024, introduced the first formal framework for regulating Clinical Research Organisations (CROs). CROs must register with the Central Licensing Authority under Rule 38A. This amendment, effective from April 1, 2025, brings accountability and traceability to clinical research.[29]

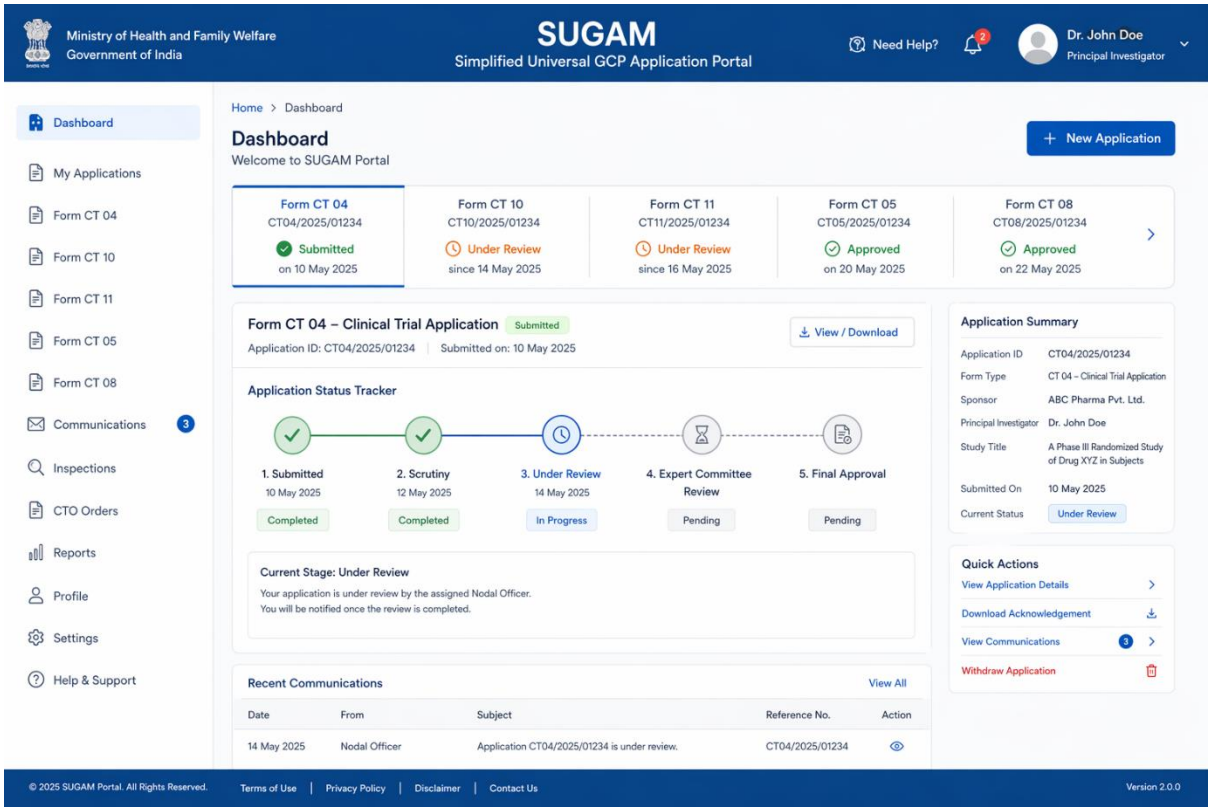

Figure 4: A Screenshot of SUGAM Portal.

Regulatory Framework in the United States

Regulatory Authority: FDA

The United States Food and Drug Administration (USFDA) is the major regulatory body overseeing the safety, quality, and effectiveness of drugs, medical devices, food, and cosmetics. It is part of the Department of Health and Human Services. The Center for Drug Evaluation and Research (CDER) regulates prescription and over-the-counter drugs. The Center for Biologics Evaluation and Research (CBER) regulates biological products such as vaccines, blood products, and cellular therapies.[30]

Legal Provisions Governing Clinical Trials

Federal Food, Drug, and Cosmetic (FD&C) Act of 1938 gives the FDA authority to oversee safety, efficacy, and quality of pharmaceuticals. The FDA assesses preclinical and clinical trial results before approving New Drug Applications.[31]

Prescription Drug User Fee Act (PDUFA) of 1992 allows the FDA to charge user fees for NDAs, using the fees to speed up review. PDUFA has been reauthorised several times (PDUFA I-VII).[31]

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Code of Federal Regulations (21 CFR) contains all current regulations. Key parts for clinical trials are

- 21 CFR Part 312: Investigational New Drug (IND) application
- 21 CFR Part 50: Informed consent
- 21 CFR Part 56: Institutional Review Boards (IRBs)
- 21 CFR Part 54: Disclosure of financial interests
- 21 CFR Part 11: Electronic records and signatures.[32]

Table 3: Evolution of US regulations.

Year	Act / Regulation	Key Purpose
1820	United States Pharmacopeia (USP)	Developed official standards for strength, quality, and purity of drugs.
1906	Food and Drugs Act	Made marketing of drugs dependent upon compliance with recognised standards.
1938	Federal Food, Drug and Cosmetic Act	Required safety testing prior to marketing (after sulfanilamide tragedy).
1962	Kefauver-Harris Amendment	Required safety and efficacy testing (after thalidomide disaster); mandated ADR reporting.
1973	Orphan Drug Act	Encouraged development of medications for rare diseases through tax incentives.
1992	Generic Drug Enforcement Act	Handled violations associated with ANDA approval.
1997	FDA Modernization Act	Collected user fees and expedited drug approval.

Good Clinical Practice and the Belmont Report

The FDA has adopted the ICH GCP guideline. The Belmont Report (1979) provides an ethical framework with three principles: respect for persons (informed consent), beneficence (maximise benefits, minimise harms), and justice (equitable selection of participants).[33]

Investigational New Drug (IND) Application

An IND is sent to the FDA requesting permission to start human tests after preclinical studies. Types of IND include Investigator IND (filed by a physician), Emergency Use IND, and Treatment IND (expanded access). Classification includes Commercial IND (for marketing approval) and Non-Commercial (Research) IND.[34]

Three main categories of information must be included: (1) Animal pharmacology and toxicology studies; (2) Manufacturing information (composition, stability, controls); (3) Clinical protocols and investigator information.[34]

Content requirements for IND application: Cover letter, Form FDA 1571, Form FDA 1572, table of contents, letter of authorization, clinical protocol, informed consent, investigator's brochure, product development statement, and additional information.[35]

IND Review Process and Approval Timeline

The IND application takes effect 30 days after FDA receipt unless the FDA places it on clinical hold. The review is centralised through CDER/CBER. IRB review may be conducted in parallel with FDA review, but EC approval must be obtained before trial initiation. Sponsors must submit one original and two copies (paper) or electronic format.[36]

Registration of Institutional Review Board (IRB)

Each IRB that reviews clinical trials must register with the Department of Health and Human Services (HHS). Registration must be renewed every three years. IRB functions include safeguarding rights and welfare of human subjects, reviewing protocols, monitoring adverse events, and disciplining noncompliant investigators.[37]

Clinical Trials Registry – USA

The Food and Drug Administration Amendments Act (FDAAA) of 2007 requires interventional clinical trials to submit results to ClinicalTrials.gov within one year of the primary completion date. The Department of Health and Human Services may expand requirements through regulatory action.[38]

Special Provisions in the USA

Accelerated approval allows the FDA to use surrogate endpoints (e.g., tumour shrinkage) instead of clinical endpoints, speeding up drug development for serious conditions.[39]

Orphan drugs are defined as those affecting fewer than 200,000 patients in the US. They receive a 50% credit toward clinical testing costs and 7 years of market exclusivity.[39]

Post-trial access has no formal federal mandate. The regulations say little about post-trial obligations, and IRBs lack clear jurisdiction to enforce access.[40]

Regulatory Fees

The FDA does not charge regulatory fees for reviewing clinical trial applications.[36]

Compensation and Safety Reporting

There is **no federal law** requiring sponsors to provide medical care or compensation for trial-related injuries. Only 16% of medical centres have such policies. Safety reporting

requires sponsors to inform the FDA and investigators of serious and unexpected suspected adverse reactions within 15 calendar days (fatal or life-threatening within 7 days).[36]

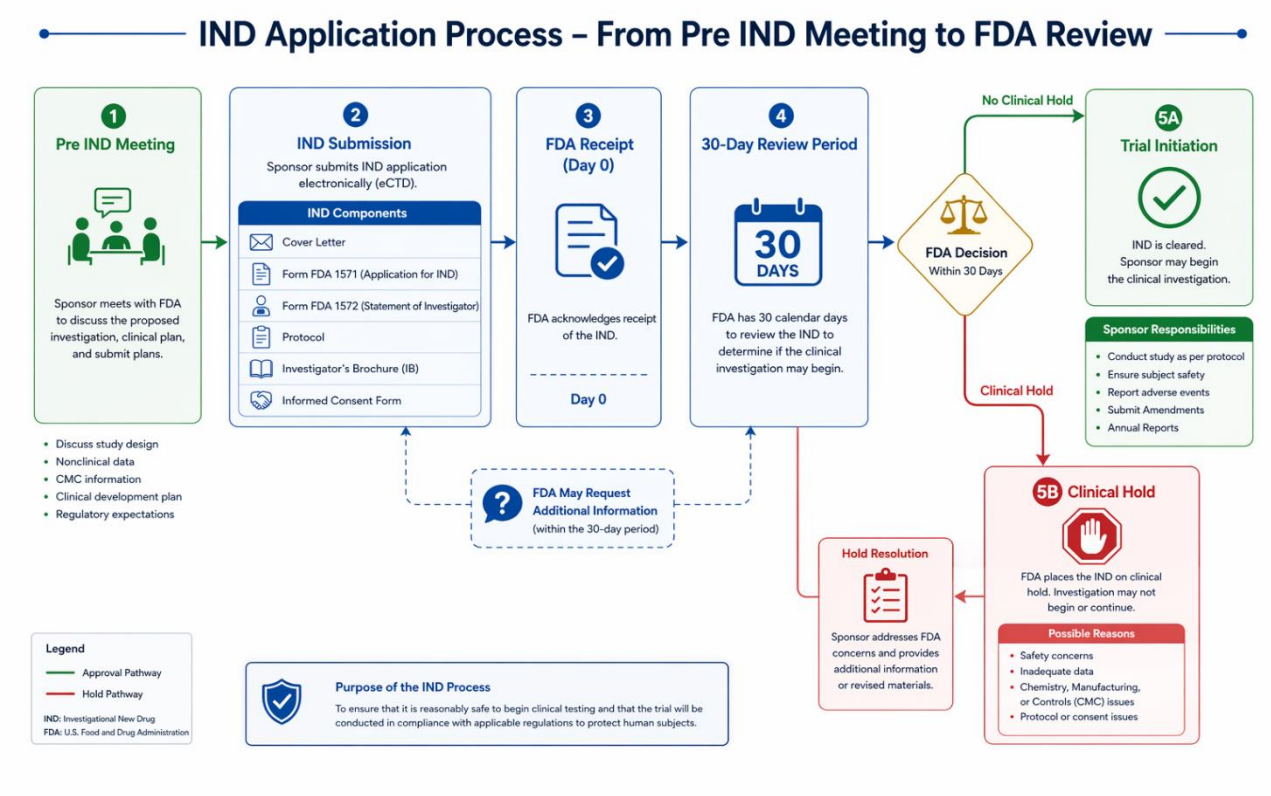

Figure 5: IND application process from pre-IND meeting through FDA review.

Comparative Analysis and Discussion

The comparative analysis reveals significant differences and similarities between India and the United States in clinical trial approval processes. Both countries pursue the common goal of protecting participant safety and data integrity, but their regulatory systems differ in structure, speed, and ethical emphasis.

Regulatory bodies: India uses CDSCO with a three-tier review (SEC → TC → Apex Committee); the US uses FDA with centralised review by CDER/CBER. The three-tier system in India ensures thorough scrutiny but may prolong timelines.

Approval timelines: In the US, the IND review takes 30 days. In India, timelines are 30 days for domestically developed drugs and 90 days for foreign-developed drugs. The longer timeline in India can affect global competitiveness for multinational trials.

Ethical review: India's EC approval takes 4–8 weeks, semi-parallel with DCGI. The US allows parallel IRB review, reducing overall time. India mandates EC registration with NECRBHR (5-year validity); the US requires IRB registration with HHS (3-year renewal).

Participant protection: India has a mandatory compensation framework under Schedule VII with a specific formula and 30-day payment timeline. The US has no mandatory compensation; only 16% of centres provide policies. This makes India stronger in ethical duty and subject protection.

Safety reporting: India mandates SAE reporting within 24 hours; the US requires 7–15 days depending on severity. India's shorter timeline enables immediate regulatory action.

Regulatory fees: India charges fees (₹200,000–300,000 per application); the US charges no fees for IND review, reducing entry barriers.

Accelerated approval and orphan drugs: Both countries have provisions. India defines orphan as <500,000 patients with fee waivers and trial waivers; the US defines orphan as <200,000 patients with 50% tax credit and 7-year exclusivity.

Post-trial access: India mandates it under certain conditions; the US has no specific mandate.

Table 4: Result and comparative analysis of various parameters (India vs. United States).

Parameter	India	United States
Regulatory bodies	CDSCO	USFDA
Regulation	Drug and Cosmetic Act 1940 and rules; NDCTR 2019	FD&C Act 1938; PDUFA 1992; 21 CFR Parts 312,50,56,54,11
Ethical framework	ICMR Guidelines 2017	Belmont Principles
Good Clinical Practice	Indian GCP (2001)	ICH-GCP
Application form	Clinical Trial application (CT-04)	IND application (Form FDA 1571,1572,3674)
Submission type	Electronic via SUGAM	Paper or electronic
Trial registration	http://ctri.nic.in	https://clinicaltrials.gov
Review process	Three-tier: SEC → TC → Apex Committee → DCGI final approval	Centralised review by CDER/CBER; IND takes 30 days
Approval timeline	90 days (foreign drug); 30 days (Indian drug)	30 days (parallel IRB review allowed)
Ethical approval	EC approval within 4–8 weeks	IRB approval parallel with FDA

	(semi-parallel)	
EC/IRB registration	Mandatory with NECRBHR; valid 5 years	Mandatory with HHS; valid 3 years
Compensation	Mandatory as per Schedule VII formula	No mandatory legal requirement
Safety reporting	SAE within 24 hours	SAE within 7–15 days
Regulatory fees	Phase I: ₹300,000; Phase II&III: ₹200,000; Phase IV: ₹200,000	No fee for IND review
Accelerated trial	Allowed for rare diseases; local waiver based on foreign data	Uses surrogate endpoints
Orphan drug	<500,000 patients; fee waiver; Phase III/IV trial waivers	<200,000 patients; 50% tax credit; 7-year exclusivity
Post-trial access	Mandatory as per NDCTR 2019	No mandatory requirement

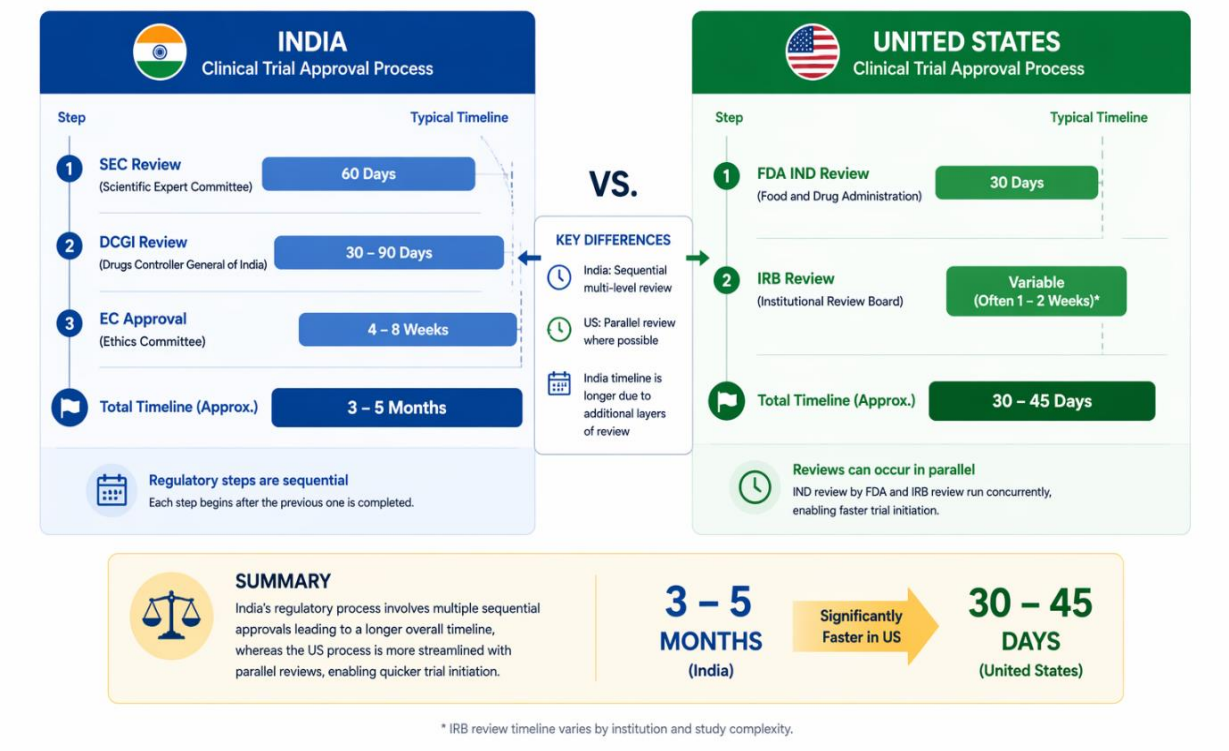

Figure 6: India and United States regulatory timelines.

The overall finding is that the US provides a more efficient, rapid approval process, making it favourable for quick clinical development. India prioritises ethical protection, participant welfare, and regulatory oversight, which is advantageous for participant well-being. Recent Indian reforms (NDCTR 2019, SUGAM portal, 2024 CRO amendment) demonstrate significant progress toward enhancing efficiency and transparency.

Challenges to Harmonisation

Despite the advantages of global harmonisationreduced duplication, improved medicine availability, and faster introductionseveral obstacles remain. Regulatory divergence exists

between countries; requirements of USFDA may not align with those of CDSCO, causing complexity. Differences in timelines and review pathways lead to asynchronous trial initiation and delays in multinational trials. Resource and infrastructure constraints in low- and middle-income countries result in longer processing times due to limited manpower and digital infrastructure. Implementation of ICH E6(R3) requires training in ethical principles, technology, innovative trial designs, and quality management systems.[12,22]

RECOMMENDATIONS

For India: Continue to refine the SUGAM portal, expand deemed approval provisions to some foreign-developed drugs, increase staffing for the three-tier system, provide clearer guidance on waiver eligibility, and streamline EC registration. For the United States: Develop clearer guidance on compensation for trial-related injuries, strengthen post-trial access guidance, enhance support for smaller sponsors and academic investigators, and continue modernising electronic submission systems. For harmonisation: Establish mutual recognition agreements for certain categories of data, align safety reporting timelines and formats, develop shared guidance on post-trial access and compensation, expand ICH implementation support, and promote joint training programs for EC/IRB members.

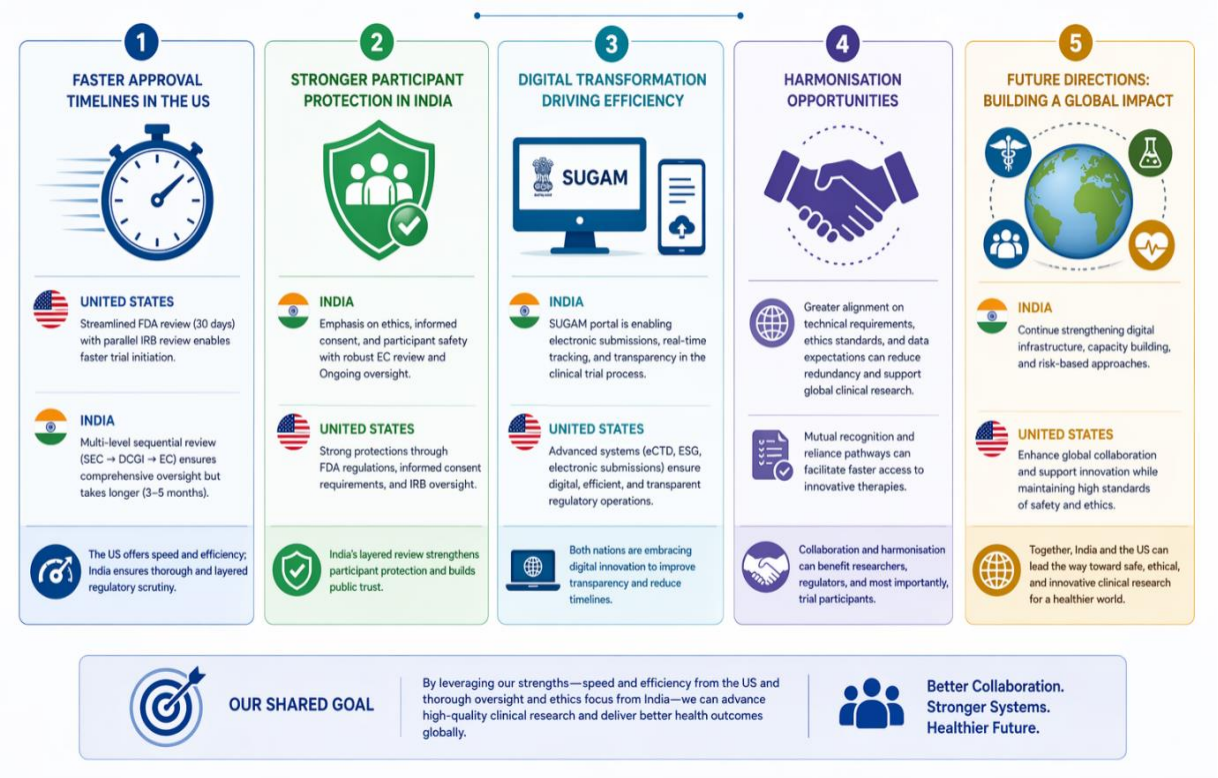

Figure 7: Summary of INDIA and USA Comparison.

CONCLUSION

This comparative study of clinical trial regulations and approval processes in India and the United States reveals significant differences that shape the conduct, administration, and timelines of clinical trials. India's regulations, governed by CDSCO under the Drugs and Cosmetics Act and NDCTR 2019, enhance transparency, participant protection, and technical efficiency. However, the three-tier system and resource limitations can delay approvals, especially for foreign drugs. The mandatory compensation framework, 24-hour safety reporting, and post-trial access demonstrate India's strong ethical commitment.

The United States regulations, governed by FDA under the FD&C Act and 21 CFR, benefit from a centralised structure, well-established accelerated pathways, and faster approval timelines. The 30-day IND review, parallel IRB process, and absence of IND fees create an efficient environment. However, the lack of mandatory compensation and limited post-trial access guidance are gaps in participant protection.

Both countries share similar ethical administration through autonomous bodies (ECs and IRBs) and have accelerated approval and orphan drug incentives. The US framework appears more mature with market exclusivity provisions, while India's framework is more explicitly focused on welfare and ethics.

The study concludes that the US maintains a faster, more resource-rich system, while India prioritises participant welfare. Recent Indian reforms, including NDCTR 2019, the SUGAM portal, and the 2024 CRO registration amendment, signal significant progress toward digitalisation, transparency, and global competitiveness. Continued harmonisation efforts will ultimately benefit global public health by accelerating access to safe and effective therapies.

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