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Review Article

Regulatory Roadmap for R&D to Market the New Drugs in India with a Special Emphasis on the NDCT Rule 2019 and the Drug and Cosmetic Act

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ABSTRACT

The stepwise overview of the regulatory approval pathway for new drugs in India, focusing on requirements and key forms mandated by the NDCT Rules, 2019. It explains how new drugs are legally defined and categorized, setting the stage for regulatory requirements. The process begins with preclinical safety testing, overseen by Animal Ethics Committees, followed by preparation of a detailed dossier and application for a test license (Form 29). Clinical trial approval is sought through the submission of Form CT-04 on the SUGAM portal and ethics committee clearance. The CDSCO and Subject Expert Committees (SEC) review each stage, requesting clarifications if needed. Successful applicants receive authorization via Form CT-06 to begin clinical trials. During these trials, all protocol changes and serious safety events must be reported. Additionally, approval for bioavailability/bioequivalence and clinical trial centers is obtained using forms such as CT 05-07 and CT 08-09. After trial completion, the sponsor submits a comprehensive marketing application (Form CT-21). With a thorough review, final marketing authorization is granted through Form CT-23. The paper highlights post-marketing requirements such as ongoing pharmacovigilance and periodic surveillance, ensuring continued patient safety. It addresses challenges like regulatory delays, ethical safeguards, and global harmonization, while emphasizing the growing role of digitalization and artificial intelligence in improving efficiency and safety monitoring. Practical recommendations for researchers, industry, and regulators are provided to streamline the new drug approval process, safeguard ethical standards, and accelerate patient access to innovative therapies in India.

Keywords: Clinical Trial Forms, India, NDCT Rules 2019, New Drug Approval, Pharmacovigilance, Regulatory affairs.

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INTRODUCTION

Drug discovery and development is a complex, multi-stage process aimed at identifying new therapeutic agents and bringing them safely to market. The journey typically begins with basic research to identify potential targets (such as proteins or genes) associated with a disease. Researchers then screen thousands of compounds to find those with promising biological activity (Biala *et al*., 2023). Only a small number of these compounds reach preclinical studies, followed by safety and efficacy assessments in laboratory and animal models. Successful candidates advance to subsequent clinical trials, which are performed on specific phases, assessing safety, effectiveness, and dosage among others in humans (BioStock, 2023). The entire process can take 10-15 years and requires significant investment and rigorous scientific evaluation. To be sure, such pre-clinical regulations deal with all aspects of the clinical safety of the investigational drug and great regulatory challenges. Regulatory agencies establish the legal and scientific framework within which pharmaceutical companies must operate (Franco *et al*., 2023). Their responsibilities include setting standards for GLPs, GCPs, and GMPs inspected; investigational new drug applications reviewed; approvals granted for clinical trials; evaluations of new drug application marketing done; and monitoring was in place (Complete-Drug-Registration-Guidance-Document-DRGD-3rd-Edition-8th-Revision-July-2024.Pdf, n.d.). drug safety through pharmacovigilance systems after approval. This oversight protects public health, ensures ethical conduct, and maintains the integrity of the drug development process (Doytchinova, 2022).

The function of the CDSCO-the apex authority in India for pharmaceuticals, medical devices, and cosmetics-comes under the provision of the Ministry of Health and Family Welfare

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(Hughes *et al.*, 2011). The CDSCO is responsible for the approval of drugs, oversight of clinical trials, framing standards, enforcement of quality control, and coordination with state drug control organizations. The CDSCO works under the direction of the DCGI, who is the chief authority for granting drug approvals, authorization of clinical trials, granting manufacturing licenses, and monitoring adherence to the Drugs and Cosmetics Act and Rules (Fogel, 2018; Smith, 2002). The DCGI also oversees pharmacovigilance and collaborates with international regulatory agencies to harmonize standards. State Drug Control Offices enforce regulations at the state level, issue licenses for manufacturing and sale, and conduct inspections to ensure compliance with national standards (Anastas and Warner, 2000).

The authority for the import, manufacture, distribution, and sale of drugs and cosmetics in India is conferred by The Drug and Cosmetic Act, 1940 and Rules, 1945. It ensures that only safe, effective, and quality products reach the market (Zhang *et al.*, 2015). The Act mandates licensing, quality control, labeling, and penalties for non-compliance. It also establishes the CDSCO and provides for advisory committees to guide regulatory decisions. New Drugs and Clinical Trials (NDCT) Rules, 2019, were introduced to enhance transparency, clarity, and efficiency in the regulation of new drugs and clinical trials (Figure 1) (Sánchez-López *et al.*, 2021). They provide detailed guidelines for the approval process, ethics committee registration, timelines for application review, compensation for adverse events, and provisions for *orphan drugs*. This Rules streamline the pathway for clinical research and market authorization, aligning Indian regulations with global standards and fostering innovation while ensuring patient safety (Girelli *et al.*, 2020).

According to the NDCT Rules, 2019, a "new drug" refers to any drug, including API or phytopharmaceutical substances, that has not been used extensively in India and has not been approved as safe and effective by the CLA for its intended claims. This includes drugs that are being introduced for the first time in the country under specific labeling conditions. A drug that has already been approved but is proposed to be marketed with modified or new claims, such as a new indication (use), dosage, dosage form, or route of administration, also falls under the category of a new drug (Government of India, 2019). A Combined Fixed Dose (FDC) of two or more drugs, previously approved individually, now proposes first-time combination or changes in ingredient proportions in already approved combinations making new claims, is considered a new drug. Modified-release or novel drug delivery systems of an approved drug, such as sustained-release or controlled-release formulations, are treated as new drugs (*India | SpringerLink*, n.d.). Certain advanced therapeutic products, including vaccines, recombinant DNA (r-DNA) derived products, monoclonal antibodies, living modified organisms, gene therapy products, xenografts, and cell or stem cell-based therapies, are also classified as new drugs. Drugs listed under the first three categories (new drugs, modified claims, and FDCs) are considered "new drugs" for a period of four years from the date of approval. However, drugs falling under the categories of novel drug delivery systems and biotechnology-based products (such as vaccines or gene therapies) are deemed "new drugs" at all times, without a time limit (Annapurna and Rao, 2020).

In India, new drugs are broadly grouped into several categories-chemical drugs, biological drugs, phytopharmaceutical drugs, and orphan drugs. Chemical drugs are the traditional medicines synthesized in labs, like most tablets and capsules we commonly use. Biological drugs are usually more complex, including vaccines, blood products, monoclonal antibodies, gene therapies, or cell-based treatments, all derived from living organisms (Clinical Research Regulation For India | *ClinRegs*, n.d.-a). Phytopharmaceutical drugs are standardized plant-based medicines where the active components are scientifically measured and defined. Biological drugs have extra checks for purity and consistency because of their complexity, and their production processes are also closely monitored (*DgSimilaBiologics25.Pdf*, n.d.). *Phytopharmaceutical drugs* must show they have well-defined, reproducible active ingredients from plants and that they are both safe and effective. Orphan drugs, since they're meant for rare diseases that affect fewer than five lakh (500,000) people in the country and may not have big markets, can get faster review, special incentives, or some relaxed approval requirements, although safety and basic effectiveness must still be ensured (Ahmed *et al.*, 2017). These category-specific regulations help make sure that, no matter how new or advanced a medicine is, it reaches patients only after thorough review and safeguards.

Intend to trace and chart all the regulatory pathways involved in the development of a new drug from research and development to marketing authorization and launch in India. It aims to identify the various regulatory forms, documents, and approvals required at each stage of this journey. Additionally, the study seeks to analyze the structured pathway for new drug approval, helping to clarify how the regulatory system works in practice to ensure that only safe and effective medicines reach patients in India (*Microsoft Word - 004*, n.d.). the study seeks to analyze the structured pathway of new drug approval, highlighting the critical checkpoints designed to maintain high standards of patient safety and drug efficacy. Beyond mapping the regulatory framework, this research also explores the challenges faced by the Indian pharmaceutical industry in developing new drugs, including financial constraints and the relatively slow pace of innovation (India, 2025; S *et al.*, 1970). It examines the perspectives of regulatory authorities regarding the industry's efforts to reduce approval times and costs, while preserving rigorous safety standards. The study aims to identify loopholes and inefficiencies within the current regulatory approval process that may contribute to delays or obstacles in bringing new drugs to

market. By uncovering these issues, the study intends to support recommendations for improving the regulatory environment to foster innovation, expedite drug approvals, and ultimately enhance access to novel treatments in India (Lo *et al.*, 2009a).

Scope and relevance

This work focuses on making the Indian regulatory framework more accessible to both experienced and new regulatory professionals. By breaking down which regulatory forms (like those needed for clinical trial approval, manufacturing, and market authorization) are needed at each phase, the study aims to remove confusion and help users confidently advance through the approval process. The relevance is high for the pharmaceutical industry, researchers, and stakeholders, as understanding these steps ensures better compliance, prevents mistakes or errors, and shortens approval timelines, allowing safe and effective medicines to reach Indian patients efficiently.

METHODOLOGY

The approval of a new drug (whether API or formulation) in India is a two-part process managed by the Central Drugs Standard Control Organization (CDSCO). The process and forms depend on whether you intend to import or manufacture the product, and the stage/type of permission required (Drug Approval Process in India, n.d.-a). Two Regulatory Pathways (CDSCO-managed via SUGAM portal; complete dossiers per Schedule Y/NDCT 2019 required) are required firstly Manufacture in India (Domestic Production) then New drugs (API/formulation) undergo preclinical testing, then Form CT-12 (API)/CT-13 (formulation) submission for clinical trial/BA/BE/test purposes (Rule 53/55), yielding Form CT-14/CT-15 permission. Post-trials, Form CT-21 application leads to Form CT-22/23 marketing authorization (Rule 81). Timeline: 90-180 days per stage. Second, if Import from another country (API/Formulation) for test/analysis, submit Form CT-16 for Form CT-17 license (Rule 68). For marketing, Form CT-18 yields Form CT-19 permission (Rule 80). Clinical trials require Form CT-04 → Form CT-06 (NDCT 2019). Waivers possible for ICH-approved drugs with Phase IV commitment. Timeline: 30-90 days (import license); 90 days (trials/marketing). This dual pathway ensures quality, safety, and efficiency, with mandatory ethics clearance and pharmacovigilance (CDSCO. gov.in; SUGAM User Manual, n.d.).

Regulatory Pathway for R&D to Marketed in-house manufactured new drug

The approval of a new drug (whether API or formulation) in India is a two-part process managed by the CDSCO. The process and forms depend on whether you intend to import or manufacture the product, and the stage/type of permission required (*Import_guidance_doc.Pdf*, n.d.).

Preclinical Stage (Discovery and Animal Testing)

The preclinical stage is a vital foundation in the development of new drugs. Before any new chemical or biological entity is administered to humans, it must undergo thorough non-clinical (preclinical) testing (*Compendium of CPCSEA.Pdf*, n.d.; *Microsoft Word - 1-56.Doc*, n.d.). The primary purpose of this stage is to establish a drug's basic safety profile, assess potential toxicity, and provide initial evidence of efficacy. This is essential to protect human trial participants from unnecessary risk and to ensure that only compounds showing a reasonable degree of safety and potential benefit move forward to clinical trials ("Institutional Animal Ethics Committee (IAEC) APPROVALS," n.d.).

Regulatory Need

In India, all animal studies related to drug development require approval from the IAEC, which operates under the CPCSEA. These committees are responsible for ensuring that animal use is justified, humane, and minimized as much as possible (Lo *et al.*, 2009b). To obtain approval, researchers must submit a detailed study protocol outlining the scientific rationale, objectives, animal use, and experimental methods, along with toxicity reports and any available prior data for risk assessment. Approval is only granted once the IAEC is satisfied that the proposed use of animals is ethically and scientifically justified (Bio, 2022).

Required Documents

All preclinical studies must follow GLP principles to guarantee data quality, reliability, and traceability. In India, GLP certification is overseen by the National GLP Compliance Monitoring Authority (NGCMA), and while this certification is voluntary, it is often essential for regulatory acceptance (GLP Certification in India Benefits, Requirements and How to Acquire the GLP Certification in India, n.d.; *PDF*, n.d.). GLP compliance applies to safety pharmacology, toxicology, and related studies. Safety pharmacology assesses the drug's effects on critical physiological systems such as the central nervous, cardiovascular, and respiratory systems, while toxicology studies evaluate single- and repeat-dose toxicity, genotoxicity, reproductive or developmental toxicity, and, where necessary, immunotoxicity (GLP-100.Pdf, n.d.; NGCMA, n.d.).

For IND enabling studies, which are designed to predict potential safety issues before clinical trials, the required data package includes pharmacology (efficacy and safety), pharmacokinetics and ADME (Absorption, Distribution, Metabolism, Excretion) studies, (GLP Certification in India, n.d.) as well as toxicological evaluations in at least two animal species. Complete documentation of study protocols, raw data, and study reports according to GLP standards is mandatory (Drug Approval in India | Essential Steps to Get Drug Registered, 2024).

Additionally, before the manufacture of any drug formulation for testing, researchers must apply for a Test License (Form 29),

which permits the manufacture of drugs only for examination, testing, and analysis never for commercial use (Good Laboratory Practices in Preclinical Research Compliance | ZeClinics, n.d.). The application process involves submitting Form 30 to the relevant State FDA, along with the necessary technical and legal documents, project protocols, manufacturing procedures, equipment details, pollution clearances, and drug specifications, especially for those already holding a manufacturing license (Table 1). The test license is valid for one year and can be renewed as needed (National GLP Compliance Monitoring Authority | STIP Compass, n.d.). All activities under this license are solely for testing or analysis and are subject to inspection by regulatory authorities (Regulatory Requirements in Clinical Trials | SpringerLink, n.d.). This stepwise approach in the preclinical phase ensures that all safety, ethical, and regulatory standards are met before a new drug progress to clinical testing in humans (RCGM Approval for Pre-Clinical Studies | Regulatory Compliance -CliniExperts, n.d.) (Figure 2).

Case in which this is avoidable

According to the NDCT Rules, 2019, preclinical animal studies are an essential precondition for most new drug approvals, but there are specific situations where such studies can be partially or wholly avoided:

When sufficient human data already exist

If a new drug contains an active ingredient with an established safety profile in humans (such as in the case of generics, certain fixed-dose combinations, or drugs already marketed in recognized jurisdictions), regulators may waive some or all animal testing requirements ("Government Waives Clinical Trial Requirement for Several Drugs Approved in Select Countries," 2024; Govt Waives Clinical Trial Requirement for Several Drugs Approved in Select Countries- The Week, n.d.).

For drugs intended for urgent unmet medical needs

In public health emergencies, NDCT 2019 allows for accelerated pathways, potentially reducing or bypassing animal data requirements when human data from other countries or strong scientific justification is provided, and the benefit-risk balance is favorable (DCGI Specifies Six Countries under Rule 101 of NDCTR, 2019 to Consider Local Clinical Trial Waiver, n.d.).

Biowaivers and Literature-Based Submissions

When a drug's preclinical safety is well documented in the published scientific literature or when a new use is proposed for an already approved drug, regulators may accept literature in place of new animal data, provided the information meets the standards set in the rules (CDSCO to Accept Pre-Clinical Toxicity Data Generated in Other Countries Subject to Conditions, n.d.; "Government Waives Clinical Trial Requirement for Several Drugs Approved in Select Countries," 2024).

Ethical Alternatives and 3Rs Principle

The NDCT Rules explicitly promote the principle of Replace, Reduce, and Refine (3Rs) animal use, encouraging validated alternatives such as *in vitro* studies and computational models, and allowing for these alternatives if they adequately answer the regulatory questions about safety and efficacy (DCGI Specifies Six Countries under Rule 101 of NDCTR, 2019 to Consider Local Clinical Trial Waiver, n.d.; India Waives Local Clinical Trials of New Drugs, n.d.). E.g., Fingolimod Capsules (0.5 mg, for Multiple Sclerosis) In a SEC meeting firm requested a waiver of local (animal) clinical trial requirements for manufacturing and marketing Fingolimod in India. The committee accepted the justification, noting the drug's well-established safety profile from its approval and use in the US/EU. The SEC agreed to the waiver because sufficient preclinical and human data were already available and accepted by stringent regulators. The

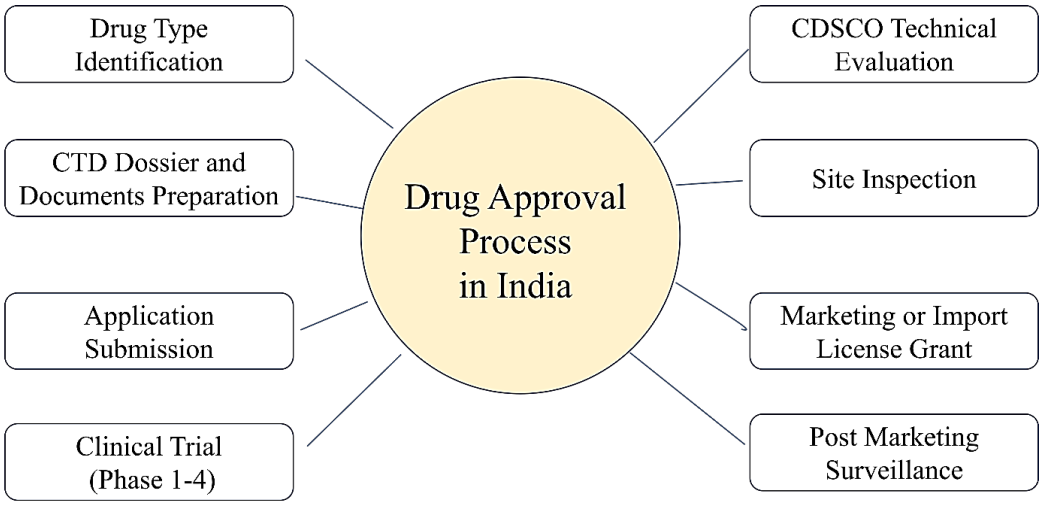

Figure 1: Stepwise schematic of the drug approval process in India under CDSCO and NDCT Rules, 2019.

Table 1: Application Form required for Import or Manufacture of API/Formulation. All applications are submitted via the SUGAM online portal. applicants must ensure all dossiers are complete and comply with Schedule Y and the NDCT 2019 (Cdsco.Gov.in/Opencms/Export/Sites/CDSCO_WEB/Pdf-Documents/SUGAM_user_manual.Pdf, n.d.).

Sl. No.	Reason of application	Application/Form	Permission Granted In	Relevant Rule
1	Conduct a clinical trial in India	Form CT-04	Form CT-06	New Drugs and Clinical Trials Rules, 2019
2	Import new drug/API/ formulation for test analysis purpose	Form CT-16 (license)	Form CT-17 (license approval)	Rule 68
3	Manufacture new drug/API/ formulation for CT/BA/BE study or test/analysis	Form CT-12 (API) / CT-13 (formulation)	Form CT-14 (API) / CT-15 (formulation)	Rule 53, 55
4	Import new drug/API for marketing	Form CT-18 (application)	Form CT-19 (permission)	Rule 80
5	Manufacture new drug/API for marketing	Form CT-21 (application)	Form CT-22/23 (permission)	Rule 81

decision emphasized that, especially for rare diseases or drugs with global approval and human exposure, some preclinical requirements can be waived to avoid redundant animal testing (45th-Technical-Committee-Meeting-Held-on-22.01.2019.Pdf, n.d.; Rajkumar, 2024). Preclinical trial requirements in India are generally mandatory, but the intent is always to protect human subjects while minimizing unnecessary animal use, aligning with global best Practices and Ethical Standards (*BioIVT*, n.d.).

Approval for Clinical Trials (Human Studies)

The application for clinical trials (human studies) is a critical regulatory step in the journey of a new drug in India. The process is meant to ensure that any medicine tested in people meets strict safety, ethical, and scientific standards, protecting both participants and the credibility of the research (Gogtay *et al.*, 2017). An application is needed for any new drug or Investigational New Drug (IND) before beginning clinical (human) studies in India and whenever a sponsor plans to conduct clinical trials, Bioavailability/Bioequivalence (BA/BE) studies, or import/manufacture new drugs for trial, even if those drugs are already approved in other countries (Elsevier | A Global Leader for Advanced Information and Decision Support in Science and Healthcare, n.d.; Faqnd.Pdf, n.d.).

The main goals are to protect human subjects through ethical review and regulatory oversight, verify that there's enough safety data (through animal research and laboratory studies) to justify human trials and make sure clinical studies are designed to produce meaningful, reliable results (ICH Official Web Site: ICH, n.d.; Stern, 2017).

Mandatory CT forms required for Clinical Trial Application Form CT-04 for analyse, inspect, and provide legitimate reasons to CDSCO for the permission of conducting clinical trials on Indian residents, Form CT-02 for Approval form issued by the registered Ethics Committee for each trial site and Form CT-07b for As of 2024, mandatory registration for Clinical Research Organizations (CROs) ensures ethical and quality standards (*CTiguride.Pdf*, n.d.), (Clinical Research Regulation For India | ClinRegs, n.d.-b).

Checklist of Mandatory Documents that required for CT approval are Investigator's Brochure for comprehensive summary of all available data on the investigational drug, Clinical Protocol for Detailed study plan, objectives, methodology, inclusion/exclusion criteria, and assessment schedules, CMC Data for Information on drug's chemistry, manufacturing process, formulation, and quality control measures, Preclinical Data for Safety evidence from non-clinical/animal studies, Previous Human Data for relevant (Figure 3) if the investigational product has prior clinical use or is being repurposed, EC Approval Certificate for proof of Ethics Committee registration and protocol approval for each site using CT-02, Fee Payment Receipt for Proof of fee submission to CDSCO, Other Declarations As per Schedule Y and NDCT 2019 (Schedule 2) such as investigator CVs, site details, insurance, and safety reporting procedures (CDSCO, n.d.; Modi *et al.*, 2015).

Step-by-Step Approval Workflow

Dossier Preparation

Gather all mandatory documents as listed above. Obtain Ethics Committee approval for the study protocol at each intended site (CT-02). Ensure completeness and accuracy to minimize review delays.

Application Submission

Upload the complete application package and Form CT-04 using the SUGAM online portal or National Single Window System as

required. Pay the prescribed regulatory fee (rule 21) of 3,00,000 and obtain a receipt.

Regulatory Review

CDSCO conducts a preliminary check for completeness. Application is sent to the Subject Expert Committee (SEC) for technical and ethical review. If submitted for an investigational new drug or a major change, additional rounds of review or clarification may follow.

Deficiency and Clarification

If documentation is incomplete or queries arise, CDSCO issues a deficiency letter. Sponsor/applicant must provide clarifications or missing documents promptly for further review.

Final Decision

If all requirements are met, CDSCO grants approval in Form CT-06; permission is usually issued within 90 working days of a complete CT-04 application (or 30 days for drugs discovered and developed in India). If approval is denied, reasons are communicated in writing.

Post-Approval Obligations

Sponsor must report the trial initiation, progress, any serious adverse events, and periodic status to CDSCO and the ECs. Must adhere to Good Clinical Practice (GCP) standards, maintain regulatory compliance, and submit end-of-trial or premature discontinuation reports (NEW DRUGS ANDctrS RULE, 2019. Pdf, n.d.).

Form CT 6 shall remain valid for a period of two years from the date of its issue, unless extended by the Central Licensing Authority (Morten *et al.*, 2021).

Waivers for local preclinical or clinical data under NDCT 2019

There are special situations where some of these requirements (such as local preclinical or clinical data) may be waived or avoidable like, Case 1 is If a drug is already approved and widely used in certain major countries (like the US, UK, EU, Japan, Canada, Australia), and there's no major safety concern, the Indian authority may allow skipping some local studies, provided other rigorous data exist (Pallmann *et al.*, 2018). E.g.,

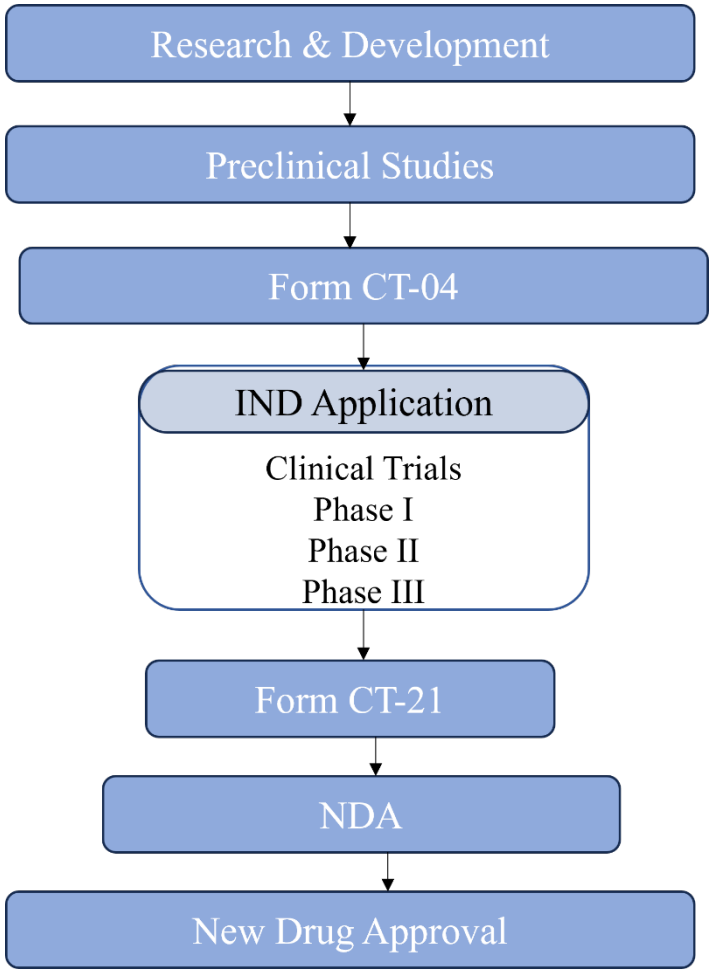

Figure 2: Step by step mapping of forms and approval stages for manufactured new drug according to NDCT act 2019.

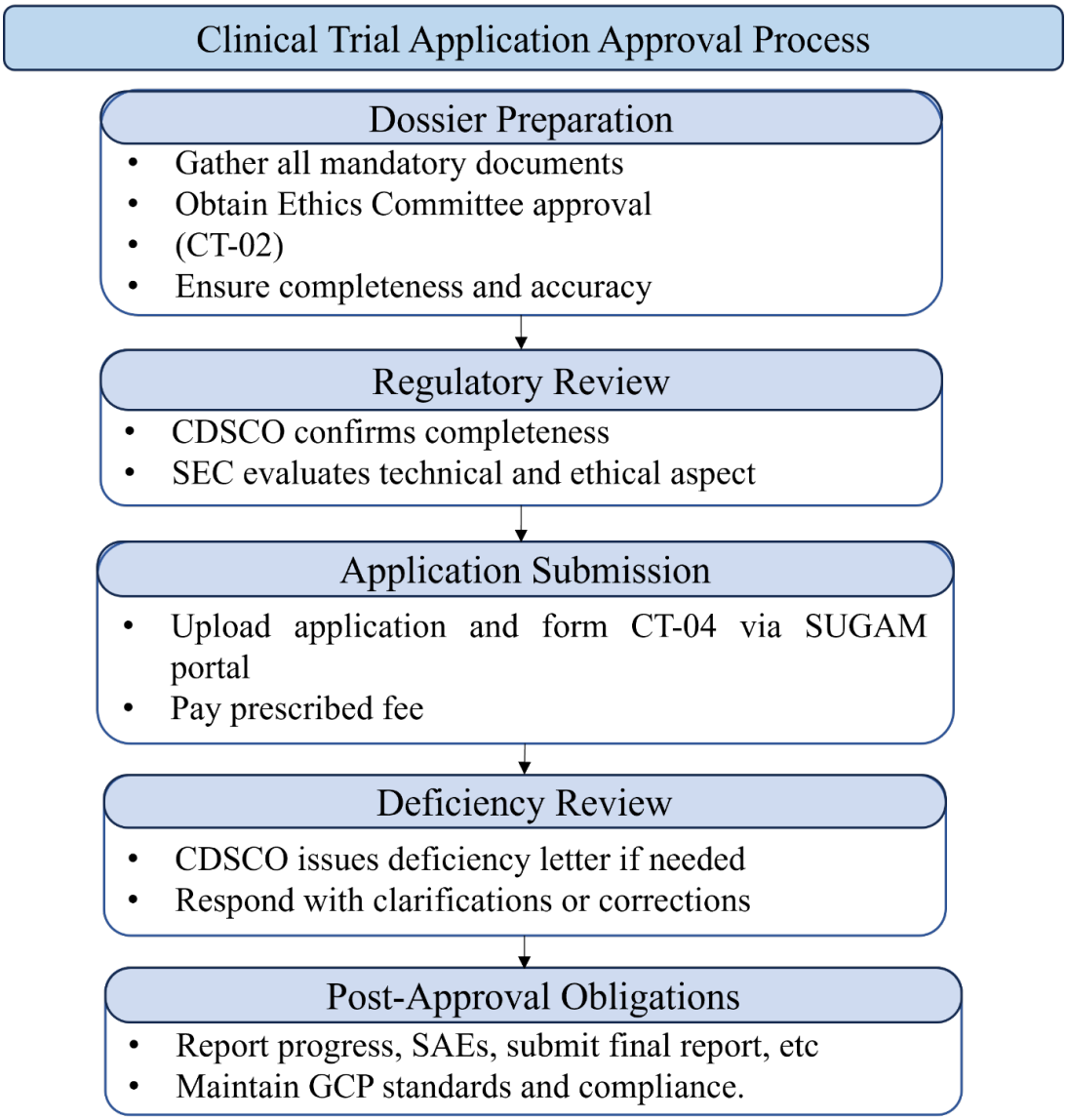

Figure 3: According to NDCT 2019 Approval Process for Clinical Trial Protocol.

Real-world Case Study for local clinical trial waiver in the SEC Neurology and Psychiatry meeting held on April 23, 2025, the committee reviewed an application for Lecanemab concentrated solution for infusion (100 mg/mL), already approved in major markets including the USA, EU, UK, and Japan. Intended for a serious neurological condition with high unmet need in India, the drug was supported by extensive global clinical trial data, including results from 295 Asian patients. Under Rule 101 of the NDCT Rules, 2019, which permits waivers for drugs approved in recognized countries without major safety concerns, the SEC recommended waiving the local clinical trial requirement. Approval for import and marketing was granted with the condition of conducting a Phase IV post-marketing safety and effectiveness study in India, involving at least 25 patients over two years. This decision illustrates India's approach of expediting access to globally proven therapies while ensuring ongoing safety monitoring in the local population (Recommendations Neurology Psychiatry 23.04.2025.Pdf, n.d.). Case 2 is that public health emergencies or rare/orphan diseases may justify faster approval with reduced data, especially if the benefit to patients outweighs the risks. E.g., Real world Case study in the SEC Oncology meeting held on July 17, 2025, Servier India requested approval for *Vorasidenib* tablets (10 mg, 40 mg), an orphan drug already licensed abroad for rare brain tumors. The SEC granted a waiver of local Phase III clinical trials, citing robust international safety and efficacy data and urgent unmet medical needs for Indian patients. Instead, the company must conduct a Phase IV post-marketing study in India and report findings to CDSCO as a condition of approval. This case illustrates how, under NDCT Rules, 2019, authorities can expedite drug access in rare/orphan diseases by relying on high-quality foreign data while ensuring Indian patient safety through post-marketing surveillance

(Colin, 2025). Case 3 is Strong scientific evidence and published literature can sometimes replace new data, if regulators are convinced safety and efficacy are already well proven. all waivers are discretionary and evaluated on a case-by-case basis, with patient safety and scientific credibility given the highest priority (Privilege Waived for Documents Voluntarily Disclosed to ASIC, 2024). Even when such waivers are granted, the sponsor may still be required to conduct post-marketing safety or surveillance studies to continue monitoring the drug's effects in the real-world setting. It is important to note that these waivers do not exempt applicants from fulfilling ethical requirements, adhering to Good Clinical Practice (GCP) guidelines, or meeting any post-approval obligations as specified by regulatory authorities (Birks *et al.*, 2014).

Phase-wise Clinical Trial Conduct and Regulatory Approval in India

Clinical trials for new drugs in India are conducted in a series of well-defined phases, each designed to answer specific scientific and safety questions before a medicine is approved for widespread use.

Phase I

Here, the drug is initially trialled on a small number of healthy volunteers (20-80) see Table 2 Regulatory phases of clinical trials in India (Phase I-IV) under NDCT Rules, 2019. The primary objective is safety, tolerability and human metabolism study. Researchers monitor for potential side effects and establish safe dosage ranges (Jhuria *et al.*, 2025).

Phase II

Once safety is established, the drug is tested in a larger group of patients who have the disease the drug is intended to treat. This phase focuses on testing efficacy (whether the drug works as intended), further evaluating safety, and determining optimal dosing. These are usually performed with a larger sample size (100 to 300 patients).

Phase III

In this phase, the drug is administered to a larger patient group (1,000 to 3,000 patients), often across multiple hospitals or clinics, to assess effectiveness, monitor for rare side effects, and compare the new treatment to the standard of care or placebo. Success in

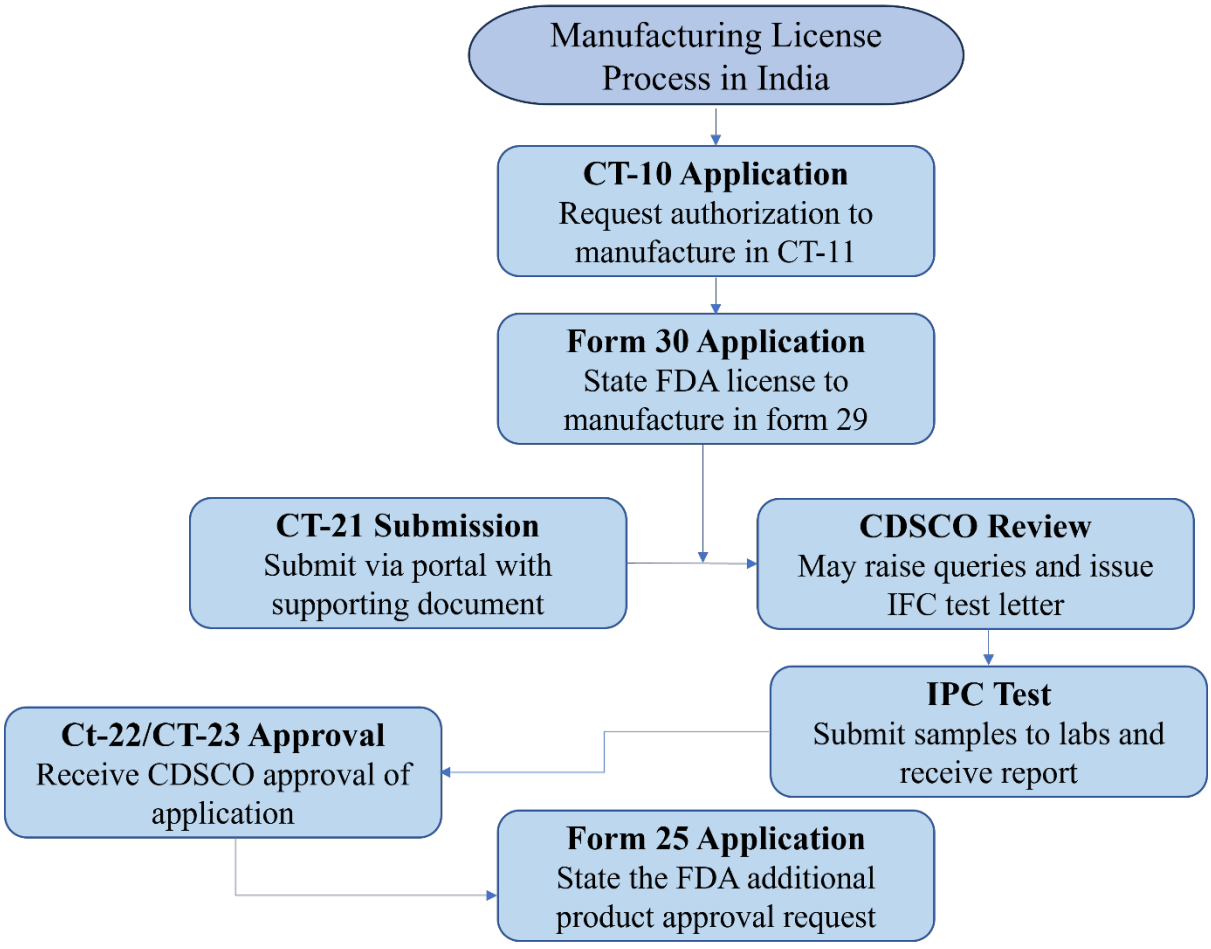

Figure 4: Regulatory Pathways for Approval of Manufactured New Drug (NDCT 2019).

Table 2: Regulatory phases of clinical trials in India (Phase I-IV) under NDCT Rules, 2019. Highlighting trial objectives, participant types, and mandatory CDSCO and ethical committee approvals required for initiation and progression. Trial protocols must be approved by an ethics committee and submitted to the CDSCO for clearances (Drug Approval Process in India, n.d.-a).

Phase	Purpose	Participants
PHASE I	Safety And Dosage	Heatly Volunteers
PHASE II	Efficacy And Side Effect	Small Patient Group
PHASE III	Confirmatory Data	Large Patient Population
PHASE IV	Post Marketing Surveillance	Real World Settings

Phase III is typically required before a drug can be considered for marketing approval *(Trivedi et al., 2025).*

Regulatory Forms and Steps to conduct these trials Form CT-06 for Permission to conduct clinical trial of new drug. This official permission is granted by the CDSCO for conducting Phase I-III clinical trials. It authorizes the trial to begin after a thorough review of the submitted data and ethics committee clearances. Form CT-07 for permission to conduct bioavailability or bioequivalence studies of a new drug. any amendments or changes to the protocol, such as modifications in trial sites, dosage, or inclusion/exclusion criteria, must be reported to CDSCO using this form (Bangera and MS, 2025; Indian Researcher, 2025) The license to conduct a bioavailability/bioequivalence study under the rule 34 and in Form CT-07 shall be valid for a period of one year from the date it is issued unless otherwise suspended or cancelled by the Central Licencing Authority. In India, SAE (Serious Adverse Events) reporting during clinical trials is governed by Appendix XI of Schedule Y of the Drugs and Cosmetics Rules (Regulatory Affairs Professionals Society [RAPS], n.d.; Indian Researcher, n.d.). At the close of the trial, investigators are essential to submit a final study report outlining all findings, adverse events, and interpretations. Provide end-of-trial declarations and notifications to CDSCO, ethics committees, and (if registered) to the Clinical Trials Registry of India (CTRI), as per regulatory requirements (Challenges in Administering a Clinical Trials Registry: Lessons from the Clinical Trials Registry-India | Pharmaceutical Medicine, n.d.). These steps are critical to demonstrate that the trial followed ethical, scientific, and regulatory standards, and to support the drug's evaluation for further approval or marketing. Additional Regulatory Safeguards, Ethics committee approval is required for each trial site before enrolling any participant. SAE reporting standards, informed consent protocols, and Good Clinical Practice (GCP) are strictly enforced. Failure to obey with these rations can result in regulatory action, suspension, or rejection of the drug approval application (PDF) India's Clinical Trial Regulatory Changes, Indian Researcher? Awareness of Recently Changed Regulations, and the Impact of the New Drugs and Clinical Trial Rules: A Review, n.d.).

Application for New Drug Approval (NDA)

In order to make and sell new Active Pharmaceutical Ingredients or New Drug formulations for trade or any type of retail, all manufacturers must obtain a license from the Zonal FDA and CDSCO. This procedure is required to gain CDSCO approval Process of Reporting Serious Adverse Events (SAE) during a Regulatory..., n.d.).

The process for approval to manufacture a new drug under NDCT 2019 begins with submitting Form CT-10 to obtain permission for manufacturing the new drug for testing and analysis via Form CT-11. Next, an application must be submitted to the state FDA using Form 30 for the manufacturing license (Form 29). The complete application, including necessary documents and government fees, should then be filed through the SUGAM portal using Form CT-21 (74). The CDSCO reviews the application and may raise queries if needed, after which it issues an Indian Pharmacopoeia Commission (IPC) testing letter refer (Figure 4) Regulatory Pathways for Approval of Manufactured New Drug (NDCT 2019). The samples are sent to IPC labs for testing, and upon receiving the IPC report, the application proceeds for final approval via Form CT-22 for APIs or CT-23 for formulations. Finally, Form 25 is submitted to the state FDA to request product approval; licenses are generally processed within 90 days. This thorough approval pathway ensures new drugs undergo comprehensive testing and scrutiny, prioritizing patient safety and therapeutic benefit (Briefing, 2025b).

The process for approval of importing a new drug under NDCT 2019 starts by identifying the purpose of import, whether for clinical trial/BA-BE study or commercial marketing. Applicants must submit the appropriate CDSCO forms: Form CT-16 for import permission related to clinical trials or BA/BE studies, resulting in approval via Form CT-17; and Form CT-18 for import permission for commercial use, with approval granted through Form CT-19 (DCC Asks CDSCO to Ensure Uniform Implementation of NDCT Rules for New Drugs Approval for Gastro-Resistant Drugs, n.d.). The application, including a dossier in CTD/eCTD format containing preclinical, clinical, CMC, and quality data, is submitted to CDSCO. Upon review, CDSCO may raise queries, which the applicant must address. For novel drugs or biologics, expert committee review may be required (Figure 5) Regulatory Pathways for Approval of Imported New Drug (NDCT 2019). Once approved by CDSCO, permission is issued in the relevant CT form. Subsequently, an Import License application is made to the State Licensing Authority (SLA) under Drugs and Cosmetics Rules, 1945, using Form 10 (import license) and Form 11 (for small quantities). The SLA grants the import license for distribution, sale, or clinical use in India (PowerPoint Presentation, n.d.).

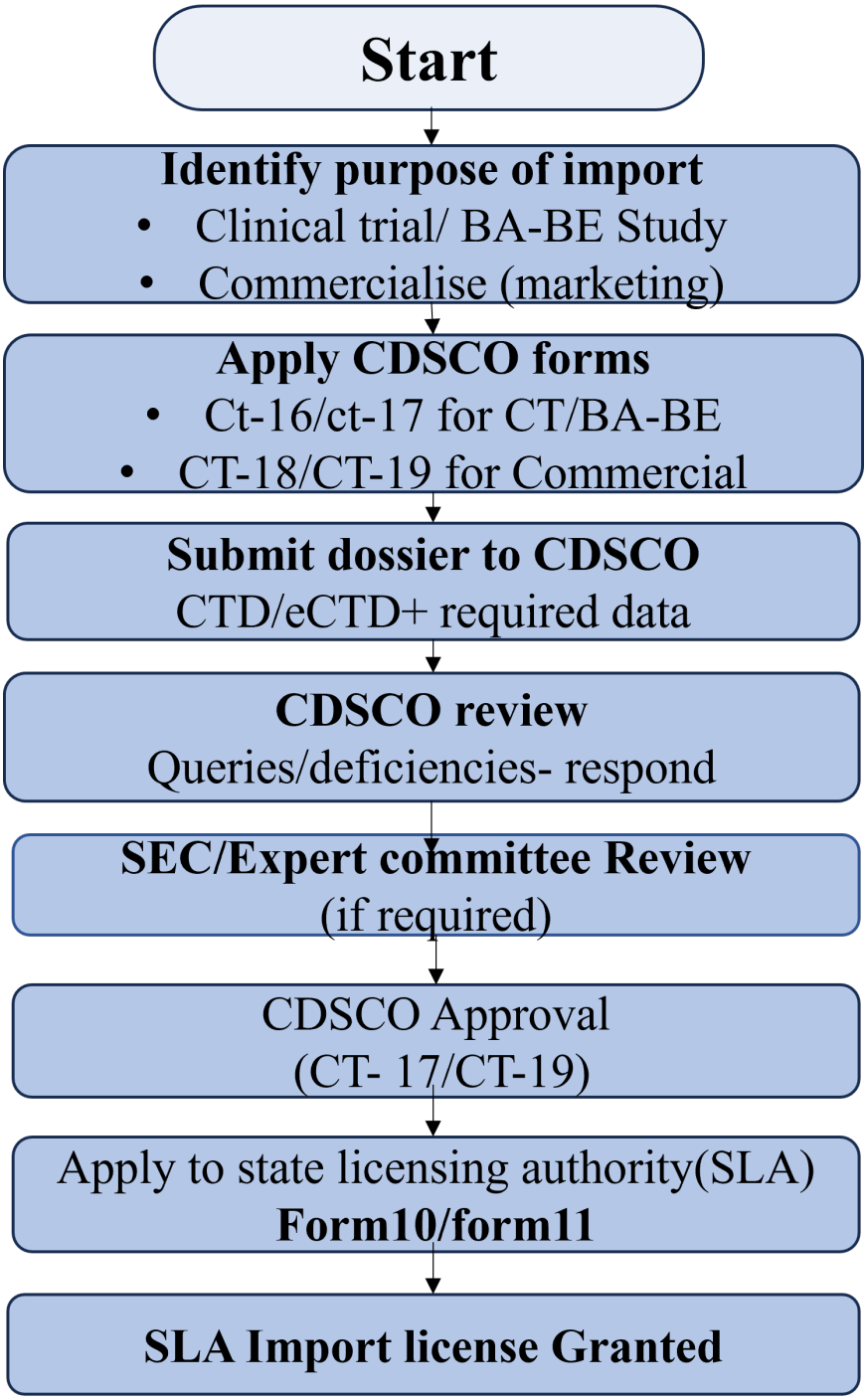

Figure 5: Regulatory Pathways for Approval of Imported New Drug (NDCT 2019).

When applying for new drug approval in India using Form CT-21, several crucial documents must accompany the application. Chemistry, Manufacturing, and Controls (CMC) data provide detailed information about the drug's ingredients, manufacturing process, quality standards, stability, and analytical methods ensuring consistent drug quality. Preclinical data present evidence from laboratory and animal studies that establish the drug's initial safety profile. Clinical trial reports encompass comprehensive findings from human studies (Phases I-III), detailing safety, efficacy, dosage, and side effects across diverse patient populations (*BEGuideline.Pdf*, n.d.). A risk-benefit analysis scientifically weighs the drug's therapeutic advantages against potential risks, demonstrating justification for approval. Drafts of the package insert and labeling include information for healthcare providers and patients such as dosing, warnings, indications, and potential side effects. Additional regulatory forms, undertakings, sample products, literature references, and proof of fee payment as per NDCT 2019 guidelines are also mandatory to complete the submission dossier (GUIDELINES FOr, n.d.).

The journey from completing drug development to obtaining marketing approval generally follows these steps: First, the sponsor compiles all required scientific, manufacturing, and administrative documentation, ensuring accuracy and completeness. Next, the complete dossier is submitted electronically through the SUGAM portal or National Single Window System using Form CT-21. Regulatory review by CDSCO, often aided by a Subject Expert Committee, involves thorough evaluation of the application's scientific and regulatory aspects (Registration Guidelines, n.d.; Union Health Ministry to Amend New Drugs and Clinical Trials Rules, 2019 for Streamlining Test Licence and BA/BE Study Applications, n.d.). Any deficiencies or queries raised must be promptly addressed by the applicant. After satisfactorily resolving all issues, CDSCO grants marketing approval if the drug meets safety, efficacy, and quality criteria. Post-approval, sponsors must comply with ongoing obligations including safety monitoring and Periodic Safety Update Reports (PSURs), as well as adherence to any imposed conditions. The regulatory guidelines state that the decision on marketing permission for a complete CT-21 application should generally be made within 90 days; however, longer timelines may result if additional data or expert inputs are required (FDC New Drugs Marketing, n.d.; List of New Drugs Approved in the Year 2025.Pdf, n.d.).

Marketing Authorization

After successful clinical trials and submission of all supporting data, the sponsor applies to the (CDSCO) for permission to market the new drug in India. The process begins with the submission of a detailed application, accompanied by clinical and quality data, via the SUGAM portal (Briefing, 2025c). Depending on the complexity of the application, such as requests for marketing authorization, clinical trials, or post-approval changes, the CDSCO may refer the file to a Subject Expert Committee (SEC), a panel of domain experts who critically examine the product's safety, efficacy, and overall benefit-risk profile. The SEC reviews can involve back-and-forth requests for additional data or clarification, and the final advisory recommendation is then sent to CDSCO, which retains the legal authority to make the final decision (01-GUIDANCE-DOCUMENTS-ON-FOR-SEC.Pdf, n.d.).

Once a product is approved for the Indian market, the official evidence of this is issued via Form CT-23, which legally permits the applicant to market the product in India. If the product or its Active Pharmaceutical Ingredient (API) is being imported, additional permissions are required. For APIs and formulations, import licensing relies on forms like CT-19 and CT-20, while Form 10 (import license) and Form 41 (registration certificate) are used to authorize foreign manufacturers and their products for import and sale in India. These checks ensure that imported products me*et al*l safety and regulatory standards before entering the Indian supply chain (CDSCO Releases Updated Version of Guidance Document for Biologicals, n.d.; India CDSCO Medical Device Registration and Regulatory Approval Process, n.d.).

Apart from securing regulatory approvals, companies must also be prepared for commercial-scale manufacturing. Scale-up and manufacturing readiness means demonstrating that the product can be produced reliably and consistently at a larger scale, not just during clinical trials or in small batches. The applicant must show robust manufacturing processes, validated quality control systems, and compliance with Good Manufacturing Practice (GMP) standards. CDSCO or its representatives may inspect manufacturing facilities or review additional technical data to confirm this readiness, further safeguarding patient health and product quality throughout the commercialization process (COVID 19 Clinical Trials and Emergency Marketing Approval Process in India, 2021; Drug Approval Process in India, n.d.-b).

Post-Marketing Surveillance (PMS)

When a new drug gets regulatory approval, its safety and effectiveness are proven mainly through clinical trials. But these trials only involve limited and carefully selected patient groups, often excluding people with complex health problems or those taking multiple medications. Real life, however, is much more varied (SELKER *et al.*, 2018). Once the medicine is on the market, it's used by people of a wide range of ages, illnesses, and backgrounds. Side effects that are rare, long-term, or specific to

Table 3: Post-marketing assessment of new drugs in India. The post-marketing assessment of new drugs in India includes multiple, overlapping layers of clinical trials, observational studies, safety updates, and real-time reporting, all with the shared goal of protecting public health and upholding public trust in new medical treatments (Post Marketing DSM, n.d.; PV_Guidance_Docs_for_MAH_Version_2_as_on_18.01.2024.Pdf, n.d.).

Requirement	Responsible person	Timeline	Details
Phase IV trial protocol	Sponsor, CDSCO, Ethics	After launch, as needed	New studies post-approval; protocol must be registered
Observational PMS study	Sponsor, CDSCO, Doctor	After launch, as needed	Data collected during routine care
Serious Adverse Event (SAE)	Sponsor/Doctor/Pharmacist	Within 15 days	Immediate reporting to CDSCO, Ethics, PvPI
PSUR submission	Sponsor	6-monthly (2 yrs), annual (next 2), or as required	Safety summary, risk management, global/local data

certain groups might only show up when thousands or millions receive the drug. That's why post-marketing surveillance is essential to catch unforeseen issues and make sure the drug remains safe and effective for everyone (Post Marketing Surveillance of Drugs, n.d.; What Are Clinical Trials and Studies?, 2023) (Table 3 post-marketing assessment of new drugs in India). Components of Post-Marketing Assessment is:

Phase IV (Post-Marketing) Clinical Trials

Phase IV trials are conducted after a drug has been launched. These studies address additional questions not fully answered by earlier trials, such as rare side effects, drug interactions, or effectiveness in broader patient populations. They follow an approved protocol and uphold strict ethical standards. In these studies, the sponsor often provides the medication free of charge to participants, unless justified otherwise (David and Kim, 2025; Turner and Hoofwijk, 2013).

Observational and Non-Interventional Studies

Regulators may also mandate observational or non-interventional studies, where the drug is prescribed as per usual care and doctors report on its effects. These studies help to identify real-world outcomes and long-term safety issues. Unlike clinical trials, such studies are less restrictive but are still conducted under an approved protocol to ensure scientific integrity.

Pharmacovigilance and Adverse Drug Reaction (ADR) Reporting

Manufacturers, importers, and marketers are required to establish a pharmacovigilance system staffed by trained professionals. This system collects, analyses, and reports adverse drug reactions, ensuring that new safety signals are detected quickly. Serious and unexpected adverse events must be reported to the regulatory authority within 15 days, and ongoing coordination with programs like the Pharmacovigilance Programme of India (PvPI) is required (Montoya and Volkow, 2024; Research, 2024).

Periodic Safety Update Reports (PSURs)

PSURs are comprehensive reports that summarise safety data for the drug, both in India and worldwide. For the first two years after marketing approval, these reports must be submitted every six months. For the next two years, they will be submitted annually. Each report details new safety information, exposure data, benefit-risk analysis, and any updates to recommendations or precautions. The timelines are strictly regulated, with reports required within 30 days of the end of every reporting period (E 3 Structure and Content of Clinical Study Reports, n.d.; Roche | What Are Clinical Trials and why you Should Get Involved, n.d.).

The sponsor or marketing authorization holder is ultimately responsible for all PMS activities, ensuring prompt and accurate reporting to CDSCO, PvPI, and ethics committees. This includes the management of Phase IV study protocols, observational study data, adverse event reporting, and PSUR submissions, as well as responding to any new safety concerns by updating product labels or usage guidelines as necessary (*76 Page.Cdr*, n.d.).

The post-marketing assessment framework serves as a safety net, ensuring that medicines remain appropriate for use as new real-world data emerges. It helps identify issues that could not be foreseen in clinical trials and allows for rapid action such as updating warnings, restricting use, or, in some cases, withdrawing products to protect patients. This ongoing vigilance is critical for upholding public trust, safeguarding health, and supporting the responsible use of new therapies in India (Post Marketing DSM, n.d.; PV_Guidance_Docs_for_MAH_Version_2_as_on_18.01.2024.Pdf, n.d.).

Special Regulatory Case study: Clinical Trial Waivers for COVID-19 Drugs in India

During the COVID-19 pandemic, India faced an urgent need for timely access to effective treatments. The CDSCO invoked provisions under the NDCT Rules, 2019, to grant waivers for local clinical trials for certain drugs that were already approved and marketed in stringent regulatory jurisdictions such as the US, UK, and the EU (Role and Responsibilities of Sponsor - Role and Responsibilities of Sponsor Introduction Sponsor - Studocu, n.d.). E.g., Favipiravir and Paxlovid (nirmatrelvir/ritonavir) received emergency use authorization in India without the usual requirement for phase-wise local clinical trials. This waiver by CDSCO was based on robust clinical trial data from global studies conducted in countries with stringent regulatory oversight. The urgency of the public health crisis and the therapeutic need during the COVID-19 pandemic further supported this decision. Sponsors committed to conducting post-marketing Phase IV studies in India to ensure ongoing safety monitoring. Additionally, strict adherence to pharmacovigilance and periodic safety update reporting was mandated as conditions of the approval. This approach allowed rapid availability of these antivirals to Indian patients, significantly aiding the COVID-19 response and demonstrating how waivers can accelerate access to critical medicines under exceptional circumstances.

The case study offers important lessons like waiving local clinical trials can significantly accelerate patient access to new drugs during emergencies, provided robust data from reliable international regulators exist, without compromising safety. Mandatory post-marketing commitments, including Phase IV studies and rigorous pharmacovigilance, are vital to monitor and manage localized safety risks. Regulatory flexibility under the NDCT Rules enables authorities to respond swiftly to urgent health needs or compelling global scientific data, benefiting public health (Bishnoi and Sonker, 2023). Pharmaceutical sponsors must be prepared to meet expedited documentation demands and fulfill safety and ethical obligations post-approval

to maintain regulatory trust. This transparent and adaptive regulatory approach not only supports current public health crises but also builds confidence, encouraging innovation and efficient introduction of novel therapies in India's future pharmaceutical landscape (COVID 19 Clinical Trials and Emergency Marketing Approval Process in India, 2021; Mehrotra and Manchikanti, 2024).

Real-world Case Study for Regulatory Recommendations for Local Clinical Trial Waivers for New Drugs Approved Outside India

The regulatory landscape in India under the New Drugs and Clinical Trials (NDCT) Rules, 2019, allows for local clinical trial waivers for certain new drugs that have already been approved in other countries with stringent regulatory authorities. Such waivers are typically granted based on robust foreign clinical data, provided post-marketing commitments, including Phase IV trials, are fulfilled to ensure safety and efficacy within the Indian population.

SEC Recommendations

This case study highlights the recommendations of the Subject Expert Committee (SEC) regarding four proposals for local clinical trial waiver requests pertaining to new drugs. All products involved have already received regulatory approval outside India E.g., *Palbociclib capsules* (75 mg, 100 mg, 125 mg) by M/s XYZ Limited are approved for use in combination with *letrozole* as an initial endocrine therapy for postmenopausal women with advanced ER+ HER2- breast *cancer*, including metastatic cases. The drug is FDA-approved and designated as a breakthrough therapy. During its SEC review in India, the sponsor requested a waiver for local clinical trials based on robust international clinical data demonstrating significant improvement in progression-free survival, nearly doubling that with *letrozole* alone. The SEC granted marketing approval with specific conditions: conducting a Phase IV clinical trial in India involving at least 100 patients, submission of the Phase IV study protocol within three months of approval, and provision of interim data to CDSCO within 12 months of protocol approval. The key regulatory lessons include reliance on comprehensive foreign data for local trial waivers, the necessity of post-marketing surveillance to assess safety in the local population, mandatory timely submissions of Phase IV protocols, and effective coordination between regulatory committees to balance expedited access and patient safety (Minutes 28th ApexCommittee 11_04_16_8.Pdf, n.d.).

Ixekizumab, a monoclonal antibody for autoimmune disorders, was imported and marketed in India by ABC Company (India) Pvt. Ltd., The regulatory journey began with submitting an application containing global clinical data and safety/efficacy data from Indian patient sites. In January 2022, the Subject Expert Committee (SEC) expressed concerns about the limited Indian patient data (only 46 patients) and recommended more extensive local safety and efficacy data before approval. ABC Company responded in December 2022 by comparing Indian and global results and requested reconsideration under rule 75 of NDCT 2019. However, the SEC maintained that the Indian data remained insufficient and upheld the request for further Indian clinical evidence prior to granting marketing authorization. Following the approval, Ferm committed to conducting a Phase 4 study in India to further evaluate safety and tolerability in patients with moderate-to-severe *plaque* psoriasis and *Psoriatic arthritis* (Colin, 2024; Kumar, n.d.).

Remdesivir was approved as a new drug in India in 2020 following the NDCT 2019 guidelines. The applicant companies, WXY Ltd., and CDE Labs Ltd., submitted a New Drug Application (NDA) to CDSCO with comprehensive data covering import, clinical trials, safety, and manufacturing standards. The Subject Expert Committee (SEC) reviewed this data and raised queries related to efficacy, safety, and manufacturing. The companies responded with additional evidence and clarifications. After thorough evaluation, the SEC recommended approval of *Remdesivir* with specific conditions for restricted or emergency use. CDSCO granted approval accordingly. The approval came during the COVID-19 pandemic as an emergency response, with the regulatory pathway allowing waivers of local clinical trials based on urgent public health need and global data. The drug was required to be used under strict medical supervision and prescribed by specialists to ensure safe administration. Post-approval, authorities monitored pricing and availability to prevent hoarding and black marketing (*CDSCO*, n.d.).

Challenges in Regulatory Approval

Timeline Delays

Delays in drug approvals often stem from unclear or inconsistent regulatory procedures, resulting in prolonged review times by expert panels such as the Subject Expert Committees (SECs). Although recent reforms introduced by CDSCO aim to streamline and speed up approvals, procedural inefficiencies and redundant compliance checks continue to extend timelines, impeding timely patient access to medicines (*Regulatory Approval in India*, 2016).

Rejections and Deficiencies

Applications may be rejected or face requests for additional information due to incomplete dossiers, insufficient scientific data, or failure to meet regulatory guidelines. Deficiencies can arise from inadequate clinical trial data, poor documentation, or non-compliance with Good Manufacturing Practices. These issues require firms to resubmit corrected applications, further delaying market entry (DrugPatentWatch, 2020).

Ethics and Patient Safety

Ethical considerations remain paramount, with regulatory bodies focusing heavily on protecting patient safety through

strict clinical trial oversight and post-marketing surveillance mandates. Requirements for Ethics Committee approvals, pharmacovigilance systems, and adherence to Good Clinical Practice (GCP) ensure that patient welfare is central to approval decisions. However, balancing rigorous safety standards with expedited access can be challenging (Raut *et al.*, 2025).

Global Harmonization

India faces challenges aligning its regulatory framework with international standards due to disparate country-specific requirements, regulatory reforms that rapidly evolve without full synchronization, and variations in dossier formats and timelines across jurisdictions. This fragmentation increases compliance complexity and can hinder multinational drug development efforts. Efforts to harmonize regulations with US FDA, EMA, WHO, and other global bodies are ongoing but not yet fully realized ("The Evolving Regulatory Framework in India," 2024).

Recent Regulatory Developments in India (2024-2025)

Updates in Drugs and Cosmetics (Compounding of Offences) Rules, 2025

By this notice issued by the Indian Ministry of Health and Family Welfare, with the Drugs and Cosmetics Compounding of Offences Rules, 2025, regarding April 2025, compounding of certain offences under drugs and cosmetics dated 1940 was legalized in India. The goal is to reduce prolonged litigation by permitting offenders such as manufacturers, importers, or distributors to pay specified fines and potentially obtain immunity from prosecution, subject to compounding authority discretion. This process can be initiated before or after prosecution starts, with designated central and state compounding authorities overseeing applications. Payments must be made within 30 days of approval, and failure to comply or concealment of facts can lead to withdrawal of immunity. This framework improves enforcement efficiency, encourages regulatory compliance, and alleviates judicial burden while safeguarding public health (*New Rules Finalized for Compounding of Offences under India's Drugs and Cosmetics Act*, n.d.).

Updates to Schedule M and GMP Enhancements

Parallelly, updates to Schedule M (which governs Good Manufacturing Practices for pharmaceuticals) in 2024-2025 have been introduced to align Indian GMP standards more closely with global benchmarks. These amendments emphasize enhanced quality control, process validation, environmental monitoring, and personnel training protocols to improve manufacturing robustness and ensure consistent product quality. Enhanced GMP adherence supports India's ambition to integrate with international pharmaceutical supply chains and increase exports while maintaining patient safety (Ipc.Gov.in/PvPI/Pub/Guidance Document for Marketing Authorization Holders.Pdf, n.d.; Press Release: Press Information Bureau, n.d.).

Strengthening Digital Portals for Submissions

The CDSCO continues to expand its digital infrastructure, such as the SUGAM Portal, facilitating streamlined electronic submission, tracking, and monitoring of clinical trial applications, marketing authorizations, and safety reports. Further integration with the emerging Online National Drug Licensing System (ONDLS) aims to unify state and central regulatory workflows, improving transparency, reducing processing times, and enabling real-time status updates for stakeholders. These e-governance initiatives enhance efficiency, reduce paperwork, and foster better regulator-industry communication (Kriti, 2025; *ONDLS|CDSCO*, n.d.).

Coordination between State and Central Regulators

To harmonize regulatory enforcement nationwide, efforts to enhance cooperation between central (CDSCO/DCGI) and state drug authorities are underway. Initiatives focus on consistent application of laws, joint inspections, centralized data sharing, and uniform implementation of licensing and compliance standards. Strengthening this coordination addresses previous regulatory fragmentation and duplication, promoting a more cohesive and efficient environment for drug approvals and market surveillance (CDSCO SUGAM Portal - Login, Forms, and Application Process, 2025).

FUTURE DIRECTION

The future outlook for India's pharmaceutical regulatory ecosystem emphasizes continuous improvement, integration of Artificial Intelligence (AI) and automation, and positioning India as a globally trusted regulatory hub. The regulatory system is evolving with a focus on enhancing efficiency, transparency, and patient safety through digital reforms and AI-powered tools that aid compliance monitoring, safety signal detection, and faster regulatory reviews (Ph.D, 2025). India is actively modernizing its regulatory framework under initiatives like the New Drugs and Clinical Trials Rules (NDCTR) 2019 and subsequent reforms, supported by enhanced digital portals such as the CDSCO's SUGAM and Online National Drug Licensing System. These platforms facilitate seamless electronic submissions, tracking, and cross-agency coordination (India's Pharma Future Relies on Regulatory Strength, n.d.). AI technologies bolster pharmacovigilance and regulatory intelligence by automating adverse event detection and documentation review, reducing manual effort and accelerating decision-making (developer, 2025). Globally, India is advancing to align more closely with international standards (e.g., EU-GMP, WHO) to strengthen its global pharmaceutical credibility and export potential. The government's emphasis on quality, innovation, and streamlined regulation supports India's ambition to be a major global

pharma player by adopting best practices and technological advancements (Briefing, 2025a). The NDCT Rules, 2019 provide a strong foundation, but research gaps remain in streamlining multi-agency coordination, enhancing real-time pharmacovigilance, and harmonizing approvals for advanced therapies such as gene or cell-based medicines. Building capacity for regulators and ethics committees, investing in robust digital platforms for data management, and developing clear guidelines for adaptive and decentralized clinical trials will help close these gaps. Collaboration between regulatory authorities, industry, and academic researchers is crucial for anticipating future trends and fostering patient-centric innovations. Enhanced transparency, updated compensation rules, and better global data sharing will further safeguard public health while accelerating access to breakthrough medicines. Continuous evaluation and reform are essential to ensure that India's regulatory environment keeps pace with evolving science and international standards (Sharma *et al.*, 2022).

DISCUSSION

India's new drug approval pathway has seen transformative change with the NDCT Rules, 2019, which created a clear, stepwise regulatory roadmap from R&D to market. The process starts with preclinical studies, followed by ethics committee review and submission of detailed dossiers to CDSCO using digital tools like the SUGAM portal. Trial protocols and safety reporting are closely monitored throughout clinical development (Phases I-IV). NDCT 2019 has standardized application forms and approval timelines, introduced special provisions for orphan and emergency drugs, and mandated post-marketing surveillance for ongoing safety. Literature highlights that these updates increased transparency, reduced delays, and better aligned India with USFDA and EMA standards, while emphasizing patient protection and compensation. Recent reviews note digitalization and AI are further streamlining approvals and pharmacovigilance, making the process more robust and patient-centric. This evolving system supports safer, quicker access to new therapies for Indian patients.

CONCLUSION

The journey of a new drug from laboratory research to patient use in India is a complex, multi-stage process guided by a robust regulatory framework aimed at ensuring public health and safety. Beginning with rigorous preclinical studies and progressing through phased clinical trials, every step is carefully monitored by regulatory bodies such as CDSCO and ethics committees to uphold the highest standards of safety, ethics, and scientific integrity. The introduction of the New Drugs and Clinical Trials Rules (NDCT) 2019 has streamlined approvals while maintaining rigorous oversight, balancing timely access to innovative therapies with comprehensive risk management through mandatory pharmacovigilance and post-marketing surveillance. Ethical considerations remain paramount throughout the drug development lifecycle, protecting patient welfare and reinforcing trust in the healthcare system. The regulatory discipline established through structured processes, clear documentation requirements, and committee reviews ensures that only safe and efficacious drugs reach the Indian market. At the same time, India's evolving regulatory landscape encourages innovation by integrating adaptive regulatory pathways, promoting digitalization, and aligning with global standards. This dynamic approach fosters an environment where pharmaceutical innovation can thrive alongside the imperative of compliance. this harmonious balance between promoting scientific advancement and enforcing stringent regulatory control enables India to deliver safe, effective medicines to patients efficiently, contributing to enhanced health outcomes and supporting the nation's growing role in the global pharmaceutical ecosystem.

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ABBREVIATIONS

NDCL: New Drug Clinical Trial; **API:** Active Pharmaceutical Ingredient; **CLA:** Clinical Licensing Authority; **R&D:** Research and Development; **CDSCO:** Central Drug Standard Control Organization; **IAEC:** Institutional Animal Ethics Committee; **CPCEEA:** Committee for Purpose of Control and Supervision of Experiments on Animal; **GLP:** Goods Laboratory Practice; **GMP:** Good Manufacturing Practice; **GCP:** Good Clinical Practices; **DCGI:** Drugs Controller General of India; **EU:** European Union; **WHO:** World Health Organization; **SEC:** Subject Expert Committee; **ITT Population:** Intention-to-Treat; **PSUR:** Periodic Safety Update Reports; **SAE:** Serious Adverse Event; **PMS:** Post-Marketing Surveillance; **PvPI:** Pharmacovigilance Programme of India; **ADR:** Adverse Drug Reaction; **CT:** Clinical Trial; **CMC:** Chemistry, Manufacturing, and Controls; **SLA:** State Licensing Authority; **CTD:** Common Technical Document; **eCTD:** Electronic Common Technical Document; **BA:** Bioavailability; **BE:** Bioequivalence; **FDA:** Food and Drug Administration; **IPC:** Indian Pharmacopoeia Commission; **CTRI:** Clinical Trials Registry of India; **ECs:** Ethics Committees; **CROs:** Clinical Research Organizations; **IND:** Investigational New Drug; **ADME:** Absorption, Distribution, Metabolism, and Excretion; **NGCMA:** National GLP Compliance Monitoring Authority; **FDCs:** Fixed-Dose Combination; **r-DNA:** Recombinant DNA; 3Rs: Replace, Reduce, and Refine; **NDA:** New Drug Application; **EMA:** European Medicines Agency; **ONDLS:** Online National Drug Licensing System; **AI:** Artificial Intelligence; **EU-GMP:** European Union Good Manufacturing Practice.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

AUTHORS CONTRIBUTIONS

Pragati jain contributed to conceptualization, writing and editing the original draft, Abhinav Srivastava, Anurag Verma and Urvashi Saxena contributed to writing, reviewing, and editing the paper.

SUMMARY

India's drug approval journey begins with rigorous preclinical studies, progresses through phased clinical trials, and requires thorough review by CDSCO and ethics committees. The NDCT Rules, 2019 have streamlined the process, strengthened oversight, and prioritized patient safety through mandatory post-marketing surveillance.

- Stepwise Mapping: First comprehensive roadmap of NDCT 2019, linking each stage with exact forms (Form 29, CT-04, CT-06, CT-21, CT-23).
- Dual Framework Integration: Explains how NDCT 2019 and Drugs and Cosmetics Act 1945 work together, clarifying overlaps and grey areas.
- Practical Guidance: Provides a usable roadmap for researchers, sponsors, and regulators, covering ethics approvals, SUGAM, and CDSCO-SEC interactions.
- Future Orientation: Highlights AI, digital tools, and e-surveillance for regulatory modernization.
- Critical Insights: Addresses delays, ethics, harmonization gaps, and offers actionable solutions for faster patient access.

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