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India's NDCTR 2019: A New Era for Drug Development and Clinical Research

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ABSTRACT

The New Drugs and Clinical Trials Rules, 2019 (NDCTR) marked a major shift in India's regulatory framework for approving new drugs, conducting clinical trials, and monitoring drug safety. Before NDCTR, the country's system — primarily governed by Schedule Y of the Drugs and Cosmetics Rules — faced criticism for its lack of clear timelines, insufficient guidance on advanced therapies, and weak oversight of ethics committees. NDCTR introduced structured approval timelines, expanded definitions to cover biologics, cell and gene therapies, enhanced participant safeguards, and established mandatory ethics committee registration. The adoption of the Central Drugs Standard Control Organization's (CDSCO) SUGAM portal further streamlined submissions, tracking, and communications, significantly reducing administrative delays.

This review discusses NDCTR's historical background, key features, and its effects on clinical trials and pharmaceutical R&D, with real-world examples including the accelerated approval of Itolizumab during COVID-19, the indigenous DNA vaccine ZyCoV-D, and India's first CAR-T therapy NexCAR19. Ethical and regulatory implications are analysed alongside criticisms — such as over-reliance on foreign data and variability in ethics committee capacity. Finally, the paper explores opportunities to strengthen India's position as a global hub for cost-effective, high-quality clinical research.

Keywords: NDCTR 2019, Clinical Trials, SUGAM Portal, Drug Development, Ethics Committees, India

1. INTRODUCTION

India's pharmaceutical sector has emerged as a global leader in the manufacture of generic medicines, vaccines, and active pharmaceutical ingredients (APIs). However, its regulatory framework for new drugs and clinical trials has historically faced scrutiny for delays, inconsistent decision-making, and insufficient protection of research participants. Until 2019, the approval of new drugs and oversight of trials were mainly governed by **Schedule Y** of the Drugs and Cosmetics Rules, 1945. While Schedule Y provided a basic structure for trial phases, application requirements, and ethics review, it lacked precise timelines for approvals, contained limited provisions for advanced therapies, and left room for variable interpretation by stakeholders.

Concerns over the safety and ethical conduct of trials became particularly visible in the early 2010s, when reports of trial-related injuries and fatalities triggered public debates and legal interventions. In 2013, the Supreme Court of India directed the Ministry of Health and Family Welfare (MoHFW) to strengthen safeguards and ensure participant protection before allowing further trials. This led to a series of amendments, the formation of expert committees, and consultations with industry, academia, and patient groups.

These reform efforts culminated in the New Drugs and Clinical Trials Rules, 2019 [11] (NDCTR), notified in March 2019 by the MoHFW under the Drugs and Cosmetics Act, 1940. NDCTR replaced

the earlier Schedule Y framework with a modernised set of rules aimed at:

- Streamlining and accelerating approval processes.
- Expanding regulatory definitions to include new categories such as biologics, gene therapies, and cell-based products.
- Strengthening ethical oversight and participant safeguards.
- Enabling digital submission and tracking via the SUGAM[3] portal.

This review provides a comprehensive analysis of NDCTR 2019[11], beginning with its historical context and key provisions, followed by an assessment of its impact on clinical trials and pharmaceutical R&D. Ethical implications, criticisms, and potential future developments are also discussed. The focus is on publicly verifiable examples and regulatory documents to ensure accuracy and transparency.

2. METHODS

This paper follows a narrative review approach rather than a systematic or scoping review, as the aim is to critically synthesise and interpret regulatory provisions, historical developments, and practical examples related to the New Drugs and Clinical Trials Rules, 2019[11] (NDCTR).

2.1 Primary Source

The full text of NDCTR 2019[11], notified by the Ministry of Health and Family Welfare (MoHFW) on 19 March 2019, was used as the primary legal reference. This document, issued under the Drugs and Cosmetics Act, 1940, contains the complete set of definitions, procedural requirements, timelines, and schedules that form the backbone of the analysis.

2.2 Supplementary Regulatory Sources

Additional official resources were used to verify interpretation and real-world application of NDCTR, including:

- **Central Drugs Standard Control Organization (CDSCO)** circulars, notifications, and guidance documents.
- The SUGAM[3] portal manuals and status reports for digital submissions.
- Public data from the **Clinical Trials Registry – India (CTRI)** to identify implementation trends.

2.3 Literature and Case Selection

To ensure that all examples are **publicly verifiable**, case studies were selected based on availability of official announcements or coverage in reputable sources. Examples include:

- Itolizumab emergency approval during COVID-19 (Biocon).
- Remdesivir restricted use permissions for COVID-19 treatment.
- ZyCoV-D[2] DNA vaccine developed by Zydus Cadila.
- NexCAR19[8] CAR-T therapy by ImmunoACT.

These were chosen because they illustrate specific NDCTR provisions such as accelerated pathways, waiver provisions, and indigenous drug development timelines.

2.4 Search Strategy

Relevant journal articles, policy analyses, and news reports were identified using databases such as PubMed, Scopus, and Google Scholar with keywords including NDCTR 2019, India clinical trial regulations, SUGAM portal, accelerated drug approval India, and ethics committee registration India. Search filters were applied to include materials published from 2013 onwards, covering the reform period leading up to and following the NDCTR notification.

2.5 Inclusion and Exclusion Criteria

Inclusion:

- Articles, reports, and data that directly discuss NDCTR provisions or related regulatory changes in India.

- Official government notifications and CDSCO updates.
- Peer-reviewed publications analysing Indian clinical trial regulations.

Exclusion:

- Unverified claims from unofficial blogs or social media.
- Non-Indian regulatory frameworks unless directly compared for context.

3. Background & History of Indian Drug Regulation

India's pharmaceutical regulatory framework has evolved significantly over the past few decades, shaped by public health needs, industrial growth, and global regulatory trends. For many years, **Schedule Y** of the Drugs and Cosmetics Rules, 1945, served as the primary legal guideline for clinical trial conduct and new drug approvals. Introduced in its modernised form in 2005, Schedule Y outlined trial phases, application requirements, and responsibilities of stakeholders. However, it had notable gaps — there were **no fixed timelines** for approvals, **limited provisions** for modern therapies like biologics or cell-based products, and **unclear processes** for ethics committee oversight.

These shortcomings came into sharper focus in the early 2010s when India witnessed a surge in global clinical trials. While this growth reflected the country's cost advantages and diverse patient pool, it also exposed weaknesses in trial monitoring and participant safety. Between 2010 and 2013, several reports of **trial-related injuries and deaths** gained media attention. The **Supreme Court of India**, responding to petitions, intervened in 2013 and directed the Ministry of Health and Family Welfare (MoHFW) to strengthen trial regulations before permitting further approvals.

In response, multiple amendments were introduced to Schedule Y between 2013 and 2016. These included mandatory registration of ethics committees, requirements for audio-visual recording of informed consent in vulnerable populations, and clearer rules for **compensation in case of trial-related injury or death**. Yet, industry stakeholders and health advocates continued to call for a **comprehensive overhaul** rather than piecemeal changes.

The reform process accelerated when the **Drugs Technical Advisory Board (DTAB)** recommended replacing **Schedule Y** entirely with a modernised set of rules. After public consultation and expert review, the New Drugs and Clinical Trials Rules, 2019[11] (NDCTR) were officially notified on 19 March 2019 under the Drugs and Cosmetics Act, 1940. NDCTR retained some foundational principles from Schedule Y but introduced clear timelines, expanded definitions, streamlined processes, and a stronger ethical framework, marking a pivotal shift in India's clinical research governance.

4. Key Features of NDCTR 2019

The New Drugs and Clinical Trials Rules, 2019[11] (NDCTR) introduced a structured, time-bound, and transparent system for drug development and clinical research in India. The changes were not merely cosmetic; they addressed critical gaps left by Schedule Y, reflecting lessons from past controversies and aligning India with global best practices. The most important features include:

4.1 Time-bound Approval Process

One of NDCTR's landmark reforms is the introduction of **fixed timelines** for regulatory decisions:

- **90 working days** for approval of new drugs developed outside India.
- **30 working days** for drugs developed indigenously.
- **45 working days** for applications involving investigational new drugs (INDs). If the Central Licensing Authority (CLA) does not respond within these timelines, the application is considered approved by default — a major step to reduce uncertainty for sponsors.

A practical example is ZyCoV-D[2], India's first DNA-based COVID-19 vaccine developed by Zydus Cadila. Its clinical trial application received approval within the fast-track timeline, allowing Phase I to commence rapidly during the pandemic. This demonstrated NDCTR's capability to expedite urgent research while maintaining oversight.

4.2 Inclusion of Advanced Therapies

NDCTR broadened the regulatory definitions to include biologics, biosimilars, cell and gene therapies, and novel drug delivery systems. This was absent in Schedule Y, which mainly focused on conventional small molecules.
A notable case is NexCAR19[8], India's first indigenously developed CAR-T cell therapy by ImmunoACT, which received regulatory guidance and trial permission under NDCTR's cell-based therapy provisions.

4.3 Provisions for Orphan Drugs

To encourage treatment development for rare diseases, NDCTR grants **application fee waivers** and **possible local trial exemptions** for orphan drugs (those intended to treat conditions affecting <5 lakh people in India). This is expected to make India more attractive for rare disease research collaborations.

4.4 Ethics Committee (EC) Registration and Accountability

Under NDCTR, **ethics committees must register with the CLA** before reviewing any clinical trial protocol. They must follow specified composition, quorum, and training standards, and submit annual status reports.
Failure to comply can lead to suspension or cancellation of registration — a mechanism aimed at ensuring quality and independence in ethical review.

4.5 Serious Adverse Event (SAE) Reporting and Compensation

NDCTR lays down strict SAE reporting timelines:

- The **investigator** must inform the sponsor, EC, and CLA **within 24 hours** of awareness.
- A **detailed analysis report** must follow **within 14 days**.

This quick reporting ensures immediate attention to participant safety.

Compensation for trial-related injury or death is determined using the **Seventh Schedule formula**, which considers factors like participant's age, risk category, and percentage of disability. Payments must be made **within 30 days** of the order. During the COVID-19 vaccine trials, CDSCO applied these rules in cases where injury reports were substantiated, ensuring that affected volunteers received compensation as per the law.

4.6 Digitalisation through SUGAM Portal

The NDCTR is fully integrated with CDSCO's SUGAM[3] portal, an online platform for submission, tracking, and communication. This has reduced paperwork, improved transparency, and allowed real-time application monitoring. For example, Biocon's COVID-19 application for Itolizumab[1]'s emergency use was submitted, reviewed, and tracked entirely via SUGAM[3], reflecting the system's operational efficiency.

4.7 Mandatory Registration of CROs with CLA–CDSCO

A significant enhancement in recent updates is the mandatory registration of Contract Research Organisations (CROs) with the Central Licensing Authority (CDSCO). This process is facilitated entirely through the SUGAM[3] portal, using **Form CT-07B**. CROs must submit required documentation, pay the applicable fee (₹5 lakh for a 5-year validity), and apply for renewal prior to expiry. By directly licensing CROs, CDSCO gains visibility over entities managing outsourced clinical trial operations, improving quality oversight, inspection readiness, and pharmacovigilance practices. This approach brings India in line with the USFDA[14], EMA[5], and other international regulators where CRO identification and compliance are mandatory.

5. Impact on Clinical Trials

The implementation of the New Drugs and Clinical Trials Rules, 2019[11] has significantly reshaped India's clinical trial environment. By addressing long-standing inefficiencies and introducing digital and ethical safeguards, NDCTR has enhanced the country's attractiveness as a research destination while strengthening participant protections.

5.1 Acceleration of Trial Approvals

Before NDCTR, clinical trial approvals often took several months to over a year, with sponsors facing unpredictable timelines. The **fixed decision deadlines** introduced by NDCTR — 30 days for indigenous drugs, 90 days for imported drugs — have reduced this uncertainty.

A practical example is the ZyCoV-D[2] vaccine trials during the COVID-19 pandemic. Zydus Cadila received regulatory clearance for Phase I trials within a matter of weeks, enabling rapid progression through subsequent phases. This was crucial for timely vaccine deployment in India's public health response.

5.2 Increased Transparency and Traceability

The integration of clinical trial applications into the SUGAM[3] portal has allowed applicants, regulators, and even the public (via published lists and CTRI entries) to track the status of trials. For example, Biocon's emergency use application for Itolizumab[1] in moderate-to-severe COVID-19 cases was submitted, reviewed, and monitored via SUGAM[3], with key decision points recorded digitally. This reduced communication gaps between sponsors and the Central Licensing Authority (CLA).

5.3 Strengthened Ethical Oversight

NDCTR's **mandatory ethics committee registration** has created a more accountable review system. Ethics committees must meet defined composition criteria, undergo training, and submit annual reports to maintain registration. This requirement has led to the de-registration of some non-compliant committees, ensuring that only qualified and accountable bodies are allowed to review trial protocols.

5.4 Enhanced Participant Safety via SAE Reporting

The NDCTR's **24-hour SAE reporting requirement** ensures immediate regulatory awareness of any trial-related death or injury. Follow-up detailed analysis reports, due within 14 days, enable timely causality assessment. This system proved effective during the COVID-19 vaccine trials, where a few adverse event cases were swiftly reported to the CLA and evaluated for compensation eligibility. In at least one publicly confirmed case, the sponsor provided compensation as per the **Seventh Schedule formula**, setting a precedent for compliance.

5.5 Facilitation of Global Collaborations

The predictable approval timelines and clear provisions for data acceptance have encouraged multinational companies to initiate or expand trials in India. Several oncology and rare disease studies now include Indian sites from early phases, which was less common prior to NDCTR.

6. Impact on Pharmaceutical Research and Development (R&D)

The New Drugs and Clinical Trials Rules, 2019[11] have not only streamlined clinical trial approvals but have also influenced the broader pharmaceutical research and innovation ecosystem in India. By introducing faster approval mechanisms, clearer guidelines for advanced therapies, and incentives for special drug categories, NDCTR has created a more research-friendly regulatory environment.

6.1 Boost to Indigenous Innovation

The **30-day approval timeline** for clinical trials of new drugs discovered or developed in India has provided a significant boost to domestic R&D. This provision is particularly beneficial for academic research institutions and small-to-mid-sized pharmaceutical companies that previously faced lengthy delays.

A prominent example is NexCAR19[8], India's first indigenous CAR-T cell therapy developed by ImmunoACT in collaboration with IIT Bombay. Approved for trials under NDCTR's provisions for cell-based therapies, NexCAR19[8] progressed from pre-clinical to early-phase trials in a significantly reduced timeframe compared to earlier norms.

6.2 Facilitation of Biosimilar Development

India is already a global leader in biosimilar manufacturing, but NDCTR's clearer definitions and approval timelines for biologics and biosimilars have further strengthened the sector. The rules now explicitly cover monoclonal antibodies, recombinant proteins, and other biologics, allowing companies to plan development with greater regulatory certainty.

For instance, the accelerated review of certain biosimilars during the COVID-19 period helped ensure timely market availability for critical therapies like **Tocilizumab** (used off-label in severe COVID-19 cases), where the domestic version underwent rapid evaluation under NDCTR guidelines.

6.3 Encouragement for Orphan Drug Research

By offering **fee waivers and trial exemptions** for orphan drugs, NDCTR encourages companies to invest in treatments for rare diseases — a previously underfunded area in India. Several rare disease studies, including enzyme replacement therapies and genetic disorder treatments, have since been initiated with Indian participation.

6.4 Support for Accelerated Pathways in Public Health Emergencies

NDCTR allows the CLA to grant marketing approval based on data from foreign trials, with or without local trials, in cases of national health emergencies. This was crucial during the COVID-19 pandemic, when drugs like Remdesivir[6] received restricted emergency use authorisation without extensive Indian Phase III data, supported by global trial evidence.

6.5 Integration of Digital Platforms for R&D Efficiency

The adoption of the SUGAM[3] portal for regulatory filings has reduced the administrative burden for researchers and companies. The ability to track applications online, receive deficiency letters electronically, and submit responses without physical visits has saved significant time, especially for smaller innovators operating outside major metro cities.

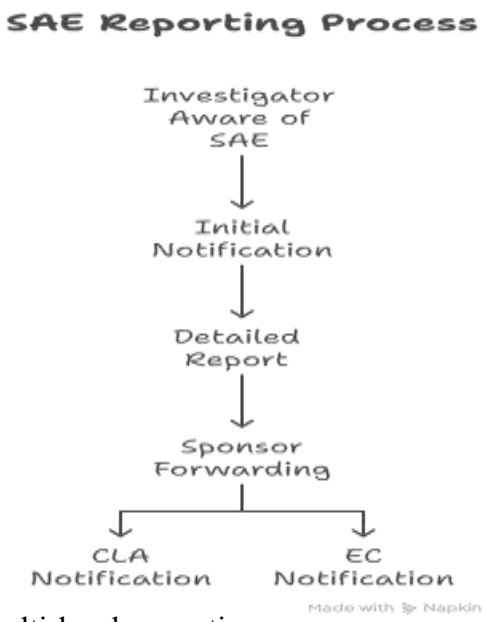
7. Ethical & Regulatory Considerations

Ethical governance is central to the New Drugs and Clinical Trials Rules, 2019[11] (NDCTR). The reforms were largely driven by public concern over participant safety, inadequate monitoring, and the need for a transparent accountability framework. NDCTR strengthens safeguards for participants, enhances oversight of trial conduct, and ensures timely reporting and compensation in case of harm.

7.1 Serious Adverse Event (SAE) Reporting

NDCTR mandates strict timelines for reporting **Serious Adverse Events** to ensure rapid regulatory and ethical oversight:

- **Initial Notification**: The *investigator* must report any SAE to the sponsor, Ethics Committee (EC), and Central Licensing Authority (CLA) **within 24 hours** of becoming aware of the event.
- **Detailed Report**: A complete analysis report, including causality assessment, must be submitted **within 14 days**.
- **Sponsor Responsibility**: Sponsors must also forward the SAE details to the CLA and EC, ensuring no delays at any step.



This multi-level reporting structure ensures that regulators and ethics bodies can intervene promptly if participant safety is at risk.

Example:
During the COVID-19 vaccine trials, at least one volunteer in India reported a serious neurological event. The sponsor, following NDCTR rules, informed the CLA and EC within the stipulated time. The case was reviewed for causality, and although found unlikely to be related to the investigational product, the transparency of the process reinforced public trust.

7.2 Compensation Provisions

NDCTR formalises and refines the **compensation mechanism** for trial-related injury or death through the **Seventh Schedule formula**. This formula considers:

- **Age of the participant** (lower age → higher base compensation)
- **Risk factor** of the disease being treated
- **Percentage of permanent disability** (for non-fatal injuries)

The rules require:

- **Payment within 30 days** of the CLA's order for compensation.
- The sponsor to bear full financial responsibility; failure to pay can result in trial suspension.

Example:
In 2021, a COVID-19 vaccine trial participant's death in Madhya Pradesh was reported in the media. The SAE was notified and investigated under NDCTR provisions. While causality assessment concluded the event was unrelated to the vaccine, the process demonstrated the clear steps and timelines for potential compensation cases.

7.3 Informed Consent & Vulnerable Populations

NDCTR strengthens informed consent requirements, particularly for:

- **Illiterate participants**: Consent must be witnessed by an impartial literate person, with explanations in the participant's language.
- **Vulnerable groups** (e.g., children, pregnant women, mentally incapacitated individuals): Additional safeguards and Ethics Committee justification are mandatory.
- **Audio-visual recording** of consent is required in certain cases, such as vulnerable

populations or high-risk studies, to ensure transparency.

7.4 Ethics Committee Responsibilities

Ethics Committees are no longer informal bodies; NDCTR requires:

- Registration with the CLA before reviewing any study.
- Defined quorum and multi-disciplinary representation (including a legal expert, social scientist, and layperson).
- Submission of **annual performance reports** to maintain registration.
- Immediate suspension or cancellation of registration in case of non-compliance.

7.5 Regulatory Accountability

For the first time, NDCTR has brought **accountability to the regulator itself** through the fixed approval timelines and the provision of "deemed approval" if deadlines are missed. This ensures that delays cannot be indefinite and that applicants have a clear legal pathway to proceed.

8. Criticisms and Challenges

While the New Drugs and Clinical Trials Rules, 2019[11] represent a significant advancement, they are not without limitations. Researchers, industry stakeholders, and ethics advocates have raised several concerns.

8.1 Reliance on Foreign Data

NDCTR allows marketing approval based on foreign clinical trial data without mandatory Indian trials in certain conditions, such as public health emergencies. While this accelerates access, critics argue it may not account for **ethnic and genetic differences** in drug response among Indian populations.

Example:
Remdesivir[6] was approved for restricted emergency use during COVID-19 based largely on overseas trial data. Although this ensured rapid access, questions remain about whether local Phase III trials should have been conducted in parallel.

8.2 Ethics Committee Capacity Gaps

Although NDCTR mandates registration and training of ethics committees, **capacity disparities** exist between large metropolitan hospitals and smaller regional centres. Some committees lack the expertise to review advanced therapy protocols, potentially slowing approvals in less-developed regions.

8.3 Compensation Rule Rigidities

While the Seventh Schedule formula brings transparency, industry stakeholders argue that it does not adequately account for **multi-factorial causality** in complex diseases. Sponsors also note the risk of discouraging investment in high-risk therapeutic areas due to potentially large, mandatory payouts even in borderline cases.

8.4 Implementation Variability

The SUGAM[3] portal has improved efficiency in urban areas, but some smaller research institutions face digital infrastructure limitations and inadequate staff training to use the system effectively. This can cause disparities in trial initiation timelines.

8.5 Public Perception and Mistrust

Historical controversies over unethical trials in India have left lingering scepticism among sections of the public. NDCTR has strong safeguards, but public awareness of these changes remains limited, potentially affecting trial recruitment rates.

8.6 Financial and Administrative Burden

Many small and mid-sized domestic CROs, particularly those supporting investigator-initiated or academic trials, face difficulty in meeting the ₹5 lakh registration fee and extensive documentation requirements. Without a tiered fee structure or exemptions for non-commercial studies, the

measure may inadvertently reduce diversity in the CRO landscape.

8.7 Inspection and Enforcement Capacity

Registration will only yield its intended benefits if backed by rigorous, standardised inspections. CDSCO's current human resource capacity for field inspections is limited compared to the volume of CROs operating nationally. In contrast, agencies such as EMA[5] and USFDA[14][14] maintain dedicated CRO audit teams with harmonised SOPs.

8.8 Alignment with Global Standards

For Indian clinical research to be internationally competitive, CRO oversight must integrate the principles of ICH GCP E6(R3), particularly risk-based monitoring, data integrity, and role clarity between sponsors and CROs. Moreover, adopting ICH E2B electronic SAE reporting formats is critical for interoperability with multinational sponsor systems.

8.9 Transparency and Public Access

While a CRO registry exists on the SUGAM[3] platform, public visibility of a CRO's scope of work, accreditation status, and inspection outcomes is limited. Greater transparency would foster accountability and enable sponsors and ethics committees to make informed choices.

8.10 Regulatory and Administrative Coordination

The successful implementation of CRO registration[4] requires close coordination between CDSCO, State Licensing Authorities, and Ethics Committees. Fragmented communication can lead to delays in application processing, duplicate requests for information, and procedural inconsistencies across regions.

8.11 Consistency in SAE Reporting and Compensation

Although NDCTR mandates SAE notification within 24 hours and a detailed report within 14 days, inconsistent compliance persists. Some stakeholders cite delays in ethics committee review and sponsor decision-making. Similarly, while the Seventh Schedule compensation formula is robust, its uniform application requires training and strict oversight.

9. Opportunities and Future Scope

NDCTR lays a strong foundation for India's growth as a competitive and ethically responsible clinical research hub. However, continuous evolution is essential.

9.1 Strengthening Ethics Committee Networks

Creating **regional ethics committee resource hubs** could support smaller institutions with limited expertise, ensuring consistent quality across the country.

9.2 Encouraging Early-Phase Research

While India is strong in late-phase, large-scale trials, NDCTR's 30-day approval for indigenous drugs can be further promoted through **funding incentives** for Phase I/II studies within academic institutions and start-ups.

9.3 Global Harmonisation

NDCTR is already closer to ICH-GCP standards than Schedule Y, but further alignment with EMA[5] and FDA[14] guidance would help Indian data gain faster global acceptance, making India an attractive site for multinational trials.

By embedding ICH E6(R3)[10] principles and ICH E2B SAE reporting standards into CRO registration[4] conditions, India can make its clinical trial data more acceptable to USFDA[14], EMA[5], and NIHR[1-2], thus expanding opportunities for multinational trial participation.

9.4 Expanding Digitalisation

The success of the SUGAM[3] portal could be replicated in post-marketing surveillance reporting and real-world evidence (RWE) collection, enabling continuous monitoring of safety and effectiveness after drug launch.

9.5 Public Engagement

A national **trial awareness campaign** could help dispel mistrust, explaining participant rights, compensation provisions, and regulatory oversight

in simple language to encourage informed participation.

CONCLUSION

The New Drugs and Clinical Trials Rules, 2019 mark a pivotal shift in India's regulatory landscape, replacing the decades-old Schedule Y framework with a modern, time-bound, and ethically robust system. By incorporating fixed approval timelines, expanding definitions to advanced therapies, mandating ethics committee registration, and ensuring swift SAE reporting and compensation, NDCTR has addressed many historical shortcomings.

NDCTR 2019 represents a landmark shift in India's approach to regulating drug development and clinical research, replacing the fragmented framework of Schedule Y with a more transparent, time-bound, and participant-focused system. The recent mandatory registration of CROs with CLA–CDSCO through the SUGAM portal addresses a critical oversight gap, recognising CROs as central players in trial execution.

Real-world cases such as ZyCoV-D, Itolizumab, NexCAR19, and the rapid authorisation of Remdesivir illustrate NDCTR's capacity to balance speed with safety. Yet, challenges remain in ensuring uniform implementation, improving ethics committee capacity, and maintaining public trust.

With continued refinement — particularly in harmonisation with global standards, capacity building, and public engagement — NDCTR has the potential to position India as a leader in cost-effective, high-quality, and ethically sound drug development and clinical research.

ABBREVIATION

Abbreviation	Full Form
CAR	Chimeric Antigen Receptor
CDSCO	Central Drugs Standard Control Organization
CLA	Central Licensing Authority
COVID	Coronavirus Disease
CRO	Contract Research Organisation
CT	Clinical Trial
CTRI	Clinical Trials Registry – India
DCGI	Drugs Controller General of India
DNA	Deoxyribonucleic Acid
DTAB	Drugs Technical Advisory Board
EC	Ethics Committee
EMA	European Medicines Agency
FDA	Food and Drug Administration
GCP	Good Clinical Practice
ICH	International Council for Harmonisation
ICMR	Indian Council of Medical Research
IIT	Indian Institute of Technology
NDCTR	New Drugs and Clinical Trials Rules (2019)
NIHR	National Institute for Health and Care Research
RWE	Real-World Evidence
SAE	Serious Adverse Event
SUGAM	Online regulatory submission portal (by CDSCO)
USFDA	United States Food and Drug Administration
WHO	World Health Organization

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