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Review Article

The evolving architecture of India's clinical-trial rules, 2019-2026: a chronological appraisal and stakeholder analysis of the New Drugs and Clinical Trials Rules and their amendments

Vijaykumar Gawali, Amrita Sankhe*, Maria Franco

Medical Research Department, Bhaktivedanta Hospital ad Research Institute, Mira Road East, Thane, Maharashtra, India

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***Correspondence:**
Amrita Sankhe,
E-mail: amritasankhe@outlook.com

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ABSTRACT

India replaced the decades-old Schedule Y regime with the New Drugs and Clinical Trials (NDCT) Rules, 2019, promising a framework that would both speed up clinical research and protect the people who take part in it. Most published accounts examine one stakeholder at a time, most often the ethics committee, and treat the Rules as a static document, even though the framework has kept changing. This paper does two things at once. First, it reads the architecture of Indian clinical-trial regulation and its amendments as a single, continuous evolution: statutory timelines and deemed approval (2019), consolidation of the as-amended text (2022), a draft and then enacted registration regime for clinical research organisations (CROs) (2023-2024), digital onboarding through the SUGAM portal and a draft Indian Good Clinical Practice text aligning toward ICH E6(R3) (2025), and a 2026 cluster easing test-licence, bioavailability/bioequivalence and ethics-committee requirements, of which two amendments are now in force and two remain in draft. A consistent direction emerges toward predictability, speed and formalisation. Second, it asks whose interests that trajectory has served, reading the text alongside India-specific implementation evidence across sponsors, CROs, investigators and sites, ethics committees, participants, and the regulator. We argue that facilitation has outpaced protection. The compensation formula has lost about a third of its real value since 2013, and ethics committees carry expanded duties without commensurate capacity. We close with three concrete recommendations: revisit the compensation formula, mandate results disclosure, and resource ethics-committee oversight.

Keywords: Clinical trials, Drug regulation, Ethics committees, Government regulation, Patient safety, India

INTRODUCTION

Over the past decade India has re-emerged as one of the world's significant destinations for clinical research, a position underpinned less by any single policy than by a sustained re-engineering of the rules that govern how trials are approved and overseen. By one recent account, the country now ranks among the leading global trial hubs.[1-4] The instrument at the centre of that re-engineering is the NDCT Rules, 2019, notified as G.S.R. 227(E) on 19 March 2019, which replaced the long-standing Schedule Y framework with a self-contained, time-bound code.[1] They came with a dual promise: faster, more predictable research, and better protection for participants.[2]

Yet the 2019 rules were neither an endpoint nor a settled balance. In the years since, the Ministry of Health and Family Welfare (MoHFW) and the Central Drugs Standard Control Organization (CDSCO) have amended, consolidated and proposed to amend the framework repeatedly: a consolidating amendment in 2022, a registration regime for CROs drafted in 2023 and enacted in 2024, digital onboarding and a draft Indian Good Clinical Practice (GCP) text in 2025, and a cluster of amendments in 2026. Most published accounts stop at

2019 or 2022, and most examine a single stakeholder, typically the ethics committee.[3] The framework, however, has kept moving, and its benefits have not fallen evenly.

This paper argues that the NDCT framework is best understood as a continuously evolving system rather than a single 2019 event. Its trajectory bends consistently toward predictability, speed and formalisation, and that trajectory has served sponsors, CROs and the regulator's ease-of-business mandate more fully than the participants the Rules exist to protect. We first trace the chronology as one continuous evolution, extending the account past 2024 to the 2026 amendments; the closest recent review explains the rules to roughly 2024, and the pre-2019 baseline is well described by Gogtay and colleagues.[4,5] We then read that trajectory distributionally, stakeholder by stakeholder, weighing facilitation against the protection questions it raises and grounding the analysis in India-specific implementation evidence where rules-on-paper and practice diverge.

FROM SCHEDULE Y TO A STATUTORY CODE

To see what changed in 2019, it helps to recall what came before. For decades, clinical trials in India were governed by Schedule Y of the Drugs and Cosmetics Rules, 1945, a relatively brief set of requirements that left much to administrative discretion and offered no statutory timelines for review.[5,6] Through the early 2010s that arrangement came under sustained criticism. The 59th report of the Parliamentary Standing Committee on Health and Family Welfare found that the drug regulator had for decades accorded primacy to facilitating the drugs industry, such that the interest of the consumer, the biggest stakeholder, had not been ensured.[7] The Ranjit Roy Chaudhury Expert Committee recommended a comprehensive overhaul of approval processes, accreditation of ethics committees, sites and investigators, and compensation for trial-related injury.[8] Litigation before the Supreme Court drew national attention to participant-protection lapses, with the Court's order of 21 October 2013 laying down criteria of risk–benefit assessment, innovation and unmet medical need for trial approval.[9]

THE EVOLVING ARCHITECTURE, 2019–2026

2019-the new architecture

The 2019 rules laid the groundwork for later regulatory changes. These rules brought together guidelines for new drugs, investigational new drugs, bioavailability and bioequivalence (BA/BE) studies, and ethics committees into a single code.[1] They also introduced a series of structured "CT" forms for all applications and permissions. Notably, the Rules set specific timelines for regulatory review. Applications for trials of new drugs discovered, researched, and developed in India must be decided within thirty working days. If no communication is issued during that time, permission is considered granted. Other applications, including those for drugs already approved elsewhere and for BA/BE studies, have a ninety-working-day window with a similar deemed-approval policy.[1,10] Applicants who receive deemed approval must still inform the licensing authority before starting the trial. The CDSCO retains the right to review a deemed-approved trial at any time.[10]

Additionally, the Rules introduced support mechanisms. One is an accelerated-approval pathway that allows reliance on surrogate endpoints for serious or rare conditions. There is also a provision that waives the local clinical trial requirement for new drugs already approved and marketed in certain countries.[1] A dual-track ethics-committee system was created: ethics committees for clinical trials register with the licensing authority under the NDCT Rules, while those for biomedical and health research register with the Department of Health Research.[1,11] The mandatory prospective registration of each trial with the Clinical Trials Registry-India, before enrolling the first participant, completed this regulatory framework.[12] Each facilitation measure has unresolved protection issues that the later amendment inherits. Deemed approval speeds up timelines but assumes proper regulatory oversight. Accelerated approval favours speed over certainty. Local-trial waivers help with market entry but raise questions about ethnic and contextual relevance.

2022-consolidation

While the 2019 regulations established the initial framework, the 2022 amendment provided essential consolidation. The amendment, notified as G.S.R. 778(E) on 14 October 2022, produced the consolidated, as-amended text currently used by practitioners, integrating previous changes into a single reference and clarifying procedural details.[[13]] For practical application, this consolidated text is as significant as any substantive amendment, as it is the as-amended version, rather than the original 2019 gazette, that should be cited and applied. During the same period, technical refinements were incorporated into the schedules: a draft notified as G.S.R. 835(E) on 22 November 2022 was finalised as G.S.R. 175(E) on 9 March 2023, amending the First Schedule to include testing methods for induced pluripotent stem cells.[14] Although these are narrow, technical adjustments, they reflect a consistent approach in which the regulatory framework is treated as a dynamic instrument, evolving in response to scientific and caseload developments.

2023-2024-formalising the ecosystem

The next phase extended formalisation beyond trial application to encompass the organisations conducting the trials. A draft notification, G.S.R. 364(E) of 11 May 2023, proposed a registration regime for CROs.[15,16] This regime was enacted through the NDCT (Amendment) Rules, 2024, notified as G.S.R. 581(E) on 19 September 2024, which introduced a definition of "Clinical Research

Organisation" and established a new chapter (rules 38A-38F) governing CRO registration, validity, renewal, and inspection.[15,16,20] Notably, earlier drafts of both manuscripts in this project had treated 364(E) as the enacting instrument and 581(E) as a refinement; however, the gazette clarifies that 364(E) is the draft and 581(E) is the amendment that formally incorporated CROs within the regulatory framework.[15,16,20]

Within the broader regulatory trajectory, the introduction of CRO registration represents a logical progression. After establishing defined timelines for trial approvals, the regulator focused on formalising the entities responsible for conducting trials and on developing an inspection regime to verify compliance.[17] This reflects a recurring balance between facilitation and protection. Formal registration provides sponsors and trial sites with greater certainty regarding eligible partners and grants official recognition to the evolving CRO sector.[18,19] However, a key issue remains whether formal registration is supported by sufficient capacity to monitor CRO conduct in practice, an area now being explored by India-specific implementation studies on site compliance and ethics-committee registration.[18,19]

2025-digital onboarding and the GCP turn

In 2025, the framework advanced through digital and global alignment. The CDSCO transitioned CRO registration to the online SUGAM portal, continuing the shift from paper-based to digital processes, notified as G.S.R. 581 (E) on 19 September 2024.[20] At the same time, a draft Indian GCP text was circulated to align India's good clinical practice standards with the updated global baseline of ICH E6(R3), emphasizing risk-based quality management, data governance, and participant-centricity. Two draft notifications, G.S.R. 587(E) and 588(E) of 27 August 2025, were issued and later incorporated into the 2026 amendments.[21,22] A corrigendum, G.S.R. 810(E) of 31 October 2025, revised a BA/BE sample-size condition in the 587(E) draft.[23,24] The changes in 2025 are significant: digitalisation reduces friction and improves traceability, while alignment with E6(R3) demonstrates India's intent to match global GCP standards.[22] Both initiatives improve predictability and formalisation, but also raise questions about whether infrastructure, training, and oversight will keep pace with regulatory changes.

2026-what is now in force, and what remains in draft?

The most recent regulatory cluster is mixed in status, with two of the four items now in force. The NDCT (Amendment) Rules, 2026 (G.S.R. 46(E), 20 January 2026) amended test-licence requirements under rule 52, enacting the earlier 588(E) draft.[26] The NDCT (Second Amendment) Rules, 2026 (G.S.R. 50(E), 21 January 2026) introduced an online intimation mechanism for BA/BE studies of unapproved drugs intended for export, amending Rule 31 and enacting the 587(E) draft as revised by the corrigendum.[27]

Two other items remain in draft, published for objections and not yet in force. G.S.R. 45(E) of 20 January 2026 would introduce an excipient-sameness proviso for BA/BE products, exempting certain animal-toxicity requirements when the test product matches the reference product in excipient composition.[25] G.S.R. 98(E) of 2 February 2026 would remove the requirement for a provisional certificate for ethics-committee registration. Rule 17(3) would be omitted and rule 17(4) substituted, so that the designated authority grants final registration to an ethics committee in Form CT-03 directly upon satisfactory review of a Form CT-01 application, or rejects it with written reasons.[28]

Collectively, the 2026 changes continue the established direction. Each amendment removes a step, digitises a process, or eases a requirement to improve efficiency. However, each simplification increases reliance on the adequacy of remaining safeguards. For ethics-committee registration, the key issue is whether single-stage registration maintains the scrutiny intended by the provisional stage.

Items marked "draft" are not in force. Every G.S.R. number, date and status should be verified against the primary gazette/CDSCO notification.

READING THE TRAJECTORY

Viewed as a sequence rather than as isolated events, the post-2019 record reveals a consistent trajectory (Table 1). This trajectory is threefold and unidirectional: toward predictability (statutory timelines, deemed approval, the consolidated text), toward speed (accelerated approval, waivers, exemptions, digital onboarding), and toward formalisation (CRO registration, the form system, alignment with ICH E6(R3)).[18] No amendment during this period reverses this trend; instead, each extends it into a new aspect of the system: beginning with the approval of trials, followed by the entities conducting them, the platforms processing them, and ultimately the remaining procedural steps.[19]

This development represents a significant achievement, resulting in a regulatory environment in India that is now substantially more navigable than during the Schedule Y era. However, a trajectory that consistently favours facilitation raises an important distributional question: if the system has become faster and more formal, who are the primary beneficiaries? Time-bound decisions, deemed approvals, and a growing registered ecosystem all presuppose that regulators and ethics committees possess sufficient resources to conduct timely scrutiny.[19] India-specific studies of ethics-committee registration, site compliance, inspection, and adverse-event causality assessment indicate that this assumption warrants empirical validation rather than acceptance.[18,29,30]

Table 1: The evolving architecture of India's clinical-trial rules, 2019-2026 (master timeline).

Years	Notification (status)	What changed	Why it matters
2019	G.S.R. 227(E), 19 Mar 2019 (in force)	NDCT Rules replace Schedule Y; CT-form system; 30/90 working-day windows with deemed approval; accelerated approval and local-trial waivers; two-track ethics-committee system; mandatory CTRI registration	The foundational, time-bound architecture
2022	G.S.R. 778(E), 14 Oct 2022 (in force)	Major consolidating amendment (the as-amended text)	Single authoritative reference for practice
2022–2023	G.S.R. 835(E), 22 Nov 2022 (draft) → G.S.R. 175(E), 9 Mar 2023 (in force)	First Schedule amendment adding testing methods relating to induced pluripotent stem cells	Technical scope refinement
2023	G.S.R. 364(E), 11 May 2023 (draft)	Draft proposing a registration regime for CROs	Signals intent to formalise CROs
2024	G.S.R. 581(E), 19 Sep 2024 (in force)	NDCT (Amendment) Rules, 2024-enacts the CRO chapter (rules 38A–38F) and the CRO definition	Brings CROs within the formal regulatory perimeter
2025	G.S.R. 581(E), 19 Sep 2024 (in force since 04 March 2025)	Digital CRO registration; GCP revision aligning toward ICH E6(R3)	Digitalisation; global GCP convergence
2025	G.S.R. 587(E) & 588(E), 27 Aug 2025 (drafts); corrigendum G.S.R. 810(E), 31 Oct 2025	Draft rules later carried into the 2026 amendments; corrigendum revises a BA/BE sample-size condition in 587(E)	Sets up the 2026 changes
2026	G.S.R. 45(E), 20 Jan 2026 (draft)	Excipient-sameness proviso exempting certain animal-toxicity requirements for BA/BE products	Would ease duplicative BA/BE testing
2026	G.S.R. 46(E), 20 Jan 2026 (in force)	NDCT (Amendment) Rules, 2026-changes to test-licence requirements (rule 52); enacts draft 588(E)	Streamlines an early gateway
2026	G.S.R. 50(E), 21 Jan 2026 (in force)	NDCT (Second Amendment) Rules, 2026 — online intimation for BA/BE of unapproved drugs for export (rule 31); enacts draft 587(E) + corrigendum	Digital, export-facilitation step
2026	G.S.R. 98(E), 2 Feb 2026 (draft)	Omits provisional EC certificate (rule 17(3) omitted; 17(4) substituted-final registration on Form CT-03)	Would streamline EC registration

WHOSE INTERESTS DO THE RULES SERVE? A STAKEHOLDER READING

A regulation can be efficient and still be unbalanced; the test is whether its benefits are distributed across the ecosystem or concentrated among a few of its actors. Reading the same trajectory stakeholder by stakeholder, with contested judgements attributed to their authors rather than asserted, shows where the balance has settled.

Sponsors

Sponsors are the clearest beneficiaries. Time-bound review, deemed approval and the local-trial waiver convert a previously open-ended, discretionary process into a predictable one and lower the cost and uncertainty of running a trial in India.[1] The net effect is a substantial gain in predictability and speed. The open concern is the mirror image of that gain: whether decisions reached within compressed windows, or deemed granted by default, receive scrutiny that participant safety assumes.

CROs

CROs moved from an informal position to a formally recognised one. The registration framework proposed in 2023 and enacted in 2024, together with SUGAM onboarding in 2025, confers official status and explicit accountability on a maturing sector.[15,16,20] The net effect is a gain in legitimacy and certainty.[15,16,20] Open concern is whether registration on paper is matched by the regulator's capacity to oversee CRO conduct in practice.

Investigators and sites

For investigators and sites, the picture is mixed. Clearer approval routes and defined timelines reduce ambiguity, but a more formal inspection regime raises the compliance burden. India-specific work on site compliance suggests that meeting documentation and process expectations remains uneven.[17] Paper by Gogtay et al it was found that most sites in Mumbai met Quality Council of India standards, yet recurrent gaps in archival space, training-adequacy systems and consent-form

comprehension persisted.[18] Net effect is clarity bought at price of a heavier compliance load; open concern is inspection readiness and the training needed to meet it.

Ethics committees

Ethics committees carry expanded responsibilities without commensurate capacity.[3] Some of these include registration, oversight of every site, and a central role in compensation and serious-adverse-event assessment. Accreditation has lagged with only 179 of 1,647 re-registered ethics committees (about 10.8%) had obtained National Accreditation Board for Hospitals and Healthcare Providers accreditation over five years, and licensing authority has not clarified whether accreditation is even required.[31] Causality assessment for adverse events, which relies on structured systems such as WHO-UMC method, remains inherently judgemental and inconsistently applied.[30] The net effect is strain. The open concern is whether ethics committees are resourced and trained to discharge the duties the rules assign them.[3,13]

Participants and patients

Participants gained mandatory consent provisions, ethics-committee oversight and a defined compensation regime, and mandatory trial registration improves accountability.[31] Yet the protection side has advanced least. The compensation formula, finalised in 2013, has no inflation mechanism.[31] Its base amount of ₹8 lakh is now worth roughly ₹5.3 lakh in real terms which is about 66% of its 2013 value.[31] Meanwhile the interest a compensation deposit earns has fallen from about 9% to 6.3%, a "double whammy" for the injured participant.[31] The earlier draft provision for upfront no-fault compensation was dropped from the final Rules, and criteria for waivers and ethnic-factor considerations were left to regulatory discretion.[2] The net effect is that participant protection has advanced more slowly than facilitation. The open concerns are compensation adequacy and the transparency of trial results.

The regulator (CDSCO)

The regulator gained a modernised, digitalised, time-bound system that advances its ease-of-business mandate and India's standing as a trial destination.[1,20] The open concern, raised since before the Rules when the Parliamentary committee found that the regulator had historically prioritised facilitating industry over protecting the consumer, is whether oversight capacity has grown in step with the volume it now processes.[2]

HOLDING THE BALANCE

Placed alongside one another (Table 2), the trend holds true. The stakeholders who have benefited the most from facilitation are the sponsors, CROs and the regulator. The stakeholder who the rules are designed to protect, however, has benefited the least. This is not an argument that facilitation was wrong. India has become a destination for clinical trials, and the growth is real and valid, with more than 11341 trials registered at CTRI up until 06 July 2026.[12] A predictable process also helps the participants, as it brings more trials and more access to investigational treatments within the country.

But the growth narrative and the protection critiques must be weighed together rather than traded off rhetorically. The critiques are specific and attributable: that the Rules tilt toward industry facilitation without matching investment in oversight; that compensation formula has eroded and needs urgent revision; and that implementation evidence on ethics-committee registration and accreditation, site compliance, inspection and causality assessment shows rules-on-paper outrunning practice.[2,18,19,30,31] Taken together, these do not negate the gains; they locate where balance has slipped.

Table 2: Stakeholder-impact matrix-the NDCT rules, 2019 and subsequent amendments.

Stakeholders	What changed	Net effect	Open concern
Sponsors	Time-bound windows; deemed approval; accelerated approval; local-trial waivers	Gain-predictability, speed	Whether speed outpaces oversight
CROs	Draft registration framework (G.S.R. 364(E), 2023) enacted by G.S.R. 581(E), 2024; SUGAM onboarding	Gain-formal status, accountability	Capacity to oversee CRO conduct in practice
Investigators and sites	Clearer approval routes; formal inspection regime	Neutral-clarity vs compliance burden	Inspection readiness; training
Ethics committees	Registration; site oversight; SAE/ compensation role; (2026 draft) single-stage registration	Strain-capacity, accreditation lag (10.8%)	Resourcing and training (Ghooi 2022; Singh et al 2020)
Participants and patients	Consent; compensation regime; CTRI registration	Slower-protections advanced least	Compensation erosion (Ghooi 2022); results transparency
Regulator (CDSCO)	Ease-of-business mandate; digitalisation (SUGAM)	Gain-efficiency, modernisation	Oversight capacity at scale (PSC 2012; Jesani et al 2019)

A WAY FORWARD

Three concrete, defensible steps would help rebalance the framework without surrendering its hard-won efficiency.

Revisit the compensation formula

Index the base amount to inflation and review the underlying interest assumption, so that compensation for trial-related injury or death holds its real value over time.[31]

Mandate results disclosure

Pair the predictability of approval with a corresponding duty to disclose trial results, which closes the transparency gap that has advanced more slowly than facilitation.[19,32]

Resource ethics-committee oversight

Clarify the status of accreditation, fund and train ethics committees, and standardise causality assessment, so that the bodies responsible for protection can actually discharge it.[3,13,30]

CONCLUSION

From the vantage of 2026, India's clinical-trial regulation is best read as an architecture under continuous construction rather than a rule book fixed in 2019, and one whose benefits have been distributed unevenly. The connection from the original Rules to the latest amendments shows a consistent move toward predictability, speed, and formalization. This shift has made the system easier to navigate and more suitable for global standards. Evidence suggests that this change has benefited sponsors, CROs, and the regulator's support role. However, it has helped the participants, the stakeholders the rules are meant to protect, at a slower pace. For the clinical-research professional, the practical lesson is to track the trajectory rather than any single clause: the next provision is likely to extend the same logic. The imbalance, however, is correctable, and correcting it need not cost India its efficiency. A compensation formula that holds its value, a duty to disclose results, and ethics committees resourced to oversee would let the next decade of reform be remembered for speed with safeguards rather than speed alone. The framers promised both speed and safeguards; delivering the second is the unfinished task.

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