

White Paper

Regulatory Data Protection in India: Current Landscape, Global Practices, and Policy Considerations

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Executive summary



Regulatory Data Protection (RDP) is a critical policy mechanism to transition India from a leader in generics to a globally competitive biopharmaceutical innovation hub, while accelerating patient access to breakthrough therapies.

The current absence of a statutory RDP framework in India allows regulatory reliance on originators' clinical and safety datasets without any protection incentives. The evidence in this paper shows that this approach is associated with weaker incentives for high-risk Research and Development (R&D) and contributes to delayed introduction of innovative products. In contrast, markets with RDP (e.g., United States [US], European Union [EU]/United Kingdom [UK], Canada, Japan, Switzerland, and South Korea) consistently outperform markets without RDP on key innovation

indicators. These markets attract more investment, conduct more clinical trials, support earlier product launches, and enable faster access to innovative medicines, without a measurable impact on overall public health budgets.

Policy recommendation

Establish a statutory RDP framework in India: This framework must grant a defined period of exclusivity for preclinical and clinical trial data, starting from the date of local product approval, during which originator data cannot be relied on for subsequent regulatory submissions. This measure will ensure investment predictability, enhance India's clinical trial competitiveness, and expedite the availability of innovative therapies for Indian patients.

Data and impact assessment yields five core findings regarding regulatory data protection

 Improves medicine availability	 Accelerates local clinical research	 Narrows launch gaps	 Catalyzes capital inflow	 No discernible budget impact
Markets with RDP provide greater access to innovative therapies; India continues to lag behind.	Markets with RDP host substantially higher clinical trials per million population annually, far exceeding India's current baseline.	Absence of RDP is strongly associated with delayed access to new medicines.	RDP is linked to stronger biopharmaceutical investment and increased R&D activity.	Empirical evidence confirms that introducing RDP has no discernible impact on overall public healthcare expenditure.

Core pillars and evidence

1. Enhancing investment attractiveness and the innovation ecosystem.

- » **Data exclusivity and predictability:** RDP protects confidential clinical data submitted for marketing approval, safeguarding the substantial investments required for drug development and providing originators with a predictable exclusivity window.
- » **Clinical trial intensity:** Markets with RDP conduct ~8.2× more clinical trials per million population annually than markets without RDP (**14.9 vs. 1.8**). India currently stands at **0.7** trials per million. Adopting RDP could drive a multi-fold increase (**estimated to be 5x**) in trial activity.
- » **Economic multiplier:** Clinical trial investments yield significant socioeconomic multipliers. Evidence from the UK shows USD 0.39-USD 0.64 in additional economic value generated via employment and capability-building per USD 1 invested in clinical trials.
- » **Investment upside:** RDP implementation in India could increase pharmaceutical R&D investment by 98%-179%, strengthening research infrastructure and creating high-value jobs.

2. Accelerating regulatory filing and launch timelines.

- » **Global prioritisation:** Time-bound exclusivity incentivises innovators to prioritise India in global launch sequencing.
- » **Addressing launch lags:** India currently experiences an **average launch delay of 3.95 years** for top innovative medicines compared to global debuts.
- » **Enabling long-term access:** Timely innovative medicine launches are also critical for long-term access. Without a reference product on the market, follow-on generic/biosimilar entry is frequently delayed.

3. Closing the gap with global peers.

- » **Global norm:** RDP is a standard regulatory pillar [e.g., US: 5 years for New Chemical Entities (NCEs) and 12 years for biologics; EU/UK: 8+2+1 years; China/South Korea: 6 years (both NCEs/biologics)].

- » **Therapeutic availability:** Between 2015 and 2025, markets with RDP experienced ~**3.1× higher innovative medicine availability** than markets without RDP (**14.7% vs. 4.8%**). Studies have demonstrated that RDP alone was responsible for **45% higher availability** of innovative medicines in markets with RDP.
- » **India's gap:** As per the study in this paper, average innovative medicine share as a percentage of total medicines available in India was 0.5%, which is significantly below global benchmarks.

4. Legal distinction and safeguards against 'evergreening'.

- » **Distinct legal frameworks:** RDP is structurally separate from patent exclusivity. Patents protect the underlying invention, whereas RDP protects proprietary regulatory datasets, demonstrating a product's safety and efficacy, from unfair commercial reliance.
- » **Concurrent timeline:** RDP runs concurrently with a product's patent life and does not extend it. For top medicines covered in the paper from 1998 to 2025, the average remaining patent life at regulatory approval was ~15 years globally versus ~8.6 years in India. Thus, a standard RDP term starting at local approval would typically operate within an existing patent duration.
- » **Targeted additional incentives:** In alignment with global best practices, India could consider additional incentives for specific cases, such as for biologics and rare/orphan drugs, to offset the high costs and complexities of these trials.

Conclusion and framework imperative

Taken together, the evidence supports the adoption of a clear, time-bound statutory RDP framework in India. By providing a defined term of RDP (non-reliance) that appropriately rewards originator investment in clinical trials, supported by robust governance and transparency safeguards, would incentivise capital inflow, expand local clinical research, and accelerate access to critical therapies. Importantly, such framework would align India with global regulatory best practices without affecting patent law, 'evergreening,' or increasing public healthcare expenditures.

India's pharmaceutical industry is at a critical juncture



Transforming India's pharmaceutical industry into a global epicentre for pharmaceutical innovation

India's generic pharmaceutical sector has emerged as a significant catalyst for the country's economic growth and an essential provider of healthcare solutions worldwide, frequently earning the designation of the 'pharmacy of the world.' As of 2025, the industry's market value is estimated at approximately United States dollars (USD) 55 billion of the USD 1.6 trillion global pharmaceutical market.^{1,2} By 2030, India's market value is expected to rise to USD 120-130 billion, increasing its global share from 3%-3.5% to nearly 5% (Figure 1).^{3,4} The industry's robust growth trajectory highlights its capacity to adapt to evolving healthcare needs, both within India and globally.³

By promoting innovation-focused policies, India can transition from its established position in generic pharmaceuticals to become a centre for advanced pharmaceutical innovation.

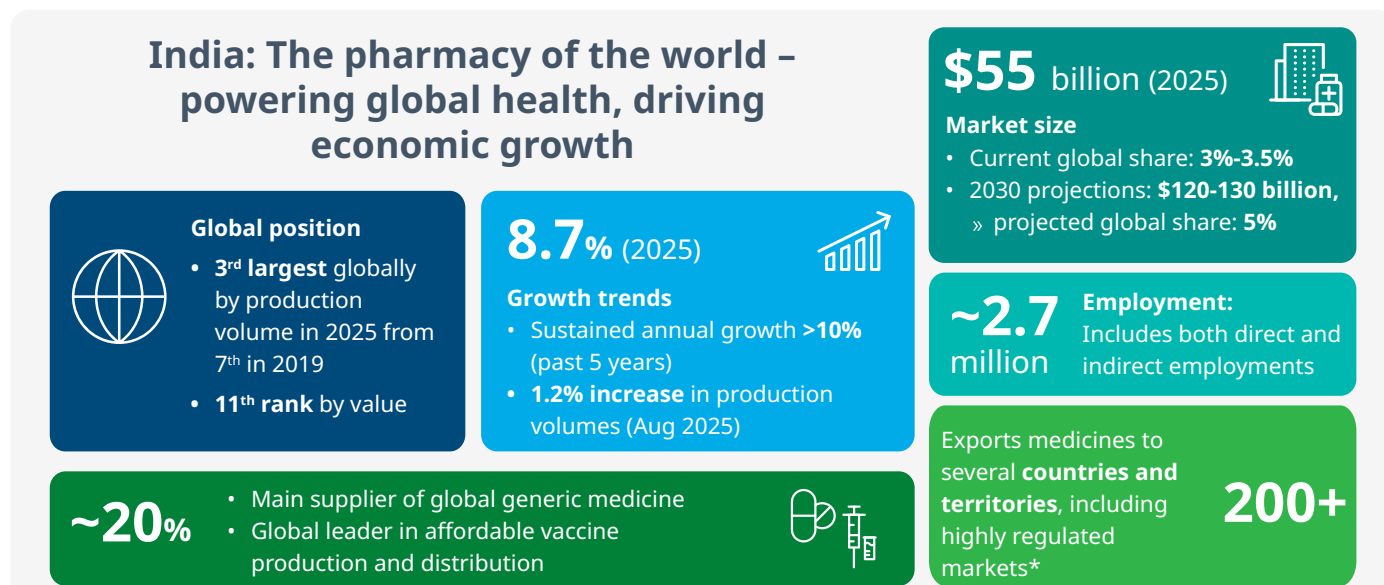
India's pharmaceutical industry (which majorly includes generic manufacturers) also ranks as the third largest globally by production volume and 11th by value, making a substantial contribution to the nation's manufacturing Gross Value Added (GVA)

and supporting approximately 2.7 million livelihoods through direct and indirect employment.^{3,5}

Beyond its contribution to national growth, the industry's global influence is evident, as India has emerged as a pivotal supplier of generic medicines, representing approximately 20% of global volume (Figure 1).³

Looking forward, the Indian pharmaceutical sector stands at a pivotal juncture in its development trajectory. While its global leadership in generics has fuelled remarkable growth, the next phase must prioritise and encourage innovation and launches of more innovative drugs to ensure sustained competitiveness, improved patient health outcomes, and long term success. Moving beyond volume-based expansion, the sector needs to embrace value creation through cutting-edge research, novel therapies, and advanced technologies. Achieving this transformation will require robust policy framework that incentivise innovation, reward research excellence, and attract strategic investments. Evidence from innovation friendly markets such as the US, EU, the UK, and Japan, where generics capture 70%-90% of market share, demonstrates that strong Intellectual Property Rights (IPRs), including Regulatory Data Protection (RDP), do not hinder the entry of generics or restrict patient access.² Thus, by fostering an ecosystem that accelerates breakthrough science, **India can truly transform from the 'pharmacy of the world' into a global epicentre for pharmaceutical innovation.**³

Figure 1: Key statistics and trends in Indian pharmaceutical market



*Highly regulated pharmaceutical markets are primarily the US, Europe (EU/UK), Japan, Canada, and Australia, which are characterized by stringent regulatory oversight, complex approval processes (e.g., FDA, EMA), high intellectual property protection, and rigorous quality standards.

Innovation at the core: Fuelling the future of pharmaceutical industries

Pharmaceutical innovation is propelled by a combination of sustained Research and Development (R&D) intensity, strong Intellectual Property (IP) protection, and a collaborative, adaptive ecosystem (Figure 2).

- **Sustained R&D intensity:** Continuous investment in R&D is essential to developing new therapies and maintaining competitiveness.²
- **Strong IP protection:** A robust IP framework ensures originators (i.e. pharmaceutical companies developing innovative medicines) are rewarded, encouraging long-term investments in breakthrough science.²
- **Collaborative and adaptive ecosystem:** Partnerships among academia, biotech firms, subject matter experts, and regulators foster knowledge-sharing and accelerate innovation.²

For example, emerging markets such as South Korea and Taiwan have enabled transformation of their pharmaceutical sectors by combining robust IP frameworks, regulatory agility, and collaborative networks spanning academia, pharmaceutical companies, and regulators.²

High-risk, high-reward reality of drug development

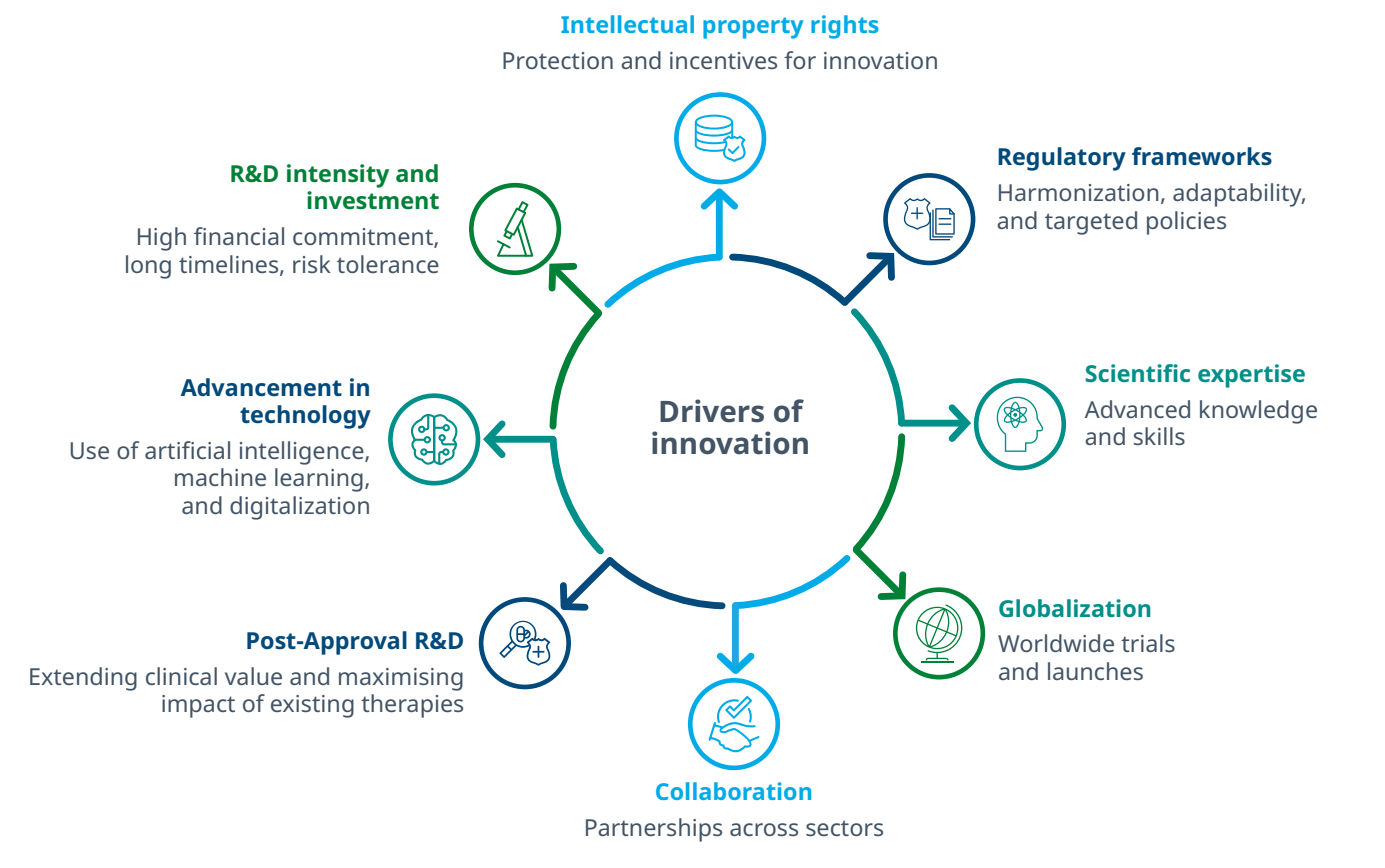
The pharmaceutical industry is the most R&D-intensive sector worldwide, surpassing all other industries in investment.²

- Leading global pharmaceutical companies invested USD 190 billion in R&D in 2024,⁶ while overall global spending is forecast to reach USD 343 billion by 2030.⁷
- R&D accounts for about 27% of research-focused pharmaceutical companies' revenues, far higher than in other sectors.²

These high investments reflect the high-risk, high-reward nature of drug development, where:

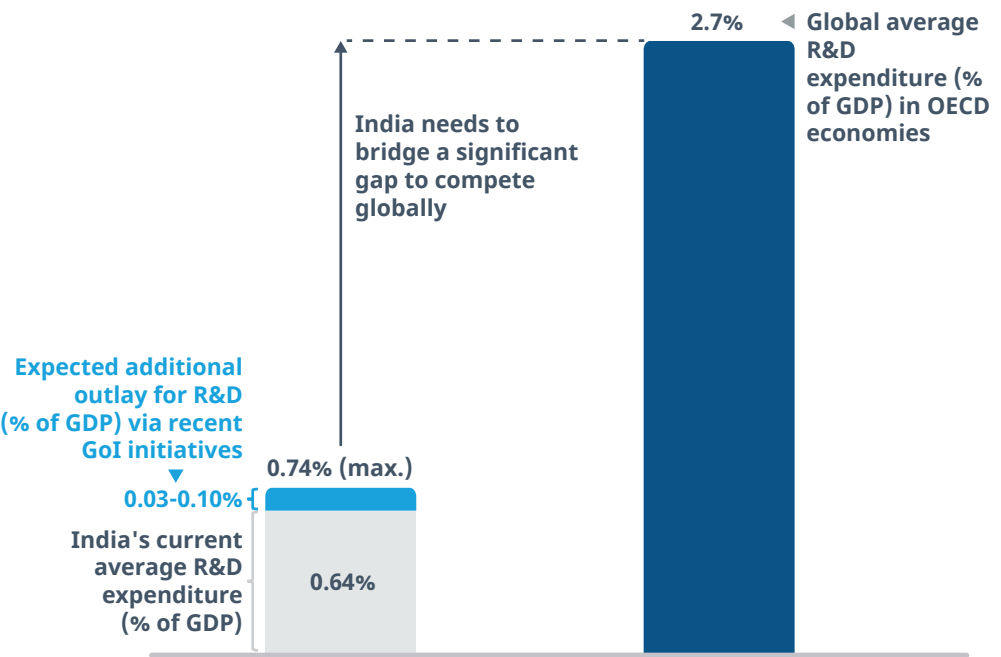
- Developing a single new therapy can take 10-12 years.²
- Costs often run into billions of dollars due to complex trials and regulatory requirements (an average investment of USD 2.6 billion to bring a single new drug into the market, considering the cost of failure).^{2,8,9}

Figure 2: Drivers of pharmaceutical innovation



In stark contrast, India's R&D expenditure remains at 0.64% of GDP (as of 2021),^{10,11} as opposed to an average of 2.7% in Organisation for Economic Co-operation and Development (OECD) economies,¹² highlighting a significant gap that must be bridged to compete globally. Initiatives undertaken by the Indian government are expected to add an outlay of 0.03%-0.10% of the GDP over the next 5-6 years, showing an increasing commitment towards and investment in R&D (Figure 3).

Figure 3: R&D expenditure in India compared to the global average



Sources: World Bank Data, GoI initiatives,^{11,12,14-16} IQVIA analysis.

To close this gap, India needs an enabling environment that incentivises and attracts high-risk capital investments.^{2,13}

India's push towards pharma excellence: Key schemes and reforms

In recent years, the Indian government has launched several initiatives to embark on its ambition to transform into a global pharmaceutical powerhouse.

- **Promotion of Research and Innovation in Pharma MedTech (PRIP) scheme:** A five-year (2023-2028) initiative by the Government of India investing USD 0.6 billion/Indian rupees (INR) 5,000 crore to transition from volume-driven growth to innovation-led development supporting Artificial Intelligence (AI)-driven drug discovery, industry-academia collaboration, and MedTech innovation.¹⁴
- **Production Linked Incentive (PLI) scheme for pharmaceuticals:** The PLI scheme (USD 1.7 billion/INR 15,000 crore) aims to boost India's manufacturing capabilities by driving investment, increasing production, and diversifying into high-value products.¹⁵
- India is also advancing biopharma innovation through the **National Biopharma Mission**,¹⁶ promoting exports via Pharmexcil,¹⁷ and hosting global innovation summits to position itself as a hub for advanced therapies.³
- **Biopharma SHAKTI:** A five-year initiative with an outlay of USD 1.1 billion/INR 10,000 crore to strengthen India's biologics and biosimilars ecosystem through expanded biopharma talent, infrastructure, clinical research networks, and enhanced Central Drugs Standard Control Organization (CDSCO) capacity.¹⁸
- **Anusandhan National Research Foundation (ANRF):** Operational since 2024, the ANRF mobilises USD 5.6 billion/INR 50,000 crore (2023-28) to drive research, innovation, and academia-industry collaboration.¹⁹
- **Research, Development and Innovation (RDI) scheme:** Launched in 2025, this scheme with an outlay of USD 11.1 billion/INR 1 lakh crore aims to provide long term, low cost financing to catalyse private sector innovation, support commercialisation, and scale high impact technologies.¹⁹

Innovation needs protection: Strong intellectual property rights matter



While these initiatives mark significant progress towards building an innovation-driven pharmaceutical ecosystem, their success ultimately hinges on robust IPRs. It empowers companies to allocate large investments to innovation by balancing scientific uncertainty with fair rewards, thus maintaining long-term R&D momentum.²⁰ For pharmaceutical innovation, patents and RDP form the basis of IPR.

Patent protection: Patents are available for all technologies in all industries and grant an exclusive right to make, use, sell, and offer for sale the patented invention for a limited term (typically a period of 20 years from the filing date of the patent application), provided the invention meets the novelty, inventiveness, and industrial applicability/utility requirements.

- Patent rights are awarded for new inventions which are designed to incentivise investment in R&D and to promote the progress of science and useful arts.
- The patent term is 20 years from the date of filing the patent application.
- For pharmaceutical products, the gap between patent filing and drug approval often exceeds a decade, leaving the effective patent life for innovative drugs at less than 10 years, substantially shorter than the overall 20-year term.²¹

Regulatory data protection: RDP is a legal mechanism that provides data exclusivity through regulatory non-reliance on an originator's proprietary test data. The regulation prevents drug authorities, within a specified timeframe, from utilising an originator's proprietary pre-clinical, clinical, safety, and efficacy data when considering approval of competing generic or biosimilar products. Typically, RDP lasts 5-12 years, depending on the country (Table 1).²⁰⁻²²

RDP does not mean mere confidentiality or non-disclosure. While confidentiality prevents public access to regulatory data, it does not prevent regulators from relying on that data. Confidentiality or non-disclosure without non-reliance allows competitors to obtain approval without generating their own safety and efficacy data and, therefore, does not prevent unfair commercial use.²⁰⁻²²

Regulatory reliance must be presumed and prevented whenever a competitor seeks approval for a competing medicine without submitting its own full safety and efficacy data, even if the application does not explicitly cite or reference the originator's data.²⁰⁻²² Preventing regulatory reliance is, therefore, an essential and operative element of RDP.

Why RDP exists

- 1. Prevention of unfair commercial use:** Originators' regulatory data are generated over many years at substantial cost, effort, and risk. Allowing competitors to rely on this data for regulatory approval constitutes regulatory free riding. RDP exists to prevent this outcome.²²
- 2. Incentivising innovation:** RDP is designed to incentivise drug development, i.e. to provide incentives to conduct the clinical trials necessary to bring a substance to market in the form of a drug. This is particularly important, given that clinical trials account for nearly two-thirds of the total investment in bringing an innovative drug to market.²²
- 3. Patient safety:** RDP provides a defined window to monitor and refine real world safety and efficacy outcomes before generic entry, strengthening overall regulatory oversight of new medicines.²²
- 4. Balanced access and competition:** Competitors may rely on originator data once the RDP term expires, enabling predictable and orderly generic entry. Evidence indicates that RDP does not appreciably increase public health expenditure.²²

A common misunderstanding is that RDP and patents serve the same purpose or that RDP simply extends patent protection. There is no relationship between RDP and patents, and one does not extend or otherwise affect the other. RDP complements patents and operates independently of them under distinct legal frameworks.²² While patents safeguard the invention itself, RDP protects a completely different attribute of pharmaceutical invention – the regulatory data generated to demonstrate a product's safety and efficacy.²² While patents incentivise investment in research, for example, on new substances, RDP compensates and encourages the development of a new substance into an actual drug. This distinction is particularly important in cases where patents are unavailable, narrow, or lapsed before market approval. RDP protects the significant investment required to generate clinical and regulatory evidence.

Together, patents and RDP serve different but equally critical roles in incentivising research and innovation in pharmaceuticals.



A patent protects the invention itself, whereas RDP safeguards the critical regulatory data, including preclinical and clinical information, that are required for drug approval. These are distinct mechanisms, both key to incentivise pharmaceutical research and innovation. The protection time of one does not extend to the other.

Regulatory reform in India: A catalyst for global pharmaceutical leadership

India's regulatory framework for pharmaceuticals, as established under the Drugs and Cosmetics Act, 1940, and the associated Rules of 1945, does not currently encompass provisions for RDP.²³ Instead, it offers limited protection only against disclosure of clinical trial data submitted for new drug approvals.²³ This gap in protection has significant implications for innovation and global competitiveness.

The Act and associated Rules regulate the approval, manufacturing, marketing, and import of drugs and mandate the submission of clinical trial data for new drugs, typically in compliance with Schedule Y.^{23,24} Under this system, the first applicant (originator) must conduct comprehensive clinical trials to demonstrate safety, efficacy, and quality. However, subsequent applicants seeking approval for the same drug can rely on relatively simple bioequivalence studies and are not required to themselves undertake these costly, time-consuming trials. Currently, CDSCO and the Drugs Controller General of India (DCGI) are permitted to rely on data submitted by the originator when considering applications from later entrants.²³

The currently followed 2016 Similar Biologics guideline relies on comparative quality, preclinical, and clinical data against a reference biologic to demonstrate similarity in safety and efficacy.²⁵ However, the 2025 draft guidelines represent a paradigm shift from a clinical-trial-heavy biosimilar approval model to a modern, globally aligned, analytics- and statistics-driven framework that minimises preclinical and efficacy trials wherever scientifically justified. This shift will inherently increase regulatory reliance on established clinical experience and the known safety-efficacy profile of the reference biologic, rather than generating new confirmatory data.²⁶

In markets that promote innovation, utilising originator data for the approval of generic or biosimilar products occurs only after an appropriate period of RDP. This allows the originator to protect and incentivise their investment in clinical trials while allowing later entrants to rely on regulatory data only after an appropriate period of protection. This provision is currently absent in India.

Indian regulators: Shifting perspectives towards reform

Indian regulators, including the CDSCO, have historically not aligned with RDP standards, as implemented in the US, EU, and other countries incentivising pharmaceutical innovation. Their primary contention is that granting RDP would allow originator pharmaceutical companies to exercise exclusive rights over clinical trial data, potentially delaying Indian manufacturers' ability to produce generics.

While Indian regulatory authorities consider non-reliance on regulatory use of clinical data as a Trade-Related Aspects of Intellectual Property Rights (TRIPS)-plus measure,²⁷ the governments of most innovative economies do not consider RDP to be optional under TRIPS or India's system to be TRIPS



compliant. The Government of India set up the Satwant Reddy Committee (2007) to propose a regulatory framework that aligns with India's TRIPS obligations while balancing innovation incentives and public health needs. The committee proposed a phased implementation of RDP: first improving data security, then introducing a 5-year protection period with public health safeguards.²⁷ These recommendations remain unimplemented thus far.

Despite varying views of regulators surrounding the implementation of RDP in India, CDSCO has acknowledged a critical gap in the current regulatory framework with respect to RDP.²⁸ To ensure a level playing field for new drug approvals, CDSCO initiated stakeholder consultations to develop a balanced policy framework that safeguards public health priorities while incentivising R&D.²⁸

Industry insights: Harmonising innovation and accessibility through RDP

Research-focused pharmaceutical companies advocate for the adoption of RDP provisions, viewing them as essential to strengthening IP protections and harmonising India's regulatory framework with international standards. RDP provides the critical incentive for originators to conduct clinical trials.

- Bringing a new medicine to the market is inherently risky and requires significant upfront investment, particularly for clinical trials, which account for approximately 70% of the total cost of development.⁹
- Clinical development is characterised by high attrition, with an estimated 80%-90% of candidates failing during trials across major markets such as the US, EU, and Japan.²⁹
- Revenues generated during the RDP period are therefore critical for recouping these investments and enabling reinvestment into ongoing R&D, future pipelines, and supporting a sustainable innovation ecosystem.
- **Exclusivity is a necessary incentive:** The anticipated date of loss of exclusivity is central to investment decision making across the pharmaceutical value chain, from funding new clinical trials and engaging in collaboration with local partner companies to licensing and acquisitions.

Beyond incentivising innovation, the absence of RDP also has practical implications for patient safety and market dynamics. Without a defined exclusivity period, an originator company's ability to adequately monitor real-world outcomes, refine clinical use, or address emerging safety signals before generic versions enter the market may be limited. This constrains proactive pharmacovigilance and evidence-based regulatory decisions.

Research-focused companies also caution that countries lacking RDP often fall lower on the priority list for new product launches, potentially delaying patient access to innovative therapies and widening global health disparities. By contrast, introducing RDP ensures that patients gain timely access to innovative therapies while also creating opportunities for generic companies to expand their portfolios and introduce more generic drugs once the RDP term expires.

Regulatory data protection is not a tool for 'evergreening'

RDP is often misunderstood and portrayed as a tool for evergreening. Yet, contrary to common misconceptions, RDP does not extend patent exclusivity (Figure 4). The Organisation of Pharmaceutical Producers of India (OPPI), in its newsletter, has also emphasised that RDP is independent of patent protection and does not prevent generic manufacturers from gaining approval by submitting their own data.³⁰ Both Indian law and international standards make a clear distinction between RDP and patent, confirming that RDP does not influence or enable evergreening in the pharmaceutical sector.

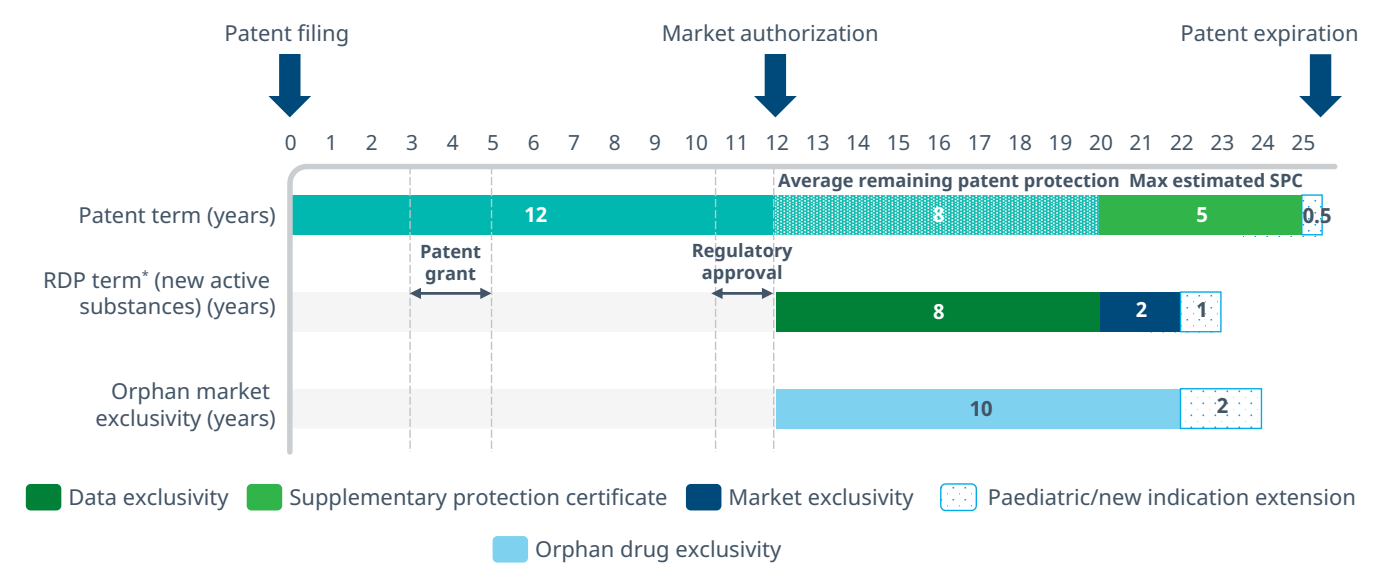
Figure 4 illustrates the pharmaceutical lifecycle in the EU, demonstrating that patents and RDP operate as distinct but complementary mechanisms. Patents are filed early in the R&D process and run for a fixed term (20 years), but a significant portion of this period is consumed by clinical development and regulatory approvals, leaving only a limited window of effective protection after market entry. In contrast, RDP begins only upon market authorisation and provides a defined period of data exclusivity to protect the substantial investment required to generate clinical evidence of safety and efficacy. Crucially, the timelines show that RDP runs independently of the patent system and largely overlaps with the remaining patent term rather

than extending it. This makes it clear that RDP does not lead to evergreening or prolong patent exclusivity. Instead, it serves a distinct purpose by preventing unfair reliance on proprietary regulatory data.

Research-focused companies emphasise the need to raise awareness among stakeholders about the distinction between the two IPR frameworks (patents and RDP). Furthermore, RDP also offers advantages for generic pharmaceutical companies with a predictable

timeline for market entry that will enable them to plan development, manufacturing, and regulatory submissions more effectively. During the RDP period, generic manufacturers can begin formulation development and bioequivalence studies ensuring readiness for launch once the protection expires. Overall, RDP fosters market stability by reducing uncertainty and litigation risks for originators as well as generic/biosimilar applicants.

Figure 4: RDP term compared to patent term in the EU
Regulatory pathway in EU (years)



SPC, Supplementary Protection Certificate.

*The revised EU model, finalised in March 2026 (not yet implemented), provides a total of up to 11 years of exclusivity (8+1+(1)+1). This comprises:

- 9 years of base exclusivity, including 8 years of data exclusivity followed by 1 year of market exclusivity.
- Variable incentives (extensions to market exclusivity):
 - +1 year for a new therapeutic indication demonstrating significant clinical benefit.
 - +1 year of conditional market exclusivity if the product meets an unmet medical need or meets certain other conditions.

Sources: [EMA pre-authorization guidance](#), [EU pharma package](#)

“A balanced, predictable IP and regulatory framework encourage sustainable development of new therapies and will strengthen India’s position as an innovation driven and innovation-led economy.”

– Anil Matai, Director General, OPPI

RDP frameworks across regions: Global markets incentivise innovation



In developed markets, RDP is well established and incentivises innovation.

- In the US, the Hatch-Waxman Act (1984) revolutionised the regulatory framework by introducing RDP (Box 1 highlights the evolution of RDP in the US). The current framework provides 5 years for new chemical entities (NCEs), 3 years for new indications, and 12 years for biologics, additional 6 months based on paediatric studies, and 180 days for first generic applicants. Since RDP in the US is integrated with the patent linkage system, in practice, most NCEs in the US receive 7.5 years of exclusivity that includes a '30-month stay' of FDA approval for generics in addition to the core 5-year RDP period.³¹ Building on the precedent set by the Hatch-Waxman Act, which proved that RDP can drive innovation without harming access, many jurisdictions have since adopted stronger, more predictable RDP frameworks better suited to modern R&D ecosystems.
- The EU/UK currently follows the 8+2+1 rule (revised EU model details mentioned in the footnote of Figure 4), granting up to 11 years of protection^{32,33} (Figure 4).
- Canada offers 8 years of data protection, including a 6 year filing bar (or no-filing period/data exclusivity).³⁴
- Japan uses a re-examination system ranging from 6 to 10 years.³⁵
- Switzerland grants 10 years of data exclusivity for new substances and paediatric indications, 3 years for line extensions such as new indications (10 years if significant clinical benefit), and 15 years for orphan drugs.³⁶
- South Korea has recently formalised their regulatory framework, moving from de facto data exclusivity to a clear, statutory data exclusivity regime with 6 years for NCEs and biologics, 4 years for new indications, and 10 years for orphan drugs (Table 1).

Emerging markets are gradually aligning with global standards. Recently, China has formally introduced a national RDP framework, effective 15th May 2026, under rules issued by the National Medical Products Administration (NMPA), restricting reliance on originator data. With no approvals until the expiry of the RDP period, China now provides 6 years of RDP for NCEs and biologics, with 4 years for new indications/line extensions. There is an additional duration of

2 years for paediatric drugs and 7 years for orphan drugs^{37,38} (Table 1). The recent adoption of RDP in South Korea,³⁹ Taiwan, and China is a testimony for other countries with ambitions in biotech innovation and who are deliberating RDP implementation.

In summary, while developed markets provide longer RDP periods, emerging markets have also begun establishing RDP frameworks.

Box 1: Evolution of RDP in US

The Hatch-Waxman Act – Revolutionizing data protection in US pharmaceuticals

Global impact

The Hatch-Waxman Act's data protection provisions have dramatically increased the availability of generic medicines, reduced healthcare costs, and expanded patient access, while maintaining strong incentives for pharmaceutical innovation. Its dual protection mechanism of patent rights and data exclusivity continues to influence regulatory frameworks worldwide.

Background

Prior to 1984, originator companies held patents, but there was no clear mechanism to protect the clinical and safety data submitted for regulatory approval.

The Hatch-Waxman Act: A paradigm shift

The Drug Price Competition and Patent Term Restoration Act, commonly known as the Hatch-Waxman Act, was enacted in 1984 to address these challenges. One of its most transformative features was the introduction of regulatory data protection, or 'data exclusivity.' Under this provision, originator companies were granted a period, typically five years, during which the clinical trial data they submitted to the FDA could not be used by generic manufacturers to support their own applications, regardless of the patent status.

Impact of data protection

- **Market exclusivity for originators:** For example, when a company like Pfizer developed a new drug, the data exclusivity period ensured that generic competitors could not rely on Pfizer's clinical data for FDA approval until the exclusivity expired. This allowed Pfizer to recoup its investment in research and development, even if the patent had expired.
- **Incentivizing research and paediatric studies:** The Act also incentivized new research, such as paediatric studies, by granting additional data exclusivity. AstraZeneca, for instance, received an additional six months of exclusivity for conducting paediatric trials on Crestor, thereby encouraging research and development.
- **Balancing innovation and access:** Once both patent and data exclusivity periods ended, generic manufacturers could use the originator's data to obtain FDA approval, leading to a rapid increase in affordable generic options for patients. This balance between innovation incentives and public access became a hallmark of the US pharmaceutical market.

Table 1: Comparison of RDP frameworks across jurisdictions

JURISDICTION	RDP/DATA EXCLUSIVITY	INCENTIVE FOR INNOVATION	CLINICAL TRIAL WAIVER FRAMEWORK	UNIQUE FEATURES
United States	5 years for new chemical entities' exclusivity; +0.5 years for paediatric; 3 years for new clinical investigations (line extensions); 12 years for biologics under BPCIA	Strong exclusivity stack, paediatric extensions, and robust early resolution	FDA can rely on foreign data; multiple expedited programmes; no routine 'waiver' concept such as India Rule 101, but reliance and bridging studies common	30-month stay before approval of generic; clear, layered exclusivities for small molecules and biologics
European Union	'8+2+1' model: 8-year data exclusivity + 2-year market exclusivity + possible 1-year extension for significant new indication (revised EU model details mentioned in the footnote of Figure 4)	Stable, predictable exclusivity; proposed 'Pharma Package' debates continue, but core framework well established	Extensive use of reliance/abridged procedures; no patent-conditioned approvals; work-sharing across EMA and NCAs	Clear separation of regulatory and patent spheres enables rapid post patent generic entry; extensive abridged pathways
Japan	Data protection is provided through the re-examination system with about 8 years for new drugs; biologics are also protected within same framework as per MHLW/PMDA practice	Strong data protection and a linkage mechanism support certainty and early resolution for originators	Acceptance of foreign data with bridging studies; expedited pathways; reliance features for global development programmes	Mature linkage tailored to domestic practice; alignment with advanced regulatory norms
United Kingdom	Mirrors EU stance post-Brexit: does not use patent linkage; maintains EU-style reliance and abridged practices; data protection aligned with legacy EU approach	Predictable exclusivity and accelerated routes support innovation; access-oriented stance without linkage	MHRA reliance/recognition routes; foreign data acceptance; multiple accelerated programmes	Post-Brexit international recognition routes with pragmatic reliance on trusted regulators
Switzerland	10 yrs (new substances), 3 yrs (new forms), 15 yrs (orphan drugs)	Strong data exclusivity	Acceptance of foreign data with extensive reliance on data and approvals from FDA and EMA	Long orphan drug protection; nuanced by product type
Canada	8 years of data protection for innovative drugs including biologics (+0.5 years for paediatric use); implemented under Food and Drug Regulations	Linkage plus data exclusivity and court-based resolution; originator incentives strengthened after earlier criticism	Foreign data reliance is common; Health Canada uses accelerated and aligned reviews; no India-style waiver list, but strong recognition mechanisms	Mature linkage with defined stay; historic debates about springboarding shaped today's rules
South Korea	Followed a re-examination system for data protection before transitioning to formal RDP in 2025. 6 yrs (new drug, new combination), 4 yrs (new indication, administration route or paediatric use), 10 yrs (orphan drug +1 yr for paediatric indication)	Recent (Feb 2025) reforms, moving from de facto data exclusivity to clear, statutory data exclusivity regime	Foreign data reliance is common	Considerable period of data protection for new indication, including new administrative route

JURISDICTION	RDP/DATA EXCLUSIVITY	INCENTIVE FOR INNOVATION	CLINICAL TRIAL WAIVER FRAMEWORK	UNIQUE FEATURES
China	6 yrs (new chemical entities and biologics), 4 yrs (new indications, line extensions), additional 2 yrs for paediatric and 7 years for orphan, 3 yrs (first-to-market generic)	Reforms improving regulatory data protection and linkage intended to attract innovation and align with FTAs and domestic policy goals	Waiver and accelerated pathways exist under NMPA for certain urgent clinical needs, harmonising with global data; details vary by country's guidance	Movement towards US-style early resolution while adapting to domestic system; part of broader IP-strengthening agenda. Formalised patent linkage system; 3 yrs of data protection of first-to-market generic
Mexico	5 yrs (new chemical entities)	Predictable exclusivity	Acceptance of foreign data with extensive reliance on data and approvals from FDA-, EMA-, and WHO-recognised agencies	Established pharmaceutical patent linkage system; regulators have strict timelines, with accelerated approvals; limited data exclusivity
Peru	5 yrs (new chemical entities)		Acceptance of foreign data with extensive reliance on data and approvals from FDA and EMA	Limited data exclusivity
Chile	5 yrs (new chemical entities and biologics) Protection for biologics largely managed through regulatory guidelines rather than explicit, separate statutory law		Acceptance of foreign data with extensive reliance on data and approvals from EMA, FDA, MHRA, TGA, and PMDA	
Brazil	No RDP regime yet	Originator incentives rely on patent term and ANVISA procedures; policy debates on test data protection persist	Case-by-case reliance pathways; expedited access for public health priorities via established regulatory mechanisms	Emphasis on TRIPS interpretation that does not mandate exclusivity; historical scepticism towards RDP exclusivity
South Africa		Originator incentives mainly via patents and fast-tracked for priority medicines; broader IP policy reforms under discussion	Waiver/abridged reviews for certain products drawing on reference authority assessments	Policy aligns with access objectives; does not support formal patent linkage
India		Incentives mainly via patents, priority review in select cases, and orphan pathways; recent policy changes seek faster access to globally licensed therapies	Rule 101 NDCTR 2019: local trial waiver for drugs already approved in the US, UK, EU, Japan, Australia, and Canada for specified categories (orphan, gene/cell therapies, pandemics, significant therapeutic advance, defence use), with Phase 4 trials and safety prerequisites	2024-2025 notifications specifying 6 reference countries for predictable waivers under Rule 101, aiming to compress access lag by 3-4 years for select products

 Markets with RDP
  Markets without RDP

Sources: United States (FDA, 2015),³¹ European Union and United Kingdom (EMA, 2018; EMA, 2024),^{32,33} Japan (SIKS and Co., 2018),³⁵ Switzerland (Swiss medic, 2019),³⁶ Canada (Health Canada, 2025),³⁴ South Korea (Son, 2025),³⁹ Mexico, Peru, Chile, and Brazil (IFPMA, 2011),⁴⁰ China (Gu et al., 2025, Che et al., 2026,^{37,38} South Africa (Truluck and Grant, 2025; Pharmexcil, 2017),^{41,42} India^{23,27}

Abbreviations: ANVISA, Agência Nacional de Vigilância Sanitária; BPCIA, Biologics Price Competition and Innovation Act; EMA, European Medicines Agency; EU, European Union; FDA, Food and Drug Administration; FTAs, Free Trade Agreement; IP, Intellectual Property; MHRA, Medicines and Healthcare products Regulatory Agency; MHLW, Ministry of Health, Labour and Welfare; NCAs, National Competent Authorities; NDCTR, New Drugs and Clinical Trials Rules; NMPA, National Medical Products Administration; PMDA, Pharmaceuticals and Medical Devices Agency; RDP, Regulatory Data Protection; TGA, Therapeutic Goods Administration; TRIPS, Trade-Related Aspects of Intellectual Property Rights; UK, United Kingdom; US, United States; WHO, World Health Organization.

Driving innovation through RDP: Learning from global standards



Globally, RDP is increasingly recognized as a key marker of competitiveness in pharmaceutical innovation. Countries seeking to attract R&D investments, expand clinical research, increase biologics investment, and secure first wave launches have consistently adopted clear, time bound RDP frameworks. In many cases, RDP has been expanded or strengthened over time to support a sustainable environment for innovation. This section covers an impact assessment to evaluate the influence of RDP on the availability of innovative medicine, its effect on the frequency of clinical trials, and its role in enabling early product launches for key markets with and without RDP (Table 2). These analyses will provide evidence based insights on the impact of RDP on various facets of the innovation ecosystem and access.

Table 2: List of countries included in impact assessment

MARKETS WITH RDP	MARKETS WITHOUT RDP
• Australia • Canada • France • Germany • Italy • Japan • Spain • Switzerland • United Kingdom • United States	• Brazil • China* • India • South Africa

*China has implemented RDP with effect from 15th May 2026; however, on account of the recency, it is considered as a market without RDP for the purpose of data analysis in this paper.

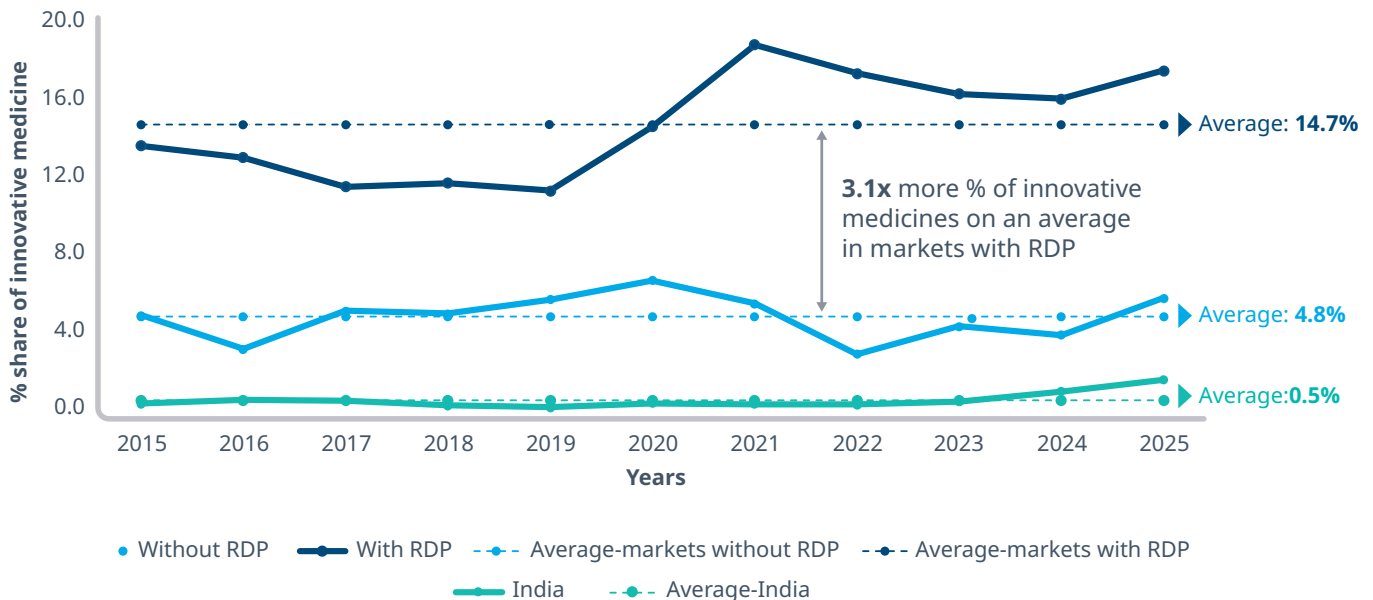
RDP, Regulatory Data Protection.

The numbers are clear: RDP markets outperform on innovative medicine availability

Today, India's innovative medicine presence is lower than the average in markets without RDP, markets with RDP offer 3 times higher availability

Figure 5: Innovative medicine availability

Innovative medicines available as a percentage of total medicines in markets with and without RDP (2015-2025*)



*Data extracted as of May 2026. Source: IQVIA MIDAS, IQVIA analysis. Innovative medicines include New Molecular Entities (NMEs) only.

- Markets with RDP consistently outperform those without RDP in innovative medicine availability:**

Across the 14 markets in Table 2, from 2015 to 2025, the average percentage of innovative medicines (innovative medicine as a percentage of total medicine in a particular market) in markets with RDP was 14.7%, nearly 3 times higher compared with markets without RDP (4.8%) (Figure 5).

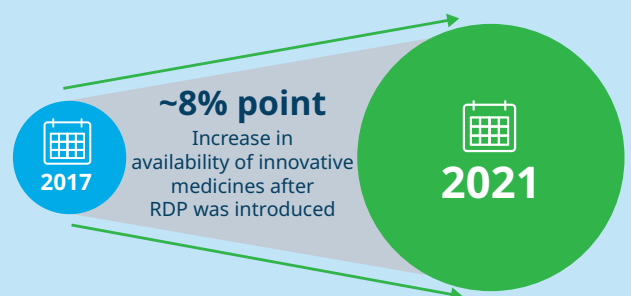
- India's innovative medicine availability is below both global averages:** The average percentage of innovative medicines in India (0.5%) remains lower than the average for markets with and without

RDP, indicating a significant difference in access to innovative therapies (Figure 5).

- Strengthening RDP could lead to a significant increase in availability of innovative medicines in India:** These findings are consistent with a study conducted across 53 markets (including India), which reported a three-fold increase in the availability of innovative medicines and demonstrated, using a dynamic panel data model over 11 years, that RDP implementation alone was associated with a 45% improvement in the availability of innovative medicines.⁴³

Taiwan's RDP framework enhances access to breakthrough treatments

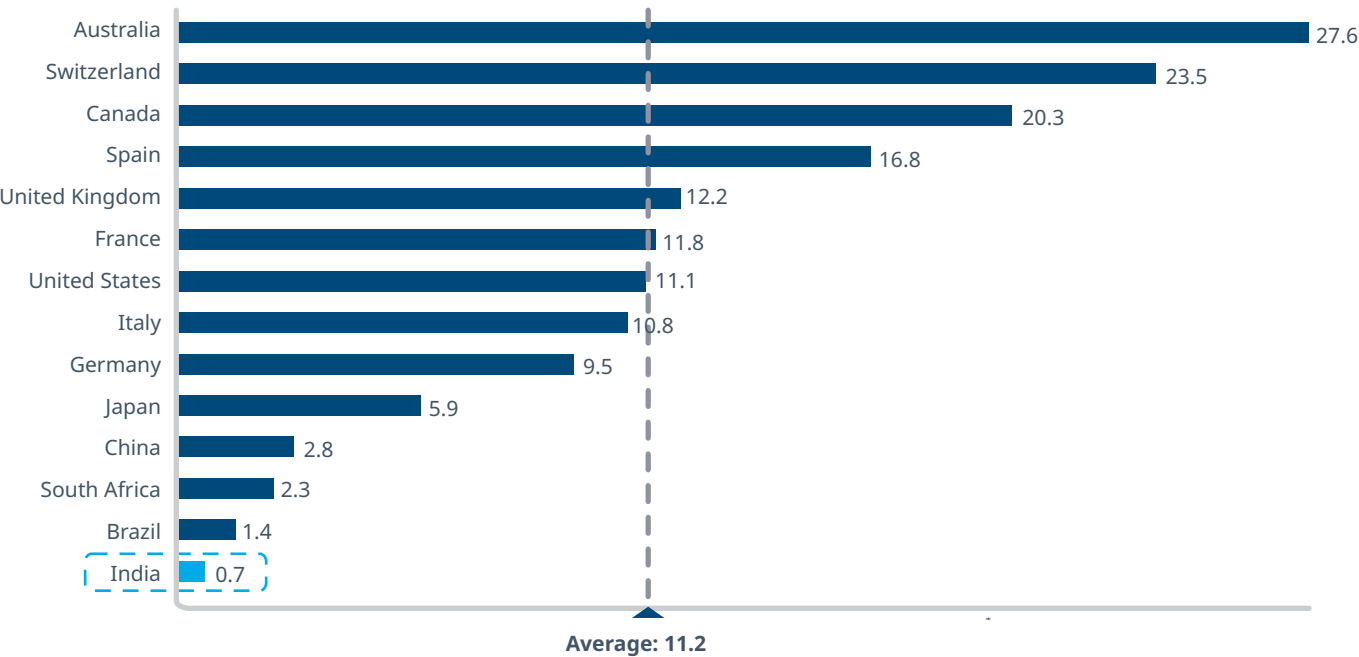
RDP was introduced in Taiwan in 2017. Implementation of RDP boosted availability of innovative medicines by nearly 8 percentage points in 2020, as reported in a case study.⁴³



Closing the gap: RDP correlates with more clinical trials

A. India lags significantly behind global counterparts in clinical trial frequency per million population

Figure 6A: Clinical trial (Phases I-III) frequency by country
Average yearly number of clinical trials per million population (2015-2025*)



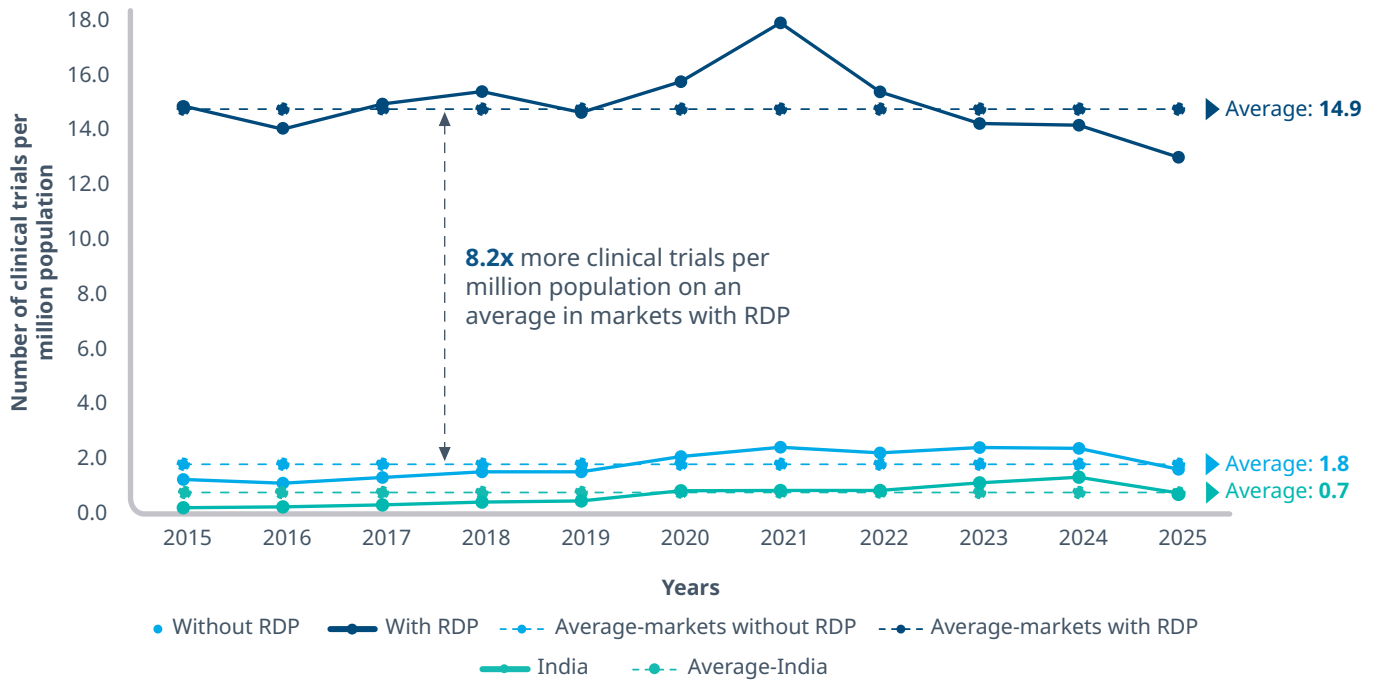
*Data as of May 2026. Includes clinical trial Phases 1 to 3, exclusive of devices. Source: IQVIA analysis.

- **India’s clinical trial frequency is among the lowest globally:** This analysis includes clinical trial data for Phases I-III (excluding devices) from 2015 to 2025. India falls far below, with only 0.7 clinical trials per million population per year, compared to the global average of 11.2 (Figure 6A). Clinical trial activity in India has increased substantially in recent years; however, participation remains predominantly concentrated in late-phase studies, with early-phase clinical research historically limited.⁴⁴
- **Developed economies conduct more clinical trials compared to India:** Leading countries such as Australia (27.6), Switzerland (23.5), and Canada (20.3) conduct nearly over 30 times more clinical trials per million population than India, while major economies such as the UK, France, and the US also far surpass India’s number, averaging between 11.1 and 12.2 clinical trials per million population annually (Figure 6A).
- **The gap highlights a significant opportunity for India:** Bridging this disparity could accelerate innovation, improve patient access to new therapies, and strengthen India’s position in global pharmaceutical research.

B. Markets with RDP have over 8 times higher clinical trials than those without RDP

Figure 6B: Clinical trial (Phases I-III) frequency across markets with and without RDP

Average yearly number of clinical trials per million population in markets with vs without RDP (2015-2025*)



*Data as of May 2026. Includes clinical trial Phases 1 to 3, exclusive of devices. Source: IQVIA analysis.

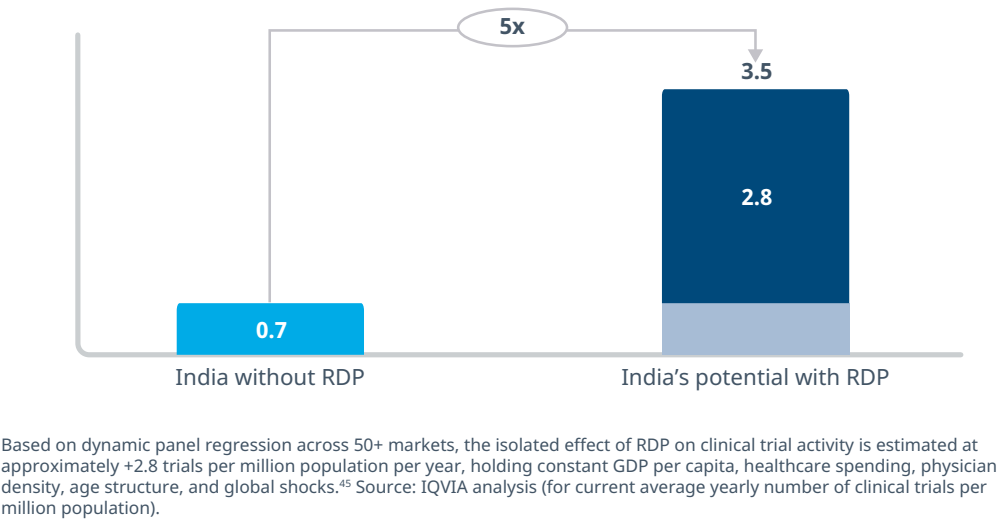
- **Markets with RDP conduct substantially more clinical trials:** On an average, markets with RDP report 14.9 clinical trials per million population annually (average clinical trials per million population between 2015-2025 across markets with RDP), compared with just 1.8 in markets without RDP (average clinical trials per million population

between 2015-2025 across markets without RDP), which is an 8.2-fold difference (Figure 6B).

- **RDP is strongly correlated with increased clinical research and innovation:** Countries that implement RDP attract more clinical trials, supporting faster development of new medicines, and greater patient access to cutting-edge therapies.

C. RDP is a potential driver for increasing clinical trial frequency in India

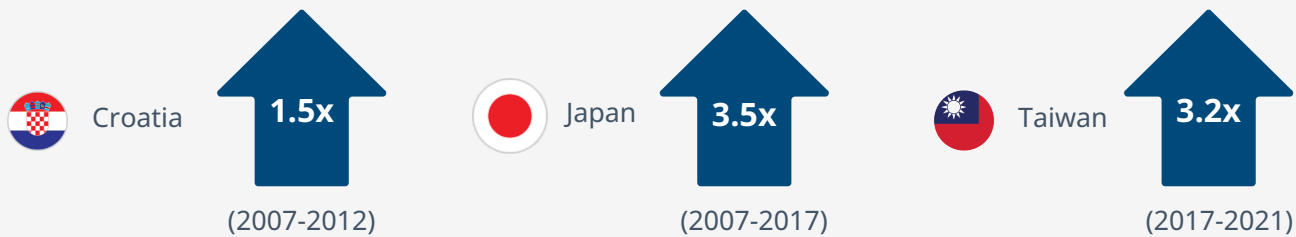
Figure 6C: Potential increase in clinical trial (Phases I-III) frequency with RDP
Potential increase in the average yearly number of clinical trials per million population with RDP



- RDP implementation could increase the number of clinical trials per million population by 2.8⁴⁵ to reach 3.5 clinical trials per million population per year.
- This means that implementing RDP in India could potentially result in a five-fold increase in the number of clinical trials per million population per year (Figure 6C).

Implementation of RDP across countries has led to a significant increase in clinical trial numbers per million capita, as reported in a case study.⁴³

- Evidence from Japan shows that meaningful gains in clinical trials per million capita were observed only after 2007, when the RDP duration was extended to 8 years,⁴³ with no observable effect during 2003-2007 under a 6-year RDP regime, underscoring that suboptimal RDP implementation does not deliver ideal outcomes.



DATA ANALYSIS 3

Earlier launches, faster access: The RDP advantage for patients

Markets without RDP, such as India, experience extended launch gaps: Access to key innovative medicines delayed by as long as 13 years

Figure 7A: Timeframe for launch of innovative medicines in India compared with global/RDP market launch
Timeline for global/RDP market launch compared to India launch



Analysis of top 50 global molecules (launched between 1998-2025) by sales based on data extracted in May 2026. Of these molecules, 40 were launched in India (exceptions: one of them does not hold a patent in India and another was launched post LoE in India). Global average calculation is based on first launches in US, EU, UK, Japan, and Canada. Source: IQVIA Analytics Link, IQVIA analysis.

India's access to innovative medicines is often delayed compared with global markets (Figure 7A):

- Data comparing the launch timelines of the top 40 innovative medicines launched in India (out of the top 50* medicines by global sales across 1998-2025) against their first global launch indicate that these medicines are first launched in global markets with RDP, well before they are launched in markets without RDP, such as India.
- Indian patients typically wait longer, on an average 3.95 years (min: 1.0 year, max: 13.0 years), for access

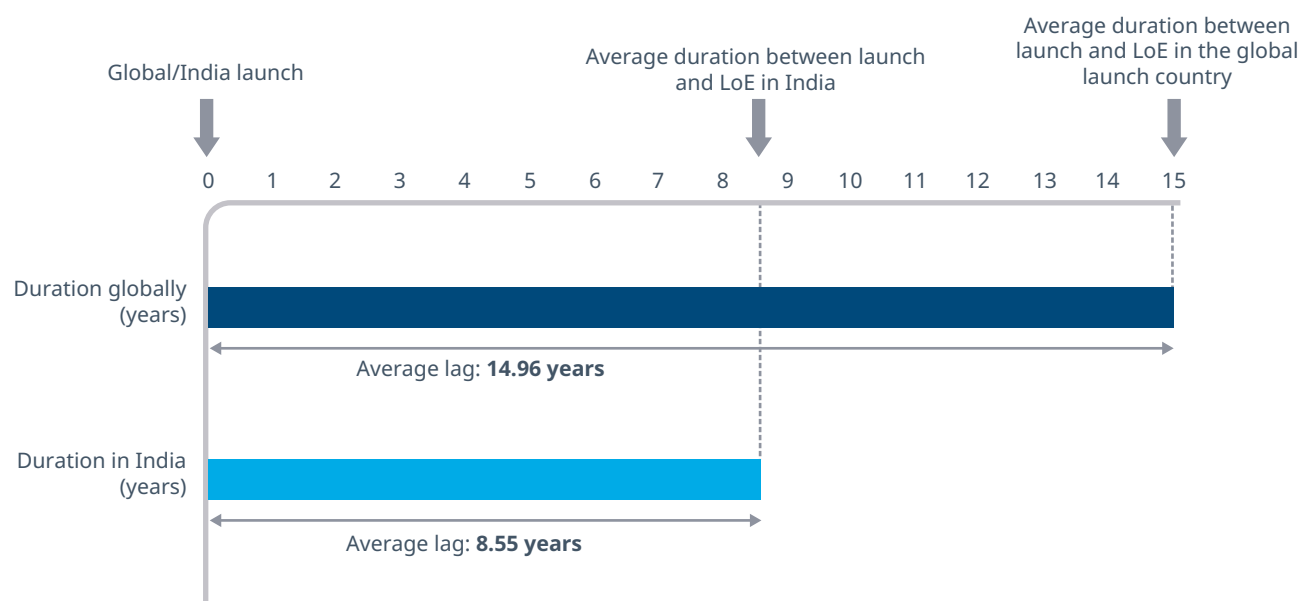
to breakthrough medicines compared with global markets. This lag is slightly longer for biologics (4.4 years) and shorter for small molecules (3.4 years). (Note: these timelines are with respect to launch, which may be impacted by regulatory approval timelines from filing to launch).

- However, for major therapeutic areas with a high burden in India, such as cardiology, oncology, haematology, and ophthalmology, the average lag in India launch is lower (1.7-3.5 years) than the overall average lag (3.95 years).

*These selected top 50 molecules represent an average annual sale of USD 17.2 billion per molecule.

Figure 7B: Remaining patent term or commercial exclusivity at time of innovative medicine launch

Timeline of innovative medicine launch and LoE (years)



Analysis of top 50 global molecules (launched between 1998-2025) by sales based on data extracted in May 2026. Of these molecules, 40 were launched in India (exceptions: one of them does not hold a patent in India and another was launched post LoE in India). Global average calculation is based on first launches in US, EU, UK, Japan, and Canada. Source: IQVIA Analytics Link, IQVIA analysis.

Evidence confirms RDP is concurrent with patent terms and does not impede patient access (Figure 7B):

- Across these top 50 innovative medicines by global sales across 1998-2025 (40 launched in India), the average remaining patent life or commercial exclusivity at the time of regulatory approval was ~15 years globally, compared with ~8.6 years in India.
- This clearly shows that, given global RDP terms of

5-12 years, data protection periods do not extend beyond the patent term or commercial exclusivity.

- Likewise, if India were to adopt RDP with a term appropriately protecting originators' investments for conducting clinical trials, it would incentivise faster launches, and would still fall within the average existing patent life or commercial exclusivity, except in rare cases, where RDP may provide effective exclusivity beyond the patent term.

RDP as an economic catalyst

Across global markets, the introduction of RDP has consistently acted as a powerful lever for innovation, investment, and economic growth. Stronger RDP frameworks translate directly into expanded patient access and accelerated scientific progress. Evidence from multiple regions demonstrates clear, measurable economic benefits:

- **Accelerated clinical research and economic returns:** UK data show that every USD 1 invested in clinical trials generates an additional USD 0.39-USD 0.64 in economic value through increased income, employment, and local capability-building, demonstrating the multiplier effect of a research-friendly ecosystem.
- **Key driver of R&D investment growth:** A similar, prospective study in China⁴⁶ shows that implementing RDP, supported by predictable market access and value-based reimbursement, can transform the innovation ecosystem by creating a stable platform for domestic and multinational investment, attracting global originators to

prioritise early launches, enabling skills, technology, and knowledge enhancement that strengthen local industry capabilities. As a result, China's pharmaceutical R&D investment is projected to increase by 157%-285%, reflecting one of the most rapid innovation expansions globally.⁴⁶

- **No meaningful impact on healthcare expenditure:** Introduction or increase in RDP term in countries such as Canada and Japan, where they have national health insurance systems (which cover majority of healthcare costs, including medicines), showed no meaningful increase in healthcare spending.⁴⁶

Today, for every USD 1 India invests in pharmaceutical R&D, China invests USD 1.6. With RDP implementation, India's own R&D investment is projected to increase by 98%-179%*, positioning the country to accelerate indigenous innovation, attract foreign capital, strengthen clinical research infrastructure, and expand high-value employment.

*IQVIA analysis



Key takeaways from data analyses

Regulatory data protection: A strategic opportunity for India



Global alignment and competitiveness: All major innovation-driven pharmaceutical markets have statutory RDP frameworks. Introducing RDP would align India with global regulatory norms and strengthen international competitiveness and support patient access to innovative medicines, as evidenced by higher availability (3.1-fold) in RDP markets (14.7%) compared with non RDP markets (4.8%).



Unlocks investment and clinical research: By protecting confidential clinical and safety datasets and providing a predictable, time limited exclusivity window, RDP strengthens incentives for high-risk R&D and clinical trials. Markets with RDP conduct ~8.2× more clinical trials per million population per year than markets without RDP (14.9 vs 1.8). India currently lags far behind (~0.7 clinical trials per million population per year). RDP ecosystems also yield measurable economic returns, with UK data showing USD 0.39-USD 0.64 generated per USD 1 invested in clinical trials through income, jobs, and capability gains. In India, RDP has the potential to boost pharmaceutical R&D investment by ~98%-179%, while attracting capital, strengthening research infrastructure, and creating skilled jobs.



Major opportunity to scale clinical trials in India: India conducts far fewer clinical trials per capita than innovation-friendly countries; adopting RDP could drive a multi-fold increase (estimated to be 5x) in trial activity, strengthening scientific capability, infrastructure, and high-skill employment.



Faster patient access with no meaningful impact on public health budgets: Absence of RDP contributes to multi-year delays in access to innovative medicines. For top innovative medicines, Indian patients face an average launch delay of ~3.95 years versus the first global launch (delay is as high as 13 years). RDP is expected to incentivise earlier filings and faster launches in India, with no discernable burden on public health budgets.



Strategic policy lever for the next phase of growth: RDP can accelerate India's transition from a generics-led market to a globally competitive, innovation-driven pharmaceutical ecosystem, supporting value creation and timely patient access to innovative medicines.

Accelerating innovation: Recommendations to align India with global best practices



Looking ahead, and in line with the Viksit Bharat 2047 vision, India aims to position its pharmaceutical sector as a global hub for innovation and manufacturing, targeting a market size of USD 450 billion. Achieving this ambition will require not only leadership in generics and vaccines but also significant advancements in pharmaceutical innovation. Building on international standards and positive impact of RDP, the following key recommendations are pivotal to transforming India's regulatory framework and fostering an ecosystem for growth.

Core recommendations for strengthening RDP in India

1 Introducing data exclusivity mechanisms

This reform is essential to incentivise innovation, ensure fair competition, and align India's practices with global standards.

Data exclusivity period: A defined duration (a term appropriately protecting originators' investments for conducting clinical trials) of data protection measured from the time of local product approval in India during which the clinical trial and bioequivalence data submitted by the originator for innovative medicines or new substances, including biologics, cannot be relied on by the generic/biosimilar manufacturer for regulatory approvals. This would help protect the originators' investment in generating safety and efficacy data.

The total duration could be segregated to include a 1 to 2 year window, following the expiry of the data exclusivity period, during which the market entry of generic versions may be restricted – for example, China and the EU have segregated their RDP term with the last 1 to 2 years as market exclusivity. This ensures a fair return on investment for the originator before generics enter the market while allowing generics to carry out their research for faster launch at the expiry of RDP.

2 Providing additional incentives for specific cases

Promote drug development in a targeted manner in line with global examples. Specific cases may include:

- **Longer protection for biologics:** Obtaining clinical data for such drugs is inherently complex and costly, suggesting that additional incentives may be needed.
- **Extended protection for orphan drugs:** Specifically encouraging drug development for rare diseases in response to a public health need.
- **Protection for a new indication of an approved drug:** Promoting the development of medicines for new indications with a significant clinical benefit to improve patient access to better treatment.

3 Preserving full RDP duration by aligning with launch authorisation

Experience from Japan (as described in Section ‘Closing the Gap: RDP Correlates with More Clinical Trials’) indicates that meaningful gains associated with RDP emerged only after its full and effective application, highlighting that partial or suboptimal implementation fails to deliver the intended benefits. In addition, to ensure fairness and maintain the intended duration of RDP, the protection term should commence from the date of the final, local regulatory approval that authorises product launch in India, rather than referencing any earlier, intermediate approval. Given that the registration process often involves multiple, sequential steps and can extend over several years in India; thus starting the RDP clock prematurely significantly shortens the effective protection period.

4 Establish clear and uniform enforcement roles for CDSCO and state authorities

- CDSCO should be formally designated as the central authority for determining and recording RDP status at the time of new drug approval, with standardised guidance issued to State Drug Controllers on the scope and duration of protection.
- State authorities should be required to align licensing decisions with CDSCO-granted RDP, ensuring that manufacturing or marketing approvals are not issued with reliance on protected originators’ data during the applicable RDP period.

Supplementary recommendations to reinforce robust RDP framework

1. Strengthening transparency and data governance

- » Leverage the National Single Window System (NSWS) and create awareness of this digital platform to improve transparency and regulatory coordination.
- » Pair drug registry with standard operating procedures aligned with the New Drugs and Clinical Trials Rules (NDCTR) to enable predictable and auditable decision-making.
- » Link manufacturing approval to RDP status, such that manufacturing licences for generic drugs are granted only after verifying the expiry of exclusivity.

This integration would not only protect originators' investments in clinical trials and regulatory data but also provide clarity and predictability for generic manufacturers, ultimately fostering a balanced, innovation-friendly pharmaceutical ecosystem.

2. Enhancing institutional infrastructure and skills

- » Invest in advanced digital infrastructure and cybersecurity for clinical data management.
- » Harmonise regulatory standards with international bodies (e.g. International Council for Harmonisation, US Food and Drug Administration, European Medicines Agency).
- » Strengthen pharmacovigilance programmes.



Advancing towards a globally aligned RDP framework for the transformation of India's pharmaceutical sector



India's pharmaceutical sector is poised for transformative growth, but achieving its full potential will require a paradigm shift in regulatory policies. The evidence presented in this paper demonstrates that adoption of RDP is a strategic imperative for India's ambition to foster an innovation-friendly ecosystem, directly linked to accelerated clinical research and improved patient access to innovative therapies.

Global best practices show that robust RDP frameworks consistently correlate with higher availability of innovative medicines, increased clinical trial frequency, and earlier launches of innovative medicines. Reports from countries that have adopted RDP indicate measurable improvement in patient access and subsequent industry growth following implementation.

India's current regulatory landscape lacks RDP, resulting in limited clinical research, reduced incentives for innovation, and delayed launches. This can be addressed largely by adopting a globally harmonised RDP framework, safeguarding proprietary data, fairly incentivising originators, and simultaneously ensuring public health interests. Enhancing transparency, data governance, and institutional infrastructure, will enable India to establish an ecosystem that appropriately incentivises pharmaceutical research while upholding its commitment to accessible medicines.

In conclusion, strengthening RDP is the key driver to bridge the innovation gap, enhance global competitiveness, and deliver early patient access to transformative therapies. Policymakers, regulators, and industry stakeholders should work together to create a progressive RDP framework, positioning India as a leader in global pharmaceutical innovation.

References

1. Global medicine spending set to reach \$US1.6 trillion by 2025. PharmacoEcon Outcomes News. 2021;878(1):12.
2. International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). Always Innovating: Pharmaceutical Industry Facts & Figures 2024 [Available from: <https://www.ifpma.org/initiatives/alwaysinnovating-pharmaceutical-industry-facts-figures/>].
3. India Brand Equity Foundation. Pharmaceuticals 2025 [Available from: <https://www.ibef.org/industry/indian-pharmaceuticals-industry-analysis-presentation>].
4. Bain and Company. Healing the World: A Roadmap for Making India a Global Pharma Exports Hub 2025 [Available from: https://www.bain.com/globalassets/noindex/2025/bain_report-healing_the_world_a_roadmap_for_making_india_a_global_pharma_exports_hub.pdf].
5. Press Information Bureau. India's Pharmaceuticals in Global Healthcare-'From Domestic Production to International Markets' 2026 [Available from: <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2243248®=3&lang=2>].
6. IQVIA Institute for Human Data Science. Global Trends in R&D 2025: Progress in recapturing momentum in biopharma innovation. 2025 [Available from: <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/global-trends-in-r-and-d-2025/iqvia-institute-rd-trends-2025-forweb.pdf>].
7. Smart Pharma Consulting. Global Pharma R&D Overview 2025 [Available from: <https://smart-pharma.com/wp-content/uploads/2025/12/Global-Pharma-RD-Trends.pdf>].
8. DiMasi JA. Research and Development Costs of New Drugs. JAMA. 2020;324(5):517.
9. DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. J Health Econ. 2016;47:20–33.
10. World Bank Group. Research and development expenditure (% of GDP) - India 2020 [Available from: <https://data.worldbank.org/indicator/GB.XPD.RSDV.GD.ZS?locations=IN>].
11. Ministry of Science and Technology. Parliament question: R&D investment in India 2025 [Available from: <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2153547>].
12. SSTI. Useful Stats: An international comparison of R&D expenditures 2025 [Available from: <https://ssti.org/blog/useful-stats-international-comparison-rd-expenditures>].
13. Gawel CR. Patent protection as a key driver for pharmaceutical innovation. Pharmaceuticals Policy and Law. 2016;18(1-4):45–53.
14. Department of Pharmaceuticals. Scheme for Promotion of Research and Innovation in Pharma MedTech sector 2025 [Available from: <https://prip.pharma-dept.gov.in/>].
15. Press Information Bureau. Production Linked Incentive (PLI) scheme for the Pharmaceutical Sector 2021 [Available from: <https://www.pib.gov.in/PressReleasePage.aspx?PRID=1775321®=3&lang=2>].
16. Press Information Bureau. NBM -- an industry-Academia Collaborative Mission for accelerating biopharmaceutical development 2020 [Available from: <https://www.pib.gov.in/PressReleasePage.aspx?PRID=1606249®=3&lang=2>].
17. Pharmexcil. Pharmaceuticals Export Promotion Council of India - Role Of Council 2009 [Available from: <https://pharmexcil.com/content/role-of-council/442/8cfa6997d4cd231b69d5c1526cbd90d0.html>].
18. Press Information Bureau. Transforming India into a Global Biopharma Hub 2026 [Available from: <https://www.pib.gov.in/PressNoteDetails.aspx?NoteId=157147&ModuleId=3®=3&lang=1>].

19. Press Information Bureau. India's Leap in Research and Innovation 2025 [Available from: <https://www.pib.gov.in/PressReleasePage.aspx?PRID=2186327®=3&lang=2>].
20. Pharma Regulatory. Regulatory Data Protection in Pharma: Global Guide to Exclusivity and Compliance 2025 [Available from: <https://www.pharmaregulatory.in/regulatory-data-protection-rdp-explained-complete-guide-to-exclusivity-global-frameworks-and-compliance-strategy/>].
21. European Federation of Pharmaceutical Industries and Associations (EFPIA). Intellectual Property 2025 [Available from: <https://www.efpia.eu/about-medicines/development-of-medicines/intellectual-property/>].
22. Cook T. Regulatory data protection in pharmaceuticals and other sectors. In: A Krattiger RM, L Nelsen, et al, editor. Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices: MIHR: Oxford, U.K., and PIPRA: Davis, USA; 2007.
23. Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Government of India. The Drugs Rules, 1945 [As amended vide G.S.R. 360(E) dated 01-07-2024 (w.e.f. 01-07-2024)].
24. Yesh Kumar, Mukesh Maithani, Yadav R. Initiatives and Challenges in Schedule Y Regulation in India: Still Long Way to go International Journal of Pharmaceutical Sciences and Research. 2024;15(6):1558–71.
25. Central Drugs Standard Control Organization. Guidelines on similar biologics: Regulatory requirements for marketing authorization in India, 2016 [Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/biologicals/CDSCO-DBT2016.pdf].
26. Central Drugs Standard Control Organization. Guidelines on similar biologics: Regulatory Requirements for Marketing Authorization in India, 2025 [Available from: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/DgSimilaBiologics25.pdf].
27. Reddy S, Sandhu GS. Report on Steps to be taken by Government of India in the context of Data Protection Provisions of Article 39.3 of TRIPS Agreement 2007 [Available from: <https://chemicals.gov.in/sites/default/files/Reports/DPBooklet%5B1%5D.pdf>].
28. Government of India DGoHS, Central Drugs Standard Control Organization. Notice: Inviting comment to ensure a level playing field in new drug approval in India-reg. 08 October, 2025 [Available from: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=MTM0ODA=].
29. Yamaguchi S, Kaneko M, Narukawa M. Approval success rates of drug candidates based on target, action, modality, application, and their combinations. Clin Transl Sci. 2021;14(3):1113–22.
30. Organisation of Pharmaceutical Producers of India. OPPI Newsletter October-December 2024 [Available from: https://www.indiaoppi.com/wp-content/uploads/2025/12/OPPI_Newsletter_issue02.pdf].
31. Food and Drug Administration. Patents and Exclusivity. CDER SBIA Chronicles. May 2015 <https://wayback.archive-it.org/7993/20170406032014/https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM447307.pdf>.
32. European Medicines Agency. Data exclusivity, market protection, orphan and paediatric rewards 2018 [Available from: https://www.ema.europa.eu/en/documents/presentation/presentation-data-exclusivity-market-protection-orphan-and-paediatric-rewards-s-ribeiro_en.pdf].
33. European Commission. EU Pharmaceutical Reform: Incentives to steer innovation and achieve public health objectives 2024 [Available from: https://health.ec.europa.eu/latest-updates/factsheet-incentives-steer-innovation-and-achieve-public-health-objectives-2024-03-11_en].
34. Health Canada. Guidance Document Data Protection under C.08.004.1 of the Food and Drug Regulations 2025 [Available from: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/applications-submissions/guidance-documents/guidance-document-data-protection-under-08-004-1-food-drug-regulations.html>].

35. SIKs and Co. Data Exclusivity 2018 [Available from: https://www.siks.jp/wp-content/uploads/2018/01/Data_exclusivity.pdf].
36. Swissmedic. Guidance document Description of document protection 2019 [Available from: https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/authorisations/information/anpassung_wl_unterlagenschutz.html].
37. Aaron Gu, Cathy Zheng, Matt Zhang, Franky Yu, Naifang Zhang, Shuwen Sun, et al. Analysis of China's New Draft of Drug Regulatory Data Protection Rule: A New Perspective on Innovative Drug Transactions 2025 [Available from: <https://www.hankunlaw.com/en/portal/article/index/cid/8/id/15702.html>].
38. Jennifer Che JD, Yolanda Wang. China Released Drug Trial Data Protection Implementation Measures 2026 [Available from: <https://chinapatentstrategy.com/breaking-china-released-drug-trial-data-protection-implementation-measures/>].
39. Son M. New Korean regulatory data protection system allows reinforced data exclusivity for pharmaceuticals 2025 [Available from: <https://www.managingip.com/article/2ebi5vx1e18wmumugkum8/sponsored-content/new-korean-regulatory-data-protection-system-allows-reinforced-data-exclusivity-for-pharmaceuticals>].
40. International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). Data Exclusivity: Encouraging Development of New Medicines 2011 [Available from: https://www.ifpma.org/wp-content/uploads/2023/01/i2023_IFPMA_2011_Data_Exclusivity__En_Web.pdf].
41. Truluck C, Grant T. South Africa: winning strategies to keep pace with evolving pharma sector 2025 [Available from: <https://www.iam-media.com/guide/global-life-sciences/2025/article/south-africa-winning-strategies-keep-pace-evolving-pharma-sector>].
42. Pharmexcil. Regulatory and Market Profile of South Africa 2017 [Available from: https://pharmexcil.com/uploadfile/ufiles/South_Africa_Regulatory_Market_Profile.pdf].
43. Copenhagen Economics. Regulatory data protection for pharmaceuticals. How adopting regulatory data protection will impact patients, industry, and Brazilian society 2023 [Available from: https://copenhageneconomics.com/wp-content/uploads/2023/03/Regulatory-Data-Protection-for-Pharmaceuticals-in-Brazil_Final.pdf].
44. Cherian JJ, Poomali A, Mukherjee A, Gupta TM, Medhi B, Mukherjee S, et al. Increasing early phase clinical trials capacity in India. *Commun Med (Lond)*. 2025;5(1):255.
45. Copenhagen Economics. Regulatory data protection. How adopting regulatory data protection can increase medicine availability, innovation, and investment 2023 [Available from: <https://copenhageneconomics.com/wp-content/uploads/2023/09/Regulatory-Data-Protection-RDP-International-Report.pdf>].
46. Copenhagen Economics. Regulatory data protection for Pharmaceuticals. How implementing RDP in China will benefit society, industry and the Chinese economy 2024 [Available from: https://copenhageneconomics.com/wp-content/uploads/2024/07/Copenhagen-Economics_RDP-for-pharmaceuticals-in-China_JULY2024-_final.pdf].

Abbreviations

AI – Artificial Intelligence

ANRF – Anusandhan National Research Foundation

CDSCO – Central Drugs Standard Control Organization

DCGI – Drugs Controller General of India

EMA – European Medicines Agency

EU – European Union

FDA – Food and Drug Administration

GDP – Gross Domestic Product

GVA – Gross Value Added

IP – Intellectual Property

IPRs – Intellectual Property Rights

NCE – New Chemical Entity

NDCTR – New Drugs and Clinical Trials Rules

NMPA – National Medical Products Administration

OECD – Organisation for Economic Co-operation and Development

OPPI – Organisation of Pharmaceutical Producers of India

PLI – Production Linked Incentive

PMDA – Pharmaceuticals and Medical Devices Agency

PRIP – Promotion of Research and Innovation in Pharma MedTech

R&D – Research and Development

RDI – Research, Development and Innovation

RDP – Regulatory Data Protection

TRIPS – Trade-Related Aspects of Intellectual Property Rights

UK – United Kingdom

US – United States

USD – United States Dollar

WHO – World Health Organization

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