International Journal of Science and Research (IJSR)
ISSN: 2319-7064
Impact Factor 2025: 7.089

CRISPR-Oriented Theranostics: A Blueprint for Affordable Integration into the Indian Market

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Abstract: ***Recent regulatory approvals of the first CRISPR-based therapy (exa-cel/Casgevy) have validated genome editing as a clinical reality. Yet, multi-million-dollar pricing exposes a major access gap for low- and middle-income settings. India carries a high burden of hemoglobinopathies, infectious diseases, and cancers-precisely the domains where CRISPR diagnostics (e.g., SHERLOCK / DETECTR) and therapeutic platforms (ex vivo gene editing, cell therapies) can deliver outsized public-health gains. This manuscript presents a policy-to-practice blueprint for affordable and equitable integration of CRISPR-oriented theranostics in India. Using a structured literature and policy review, the article deconstructs the main cost drivers (autologous 'one patient-one batch' manufacturing, vector/reagent supply, clinical trial and long-term follow-up costs, and complex IP landscapes). It then proposes a four-pillar strategy: (1) agile but rigorous regulation with regulatory sandboxes and fast-track pathways for national-priority indications; (2) indigenous, frugal innovation focused on scalable processes (non-viral delivery, platform manufacturing) and public-private partnerships; (3) innovative financing through Ayushman Bharat, outcome-linked payments, and CSR-supported access programs; and (4) ecosystem building via accredited hubs, cold-chain logistics, ABDM-linked registries, and workforce development. A phased 10-year roadmap is provided to operationalize this strategy and to position India as a global hub for affordable gene therapy and CRISPR diagnostics.***

Keywords: CRISPR, theranostics, gene therapy, point-of-care diagnostics, affordability, India, public-private partnership, Ayushman Bharat

1.Introduction

In late 2023, CRISPR-based genome editing entered routine clinical discourse when regulators in the UK, US and Europe approved exagamglogene autotemcel (exa-cel/Casgevy) for sickle cell disease and transfusion-dependent beta-thalassemia (FDA; 2023). This milestone established that targeted 'search-and-replace' biology can translate into durable patient benefit. However, current pricing (multi-million US dollars per treatment) makes the promise of curative editing inaccessible to most patients globally, and particularly to India. India's public-health landscape-high prevalence of hemoglobinopathies, persistent infectious disease burden (e.g., TB), and a growing cancer load-creates both urgency and an opportunity to design a uniquely Indian, equity-first deployment model for CRISPR-oriented theranostics.

2.Material and Methods

This work is a narrative review and policy analysis. Evidence was synthesized from: (i) regulatory and public documents (e.g., Indian national guidance on gene therapy (ICMR; 2019) and policy notes on digital health (Narayan et al.; 2024)); (ii) peer-reviewed literature on CRISPR therapeutics, diagnostics, and manufacturing economics; and (iii) credible reports on India's indigenous advanced-therapy initiatives. The analysis focuses on implementation-relevant determinants: feasibility within Indian infrastructure, scalability, cost drivers, and ethical/governance requirements for genomic data.

3.Observations / Results

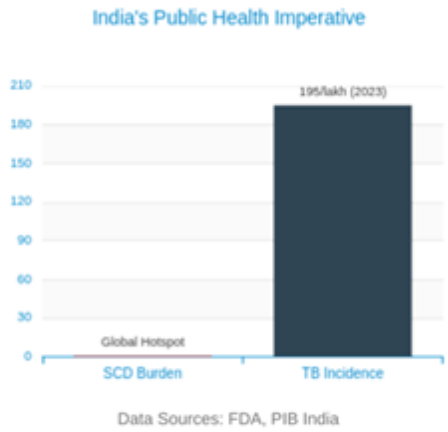
1. Technology Primer: Crispr as Therapeutics and Diagnostics

CRISPR-Cas systems combine a programmable guide RNA with an effector nuclease (Cas9/Cas12/Cas13). For therapeutics, Cas9-mediated DNA cutting can disrupt pathogenic genes or enable repair via cellular DNA repair pathways; ex vivo editing of hematopoietic stem cells is the current leading clinical paradigm. For diagnostics, collateral cleavage properties of Cas12/Cas13 power platforms such as DETECTR and SHERLOCK, enabling rapid, sensitive detection of pathogen nucleic acids or cancer biomarkers at point of care.

2. The Indian Imperative

India's burden of sickle cell disease and beta-thalassemia creates a strong health-economic rationale for curative interventions. CRISPR diagnostics are particularly relevant for high-throughput, field-deployable testing for TB and emerging infections. In oncology, CRISPR-enabled liquid biopsy workflows and improved cell therapies may enhance earlier detection and access to advanced treatment. India's approval of an indigenous CAR-T therapy (NexCAR19) demonstrates (PIB India; 2024): domestic readiness for advanced cell and gene therapy manufacturing and regulated clinical delivery.

The Infectious Disease Challenge



India continues to battle a heavy burden of infectious diseases, including tuberculosis (TB), malaria, and dengue. A major hurdle in controlling these diseases is the lack of rapid, affordable, and field-deployable diagnostic tools, particularly in rural and resource-limited settings. Traditional methods like PCR require centralized labs and skilled technicians. CRISPR-based diagnostics offer a powerful alternative. Platforms like SHERLOCK and DETECTR can be adapted into simple, paper-strip tests that provide results quickly and accurately, enabling early treatment and curbing transmission . This is particularly crucial for India's National TB Elimination Programme, which has made significant strides but still requires better diagnostic tools to reach its goals . Furthermore, this technology is vital for future pandemic preparedness.

The Rising Tide of Cancer

Like many developing nations, India is facing a growing cancer epidemic. CRISPR technology offers a multi-pronged approach to combat this challenge:

- **Early Diagnosis:** CRISPR-based liquid biopsies can detect circulating tumor DNA (ctDNA) with high sensitivity, enabling non-invasive and early diagnosis of various cancers, which is critical for improving survival rates .
- **Affordable Cell Therapies:** While Western CAR-T therapies are prohibitively expensive, India is already making strides in developing indigenous, low-cost versions. IIT Bombay and ImmunoACT';s development of India's first approved CAR-T therapy is a testament to this potential . CRISPR can further enhance the efficacy and reduce the cost of these homegrown therapies.

Figure 1: India’s Public Health Imperative (Illustrative Charts).

3. Affordability Conundrum: Drivers of Current Cost

Current CRISPR therapies are predominantly autologous, requiring individualized manufacturing (cell harvest, shipment, editing, expansion, quality control, and return logistics). Clinical-grade reagents and viral vectors remain major cost bottlenecks. Development costs are amplified by multi-phase trials and mandated long-term follow-up. A complex IP and licensing landscape further increases final pricing.

- **Advanced Research:** The technology allows researchers to create more accurate cancer models in the lab, accelerating the discovery and validation of new drugs tailored to the genetic makeup of Indian populations .

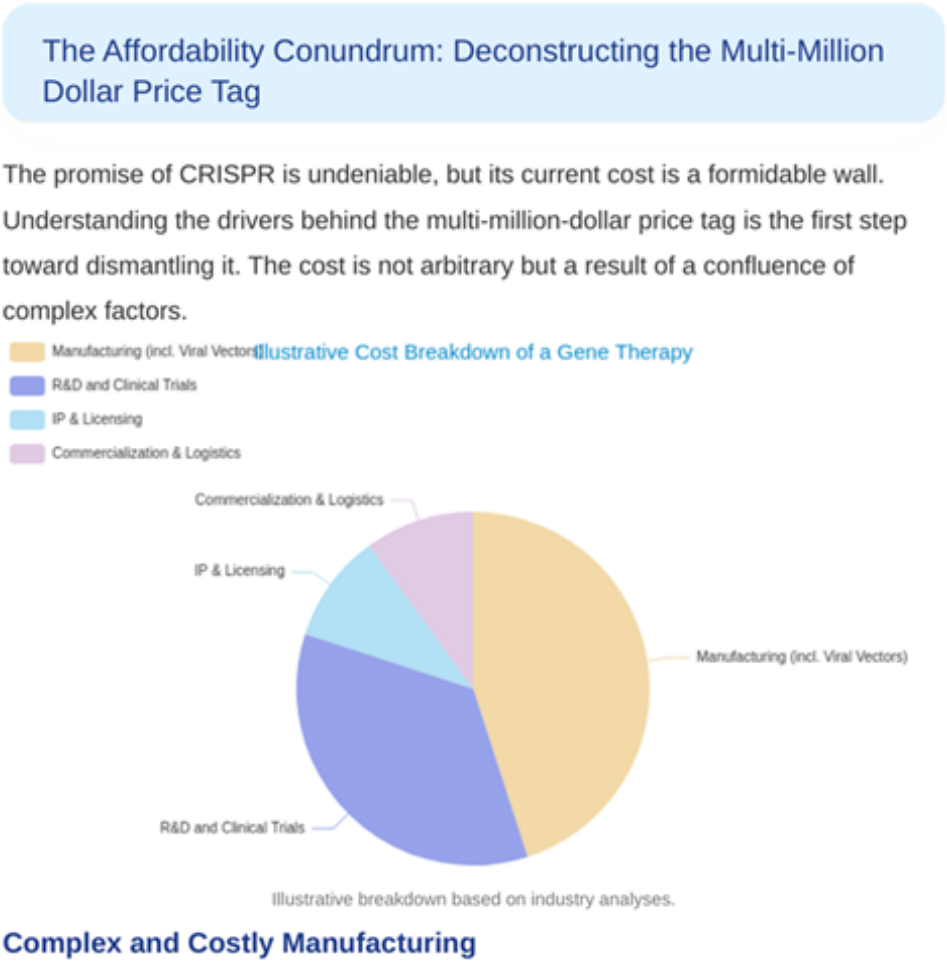


Figure 2: Illustrative Cost Breakdown of a Gene Therapy

Figure 2 provides an illustrative cost decomposition commonly attributed to manufacturing, R&D/clinical trials, IP/licensing, and commercialization/logistics.

4. Strategic Blueprint: Four Pillars for Affordable Access

Pillar 1-Policy and regulation: establish clear, unified regulatory pathways; create sandboxes for low-risk CRISPR diagnostics; and enable fast-track approvals for national-priority indications.

Pillar 2-Indigenous innovation and frugal science: prioritize scalable, low-cost processes (including non-viral delivery and platform manufacturing), and use public-private partnerships to build shared cGMP facilities and clinical trial networks.

Pillar 3-Financing and reimbursement: integrate therapies into Ayushman Bharat where feasible; adopt outcome-linked installment models; and leverage CSR for infrastructure and patient access.

Pillar 4-Ecosystem building: develop accredited hubs for collection/manufacturing, reliable cold-chain logistics, ABDM-linked registries for outcomes, and a trained workforce of clinicians, genetic counselors, and bioprocess engineers.

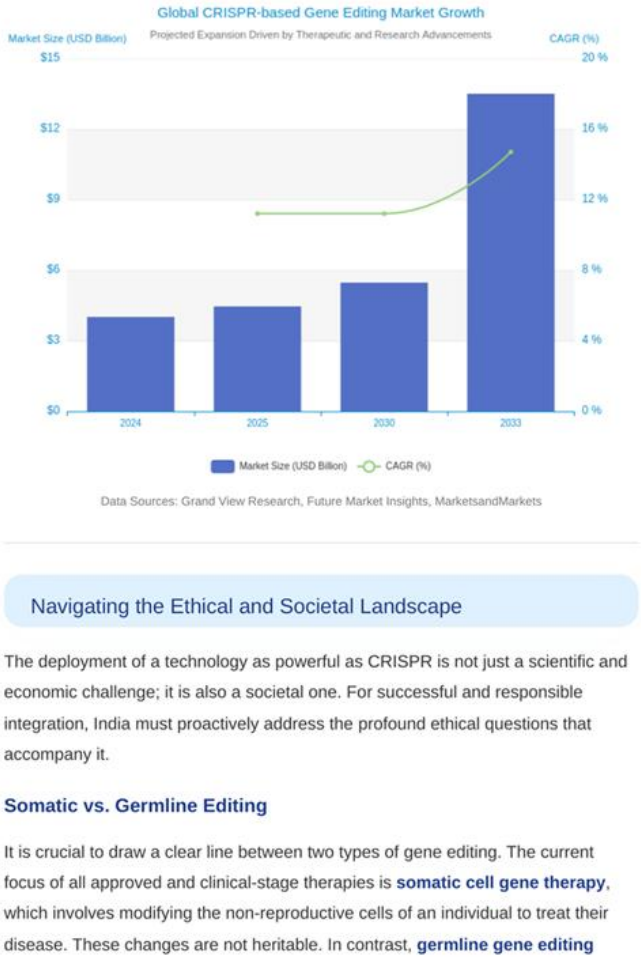


Figure 3: Global Crispr Gene Editing Market Growth (Illustrative)

Figure 3 (illustrative) emphasizes the rapid global expansion of CRISPR-based platforms, reinforcing the need for early ecosystem readiness.

5. Operational Roadmap (10-Year, Phased)

Phase	Domain	Key actions (illustrative)	Core outcomes / KPIs
Years 1-3 (Foundational)	Policy & regulation	Operationalize a national gene-therapy advisory pathway; publish harmonized trial guidance; create regulatory sandbox for CRISPR POC diagnostics.	Guidance published; sandbox operational; ≥5 diagnostic products enter sandbox.
Years 1-3 (Foundational)	R&D and tech transfer	Launch mission-mode CRISPR programs for SCD/thalassemia and TB diagnostics; establish 3-5 PPP Centers of Excellence.	10-15 funded projects; 2-3 process-innovation patents filed.
Years 4-6 (Scaling)	Infrastructure & talent	Hub-and-spoke model for cell collection/processing; regional training centers; accredited cold-chain logistics.	Network covers ≥10 states; ≥2,000 personnel trained annually.
Years 4-6 (Scaling)	Financing & market access	Pilot reimbursement under Ayushman Bharat; introduce outcome-linked payments with insurers.	≥1,000 patients covered in pilots; first outcome-linked contract executed.
Years 7-10+ (Democratization)	Standard of care & governance	Integrate proven CRISPR diagnostics/therapies into national programs; strengthen genomic data privacy enforcement.	>50% eligible patients have access; robust genomic governance implemented.
Years 7-10+ (Democratization)	Manufacturing self-reliance	Domestic manufacturing of critical reagents/vectors; invest in next-gen editing (in vivo, prime editing).	>80% key reagents made in India; first in vivo candidate enters trials.

4.Discussion

CRISPR-oriented theranostics offers India a rare opportunity to leapfrog legacy constraints by coupling frugal innovation with digital public infrastructure. The largest risks are predictable: inequitable access, supply-chain fragility for vectors and enzymes, and regulatory fragmentation. Proactive governance is required, particularly to delineate permissible somatic editing from prohibited germline interventions and to protect sensitive genomic data under India's evolving privacy framework. India's indigenous advanced-therapy experience (e.g., domestic CAR-T) indicates that a 'Serum Institute model'-process innovation plus scale-can be replicated for gene therapy, provided the ecosystem is built deliberately.

Ethical and Societal Considerations

Somatic therapies should remain the ethical and regulatory focus; germline editing should remain prohibited. Informed consent must be strengthened given long-term uncertainties. Equity must be treated as a design constraint (not an afterthought), with public financing and geographically distributed delivery. Genomic data stewardship should include clear purpose limitation, access control, audit trails, and registry-based outcome monitoring.

5.Conclusion

The translation of CRISPR from revolutionary science to an accessible Indian reality is achievable if India aligns regulation, indigenous manufacturing, financing, and ecosystem capacity under a mission-mode roadmap. By targeting high-burden diseases, leveraging ABDM for outcomes learning, and adopting innovative payment models, India can reduce costs dramatically and provide a global blueprint for equitable access to next-generation theranostics.

Acknowledgements

None.

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