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Cell and Gene Therapy: How Close Is India to the Frontier?

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India now has approved cell therapies and internationally published gene therapy research. Its next phase of progress will depend not only on scientific discovery, but on whether advanced therapies can be evaluated, manufactured and delivered consistently at scale.



India's position depends partly on how the frontier is defined. One measure is scientific novelty, reflected in advances in cell engineering, gene editing and delivery technologies. Another is translation, meaning whether a therapy can move from laboratory to regulated manufacturing and clinical use at a cost and level of complexity that a health system can absorb.

India is advancing on both measures, although at different speeds. Its strongest emerging proposition may lie in translation, particularly in models that reduce manufacturing cost and logistical complexity. That is also where regulatory capability, research funding and specialised infrastructure are likely to have the greatest near-term effect.

A demonstrable path to patients

Developments since late 2023 show that a route from Indian research to clinical application is beginning to take shape. In October 2023, the Central Drugs Standard Control Organisation (CDSCO) approved NexCAR19, India's first approved CAR-T cell therapy, developed by ImmunoACT, a company incubated at IIT Bombay, through work involving the Tata Memorial Centre. In January 2025, a second CAR-T therapy was approved in India. Manufactured in Bengaluru, it was clinically developed in India using technology licensed from Hospital Clínic de Barcelona, and its phase 2 study reported an overall response rate of 83.3 per cent at 90 days.

Indian researchers have also generated early evidence in gene therapy. A first-in-human study at Christian Medical College (CMC) Vellore treated five participants with severe haemophilia A using their own haematopoietic stem cells modified with a lentiviral vector. All five recorded an annualised bleeding rate of zero during the observation period. The results were published in the New England Journal of Medicine. The findings are encouraging, although the cohort was small, the study was conducted at a single centre, and longer follow-up will be important in assessing durability and safety.

The GenomeIndia Project provides a complementary foundation. Whole genome sequencing of 10,000 samples has created a controlled-access resource at the Indian Biological Data Centre that could support identification of population-specific variants and more representative precision-medicine research.

Read together, these developments show that the journey from Indian research institutions to regulated advanced therapies is possible. The larger question is how repeatable and how scalable that journey can become.

Affordability as a field of innovation

One area of Indian experimentation deserves attention: manufacturing close to the point of care.

In the phase 1 VELCART study at CMC Vellore, anti-CD19 CAR-T cells were produced on a closed, automated platform sited near the treating centre. Eight of ten participants remained free of disease progression at a median follow-up of 15 months. The published analysis estimated the manufacturing cost at approximately Rs 30 lakh and the median healthcare-resource cost near Rs 11 lakh per patient.

The ten-patient study offers early evidence rather than an established economic model. Evidence across more patients and centres would help determine whether the potential logistical and economic benefits hold at scale.

The question matters because the potential need is considerable. National Health Mission guidance estimates that roughly 1 - 1.5 lakh children in India have thalassemia major, alongside a substantial carrier population. Under the National Sickle Cell Anaemia Elimination Mission, the Ministry of Health and Family Welfare reported more than 6.07 crore screenings as of July 31, 2025. Advanced therapies will not substitute for public health measures, but affordability and delivery capacity will shape how many eligible patients can eventually benefit.

Building regulatory capability

Policy direction has been increasingly attentive to the efficiency of pharmaceutical research. The New Drugs and Clinical Trials Rules, 2019 established defined pathways and timelines for clinical research and new drug approvals. Amendments notified in January 2026 introduced prior intimation for certain categories of non-commercial manufacture and reduced the statutory processing period for specified test licences from 90 to 45 working days. These changes strengthen the broader research environment, although the simplified route does not apply to certain specified categories and advanced therapies will continue to warrant risk-appropriate scrutiny.

A further opportunity lies in deepening specialised review expertise and coordination. Cell and gene therapy products may engage CDSCO, institutional committees and, where genetically modified material is involved, biotechnology oversight mechanisms. Dedicated expert capability for this category was anticipated in the 2019 national guidelines on gene therapy products. Coordinated scientific advice could give developers greater predictability without altering safety standards.

As manufacturing moves closer to the point of care, greater clarity on how existing requirements apply across hospital-based sites could support consistent implementation. Responsibility for oversight, release testing, chain of identity, comparability between sites and long-term pharmacovigilance needs to remain unambiguous in that setting.

Shared foundations and specialised infrastructure

India's early outcomes have come largely from concentrated programmes involving academic centres, hospitals and biotechnology companies. The next stage calls for capabilities that support several products rather than one.

These include domestic access to viral vectors, plasmids and GMP-grade pilot manufacturing, alongside quality control and release testing capacity. Shared platforms for vector design, delivery technologies and gene editing tools could reduce duplication and let later programmes build on established foundations. The BioE3 Policy offers a relevant enabling framework, with precision biotherapeutics among its thematic sectors and provision for biofoundries and biomanufacturing hubs. Their value will depend on effective links between research, regulation and manufacturing.

Clinical capacity must expand in parallel. As use grows, the specialised capabilities required for delivery, including apheresis, cryogenic logistics, laboratory support, toxicity management and long-term follow-up, will need to develop beyond the present network of experienced centres. Widening that network carefully is what turns individual approvals into broader clinical capability.

Reading the trajectory

India is closer to the cell and gene therapy frontier than it was a few years ago, with approved products, internationally published early-stage outcomes, and a policy environment increasingly attentive to advanced biomanufacturing.

The evidence base nevertheless remains early and concentrated in a small number of programmes. The immediate opportunity is not to claim leadership across every scientific dimension, but to build a credible model for translating advanced therapies within a resource-conscious health system.

If scientific capability can be combined with predictable review, dependable manufacturing and trained clinical networks, India's contribution could extend beyond individual therapies. It could help show how sophisticated treatments move closer to patients while remaining workable for large and diverse health systems.

Srikanth Mahadevan, Director, Strategy, Risk & Transactions, Monitor Deloitte