

New Approach Methodologies (NAMs) as an emerging Sunrise R&D Sector for India



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Executive Summary

Drug discovery and development is undergoing a global shift away from animal testing toward human-relevant, predictive science. This shift is driven by the poor translatability of animal models: only 10–14% of drugs entering Phase I trials ultimately gain approval. In addition, the growing demands of personalized medicine, where animal models cannot adequately capture the nuances of patient-specific biology are further driving this shift. New Approach Methodologies (NAMs) — including organ-on-chip systems, organoids, iPSC-derived models, in silico/AI modeling, and human cell-based assays — offer a paradigm shift toward more mechanistic, patient-relevant drug development and safety testing.

This shift is already reflected in major regulatory and funding action worldwide. The US has passed the FDA Modernization Acts 2.0 and 3.0, released a roadmap to reduce animal testing, and committed \$400M through the NIH's Complement-ARIE program. The UK has proposed £75M toward a national NAMs strategy, while the EU has adopted a roadmap to phase out animal testing for chemical safety with over 30 legislative recommendations, alongside its Biotech Act fast-tracking NAMs. South Korea and China have launched parallel national initiatives, underscoring that NAMs adoption is now a global regulatory and scientific priority.

India has also made meaningful early progress — from ICMR's 2017 roadmap and over 100 supported research projects, to working groups at the Indian Pharmacopoeia Commission and Bureau of Indian Standards, and a growing ecosystem of 60+ labs and start-ups developing NAMs. Several NAM-based technologies developed globally have already achieved regulatory acceptance across indications including cancer, rare diseases, drug-induced liver injury, cardiovascular disease, and vaccine quality control, demonstrating clear scientific and regulatory viability.

However, India risks falling behind without a coordinated national strategy. The paper recommends five priority actions: establishing a National Centre to coordinate NAMs efforts across ministries and agencies; dedicated investment in validation and commercialization to move technologies out of the developmental bottleneck; building an indigenous supply chain for reagents and equipment to reduce cost and import dependency; early engagement with industry and regulators to ensure end-user adoption and regulatory acceptance; and training and awareness programs to build a skilled workforce for these emerging technologies.

With coordinated action on these fronts, India has a genuine opportunity to become a global leader in the development, validation, and regulatory implementation of NAMs — advancing a new, human-relevant paradigm for drug development and testing.

New Approach Methodologies

Introduction:

Drug discovery and development is undergoing a fundamental global shift toward human-centric, predictive, and mechanistic science, driven by the growing recognition of the scientific, ethical, and translational limitations of animal models. Recent analyses indicate that only 10–14% of drug candidates that enter Phase I trials achieve regulatory approval, indicating the translational

disconnect. In addition, the rapid advancements in personalized medicine call for an urgent need to develop human-relevant models, where animal models may have a very limited ability to capture genetic, molecular, and physiological diversity that underlies patient-specific responses to disease and treatment.

Thus, New Approach Methodologies or NAMs represent a paradigm shift towards how drug development and safety testing are increasingly performed. (Figure 1).

These include:

- Complex in vitro models (CIVMs) such as organoids, organ-on-chip platforms, spheroids and bioprinted tissues to mimic the structure and function of a tissue or organ.
- Patient-derived induced pluripotent stem cells (iPSCs) models reflecting individual genetic backgrounds.
- In silico technologies, including AI-driven disease modelling, virtual patient simulations and digital twins.
- Ex vivo human models that use cells, tissues, or organs removed from an organism and maintained or studied outside the body under controlled laboratory conditions.
- Human cell-based assays to measure a specific biological response, pathway, or functional endpoint.
- Real-world human data.

NAMs may refer to a single approach or a combination of in vitro and in silico approaches to understand a specific biological mechanism, drug/chemical/vaccine response.

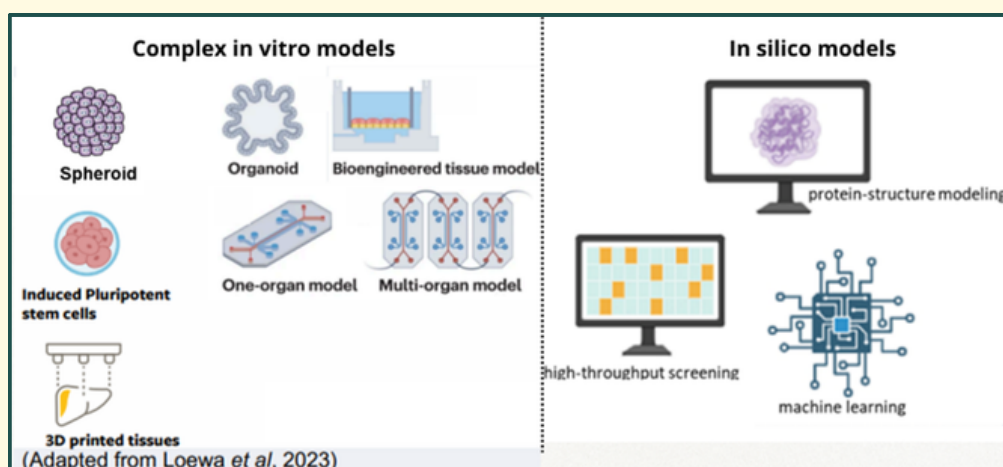


Figure 1: New Approach Methodologies

Global shift towards NAMs in research and testing

United States FDA (US FDA)

US Food and Drug Administration (FDA) Modernization Act 2.0 authorises the use of certain alternatives to animal testing, including cell-based assays and computer models, to investigate the safety and effectiveness of a drug. FDA Modernization Act 3.0, which was also recently passed by the Senate, requires the FDA to update its IND regulations, replacing any references to 'animal' tests, studies, research, data, and models with 'nonclinical' tests, studies, research, data, and models. In 2025, US FDA released a "[Roadmap to Reducing Animal Testing in Preclinical Safety Studies](#)",

that outlined the strategy to phase down animal testing by promoting NAMs, including AI models, organ-on-chip systems, and cell-based assays. In addition, [NIH announced](#) it will no longer develop new funding opportunities focused exclusively on animal models of human disease. The Center for Drug Evaluation and Research (CDER) also released a Guidance document for industry on the "[General Considerations for the Use of New Approach Methodologies in Drug Development](#)".



Figure 1: Regulation, Policies, and Funding for NAMs in the US

In 2024, the NIH Common Fund announced the \$400 M funding program "[Complement Animal Research In Experimentation \(Complement-ARIE\)](#)" program to accelerate the development, standardization, validation, and use of human-based New Approach Methodologies (NAMs).

“Through New Approach Methodologies (NAMs) — including AI-powered models, human organ-on-a-chip systems, and real-world data— we're accelerating safer treatments to patients faster while reducing costs and sparing thousands of laboratory animals annually. This represents a win for patients, innovation, and ethics. — US FDA”

United Kingdom (UK)

In 2025, the UK government released a Roadmap towards a strategy to support the development, validation and uptake of alternative methods and replace animals in science. The roadmap identifies opportunities to replace certain animal

uses with scientifically robust and validated alternative methods both immediately and over the longer term (Figure 2). It also proposed £75 million funding towards this initiative.

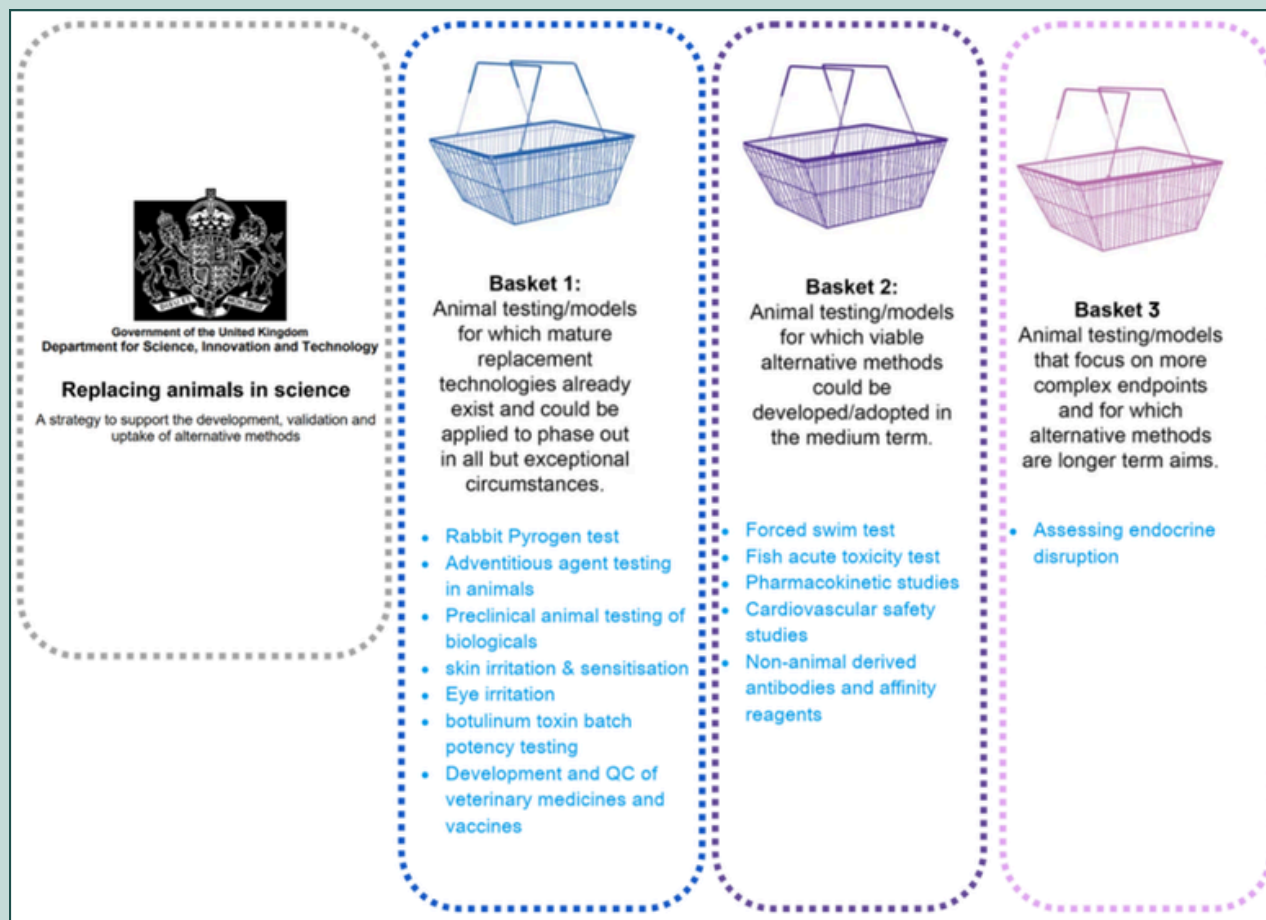


Figure 2: The UK Roadmap to Support the development, validation, and uptake of NAMs

European Union (EU)

On 1 June 2026, the European Commission adopted the Roadmap towards phasing out animal testing for chemical safety assessments. The document includes a wide range of legislative domains, including industrial chemicals, pharmaceuticals, and food additives, and outlines over 30 key recommendations to facilitate the

transition to alternative testing methods. The European Union (EU) has also recently passed the EU Biotech act in 2025, which identifies the use of NAMs as one of their "high-impact strategic projects," offering faster regulatory approvals, regulatory sandboxes, and prioritized funding.



Figure 3: The EU Roadmap to phase out animal testing for chemicals

PILLAR 1 OPPORTUNITIES			
High-level Goal	Specific-linked action	Sector	Timeline
Replacement	Computational models for acute oral toxicity, pharmacokinetic modelling	Industrial chemicals	Short-term
Replacement	In vitro assays - developmental neurotoxicity, embryofoetal lethality, pyrogenicity, sensitisation	Cross-sectoral	Short-/mid-term
Reduction/Replacement	Reduce / replace animal studies for genotoxicity or carcinogenicity	Cross-sectoral	Mid-term
Reduction/Replacement	Reduction of repeated dose toxicology (RDT) studies for advanced cancers	Pharmaceuticals	Short-/mid-term
Reduction/Replacement	Complex in vitro models to predict drug-induced liver injury/ pharmacokinetics/ cardiotoxicity / immunotoxicity	Pharmaceuticals	Short-/mid-term

PILLAR 1 OPPORTUNITIES

High-level Goal	Specific-linked action	Sector	Timeline
Reduction/Replacement	Virtual control group	Pharmaceuticals	Short-/mid-term
Reduction/Refinement	Use of evident toxicity rather than lethality as endpoint in acute toxicity studies	Cross-sectoral	Short-term

South Korea

South Korea's Ministry of Environment has introduced its "[2030 Chemical Safety and Animal Welfare vision](#)" with a goal of more than 60% of data use for chemical assessment by 2030 to be using non-animal methods.

China

In July 2026, China's Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) announced a pilot programme called PIONEER: Propel Innovation and Operation of NAMs to Enhance Efficiency in R&D. The CDE published draft documents for public consultation covering the application guidelines, application form and implementation framework



Figure 4: China's R&D Program in NAMs

Status in India

There have been a lot of advancement in the last few years in NAMs in India.

These are highlighted below:

1. In 2017, Indian Council of Medical Research (ICMR) set-up an expert committee which produced a white paper on "INDIAN ROAD MAP for Alternatives to Animals in Research: Past, Present, and Future" under the guidance of the then DG ICMR Dr Balram Bhargava.
2. Dr Soumya Swaminathan, ex DG ICMR wrote a [perspectives paper](#) in Indian Journal of Medical Research (IJMR). She recommended the creation of "Centers of Excellence (COE) where 'Alternatives to Animals' research in India can be compared and compete with the elite COE in western countries.
3. In 2020, a Rajya Sabha Parliamentary Standing Committee on Health and Family Welfare recommended the follow-up actions mentioned in ICMR White paper.

4. ICMR has supported a total of [109 research projects](#) in the area of NAMs, including organ-on-chip, three-dimensional (3D) tissue models, and computer-based approaches, through its various research schemes.
5. Indian Pharmacopoeia Commission (IPC) has set-up a "[Non-Animal Methods Working Group](#)" to deliberate the incorporation of NAMs in Indian Pharmacopoeia.
6. The Bureau of Indian Standards (BIS) has set up a Working Group on "[Organoids and Microphysiological Systems](#)" to develop National Standards in this area.
7. In 2026, Indian Pharmaceutical Alliance (IPA) has set-up a NAMs Industry Consortium.

Landmark Amendment to NDCT Rules, 2019

In 2023, MINISTRY OF HEALTH AND FAMILY WELFARE brought about an Amendment in New Drugs and Clinical Trial Rules (2019), now termed as New Drugs and Clinical Trials (Amendment) Rules, 2023 which permitted the use of the following nonclinical methods to assess a new drug's safety and efficacy:

- (i) Cell-based assay;
- (ii) Organ chips and micro physiological systems;
- (iii) Sophisticated computer modeling;
- (iv) Other human biology-based test methods to assess safety and efficacy of drugs.

14. There are currently 60+ labs, companies, start-ups developing NAMs for various Contexts of Use in India at Technology Readiness Level (TRL) 4 and above (Figure 5)

Ecosystem Snapshot: Organisations at TRL $\geq$ 4

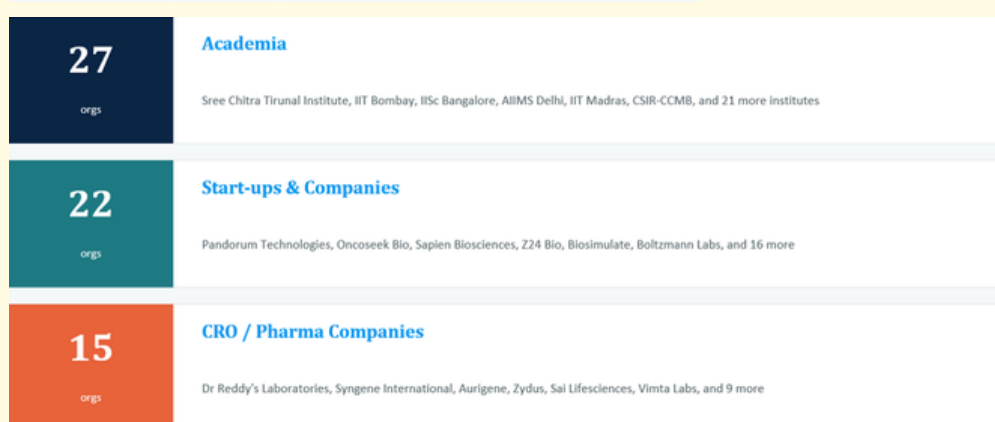


Figure 5: Status of development of NAMs in India

Success Stories

In the below Table, there are some prominent examples where NAMs have already received or at an advanced stage towards receiving regulatory acceptance

Indication	NAM developer	Modality	In vitro or In silico model	Regulatory status
Cancer	SillaJen	Small molecule (BAL0891) + antibody (Tislelizumab)	Tumor Organoid - vTIME™ vascularized tumor-immune microenvironment organoid model	Accepted by US FDA as a part of package for Phase I trials
Rare diseases	Sanofi	Antibody (TNT005)	Organ-on-chip data accepted in IND submissions for advanced therapies.	Proceeded to Phase I trials based on efficacy data from NAM
Drug-induced liver injury (DILI)	Emulate	Small molecule	Liver-on-chip	Currently in Phase 3 of FDA I STAND program
			AI-driven digital liver model	Accepted in FDA I STAND program

Skin irritation, eye irritation, skin sensitisation	L'oreal MatTek	Small molecules, cosmetic ingredients, chemicals, pesticides/industrial chemicals	Reconstructed human epidermis (RhE)	Accepted by OECD
			Reconstructed Human Cornea-like Epithelium (RhCE)	Accepted by OECD
Cardiovascular diseases	CiPA program by FDA and other	Small molecule	Combination of in vitro and in silico methods developed to assess arrhythmia risk	In vitro + in silico approaches recognized in 2022 ICH E14/S7B regulatory guidance.
COVID-19	Harvard University (Wyss)	Small molecule	A human "lung-on-chip" developed to identify and evaluate therapeutic candidates for COVID-19	Several candidates subsequently progressed to clinical trials.
Pyrogen testing	Lonza, Merck, MAT Research etc.	Small molecule, vaccines, biologics, cell & gene therapy, medical devices, radiopharmaceuticals, water	Monocyte Activation Test (MAT)	Accepted in Eu, US, Indian, Brazil Pharmacopeia
Endotoxin testing	BMX, Lonza, BioEndo	Small molecule, vaccines, biologics, cell & gene therapy, medical devices, radiopharmaceuticals, water	Recombinant Factor C Recombinant Cascade reagent	Accepted in Eu, US, Indian, Brazil Pharmacopeia
Physiologically based pharmacokinetic and pharmacodynamic (PK-PD) modelling	Certara, Simulation Plus, Open Systems Pharmacology (OSP)	Small molecule, biologics, mAbs, etc	In silico models	<u>PBPK Program by US FDA</u> <u>US FDA's Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products</u>
In vitro potency Rabies vaccine (QC)	Serum Institute of India	Vaccines	In vitro antibody-based ELISA	Accepted by Eu Ph, USP, Indian Pharmacopoeia

Recommendation

1. National Centre for Human-relevant Research

Globally, many countries, such as the US, UK, EU, Japan, South Korea, and Brazil have set up National Centers to coordinate NAMs work and work towards a defined strategy and vision towards phasing in human biology-based pipeline for drug development and testing. In India, such a Centre could play a crucial role in streamlining the activities currently spread across different Ministries and Government bodies. For example, NIH formally launched Office of Research Innovation, Validation, and Application (ORIVA) to coordinate NIH-wide efforts to develop, validate and scale human-based research technologies.

2. Dedicated investment – validation and commercialization

Despite an exponential growth in the development of these models in India in the last 6-7 years, most of these technologies are stuck in the validation and commercialization stages due to lack of dedicated investment. To make these technologies accessible to Indian stakeholders, dedicated investment models may be needed to ensure these methods are accessible and

available at a cost-effective price point.

3. Indigenous supply chain

As these technologies are currently imported from global north countries, it reduces their accessibility due to cost and timelines. With the changing global landscape, the advantages of having an indigenous supply chain, including reagents, Matrigel, advanced microscopy etc – have never been more apparent.

4. Early engagement with regulators and industry

To ensure the adoption of these technologies post-development, there is an urgent need to have early engagement with both industry and regulators during the development stages to ensure these technologies have end-users and regulatory acceptance.

5. Training and awareness

These are also critical parameters to ensure adoption as these are emerging, next generation technologies, and thus, not many personnel are trained to work in them.

Conclusion

New Approach Methodologies represent an important transformation in the way biomedical research, drug development and safety assessment are being undertaken globally. The transition is being driven not merely by the objective of reducing dependence on animal experimentation, but increasingly by the scientific imperative to develop models that are more predictive of human biology, disease mechanisms and therapeutic responses. Technologies such as organoids, organ-on-chip systems, patient-derived cellular models, human cell-based assays, advanced computational modelling, artificial intelligence and real-world human data offer the potential to improve the quality, speed and relevance of decision-making across the drug-development lifecycle.

The international landscape is evolving rapidly. Regulatory agencies, research funding organisations and governments are increasingly establishing frameworks to encourage the development, validation and regulatory use of NAMs. Initiatives in the United States, United Kingdom, European Union, China and South Korea demonstrate a clear movement towards integrating human-relevant methodologies into mainstream research and regulatory science. Importantly, this transition is being supported through dedicated funding, regulatory guidance, national roadmaps, validation programmes and coordinated institutional mechanisms. The growing number of NAMs already accepted or being evaluated for regulatory applications demonstrates that these technologies are moving beyond proof-of-concept research towards practical deployment.

India has developed a promising foundation in this area. Initiatives undertaken by ICMR, the Indian Pharmacopoeia Commission, Bureau of Indian Standards, academic institutions, industry and start-ups have helped create an emerging ecosystem of human-relevant research technologies.

The presence of more than 60 laboratories, companies and start-ups developing NAM platforms at meaningful levels of technology readiness, along with significant research supported by ICMR, reflects the growing scientific capability available within the country. The establishment of industry-led initiatives such as the NAMs Industry Consortium further provides an opportunity to connect technology developers with potential users.

The next phase, however, requires moving systematically from technology development to validation, regulatory acceptance, commercialisation and widespread adoption.

Addressing this gap will require coordinated action across government, regulators, research institutions, industry, funding agencies and standards organisations.

Early and continuous engagement between developers, regulators and end-users should become an integral part of NAM development. Regulatory expectations and industry requirements need to be incorporated at the design stage rather than after a technology has been developed. India will also need a strong national programme for training and capacity building so that researchers, regulators and industry scientists acquire the multidisciplinary capabilities required to effectively develop, evaluate and deploy these emerging platforms.

With its strengths in pharmaceuticals, biotechnology, information technology, artificial intelligence, engineering and a large scientific talent base, India has an opportunity not only to adopt NAMs but also to become a significant global developer and supplier of human-relevant research technologies. A coordinated national effort can accelerate drug development, improve patient relevance, strengthen regulatory science, reduce dependence on imported technologies and create new high-value biotechnology and deep-tech opportunities.

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