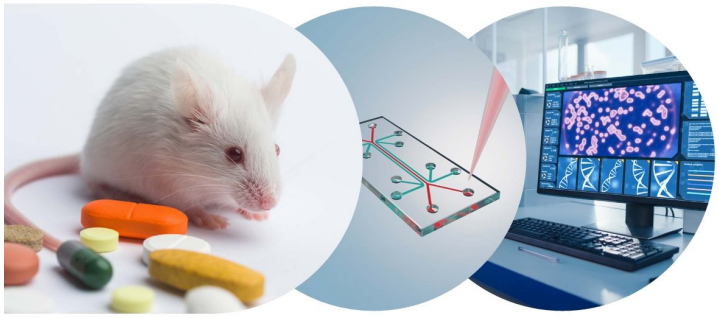
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Industry seeks establishment of central agency for non-animal testing methods

05 February 2026 | News

Landscape analysis on alternatives to animal testing for drug development in India



As India's pharmaceutical industry moves towards becoming a $500 billion global powerhouse by 2047, as part of the country's Viksit Bharat vision, a new multi-stakeholder report highlights the growing role of **non-animal, science driven**

testing methods in strengthening drug development, improving translational science, and accelerating innovation.

The report titled *"Landscape Analysis on Alternatives to Animal Testing for Drug Development in India"*, was jointly developed by **Humane World for Animals India, DBT-InSTEM, Animal Law and Policy Network and Dr. Reddy's Laboratories Limited.**

Key sector-specific findings from the report highlight significant opportunities across categories:

- **Establish an industry-led consortium** to advocate for adoption of the **3Rs—Replace, Reduce and Refine**, raise awareness of global best practices, and enable structured engagement with regulators
- **Create a central agency for Non-Animal Methods (NAMs)** to support validation, standardisation, and integration of NAMs into regulatory review and submissions
- **Accelerate replacement of animal-based pyrogen testing** by promoting validated alternatives such as the **Monocyte Activation Test (MAT)** and **recombinant Factor C (rFC) assay**, supported by training, standardisation, and improved reagent availability
- **Invest in indigenous infrastructure**, including local biobanks, reagents, culture media, software platforms, and testing tools, to reduce costs and logistical barriers
- **Establish hub-and-spoke Centres of Excellence (CoEs)** to support NAMs research, infrastructure development, and workforce training across the country
- **Strengthen capacity building and awareness**, through workshops, training programmes, and multi-stakeholder engagement to build confidence in NAMs
- **Enhance regulatory engagement and policy alignment**, including strengthening 3R-related language in the New Drugs and Clinical Trials (NDCT) Rules, updating guidance on NAM adoption, and enabling routine inclusion of validated NAMs in regulatory submissions