

PARLIAMENT QUESTION: Promotion of Non-Animal Methods in Scientific Research

प्रविष्टि तिथि: 06 AUG 2026 2:54PM by PIB Delhi

The Government recognizes that limited availability of validated human-relevant, non-animal models can affect the pace and efficiency of drug discovery and pre-clinical research, increase dependence on conventional animal studies and influence research costs and clinical translation. Laboratories across ministries namely, CSIR, ICMR and DBT are therefore promoting and strengthening use of advanced in-vitro, 3D tissue/organoid, cell-based and computational approaches for drug discovery, toxicity assessment and biomedical research. However, these methodologies currently complement, rather than fully replace, animal models, particularly for complex biological studies. The details are as below:

1. ICMR has supported a total of 109 research projects in the area of non-animal testing methods, including organ-on-chip, three-dimensional (3D) tissue models, and computer-based approaches, through its various research schemes. These projects are being implemented across 71 institutes/laboratories throughout the country
2. Council of Scientific and Industrial Research (CSIR) recognises the growing importance of New Approach Methodologies (NAMs), including advanced in-vitro and cell-based systems, 3D tissue models/organoids, organ-on-chip platforms and in-silico approaches, as alternatives to animal experimentation. Eight CSIR laboratories have reported capabilities/activities in one or more such alternative approaches, with facilities varying across laboratories.
3. The autonomous institutions of the Department of Biotechnology (DBT), engaged in medical research, are equipped with advanced infrastructure and state-of-the-art facilities for supporting cutting edge research in biotechnology including research on development and validation of non-animal methods and models.
4. One of the DBT autonomous institutions, namely BRIC- Institute for Stem Cell Science and Regenerative Medicine (inStem) at Bengaluru has dedicated infrastructure to support non-animal studies that includes Biological platforms for cell culture facilities and organoids; labs for 2D/3D cultures and co-cultures; micro-physiological systems (organ-on-a-chip) and bioreactors; analytical and measurement tools; high throughput screening and automation and computational resources including data storage and integrative analysis pipelines.
5. In addition to the infrastructure, the inStem also has established institutional programs such as Programme in Women's Reproductive Health (WoRtH), Platform Enabling Stem Cell and Organoid Research and Training (ESCORT) to develop expertise and capabilities in this area.
6. At inStem, early embryonic models are also being developed to test the developmental toxicity of potential drug candidates *in vitro*, thereby eliminating the use of animals.
7. Another institution, i.e BRIC-Translational Health Science & Technology Institute (THSTI) at Faridabad, has recently developed an organoid platform which may be used for drug screening, disease modelling, and the development of therapeutics for liver diseases as an alternative to animal experiments.

8. Biotechnology Industry Research Assistance Council (BIRAC), a not-for-profit Section 8, Schedule B, Public Sector Enterprise established by DBT, supports Centre for Predictive Human Model Systems (CPHMS) at Centre for Cellular and Molecular Biology (CCMB), Hyderabad. This Centre supports development of human-relevant non-animal testing platforms, including organoids, stem cell-based models and other advanced cell-based systems.

The Government recognizes the impact of limited availability of validated non-animal models on drug discovery, research costs and clinical translation. Accordingly, it continues to promote research, innovation, and capacity building for the development and adoption of such technologies in the country.

The Government continues to support research and innovation to develop non-animal testing methods to reduce dependence on conventional animal methods and enhance the efficiency of drug testing and preclinical research. The details are as below:

1. Department of Biotechnology through its Medical Directorate & BIRAC supports cutting-edge research in the various areas of medical biotechnology, including research on development & validation of non-animal testing methods & models. Several projects are ongoing for the development and validation of different non-animal models such as, a lung-on-chip platform for assessment of monoclonal antibodies, a lab-on-chip device that mimics the function of the human kidney, etc.
2. BIRAC in recent years has announced a focused Call inviting proposals on “Establishment of Preclinical Models for Drug Discovery” to provide funding support for the development of robust preclinical models including organoids and organ-on-chip platforms, along with other innovative *in vitro* approaches.
3. BRIC-InStem, at Bengaluru conducts frequent stem cell workshops to give robust training in this area to researchers from across the country.
4. The Centre for Predictive Human Model Systems at CCMB Hyderabad maintains a database, mapping researchers across India working on human-relevant systems such as organoids, organs-on-chip, 3D tissues and related technologies. This database is publicly accessible to integrate the research community.

This information was given by the Minister of State (Ind. Charge) Science & Technology; Earth Sciences and Minister of State PMO; Personnel, Public Grievances and Pensions; Atomic Energy, Space Dr. Jitendra Singh in a written reply in Rajya Sabha today.

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