# Removing Animals from Drug-Testing Process

**For Prelims:** Organoids, Organs-on-Chip, 3D Bioprinting, New Drugs and Clinical Trial Rules 2019, Drugs and Cosmetics Act, 1940, Drugs Controller General, India.

**For Mains:** Key Emerging Alternative Testing Methods,Regulatory Mechanism of Clinical Trials in India.

**Source: TH**

## Why in News?

The Government of India has recently introduced an **amendment to the New Drugs and Clinical Trial Rules, 2023.** The amendment addresses the **ethical and scientific concerns surrounding the** use of animals in research, particularly in drug testing.

- This step authorizes researchers to utilize **innovative non-animal and human-relevant methods** for testing new drugs, ushering in an era of more accurate, efficient, and **ethically aligned** drug development **processes.**

## What is the Current Drug-Development Landscape?

- The journey of every drug from **conception to market involves a series of rigorous tests** to assess its efficacy and potential side effects. Traditionally, this process has involved testing candidate molecules on animals, **typically rodents like mice or rats, as well as non-rodents such as canines and primates.** However, this approach has significant limitations:
    - **Species Mismatch:** Humans exhibit intricate biological variations due to factors such as **age, genetics, diet, and pre-existing diseases.**
        - Animal models, even non-rodents, **cannot fully replicate the complex human response to drugs.**
    - **High Failure Rates:** The considerable divergence between animal and human responses contributes to the high failure rate of drug development.
        - Despite advancements in the pharmaceutical sector, **most drugs that pass animal testing fail during human clinical trials.**
- Recognizing these limitations, researchers globally have been exploring alternative testing methods that better replicate human biology and responses.

## What are the Key Emerging Alternative Testing Methods?

- **Organoids: Organoids** are **three-dimensional cellular structures** that emulate specific organs of the body.
    - These miniature organs, **developed from human cells or stem cells,** provide a more accurate representation of human physiology, enabling researchers to study drug interactions in a human context.
- **Organs-on-Chip:** Organs-on-chip are **small devices lined with human cells, mimicking the blood flow** and cellular interactions within the body.

    - These chips **replicate key physiological aspects** and allow researchers to **analyze tissue-tissue interactions** and chemical signals, providing a platform for more accurate drug testing.
- **3D Bioprinting:** 3D bioprinting technology enables the **creation of complex human tissues and organs** using patient-specific cells.
    - This advancement allows for the **development of personalized drug testing approaches,** catering to individual variations in biology.

## What are the Global Regulatory Shift to Accommodate Emerging Methods?

- The European Union passed a resolution in 2021 to **transition towards non-animal testing methods.**
- The U.S. introduced the **FDA Modernization Act 2.0 in 2022,** allowing the use of human-relevant systems for drug testing.
- **South Korea and Canada** also introduced legislation to promote alternatives to animal testing.
- In **March 2023**, India joined this global shift by amending the **New Drugs and Clinical Trial Rules 2019**, enabling the **incorporation of human-based testing methods into the drug development pipeline.**

## What is the Regulatory Mechanism of Clinical Trials in India?

- The major legislations that govern clinical trials in India are: Drugs and Cosmetics Act, 1940, Medical Council of India Act, 1956 **and Central Council for Indian Medicine Act, 1970, Guidelines for Exchange of Biological Material (MOH order, 1997).**
- Prerequisites of conducting a clinical trial in India are:
    - Permission from the **Drugs Controller General, India (DCGI)**
    - Approval from the **Ethics Committee** established **under Drugs and Cosmetics Rules.**
    - Mandatory registration on the **ICMR** maintained website

## What are the Challenges and Opportunities Related to Regulatory Shift for India?

- **Multidisciplinary Expertise:** Developing and implementing technologies like organoids and organs-on-chip demand **diverse expertise, ranging from cell biology and materials science to electronics and pharmacology.**
    - India must invest in multidisciplinary training and resource-building to bridge existing knowledge gaps.
- **Resource Localization**: The current reliance on **imported reagents, cell-culture materials, and instruments poses a resource challenge.**
    - To establish a self-sufficient ecosystem, India should focus on developing a robust infrastructure in areas like **cell culture, material science, and electronics.**
- **Standardization and Guidelines:** Variability in laboratory protocols can lead to inconsistent data.
    - **Clear guidelines and quality criteria** are essential to ensure reliable and comparable results across different labs.
    - Regulatory bodies must adapt to the advancements in cell-based and gene-editing-based therapeutics.