New Approach Methodologies (NAMs)

How scientists use NAMs and animal research to excelerate discovery

New Approach Methodologies (NAMs) are tools that help researchers study the safety of drugs and medical devices while using fewer animals. These approaches support the **3Rs of animal research: Reduction, Refinement, and Replacement**

Cell-Based Models

In Vitro

What They Do

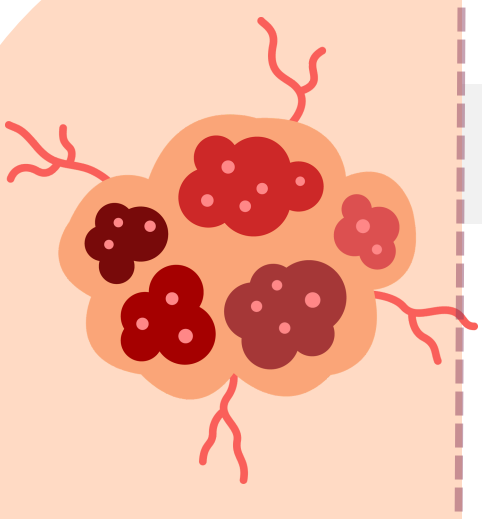
Use cells grown in the lab to study irritation or toxicity

Limitations

Show effects on cells, not the whole body

Why They're Useful

- Faster and lower cost
- Reduce animals needed
- Helpful in early stages of research



Animal Studies

In Vivo

Why They're Sometimes Needed

Some safety questions require understanding how a drug or device affects the entire body.
In addition, animals are sometimes needed to study long-term effects, immune responses, and complex biological processes that cannot yet be fully modeled outside a living system.



Key Point

When animals are studied, it is done humanely, ethically, and only when needed to protect human and animal health.

Computer Models

In Silico

What They Do

Use existing data and computer simulations to predict toxicity

Limitations

- Accuracy depends on available data and underlying assumptions
- Limited insight into whole-body effects

Why They're Useful

- No live testing required
- Can guide early decision-making



FDA & the Future of NAMs

In 2025, the U.S. Food and Drug Administration (FDA) announced plans to expand acceptance of NAMs in drug development.

What This Means

- New methods must be qualified to show they are reliable
- Researchers, industry professionals, and regulators are working together
- Goal: fewer animals and better safety predictions

Will Animals Ever be Fully Replaced?

Maybe - but not yet. While new approach methodologiess continue to advance, not enough are fully qualified to replace animals in all areas of biomedical research. Progress is ongoing, and animal care and welfare remain a top priority.

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