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Cell Biology

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April 5, 2026

### **New Approach Methods (NAMs)**

New approach methodologies (NAMs) can be defined as complementary approaches to animal testing, which are becoming increasingly more popular in the scientific world (National Institutes of Health, 2025). Certain countries and organizations have begun to reduce the number of animals used during testing, simply because there are more efficient methods for research. In a study conducted by the United Kingdom, the number of animal subjects used during scientific testing fell from 4.14 million to 2.64 million in 2024 (Kwon, 2026). New approach methods, such as 3-D organoids, organs-on-chips, and generative AI systems, are more successful than animal models because they are able to replicate human biology with more accuracy. These NAMs can be classified as both *in vitro*, which is performed in a controlled environment outside of the living organism, or *in silico*, which is performed via virtual simulation (MPKB, n.d.)

To begin, some new approach methodologies, such as the creation of 3-D organoids, use induced pluripotent stem cells (iPSCs) to replicate these human systems. iPSCs are adult somatic cells that have been reprogrammed with the ability to transform into any cell type in the body through genetic engineering (Swingen et al., 2013). Organoids created through iPSCs have proven to be efficient while studying developmental stages, as well as disorders and diseases. Because iPSCs carry a genetic code that is specific to each subject, these organoids are biologically related to each subject, making testing more accurate compared to animal models (UCLA Broad Stem Cell Research, n.d.) Another similar NAM, outweighing animal testing, is microfluidic organs-on-chips. These are defined as microfluidic devices that replicate the structure and function of certain systems, like tissues or organs (Dasgupta et al., 2024). These microfluidic devices can control fluids through specific channels, accurately replicating a specialized environment for testing. In 2022, a study was conducted using a “liver-chip”, where liver cells grow in small channels to identify which drugs had the ability to cause liver damage. This liver-chip identified harmful drug compounds with 87% accuracy, and in 2024, it was accepted into the FDA’s IStand pilot program to undergo advancement (Kwon, 2026). These *in vitro* models show that new approach methodologies are more precise and humane than animal models.

Next up, computer models and AI systems are able to replace animal testing through more accurate data predictions. Computational systems are created with human data through programming, creating a compatible environment for testing (Kwon, 2026). Because animal biology is not consistent with humans, it can lead to unpredictable outcomes during and after testing. In a study from 2021, these computational models temporarily replaced conventional animal models when testing for a compound causing skin sensitivity through a virtual test, which

is a necessary safety test for certain products. The outcome was successful, and the virtual method was accepted by the Organization for Economic Co-operation and Development (Kwon, 2026). Another article spoke about testing heart medication through computer models, which yielded 92% accuracy compared to 80% with animal testing (Passini et al., 2018). These *in silico* methods prove to be more precise than animal models as well.

The NAMs mentioned above have proven to be more accurate than animal testing, but they have their limitations as well. For starters, some NAMs are very costly, such as the microfluidic organ-on-chip, which can be over \$1000, making them inefficient for long-term use (Dixit, 2025). One of the major restrictions, though, is the inability to replicate complex systemic interactions due to the simplification of the models created. These interactions include multiple organs and systems, whereas NAMs can only replicate specific structural functions. For example, an organoid created from induced pluripotent stem cells (iPSCs) is isolated and therefore unable to send or receive signals without being integrated into a bigger system.

In conclusion, new approach methods like 3-D organoids and computer modeling systems are more effective at producing usable results. As NAMs progress forward and scientists continue to discover new methods, animal testing should continue to be phased out due to its unreliable and unethical practices.

## References

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