AIMBE

ALTERNATIVES TO ANIMAL MODELS IN BIOMEDICAL RESEARCH:

INNOVATIONS IN NEW APPROACH METHODOLOGIES (NAMs)

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Lab or computer-based research approaches, such as Machine Learning/Artificial Intelligence (AI), "Organ-on-a-Chip", and Digital Twins, to model human biology and study diseases. These innovative approaches complement, or in some cases, replace traditional animal models.

STUDYING DISEASES WITH NAMs

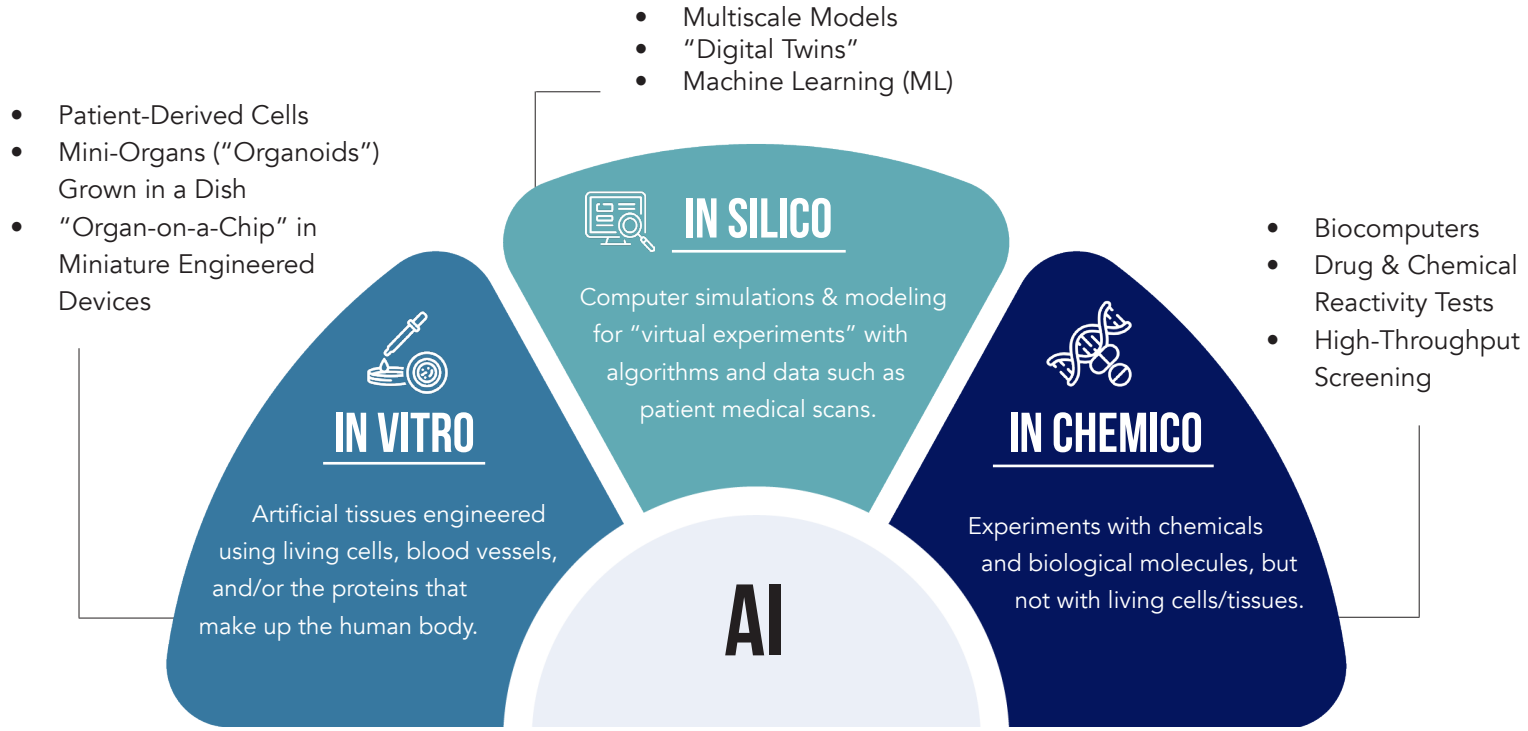
NAMs can be used to study how diseases develop, test the safety and efficacy of new drugs, and even explore ways to fix or replace damaged organs. The advantages of using NAMs over traditional animal models include opportunities for personalized medicine, faster and cheaper results, and improved reproducibility for experimentation.

EXAMPLES OF DISEASES STUDIED WITH NAMs:

- **Cancer**
- **Dementia**
- **Diabetes**
- **Alzheimer's Disease**
- **Cardiovascular Disease**
- **Immune Disorders**
- **Skin Disorders**
- **Liver Toxicity**
- **Rare Genetic Diseases**

THREE MAIN TYPES OF NAMs

Broadly, NAMs fall into three categories that capture different biological and/or computational aspects of human biology, with each using Artificial Intelligence (AI).



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ROLE OF ARTIFICIAL INTELLIGENCE (AI):

New advances in AI are helping researchers make sense of enormous datasets collected from NAMs and patients by streamlining their analyses. As AI continues to improve and interplay with NAMs, they can help researchers predict how diseases start, determine how a patient may respond to new treatments, and even make discoveries that could speed up medical innovation.

WHY INVEST IN NAMs?

Continued development and validation of new NAMs will ensure that biomedical research can better address and treat a broad range of diseases.

Sustained investments in NAMs can help ensure they are widely used by researchers to study complex diseases ("large-scale biomanufacturing").

Personalized medicine will depend on NAMs to better understand diseases and provide individualized treatments to patients to improve health outcomes.

FEDERAL PRIORITIES FOR NAMs RESEARCH APPROACHES

Both the FDA and NIH are now expanding opportunities for human-based research using NAMs. Currently, NAMs and animal models are complementary research approaches and play important roles in advancing biomedical research.