NAMenclature: A Quick Introduction to NAM

New Approach Methodologies (NAM) represent a paradigm shift in biomedical research, toxicology, and regulatory science. By replacing or reducing reliance on animal testing, NAM leverages cutting-edge technologies to generate human-relevant data and align with modern scientific standards.

Item	Description	Application
In Chemico	Non-biological chemical testing using synthetic systems (e.g., peptides, proteins).	Replaces Draize, GPMT, and phototoxicity tests. Modernized via HTS.
In Silico	Computational modeling and simulations to predict biological outcomes.	Used for PBPK modeling and AI/ML-driven drug discovery.
In Vitro	Lab methods using human cells/tissues (organoids, organ-on-a-chip).	Mimics human physiology for drug testing and disease modeling.
Bioprinting	3D printing of functional human tissues using bioinks.	Tissue engineering, drug testing, and regenerative medicine.
Omics	Systems-level analysis of biological molecules (genomics, proteomics, metabolomics).	Enables systems biology and personalized medicine.

Core Strategic Callouts

For Scientists

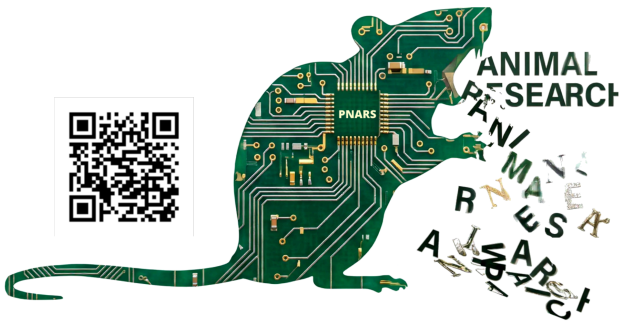
Produce Human-Relevant Data. NAM enables human-predictive data that animal models cannot. By adopting In Silico (PBPK, AI/ML), In Vitro (organoids, organ-on-a-chip), and Omics, you eliminate species-specific biases and accelerate breakthroughs. In Chemico replaces outdated animal tests. Laboratories embracing NAM gain a competitive edge and align with precision medicine.

For Educators

Equip Students for the Biotech Revolution. Animal dissection teaches obsolete skills. Today's biotechnology demands expertise in In Silico, In Vitro, and Omics. By integrating NAM into your curriculum, you prepare students for careers where human-relevant methods drive discovery and align with industry needs.

For Policymakers

Modernize or Risk Falling Behind. The U.S. (FDA Modernization Act 2.0) and E.U. actively phase out animal models. Canada's frameworks remain stagnant. In Chemico and In Silico methods already replace animal tests with faster, cheaper, and more accurate alternatives. In Vitro, Bioprinting, and Omics are revolutionizing drug development. Modernizing public funding to mandate NAM infrastructure is a matter of national economic survival.



Frequently Asked Questions

What is In Chemico?

Non-animal, cell-free chemical experiments conducted in laboratory vessels to test a substance's reactivity. These methods are particularly effective for assessing skin sensitization and phototoxicity. Direct Peptide Reactivity Assay (DPRA), assess chemical reactivity using synthetic peptides, eliminating the need for animal subjects. This approach is faster, more cost-effective, and ethically superior to traditional tests like the Draize test or Guinea Pig Maximization Test (GPMT). Modernization through High-Throughput Screening (HTS) enables rapid assessment of thousands of chemicals.

What is In Silico?

Computational models and simulations, including Physiologically Based Pharmacokinetic (PBPK) modeling and Quantitative Structure-Activity Relationship (QSAR) analysis, to predict biological outcomes, drug behavior, and toxicity without relying on animal or traditional laboratory testing. These methods leverage human-specific data and computational power to improve predictive accuracy while significantly reducing costs compared to animal testing, which is resource-intensive and often fails to predict human responses due to species differences.

What is In Vitro?

Laboratory-based methods using human-derived cells or tissues, including organoids, 3D cell cultures that closely mimic the structure and function of human organs, enabling accurate disease modeling and drug testing at a fraction of the cost and time of animal studies. Organ-on-a-chip systems combine these cells with microfluidic technology to replicate the dynamic environment of human organs, including blood flow and mechanical forces. These systems provide real-time, high-throughput data with superior human relevance, reducing reliance on animal models while delivering faster, more cost-effective, and predictive results.

What is Bioprinting?

Uses bioinks, mixtures of living cells and biocompatible hydrogels to fabricate functional, three-dimensional human tissue structures layer by layer. By precisely depositing these cell-laden materials, bioprinting enables the creation of complex, organ-like architectures for tissue engineering, drug testing, and regenerative medicine.

What are the main components of Omics technologies?

Genomics (study of DNA), transcriptomics (study of RNA), proteomics (study of proteins), and metabolomics (study of metabolites). Each provides a systems-level understanding of biological processes, enabling researchers to analyze the complex interactions that drive health and disease.

How does Omics enable systems biology and personalized medicine?

Omics technologies provide a holistic view of biological systems, allowing researchers to identify biomarkers, understand disease mechanisms, and develop targeted therapies. This systems-level approach is the foundation of personalized medicine, where treatments are tailored to an individual's unique biological profile. Omics also enables the development of digital twins—virtual models of a patient's physiology that can be used to simulate and optimize treatments.

What are digital twins?

Virtual replicas of biological systems or patients that use real-time data, computational models, and simulations to predict physiological responses, disease progression, and treatment outcomes—without direct human or animal testing. They are deeply intertwined with omics, as they rely on genomic, proteomic, metabolomic, and other omics datasets to build and refine these virtual models.

For the full document and resources, scan the QR code to visit our website.