# From Animal Models to NAMs: How the FDA Modernization Act 2.0 is Shaping Clinical Trials and Cancer Research

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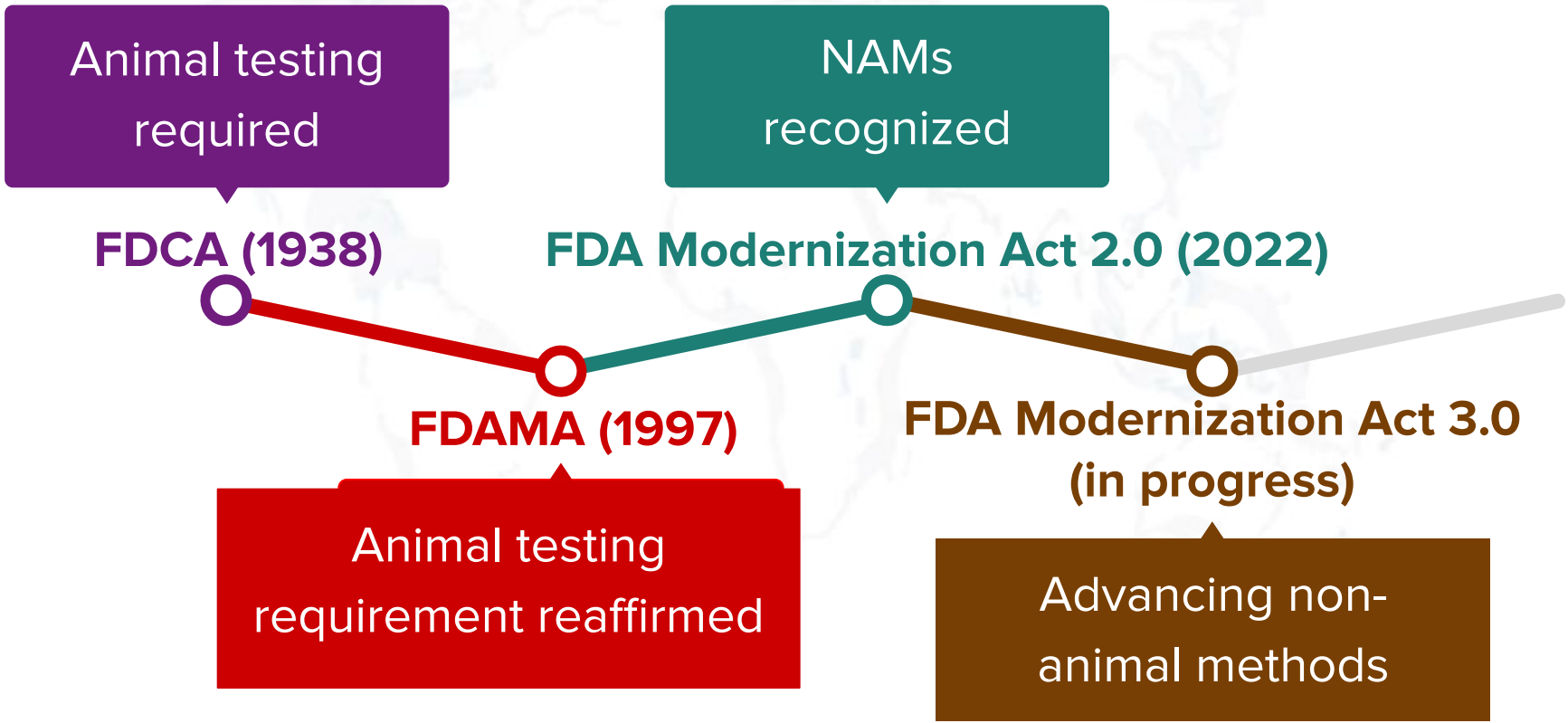
# Agenda

- Background and Context of the FDA Modernization Act 2.0
- New Approach Methodologies (NAMs)
- Implications for Cancer Research
- Why and How Labs Need to Adapt

# The Origin of the Act



# Concerns with Animal Testing

- Results often fail to translate to human benefit
- Ethical debates on animal use
- Poor fit for modern drug modalities
- Time- and cost-inefficient

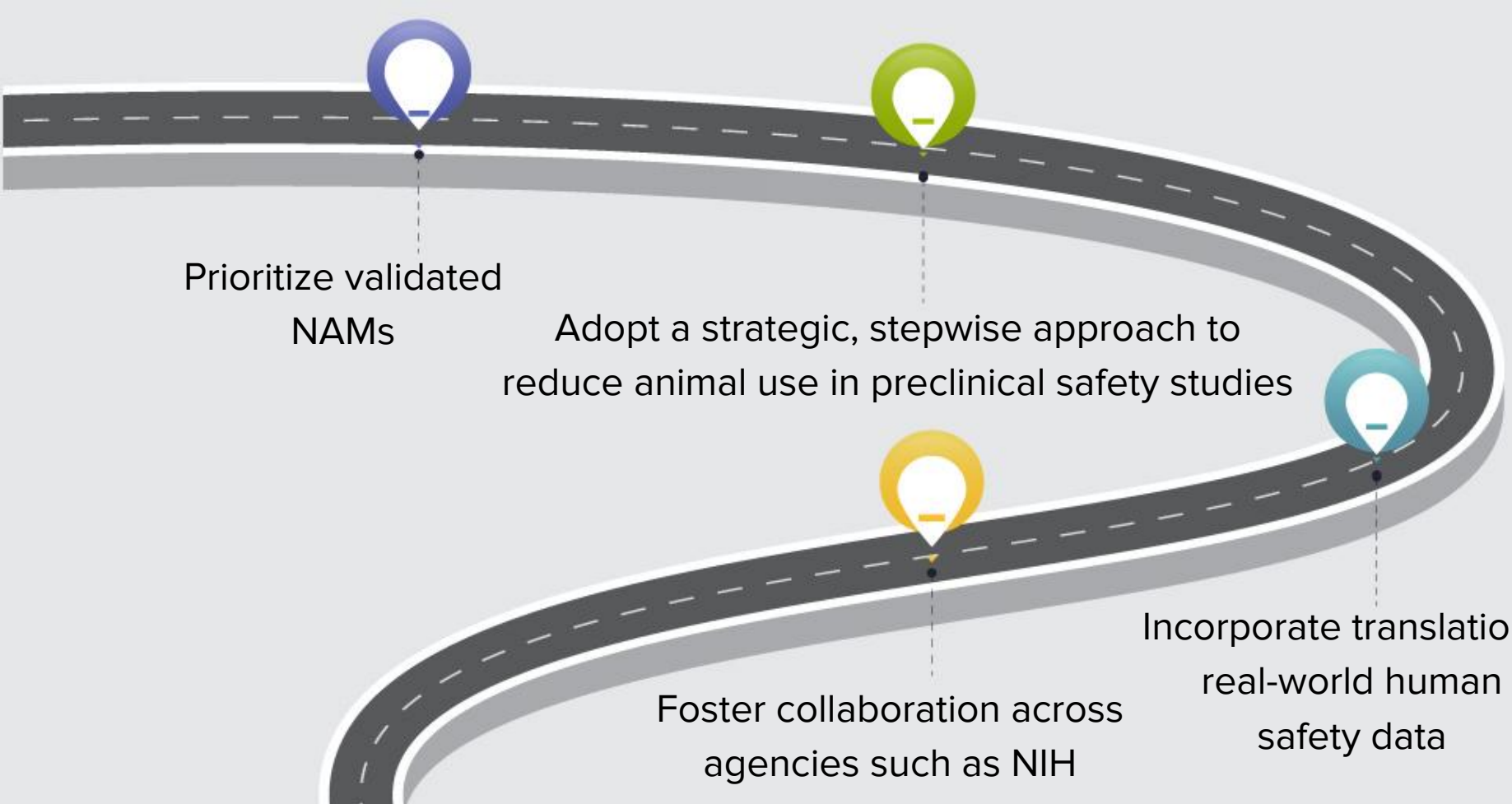
# FDA Modernization Act 2.0 Introduced

- Enacted in 2022
- Updates FDCA and FDAMA

# FDA Modernization Act 2.0: Major Changes

- Authorizes the use of non-animal alternatives for drug safety and effectiveness
- Removes mandatory animal studies for drug development

# The FDA Roadmap for Reducing Animal Testing



# Introducing New Approach Methodologies (NAMs)

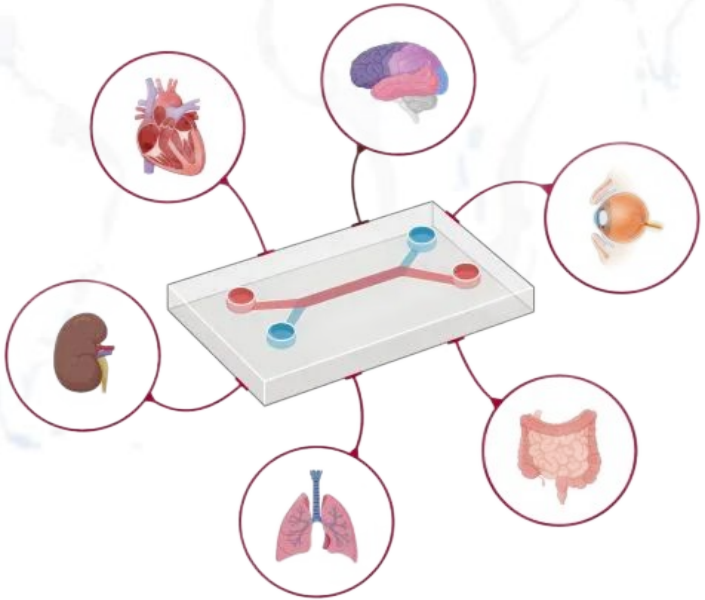
Innovative methods designed to reduce, refine, or replace animal testing

Offer faster, more human-relevant insights during safety assessment

Must be scientifically validated and fit for regulatory decision-making

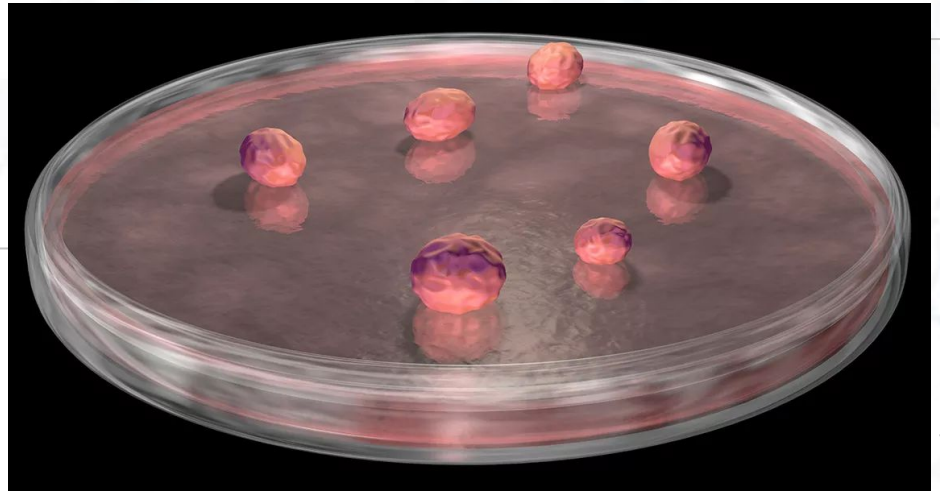
# New Approach Methodology #1: Organs-on-a-Chip

- Microphysiological systems
- Human cell–based organ simulation
- Dynamic tumor microenvironments



# New Approach Methodology #2: Organoids & Tissue Chips

Use 3D organs grown from human stem cells

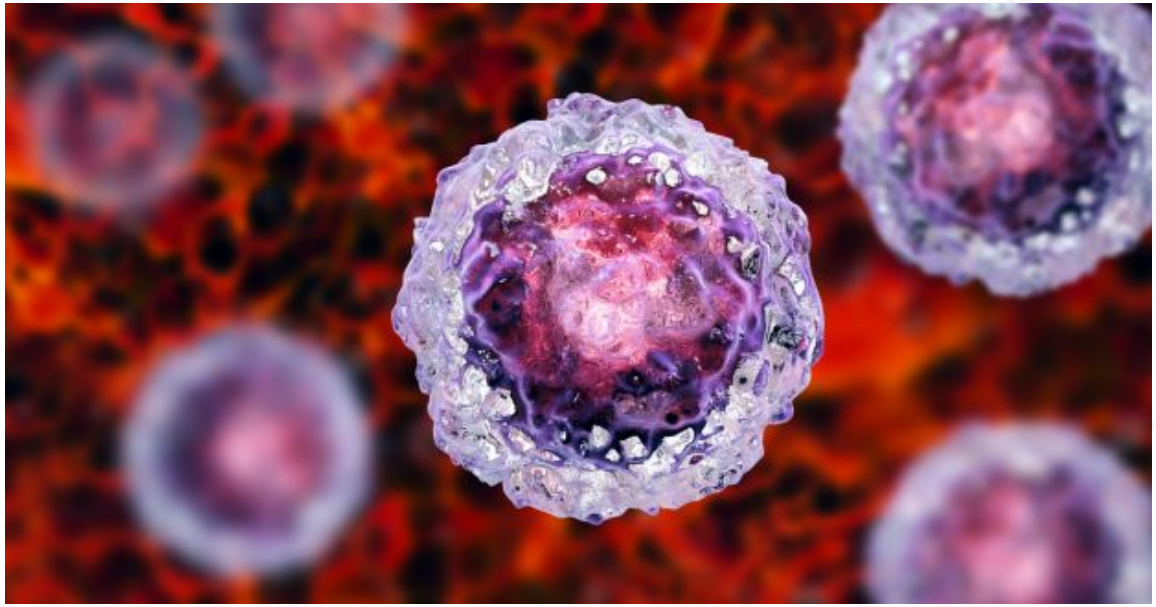


Mimic the architecture and function of real organs

Provide scalable platforms for studying drug safety and biology

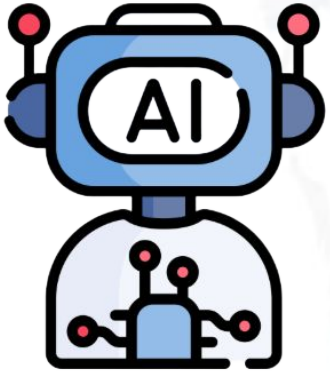
# New Approach Methodology #3: Induced Pluripotent Stem Cells (iPSCs)

- Create patient-specific models
- Enable genetic disease modeling
- Offer unlimited self-renewal



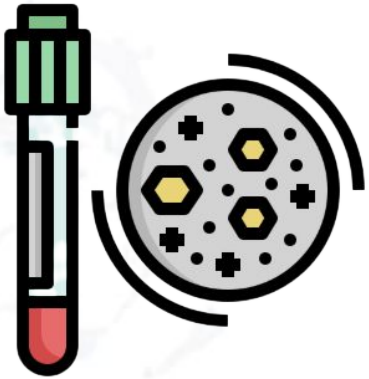
# New Approach Methodology #4: In Silico Modeling

Leverage AI and machine learning



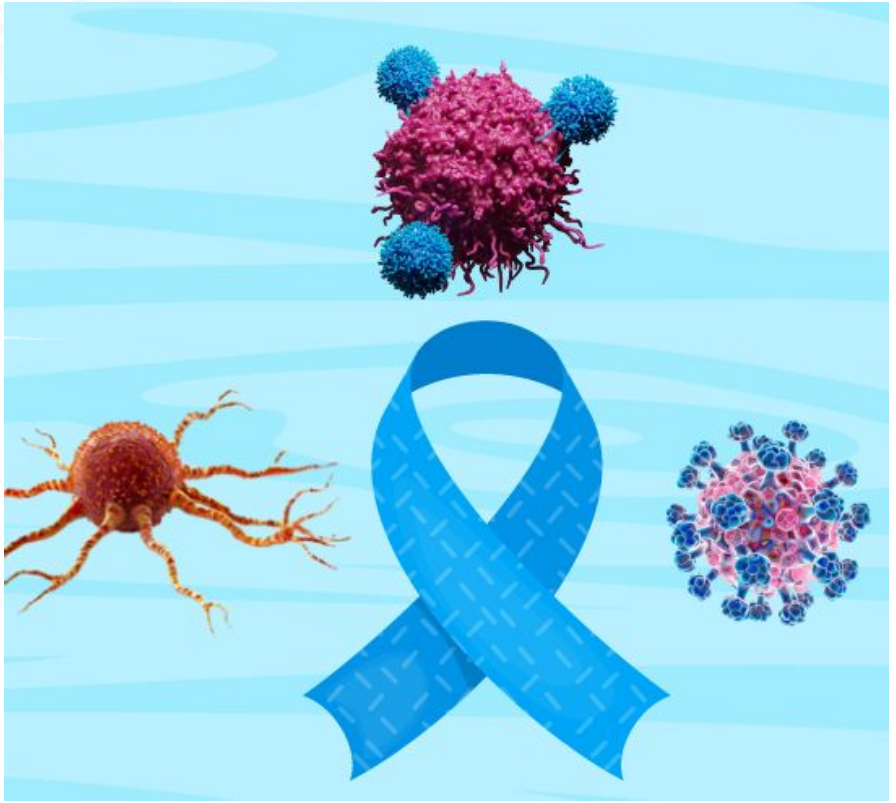

Conduct virtual patient trials

Support predictive toxicology



# Limitations of Animal Models in Cancer Research

- <15% of oncology trials progress beyond Phase I
- Translation from mouse to human treatments <8%
- Personalized medicine exposes further limitations

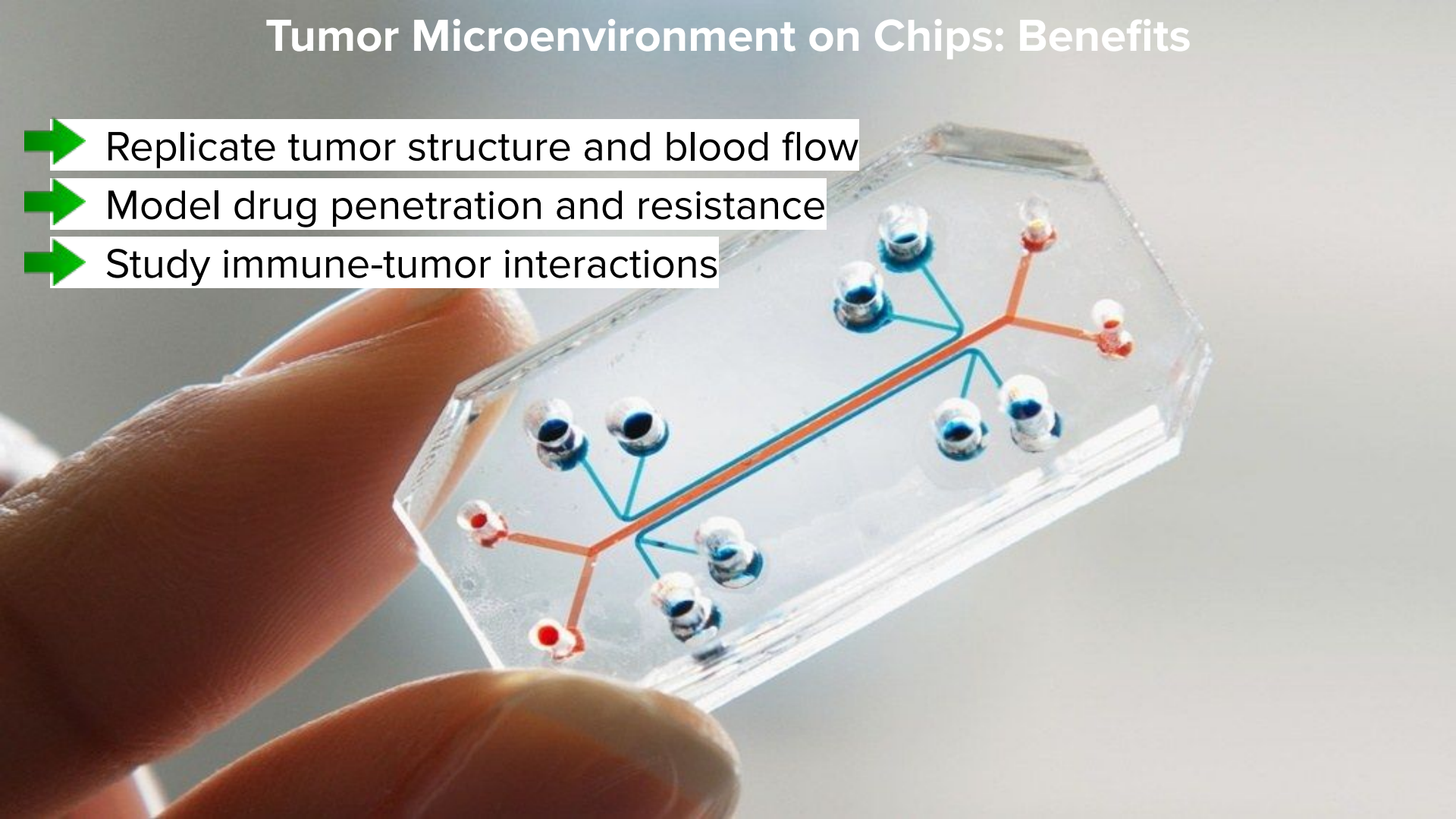


# Benefits of NAMs in Cancer Research

- Improve predictability in oncology research
- Offer human-relevant insights beyond animal models
- Support faster, safer therapy development

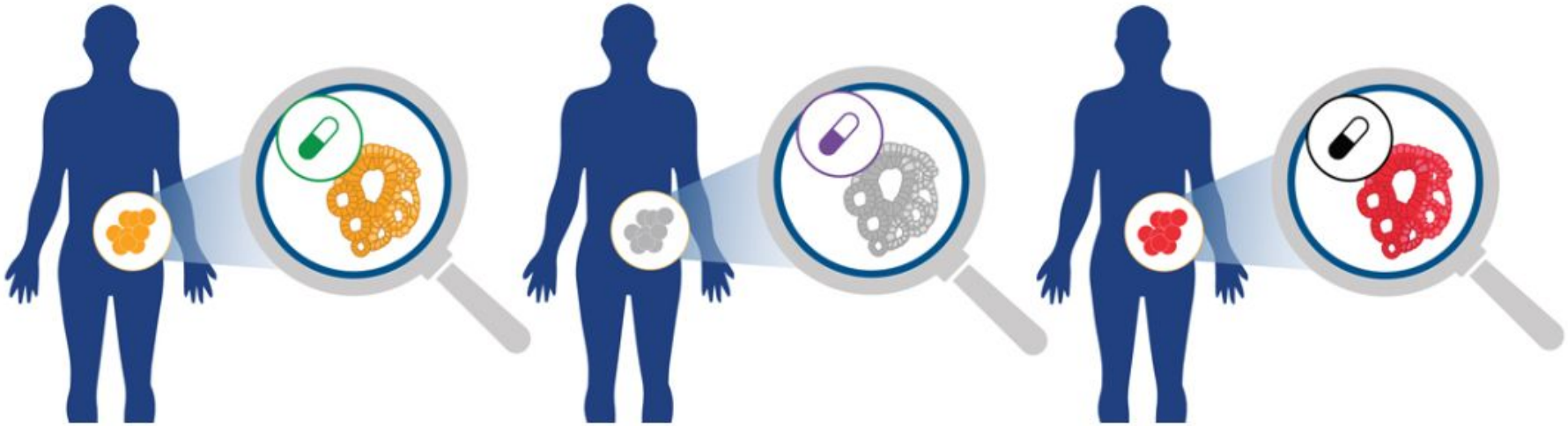
# Tumor Microenvironment on Chips: Benefits

- Replicate tumor structure and blood flow
- Model drug penetration and resistance
- Study immune-tumor interactions



# Organoids for Precision Oncology: Benefits

- Use patient-derived tumor organoids
- Test multiple therapies ex vivo
- Help identify personalized treatment options



# In Silico Cancer Models: Benefits

Help conduct virtual trials with digital patient cohorts

Predict toxicity and efficacy profiles

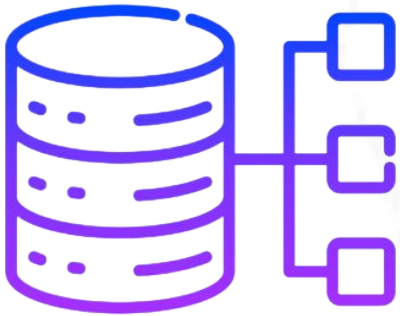
Accelerate early-phase decision-making

# Implications for Clinical Research Labs

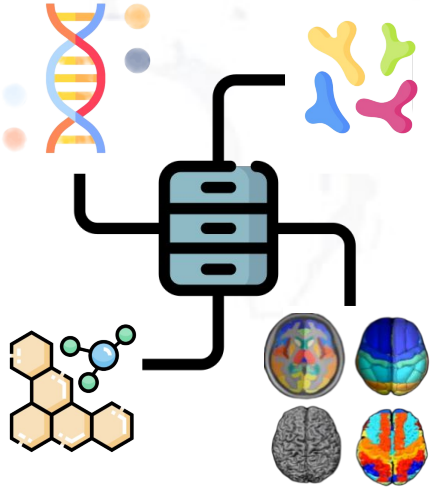
- NAMs are reshaping the research landscape
- Labs need to shift from animal-first to human-relevant models
- Operational changes are becoming unavoidable

# Challenges of NAM Adoption

Larger datasets from NAMs

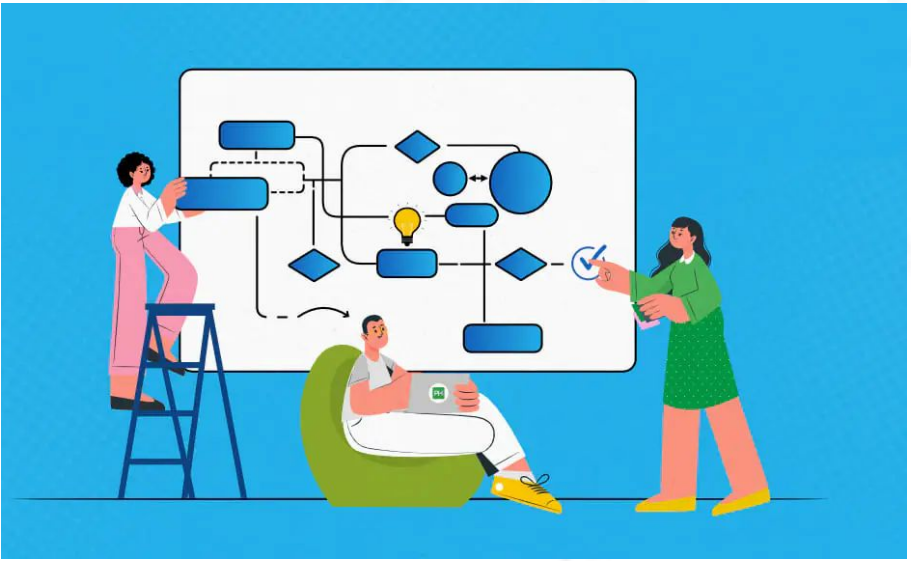


Diverse data types (omics, imaging, simulations)



Higher reporting and compliance demands

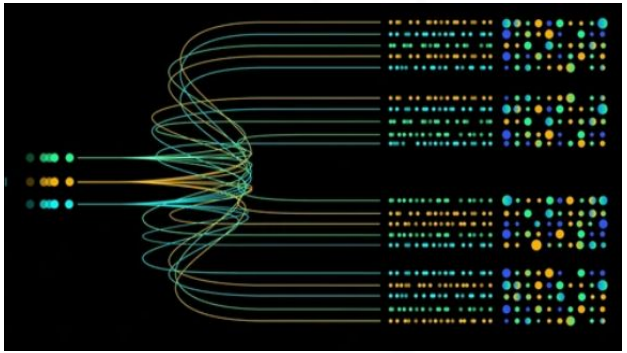
# Challenges of NAM Adoption (Continued...)



- Multiple methodologies
- Hybrid phase: NAMs + animals
- Increased validation demands

# Challenges of NAM Adoption (Continued...)

Risk of fragmented datasets



Data interoperability challenges

# Why Digitization is Essential

- Manual processes are no longer sustainable
- Automation ensures efficiency and accuracy
- Digitization makes compliance and collaboration easier

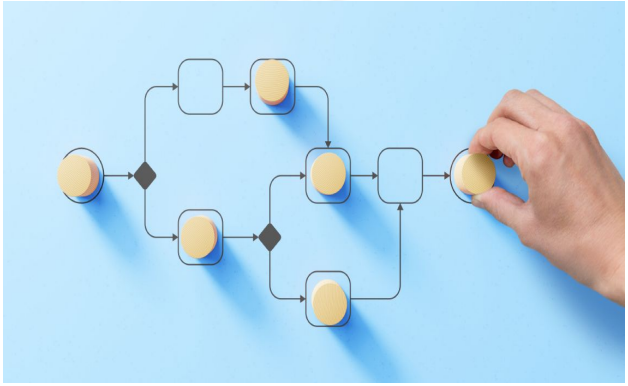
# Why Modern Labs Need a LIMS

FDA Modernization Act 2.0 drives complex data generation and compliance demands

Manual or outdated tools increase error risk, inefficiency, and compliance issues.

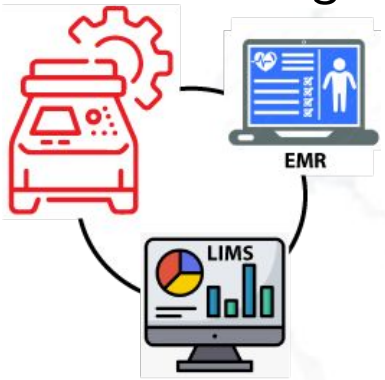
# A LIMS Supports NAM Workflows

- Integrates heterogeneous datasets from NAMs
- Enables easy configuration for new assays
- Supports hybrid NAM + animal model workflows



# LIMS - Integration, Data Security, & Collaboration

Supports instrument and software integration



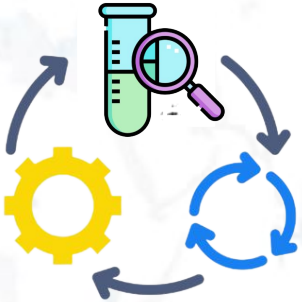

Enables remote collaboration

Ensures data security (MFA, role-based access)

# Features to Look For in a LIMS

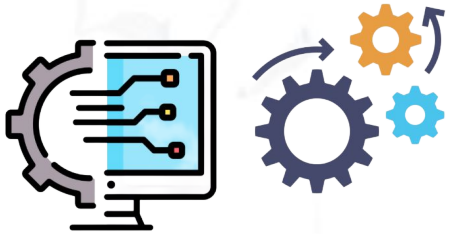
Regulatory compliance & data security support

Sample lifecycle management

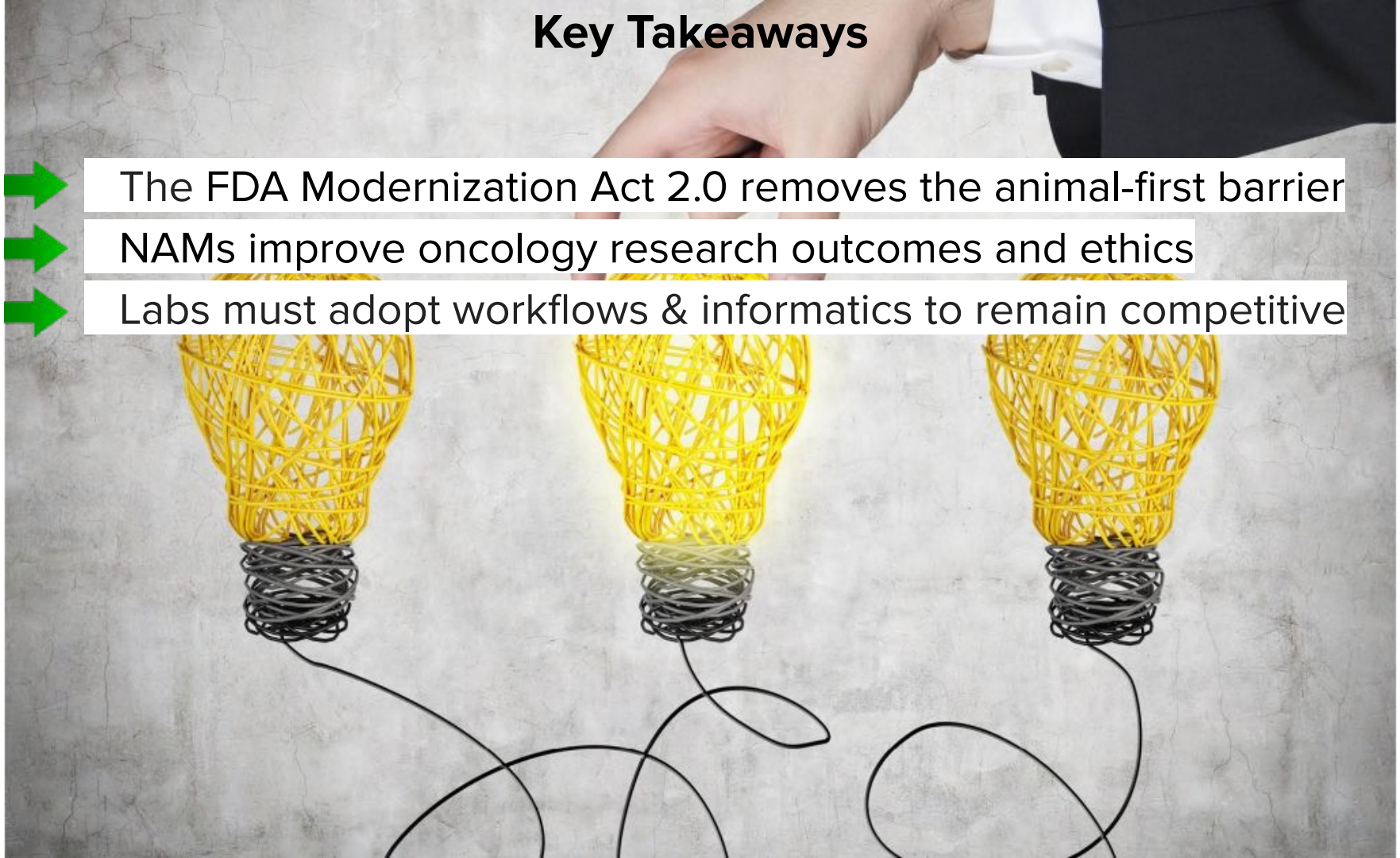


Real-time data access & collaboration capabilities

Workflow configuration & automation



# Key Takeaways



- The FDA Modernization Act 2.0 removes the animal-first barrier
- NAMs improve oncology research outcomes and ethics
- Labs must adopt workflows & informatics to remain competitive

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