NIST/NIBIB Symposium on Medical Metrology and Standards for American Healthcare and Commerce

Medical Imaging, Devices, & Diagnostics

Healthcare Needs and Challenges


Jennifer Jackson


Afrouz Anderson


Martin Tornai


Guoying Liu


Winona Nice

Bruce J. Tromberg, Ph.D.

Director, National Institute of Biomedical Imaging and Bioengineering

Establishing NIBIB: *Imaging and Engineering*

1991

AIMBE leadership
Bob Nerem
Shu Chien
Bill Hendee

Engineering + Medicine Communities

Academy leadership
Charlie Putnam
Doug Maynard
Stan Baum

1995

Congress



PL 106-580: NIBIB Success Dec 29, 2000

Richard Burr, R-NC
Anna Eshoo, D-CA

Public Law 106–580
106th Congress

An Act

Dec. 29, 2000
[H.R. 1795]

To amend the Public Health Service Act to establish the National Institute of Biomedical Imaging and Bioengineering.

National Institute of Biomedical Imaging and Bioengineering Establishment Act.
42 USC 201 note.
42 USC 285r note.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "National Institute of Biomedical Imaging and Bioengineering Establishment Act".

SEC. 2. FINDINGS.

The Congress makes the following findings:

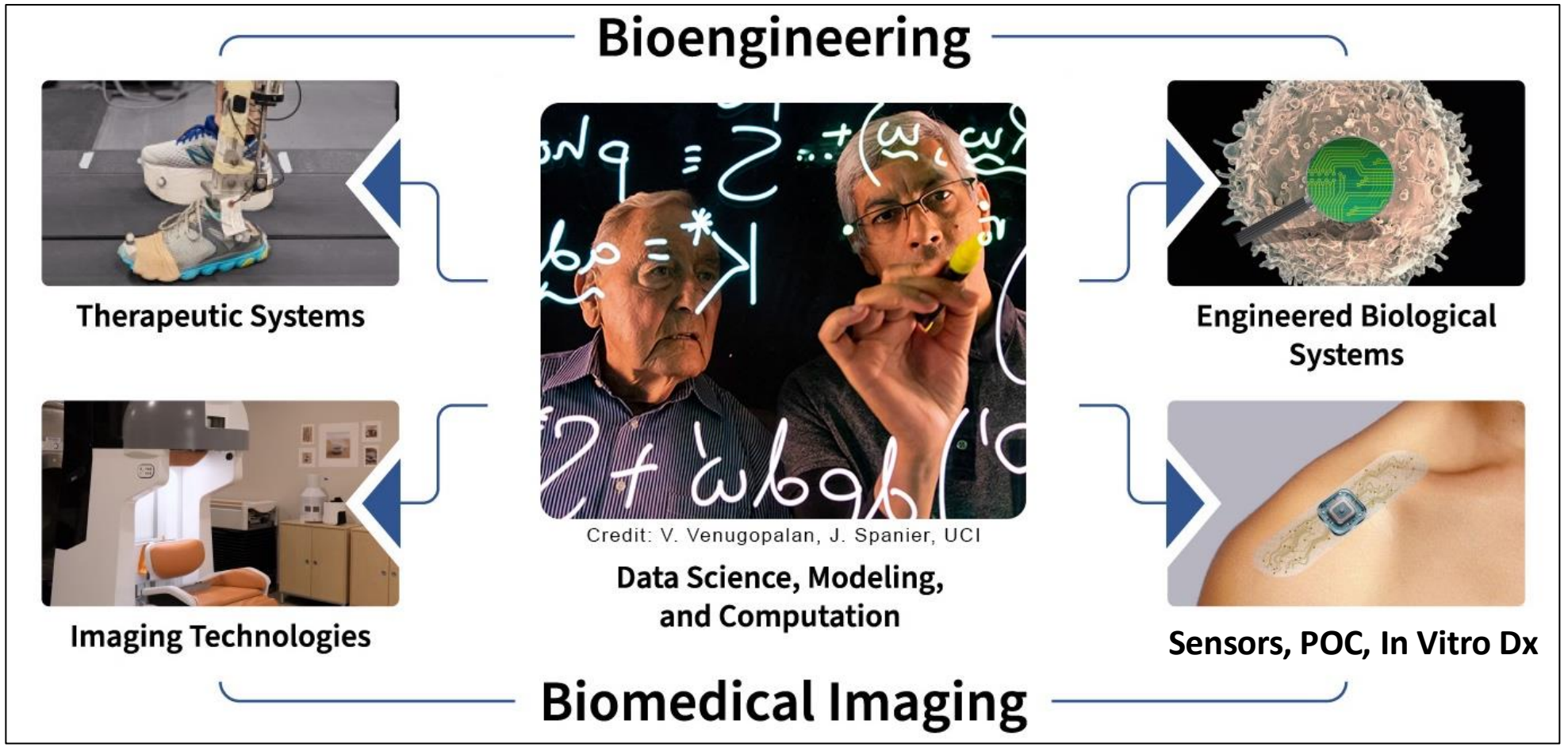
(1) Basic research in imaging, bioengineering, computer science, informatics, and related fields is critical to improving health care but is fundamentally different from the research in molecular biology on which the current national research institutes at the National Institutes of Health ("NIH") are based. To ensure the development of new techniques and technologies for the 21st century, these disciplines therefore require an identity and research home at the NIH that is independent of the existing institute structure.



Rod Pettigrew, MD, PhD

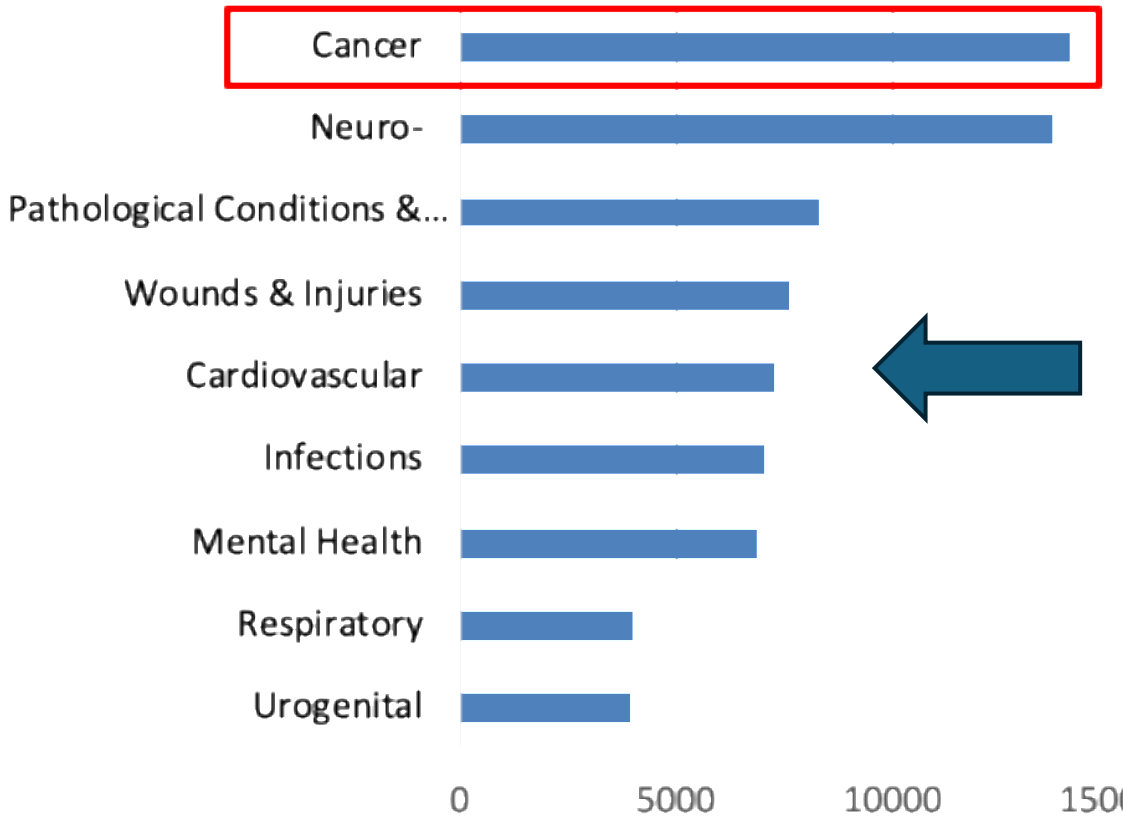
NIBIB Impact: *Technology & Innovation*

NIBIB: *No Disease Focus, Bio-hypothesis Not Needed*



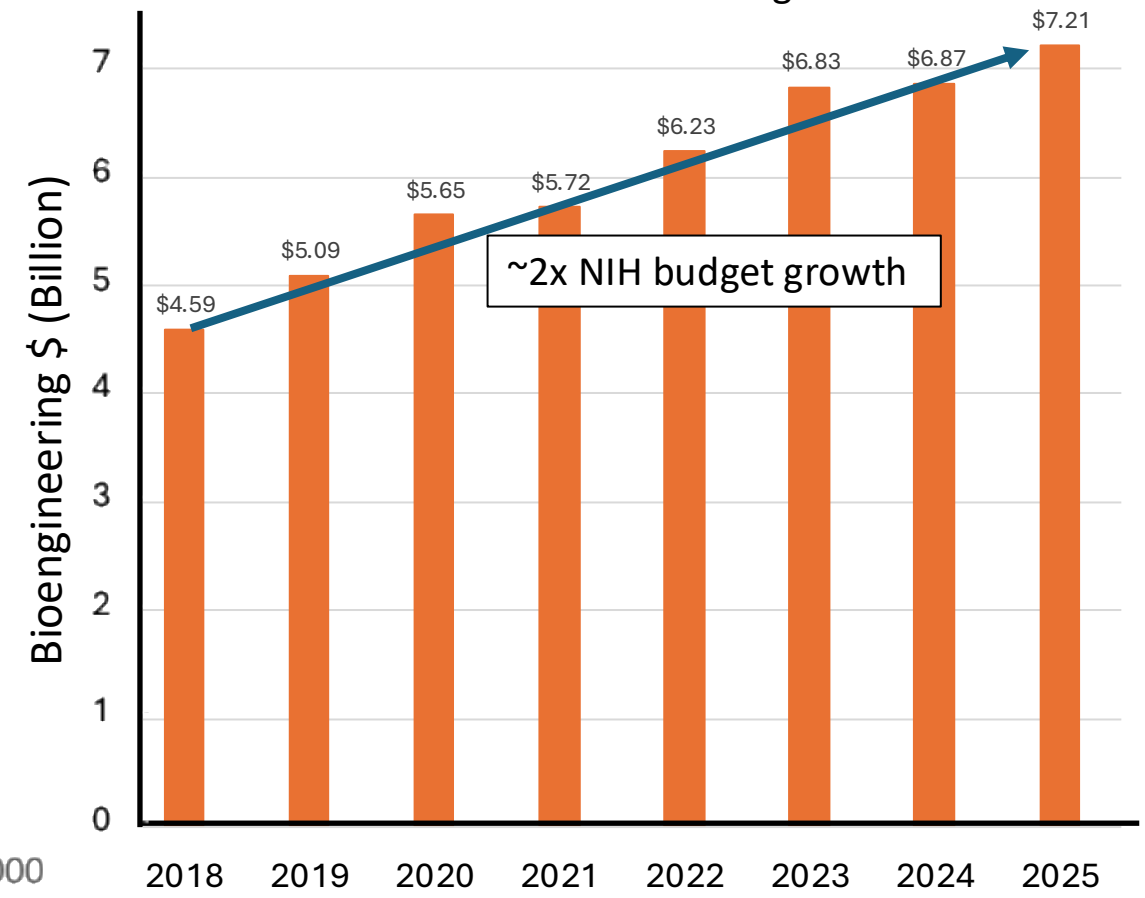
NIBIB: *Bioengineering Impact at NIH*

Top NIH Bioengineering $



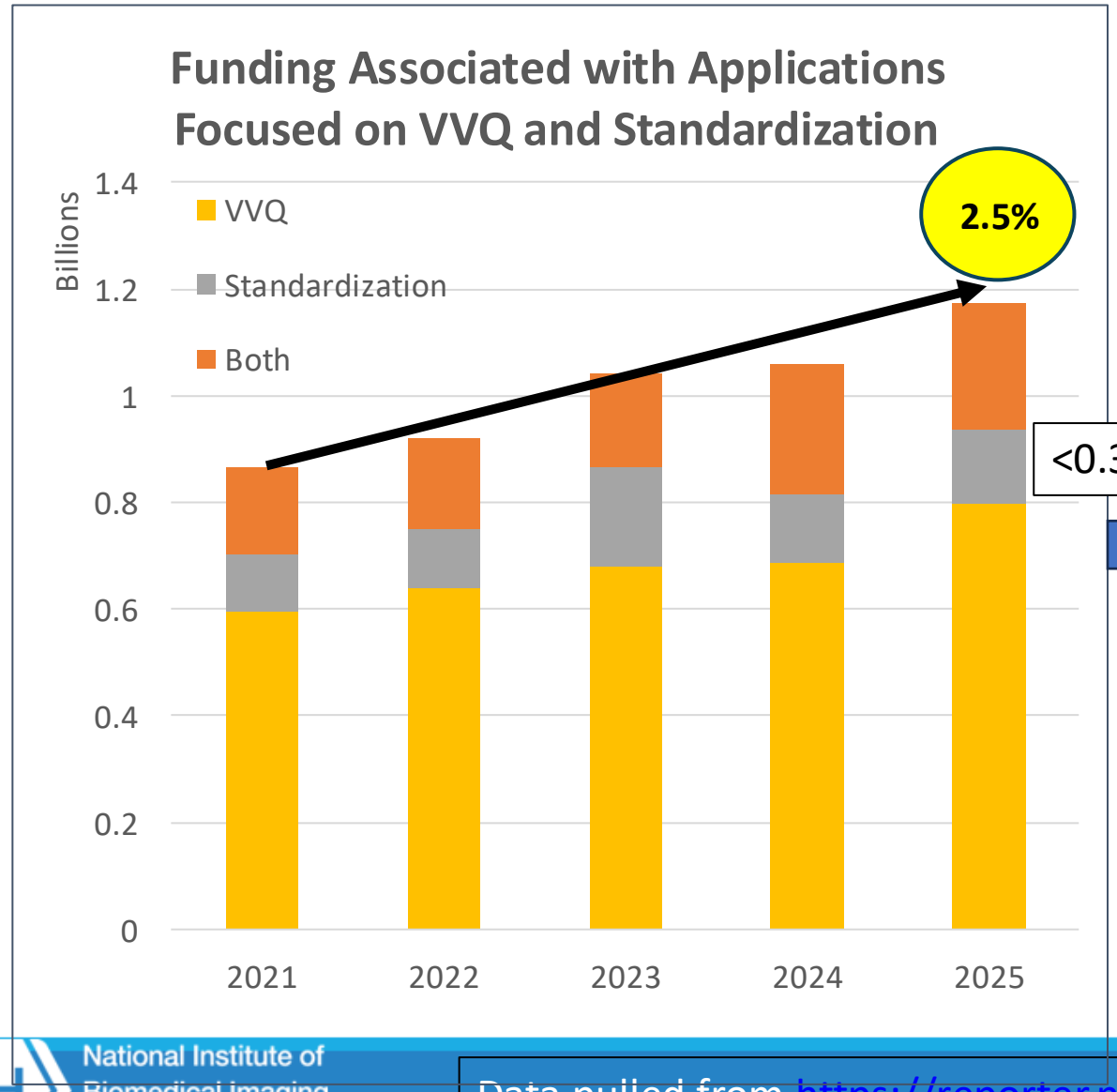
Total NIH Bioengineering $

NIBIB <1% total NIH Budget

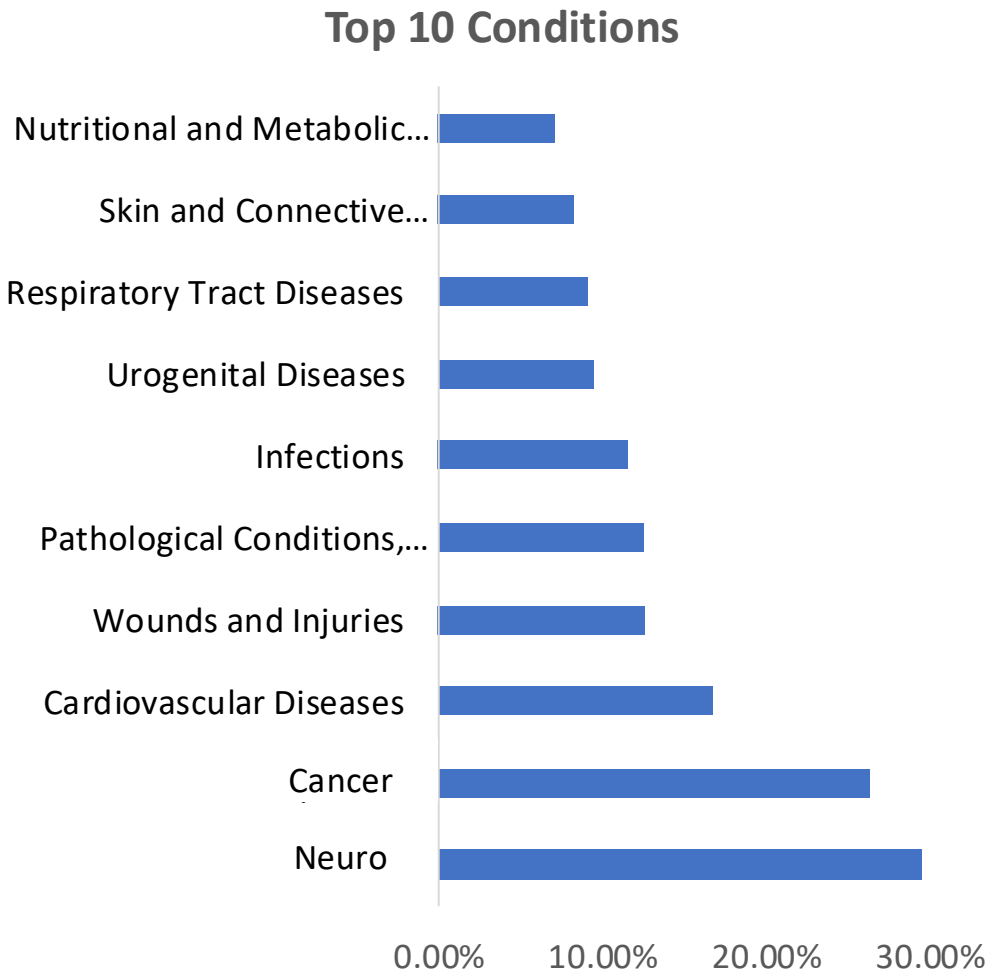


Data pulled from https://reporter.nih.gov/ September, 2026

VVQ and Standards at NIH



<0.3%

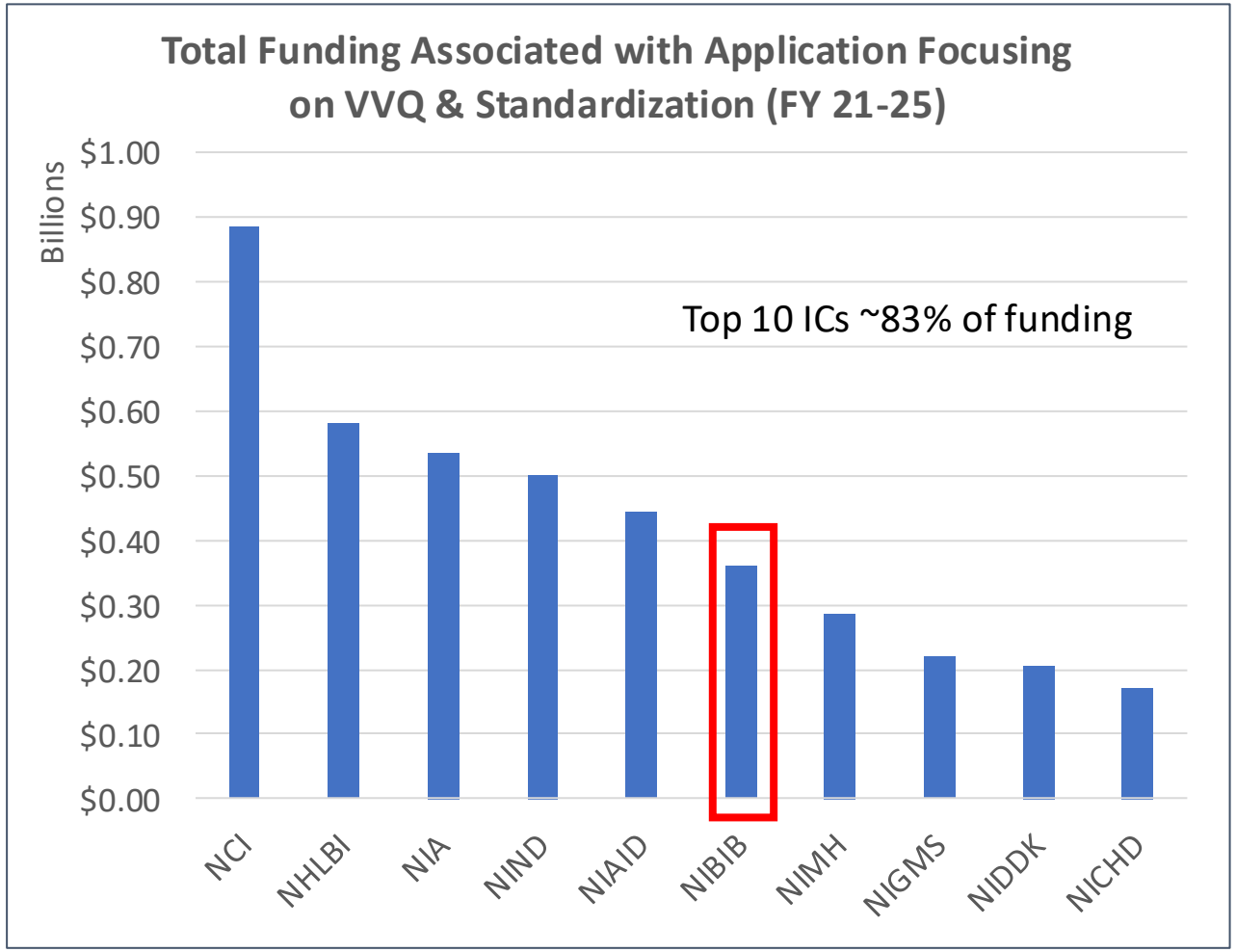


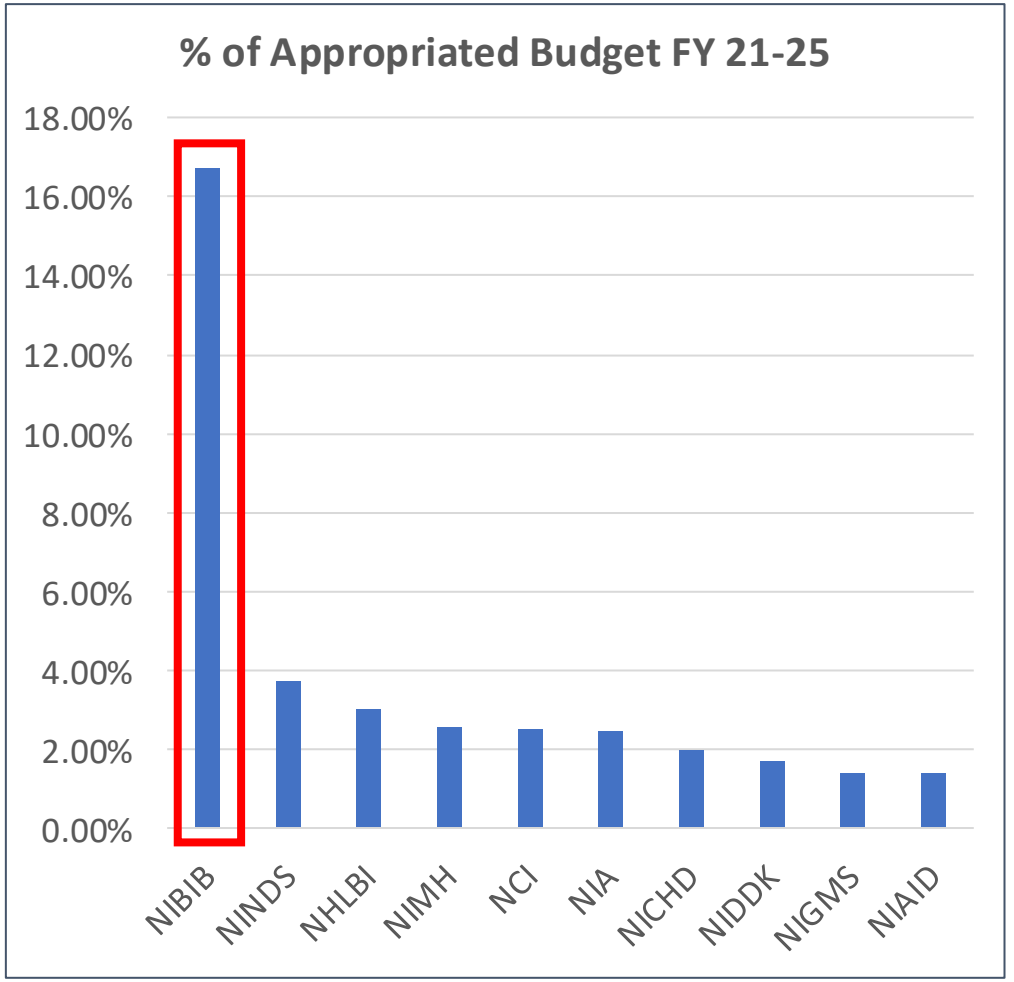
Data pulled from https://reporter.nih.gov/ September, 2026

Based on RCDC and AI tech agent for standards and VVQ.

VVQ and Standards at NIH

Top 10 Funding Institutes





Data pulled from https://reporter.nih.gov/ September, 2026

VVQ and Standards at NIH

1) National Biomedical Technology Centers (P41)
www.nibib.nih.gov/programs/national-centers-biomedical-imaging-bioengineering

2) Medical Imaging Data Resource Center (MIDRC)
www.MIDRC.org

3) National Biomaterials Technology Network (U24)
www.humanityunlockingbiomaterials.org

4) Point of Care Technology Research Network (POCTRN U54)
www.POCTRN.org

5) Rapid Acceleration of Diagnostic Technology (RADx Tech)
https://cimit.org/initiatives/radxtech/

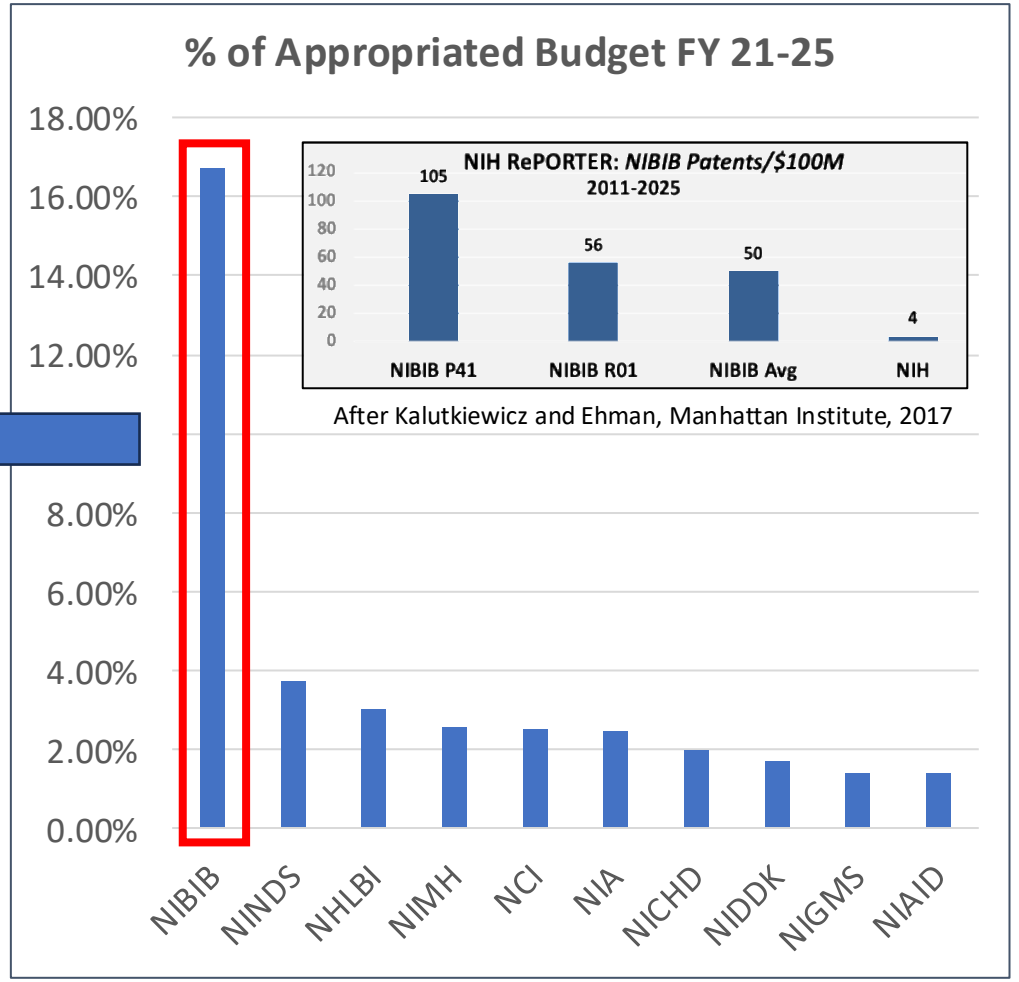
6) NIH Common Fund: PRIMED AI and Bridge to AI
https://commonfund.nih.gov/primed-ai; https://commonfund.nih.gov/bridge2ai

7) National Medical Phantom Library
https://www.nist.gov/programs-projects/national-medical-phantom-library-nmpl-nist-branch

8) Interagency Modeling and Analysis Group (IMAG)
www.imagwiki.nibib.nih.gov

Soft Materials

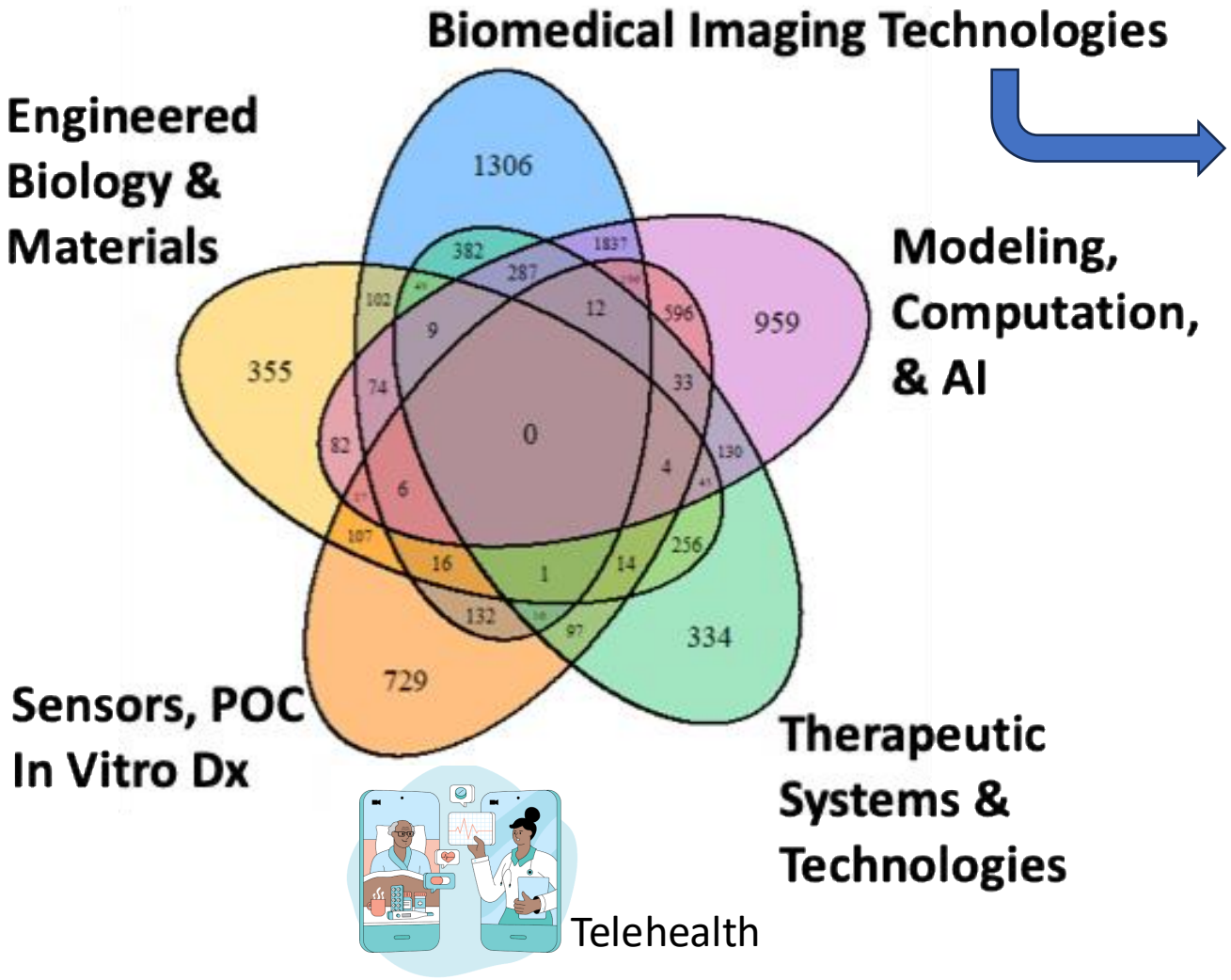
NCATS, Complement-ARIE, R3PEATS, SOM, ORIVA

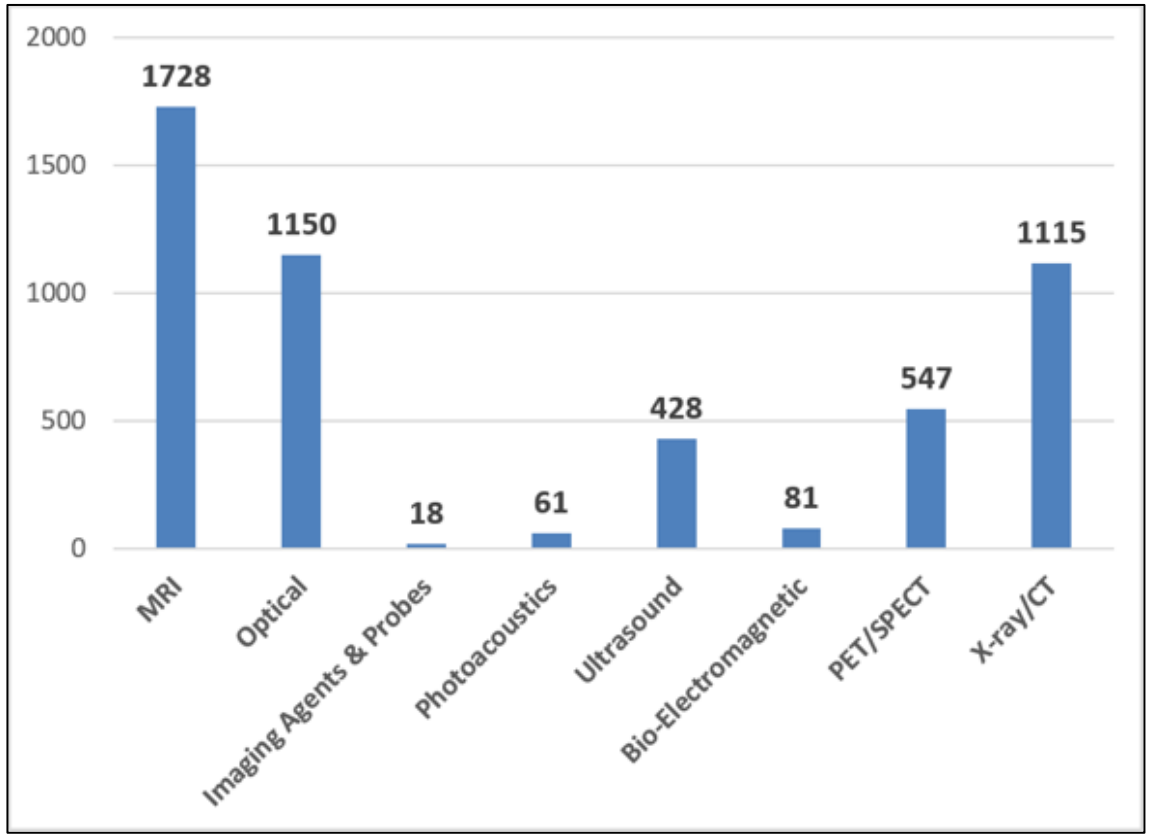


Data pulled from https://reporter.nih.gov/ September, 2026

VVQ and Standards at NIH: *Tech Areas*

FY 21-25; 8276 grants





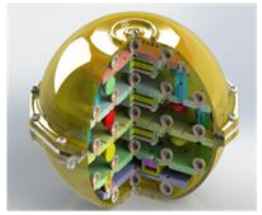
National Medical Phantom Library (NMPL)

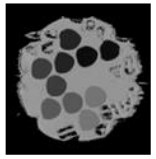
A Unique Government Resource to Support a Broad Biomedical Research Community to borrow medical phantoms and/or disseminate their existing phantoms

Site 1: NIBIB/NIST Medical Imaging Phantom Lending Library
(Mainly MRI Phantoms)

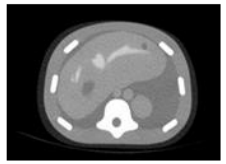
Site 2: NIBIB BETA Center
(Other imaging modalities such as Optical, US, PAT

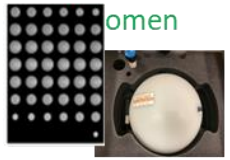

MRI Breast Phantom


MRI System Phantom



MRI Diffusion Phantom

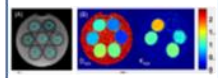

Cardiac T1 Phantom

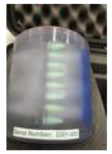

Triple modality


fMRI


MRS Phantom

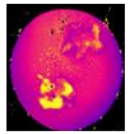

Brain Health Phantom


Kurtosis Phantom


MSK (knee) Phantom

PET/MR Cone Beam CT Phantom

OCT Phantom

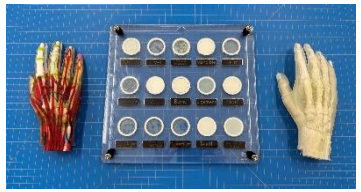

Biomimetic Tumor Mimic

AO lateral resolution Phantom


Retina phantom

Community Requested Phantoms!!

Anthropomorphic Phantoms





Madison Brookfield
NMPL Manager

2021 → 2026

National Institute of Biomedical Imaging and Bioengineering

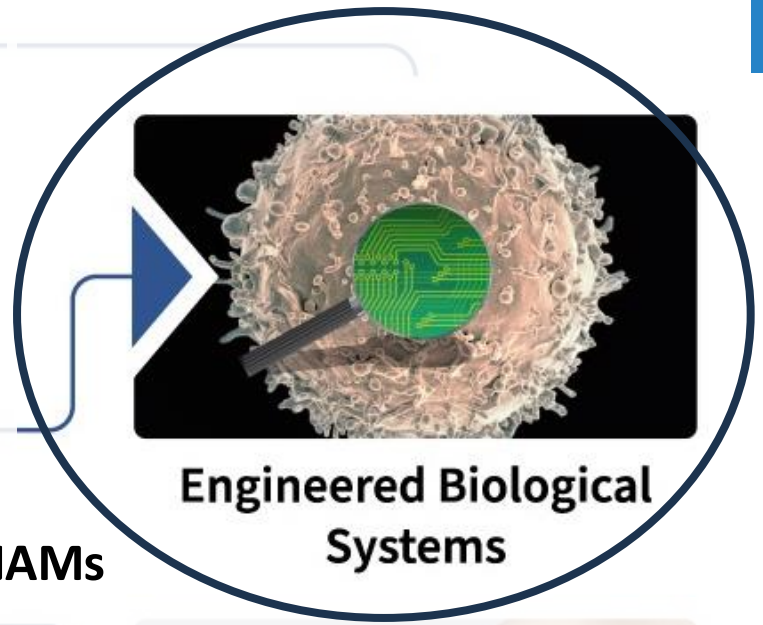
https://www.nist.gov/programs-projects/nistnibib-medical-imaging-phantom-lending-library
https://www.nibib.nih.gov/labs-at-nibib/center-for-biomedical-engineering-technology-acceleration-beta/national-phantom-library-npl

NAMs Standardization Challenges

U.S. FOOD & DRUG ADMINISTRATION

April 10, 2025

FDA Announces Plan to Phase Out Animal Testing Requirement for Monoclonal Antibodies and Other Drugs



FDA will reduce, refine, or potentially replace animal testing requirements using a range of NAMs

NIH Role in FDA Roadmap includes:

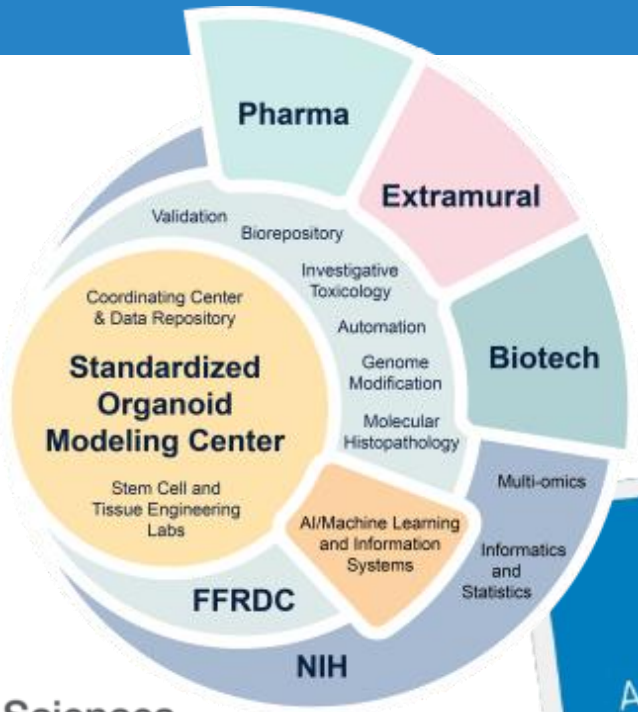
- NAM funding and research support: *Complement-ARIE CF initiative*
- Shared data and databases
- Agency coordination, training, workgroups, outreach
  - *Office of Research Innovation, Validation, and Application (ORIVA)*
- Public-private partnerships (PPP) via federal consortia

Who Is Developing NAMs?

National Toxicology Program
National Institute of Environmental Health Sciences
National Center for Computational Toxicology
United States Environmental Protection Agency
Tox21
National Human Genome Research Institute

UNITED STATES
ICCVAM
Advancing Alternatives to Animal Testing

ARPA-H
Animal Toxicology



BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY
BARDA

NCGC
NIH Chemical Genomics Center

NIH National Institute of Environmental Health Sciences

In vitro cell-based assays, quantitative high-throughput screening and informatics

NIH National Center for Advancing Translational Sciences

NIH The Common Fund



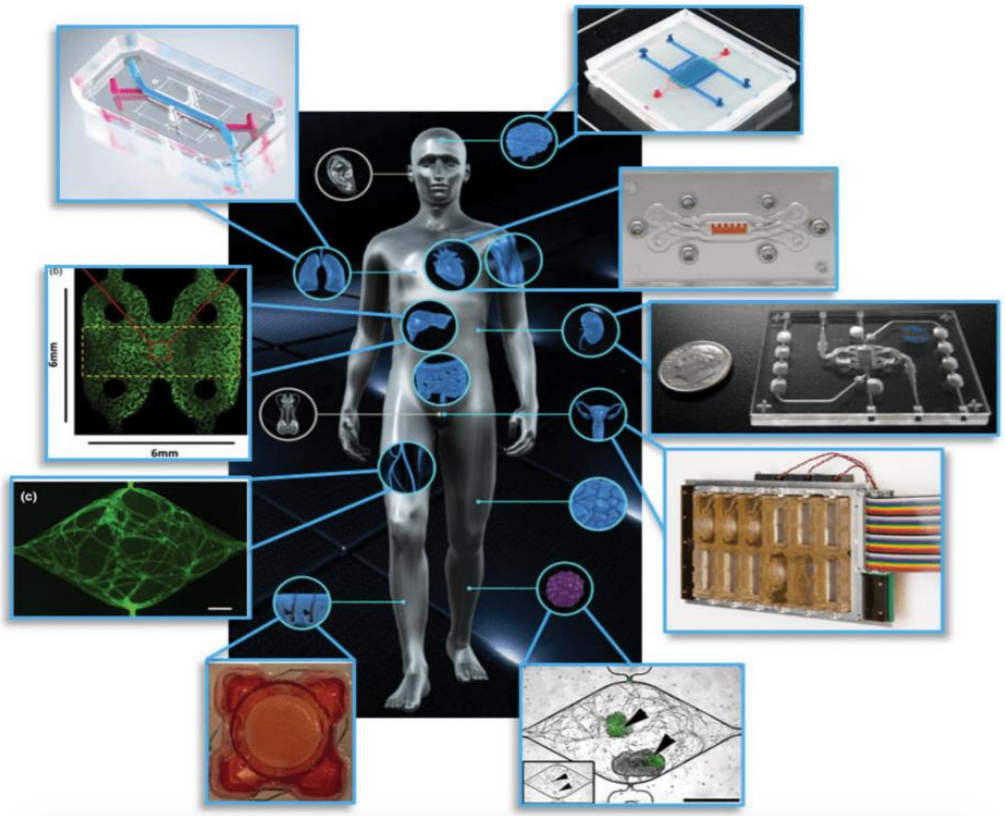


NIH National Institute of Biomedical Imaging and Bioengineering

NAMs Standardization Challenges

Addition of engineering paradigms to NAMs essential for optimizing performance, reproducibility, scalability

- Sensors + imaging, fluidics, and process engineering for NAMs feedback-control
- Combination in silico and in vitro NAMs for Digital twins w/measurable free parameters
- Personalizable, manufacturable, scalable NAMs (adjustable cell types and materials)
- Syn-bio, Mechano-bio to optimize function



Tissue chips – innovative tools for drug development and disease modeling - Lab on a Chip (RSC Publishing) 2017

Summary & Conclusions

Rapid growth of Bioengineering and Bioimaging Tech Across NIH: ~15% of NIH budget in 2025

- *Engineering Tech creation high; funding VVQ & Standards low: innovate vs replicate dilemma*

VVQ/S >16% of NIBIB budget, mostly hard materials/AI computation; strong NIBIB patent rate, regulatory and market success. New healthcare opportunities:

- *Standards for home and POC metrology to inform Telehealth;*
- *Multimodal data repositories for validated AI algorithm development*

New demand for standards in soft materials/NAMs: *FDA and Biomanufacturing*

- *Lagging behind hard materials due to bio + regulatory complexity, evolving markets, "boutique" labs*
- *Standards improve efficiency, lower cost, expand access to cell and regenerative therapies*

Convergence:

- *Lessons and tech from Imaging/sensing, engineering, computation, materials, etc. essential for defining VVQ/S features in NAMS/Engineered Biology*

Form partnerships across Academia, Gov't and Private sector to prioritize, expand impact