61st Meeting of the National Institutes of Health (NIH) Advisory Committee on Research on Women's Health (ACRWH)
October 8th, 2024

Accelerating Innovation and Technology Development in Women's Health through Engineering-Medicine Partnerships

Jennifer Jackson, Zeynep Erim, Afrouz Anderson, Behrouz Shabestari, Jonathan Kulwatno, Rui Sa, Brad Bower, Qi Duan, Randy King, Tatjana Atanasijevic, Kari Ashmont, Robert Barry, Taylor Gilliland, Asha Storm, Shumin Wang, Martin Tornai, David Gutekunst, Khalil Chughtai

Bruce J. Tromberg, Ph.D.

Director, National Institute of Biomedical Imaging and Bioengineering

Bioengineering at NIH

NIBIB and BME Growth

2000: *Creation of NIBIB*

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.

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

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

SECTION 1. SHORT TITLE.

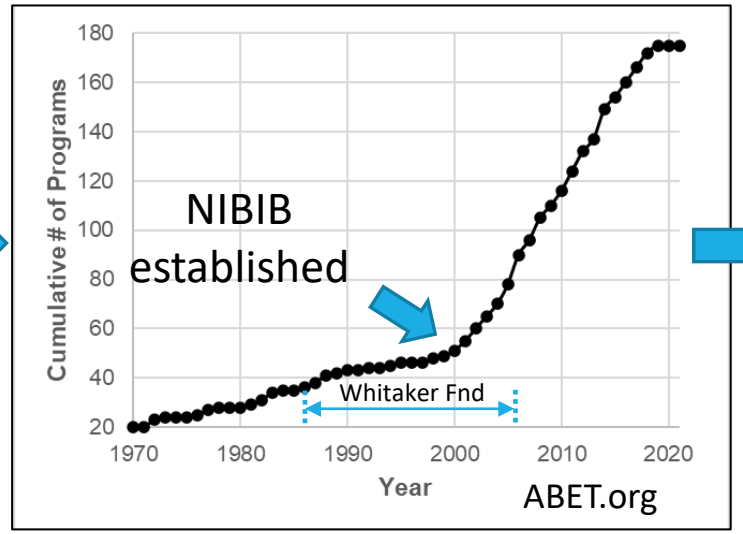
This Act may be cited as the "National Institute of Biomedical Imaging and Bioengineering Establishment Act".

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.

- 175+ accredited BME-related programs
- > 200 graduate programs

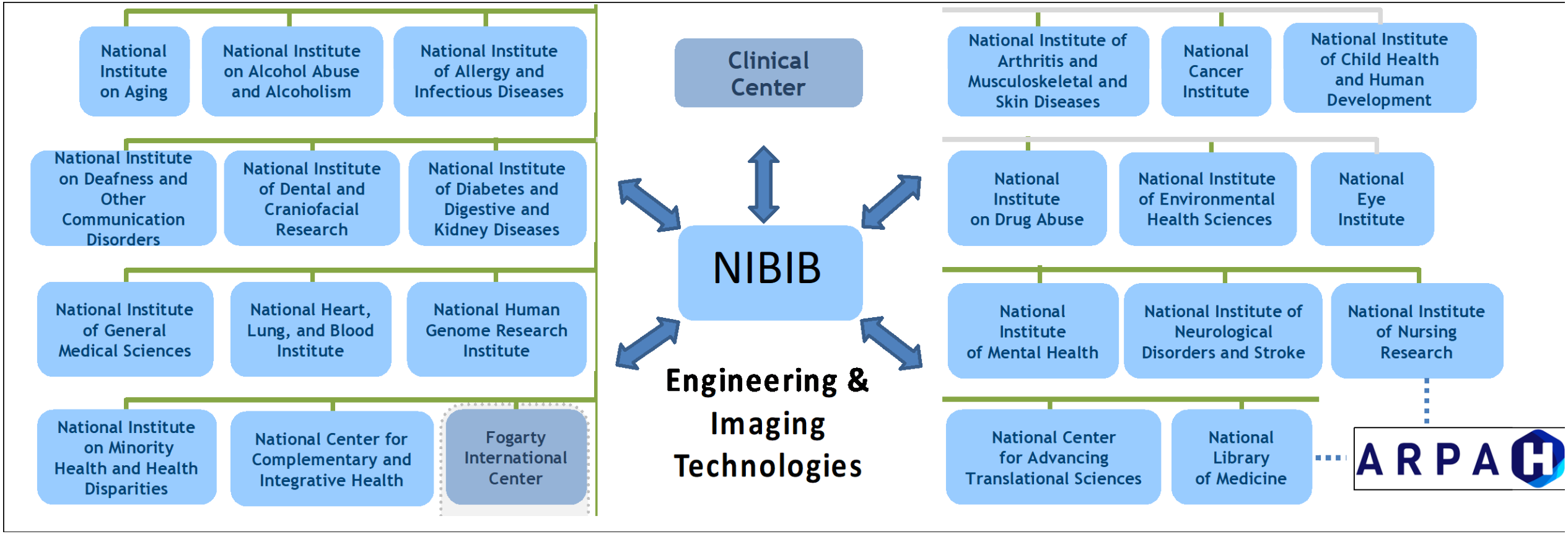


- **Human Health top priority of Engineering**
- **Medicine-Engineering partnerships:** ***Physicianeers***
  - BME Centers SOM/SOE
  - University of Illinois Urbana - Champaign
  - Texas A&M University
- ***Drive Innovation, Entrepreneurship, Diversity***

https://blog.collegevine.com/us-colleges-with-biomedical-engineering-major/

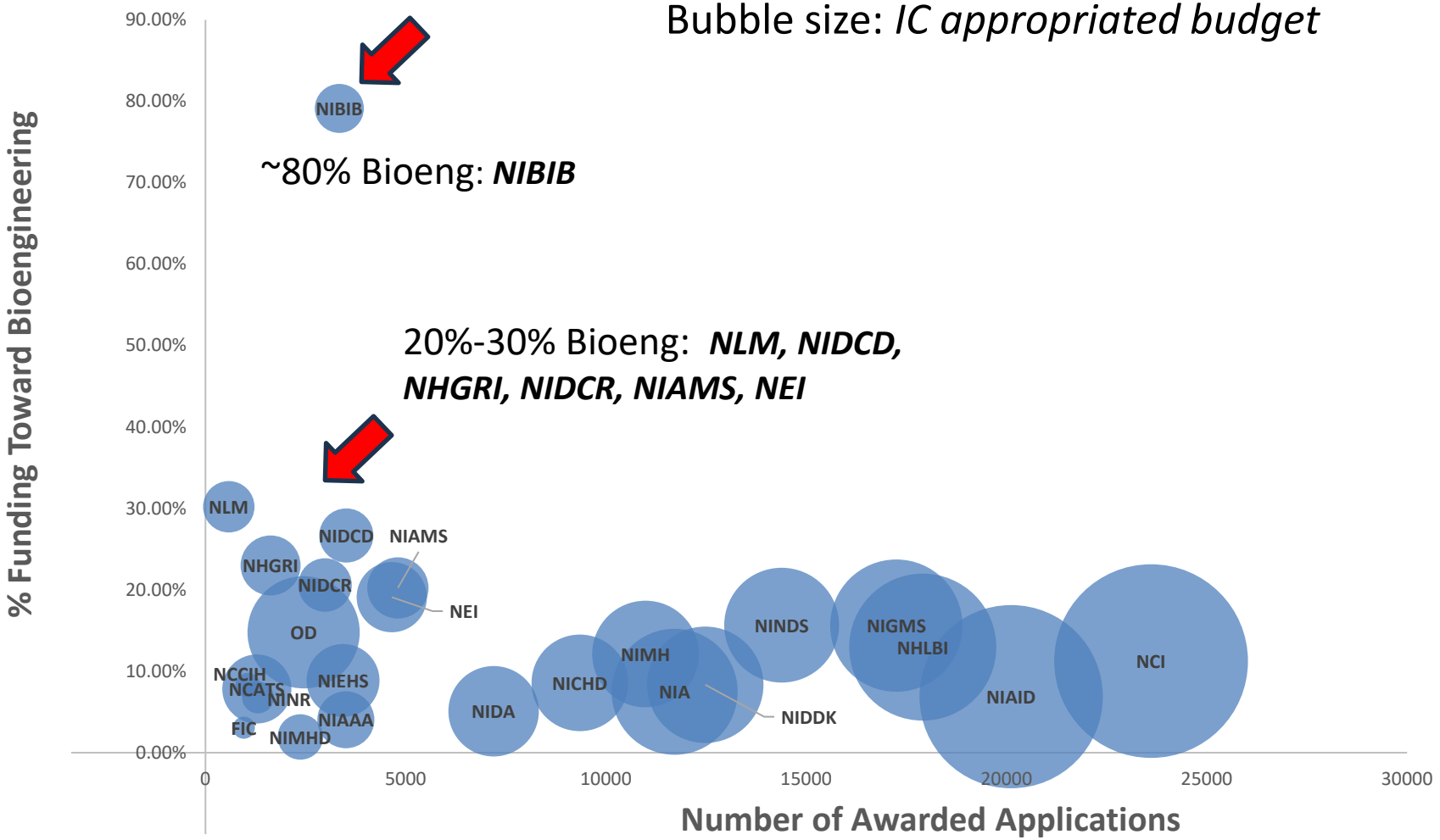
NIBIB @ NIH

NIBIB: ~1% NIH Budget→ *Partnerships and Collaboration*



NIH RCDC Bioengineering Portfolio

% Funding to ***Bioengineering*** vs. all funded awards, FY13-23 *~55.6B total*
Bubble size: *IC appropriated budget*



NIH RePORTER

NIH RCDC Bioengineering Portfolio

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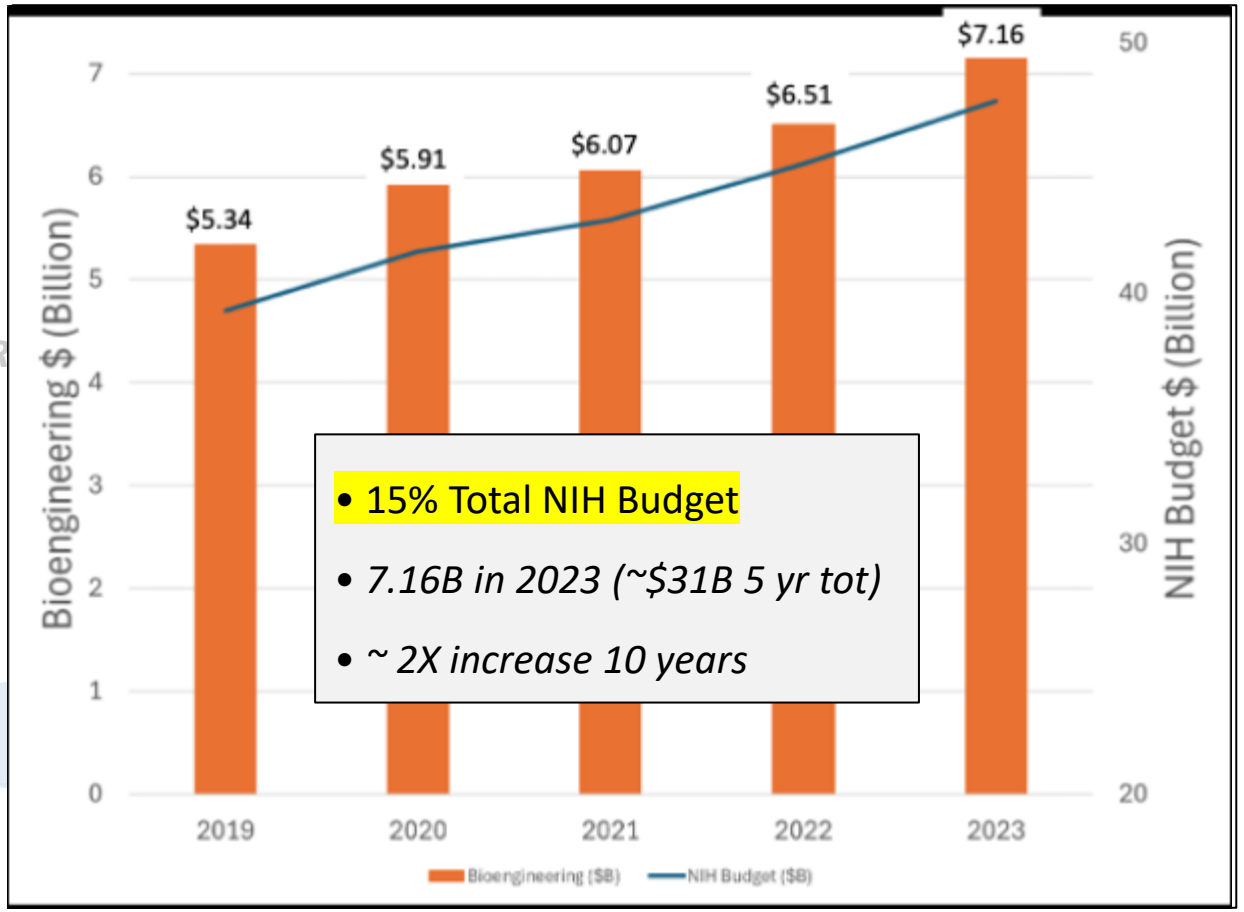
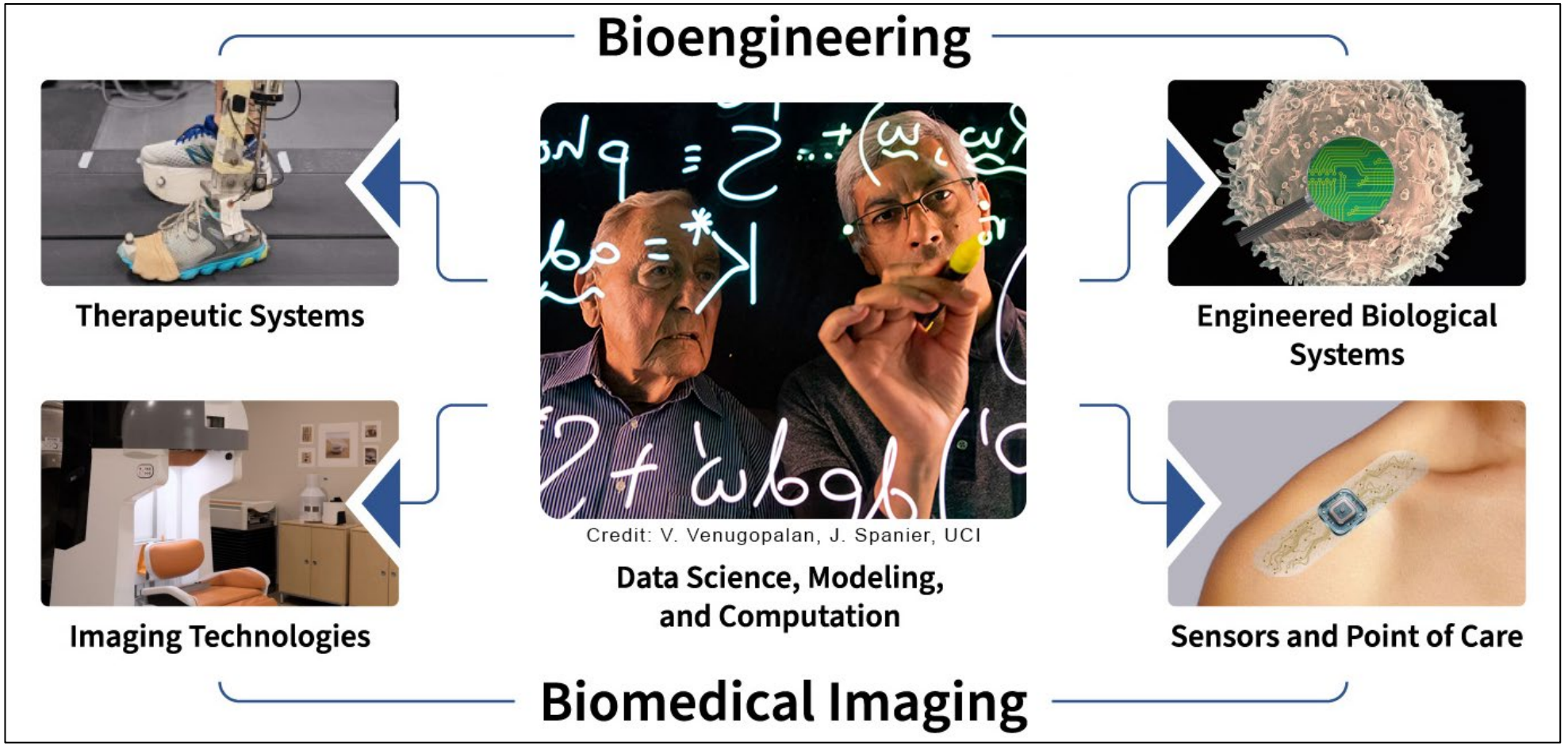


NIH RePORTER

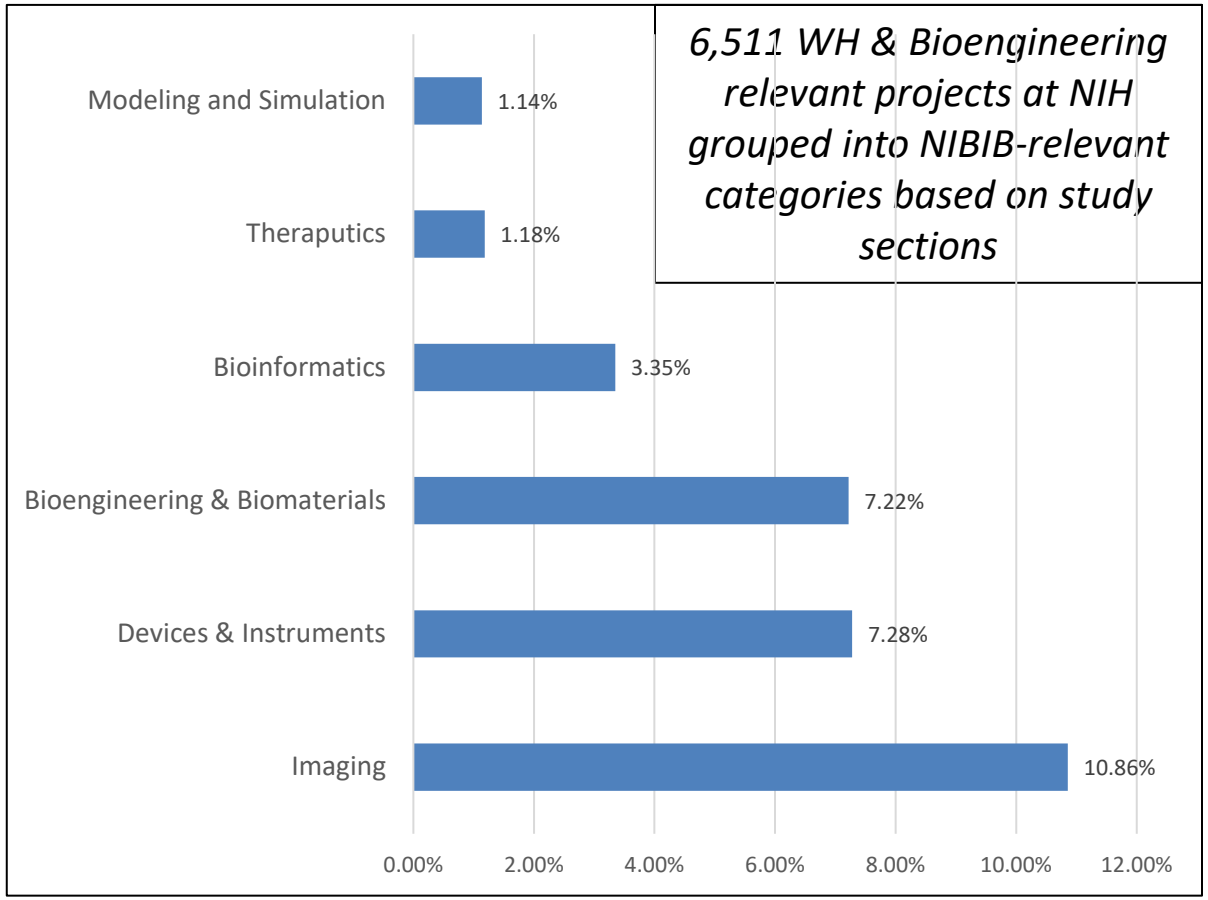
NIBIB Mission: *Technology & Innovation*

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



NIH Bioengineering and Women's Health

Women's Health (WH) & Bioengineering RCDC awards at NIH (FY19-23)



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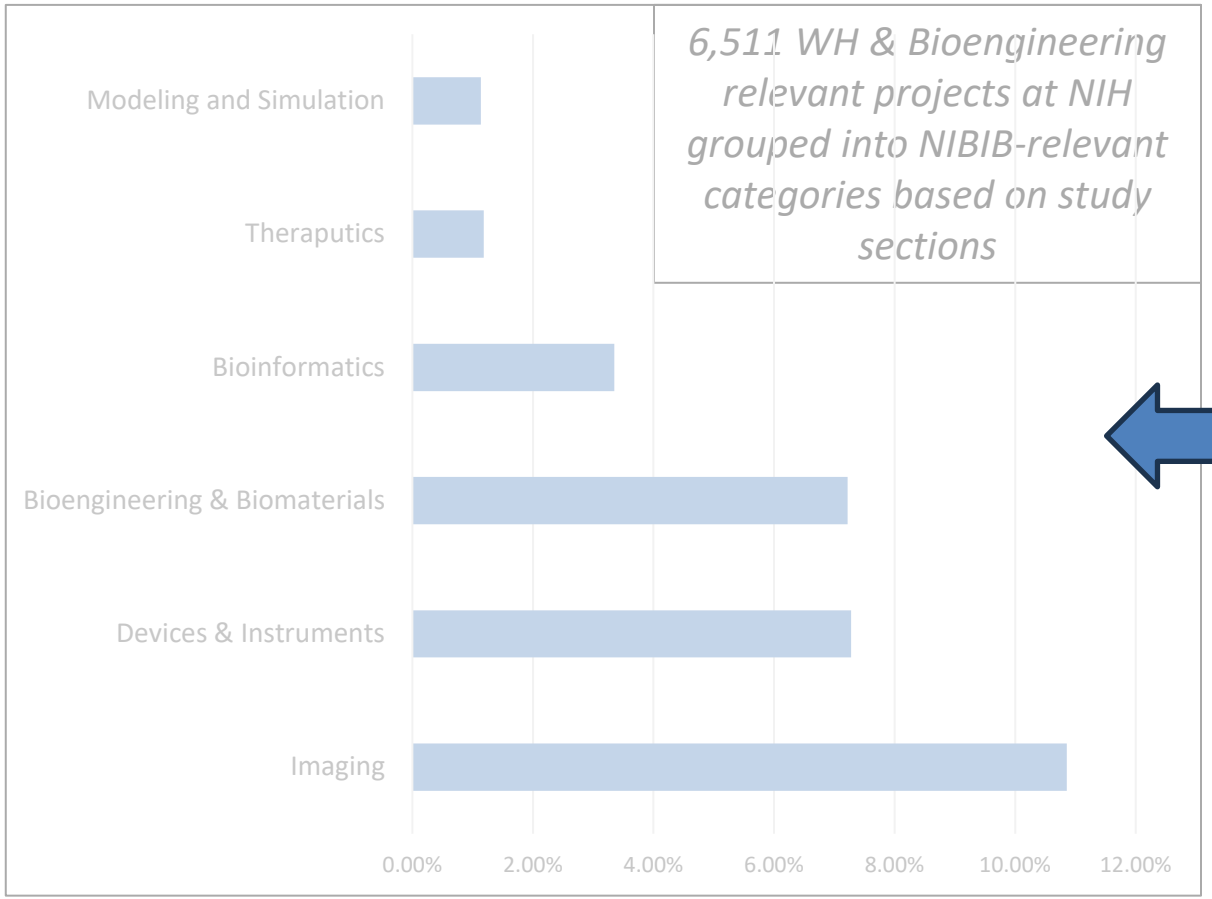
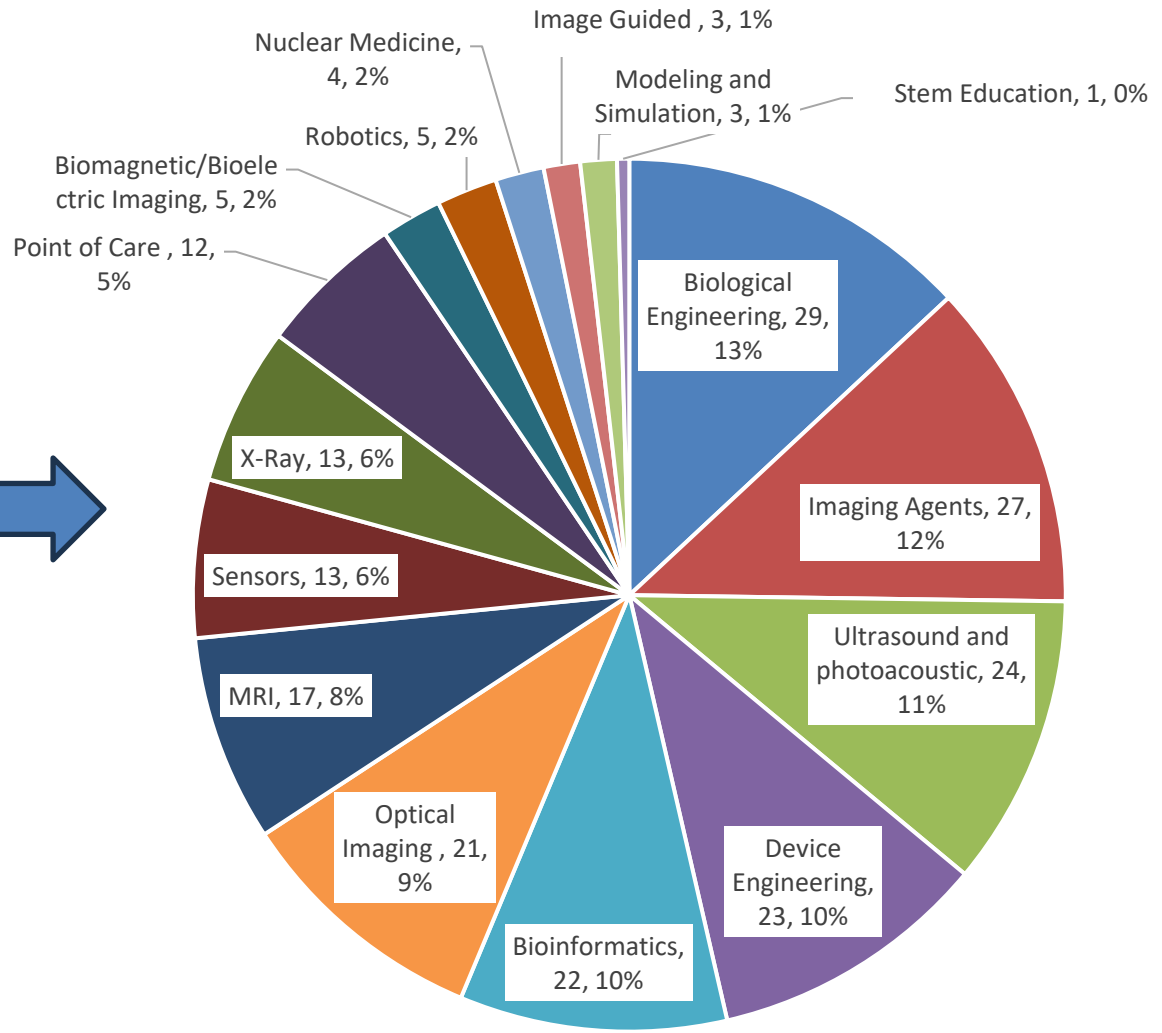


NIBIB funded awards relevant to Women's Health (FY19-23)



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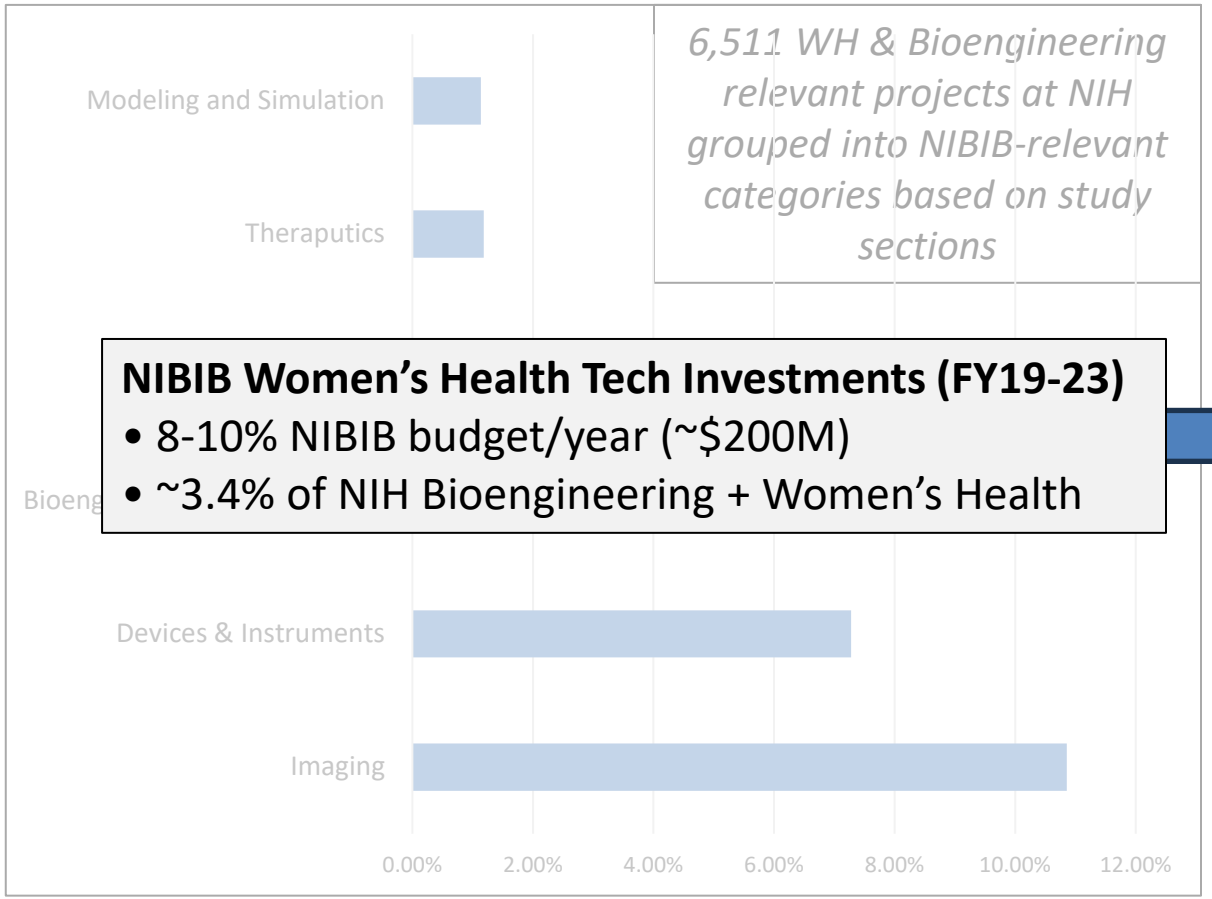
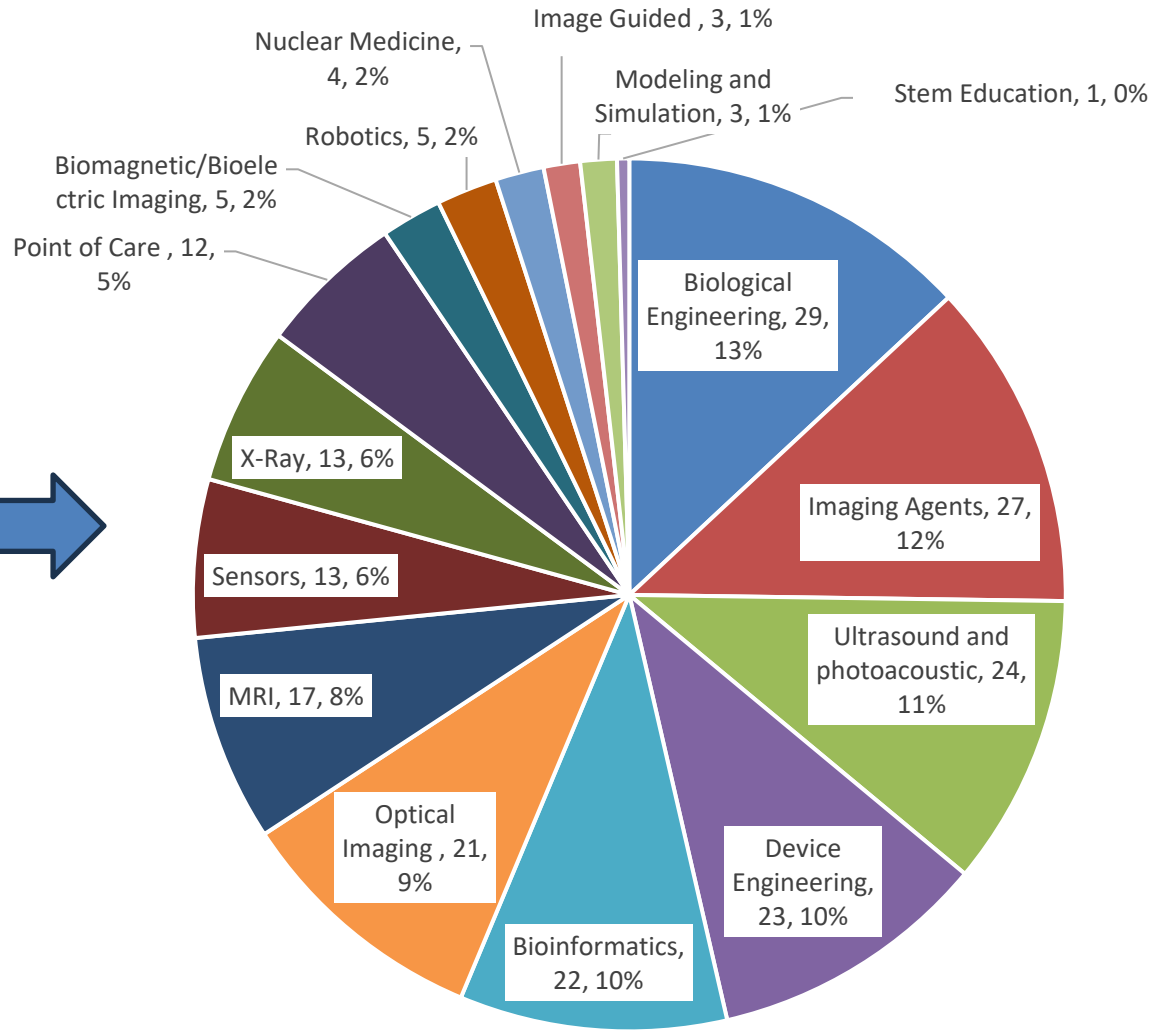


6,511 WH & Bioengineering relevant projects at NIH grouped into NIBIB-relevant categories based on study sections

NIBIB Women's Health Tech Investments (FY19-23)

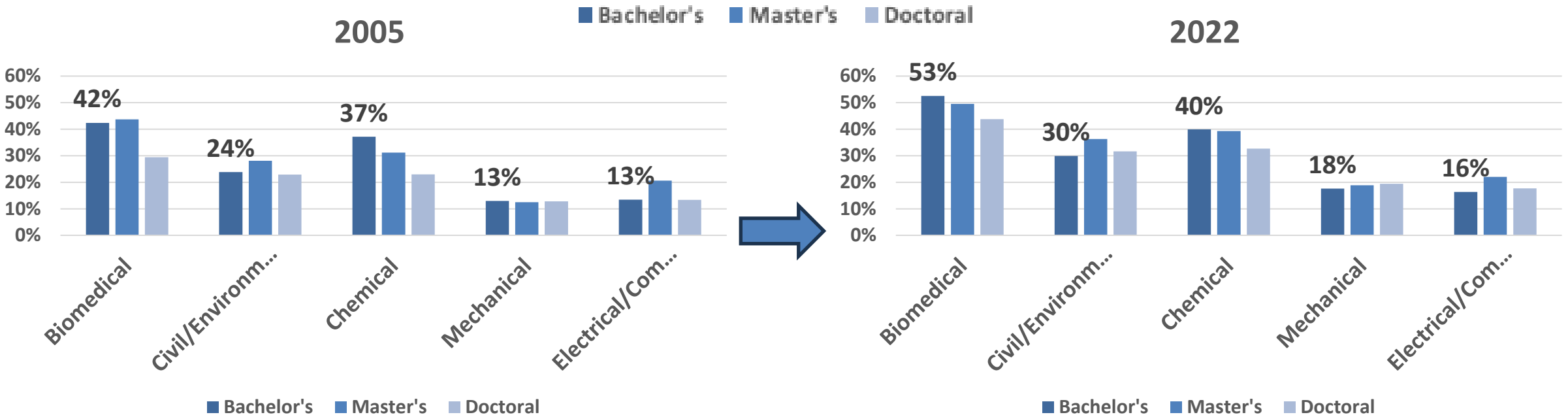
- 8-10% NIBIB budget/year (~$200M)
- ~3.4% of NIH Bioengineering + Women's Health

NIBIB funded awards relevant to Women's Health (FY19-23)



Women in Engineering: *Students*

Percentage of Engineering Degrees Awarded to Women



Women	Bachelor's	Master's	Doctoral
Biomedical	1022	440	98
Civil/Environmental	2141	1288	196
Chemical	1682	438	185
Mechanical	1943	596	123
Electrical/Computer	2796	2352	252

~3.9X increase

(all other depts 1.8X)

Women	Bachelor's	Master's	Doctoral
Biomedical	4184	1471	498
Civil/Environmental	4700	1844	449
Chemical	3569	602	381
Mechanical	5789	1259	366
Electrical/Computer	4060	2114	479

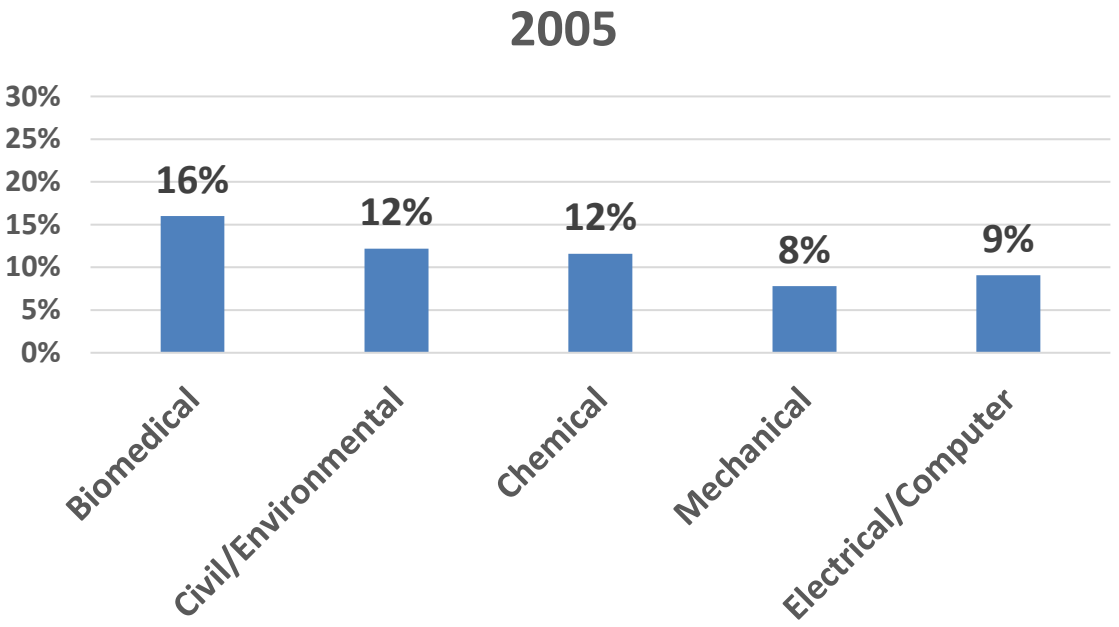
5X

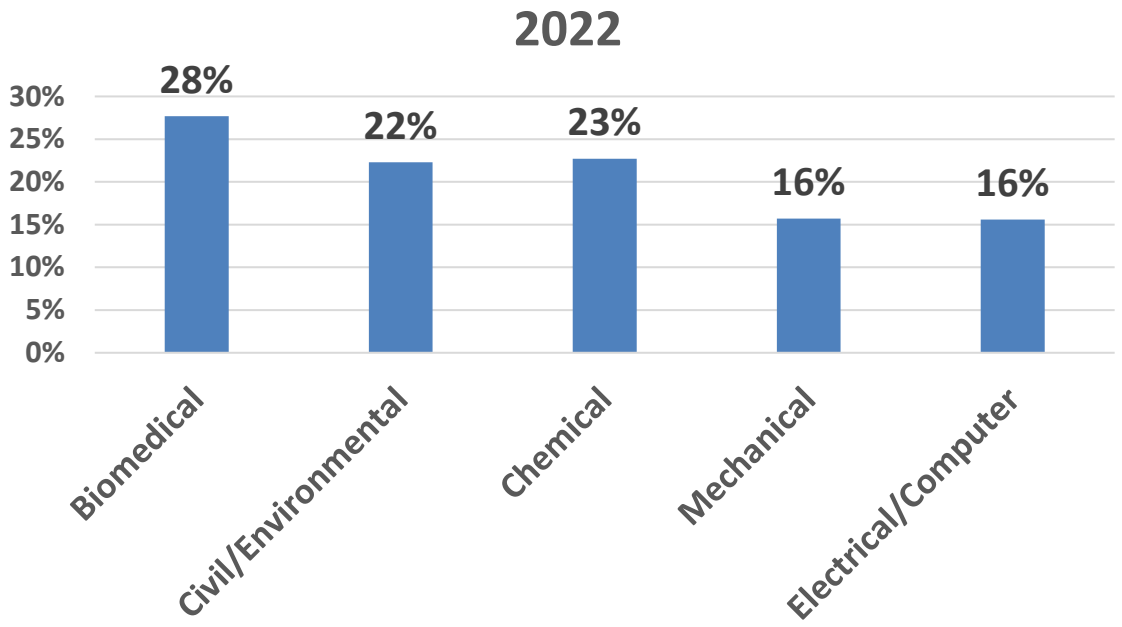
Based on data from https://www.dropbox.com/scl/fo/pzjo0hzobv8r5urirhrwu/ACtl-y9K2hIBiOQkpRHpiAo?e=3&preview=2005+Profiles+-+Full+Front+Section.pdf&rlkey=5l4wecv34x70w4r4g2qgkr07b&st=mijc1v6l&dl=0

Based on data from https://ira.asee.org/wp-content/uploads/2024/03/Engineering-and-Engineering-Technology-by-the-Numbers-cover-combined.pdf

Women in Engineering: *Faculty*

Percentage of Female Tenured/Tenure-Track Faculty





	Women
Biomedical	149
Civil/Environmental	455
Chemical	219
Mechanical	355
Electrical/Computer	576

~3.4X increase

(all other depts ~1.9X)

	Women
Biomedical	500
Civil/Environmental	849
Chemical	482
Mechanical	821
Electrical/Computer	938

Based on data from https://www.dropbox.com/scl/fo/pzjo0hzobv8r5urirhrwu/ACtl-y9K2hIBiOQkpRHpiAo?e=3&preview=2005+Profiles+-+Full+Front+Section.pdf&rlkey=5l4wecv34x70w4r4g2qgkr07b&st=mijc1v6l&dl=0

Based on data from https://ira.asee.org/wp-content/uploads/2024/03/Engineering-and-Engineering-Technology-by-the-Numbers-cover-combined.pdf

Design by Biomedical Undergraduate Teams Challenge

DEBUT

*Total prize purse of $**160,000** in 2024 for 16 winning teams*

NIH National Institute of Biomedical Imaging and Bioengineering

$20,000, $15,000, $10,000 +

5 HM prizes ($1,000 each)

VENTUREWELL™ idea to impact $15,000 and $5,000

Award Ceremony on October 25th at BMES conference in Baltimore

Six $15,000 prizes provided by ICO partners

- NIH National Institutes of Health — *Office of AIDS Research*
- NIH National Institute on Minority Health and Health Disparities
- NIH National Cancer Institute
- NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development
- NIH National Institute of Nursing Research
- NIH National Institute of Diabetes and Digestive and Kidney Diseases

Dave Gutekunst

Design by Biomedical Undergraduate Teams Challenge

DEBUT

*Total prize purse of $**160,000** in 2024 for 16 winning teams*

Eight prizes awarded by NIBIB: $20,000, $15,000, $10,000
+ 5 Honorable Mention prizes ($1,000 each)

Six $15,000 prizes provided by ICO parners

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development

National Institute of Nursing Research

National Institute of Diabetes and Digestive and Kidney Diseases

DEBUT 2024

85 applications from 362 students at
48 universities in 24 states

DEBUT 2025

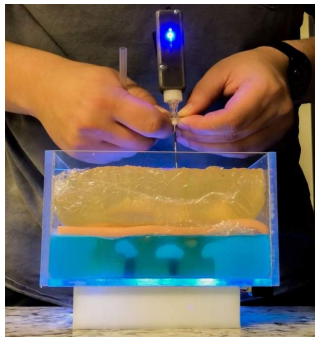
$190k, 18 prizes, 2 new sponsors:
ORWH & NIA

Award Ceremony on October 25th at BMES conference in Baltimore

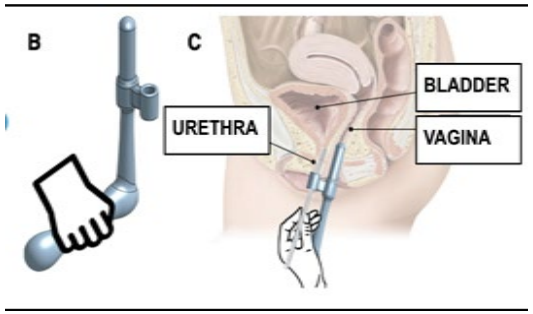
Dave Gutekunst

DEBUT Design by Biomedical Undergraduate Teams Challenge

2018 Neuraline ***GeorgiaTech Needle Delivery System***



2019 The Cath Path ***Stanford University*** **self catheterization** ***Device***

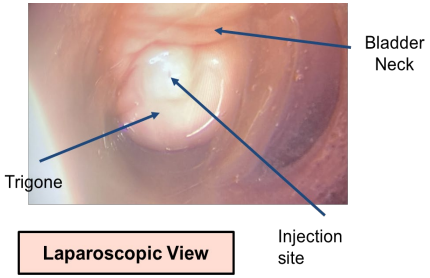


2019 The Hera Bra ***Columbia University*** **Detection of subclinical mastitis**

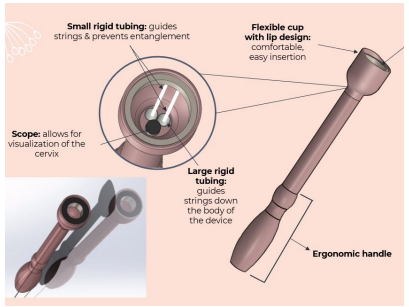
2020 At Your Cervix ***Rice University:*** **Universal Obturator for Brachytherapy**

Video

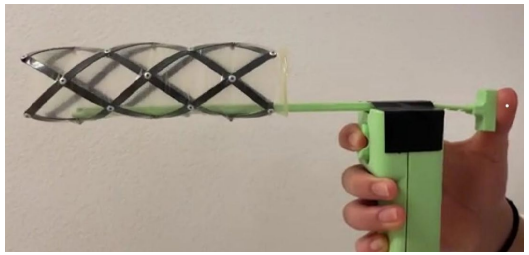
2021 Team PCR ***Stanford University:*** **ultrasound-guided transvaginal medication delivery**



2022 CERV ***Columbia University:*** **device to measures cervical stiffness and visualize the cervix**

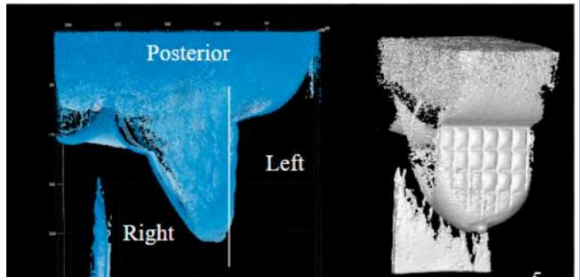


2023 Feminora ***OneSpec. University of California-Irvine:*** **vaginal speculum** ***device to reduce pain***

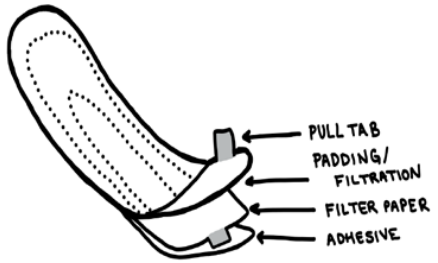


Video

2023 Breast MRI Biopsy Positioning and Immobilization Device. ***University of Wisconsin-Madison***

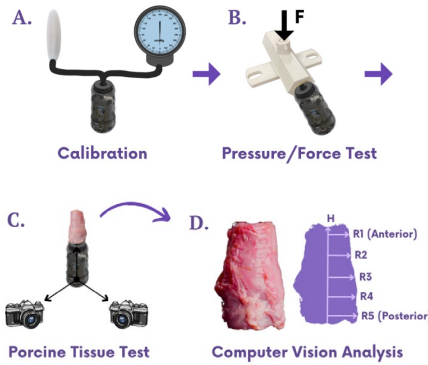


2023 FADPad ***Georgia Institute of Technology:*** **The Filter Adhesive Diagnostic pad is an at-home menstrual blood diagnostic**



Video

2023 MiaFit ***University of California-San Diego*** **affordable vaginal dilator for vaginal stenosis** Video



DEBUT Design by Biomedical Undergraduate Teams Challenge

2024 NIBIB 3rd Prize *($10,000)* ***Northwestern University***

Cesarean Delivery Glove is a cost-effective, reusable device that allows a single operator to safely and effectively prevent impaction of the fetal head within a mother's pelvis during the cesarean section procedure.

Video

Honorable Mention *($1,000)* ***Washington University in St. Louis***

CERV: Cervical Dilation Monitor is a device that uses an endoscope held in the vaginal canal by a silicone cup to image the cervix and compute dilation.

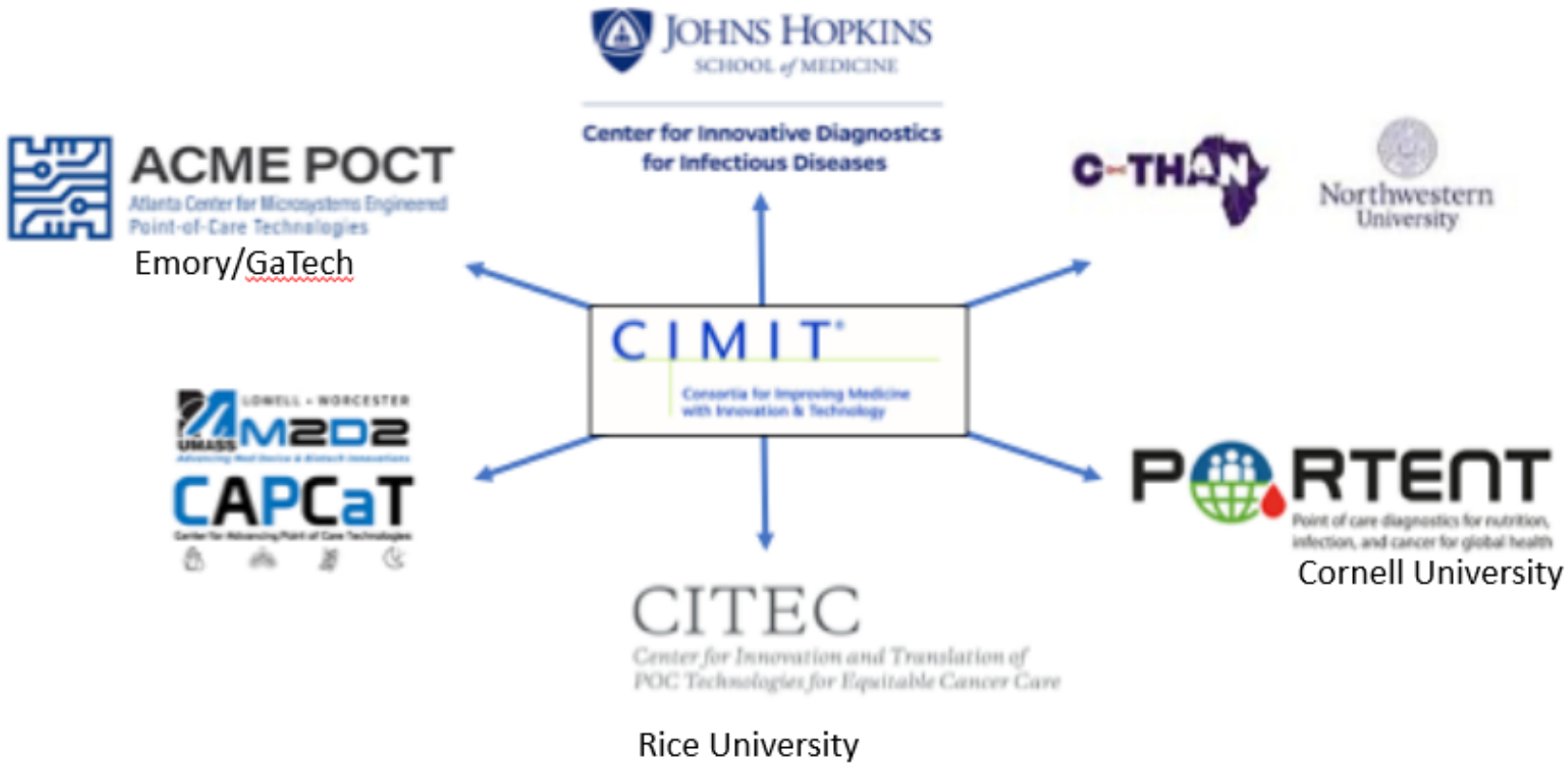
Video

Point of Care Technologies Research Network (U54)

POCTRN
POINT OF CARE TECHNOLOGIES RESEARCH NETWORK

- National Institute of Biomedical Imaging and Bioengineering
- National Heart, Lung, and Blood Institute
- National Institute of Allergy and Infectious Diseases
- National Center for Complementary and Integrative Health
- Fogarty International Center
- Office of Behavioral and Social Sciences Research
- Office of AIDS Research
- Office of Disease Prevention

www.poctrn.org



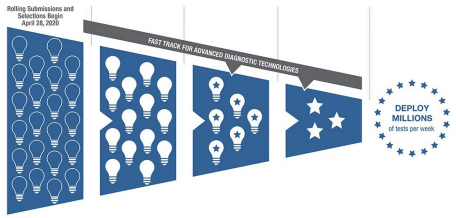
Rapid Acceleration of Diagnostic Technology (RADx Tech)

NIBIB Point of Care Tech Research Network (POCTRN U54)

April 29, 2020: >900 RADx experts & contributors: (USG, Academia, Industry, NFP)

https://www.nibib.nih.gov/covid-19/radx-tech-program

Innovation Funnel
(shark tank)



>1000 applications

VENTUREWELL idea to impact

GaTech/Emory
- ✓Engineering
- ✓Design/Prototype
- ✓Clinical Validation
- ✓Biobank samples
- ✓In-Home Validation

Johns Hopkins
- ✓Public Health/STD
- ✓Global Health
- ✓Clinical Validation
- ✓Biobank samples
- ✓Validation in LMICs

CIMIT/MGH
- ✓Coordinating Center
- ✓Collaboration/Management Platform
- ✓Business/Commercialization

Northwestern
- ✓HIV/AIDS
- ✓Engineering
- ✓Global Health
- ✓Clinical Validation
- ✓Validation in LMICs

UMass
- ✓Heart, lung, blood
- ✓Engineering
- ✓Clinical Validation
- ✓Biobank samples
- ✓Clinical Trials
- ✓Business/Commercialization

C BIO M C3i

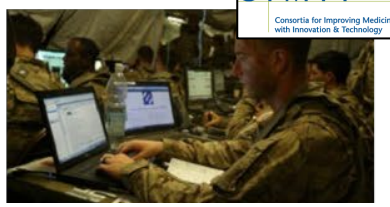
https://www.poctrn.org

Validation Core

>1000 projects complete, >10,000 participants

Clinical Studies Core

Standard Trial Design, Digital Health Platform, Single IRB, Center Network



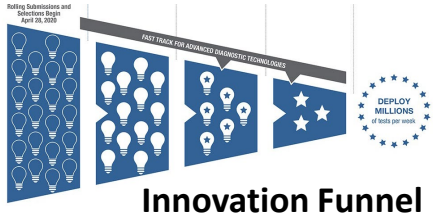
Deployment Core

Supply chain, Manufacturing, User Community, *whentotest.org* My COVID Toolkit

RADx Tech: *Programs*

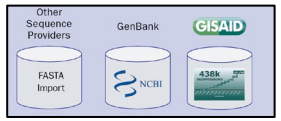
NIBIB Point of Care Tech Research Network (POCTRN U54)

April 29, 2020: >900 RADx experts & contributors: (USG, Academia, Industry, NFP)



Innovation Funnel

RADx MARS
Digital Health



Variant Task Force
Project Rosa

Independent Test Assessment (ITAP)

makemytestcount.org

https://www.access-board.gov/tad/radx/

Test Accessibility

https://www.nibib.nih.gov/covid-19/radx-tech-program

https://www.poctrn.org

>1000 projects complete, >10,000 participants

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Standard Trial Design, Digital Health Platform, Single IRB, Center Network

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Deployment Core

RADx Tech: *Impact*

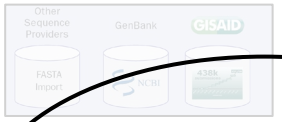
NIBIB Point of Care Tech Research Network (POCTRN U54)

April 29, 2020: >900 RADx experts & contributors: (USG, Academia, Industry, NFP)

https://www.nibib.nih.gov/covid-19/radx-tech-program

Innovation Funnel

RADx MARS
Digital Health



Variant Task Force
Project Rosa

Independent Test Assessment (ITAP)

makemytestcount.org

https://www.access-board.gov/tad/radx/

Test Accessibility

Test Capacity

>7.8 billion Tests and products produced	56 EUAs 19 OTC, 17 POC
15 Multiplex COVID-19/Flu Test EUAs via ITAP	Paradigm Shift: **OTC, POC >> Lab**

https://www.poctrn.org

>1000 projects complete, >10,000 participants

Validation Core

Standard Trial Design, Digital Health Platform, Single IRB, Center Network

Clinical Studies Core

Supply chain, Manufacturing, User Community, *whentotest.org* My COVID Toolkit

Deployment Core

RADx Tech: *What's Next?*

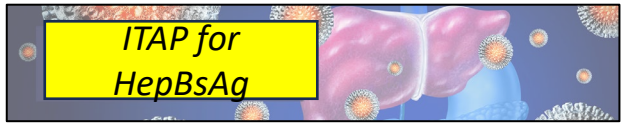
NIBIB Point of Care Tech Research Network (POCTRN U54)

https://www.nibib.nih.gov/covid-19/radx-tech-program

Infectious Disease

HCV PCR de novo 510k (POC, 6/27/24)

2 MPox PCR EUAs (POC, Home swab)



Chronic Disease+Prevention

Partners

NIH: *OD, NIAID, NCI, NIDA, NICHD, ORWH, NINR, OAR, BluePrint (NINDS + 10 NIH institutes)*

USG: *FDA, CDC, BARDA, ASPR,*

NFP: *Gates Foundation*

Taylor Gilliland, Ph.D.
RADx/Prize Structure

RADx® Tech for Maternal Health Challenge

- $8 million in cash awards to accelerate the development of maternal health diagnostic devices, wearables, or other remote sensing technologies for use in maternity care deserts.
- Focuses on improving maternal health outcomes during the first year of the postpartum period (<1 year from the day of birth or end of pregnancy)

NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

NIH National Institute of Biomedical Imaging and Bioengineering

RADx Tech Innovation Funnel Challenge

Rapidly de-risk and validate technologies with stage-gated, milestone-based, cash prize awards

Kari Ashmont, Ph.D.

Total Prizes: $8 million

Innovator Proposals
Prototype technology description and plans for cont'd development

Viability Assessment
Administrative Triage
Intro. Meeting
Viability Panel
Judging Panel A
Award Approving Official
$20k

Deep Dive Assessment
Deep Dive
Steering Panel
NIH Judging Panel B
Award Approving Official
$75k

15 Innovators

Technology Assessment
Project Team
Steering Panel
NIH Judging Panel B ★
Award Approving Official
FINALISTS
$525k

10 Innovators

6 grand prizes &
2 runners-up

Transition to NIH networks for potential clinical studies and implementation research support

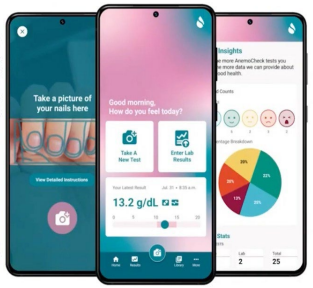
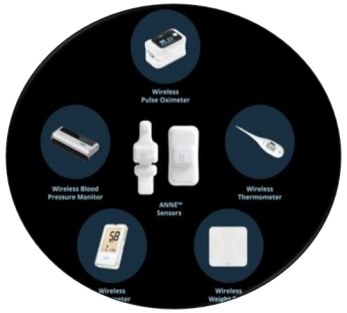
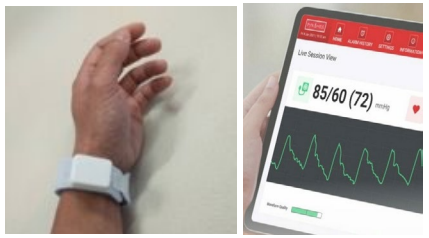
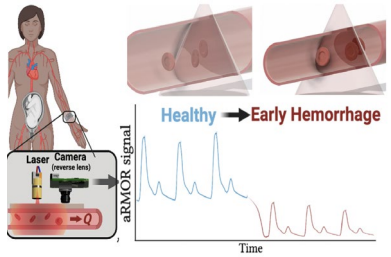
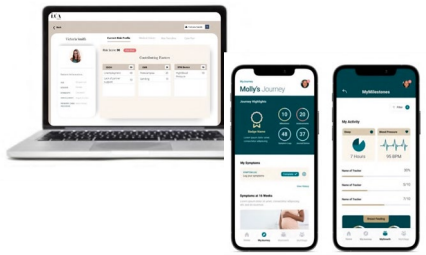
IMPROVE CoE

= award payment

RADx Tech for Maternal Health: Summary of Technologies

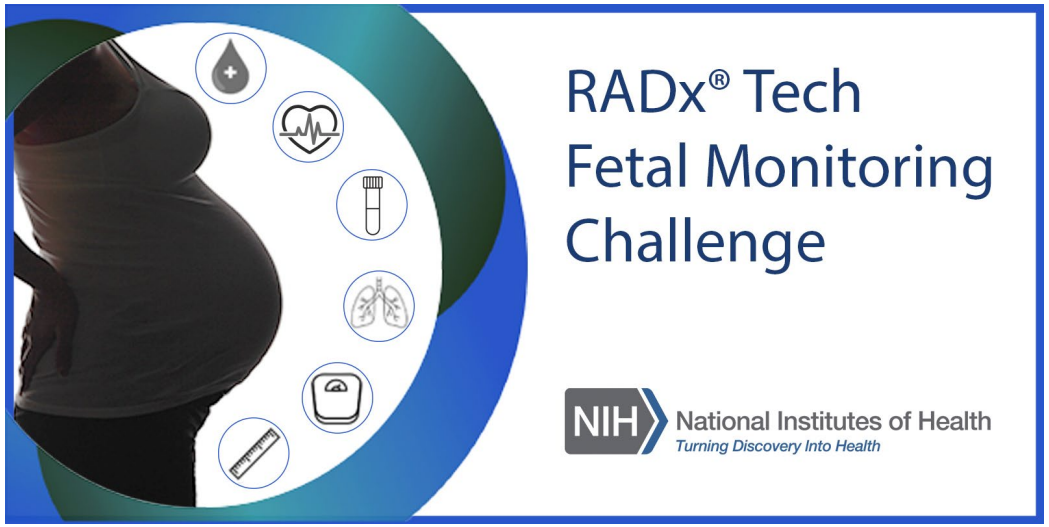
Clinical Performance Assessment Phase

NIH NICHD

Sanguina  Anemia mHealth	**Sibel Health**  CV Monitor Wearable	**Caretaker Medical**  CV Monitor Wearable	**Global Access Dx**  UTI Point of Care Dx	**Dionysus Digital Health**  PPD Test + mHealth
PyrAmes  BP Monitor Wearable	**CardieX**  BP Monitor Wearable	**HemoSonics**  Hemorrhage Point of Care Dx	**Wash U St. Louis**  Hemorrhage Wearable	**MyLUA Health**  Care management mHealth

RADx® Tech Fetal Monitoring Challenge

The unacceptable state of fetal health outcomes both within the U.S. and around the world especially in areas where there is limited access to high-quality prenatal healthcare.



Total Prizes: $2 million

- innovative and accessible technologies to enable earlier and more accurate diagnosis, detection, and monitoring of fetal health status in low-resource settings.
- Improving fetal health outcomes during the late antepartum and intrapartum periods of pregnancy

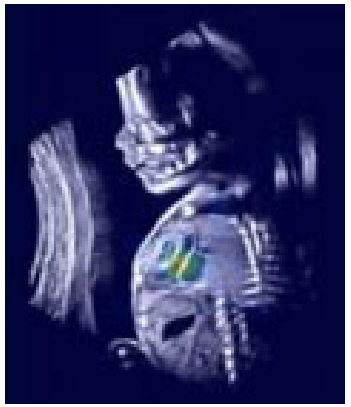
NIH National Institute of Biomedical Imaging and Bioengineering

NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

BILL & MELINDA GATES *foundation*

Currently Supported Technologies

https://www.nibib.nih.gov/news-events/newsroom/nih-awards-interim-prizes-fetal-diagnostic-and-monitoring-technology-competition

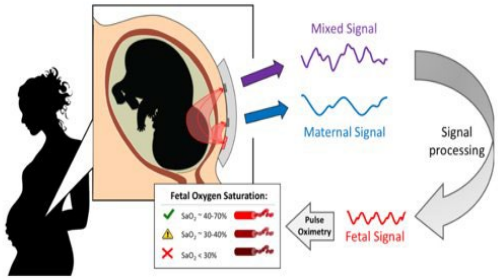


NextGen, UCSF

Deep learning model for ultrasound detection of congenital heart disease

Mayo Clinic

Quantitative micro-miniature intrapartum monitor



Storx Technologies

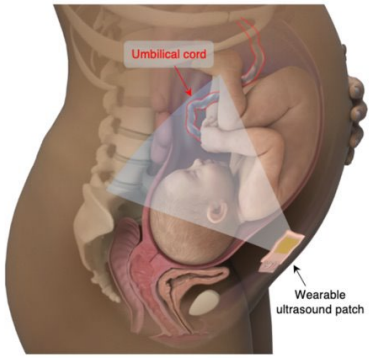
Transabdominal Fetal Oximetry

Raydiant Oximetry

Transabdominal Fetal Oximetry

Bloomlife

Wearable patch for fetal monitoring



Softsonics

Wearable ultrasound patch

RADx® Tech ACT ENDO Challenge

- $3 million in cash prizes to accelerate development of non-invasive technologies to improve diagnosis of endometriosis.
- Technologies should shorten the time to endometriosis diagnosis, eliminate the invasiveness of current techniques, and/or improve accessibility, safety, convenience and costs of diagnosis.

Submission Deadline: **October 11, 2024**

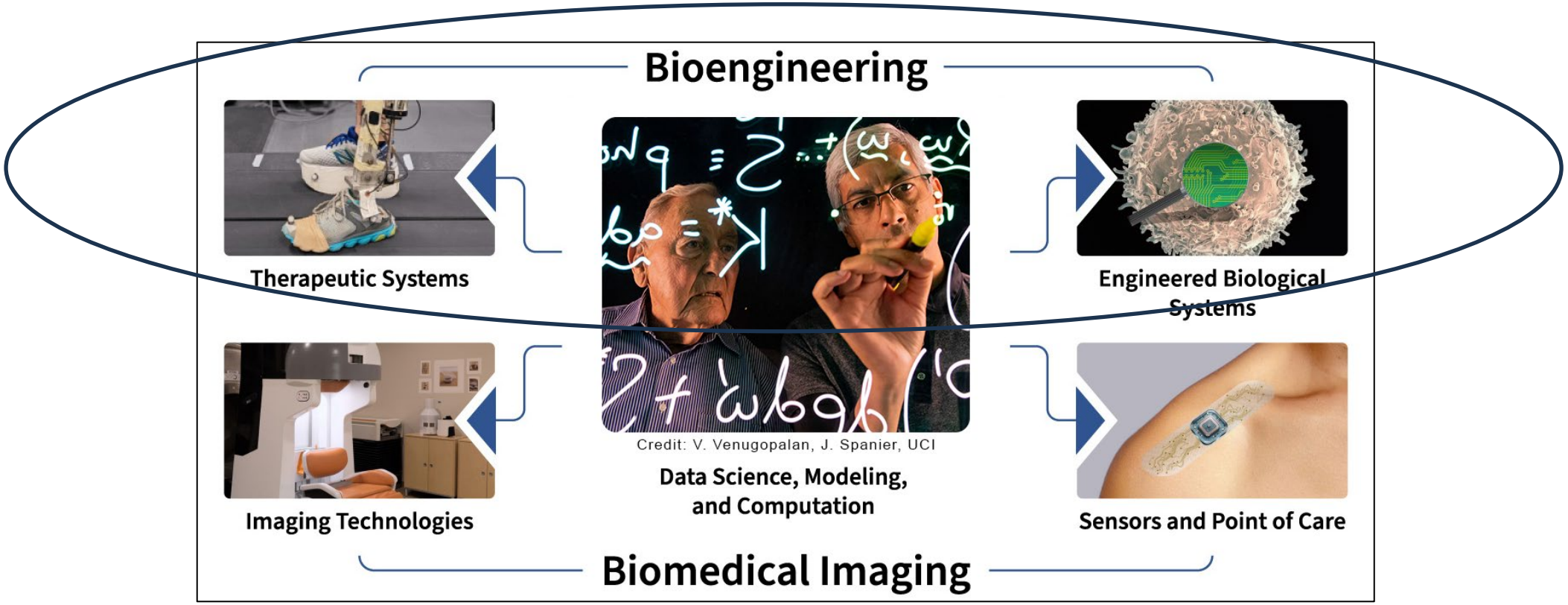
NIH National Institutes of Health
Turning Discovery Into Health

NIH *Eunice Kennedy Shriver* National Institute of Child Health and Human Development

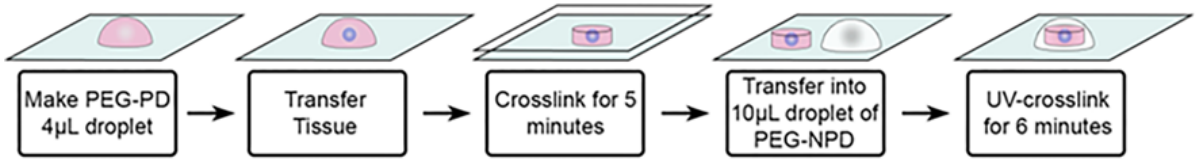
NIH National Institute of Biomedical Imaging and Bioengineering

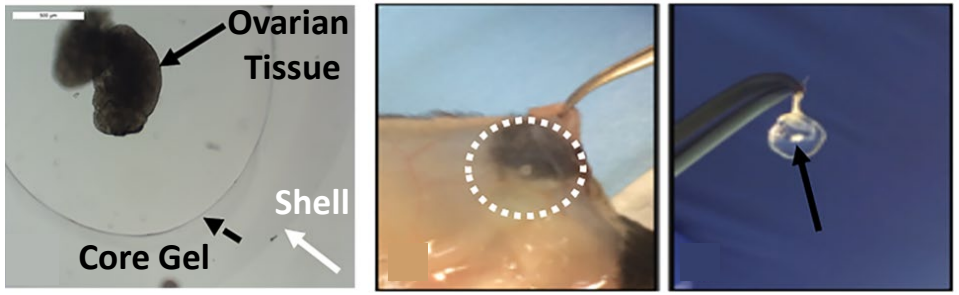
www.challenge.gov/?challenge=radx-tech-act-endo

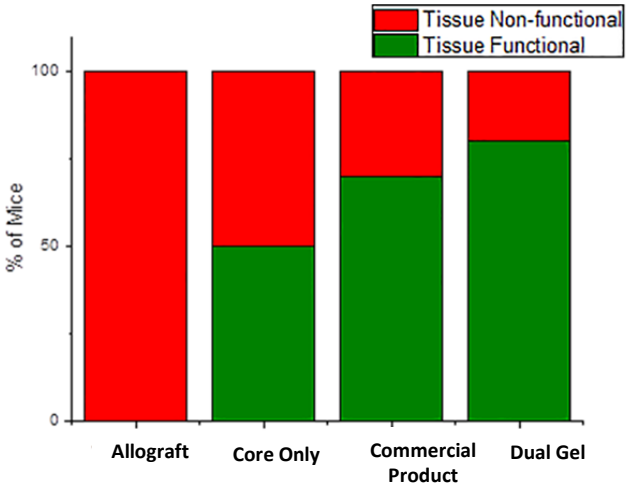
Engineered Biological Systems: *Materials & Therapies*

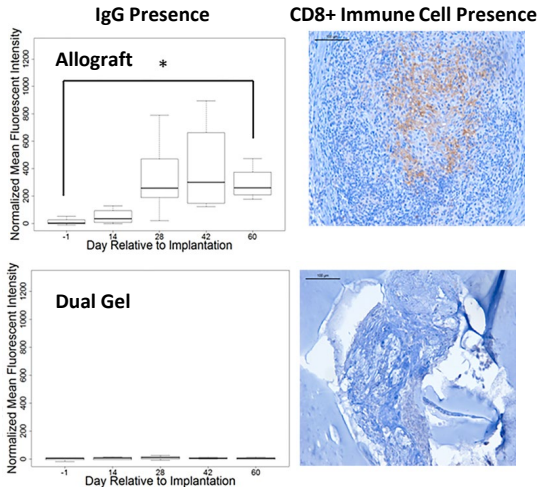


Engineering an Immuno-isolating Hydrogel for Restoring Ovarian Endocrine Function









Day, J. R., et al. (2019). Encapsulation of ovarian allograft precludes immune rejection and promotes restoration of endocrine function in immune-competent ovariectomized mice. Scientific Reports, 9(1), 16614.

NEED: Improvements in cryopreservation and auto-transplantation of ovarian tissue by preventing/reducing immune activity such as rejection.

METHOD: A dual gel consisting of ovarian tissue encapsulated in a core gel and then a shell gel.

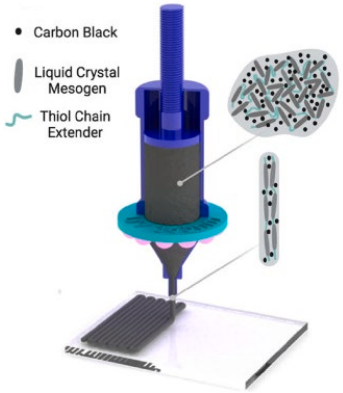
RESULTS: When implanted in mice, the ovarian tissue was able to regulate follicle-stimulating hormones and had consistent estrous cyclicity ("Functional"), while eliciting minimal immunogenicity (low IgG and CD8+).

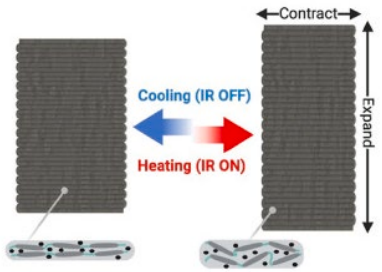
Ariella Shikanov (Assoc. Prof., U Michigan

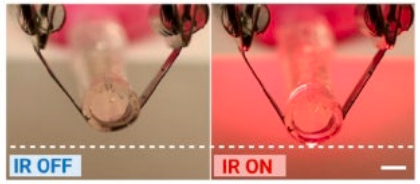
National Institute of Biomedical Imaging and Bioengineering

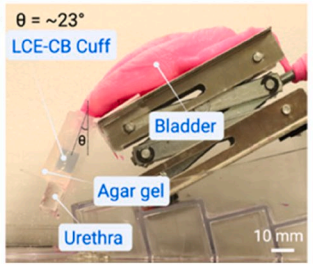
R01 EB022033-01A1 (FY2016)

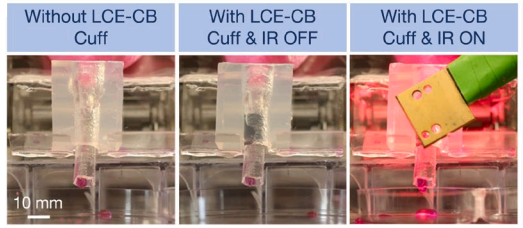
Liquid Crystal Elastomer as a Dynamic Treatment of Incontinence in Women

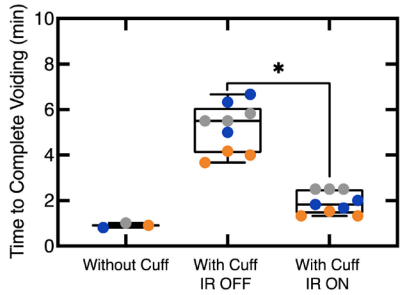


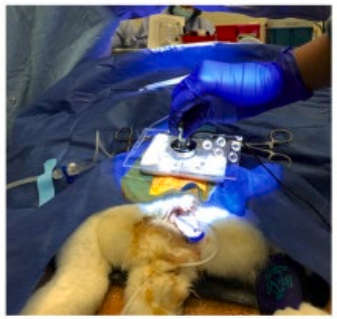


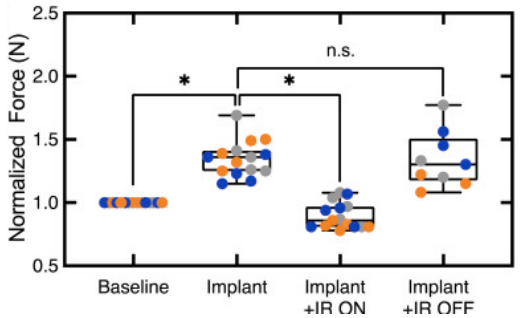










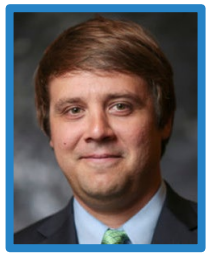


Tasmim, S., et al. (2023). Liquid crystal elastomer based dynamic device for urethral support: Potential treatment for stress urinary incontinence. Biomaterials, 292, 121912.

NEED: Improvements of urethral sling designs to better treat stress urinary incontinence (high prevalence in women) and avoid the potential complications of the current gold standard.

METHOD: 3D printing of liquid crystal elastomers that act as artificial muscles and are dynamic in shape when exposed to thermal energy.

RESULTS: *In vitro* and *in vivo* models demonstrated the ability of this technology to dynamically regulate bladder voiding while increasing urethral resistance to leakage, respectively.

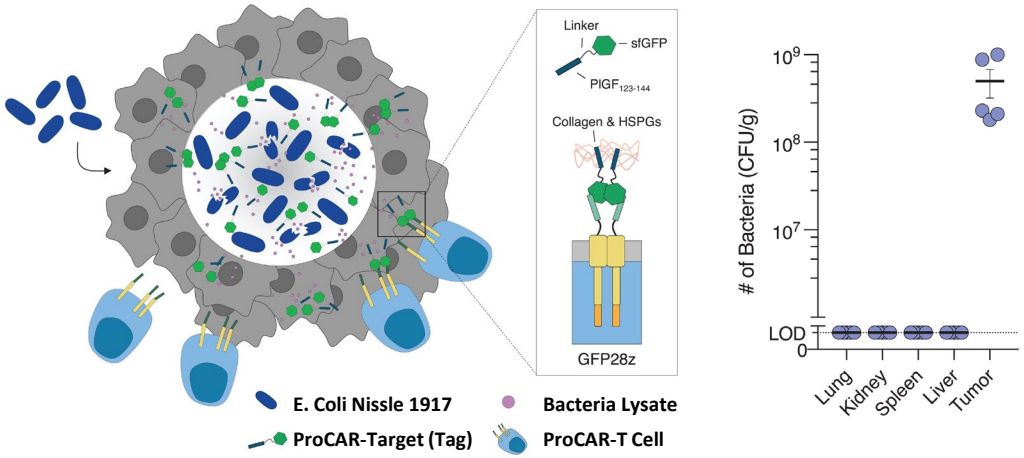


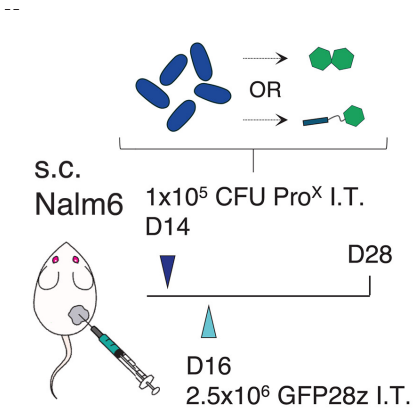
Taylor Ware (Assoc. Prof., Texas A&M)

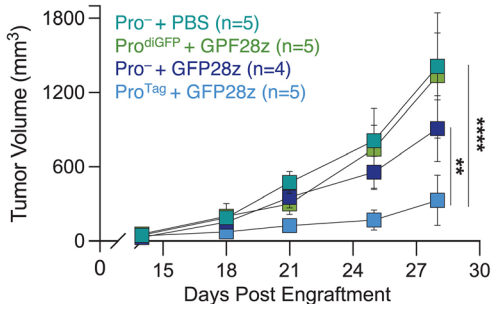
National Institute of Biomedical Imaging and Bioengineering

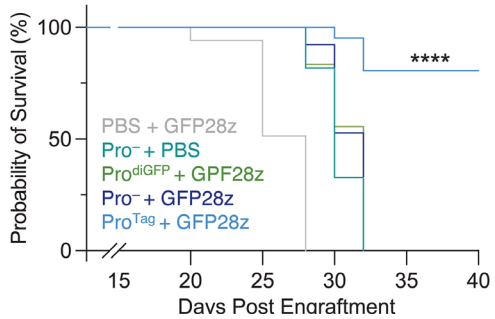
R21 EB028547-01 (FY2019; Trailblazer)

Probiotic guided CAR-T Therapy (ProCARs) for Breast Cancer









Vincent, R. L., et al. (2023). Probiotic-guided CAR-T cells for solid tumor targeting. Science, 382(6667), 211-218.

NEED: Methods to better target solid tumors (such as many forms of breast cancers) and reduce off-tumor target toxicity.

METHODS: Engineering bacteria to selectively colonize tumors and release payloads that enhance CAR-T cell targeting.

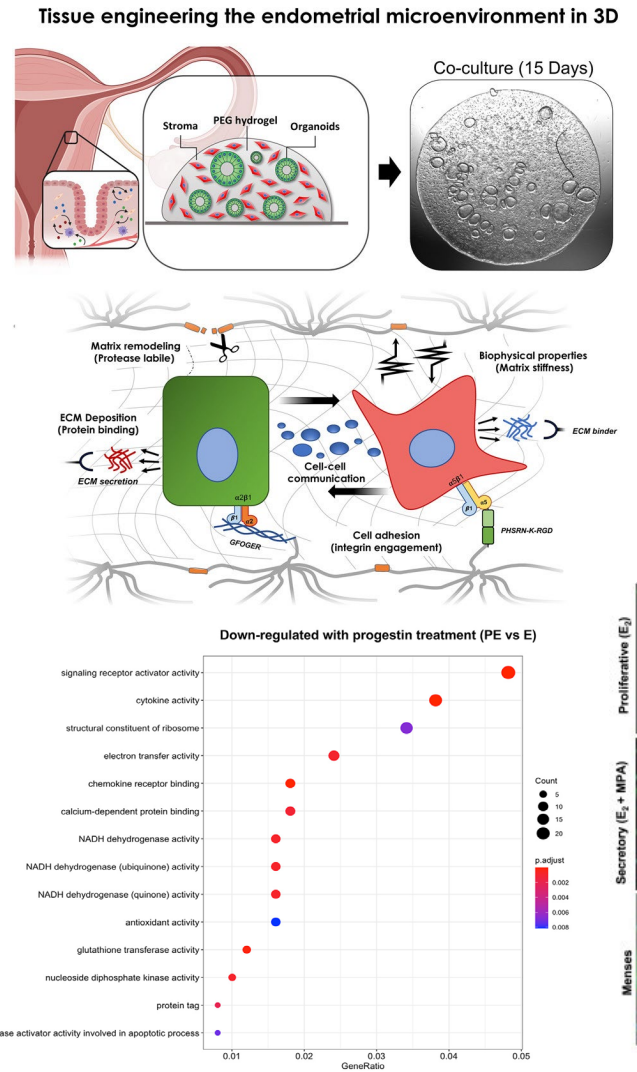
RESULTS: In xenograft models of different human cancers (breast included), the use of bacteria was specific to the tumor and beneficial to guide CART-T cells, showing success in reducing tumor burden and increasing animal survival.

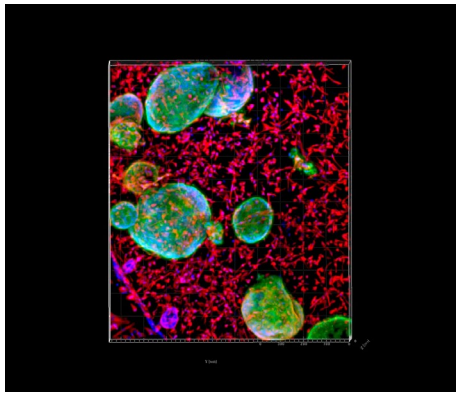
Tal Danino (Assoc Prof., Columbia)

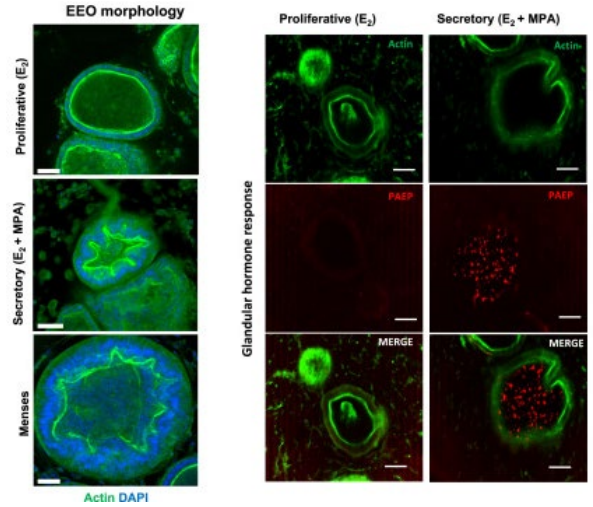
National Institute of Biomedical Imaging and Bioengineering

R01 EB030352-01 (FY2020)

Microvascular Permeability, Inflammation, and Lesion Physiology in Endometriosis: A Microphysiological Systems Approach







Gnecco, J. S., et al. (2023). Organoid co-culture model of the human endometrium in a fully synthetic extracellular matrix enables the study of epithelial-stromal crosstalk. Med, 4(8), 554-579.

NEED: Novel materials (vs. Matrigel) to better engineer *in vitro* models of the endometrium for the dynamic responses to hormones and the stages of the menstrual cycle.

METHOD: A thorough analysis of the native ECM to then engineer a synthetic ECM that better mimicked the biophysical and molecular properties, to then introduce endometrial epithelial cells and stromal cells.

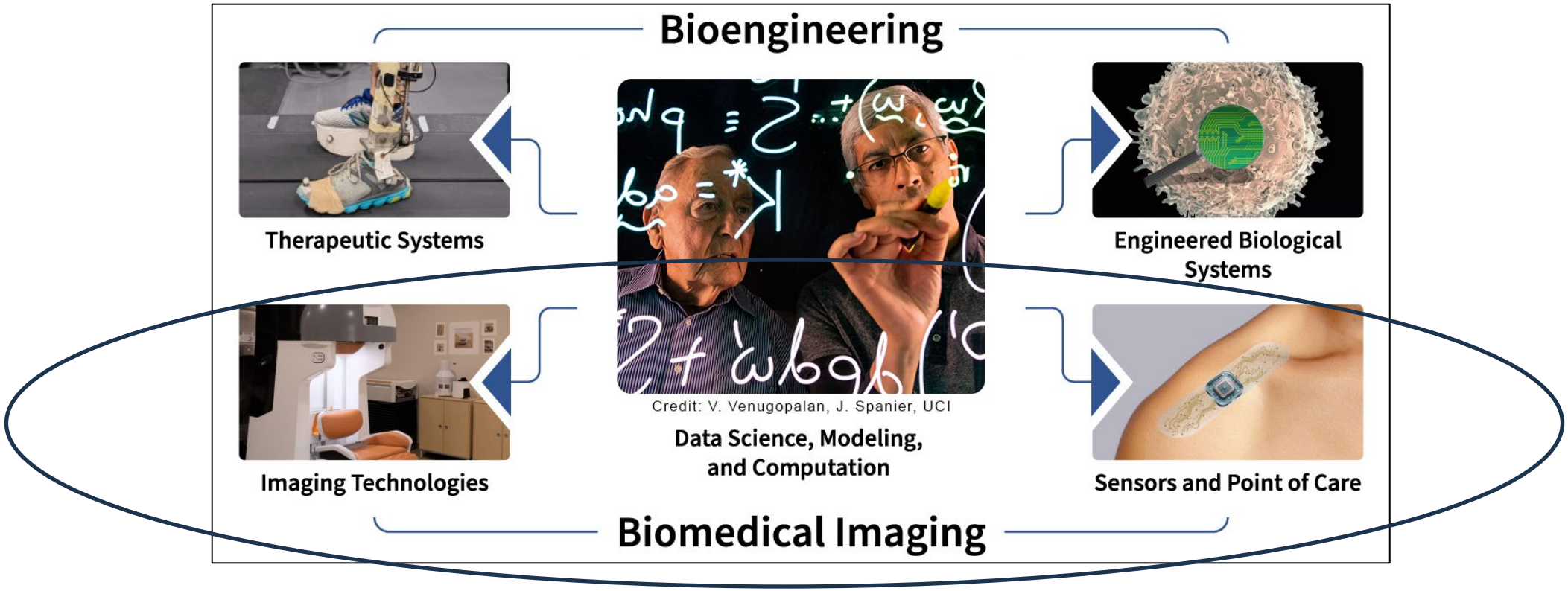
RESULTS: A novel synthetic matrix that allowed a co-culture of endometrial organoids with stromal cells to remodel their microenvironment, recapitulate their hormone-dependent behaviors, and exhibit the specific morphologies resembling the different stages of the menstrual cycle.

Linda Griffith (Professor, MIT)

National Institute of Biomedical Imaging and Bioengineering

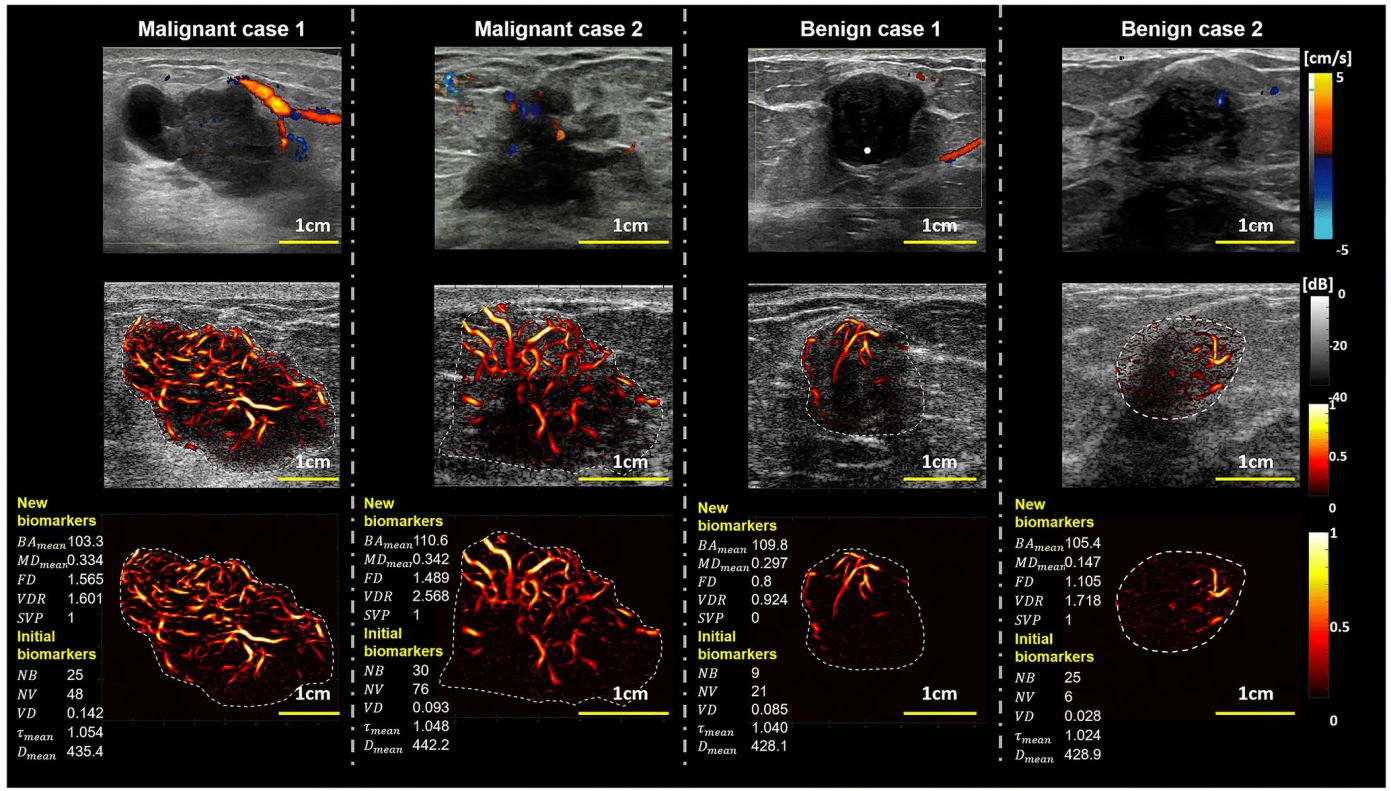
U01 EB029132-01 (FY2019)

Biomedical Imaging, Sensing, POC Devices



Doppler Ultrasound Breast Cancer Imaging

High-def microvasculature imaging (HDMI) in Breast Cancer Dx



Low-cost, noninvasive HDMI solution uses computational model to accurately evaluate tumor microvasculature

600 fps model-based Doppler ultrasound renders vasculature, classifies tumor based on vessel features

In 521 patient study, biomarker performance: 93.8% sens, 89.2% specificity

Demos in Kidney, Liver, Thyroid, Breast

MAYO CLINIC

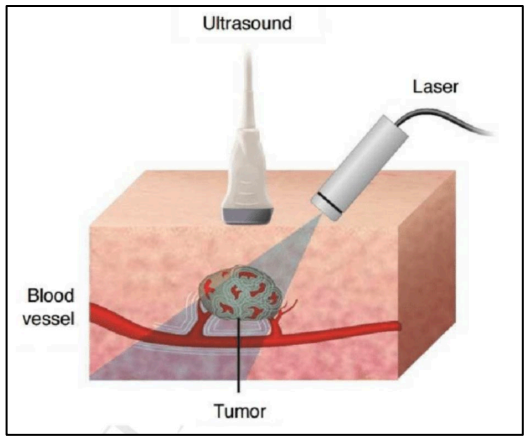
Azra Alizad and
Mostafa Fatemi team

Melisa Kurti et al. Quantitative Biomarkers Derived from a Novel Contrast-Free Ultrasound High-Definition Microvessel Imaging for Distinguishing Thyroid Nodules. Cancers (2023). DOI: 10.3390/cancers15061888.

NIH National Institute of Biomedical Imaging and Bioengineering

R01CA239548 and R01CA195527

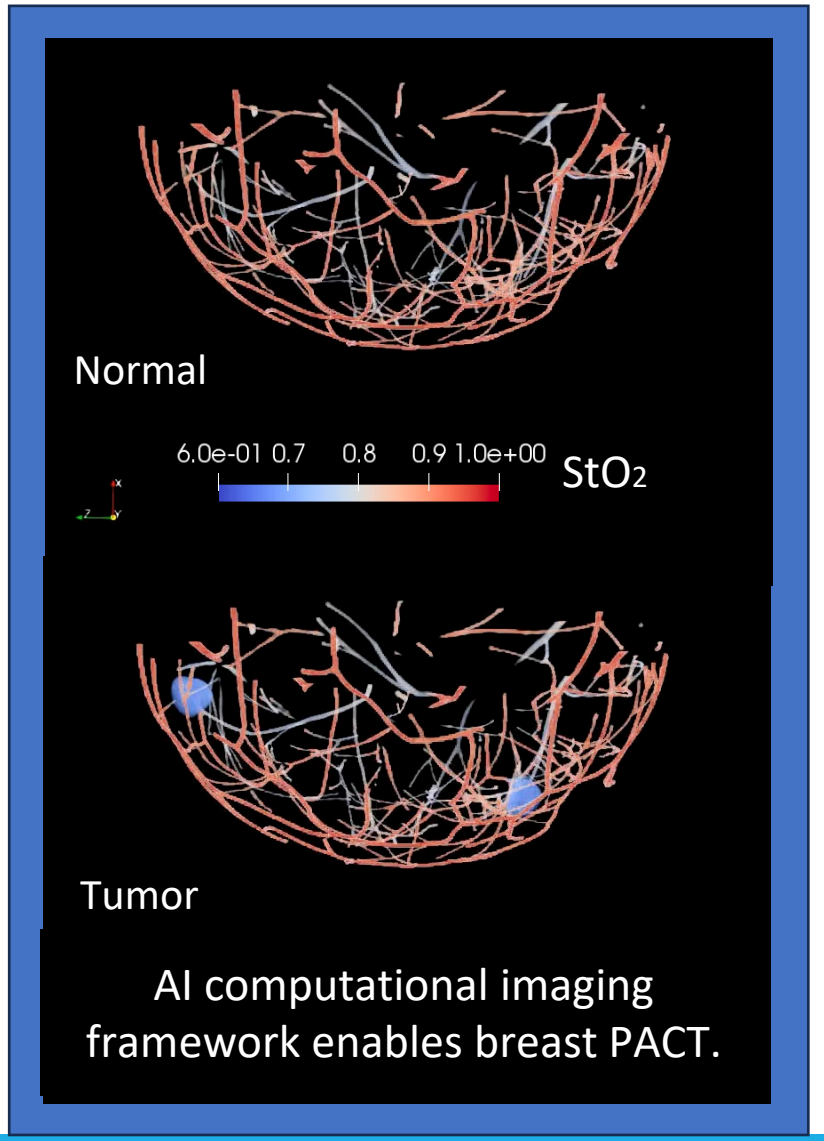
Quantitative Breast Photoacoustic Computed Tomography (PACT) using AI



ResearchGate

Distinguishes cancerous from healthy tissue, maps StO2 and hemoglobin contrast

Deep learning approach estimates %oxygen saturation (StO_2) and differentiate between veins and arteries.

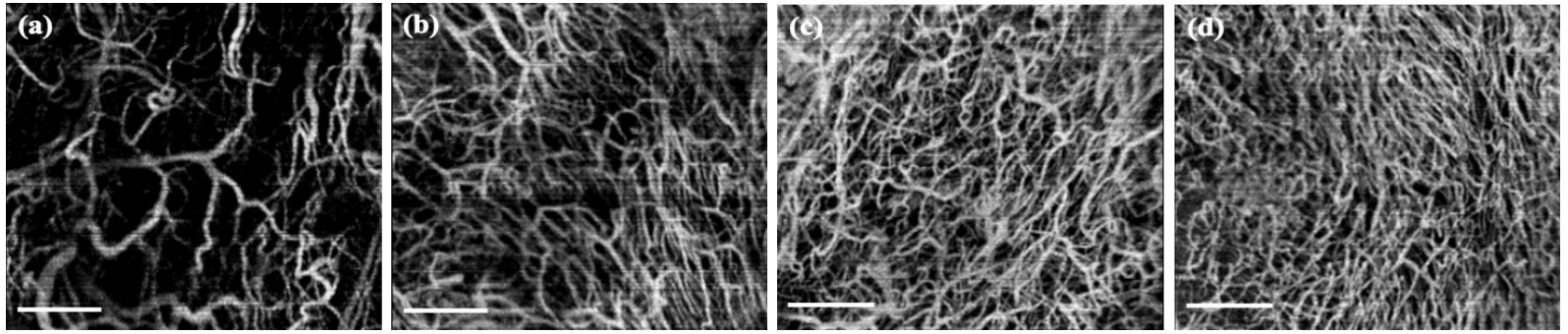


ILLINOIS (S. Park, U. Villa and M.A. Anastasio)

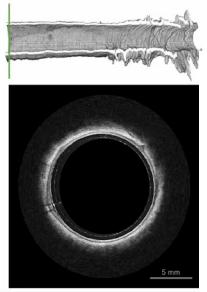
OCT Guided Laser Treatment of Genitourinary Syndrome of Menopause (GSM)

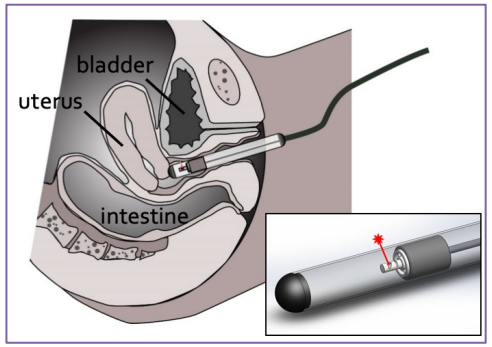
- **GSM affects up to 50% of postmenopausal women**
- **Develop OCT/OCTA for objective outcome measure for laser therapy**
  - Vagina epithelial thickness (VET)
  - Blood vessel density (BVD)
  - Collagen content
  - Elasticity
- **The system can be used to**
  - screen patients who can benefit most from the laser treatment
  - guide the laser therapy and optimize laser dose
  - monitor the treatment efficacy

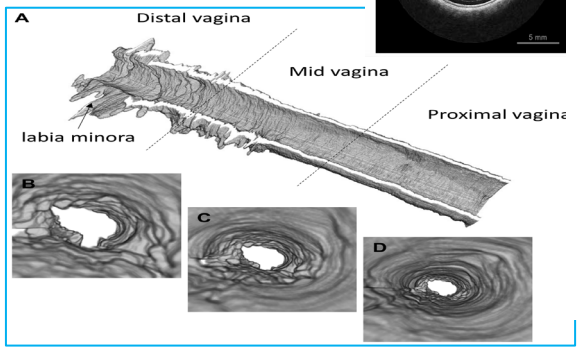
Vaginal epithelial thickness (VET) and blood vessel density (BVD) change following laser therapy (4-week intervals)



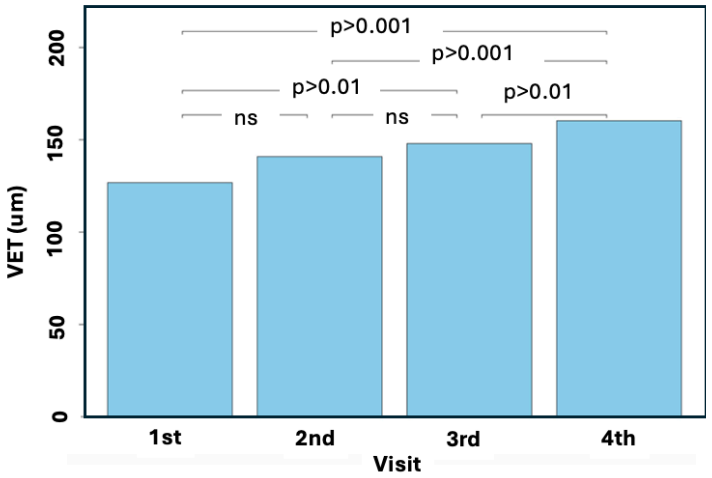
Before laser | post 1st laser | post 2nd laser | post 3rd laser (12 wks)



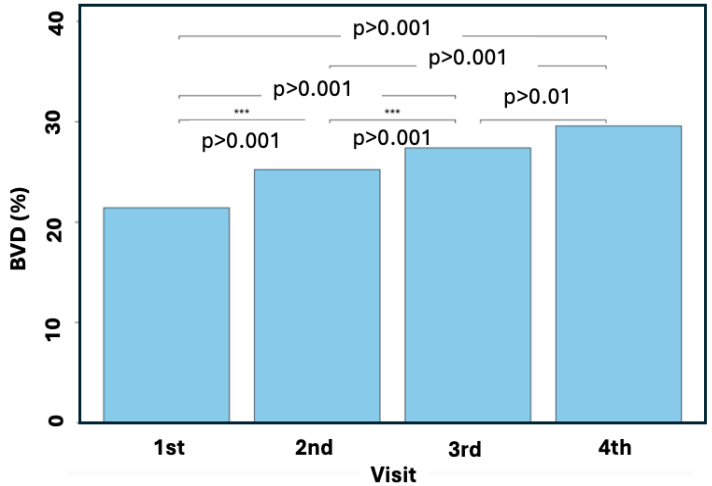




Average VET post laser therapy



Average BVD post laser therapy

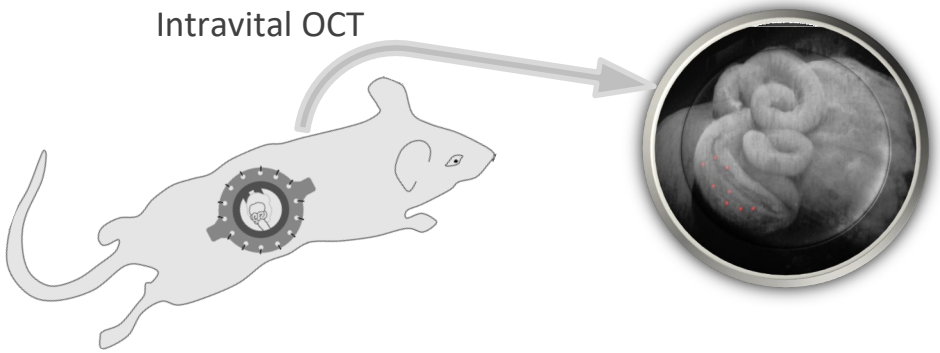


S. Qiu, et al., "OCT angiography in the monitoring of vaginal health", APL Bioeng. 7, 046112 (2023)

National Institute of Biomedical Imaging and Bioengineering

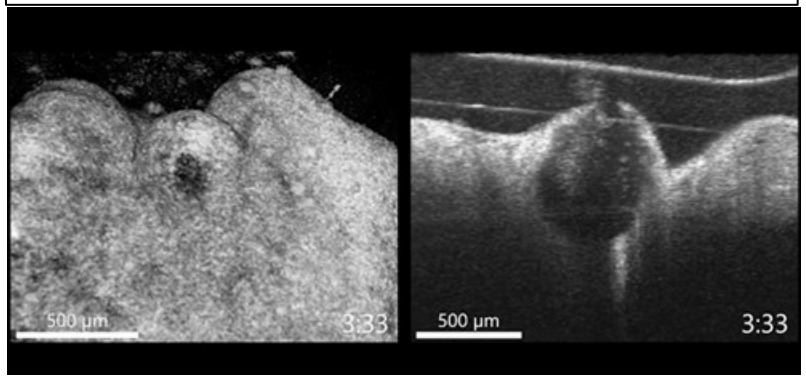
R01EB-030558 PI: Zhongping Chen, PhD; Felicia Lane, MD, UC Irvine

In vivo analysis of mammalian fertilization

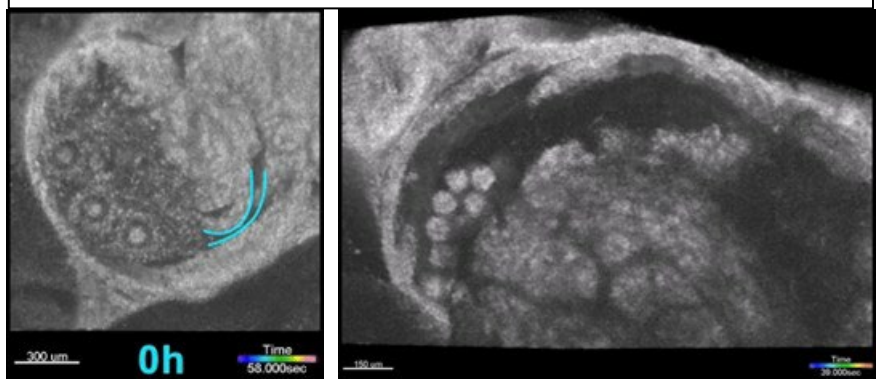


- **New *in vivo* technology** for high-speed, volumetric, dynamic OCT imaging of oocyte and embryo transport in the mouse fallopian tube, not possible with other methods.
- **Novel functional method** for depth resolved imaging of cilia beating and cilia coordination without application of contrast agents.
- **Biological discoveries:** uncovered novel roles of smooth muscle contractions and oviductal cilia in the fallopian tube. These findings can potentially inform improved management of infertility and ectopic pregnancies.
- The videos of what really happens in the fallopian tubes during embryonic transport are being **integrated into reproductive biology courses around the world**, changing the way reproductive clinicians and biologists are educated.
- **A platform for clinical translation:** In collaboration with Dr. Jennifer Barton (University of Arizona), we are now developing a strategy for translation of functional cilia imaging developed under this grant into clinical endoscopic scanners for diagnosis of female reproductive pathologies.

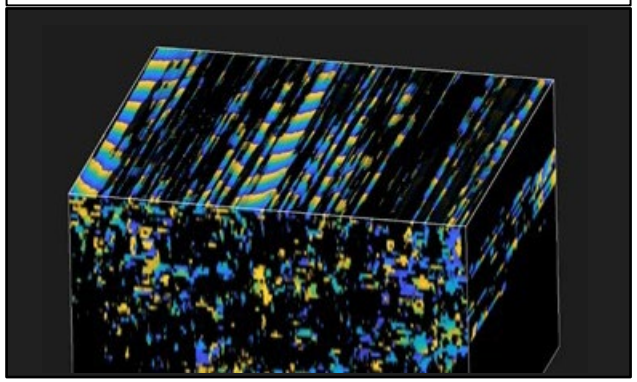
In vivo imaging of ovulation



In vivo imaging of oocyte/embryo transport



Imaging cilia metachronal wave (in vivo)



Moore, et al, Journal of Biophotonics 2019 PMC6470020
Wang and Larina, Cell Reports 2021 PMC8344084
Umezu, et al. Molec Reprod and Development 2023 PMC9877170

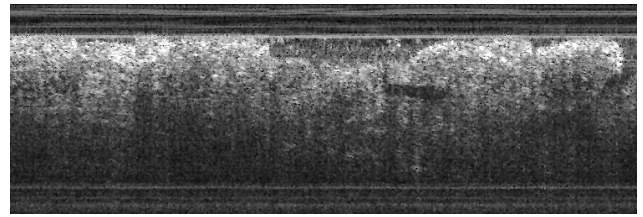
Wang and Larina, Reproduction 2023 PMC9827618
Xia, et al. Optica 2023 PMC11044847
Umezu, et al. Biology of Reproduction 2024 PMC10873499

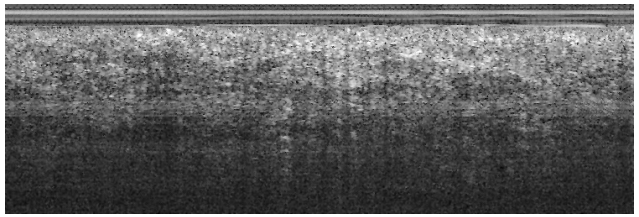
National Institute of Biomedical Imaging and Bioengineering

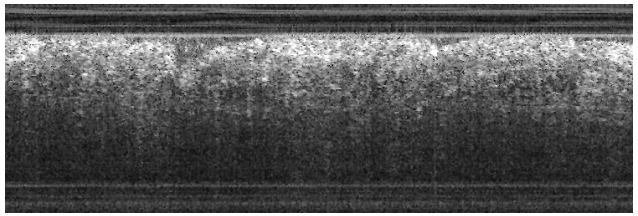
R01 EB027099 PI: Irina V. Larina, Univ. Houston

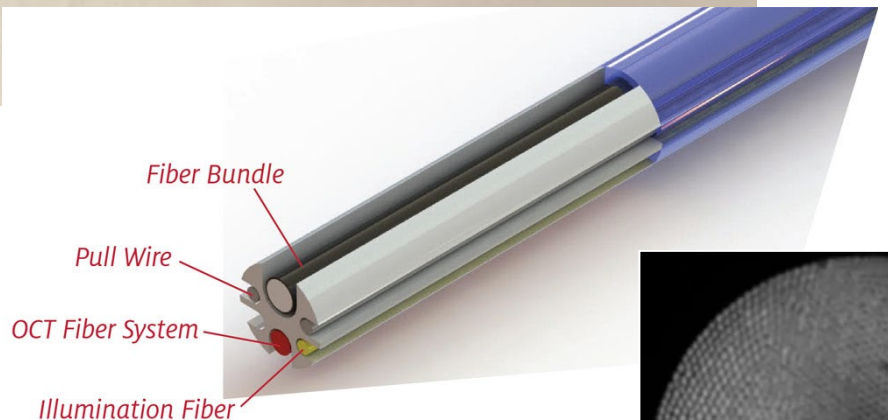
Early OvCa Detection- Imaging the Fallopian Tube

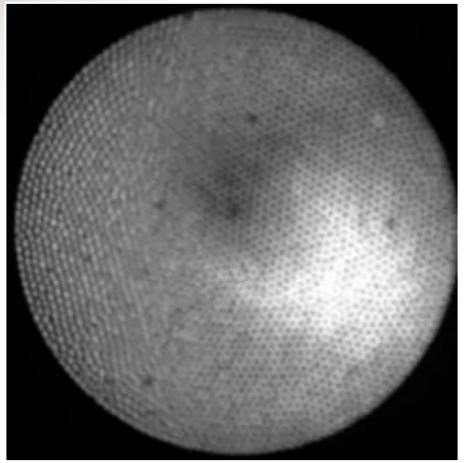
Imaging precancer/disease in the fallopian tube, sub-mm diameter endoscope design

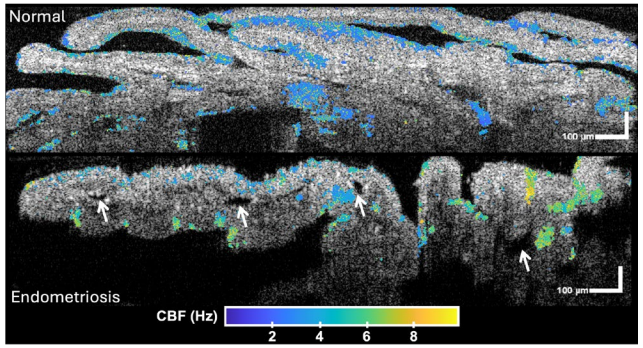








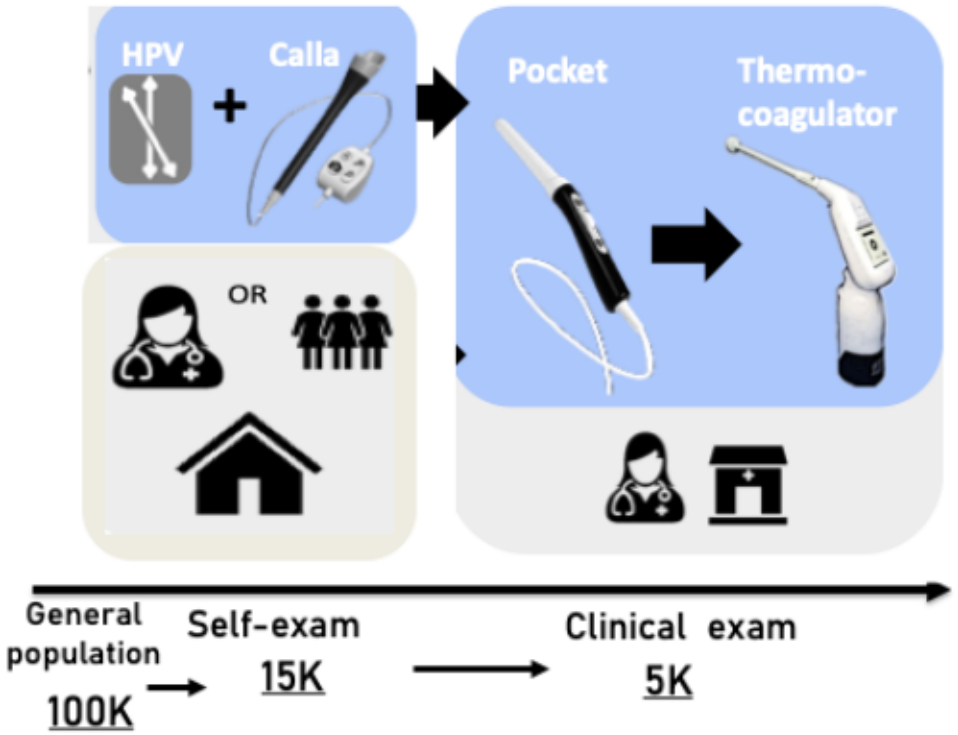


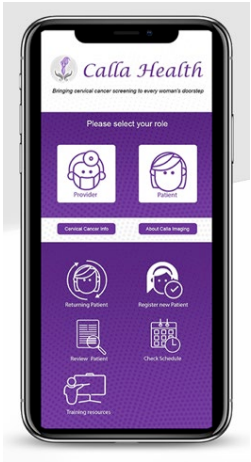


Rocha et al "Iterative prototyping based on lessons learned from the falloposcope in vivo pilot study experience," J. Biomed. Opt. 28:121206, 2023. DOI: 10.1117/1.JBO.28.12.121206

Low Cost, Accessible Cervical Imaging Technologies

Single-visit cervical cancer prevention program scaled to 15 community clinics in Cajamarca, Peru





M-Health + Automated Risk Algorithm

Global Impact: 11 research sites, 5 continents

https://callahealthfoundation.com

Pocket colposcope (Pocket)

FDA cleared 2018

Callascope (Calla)

Acetic acid enhancement

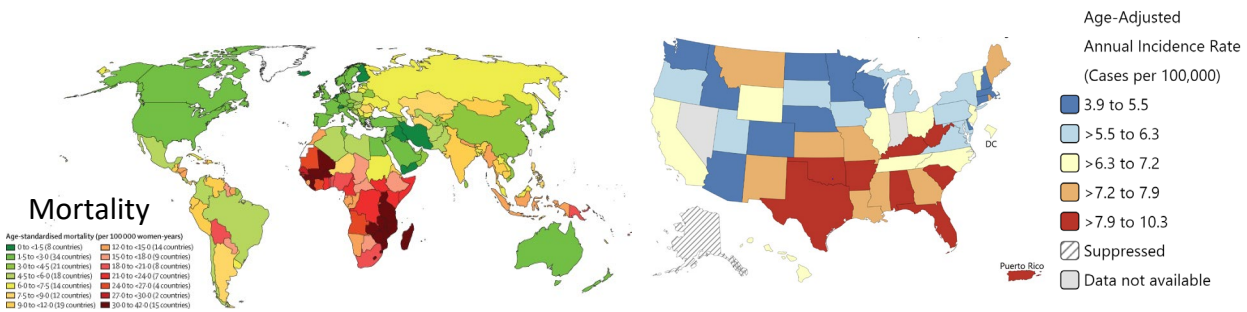
Self-insertion and imaging

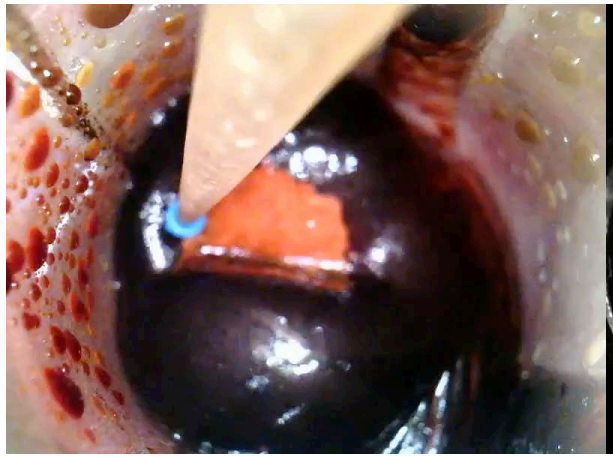
National Institute of Biomedical Imaging and Bioengineering

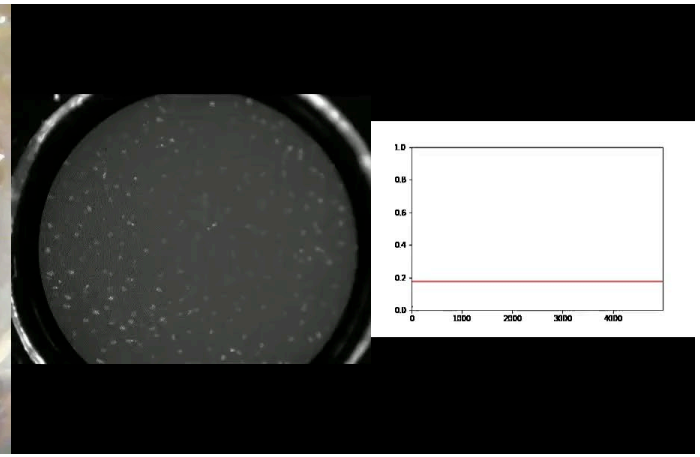
1R01CA239268-01, 1R01CA193380-01, PI: Nimmi Ramanujam, Duke

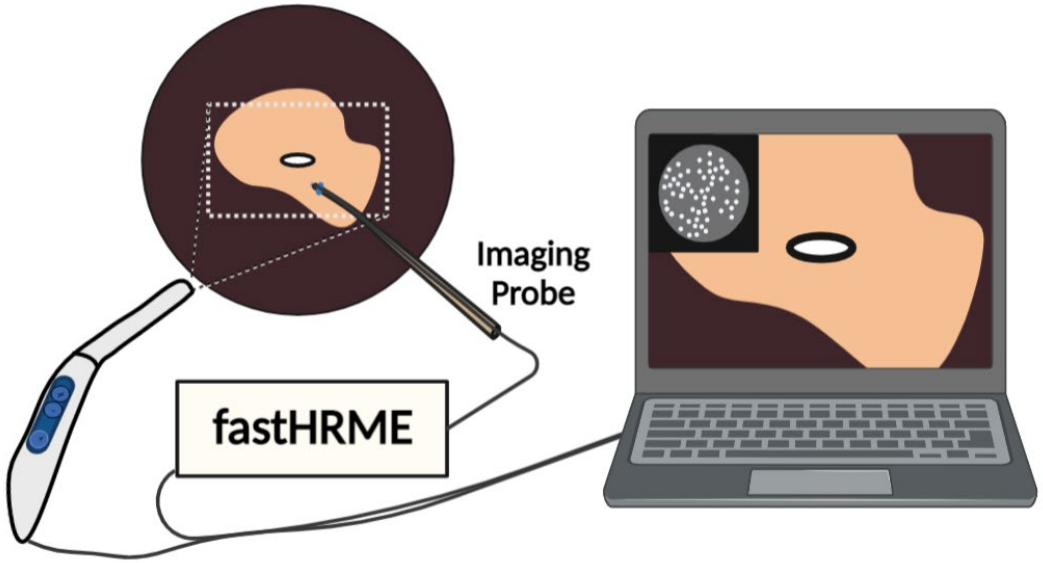
Multi-Modal Imaging for Early Detection of Cervical Pre-Cancer

Cervical Cancer is Preventable.
Global Prevention Strategies are Failing!

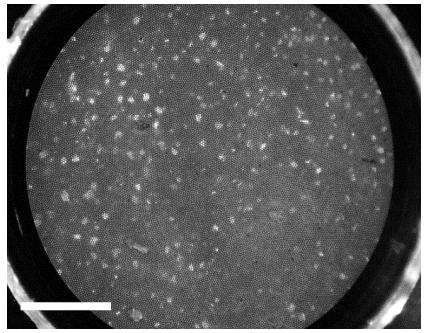




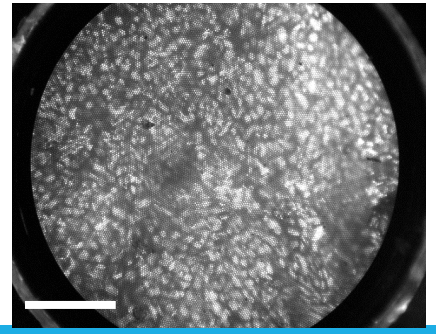




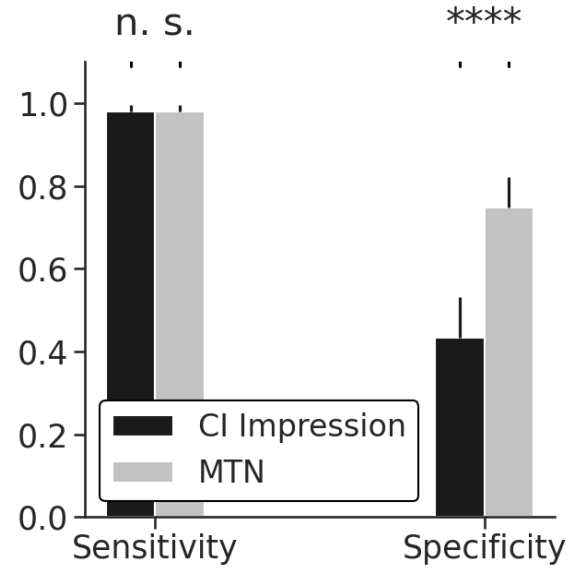
Coole et al "Development of a multimodal mobile colposcope for real-time cervical cancer detection," Biomed. Opt. Express 13(10) 5116 (Oct 2022)



Negative



High Grade
Pre-Cancer

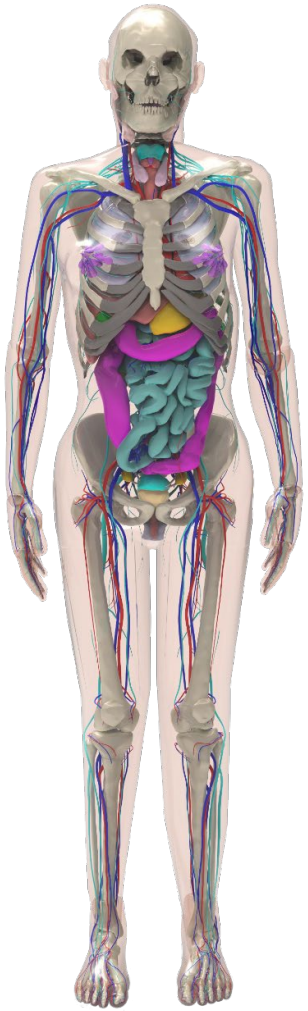


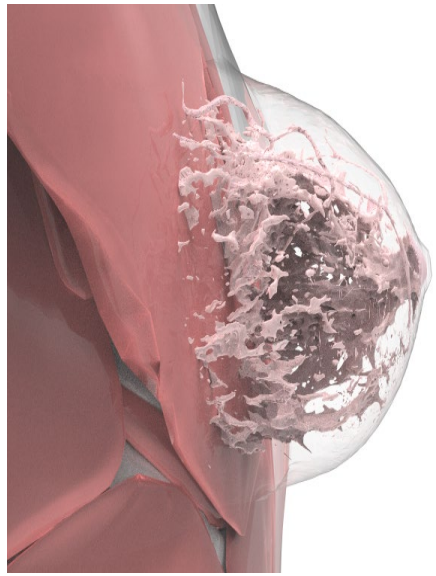
Analysis using data from a 300 patient study in Brazil.

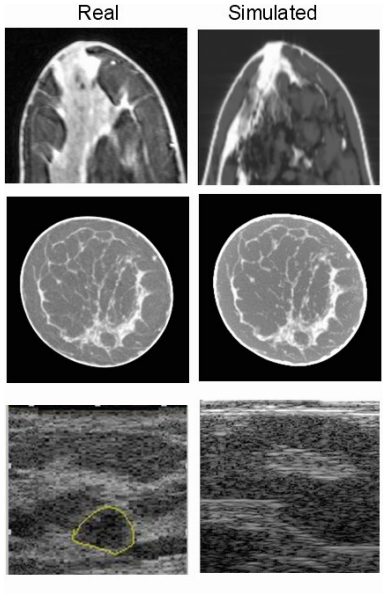
National Institute of Biomedical Imaging and Bioengineering

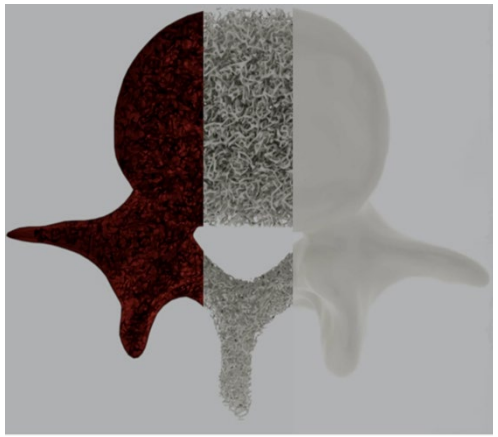
R01 CA232890, PI: Rebecca Richards-Kortum, Rice

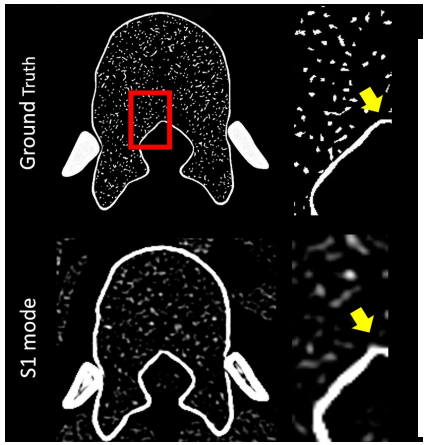
A Virtual Platform for Evaluating Medical Imaging Tech from Design to Use: Female Computational Models

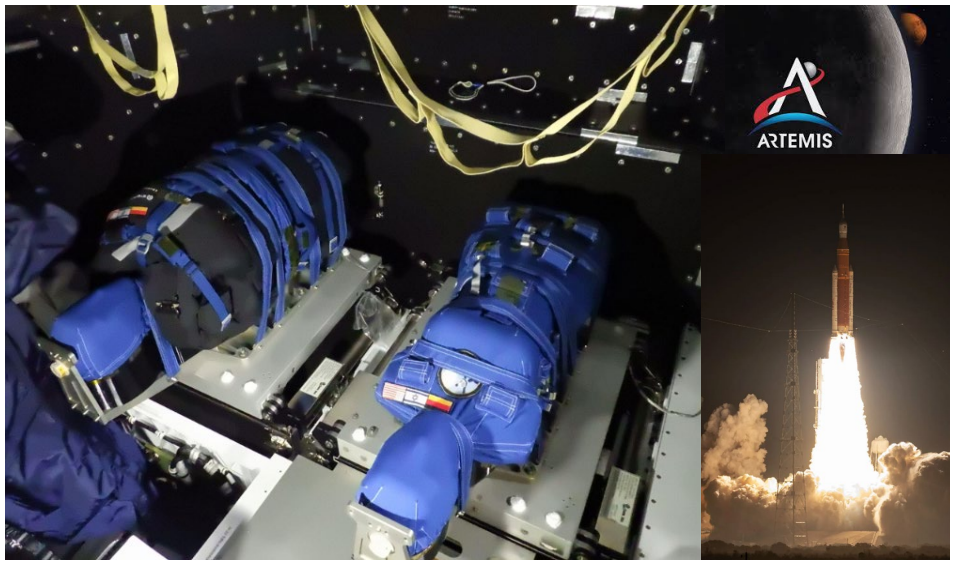


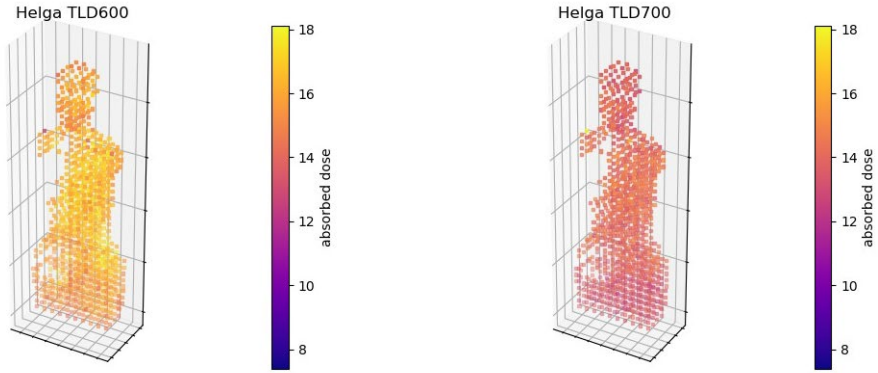












~1000 virtual patient models for females, incl. detailed structures in breasts and bones to optimize imaging technology

cvit.duke.edu

Female astronaut models to assess radiation dose in deep space missions – paired with physical phantoms that flew on Artemis around the moon

Summary and Conclusions

Bioengineering technologies

- ~15% of total NIH (all ICOs) in 2023 (~$7B) and growing

Bioengineering Workforce

- Women Engineers are key drivers of BME growth at all levels
- 2005-2022: *5X increase in women BME PhDs; 3.9X increase in total BME students; >50% BME undergrads*
- Growth of women in BME (student, faculty): *outpacing, influencing all engineering disciplines*

Bioengineering + Women's Health

- Growth in purpose-driven Bioengineering technologies for Women's Health (8-10% NIBIB budget)
- Contributions from undergrad design, academic innovation/entrepreneurship, FEMTECH sector
- Is growth of women in Engineering a key driver of innovation in Women's Health technologies?

Challenges

- Continue to increase # of women BME faculty (28%) to reflect PhDs (44%); PhDs to reflect >50% undergrads
- Expand development, validation and clinical adoption of Women's Health technologies
- Create new opportunities for innovation, commercialization, and Engineering-Medicine Partnerships