Advancing Cures and Therapies and ending ENDOmetriosis diagnostic delays (ACT ENDO)

RADx® Tech ACT ENDO Challenge Informational Webinar

August 28, 2024

Eunice Kennedy Shriver National Institute of Child Health and Human Development

Welcome

Today's Agenda

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- **RADx Tech ACT ENDO Challenge**
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- **Live Q&A Session**

Reminder

- Please type questions you have throughout the webinar in the Q&A box.
- Questions submitted via the Q&A box will be answered at the end of the presentation.
- Participants should remain muted.
- The webinar will be recorded and made publicly available.

Today's Speakers

Diana W. Bianchi, M.D.
Director, NICHD

Candace Tingen, Ph.D.
Chief, Gynecologic Health and Disease Branch (GHDB), NICHD

C. Taylor Gilliland, Ph.D.
Senior Advisor for Innovation Programs, Office of the Director, NIBIB

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

NIH National Institute of Biomedical Imaging and Bioengineering

Opening Remarks

Diana W. Bianchi, M.D.
Director, NICHD

RADx® Tech
ACT ENDO Challenge

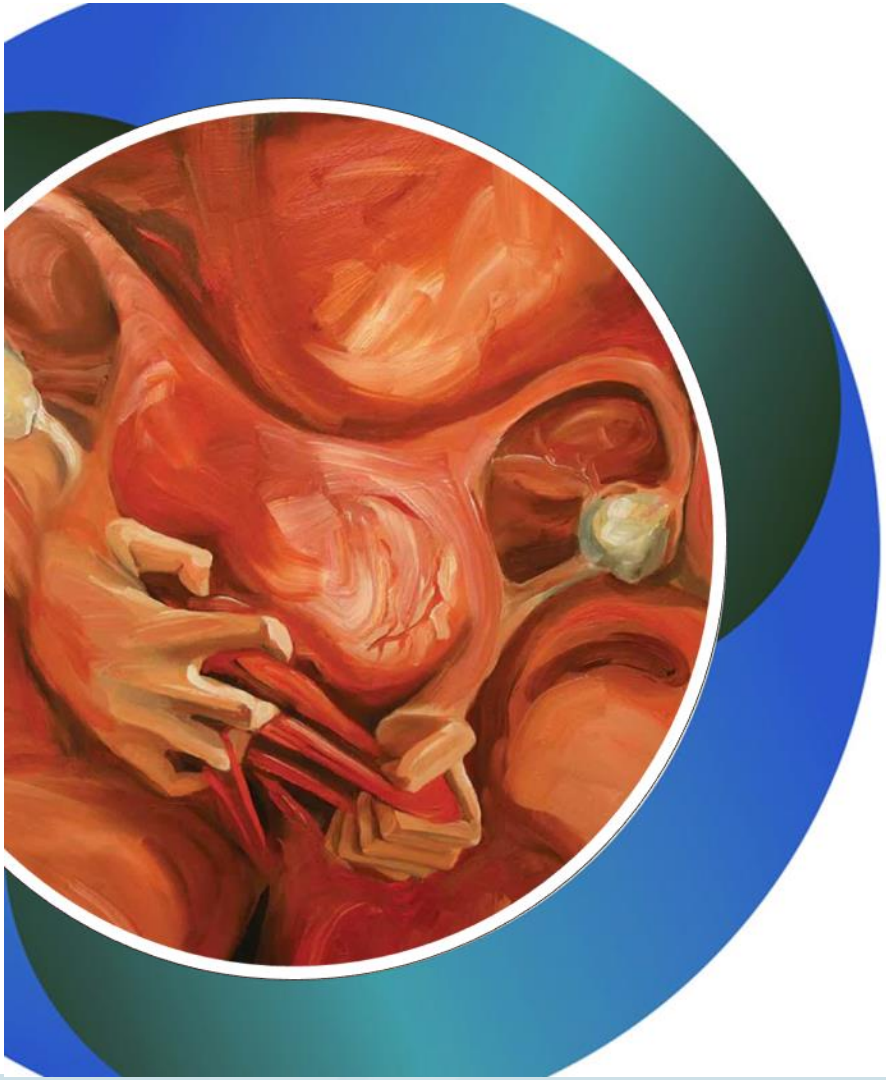
Advancing Cures and Therapies and ending ENDOmetriosis diagnostic delays

NIH National Institutes of Health
Turning Discovery Into Health


NIH
Eunice Kennedy Shriver National Institute
of Child Health and Human Development
Diana W Bianchi/NICHD

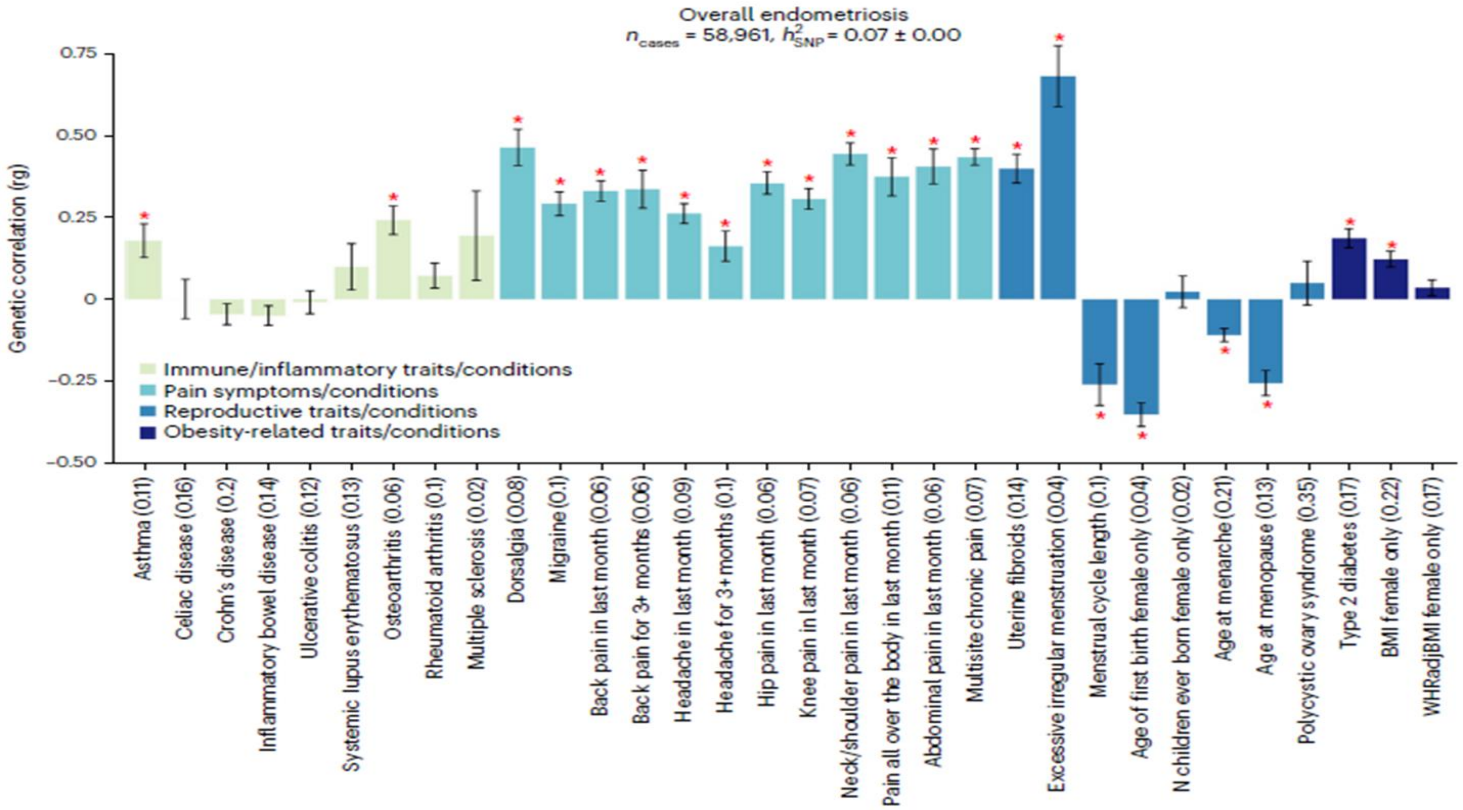
ACT ENDO Background Information

Demand for Innovation in the Diagnosis of Endometriosis



- Endometriosis can cause a wide range of symptoms, including pelvic pain, heavy periods, and infertility. But these symptoms can also be caused by other conditions. This overlap makes it hard to pinpoint endometriosis early on.
- There's currently no reliable blood test or other non-invasive way to diagnose endometriosis. Gold standard diagnostics depend on laparoscopic visualization. Without surgery, clinicians are forced to rely on a combination of a patient's medical history, a physical exam, and imaging tests like ultrasound or MRI; but these imaging tests cannot detect many forms of endometriosis especially in smaller lesions.
- The innovation gap lies in developing reliable, non-invasive tests that can accurately diagnose endometriosis early on, reducing years of chronic pain and medical costs.

Endometriosis as a whole-body condition



- NICHD research shows endometriosis is associated with a slew of comorbidities. It is NOT just a reproductive system problem.

Association of laparoscopically-confirmed endometriosis with long COVID-19: a prospective cohort

Article https://doi.org/10.10

The genetic basis of endometriosis and comorbidity with other pain and inflammatory conditions

Original Article

Endometriosis and Risk of Coronary Heart Disease

Epidemiology/Population

Association Between Endometriosis and Hypercholesterolemia or Hypertension

Original Investigation | Obstetrics and Gynecology

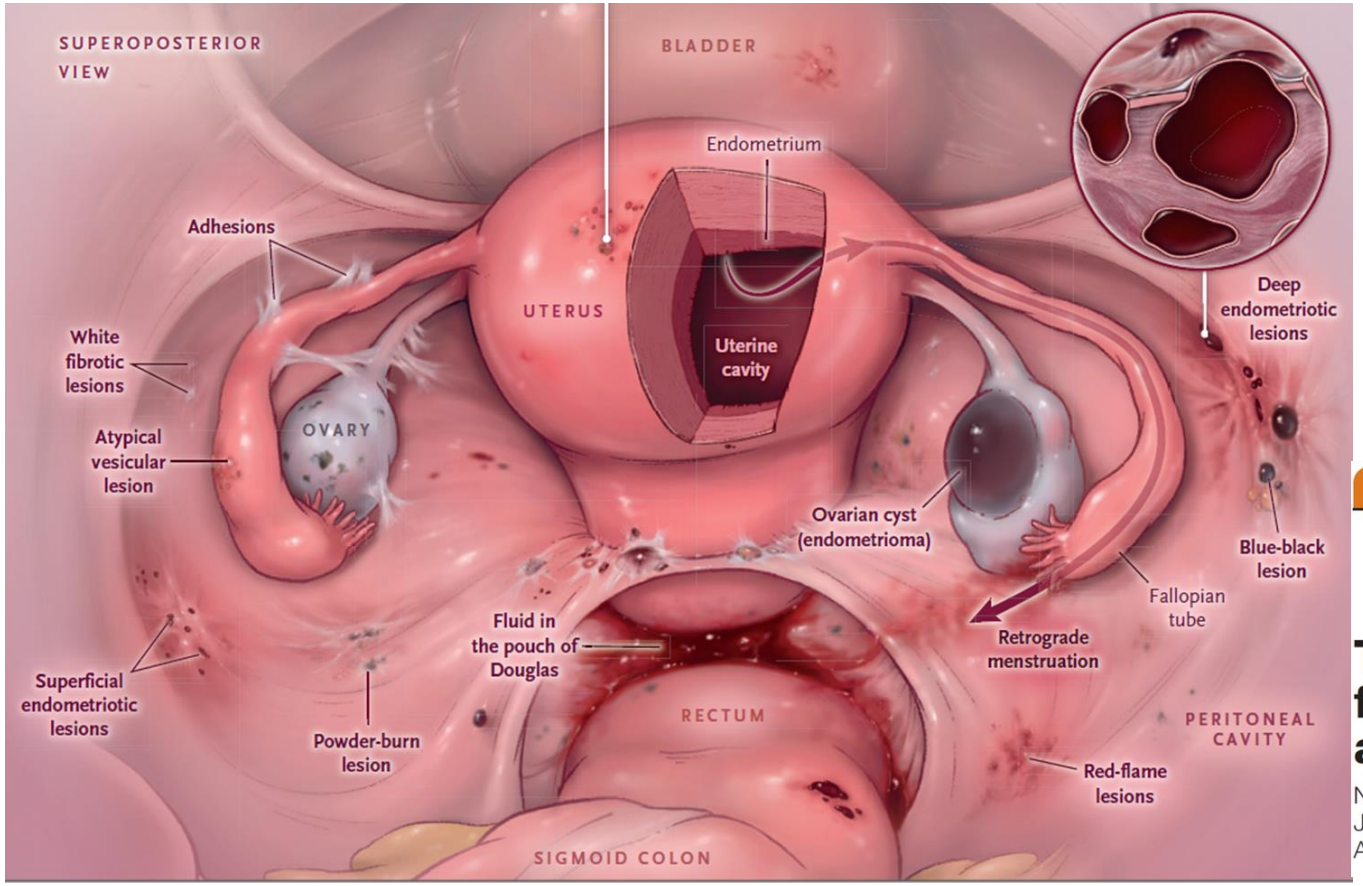
Association Between Laparoscopically Confirmed Endometriosis and Risk of Early Natural Menopause

Madhavi Thombre Kulkarni, MS, PhD; Amy Shafrir, ScD; Leslie V. Farland, ScD; Kathryn L. Terry, ScD; Brian W. Whitcomb, PhD; A. Heather Eliassen, Sc
Elizabeth R. Bertone-Johnson, ScD; Stacey A. Missmer, ScD

EXTENDED REPORT

Endometriosis and the risks of systemic lupus erythematosus and rheumatoid arthritis in the Nurses' Health Study II

Endometriosis is NOT A condition; it is many (and that matters!)



OXFORD human reproduction

Human Reproduction, 2023, 00(0), 1–11
https://doi.org/10.1093/humrep/dead099
Original Article

Gynaecology

Plasma proteomic profiles of pain subtypes in adolescents and young adults with endometriosis

Research Paper

PAIN®

Trends in pelvic pain symptoms over 2 years of follow-up among adolescents and young adults with and without endometriosis

Naoko Sasamoto[a,b,*], Amy L. Shafrir[b,c], Britani M. Wallace[a,b], Allison F. Vitonis[a,b], Cameron J. Fraer[a,b], Jenny Sadler Gallagher[b,c], Mary DePari[a,b], Marzieh Ghiasi[d], Marc R. Laufer[a,b,e], Christine B. Sieberg[f,g,h], Amy D. DiVasta[b,c], Andrew Schrepf[i], Sawsan As-Sanie[j], Kathryn L. Terry[a,b,k], Stacey A. Missmer[b,c,k,l]

- Heterogeneity has not been incorporated into clinically relevant classification nor pathophysiologic discovery
- NICHD research is discovering biomarkers and prognostic trajectories that subclassify patients
- Predictive subphenotyping could be used for personalized treatments and adolescent disease diagnosis.

Background

Advancing Cures and Therapies and ending ENDOmetriosis diagnostic delays

Problem

Endometriosis effects approximately 1 in 10 reproductive-aged women, showing symptoms like chronic, debilitating pelvic pain, infertility, an increased risk for ovarian cancer and other autoimmune diseases. Despite the severe impact of this disorder on quality of life, diagnosis can be delayed up to 10 years due to a normalization of intense menstrual pain by patients and healthcare providers and the requirement for surgical visualization to diagnose.

Solution

NICHD, in partnership with NIBIB, is leveraging the Rapid Acceleration of Diagnostics Technology (RADx® Tech) "innovation funnel" program to speed innovation in diagnostic technologies that will shorten the time to diagnosis, eliminate the invasiveness of current techniques, and/or improve accessibility, safety, convenience, and costs of diagnosis.

Approaches *(not exclusive)*

- Utilize new or existing biomarkers from serum, saliva, or menstrual effluent
- Distinguish between benign and malignant endometriosis
- Utilize epigenetic or genomic data with machine learning to diagnose early disease states

Technologies *(examples, not exclusive)*

- Imaging; Ultrasound
- Computational approaches (AI/ML)
- *In vitro* diagnostics
- Wearables
- Digital health platforms

RADx Tech ACT ENDO Challenge

Challenge Overview

The Rapid Acceleration of Diagnostics Technology (RADx® Tech) Advancing Cures and Therapies and ending ENDOmetriosis diagnostic delays (ACT ENDO) Challenge will award $3.0 million in prizes to accelerate the development of innovative technologies for the diagnosis of endometriosis.

RADx Tech ACT ENDO Challenge Overview

1. Innovators will **submit a proposal** describing in detail their prototype diagnostic technology, anticipated clinical impact, and plans for continued development and implementation.
2. Winners of Phase 1 will be invited to deliver a **virtual presentation and technology demonstration** in Phase 2.
3. Winners of Phase 2 will receive a **$100,000 cash prize each** and advance to the Phase 3 **technology development sprint** where they will de-risk and further mature their technologies with support by a RADx Tech Project Team of healthcare technology commercialization and content experts.
4. Participants in Phase 3 will compete for interim and final cash prizes ranging from a **cumulative $350,000 - $850,000 each**.

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

RADx Tech ACT ENDO Challenge Overview

Total Prizes: $3 million

Challenge Launch: Aug. 12, 2024

Innovator Submission

Prototype technology description, clinical impact, and plans for cont'd development

Deadline: Oct. 11, 2024

Phase 1
Entry Submission

- Administrative Triage
- Evaluation Panel
- NIH Judging Panel
- Award Approving Official

8 Innovators

Phase 2
Tech Demo & Pitch Event

- Tech Demo & Pitch
- Evaluation Panel
- NIH Judging Panel
- Award Approving Official

$100,000 each

4 Innovators

Phase 3
Technology Development Sprint

Technology De-Risking + SME Consultants

- Evaluation Panel
- NIH Judging Panel
- Award Approving Official

Interim Milestone Prize: $250,000 each

1st - $600,000
2nd - $500,000
3rd - $400,000
Runner-Up- $100,00

= cash prize award

Challenge Timeline

Phase 1

August 12, 2024: Challenge Launched; Registration & Submission Portal Opened
October 11, 2024: Submission Deadline
October – December 2024: Judging Period
December 16, 2024 (anticipated): Winners Announced

Phase 2

January 23, 2025: Technology Demonstration and Pitch Presentation Event
February 2025: Judging Period
March 1, 2025 (anticipated): Winners Announced

Phase 3

March 2025: Technology Development Sprint Begins
July 1, 2025: Interim Milestone Prize Deadline
September 2025: Interim Milestone Winners Announced
January – February 2026: Final Judging Period
March 2026 (anticipated): Final Winners Announced

Participant Eligibility

Team

Identify a **Team Captain** who will submit on behalf of a group of individuals.

If the Team wins, the **Team Captain** will be paid the cash prize in full.

The **Team Captain** must be a U.S. citizen or permanent resident to be eligible to receive a cash prize*.

**Non-U.S. citizens and non-permanent residents are not eligible to win a monetary prize (in whole or in part). Their participation as part of a winning team, if applicable, may be recognized when the results are announced.*

Entity

Identify a **Point of Contact** who will submit on behalf of a legally established organization, institution, or corporation.

If the Entity wins, the **Entity** will be paid the cash prize directly.

The **Entity** must be incorporated in and maintain a primary place of business in the United States to be eligible to receive a cash prize.

A Note About Using Federal Funds to Compete

An Innovator **may <u>not</u> use Federal funds** from a grant award, cooperative agreement, or other transaction (OT) award to develop their Challenge submissions or to fund efforts in support of their Challenge submissions **<u>unless</u> use of such funds is consistent with the purpose, terms, and conditions** of the grant award, cooperative agreement, or OT award.

IF

… you intend to use Federal funds, <u>and</u>

… the use of such funds is consistent with the purpose, terms and conditions of the award

THEN

… you must register for and participate in the Challenge as an **Entity** on behalf of the awardee institution or organization, <u>and</u>

… the prize must be treated as program income for purposes of the original grant, cooperative agreement, or OT award in accordance with applicable Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (2 CFR § 200)

Submission Process

1. All **Team** or **Entity** members must carefully review the complete Challenge Announcement posted on Challenge.gov.

2. The **Team Captain** or **Entity Point of Contact** must create an account in the Challenge submission portal. From the Challenge.gov post, click on "*Apply on external website*" and then navigate to "*How to Participate*" for instructions.

3. Provide all requested information and submit an entry in the portal no later than **October 11, 2024, at 11:59 PM ET.**

Submission Requirements

- ✓ Project Title, Executive Summary, and description of Team/Entity
- ✓ Description of the prototype technology, stage of development/maturity, and available analytical, clinical, or usability data on performance
- ✓ Description of how the technology will shorten the time to diagnosis, decrease the invasiveness of current techniques, and/or improve accessibility, safety, convenience, and costs of diagnosis.
- ✓ Regulatory, intellectual property, manufacturing, and commercialization status and/or plans
- ✓ Anticipated deliverables during Phase 3 - Technology Development Sprint (if selected) and proposal for continued development to enable market entry

Technology Requirements

Diagnostic technologies submitted to the RADx Tech ACT ENDO Challenge must be:

- Be a working prototype*
- Be non-invasive
- Detect endometriosis in adults and/or adolescents, differentiating from a profile/marker of pain
- Incorporate existing standards and consider regulatory requirements
- Be capable of efficient integration into the intended healthcare environments and processes or capable of overcoming barriers to the entry of novel approaches within current clinical care settings
- Possess additional technical features such as: reliability, accuracy, precision, robustness, safety, simplicity, reliance on the appropriate baseline information, contextual awareness, and inclusion of software to support decision-making where appropriate
- Have a reasonable likelihood of market entry within the next 10 years.

Areas of high priority for the RADx Tech ACT ENDO Challenge include, but are not limited to, technologies that:

- Utilize new or existing diagnostic biomarkers from serum, saliva, cervicovaginal secretions, or other samples that can be collected non-invasively. The use of menstrual effluent as a source of samples is of particular interest
- Are implementable at the point-of-care
- Accurately distinguish between non-malignant endometriomas and malignancy.
- Can be utilized in an adolescent population
- Are applicable to diverse and understudied populations

** "Prototype" refers to an early version of a medical device that can be tested in controlled laboratory settings. For the purposes of this Challenge, this can include pre-clinical devices or a workflow utilizing existing analysis devices for new clinical tests, such as biomarker panels.*

Phase 1 Evaluation Criteria

Scientific/ Technological

Scientific foundation and technical performance for diagnosis or monitoring

Clinical

Potential for real-world clinical utility to deliver actionable health information and improve diagnosis

Commercialization & Regulatory

Strategy for achieving applicable regulatory approval and market entry

Innovation

Significant advancement over current approaches

Team

Scientific, clinical, and business expertise and resources to bring a new diagnostic technology to market

Go to Challenge.gov for complete Evaluation Criteria

RADx Tech ACT ENDO Challenge Team

RADx Tech ACT ENDO Leadership

NICHD

- **Candace Tingen** *Program Official (PO)*
- **Dave Clark** *Program Official (PO)*
- **Elizabeth Walsh** *NICHD Staff Lead*

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

NIBIB

- **Taylor Gilliland** *NIBIB Sr. Advisor for Innovation Programs*
- **Adrianna Aliquo** *NIBIB Innovation Program Specialist*

NIH National Institute of Biomedical Imaging and Bioengineering

RADx Commercialization Center (VentureWell)

- Megan Aanstoos
- Randy Block
- Emily Kennedy
- Pamela Miller
- Rebekah Neal

RADx Coordination Center (Cimit)

- Marshall Collins
- Michele Liston
- Tracy McMahon
- Santosh Savaliya
- Paul Tessier

Project Management (Deloitte)

- Eunjung Nam
- Taylor Scott

Frequently Asked Questions

Question & Answer

I have an idea or design for a diagnostic technology that addresses the requirements of the Challenge, but I don't have a working prototype yet. Would I be successful in this Challenge?

Technologies at the design or idea stage will not be considered responsive to this Challenge and are unlikely to be selected to advance. Innovators must have a working prototype with proof-of-concept data.

Can I participate if I am not based in the U.S.?

Yes, non-U.S. citizens and non-permanent U.S. residents may register for and participate in a challenge as members of a Team or Entity. However, non-U.S. citizens and non-permanent U.S. residents are not eligible to win a cash prize (in whole or in part). Such individuals may participate as part of a Team or Entity that otherwise satisfies the applicable eligibility criteria and may be recognized when the results are announced.

How is the Challenge mechanism different from the NIH grant award process?

Challenges are a distinct mechanism from grants and are used to retrospectively award prizes to winners for the demonstrated and successful accomplishment of objectives set forth in the challenge. This Challenge will award cash prizes and provide in-kind support directly to teams or entities. There are no restrictions on how the prize award is to be used, except when federal funds are used to develop the challenge submission.

Live Q&A Session

Please type your questions in the Q&A box.

Participants should remain muted.

The webinar will be recorded and made publicly available.

If your question was not answered during the Q&A session:

1. Carefully review the complete Challenge details at http://www.challenge.gov/?challenge=radx-tech-act-endo
2. Check the FAQ page which will be updated regularly, https://www.cimit.org/radx-tech-act-endo-faqs
3. Send content questions about the challenge to nichdactendo@mail.nih.gov

Thank you!

Find more Information

Read the full Challenge Announcement at:
www.challenge.gov/?challenge=radx-tech-act-endo

Email us at:
nichdactendo@mail.nih.gov

Question & Answer

What is a Prototype?

"Prototype" refers to an early version of a medical device that can be tested in controlled laboratory settings. For the purposes of this Challenge, this can include pre-clinical devices or a workflow utilizing existing analysis devices for new clinical tests, such as biomarker panels.

What is the difference between a pain profile and identifying Endometriosis?

For purposes of the RADx Tech ACT ENDO Challenge, technologies must detect endometriosis in adults and/or adolescents, differentiating from a profile/marker of pain. Detection and discernment may be specifically for symptomatic women or as a screening tool for asymptomatic and symptomatic women.

What does "non-invasive" mean?

"Non-invasive" is defined as approaches that do not require incision, [non-blood] medical tissue removal, or contact with a bodily orifice beyond natural orifices. For example, venipuncture, finger pricks, analysis of menstrual effluent, and transvaginal imaging modalities will be considered within scope of this Challenge, but endometrial biopsies will be considered "invasive" and therefore non-responsive.

Question & Answer

What can I expect during the Pitch Event?

Phase 1 winners will be invited to deliver a virtual presentation and demonstration of their technology as well as plans for further development and maturation. The presentation event will take place on January 23, 2025. Presentations will be evaluated by the Evaluation Panel composed of scientific/technical, clinical, regulatory, and commercialization experts from NIH, and other organizations under contract with NIBIB through the RADx Tech program. The NIH Judging Panel will review these recommendations and select the winners, pending final decisions by the Award Approving Official. Up to four (4) winners will be selected as finalists to receive a cash prize of $100,000 each and advance to Phase 3 of the Challenge. Only winners of Phase 2 will be eligible to compete in the Phase 3 Technology Development Sprint.

NIH will not provide coverage or reimbursement of any expenditures or costs associated with participation in the event. Further details on the logistics, timing, and format of the presentations will be provided to the Phase 1 winners at a later date.

Question & Answer

What can I expect during Technology Development Sprint Phase?

A RADx Tech Project Team of healthcare technology commercialization and content experts will engage directly with each Innovator as part of a “deep dive” process to assess the prototype technology, identify key risk factors for accelerated development, and establish strategies to mitigate these risks, subject to final decisions by NIH. The goal of this Phase is to support Innovators as they rapidly advance the development of their technologies over a period of 12 months and increase their likelihood for making a clinically meaningful impact in the diagnosis of endometriosis. The Project Team will continue to advise and guide each Innovator throughout the Technology Development Sprint. Each Innovator will also receive free access to subject-matter expert consultants and key opinion leaders across a range of domains as part of their participation in the Challenge.