NIH Office of Research on Women's Health (ORWH)



# MIDLIFE Health Introductory Webinar

November 23, 2026

National Institutes of Health
Office of Research on Women's Health

www.nih.gov/women

# Agenda

1. Welcome
2. Background & Program Overview
3. Program Details
4. Navigating the Application Portal
5. Moderated Q&A

## Housekeeping

- ✓ 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.
- ✓ This recorded webinar will be made publicly available.

# Welcome

Thank you so much for joining today's meeting! Before we begin, we will take a moment to introduce our speakers.



**Janine Clayton**
*Director*
***Office of Research on Women's Health (ORWH)***



**Raven Hardy Richard**
*Health Science Policy Analyst*
***ORWH***



**Elizabeth Barr**
*Senior Science Advisor*
***Office of AIDS Research (OAR)***



**Kari Ashmont**
*Translational Team Lead*
***National Institute of Biomedical Imaging and Bioengineering (NIBIB)***



**Emily Kennedy**
*Program Facilitator*
***RADx®***

# Welcome

Introductory remarks from Dr. Janine Clayton, Director, ORWH.



# Midlife Women's Health Opportunity and Need

About **one in four women** are currently **between the ages of 45 and 65 years old**, a period typically referred to as **midlife.** Midlife is an inflection point often accompanied by a host of **unique symptoms,** and an **increased risk for emerging chronic diseases,** many of which could be prevented or mitigated by timely interventions.

## Menopause symptoms are common.



**80%** **Of women experience disruptive symptoms such as:**

- Hot flashes
- Sleep disturbances
- Mood changes

## Seeking care is not.



**20%** **Of women seek medical care for symptom relief**



**15%** **Of women receive the treatment they need**

**Stigma**, lack of **awareness**, **resources**, and **physician knowledge** can keep women from getting support.

Gold EB, et al. Am J Public Health. 2006;96(7):1226-35.; The Menopause Society. Menopause symptoms.; Zerbinati N, et al. Eur J Obstet Gynecol Reprod Biol. 2017;215:97-102.; US Food and Drug Administration. Summary review for NDA 216578. 2023. Vahratian A, Clayton JA. NCHS Data Brief. 2026;(575).

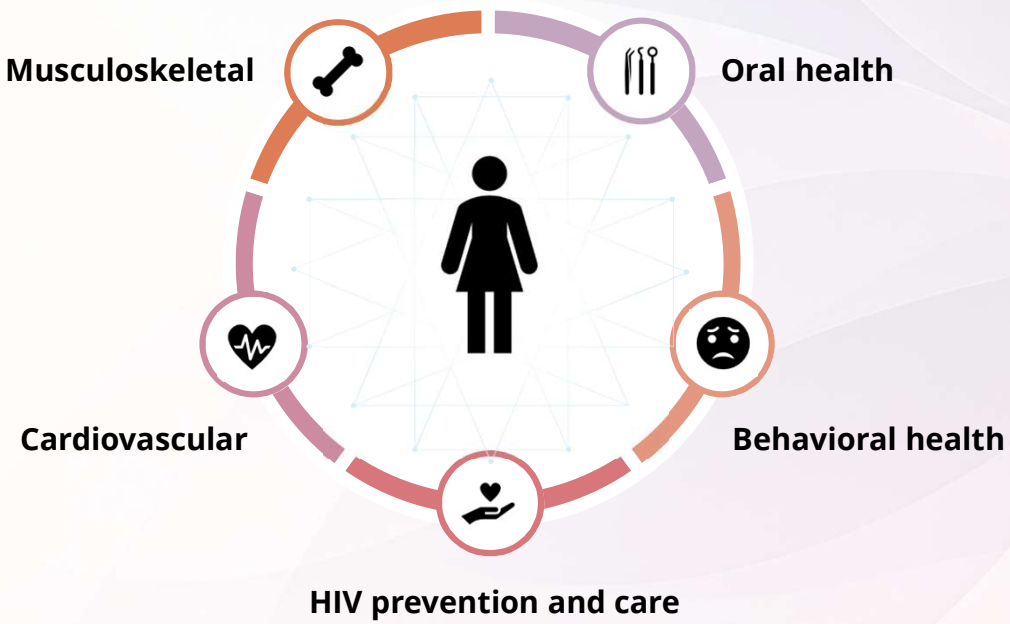


NIH National Institutes of Health Office of Research on Women's Health

# Understanding the Impact of Midlife Health

Midlife health is **interconnected across multiple areas,** yet important symptoms and population-specific needs **remain understudied and underserved.**

**Hormonal shifts, changing lifestyles, and caregiving demands can affect health across multiple areas.**




## Conditions and Symptoms

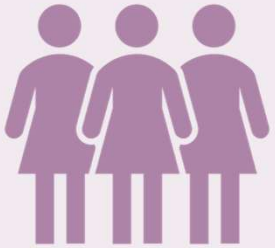
- Sleep and cognitive changes
- Perimenopausal depression and anxiety
- Musculoskeletal pain and osteoporosis
- Cardiovascular disease
- Autoimmune and metabolic conditions
- Sexual health and non-vasomotor symptoms



NIH National Institutes of Health
Office of Research on Women's Health

# Populations of Women Who May Be Overlooked

Women with existing health disparities may see midlife-related symptoms persist or become more pronounced over time.



**Certain populations of midlife women may be overlooked including:**

- Women living with sickle cell disease
- Women experiencing health disparities or access barriers
- Differences in skin tone, hair density, and anatomy that may affect technology performance and usability
- Women living with HIV
- Women with autoimmune conditions
- Women with a history of cancer

NIH National Institutes of Health
Office of Research on Women's Health

# Interacting with the Healthcare System

**Frequent touchpoints across care settings** create opportunities to improve coordination and continuity for women in midlife, experiencing menopause-related symptoms.

### Frequency of healthcare interactions

Compared to midlife men and younger women, women in midlife tend to have more frequent interactions with the health care system due to:

1. Onset of chronic conditions
2. Preventative screening
3. Symptom management
4. Other related health outcomes

### Women seek care for midlife health at:

- Primary care practices
- Obstetrics and gynecology clinics
- Specialty care settings
- Community health centers
- Telehealth platforms
- Retail health clinics
- Workplace-based health services

### Fragmented care

Because care for midlife health needs is often distributed across multiple settings and providers, women may encounter fragmented care pathways, inconsistent information, and challenges coordinating treatment and preventive services.



National Institutes of Health
Office of Research on Women's Health

# Engaging with Innovative Technologies

While women are increasingly utilizing health technologies that target midlife care and symptom relief, they face unique barriers to engaging with health technologies.

## Key Barriers

- Privacy and trust
- Usability and accessibility
- Historic lack of products tailored to their needs and lived experiences

## How to Overcome Key Barriers

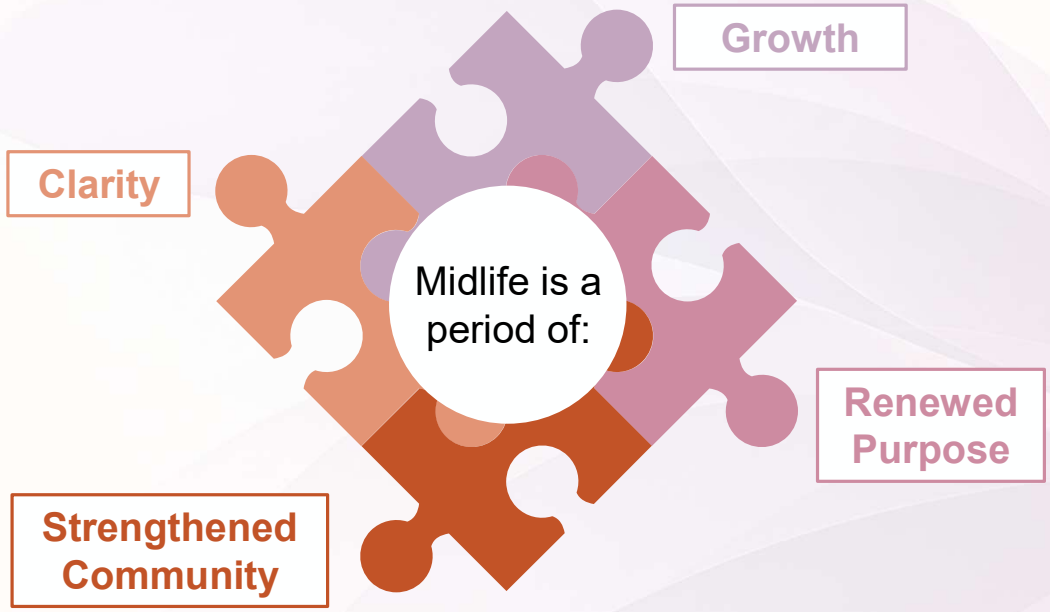
Engage directly with women and integrated approaches that consider the roles of healthcare providers, employers and insurers.

## The Current State

Commercial and public-facing midlife health offerings for women are rapidly growing, but limited evaluation leaves their effectiveness uncertain and may hinder progress.

# The Midlife Transition

Menopause can bring disruptive symptoms and unmet health needs, but midlife can also be a time of **resilience**.




Women are increasingly advocating for themselves and seeking resources, tools, and communities to support their health and quality of life.

Access to affordable tools and communities remains limited, leaving many women without support during this pivotal stage.

To fully realize these positive dimensions, innovations intentionally designed to elevate and sustain the thriving aspects of midlife are urgently needed.

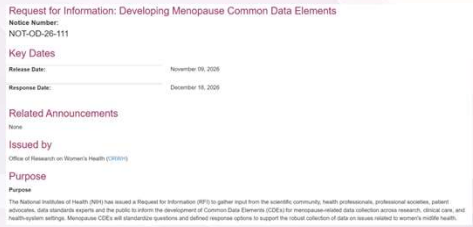
# Office of Research on Women's Health: Key Efforts and Priorities

ORWH is **advancing women's health** through various priorities, including **menopause education**, **standardized data research and collection**, and **prevention research**.



## COMMIT Challenge

ORWH launched the COMpetency in Menopause & Integrated Therapy (COMMIT) Challenge to recognize menopause education to help health professionals deliver comprehensive, coordinated care.


Request for Information: Developing Menopause Common Data Elements

Notice Number:
NOT-OD-26-111

Key Dates

Release Date: November 09, 2026

Response Date: December 18, 2026

Related Announcements

None

Issued by

Office of Research on Women's Health (ORWH)

Purpose

Purpose

The National Institutes of Health (NIH) has issued a Request for Information (RFI) to gather input from the scientific community, health professionals, professional societies, patient advocates, data standards experts and the public to inform the development of Common Data Elements (CDEs) for menopause-related data collection across research, clinical care, and health-system settings. Menopause CDEs will standardize questions and defined response options to support the robust collection of data on issues related to women's midlife health.

## Menopause Common Data Elements

NIH is seeking public input from scientists, clinicians, patient advocates, and the public to develop standardized menopause data elements (CDEs) for research, clinical care, and health systems.




## Pathways to Prevention

The NIH Office of Disease Prevention Pathways to Prevention (P2P) program held a workshop in April 2026 to assess the science on the menopausal transition and identify research gaps. An independent panel recommended future research and practice.

# MIDLIFE Health: Program Overview

The goal of the MIDLIFE (**M**idlife **I**nnovations **D**riving **L**ong-term **I**mprovements in **FE**male) Health supports the development of health technologies that are **evidence-based** and **designed for real-world adoption and use.** MIDLIFE will incentivize solutions that prioritize prediction, detection, diagnosis, and monitoring of **understudied midlife health conditions and symptoms.**

## Examples of Innovations

### Wearables, Remote Monitoring, and Symptom Tracking

Wearable neuromodulation, nutrition-measurement tools, continuous symptom tracking, and technologies for early detection and management of heart, lung, blood, and sleep conditions.

### Super Intelligence, Imaging, and Predictive Analytics

A data-powered approach that integrates oral health with whole-body data and advanced imaging to improve diagnosis, tracking, prediction, and care referrals for midlife women, including those with TMD.

### Digital Therapeutics and Disease Management

Sickle cell management, earlier cancer detection, passive home monitoring of health biomarkers, and integrated data platforms that support personalized risk assessment and coordinated care.

### Therapeutic Interventions and Prevention Strategies

Non-hormonal treatments for vasomotor, sleep, and cognitive symptoms, alongside drug-device combinations that personalize, deliver, or monitor therapy.

### Telehealth and Virtual Care Delivery

Solutions that can expand comprehensive midlife care for rural women and provide employer-sponsored transition support, coaching, and care for weight, sleep, and bone and joint health.

### Clinical Workflows, Interoperability, Care Coordination, and Navigation

Interoperable EHR workflows and tech-enabled community or peer navigation can coordinate referrals and strengthen preventive, menopause, chronic disease, and HIV care for women aging with HIV.

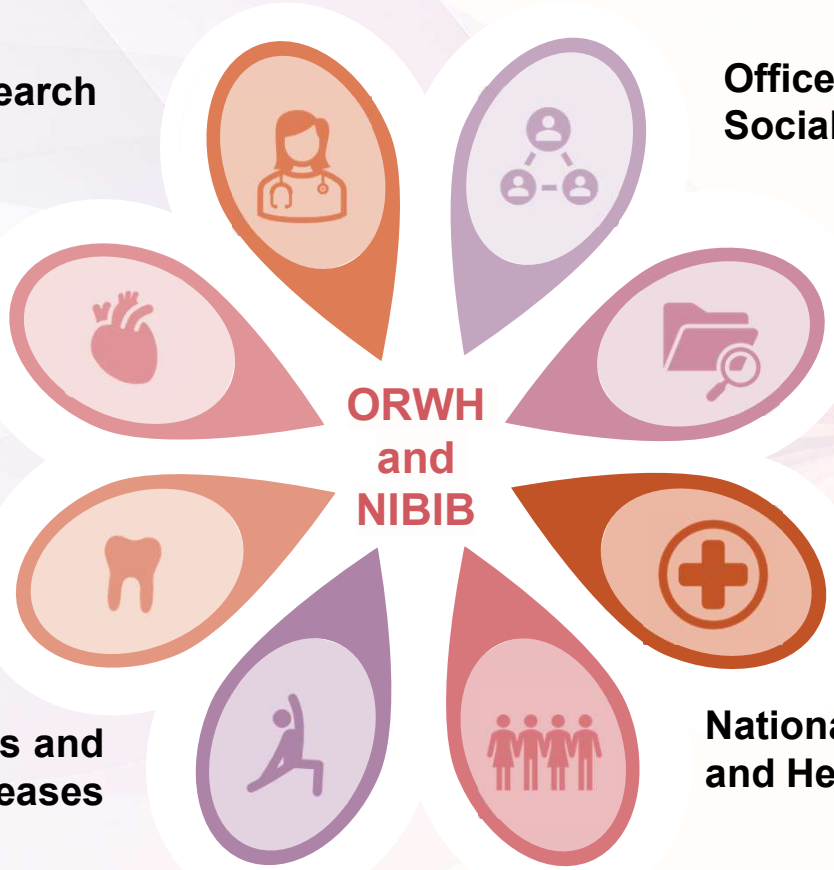
# MIDLIFE Health: Funding Partners

The initiative is funded through a **cross-agency federal partnership,** bringing together expertise spanning HIV, cardiovascular, oral, behavioral, musculoskeletal, nursing, and health disparities research, alongside healthcare quality and implementation.

**Office of AIDS Research**

**Office of Behavioral and Social Sciences Research**

**National Heart Lung and Blood Institute**




**Agency for Healthcare Research and Quality**

**National Institute of Dental and Craniofacial Research**

**National Institute of Nursing Research**

**National Institute of Arthritis and Musculoskeletal and Skin Diseases**

**National Institute on Minority Health and Health Disparities**

# Coordinating the National Institutes of Health HIV Research Program

The NIH Office of AIDS Research's (OAR) primary goal is to coordinate HIV/AIDS research across ICs.




**20+** NIH Institutes, Centers, and Offices award grants with HIV/AIDS funding.

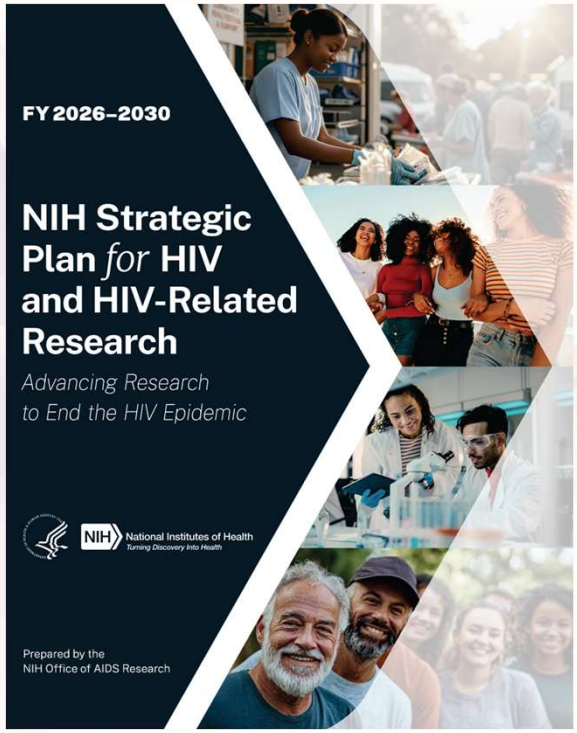
**$3.29B** in HIV/AIDS funding supported **3,800+** projects across NIH in FY 25.

# Office of AIDS Research Priorities

OAR developed the Strategic Plan for HIV and HIV-Related Research to provide a roadmap for the NIH HIV research program, ensuring that funds are allocated in accordance with established NIH scientific research priorities.

**Now available!**

go.nih.gov/nihhivstratplan



# Barriers for Women Living with HIV

Despite significant progress, women continue to face unique challenges related to HIV research and care.

## Social and Contextual Factors



## Comorbidities and Life-Course Considerations



## Biological and Clinical Considerations



## Evidence Gaps





Meyers-Pantele et al. Stigma Health. 2026.; Hastie et al. Am J Reprod Immunol. 2026.; Collins et al. Open Forum Infect Dis. 2022.; Lathrop et al. Int J Gynaecol Obstet. 2014.

# The Connection Between HIV and Menopause

Women living with HIV may experience menopause differently.

- Earlier onset, more severe symptoms
- Reduced antiretroviral therapy adherence
- Increased comorbidity burden
- Bone loss, cardiovascular disease, neurocognitive decline





Chakalisa UA et al. Curr Opin Infect Dis. 2026;39(1):16-21.; Abelman R. *Curr Opin HIV AIDS*. 2026;21(1):82-88.; Kentoffio K et al. *Curr Opin HIV AIDS*. 2022;17(5):270-278.

NIH National Institutes of Health
Office of Research on Women's Health

# Eligibility

Eligible applicants for the MIDLIFE Health initiative may include individuals, teams, nonprofit organizations, community-based organizations, academic institutions, and for-profit companies that meet the requirements outlined below.



Applicants must have a place of business located in the United States, which operates primarily within the United States, or which makes a significant contribution to the United States economy through payment of taxes or use of American products, materials or labor.



Organizations should be more than 50% directly owned and controlled by individuals who are citizens or permanent resident aliens of the United States.



Projects must be original and developed for this initiative (or substantially adapted for it).



To be eligible for funding with OAR funds, solutions must be relevant for women with HIV (FY 2026–2030 NIH Strategic Plan for HIV and HIV-Related Research)

# Submission Requirements (1 of 2)

**Responsive submissions** must comply with the structural and content requirements below.

## Structural Requirements

- ✓ Demonstrate potential to extend, improve, or enhance care for women in midlife.
- ✓ Focus ≥1 midlife health condition.
- ✓ Show potential for efficient integration into the intended use settings.
- ✓ Involve (or have clear plans to involve) women in midlife with lived experience or their support networks.
  - ✓ All stages of product development.
  - ✓ Decision-making authority, defined roles and project effort.
  - ✓ Resources commensurate with contributions.
  - ✓ Shared responsibility for interpreting results and guiding community implementation and dissemination.
- ✓ Involve (or have clear plans to involve) clinicians.

## Content Requirements

- ✓ Address potential barriers to adoption.
- ✓ Have a likelihood to reach market in 3-5 years.
- ✓ Provide analytical and/or clinical performance data.
- ✓ Incorporate existing standards and consider regulatory requirements and reimbursement strategies.
- ✓ Propose quantitative go/no-go milestones and deliverables for further technology development and optimization.
- ✓ Have a reasonable IP strategy.

# Submission Requirements (2 of 2)

**Highly competitive submissions** should comply with the guidance below.

## Highly Competitive Submission Guidance

- ✓ Demonstrate an interdisciplinary approach, ideally combining multiple fields or disciplines.
- ✓ Describe the structured innovation pathway. This includes describing the concept of moving from validation to operational adoption and financing.
- ✓ Capable of overcoming barriers to the entry of novel approaches within current clinical care settings.
- ✓ Provide usability data and/or evidence of user-centered design.

# Evaluation Criteria: Phases 1 and 2

Phases 1 and 2 of the MIDLIFE Health initiative will be evaluated based on the following categories.

## 01

### Scientific / Technological

- Technological feasibility and proof of concept
- Technical performance
- Technology readiness
- Innovation and advancement; Interdisciplinary collaboration

## 02

### Clinical

- Clinical impact
- Unmet needs Implementation
- Home-based technologies
- Integration into healthcare workflows

## 03

### Access and User-Experience

- User-centered design
- Partnership and engagement
- Reach and relevance
- Implementation
- Sustainability

## 04

### Commercialization

- Market readiness
- Scalability
- Growth and sustainability
- Intellectual property

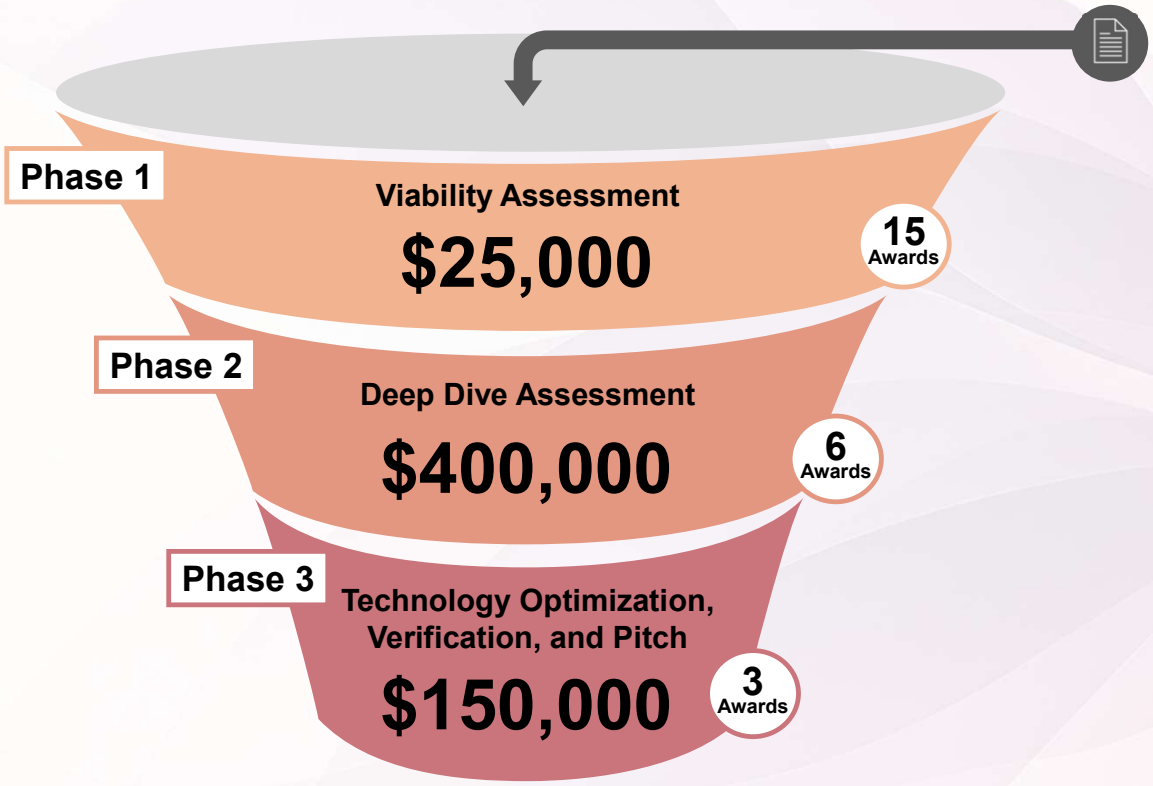
## 05

### Regulatory and Reimbursement

- Regulatory readiness
- Regulatory risk mitigation
- Payment and reimbursement strategy

# MIDLIFE Health Structure: Overview

The MIDLIFE Health initiative consists of three phases and only those Innovators selected to receive an award at the close of each phase will be advanced to the subsequent phase.

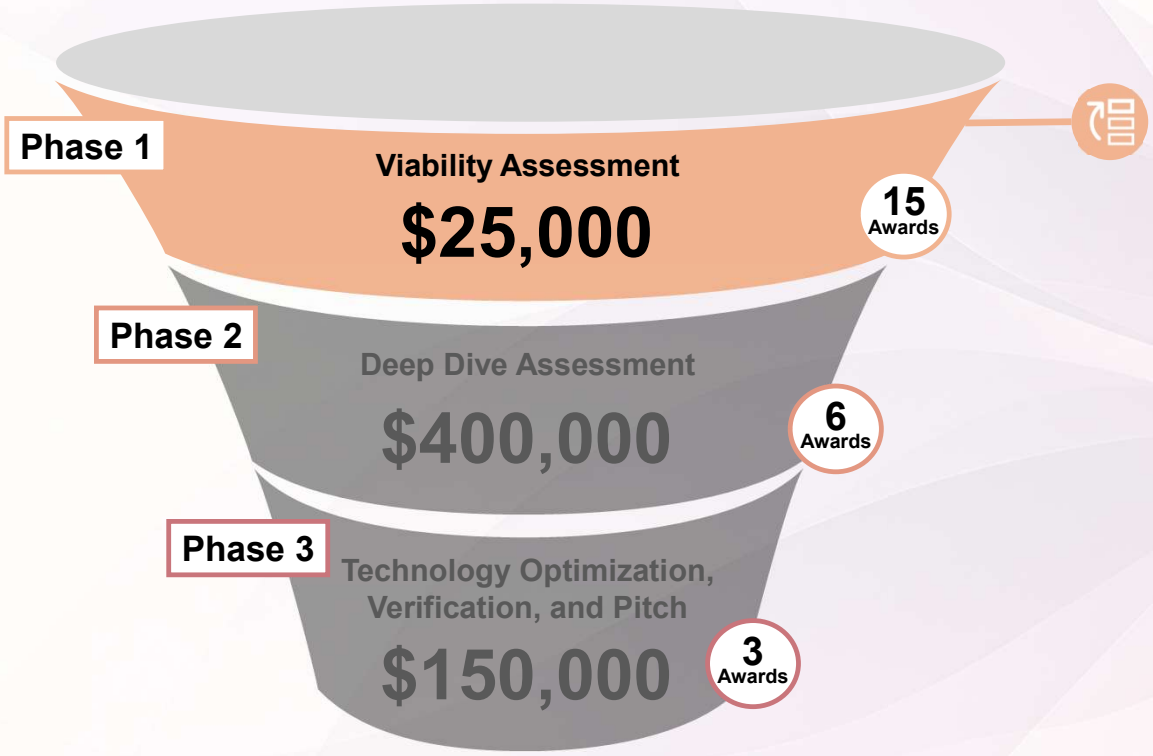



**Innovator Submissions (November 16, 2026 – January 29, 2027)**

- Solicitation, FAQs, and link to application portal at https://cimit.org/midlife/

# MIDLIFE Health Structure: Phase 1

The MIDLIFE Health program consists of three phases and only those Innovators selected to receive an award at the close of each phase will be advanced to the subsequent phase.

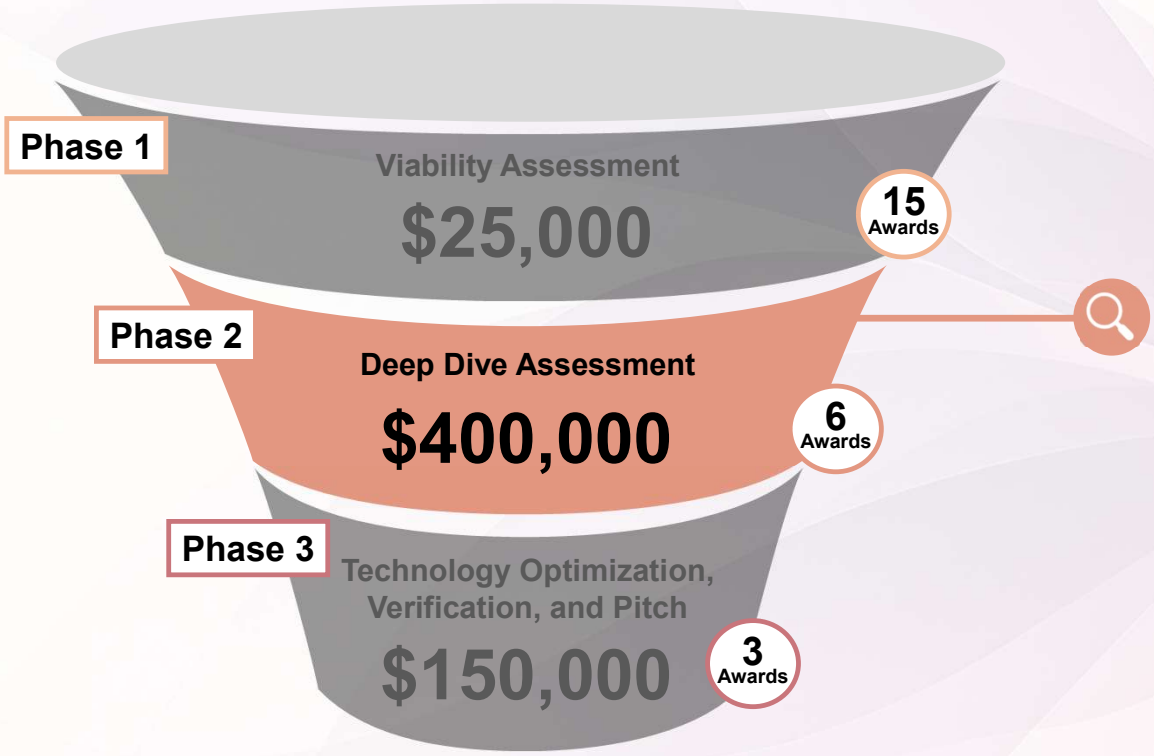



**Viability Assessment (February – March 2027)**
*Focus: Initial Screening*

- Submissions are screened to confirm Innovator eligibility and satisfaction of minimum requirements
- Reviewers score viable submissions using published evaluation criteria
- Up to 15 Innovators are selected to receive a lump sum award payment and invited to participate in Phase 2

# MIDLIFE Health Structure: Phase 2

The MIDLIFE Health program consists of three phases and only those Innovators selected to receive an award at the close of each phase will be advanced to the subsequent phase.

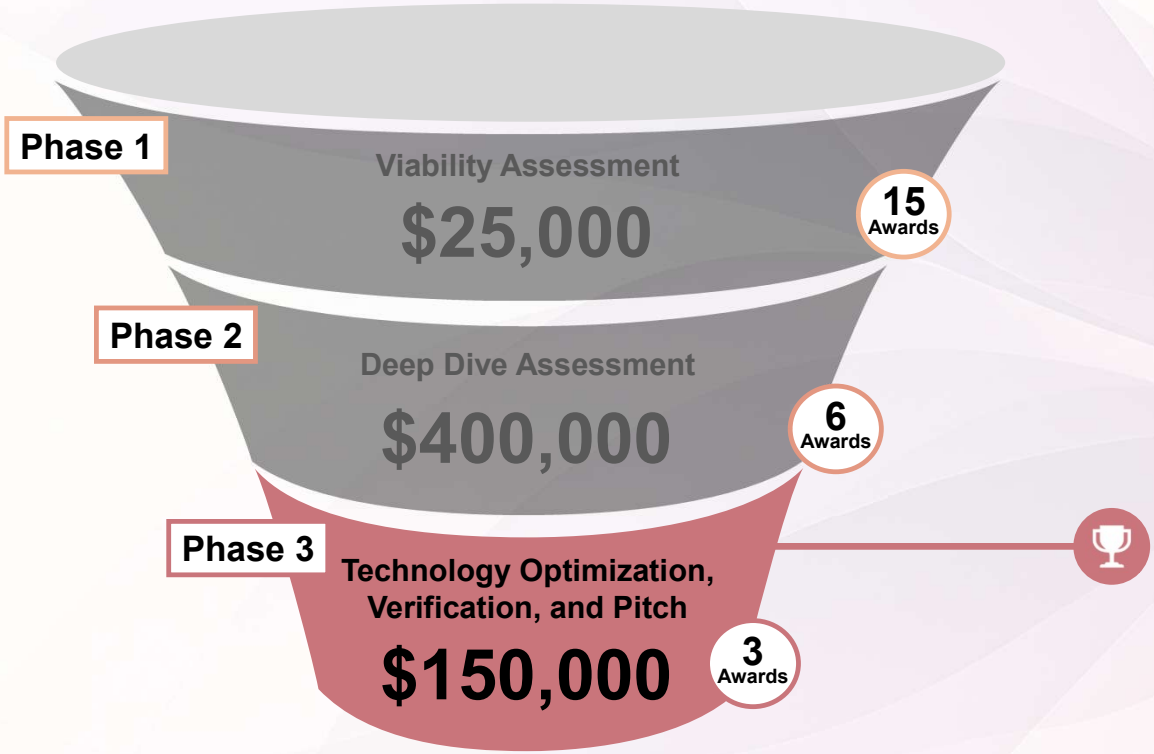



**Deep Dive Assessment (April – May 2027)**
*Focus: Examine Innovation and Team*

- Innovators collaborate with a team of healthcare technology experts to identify risk factors and mitigation strategies, and refine a milestone-based workplan for the technology optimization phase
- Reviewers score Innovators using published evaluation criteria
- Up to 6 Innovators are selected to receive a milestone-based award payment and invited to participate in Phase 3

# MIDLIFE Health Structure: Phase 3

The MIDLIFE Health program consists of three phases and only those Innovators selected to receive an award at the close of each phase will be advanced to the subsequent phase.




**Technology Optimization, Verification, and Pitch (June 2027 – October 2028)**

*Focus: Strengthen and Independently Verify*

- **Phase 3A: Technology Optimization**
- **Phase 3B: Verification**
- **Phase 3C: Pitch**

# MIDLIFE Health Structure: Phase 3 Deep Dive

A closer look at Phase 3: Technology Optimization, Verification, and Pitch

## 3A Technology Optimization
June 2027 - April 2028

**Innovators, with project-specific support:**

1. Execute the milestone-based workplan developed during Deep Dive
2. Co-develop an independent verification testing protocol
3. Build, QC, and deliver prototypes and associated instructions for use to the verification center by April 2028

## 3B Verification
May - Early October 2028

**Verification center:**

1. Implements independent testing protocol to evaluate the prototypes and associated instructions:
    1. Analytical
    2. Clinical
    3. Human Factors
2. Reports results to innovator

## 3C Pitch
Late October 2028

**Innovators deliver a virtual pitch, including:**

1. Technology demo, results of independent verification testing, plans for further development and commercialization
2. Reviewer evaluation criteria will be based on Phase 3 technology portfolio
3. Up to 3 Innovators are selected to receive a lump sum $150,000 final award payment

# Timeline

Please review the timeline below and stay up to date with key milestones throughout MIDLIFE Health.

**Submission Period**
*November 2026 - January 2027*

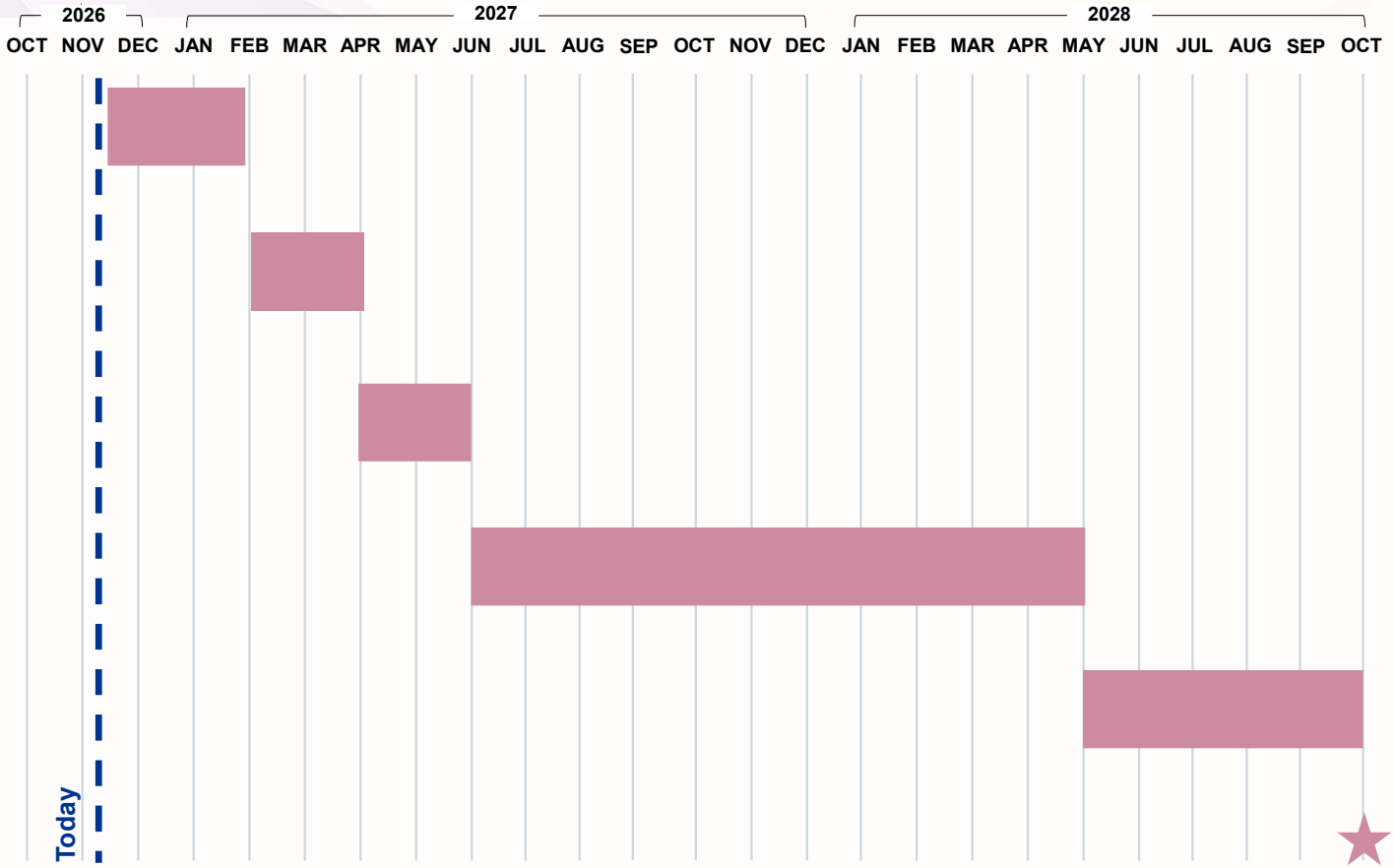
**Phase 1: Viability Assessment**
*February - March 2027*

**Phase 2: Deep Dive Assessment**
*April - May 2027*

**Phase 3A: Technology Optimization**
*June - April 2028*

**Phase 3B: Verification**
*May - October 2028*

**Phase 3C: Pitch**
*October 2028*



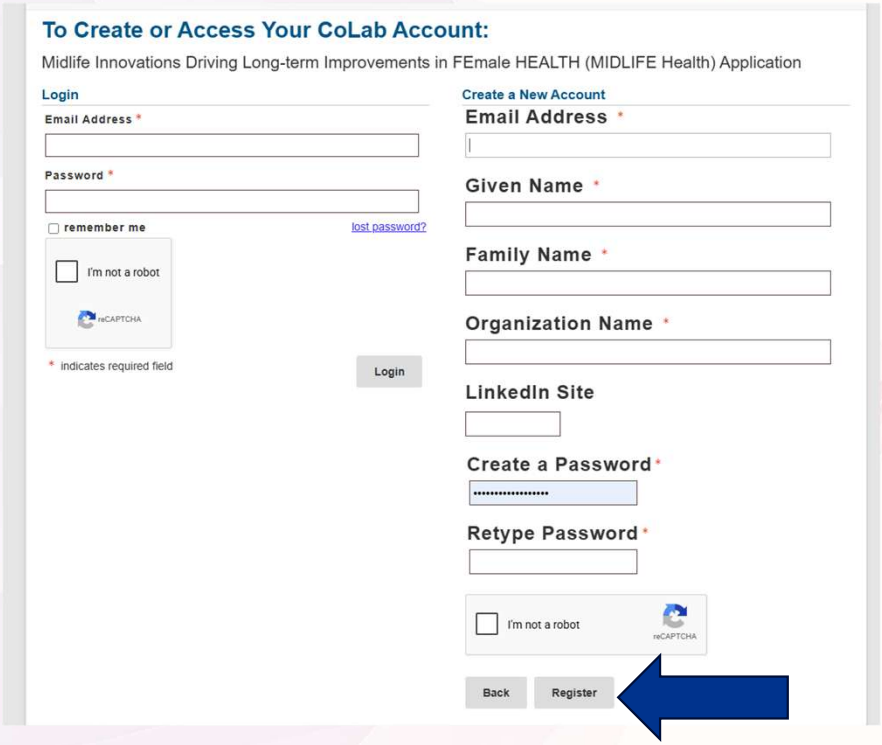

*The timeline is subject to change.



NIH National Institutes of Health
Office of Research on Women's Health

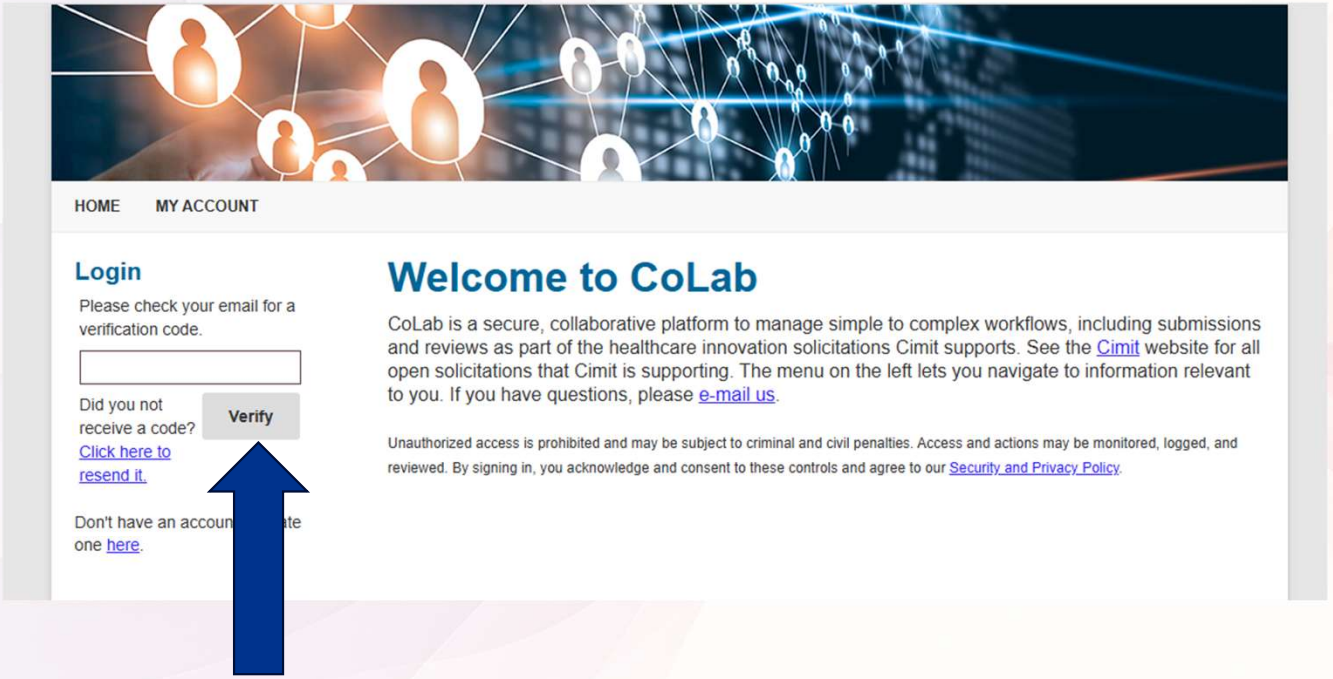
# How Do I Submit a Proposal?

To submit a proposal, first navigate to https://colab.secure-platform.com/a/solicitations/197/home. Then create a login using your name, email address, and password.



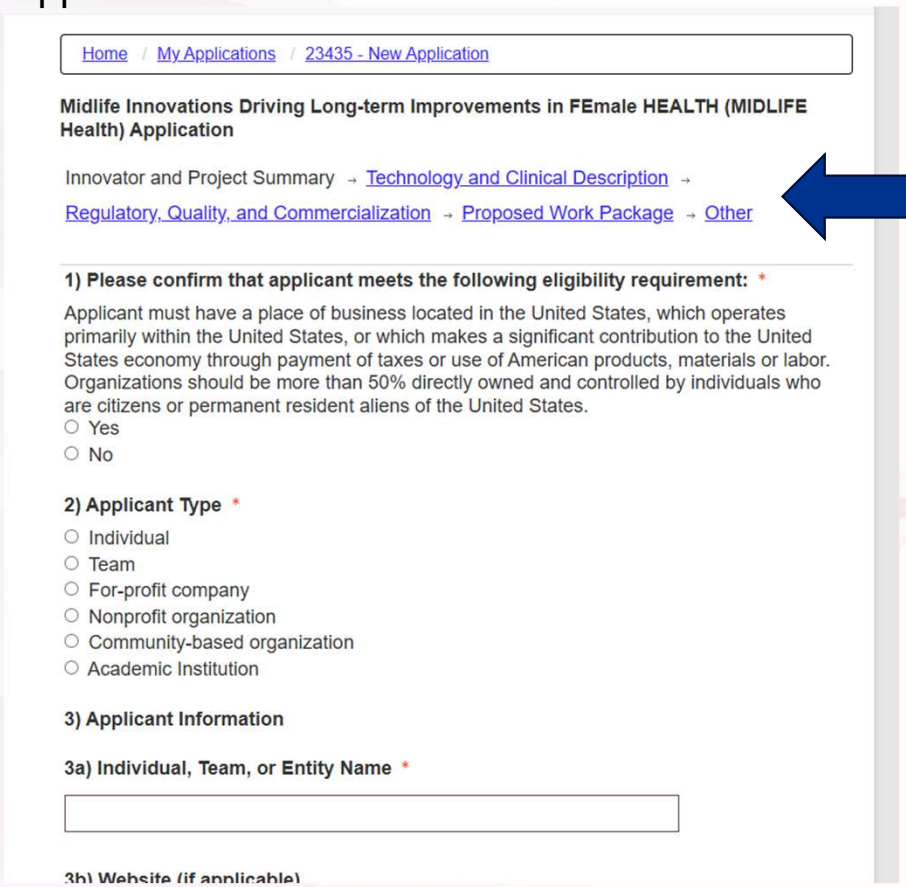
# How Do I Submit a Proposal?

Login with the profile you created.



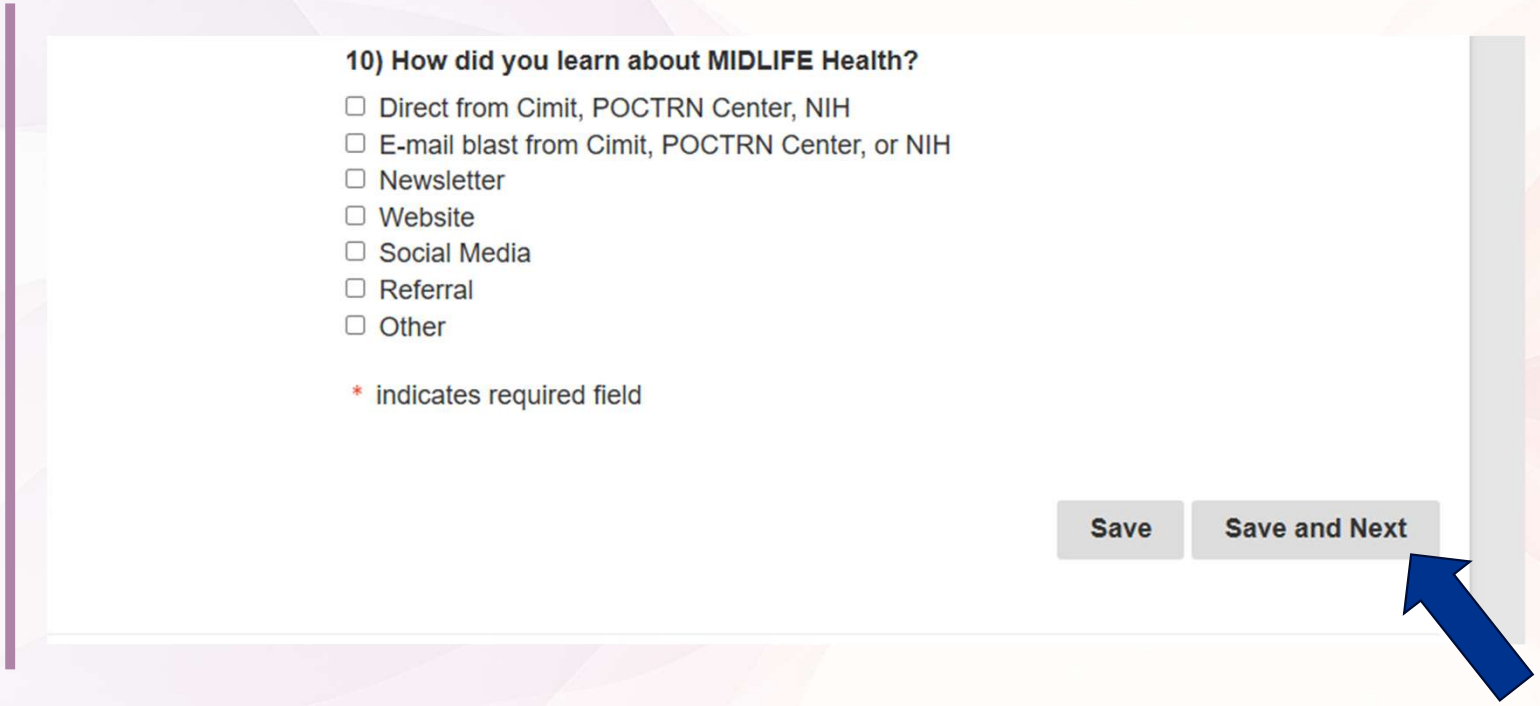
# How Do I Submit A Proposal?

Begin to fill out the MIDLIFE Health application.



# How Do I Submit A Proposal?

Once you arrive at question 10, remember to click “Save and Next”.



# How Do I Submit A Proposal?

Please indicate whether you used generative super intelligence (SI) tools to prepare your submission.





## Upcoming Events

This is the first webinar in our three-part series on MIDLIFE health. Join us for the next two sessions to hear our partners share their perspectives on key research priorities and opportunities to contribute to the initiative.

- [x] MIDLIFE Health Introductory Webinar
  November 23, 3:00 – 4:00 pm ET
- [ ] MIDLIFE Health Informational Webinar and Scientific Landscape Session 1
  November 30, 3:00 – 4:00 pm ET
- [ ] MIDLIFE Health Informational Webinar and Scientific Landscape Session 2
  December 7, 3:00 – 4:00 pm ET

**For more information, visit Midlife Innovations Driving Long-term Improvements in Female Health.**

## Moderated Q&A

Now we will take a moment for you to ask questions! Please use the Q&A function in Teams to do so.



# Submit Your Questions Now!

**If your question is not answered today:**

1. Thoroughly review the MIDLIFE Health solicitation and FAQs, at: https://cimit.org/midlife/
2. Email us at: RADx_MIDLIFE@mail.nih.gov