Thank you for joining OCULAB Proposers' Day!
The presentation will begin soon.

ARPA H

OCULAB Proposer's Day

Ocular Laboratory for Analysis of Biomarkers

Advanced Research Projects Agency for Health (ARPA-H)

Program Manager: Dr. Calvin W. Roberts
Health Science Futures (HSF), Mission Office (MO)

December 12, 2024 | St. Petersburg, FL

Agenda

9:00 – 9:15 am Welcome Remarks
Cal Roberts, *OCULAB Program Manager*

9:15 – 9:30 am ARPA-H Goals
Amy Jenkins, *Director, Health System Futures Office*

9:30 – 10:15 am OCULAB Overview
Cal Roberts, *OCULAB Program Manager*
Cynthia Steel, *Technical SETA*

10:15 – 10:30 am Acquisitions & Business Overview
Georgina Perry, *Contracting Officer*
Bill Woodcock, *Business & Financial Manager*

10:30 – 10:45am BREAK

10:45 – 11:15 am ARPA-H Panel Q&A
Amy Jenkins, Cal Roberts, Bill Woodcock, Cynthia Steel, Chris Smith

11:15 – 11:45 am Dry Eye Disease Clinical Perspective
Nora Lee Cothran, OD
The Eye Institute of West Florida

11:45 am – Noon Closing Remarks
Cal Roberts

12:00pm Lunch

1:30 – 3:30 pm *Poster Session*
1:00 – 4:00 pm *Sidebars by appointment*

ARPA-H

ARPA-H: The Mission

Advanced Research Projects Agency for Health (ARPA-H)

Amy Jenkins, HSF Director

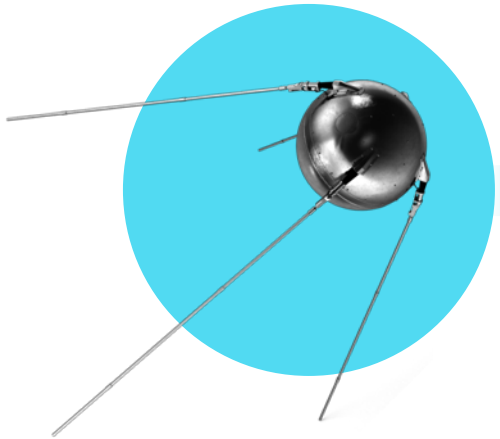
ARPA-H

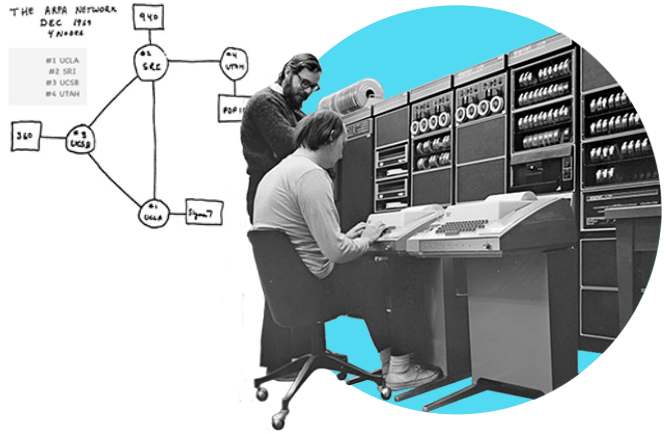
Mission

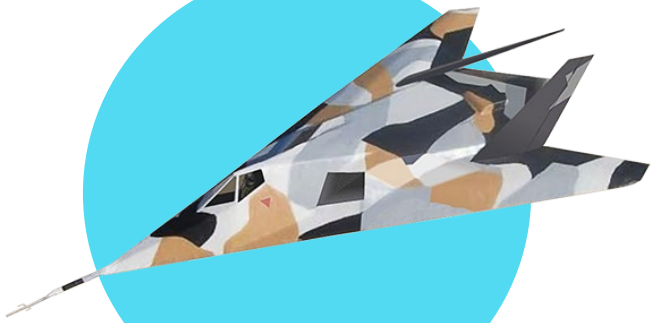
Accelerate better health outcomes for everyone.

ARPA-H

The Promise of the ARPA-H Model

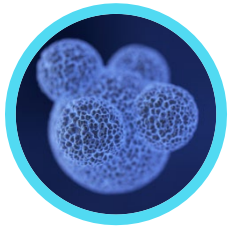






ARPA-H

ARPA-H: the ARPA Model at Work for Health



HOW?

We are a unique funding agency *by design*

WHO?

Problem-focused Program Managers drive innovation

WHAT?

We are seeking radical change

Attributes that Support the Mission

Radical Change

ARPA-H investments should seek to address seemingly impossible barriers in demonstrating "proof of concept" for solutions to major challenges—not incremental advances.

Autonomy

PMs practice "full contact" management to maintain vision and deliver results, with metrics/ milestones for program, empowered to stop underperforming projects.

Term limits

Terms limited to 3 years (renewable once for 6 total years) for PMs, Office Directors, and Deputy Directors, allowing inflow of new ideas.

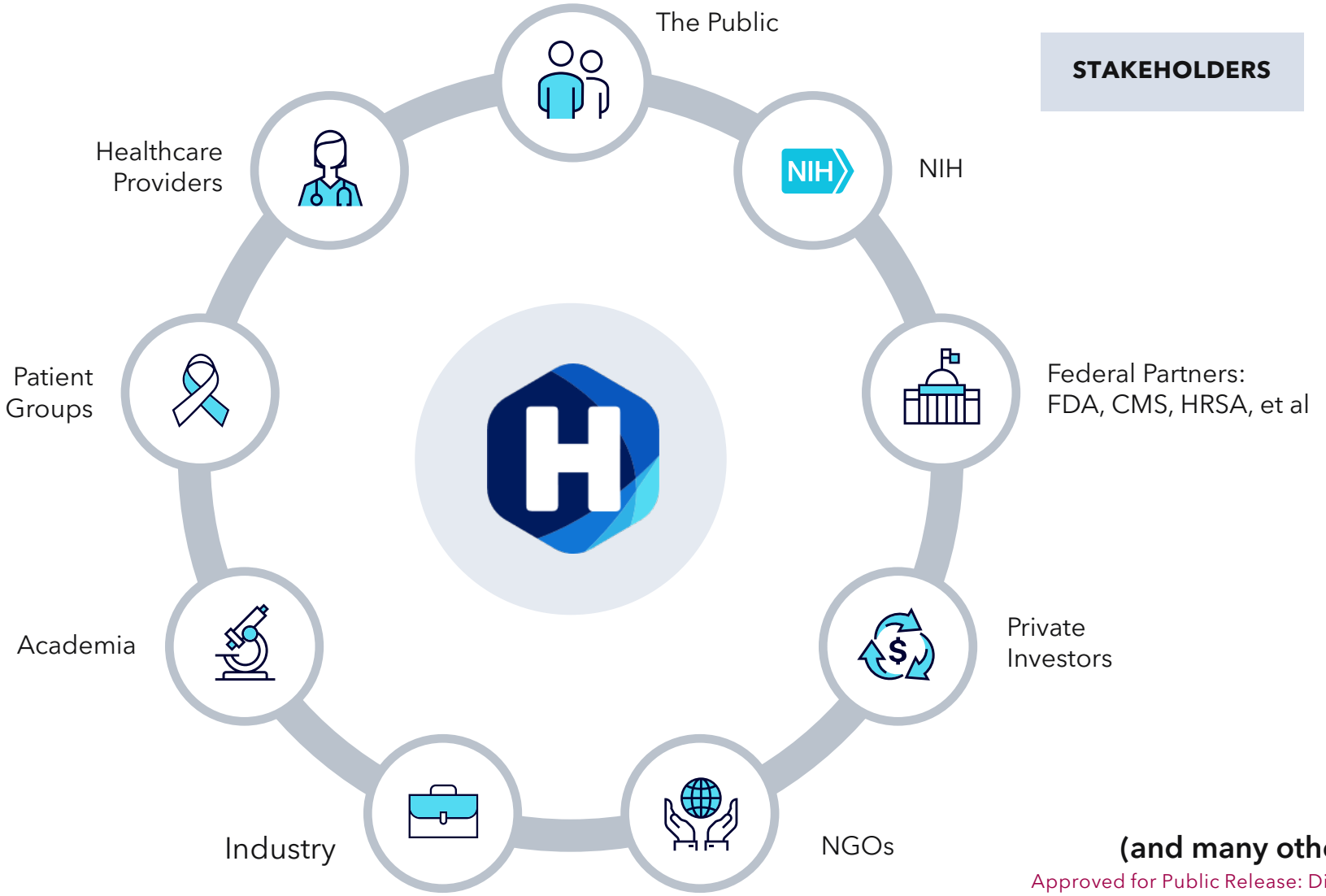
Success for ARPA-H is defined by real-world impact

ARPA-H

ARPA-H Accelerates the Entire Health Ecosystem

CUSTOMERS

PERFORMERS



STAKEHOLDERS

(and many others …)

ARPA-H

ARPA-H Model: Program Lifecycle

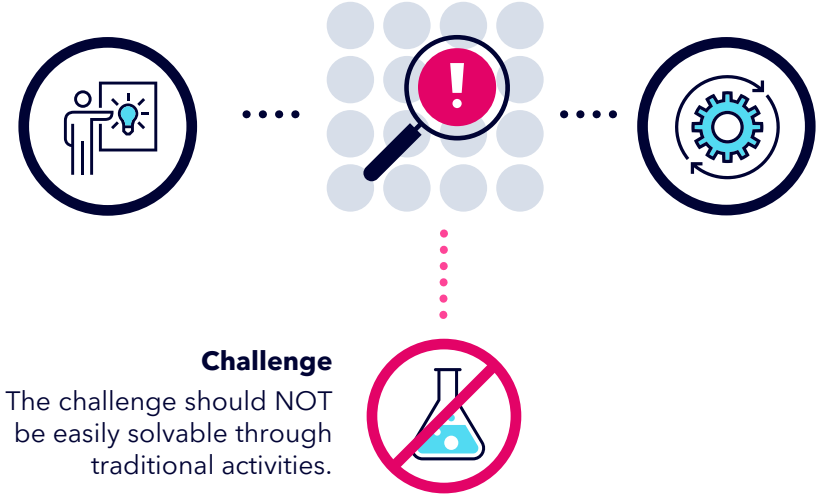
Launch

Program Manager

Program Manager identifies a difficult health-related challenge that is ripe for solving.

Program Launch

A Program Manager seeks – and oversees – several groups of performers aiming to solve the same problem in unique ways.

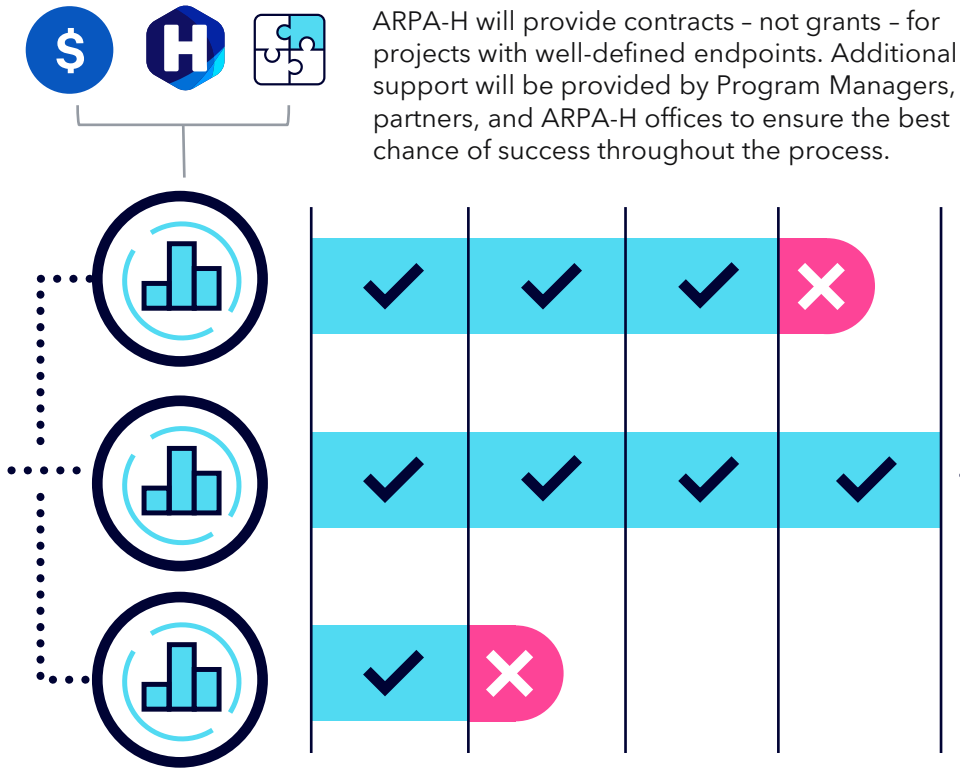


Challenge

The challenge should NOT be easily solvable through traditional activities.

Support

ARPA-H will provide contracts – not grants – for projects with well-defined endpoints. Additional support will be provided by Program Managers, partners, and ARPA-H offices to ensure the best chance of success throughout the process.



Perform

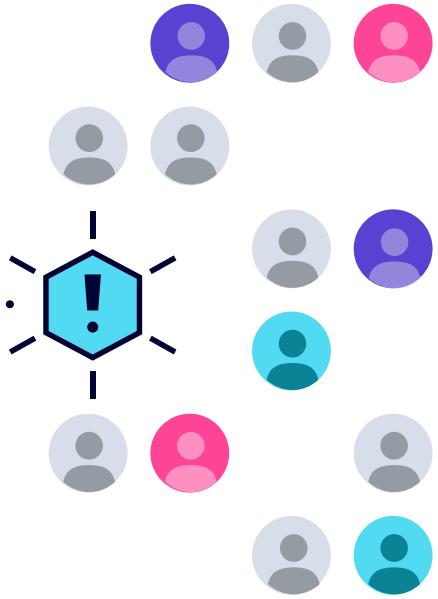
Performers

Performers compete to carry out their potential innovative solutions to the challenge.

Performance

Contract performance will be regularly evaluated to allow ARPA-H to concentrate resources on the most effective approaches to reaching the desired goals.

Transition



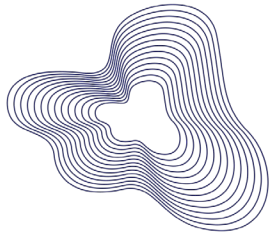
Graduation

Graduation occurs when the challenge is solved. The project then transfers to partners, who have been involved from the start and can scale the solution for large, diverse communities everywhere.

ARPA-H

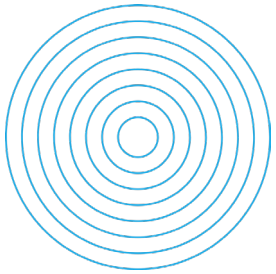
Mission Focus Areas and Ideation

Further ARPA-H investment in these areas will generate **asymmetrical benefits** to the health ecosystem



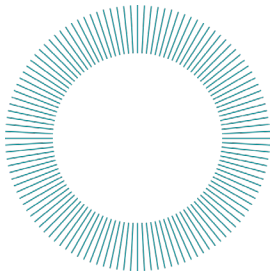
Health Science Futures

Expanding what's technically possible



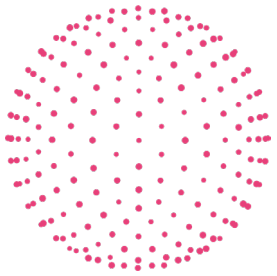
Scalable Solutions

Reaching everyone quickly



Proactive Health

Keeping people from being patients



Resilient Systems

Building integrated healthcare systems

Project Accelerator Transition Innovation

Ensuring programs survive in the wild

Ideation at ARPA-H

- **Programs:** Initiated by Program Managers to address major health challenges.
- **Projects:** Sourced from community via the Innovative Solutions Openings (ISOs), enabling grassroots innovation.

ARPA-H

Health Science Futures (HSF) Mission Office

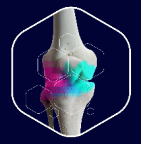
- HSF **aims to accelerate** advances **across research areas** and **remove limitations** that stymie progress toward solutions

- The innovative **tools, technologies, and platforms** from HSF programs will apply to a broad range of diseases that affect large populations, rare diseases, or diseases with limited treatment options

- HSF addresses key unmet needs in **health care today** and pushes innovative medical technology forward for a **healthier tomorrow**

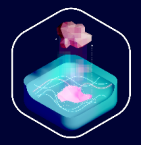
ARPA-H

Expanding what's technically possible



NITRO

What if we could make our joints heal themselves?

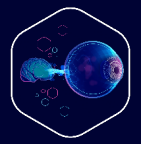


PSI

What if surgeries fixed problems flawlessly, the first time?

APECx

What if we could eliminate viruses as current and future health threats?

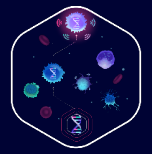


THEA

What if we could cure blindness?

PRINT

What if we could bioprint any organ on demand?



EMBODY

What if your own immune system could manufacture cures for devastating diseases?

LIGHT

What if we could make the invisible lymphatic system visible?

POSEIDON

What if a simple test could save millions of lives by catching cancer early?

GLIDE

What if doctors were able to prevent and cure human disease by targeting the lymphatic system?

EHI

What if early career investigators and community health innovators were empowered to develop cutting-edge biomedical and health research that will transform health care for all?

CATALYST

What if we could predict drug safety and efficacy accurately before clinical trials even begin?

OCULAB

What if your eyes were a window to your health?

INDEX

What if high-quality, diverse, and representative imaging data were easily available for medical AI development?

OCULAB:

Ocular Laboratory for Analysis of Biomarkers

Calvin W. Roberts, MD, Program Manager
Cynthia L. Steel, PhD, MBA, Tech SETA *[CTR]*

ARPA H

What if your eyes were a window to your health?

Program Vision

THE PROBLEM: Today, medical decisions are made on incomplete point in time data, and treatment requires patient adherence and compliance.

OCULAB OCULOMICS PLATFORM: Integrates tear biomarkers and biosensor data for 24/7 physiological monitoring and ultra-precise therapeutic delivery.

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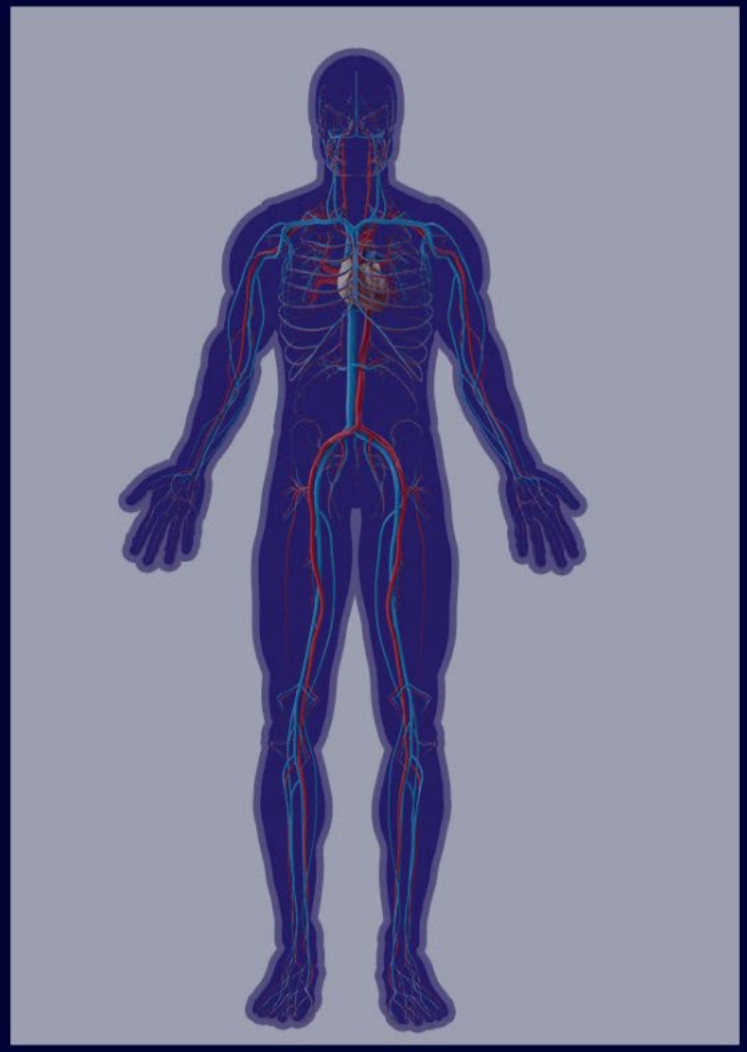
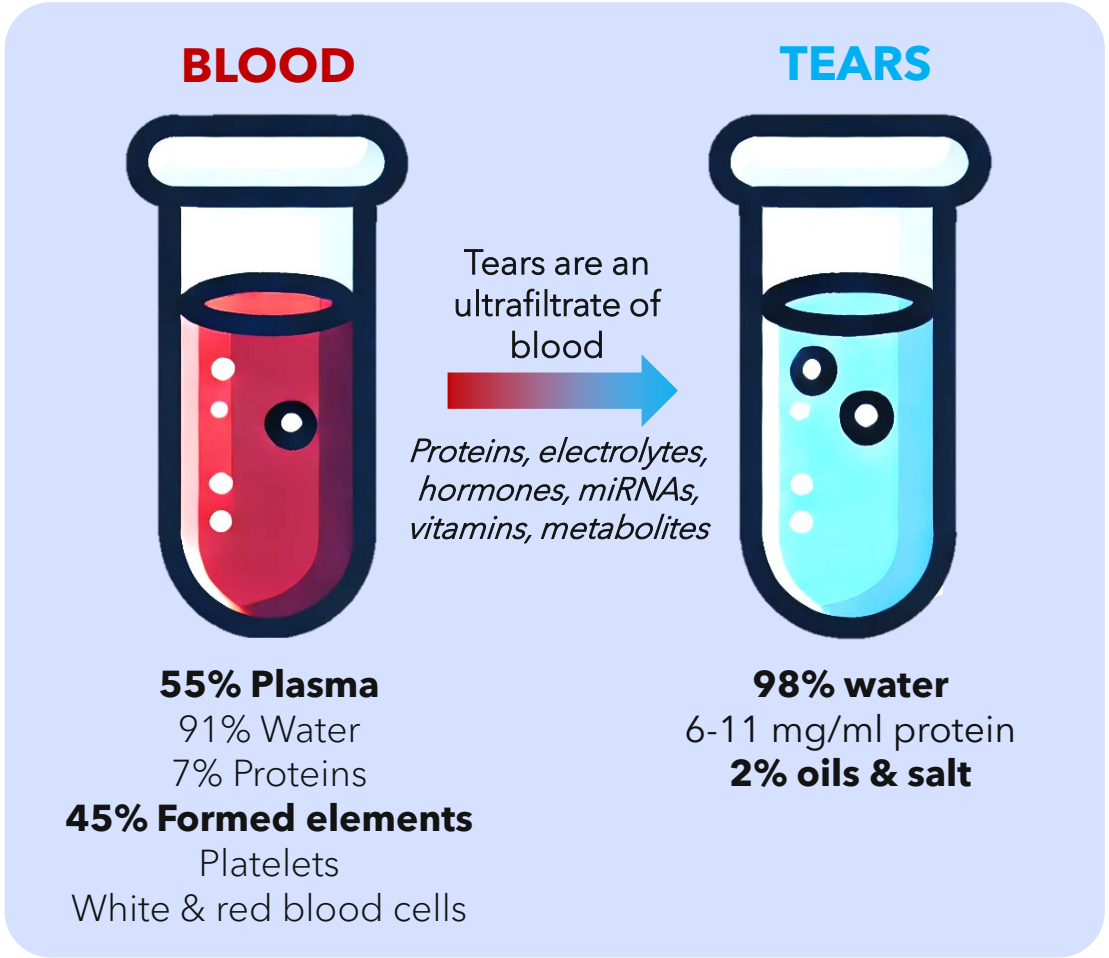
Blood is full of **biomarkers**, which can be measured to indicate the presence of disease or infection.



Tears may be the *solution* to continuous monitoring



	Blood	Urine	Saliva	Sweat	Tears
No pre-processing	X	✓	✓	✓	✓
Non-invasive	X	✓	✓	✓	✓
Transparent	X	X	✓	✓	✓
Cell-free	X	X	X	✓	✓
High concentration of low MW proteins	X	X	X	✓	✓
Measurements *in situ*	X	X	X	✓	✓
Continuous monitoring	X	X	X	✓	✓
Anti-Fouling	X	X	X	✓	✓
Extended duration (6 months +)	X	X	X	X	✓

MW: molecular weight

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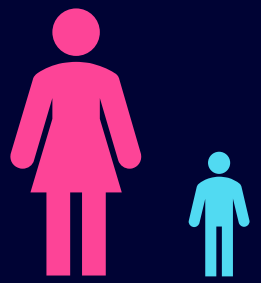
First OCULAB Platform Disease Target: Dry Eye Disease (DED)

2:1 Overall Incidence
(women : men)



Risk Increases With:

Menopause

Androgen Insensitivity

Androgen Deprivation Therapy

In clinical trials, topical treatment with androgens improves:

Dry eye disease symptoms
Dry eye test results
Meibomian gland secretions
Contact lens wear time

20 million US patients
(still very underdiagnosed)

Symptoms Range From:

- Sandy or gritty feeling
- Pain and itching
- Redness
- Light sensitivity
- Reading difficulties
- Vision fluctuation

$59.2 billion per year

$3.84 billion	$55.4 billion
Medical care	**Patient behavior**
• Ocular lubricants • Prescriptions • Physician visits • Punctal plugs • Nutritional supplements	• Absenteeism • Reduced productivity • Reduction in health-related quality of life • Increased psychological stress

In-office testing of tear biomarkers (tear osmolarity, MMP-9, lactoferrin) is the standard of care for diagnosis of DED.

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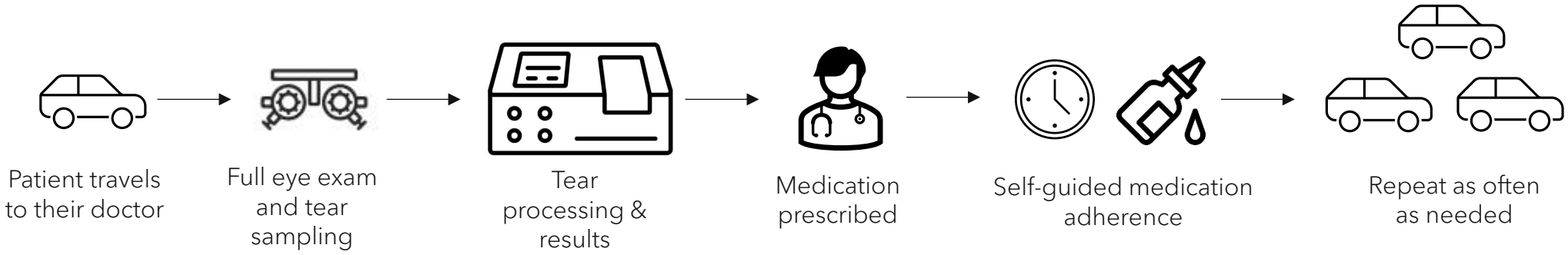
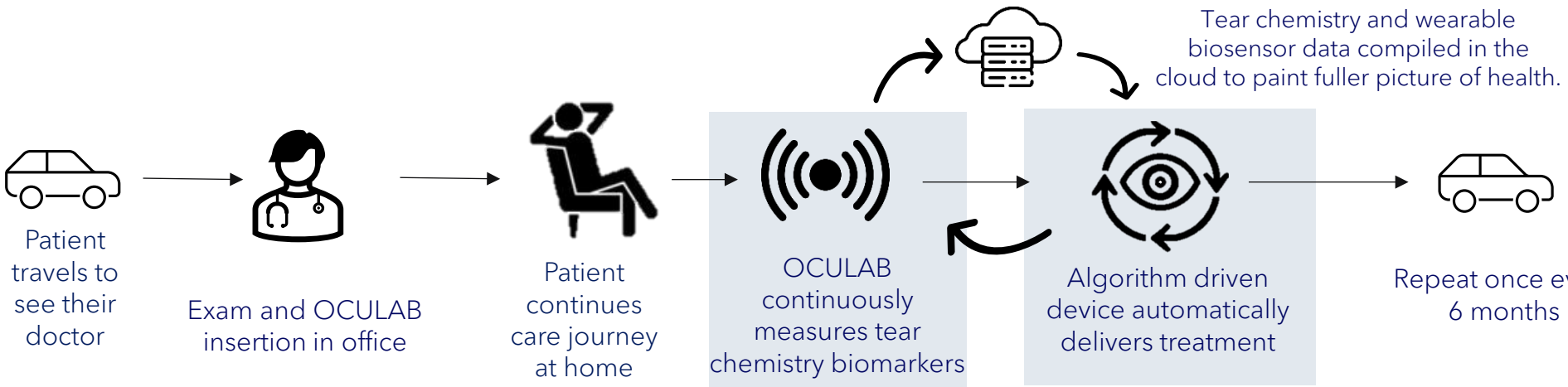
A Dry Eye Patient's Journey

Current Diagnosis & Treatment Paradigm



Ocular Laboratory for Analysis of Biomarkers (OCULAB) platform proposes an automated diagnostic and therapeutic solution using a novel source of diagnostic biomarkers and integration with other wearable biosensors.

Future with OCULAB Platform



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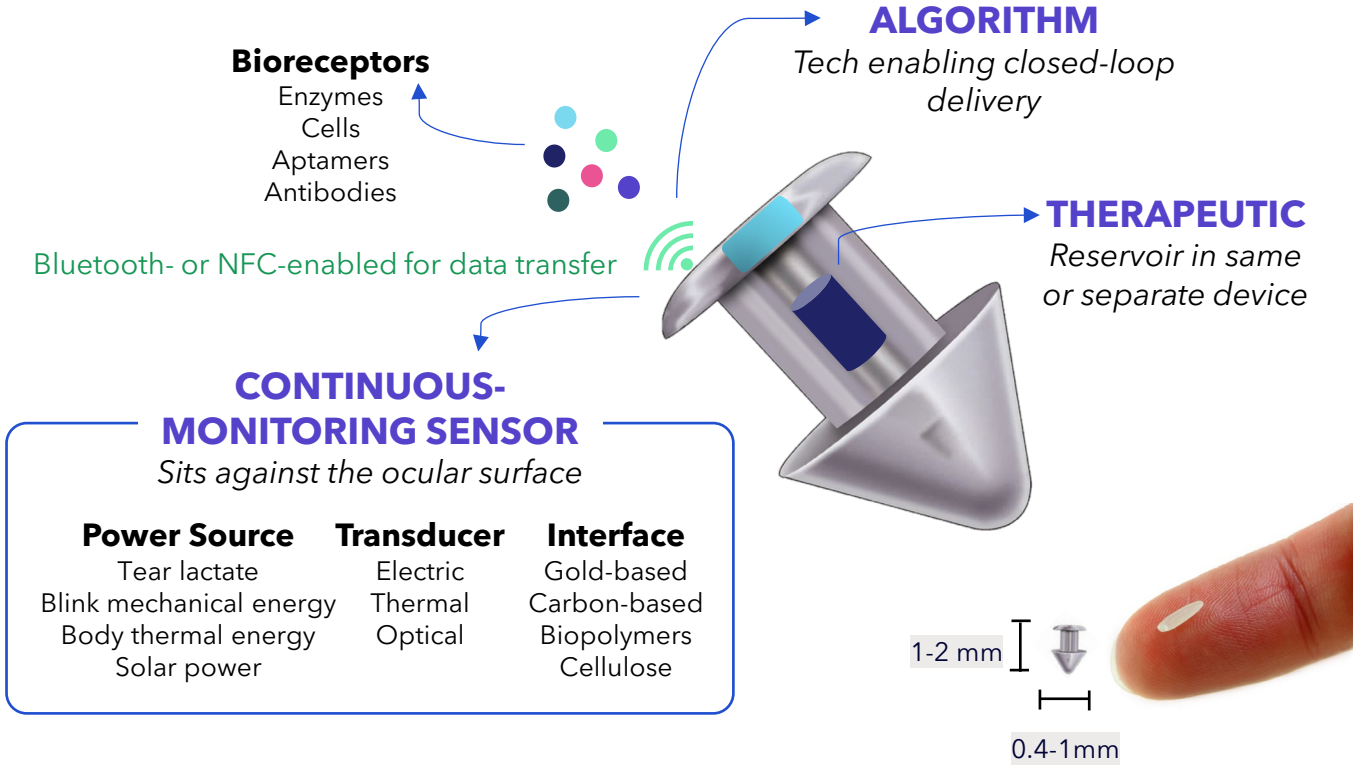
What can the OCULAB Platform do?

What can we continuously detect?

- Hormones
- Proteins
- Lipids
- Ions



What can we sustainably deliver?

- Hormones
- Proteins
- Small RNAs
- Pharmaceuticals

OCULAB will be the first:

- *In situ* tear biomarker measurement system
- Simultaneous continuous monitor of multiple systemic chemistry biomarkers
- Closed loop ultra-precise medication delivery system

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Images are for illustrative purposes only.

Punctal Plug Insertion is quick and painless!

OCULAB Platform Program Concept: Technical Areas (TAs)

Automated dosing of disease-modifying therapeutics in response to changes in tear biomarker concentration.

TA1

Continuous Monitoring Nanosensor

TA2

Closed-Loop Therapeutic Dosing

ARPA H

TA1: Continuous Monitoring Nanosensor

CONDITIONS

Tear duct based nanosensor

≥ 6 months before replacement

Continuous monitoring of ≥ 2 established biomarkers

Communication with delivery device via Bluetooth or Near-Field Communication (NFC)

Communication with the cloud for data analysis

POTENTIAL APPROACHES

Sensor Type Electrochemical, Immunosensor, Cell-based, Aptamers
Biomarkers Tear osmolarity, MMP-9, Lactoferrin, Hormones, MicroRNA species
Algorithm and Data Collection/Storage Bluetooth or NFC transfer, interim storage on local device, Secure cloud data storage
Powering Mechanism Tear lactate, Blink mechanical energy, Thermal energy, Solar power

METRICS

Develop ≥ 1 multiplex sensor prototype

Interim:

- Continuous (≥ twice/hour) data collection and feedback loop
- Longevity of 1-3 months
- Sensitivity and selectivity in biomarker detection ≥ 85%
- Turnaround time of ≤ 30 minutes

Goal:

- More frequent (≥ 4X/hour) data collection and feedback loop
- Longevity of ≥ 6 months
- Sensitivity and selectivity in biomarker detection ≥ 98%
- Turnaround time of ≤ 10 minutes

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TA1 Tracks

TRACK A
Sensor for DED

MULTIPLEXABILITY
DED: 2+ biomarkers
(required: tear osmolarity)

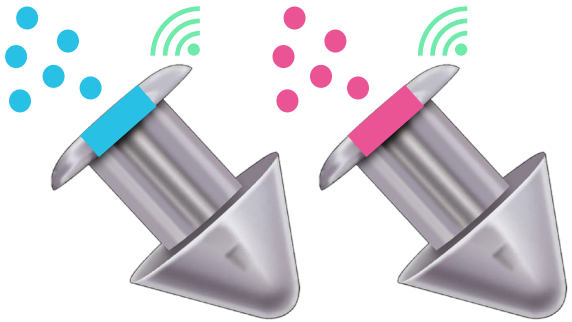
ADVANCED STUDIES TRACK
REQUIRED

TRACK B
Hybrid sensor for DED and one other indication

MULTIPLEXABILITY
DED: 2+ biomarkers
(required: tear osmolarity)
Other Indication: 2+ biomarkers

ADVANCED STUDIES TRACK
OPTIONAL

TRACK C
Separate sensors for DED and one other indication



MULTIPLEXABILITY
DED: 2+ biomarkers
(required: tear osmolarity)
Other Indication: 2+ biomarkers

ADVANCED STUDIES TRACK
OPTIONAL

ADVANCED STUDIES TRACK

MULTIPLEXABILITY
15+ exploratory biomarkers
Single or multiple disease/ inflammatory states
Chemical/biological threats

OTHER EXPLORATORY OPTIONS
Power Source
Transducer
Interface

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Images are for illustrative purposes only.

TA1 Metrics

Pre-Program			Phase 1 (18 months) **R&D**							Phase 2 (12 months) **Pre-clinical**				Phase 3 (18 months) **Clinical**						
FY25				FY26						FY27				FY28				FY29		
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3		
Device			Produce **≥ 1 ocular nanosensor device prototype** (i.e., punctal plug or comparable tear duct insert). Device dimensions must meet physiological size restrictions of the **lacrimal canal** and must be **hollow or permeable** to allow for the free flow of tears through the sensor.						Validate ≥ 1 ocular nanosensor device prototype **in large animals**.				Validate ≥ 1 ocular nanosensor device prototype **in humans**						
Longevity (how long the implant should last)			Demonstrate device longevity **≥ 1 month post insertion**						Demonstrate device longevity **≥ 3 months post insertion in large animals**				Demonstrate device longevity **≥ 6 months post insertion in humans**						
Monitoring Rate (number of times a day sensor will detect biomarkers)			Minimum read rate of **twice per hour**						Minimum read rate of **four times per hour in large animals**, increasing in frequency if biomarker levels read outside the normal/healthy range.				Minimum read rate of **six times per hour in humans**, increasing in frequency if biomarker levels read outside the normal/healthy range.						
Response Time (time interval between analyte detections)			**≤30 min**						**≤15 min** but increasing to ≤ 10 min if biomarker levels read outside the normal/healthy range in large animals				**≤ 10 min** in humans but increasing to ≤ 5 min if biomarker levels read outside the normal/healthy range in humans.						
Multiplexing Capability (ability to detect multiple biomarkers simultaneously)			**Minimum requirement of 2-plex. Up to 10-plex** based on min number of biomarkers required for accurate disease monitoring						Min: 2-plex, Max: 10-plex device in **large animals**				Min: 2-plex, Max: 10-plex device in **humans**						
Limit of Quantification (lowest detectable level of biomarker in tears)			Reliably detect (**within 5%**) lowest physiologically relevant value of each analyte and establish linear range of detection. Lowest values may occur in either healthy or diseased states.						Reliably detect (within 5%) of lowest physiologically relevant value **in large animals**. Validate linear range of detection.				Reliably detect (within 5%) of lowest physiologically relevant value in **humans**.						
Sensitivity (accuracy in identifying amount of biomarker present)			Establish **≥ 85% sensitivity** in biomarker detection						Validate **≥ 95% sensitivity** in biomarker detection				Validate **≥ 98% sensitivity** in biomarker detection						
Specificity (accuracy in identifying only specific biomarker of interest)			Establish **≥ 85% specificity** for each analyte of interest						Validate **≥ 95% specificity** for each analyte of interest				Validate **≥ 98% specificity** for each analyte of interest						
Algorithm			**Produce framework and training data** for algorithm using any platform. **Establish boundaries and thresholds for biomarker of interest** based on disease indication. Validate algorithm performance and accuracy against biomarker of interest. Produce plan for **data privacy and security**.						**Validate** algorithm response to sensor readings. **Establish physiological baselines and demonstrate accuracy** in therapeutic dose delivery.				**Finalize algorithm** response to sensor readings. **Validate physiological baselines** and demonstrate accuracy in therapeutic dose delivery.						

TA2: Closed Loop Therapeutic Dosing

CONDITIONS

Established disease-modifying therapy

Connect to sensor via Bluetooth or NFC

Therapeutic delivery only in response to signal from sensor

Failsafe in place if connection is lost

Must reside in or around the eye

Device placement should be in one or both eyes as dictated by symptoms

POTENTIAL APPROACHES

Disease-Modifying Therapy
DHEA or Testosterone
Other (justification/preliminary data required)

Reservoir Placement
Same housing as sensor or separate
Placement in conjunctival fornix, other punctum, etc.

METRICS

Produce ≥ 1 device prototype containing disease-modifying therapeutic for dry eye disease

Interim:
- Longevity of 1-3 months
- Response time of ≤ 15 minutes
- Dosage accuracy of ≥ 80% target in humans

Goal:
- Reduction of tear osmolarity and biomarkers of interest to healthy baseline with device
- Longevity of ≥ 6 months
- Response time of ≤ 5 minutes
- Dosage accuracy of ≥ 98% target in humans

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TA2 Metrics

Pre-Program			Phase 1 (18 months) **R&D**							Phase 2 (12 months) **Pre-clinical**				Phase 3 (18 months) **Clinical**						
FY25				FY26				FY27				FY28				FY29				
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3		
Device and therapeutic			**Identify ≥ 1 disease-modifying therapeutic for DED.** **Produce ≥ 1 ocular therapeutic device prototype** (i.e., same device as TA1, other lacrimal canal insert, conjunctival insert, or other extraocular device) for delivery of disease modifying therapy for DED.						Validate ≥ 1 ocular therapeutic device prototype in **large animals**.					Validate ≥ 1 ocular therapeutic device in **humans**.						
Therapeutic efficacy (% decrease in symptom onset in patients)			**N/A**						**Restoration of tear osmolarity and biomarkers of interest** to physiological baselines in **large animals.**					**Restoration of tear osmolarity and biomarkers of interest** to physiological baselines **in humans**						
Response time (time taken to administer therapeutic dosage after sensor detection)			**≤15 min**						**≤5 min in large animals**					**≤5 min in humans**						
Longevity (how long the implant should last)			Demonstrate device longevity **≥ 1 month post insertion**						Demonstrate device **longevity ≥ 3 months** post insertion in **large animals**					Demonstrate device longevity **≥ 6 months post insertion in humans**						
Dosage accuracy (appropriate amount of therapeutic applied)			**Performer set metric** for disease indication and biomarker.						**≥ 80%** target in large animals					**≥ 98%** target in humans						

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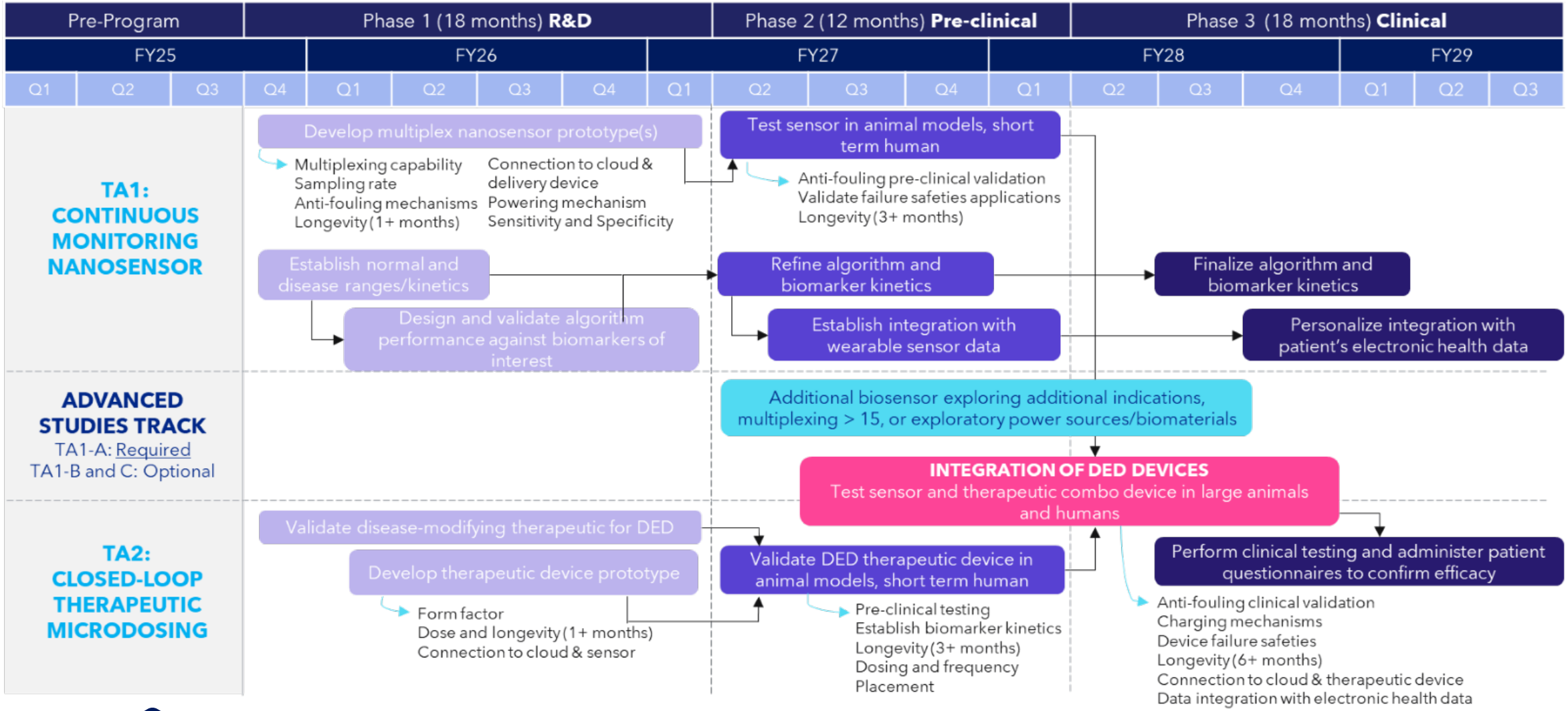
Program Timeline



ARPA-H

OCULAB is a Health Platform

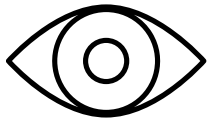
OCULAB has the potential to make continuous monitoring of other validated disease biomarkers a reality.

NEUROLOGICAL DISORDERS

Alzheimer's (Amyloid-β)

Huntington's (Mutant huntingtin)

Multiple Sclerosis (Transcobalamin-1)

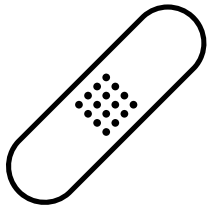


OPHTHALMOLOGICAL DISORDERS

Glaucoma (Cystatin S, CNTF)

Thyroid Eye Disease (IL-10, IL-6, TNFα)

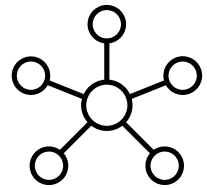
Ocular Allergies (IL-1α, MUC1, IL-17)



INFLAMMATORY DISORDERS

Viruses (COVID-19)

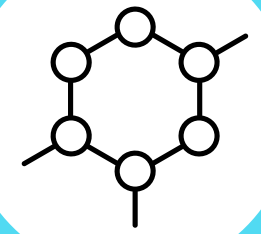
Sjogren's Syndrome (IL-2, CCL5, IFNγ)



METABOLIC AND METASTATIC DISEASE

Breast Cancer (S100A8, S100A9, LG3BP)

Diabetes (Glucose, Leptin)



HORMONAL DISORDERS

Dry Eye Disease (Androgens)

Infertility (Estrogens or Progesterone)

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OCULAB Solicitation Timeline

DECEMBER 12
Proposer's Day

JANUARY 27
Solutions Summaries Due

MARCH 3
Invitations for Full Proposals

APRIL 14
Full Proposals Due

SUMMER 2025
Performers Selected

FALL 2025
Program Kick-off

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Impact of OCULAB Platform

On Patients

LOWER HEALTHCARE COSTS
Fewer doctor visits and lab tests

IMPROVED MEDICATION COMPLIANCE
Better symptom control

BETTER SAFETY MARGINS
Closed-loop consistent local drug conc

On Researchers

REDUCED R&D COSTS
Less preclinical testing and risk to humans through microdosing

UNIQUE HEALTH ASSESSMENT
Better symptom control

On Physicians

ACCELERATING DIGITAL HEALTH
Less frequent and more targeted testing

BETTER DISEASE CONTROL
In remote/ underserved areas

EASY IN-OFFICE CARE
Simple device insertion procedure

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In 5 years...

- OCULAB technologies in final stages of clinical development and commercialization for dry eye disease
- Newly identified tear biomarkers open OCULAB platform to multiple ocular and systemic diseases
- Development of OCULAB ocular sensor for chemical threat detection

In 10 years...

- OCULAB technologies in broad clinical practice for dry eye disease
- Technologies in development for simultaneous detection and treatment of multiple disorders
- Measured biomarkers fully integrated into personal health diagnostics
- A low-cost solution to track health outcomes and evaluate performance of interventions

Innovative Solutions Opening ARPA-H-SOL-25-115

Georgina Perry
Agreements Officer
Business Innovation Division (BID)

ARPA-H

ARPA-H Innovative Solutions Openings (ISOs)

Allow for merit-based awards

Allow the Gov't to focus award decisions on technical quality

Best Ideas > Best Price

Allow for a variety of approaches to a problem, not one singular solution

Are flexible and allow for a variety of award instruments to be considered

OCULAB ISO Summary

- All awards will be either Other Transactions (OTs) or Cooperative Agreements (CAs) and all entity types and teaming arrangements are encouraged.
- No funding limits (or range) for individual awards
- Solution Summaries are mandatory, and the Government may only consider those submitted by the Submission date.
- Proposers who submitted a Solution Summary may submit one (1) full proposal as the Prime awardee but may also be a sub-awardee on two (2) additional proposals.
- The Government does not anticipate reviewing non-conforming Solution Summaries or evaluating non-conforming full proposals. Please **READ the ISO and ask questions as necessary**.
- **Solution Summary feedback estimated to be completed in Q1FY25**; Full proposal evaluations are estimated to be completed in Q3FY25. Notifications will be sent shortly thereafter; and award negotiations will commence.

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Award Types – Cooperative Agreements

Financial Assistance

- Financial assistance instrument to carry out a public purpose authorized by a U.S. law rather than to acquire supplies/services for the benefit of the Government
- Cooperative Agreements follow:
  - 2 CFR Part 200, 45 CFR Part 75, and the HHS Grants Policy Statement

Substantial Involvement

- Includes "substantial involvement" from the federal agency (ARPA-H) that may be ongoing throughout the project
- Both parties are responsible for achieving the agreed-upon outcome, progress and results

Award Types – Other Transactions (OTs)

What are OTs?

- ARPA-H has authority to award OTs when "*use of such authority is essential to promoting the success of the project*"
- OTs are contracts (e.g., mutual assent, expressed by a valid offer and acceptance; adequate consideration; capacity; and legality)
- OTs reflect commercial contracting rather than traditional FAR procurement contracts

OTs are collaborative

- Increased collaboration and partnership, leading to more effective use of resources and knowledge sharing.
- Free-flowing negotiations and less restrictive than FAR based procurements.

Eligibility Information (See ISO Section 3)

- See ISO Section 3.1 if you are or are considering partnering with a government entity (e.g., FFRDC)

- SAM registration required for 'Performer/Awardee'
  - Principal Investigator = Key Personnel (not an entity/proposer)
  - Not required for all performer team members (e.g., subawardees)

- See ISO Section 3.2 if you are considering partnering with a Non-U.S. Entity

- Awards, at any level, cannot be made to entities who are suspended or debarred, including key personnel

Solution Submission and Selection Process Overview
(See ISO Sections 4 and 5)

Solution Summary

- Solution Summary submission is mandatory
- Submission deadline of 27 Jan 25
- **Appendix A Template**
- **Appendix B Supplementary Table**
- Evaluated against criteria 1-2
- All eligible submissions received by the Due Date will receive a response

Full Proposal

- Only eligible following a Solution Summary submission
- Must follow guidance in **Appendix C** and include submission of **Appendix D** as well as templates provided in feedback emails (e.g., cost proposal spreadsheets)
- Evaluated against criteria 1-4

Highlights

- Solution Summaries and Full Proposals will be independently reviewed and evaluated (not comparatively)
- Each step, including notifications, will occur as quickly as possible.
- Process crafted to reflect the urgency of this Program and to respect the effort/time it takes to draft and evaluate full proposals (e.g., eligibility & conformance sheet)

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Evaluation Criteria for Full Proposals

(in descending order of importance)

1

Overall Scientific and Technical Merit (Solution Summary and Full Proposal)

- Innovative, feasible, achievable, and complete
- An outcome that achieves the expected goals
- Technical risk(s) identification with a feasible mitigation strategy

2

Potential Contribution and Relevance to ARPA-H Mission (Solution Summary and Full Proposal)

•-Future application, including unmet needs within biomedicine and to improve health outcomes

•-Potential for interdisciplinary approach

3

Proposers' Capabilities and/or Related Experience (Full Proposal)

- Team expertise and experience
- Experience in managing similar efforts

4

Price Analysis (Full Proposal)

- Price analysis will be performed to assess the reasonableness and value of the overall proposed price
- Cost realism analysis may also be performed.

Final Guidance

- Nothing discussed today should be construed as amending the ISO. Any changes will be issued as formal amendments posted to SAM.gov

- Ask questions to OCULAB@arpa-h.gov after checking posted Q&A/FAQs
  - FAQs are posted on the OCULAB page (https://arpa-h.gov/research-and-funding/programs/OCULAB)
  - Government does not intend to respond to inquiries via email; posting responses to questions on SAM.gov and OCULAB FAQs, as appropriate

- Register, or update registration, in SAM.gov as early as possible

- **Read the ISO**

ARPA H

Cost & Administrative Requirements Overview

Bill Woodcock, MSB, PMP *[CTR]*
Business & Financial Manager
Health Science Futures (HSF) Office

ARPA-H

Cost and Administrative Requirements

1. **Solution Summary: Rough Order of Magnitude (ROM)**
   - One page summary (template provided, Appendix B) - Basis of Estimate to support the proposed budget
   - Include resource/cost sharing, if applicable
2. **Full Proposal: Volume II, Cost Proposal**
   - ARPA-H Cost Proposal Spreadsheet
   - Cost and Pricing Data Support Data
3. **Full Proposal: Volume III, Administrative & Policy Requirements**
   - Team Member Identification
   - Conflicts of Interest
   - National Security Disclosure (includes Other Support and Biosketches for Senior/Key Personnel)
   - Intellectual Property
   - Human Subjects Research/Animal Subjects Research
   - Representations regarding unpaid delinquent tax liability or felony conviction under any federal law

Solution Summary – Rough Order of Magnitude (ROM)*

Categories	Phase I	Phase II	Phase III	Total
Labor (Fully burden)				
Labor hours				
Sub-performers				
Materials				
Equipment				
Travel				
Other Direct Costs				
Profit				
Total				
Cost Sharing (if applicable)				

*Per ISO, Appendix B

Volume II, Cost Proposal

1. **ARPA-H Cost Proposal Excel (Template)**
   - Template will be distributed with Solution Summary feedback
   - Includes all personnel costs, equipment, supplies, travel, indirect, ODCs, subcontractors, consultants and cost/resource sharing
   - Full template must be used by prime and all subcontractors
   - Subcontractors must provide same level of detail as the prime
   - Prime ultimately responsible for ensuring all documents are submitted; however, subcontractor may submit directly via email to OCULAB@arpa-h.gov if privacy concerns. Clearly title subject line of email: Prime_Sub_Cost Proposal
2. **Cost and Pricing Data Support (No Template)**
   - Vendor quotes
   - Cost and Pricing Data Support
   - Value Analysis Supporting Information
3. **Summary Information**
   - No funding limit or range for individual awards
   - All reasonable proposals will be evaluated and considered for award
   - Awards are expected to be issued with negotiated milestone, with payments tied to actual progress/milestone completion

ARPA-H Cost Proposal Suggestions and Reminders

Do's

- Be mindful of Phase **duration** (18 months for PH I / 12 months for PH II / 18 months for PH III
- Provide **all** requested information on the cost proposal cover sheet in your proposal submission
- Include:
  - A **cost estimate of total funds requested** from ARPA-H and the **amount of any cost share** (if any);
  - Cost breakdown **base and options**
- **Include supporting documentation**
- Include an **itemization of Subcontracts**
- If consultants are to be used, the proposer must provide a consultant agreement or other document that verifies the proposed loaded daily/hourly rate
- Consider **timing** for equipment purchase needs; consider timing for animal subjects' research
- Ensure proposed costs are consistent with the Scope of Work
- Reflect a sufficient understanding of the costs and level of effort needed to accomplish the proposed technical approach
- Include resource/cost sharing, if applicable. **It will be considered favorably**
- **State how the proposed costs are realistic for the technical and management approach** and accurately reflect the technical goals and objectives of the solicitation

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ARPA-H Cost Proposal Suggestions and Reminders

- **Don't change formulas given in spreadsheet and submit in Excel (not pdf) format**
  - If the formulas must be changed to match your business practices, please make sure the "total amount" tab accurately reflects the costs correctly

- **Don't delete a row, column, or worksheet in the spreadsheet** if it is not needed for your proposal. Just ignore or hide it.
  - Deleting will break the formulas and increase processing time.

- **Don't cost strategize!** ARPA-H recognizes that undue emphasis on cost may motivate proposers to offer low-risk ideas with minimum uncertainty and to staff the effort with junior personnel to be in a more competitive posture. ARPA-H discourages such cost strategies.

Break

Please return at 10:45 am

ARPA H

FAQs & ARPA-H Panel

Christopher Smith, PhD *[CTR]*
OCULAB Tech SETA

ARPA-H

FAQ: Teaming

Can one group be part of multiple proposals? Can one person be part of multiple proposals?

Yes, you may submit (and be awarded as) the prime on ONE (1) proposal and a sub-proposer on TWO (2) other proposals. You may not participate in research and development activities for more than three (3) proposals. You can provide an agent/device at cost for more than two (2) teams, as long as there are no development efforts for any teams past two (2).

Do we have to have a partner from industry/academia/something else?

No. Teams can have participants from any mix of institutions.

Is there a limit to how many institutions can team?

No, but be sure to include detailed budget information for each institution as per the ISO and include in your proposal a program management structure that explains how the teams will be coordinated.

FAQ: Teaming, cont'd

Can we have multiple Principal Investigators (PIs)?

No, there will be ONE (1) PI, the rest will be Co-Investigators.

Can we change teams partway through the program?

Teaming changes may be allowed with ARPA-H's approval in response to specific needs arising from the program's progress. Requests will be dealt with on a case-by-case basis.

Will you establish teams for us? I'm looking for a partner to complement our capabilities.

We are glad that you are looking to assemble a diverse and capable team! We cannot make introductions for you, but we encourage you to talk to people at Proposers' Day and to use our teaming website, where you can submit your profile and find the contact information for potential teammates.

Are you or your organization interested in forming a team to propose to the OCULAB Program?

Submit your information via the form in the QR Code below.

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FAQ: Metrics

The requirements/timeline seem aggressive. Do you really intend for us to hit these metrics?

We want you to work hard to meet them. We aim to set our goals high, with the understanding that advancements in science cannot be made without failures along the way.

What if I do not meet the metrics at one point in my project? Will you stop my project?

We have three Phases, and not all offerors are guaranteed to continue to subsequent phases. However, the metrics are not necessarily rigid Go/No-Go criteria, and instead are used to help make decisions about whether sufficient progress has been made. In other words, the answer to these questions will depend on the state of the technical program and how much progress has been made.

FAQ: Metrics, cont'd

We have an advanced prototype; can we go faster than the milestones you have scheduled?

Yes, absolutely, provided you are meeting/exceeding all technical metrics and guidelines!

Do you have any preferred technological approaches for OCULAB?

We will entertain all approaches that are proposed, as long as they fit within the TA guidelines and can be used to satisfy the metrics proposed in the ISO.

What if I want to use metrics that are not mentioned in the ISO?

We are open to other approaches that would define success in each TA as long as they are a logical fit to satisfy the TA.

FAQ: Meetings and Technical

Can you meet with us to discuss our idea?

We are unable to discuss concepts that a potential applicant is considering submitting to the ISO.

Can you tell us if you like our technical approach?

We will evaluate and provide feedback on technical concepts once they have been officially submitted as solution summaries/proposals.

What if I have an idea that is outside the scope of OCULAB?

If your proposal is not a good fit for the OCULAB program, the Mission Office Innovative Solutions Openings (ISOs) pursue innovative high-impact biomedical and health research proposals.

ARPA-H

FAQ: International Proposers

Are foreign entities eligible for award?

ARPA-H will prioritize awards in accordance with Public Law No. 117-328 (Section 499A(n) of the PHSA). Without limiting the foregoing ARPA-H will prioritize awards to domestic entities (organization and/or individuals) that will conduct funded work in the US. However, **non-US entities may participate** to the extent such participants comply with nondisclosure agreements, security regulations, export control laws, and other governing statutes and regulations applicable under the circumstances. **Non-US entities are encouraged to collaborate with domestic US entities**. In no case will awards be made to entities organized under the laws of a covered foreign country (as defined in section 119C of the National Security Act of 1947 (50 U.S.C. § 3059)) or entities suspended or debarred from business with the Government.

Foreign entities are subject to a clearance review prior to beginning work on an award, whether as a prime or sub. Where the foreign entity is a sub, awards may still be made with the foreign support restricted until the clearance process is completed.

FAQ: Government Proposers

Are federal entities and federally sponsored entities eligible for award?

In certain circumstances, FFRDCs and Government Entities may have unique capabilities that are not available to proposing teams through any other resource. Accordingly, the following principles will apply to this solicitation:

- FFRDCs and Government entities, including federal Government employees, are **not permitted to respond to this solicitation as a prime or sub-performer** on a proposed performer team.
- If an FFRDC or Government entity has a **unique research idea that is within the scope** of this solicitation; OR, if an FFRDC or Government entity, including a federal Government employee, is interested in **working directly with the OCULAB team**, contact OCULAB@arpa-h.gov.
- If a potential prime performer believes an FFRDC has a **unique capability** without which their solution is unachievable, they may provide documentation as part of their Solution Summary submission demonstrating they have exhausted all other options.

FAQ: Solution Summaries Timelines and Feedback

Will feedback be provided for all solution summaries? When?

Feedback will be provided on all responsive solution summaries; we will provide brief comments on overall scientific and technical merit.

We will also provide one of two decisions:

1. ARPA-H **encourages** the proposer to submit a full proposal
2. ARPA-H **discourages** the proposer from submitting a full proposal

Solution Summaries are due January 27, 2025 5:00 PM ET; we aim to provide feedback and notice of selection a few weeks after that date.

FAQ: Full Proposal Submission Timelines and Feedback

May I submit a full proposal even if it is not recommended? You may submit a full proposal if ARPA-H does not request one.

May I submit a full proposal if I do not submit a solution summary?

No, ARPA-H will only evaluate a full proposal for the proposers who submit a solution summary.

Will feedback be provided for all full proposals? When?

Feedback will be provided for all full proposals; see the ISO for the selection criteria.

Full proposals are due April 14, 2025, 5:00 PM ET. We aim to make selections by July; however, we expect many high-quality proposals and will take the time necessary to ensure we consider them thoroughly.

FAQ: Budget

How big can our program be? What is the overall budget for OCULAB?

- Proposers are encouraged to propose a realistic, justifiable, comprehensive, and reasonable budget that aligns with the proposed solution. The proposed budget should align with the technical scope. **No budget ceiling has been established.**
- We are not able to provide budgetary details for OCULAB or a target number for your budget.
- ARPA-H discourages strategies such as using only junior staff or proposing only low-risk ideas to cut costs.

Can you explain the rules around the salary cap in our cost proposal?

Since 1990, Congress has legislatively mandated a limitation on direct salary for individuals under NIH grant and cooperative agreement awards. The Consolidated Appropriations Act, 2023 (Public Law 117-328) restricts the amount of direct salary to Executive Level II of the Federal Executive pay scale. Effective January 1, 2023, the salary limitation is $221,900.

This means that the maximum for any one person in one year, for any labor category, and any level of effort, the maximum is $221,900.

FAQ: Intellectual Property

Who will own the IP?

Generally, the government **does not** take ownership of intellectual property produced under awards.

- Under **Cooperative Agreements**, performers retain ownership of IP created under an award, but the government receives a license to use the IP for federal purposes.
- For **Other Transaction Agreements**, there is more flexibility, and IP will be subject to negotiations between the proposer and ARPA-H.

At a minimum, ARPA-H wants to ensure that IP restrictions do not keep breakthrough technologies from the people who can benefit from those technologies.

These materials will be available online

We will make this slideshow and a video of this talk available at the OCULAB program website (QR code below):

Read the Innovative Solutions Opening (ISO)

The answers to many questions are in the ISO. The ISO is at SAM.gov.

We also link to it on our website, OCULAB | ARPA-H.

Still have questions? Check the FAQ!

The OCULAB FAQ will be updated periodically on our website and on SAM.gov.

Still have questions that are not answered in the ISO or FAQ?

Email us at OCULAB@arpa-h.gov. We will try to get back to you with an answer as soon as possible. Relevant and generally applicable questions will be published to the FAQs on the website.

ARPA-H

Dry Eye Disease Clinical Perspective

Cal W. Roberts, MD
Nora Lee Cothran, OD
(The Eye Institute of West Florida)

ARPA H

Thank you for joining us today! This concludes the presentation portion of OCULAB Proposers' Day.

Please join us for the poster sessions after lunch, beginning at 1:30 pm. Poster setup will take place starting at 1:15 pm.

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Lunch Break

Please return by 1:30 pm

ARPA H


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