Making Joints Heal Themselves

Novel Innovations for Tissue Regeneration in Osteoarthritis (NITRO)
Advanced Research Projects Agency for Health (ARPA-H)

Dr. Ross Uhrich, Program Manager
Health Science Futures (HSF), Mission Office (MO)
June 15, 2023

ARPA-H

The ARPA-H Model

Transforming Health for All

Amy Jenkins, PhD
Director, Health Science Futures Office

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President Biden's Vision

"ARPA-H will **pursue ideas that break the mold on how we normally support fundamental research and commercial products** in this country."

"Ideas so audacious that people say they just might work only if, only if, we could try. Well, we're about to try in a big way."

– President Biden Remarks, March 18, 2022

Mission

Accelerate better health outcomes for everyone.

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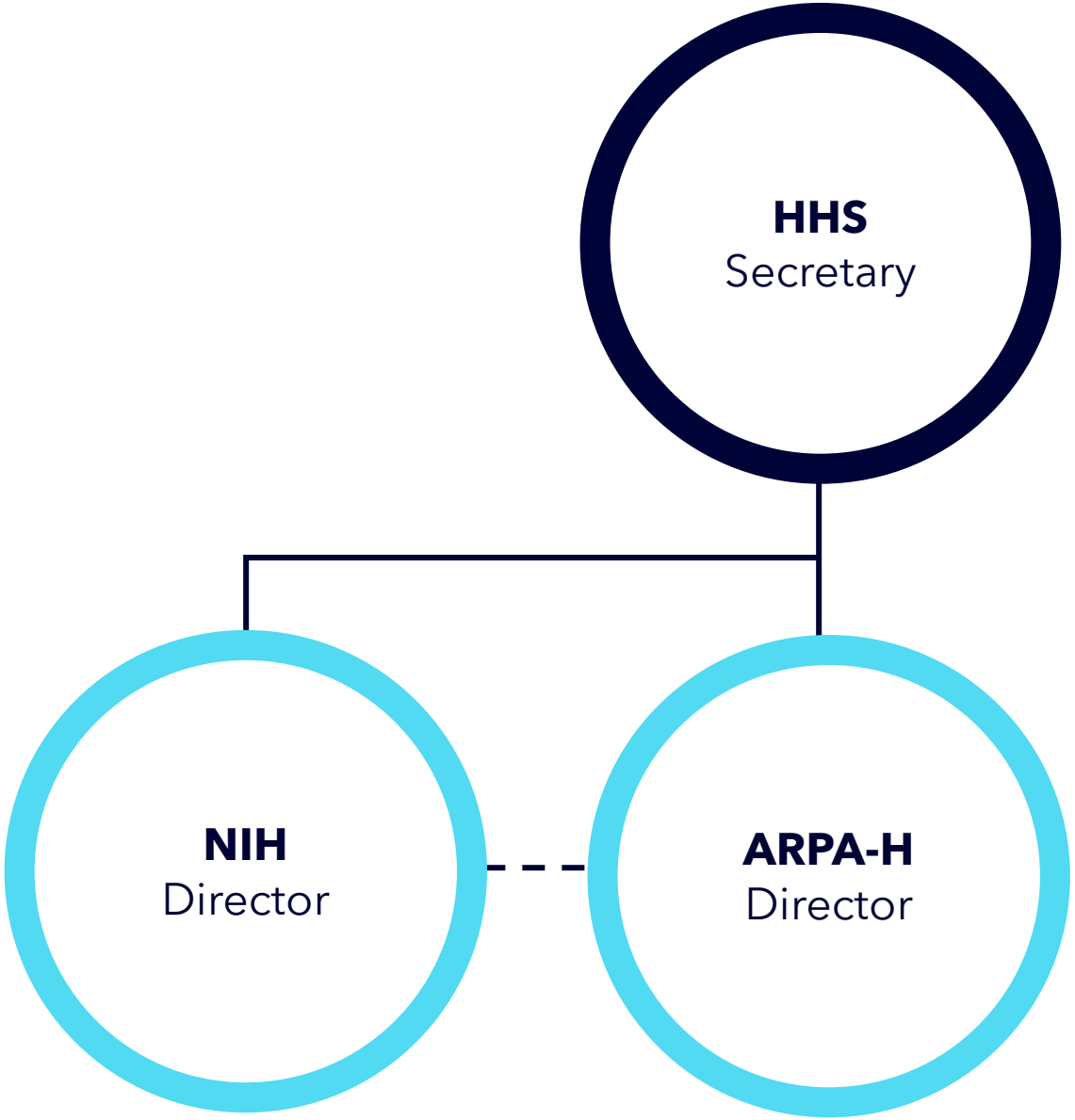
ARPA-H Organization within HHS

- Independent component of HHS within NIH; not an Institute
- ARPA-H Director reports directly to HHS Secretary
- No internal research labs; disease agnostic
- $2.5B initial appropriation; budget independent from NIH
- Generally funds contracts, not grants
- Ability to directly reimburse FDA



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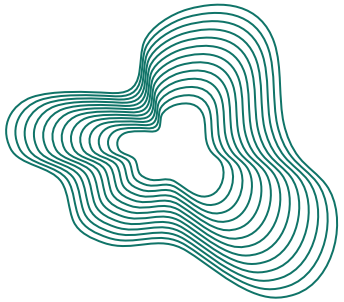
Initial Mission Focus Areas



Health Science Futures

Expanding what's technically possible

Accelerate advances across research areas and remove limitations that stymie progress towards solutions. These tools and platforms apply to a broad range of diseases.

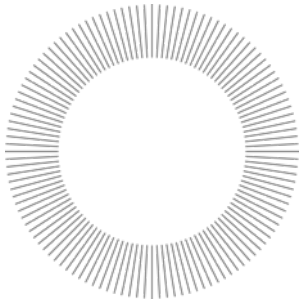
Advancements in cell-free systems that enable rapid prototyping, modularity, and easier manipulation

Scalable Solutions

Reaching everyone quickly

Address health challenges that include geography, distribution, manufacturing, data and information, and economies of scale to create programs that result in impactful, timely, and equitable solutions.

Digital cellular twin capabilities that are accurate surrogates for wet lab testing and can drive training data for AI/ML tools.

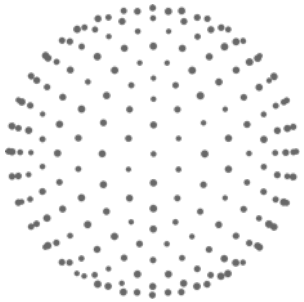


Proactive Health

Keeping people from being patients

Preventative programs will create new capabilities to detect and characterize disease risk and promote treatments and behaviors to anticipate threats to Americans' health, whether those are viral, bacterial, chemical, physical, or psychological.

New detection modalities that are more precise, sensitive, and have broader capabilities than existing methods



Resilient Systems

Building integrated healthcare systems

Create capabilities, business models, and integrations to weather crises such as pandemics, social disruption, climate change, and economic instability. Systems are sustained between crises—from the molecular to the societal—to achieve better health outcomes.

Novel techniques to **improve the efficiency and cost of manufacturing gene and cell therapeutics** from small batch to scale-up

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Focus Areas

Unlock new ways to collaborate and attack problems

Health Science Futures

Expand What's Technically Possible

Develop approaches that bring radically new insights and paradigms. These **innovative tools, technologies, and platforms** can apply to a broad range of diseases that affect large populations, rare diseases, or diseases with limited treatment options.

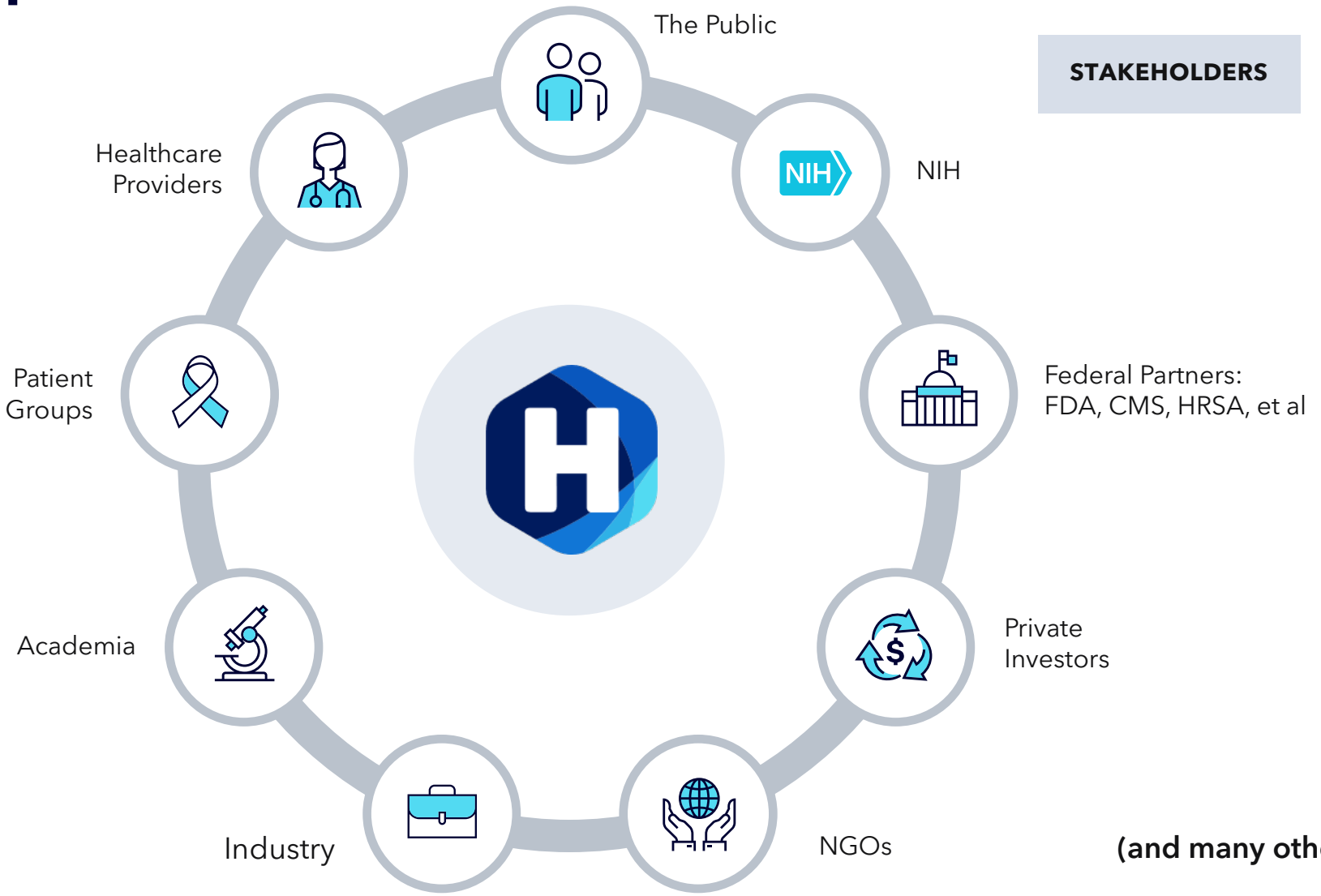
Examples include:

- Novel molecular platform approaches
  - Modulation of host systems
  - Delivery to targets with special and temporal precision
  - Mitigation of off-target effects to accelerate interventions
- Approaches to accelerate mammalian and microbial cellular engineering to enable next generation therapeutic applications.
- Interventions that target and reverse disease pathogenesis or enhance plasticity to address degenerative diseases.
- Advances in genetic, cellular, tissue, and organ replacement therapies.

ARPA-H Health Ecosystem

CUSTOMERS

PERFORMERS



STAKEHOLDERS

(and many others …)

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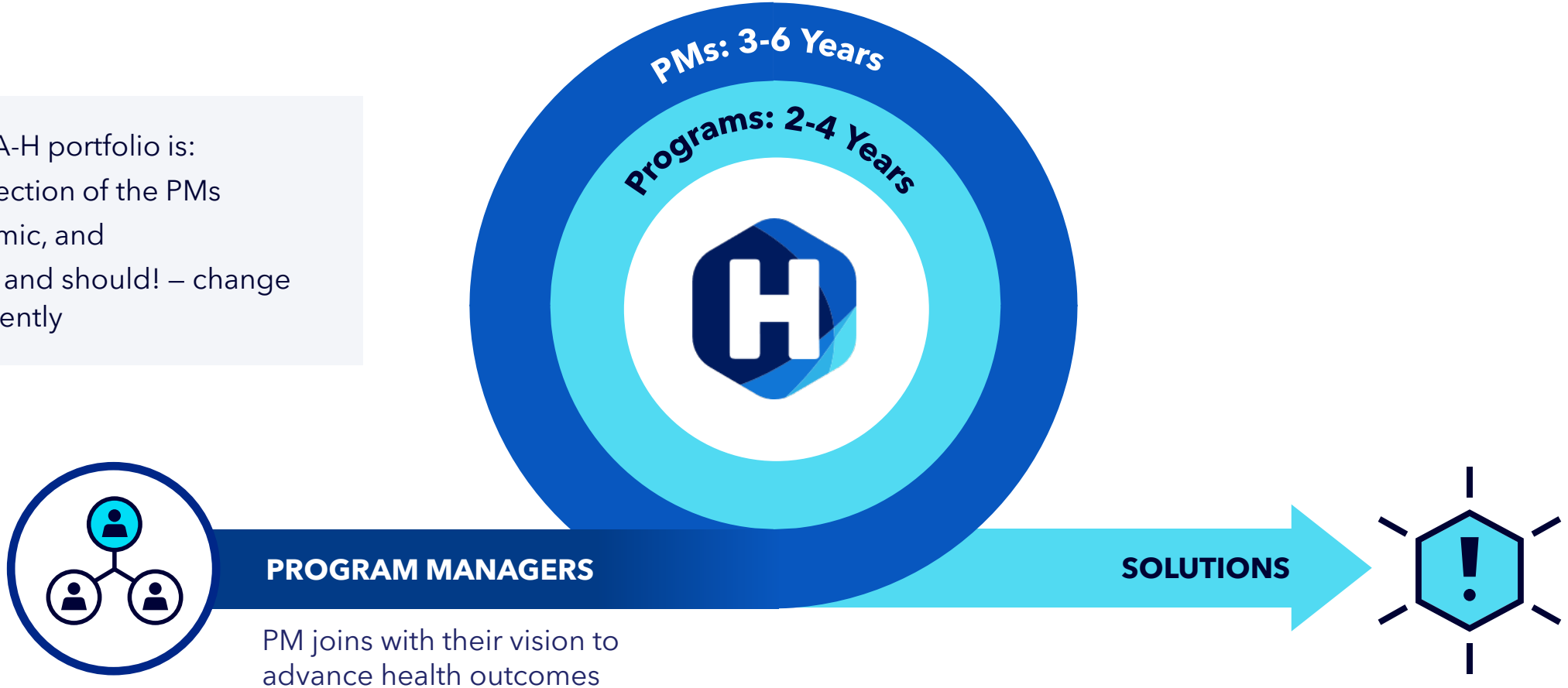
The Program and Program Manager Flywheel

The ARPA-H portfolio is:

(1) a reflection of the PMs

(2) dynamic, and

(3) will – and should! – change frequently



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ARPA-H Model: Program Formation

Program Manager

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

Challenge

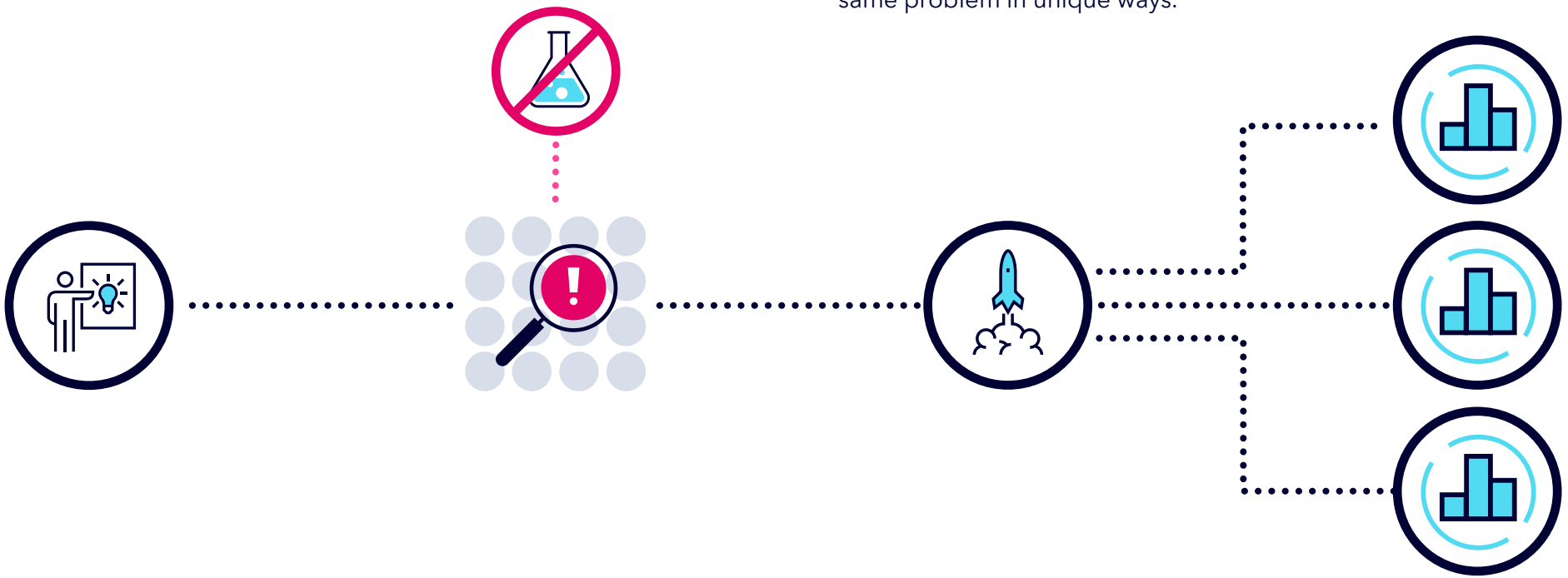
The challenge should NOT be easily solvable through traditional activities.

Program Launch

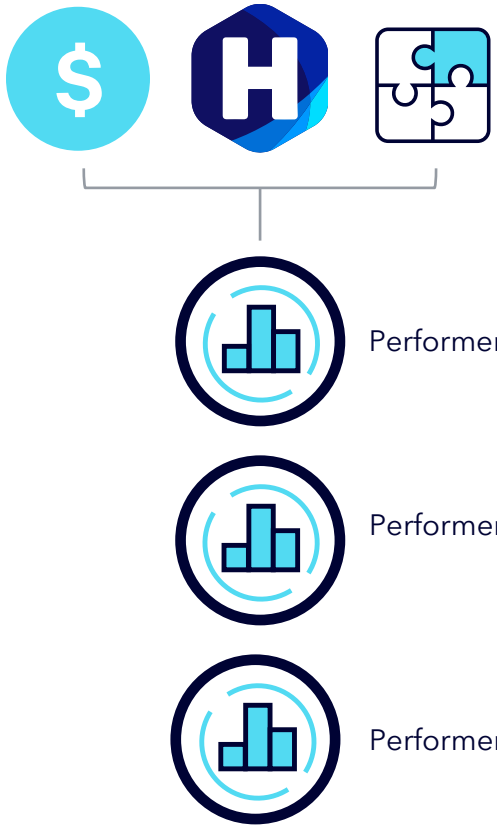
A Program Manager seeks – and oversees – several groups of performers aiming to solve the same problem in unique ways.

Performers

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

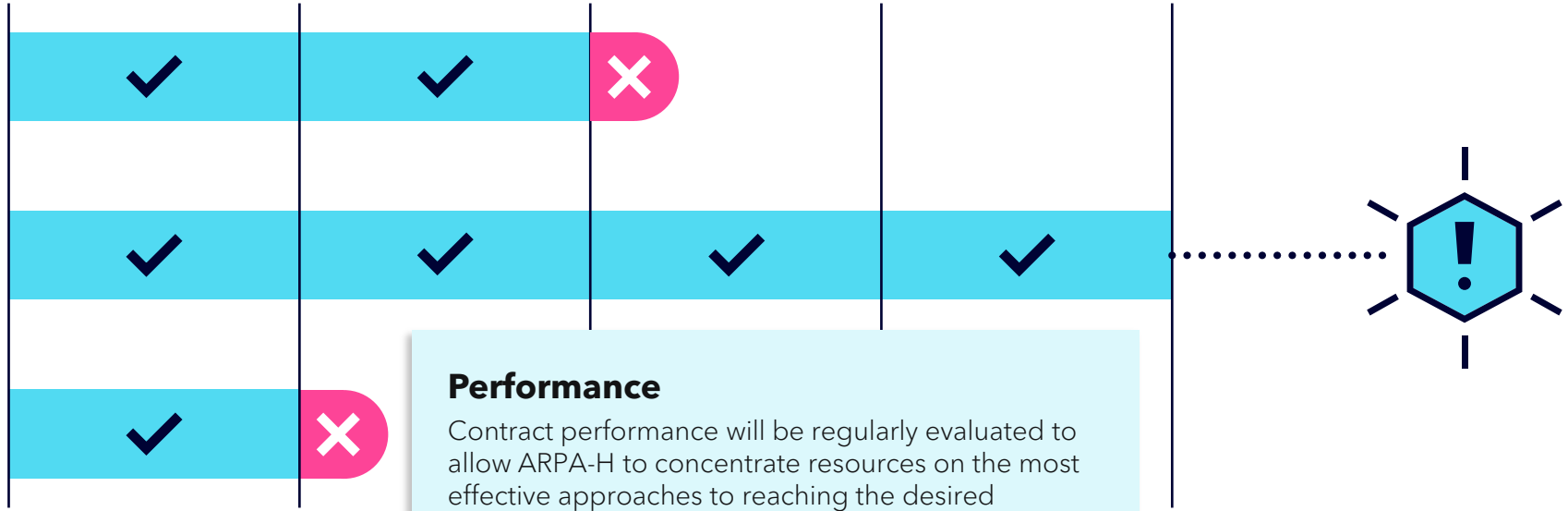


ARPA-H Model: Support and Evaluation



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.



Performance

Contract performance will be regularly evaluated to allow ARPA-H to concentrate resources on the most effective approaches to reaching the desired goals. Valuable lessons are learned and shared from each project.

First Program Launch!

Novel Innovations for Tissue Regeneration in Osteoarthritis (NITRO)

Vision: To eradicate OA through targeted, regenerative therapeutics that will revolutionize the care algorithm, prevent pain, decrease the economic burden, and eliminate the need for repeat joint surgery.

Technology focus areas

- Needle-based and/or non-invasive bone regeneration
- Needle-based and/or non-invasive cartilage regeneration
- Replacement joints built from human cells

How to apply

- Submit abstract and, if invited, full proposal
- **Visit arpa-h.gov** for more information about NITRO and applying to the BAA or email: **NITRO@arpa-h.gov**

Important Dates

- Today! Proposers' Day for interested research teams
- **Program BAA will close on July 28, 2023, at 11:59pm ET**

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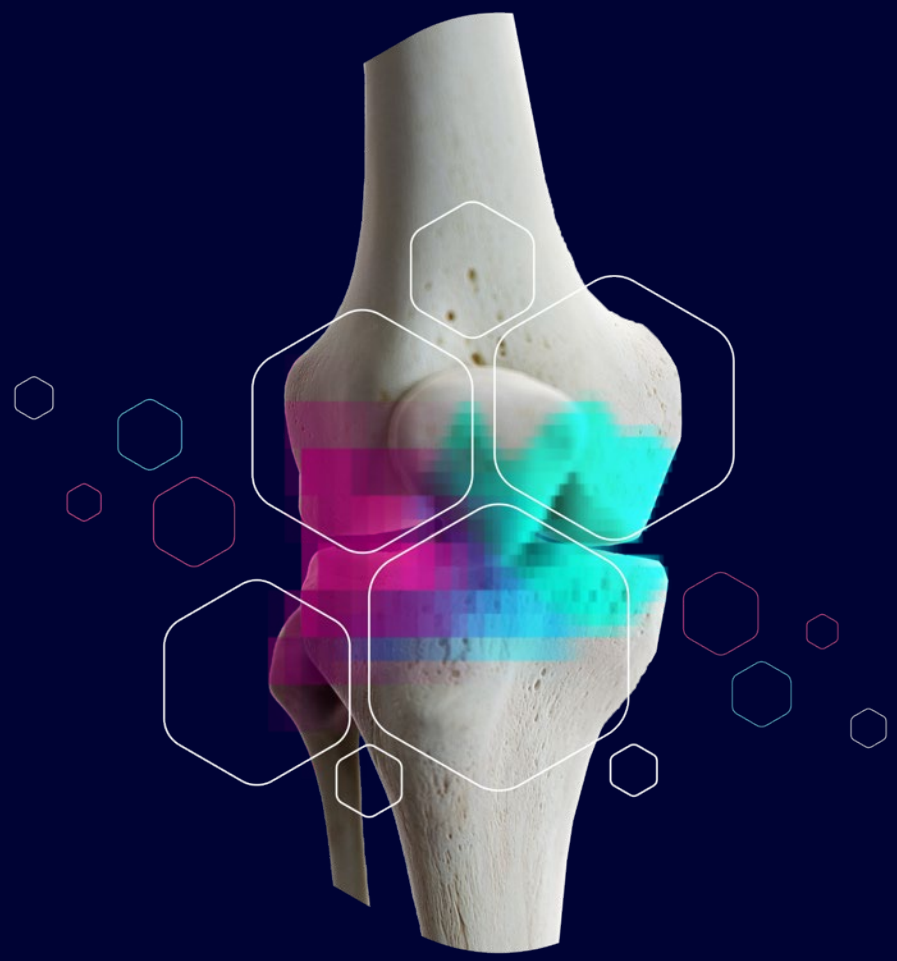

What if we could make our joints heal themselves?

Accelerated Transition

Path to Success

Craig Gravitz, JD
Director, Project Accelerator Transition
Innovation Office (PATIO)

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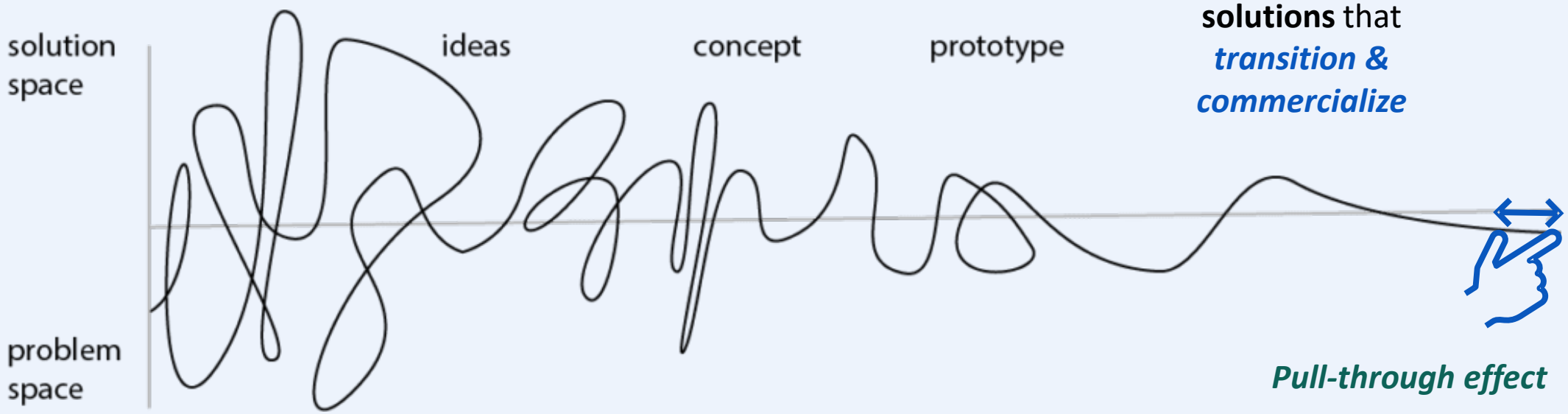
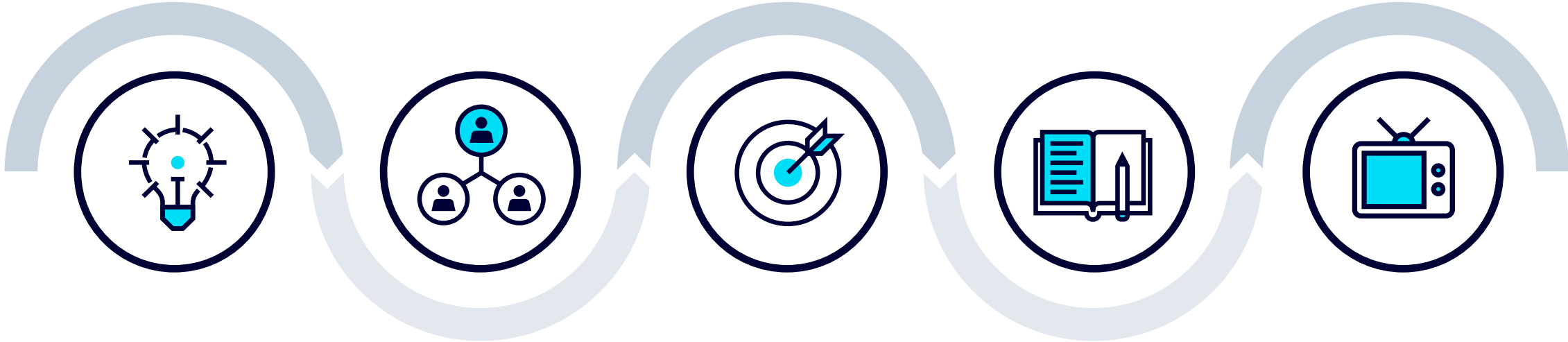
The Path to Success for Health Solutions is Complex



Project Accelerator Transition Innovation Office (PATIO)

Increase the probability - at each step - that solutions can drive positive health outcomes & “survive in the wild"

SERVICES DURING PROGRAM LIFECYCLE



Program Design

- Identify opportunities and gaps
- Market/IP assessment
- Regulatory assessment

BAA Development

- Who are possible performers? Innovation Hubs?
- Develop technical areas
- Validate transition potential

Early Program Performance

- De-risk for investors
- Design MVPs to drive adoption
- Demystify regulatory process

Mature Projects

- Safeguard IP
- Help company formation
- Business strategy, legal and marketing services

Transition and Commercialize

- SBIR/STTR
- Transition partner/third-party investment
- Ongoing mentorship
- Access to key customers and investors

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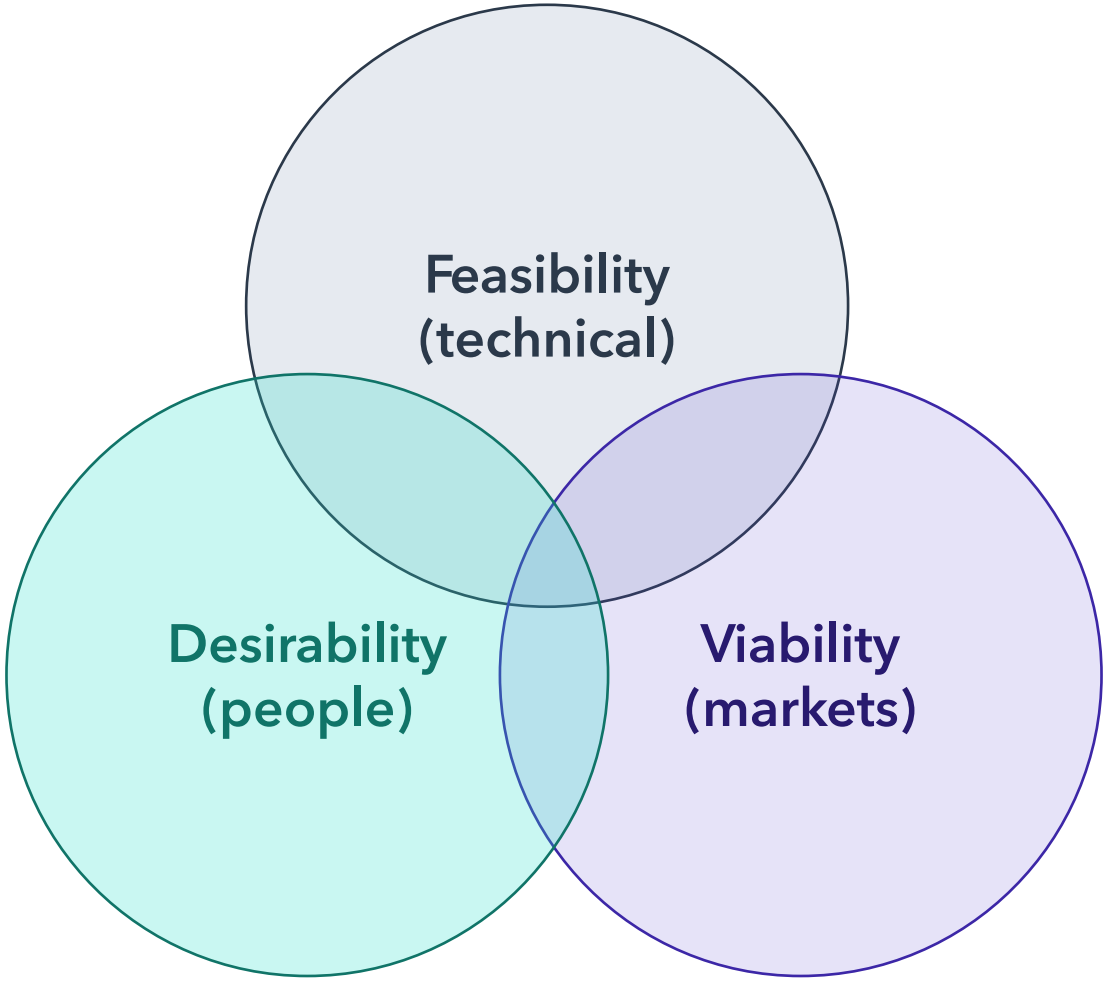
Core Approach: Design Framework

Three Vectors



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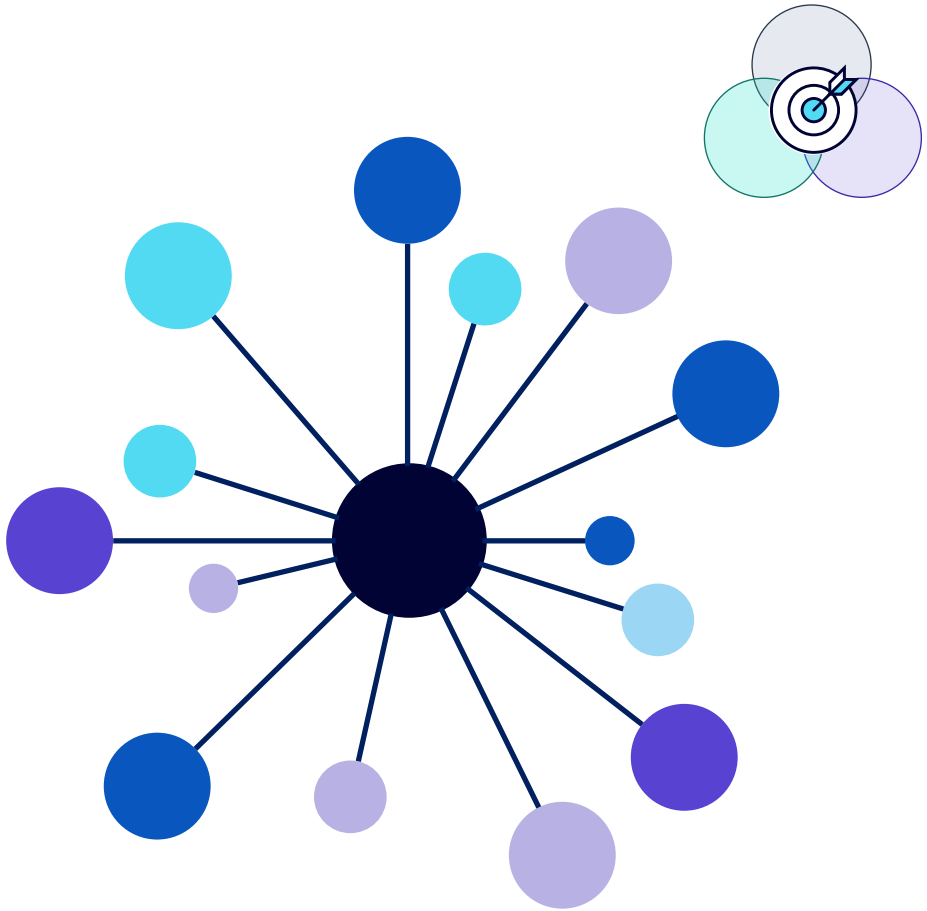
ARPANET-H

DVF in Practice

The **2023 Consolidated Appropriations Act** directs the agency to establish sites in **at least three geographic areas**.

The hub and spoke model will form a **network of people, institutions, and capabilities** across the country.

- **Hub**: To ensure the active transition of health innovation in an expedient, cost-effective, accessible and sustainable manner that reaches all Americans.
- **Spoke:** To ensure that Americans in every community benefit from ARPA-H solutions. Spokes are connected to appropriate hubs on an ongoing basis.



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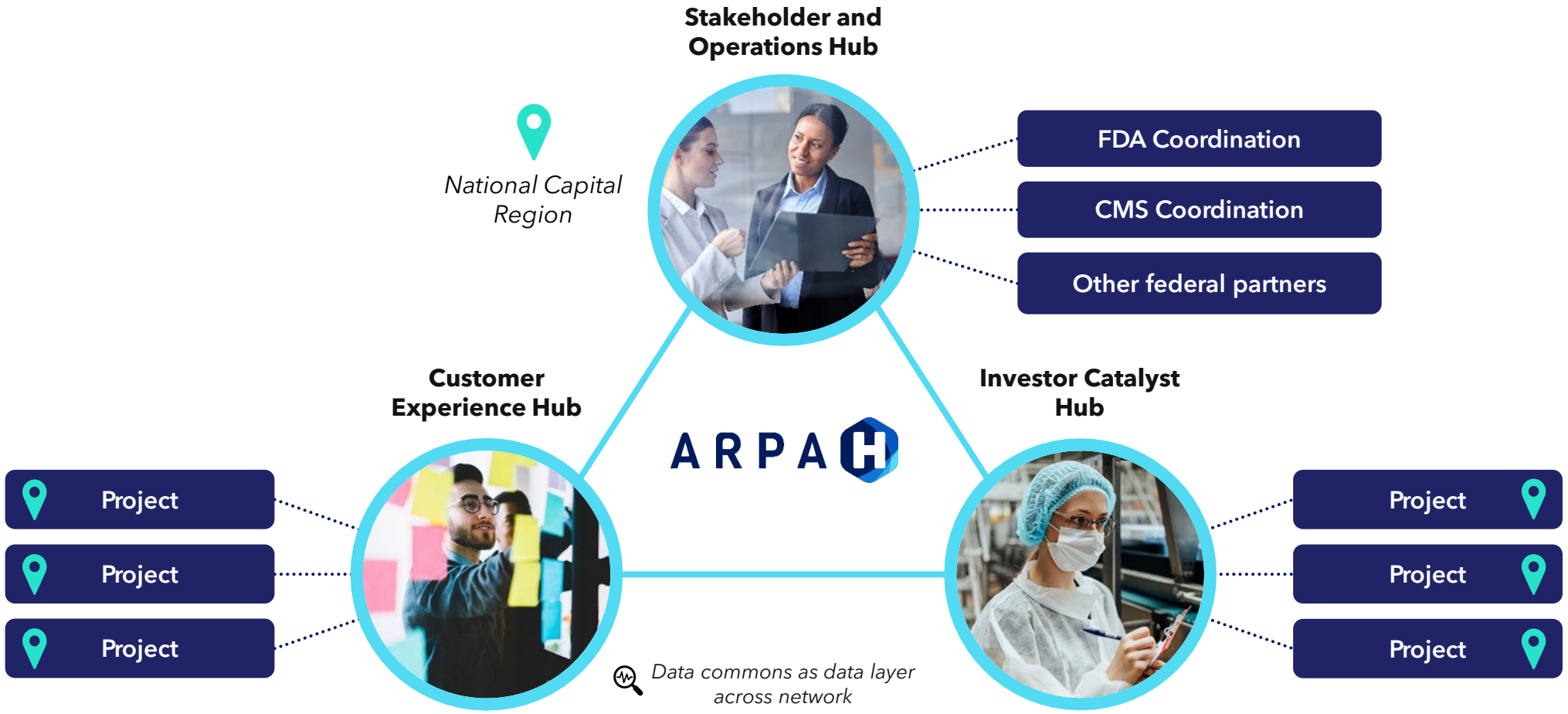
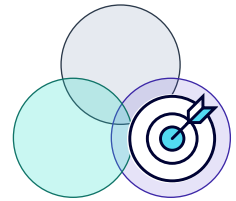
Hub and Spokes to enable a Nationwide Network

ARPA-H projects will run through the hubs with members in various locations across the country



Experts in Residence Program: **Private sector expertise**

Increase viability through expert advisors & support

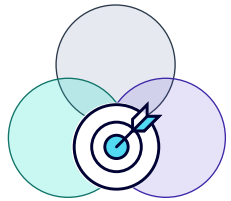


Allows ARPA-H to provide **highly specific and customized services** to support ARPA-H, PMs, and their programs for transition and commercialization.

- Horizon scanning to forecast emerging trends
- Analyses that address market dynamics, consumers, pricing, IP, regulatory, barriers to entry, and more
- Commercial-focused XIRs for ongoing development and support

Health Ecosystem Engagement

Access the resources & expertise of the health ecosystem through a network on demand



Allows ARPA-H to provide **leverage the institutional knowledge, and innovations** in the broader health ecosystem.

- Impactful events with the health ecosystem to develop new partnership opportunities
- Two-way street for program managers to gather customer insights, and for stakeholders to learn about new developments at the agency
- Institutional knowledge and connections over time for future program managers

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ARPA-H NITRO

Novel Innovations for Tissue Regeneration in Osteoarthritis

Approved for Public Release: Distribution Unlimited

A Possible Challenge to Solve

Raising our quality of life and eradicating the disease

Osteoarthritis

#3
Cause of disability

Prevalent

	2023	2040
US	32.5M	78.8M
Global	**242M**	**1.9B**

Individuals with OA

Expensive

Total cost	**$136B**
Absenteeism	$10.3B
Per capita	$11k

Data in the US alone & annually

Debilitating

Sleep quality

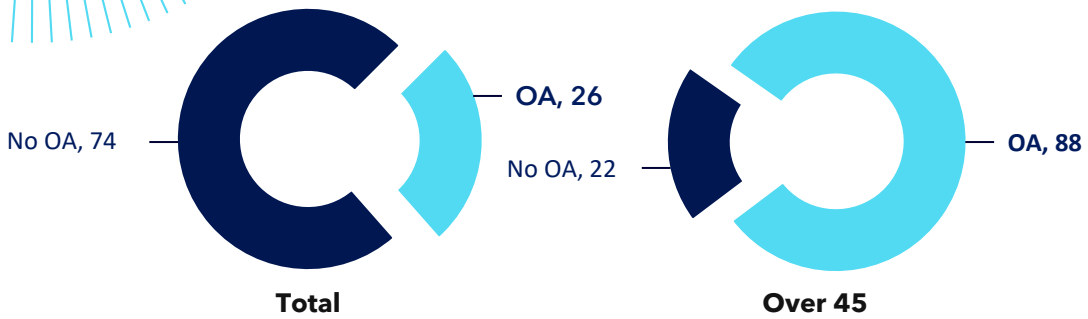
Decreased Mood

Everyday activity

Painful

High Pain

Percent of US Population



- OA **highest** for Multi-Racial Non-Hispanic and Native American / Native Alaskan populations
- OA **2x** more common in women
- By 2030, **half of the US** will be obese and 24% will be severely obese, increasing OA
- OA increases the risk of heart disease by **50%**
- USA knee OA population generates **$14.0 billion** in opioid-related costs

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Set Up for Success with Room for Improvement

MACI and Other Regenerative Therapy

LIMITATIONS

- Two Surgeries Required
- Provider-Dependent Outcomes
- 6-8 weeks Between Surgeries
- Arthrofibrosis and/or Ankylosis
- Graft Failure

MACI: Matrix-Induced Autologous Chondrocyte Implantation

Total Joint Replacement (TKAs and THAs)

LIMITATIONS

- Infection (26%)
- Hardware failure (~26%)
- Range of motion limitations
- Persistent pain
- Nerve damage
- Thrombosis

TKA: Total Knee Arthroplasty; THA: Total Hip Arthroplasty

Current OA Treatments Require **Open Joint Surgery** & Typically **Proceed to Full Replacement**

3,500,000

TKAs by 2040

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Vision for the Future

Novel Innovations for Regeneration in Osteoarthritis

ARPA-H's **first Health Science Futures program-specific BAA** seeks funding proposals for research aiming to:

Eradicate osteoarthritis (OA) through targeted, regenerative therapeutics that will **revolutionize** the care algorithm, prevent pain, decrease the economic burden, and eliminate the need for repeat joint surgery with equitable access for all Americans.

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ARPA-H NITRO

Novel Innovations for Tissue Regeneration in Osteoarthritis

"The ERA of ARPA-H is here."

– Secretary Becerra, HHS

The ARPA-H NITRO program will revolutionize the entire field of regenerative medicine.

Eradicating the Disease

- Reversing Damage
- Eliminating reliance on replacements
- If replacement needed, no revisions necessary

Deliberate, Efficient, and Effective Forward Progress

- OA Clinical Trial Stakeholders
- Community-wide OA Model Symposium
- Immediate FDA Involvement
- Accelerated Transition from PATIO
- Public Market buy-in
- Integrated Equity Metrics

Equitable Access

- Designated Equity Officer
- Established Key Performance Indicators
- Developed Road Map to Equity
- Enforced Insurance Action Plan
- Defined demographics Requirements
- Partnered with Affordable Care Act

Help All Americans

ARPA-H is powered and backed for program success.

HHS: Department of Health and Human Services
PATIO: Project Accelerator Transition Innovation Office

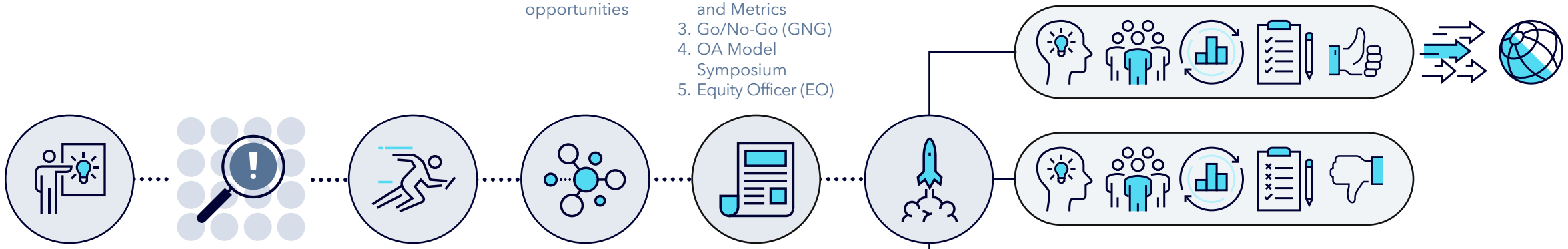
NITRO within the ARPA-H Model

Program Manager	ARPA-H Challenge	NITRO BAA Release	Proposers' Day	Applications Reviewed	Program Launch	Performers and NITRO Team	Transition to Practice
Identifies a difficult health-related challenge that is ripe for solving.	The challenge should NOT be easily solvable through traditional activities.	Official announcement to seek proposals to solve the NITRO challenge.	Program informational session and opportunity for establish proposal teams.	Abstracts welcome and full proposals (40-pages) are strongly recommended.	NITRO team selects and manages performers aiming to solve the problem.	Groups of performers compete to carry out their potential innovative solutions to the challenge.	Performers meet metrics and GNG milestones then transition with PATIO support.

- Abstract and proposal due dates released
- Informational talks
- Teaming opportunities

1. Technical Areas (TA)
2. Program Goals and Metrics
3. Go/No-Go (GNG)
4. OA Model Symposium
5. Equity Officer (EO)
6. Contracting
7. Cost Proposals

- Performers must meet Program Goals and Metrics and GNG Milestones



Topics covered today

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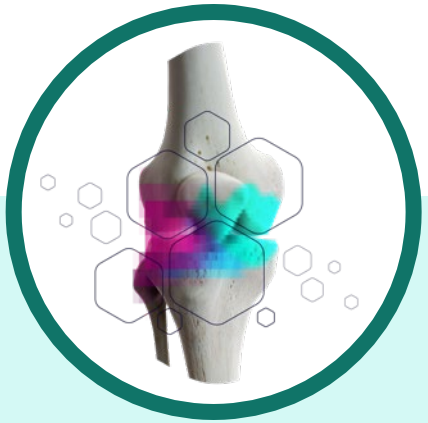
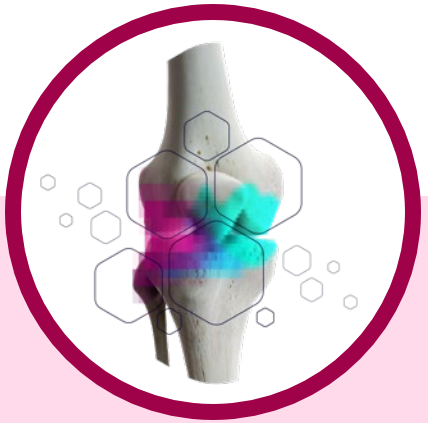
NITRO Technical Areas (TA)



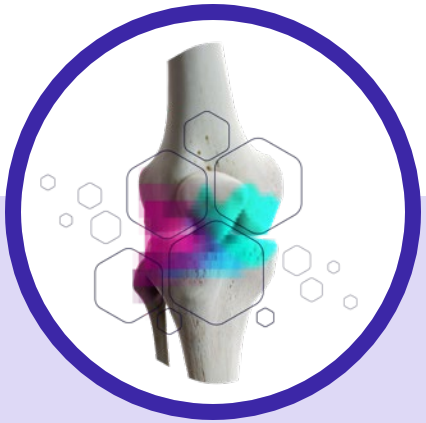
TA1: Needle-based and/or non-invasive subchondral (SC) bone regeneration

Development of an intra-articular (IA) therapeutic to fully regenerate SC bone in all synovial joint(s) in all cases of primary OA as well as trauma- and obesity-induced secondary OA.



TA2: Needle-based and/or non-invasive cartilage regeneration

Development of therapeutics (both IA and systemic) to fully regenerate cartilage in all synovial joints in all cases of primary OA as well as trauma- and obesity-induced secondary OA.



TA3: Allogeneic and autogenous non-immunogenic, load-bearing and osteochondroinductive total replacement joints

Development of autogenous and allogeneic, non-immunogenic, osteo- and chondro-inductive, load-bearing total knee replacements that requires no permanent foreign body implantation and performs at or above the current standard set for artificial total knee implants.

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Board of Potential NITRO Approaches

TA1

*Performers may propose a variety of approaches to **regenerate SC bone** (separate or combined) that may include but are **not limited to**:*

- ❑ Implantable scaffolds
- ❑ Genetic engineering
- ❑ Cell therapy
- ❑ Nanoparticles
- ❑ Small molecules
- ❑ Injectable biomaterials or biologics

TA2

*Performers may propose a variety of approaches to **regenerate cartilage** (separate or combined) that may include but are **not limited to**:*

- ❑ Chondrospheres
- ❑ Therapeutic proteins
- ❑ Implantable scaffolds
- ❑ Genetic engineering
- ❑ Cell therapy
- ❑ Nanoparticles
- ❑ Small molecules
- ❑ Injectable biomaterials or biologics

TA3

*Performers must **generate allografts and autografts** using a variety of approaches (separate or combined) that may include but are **not limited to**:*

- ❑ Computerized numerical control (CNC) multiscale milling
- ❑ Bioreactors (*in vivo* and/or *in vitro*)
- ❑ Genetic engineering
- ❑ Off-the-shelf products
- ❑ 3D and/or bio-printed constructs
- ❑ Anatomical materials
- ❑ Multi-functional designs
- ❑ Cell therapy

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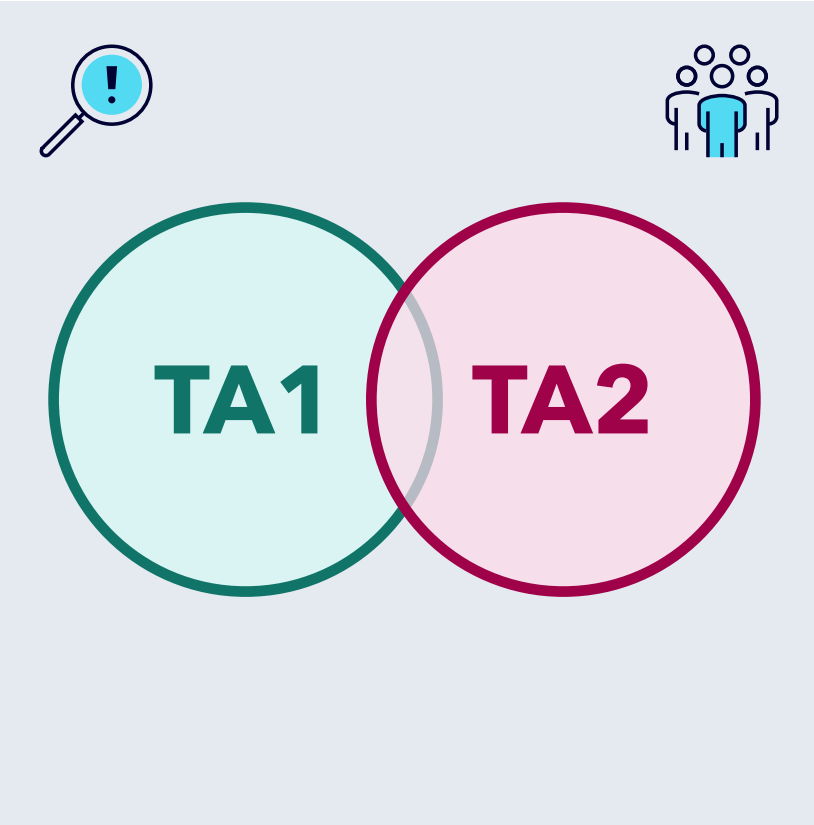
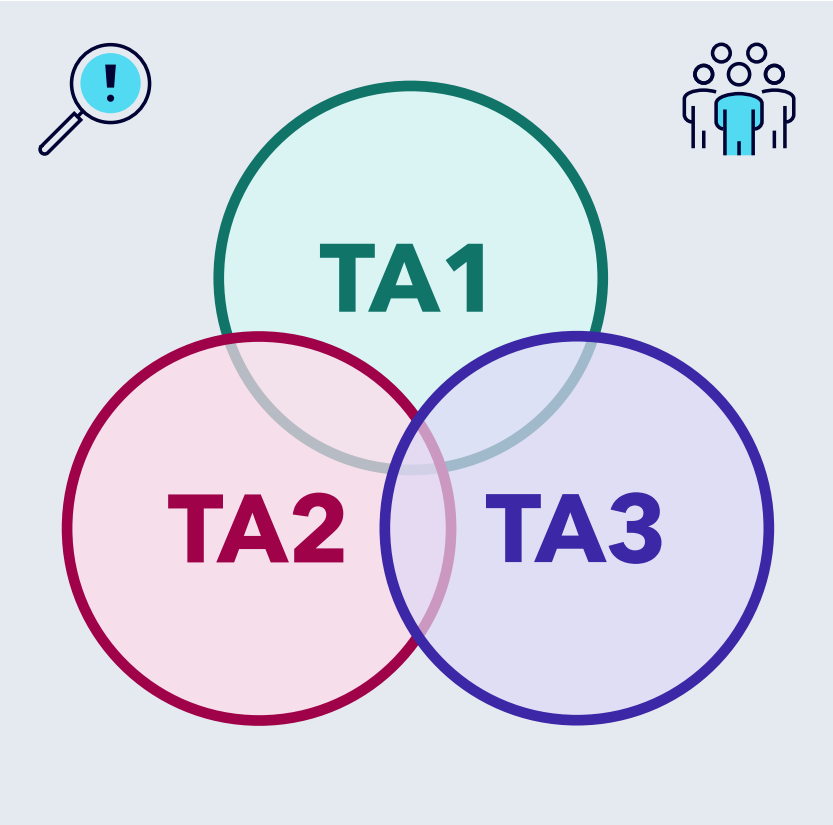
Teams Must Address Specific TAs

- **Teams** can include academia, small business, large business, contract research organizations, manufacturers, and more!
- Teaming is considered **necessary** to accomplish the program goals and metrics.





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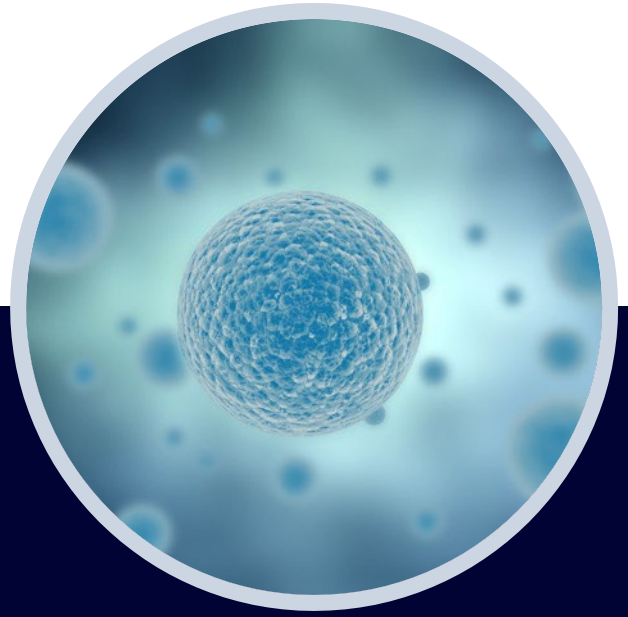
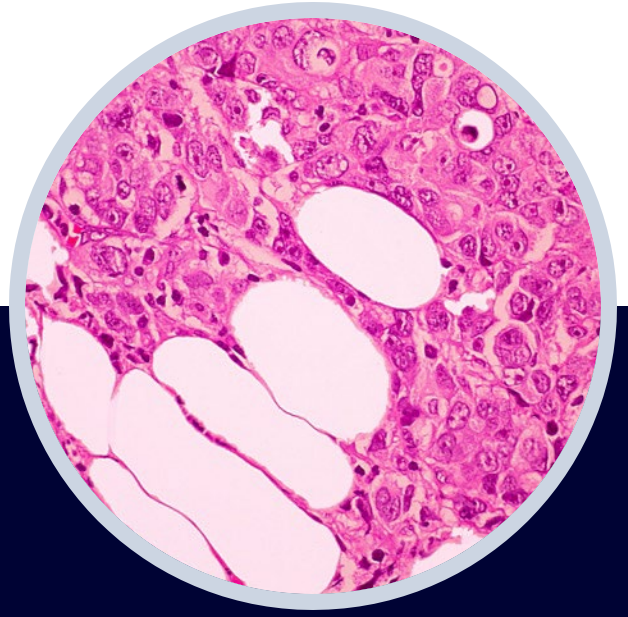
Advanced Research to Transition Timeline



Therapeutic Discovery

24 months



Pre-Clinical

18 months

Phase 1 Clinical Trial

18 months

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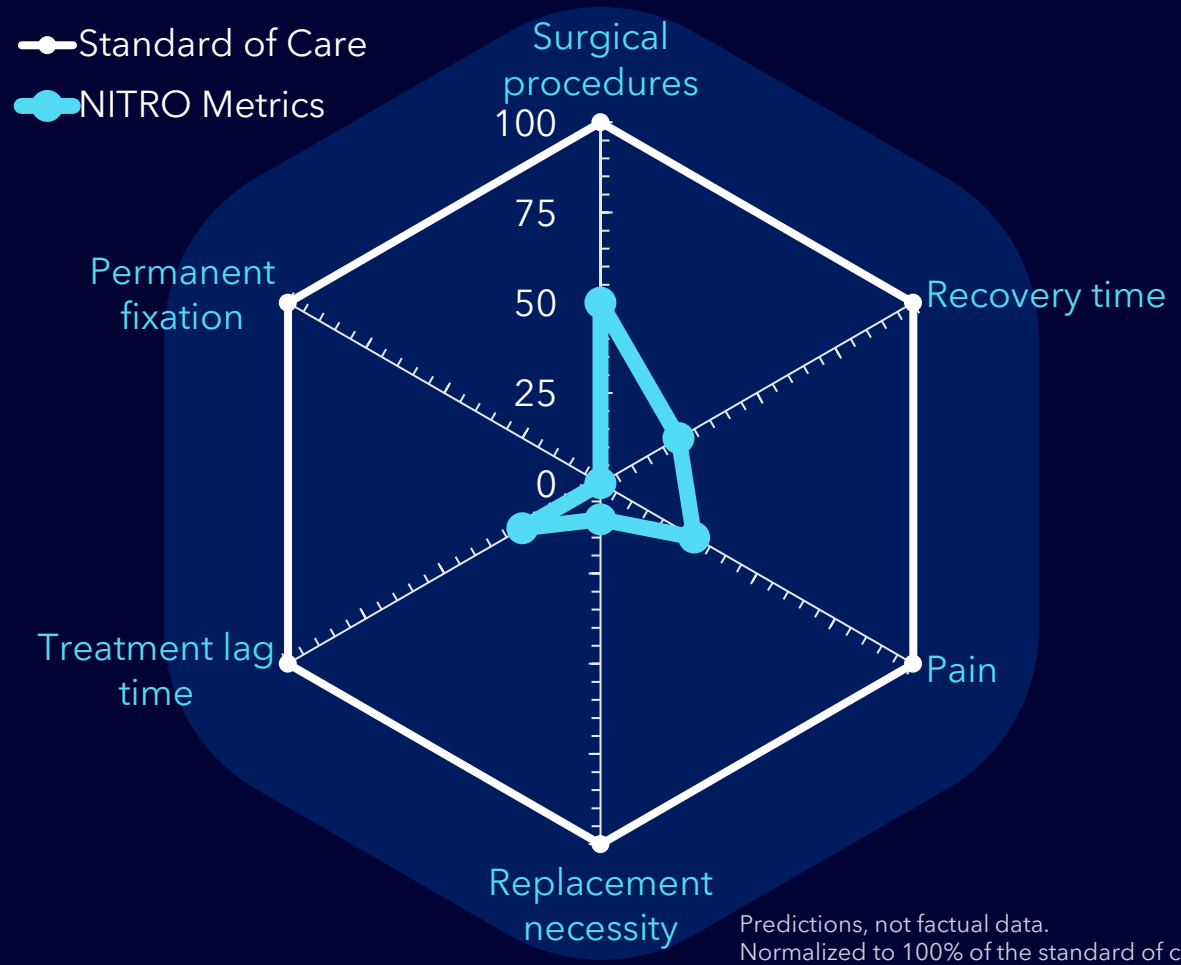
Revolutionized Standard of Care



Predictions, not factual data.
Normalized to 100% of the standard of care.

Metrics Designed to Supersede the Standard of Care and Advance Transformative Therapeutics

- **Variety of approaches for disease heterogeneity:** Intraarticular (IA) or intravenous (IV) single-joint and/or multi-joint approaches
- **Standardized delivery with minimal repeat procedures:** Needle-based and/or non-invasive with no recipient harvest (single procedure) and minimal dosing
- **Effective across the entire disease spectrum:** End-grade OA to Grade 0 with reduced pain for defects at and beyond critical size
- **Advancing bio-mimics to the clinic and departing from a titanium past:** Patient-specific and osteochondroinductive with no permanent fixation or immunogenicity
- **Meeting diverse patient needs at their doorstep:** Allograft in <24hours and autograft in <30 days for rapid load-bearing, graft manufacturing
- **Accelerated recovery time & long-term stability:** Functional recovery windows better than standard of care
- **From the gate, ready for successful commercialization:** Mandatory investigational new drug (IND) application and good laboratory/manufacturing/clinical practice (GLP/GMP/GCP)

Critical size defects: those that would not spontaneously heal completely

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TA1 Metrics

Abstract and Proposal Options:
A) TA1 and TA2 –or-
B) TA3 –or-
C) TA1, TA2, and TA3

Pre-Program				Phase 1 (24 Months)								Phase 2 (36 Months)											
FY23				FY24				FY25				FY26				FY27				FY28			
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Timeline				Therapeutic Discovery & In Vitro (24mo)								Pre-Clinical (18mo)								Phase I Clinical Trials (18mo)			
TA1 Metrics (SC Bone)				**SJ & MJ** Produce ≥1 therapeutic for IA bone regeneration • No Surgical Donor/Recipient Harvest • Regenerate Defects At AND Beyond "Critical Size Defects" • Regenerate End-Grade OA to Grade 0 in ALL Synovial Joints • Needle-Based (including arthroscopic) and/or Non-Invasive Approach • Ideally ≤1 dose per year (in tandem with TA2)								Meets/Exceeds All Prior Criteria **<u>Using Appropriate OA Large Animal Model</u>**: • Sustains physiologically-relevant* load (per ICS 11.040) • Full function ≤3mo post-op with ≥85% success • Pain < 3/10								Meets/Exceeds All Prior Criteria in Human Clinical Phase I Trials			

*Physiologically relevant load = ISO 14243 knee

TA2 Metrics

Abstract and Proposal Options:
A) TA1 and TA2 –or-
B) TA3 –or-
C) TA1, TA2, and TA3

Pre-Program				Phase 1 (24 Months)								Phase 2 (36 Months)											
FY23				FY24				FY25				FY26				FY27				FY28			
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Timeline				Therapeutic Discovery & In Vitro (24mo)								Pre-Clinical (18mo)								Phase I Clinical Trials (18mo)			
TA2 Metrics (Cartilage)				**SJ** Produce ≥1 IA therapeutic for cartilage regeneration **&** **MJ** Produce ≥1 systemic therapeutic for cartilage regeneration • No Surgical Donor/Recipient Harvest • Regenerate Defects At AND Beyond "Critical Size Defects" • Regenerate End-Grade OA to Grade 0 in ALL Synovial Joints • Needle-Based (including arthroscopic) and/or Non-Invasive Approach • Ideally ≤1 dose per year (in tandem with TA2)								Meets/Exceeds All Prior Criteria **Using Appropriate OA Large Animal Model**: • Sustains physiologically-relevant* load (per ICS 11.040) • Full function ≤3mo post-op with ≥85% success • Pain <3/10								Meets/Exceeds All Prior Criteria in Human Clinical Phase I Trials			

*Physiologically relevant load = ISO 14243 knee

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TA3 Metrics

Abstract and Proposal Options:
A) TA1 and TA2 –or-
B) TA3 –or-
C) TA1, TA2, and TA3

Pre-Program				Phase 1 (24 Months)								Phase 2 (36 Months)											
FY23				FY24				FY25				FY26				FY27				FY28			
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Timeline				Therapeutic Discovery & In Vitro (24mo)								Pre-Clinical (18mo)								Phase I Clinical Trials (18mo)			
TA3 Metrics (Total Joint)				• Load-bearing TKA allograft AND autograft • Patient-Specific • No permanent fixation • Osteoinductive/Chondroinductive								Meets/Exceeds All Prior Criteria • Allograft: Custom osteochondral graft in <24 hours • Autograft: Custom osteochondral graft in <30 days • Full function ≤4-6 weeks post-op ≥85% success • Sustains physiologically-relevant* load (per ICS 11.040) Stability of the implant ≥12mo								Meets/Exceeds All Prior Criteria in Human Clinical Phase I Trials			

TKA = Total knee arthroplasty
*Physiologically relevant load = ISO 14243 knee

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Metrics for all TAs

Abstract and Proposal Options:
A) TA1 and TA2 –or-
B) TA3 –or-
C) TA1, TA2, and TA3

Pre-Program				Phase 1 (24 Months)								Phase 2 (36 Months)											
FY23				FY24				FY25				FY26				FY27				FY28			
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Timeline				Therapeutic Discovery & In Vitro (24mo)								Pre-Clinical (18mo)								Phase I Clinical Trials (18mo)			
Requirements Across <u>ALL TAs</u>				• Begin IND Application • Identify Potential GLP and cGMP Manufacturing Partners • By Q4 FY24: Submit INTERACT meeting package and incorporate feedback • By Q3 FY25: Submit Pre-IND meeting package and incorporate feedback								• GLP Manufacturing • GCP & cGMP material for 20-100 patients • Complete IND-enabling studies & application								• Ensure scalable cGMP manufacturing partner for Phase II/III/Commercial (1000+ patients)			
Commercialization Plan				Work with PATIO assets to develop commercialization plan (including an engagement plan with XIR/EIRs)								Use PATIO assets to commence commercialization plan, secure IP, streamline regulatory pathway (FDA consultants), scale manufacturing capabilities etc.								Use PATIO assets to commercialize therapeutics and exit Program			

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Equity Requirements for all TAs

Goal: Integrated Equity Officers (EO) develop and enforce equity plans and ensure complete ownership of equitable research and transition

There will be one EO per performer team. The EO for each team will be responsible to guiding performers towards successfully meeting the equity metrics in the BAA. The information here is only a summary and does not encompass all of requirements in the BAA.

Pre-Program				Phase 1 (24 Months)								Phase 2 (36 Months)											
FY23				FY24				FY25				FY26				FY27				FY28			
Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Timeline				Therapeutic Discovery & In Vitro (24mo)								Pre-Clinical (18mo)						Phase I Clinical Trials (18mo)					
Equity Requirements				• Define Equity KPIs, >5 demo-specific listening sessions • Prepare "**Road Map to Equity**" Report (Deliver at Equity Symposium) • Create **Insurance Action Plan** (CMMI, CMS, IHS) • Partner with Animal Care Act Stakeholders								• Co-Manage Equity Symposium and publish the proceedings • Ensure prior KPIs enforced • ***Clinical Trial **GNG DEMOGRAPHIC REQUIREMENTS ENROLLMENT:** >50% women; **(±5%):** 20.7% Multi-NH; 20.1% Native Am/AK; 18.6% NHW; 18.2% NHB; 12.7% LAT; 9.7% AAPI*											

*GNG: Go/No-Go; Multi-Racial Non-Hispanic; Native American / Native Alaskan; Non-Hispanic White; Non-Hispanic Black; Latino; Asian American Pacific Islander

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De-Risk Translation: NITRO OA Model Symposium

Goal: Establish early consensus surrounding the ideal OA model to mitigate risk for translation

The first Symposium will take place on September 6, 2023. We strongly recommend all potential performers plan to attend. The below information is only a summary and does not encompass all of requirements in the BAA.

- Who will attend
  - Academia to industry, members of the Food and Drug Administration (FDA), veterinarians, contract research organizations (CROs), and manufacturers.
- What will be discussed
  - The current data and technology for OA Models to provide consensus surrounding the ideal OA model for translation.
- Outcomes
  - Single large animal model of OA to streamline preclinical testing and regulatory approval
  - Publication on the consensus OA model
  - Risk mitigation for NITRO performers and the broader OA research community in translational studies




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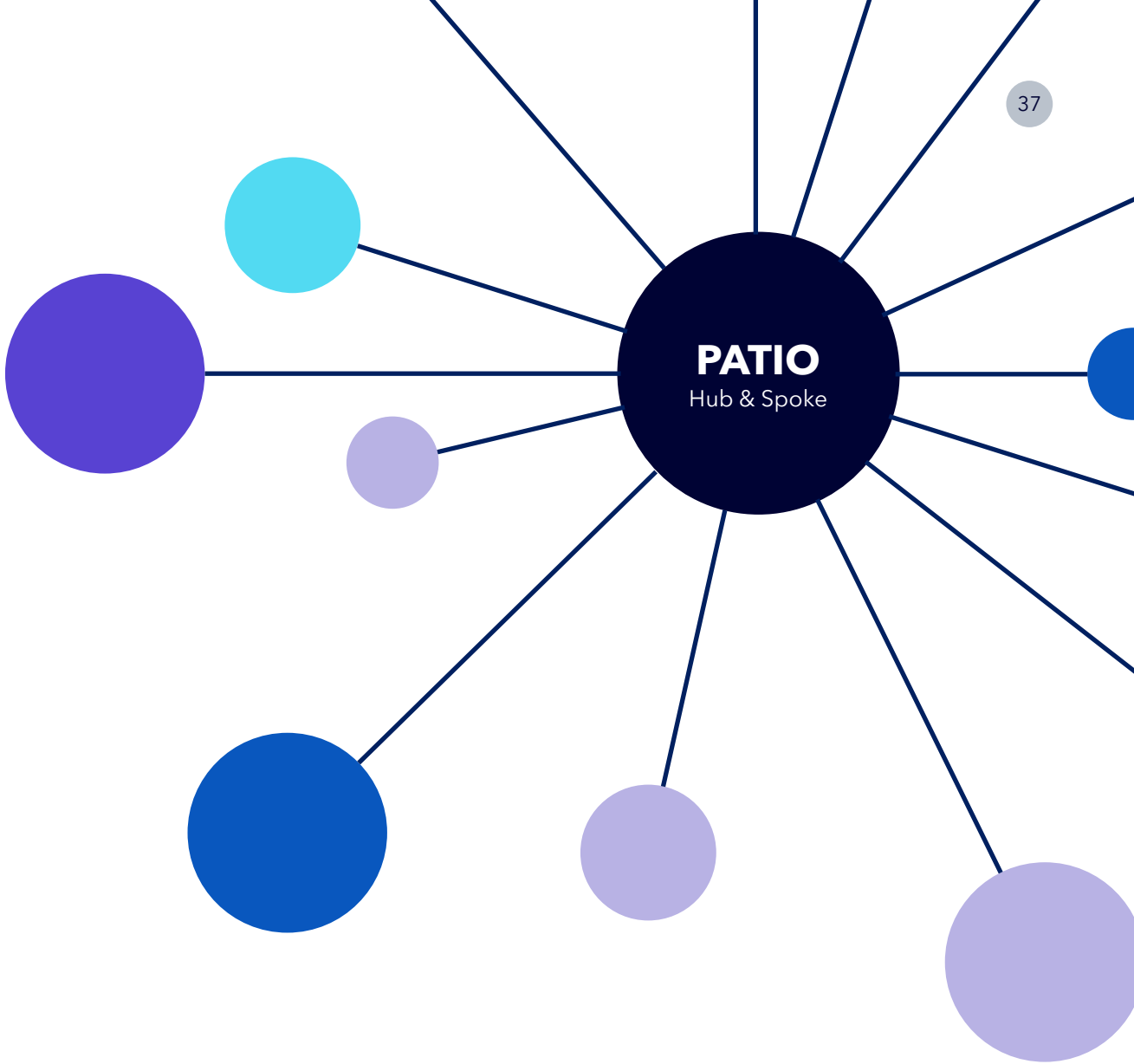
NITRO Commercialization

Goal: Performer and Program Transition

- ARPA-H PATIO team
- Expert/Entrepreneur in Residence (XIR & EIR) Network
- Minimum Viable Product (MVP) Testing for Market Adoption
- Scalability with Hub and Spoke
- Venture Capital (VC) Panel
- Successful exit from NITRO means established path towards patient care with product(s) entering market



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NITRO Broad Agency Announcement

Vision

ARPA-H's first Health Science Futures program-specific BAA seeks funding proposals for research aiming to: eradicate osteoarthritis (OA) through targeted, regenerative therapeutics that will **revolutionize** the care algorithm, prevent pain, decrease the economic burden, and eliminate the need for repeat joint surgery.

How to apply

- **Visit arpa-h.gov** for more information about NITRO and applying or email: **NITRO@arpa-h.gov**
- Abstracts (6-pages) are optional
- Full proposals (40-pages) are strongly encouraged and should investigate unconventional approaches and challenge accepted assumptions to enable leaps forward in science, technology, systems, or related capabilities.

The information on this page is only a summary and does not encompass all the requirements in the BAA.

Significant Dates and Times		
Event	**Date**	**Time**
Abstracts due	June 23, 2023	5:00 PM EDT
Full Proposals due	July 28, 2023	5:00 PM EDT
OA Model Symposium	September 6, 2023	**Location:** Washington, DC

Acquisitions Details

The Application Process

Traci Newsom, Contracting Officer
Business Innovation Division

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NITRO Solicitation/Funding Opportunity Basics

- BAAs are a flexible and recognizable method to solicit proposals for R&D
- The NITRO BAA provides for a competitive process while complying with all Funding Opportunity Notice requirements of 45 CFR Part 75 and 2 CFR Part 200 for Cooperative Agreements.
- ARPA-H anticipates meaningful proposals with varying technical/scientific approaches
- BAA technique allows for a variety of award instruments

75N99223R0003 Basics

Award Types

- Awards will be Cooperative Agreements and Other Transactions.
- Selection of award type will be based on best fit for the project.

Award Timeline

- Estimate full proposal evaluations to be complete by 11 September. At that point, ARPA-H will begin negotiating award instrument SOWs and T&Cs with selected proposers.

Award Funding

- There is no funding limit for individual awards, no ceiling or award range for individual awards, or an overall ceiling for the BAA.

Award Types – Cooperative Agreements

Financial Assistance

- Financial assistance mechanism where the principal purpose is to carry out a public purpose authorized by a U.S. law rather than to acquire supplies/services for the benefit of the Government.

Substantial Involvement

- Cooperative Agreements are distinguished from grants because of the Government's substantial involvement. This is broadly outlined in the BAA (e.g., 6.3 Reports) and will be specifically established in the Terms and Conditions of each award.

Benefits

- Parties work together to achieve a specific set of objectives or outcomes.
- Flexibility and discretion in project design and implementation, allowing for more innovative and customized solutions to complex problems.
- Enhanced accountability and transparency.

Award Types – Other Transactions (OT)

OTs are agreements

- Mutual assent, expressed by a valid offer and acceptance; adequate consideration; capacity; and legality (i.e., these are contracts, but not FAR procurement contracts.)
- Leverage commercial business practices more so than traditional FAR procurements.

Collaborative

- Increased collaboration and partnership, leading to more effective use of resources and knowledge sharing.

Flexible

- Many typical contract laws and regulations don't apply (e.g., CICA, FAR, CAS).
- Greater flexibility in project design and implementation.
- May fully negotiate data rights, patents, payment structure, etc.

Process Overview

Abstract Submission

(BAA page 28)

- OPTIONAL
- Length should not exceed 6 pages (excludes cover page & ROM).
- Abstract should include all sections as specified in the BAA.
- Abstract evaluation criterion – scientific and technical merit.
- All Abstracts to be submitted in eCPS

Full Proposal

(BAA page 30)

- Government will recommend or discourage submission based on abstract review.
- Submitted in eCPS for OTs
- Submitted in Grants.gov for Cooperative Agreements
- Summary of Proposal & Detailed Proposal Info – no more than 40 pages in length (excludes SOW).

Evaluation and Selection

(BAA page 41)

- The Government will review each conforming abstract against criterion 1, and each full proposal against criteria 1–4.
- Selection for award will be made as outlined in the BAA.

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Evaluation Criteria

Overall Scientific and Technical Merit (Abstract and Full Proposal)

- Innovative, feasible, achievable, and complete.
- A final outcome that achieves the goal can be expected as a result of award
- Risk identification with mitigation strategy.

Proposer's Capabilities and/or Related Experience (Full Proposal)

- Team expertise and experience.
- Experience in managing similar efforts.

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

- Future application, including unmet needs within biomedicine and to improve health outcomes.
- Potential for interdisciplinary approach.

Evaluation Criteria (continued)

Reasonableness/Realism/Funding Availability/Affordability (Full Proposal)

- **Submissions must include the specified spreadsheets**
  - Amendment forthcoming to provide both in SAM.gov

- **Price Reasonableness**

- **Cost Realism**

- **Availability/Affordability**
  – May only acquire goods or services that meet needs and are within budgetary constraints.
  – IP considerations.

Final Application Guidance

Continue to monitor SAM.gov

- Amendment posted 14 June
- Anticipate next Amendment week of 26 June to provide the required Cost Proposal Spreadsheets

Posting in Grants.gov

Conform to all BAA Requirements

- Eligibility (BAA pg. 25).
- Special requirements for cooperative agreement awardees (BAA pg. 39).

Any/all changes to the BAA will be made in formal Amendments posted online at SAM.gov

- No information discussed or viewed at Proposers' Day shall be construed as modifying the terms and conditions of the BAA

Cost Proposal

Templated Spreadsheet

Joshua Brown (CTR), Business Finance Manager

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ARPA-H Cost Proposal Spreadsheet

Purpose: assist the Government in completing a rapid analysis of your proposed costs and, if your proposal is selected for award, speeding up the negotiation and award execution process..

- The basis and rationale **for all proposed costs** should be provided as part of the proposal.
- Using the cost proposal spreadsheet:
  - Enter the proposed cost detail for Phase 1 and Phase 2.
    - The tab entitled, "Total Amount" will automatically calculate from the Phase 1 and Phase 2 tabs.
  - **Data entry:** Yellow and Clear cells.
  - **References or formulas:** Gray cells.
    - Do not change, unless the formula does not match your organization's business rules.
    - If you change these formulas, you must ensure the change does **not** affect the final outputs.
  - Proposers may add additional specific cost categories (Sub-proposers, ODC types, etc.) as needed but must ensure those new cost categories track to the Total Amount tab.
  - If a row, column, or worksheet in this spreadsheet is not needed for your proposal, either ignore it or Hide it; **do not delete it.**

Lightning Talks

Round 1
3 minutes with a **hard stop** to stay on schedule
1 speaker only per lightning talk

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