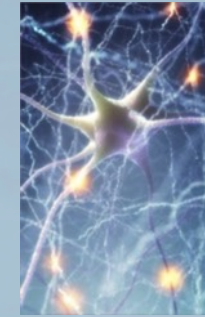


Department of Defense Vision Research Funding Opportunities

CUTTING EDGE RESEARCH

Q. Tian Wang, Ph.D.

Program Manager, Vision Research Program



The views expressed in this presentation are those of the author and may not reflect the official policy or position of the Department of the Army, Department of Defense, or the U.S. Government

CDMRP
Department of Defense



May 19, 2020

Disclaimer

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Congressionally Directed Medical Research Programs (CDMRP)

» CONGRESSIONAL PROGRAMS

- » Manages extramural research programs directed by Congress since 1992
- » FY20: 35 research programs, \$1.2B total appropriation

» DoD PROGRAMS

- » Provides intramural/extramural research management support to Program Area Directorates (PADs)/Joint Program Committees (JPCs)

» DIRECTOR

- » COL Stephen J. Dalal



Website: cdmrp.army.mil

FY20 CDMRP Funding

Program	\$M	Program	\$M
Amyotrophic Lateral Sclerosis	\$20.0	Neurofibromatosis	\$15.0
Autism	\$15.0	Neurotoxin Exposure Treatment Parkinson's	\$16.0
Bone Marrow Failure	\$3.0	Orthotics and Prosthetics Outcomes	\$15.0
Breast Cancer	\$150.0	Ovarian Cancer	\$35.0
Breast Cancer Research Semipostal	TBD	Pancreatic Cancer*	\$6.0
Chronic Pain	\$15.0	Peer Reviewed Alzheimer's	\$15.0
Combat Readiness	\$10.0	Peer Reviewed Cancer (14 Topics)	\$110.0
Duchenne Muscular Dystrophy	\$10.0	Peer Reviewed Medical (44 Topics)	\$360.0
Epilepsy	\$12.0	Peer Reviewed Orthopaedic	\$30.0
Gulf War Illness	\$22.0	Prostate Cancer	\$110.0
Hearing Restoration	\$10.0	Rare Cancers*	\$7.5
Joint Warfighter Medical	\$40.0	Reconstructive Transplant	\$12.0
Kidney Cancer	\$40.0	Scleroderma*	\$5.0
Lung Cancer	\$14.0	Spinal Cord Injury	\$40.0
Lupus	\$10.0	Tick-Borne Disease	\$7.0
Melanoma	\$20.0	Tuberous Sclerosis Complex	\$6.0
Military Burn	\$10.0	Vision	\$20.0
Multiple Sclerosis	\$16.0		

* New for FY20

TOTAL = \$1.2B

Unique Public-Private Partnership

Consumers

- » Demonstrate need
- » Participate at all levels
- » Bring passion and perspective



**IMPROVE
HEALTH
OUTCOMES**



Congress

- » Adds funds to budget
- » Provides targeted guidance

Researchers

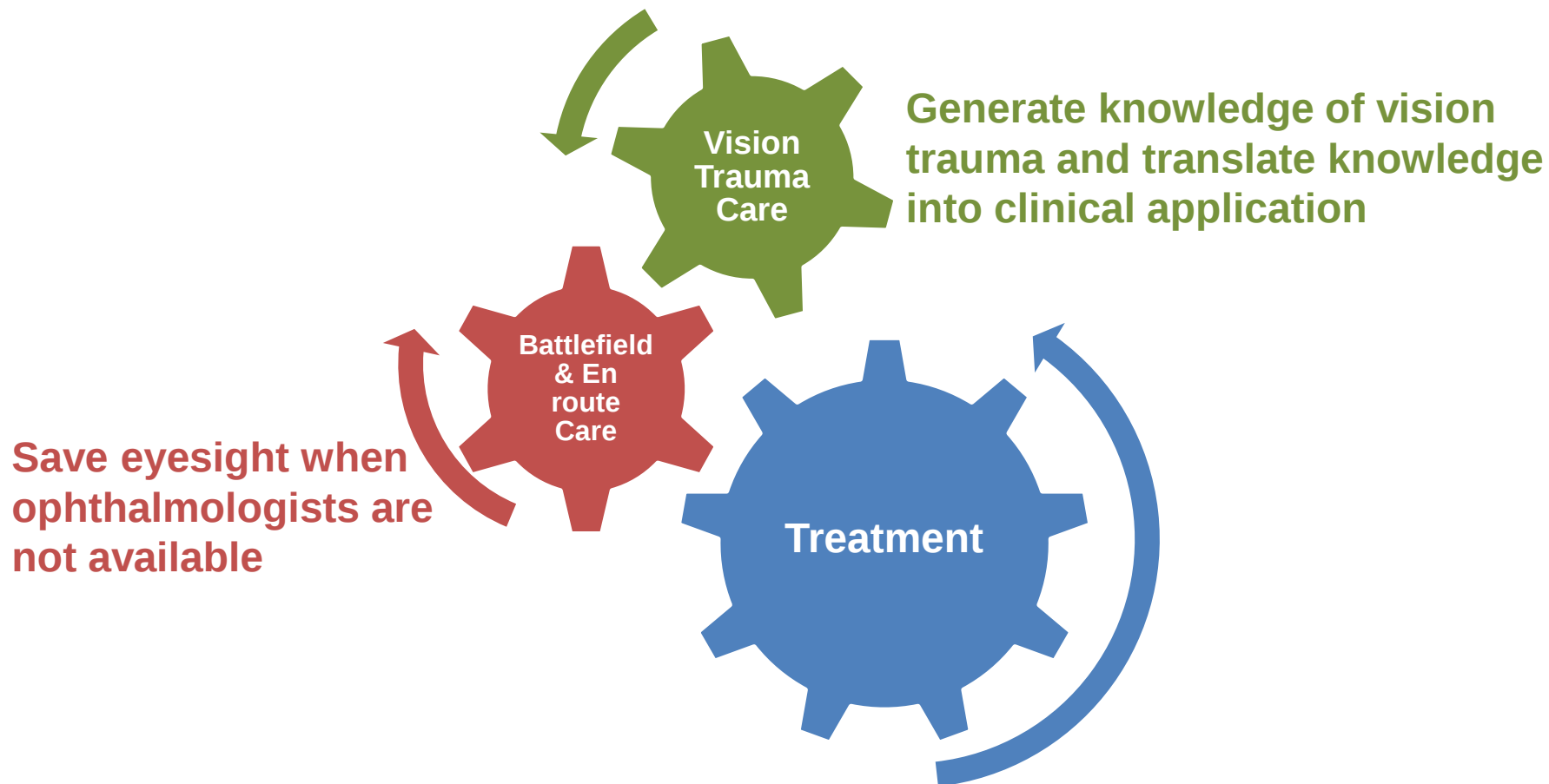
- » Carry out research
- » Peer review
- » Subject matter experts



DoD

- » Oversees program management
- » Contracting actions
- » Regulatory requirements

Challenges of Military-Relevant Vision Trauma Care



Preservation of eyesight of Warfighters requires:
Clinically relevant mechanisms & therapeutics
+ Battlefield/en route care capability

VRP Program Priorities

1. Accelerate research in eye injury and vision dysfunction due to military-relevant trauma

- » For example (more examples are provided in FTTSA PA):
 - » Identification of significant changes in pathophysiology over time after trauma to inform targeted treatments
 - » Elucidation of molecular, cellular, and biophysical mechanisms of a military-relevant trauma
 - » Development or improvement of clinically relevant trauma models

2. Advance diagnosis and treatment of eye injuries in both a forward operating environment and a prolonged field care setting

- » Diagnostics and interventions that enable decision-making, triaging, stabilization, and management in austere conditions such as prolonged evacuation time and limited specialty care.
- » Research addressing #1 can inform those addressing #2

Vision Research Program

News & Highlights

Defense Health Program
Department of Defense
Vision Research Program
Anticipated Funding
Opportunities for Fiscal Year
2020 (FY20)

FY19 VRP Recommended
for Funding List

CAPT Walter Steigleman,
MD - Advancing Research
for Military Vision Trauma

MAJ Thomas Zampieri (USA
Ret.), PhD, PA - Restoring
Hope for Service Members
with Eye Trauma

2019 Military Health
System Research
Symposium Call for
Abstracts for Vision-
Associated Breakout
Sessions

VRP Program Summary
Sheet

More...

Vision

*Transform visual system trauma
care for our armed forces and the
nation*

Mission

*To identify and address clinical
needs through directed medical
research to improve the health
and readiness of military
personnel affected by eye injuries
and vision dysfunction*

Vision

Vision - Transform visual system trauma care for our armed forces and the nation

Eye injury and visual dysfunction resulting from battlefield trauma affect a large number of Service members and Veterans. Surveillance data from the U.S. Department of Defense indicate that eye injury accounts for approximately 15% of all injuries from battlefield trauma sustained during the wars in Afghanistan and Iraq, resulting in more than 182,000 ambulatory patients and 4,000 hospitalizations between 2000 and 2011. In addition, traumatic brain injury (TBI), which affects more than 380,000 Service members between 2000 and 2018, can have significant impact on vision even when there is no injury to the eye. Research sponsored by the U.S. Department of Veterans Affairs showed that as many as 75% of Service members who had suffered a TBI had visual dysfunction.

The Vision Research Program (VRP) was established by Congress in fiscal year 2009 (FY09) to fund impactful military-relevant vision research that has the potential to significantly improve the health care and well-being of Service members, Veterans, their family members and caregivers, and the American public. The VRP's program area aligns with the Sensory Systems task area of the [Clinical and Rehabilitative Medicine Research Program](#), a core research program of the Defense Health Agency. The VRP was administered by the [US Army Medical Research and Materiel Command's](#) Telemedicine and Advanced Technology Research Center from FY09 to FY12 and was transitioned to the [Congressionally Directed Medical Research Programs \(CDMRP\)](#) for administration starting with the FY13 program cycle.



» Click on Image to View Program Booklet



» Click on Image to View Strategic Plan

Resources for Investigators:

- [A Beginner's Guide to Army Healthcare System](#)
- [Joint Health Services Publication JP 4-02](#)
- [Blast Term Dictionary and Guidance Documents for Blast Injury Research](#)
- [A Primer for Conducting DoD Funded Human Research with Military Populations](#)

- *What is austere environment?*
- *What is prolonged field care?*
- *What medical care capability is available in the military operational environment?*



Congressional Appropriations

\$104.95 million
FY09-FY19

\$20 million
FY20



Funding Summary

94 Awards in FY09-18

Recent Applications
Recommended for
Funding



Programmatic Panels

FY20 Programmatic
Panel

Previous Years'
Programmatic Panels

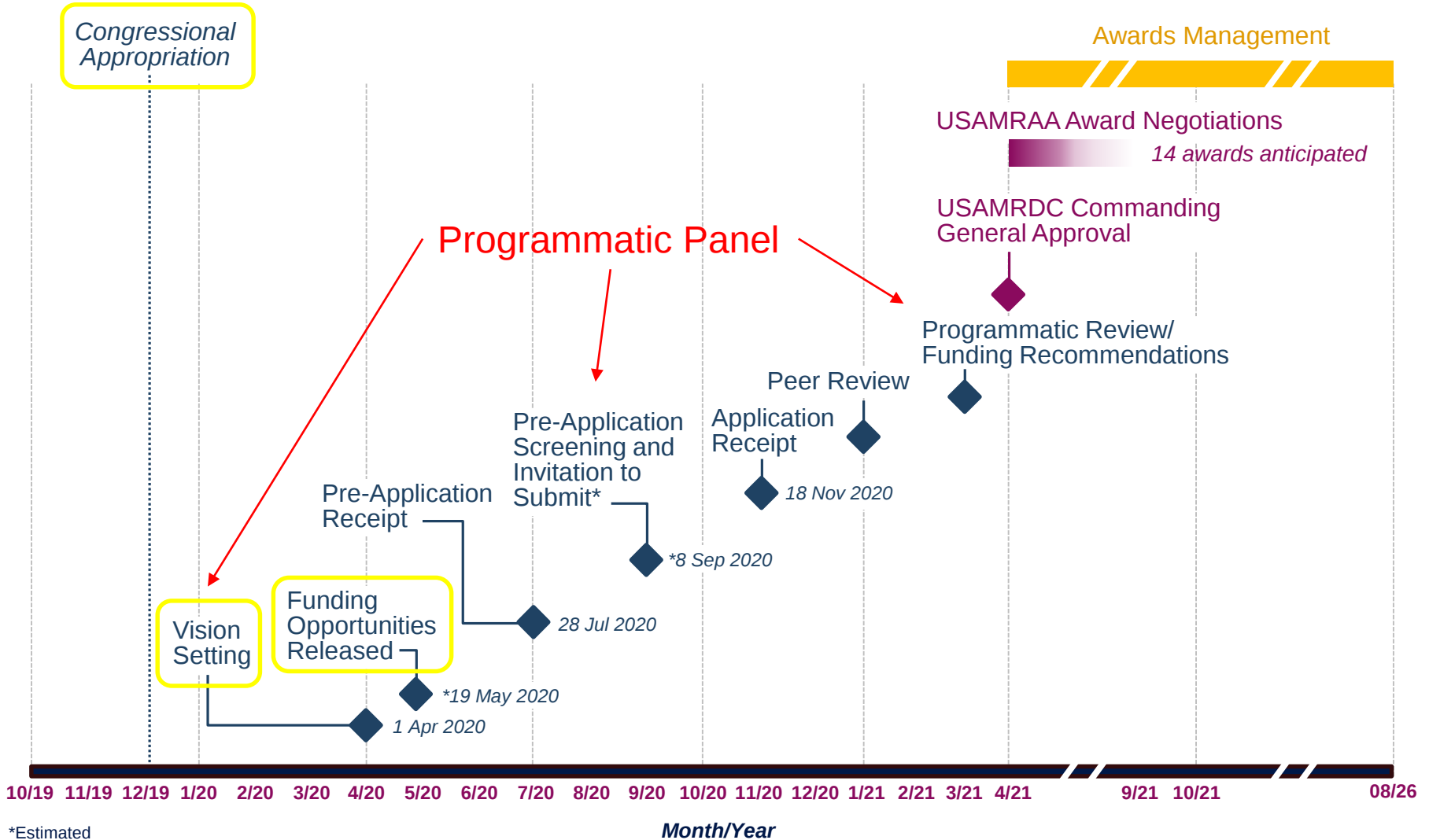


Peer Review Participants

FY19 Peer Review
Participants

Previous Years' Peer
Review Participants

1. Creation and Release of Funding Opportunities

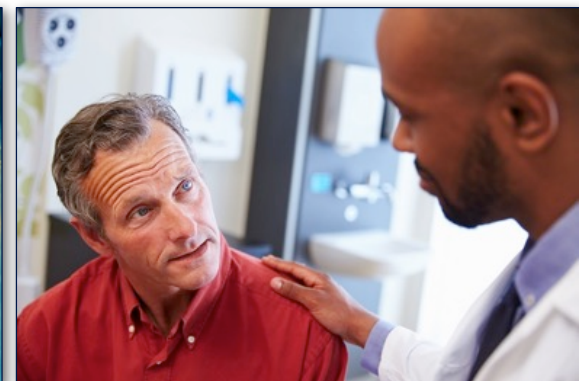
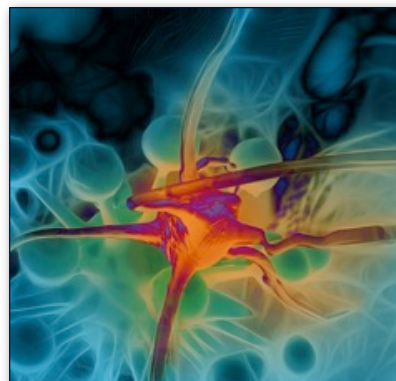


*Estimated

Vision Setting

At Vision Setting each year, the Programmatic Panel recommends an investment strategy, considering factors such as:

- » Congressional language
- » Current research landscape
- » Emerging technologies
- » Research gaps
- » Impact
- » Portfolio composition



FY20 VRP Investment Strategy

Award Mechanism	Funding Level	Direct Costs	Number of Awards*
Investigator-Initiated Research Award (IIRA)	FL1	\$0.260M	7
	FL2	\$0.750M	4
Translational Research Award (TRA)	N/A	\$1.0M	2
Focused Translational Team Science Award (FTTSA)	N/A	\$5.0M	1

*estimated

Funding Opportunity Documents

Program Announcement

I. OVERVIEW OF THE FUNDING OPPORTUNITY

Program Announcement for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Vision Research Program

Investigator-Initiated Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-20-VRP-IIRA

Catalog of Federal Domestic Assistance Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), July 28, 2020
- **Invitation to Submit an Application:** September 2020
- **Application Submission Deadline:** 11:59 p.m. ET, November 18, 2020
- **End of Application Verification Period:** 5:00 p.m. ET, November 23, 2020
- **Peer Review:** January 2021
- **Programmatic Review:** March 2021

This Program Announcement must be read in conjunction with the General Application Instructions, version 501. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

General Application Instructions

General Application Instructions

Version 501

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

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This General Application Instructions document must be read in conjunction with the Program Announcement for this funding opportunity, which is available for downloading from Grants.gov and eBRAP.org.

Conceiving a Project

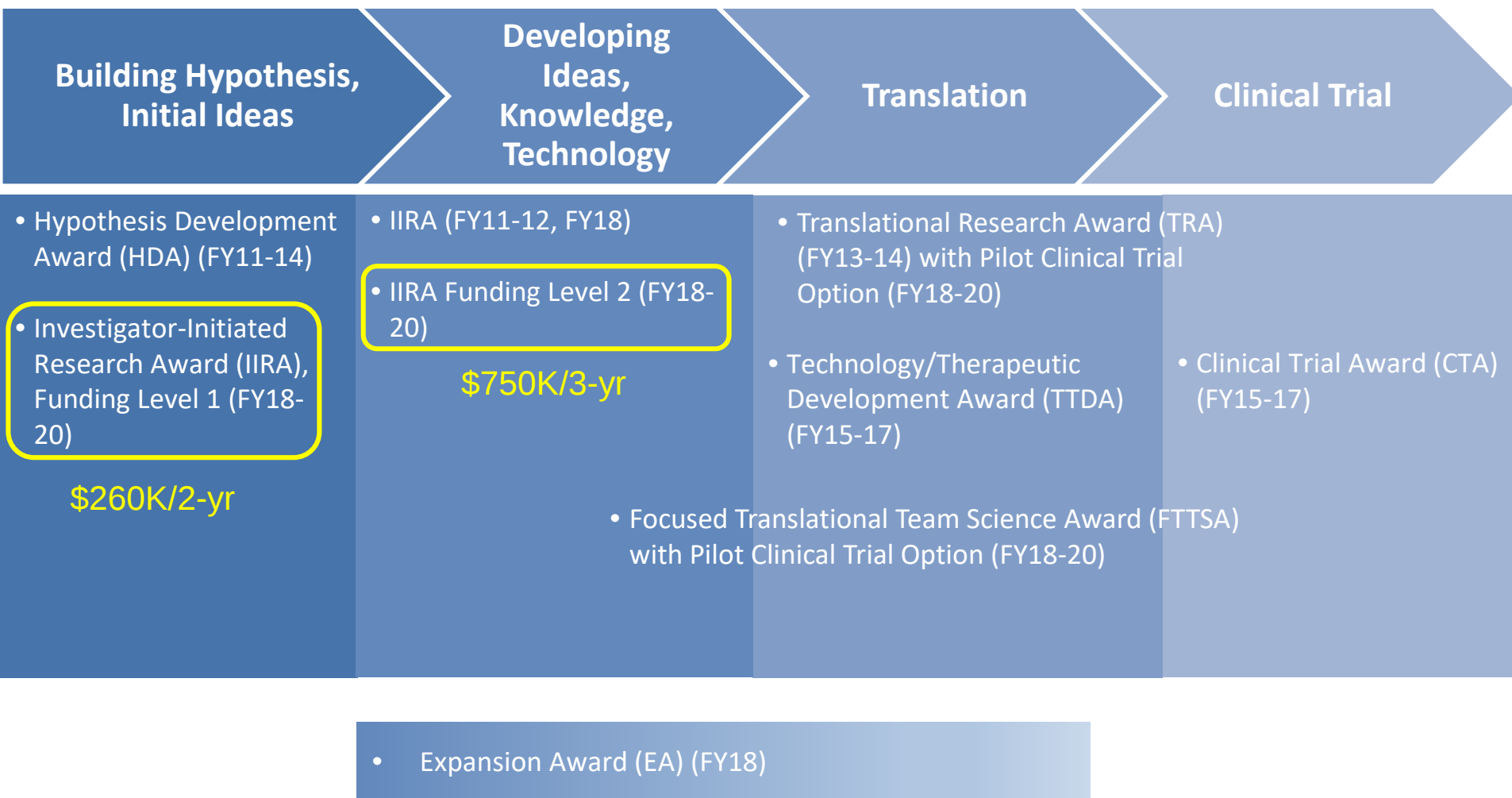
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FY20 VRP IIRA

- » **Supports studies that will yield highly impactful discoveries or major advancements.**
- » **Funding Level 1 supports exploratory, high-risk/high-reward research in the earliest stages of idea development.**
 - » Research must have the potential to yield new avenues of investigation, such as new approaches, new research tools, or new paradigms.
 - » While preliminary data are NOT required, applicants must provide solid rationale of the research idea.
 - » The investigating team must have sufficient expertise to test the idea.
- » **Funding Level 2 supports the advancement of more mature research that has the potential to make significant advancements toward clinical translation.**
 - » Applications may focus on any phase of research from basic through translational.
 - » Preliminary data supporting the readiness and feasibility of the proposed research are required.
- » **Research involving human subjects and human anatomical substances is permitted.**
- » **Clinical trials are not allowed.**
- » **Following selection of projects for VRP funding, the VRP may share FY20 IIRA applications and reviews with the NEI for independent funding consideration.**

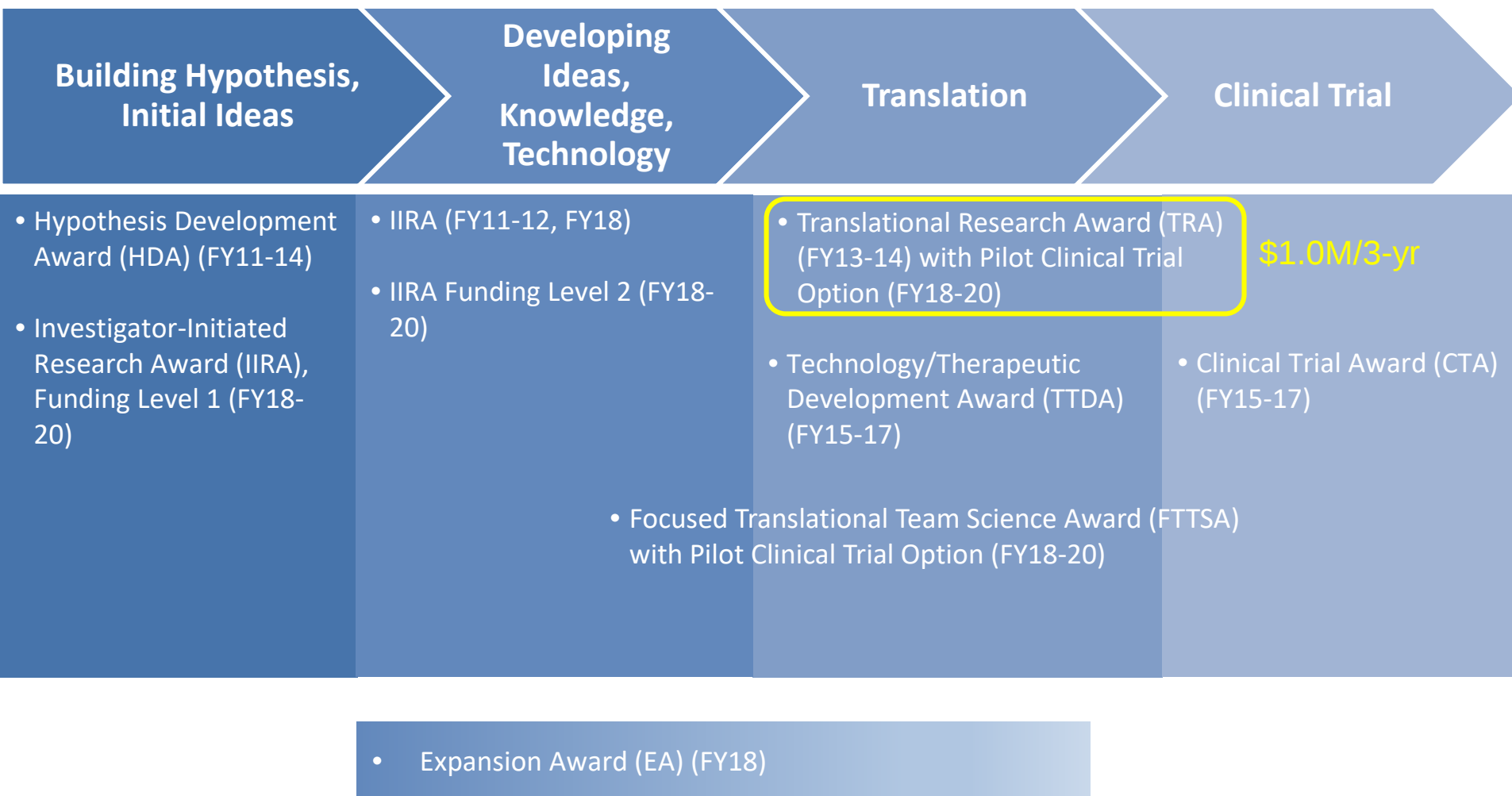
VRP Award Mechanisms and the Research Pipeline



FY20 VRP TRA

- » Supports translational research that moves promising laboratory research into clinical applications.
- » **It is expected that an IND or IDE application will be submitted during or by the end of the period of performance.**
- » Preliminary data are required.
- » May include, as a portion of the proposed research, a pilot clinical trial (PCT) component.
 - » In contrast to full-scale clinical trials that are designed to determine safety or efficacy, the purpose of the PCT is generate preliminary data to inform the feasibility, rationale, and design of subsequent clinical trials through limited clinical testing of a novel intervention.
 - » Applications that include a PCT as part of the proposed research will have additional submission requirements (Pilot Clinical Trial Plan, Regulatory Strategy) and review criteria.
- » Following selection of projects for VRP funding, the VRP may share FY20 TRA applications and reviews with the NEI for independent funding consideration.

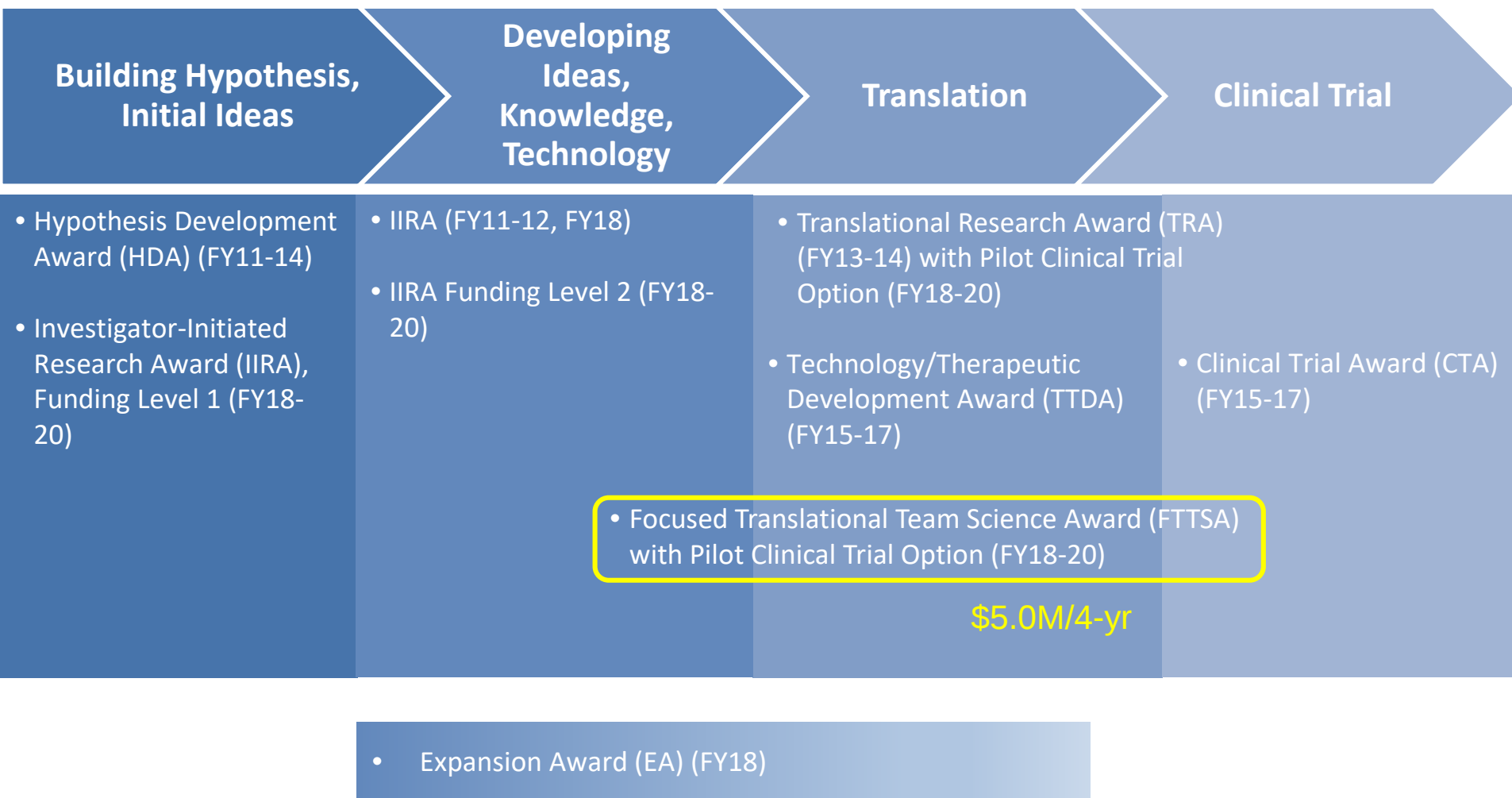
VRP Award Mechanisms and the Research Pipeline



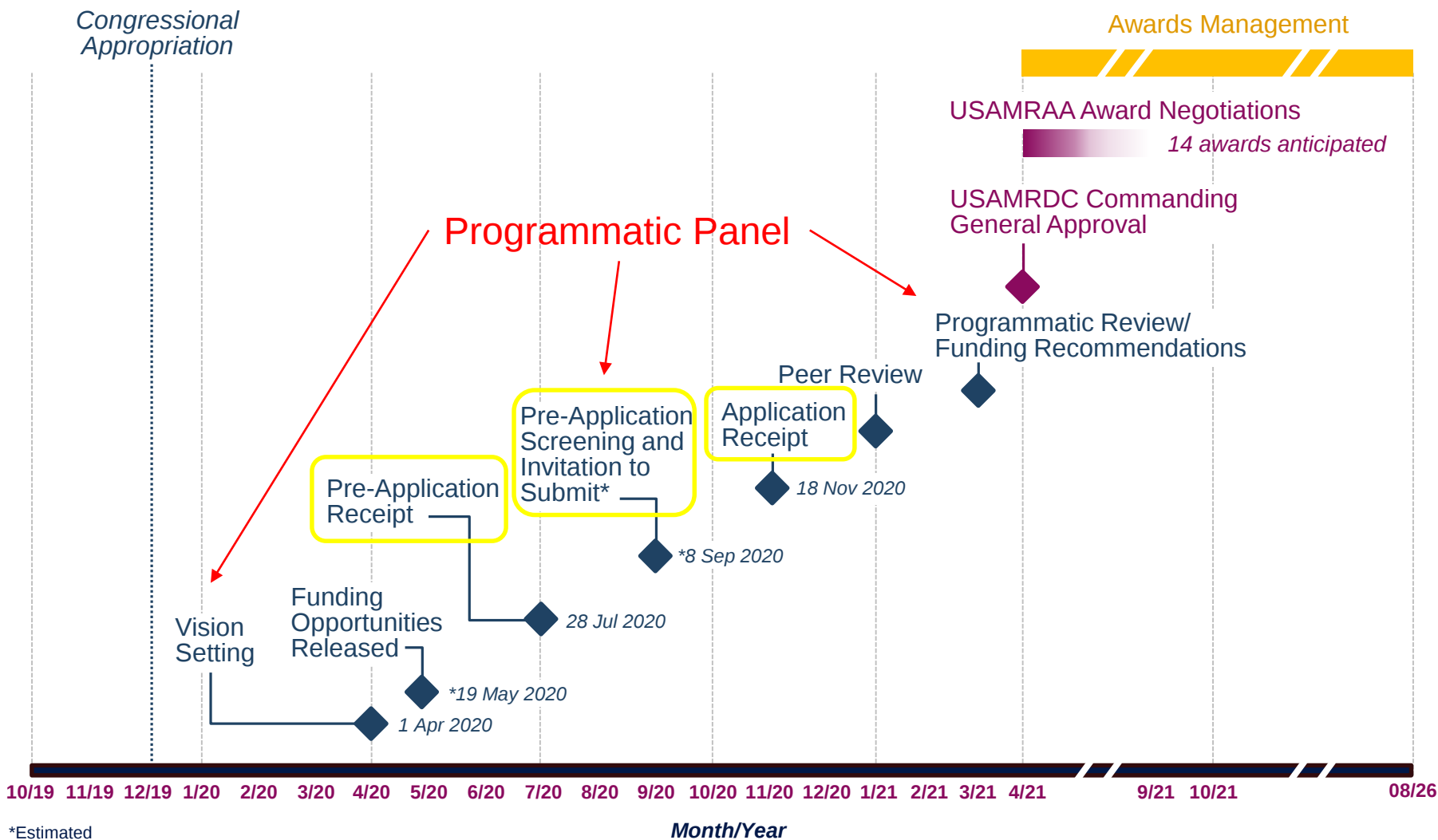
FY20 FTTSA

- » Supports a team initiative that leverages the strengths of investigators specializing in different fields to address an overarching scientific challenge or question and fundamentally advance the understanding and treatment of military-relevant vision trauma.
- » **Overarching Challenge**
 - » Consider barrier(s) to and/or gap(s) in the understanding, prevention, diagnosis, mitigation, and/or treatment of eye injury or visual dysfunction associated with a military-relevant trauma and envision what may be achievable in 10 to 15 years.
 - » Identify, based on the long-term vision, what should and can be achieved in the near term.
 - » Design projects and research teams around these considerations.
- » **Research Projects**
 - » 3-5 distinct research projects, each representing a unique approach to address the overarching challenge
 - » Individual projects must be capable of standing on their own scientific merits and not dependent on the success of any other project.
 - » Preliminary data to support the feasibility of each project are required.
 - » Synergy between project will advance a solution beyond what would be possible through individual efforts.
 - » May include, as a portion of the proposed research, a pilot clinical trial component that collects preliminary data to inform the feasibility, rationale, and design of subsequent clinical trials.
- » **Research Team**
 - » The overall lead PI: Associate Professor or above, with experience in leading large collaborative research projects; a minimum of 20% effort.
 - » Each project leader, including the overall lead PI, may lead only one project.
 - » Must have a detailed Implementation Plan for participating research groups to coordinate efforts, facilitate collaboration, and create synergy.

VRP Award Mechanisms and the Research Pipeline



2. Pre-application and Application Submission



Pre-Application Screening Criteria

IIRA	TRA	FTTSA
- Research Idea/Rationale <i>(Including alignment to FY20 VRP Focus Areas)</i> - Objectives/Hypothesis(es), Specific Aims, and Approaches - Impact - Personnel	- Research Idea/Rationale <i>(Including alignment to FY20 VRP Focus Areas)</i> - Objectives/Hypothesis(es), Specific Aims, and Approaches - Translational Potential: <i>How well the proposed research presents a clear path to transform a promising discovery into new drugs, devices, or clinical practice guidelines that are ready for definitive testing in clinical trials.</i> - Impact - Personnel	- Overarching Challenge - Research Strategy - Projects ↔ overarching challenge - Rationale - Objectives/Hypothesis(es), Specific Aims, and Approaches - Synergy - Research Team - Leverage strengths of investigators specializing in different fields - Have sufficient expertise - Interaction and collaboration - Impact

- » Applicants do not receive feedback on pre-application
- » Submission of full application is by invitation only

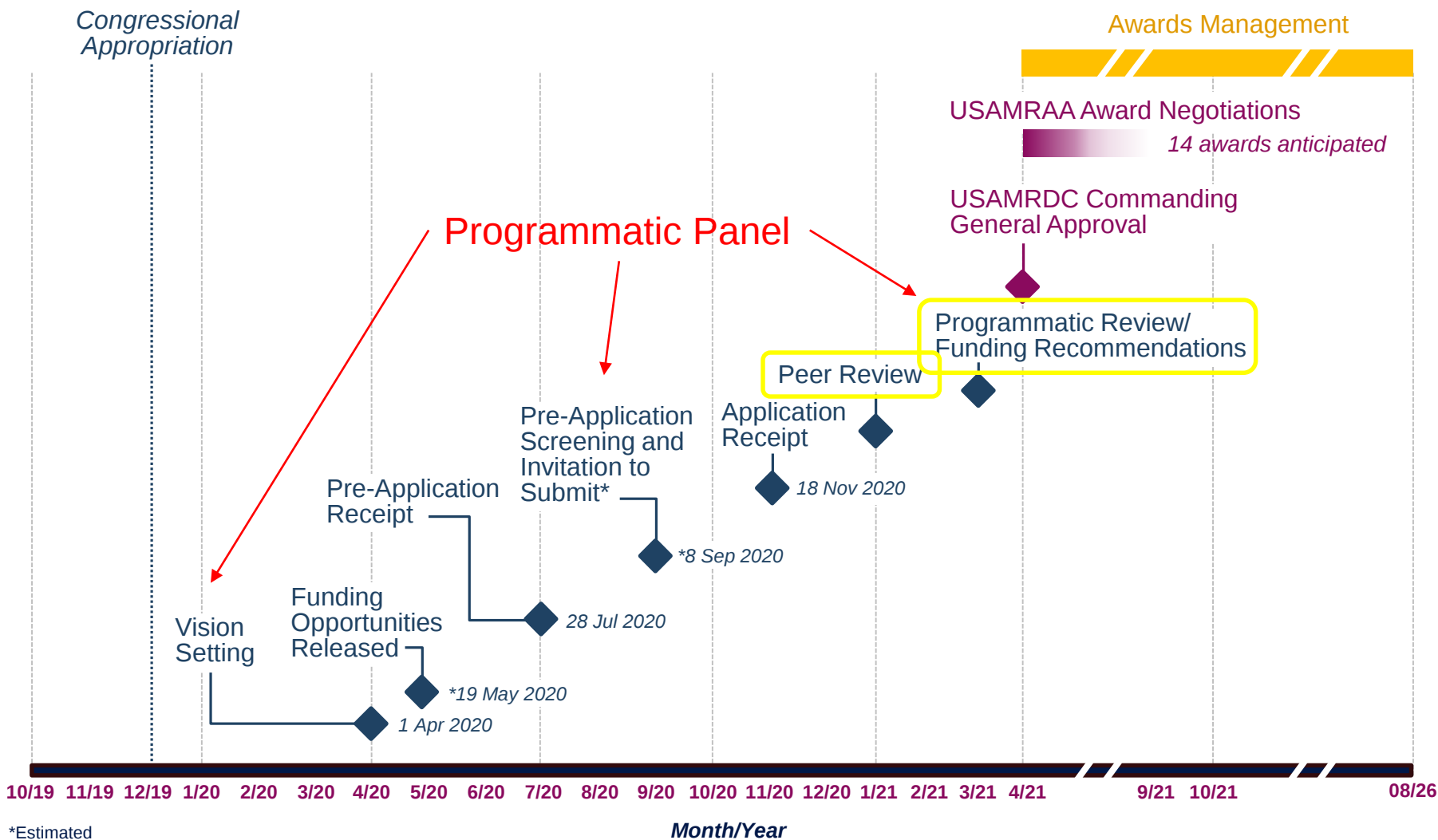
Content and Form of the Full Application Submission

» Full Application Submission Content

Take advantage of Application Submission Checklist

Application Components	Action	Completed
SF424 (Extramural only)	Complete form as instructed	
Attachments	Project Narrative Supporting Documentation Technical Abstract Lay Abstract ...	
Personal Data	Complete form as instructed	
Senior/Key Person Profile	Biographical Sketch Previous/Current/Pending Support	
Budget (Extramural only)	Complete as instructed. Attach Budget Justification.	
Performance Site Locations Form	Complete form as instructed	
Subaward Budget Attachments	Complete form as instructed	

3. Review Process



*Estimated

Goal of the Two-Tier Review Process

To find *scientifically meritorious* proposals and fund those that *best fulfill program goals*



First Tier: Peer Review

- » How the evaluation process works
 - » Technical merit assessment based on an ideal application
 - » Criteria-based evaluation of entire application
- » Peer reviewers
 - » Scientists, clinicians, consumers, specialists (e.g., statisticians and tech transfer specialists)
 - » No standing panels
 - » Recruited based on expertise needed
 - » Identities are unknown to applicants; contact between applicants and reviewers are not permitted



**Outcome:
Summary
Statements**

Peer Review Criteria

	IIRA	TRA	FTTSA
Scored (Equal Importance)	• Impact • Research Idea • Research Strategy • Personnel • Environment	• Translational Potential • Impact • Research Idea • Research Strategy • Post-Award Transition Plan • Personnel • Environment	• Overarching Challenge • Overall Strategy • Impact • Team and Personnel • Implementation Plan • Project-Specific Strategy • Translation • Post-Award Transition Plan
Unscored	• Budget • Data and Resource Sharing • Application Presentation		• Environment • Budget • Data and Resource Sharing • Application Presentation

Writing Proposals with Reviews in Mind

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Writing Proposals with Reviews in Mind

II.D.2.b.ii. Full Application Submission Components

- **Background/Rationale:** Provide a sound scientific rationale for the proposed research.
- **Funding Level 1:** Describe the **idea** that the proposed research will explore and develop, clearly stating the **objective(s)** to be reached and/or the **hypothesis(es)** to be tested. Present sufficient **literature** to support the **rationale** for testing the idea. Explain how the proposed research has the **potential to yield new avenues of investigation**, such as new approaches, new research tools, or new paradigms. *Preliminary data are allowed but not required.*

II.E. Application Review Information

- **Research Idea**
 - **Funding Level 1:**
 - To what extent the **idea** of the proposed research, including the **objective(s)** and/or **hypothesis(es)**, is based on sound **rationale** and **critical analysis of literature**.
 - To what extent the proposed research has the **potential to yield new avenues of investigation**.

Second Tier: Programmatic Review

- » How the evaluation process works
 - » Comparison-based
 - » Strong scientific merit
 - » Program relevance
 - » Adherence to award mechanism's intent
 - » Impact
 - » Relevance to military health
 - » Consideration of portfolio composition
- » Programmatic reviewers
 - » VRP Programmatic Panel
 - » Ad hoc reviewers



**Outcome:
Funding
Recommendations**

Involvement of Programmatic Panel member in the design or performance of the proposed project is PROHIBITED and would result in ADMINISTRATIVE WITHDRAWAL

Programmatic Review Criteria

- » **Ratings and evaluations of the peer reviewers**
- » **Relevance to the mission of the DHP and FY20 VRP, as evidenced by the following:**
 - » Adherence to the intent of the award mechanism
 - » Relative impact
 - » Relevance to military health **Check out Resource Document!**
 - » Program portfolio composition

Funding Opportunities Beyond the VRP

» **Small Business Innovative Research (SBIR) Program**

- » SBIR topics posted on DoD SBIR/STTR Portal

» **Broad Agency Announcement (BAA)**

- » Posted on Grants.gov

- » Current active BAA: W81XWH18SBAA1 (closing date September 30, 2022)

- » Check Appendix 1 for Research Areas of Interest

» **Request for Information (RFI) / Request for Project Proposals (RPP)**

Example: a portable ocular diagnostic device/system RFI,
posted April 18, 2019

Subject: JUST RELEASED! FY19 DoD USAMMDA RFI

This email is to notify the medical research and development (R&D) community of a recently released Fiscal Year 2019 Request for Information (RFI) for the Department of Defense (DoD) U.S. Army Medical Materiel Development Activity (USAMMDA) for a portable ocular diagnostic device / system. This RFI is issued solely for information and planning purposes.

The USAMMDA develops and delivers quality medical capabilities to protect, treat, and sustain the health of our Service Members. The USAMMDA enhances the DoD by facilitating further development of promising industry and academic efforts and reviews a broad spectrum of R&D efforts on an ongoing basis.

A detailed description of this RFI and the submission requirements can be found at the following website:

<https://www.fbo.gov/index?s=opportunity&mode=form&id=3f13f034debc370664a49db195b242a8&tab=core&cvview=0>

Please do not respond directly to this message. To be added or removed from this email list please use the "Subscribe to program specific news and updates" or "Unsubscribe" links available at <https://ebrap.org>.



Coming soon on MTEC:
RPP on Temporary
Corneal Repair prototype

Resources

» CDMRP Website

» <https://cdmrp.army.mil/>

» CDMRP Videos and Webinar Series

» https://cdmrp.army.mil/pubs/video/CDMRP_overview

» https://cdmrp.army.mil/pubs/video/CDMRP_fundingreviewprocess.aspx

» https://cdmrp.army.mil/pubs/webinars/webinar_series

» VRP Homepage

» <https://cdmrp.army.mil/vrp/default>

» DoD SBIR/STTR Portal

» <https://www.dodsbirsttr.mil/submissions/login>

» MTEC

» <https://www.mtec-sc.org/>