



Office of Regulatory and Emerging Science (ORES)

Preparedness Research Staff (PRS)

BAA Overview and Priorities

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BAA Day

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What Are Medical Countermeasures?



MEDICAL COUNTERMEASURES (MCMS)

FDA-REGULATED MEDICAL PRODUCTS

Medical countermeasures, or MCMS, are FDA-regulated products that may be used in a **PUBLIC HEALTH EMERGENCY** stemming from a terrorist attack with or accidental release of a biological, chemical, or radiological/nuclear agent, or a naturally occurring emerging infectious disease.

WHAT ARE MCMS?

PREVENT, PROTECT AGAINST, TREAT OR DIAGNOSE
DISEASES OR HEALTH EFFECTS CAUSED BY **CBRN**
THREAT AGENTS



C CHEMICAL
B BIOLOGICAL
R RADIOLOGICAL
N NUCLEAR

& EMERGING INFECTIOUS DISEASES

EXAMPLES OF MCMS



BIOLOGIC PRODUCTS

- Vaccines
- Blood products
- Antibodies



DRUGS

- Antimicrobials
- Chemical threat antidotes
- Treatments for radiation injury



DEVICES

- Diagnostic tests
- Personal protective equipment (PPE)
 - Gloves
 - Respirators/certain masks
 - Gowns

MCM Regulatory Science

Goals

- Developing the tools, standards, and approaches to assess MCM safety, efficacy, quality, and performance
- Translating cutting-edge science and technology into innovative, safe, and effective MCMs



Funding Activities

- Extramural research: Research Contracts, Grants
- Intramural research: Internal Funding
- Partnerships/Collaborations: IAAs



ORES PREP BAA Contracts

- BAA contracts are typically structured with a BASE period of performance and a variable number of OPTIONS
 - BASE period of 1-2 years
 - Option periods vary
 - Overall period of performance cannot exceed 5 years
- Performers are advised to structure proposals accordingly
- Managed by subject matter experts that also serve as CORs
- Typically, monthly meetings and either monthly or quarterly progress reports



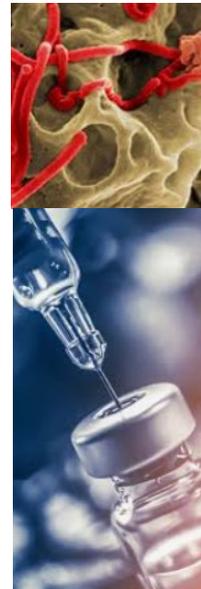
ORES BAA Contracts

- Considered “high complexity”; as defined in the Contractor Performance Assessment Rating System (CPARS)
- Contract Type: Cost Reimbursement (CR)
- What is *not* in scope: product development/post-market product surveillance
- Can be co-funded with other government agencies
 - FDA ORES utilizes interagency agreements
 - Co-funding may impact timelines for contract awards/modifications
- Deliverables are typically knowledge products (technical reports, data summaries or collections in databases)
- Publications and presentations are encouraged



ORES BAA Contract Areas

- MCMi research areas of interest are listed in III, A: **Reinforce Medical Countermeasures Initiative (MCMi) to Increase Preparedness and Response for Emerging Public Health Threats**
- Primary research areas of interest are:
 1. Develop and fully characterize tools to support MCM development under the Animal Rule, Accelerated Approval, or Emergency Use Authorization (EUA)
 2. Enhance the agility, quality, and utility of diagnostics and diagnostic data
 3. Modernize tools to evaluate MCM product safety, efficacy, and quality; and secure the MCM supply chain
 4. Advance the development of tools to enable the rapid development and availability of investigational MCMs



Develop and characterize tools to support MCM Development



- Alternative methods to animal testing, including in vitro systems (e.g. microphysiological systems) for countermeasure development
- Characterization of disease progression, applied to regulatory framework, e.g. mechanisms of infection, morbidity/mortality, and virulence
- Identify and qualify biomarkers for both MCMs (to enhance understanding and aid in guidance) and pathogens/biothreats (predictors of harm, virulence, susceptibility, etc)
- Studies to address knowledge gaps and “bridging data” between animal models and clinical data from humans
- Develop, qualify, and/or facilitate innovative analytical technology of tissues/cells infected with emergent diseases and biological threats



Enhance the agility, quality, and utility of diagnostics and diagnostic data:



- Support enhanced regulatory science tools and data for novel diagnostics and diagnostic approaches, for example
 - next-generation sequencing
 - real-world evidence (RWE)
- Support regulatory science approaches toward diagnostics in the context of advanced manufacturing
- Support enhanced data agility of data collection through enhanced methods associated with medical products that could be harnessed during public health emergencies



Modernize tools to evaluate MCM product safety, efficacy, and quality; and secure the MCM supply chain



- Enhance capabilities to rapidly assess the safety, efficacy and/or effectiveness of MCMs used during public health emergencies (includes use of Real-world evidence (RWE))
- Develop and validate reference materials and datasets to facilitate the development of medical products related to relevant CBRN threat agents and emerging infectious diseases
- Develop new tools and methodologies to leverage large, unstructured data sets for analysis of MCM-relevant safety and efficacy endpoints
- Develop technologies that can rapidly detect counterfeit, substandard, or adulterated MCMs;



Advance the development of tools to enable the rapid development and availability of investigational MCMs



- Develop and validate rapid testing methods to speed characterization, in-process testing, and/or lot release for MCMs
- Develop technologies and methods to accelerate collection of MCM-relevant clinical safety and efficacy endpoints
- Develop methods using digital design and manufacturing data to increase efficiency of review
- Develop technologies to support the adoption of advanced manufacturing technologies for MCMs
- Explore methods for facilitating and incentivizing the production and development of MCMs or MCM supply chain within the U.S



Ongoing Extramural Projects



Project Title	Performer	BAA Area
(H2O) A Next Generation Medical Countermeasures Scientific Platform for Regulatory Evaluation and Preparedness	DNAHIVE	III.A.2
Development of a Parenteral Challenge Model of Systemic Botulinum Neurotoxin Intoxication	Battelle Memorial Institute	III.A.1
Noninvasive Fingerprinting of Aluminum-adjuvanted Vaccines	University of Maryland	III.A.3,4
Strengthening Coronavirus Models with Systems Biology and Machine Learning	Commonwealth Science and Industry Research Organization	III.A.1-3

Ongoing Extramural Projects, cont.



Project Title	Performer	BAA Area
Expanding Next-generation Sequencing Tools to Support Pandemic Preparedness	Embleema, Inc and George Washington University	III.A.2
Cellular Signaling and Immune Correlates for SARS-CoV-2 Infection	Stanford University	III.A.1-3
FDA and Global Partners to Analyze Coronavirus Samples	University of Liverpool	III.A.1,3



U.S. FOOD & DRUG
ADMINISTRATION

Completed Extramural Projects

Project Title	Performer	Date of Completion
Survivor Studies: Better Understanding Ebola's After-Effects to Help Find New Treatments	Stanford University	8/2022
Comparison of Host Responses to EBOV Disease	United Kingdom Health Security Agency (UK HSA)	10/2022
A New Approach for Understanding Ebola Virus Pathogenesis	The Broad Institute of MIT and Harvard	9/2021
Developing a Toolkit to Assess Efficacy and Safety of Ebola Vaccines and Therapeutics	UK HSA	3/2021
Melioidosis Modeling: Research to Support a Tricky Pathogen	Defense Science and Technology Laboratory	9/2019

Completed Extramural Projects



Project Title	Performer	Date of Completion
Investigating Decontamination and Reuse of Respirators in Public Health Emergencies	Battelle	7/2016
Supporting Field Laboratory Testing of Ebola Antibodies	National Institute for Infectious Diseases	9/2015
Ensuring Appropriate Public Use of Medical Countermeasures Through Effective Emergency Communication	University of Pittsburgh Medical Center	9/2021
Organ-on-Chip Countermeasures	The Wyss Institute at Harvard University	3/2015
Cross Species Immune Reference	Stanford University	6/2015

Completed Extramural Projects



Project Title	Performer	Date of Completion
Streamlining Countermeasure Data Collection During Public Health Emergencies	Discovery Critical Care Research Network	9/2019
Optimizing Respirator Decontamination to Ensure Supplies for Emergency Preparedness	Applied Research Associated (ARA)	7/2016
Human Organ Chips for Radiation Countermeasure Development	The Wyss Institute at Harvard University	3/2024

BAA Contract Award Summary

MCMi Regulatory Science Program Awards Under the BAA FY 12 - 25 (\$ millions)

	Total	Average	Range
Base Contract¹	\$53.01	\$2.52	\$0.31 – \$5.62
Contract Option²	\$5.66	\$0.70	\$0.25 – \$1.09
Contract Modification³	\$22.83	\$1.03	\$0.25 – \$3.51
Total Award	\$81.5	\$4.25	\$0.31 – \$8.91

1. 21 base contracts
2. 9 contract options
3. 23 contract modifications

