

Office of Counterterrorism and Emerging Threats Overview of the BAA

Robert Orr, M.S. Program Manager OCET
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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

The MCMi Regulatory Science Program

- **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

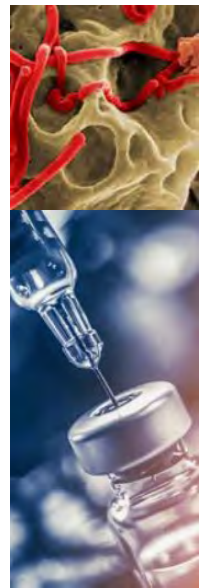
- **Funding Activities**

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



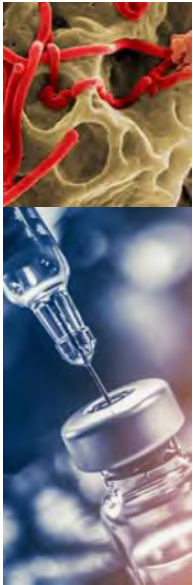
OCET BAA Contracts

- BAA contracts for OCET are typically structured with a BASE period of performance and a variable number of OPTIONS
- OCET BAA contracts are primarily managed by subject matter experts that also serve as CORs
- Typically, monthly meetings and either monthly or quarterly progress reports
- Modifications have been used for prioritized regulatory science objectives or opportunities (within scope). Some completed examples:
 - 2017: Modification of HHSF223201610018C, Sequelae and Immunopathology of Ebola Virus Infection to study Zika Virus Infection
 - 2020: Modification of HHSF223201710194C, “Comparison of EBOV Infection and Ebola Virus Disease in Animals and Humans” for SARS-CoV-2 reagent development



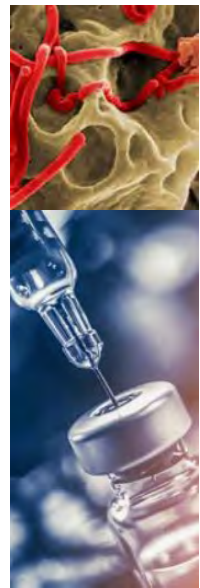
OCET BAA Contracts

- All OCET BAA contracts are considered “high complexity”; interim/final reports are provided to the Contractor Performance Rating System (CPARS)
- Contract Type: Cost Reimbursement (CR)
- For co-funded contracts (with other government agencies) FDA OCET utilizes interagency agreements to combine funds, citing the Economy Act
 - This can impact timelines for contract awards/modifications
- Maximum period of performance is 5 years
- Deliverables are typically knowledge products (technical reports, data summaries or collections in databases)
- Publications are encouraged



OCET BAA Contract Areas

- OCET 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 of the 2023 BAA.”
- Primary research areas of interest are:
 1. Develop and fully characterize tools to support MCM development under the Animal Rule or Accelerated Approval
 2. Enhance the quality and utility of 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 (includes OCET Advanced Manufacturing)



Ongoing Extramural Projects

Project Title	Performer	BAA Area
Characterizing Immunity to Ebola and Marburg to Support MCM Development	University of California, Los Angeles School of Public Health	III.A.1,3
Human Organ Chips for Radiation Countermeasure Development	The Wyss Institute at Harvard University	III.A.3, 4
FDA and Global Partners to Analyze Coronavirus Samples	University of Liverpool	III.A.1,3
Cellular Signaling and Immune Correlates for SARS-CoV-2 Infection	Stanford University	III.A.1-3
Expanding Next-generation Sequencing Tools to Support Pandemic Preparedness	Embleema, Inc and George Washington University	III.A.2
Strengthening Coronavirus Models with Systems Biology and Machine Learning	Commonwealth Science and Industry Research Organization	III.A.1-3
Development of a Model to Predict and Mitigate the Post-acute Sequelae of COVID-19	Children's Hospital of Los Angeles (CHLA)	III.A.1

Completed Extramural Projects

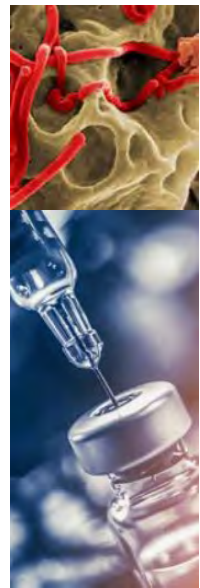
Project Title	Performer	Date of Completion
Survivor Studies: Better Understanding Ebola's After-Effects to Help Find New Treatments	Stanford University	8/2022
Comparison of Host Responses to EBOV Disease	United Kingdom Health Security Agency (UK HSA)	10/2022
A New Approach for Understanding Ebola Virus 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
Streamlining Countermeasure Data Collection During Public Health Emergencies	Discovery Critical Care Research Network	9/2019

Completed Extramural Projects (Cont.)

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
Optimizing Respirator Decontamination to Ensure Supplies for Emergency Preparedness	Applied Research Associated (ARA)	7/2016

Accomplishments Under the BAA

- Since 2012, the BAA has led to many of the successes of the MCMi:
 - 19 contract awards, including domestic and international academic/industry
 - Cutting-edge tools for development and evaluation of MCMs
 - Extensive publications (103+ from the current program of MCMi performers)
 - Partnerships:
 - NIAID has supported 3 FDA BAA contracts to advance Ebola, SARS-CoV-2, and development/qualification of Organs-on-Chips
 - Contract 75F40119C10128, “Using Vaccinated and Survivor Population of Filovirus Disease to Inform Regulatory Science” led to 2021 collaboration with DTRA for Marburg research
 - FDA/OMHHE, Contract 75F40120C00176, “Cellular Signaling and Immune Correlates for SARS-CoV-2 Infection ” is a collaboration to study COVID-19 illness in diverse populations

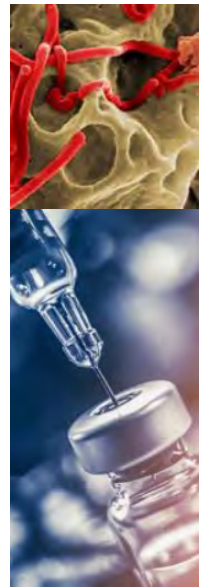


OCET BAA Contract Award Summary

MCMi Regulatory Science Program Awards Under the BAA (\$ millions)

	Total	Average	Range
Base Contract ¹	\$48.08	\$2.53	\$0.31 – \$5.62
Contract Option ²	\$2.67	\$0.67	\$0.25 – \$1.09
Contract Modification ³	\$19.53	\$1.39	\$0.25 – \$3.51
Total Award	\$70.27	\$3.70	\$0.31 – \$8.91

1. 19 base contracts
2. 4 contract options
3. 14 contract modifications



MCM Extramural Regulatory Science Applications

- **Respirator Decontamination for Emergency Reuse (2016)**
 - Applied Research Associates developed first consensus standard for UV surface decontamination (2018)
 - Battelle Memorial Institute’s hydrogen peroxide vapor decontamination method led to Critical Care Decontamination System (EUA March 2020)
- **Understanding Zika Distribution and Duration for Donor Screening (2016)**
 - UC Davis NHP studies supported FDA Guidance “Donor Screening Recommendations to Reduce the Risk of Transmission of Zika Virus from Human Cells, Tissues and Cellular-Based Products” (2017)
- **Assessing Ebola Host Response and MCM Efficacy (2018)**
 - Conducted bridging studies for FANG and WHO Ebola immune assays in collaboration with UCLA
 - Early COVID-19 studies helped establish vital ferret and NHP models through collaboration with public private sector partners (March 2020)
- **Expanding NGS Tools to Support Pandemic Preparedness and Response (2021)**
 - Developing a quality tool to allow for accurate and rapid review of regulatory-grade sequences for product development

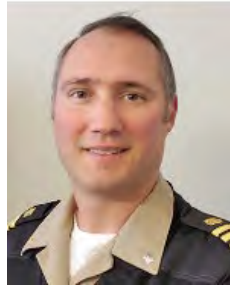
Regulatory Science Team



Tracy MacGill



Bobby Orr



Todd Myers



Tom Maruna



Mike Wagner



Susan Zhao

For More Information

www.fda.gov/medicalcountermeasures

AskMCMi@fda.hhs.gov

 @FDA_MCMi

