

Our vision is a U.S. Military Force that has a full medical countermeasure capability to fight and win in any CBRN battlespace worldwide.

Medical Chemical, Biological, Radiological, and Nuclear (CBRN) Defense Other Transaction Agreement

Presented to:
**Chemical Biological Defense Acquisition
Initiatives Forum**

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Contract Support to JPEO-CBD

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**ADVANCED DEVELOPMENT &
MANUFACTURING CAPABILITIES**

What is an Other Transaction Agreement (OTA)?



- **As the name implies – a transaction *other than* contracts, grants or cooperative agreements**
 - It is an acquisition instrument
 - Delivers a prototype that enhances mission effectiveness
 - Not subject to laws and regulations (such as the FAR) applicable to traditional procurement contracts
 - Offers great flexibility in communication with industry
 - Attracts innovative entities that have not worked with the Government/DoD
- **Authority: 10 U.S.C. §2371B**

Other Transaction Agreement Overview



- **The Medical CBRN Defense OTA was awarded by Army Contracting Command, New Jersey on 8 April 2016**
 - Term of the Agreement is 20 Years
 - Not to Exceed \$10,000,000,000
- **JPM MCS recognizes the advantages of using the OTA**
 - Encourages participation of technological innovators not accustomed to working with the Department of Defense
 - Communication with Industry is more open than in traditional Federal Acquisition Regulations (FAR) based contracts
 - Streamlined Processes
- **Joint Science and Technology Office (JSTO) are partners in the OTA**

Requirements for OTA Use



- **One of the following conditions must be met:**
 - a. There is at least one Non-Traditional Defense Contractor (NTDC) or non-profit research institution participating *to a significant extent or*
 - b. All significant participants in the transaction other than the Federal Government are small businesses or NTDCs or
 - c. At least 1/3 of the total cost of the project is paid by funds provided by sources other than the Federal Government or
 - d. The Senior Procurement Executive determines that exceptional circumstances justify the use of a transaction
- **Competitive procedures must be used**
- **Must deliver a prototype**
 - The OTA is an acquisition instrument which delivers something of direct benefit to the Government
 - Terms such as “support” or “stimulate” are not appropriate for OTAs

Key Players



- **Army Contracting Command Picatinny, NJ – Warranted Agreements Officer**
- **Joint Project Manager, Medical Countermeasures Systems**
- **Assistant Program Manager (APM)/Agreements Officer's Representative**
- **OTA Program Manager**
- **Medical CBRN Defense Consortium (MCDC)**
- **Consortium Management Firm (CMF) – Advanced Technology International (ATI)**

OTA Prototype Projects to Date



- **FY16 RPP (6 projects)**

- PRE 16-01 Fill finish of VEE Virus Like Particle (VLP) Bulk Drug Product - **Awarded**
- PRE 16-02 Development of Monoclonal Antibodies (mAbs) Against Aerosolized Botulinum Toxin Serotypes- **Awarded**
- TRE 16-03 D4 Autoinjector – **Awarded**
- PRE 16-04 Lyophilized Formulation and Manufacturing for WEVEE Vaccine – in basket
- PRE 16-05 VEE Monovalent VLP Phase I Clinical Study – **Awarded**
- PRE 16-06 EEEV ATD - in basket

- **RPP 17-01 (2 projects)**

- TRE 17-01 Alphavirus Monoclonal – in basket
- TRE 17-02 Efficacious Antiviral Countermeasures - Basis of Selection pending

- **RPP 17-02 (3 projects)**

- PRE 17-03 Marburg – selection announced, in negotiation
- PRE 17-04 Multi-target VEEV – in final negotiation, funding obligated
- DET 17-05 Man Portable Diagnostics – **Awarded**

- **RPP 17-03 (3 projects)**

- PRE 17-06 VEE VRP Phase 1 Clinical – in basket
- DET 17-07 Man Portable Diagnostic System, Expanded Scope - selection announced, in negotiation
- DET 17-08 Chem Exposure In Vitro Dx –selection announced, in negotiation

❖ **Total Awarded to date - \$101,260,000; Funded \$32,268,000**

OTA Prototype Projects to Date



- **FY 18 - 8 Projects Released,**

- **18-01: 3 projects,**

- **(DET 18-01):** Rapid Single-molecule-based Diagnostic Platform Assessment of Pathogen Susceptibility to Anti-microbial Agent
- **(DET 18-02):** Development of Multiplex Molecular Diagnostics Based on CRISPR-Cas and other Synthetic Biology Approaches
- **(TRE 18-03):** Late Discovery and Development of Therapeutics to Treat Symptoms of Exposure to Organophosphorus Chemical Warfare Nerve Agents

- **18-02: 2 Projects,**

- **(TRE-18-04):** Relevant Large Animal Model Prototypes for Organophosphorus (OP) Nerve Agent (NA) Intoxication and Therapeutic Evaluations
- **(TRE-18-05):** Development of a Food and Drug Administration (FDA)-approved medical countermeasure (MCM) for treatment of multi-drug resistant bacterial biological warfare agents delivered via an aerosol route of exposure.

- **18-03: 3 Projects,**

- **(PRE-18-06):** Enhanced circulatory stability and GMP manufacturing of phosphotriesterase (PTE) / organophosphorous hydrolase (OPH) variants as prophylaxis against a broad-spectrum of organophosphorus nerve agents (OPNAs)
- **(TRE-18-07):** Discovery and Development of New Therapeutics to Treat Symptoms of Exposure to Organophosphorus Chemical Warfare Nerve Agents
- **(TRE-18-08):** Proof of Concept Formulations for CBRN Medical Countermeasures to be administered via Autoinjector

OTA Prototype Projects to Date



- **FY 18 – 7 Additional Projects Planned for Release**
- **Planned Release 18-04: 6 Projects**
 - **(DET-18-10):** Multiplex Vertical flow Paper-based Immunoassay (VPI) Diagnostic System
 - **(DET-18-11):** Assay Development for the Identification of Markers of Venezuelan Equine Encephalitis Virus Infection in Animal Models
 - **(Det-18-12):** Burkholderia Species Immune Assays
 - **(TRE-18-13):** Prophylaxis/Pretreatment Against Francisella tularensis
 - **(PRE-18-14):** Next Generation Devices for Delivery of Nucleic Acid Vaccines
 - **(PRE-18-15):** Francisella tularensis Immune Assays
- **Planned Release 18-05: 1 Project**
 - **(PRE-18-09):** Development of monoclonal antibodies as medical countermeasures (MCM) against aerosolized Plague infection.

Typical Procurement Timeline



Planned Schedule:

Project Planning Phase	79d	} Total Schedule from Data Call to Project Agreement 225 Working Days
RPP Phase	1d	
White Paper Phase	27d	
Proposal Phase	58d	
Selection & Negotiation Phase	59d	
Execution	1d	

Actual Timeline for 5 Awards*
Average - 210.2d

Actual Lead Time for Pending Awards *
Average – 217.6d

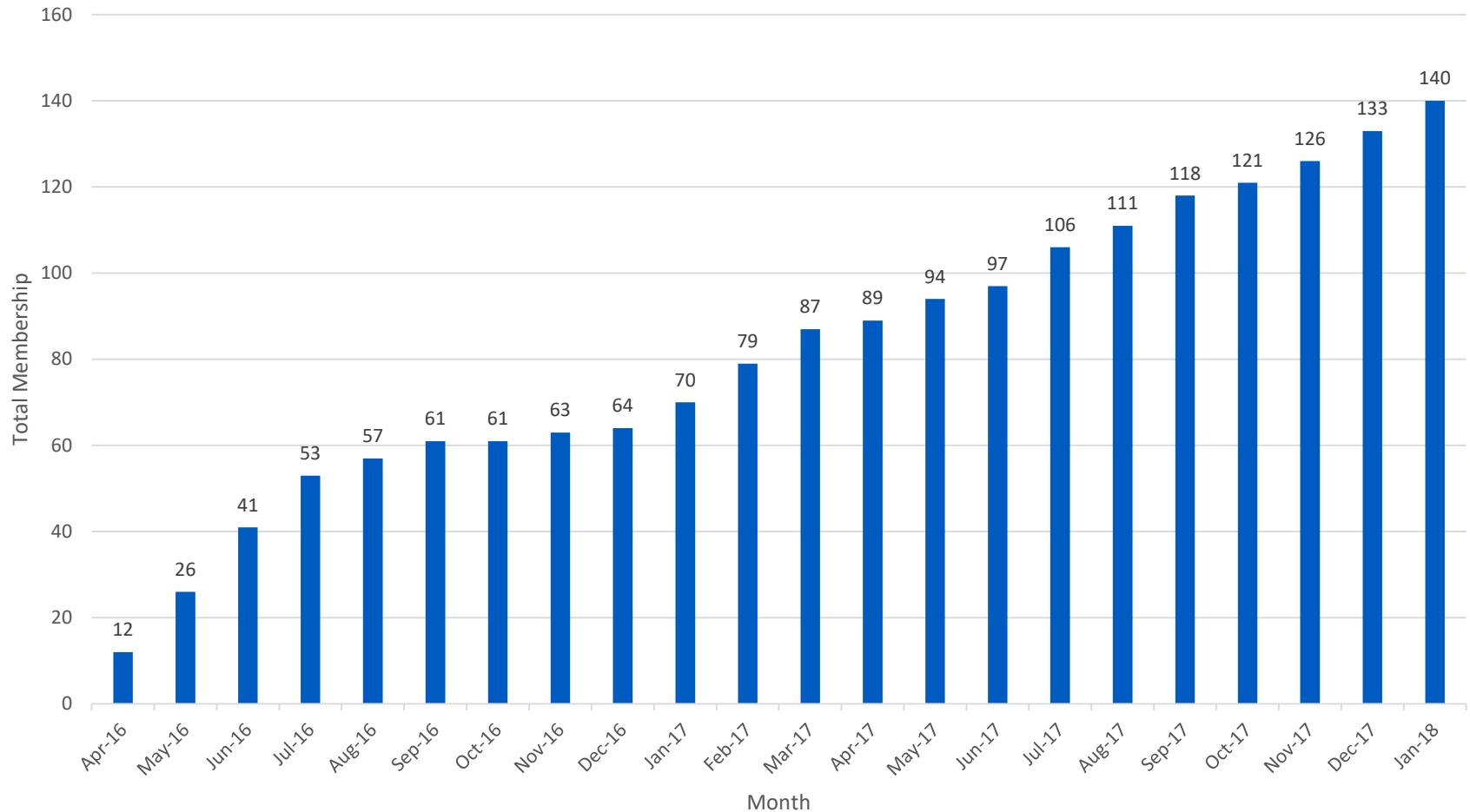
Actual Lead Time for Basket Decision (8ea)*
Average – 161.8d

* Actual Timelines do not include Project Planning Phase

Medical CBRN Defense Consortium (MCDC)



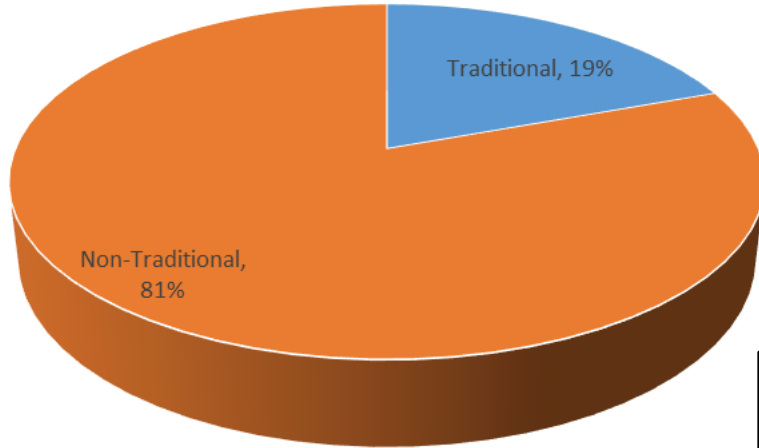
MCDC Membership Growth Trend



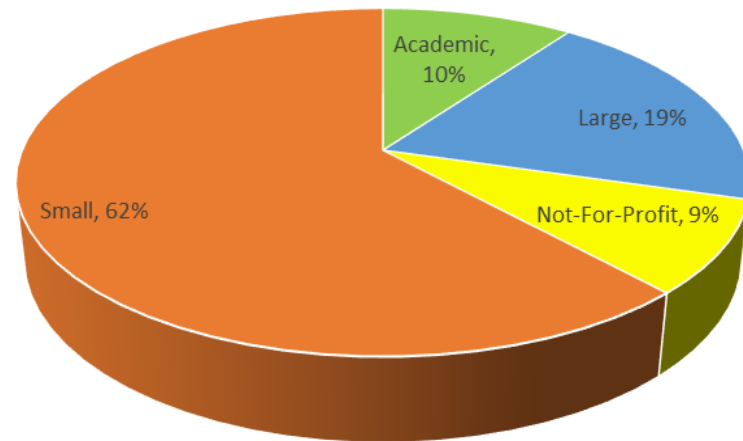
MCDC Membership Distribution



MCDC - Non-Traditional / Traditional Distribution



MCDC Business Class Distribution



How to Join Medical CBRN Defense Consortium



- Visit <http://www.medcbrn.org/members.html#howtojoin>
 - Complete and sign the Membership Application
 - Review and sign the Articles of Collaboration
 - Provide DD2345 Certification Number
 - Military Critical Technical Data Agreement
 - Instructions available at www.medcbrn.org
 - If operating under Foreign Ownership, Control Or Influence (FOCI)
 - DSS approved mitigation plan OR signed Export Compliance Acknowledgement Form
 - Membership limited to US firms/entities or US-based affiliates of foreign firms/entities
 - Email completed application to MCDC@ati.org
- For all inquiries contact Mike Stebbins
 - mike.stebbins@ati.org



MCDC
Medical CBRN
Defense Consortium
Prevent | Diagnose | Treat