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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CACI International
Contract Support to JPEO-CBD

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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
• 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
• 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 Antibacterial 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,**
  
  • **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-18-12): 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:**

<table>
<thead>
<tr>
<th>Phase</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Planning Phase</td>
<td>79d</td>
</tr>
<tr>
<td>RPP Phase</td>
<td>1d</td>
</tr>
<tr>
<td>White Paper Phase</td>
<td>27d</td>
</tr>
<tr>
<td>Proposal Phase</td>
<td>58d</td>
</tr>
<tr>
<td>Selection &amp; Negotiation Phase</td>
<td>59d</td>
</tr>
<tr>
<td>Execution</td>
<td>1d</td>
</tr>
</tbody>
</table>

Total Schedule from Data Call to Project Agreement: 225 Working Days

**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*
MCDC Membership Distribution

MCDC - Non-Traditional / Traditional Distribution

- Non-Traditional, 81%
- Traditional, 19%

MCDC Business Class Distribution

- Small, 62%
- Large, 19%
- Academic, 10%
- Not-for-Profit, 9%
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