Diagnostics and Biodosimetry Programs

BARDA / CBRN Medical Countermeasures Division

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Branch Chief, CBRN Diagnostics

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Procurement Sensitive - FOUO
Topics

• BARDA Diagnostics Programs
  — Open solicitations
  — Overarching Strategy
  — Dx Usage Scenarios

• CBRN Diagnostics Program Details
  — Radiation Diagnostics Program
  — Biological Agent Diagnostics
  — Chemical Agent Threat Diagnostics

• CBRN Rolling BAA
  — Secrets to Success for Dx White Paper Submissions
BARDA Diagnostics Programs

Office of the Secretary

Assistant Secretary
Preparedness & Response

Diagnostics Functions within these groups

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Open Diagnostics Solicitations

• Influenza Division
  – BAA-BARDA-11-100-SOL-00013 (Announcement)

• Strategic Science and Technology (SSTD)
  – BARDA_BAA_11-100-SOL-00001

• CBRN Division
  – BARDA-CBRN-BAA-11-100-SOL-00009
Overarching Strategy

• Purpose - discrimination of disease resulting from exposure to CBRN agents, pandemic influenza, or other emerging threats during an outbreak or CBRN incident
  – Informed treatment decisions for use of medical countermeasures:
    • Vaccines, antibiotics
    • Therapeutics
  – Targeted U.S. population:
    • General population, pediatrics, geriatrics
    • Special populations (pre-existing conditions, underlying diseases)
  – Sample types:
    • Clinical specimens (blood, swabs, urine,....)
  – Regulatory authority: FDA

• Product Development Phases
  – Advanced Development (Initiation of Design Control to FDA filing)
  – Potential Acquisition
Diagnostic Use Scenarios

• **Point of Care Diagnostics**
  - Limited availability of diagnostic platforms
  - Fund development:
    - Assays
    - Diagnostic platforms
    - New/advanced diagnostic approaches
  - Intended settings for use:
    - Physician’s office/labs, rural & public health clinics
    - Community hospitals
    - Emergency rooms
    - First responders in temporary facilities (tents, shelters, schools, RTR*, etc.)

*RTR = Radiation Triage, Treatment, and Transport
Diagnostic Use Scenarios (continued)

• High Throughput Laboratory Diagnostics
  — Wide availability of diagnostic platforms in clinical diagnostic labs
  — Fund development:
    • Assays for use on existing diagnostic platforms
    • Platform development only if technology not compatible with existing platforms
  — Intended settings for use:
    • Clinical diagnostic laboratories (LRN, commercial hospital labs, commercial reference labs, expert federal, state and local government labs)
CBRN Diagnostic Programs
## CBRN Diagnostics Programs

<table>
<thead>
<tr>
<th>Program</th>
<th>FY09</th>
<th>FY10</th>
<th>FY11</th>
<th>FY12</th>
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</thead>
<tbody>
<tr>
<td>Radiation Diagnostics</td>
<td>I</td>
<td>A</td>
<td>E</td>
<td>E</td>
</tr>
<tr>
<td>Biological Agent Dx</td>
<td>I</td>
<td>A</td>
<td>E</td>
<td></td>
</tr>
<tr>
<td>Chemical Agent Dx</td>
<td>I</td>
<td>A?</td>
<td></td>
<td></td>
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</tbody>
</table>

I = Program Initiation  
A = Initial Program Awards  
E = Program Execution
Radiation Diagnostics
Radiation Diagnostics
Programs of Interest

• Active:
  – Biodosimetry – 10 Awards, 7 Active Programs
    • Interested in additional promising technologies

• Additional Development Interests
  – Self Assessment tool
    • Device to be carried by interested parties to detect the quantity of radiation received.
  – Improvements to “Gold Standard” Dicentric Chromosome Assay
    • Automation
    • Image Processing
  – RadioBioassay
    • Measurement of inhaled or ingested fallout
## BARDA Biodosimetry Program
(Active Programs)

<table>
<thead>
<tr>
<th>Active</th>
<th>Contract</th>
<th>POC or HT</th>
<th>Protein Exp</th>
<th>DNA Damage</th>
<th>DNA Exp</th>
<th>VOCS</th>
<th>Ocular</th>
<th>EPR</th>
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<tbody>
<tr>
<td>✓</td>
<td>MesoScale Diagnostics, LLC</td>
<td>Both</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>✓</td>
<td>SRI International</td>
<td>POC</td>
<td>✓</td>
<td></td>
<td></td>
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<tr>
<td>✓</td>
<td>Northrop Grumman</td>
<td>HT</td>
<td></td>
<td>✓</td>
<td></td>
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<tr>
<td>✓</td>
<td>Duke University</td>
<td>HT</td>
<td></td>
<td></td>
<td>✓</td>
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<tr>
<td>✓</td>
<td>Arizona State Univ</td>
<td>HT</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
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<tr>
<td>✓</td>
<td>ChromoLogic, LLC</td>
<td>POC</td>
<td></td>
<td></td>
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<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>✓</td>
<td>Menssana, Inc.</td>
<td>POC</td>
<td></td>
<td></td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Biodosimetry Preferred Attributes

<table>
<thead>
<tr>
<th></th>
<th>Point of Care Device (POC)</th>
<th>High Throughput Device (HT)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type of result:</strong></td>
<td>Qualitative</td>
<td>Quantitative (accuracy $\pm 0.5\text{Gy}$)</td>
</tr>
<tr>
<td><strong>CONOPs:</strong></td>
<td>Initial Triage / Sorting</td>
<td>Injury Assessment / Treatment</td>
</tr>
<tr>
<td><strong>Exposure level:</strong></td>
<td>2 Gy (200 rad) (threshold)</td>
<td>Range: 0.5 – 10 Gy</td>
</tr>
<tr>
<td><strong>Ease of operation:</strong></td>
<td>Easy to operate, minimal complexity (requires minimal training; CLIA waived)</td>
<td>Laboratory instrument—more labor intensive, requires training</td>
</tr>
<tr>
<td><strong>Device characteristics:</strong></td>
<td>Integrated components—no separate sample preparation</td>
<td>May include separate components as needed. High automation desired.</td>
</tr>
<tr>
<td><strong>Intended use:</strong></td>
<td>Tents, shelters, open settings</td>
<td>Labs, hospitals, fixed facilities</td>
</tr>
<tr>
<td><strong># Patients / Event</strong></td>
<td>Up to 1,000,000 in 6 days</td>
<td>Up to 400,000 (may need multiple assessments)</td>
</tr>
<tr>
<td><strong>Time to result:</strong></td>
<td>Rapid but individual sample result (&lt; 30 minutes)</td>
<td>Up to 24 hours</td>
</tr>
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</table>
Biologic Agent Diagnostics
## Biological Agents of Interest
### (In Clinical Samples)

<table>
<thead>
<tr>
<th>Threat Agents – PHEMCE Implementation Strategy</th>
<th>PHEMCE</th>
<th>CDC</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bacillus anthracis</strong> (Anthrax)</td>
<td>✓</td>
<td>A</td>
</tr>
<tr>
<td>Botulinum neurotoxin (Botulism)</td>
<td>✓</td>
<td>A</td>
</tr>
<tr>
<td><strong>Burkholderia mallei</strong> &amp; <strong>pseudomallei</strong> (Glanders &amp; Meloidosis)</td>
<td>✓</td>
<td>B</td>
</tr>
<tr>
<td>Filoviruses (Ebola &amp; Marburg)</td>
<td>✓</td>
<td>A</td>
</tr>
<tr>
<td><strong>Francisella tularensis</strong> (Tularemia)</td>
<td>✓</td>
<td>A</td>
</tr>
<tr>
<td>Junin virus (Argentine Hemorrhagic Fever)</td>
<td>✓</td>
<td>A</td>
</tr>
<tr>
<td><strong>Rickettsia prowazekii</strong> (Typhus)</td>
<td>✓</td>
<td>B</td>
</tr>
<tr>
<td>Variola virus (Smallpox)***</td>
<td>✓</td>
<td>A</td>
</tr>
<tr>
<td><strong>Yersinia pestis</strong> (Plague)</td>
<td>✓</td>
<td>A</td>
</tr>
</tbody>
</table>

*** Future Needs in Review

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Biological Agent
Additional Topics of Interest

• High Throughput: Candidate clinical reagents for use on existing, fielded high throughput platforms
• Point of Care: Platforms and Assays for diagnosis of diseases from threats of interest

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Chemical Agent Diagnostics
Chemical Agents of Interest

• Agents where Dx in clinical samples could inform treatment following low level exposure

• Candidates – Draft
  — Phosgene
  — VX
  — Sulfur Mustard
Secrets to Success

Diagnostic white papers submitted under
BARDA-CBRN-BAA-11-100-SOL-00009
Advanced Research And Development Funds

• Funding may be used to further the development and maturity of Diagnostic Systems toward FDA clearance/approval.

• These funds should not be used beyond the FDA clearance/approval milestone.

• Development of Manufacturing Capabilities, beyond those needed to manufacture materials for clinical studies, are not appropriate with these funds.

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Secrets to Success

1. Propose development of a product, not just a technology
2. Provide data to establish current TRL of the product
   - Both Hardware and Biologics / Assay
   - TRL 4 or greater (Defined in Attachment 1)
   - Specific data for threats proposed to address
3. Describe Entire Path from Current State to FDA submission
   - Address Team Members and Capabilities
   - Include a well thought-out regulatory plan
   - Address technical improvements and challenges
4. Manufacturing & Commercialization Plan
   - Volume manufacturing is not covered with AR&D funds, but describe your plan for production and commercialization
5. Review Biodosimetry information in Attachment 8
   - Provides insight into USG’s envisioned ConOps for a large scale event
Point of Contract

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