BARDA Diagnostics & Medical Devices Overview

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BARDA Industry Day
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Diagnostics & Medical Device (DMD) Division: Product Areas

Diagnostics

- Influenza Diagnostics
- Radiation Exposure Dx (Biodosimetry)
- Biothreat Agent Diagnostics
- Antimicrobial Resistance Diagnostics
- Innovation

Medical Devices

- Ventilators
- Respiratory Protection Devices
Key Initiative: Point of Care Molecular Diagnostics

- Innovation to bring diagnostics into the Physicians Office and the home
- Empower patients, reduce spread of disease, and reduce overall health care costs
- Broad Applicability to DMD Portfolio
  - Influenza
  - Biothreats
  - Antimicrobial Resistance
  - Emerging Disease
- Improved Sensitivity and Specificity
- Utility
  - Physician’s Offices
  - Emergency Departments
  - Remote Settings
  - Home Use
- Current Projects
  - Abbott (Alere) - NextGen Isothermal Influenza Diagnostic
  - Roche LIAT – C. diff + MRSA assays
  - Tangen - Anthrax
Key Initiative: Simplified Sequencing

- Broad Applicability
  - Influenza Subtyping
  - Antimicrobial Resistance
  - Emerging Infectious Disease (Rapid Deployment)
  - Biothreat Diagnostics
- Rapid Identification of Dangerous Pathogens & Subtyping
- Simplified Interface Appropriate for Clinical Lab Use
- Current Projects
  - DNA Electronics PISCES
Influenza Dx

Overview
- Initiated development in 2006
- $120M Invested
- 4 FDA clearances
- Current Projects
  - Point of Care
    - Flu A/B Molecular + Seasonal (Abbott (Alere))
  - Laboratory
    - Flu Subtyping (InDevR & DNAe)

Funding Interest
- Point of Care - Flu A/B + Seasonal
- Home – Flu A/B
Overview

- Initiated development in 2009
- $365M Invested
- 4 Products Transitioned to Project Bioshield
- 1 Pre-EUA package submitted
- 510K filings expected 2018-2019

Funding Interest

- Self assessment tools with no specialized pre-distribution required
- Biodosimetry systems – significantly improve clinical response capability over PBS products
### Biodosimetry: Project BioShield

In Development

<table>
<thead>
<tr>
<th>Type</th>
<th>Developer</th>
<th>Key Partners</th>
<th>Technology</th>
<th>FDA 510K Filing</th>
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<tbody>
<tr>
<td>Lab</td>
<td>DxTerity</td>
<td>Duke University, Thermo-Fisher</td>
<td>Gene expression</td>
<td>2018 *</td>
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<tr>
<td>Lab</td>
<td>MRI Global</td>
<td>Arizona State U, Thermo-Fisher</td>
<td>Gene expression</td>
<td>2018</td>
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<td>Lab</td>
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<td>Meta Systems</td>
<td>Cytology – micronuclei</td>
<td>2019</td>
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<tr>
<td>POC</td>
<td>SRI International</td>
<td>DCN, Gener8, Web Industries</td>
<td>Protein Expression</td>
<td>2019</td>
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</tbody>
</table>

* Pre-EUA submitted
Anthrax Diagnostics

Overview

• Development initiated in 2012
• $60M Invested to date
• 1st FDA 510K filing scheduled in 2018
• Natural history studies & antibody development @ CDC
• Point of Care Diagnostics
  • Toxin Detection (SRI, InBios)
  • Molecular (Tangen)
• Laboratory Diagnostics
  • Toxin Detection (First Light Bioscience)
  • Molecular (MRI Global)
  • Sample Concentration (DNAe)

Funding Interest

• Point of Care Diagnostics – Molecular & toxin diagnostic solutions
• Laboratory Diagnostics – High throughput diagnostic solutions
Overview

- Initiated Development in 2012
- $20M Invested to date
- 2 FDA Emergency Use Authorizations (EUA)
- BoNT MS assay for LRN Labs
- Ebola Lateral flow with OraSure
- Burkholdaria & Plague Marker Studies with SRI

Funding Interests

- Extensive Investment Needed
  - Marker Characterization
  - Point of Care Diagnostics
  - Lab Diagnostics

Threats

- *Botulinum toxin* (botulism)
- *Burkholderia mallei* (glanders) & *pseudomallei* (melioidosis)
- Ebola and Marburg viruses
- *Francisella tularensis* (tularemia)
- *Rickettsia prowazekii* (typhus)
- *Yersinia pestis* (plague)
- Smallpox (orthopox genus virus assays acceptable)
Overview

- Development initiated in 2016
- $38 M Invested to date
- 1 FDA Clearance
- Point of Care Diagnostics (POC)
  - Roche LIAT C. difficile & MRSA
  - Laboratory Diagnostics
    - ID & AST with First Light Biosciences (Anthrax + UTI)
    - Molecular (Targeted Sequencing) with DNAe

Funding Interests

- Extensive Investment Needed
  - Laboratory & POC
  - Viral vs. Bacterial
  - ID & AST
  - Molecular
  - Phenotypic Susceptibility
  - Speed up clinical Trials
• BARDA & NIH Funded - $20M total of all Prizes
• 3 Tiered System
  • Stage 1 Semifinalists named in March 2017
  • 3 years to deliver prototype diagnostics
• Managed by Capital Consulting Group

Semifinalists
• Richard Anderson, Becton, Dickinson and Company
• Sophia Koo, Brigham and Women's Hospital
• Don Straus, First Light Biosciences, Inc
• Ephraim Tsalik, Duke University,
• Joe Frassica, Philips North America,
• Gregory Loney, Click Diagnostics, Inc
• Ravi Kant Verma, Spectral Platforms, Monrovia, California
• Ken Babock, Affinity Biosensor
• Ann Falsey, University of Rochester
• Ellen Foxman of Yale University
Emerging Disease: Zika Dx + Blood Screen

Overview

- Initiated Development in 2016
- $39M Invested to date
- 4 EUA’s, 1 FDA Approval, 2 INDs
- Laboratory Dx
  - InBios International (EUA)
  - DiaSorin Inc. (EUA)
  - Siemens (EUA)
- Point of Care Dx
  - ChemBio Diagnostics (EUA)
  - OraSure Technologies
  - InBios International
- Blood Screening
  - Roche (FDA Approved)
  - Grifols (IND)

Funding Interest

- No Additional Funding Available
Overview:
- New For FY2018 BAA
- Less Mature Technologies
- Needed to enable the next generation of diagnostics

Funding Interests:
- Innovative Sample Collection Devices
- Host & Pathogen Markers
- Wearable Sensors
- Novel Device Technology
- Improved Assay Chemistries
Respiratory Support

Overview
- Initiated Development in 2010
- $31M Invested to date
- 1 FDA cleared product
- Current Projects
  - Ventilators
    - Next generation stockpile ventilator (Philips)
  - Respiratory Protective Devices (RPDs)
    - Reusable Mask (ARA)
    - High Speed Mask Production Line (Halyard)

Funding Interests
- Ventilators & RPD technologies that substantially reduce the cost of preparedness for these devices - purchase, storage, and /or distribution cost
Questions?

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Solicitation: BAA-18-100-SOL-00003
Online Resources

https://www.medicalcountermeasures.gov/home.aspx
  • Portal to BARDA: Register to request a TechWatch meeting

https://www.fbo.gov/ ("FedBizOpps")
  • Official announcements and info for all government contract solicitations

https://www.usajobs.gov/
  • Join the team!

https://www.phe.gov/about/BARDA/Pages/default.aspx
  • Program description, information, news, announcements