

Chemical Biological Defense Acquisition Initiative Forum (CBDAIF)

Medical Sector Report

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Companies in Sector

Abbott IBIS	Emergent Biosolutions	PharmAthene
AETHLON MEDICAL INC	Galloway & Associates, LLC	Rapid Pathogen Screening, Inc. (RPS)
Battelle	GLAXOSMITHKLINE	Research International, Inc.
Baxter Pharmaceuticals	IITRI	Sarepta Therapeutics
BBI Research, Inc.	InBios	SAS Support, LTD.
BioFire	INHIBIKASE THERPAEUTICS	Soligenix
CEMPRA PHARMACEUTICALS INC	Luminex	Southwest Research Institute
Chem Bio Diagnostics (CBDx)	Matrix Sensors, Inc.	Synprosis, S.A.
Chimerix	Mesoscale Diagnostics (MSD)	Tekmira Pharmaceuticals
Colorado State Univerity	MSP Corporation	Texas Biomedical Research Institute
Conafay and Associates	Murtech, Inc.	The East End Group
Corium International, Inc.	Nanotherapeutics	Rempex Pharmaceuticals
Crucell N.V. (a Johnson and Johnson company)	Novartis Pharmaceuticals	Tiber Creek Partners
CytoSorbents Corporation	Parabon NanoLabs	University of Wisconsin
Dynport Vaccine Company (DVC)	PaxVax	VAXIN INC
Elusys	Pfenex Inc	Xoma, LTD.

This remains a “work-in-progress”
OTA consortia and their respective Team-mates are not listed

Health of Sector



- I would assess the Health of the Medical Sector to be “Good”
 - Very few of these companies are solely reliant on DoD Programs or funding
 - Most have a diversified government portfolio which includes work for NIAID or BARDA (more so than DoD)
 - Identification of “New Medical Sector Companies” remains a challenge
 - Medical Sector Lead transition to Sean Kirk (SVP & COO, Emergent Biodefense) should be smooth and relatively painless

Major Sector Concerns

- JPM-MCS plan to implement and use Other Transaction Agreement (OTA) under 10 U.S.C. §845 for Detection (Diagnostics), Prevention, and Treatment remains somewhat of a mystery:
 - There are currently three OTA Consortia “in play” and aggressively Teaming to portray a full suite of capabilities anticipated medical capabilities
 - It is not at all clear just how JPM-MCM is going to make a selection to award an OTA vehicle to one of these, or when
 - In my discussions with the respective leads for both Consortia, I am not sure that even THEY understand how Tasks or Pilot Projects will work downstream
 - It’s not altogether clear exactly what ‘problem’ JPM-MCS believes will be mitigated by this acquisition approach, aside from the continual lack of a compelling business model for vaccine and pharmaceutical firms to develop and pursue CB Medical Countermeasures
 - For instance, BARDA has had OTA authority for a decade and has exercised only five times – for very focused product engagement with industry
 - Uncertainty is further increased by confusion on how the new ADM (Advanced Development/Manufacturing) facilities will be incorporated: if the early developmental burden is on the drug company and there’s a potential that DoD will ultimately want to produce the product in the ADM, what’s left in the middle (Pilot Scale through early Phase 1 trials) is anything but a “sweet spot”

Major Sector Concerns

- “Utilization Plan” for the ADM facility remains a concern and/or uncertainty for those companies with their own manufacturing capabilities
- Roadmaps in the 30 year S&T Plan helpful, however is remains unclear “where” Medical Sector companies should enter:
 - early S&T? Academic Collaboration?
 - Product development on their own?
- It is virtually impossible for any firm to ‘lean into’ development and test of a medical countermeasure against “Emerging” threats (C or B) without far more definition of those threats and their relative priorities

Sector Expectations for CBDAIF Meeting Outcomes

- Continued, if not expanded, candid and forthcoming discussions with Industry that allow for:
 - Articulating the Medical CB Business Case to corporate management
 - More rational projection and application of internal R&D resources in anticipation of needed products and testing models in a *timely* manner
 - Prioritization and development of natural history and animal models *far in advance* of product testing needs