



Chemical Biological Defense Acquisition Initiatives Forum (CBDAIF)

MEDICAL COUNTERMEASURES (MCM) SECTOR REPORT

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Presented by Sector
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Companies in Sector

- **Big Pharma**
 - Examples are Janssen, Sanofi, GSK, Merck, and Pfizer
- **Specialty Pharma**
 - Examples are Emergent Biosolutions, Bavarian Nordic and Ology
- **Small Companies**
 - Examples are Profectus, Kineta, AktiVax and Mapp Pharmaceuticals
- **CMOs**
 - Examples are ABL and Fujifilm Pharmaceuticals,
- **CROs**
 - PPD, IITRI, SRI
- **Non-profits**
 - Examples are Battelle, MRI Global, SwRI, and CUBRC
- **Consultants**
 - Examples are Latham, Tiber Creek, and SMI
- There are 191 members in the MCDC Consortium at this point in time, 84% NTD and 16% Traditional, majority of Traditional are Non-profits. Not all company examples in the sector types above have joined MCDC.

MCM Sector Health

- **Current Health**

- Medical Countermeasure Sector capability to support DoD and others remains stronger in certain areas where there is a synergistic commercial need like infectious disease and weaker in other areas such as chemical and radiological. Of note, there has been a **weakening of the infectious disease capabilities in the pharma market due to market forces, and a potential strengthening in the diagnostic device market due to positive shift in FDA regulation**

- **Future Health**

- Medical Countermeasure Sector capabilities remain threatened due to lack of clarity on future business opportunities, lack of clarity on funding, unexpected shifting of funds, lack of coordination between agencies, lack of granularity on procurement volumes, low margins on small procurement volumes and the lack of other incentives beyond low sales

- **Notable**

- ***Bad News: Pharma has given strong indications (Sanofi, GSK, Merck, Novartis) of exiting from the infectious disease arena***

- *Example - Novartis, a Switzerland-based pharmaceutical company, announced in July that it will shut down its antibacterial and antiviral research programs and lay off approximately 140 employees.*
- *Example – Evotec signed on 15 June 2018, to integrate Sanofi's infectious disease unit including licensing-in the majority of Sanofi's infectious disease research portfolio, has been successfully closed with effect from 01 July 2018.*

- ***Good News: Diagnostics***

- *“In pursuing a new framework for the appropriate regulation of diagnostics, there will be difficult policy decisions to make and tradeoffs on any path to legislation. We know that the FDA must be flexible and open minded to new approaches that best meet the needs of patients so that patients can have confidence in the results and the treatment that comes from it. That’s the spirit of our proposed reforms.” Remarks by Scott Gottlieb, M.D., Commissioner of Food and Drugs*

Major Sector Concerns

- Shifting priorities and funds make it difficult to align with programs and priorities
- Continue to request greater transparency on requirements (BOT eg)
- PRISM excited many but lack of clarity has slowed industry interest
- Lack of feedback on responses from certain RPPs of concern to team members
- Lack of ability to participate by foreign entities in MCDC
- Request more time between WPs and RPPs for open conversation
- Speed of contracting slow on majority of RPPs, not the promised speed
- MCDC Project Status sheet should be updated on the website
- Would like greater clarity on future Synthetic Bio requirements
- Questions remain on if partnership with ADM is required to be successful on certain programs

Other Sector Issues

- Award announcements for MCDC would be welcomed to show progress and where the work is going
- Encourage a mechanism for fast small funding to evaluate innovative state of the art technology to show POC, similar to DRIVe EZ BAA.
- Better definition of what it means to be in MCDC basket and if MCDC will be using the basket
- Overlap between X number of consortia and outlay of funds for small businesses
- Better definition of priorities
- Request updated plans to industry on where JPEO is now going (i.e. revision of 5 yr plan)
- Small companies are still finding the volume and timing of proposals between and amongst agencies to be difficult to manage
- Desire for more combined funding and communication amongst the agencies for similar or same products

Positive Feedback

- Priority review vouchers continue to be well received and other similar mechanisms should be considered
- Open dialogue within the MCDC Consortium has been welcomed and received positive accolades throughout the WP, RPP and negotiation process
- Non-profits are partnering with teams more often due to the change in the OTA regulations and are more aggressively pursuing business in this arena