

Advanced Planning Brief to Industry

8-9 September 2010



Transformational Medical Technologies
“Protecting the Warfighter and the Nation”



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Transformational Medical Technologies



Mission: *Protect the Warfighter from Emerging and Genetically Engineered Biological Threats by Providing a Novel Response Capability from Identification of Pathogens to the Development of Medical Countermeasures (MCM)*



DoD Medical Countermeasures Advanced Development Overview



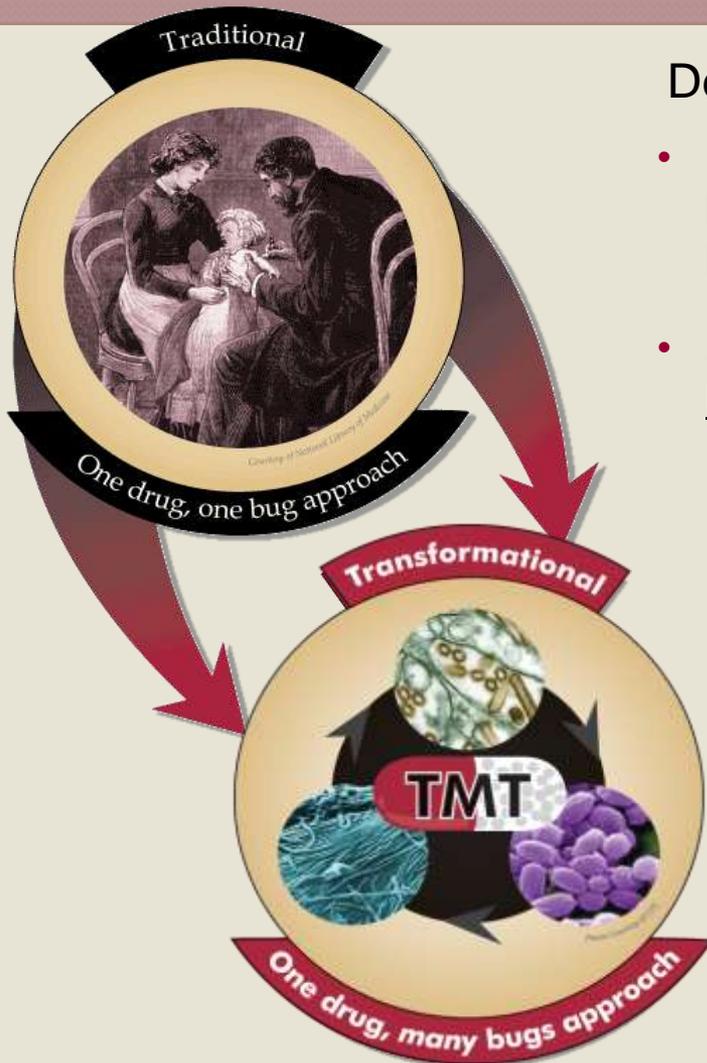
- Background on DoD Medical Countermeasures Advanced Development
- Tailoring of Medical Advanced Development within DoD
- Tailoring of DoD/CBD Medical Countermeasures FDA approval process – Animal Rule
- Acquisition Reporting Requirements
- Integrated Product Team Approach

Vision



- **Vision:** Protect the Warfighter and the Nation
- TMT is Especially Focused on **Advanced** Biological Threat Agents
 - *De Novo* or Genetically Engineered Pathogens
- Requirements derive from:
 - Quadrennial Defense Review – 2006
 - HSPD-18: Medical Countermeasures Against Weapons of Mass Destruction - January 2007
 - Chemical and Biological Defense’s Medical Research, Development, Test & Evaluation Plan – December 2007
 - National Strategy for Countering Biological Threats – November 2009

TMT is...



Designed to Spur Innovative Research to Develop:

- *Technologies* to Characterize Unknown Pathogens and Rapidly Develop medical Countermeasures to Newly Identified Threats
- *Broad Spectrum Countermeasures* (One Drug, Many Bugs)

A Program to Develop Platform Technologies to Accelerate MCM Development. Platforms should Produce MCMs that are:

- FDA Approved
- Broad Spectrum
- Produced Using a Rapid Response Capability Adaptable to New Threats

Critical Path for Biothreat Incident Responsiveness



Characterize Pathogenic Agent

- *Pathogen Identification*
- *Genetic Sequencing*
- *Informatics Analysis*
- *Validation of Agent*



Assess MCM Intervention Strategy

- *Disease Pathogenesis*
- *MCM Strategy Analysis*
- *Choice of Drug Target*
- *Risk Mitigation*



Enable Rapid MCM Deployment

- *Platform Suitability*
- *Evaluation & Validation*
- *Formulation & Delivery*
- *Regulatory Compliance*



TMT Funding Profile

(Pres Bud)



	FY11	FY12	FY13	FY14	FY15
S&T (BA 6.1 – 6.3)	\$142.9M	\$141.9M	\$142.3M	\$129.3M	\$95.9M
Adv Dev (BA 6.4 – 6.5)	\$121.0M	\$104.2M	\$119.2M	\$174.4M	\$204.5M



Opportunities

- Pathogen Characterization
 - Capability to Identify Unknown Pathogens (Bacterial/Viral)
- New and Improved Countermeasure Discovery Platforms
- Technologies to Enhance the Drug Evaluation Process (e.g. Evaluation of Efficacy and Safety using Computer Modeling and Simulation, Surrogate Markers, or *In Vitro* Models)
- Host Directed Therapies
 - Targeting Host Factors Essential to Pathogen Life Cycle
 - Enhancing of Innate Immunity
 - Attenuating Common Final Pathways of Pathogenesis
- Focused Systems Biology
- *In vivo* Evaluation



Opportunities

- Systems Biology of Pathogenesis, Toxicology
 - Systems Immunology of Bacterial / Viral Infection to Identify Host Pathways that Inform MCM Discovery and Intervention Strategy
 - Computational Approaches to Identify Key Pathways in Toxicological Response to Therapeutics
- Pre-symptomatic Detection and Disease Surveillance
 - Profiling of Health Status to Monitor Disease State and Pathogen Exposure (“Immuno-signaturing”, Transcriptome Profiling)
 - Evaluation of Military Populations to Assess and Correlate Disease Events with Duty and Environmental factors
- Genetic Approaches to Evaluate Immune Responsiveness and Susceptibility to Infectious Disease
 - Deep Sequencing of MHC (HLA and Other Genes) that May Influence Immune Response to Pathogens
 - Use of Outbred Animal Models to Study Pathogen Sensitivity and Resistance, Thereby Supporting Therapeutic Strategy Development



Opportunities

- Immunomodulatory Therapeutic Approaches
 - Enhancement and Attenuation of Immune Responses to Achieve Therapeutic Need, and to Direct Response to Specific Pathogens
 - Development and Validation of Biomarkers that Reflect Adverse Effects of Immunomodulatory Intervention
- Adequacy of Animal Models to Approximate Pathogenesis in Humans
 - Differences in Biological Responses (e.g. Immune Systems)
 - Clinical Correlates of Human Disease



Upcoming Business Opportunities

Business Opportunity	Estimated Release Date
DTRA Chem/Bio BAA (FY12/13 Program Build)	Q4 FY10
DTRA Innovation BAA FedBizOpps.gov – Solicitation Number HDTRA1-07-RDINO-BAA	Open BAA
Small Business Innovation Research (SBIR) Solicitation 2010.3 (DTRA Topics) www.dodsbir.net/solicitation/sbir103/default.htm	Open – 17 AUG 2010 Close – 15 SEP 2010
Small Business Innovation Research (SBIR) Solicitation 2011.1 (Chem Bio Defense Topics) www.dodsbir.net/solicitation/default.htm	Open – 13 DEC 2010 Close – 12 JAN 2011