Transformational Medical Technologies Initiative (TMTI)

“To protect the Warfighter and the Nation from biothreats”

Advanced Planning Briefing to Industry

May 7-8, 2009
Report Documentation Page

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<td>Office of the Under Secretary of Defense for Acquisition, Technology and Logistics. Transformation Medical Technologies Initiative,Frederick,MD</td>
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Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std Z39-18
Protect the Warfighter from bioengineered or newly emergent biological threats by providing a response capability from identification of pathogens through the development of Medical Countermeasures (MCM).

- TMTI is especially focused on advanced biological threat agents
  - de novo or genetically engineered pathogens

- Requirements derive from:
  - Chemical and Biological Defense’s Medical Research, Development, Test & Evaluation Plan – December 2007
TMTI Delivers Innovative Solutions to the Warfighter

TMTI is an initiative that will translate into a program to produce medical countermeasures that are:

- **FDA approved**
- **Broad spectrum**
- Produced using an approach rapidly adaptable to new threats

- **Technologies** to identify unknown pathogens and rapidly develop medical countermeasures to newly identified threats
- Pathogen identification, characterization, and evaluation system
- **Broad-spectrum countermeasures** (one drug, many bugs)

TMTI is an initiative that will translate into a program to produce medical countermeasures that are:

- FDA approved
- Broad spectrum
- Produced using an approach rapidly adaptable to new threats
Pharmaceutical drug discovery and development is lengthy and expensive
- Takes an estimated 8-12 years and up to $1.2B to bring one drug to FDA licensure
- Less than 8% of new drugs put into pre-clinical trials ever reach consumers (Bain & Co.)
  - Costs increase greatly over time
    - For pre-clinical animal experiments
      - One mouse costs ~$15 … hence ~$100,000 is required for an early animal study
      - One non-human primate costs ~$10,000 … hence ~$3M is required for a later stage animal study
    - Human clinical trials are more expensive
      - $100-800M for Phase I-III human clinical trials
- Limited commercial market for most biodefense pharmaceuticals
Research Areas of Interest

• High throughput screening technologies for drug candidates

• Drug design capabilities that push the state of the art

• Technologies to enhance the drug evaluation process (e.g. computer modeling and simulation)
Therapeutic and Technologies Functional Areas

Systems Engineering – Internal and External to TMTI

Biological Event

Yes
Identify Agent?

No

Genomic Sequencing

Target Identification

Drug Discovery

Drug Evaluation

Manufacturing

Existing Therapeutic?

YES

Drugs in pipeline?

YES

Deliver to Warfighter

NO

NO

Drug in stock?

YES

NO

No

Yes

Known

UNKNOWN

Identify Agent?

Database / Processing / Tools - Informatics

Exercise / Demonstration

Evaluation: Processes, Tools, Lab Procedures
TMTI RDT&E Budget: Breakdown by Fiscal Year

Fiscal Year

- FY06
- FY07
- FY08
- FY09
- FY10
- FY11

Millions

- $0
- $50
- $100
- $150
- $200
- $250
- $300
- $350

Fiscal Year

- FY06
- FY07
- FY08
- FY09
- FY10
- FY11
**Program Breakdown**

**Funding Recipients**

- **Industry**: 38%
- **Academia**: 5%
- **Other**: 5%
- **Intramural**: 52%

**Investment Dollars (FY06-Present)**

- **Therapeutics**: 86%
- **Technologies**: 14%

**Project Distribution FY09**

- **Therapeutics**: 41%
- **Technologies**: 59%

*Other = nonprofit, foreign government*
TMTI: A Nationwide Team
FY06-FY10 Performers/Contracts and Subcontractors

Integrating the best efforts within government, academia, DoD, biotech industry, and pharmaceutical industry
# Upcoming Business Opportunities

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<th>Program</th>
<th>Estimated Target BAA Release</th>
<th>Target Funding Year</th>
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<td>FY12-13</td>
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<td>Email: <a href="mailto:TMTIwebsite@dtra.mil">TMTIwebsite@dtra.mil</a> Website: <a href="http://www.TMTI-cbdefense.org">www.TMTI-cbdefense.org</a></td>
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Summary

• TMTI is developing a response capability to support the Warfighter against biological threats
• Industry is needed to contribute technologies and innovative solutions in order for this effort to be successful
• Key focus areas:
  • Drug candidate high throughput screening
  • Drug design
  • Drug evaluation
How to Contact Us

- The TMTI website provides general information about the TMTI program, its mission, and goals – www.tmti-cbdefense.org

- Official government solicitations can be found at www.fedbizops.gov

- E-mail us directly – tmtiwebsite@dtra.mil

- Call us – 703-767-2347