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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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Mission



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:
 - Quadrennial Defense Review (QDR) – 2006
 - Chemical and Biological Defense's Medical Research, Development, Test & Evaluation Plan – December 2007

TMTI Delivers Innovative Solutions to the Warfighter



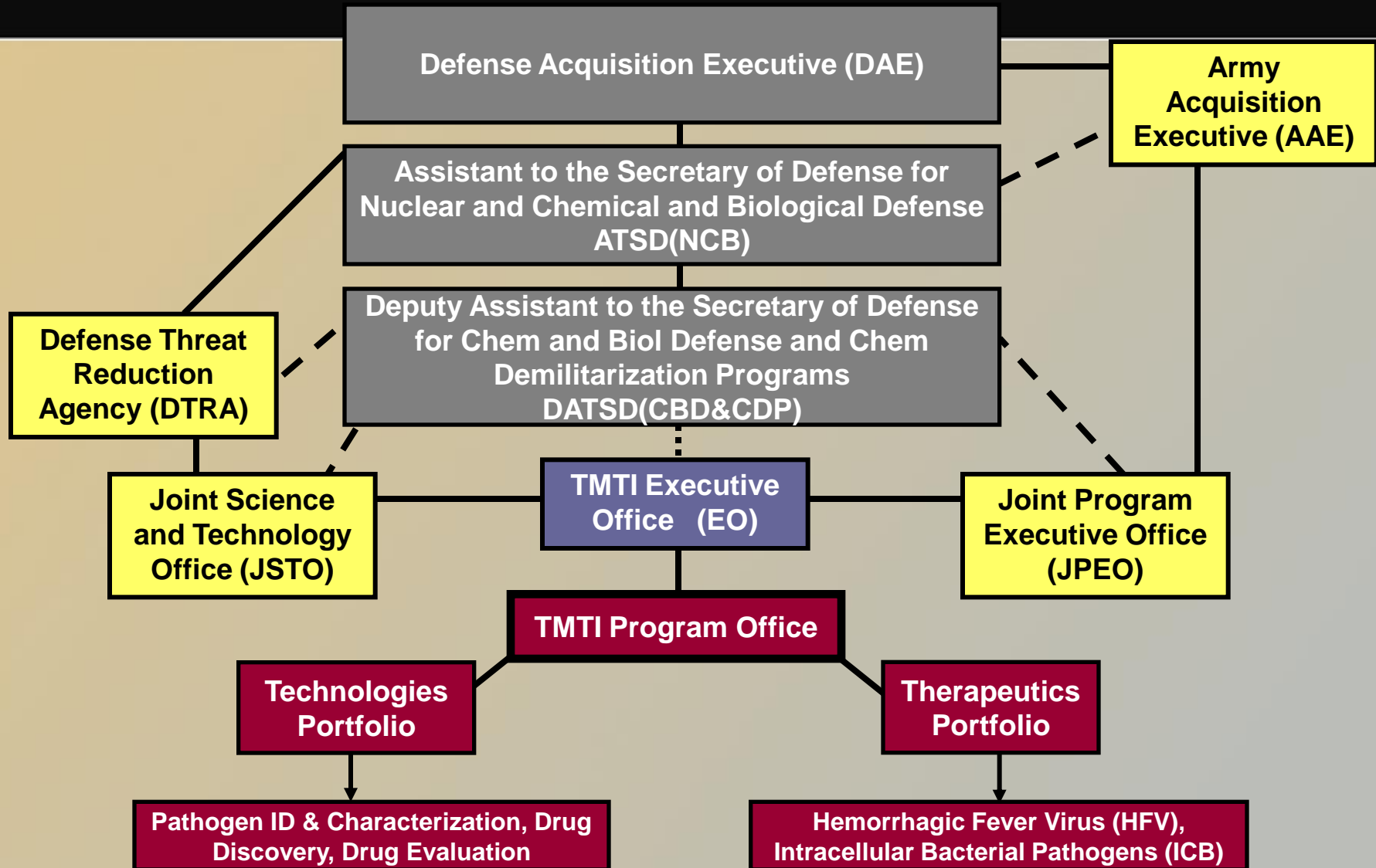
Designed to spur innovative research to develop:

- **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

Organization Chart

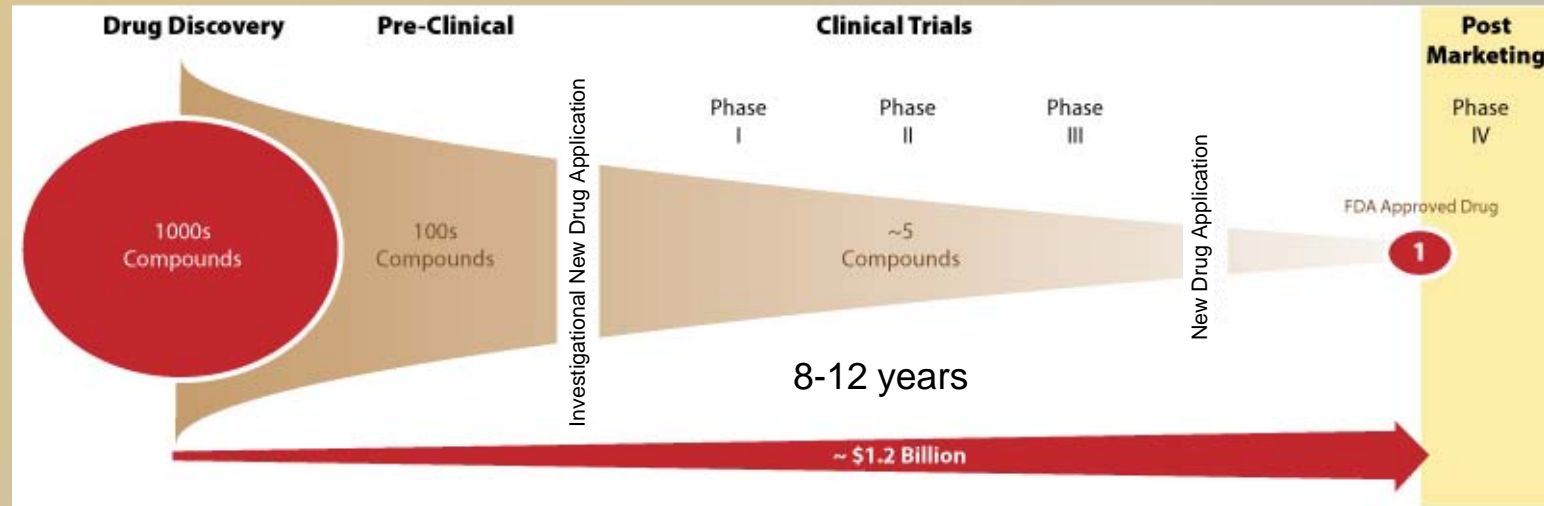


Commercial Drug Development Strategy

Limited Flexibility, Limited Responsiveness, Nonlinear



- The traditional “one drug, one bug” strategy is designed against known pathogens and diseases



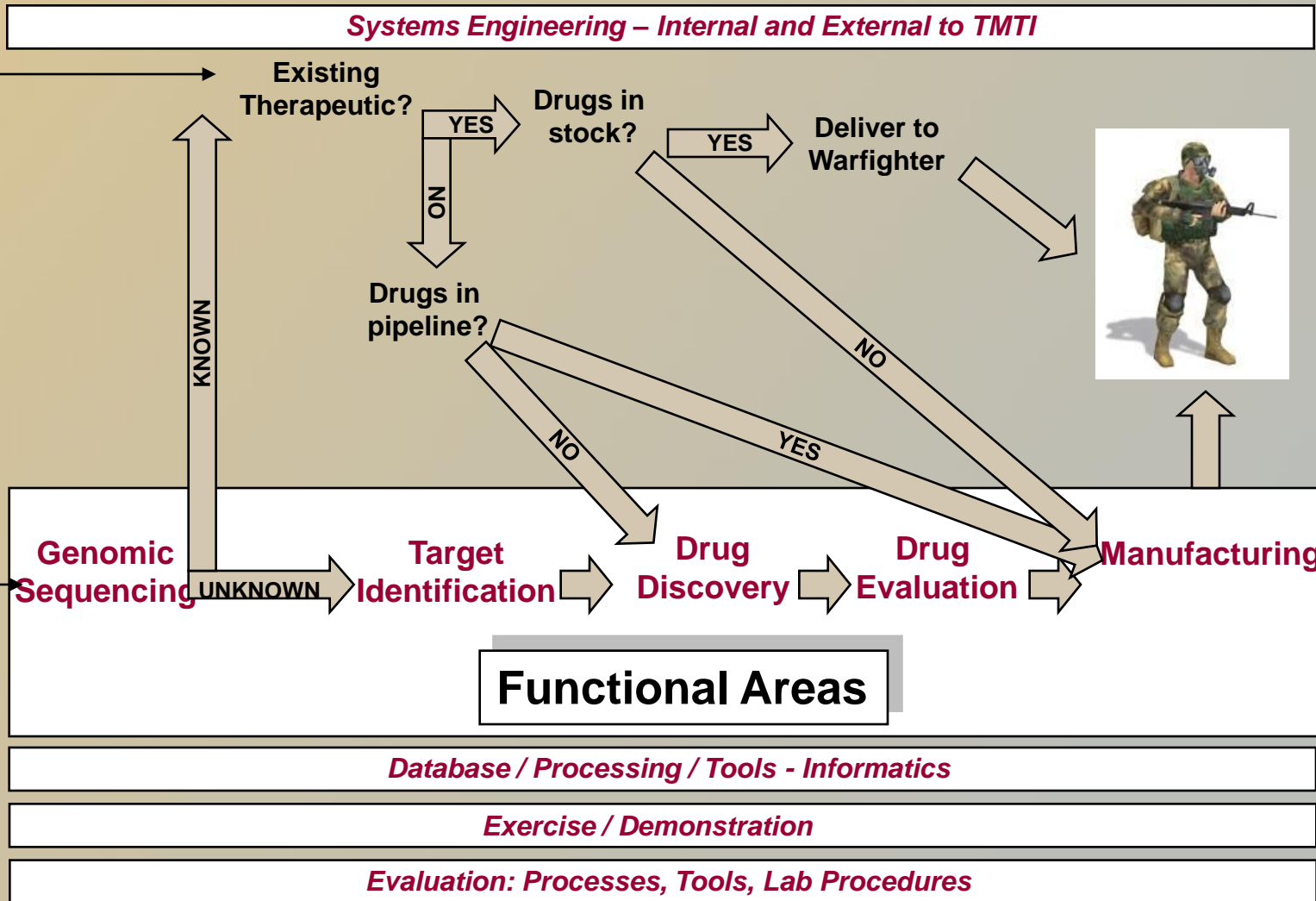
- **Pharmaceutical drug discovery and development is lengthy and expensive**
 - Takes an estimated 8-12 years and up to \$1.2B to bring one drug to FDA licensure
- **Less than 8% of new drugs put into pre-clinical trials ever reach consumers (Bain & Co.)**
 - Costs increase greatly over time
 - For pre-clinical 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



Functional Areas

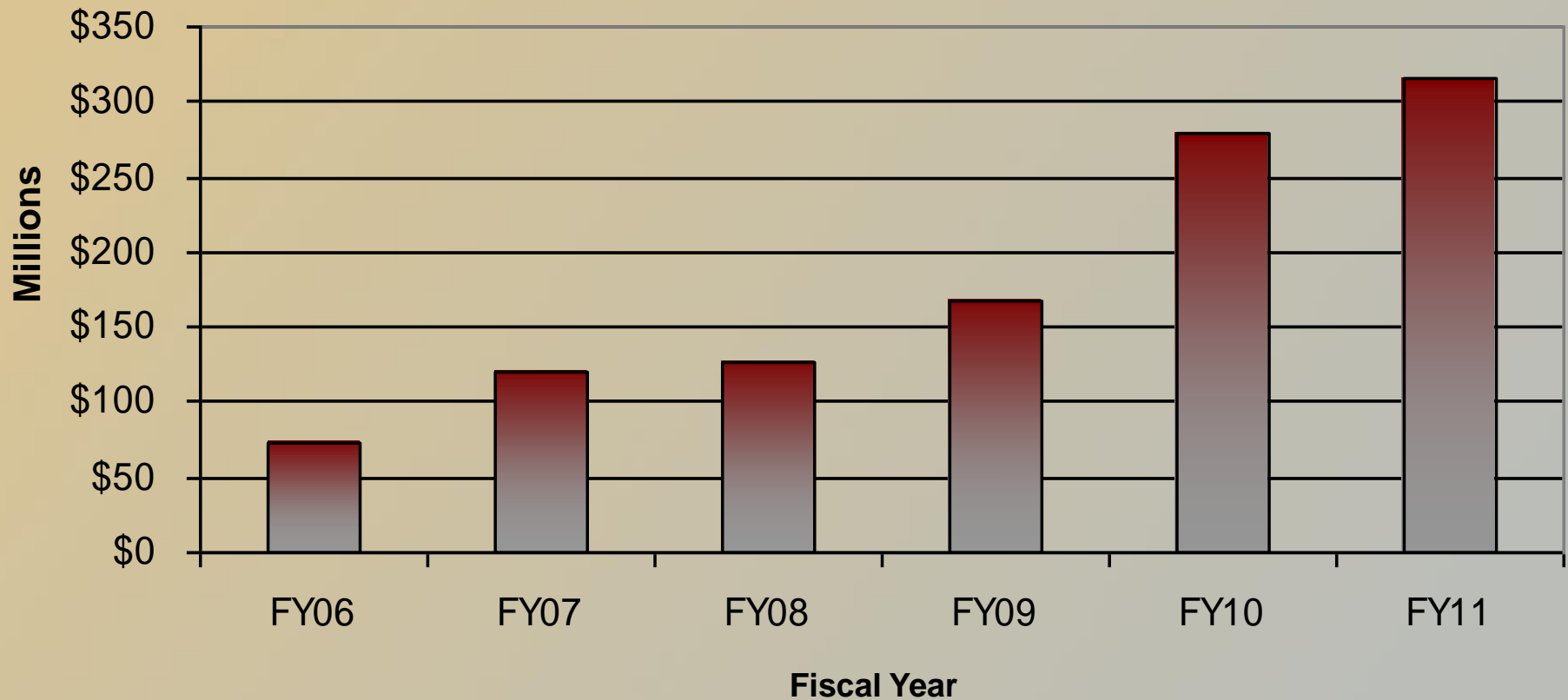
Database / Processing / Tools - Informatics

Exercise / Demonstration

Evaluation: Processes, Tools, Lab Procedures

TMTI RDT&E Budget:

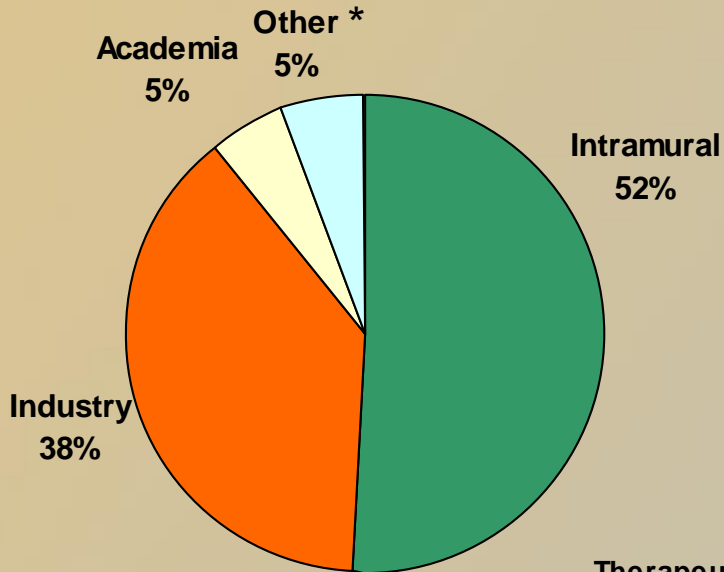
Breakdown by Fiscal Year



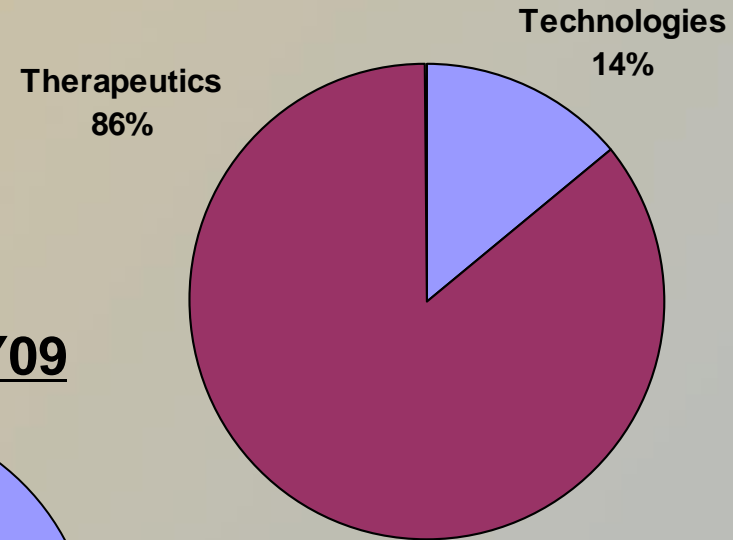
Program Breakdown



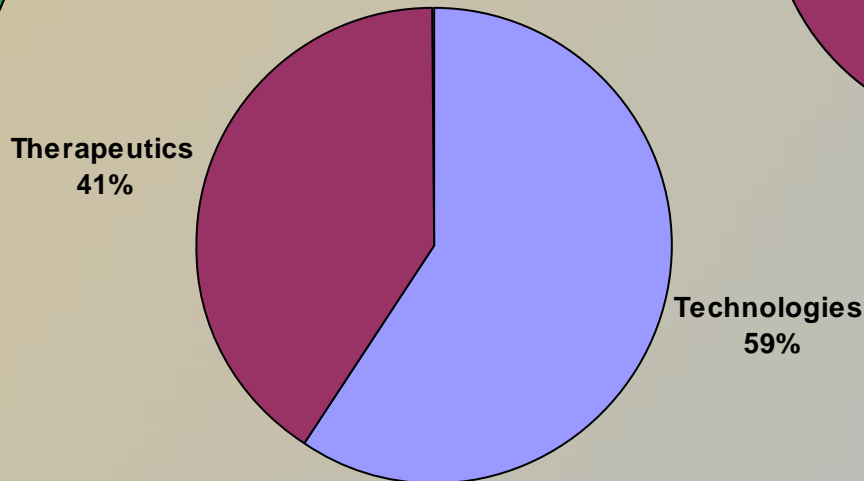
Funding Recipients



Investment Dollars (FY06-Present)



Project Distribution FY09



* Other = nonprofit, foreign government

TMTI: A Nationwide Team

FY06-FY10 Performers/Contracts and Subcontractors



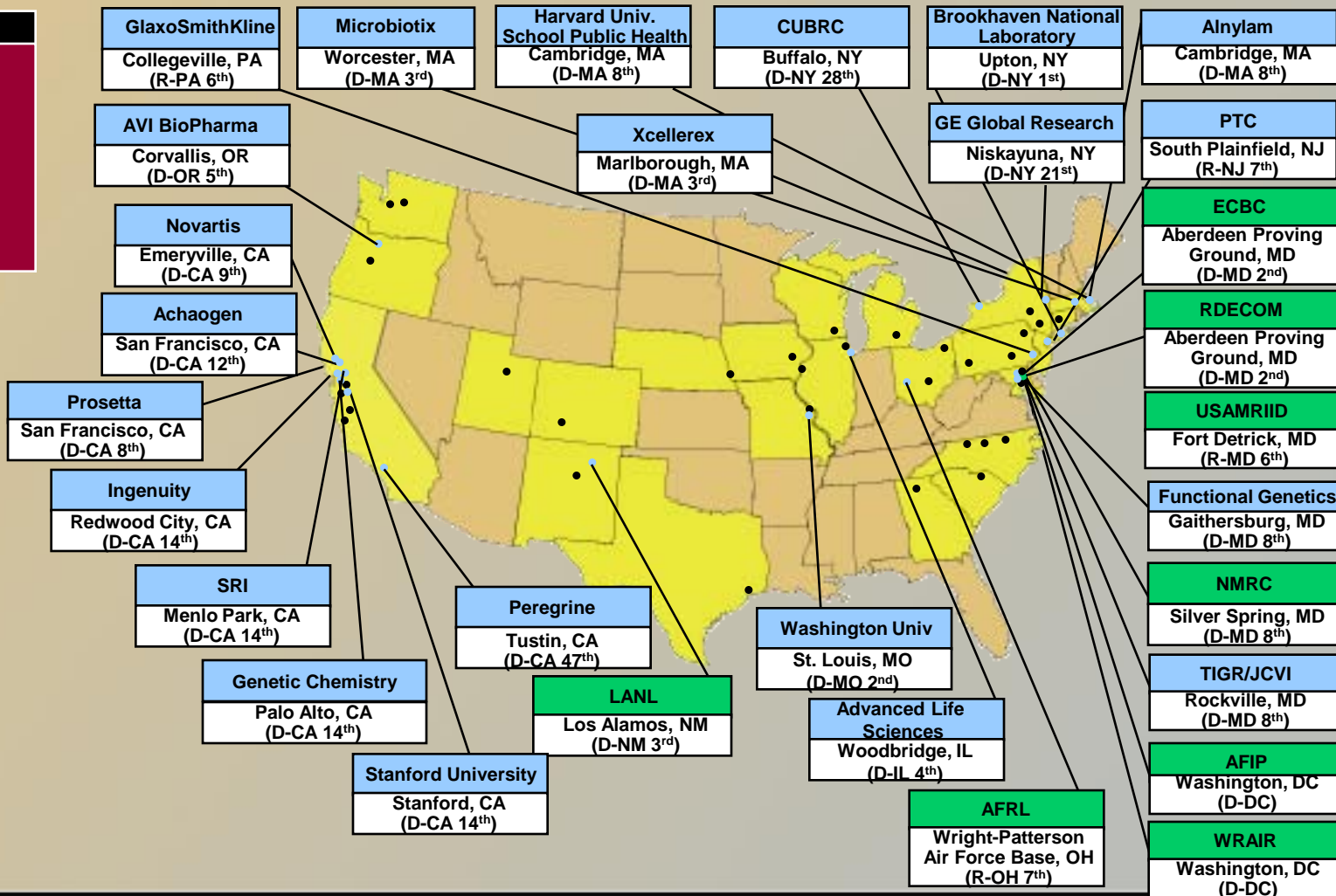
Integrating the best efforts within government, academia, DoD, biotech industry, and pharmaceutical industry

Key

- Intramural
- Extramural
- Performer States
- Subcontractor

International

- Evolve**
Allschwil, Switzerland
- Affinium**
Toronto, Canada
- Dstl**
Porton Down, UK
- Implicit Bioscience**
Brisbane, Australia



Upcoming Business Opportunities



Program	Estimated Target BAA Release	Target Funding Year
Transformational Medical Technology Initiative (TMTI) Email: TMTIwebsite@dtra.mil Website: www.TMTI-cbdefense.org	2QFY10	FY12-13
DTRA “Innovation” BAA FedBizOpps-HDTRA1-07-RDINO-BAA https://www.fbo.gov	Open BAA	FY11
Small Business Innovation Research (SBIR)	1QFY10	FY11
CB Defense Medical S&T Program https://www.fbo.gov	1QFY10	FY11

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

TRANSFORMATIONAL MEDICAL TECHNOLOGIES INITIATIVE

A Bold Journey

In 2006, The Department of Defense (DoD) pioneered the **Transformational Medical Technologies Initiative (TMTI)** program to better prepare and protect the warfighter and the nation from emerging, genetically engineered, and unknown bioterror agents. The DoD's approach to developing biodefense countermeasures has traditionally targeted specific disease-causing pathogens and their effects, effectively implementing a "one bug, one drug" approach.

The TMTI program represents a shift in focus toward enhancing the medical research, development, test and evaluation of broad-spectrum countermeasures, aimed at providing multivalent solutions ("one drug, multiple bugs") effective against a range of pathogens that threaten the lives of our warfighters today. The ultimate goal of TMTI is to provide a sustainable capability to rapidly respond to emerging or unknown biological threats.

"The health of the people is really the foundation upon which all their happiness and all their powers as a state depend."

- Benjamin Disraeli, former Prime Minister of Great Britain

Beyond the development of broad-spectrum countermeasures, TMTI will revolutionize drug development processes and technologies for rapid response for the warfighter and the nation.

TMTI Highlights

DoD CBOP