Medical Countermeasure Test & Evaluation (MCMT&E) Facility

(U.S. Army Medical Research Institute for Infectious Diseases [USAMRIID] Recapitalization Project: Phase 2)

Briefing for National Academy of Sciences Public Meeting

21 March 2011

First Things First

- **What is a Medical Countermeasure (MCM)?**
  - A vaccine or drug used to prevent or treat an infectious disease
  - Naturally occurring (emerging) or man-made/released
- **Is this Capability a New Requirement?**
  - No – it represents a rebranding of the initial USAMRIID Stage II Concept
- **Why is a special facility needed?**
  - Drugs and vaccines designed to protect against some infectious disease require unique federal approval processes
  - Testing using traditional means impossible because there are insufficient numbers of human cases and because of ethical considerations
  - Food and Drug Administration Animal Rule
- **Will this effort require any changes in National Environmental Policy Act documentation**
  - Yes

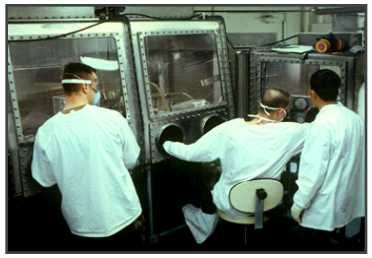
USAMRIID Recapitalization Drivers

- Age - Original Construction of 1956 (Bldg. 1412) and 1969 (Bldg 1425).
- Size – Undersized by current lab standards; lack of adequate Biosafety Level (BSL)-2 space to support current science missions
- Capacity – Maintain ability to respond to traditional and future biological threats
- Safety – Aging facility becoming increasingly more expensive to maintain; increased government regulation of select agent use (biosafety and biosurety)
- National need for testing and evaluation capability

Recapitalization Drivers

Research

Product Testing



Development

- Government
- Universities
- Industry

Increased Investments Since FY02

Effectiveness Testing

Pharma Industry

Vaccines

BioShield Increases $$ Incentives to Manufacturers

Medicines

Product Development Bottleneck

- Large-scale medical product testing capability
- High-containment labs and animal facilities
- Aerosol challenge for large studies
- Food and Drug Administration -regulated safety and effectiveness

USAMRIID Recapitalization Planning History

- **2000 - Facilities Master Plan undertaken.**
- **October 2001 – Anthrax Attacks**
- **December 2001 - House Report 107-350 directs detailed USAMRIID Feasibility Study:**
  - "…. The conferees provide$1,000,000 to the Army, only for the purpose of conducting a feasibility study to finalize the mission of USAMRIID and determine the infrastructure requirements and associated costs needed to accommodate USAMRIID's expanded role. The conferees direct the Secretary of the Army to submit a report on the results of this study and plans for including a facility expansion in the Future Years Defense Plan (FYDP) to the congressional defense committees no later than March 15, 2002.. "
- **April 2002 – Interim Report delivered, with total replacement cost at ~ $1B.**
- **December 2004 – Program Budget Decision 753 provides funding for USAMRIID in Medical Military Construction Future Years Defense Program**
- **October 2005 – Final Report submitted to Congress**

USAMRIID – Two Stage Project

Stage 1

- Accommodate USAMRIID's most critical missions and National assets
- Decompress overcrowded biocontainment laboratories
- Expand medical test and evaluation (T&E) capacity to meet immediate DoD and National demands

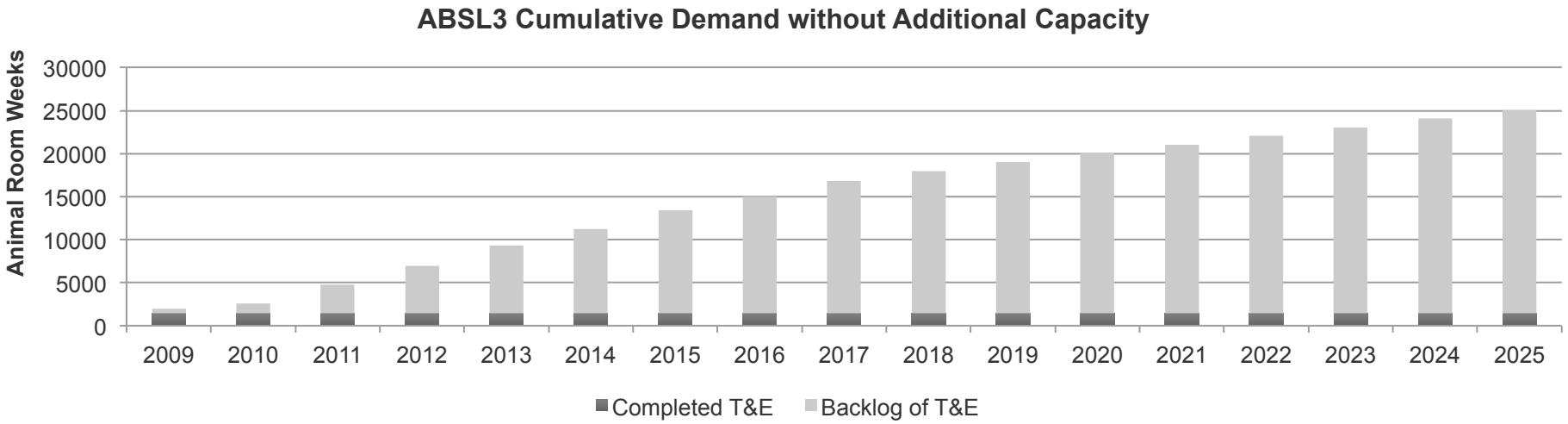
Stage 2

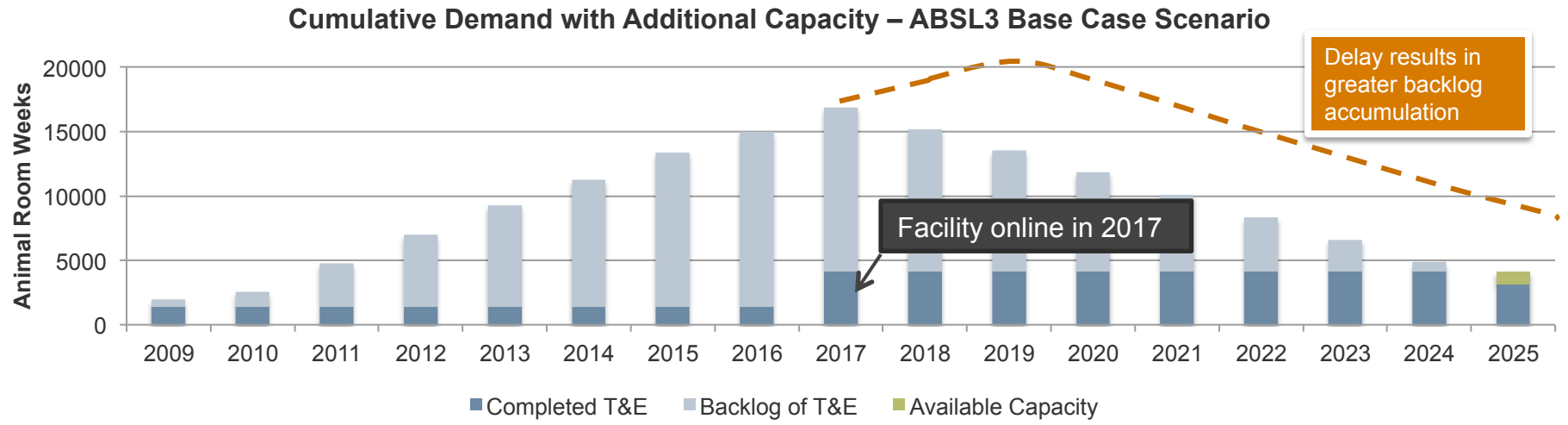
- Accommodate the balance of USAMRIID's expanded mission
- Provide capability to meet the projected National requirements for medical T&E generated by increased investment in basic sciences

2007/2009 Requirements Assessment Studies - Findings

- Current national investment in biodefense research, if continued into the future, is projected to result in an annual flow of medical countermeasure candidates for T&E that is likely to substantially exceed the capacity of current and planned federal biocontainment laboratories, including USAMRIID Stage I
- The estimated demand for T&E that is in excess of capacity may be considered to represent a national requirement for additional biocontainment facilities

The MCM T&E facility addresses a critical and growing gap in national animal T&E capacity





The MCM T&E facility will be a national center of excellence for animal test and evaluation

Dedicated animal T&E facility for biodefense and infectious disease countermeasure development

- Initial and final "Animal Rule[1]" T&E studies, animal model refinement
- Infectious Disease Countermeasures ONLY (no chemical or radnuc)

National COE, with unique state of the art capabilities

- High containment (ABSL3/4)[2]
- Non human primate (NHP) studies
- Good Laboratory Practice (GLP) compliance
- Aerobiology and remote monitoring of animals
- Sufficient scale and throughput to handle multiple MCMs concurrently

Foster collaboration through public private partnerships

- Critical mass of expertise and shared workspace
- Services and support for biotech companies
- Collaboration with other COEs (Advanced Development & Manufacturing, FDA, Training)

Provide federal capability for T&E required to deliver safe and effective MCMs to warfighter and nation

- Rapid response capability for health security

Images courtesy of HDR-CUH2A

[1]Alternative Regulatory Pathway for products which cannot be tested in humans due to ethical considerations
[2]Animal Bio Safety Level 3 and 4

The MCM T&E facility is an integral component of the National Interagency Biodefense Campus (NIBC) strategy

DoD-owned facility with fee-for-service tenants

- 492,000 GSF for ~$600M
- Programming underway, 2013 construction start, 2018 facility online
- Fast track program (2018 vs. 2020) to mitigate animal T&E study backlog

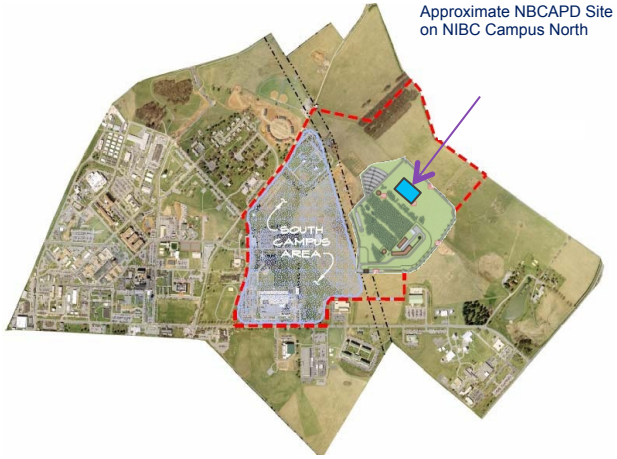
Facility addresses DoD and HHS T&E needs for common requirements

- May need additional capacity (or commercial expansion) for other demand

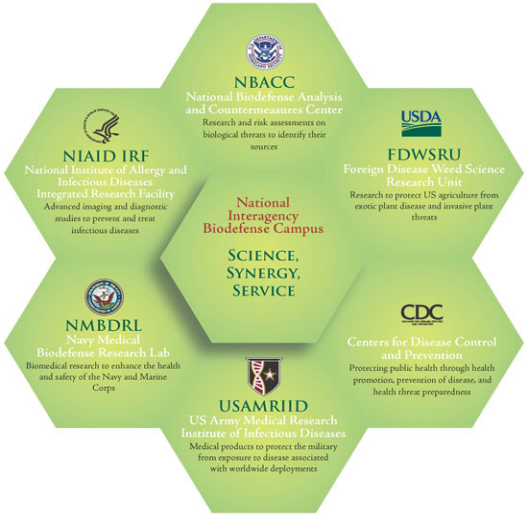
Advantages of Fort Detrick location

- Facility security assured
- Leverage DoD capabilities infectious disease threats
- Collaboration with Biodefense Campus partners
- Fulfill distinct mission and complements NIBC capabilities

Proposed facility alignment with US Army Medical Materiel Development Activity



Planned Location: NIBC North Campus



National Interagency Biodefense Campus (NIBC)

The MCM T&E facility program is well underway

Fiscal planning

- Funding budgeted in FY12-17 Program Objective Memorandum (POM – DoD fiscal planning process)

Facility programming

- Preliminary scope and scale defined, detailed space and equipment programming complete
- Architectural and Engineering firm in selection process

Environmental Impact Statement Process

- Required due to size and location changes and mission clarification toward fulfillment of national requirement
- USAMRMC is the primary EIS proponent – Not USAMRIID
- Contract in place
- Will follow recommendations of the National Academy of Sciences study

Business plan development

- Interagency Steering Committee
- Business plan initiated to address operational model, governance, financial plan etc.