

Our Vision is a U.S. military force that is fully sustained to fight and win in any CBRN battlespace worldwide.

Chemical Biological Medical Systems Overview

May 18, 2011

Presented to:

CBRN Survivability for Weapon Systems Conference
National Defense Industrial Association (NDIA)

LTC Philip L. Smith
Joint Product Manager
Joint Vaccine Acquisition Program (JVAP)
Chemical Biological Medical Systems (CBMS)
philip.l.smith@us.army.mil



Chemical Biological Medical Systems



Agenda

CBMS Overview



- **Mission/Organization**
- **Core Competencies**
- **Warfighter Needs**
- **Integrated DoD Acquisition & FDA Regulatory Processes**
- **Product Development**
- **CBMS Products**
- **Medical Capabilities**
- **Take Aways**





Chemical Biological Medical Systems (CBMS) Organization



Deliver safe, effective and robust medical products that protect U.S. forces against validated CBRN threats. We apply government and industry best practices to develop or acquire FDA-approved products within rigorously managed cost, schedule and performance constraints.



Develop, produce & stockpile FDA-Licensed vaccine systems to protect the Warfighter from biological agents



Develop and integrate chemical, biological, radiological, and nuclear (CBRN) technologies to enable early warning, identification, and continued situational awareness of potential global health threats

--- Provisional



Rapidly provide the Warfighter and the Nation robust & affordable FDA-approved lifesaving medical countermeasure drug capabilities against chemical, biological, radiological & nuclear threats

Meeting the Warfighter needs through the development of FDA-approved products



CBMS Command Staff




| | |
|---|---|
|  |  |
| COL Charles Millard CBMS | Dr. Ed Clayson CBMS |



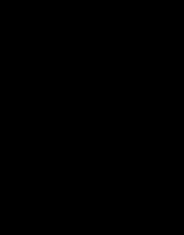
| | |
|---|---|
|  |  |
| LTC Philip Smith JVAP | Rick Nidel JVAP |



| | |
|---|--|
|  |  |
| Dr. Jason Roos BSV | Jennifer McLaughlin BSV |



| | |
|---|---|
|  |  |
| LTC Nanette Patton MITS | Renae Malek MITS |

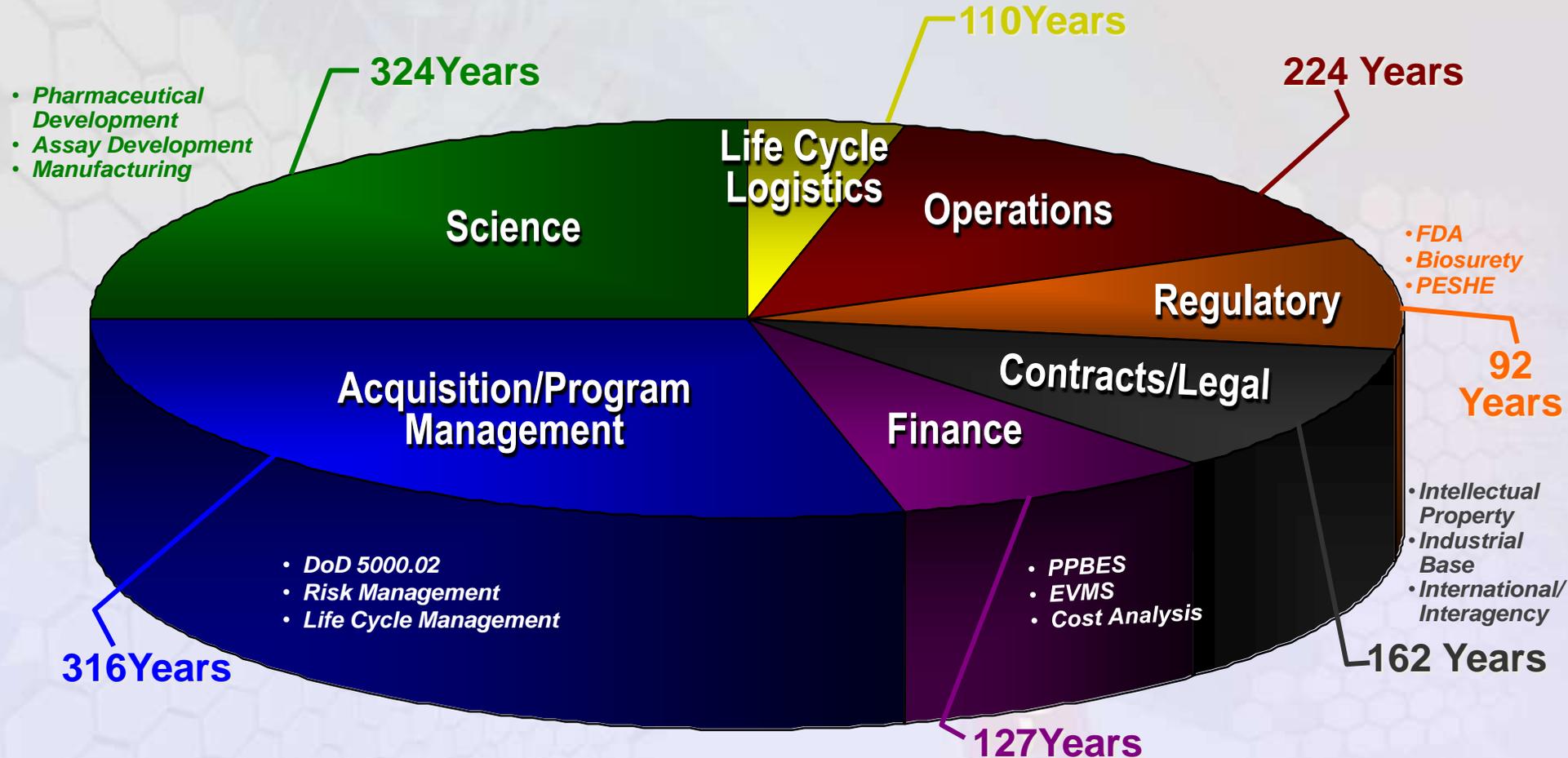
| | | | | | | | | |
|--|---|---|---|--|---|---|---|---|
|  |  |  |  |  |  |  |  |  |
| Teri Baal | Vacant | Cicely Levingston | Eric Life | Laurie Lowry | Cassandra McFadden | Vacant | Linda Sheffer | Lori Walton |
| Operations | Chief Scientist | Congressional | Legal | Acquisition | Logistics | Contracting | Finance | RA/QA |



CBMS Core Competencies



1355 Person Years of Advanced Drug Development Experience
All functional units are co-located!





Warfighter Needs



Requirements Identified

- Acquisition Documents
- Initial Capabilities Document (ICD)
 - Capability Development Document (CDD)
 - Capability Production Document (CPD)
 - Key Performance Parameter = FDA Licensure

Science & Technology (S&T) Development



Advanced Development

FDA Licensure Process





Product Development and the Animal Rule



TRADITIONAL LICENSURE PATHWAY



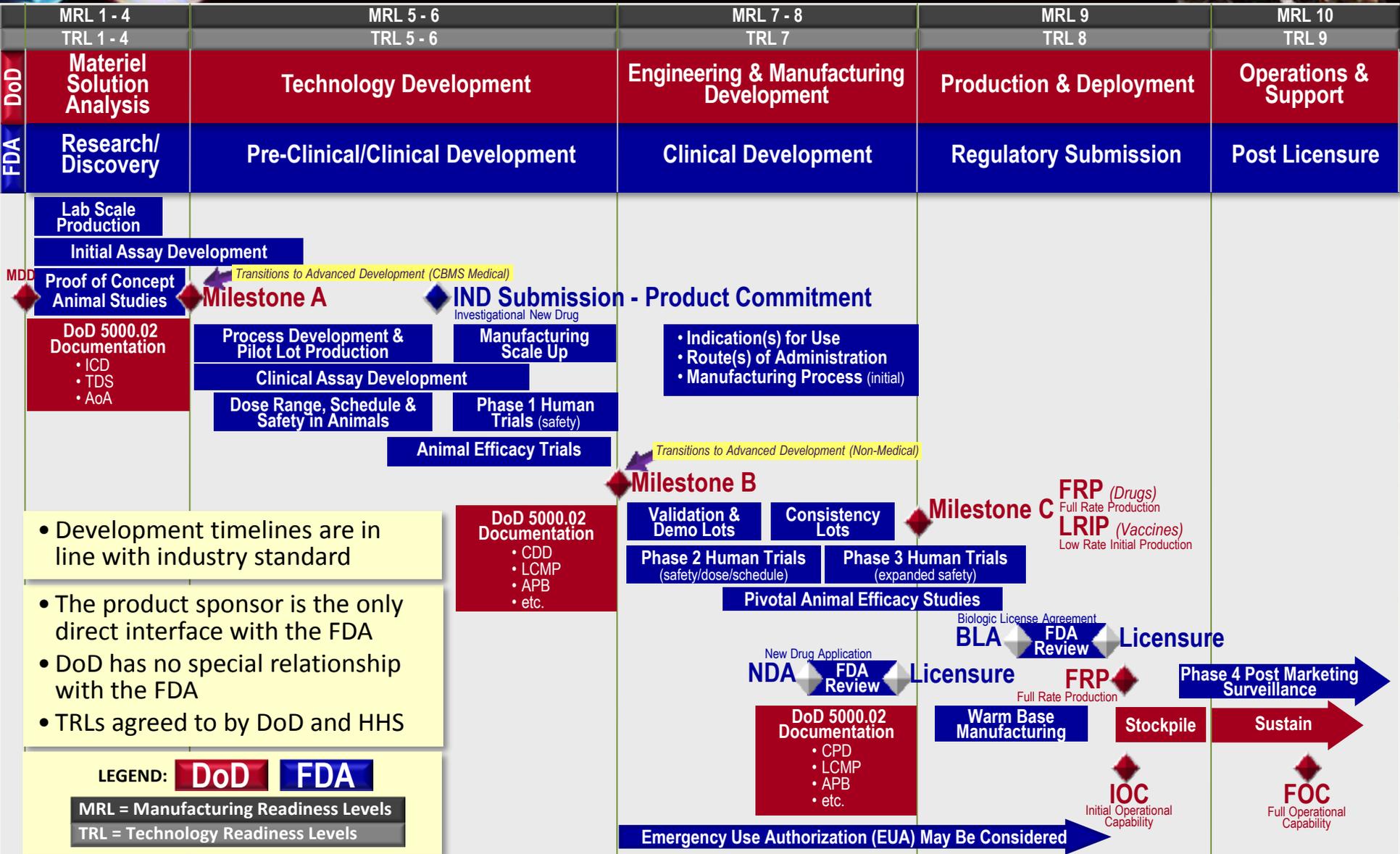
ANIMAL RULE LICENSURE PATHWAY



- **Allows for approval of products in which efficacy testing in humans is unethical**
- **Extensive Animal Model Development**
 - Efficacy is demonstrated in more than one, well defined animal model
 - Well controlled animal studies provide data that are likely to predict a benefit in humans



Integration of DoD Acquisition Model & FDA Regulatory Process



- Development timelines are in line with industry standard
- The product sponsor is the only direct interface with the FDA
- DoD has no special relationship with the FDA
- TRLs agreed to by DoD and HHS

LEGEND: **DoD** **FDA**

MRL = Manufacturing Readiness Levels
TRL = Technology Readiness Levels



CBMS Products



- **Joint Vaccine Acquisition Program (JVAP)**
 - Anthrax Vaccine Adsorbed
 - Filovirus Vaccine
 - Plague Vaccine
 - Recombinant Botulinum A/B Vaccine
 - Smallpox Vaccine
 - Vaccinia Immune Globulin
- **Biosurveillance**
 - Critical Reagents Program (CRP)
 - Joint Biological Agent Identification & Diagnostic (JBAIDS)
 - Next Generation Diagnostic System (NGDS)
- **Medical Identification & Treatment Systems (MITS)**
 - Advanced Anticonvulsant System (AAS)
 - Bioscavenger
 - Centrally Acting Nerve Agent Treatment System (CANATS)
 - Improved Nerve Agent Treatment System (INATS)
 - Inhalation Atropine (IA)
 - Medical Radiation Countermeasures (MRADC)

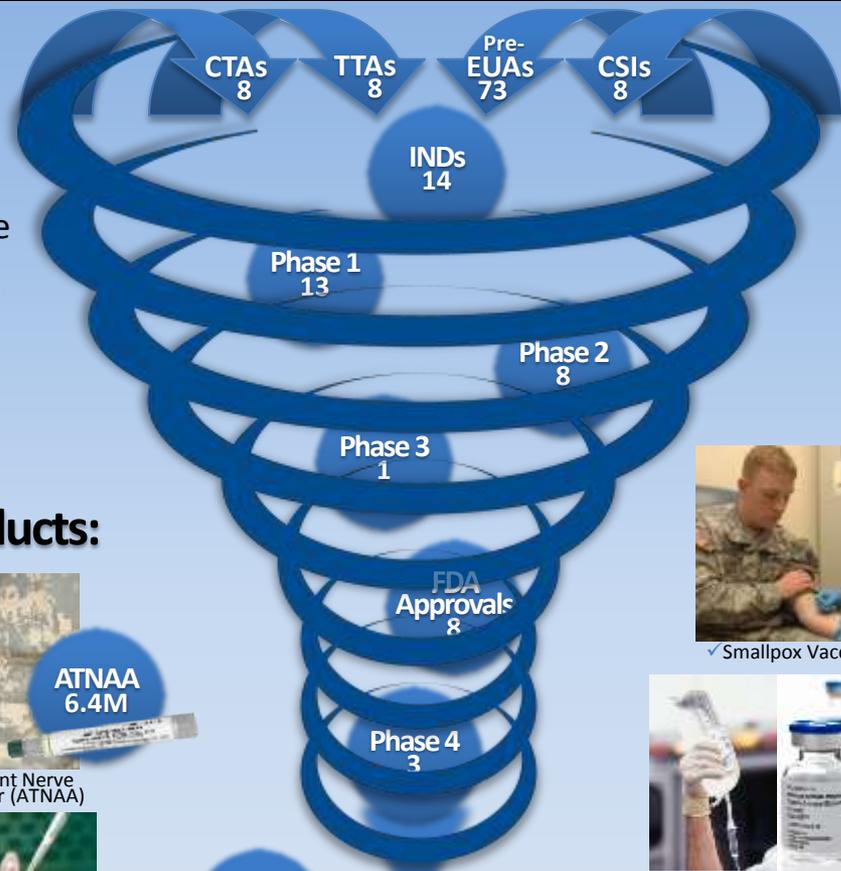


Medical Capabilities Delivered to the Warfighter



Partner Inputs:

- ✓ 8 – Capability Transition Agreements (CTAs)
- ✓ 8 – Technology Transition Agreements (TTAs)
- ✓ 73 – Assays for Pre-Emergency Use Authorization (EUAs)
- ✓ 8 – Relevant Congressional Special Interest Projects (CSIs)



CBMS Expertise:

- ✓ 14 – Investigational New Drugs (INDs)
- ✓ 13 – Phase 1 Clinical Trials
- ✓ 8 – Phase 2 Clinical Trials
- ✓ 1 – Phase 3 Clinical Trials
- ✓ 3 – Phase 4 Clinical Trials
- ✓ **8 – Food & Drug Administration (FDA) Approvals**
 - ✓ 1 – New Drug Application (NDA)
 - ✓ 1 – Biological License Application (BLA)
 - ✓ 6 – 510(k)s

Results in Fielded Products:



✓ Convulsant Antidote for Nerve Agents (CANA)



✓ Antidote Treatment Nerve Agent Autoinjector (ATNAA)



✓ Soman Nerve Agent Pretreatment Pyridostigmine (SNAPP)



✓ Critical Reagents Program (CRP) Assay Kits: Electrochemiluminescence



✓ Joint Biological Agent Identification Diagnostic System (JBAIDS)



✓ Joint Biological Agent Identification Diagnostic System (JBAIDS)



✓ Critical Reagents Program (CRP) Assay Kits: Lateral Flow Immunoassays (LFI)



✓ Critical Reagents Program (CRP) Assay Kits: Polymerase-Chain Reaction (PCR)



✓ Smallpox Vaccine (SPX)



✓ Anthrax Vaccine Adsorbed (AVA)



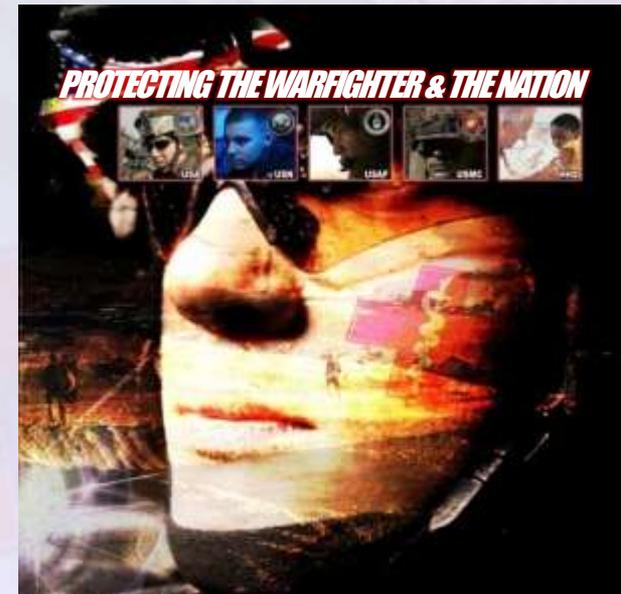
✓ Vaccinia Immune Globulin (VIG)



Take Aways



- **CBMS protects the Warfighter by developing and delivering FDA licensed CBRN medical countermeasures**
- **Focus on shortening the requirement to fielding timeline**
 - Partnering with international and other government agencies
 - Using DoD and industry best practices
 - Seamless transition from Science & Technology to Advanced Development
 - Total Life Cycle management
- **Successes from FY2002 to date**
 - 8 Food & Drug Administration (FDA) Approvals
 - 14 Investigational New Drugs (INDs)
 - 1 Emergency Use Authorization (EUA)
 - 73 Pre-Positioned EUAs
- **12 FDA Approvals in the next 5 Years**





COL Charles B. Millard

Joint Project Manager, CBMS

301-619-7400

charles.b.millard@us.army.mil

Dr. Edward T. Clayson

Deputy, Joint Project Manager, CBMS

301-619-7400

edward.clayson@us.army.mil

