

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

INATS Program Overview

February 8, 2013

Ms. Lisa Mobley
Pharmaceutical Manager
Medical Identification & Treatment Systems (MITS)
lisa.r.mobley.civ@mail.mil





Purpose



- **Purpose**

- To provide an overview of the Improved Nerve Agent Treatment System (INATS) program objectives and solicit feedback from industry on the Draft Request for Proposal

- **Agenda**

- INATS Program Overview
- Requirements Overview
- Government Furnished Information (GFI) Description
- Animal Rule & Countermeasure Development
- Draft RFP Overview
- Submitted Questions



Disclaimer



- **Discussions today by Government officials involved in the INATS acquisition should not be considered a guarantee of or commitment by the Government to a particular course of action in proceeding with the program**
- **The information shared today reflects current Government intentions and is subject to change based on a variety of circumstances including internal and external comments. The formal solicitation, when/if issued, is the only document that should be relied upon in determining and responding to the Government's requirements**
- **Any costs incurred prior to receipt of a contract signed by the contracting officer is at your own expense**



Introductions

Government Points of Contact



- **LTC Nanette Patton** **Joint Product Manager (JPM), MITS**
- **Dr. David Smith** **Deputy Joint Product Manager (DJPM), MITS**
- **Dr. Renae Malek** **Chief Technical Officer, MITS**
- **Mr. Richard Totten** **Contracting Specialist, Army Contracting Command**
- **Ms. Lisa Mobley** **INATS Pharmaceutical Manager**
- **Ms. Mona Atkinson** **INATS Science Manager**
- **Mr. Corey Ellis** **INATS Science Manager**



Ground Rules



- **Questions provided in writing via the Natick website or emailed to Mr. Richard Totten by 22 Jan 2013 will be addressed at this PSC**
 - Other questions shall be written on **index cards**. The Government will reply as time permits
- **Official answers to all questions will be published on the Natick website**
- **The final RFP will have adjudicating authority and will take precedence over anything discussed here that may be inconsistent with the draft RFP**
- **This brief will be posted on the Natick and FedBizOpps websites**
- **No recording devices please**



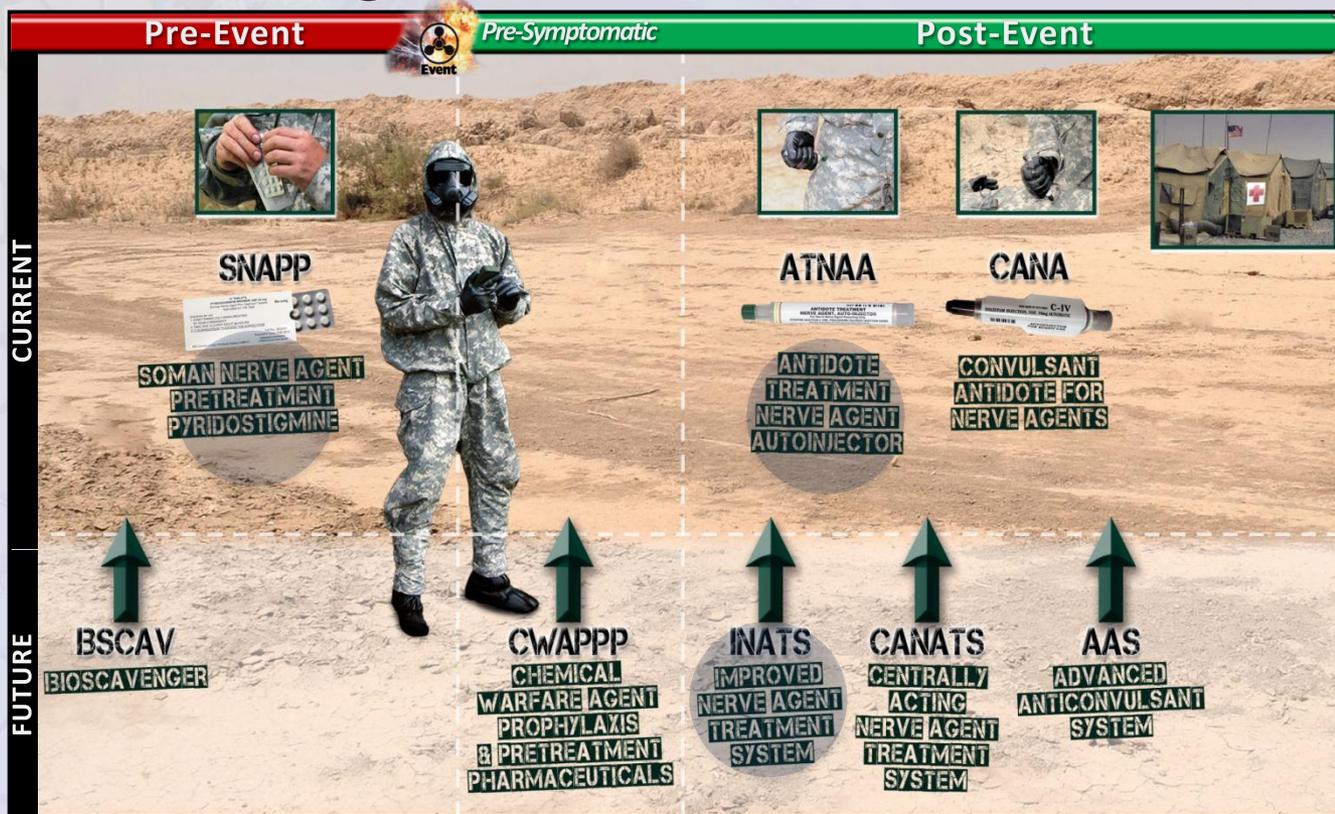
Program Overview



INATS Fit in the MITS Portfolio



- INATS is a broad spectrum therapeutic that works in conjunction with pre and post-medical countermeasures to provide increased survival, against traditional and nontraditional agents



* With typical dose & against various agents of interest



Product Description



- **Mission Description:** A nontraditional agent relevant program to replace and provide improved product performance over the currently fielded Antidote Treatment Nerve Agent – Autoinjector (ATNAA) for the treatment of nerve agent intoxication. This includes developing product formulation enhancements to increase product efficacy and stability. The INATS program effort also includes expanded pretreatment indications for Pyridostigmine Bromide (PB).
- **Oversight/Special Interest:** FDA
- **Users:** USA, USN, USAF, USMC
- **Next Milestone/Date:** Milestone B/1QFY14
- **Technology Development Phase Contractors:** Battelle Memorial Institute, West Jefferson, OH; Southwest Research Institute, San Antonio, TX





Requirements Overview



Capability Gap & Product Description



- **Capability Gap**

- Fielded nerve agent antidotes do not fully protect the operational force against traditional nerve agents and NTAs
- Pyridostigmine Bromide (PB) is only FDA approved as a pretreatment for soman
- Pralidoxime (2-PAM), FDA-approved for the treatment of nerve agent intoxication, may not provide complete treatment against all traditional and non-traditional agents

- **Product Description**

- An enhanced treatment regimen consisting of a broad spectrum oxime to replace the fielded oxime 2-PAM and expanded pretreatment indications for PB
- This is a replacement product to the currently fielded Antidote Treatment Nerve Agent – Autoinjector (ATNAA), atropine and 2-PAM
- Temperature stable formulation that offers increased chemical stability and shelf life



Government Furnished Information (GFI)



Government Candidate



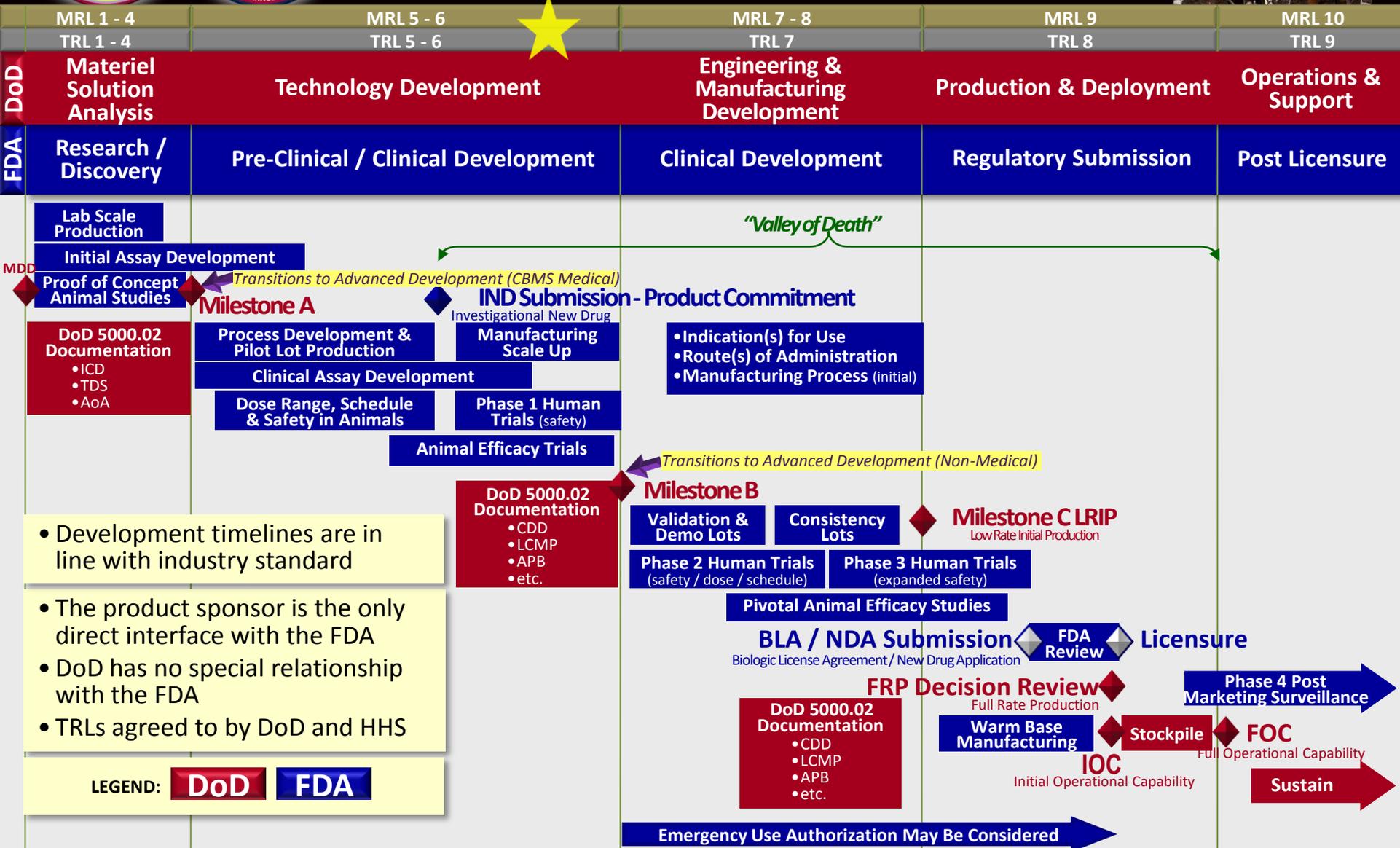
- **The Government furnished candidate is MMB4-DMS Enhanced Formulation**
- **A Technical Data Package for development of MMB4-DMS will be provided in the Information Reading Room for potential Offerors' reference**
- **MMB4-DMS has undergone animal toxicity and efficacy studies, a Phase 1 clinical trial and IND submission**
- **In animal studies, MMB4-DMS works to provide increased survival against multiple traditional and NTAs**



Animal Rule & Countermeasure Development



Integration of DoD Acquisition Model & FDA Regulatory Process





The Animal Rule

Background



- **Allows for approval of medical countermeasures in which efficacy testing in humans is unethical**
- **Applies only when mechanism of agent is reasonably well understood**
 - Mechanism by which the product prevents disease, lessens effects of disease, or provides a clinical benefit
 - Efficacy is demonstrated in more than one, well-defined animal model
 - Progression of the disease/condition should be similar to that of humans
 - Immunogenicity data in animals/humans allow for selection of an effective animal dose
 - Well controlled animal studies will provide data that are likely to predict a benefit in humans



The Animal Rule DOES NOT



- **Apply to products when approval can be based on a demonstration of efficacy as described in other regulations**
 - 21 CFR 601.41 – accelerated approval based on surrogate markers or clinical endpoints other than survival or morbidity
- **Address evaluation of safety**
 - To be demonstrated in human volunteers – drugs/biologics licensed under the “Animal Rule” will still require a safety database of hundreds to thousands of volunteers (Expanded Safety and Immunogenicity Phase 3 clinical trial)
- **Accelerate the FDA licensure process**
- **Decrease the product development cost**



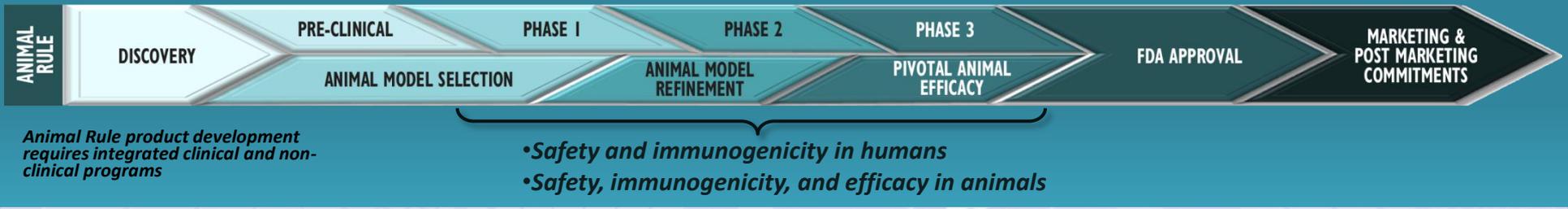
Product Development & the Animal Rule



TRADITIONAL LICENSURE PATHWAY



ANIMAL RULE LICENSURE PATHWAY



• 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



Draft FDA Guidance



Guidance for Industry Animal Models — Essential Elements to Address Efficacy Under the Animal Rule

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact Rosemary Roberts, CDER, at 301-796-2210 or the Office of Communications, Training, and Manufacturers Assistance (CBER), 301-827-1800 or 800-835-4709.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

January 2009
Pharm/Tox

G:\83246\doc
01/13/09

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm078923.pdf>



Draft RFP Overview

Richard Totten
Contracting Specialist