



USAMRMC

Advanced Development and Program Management Overview

MILITARY MEDICINE PARTNERSHIP DAYS
UNCLASSIFIED

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Why?



We are looking for Partners to Protect, Heal, and Restore



Agenda



- US Army Medical Research and Development (R&D) Priorities [includes priorities funded by the US Army, the Defense Threat Reduction Agency (DTRA), and by the Defense Health Program (DHP)]
- US Department of Defense (DoD) Acquisition Materiel Lifecycle
- Pharmaceutical Model (Drug Development)
- US Food and Drug Administration (FDA) Approval Process
- US Army Medical Research and Materiel Command (USAMRMC) Integration Model = Decision Gate (DG)
- USAMRMC Success Stories
- Partnering



The views expressed in this presentation are of the authors and may not necessarily be endorsed by the US Army.



Advanced Development Product Development Priority



Sec Army Top Priorities

Medical AD Priorities

Alignment
with Sec Army
Priorities

1. Prevent Sexual Assault
2. Balance and Transition the Army
3. Champion Soldiers, Civilians and Families
4. Continue to bolster Army activities in the Asia-Pacific region
5. Ensure personal accountability on and off the battlefield
6. Tell the Army Story
7. Implement Army Total Force policy
8. Prudently manage reset, modernization, research and development
9. Strengthen the defense of Army networks and build the Army cyber force
10. Strengthen installations through effective energy solutions

1. Warfighter (Combat Casualty Care): Priority of Life, Limb, and Eye
2. Post Traumatic Stress / Traumatic Brain Injury (TBI)
3. Human Performance Optimization
4. Pacific Region: Prolonged Enroute Care, Tele-Behavioral Health, Infectious Diseases
5. Infectious Disease Products**
6. Military Operational Medicine

2, 3, 7, 8
2, 3, 8
2, 3, 8
2, 4, 8
2, 4, 8
2, 3, 8

** Sub elements a part of Pacific region

***Additionally integrated with Force 2025 and Beyond**



Medical R&D Priorities – Examples I



- Infectious Diseases
 - Malaria, Dengue, and Diarrhea
 - Diagnostics, Drugs, and Vaccines
- Combat Casualty Care
 - Hemorrhage Control – Drugs, Devices, Blood
 - Traumatic Brain Injury – Diagnostics, Treatment
- Military Operational Medicine
 - Post Traumatic Disease Syndrome (PTSD)
 - Human Performance Optimization





Medical R&D Priorities – Examples II



- Regenerative and Rehabilitative Medicine
 - Vascular Composite Allograft (VCA) – Face, Hand
 - Bone, Nerve, and Muscle graft/stem cell
- Chemical and Biological Weapon Defense
 - Ebola
 - Nerve Agents
- Radiation Health
- Medical Modeling and Simulation

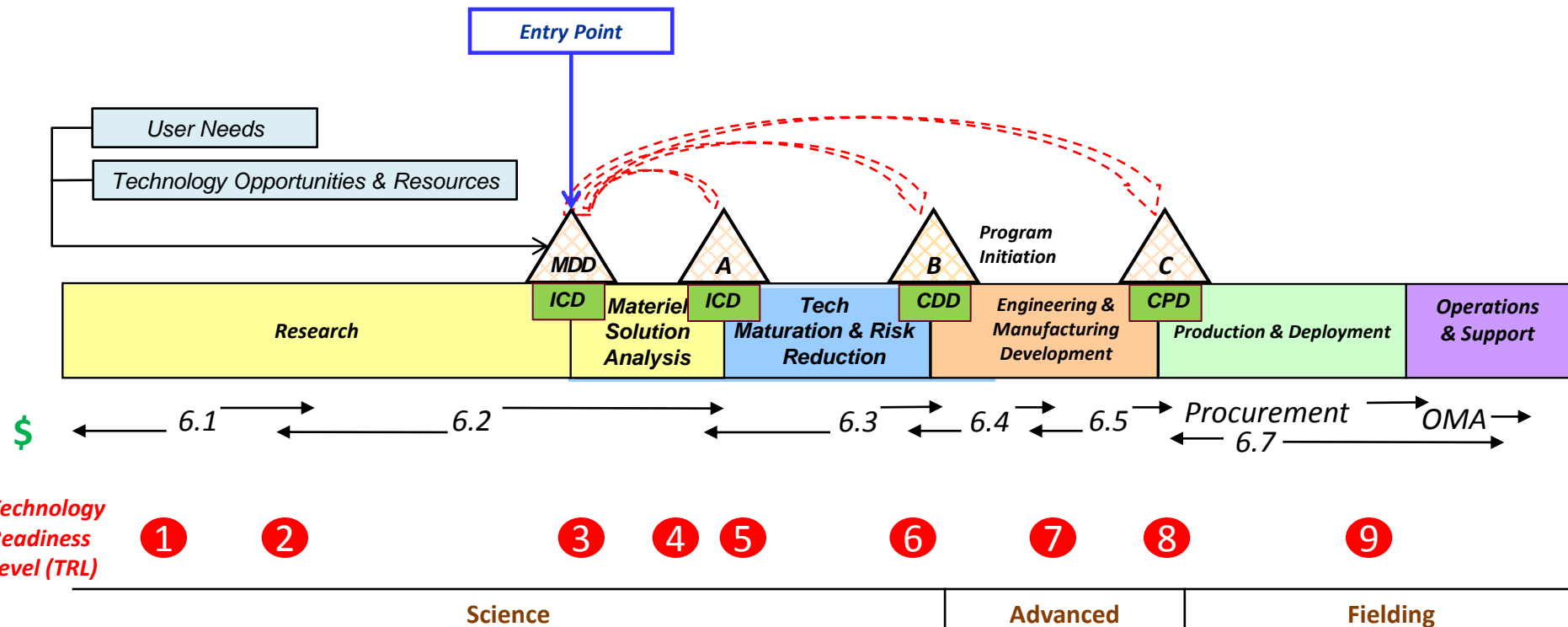




DoD Acquisition Materiel Lifecycle



A consistent product lifecycle w/ clearly defined Milestones



MDD – Materiel Development Decision
 ICD – Initial Capabilities Document
 CDD – Capability Development Document
 CPD – Capability Production Document





USAMRMC Core Competencies



- Basic and Applied Biomedical Research
 - Intramural labs and scientific expertise
 - Worldwide field sites
- Advanced Biomedical Development
 - FDA Regulatory expertise
 - Clinical trials, intramural and extramural
 - Worldwide field sites (infectious diseases)
 - Access to military populations and military health system beneficiaries (clinics, medical centers)
- Procurement and Fielding
 - Medical drugs, vaccines, devices, supplies
 - Assemble and field deployable hospitals

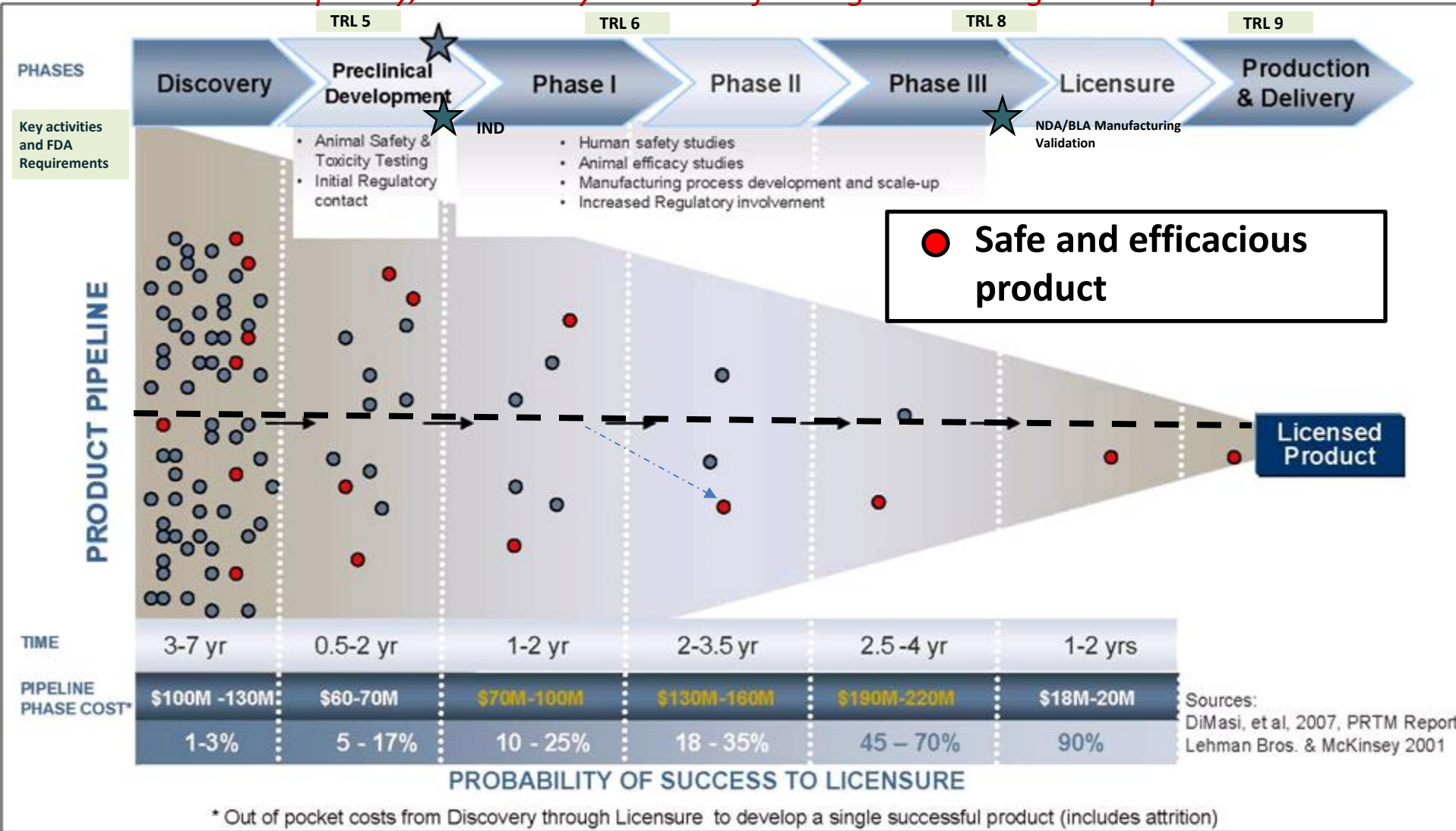




Drug Development Process and Timeline

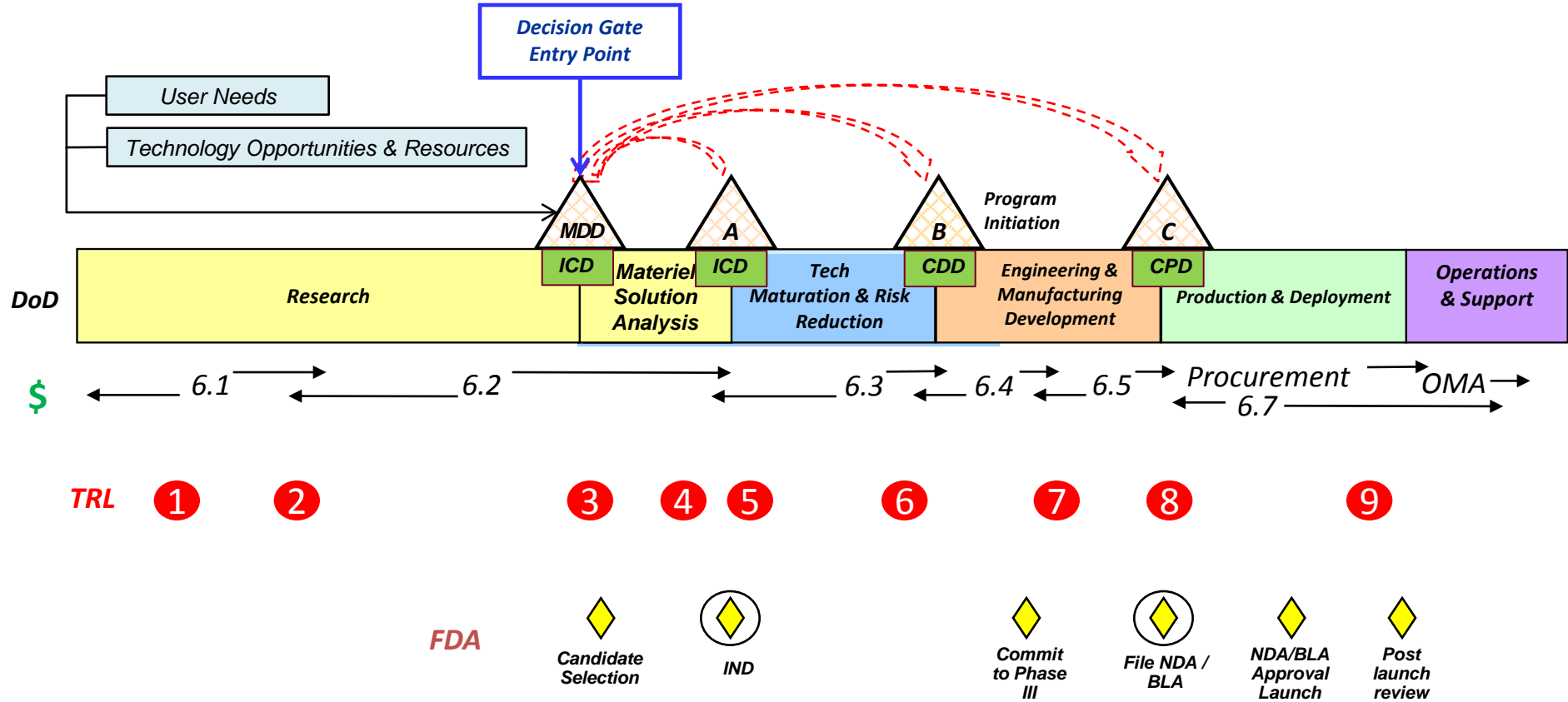


Complexity, uncertainty and cost of biologics and drug development





FDA Approval Process: Focus → Safety and Efficacy





IND – Investigational New Drug
 NDA – New Drug Application
 BLA – Baseline Agreement

Human* Clinical Trials



Decision Gate



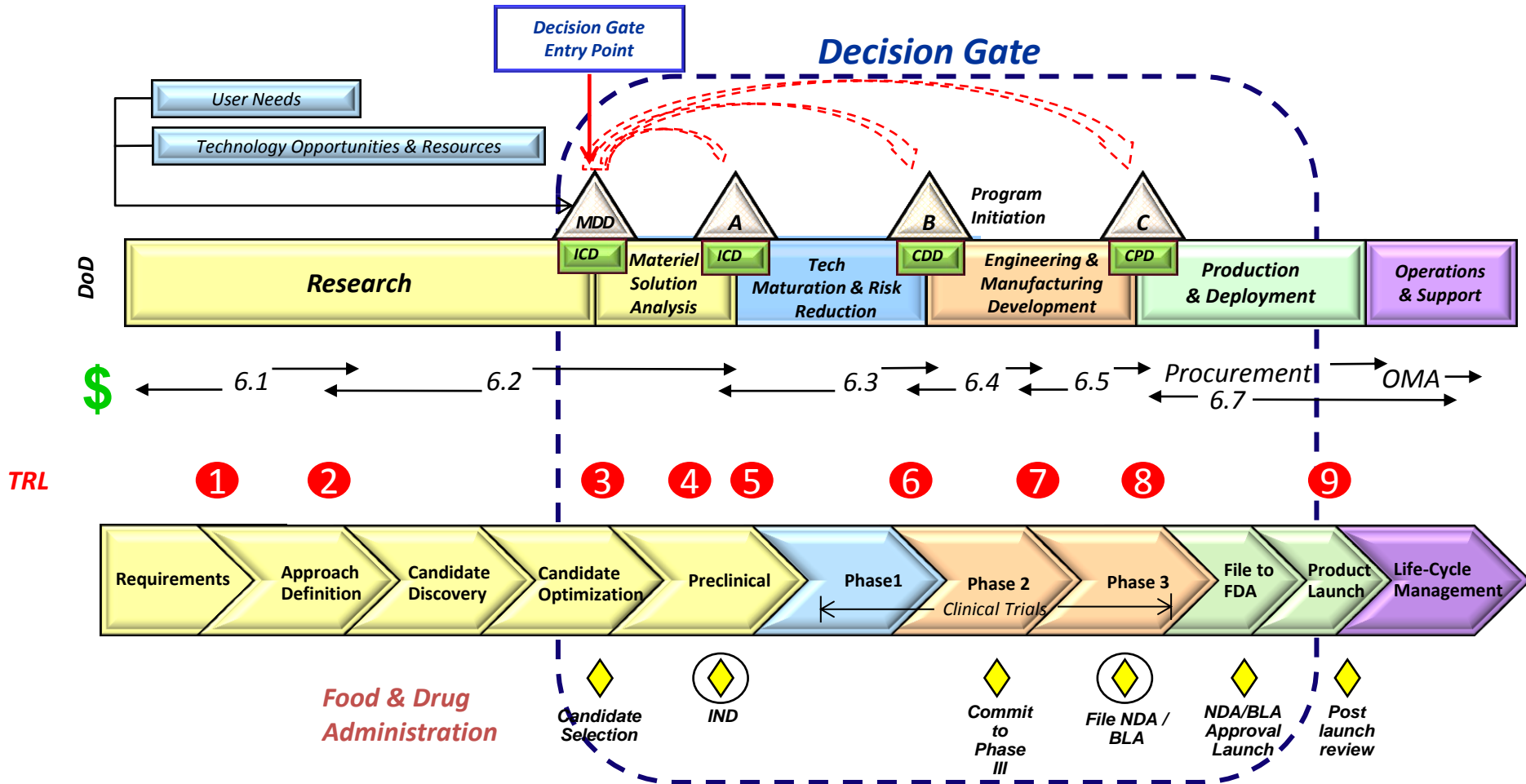
- USAMRMC Management Process
 - Integrates, aligns, and enforces DoD Acquisition and FDA Regulations/Policy
 - Also integrates pharmaceutical model 
 - Facilitates development of medical products for the War 
 - Establishes product development governance structure
 - Provides integrated guidance & decisions regarding product development, acquisition, and funding
 - It's **not** a separate/additional acquisition or regulatory system

Eliminates stovepipe development efforts;
reduces the “valley of death” risk between Science & Acquisition





Decision Gate





Decision Gate Capabilities/Products



Portfolio Category



Research*	Material Solutions Analysis*	Technology Maturation & Risk Reduction	Engineering & Manufacturing Development	Production & Deployment (Procurement)	Operations & Support (OMA)	Portfolio Category
6.1	6.2	6.3	6.4	6.5	6.7	
<p>PCR Assays – NGDS</p>	<p>Rapid Human Diagnostic Devices Arthropod Vector Assays</p> <p>Bacteriophage Treatments for Drug-Resistant Infections</p> <p>Improved Vector Traps</p> <p>Malaria Vaccines (P. falciparum & P. vivax combined)</p> <p>Next Generation Malaria Drug</p>	<p>Carbon Dioxide Generator</p> <p>HIV-1 Vaccine Global (multi), Inc 2</p> <p>Transfusion Transmitted Disease Rapid Diagnostic Device</p> <p>Alternate Dengue Vaccine Inc 2</p> <p>Hemorrhagic Fever w/ Renal Syndrome Vaccine</p> <p>Vaccines to Prevent Diarrhea</p>	<p>Topical Antileishmanial Drug Paromomycin + Gentamicin</p> <p>Dengue Tetravalent Vaccine (Inc 1)</p> <p>Antimalarial, IV Artesunate</p> <p>Malaria Prophylaxis (Tafenoquine)</p> <p>HIV-1 Vaccine Global Regional (Inc 1)</p> <p>Whole Blood Pathogen Reduction Technology</p>	<p>Adenovirus (Types 4 & 7)</p> <p>Leishmania Rapid Diagnostic Device</p>		Military Infectious Disease
<p>Intra-thoracic Pressure Relief Therapy</p> <p>Wound Stasis System (Intracavitary)</p> <p>Temporary Corneal Bandage</p> <p>Endovascular Hemostasis Device</p> <p>Advanced Physiological Monitor</p>	<p>Junctional Hemorrhage Control (XSTAT)</p> <p>Future Medical Shelters</p> <p>Extremity Repair</p> <p>Portable Neuromodulation Stimulator</p> <p>Pharmacological Treatment for PTSD</p> <p>Platelet Derived Hemostatic Agent</p> <p>Intracompartmental Pressure Relief</p> <p>Burn Treatment Skin Replacement</p> <p>Physiologic TBI Neuro Diagnostic</p> <p>Neuro-Cognitive TBI Diagnostic</p>	<p>Antiplateau Chewing Gum</p> <p>IV Drug Treatment for TBI (Neuren NNZ-2566)</p>	<p>Lab Assays for TBI (Manual & Bench-Top)</p> <p>Remote Physiological Status Monitor</p> <p>15LPM O2 Generator (DOGS)</p> <p>Freeze Dried Plasma</p> <p>Cryopreserved Platelets</p> <p>RBCs Extended Life</p>	<p>Noise Immune Stethoscope</p> <p>Steam Sterilizer – Field Portable</p> <p>O2 Generator Field Portable</p> <p>Burn Resuscitation Decision Support System - Mobile</p>		Combat Casualty Care
<p>Hydration Status Monitor</p> <p>Coliform Analyzer</p> <p>PTSD Diagnostic Panel</p>				<p>Environmental Sentinel Biomonitor</p>		Military Operational Medicine
		<p>Battlefield Pain Management (Inc 1 – Sufentanil NanoTabs)</p>				Clinical and Rehabilitative Medicine
		<p>Transport Telemedicine</p>				Industry

OWNER
 PHARM
 ICS
 MD
 MSS
 IM/IT
 HIVV
 TIRM
 NPH

*Not all S&T Products are documented



Blood Products In Decision Gate



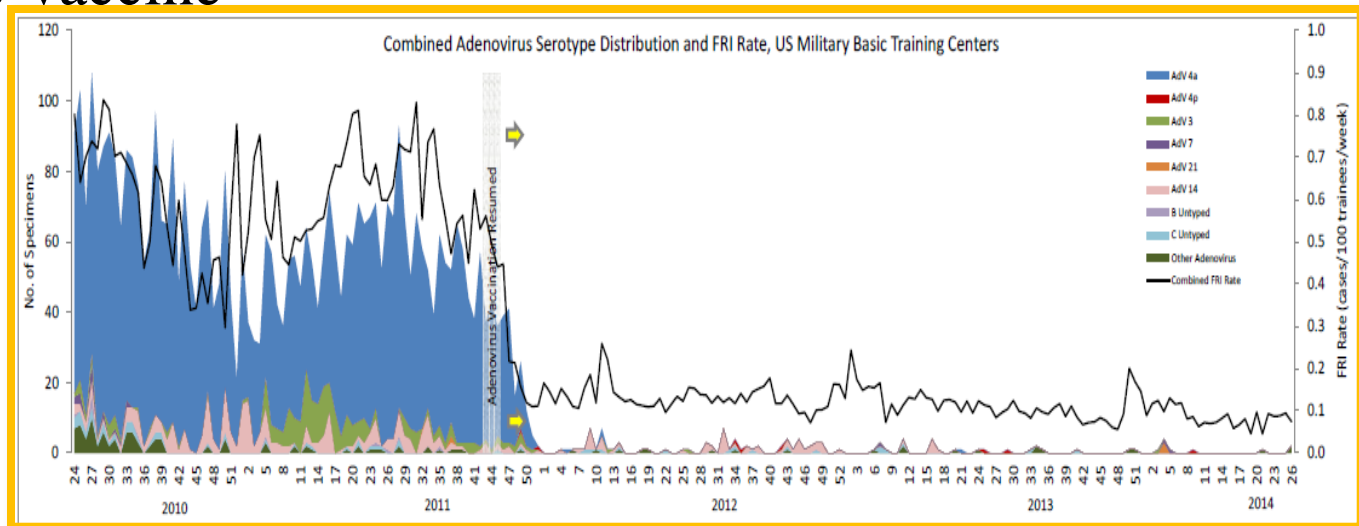
	Matériel Development Decision	Milestone A	Milestone B	Milestone C	Full Rate Production
Red Blood Cells Extended Life					FY13 FDA approved No formal MS C
Cryopreserved Platelets			MS B July 2014		
Freeze Dried Plasma			MS B August 2014		
Platelet Derived Hemostatic Agent					
Whole Blood Pathogen Reduction Device					
Transfusion Transmitted Disease Rapid Diagnostic Device			Functionally post-MS A		
Junctional Hemorrhage Control Agent (Pellets)					
Wound Stasis System (Foam)		MDD May 2015			



Examples of Recent USAMRMC Successes



- Leishmaniasis Rapid Diagnostic Device
- Noise Immune Stethoscope
- Malaria Rapid Diagnostic Device
- Oxygen Generator
- Steam Sterilizer
- Burn Resuscitation Decision Support System - Mobile
- Adenovirus Vaccine





Ways to Collaborate



- Science
- Advanced Development
- Purchasing
- Fielding
- Funding – Government; Industry; Non-Government Organization
- Contracts, Grants, Cooperative Research and Development Agreements



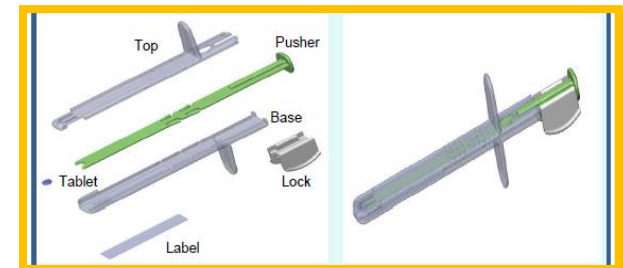
Noise Immune Stethoscope



Next Generation Malaria Prophylaxis



Bed Net



Sufentanil NanoTab Single Dose Applicator





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 - <https://mrmc.amedd.army.mil>
- To submit a product or idea, please visit:
 - <http://mrmc-npi.amedd.army.mil/>





U.S. ARMY

The Real Bottom Line!





Questions?



For additional questions after the conclusion of the conference, send an email message to usarmy.detrick.medcom-usamrmc.mbx.mmpd@mail.mil

