USAMRMC
Advanced Development and Program Management Overview

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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.
### Sec Army Top 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

### Medical AD Priorities

<table>
<thead>
<tr>
<th>Priority</th>
<th>Alignment with Sec Army Priorities</th>
</tr>
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<tbody>
<tr>
<td>1. Warfighter (Combat Casualty Care): Priority of Life, Limb, and Eye</td>
<td>2, 3, 7, 8</td>
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<tr>
<td>2. Post Traumatic Stress / Traumatic Brain Injury (TBI)</td>
<td>2, 3, 8</td>
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<tr>
<td>3. Human Performance Optimization</td>
<td>2, 3, 8</td>
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<tr>
<td>4. Pacific Region: Prolonged Enroute Care, Tele-Behavioral Health, Infectious Diseases</td>
<td>2, 4, 8</td>
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<tr>
<td>5. Infectious Disease Products**</td>
<td>2, 4, 8</td>
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<tr>
<td>6. Military Operational Medicine</td>
<td>2, 3, 8</td>
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** Sub elements a part of Pacific region

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

- **User Needs**
- **Technology Opportunities & Resources**

- **Entry Point**

- **Research**
  - MDD
  - ICD
  - Material Solution Analysis
  - ICD
  - Technology Maturation & Risk Reduction
  - ICD
  - Engineering & Manufacturing Development
  - CPD
  - Production & Deployment
  - Operations & Support

- **Technology Readiness Level (TRL)**: 1, 2, 3, 4, 5, 6, 7, 8, 9

- **Science**
- **Advanced Development (AD)**
- **Fielding**

**Acronyms**:
- MDD – Materiel Development Decision
- ICD – Initial Capabilities Document
- CDD – Capability Development Document
- CPD – Capability Production Document

**Notes**:
- MDD – Materiel Development Decision
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**Process**
- **Procurement**
  - 6.3
  - 6.4
  - 6.5
  - Procurement
  - 6.7
  - OMA
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

Key activities and FDA Requirements

Safe and efficacious product


* Out of pocket costs from Discovery through Licensure to develop a single successful product (includes attrition)
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 Warfighter
    - 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 Capabilities/Products

### Portfolio Category
- **Military Infectious Disease**
- **Combat Casualty Care**
- **Military Operational Medicine**
- **Clinical and Rehabilitative Medicine**

### Technology Maturation & Risk Reduction
- **Research**
  - PCR Assays – NGDS
  - Intra-thoracic Pressure Relief Therapy
  - Wound Stasis System (Intracavitary)
  - Temporary Corneal Bandage
  - Endovascular Hemostasis Device
  - Advanced Physiological Monitor
  - Intra-thoracic Pressure Relief
  - Physiologic TBI Neuro Diagnostic
  - Neuro-Cognitive TBI Diagnostic
  - IV Drug Treatment for TBI (Neuren NNZ-2566)
  - Lab Assays for TBI (Manual & Bench-Top)
  - Remote Physiological Status Monitor
  - 15LPM O2 Generator (DOGS)
  - Freeze Dried Plasma
  - Cryopreserved Platelets
  - RBCs Extended Life

### Engineering & Manufacturing Development
- **Material Solutions Analysis**
  - Rapid Human Diagnostic Devices
  - Arthropod Vector Assays
  - Bacteriophage Treatments for Drug-Resistant Infections
  - Improved Vector Traps
  - Malaria Vaccines (P. falciparum & P. vivax combined)
  - Next Generation Malaria Drug
  - Junctional Hemorrhage Control (XSTAT)
  - Future Medical Shelters Extremity Repair
  - Portable Neuromodulation Stimulator
  - Platelet Derived Hemostatic Agent
  - Burn Treatment Skin Replacement
  - Physiologic TBI Neuro Diagnostic
  - Neuro-Cognitive TBI Diagnostic

### Production & Deployment (Procurement)
- **Material Solutions Development**
  - Carbon Dioxide Generator
  - HIV-1 Vaccine Global (multi), Inc 2 Transfusion Transmitted Disease Rapid Diagnostic Device
  - Alternate Dengue Vaccine Inc 2 Hemorrhagic Fever w/ Renal Syndrome Vaccine
  - Vaccines to Prevent Diarrhea

### Operations & Support (OMA)
- **Material Solutions Analysis**
  - Topical Antileishmanial Drug Paromomycin + Gentamicin
  - Dengue Tetravalent Vaccine (Inc 1)
  - Antimalarial, IV Artesunate
  - Malaria Prophylaxis (Tafenoquine)
  - HIV-1 Vaccine Global Regional (Inc 1)
  - Whole Blood Pathogen Reduction Technology

### Operations & Support (OMA)
- **Material Solutions Analysis**
  - Adenovirus (Types 4 & 7)
  - Leishmanina Rapid Diagnostic Device

### Not all S&T Products are documented

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**OWNER**
- PHARM
- ICS
- MD
- MSS
- IMIT
- HIV
- TIRM
- NPH
# Blood Products In Decision Gate

<table>
<thead>
<tr>
<th>Blood Product</th>
<th>Materiel Development Decision</th>
<th>Milestone A</th>
<th>Milestone B</th>
<th>Milestone C</th>
<th>Full Rate Production</th>
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<tbody>
<tr>
<td>Red Blood Cells Extended Life</td>
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<td>FY13 FDA approved</td>
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<td>Cryopreserved Platelets</td>
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<td>Freeze Dried Plasma</td>
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<td>Platelet Derived Hemostatic Agent</td>
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<td>Whole Blood Pathogen Reduction Device</td>
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<td>Transfusion Transmitted Disease Rapid Diagnostic Device</td>
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<td>Junctional Hemorrhage Control Agent (Pellets)</td>
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<td>Wound Stasis System (Foam)</td>
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| Functionally post-MS A                             |                               |             | A           |             |                      |
| 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

Next Generation Malaria Prophylaxis

Noise Immune Stethoscope

Sufentanil NanoTab Single Dose Applicator

Bed Net
Contact Information

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- For more information about the USAMRMC, please visit
  - https://mrmc.amedd.army.mil

- To submit a product or idea, please visit:
The Real Bottom Line!
For additional questions after the conclusion of the conference, send an email message to usarmy.detrick.medcom-usamrmc.mbx.mmpd@mail.mil