



Medical Product Development Gaps Requiring Industry Support





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Agenda



- Overview of USAMRMC Medical Product Development Program – Dr. Tyler Bennett and Ms. Kathleen Berst
- United States Army Medical Materiel Development Activity Gaps
 - Pharmaceutical Systems Dr. Kendra Lawrence
 - Neurotrauma and Psychological Health LTC Jose Manuel Pizarro
- United States Army Medical Materiel Agency Gaps Ms. Nicolle Perez







Overview of USAMRMC Product Development Program

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Dr. Tyler Bennett Deputy for Acquisition United States Army Medical Materiel Agency

Ms. Kathleen Berst Deputy for Acquisition United States Army Medical Materiel Development Activity



Why is Army Medicine Involved?



We select, modify, and procure commercial medical materiel solutions when appropriate or we partner to develop.

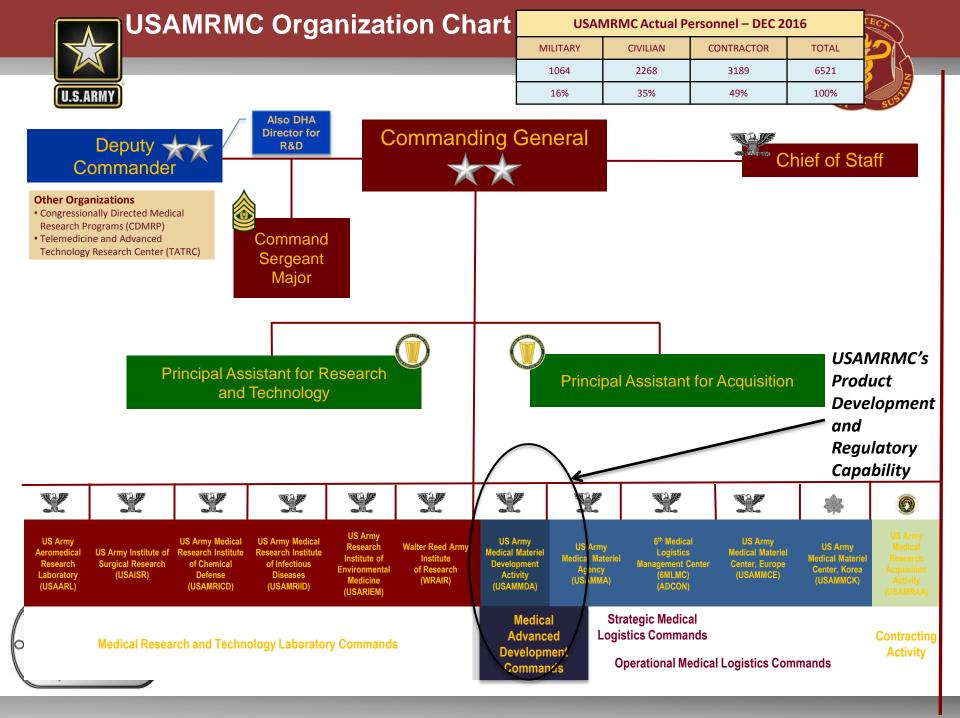
We take the lead in R&D when:

- The issue is unique to the military
- Industry/academia lack interest
- Military needs require acceleration of solution
- Directed by Congress
- Available commercial product cannot be sustained in military environment



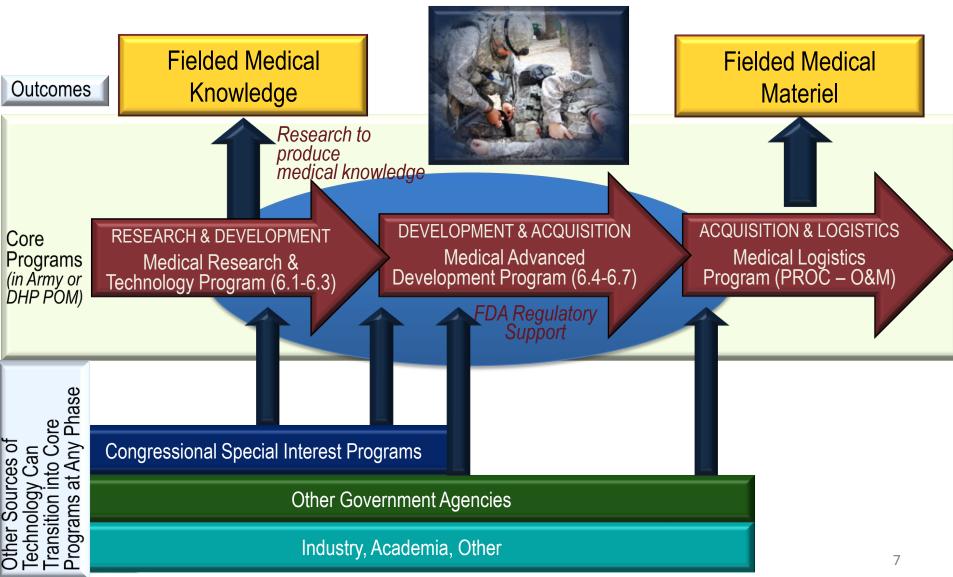






USAMRMC Operational Scope



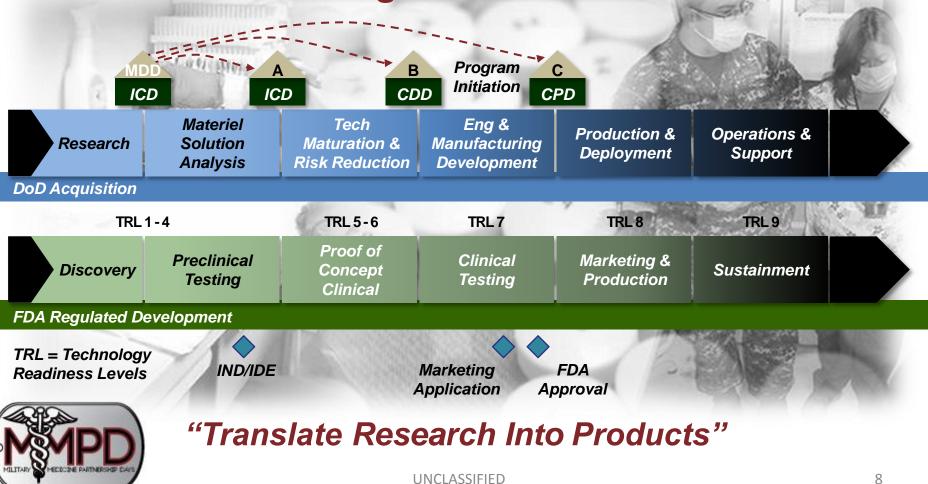




Governing Processes



Integration of DoD 5000 and FDA Regulation Process





How to Work with Us



- **Commercial Off The Shelf (COTS)** items
 - General Supply Schedules (i.e. E-CAT, E-MALL, GSA Advantage)
 - Direct Contract
- **Developmental Items**
 - Cooperative Research and Development Agreement (CRADA)
 - Broad Agency Announcement (BAA)
 - Small Business Innovation Research (SBIR)
 - Small Business Technology Transfer (STTR)
 - Other Transaction Authority (OTA)
 - Direct contract

Submit your ideas via the "New Products & Ideas" web portal http://mrmc-npi.amedd.army.mil/



USAMRMC New Products and Ideas

Inited States Army Medical Research and Materiel Command (USAMRMC) utilizes the Ne Products and Ideas (NPI) system as a mechanism to have visibility and evaluate new products and deas, currently configured or in development, that support our mission. The NPI provides a means for ur subject matter experts to assess these products and ideas, evaluate their applicability to JSAMRMC's mission, and provide feedback to the submitter. It provides the vendor an opportunity to showcase their product or idea without needing to travel to Fort Detrick and without giving anyone an nfair competitive advantage

on to the NPI is not a substitute where other vehicles are more app to Requests for Proposals (RFPs), the Broad Agency Announcement (BAA) or Program Announcements PAs), nor does it take the place of a pre-proposal that may be required by a BAA or PA.

USAMRMC does not award contracts, provide research grants, or offer other forms of financia support through the NPI. Likewise, USAMRMC does not purchase or obtain programs, services or products through the NPI. All requirements and funding opportunities are advertised through edbizopps.gov and grants.gov. Please visit those sites to view current solicitations and

Frequently Asked Question

Is there a place where I can showcase my medical products and supplies to USAMRMC "Vendor Day" provides opportunities for vendors to showcase their medical products and supplie This cooperative venture is a series of dates set aside for vendors of medical equipment and supplies to display their products to multiple service organizations at one time. To register for a place at an upcoming Vendor Day, go to https://www.dmsb.mil/VDay/vendorDay.asc

Please Read

his website uses SSL encryption on all pages except the H There is an issue with most commercial web browsers (IE, FireFox, hrome, etc.) that might display a certificate security warning when you tr reach an SSL-protected page

you get this warning on the MRMC-NPI website and your full displa omain name is mrmc-npi.amedd.army.mil, you are not at risk.

he safest and preferred way to resolve this issue is to install DoD roo rtificates into your browser (see MRMC page Problem with this V ecurity Certificate? for detailed instructions). You can also proceed at the ertificate warning -- which creates a security exception in your browser but does create a potential vulnerability where someone could read the you are submitting through this website



Sign up for Vendor Days http://www.health.mil/VendorDay







United States Army Medical Materiel Development Activity (USAMMDA)

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Where Our Products Touch the Lives of Warfighters







Cutaneous Leishmaniasis Topical Cream

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Dr. Kendra Lawrence

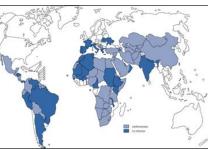
Product Manager

Pharmaceutical Systems Project Management Office USAMMDA



- CL is caused by *Leishmania spp.*, single-cell protozoan parasites transmitted through sand fly bites
- > The WHO estimates that:
 - Over 430M people live in endemic areas
 - ▶ 12M currently infected; 700K to 1.3M new cases yearly
- Lesions typically form on the face, arms, or legs producing potentially disfiguring ulcers and scaring
- Available treatments have toxic and painful side effects, are expensive, and can be difficult to administer
 - ➤ Treatments generally last ~20 days and administered in a medical facility
 - ➢ Military patients require higher echelons of care and/or evacuation









- In Phase 3 clinical trials (Tunisia (2011), Panama (2016)), Topical Paromomycin demonstrated an ~80% cure rate and an excellent safety profile
- Topical, <u>self-application</u> (once daily x 20 days) represents a significant improvement over current standard of care
 Facilitates immediate return to duty for deployed military
- Clinical development complete; in late-stage manufacturing
- FDA has granted Orphan Drug and Fast Track Designation
- Anticipate NDA submission in late 2018
- Topical Paromomycin will be available for licensing











Neurotrauma and Psychological Health Gaps

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LTC Jose Pizarro

Deputy Project Manager

Neurotrauma and Psychological Health Project Management Office



Neurotrauma & Psychological Health



Mission: To develop suitably mature materiel products for the treatment and diagnosis of Neurotrauma and Psychological Health conditions, such as traumatic brain injury (TBI), Post-Traumatic Stress Disorder (PTSD), and suicidality.

Neurotrauma Gaps

- TBI treatments/therapies
 - Pipeline; Delivery
 - Mild TBI/Prevent PCS
- Enhanced Classifications
- Blast dose to injury
- Genetic predisposition
- Novel biomarkers for prognosis, diagnosis and treatment efficacy

Psych Health Gaps

- Treatments and preventions PTSD
 - pathophysiology of PTSD using neuroimaging, genetics/genomics, and physiological measures
- Subtypes of PTSD
 - Identification; Treatment specific
- Validated measures for symptoms and impairment in military population
- Suicide prevention







United States Army Medical Materiel Agency (USAMMA)

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Ms. Nicolle Perez

Biomedical Engineer US Army Medical Materiel Agency





- Hemorrhage and Resuscitation
- Traumatic Brain Injury (TBI) Diagnostics and Treatments
- Post Traumatic Stress Disorder (PTSD) Diagnostics and Treatments
- Ocular Salvage Devices
- Wearable Sensors
- Telehealth
- Medical Evacuation
- Reduction of Weight, Cube and Cost for Items in Medical Sets, Kits and Outfits
- Modernization of Obsolete and Discontinued Medical Equipment
- Standardization of integrated clinical technologies





Areas of Interest (cont.)



Hemorrhage control

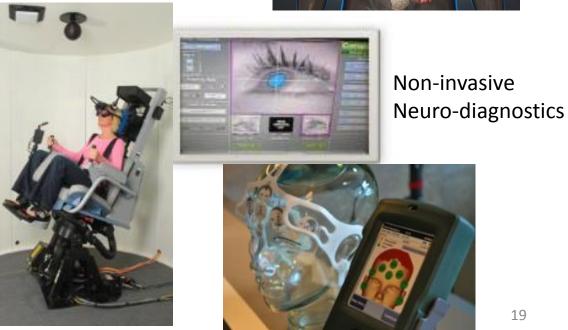


ResQFoam - An Intracavitary Noncompressible Hemorrhage Control Agent



Traumatic Brain Injury **Diagnostics and** Treatments







Telehealth

Areas of Interest (cont.)



Wearable sensors



Sotera ViSi Mobile



Athena GTX WVSM

Medical evacuation







Questions?



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

