



# Translating Research into Medical Products for Service Members

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# Agenda



- » Why does the DoD develop medical products?
- » Who are we?
- » What do we do?
- » How do we do it?
- » How can we work with you?



# Why?



## We save lives by delivering medical solutions that:

- Increase warfighter readiness
- Improve fitness, health, protection, and resilience
- Improve downrange health delivery
- Enhance recovery, rehabilitation or reintegration

USAMRMC: We Save Lives!





# Why is Army Medicine Involved?



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



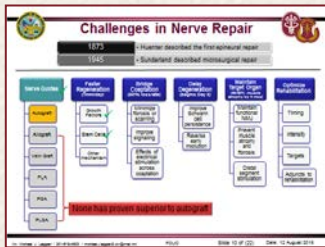
**We take the lead in R&D when:**

- 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





# This Work is Too Important to Leave to Chance



**Science**

**Business**

**Manufacturing**

**Change Practice**



**Regulatory**

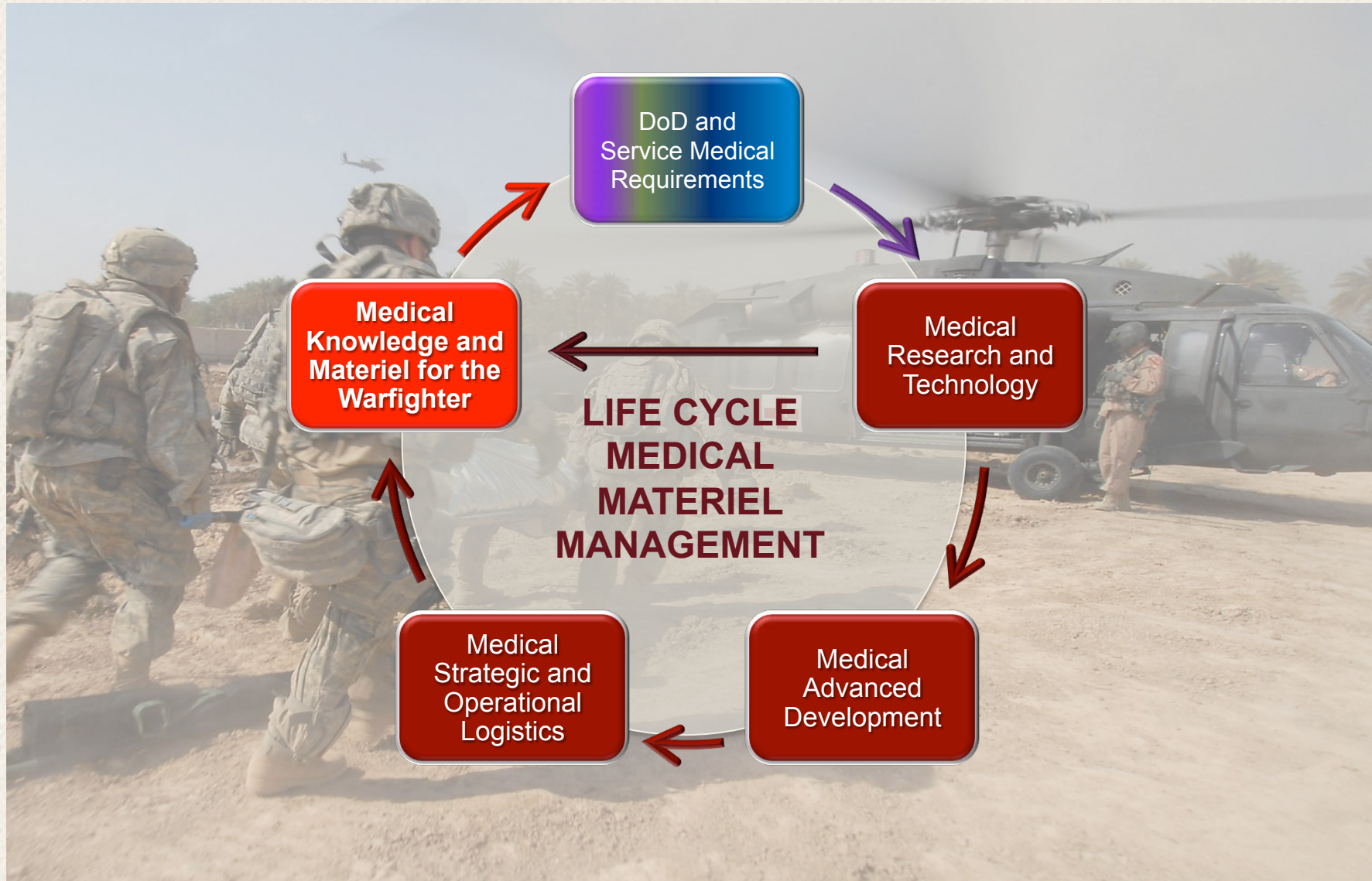
**Other funding**

**Reimbursement**





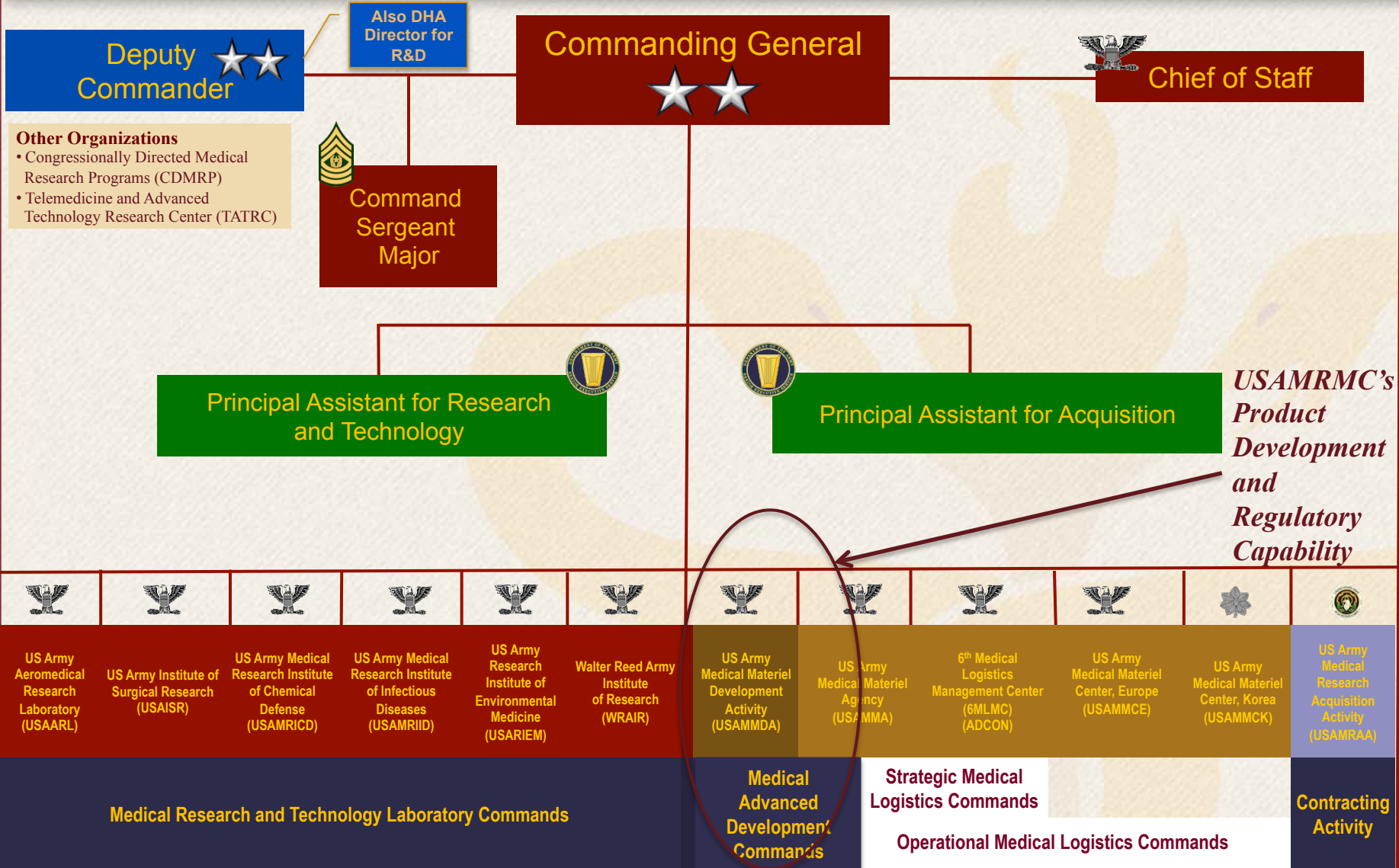
# US Army Medical Research and Materiel Command





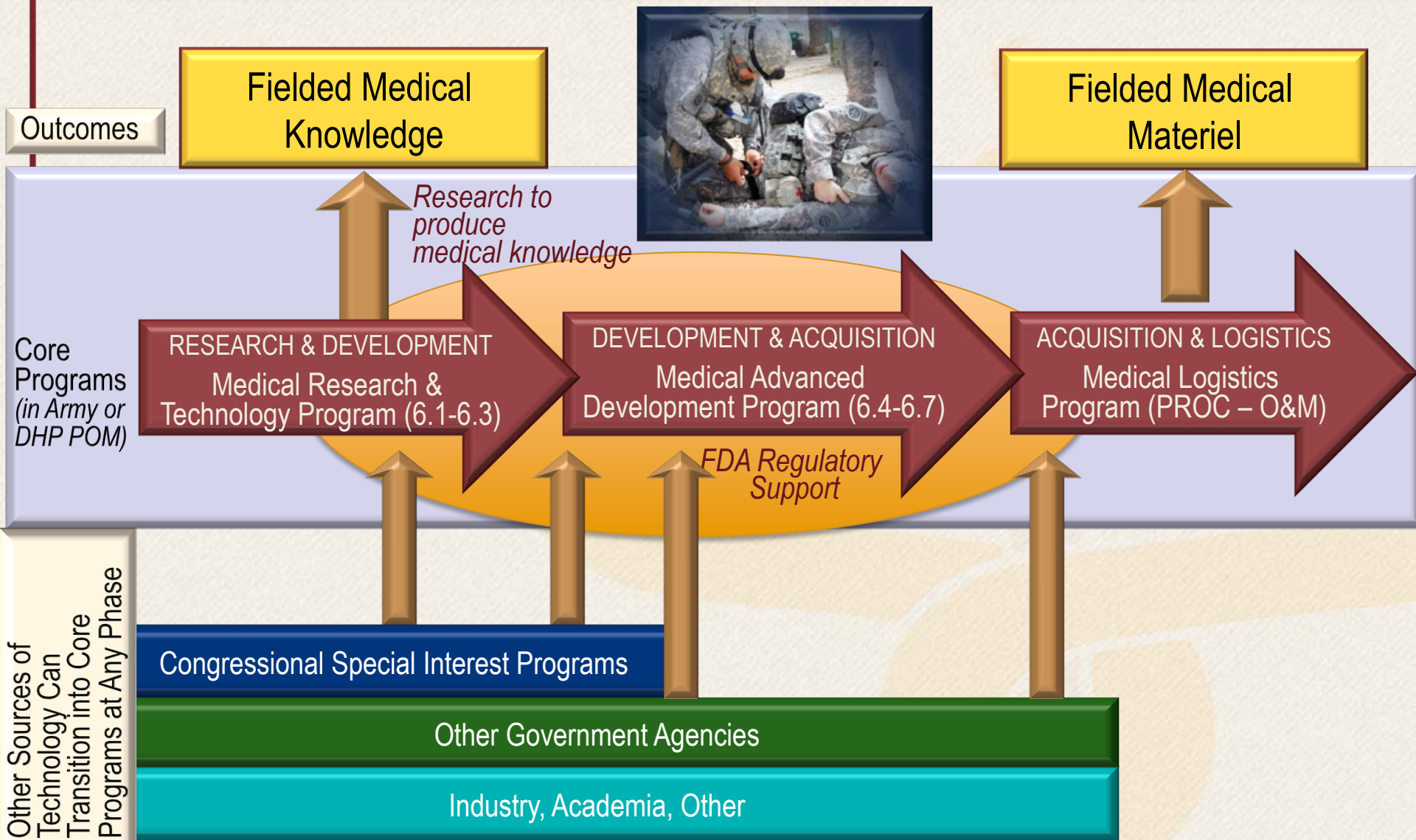
# USAMRMC Organization Chart

USAMRMC Actual Personnel – DEC 2016			
MILITARY	CIVILIAN	CONTRACTOR	TOTAL
1064	2268	3189	6521
16%	35%	49%	100%





# USAMRMC Operational Scope







# Product Development Competencies



**Advanced Development Translates Research Into Fielded Products = *Medically Ready Force***

RESEARCH → ADVANCED DEVELOPMENT → FIELDED PRODUCT

**Medical Product Development**

**FDA Regulatory Management**

**Clinical Development**

**Force Health Protection**

**Advanced Development's Core Competencies**  
*Bridging the Valley of Death*





# Balancing Technology and Requirements



## TECHNOLOGY PUSH

- Intramural and Extramural Partners - Technology Transition Agreement (TTA)
- Industry and Academia – SBIRs, STTRs, etc.
- Other Federal Departments/Agencies (i.e. HHS, DHS, DoD)



## REQUIREMENTS PULL

- Strategic Guidance Documents
- Joint Capabilities Integration and Development (JCIDs) Documents
- Congressional Direction



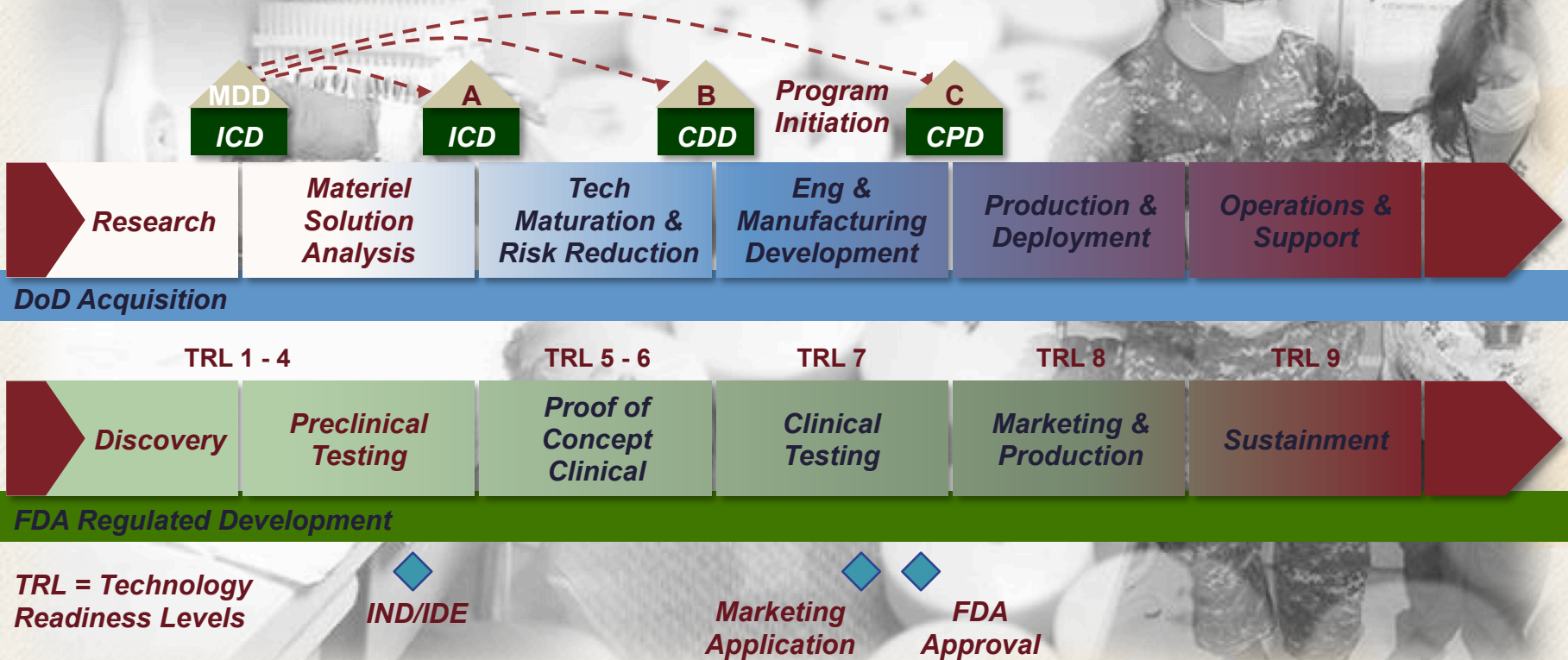
**End Goal: FDA approved, safe, effective, militarily relevant, affordable, and sustainable fielded product.**



# Governing Processes



## Integration of DoD 5000 and FDA Regulation Process



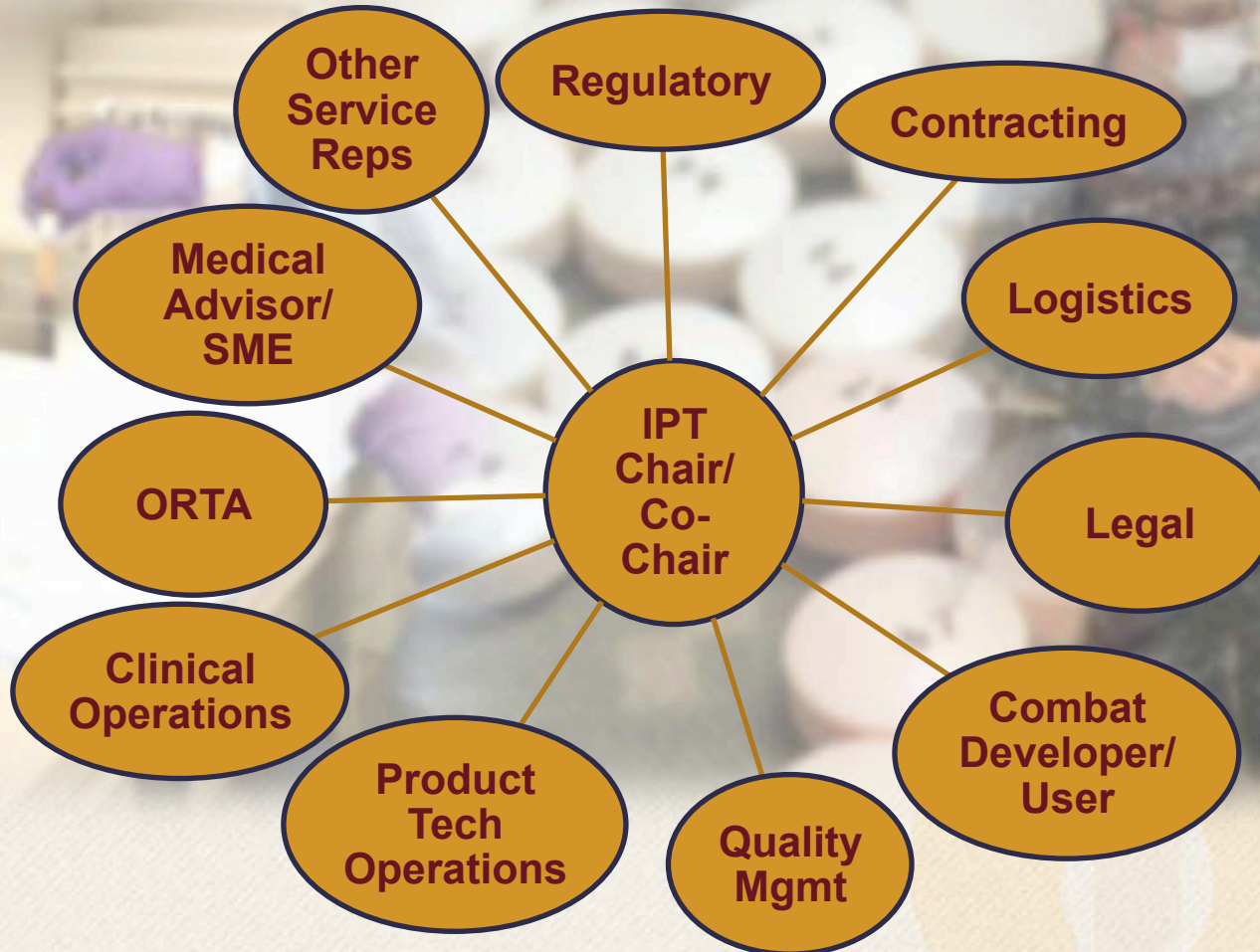
**“Translate Research Into Products”**



# Integrated Product Teams



*IPTs are critical because broad expertise is needed to develop and field medical products*





# USAMRMC's Medical Product Portfolio



## Where Our Products Touch the Lives of Warfighters



Prevention

Diagnose and Treat

Rehabilitate & Restore





# USAMRMC Materiel Development Portfolio



MDD	A	B	C	FRP
Materiel Solution Analysis	Technology Maturation and Risk Reduction	Engineering & Manufacturing Development	Production & Deployment	Operations & Support
<ul style="list-style-type: none"> <li>• Bacteriophage Treatment for Bacterial Infections</li> <li>• Intra-Compartmental Pressure Relief</li> <li>• Drug Treatment for Post-Traumatic Stress Disorder</li> <li>• Extremity Injury Repair</li> <li>• Improved Flying Vector Trap</li> <li>• Intrathoracic Pressure Regulation Therapy</li> <li>• Next Generation Malaria Drugs</li> <li>• Non-invasive Neuro-Assessment Device (TBI)</li> <li>• Platelet Derived Hemostatic Agent</li> <li>• Temporary Corneal Repair</li> <li>• Transfusion Transmitted Disease Rapid Diagnostic Device</li> <li>• Transport Telemedicine</li> </ul>	<ul style="list-style-type: none"> <li>• Alternate Dengue Vaccine</li> <li>• Anti-Plaque Chewing Gum</li> <li>• Bacterial Diarrhea Vaccine(s)</li> <li>• Burn Treatment Skin Repair</li> <li>• Drug Treatment for TBI</li> <li>• Hemorrhagic Fever w/ Renal Syndrome Vaccine</li> <li>• HIV Vaccine (Global)</li> <li>• Intracavitary Non-Compressible Hemorrhage Control Agent</li> <li>• Malaria Vaccines</li> <li>• Next Gen Diagnostic System Infectious Disease Assays</li> <li>• Portable Neuromodulation Stimulator (PoNS)</li> <li>• Rapid Human Diagnostic Devices</li> </ul>	<ul style="list-style-type: none"> <li>• Anti-Malarial IV Artesunate</li> <li>• Carbon Dioxide Generator</li> <li>• Cryopreserved Platelets</li> <li>• Dengue Tetravalent Vaccine</li> <li>• Freeze Dried Plasma</li> <li>• HIV Vaccine (Regional)</li> <li>• Lab Assay for TBI</li> <li>• Malaria Chemo-Prophylaxis - Tafenoquine</li> <li>• Topical Anti-Leishmanial Drug</li> <li>• Whole Blood Pathogen Reduction Device</li> <li>• Battlefield Pain Management - Sufentanil</li> </ul>	<ul style="list-style-type: none"> <li>• Environmental Sentinel Biomonitor</li> <li>• Noise Immune Stethoscope</li> </ul>	<ul style="list-style-type: none"> <li>• Adenovirus Vaccine (DHP funding)</li> <li>• Burn Resuscitation Decision Support System – Mobile</li> <li>• Leishmania Rapid Diagnostic Device</li> <li>• Oxygen Generator Field Portable</li> <li>• Steam Sterilizer Field Portable</li> <li>• Rigid Wall &amp; Soft Wall Shelters</li> <li>• &gt;214 LINs including ~130 Medical Equipment and Medical Materiel Sets               <ul style="list-style-type: none"> <li>• Prehospital e.g., Combat Medic, Air Ambulance</li> <li>• Combat Support Hospital</li> <li>• Chemical Agent Patient Decontamination</li> <li>• Chemical Agent Patient Treatment</li> </ul> </li> <li>• Ground Ambulance</li> <li>• Air Ambulance</li> <li>• JBAIDS Special Materiel</li> <li>• Entomology, Field</li> <li>• Water Quality Analysis</li> <li>• CSH 44-Bed Water Distribution and Wastewater Management</li> </ul>
<p style="text-align: center;"><b>Programs supporting other Program Executive Offices (PEO)</b></p> <ul style="list-style-type: none"> <li>• Junctional Hemorrhage Control Agent - XSTAT (USAF program - Army support)</li> <li>• Deployable Oxygen Generator System-Small (USAF program - Army support)</li> <li>• Improved First Aid Kit (PEO Soldier)</li> <li>• Maxx PRO Plus Ambulance Litter Lift System (PEO CS&amp;CSS)</li> <li>• Armored Multipurpose Vehicle Ambulance &amp; Treatment Mission Essential Packages (PEO GCS)</li> <li>• Remote Physiological Status Monitor (PEO Soldier)</li> <li>• Solider Optimization Decision Aids (PEO Soldier)</li> </ul>				
<p><b>Programs in purple: = Army executing DHP funds; Milestone Decision Authority is the Defense Health Agency Component Acquisition Executive</b></p>				



# Considerations in Development Planning



- **Begin with the end in mind**
  - Understand the Army need
  - “Good enough” now is better than perfect later
  - Avoid losing focus on what is really important
- **Regulatory strategy**
  - Early research decisions can have significant impact on future regulatory strategies
  - Focus on the target indication can avoid unnecessary money and time spent on studies not aligned to end goal
- **Financial planning**
  - DoD funding process starts years in advance of transition
  - We have already built the Army FY19-23 financial plan and are building the DHP FY19-23 financial plan now
- **Requirements documents**
  - It takes time to identify and develop the necessary requirements documents
  - Development and staffing of requirements documents can take 1-2 years – must be done in advance of acquisition decisions
- **Execution vehicles**
  - Well planned research and development contracts with appropriate options can take ~12-18 months (depending on value)



# Examples of Products in Development



## Freeze-Dried Plasma



## Whole Blood Pathogen Inactivation



Device to eliminate the risk of disease transmission of pathogens

## Intracavitary Non-Compressible Hemorrhage Control Agent



## Cryopreserved Platelets



Improved platelet

## Burn Treatment Skin Repair



## Anti-Malarial IV Artesunate



## Lab Assay for TBI



non-invasive medical device to identify & assess internal brain injuries

## Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA)



FDA Cleared 2016 -Balloon catheter to stop bleeding

## Topical Anti-Leishmanial Drug



## Battlefield Pain Mgmt







# Products Fielding Since 2010



## Adenovirus Type 4 & Type 7 Vaccine (2011)



## Burn Resuscitation Decision Support System – Mobile (2013)



## Improved First Aid Kit Generation II (2014)



## Modular Lightweight Load-carrying Equipment (MOLLE) Medic Bag (2014)



## Oxygen Generator Field Portable (2014)



## Medical Evac Mission Essential Package (2015)



## Environmental Sentinel Biomonitor (2016)



## Soft-walled Shelter for CSH/FH (2017)



## Steam Sterilizer Field Portable (2016)



**USAMRMC: Where Saving Lives Begins**

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# How to Work with Us



- » **Acquisition strategies are tailored to unique aspects of program – technical maturity, commercial market, risk, etc.**
- » **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 Area Announcement (BAA)
  - » Small Business Innovation Research (SBIR)
  - » Small Business Technology Transfer (STTR)
  - » Other Transaction Authority (OTA)
  - » Direct contract
- » **Participate in Vendor Days** <http://www.health.mil/VendorDay>



# What Are Current Opportunities?



## United States Army Medical Research Acquisition Activity USAMRAA

PRODUCTS | CUSTOMERS | ORGANIZATION | BUSINESS | REFERENCES | COMMUNITY | TOOLS | LINKS | SITEMAP |

- OSBP
- Assistance Agreements
- Forms
- Assistance Advisory Notices
- Procurement Advisory Notices
- New Products & Idea Submissions
- BAA
- Contact Webmaster
- iSalute
- PRWeb Help

- MRMC
- MEDCOM
- ARMY.MIL

- SHARP
- National Suicide

### IMPORTANT LINKS

- Center of Excellence
- CMRA
- USAMRAA Contract Requirements Matrix
- PRCentral Training Presentations
- HBCU-MI Briefing Presentations
- Advanced Acquisition Forecast (AAF)
- Trouble Accessing the USAMRAA website(s)
- AbilityOne E-Commerce Website (USAMRMC Base Supply Program)
- Fort Detrick Contracting Community Portal
- Sample Contract Supporting Documents
- VCE-COR website
- Vendor Day
- General Guidelines for Awards Funded by the DOD



### NEWS

#### USAMRAA BRANCH POC - CUSTOMER ASSIGNMENT LIST

#### PROGRAM ANNOUNCEMENT (PA) POSTINGS & UPDATES

For a complete listing of Assistance Agreement Funding Opportunities posted by the U.S. Army Medical Research Acquisition Activity, please see [Grants.gov](http://Grants.gov) and perform a search using CFDA# 12.420.

NOTICE: Any assistance instrument awarded under these Funding Opportunities will be governed by the award terms and conditions, which conform to DoD's implementation of OMB circulars applicable to financial assistance. Terms and conditions of new awards made after [December 26, 2014, may include revisions to reflect DoD implementation of new OMB guidance in 2 CFR part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."](#)

#### SOLICITATIONS POSTINGS & AMENDMENTS

For a complete listing of Solicitations posted by the U.S. Army Medical Research Acquisition Activity, please see [FedBizOpps](http://FedBizOpps) or the Army Single Face to Industry (ASFI) website and perform a search for W81XWH. Additionally, announcements with J&A's can be found on [FEDBIZOPPS](http://FEDBIZOPPS) and ASFI.

#### SOLICITATIONS \$15,000 TO \$25,000

Pursuant to FAR 5.101(a)(2) all solicitations issued by this activity expected to exceed \$15,000 and not expected to exceed \$25,000 will be posted on Federal Business Opportunities at <https://www.fbo.gov>. Choose the "Opportunities" tab, then enter "Department of the Army / U.S. Army Medical Research Acquisition Activity" in the Agency search field.

Contracting Activity Website - <https://www.usamraa.army.mil>



# Other Opportunities



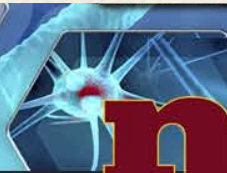
- » Medical Technology Enterprise Consortium
  - » What is it?
    - » 501 (c)(3) nonprofit, tax exempt corporation
    - » Advanced research for prototype development
    - » Other transaction authority
  - » What opportunities exist?
    - » Multi-topic Solicitation – May 2017
    - » Dengue Human Infection Model – May 2017
    - » Vascular Injury Repair – May 2017
    - » Combating Antibiotic Resistant Bacteria
- » Medical Product Research and Development, Indefinite Delivery/Indefinite Quantity Contract



# New Product Ideas



USAMRMC New Products & Ideas



# npi

Home

Submit Product/Idea

Resources

## USAMRMC New Products and Ideas

The United States Army Medical Research and Materiel Command (USAMRMC) utilizes the New Products and Ideas (NPI) system as a mechanism to have visibility and evaluate new products and ideas, currently configured or in development, that support our mission. The NPI provides a means for our subject matter experts to assess these products and ideas, evaluate their applicability to USAMRMC'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 unfair competitive advantage.

Submission to the NPI is not a substitute where other vehicles are more appropriate, such as responding 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 financial 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 [fedbizopps.gov](http://fedbizopps.gov) and [grants.gov](http://grants.gov). Please visit those sites to view current solicitations and announcements.**

### Need More Information?

The "Gateway to Partnerships Brochure," prepared by the Strategic Planning Office, describes some resources for doing business with USAMRMC. We suggest reviewing this brochure and contacting the

#### Please Read!

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

If you get this warning on the MRMC-NPI website and your full displayed domain name is [mrmc-npi.amedd.army.mil](http://mrmc-npi.amedd.army.mil), you are not at risk.

The safest and preferred way to resolve this issue is to install DoD root certificates into your browser (see MRMC page [Problem with this Website's Security Certificate?](#) for detailed instructions). You can also proceed at the certificate warning -- which creates a security exception in your browser -- but does create a potential vulnerability where someone could read the information you are submitting through this website.

Proceed to login

New Product Ideas Website - <http://mrmc-npi.amedd.army.mil/>



# Areas of Interest for Future Development



- » 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



# Other Questions?





# Current Research Opportunities



- » Grants or cooperative agreements - advertised on <http://Grants.gov>
- » Congressionally Directed Medical Research Program <http://cdmrp.army.mil>
- » USAMRMC Broad Agency Announcement [https://www.usamraa.army.mil/pages/Baa\\_Forms/index.cfm](https://www.usamraa.army.mil/pages/Baa_Forms/index.cfm)