Welcome

to the

2nd San Antonio Military Medical Industry Day

<u>Wi-Fi Connection</u>: Username is MilMed Industry Day and Password is Bio2020

MILITARY MEDICAL INDUSTRY DAYS

featuring the

Naval Medical Research Unit San Antonio
59th Medical Wing
and
U.S. Army Institute of Surgical Research

Hosted by:

City of San Antonio and
San Antonio Economic Development Corporation

BACKGROUND

Why are we here?

How did we get here?

What is next?

THANK YOU

SwRI®
SOUTHWEST RESEARCH INSTITUTE

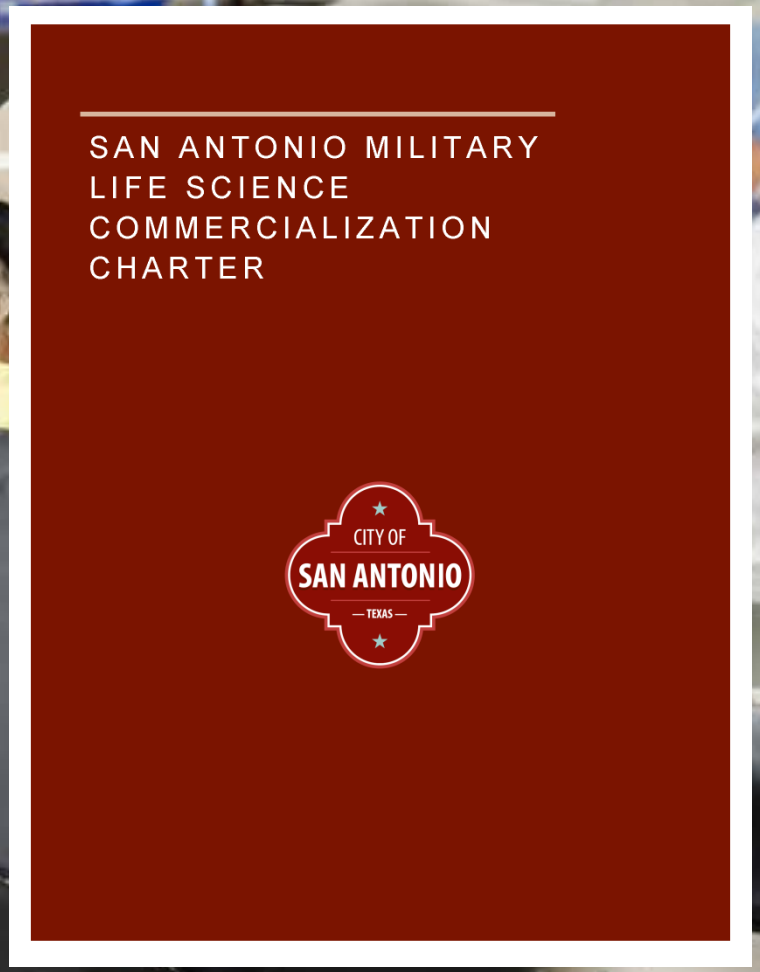
BioBridge
GLOBAL

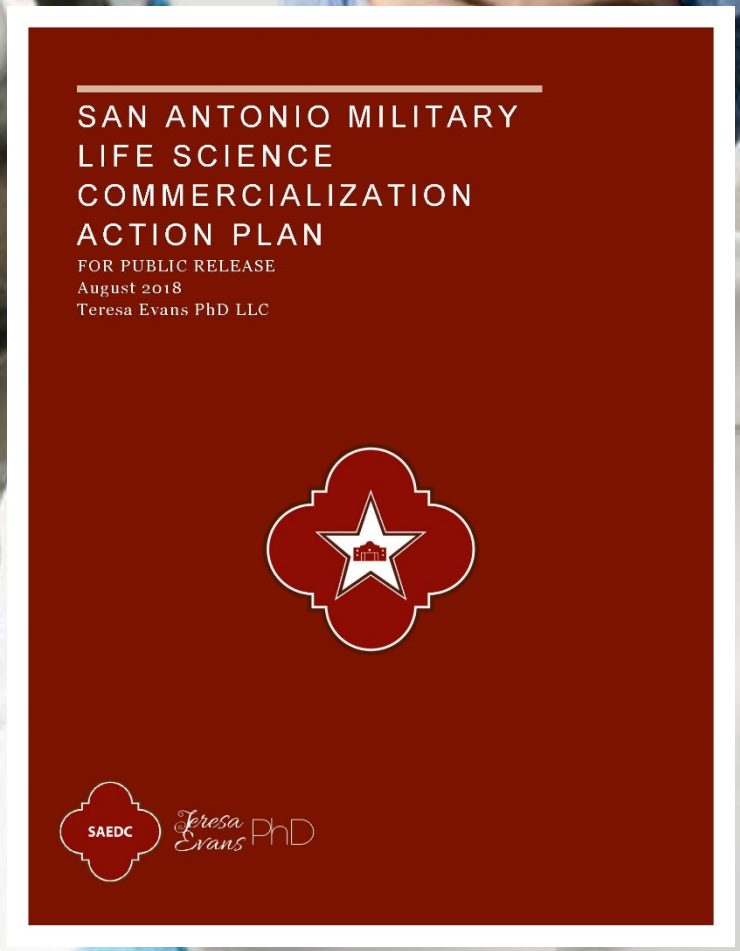
TEXAS BIOMEDICAL
RESEARCH INSTITUTE

A NEW ROLE WITHIN SAEDC

Corey Levenson, PhD
San Antonio Military Medical Innovation (SAMMI) Director
corey@saedc.org

CHARTER & ACTION PLAN





https://www.sanantonio.gov/EDD/Military-Life-Science-Commercialization

SAMMI DIRECTOR MANDATES

"The San Antonio Military Medical Innovation (SAMMI) Director will support the growing military life science ecosystem in San Antonio by facilitating partnerships and innovations that **help the military meet their medical mission requirements**, and at the same time, **create commercialization opportunities for the community.**"

KEYS TO SUCCESS

- Identification and licensing of **novel technologies** with applications in broad markets
- Recruitment of **experienced leadership** to drive commercialization efforts
- Ensuring **infrastructure** to support new ventures
- Identification of sources of **funding** to jump-start companies and support their growth
- **Raising awareness** of the potential value of San Antonio's local military medical both locally and nationally

KEY PLAYERS IN SAN ANTONIO

- Military Medicine Centers of Excellence
- Academic Institutions
- Not-for-Profit Research Institutions
- Foundations
- Private Sector Companies
- Infrastructure Providers
- Investors

BUILDING A MASTER MAP

Meet with Key Players and create a database capturing:

- Organizational structure & key points of contact
- Capabilities, research interests, competencies and resources
- Areas where new/additional collaboration is ongoing and desired

PUTTING THE PIECES TOGETHER

Facilitate technology commercialization by:

- Fostering collaborations between parties with complementary interests and capabilities
- Identifying sources of funding to initiate and sustain corporate growth
- Leveraging our unique military medical assets to create value

Make something good happen!

Welcome

to the

2nd San Antonio Military Medical Industry Day

CITY OF SAN ANTONIO TEXAS

59TH MEDICAL WING

NAVAL MEDICAL RESEARCH UNIT SAN ANTONIO

UNITED STATES ARMY INSTITUTE OF SURGICAL RESEARCH

59th Medical Wing

Research Overview:

A Model Platform for Medical Innovations

Dr. Deb Niemeyer
Chief Scientist
59MDW/ST

15 October 2019

Disclaimer:

The opinions expressed in this presentation are solely those of the author(s) and do not represent an endorsement by or the views of the United States Air Force, the Department of Defense, or the United States Government.

"Drive innovations in patient care and readiness"

SAMHS
San Antonio Military Health System

59th MEDICAL WING

59th MEDICAL WING
CHIEF SCIENTIST

Research – Continuum of Casualty Care

Research – Continuum of In-Garrison Care

Critical National and Local Resource

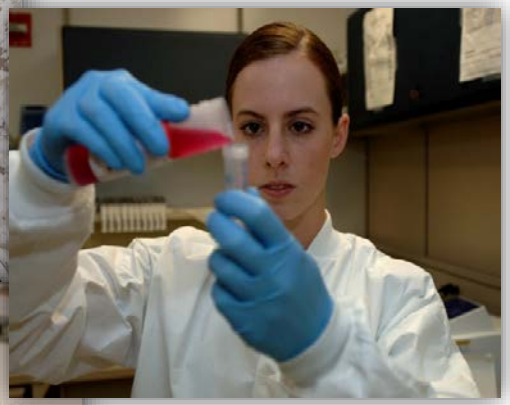
- Strategic Asset
  - "Home of Military Medicine"—SA Chamber of Commerce assessed $4B direct, $1B indirect economic impact
- 12 MTFs/$1.2B Budget /12,000 staff/250,000 beneficiaries
- 37 GME programs--600 residents, 22 GHSE programs--78 residents
- Contingency/Humanitarian response -- Teams on call 24/7 and ~150 Service Members deployed
- Significant Medical Innovation, Research, Education, Training
- San Antonio Military Medical Center
  - DoD's most productive inpatient facility
  - DoD's only CONUS Level 1 Trauma Center
  - DoD's only Bone Marrow Transplant Unit
  - DoD's only Burn Center
  - Center for the Intrepid
- Wilford Hall Ambulatory Surgical Center and Clinics
  - DoD's largest outpatient facility
  - DoD's largest Blood Donor Center
- DoD's largest centralized appointment/referral management system

Patients First, Partners Always

https://www.health.mil/Military-Health-Topics/Access-Cost-Quality-and-Safety/Access-to-Healthcare/Multi-Service-Markets/San-Antonio-Military-Health-System

ST Enables across Mission Areas, Trusted Care and HRO

Warrior Medics – Mission Ready – Patient Focused

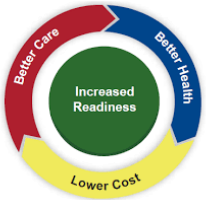


- Largest of 15 clinical training sites in the USAF
- Air Force's most productive Clinical Investigation Program
  - ~400 protocols (JBSA-Lackland)
  - Readiness Training
  - Regulatory Oversight/Compliance
- Clinical Research Platform
- Mission/Gap Aligned Research
- Major Focus Areas
  - Clinical Investigations
  - Trauma Clinical Care
  - Diagnostics & Therapeutics
  - Nursing Research
  - Dental Research
  - Technology Transfer/Transition
  - Research Education & Training

https://www.59mdw.af.mil/

Science & Technology

Warrior Medics – Mission Ready – Patient Focused



Vision: *Grow Medical Leaders, Drive Innovations in Patient Care and Readiness*

Mission: *Conduct clinical studies and translational research and apply knowledge gained to enhance performance, protect the force, and advance medical care and capabilities across the global health system*

Chief Scientist
Science and Technology
Providing operational capability through…

- *Lead & Support Research*
- *Advance Modernization Efforts*
- *Foster Collaboration*
- *Address End User Needs*
- *Ensure Scientific Excellence*

Readiness, Healthcare, Education, Training, and Research

Wing, SAMHS, AFMS / Services ASD/OSD, Joint Cmts / S&T, Adv Dev

https://www.59mdw.af.mil/Units/Chief-Scientist-ST/

JBSA Main Office: (210) 292-2097

Theater of Operations ↔ Garrison Care

Warrior Medics – Mission Ready – Patient Focused

Air Force Expeditionary Medicine
Joint Austere Medicine

Role 1
Point of Injury

Role 2
Mobile Field Surgical Team/EMEDS

Role 3
EMEDS +25
AF Theater Hospital

Role 4
OCONUS Definitive Care

Role 5
US-based MTF Full Range/ Definitive Care

Post-Acute Care
Dept of Veteran Affairs

VA Health

Air Force Integrative Clinical Medicine
Joint Integrative Clinical Medicine

Performing Research and Providing Deliverables to Address AFMS and Joint Medical Priorities across the Continuum of Care

Representative Research

Austere Medicine & Integrative Clinical Care

San Antonio -- Home of Military Medicine and Critical National Resource for Battlefield Health and Trauma Research

- En Route Care Research Center, Adult ECMO Center and Acute Lung Rescue Transport Team (ALRT)
- Regenerative Medicine and Scaffolds; Organ perfusion; Targeted Therapeutic, Monitoring/Diagnostic Strategies
- Biosensing platforms to improve Combat Medic Management and Triage
- Ocular Trauma Triage Stabilization and Telemedicine
- Non-Opioid Pain Management for Patient-Centered Medical Care
- Directed Energy Models and Clinical Diagnoses, and Interventions
- Cross-Service Readiness Research and Training for Critical Care Personnel

Major Programs/Capabilities

Warrior Medics – Mission Ready – Patient Focused

- **Clinical Investigations and Research Support**
  - Clinical Investigations Program, Readiness & Certification Training
- **Nursing Research / Center of Clinical Inquiry**
  - Chief Nurses consultation/24 MTFs; Research & Evidence Based Practice
- **Dental Education, Research and Consultation**
  - USAF Post Graduate Dental School and Clinics, JBSA-Lackland
  - Dental Research and Consultation Service, JBSA-Fort Sam Houston
- **Integrated Clinical Medicine / Center for Molecular Detection**
  - Rapid Pathogen Detection/Analysis & Precision Medicine Research
- **En Route Care Research Center**
  - Co-located at USAISR; AE-ERC research in Collaboration with other Organizations
- **Clinical Resuscitation, Emergency Science & Toxicology Program**
  - Animal research conducted at CIRS, JBSA-Lackland
  - Emergency Medicine Residents participate to fulfill graduation requirements
- **Trauma and Regenerative Medicine Research**
  - Clinical Investigations, JBSA-Lackland; USAISR/BHT & TSRL, JBSA Fort Sam Houston

59MDW Collaborative Research Platform

Warrior Medics – Mission Ready – Patient Focused

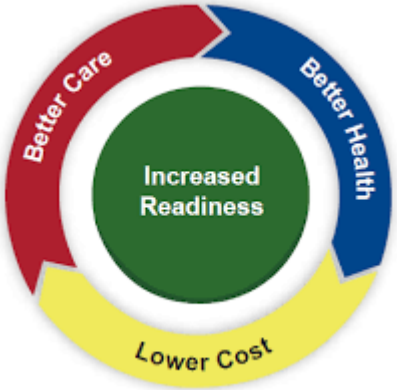
PEOPLE **MISSION** **INNOVATION**

Representative Research Areas

- **Trauma Critical Care-En Route Care**
  - Trauma, Hemostasis & Resuscitation/Point of Injury Care
  - Immunomodulation of Trauma
  - Regenerative & Restorative Medicine
  - Neuroradiology
- **Trainee Healthcare, Infectious Diseases**
  - Preventative/Early Mitigation; Rapid Detection & Surveillance
  - Vector-borne and Zoonotic Diseases
- **Clinical Medicine and Omics**
  - Disease Genetics, Genomics, Proteomics, and Bioinformatics
  - Precision Medicine
- ***New Focus Areas/Partnerships—Research Enablers***
  - Semi/Autonomous Systems, AI, Sensors, Synthetic Biology, Virtual Reality

Representative Research Areas

- **Health Services Research – New DHA Initiative**
  - Established to address factors that influence health care delivery.
  - Research will integrate epidemiologic, sociologic, economic and other analytic sciences to better understand relationships between need, demand, supply, use, and outcomes of health care.
  - Knowledge obtained supports evidence-based policy and leadership decision-making at both the strategic and front-line levels.
  - Enable decreasing system variations in terms of cost, quality, health care outcomes, and health readiness that can be compared to private sector best practice.
  - Areas of interest include:
    - Health Care Cost and related Economics
    - Variation in Health Care Quality
    - Health Readiness
    - Health Care Outcomes



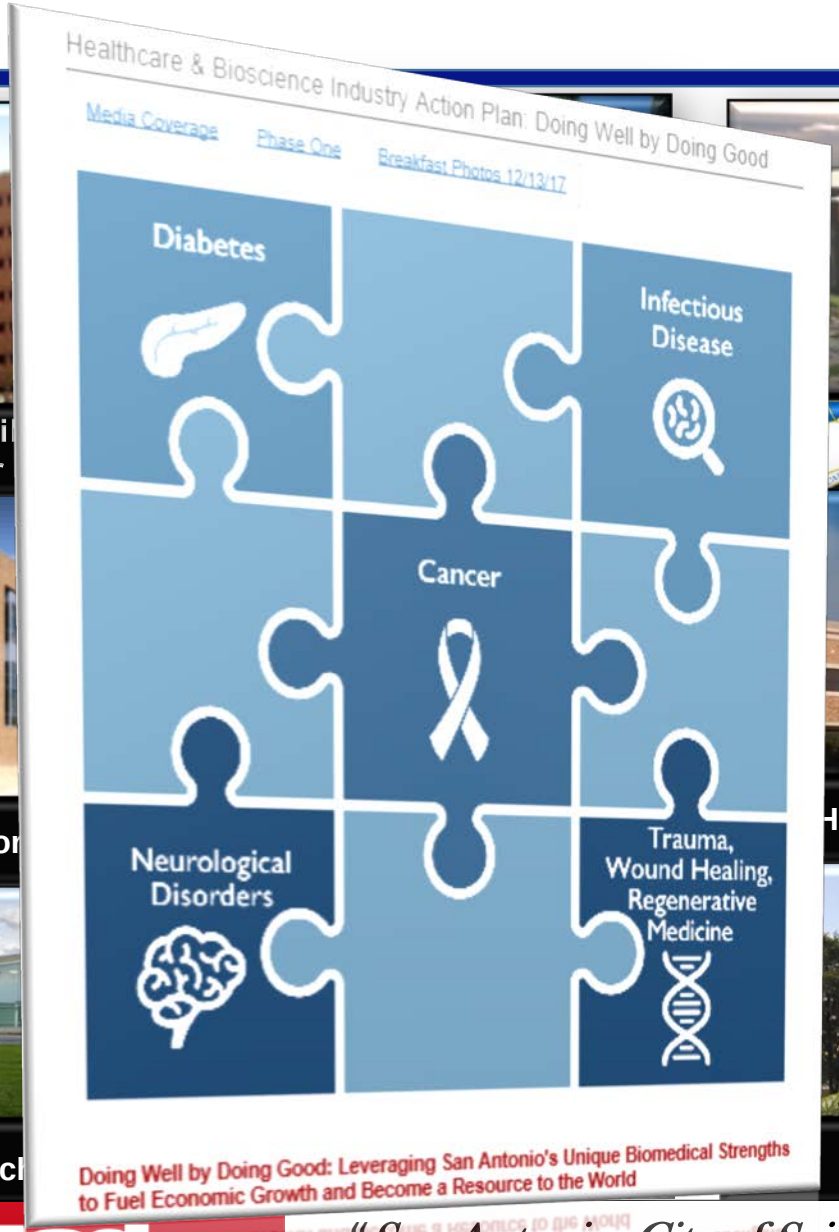
San Antonio Military Medical Research

Strong DoD-Federal-Academia-Industry Synergy

San Antonio Mi
Medical Center

Audie L. Murphy VA Memor

AF Post-Graduate Dental Sc



Wilford Hall
Ambulatory Surgical Center

Center for Molecular Detection

Clinical Research Support

Health Science Center San Antonio

UT San Antonio

"San Antonio. City of Science and Health."

Animal Research Locations

Warrior Medics – Mission Ready – Patient Focused

Animal Research Program Capabilities

1

Clinical Investigation Research Support (CIRS)

2

USA Institute for Surgical Research-Battlefield Health and Trauma

3

Tri-Service Research Laboratory

4

Bridge Preclinical Test Services/Geneva Foundation/University of the Incarnate Word

5

Texas Biomedical Research Institute

6

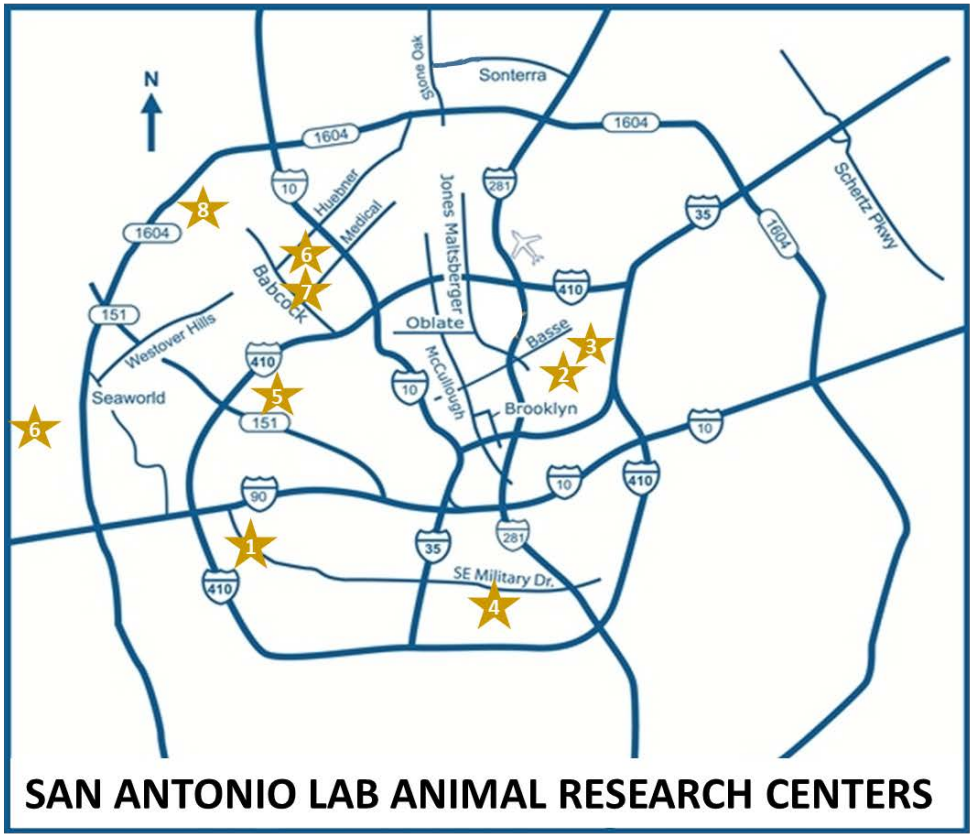
UT Health Science Center San Antonio

7

Audie L. Murphy VA Hospital

8

University of Texas San Antonio Laboratory Animal Resources Center



Laboratory Research Locations

Warrior Medics – Mission Ready – Patient Focused

Clinical Investigation Research Support (CIRS)

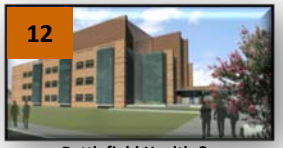
Center for Advanced Molecular Detection (CAMD)

Wilford Hall Ambulatory Care Center (WHASC) Hearing COE

59DTS / AF Post Graduate School & Clinics

USAF Dental Evaluation & Consultative Service (DECS)

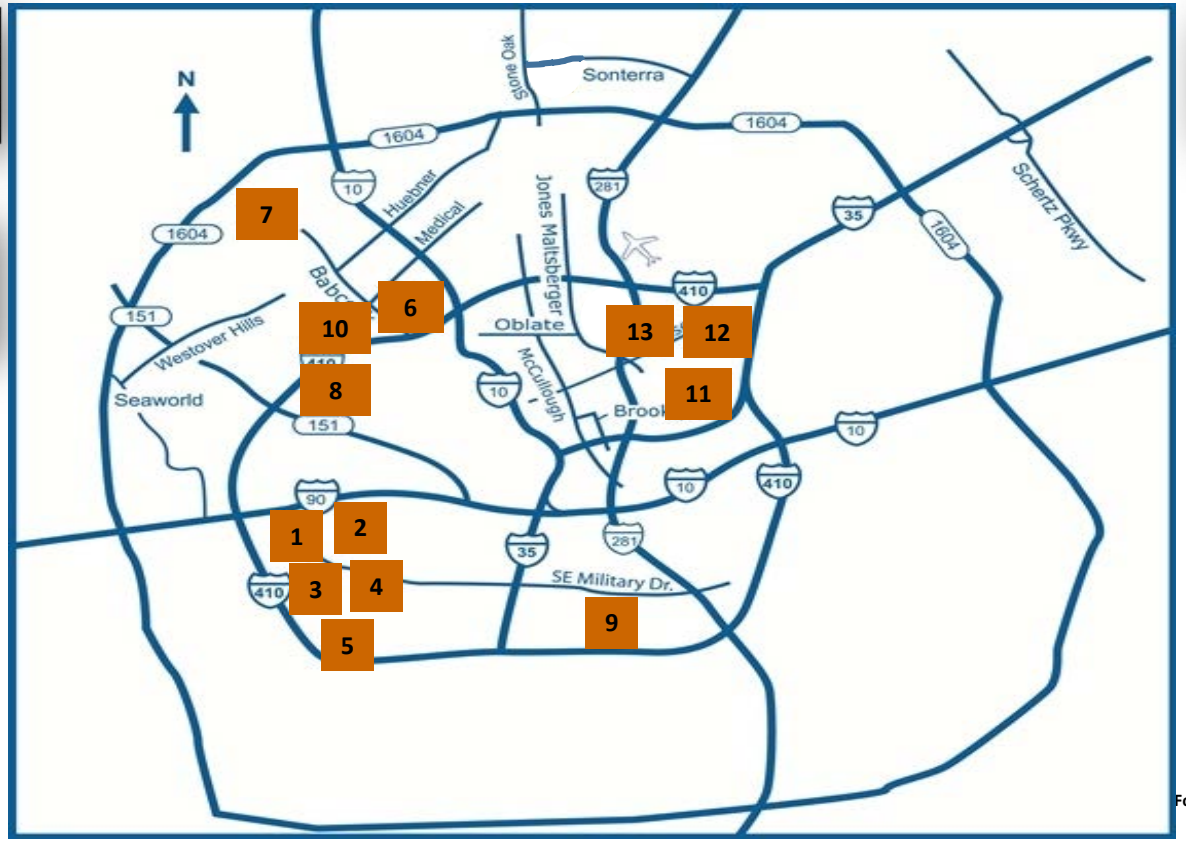
Tri-Service Research Laboratory



Battlefield Health & Trauma Research Institute

San Antonio Military Medical Center DCI

Audie L. Murphy VA Hospital



UT Health Science Center San Antonio

UT San Antonio

Texas Biomedical Research Institute

Bridge Preclinical Test SVS/Geneva Foundation Univ. of the Incarnate Word

59th Medical Wing
Product Pipeline and Stakeholders

Warrior Medics – Mission Ready – Patient Focused

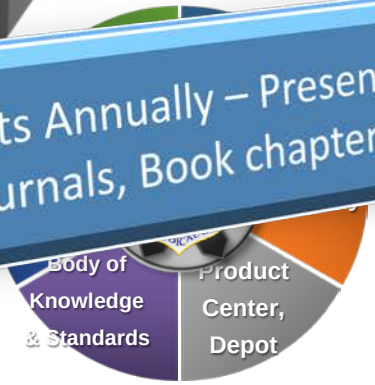
Examples/NOT all inclusive

Forward Operating Base Ocular Trauma Telemedicine Triage and Stabilization
Stakeholder: ACC
Transition Type: Knowledge
Transition Timeframe: 3 yrs

Biomeme Sample Prep and Assay Panel Vector-Borne Disease
Stakeholder: ACC, JPEO-CBD
Transition Type: Industry / Materiel
Transition Time: 12 months

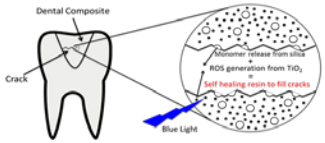
Strategies to Treat Occult Non-Compressible Torso Hemorrhage
Stakeholder: AFSOC, ACC
Transition Type: Knowledge / Material
Transition Timeframe: 3 yrs

900+ Knowledge Products Annually – Presentations at medical societies, Publications in Peer-reviewed Journals, Book chapters, Stakeholder technical reports, etc.

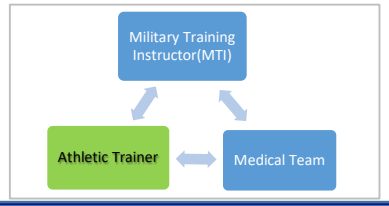


An Integrative Approach to Non-Opioid Pain Management in Air Force Patient-Centered Medical Homes
Stakeholder: AETC, AFDW, ACC
Transition Type: Knowledge / Training
Transition Timeframe: 2 yrs

Silica Encapsulated Monomers for Self-Healing Dental Materials
Stakeholder: USAF DC
Transition Type: Knowledge / Materiel
Transition Timeframe: 2 yrs



Athletic Trainer Integration in U.S. Air Force Basic Training
Stakeholder: 2d AF/AETC/USAF Basic Military Trainees (All six Basic Trainee Sqs)
Transition Type: Knowledge / Training Practices
Transition Timeframe: 12 months



First study to validate and quantify the extent of clinical improvement of PTSD patients receiving the Battlefield Acupuncture technique; clinical training in progress. A follow-on clinical trial is in preparation for a compressed PTSD acupuncture regimen

PEOPLE **MISSION** **INNOVATION**

Wartime Skills Sustainment Platform

Burn Center and Level I Trauma Center

- Both verified at highest National level
- Integrated Battlefield Health & Trauma Research
- Growing Research Education and Training Programs
- Support both Military and Civilian Fellowship training programs in Emergency Medicine, Trauma & Critical Care

"Drive innovations in patient care and readiness"

SAMHS
San Antonio Military Health System

59th MEDICAL WING

59th MEDICAL WING
CHIEF SCIENTIST

59th Medical Wing

Warrior Medics – Mission Ready – Patient Focused

"Grow Medical Leaders, Drive Innovations in Patient Care and Readiness"

ST Organizational Chart

59MDW/CC
(and Human Research Protection Institutional Official)
Maj Gen John DeGoes

59MDW/ST
CHIEF SCIENTIST
(and HRP AIO)
Dr Debra Niemeyer

DEPUTY CHIEF SCIENTIST
(dual-hatted/STN2)
Lt Col Jacqueline Killian

MAIN OFFICE
EXEC ASST
(all ST support)

Quality Improvement/
Patient Safety Support
(QIPS) Cell

STRATEGY
(Leads Science)

Clinical Research Innovation Center: Leading, Conducting, and Supporting Clinical Studies and Translational Research, Research Education and Training enabling the Quadruple Aim

"Leveraging the best market in the MHS for Full Spectrum Readiness, Education and Training, and Research and Development." Maj Gen John J. DeGoes

OPERATIONS
(Leads Execution)

59MDW/SAMHS/80+ sites supported Worldwide

RESEARCH BUDGET & ACQUSITIONS
Mr Michael Dinkins

Budget, Contracts, Financial, Logistics, Medical Administration Support

Committees
-Scientific Advisory Cmte
-Research ACQ & Advisory Cmte
-HRPP Steering Committee
-Scientific Ethics SubCmte
-New Technologies SubCmte
-Other SubCmtes as Needed
-SAMHS-Universities Research Forum
-BioMedSA Board of Directors

HRPP & CONFLICT OF INTEREST OFFICE
Ms Michele Tavish
Dr Wayne Deutsch

SENIOR RESEARCH PROGRAM ANALYST & CELL MNGR
Mr Jerry Spencer
-Internal and External Tasks Lead; PAO Interface
-Technical Program Mngmnt & Project Analysis

Research Cell – Strategic Plans/Programming, Scientific and Technical Support

-Dental Liaisons: AF-Post Graduate Dental School & Clinics; GDE (Dr Kraig Vandewalle) and Dental Research & Consultative Support (DRCS) (Col Daniel Savett)
-San Antonio Uniform Services Health Education Consortium, GME/GHSE (Col Mark True)
-Centers (DHA HCE; Diabetes CoE; Sleep Ctr; Bone Marrow Trnsplnt; Burn Ctr, etc.)

TECH BASE - SAMHS
(Lead Technical Programs)

DIRECTOR, TRAUMA & CLINICAL CARE RESEARCH, Dr Amber Mallory

AF EM Research Thrust Area
Joint Austere Medicine Research

- Surgical and Technological Advancements for Traumatic Injuries in Combat (STATIC)
-Forward Applications for Circulatory Trauma and Stabilization (FACTS)
-Restorative Endeavor for Service Members Thru Optimization of Reconstruction (RESTOR-EM)
- Provider Scientist-Investigator Opportunity Network (PSION)

Director, ECRC
En Route Care Research Center

TECHNICAL DIRECTOR,
Dr Scott Walter

Product Transfer, Transition, Partnerships & Commercialization

-Technology Transfer Focal Point
-FDA Consultation/Support
-Extramural Outreach/Partnerships
-Military Medical Industry Days Lead
-Knowledge & Material Transition
-Advanced Development Lead
-Product Commercialization

Office of Research and Technology Applications (ORTA)

DIRECTOR, CLINICAL INVESTIGATIONS & RESEARCH SPT, Col Carol Walters

Clinical Investigations Program Lead & DHP RDT&E Support

-Clinical Research Laboratory
-Clinical Research Operations
-Clinical Research Support

Research & Regulatory Compliance (IRB/IACUC)

Clinical Investigations Facility (CIF)

DIRECTOR, DIAGNOSTICS, THERAPEUTICS AND 'OMICS, Dr Carl Brinkley

AF ICM Research Thrust Area
Joint Integrative/Clinical Medicine Research

-Precision Medicine & Patient Centered Care
-Military and Family Health & Resilience
-Restorative Endeavor for Service Members Thru Optimization of Reconstruction (RESTOR-ICM)
-Disease Injury & Pain Management
-Emerging Knowledge & Research Technology
-Trainee Health & Fitness
-Sustainment / Proficiency Training
-Research Education Academy ("Grant Camp")

Director, CAMD
Center for Molecular Detection

DIR, NURSING RESEARCH & CTR FOR CLINICAL INQUIRY, Col Antoinette Shinn

Clinical Research-QI/PI-EBP

-Nursing Research
-Quality Improvement (QI)
-Process Improvement (PI)
-Evidence Based Practice (EBP)
-Consultation

Center for Clinical Inquiry (C2I)

Research Surgical Capabilities

Clinical Investigations & Research Spt, JBSA-Lackland

Warrior Medics – Mission Ready – Patient Focused

Three operating room suites:

- General and vascular surgery
- Orthopedic
- Ophthalmic
- Maxillofacial/dental
- Microsurgery

DaVinci robotic surgical system

Radiology (digital)

C-Arms

Fluoroscopy

Ultrasound

Research Laboratory Capabilities

Clinical Investigations & Research Support, JBSA-Lackland

Warrior Medics – Mission Ready – Patient Focused

Clinical Research Laboratory
- Immunology
- Hematology/Chemistry

Instron Testing
- Determine fatigue, impact, and/or resistance of materials

Hyperbaric/Hypobaric Medicine
- Study effects of altitude

Fully capable laboratory facilities

Expanded Toxicology Capabilities
- Highly specific
- Medical Toxicology studies
- Tandem Mass Spectrometer

Molecular Biology/Genomics
- Next Generation Sequencing
- Real Time PCR
- Multi-Plex Assays

Cell Biology
- Flow Cytometry

Microbiology

Coagulation and Hematology

Scanning Electron Microscope

CAMD (specialty laboratory)

JBSA-Lackland

Warrior Medics – Mission Ready – Patient Focused

Molecular Biology/Genomics*

- Next Generation Sequencing
- Real Time PCR
- Multi-Plex Assays

Molecular Biology/Proteomics*

- Protein Detection/Immunoanalysis
- Western Blot/Immunogenetics

Microbiology

Laminar flow biosafety level-2 cabinet

*Multiple instruments

Dental Research & Consultative Support

JBSA-Fort Sam Houston

Warrior Medics – Mission Ready – Patient Focused

Trauma Research

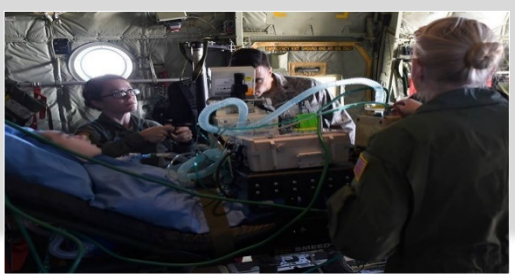
JBSA-Fort Sam Houston

Warrior Medics – Mission Ready – Patient Focused

- Haemonetics TEG Hemostasis Analyzer System (x2)
- BioTek ELx808 Absorbance Plate Reader
- Leica CM1520 Cryostat
- Biorad Chemidoc Imaging System
- Applied Biosystems QuantStudio3 Real-Time PCR System
- MagPix Multiplexing Immunoaassay System
- Attune NxT Flow Cytometer 3-laser system (*4th laser pending)
- ABL90 Flex Plus Blood Gas Analyzer
- Heska Element DC5X Chemistry Analyzer (*purchase pending)
- Sysmex CS-2500 Coagulation Analyzer (*purchase pending)

Summary

Warrior Medics – Mission Ready – Patient Focused



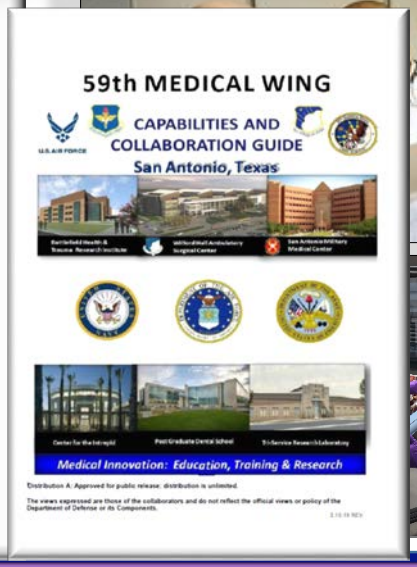
- **Lead AF Clinical Research Platform; Largest DoD GME/GHSE Platform**
- **Joint DHP Integrated – Programs and Partners (i.e., Across JPCs; USAISR, NAMRU-SA, Others)**
- **GME/**

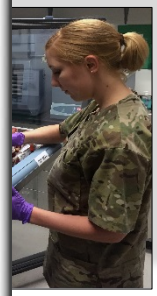
Clinical Research Innovation Center:

Focused on Increasing Readiness and Improving the Benefit

Accomplished through Clinical Studies, Translational Research, Research Education & Training

- **CIRB site / implementation, Preparing for "eIACUC"**
- **First and Only DoD Accredited HRPP (AAHRPP)**
- **Long-standing AAALACi Accreditation with Merit**
- **Broad & Deep System Capabilities, Clinical Competencies/Collaborations**





Grow Medical Leaders, Drive Innovations in Patient Care and Readiness

Naval Medical Research Unit San Antonio (NAMRU-SA)

Mission & Command Brief

Commanding Officer
CAPT Andrew F. Vaughn

Executive Officer
CAPT Michele A. Kane

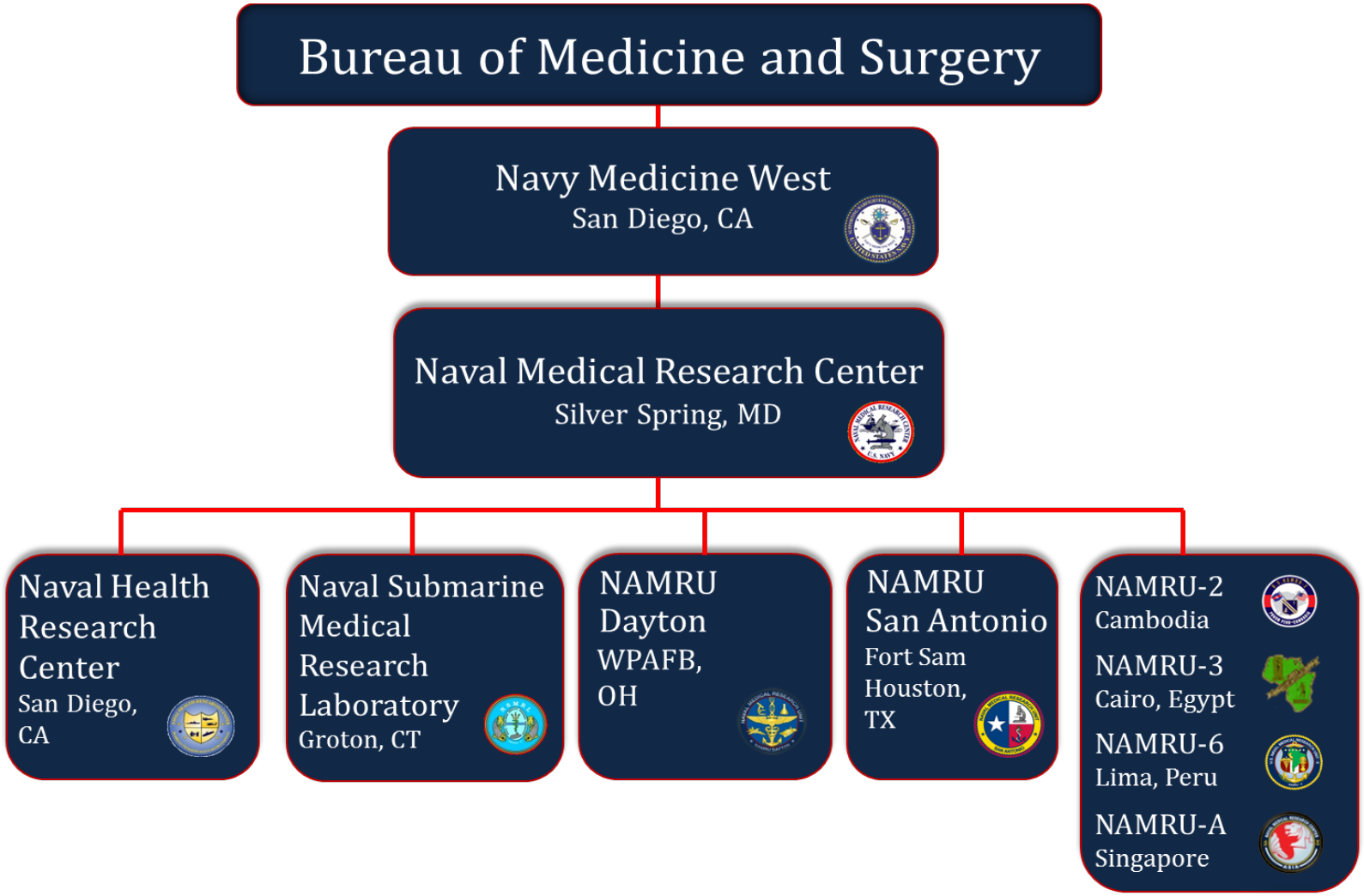
Chief Science Director
Dr. Sylvain Cardin

NAMRU-SA

Mission:

To conduct gap driven combat casualty care, craniofacial, and directed energy research to improve survival, operational readiness, and safety of Department of Defense personnel engaged in routine and expeditionary operations

Navy Medicine Research Enterprise



NAMRU-SA Supports
US Navy Surgeon General's Goals for Navy Medicine

Readiness
Preventive health

Health
Advancing capabilities in casualty care; Rapid delivery of new treatments and technologies

Partnerships
Robust research collaborations and partnerships

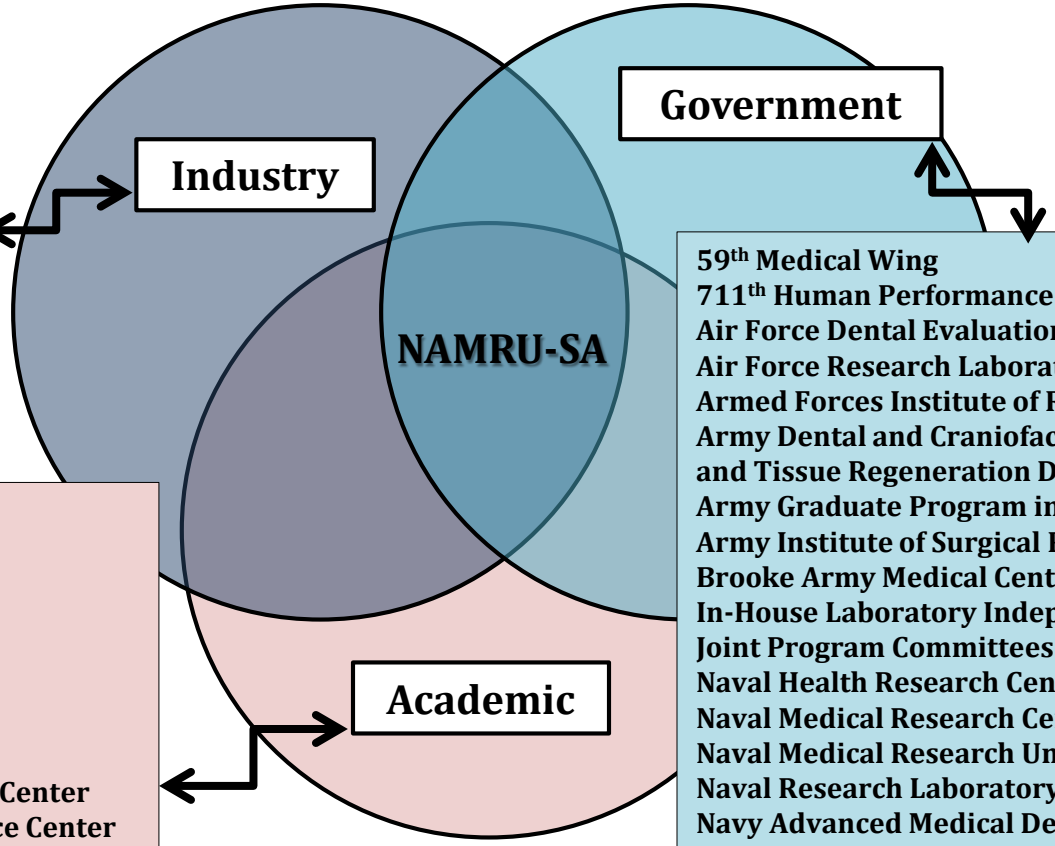
NAMRU-SA
Scope of Research

NAMRU-SA scientists conduct **basic, applied, and advanced technology** research and development. Some work has extended into prototype demonstration in an operational environment.

NAMRU-SA Funding and Research Approach

- Competitive funding
- Internal collaborations
- Inter-service and university collaborations

PARTNERSHIPS



Industry

ARMR TAC
Nanocomposix
NeuroFx
Rochal Industries LLP
Smith & Nephew
Stemion
The Geneva Foundation
Lynch Biologics
SPRI

Government

59th Medical Wing
711th Human Performance Wing/RHDV
Air Force Dental Evaluation & Consultation Service
Air Force Research Laboratory
Armed Forces Institute of Regenerative Medicine
Army Dental and Craniofacial Trauma Research and Tissue Regeneration Directorate
Army Graduate Program in Anesthesia Nursing
Army Institute of Surgical Research
Brooke Army Medical Center
In-House Laboratory Independent Research
Joint Program Committees 2, 5, 6, 8
Naval Health Research Center
Naval Medical Research Center
Naval Medical Research Unit Dayton
Naval Research Laboratory
Navy Advanced Medical Development
Office of Naval Research
Uniformed Services University of the Health Sciences

Academic

James Cook University, Australia
Ohio State University
Texas A&M at Kingsville
Texas Tech University
University of California Davis
University of Georgia
University of Maryland
University of Montana
University of Pittsburgh Medical Center
University of Texas Health Science Center
University of Texas at Dallas
University of Texas at San Antonio
Wake Forest University

NAMRU-SA Facilities

Battlefield Health and Trauma Research Institute (BHT)

- NAMRU-SA shares the BHT with the US Army Institute of Surgical Research and the US Air Force Dental Evaluation and Consulting Service

Tri-Service Research Laboratory (TSRL)

- NAMRU-SA also shares joint facilities at TSRL with the US Air Force 711th Human Performance Wing

NAMRU-SA
Staffing and Organization

Military (Navy Officers/Army Vet support)-15, civilian-27, and contractor-71

- **Combat Casualty Care and Operational Medicine (CCC&OM)**
  - Biomedical Systems Engineering and Evaluation
  - Cellular and Immune based Adjuncts For Casualty Care
  - Directed Energy
  - Expeditionary and Trauma Medicine
- **Craniofacial Health and Restorative Medicine (CH&RM)**
  - Biomaterials and Epidemiology
  - Environmental Surveillance
  - Maxillofacial Injury and Disease
- **Veterinary Sciences**
- **Acquisitions**
- **Administrative Operations**
- **Resource Management**

NAMRU-SA
Medical Program

❑ Combat Casualty Care and Operational Medicine (CCC&OM)

- Biomedical Systems Engineering and Evaluation
  - Development of a camera-based system to image the distribution of blood in dental pulp and assess pulp vitality
  - Testing and improvement of different devises
    Ex:
    - Tourniquets
    - Endotracheal tubes
  - Use of machine learning algorithms to improve combat casualty care

NAMRU-SA
Medical Program

❑ Combat Casualty Care and Operational Medicine (CCC&OM)

- Cellular and Immune Based Adjuncts for Casualty Care
  - Evaluation and comparison of the regenerative potential of different stem/multiprogenitor cell types seeded on a novel self-fitting shape memory polymer scaffold for craniomaxillofacial critical size bone defects
  - Use of new nanotechnology platforms to promote early fracture healing

NAMRU-SA
Medical Program

❑ Combat Casualty Care and Operational Medicine (CCC&OM)

- Directed Energy
  - Development of the mechanistic understanding of DE injuries to develop a diagnosis, treatment plan, and clinical practice guideline for battlefield, en route, and prolonged care scenarios.
  - Investigation of the bioeffects of acoustic and non-ionizing directed energy on shipboard injuries
  - Investigation of triage efforts for directed energy injuries on the battlefield
  - Investigation of the range of injuries expected relevant to the use of high-energy laser systems in the Navy inventory

NAMRU-SA
Medical Program

❑ Combat Casualty Care and Operational Medicine (CCC&OM)

- Expeditionary and Trauma Medicine
  - Investigation of maritime and shipboard hemorrhage control: REBOA and adjunct treatment strategies
  - Investigation of maritime and shipboard hemorrhage control and investigative of relevant hemostatic adjuncts
  - Expanding the duration and indication of use for XSTAT using quality improvement reports and in vivo animal model data
  - Investigation of multi-function resuscitation fluid prolonged care scenarios

NAMRU-SA
Staffing and Organization

Military (Navy Officers/Army Vet support)-15, civilian-27, and contractor-71

- **Combat Casualty Care and Operational Medicine (CCC&OM)**
  - Biomedical Systems Engineering and Evaluation
  - Cellular and Immune based Adjuncts For Casualty Care
  - Directed Energy
  - Expeditionary and Trauma Medicine
- **Craniofacial Health and Restorative Medicine (CH&RM)**
  - Biomaterials and Epidemiology
  - Environmental Surveillance
  - Maxillofacial Injury and Disease
- **Veterinary Sciences**
- **Acquisitions**
- **Administrative Operations**
- **Resource Management**

NAMRU-SA
Medical Program

❑ Craniofacial Health and Restorative Medicine (CH&RM)

- Biomaterials and Epidemiology
  - Investigation of dental emergencies and dental readiness for new process improvement and clinical practice guidelines
  - Development of a mineralized 3D collagen-based nanofibrous scaffold for ridge preservation prior to dental implant therapy (electrospinning technology)

NAMRU-SA
Medical Program

❑ Craniofacial Health and Restorative Medicine (CH&RM)

- Environmental Surveillance
  - NAMRU-SA is the NAVY's designated agent for mercury abatement
  - Evaluation of Environmental Protection Agency (EPA)-compliant amalgam separation systems and cleaner testing
  - Evaluate cleaners and treatments for heavy metals solubility via inductively coupled mass spectroscopy

NAMRU-SA
Medical Program

❑ Craniofacial Health and Restorative Medicine (CH&RM)

- Maxillofacial Injury and Disease
  - Evaluation of nanoparticle-targeted laser therapy against in vivo bacterial biofilm infections
  - Evaluation of engineered phages technology for casualty care

NAMRU-SA
Staffing and Organization

Military (Navy Officers/Army Vet support)-15, civilian-27, and contractor-71

- **Combat Casualty Care and Operational Medicine (CCC&OM)**
  - Biomedical Systems Engineering and Evaluation
  - Cellular and Immune based Adjuncts For Casualty Care
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  - Maxillofacial Injury and Disease
- **Veterinary Sciences**
- **Acquisitions**
- **Administrative Operations**
- **Resource Management**

NAMRU-SA
Medical Program

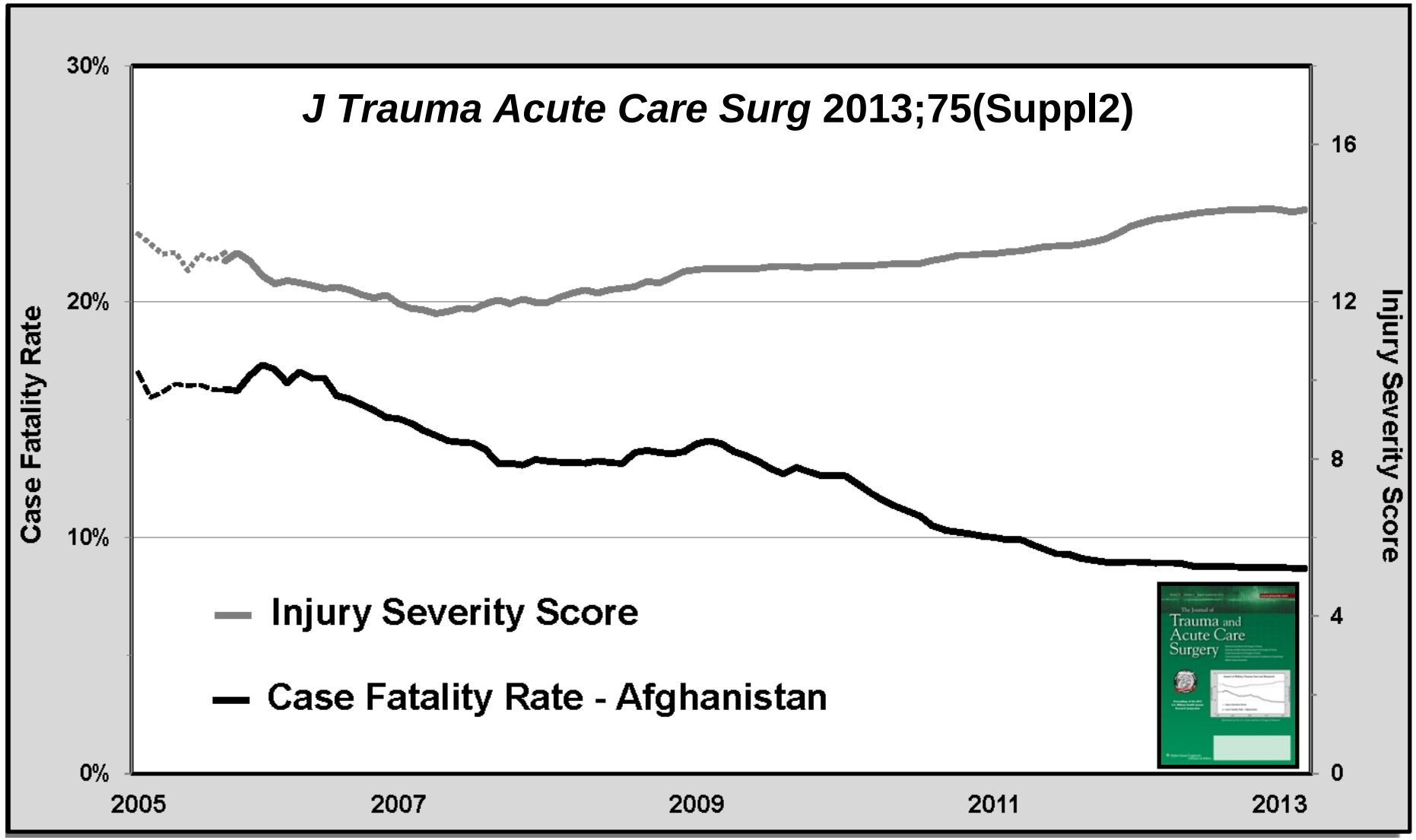
❑ Veterinary Sciences (VSD)

- Veterinary Sciences
  - Support all NAVY protocol
  - Support Air Force protocols (59th Medical Wing and &711th Air Force Human Performance Wing)
  - Support nurse anesthetist training program for the ARMY

NAMRU-SA
Highlighted Capabilities

- ❑ Developed and utilizes the only Department of Defense Non-Human Primate Poly-trauma model
- ❑ High energy laser capability
- ❑ Large anechoic chambers
- ❑ Radio frequency specific exposure rate measurement using Phantoms program
- ❑ High-end 3D bioprinting capability
- ❑ Fully customizable bench top electrospinning system
- ❑ Multi-Photon confocal microscope
- ❑ Portable CT Scan

Lives Saved


J Trauma Acute Care Surg 2013;75(Suppl2)
30%
20%
10%
0%
Case Fatality Rate
16
12
8
4
0
Injury Severity Score
2005
2007
2009
2011
2013
Injury Severity Score
Case Fatality Rate - Afghanistan
Trauma and Acute Care Surgery

Thank you!

Contacts

Commanding Officer

Andrew F. Vaughn, CAPT, MC, USN

Andrew.F.Vaughn2.mil@mail.mil

(210) 539-0960 DSN 389-0960

Executive Officer

Michele A. Kane, CAPT, NC, USN

Michele.A.Kane.mil@mail.mil

(210) 539-5624 DSN 389-5624

Chief Science Director

Sylvain Cardin, Ph.D.

Sylvain.Cardin.civ@mail.mil

(210) 539-8918 DSN 389-8918

http://go.usa.gov/xRQHc

U.S. Army Institute of Surgical Research

"For Combat Wounded"

Research Program Overview

Anthony E. Pusateri, PhD

Director of Research and Chief Science Officer

15 October 2019

Email: anthony.e.Pusateri.civ@mail.mil

UNCLASSIFIED

Disclaimer

- The opinions or assertions presented here are those of the author and do not represent those of the US Army or the Department of Defense.

- Conflicts of Interest: None

Purpose

- Overview of the US Army Institute of Surgical Research
  - Mission, Capabilities, Programs
  - Emphasis on Research Capabilities and Programs
  - Partnering

A Long History of Research - Clinical Collaboration

Established as Surgical Research Unit at Halloran General Hospital, Staten Island, New York
1943 – 1947 (Staff 12)

Evolving Mission

1943 - Antibiotics in Wound Care

1947 - Innovative Surgical Techniques

1949 - Thermal Injury

1996 - Full Spectrum Combat Casualty Care

Move to Brooke Army Medical Center – 1947

Renamed US Army Institute of Surgical Research – 1970

Army Burn Unit
Brooke General Hospital
1949 – 1996

U.S. Army Institute of Surgical Research at Brooke Army Medical Center
1996 to Present (Staff >800)

Battlefield Health and Trauma Research Institute – Joint and Interagency Cooperation

- The Base Realignment and Closure 2005, established the BHT at Fort Sam Houston - Brings together all Department of Defense (DoD) combat casualty care research

- Joint Synergy
  - USAISR
  - NAMRU-SA
  - 59th MDW
  - USAISR Burn Center – DoD's only Burn Center
  - BAMC – Only DoD Level I Trauma Center

- USAISR also works closely with Biomedical Advanced Research and Development Authority and NHLBI

Mission and Vision

Mission

Optimize Combat Casualty Care

Vision

The World's premier research organization enabling readiness and delivering evidenced based solutions for optimal care of the combat wounded

- **Research** – Conduct a comprehensive and sustainable research and development program to deliver knowledge and material solutions to optimize survival and functional recovery in combat casualties and civilian patients with trauma and burns, while also providing expert analysis and input to shape future requirements and directions in combat casualty care.

- **Burn Center** - Serves as the sole facility caring for combat burn casualties, beneficiaries and civilian emergencies within the Department of Defense. The Burn Center provides interdisciplinary care by a team of approximately 300 medical professionals providing cutting edge surgical services and promoting optimal recovery, restoration of function, and community reintegration of our burn survivors.

OPERATIONALLY
Relevant & Responsive Research

Increased Relevance of Laboratory Research (6.1-6.3)

Rapid Clinical Translation

Combat Casualty and Burn Research

Operational Experience

Development of Military Clinician Researchers

Clinical Care and Research

Essential Synergy between Clinical Care, Laboratory Research, and the Battlefield

UNCLASSIFIED

Previous Approach to Combat Casualty Care

- Recent conflicts in Afghanistan and Iraq – US and Allied Forces have had near continuous superiority of air, land, and maritime domains, and communications
  - Rapid air evacuation to surgical care was possible
  - Approach – immediate stabilization and rapid evacuation ("Golden Hour")
  - Median Evac Time: 42 min (2009 to present); 90 min (2003-2009)

New Challenge in Combat Casualty Care

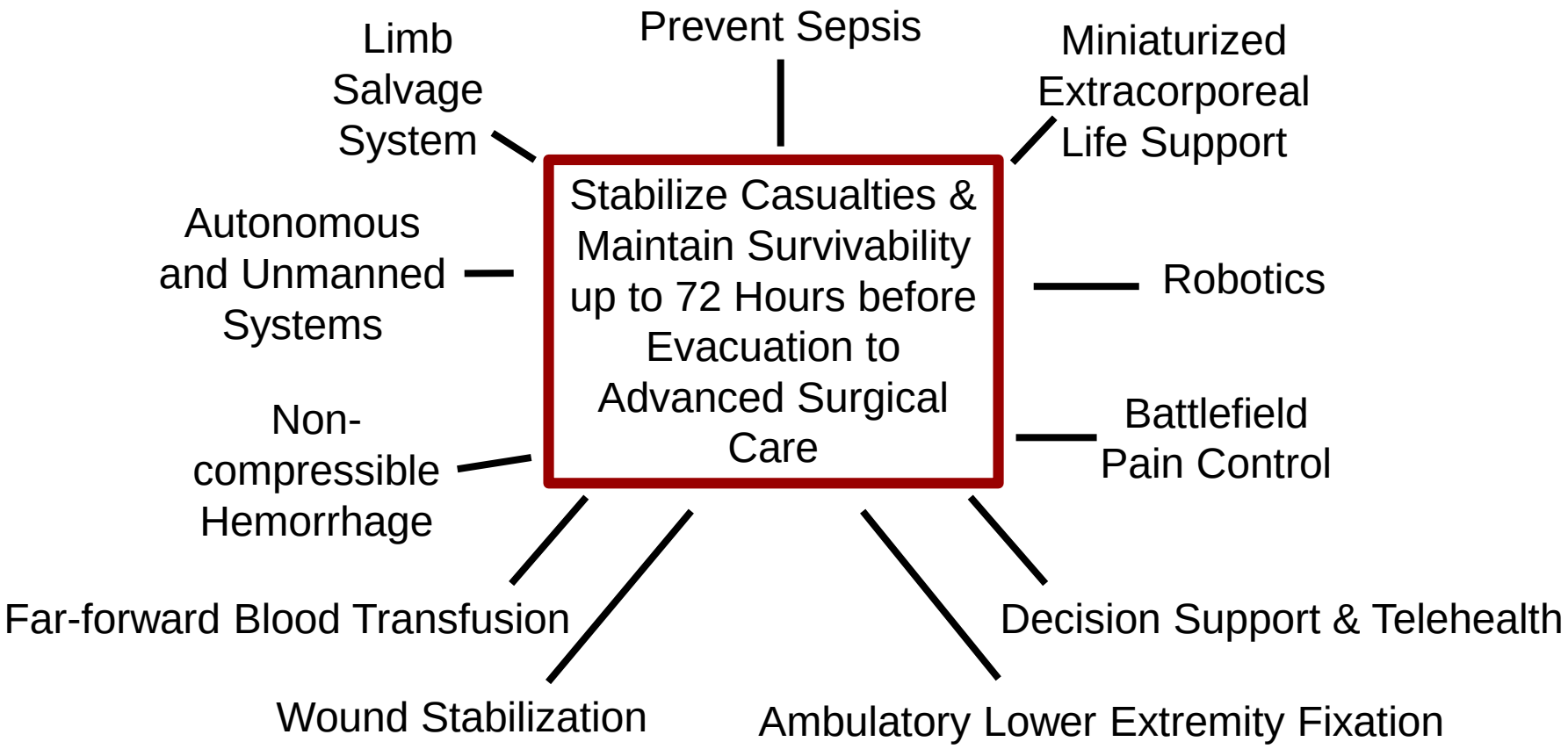
- Future conflicts against a near peer enemy - continuous dominance across all five domains (land, maritime, air, space and cyberspace), the EMS, and the information environment will not be possible
  - Rapid air evacuation not always available
  - Need sustain casualties for up to 72 hours before definitive surgical care
  - “Prolonged Field Care” in multi-domain operations (MDO)

Research Program Overarching Objectives

- 1) **Increase capabilities of forward medical personnel with smart diagnostics, decision support, and robotic assist, as well as advanced drugs and other technologies.** The purpose is to increase forward capabilities while decreasing cognitive burden on medics, minimizing the burden of combat casualty care on operational units, and, where possible, keeping soldiers in the fight.
- 2) **Prevent wound progression** (prevent relatively minor, survivable wounds from becoming life, limb, or eye-sight threatening).
- 3) **Maintain survivability of casualties during prolonged care and evacuation**.

Prolonged Field Care =
Need to Move Medical Capabilities Further Forward

On the multi-domain battlefield, casualty movement may be significantly delayed depending on the balance of US dominance across domains



USAISR Research Programs: Competencies & Capabilities

USAISR Personnel and Facilities

USAISR Total Personnel

Military	Civilians	IPAs	Contractor	TOTAL
173	**237**	**1**	**419**	**830**

Animal Research Facilities: **53,170 sf;** large and small animal experimental surgery, imaging, ICU, housing (Bldg 3611 (BHT1) 31,037sf; Bldg 3610 (BHT2) 22,033sf)

Laboratory Facilities: **53,179 sf;** shared with NAMRU-SA, USAF **(**Bldg 3611 (BHT1) 17,371 sf; Bldg 3610 (BHT2) 35,808 sf)

Clinical Space: 102,000 sf; U.S. Army Burn Center (4th Floor, BAMC)

Research Directorate Personnel

Military	Civilians	IPAs	Post Docs	Contractors	TOTAL
71	**66**	**1**	**44**	**180**	**318 (38%*)**

* percent of 28 FEB 2018 totals

Research Directorate
Organizational Structure *(Provisional)*

IOC: 15 JUN 2019
FOC: 01 OCT 2019

Research Directorate (RD)

- **Acute Combat Casualty Care Division (ACCCD)**
  - Blood Coagulation Research Dept. (BCRD)
  - Expeditionary Critical Care Research Dept. (ECCRD)
  - Hemorrhage Control & Resuscitation Research Dept. (HCRRD)
  - Tactical & Enroute Care Research Dept. (TECRD)
- **Stabilization of Tissue & Return Division (STARD)**
  - Burn & Soft Tissue Research Dept. (BSTRD)
  - Dental & Cranio-maxillofacial Trauma Research Dept. (DCTRD)
  - Orthopaedic Trauma Research Dept. (OTRD)
  - Sensory Trauma Research Dept. (STRD)
- **Research Support Division (RSD)**
  - Research Support Services Dept. (RSSD)
  - Clinical Decision Support & Automation Research Dept. (CDSARD)
  - Clinical Research Support Dept. (CRSD)
  - Plans, Programs, & Pipeline Management Dept. (PPPMD)

Research Therapeutic Areas

- Airway Management
- Battlefield Pain Management
- Blood and Coagulation
- Burn Injury
- Clinical Decision Support and Automation
- Combat Trauma to Soft Tissue
- Dental and Craniomaxillofacial Trauma
- Enroute Casualty Care
- Extracorporeal Life Support
- Hemorrhage Control and Resuscitation
- Orthopaedic Trauma (Extremities)
- Prolonged Field Care
- Sensory Systems Trauma
- Tactical Casualty Care
- Medical Effects of Directed Energy
- Combined Radiation and Trauma Injury

USAISR capabilities and competencies uniquely poised to address the spectrum of casualties from MDO combat and future operational realities

Development Pipeline Approach to S&T Management

Blood & Coagulation Research

Development Pipeline – Current Snapshot of Functional R&D Stages

Discovery-Knowledge (6.1/6.2/6.3)
Topic Areas
TRL 1-3

Discovery-Product (6.2/6.3)
Specific Candidate Concepts/Drugs/Devices
TRL 3-4

Late Discovery/Transition (6.3)
Pre-clinical & Early Clinical Studies *on Selected Lead Concept/Drug/Device Expected Transition w/in 2 yrs*
TRL 4-5

Full (Clinical) Development (6.4/6.5)
Specific Product
TRL 5-9

MDD | MSA | MSB | MSC

- Mechanisms of Coagulopathy
- Mechanisms of Blood Product Function
- Mechanisms of Bl Storage Lesions

- Metho elet Pr on ugs & stics fo Coagu Synt ood Pr
- M ymal St s nunom on auma duce/M Thromb ty in EC ATC/ Diagnostics

- Cold Platelets i latelet Ad olution
- d shelf lif blood dried pla RDA)

- Spray d Solvent nt Pla
- derived atic Agent
- ilized Pla preserv lets hole Blo logen Reduction Device)
- Zika tic Assay*

Nondisclosure Agreement
Cooperative Research and Development Agreement
Material Transfer Agreement
Technology Transfer
Contracts
Licensing Agreement
FDA Regulatory Assistance

Knowledge Products That Support Clinical Practice/Operations

- Walking Blood Bank SOP (Fresh Whole Blood CPG)
- Blood Use CPG, Other Guidance (Refrig WB, Initial Entry Ops, etc.)
- Coagulation diagnostic device evaluation and fielding/use recommendations
- Direct SME support to operational units

*FDA A al (Roche, Oct 17)

anthony.e.pusateri.civ@mail.mil

Research Therapeutic Areas (Focused on Capabilities)

- **Blood & Coagulation**

  (CAM – COL Cap)

  (Dept. Chief - Dr. James Bynum, *acting*)

  - Improve the safety, efficacy, and logistical supportability of blood products, identify mechanisms of coagulation dysfunction in trauma, diagnostics and therapeutics to restore normal function

- **Hemorrhage Control & Resuscitation**

  (Dept. Chief - Dr. Michael Dubick)

  - Develop methods and products to stop bleeding,
  - replace lost blood volume, and mitigate the pathophysiologic consequences of severe bleeding
  - Long-term development of capabilities for vascular access, endovascular hemostatic and resuscitative procedures, and enable endovascular organ support with applications at all levels of care

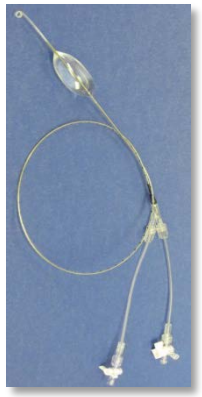
Research Therapeutic Areas (Focused on Capabilities)

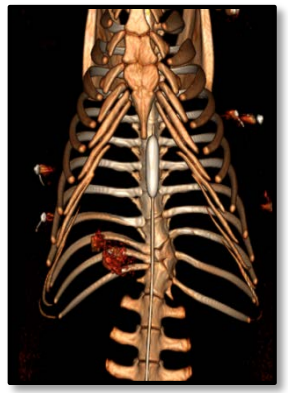
- **Extracorporeal Life Support**

  (Dr. Andre Batchinsky/

  Dr. Thomas Walters)

  - Comprehensive research and development to develop and optimize methods to minimize damage and sustain vital organ function following severe trauma in a setting of delayed definitive care

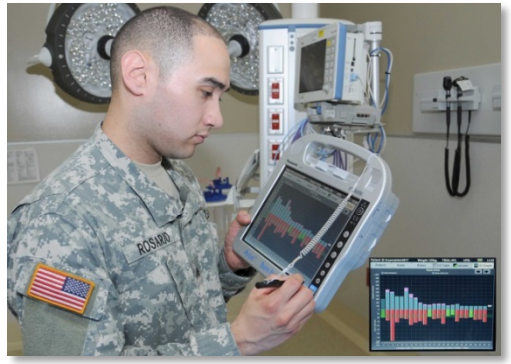


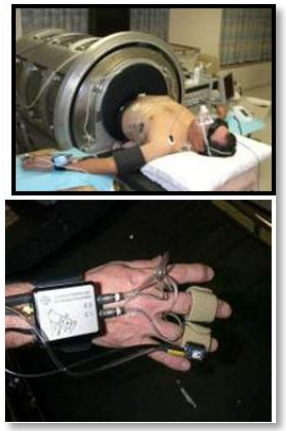


- **Tactical Combat Casualty Care/Airway and Early Life Saving Intervention**

  (CAM / Dept. Chief - Dr. Kathy Ryan)

  - Integrative and translational research focused on patient care under the unique set of tactical, environmental, and patient factors associated with the pre-ROC 2 environment, including ground and air transport.





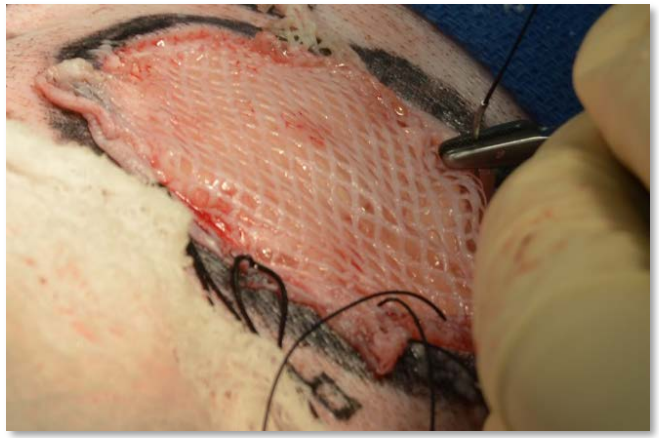
Research Therapeutic Areas (Focused on Capabilities)

- **Burn Wound Management**

  (CAM – Dr. Kai Leung)

  (Dept Chief: Dr. Robert Christy)

  - Improve burn wound stabilization, repair, healing, scar minimization, and functional recovery. Also includes study of the molecular mechanisms and improved treatments for battlefield pain control



- **Orthopaedic Trauma**

  (CAM / Dept. Chief - Dr. Josh Wenke)

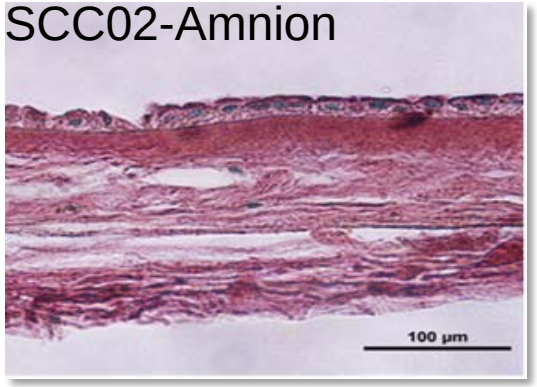
  - Focused on infection control and healing in extremity trauma; Reconstruction/regeneration of volumetric and segmental defects of muscle and bone; and rehabilitation following extremity trauma.

Research Therapeutic Areas (Focused on Capabilities)

- **Sensory Trauma**

  (Dept. Chief – LTC(P) Wells)

  - Procedures and products to repair and restore the eye and vision following severe injury.
  - Expanding into auditory trauma.



- **Dental and Craniomaxillofacial Trauma**

  (Dept. Chief – LTC Decker)

  - Develop knowledge and materiel solutions to stabilize patients and improve healing, function, and aesthetic outcomes after severe combat-related cranio-maxillofacial injury

Research Therapeutic Areas (Focused on Capabilities)

- **Prolonged Field Care/Expeditionary Critical Care**

  (CAM / Dept. Chief - Dr. Thomas Walters)

  - Conduct a focused research program focused on key capability gaps in PFC
  - Monitor, coordinate, and provide programmatic recommendations regarding PFC efforts in other Task Areas and the Joint Program

- **Battlefield Pain Management**

  (CAM: Dr. Robert Christy)

  - Program to identify and develop battlefield pain management options for effective and safe pain management at all levels of care, by understanding and exploiting key physiologic mechanisms in acute and chronic pain that results from combat injury

Research Therapeutic Areas (Focused on Capabilities)

- **Medical Effects of Directed Energy**

  (Branch Chief: TBD, under LTC(P) Wells direction)

  - Conduct a research program focused on key gaps in detecting and developing countermeasures to prevent medical effects of directed energy exposure
  - Monitor, coordinate, and provide programmatic recommendations regarding DE multi-organ injury in other Task Areas and the Joint Program
  - Army program ***conducted in a fully joint setting at the Tri-Service Research Laboratory (JBSA) ICW NAMRU-SA, 711th HPW, and the 59th MDW***

Points of Contact

- Tammy Crowder, PhD - alicia.t.crowder.civ@mail.mil
- COL Andre Cap, MD, PhD - andrew.p.cap.mil@mail.mil
- Robert Christy, PhD - robert.j.christy12.civ@mail.mil
- Kai Leung, PhD - kai.p.leung.civ@mail.mil
- MAJ David Kingery, PhD - david.a.kingery5.mil@mail.mil
- Kathy Ryan, PhD - kathy.l.ryan.civ@mail.mil
- Thomas Walters, PhD - thomas.j.walters22.civ@mail.mil
- LTC(P) Kenney Wells - kenney.h.wells.mil@mail.mil
- Joseph Wenke, PhD - joseph.c.wenke.civ@mail.mil

Comments and Questions

DoD Medical Research: A Gap Driven Enterprise

Sylvain Cardin, Ph.D.
Chief Science Director
Naval Medical Research Unit San Antonio

Ashley Dory, M.S.
Deputy to the Chief Science Director
Naval Medical Research Unit San Antonio

15 October, 2019

Military Medical Research

- **Should address a validated military capability gap**
  - The Department of Defense does not do research for the sake of doing research.
  - Military *medical* research is no different.
- **Ideally involves more than one organization**
  - Military (more than one Service), Academia, and/or Industry.

When approaching a San Antonio military medical partner, it is imperative that your proposed project/solution addresses a military medical gap.

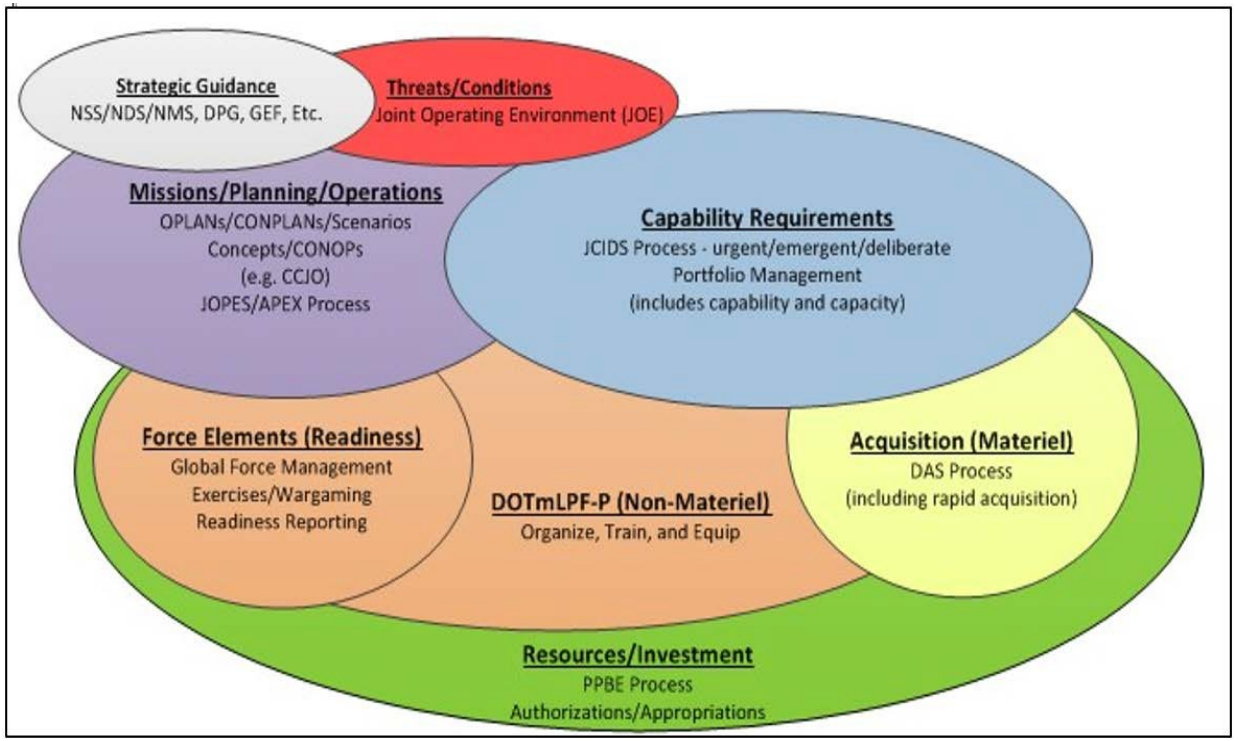
If you are in doubt, contact one of the San Antonio military medical partners.

CJCSI 5123.01H
31 AUGUST 2018

CHARTER OF THE JOINT REQUIREMENTS OVERSIGHT COUNCIL (JROC) AND IMPLEMENTATION OF THE JOINT CAPABILITIES INTEGRATION AND DEVELOPMENT SYSTEM (JCIDS)

JOINT STAFF
WASHINGTON, DC 20318

DoD Process Interaction



- Requirements (JCIDS), acquisition (DAS), and resources (PPBE) are the most tightly interactive and must work in concert to ensure consistent decision-making while delivering timely and cost-effective capability solutions to the Warfighter.

- Together, the three processes provide a means to determine, validate, and prioritize capability requirements and associated capability gaps and risks, and then fund, develop, field, and sustain capability solutions for the Warfighter in a timely manner.

DEPARTMENT OF THE NAVY
OFFICE OF THE SECRETARY
1000 NAVY PENTAGON
WASHINGTON, D.C. 20350-1000

SECNAVINST 5000.2F
ASN (RD&A)
26 Mar 2019

SECNAV INSTRUCTION 5000.2F

From: Secretary of the Navy

Subj: DEFENSE ACQUISITION SYSTEM AND JOINT CAPABILITIES INTEGRATION AND DEVELOPMENT SYSTEM IMPLEMENTATION

Encl: (1) References
(2) Responsibilities
(3) Acquisition Categories and Compliance Requirements
(4) Systems Engineering
(5) Test and Evaluation
(6) Life-Cycle Sustainment
(7) Information Technology Requirements
(8) Joint Requirements and Capabilities Development
(9) Two Pass, Seven Gate Governance
(10) Glossary

1. Purpose. This instruction and its enclosures:

a. Implement references (a) through (c) and (bo) within the Department of the Navy (DON).

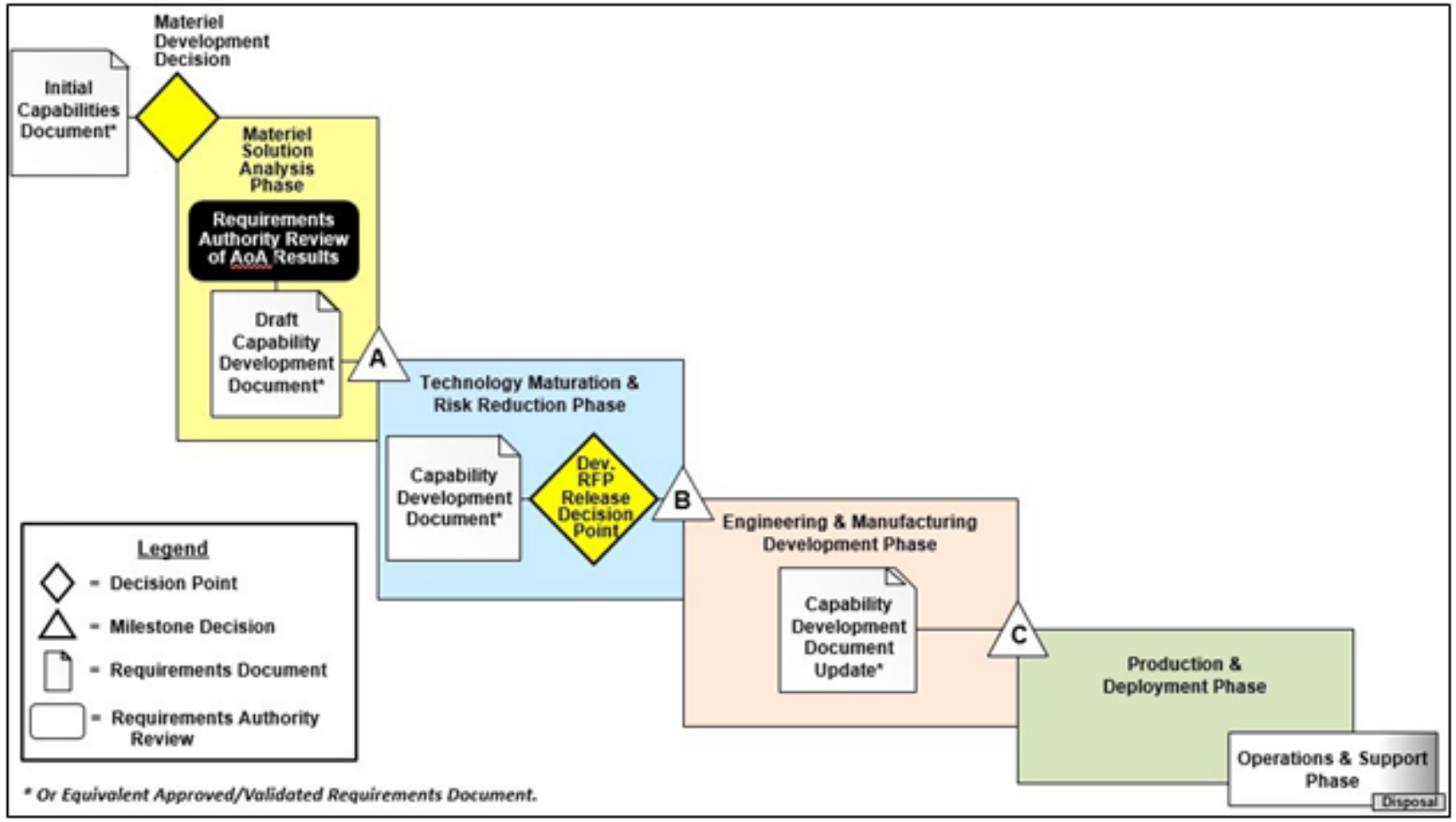
b. Prescribe DON-specific acquisition policies and procedures that supplement references (a) through (ci) to provide for the integrated, efficient, and successful operation of the Joint Capabilities Integration and Development System (JCIDS) and Defense Acquisition System (DAS) within the DON.

c. Authorize Milestone Decision Authorities (MDAs) for DON acquisition programs to waive or tailor non-statutory procedures in reference (b) and the enclosures to this instruction, as appropriate, to more efficiently achieve program objectives.

2. Cancellation. SECNAVINST 5000.2E.

3. Background. This instruction must be read together with reference (b).

JCIDS and DAS Interactions (Deliberate Process)



PRE-DECISIONAL DRAFT

DoD Instruction 5000.02

Operation of the Adaptive Acquisition Framework

Originating Component:	Office of the Under Secretary of Defense for Acquisition and Sustainment
Effective: ***PRE-DECISIONAL DRAFT:*** v 9/13/19	
Releasability:	Cleared for public release. Available on the Directives Division Website at https://www.esd.whs.mil/DD/.
Reissues and Cancels:	DoD Instruction 5000.02, "Operation of the Defense Acquisition System," January 7, 2015
Approved by:	<EML,> Under Secretary of Defense for Acquisition and Sustainment

Purpose: In accordance with the authority in DoD Directive (DoDD) 5134.01 and the July 13, 2018 Deputy Secretary of Defense memorandum, this issuance:

- Establishes policy and procedure for managing acquisition programs, pursuant to the relevant sections of Titles 10, 40, and 44, United States Code (U.S.C.).
- Assigns program responsibilities in accordance with the authority in DoDDs 5134.01 and 5000.01
- Restructures DoD Instruction (DoDI) 5000.02 to improve process effectiveness and implement the Adaptive Acquisition Framework.. As a result of that restructuring, the document has been renamed "Operation of the Adaptive Acquisition Framework," to better reflect the current content.

DISTRIBUTION STATEMENT D. Distribution authorized to the Department of Defense and U.S. DoD contractors only (fill in reason) (date of determination). Other requests shall be referred to (insert controlling DoD office).

SECTION 1: GENERAL ISSUANCE INFORMATION

PURPOSE OF THE ADAPTIVE ACQUISITION FRAMEWORK (AAF). The AAF supports the Defense Acquisition System (DAS) with the objective of delivering effective, supportable and affordable solutions to the end user in a timely manner. To achieve those objectives, Milestone/Decision Authorities/Decision Authorities (MDAs/DAs) and Program Managers (PMs) have broad authority to plan and manage their programs consistent sound business practice. The AAF acquisition pathways provide opportunities for MDAs/DAs and PMs to develop acquisition strategies that match the characteristics of the capability being acquired.

APPLICABILITY. This issuance applies to OSD, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff and the Joint Staff, the Combatant Commands, the Office of the Inspector General of the Department of Defense, the Defense Agencies, the DoD Field Activities, and all other organizational entities within the DoD (referred to collectively in this issuance as the "DoD Components"). The policies in this instruction are applicable to all programs acquired via the DAS.

POLICY. The DAS supports the National Defense Strategy through the development of a lethal and effective force based on American technological innovation and a culture of performance that yields decisive and sustained U.S. military advantage. To achieve that objective, the department will employ an adaptive acquisition framework. This instruction describes the responsibilities of principal acquisition officials and the purpose and key characteristics of the process pathways.

Definitions

Capability Gap -- The inability to meet or exceed a capability requirement, resulting in an associated operational risk until closed or mitigated. The gap may be the result of no fielded capability, lack of proficiency or sufficiency in a fielded capability solution, or the need to replace a fielded capability solution to prevent a future gap.

Capability Gap Assessment (CGA) -- A deliberate assessment of the future year's defense program that reviews CCMD IPLs and other issues and perspectives from the Services and other DoD components, relative to fielded materiel and non-materiel capability solutions, and development efforts, which may already be underway to address capability gaps.

Capability Requirement -- A capability required to meet an organization's roles, functions, and missions in current or future operations.

Definitions

Materiel solution - - A new item developed or purchased to satisfy one or more capability requirements (or needs) and reduce or eliminate one or more capability gaps.

Medical material solutions – Includes but not limited to: pharmaceuticals (drug, biologics, vaccine, blood/blood product), devices, and/or medical support systems/devices.

Non-materiel solution - - A capability required to meet an organization's roles, functions, and missions in current or future operations to satisfy one or more capability requirements (or needs) and reduce or eliminate one or more capability gaps, without the need to develop or purchase a new materiel solution.

Medical non-materiel solutions - Include, but not limited to: clinical practice guidelines (CPGs) and other knowledge products, training, doctrine, education, and leadership.

Definitions

Capability Requirements Document(s) -- Any document(s) used to articulate deliberate or urgent/emergent capability requirements and associated information pertinent to review and validation.

Requirements must align to the "Requirement" of the Services, Combatant Commands, and other DOD Components.

Must address (reduce or eliminate) a validated capability gap.

Requirement Identification

- Origination of requirement
  - Services, Combatant Commands, and other DoD components conduct Capability Based Assessments (CBAs) or other studies to assess capability requirements and associated capability gaps and risks.
    - Informed and align with National Security Strategy (NSS), National Defense Strategy (NDS), National Military Strategy (NMS) and other overarching guidance.
  - Capability requirements with significant capability gaps typically lead to an Initial Capability document (ICD).

- Source material underlying requirements
  - CBAs provide recommendations to pursue a materiel or non-materiel solution to an identified capability gap that meets an established capability need.
  - Wargames and Exercises (e.g., Unmanned Logistics Systems Wargame 2016, Expeditionary Medicine 2017 Final Report).
  - After action reports (AARs).
  - Other studies (e.g., Comprehensive Review of Recent Surface Fleet Incidents).

Medical Requirements Documents

- *Initial Capability Documents (ICDs) <u>to include:</u>*
  - *DRAFT* NEHSS for Distributed Maritime Operations (DMO) ICD
    - Validated Gaps summarized in NEHSS RET Prioritized Gaps (1 OCT 2018)
  - Naval Expeditionary Health Support Services (NEHSS) ICD (20 DEC 2012)
  - USMC Expeditionary Health Service Support ICD (12 AUG 2011)
  - ICD for Military Operational Medicine (20 Oct 2017)
  - Infectious Disease Countermeasures ICD (Feb 2007)
  - Theater Combat Casualty Care ICD (5 Oct 2007)
  - ICD for Combat Casualty Care Devices and Products (12 Mar 2015)
  - ICD for Department of Defense (DoD) Combat Casualty Care Medical Research and Development (12 Mar 2015)
- Wargames/Reports *<u>to include</u>:*
  - Dense Urban Environment 2018, Final Report (May 2018)
  - Expeditionary Medicine 2017, Final Report (May 2017)
  - Comprehensive Review of Recent Surface Force Incidents (26 Oct 2017)
  - Expeditionary Medicine 2016, Final Report (June 2016)
  - Unmanned Logistics Systems Wargame 2016, Final Report (2016)
  - AFMS CBA Report, 2017

GAP Memo

Annex F. Gap Memo Example

DEPARTMENT OF THE ARMY
HEADQUARTERS, U.S. ARMY MEDICAL DEPARTMENT CENTER AND SCHOOL
U.S. ARMY HEALTH READINESS CENTER OF EXCELLENCE
3630 STANLEY ROAD
JBSA FORT SAM HOUSTON, TEXAS 78234-6100

MCCS-FG 01 March 2018

MEMORANDUM FOR RECORD

SUBJECT: (ICDT) Gap # 203651 - Specialty Dental Care

1. Gap #: 203651 Specialty Dental Care

2. Gap Statement: Army Medical Units lack the ability to provide theater wide specialty dental care from the point of injury throughout the continuum of care in order to avoid 95% of unnecessary medical evacuations for treatable dental injury.

3. Gap EXSUM: Dental Specialty include the AOC Comprehensive Dentist - 63B, Periodontist - 63D, Endodontist - 63E, Prosthodontist - 63F, lack the needed providers organic to the deployed units to provide dental specialty care throughout the theater of operations. There is a lack of deployed trained providers and the necessary Class VIII that supports the mission. Research areas should focus on expanding dental equipment to ensure the key system capabilities are met in order for a system to meet its operational goals and remain durable all while minimizing the cube, weight and size.

4. Gap Type: The gap is a result of several factors.

a. No fielded Capability

b. The need to replace a fielded capability solution to prevent a future gap

c. Policy Limitations

5. Recommended priority: Moderate Risk

6. Recognized Sources of a Capability Gap (in addition to the CBA, the JCIDS Manual describes several other approaches for identifying capability requirements (see JCIDS manual for additional information).

a. Army, AMEDD Lessons Learned:
AMEDD Lessons Learned Trends Analysis: BCT collection reports and Medical Brigade/TF AARs 2011-2012
1- Dental trends establish the need for a review of Role 2 dental services doctrine, staffing, organizational structure, and equipment to establish the proper role of dental support in any given area of operations to ensure the

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U.S. ARMY HEALTH READINESS CENTER OF EXCELLENCE
3630 STANLEY ROAD
JBSA FORT SAM HOUSTON, TEXAS 78234-6100

MCCS-FG 8 March 2018

MEMORANDUM FOR RECORD

SUBJECT: Combat Casualty Care (CCC) Integrated Capabilities Development Team (ICDT) Gap # 501244: Army Units with medical capability (Role 1, 2, 3) possess limited capability and capacity to provide prolonged care. *(from BLCSE database)*
OR
Gap # 501244 "Army Units lack the capability to provide prolonged (>60 minutes) care at the point of need (when evacuation is delayed) to decrease patient mortality and morbidity in 100% of patients with survivable wounds." *(from Prolonged Care CBA)*

1. Gap # 501244: Prolonged Care.

2. Gap Statement: Army Medical Units lack the capability to provide prolonged care (> 60 minutes) at the point of need when evacuation is delayed to decrease patient mortality and morbidity in 100% of patients with survivable wounds to preserve combat power.

3. Gap EXSUM: Recent combat operations in Iraq and Afghanistan were characterized by air superiority which enabled rapid evacuation of casualties from point of injury to Forward Surgical Teams and Combat Support Hospitals. Delayed evacuation will impact all roles of care by requiring medical personnel to provide ongoing medical care for extended periods of time. Impacts to Mission: Increasing the medical capabilities and resources farther forward on the battle field to perform prolonged field care to increase the survival rate of casualties with potentially survivable injuries.

4. Gap Type: The gap is due to a lack of sufficiency (capacity) AND proficiency (capability) in the fielded capability solution. Current policy limitations will also inhibit progress in filling prolonged care-related capability gaps.

5. Recommended priority: (Extremely) High Risk.

6. Recognized source of the capability gap is the "Prolonged Care in Support of Conventional Military Forces Capabilities-Based Assessment" (Prolonged Care CBA), approved by Commander, United States Army Medical Department Centre and School (AMEDDC&S) on 14 Apr 17. The highly developed theaters of recent Coalition Operations in Southwest Asia have afforded major advantages including fixed medical treatment facilities (MTFs) and air supremacy that allowed uncontested lines of communication for patient movement and medical resupply. The link between rapid medical evacuation to higher care and casualty survival, has been well established. However, medical support to combined arms forces engaged against a near peer

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Initial Capabilities Document for Department of Defense (DoD) Combat Casualty Care Medical Research and Development

12 March 15

Proposed MDA: Secretary of Defense for Health Affairs

Proposed JSD: JROC Interest

Sponsor: Deputy Assistant Secretary of Defense, Force Health Protection & Readiness

Primary Point of Contact: Dr. Terry M. Rauch, Director of Research and Development Policy & Oversight OSD (Health Affairs); terry.rauch@ha.osd.mil, (703) 681-8390.

This report contains pre-decisional information for deliberative use in support of the Medical Research Capabilities Based Assessment sponsored by the Deputy Assistant Secretary of Defense, Force Health Protection & Readiness. The information in this report is exempt from public disclosure in accordance with Title 5 USC § 552(b) (5) (Freedom of Information Act Exemption (b)(5)).

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Table 4: Task Priority for R&D Efforts

Tier 1	Tier 2	Tier 3
Manage blood circulation/control hemorrhage	Maintain psychological functioning	Identify and manage fractures/wounds
Treat for shock	Recognize signs of psychological trauma	Identify and manage infectious/contaminated patients
Preserve life	Treat disease	Evaluate casualty for return to duty
Manage breathing/manage the airway	Maintain tissue viability	Conduct mental rehabilitation to restore psychological functionality
Maintain brain function	Manage head and spine	Patient documentation and communication
	Pain management	
	Repair physical injuries throughout the body	
	Maintain sensory systems (e.g. eyesight, hearing, balance)	
	Triage Initial Injuries	
	Prevent loss of use of limb(s)	

Army Future Requirements

- Prolonged Field Care (Sustaining injuries for up to 72 hours with delayed evacuation, Impact of CBRN exposures)
- Improved Human Performance (Physiological monitoring, Enhancement of human performance)
- Artificial Intelligence (Autonomous Evacuation, Automated machinery (closed loop ventilation and other support systems), Remote monitoring/Decision Aids/Tele-medicine)
- Modernization (Optimization/Enhancement)
- Enhanced Regenerative Medicine Capabilities at Role Of Care 1 - 3
- Incorporating Advanced Computing (“big data”, analytics)
- Hemorrhage and Resuscitation
- Traumatic Brain Injury (TBI) Diagnostics and Treatments
- Post Traumatic Stress Disorder (PTSD) Diagnostics and Treatments
- Ocular Salvage Devices
- Reduction of Weight, Cube and Cost for Items in Medical Sets, Kits and Outfits

Air Force Future Requirements

- Far Forward Blood, Blood Components, Blood Substitutes
- Multi-Channel IV Capability
- Austere Resuscitation and Surgical Support
- Fluid Resuscitation in an Anti-Access/Area Denial (A2AD) Environment
- Automated/Autonomous Intervention for Patient Care
- Clinical and Infectious Disease Diagnostics
- Prevent Wound Infection
- Guidance to Transport Highly Infectious Disease Patients
- Tele-Mentoring/Medicine/Monitoring
- Tactical Sensing, Pilot Vision Standards, Field of View, Levels of Glare Situational Awareness & Flight Safety

Navy Future Requirements

- Inability to provide extended en route care in excess of 96 hrs
- Insufficient training to handle large mass casualty operations
- Insufficient personnel and training to support en route care
- Insufficient capacity to provide en route care from the point of injury to the various roles distributed locations supporting roles of care
- Insufficient capability to coordinate and move patients to, from and within the maritime domain
- Inability of all assets used for medical transport to safely transfer patients to and from all afloat medical platforms
- Insufficient holding capability to support DMO casualty movement requirements
- Insufficient scalable, modular, mobile and deployable capability to support distributed operations
- Insufficient mobile/agile surgical capability

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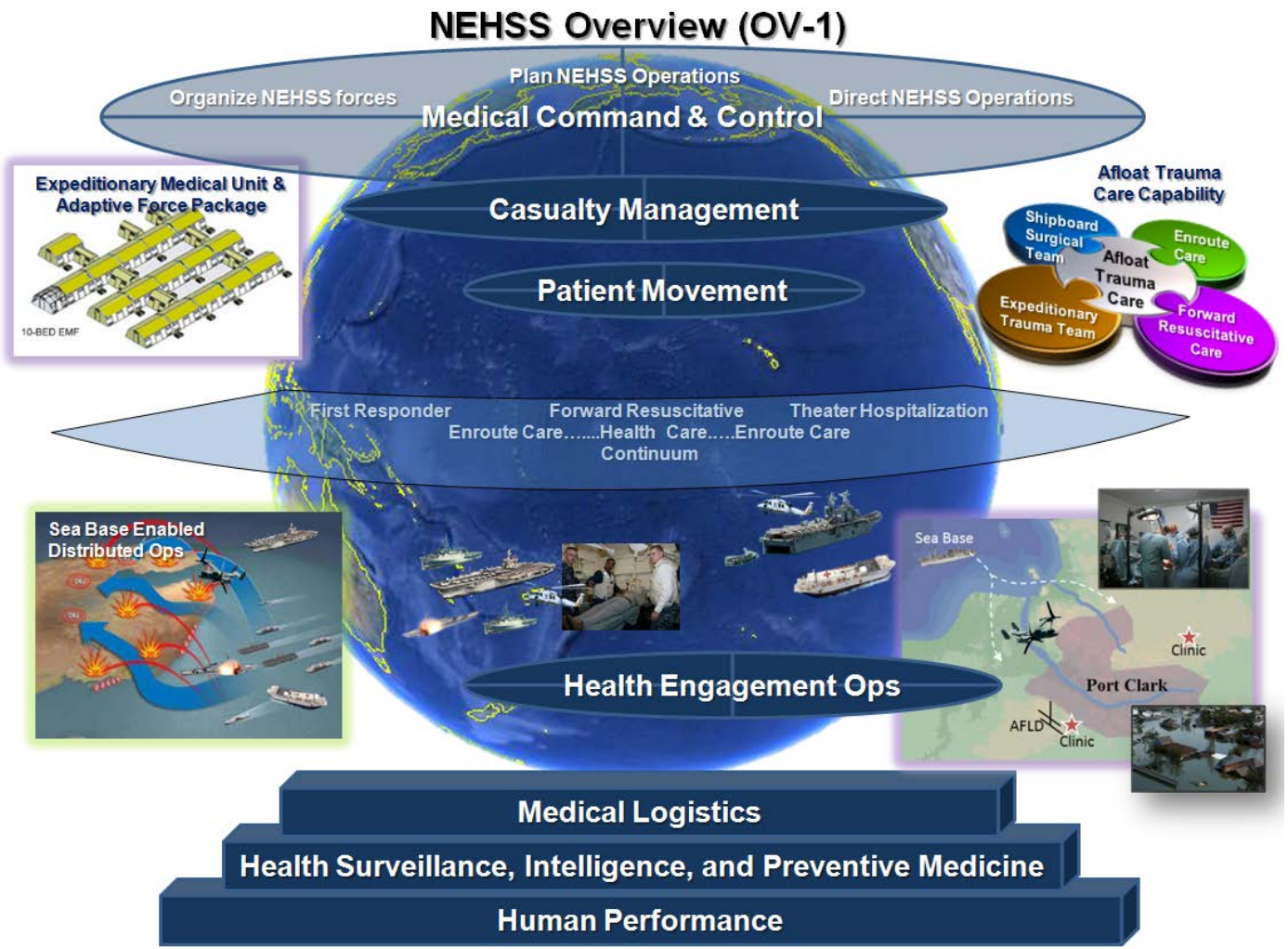
JTS Poll: 107 SME responses
(DCOT and CCMD SG staff, 1 Mar 2019)

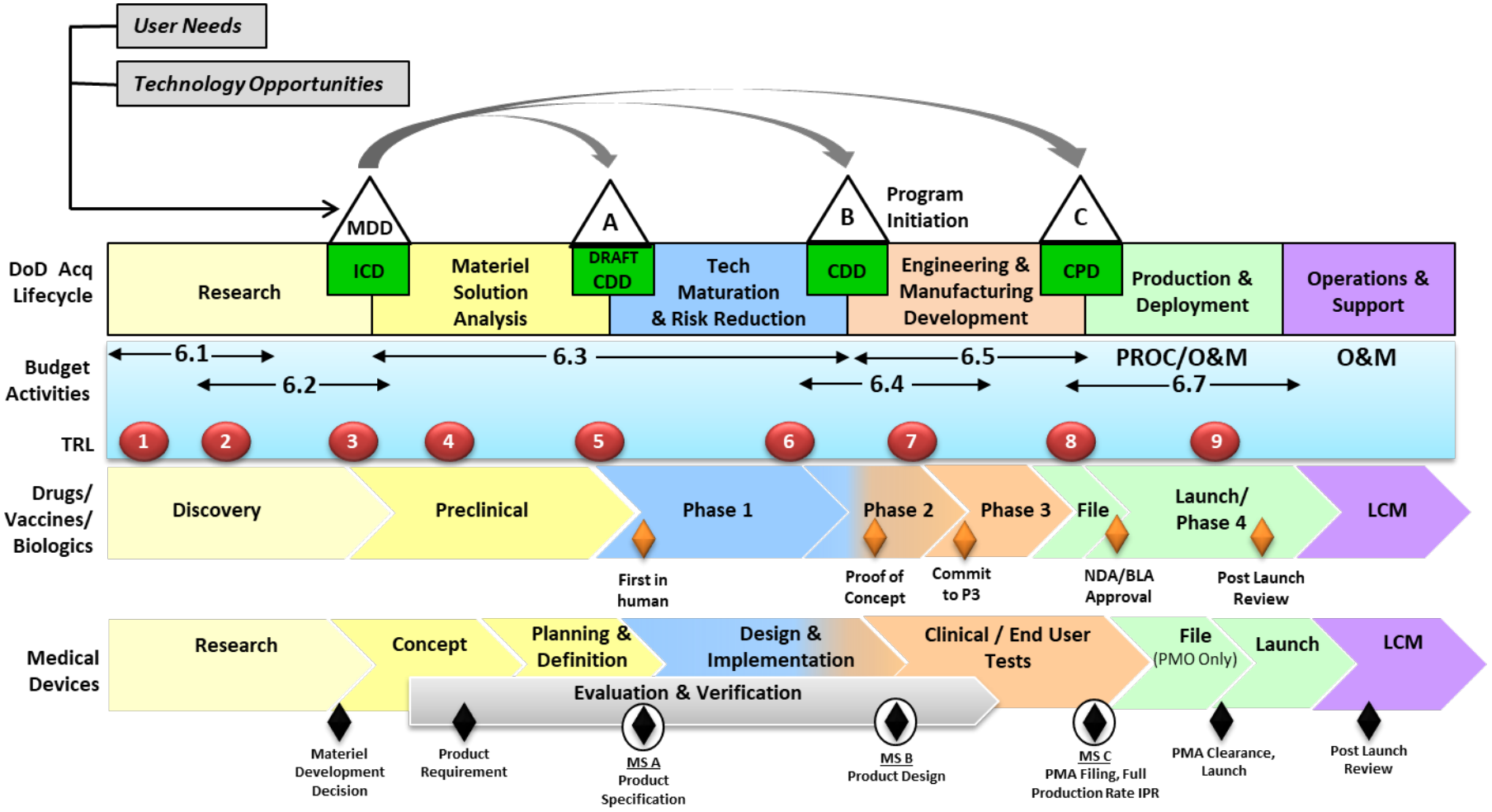
Defense Health Agency

Top 10 CURRENT Battlefield Issues (Preliminary):
1. Improve capability and capacity for Whole Blood transfusion throughout the continuum.
2. Improve ways to sustain trauma skills.
3. Recruit and retain medical personnel to support operations.
4. Facilitate documentation and data collection.
5. Standardize trauma care training across the Services.
6. Facilitate interoperability and standardization of devices for patient movement items (monitors and materiel products) throughout the continuum.
7. Standardize joint evacuation platforms and communication plans.
8. Optimal number, mix, and training of personnel for variety of missions/scenarios.
9. Improve capability and capacity for FDP transfusion throughout the continuum.
10. Relationship between time to definitive care and outcomes - validating and clarifying the "golden hour" concept.

Navy Expeditionary Health Services Support



Defense Acquisition System (DAS) & Medical R&D



Research, Development, Test, and Evaluation (RDT&E) Appropriation Classification

Budget Activity	Classification	Acquisition Phase Alignment	Description
Budget Activity 1	**Basic Research**	**Pre-Milestone A**	Systematic study directed toward greater knowledge or understanding, scientific study and experimentation
Budget Activity 2	**Applied Research**	**Pre-Milestone B** (Concept and Technology Development)	Systematic study to understand the means to meet a recognized and specific need
Budget Activity 3	**Advanced Technology Development (ATD)**	**Pre-Milestone B** (System concept demonstration or technology demonstration	Development of subsystems and components and efforts to integrate subsystems for field experiments and/or tests in a simulated environment
Budget Activity 4	**Advanced Component Development and Prototypes (ACD&P)**	**Pre-Milestone B**	Evaluate integrated technologies, representative modes or prototype systems in a high fidelity and realistic operating environment
Budget Activity 5	**System Development and Demonstration (SDD)**	**Post-Milestone B** in support of Milestone C	Engineering and manufacturing development tasks aimed at meeting validated requirements
Budget Activity 6	**RDT&E Management Support**	N/A – tasks aligned with basic research, applied research, ATD or as appropriate	Research, development, test and evaluation efforts and funds to sustain and/or modernize the installations or operations
Budget Activity 7	**Operational System Development**	**Post-Milestone** C, Fielded or anticipate production within next FY	Development efforts to upgrade systems that have been fielded

Conclusions

- ✓ Military medical research should address a capability requirement.
- ✓ Requirements guide the type of research and development.
- ✓ Addressing requirements results in sound research and development of materiel and non-materiel solutions that directly benefits our warfighters.
- ✓ If you are in doubt about a requirement, or have questions, contact one of the military medical partners.

THANK YOU!

Sylvain Cardin, Ph.D.
Naval Medical Research Unit San Antonio
sylvain.cardin.civ@mail.mil

Scott Walter, Ph.D.
US Air Force 59th Medical Wing
scott.f.walter.civ@mail.mil

Tony Pusateri, Ph.D.
US Army Institute of Surgical Research
anthony.e.pusateri.civ@mail.mil

Defense Health Agency

Medically Ready Force - Ready Medical Force

Partnering with the San Antonio Military Medical Research Community 101

Scott F. Walter, PhD, PE
Director of Technology
Chief Scientist's Office
October 2019

PAO Approved 7 Oct 2019, #20013

Disclaimer

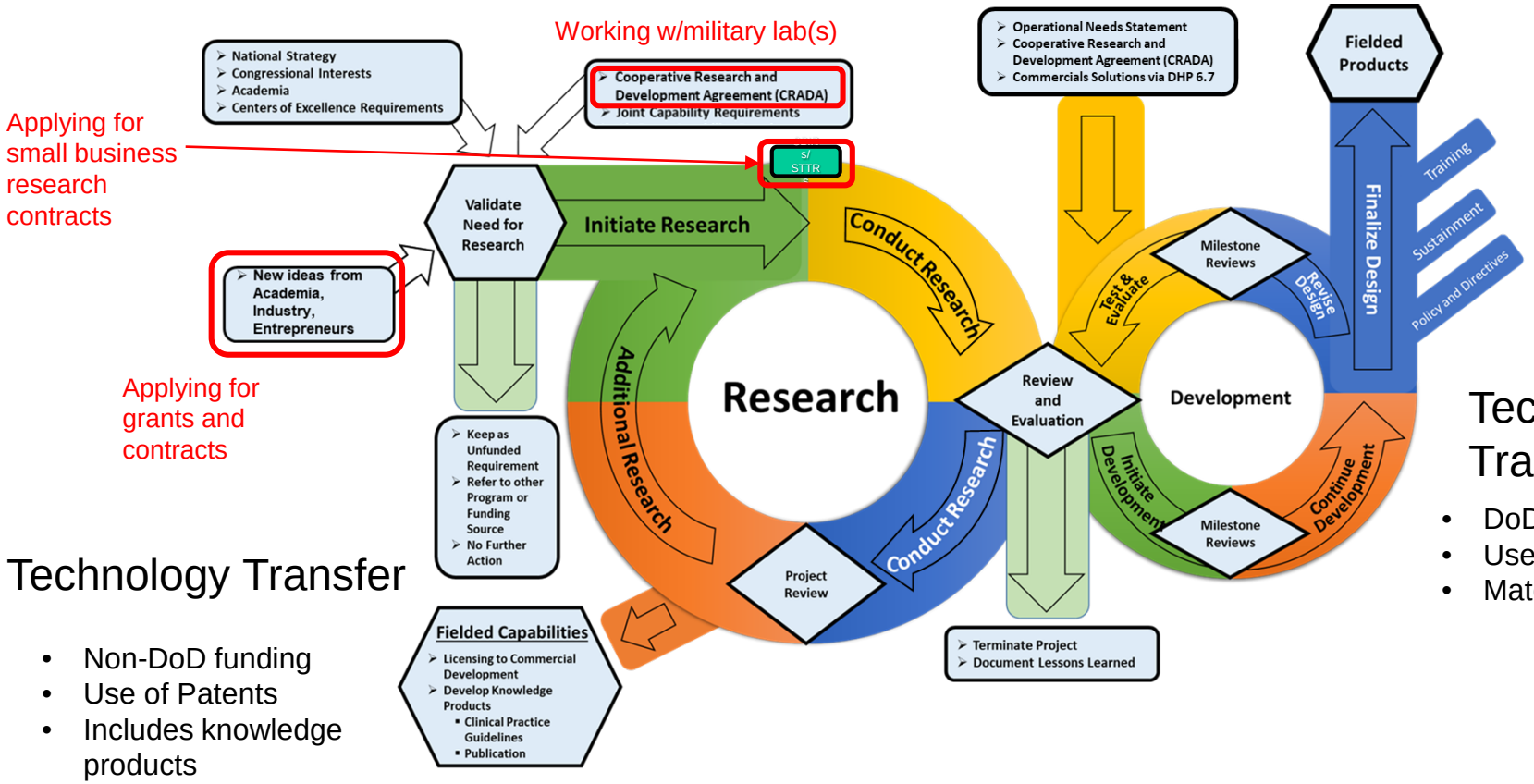
- “The views and opinions expressed in this presentation are solely those of the author and do not represent an endorsement by or the views of the United States Air Force, the Department of Defense, Defense Health Agency (DHA), or the United States Government.”

- "The views of TechLink are not necessarily the official views of, or endorsed by, the U.S. Government, the Department of Defense, or the Department of the Air Force. No Federal endorsement of TechLink is intended."

Main Topic Areas

- Overview of DoD Research and Development Cycle
- Applying for DoD Grants and Contracts
- Current CDMRP Research Programs & Example
- CDMRP Funding Opportunities Webinar Series
- Tips for Successful Proposals
- Collaborating with Military Labs
- Licensing of DoD Patents
- Small Business Pathway to Development
- Marketing Ideas to DoD Customers
- Enlist Users to Cross the Valley of Death
- Tips for Successful Project Completion
- Online Resources Available

Overview of DoD Research and Development Cycle



Technology Transfer

- Non-DoD funding
- Use of Patents
- Includes knowledge products

Technology Transition

- DoD funding
- Use of contracts
- Materiel solutions

Applying for DoD Grants & Contracts

- Continuously scan FedBizOps, Grants.gov, Electronic Biomedical Research Application Portal (https://ebrap.org) and other online sources for medical research and development opportunities to submit proposals
  - Seek out Program Announcements (PAs) & Broad Area Announcements (BAAs)
  - Some DoD organizations have their own BAAs/PAs like SOCOM
- Scan for opportunities such as Small Business Innovation Research (SBIR) & Small Business Technology Transfer (STTR)
- Look for other opportunities such as Rapid Innovation Funding (RIF)
- Frequent the Congressionally Directed Medical Research Program (CDMRP) website
  - Well-established processes for managing the review and selection of proposals/applications for funding medical research programs
  - Can subscribe to receive email notifications of when program announcements are released
  - Tailored to DoD program goals – may vary from year to year
  - Usually a two-tier process: white papers then full proposals

Current CDMRP Research Program Opportunities

★ Currently Has Open Funding Opportunities

Alcohol and Substance Abuse Disorders	Joint Warfighter Medical	Peer Reviewed Alzheimer's
Amyotrophic Lateral Sclerosis	Kidney Cancer	Peer Reviewed Cancer
Autism	Lung Cancer	Peer Reviewed Medical
Bone Marrow Failure	Lupus	Peer Reviewed Orthopaedic
Breast Cancer	★Melanoma	Prostate Cancer
★Chronic Pain Management	Military Burn	★Reconstructive Transplant Research
★Combat Readiness-Medical	Multiple Sclerosis	Spinal Cord Injury
★Duchenne Muscular Dystrophy	Neurofibromatosis	Tick-Borne Disease
Epilepsy	Orthotics and Prosthetics Outcomes	Tuberous Sclerosis Complex
Gulf War Illness	Ovarian Cancer	★Vision
★Hearing Restoration	Parkinson's	

Accessed from https://cdmrp.army.mil/ on 4 Oct 2019

CDMRP Website for FY19 Combat Readiness-Medical Research Program (CRRP)

CDMRP Transforming Healthcare through Innovative and Impactful Research

Home | Research Programs | Funding Opportunities | Consumers | Search Awards & Publications | About Us | Search... | Submit

Home / Funding Opportunities / Program Funding Opportunities / Combat Readiness-Medical Research Program

Program Funding Opportunities

FY19 Combat Readiness-Medical Research Program (CRRP)

Synopsis of FY19 CRRP Award Mechanisms - (Adobe PDF) - provides a brief description and key elements of the award mechanism.

Mechanism	Release Date	Program Announcement/Instructions	Submission Deadline	
Rapid Development and Translational Research Award	September 10, 2019	Broad Agency Announcement General Submission Instructions	**Pre-Application (Letter of Intent):** October 23, 2019 **Proposal/Application:** November 13, 2019	Submit Pre-Application

Quick Links:

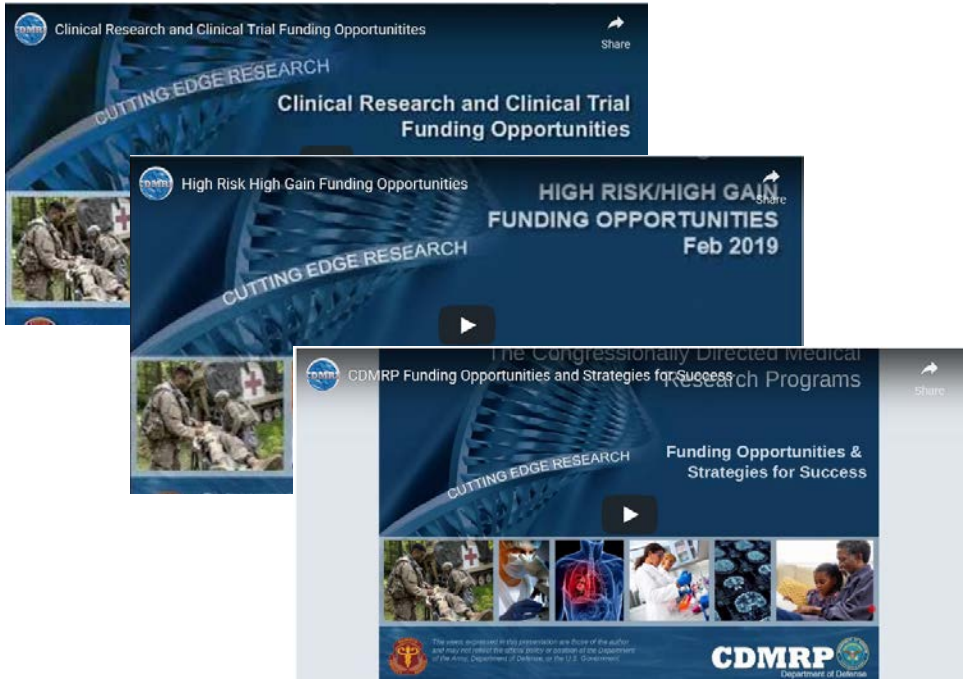
- CRRP Home Page
- U.S. Department of Education Accredited Postsecondary Minority Institutions List
- CRRP Program Funding Opportunities Archives
- Webinar Series

For further information, please send e-mail to:

cdmrpwebmaster@webcdmrp.org - for download related questions
Help@ebrap.org - for program announcement related questions

Multiple ways to engage for learning more/applying

CDMRP Funding Opportunities Webinar Series



Webinar Title
Funding Opportunities and Strategies for Success
High Risk/High Gain Funding Opportunities
Team Science Funding Opportunities
Clinical Research and Clinical Trial Funding Opportunities
Funding Opportunities for the Development of Technology and/or Resources
Funding Opportunities for Early Career Investigators
Consortium-Type Funding Opportunities

https://cdmrp.army.mil/pubs/Webinars/webinar_series

Info on Two-Tier Review Process: https://cdmrp.army.mil/about/2tierRevProcess

Tips for Successful Proposals

- Seek out collaborations from federal and academia researchers, possibly list them as collaborators on proposals
  - Federal researchers will have an Office of Research and Technology Transfer (ORTA) or Technology Transfer (T2) office to establish cooperative research agreements
  - Collaborative research proposals are more likely to be selected for funding
  - Some federal labs may have intermural funding to award via a contract
- When applying for research contracts/grant funding/announcements:
  - Need to align with an established service capability need, gap, or requirement
  - Best to identify a customer/end user and possibly secure letter of support
  - Clearly identify all deliverables and impacts in proposal (state “will cause ____ effect, if successful” versus “May cause _____ effect”)
  - Conduct a market assessment of existing capabilities and similar research efforts
  - Include a realistic regulatory strategy for entering product into market (if applicable)
  - Provide a transition strategy for how the results of research will be applied/used
- Nearly all DoD medical R&D must have a commercial use/application

Collaborating with Military Labs

- Collaborate with a federal researcher to evaluate your technology/ideas for applicability to the military or collaborate to advance it/them
- They will work with ORTA to establish the appropriate agreement to establish the best relationships between collaborators
- Cooperative Research and Development Agreements (CRADAs):
  - Bilateral agreements for R&D collaboration with industry, academia, or nonprofits
  - Federal lab can commit resources, e.g. personnel, facilities, equipment, and intellectual property (w/ or w/o reimbursement), <u>but no funds</u> to non-federal party
  - Non-federal party can commit similar resources to including funding
- Material Transfer Agreements (MTAs):
  - Allow sharing of tangible research materials including technology, supplies, samples, etc. in one direction: from industry to researchers (no funding)
- Other agreements include non-disclosure agreements, commercial test agreements, bailment agreements, etc..

Licensing of DoD Patents

- DoD may file for patents to secure new intellectual property (IP) from R&D
- Companies may learn of available technologies from inventors, trade organizations, scientific publications, etc. or through TechLink
  - TechLink is a DoD partner via Partnership Intermediary Agreement (PIA)
  - TechLink directly markets licensing opportunities to companies and maintains a robust searchable website
  - Direct marketing engages companies operating in the specific technical field to develop the "better, faster, cheaper" solution in business-friendly language to business leaders
- Companies can work with organization's ORTA or tech transfer (T2) office to initiate licensing agreements for developing medical products
- Recent examples:
  - REBOA: Resuscitative Endovascular Balloon Occlusion of the Aorta device
  - TS-VIS: Trauma Specific Vascular Injury Shunt
- Companies must submit a commercialization plan describing how they will develop, manufacture, market, and sell the medical product
- Adds value for securing private sector partners who provide added technical refinement, funding, manufacturing, and a sustainable supply chain

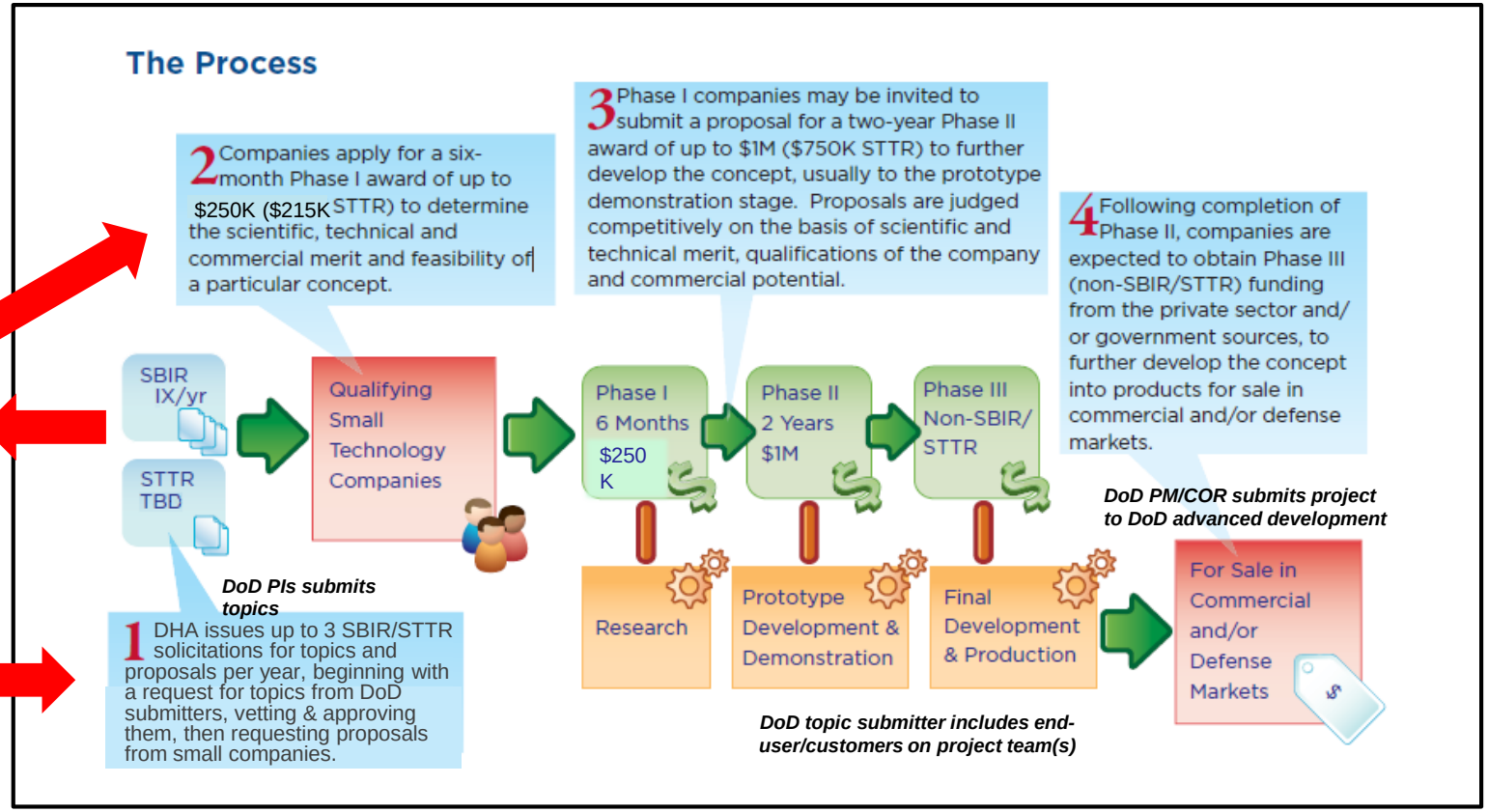
Small Business Pathway to Development

- Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Program
  - SBIR: Proposals written by small businesses & academia
  - STTR: proposals written by small businesses and academia
- Government researcher develops & submit 3 – 5 page topic (DHA holds topic calls 3/year)
- Topics selected for funding are published online in FedBizOps
- MHS SBIR/STTR Program managed by Ms Colleen Gibney at Fort Detrick
- Other SBIR/STTR opportunities from different services and organizations (Army, AF, DARPA, DHA)
- SBIR company owns IP and can patent new technologies, may include researcher as a co-inventor (even on active duty)
  - Creates potential conflict of interest that limits researcher's ability to participate in proposal reviews and selection for funding

MHS SBIR/STTR Process Overview

Companies may submit SBIR proposals online (w/academia for STTRs)

Government must develop and publish an applicable topic



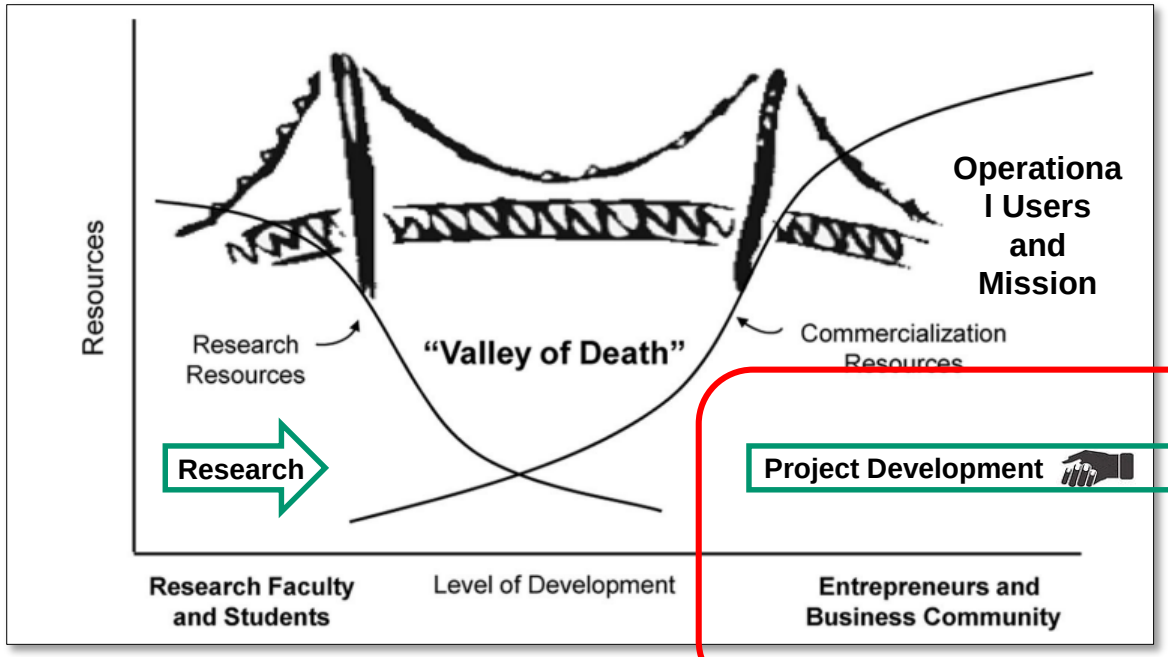
Marketing Ideas to DoD Customers

- Why: garnish support from user community, ensure medical R&D will provide a capability the military will use, obtain invaluable user input
- Military Health System (MHS) Vendor Days at Fort Detrick
  - Conducted monthly at Fort Detrick ~9 months of the year, no costs to attend or present/secure a table, targets military logisticians & program managers, register online, next one is November 21, 2019
- Military Health System Research Symposium (MHSRS)
  - Annual event, usually in August and in Orlando, Florida; includes vendor tables/section (at a cost), ability to submit abstracts (online), attended by ~3K attendees to include DoD R&D senior program managers, opportunity to attend briefings on military medical issues and co-mingle w/military end users
- Other medical R&D conferences with military implications:
  - Example1: 32nd Annual Southern Region Burn Conf 5-8 Dec 2019
  - Example 2: AMSUS - the Society of Federal Health Professionals, regional seminars/meetings

Enlist Users to Cross the Valley of Death

Align research to end-user gaps, needs, priorities or…

Plan to demonstrate how results of research will (*not may*) make a significant impact if successful



$ Need funding programmed for development and fielding

Need end-user to "pull" research it through the valley of death (development and acquisition processes)

- **Problem**: researchers, developers, manufacturers, end-users/customers, funding, and desired outcomes are not always aligned
- **Results**: wasted funding, missed opportunities, minimal to no impact

Tips for Successful Project Completion

- Understand end user needs, make them the goals of the project, balance it with what's feasible, establish a commitment from a potential end user
  - Who needs it, where will it be used, how will it be used
- Form a project team and hold reoccurring meetings to keep customers involved, stakeholders engaged and create advocacy
  - Evaluate concepts and prototypes to collect constructive feedback for improvement
  - Reassess project periodically and use results to revise requirements & realign project
- Know the strengths & weaknesses of your partners; if you don't have what you need, go find it, make partnerships happen, ask for help
- Ensure the end-products are commercially marketable to reduce costs per unit, expendables, supplies, and servicing
- Clearly communicate the expected impact with caveat "if successful" for improving in-garrison care, readiness, training/education, or deployed medical operations

Online Resources

- **Military Health System (MHS) Vendor Days at Fort Detrick: https://health.mil/Military-Health-Topics/Combat-Support/Medical-Logistics/Vendor-Day**
- **Small Business Innovation Research/Technology Transfer (SBIR/STTR): https://www.acq.osd.mil/osbp/sbir/**
- **Broad Agency Announcements (BAAs): continuously open pre-proposal/pre-application submissions for basic and applied research: https://www.grants.gov/web/grants/search-grants.html?keywords=BAA**
- **Congressionally Directed Medical Research Programs (CDMRP): http://cdmrp.army.mil/default**
- **CDMRP Overview: https://www.ncbi.nlm.nih.gov/books/NBK424514/**
- **FedBizOpps: Listing of all active federal solicitations https://www.fbo.gov**
- **Grants.Gov: Online access to search, apply and compete for federal grants: https://www.grants.gov/**
- **Gateway to Partnerships: A USAMRDC Guide to navigate partnership mechanisms to Innovate, Collaborate and Connect with military researchers http://mrmc.amedd.army.mil/assets/docs/G-3-5-Guide-to-Doing-Business.pdf**
- **United States Army Medical Research and Development Command (USAMRDC) open BAA: http://www.usamraa.army.mil/Pages/BAA.aspx**
- **Special Operations Forces (SOF) Biomedical Research BAA: https://www.grants.gov/web/grants/search-grants.html?keywords=W81XWH-USSOCOM**
- **Contests open to the public to meet an unmet need of the government: https://www.challenge.gov/list/**
- **USAMRMC method for submitting new products and ideas for consideration: https://mrmc-npi.amedd.army.mil/**
- **Techlink (available patents, info, and support): https://techlinkcenter.org/**

Thank You!

Military Health System
Small Business Innovation Research (SBIR) & Small Business Technology Transfer (STTR) Programs

Ms. Colleen Gibney
USAMRDC SBIR Deputy Project Manager
15 October 2019

DoD Disclaimer

The views and opinions expressed in this presentation are those of the authors and do not reflect official policy or position of the Department of the Army, Department of Defense or the U.S. Government

Today's Agenda

- Federal SBIR/STTR Funding: Quick Program Basics
- Military Health System SBIR/STTR Programs
- The DoD SBIR/STTR Broad Agency Announcement (BAA) Portal: Watch for changes this winter!
- Proposal Best Practices for Defense Health Agency (DHA) and Army/Medical Submissions
  - How to decipher a SBIR/STTR topic
  - How to address dual-use commercialization
  - How to submit a topic idea for future consideration
  - How to share an 'outside' medical Phase II project with our office
- Additional SBIR/STTR Resources

Federal SBIR/STTR Funding: Quick Program Basics

Federal Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs

- Congressionally-mandated Programs intended to promote technological innovation and economic growth through Federal investment
- 11 Federal Government Agencies participate in the SBIR Program (DoD, DoE, DHS, DoT, etc.)
- Funded through a proportional SBIR/STTR assessment of extramural RDT&E budget
- Small Business Administration holds programmatic authority as expressed in SBIR/STTR Policy Directives

SBIR/STTR Eligibility Requirements

SBIR Small Business Eligibility:

- Organized for profit, based in U.S., subs based in U.S.
- 500 employees or fewer
- At least 51% owned and controlled by U.S. individuals
- Minimum 2/3 of Phase I and 1/2 of Phase II performed by small business
- Principal Investigator's primary employment must be with the small business (no other entity can claim them as a full time employee)

STTR Small Business Eligibility:

- Same size and control requirements as SBIR
- STTR program **requires** participation by Universities, Federally Funded Research and Development Centers (FFRDCs), and other non-profit Research Institutions
- Formal cooperative R&D Effort
  - Minimum 40% by small business
  - Minimum 30% by U.S. Research Institution
- U.S. Research Institutions only—(non-DoD to avoid Conflict of Interest issues)

Federal Agency Participation

SBIR + STTR Programs:

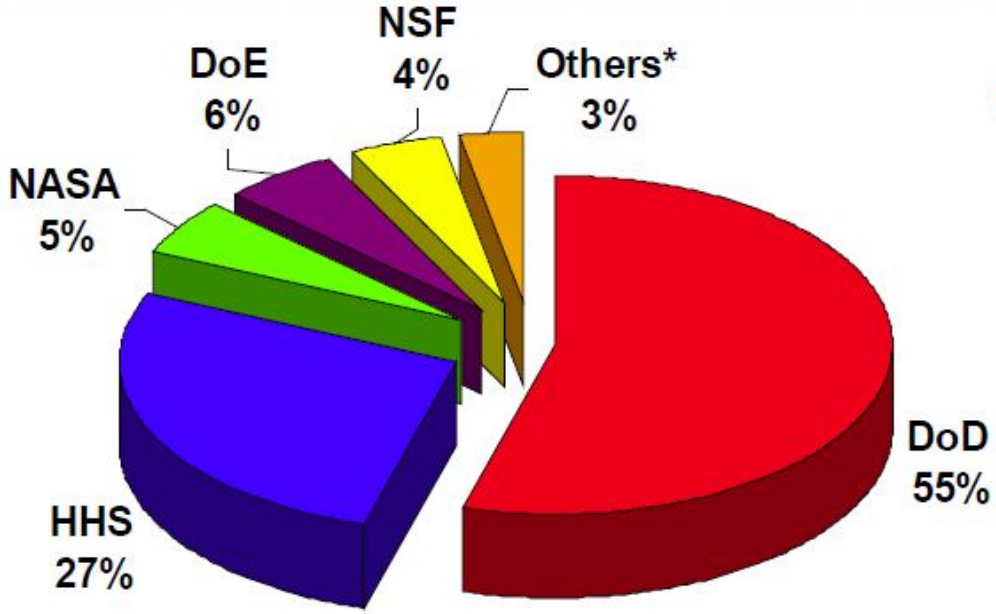
- Dept. of Defense
- Dept. of Health and Human Services
- Dept. of Energy
- National Aeronautics and Space Administration
- National Science Foundation

SBIR Program only:

- Dept. of Agriculture
- Dept. of Education
- Dept. of Transportation
- Environmental Protection Agency
- Dept. of Homeland Security
- Dept. of Commerce

Federal Agency Participation

	DoD	NASA	DOT	EPA	DHS	USDA	DOE	NSF	DOC	DoED	HHS
SBIR	●	●	●	●	●	●	●	●	●	●	●
STTR	●	●					●	●			●
Contract/ Grant	C	C	C	C	C	G	G	G	G/C	G/C	G/C



- ✓ Small Business Administration (SBA) oversees the federal SBIR/STTR programs
  - Policy Directives
  - Congressional Reports
  - Size Determination
  - Waivers

DoD Component Participation

SBIR + STTR Programs:

- Air Force
- Army
- Navy
- Defense Health Agency
- Defense Advanced Research Projects Agency
- Missile Defense Agency

SBIR Program only:

- Defense Threat Reduction Agency
- Joint S&T Office for Chemical and Biological Defense
- National Geospatial Agency
- Special Operations Command
- Defense Microelectronics Activity
- Defense Logistics Agency

Military Health System SBIR/STTR Programs

SBIR/STTR Programs Coordinated at MRDC

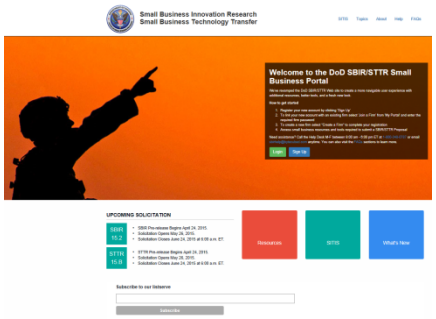
DHA SBIR/STTR Programs
CAPT Joseph Cohn, Chief
Research Program Administration, Defense Health Agency Falls Church, VA

Army SBIR Program
Mr. Monroe Harden, Acting Program Manager
CCDC, Aberdeen Proving Ground, MD

Army STTR Program
Mr. John Smith, Program Manager
ARO, Research Triangle Park, NC

DHA & Army SBIR/STTR Process Flow

Topics



DoD BAAs

SBIR: YY.1, YY.2, and YY.3
STTR: YY.A, YY.B, and YY.C
(see schedule)

Phase I

Proof of Concept

DHA: $250K, 6 months

Army SBIR only:
$111,500K, 6 months +
$56K Option, 4 months
(only if Ph. II selected)

Army STTR - $167,500K

Phase II

Prototype Development

$1.1M, 2 years

PH II Enhancement

Up to $550K to match qualified non-SBIR/STTR investment

Phase III

Commercialization

Transition to Government or private industry
No SBIR/STTR Funds
No additional competition required

USAMRDC SBIR/STTR Points of Contact

Mr. J.R. Myers, Project Manager: james.r.myers38.civ@mail.mil

Ms. Colleen Gibney, Deputy Project Manager: colleen.n.gibney.civ@mail.mil

Ms. Amanda Cecil, Operations Manager: amanda.l.cecil3.ctr@mail.mil

***Vacant,* DHA SBIR/STTR Program Analyst**: TBD

Ms. Tricia Roth, Army SBIR/STTR Program Analyst: patricia.a.roth.ctr@mail.mil

Ms. Andrea Renner, Technical Assistance Advocate: andrea.k.renner.ctr@mail.mil

The DoD SBIR/STTR Broad Agency Announcement (BAA) Portal

Watch for changes this winter!

DoD SBIR/STTR BAAs

- DoD SBIR/STTR Office establishes six DoD SBIR/STTR Broad Agency Announcements (BAA) and respective mandated dates
- Each BAA has a: Pre-release, Open and Close period
- During the pre-release period the Government does not accept proposals, but small businesses can discuss technical questions directly with the Topic Authors

SBIR 19.1 STTR 19.A	SBIR 19.2 STTR 19.B	SBIR 19.3 STTR 19.C
Pre-Release 28 Nov 18	Pre-Release 19 Apr 19	Pre-Release 23 Aug 19
Open 8 Jan 19	Open 31 May 19	Open 24 Sep 19
Close 6 Feb 19	Close 1 Jul 19	Close 23 Oct 19

Technical Questions about Topics

During Pre-Release: Firms contact Topic Authors directly.

» During the one month pre-release, Topic Authors' names, phone numbers, and e-mail addresses are listed with the topic.

» Questions are limited to specific information related to a topic's requirements.

» Offerors may not ask for advice or guidance on solution approach nor submit additional material to the Topic Author.

Once the BAA opens: Firms post questions through the SBIR/STTR Interactive Topic Information System (SITIS)

Direct communication with the Topic Author is not allowed during this period; however, offerors may submit written questions through SITIS.

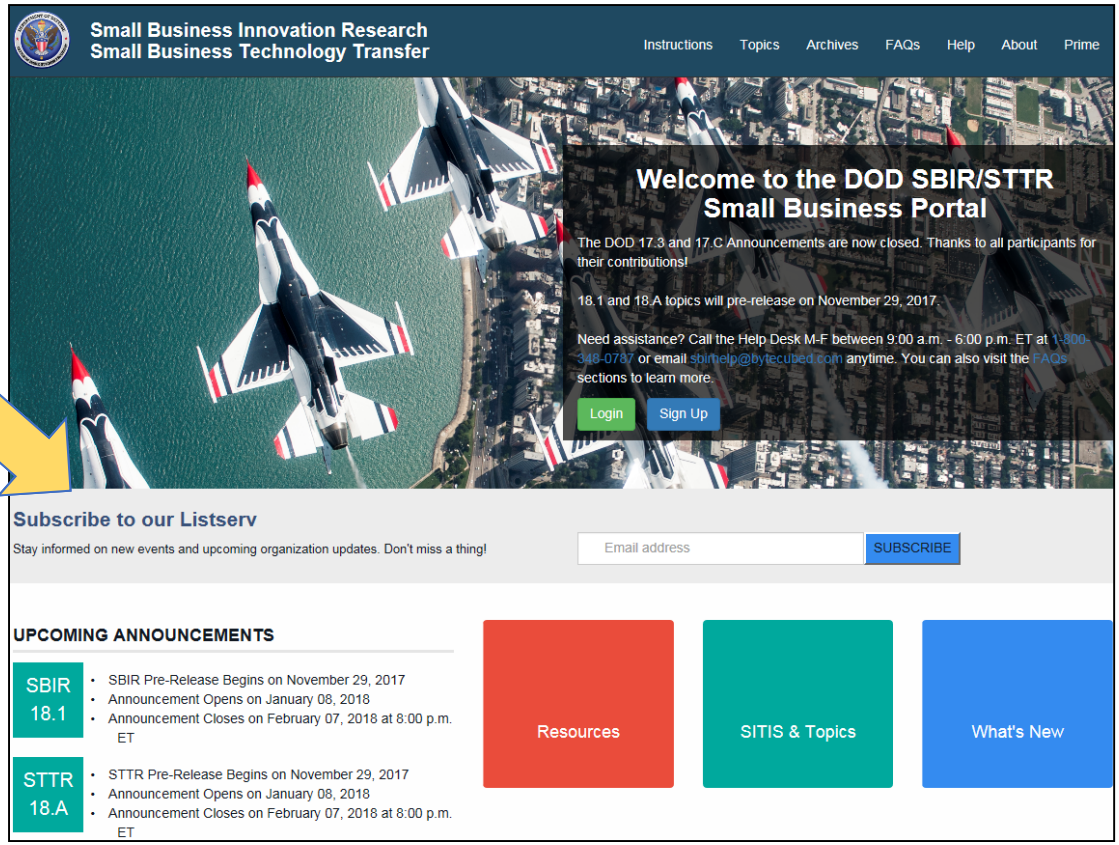
» Questioner and respondent remain anonymous, and all questions and answers are posted electronically for general viewing.

SBIR 2019.3 and STTR 2019.C BAA – Key Dates

23 Aug 19	**Pre-Release** – Direct communication with Topic Authors **SITIS** - Q&A Operational
24 Sep 19	**BAA Open** – No further direct contact between Topic Authors and Small Businesses
23 Oct 19	**BAA Closes** – All proposals must be submitted by 8:00 p.m. ET **Plan ahead and submit early**.

DoD SBIR/STTR Small Business Portal

- » Upcoming Announcements
- » Instructions
- » Topics
- » Archives
- » FAQs
- » Help
- » SITIS



https://sbir.defensebusiness.org/

Proposal Best Practices for Defense Health Agency (DHA) and Army/Medical Submissions

How do I decipher a SBIR/STTR topic? There is so much information packed into short paragraphs, and I'm not clear what all these constraints mean.

"3T" Method:

Time: Set aside enough time early in the process

Team: Bring in the right people early in the process to…

Take apart the topic and references as a group to understand as much as you can about the capability gap

Proposal Format

- » DoD Instructions provides overall proposal format
- » Specific components provide topics and item specific information

BAA Documents	Last Modified	
DoD Instructions: 2019.1 SBIR	December 21, 2018	DOC
Army	January 22, 2019	DOC
Navy	January 8, 2019	DOC
Air Force	January 18, 2019	DOC
Air Force Direct to Phase II	January 8, 2019	DOC
DHA	January 8, 2019	DOC
NGA	January 8, 2019	DOC
OSD/ManTech Direct to Phase II	January 8, 2019	DOC
USSOCOM	January 18, 2019	DOC

"This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed-in whole or in part-for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of-or in connection with-the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in pages [insert numbers or other identification of sheets]"; and

(2) Mark each sheet of data it wishes to restrict with the following legend:

"Use or disclosure of data contained on this page is subject to the restriction on the first page of this volume."

The DoD assumes no liability for disclosure or use of unmarked data and may use or disclose such data for any purpose.

Restrictive notices notwithstanding, proposals and final reports submitted through the DoD Submission Web site may be handled, for administrative purposes only, by support contractors. All support contractors are bound by appropriate non-disclosure agreements.

5.4 Phase I Proposal Instructions

a. **Proposal Cover Sheet (Volume 1)**

On the DoD Submission Web site at https://sbir.defensebusiness.org/, prepare the Proposal Cover Sheet. The Cover Sheet must include a brief technical abstract of no more than 200 words that describes the proposed R&D project with a discussion of anticipated benefits and potential commercial applications. **Do not include proprietary or classified information in the Proposal Cover Sheet**. If your proposal is selected for award, the technical abstract and discussion of anticipated benefits may be publicly released on the Internet. Once the Cover Sheet is saved, the system will assign a proposal number. You may modify the cover sheet as often as necessary until the BAA closes.

b. **Format of Technical Volume (Volume 2)**

(1) Type of file: The Technical Volume must be a single Portable Document Format (PDF) file, including graphics. Perform a virus check before uploading the Technical Volume file. If a virus is detected, it may cause rejection of the proposal. **Do not lock or encrypt the uploaded file**. **Do not include or embed active graphics such as videos, moving pictures, or other similar media in the document.**

(2) Length: The Technical Volume is limited to 20 pages. Please refer to Component-specific instructions for how a technical volume in excess of 20 pages is handled. Some Components will reject the entire technical proposal if over 20 pages.

(3) Layout: Number all pages of your proposal consecutive
wish to respond must submit a direct, concise, and infor
search or research and development proposal of no mor
pages (no type smaller than 10-point on standard 8-1/2"
with one-inch margins). The header on each page of the
Volume should contain your company name, topic num
posal number assigned by the DoD SBIR/STTR Submiss
when the Cover Sheet was created. The header may be
one-inch margin.

c. **Content of the Technical Volume (Volume 2)**

The Technical Volume should cover the following items in the
low:

(1) **Identification and Significance of the Problem or Opportunity.** Define the specific technical problem or opportunity addressed and its importance.

(2) **Phase I Technical Objectives.** Enumerate the specific objectives of the Phase I work, including the questions the research and development effort will try to answer to determine the feasibility of the proposed approach.

(3) **Phase I Statement of Work (including Subcontractors' Efforts)**

a) Provide an explicit, detailed description of the Phase I approach. If a Phase I option is required or allowed by the Component, describe appropriate research activities which would commence at the end of Phase I base period should the Component elect to exercise the option. The Statement of Work should indicate what tasks are planned, how and where the work will be conducted, a schedule of major events, and the final product(s) to be delivered. The Phase I effort should attempt to determine the technical feasibility of the proposed concept. The methods planned to achieve each objective or task should be discussed explicitly and in detail. This section should be a substantial portion of the Technical Volume section.

b) This BAA may contain topics that have been identified by the Program Manager as research or activities involving Human/Animal Subjects and/or Recombinant DNA. In the event that Phase I performance includes performance of these kinds of research or activities, please identify the applicable protocols and how those protocols will be followed during Phase I. Please note that funds cannot be released or used on any portion of the project involving human/animal subjects or recombinant DNA research or activities until all of the proper approvals have been obtained (see Sections 4.7 - 4.9).

(4) **Related Work**. Describe significant activities directly related to the proposed effort, including any conducted by the principal investigator, the proposing firm, consultants, or others. Describe how these activities interface with the proposed project and discuss any planned coordination with outside sources. The technical volume must persuade reviewers of the proposer's awareness of the state-of-the-art in the specific topic. Describe

timely completion of said authorizations in support of Phase II research or research and development effort.

(6) **Commercialization Strategy.** Describe in approximately one page your company's strategy for commercializing this technology in DoD, other Federal Agencies, and/or private sector markets. Provide specific information on the market need the technology will address and the size of the market. Also include a schedule showing the quantitative commercialization results from this SBIR project that your company expects to achieve.

(7) **Key Personnel**. Identify key personnel who will be involved in the Phase I effort including information on directly related education and experience. A concise technical resume of the principal investigator, including a list of relevant publications (if any), must be included (Please do not include Privacy Act Information). All resumes will count toward the 20-page limitation for Volume 2.

(8) **Foreign Citizens**. Identify any foreign citizens or individuals holding dual citizenship expected to be involved on this project as a direct employee, subcontractor, or consultant. For these individuals, please specify their country of origin, the type of visa or work permit under which they are performing and an explanation of their anticipated level of involvement on this project. Offerors frequently assume that individuals with dual citizenship or a work permit will be permitted to work on an SBIR project and do not report them. This is not necessarily the case and a proposal will be rejected if the requested information is not provided. Therefore, firms should report any and all individuals expected to be involved on this project that are considered a foreign national as defined in Section 3.5 of the BAA. You may be asked to provide additional information during negotiations in order to verify the foreign citizen's eligibility to participate on a SBIR contract. Supplemental information provided in response to this paragraph will be protected in accordance with the Privacy Act (5 U.S.C. 552a), if applicable, and the Freedom of Information Act (5 U.S.C. 552(b)(6)).

(9) **Facilities/Equipment**. Describe available instrumentation and physical facilities necessary to carry out the Phase I effort. Justify equipment purchases in this section and include detailed pricing information in the Cost

"3T" Inputs: 10 Parts of a Topic

1. DoD Instructions – do not skip these!
2. Component Instructions
   a. Note SBIR, Direct to Phase II SBIR, and STTR have separate instructions per component
   b. Don't miss critical Phase II proposal information in the Phase I instructions
3. Title – provisionally describes the desired product
4. Objective – further specifies the goal with more clues
5. Description – further describes how the gap measurably impacts Warfighter health, readiness, and return-to-duty status
6. Phase I – expectations for the 6 month proof-of-concept effort
7. Phase II – our blueprint for a well-defined prototype
8. Phase III – our working idea of the future state and potential $
9. References – essential background reading for your proposal
10. Keywords – useful, but not meant to be exhaustive

How do I address dual-use commercialization planning for medical topics?

Old way: focus on DoD's stated needs exclusively, and catch up with a commercially-viable product later

New way: Keep the market's needs in view from the start; but design flexibly

How do I submit a medical topic area for future consideration?

Email us or Army SBIR PMO:

DHA SBIR/STTR:

DHA_SBIR-STIR@mail.mil

Army SBIR:

usarmy.apg.rdecom.mbx.sbir-program-managers-helpdesk@mail.mil

How do I share an ‘outside’ medical Phase II project with your Military Health System Portfolio Managers and Product Developers?

- Other DoD
  - DARPA, etc.
- NIH
- NASA
- NSF

Send it to our office at the DHA address: **DHA_SBIR-STTR@mail.mil**

Alternately: contact Colleen Gibney **colleen.n.gibney.civ@mail.mil**

or Andrea Renner **andrea.k.renner.ctr@mail.mil**

Additional SBIR/STTR Resources

SBIR/STTR Resources

SBA's SBIR/STTR Website

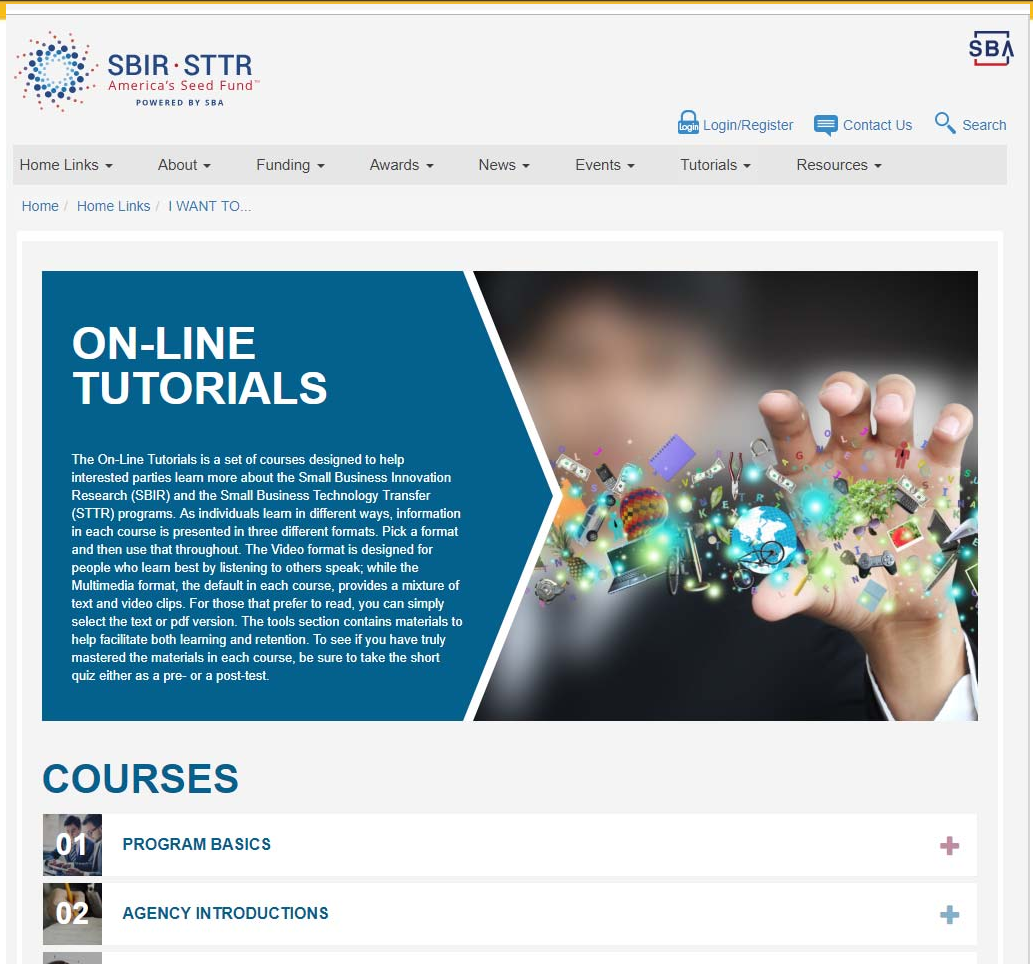
Search for:

- » Applicant Instructions
- » Awardee Information
- » Investors
- » Large Businesses
- » Agencies
- » Policy Directives

www.sbir.gov

Online Tutorials for SBIR/STTR Programs

- » 18 Main Tutorials
- » Sub-tutorials in each course
- » Various Media Options Available



https://www.sbir.gov/tutorials/

Thank you

Questions?

PRYTIME MEDICAL™

The REBOA Company™

Business Opps / Venture Capital / Angel Investment

Presented By: David Spencer

Dspencer@prytimemedical.com

210.340.0116

WWW.PRYTIMEMEDICAL.COM

Agenda

- My Background Drives My Perspective
- Military Medical in San Antonio
  - Is There an Extraordinary Opportunity Here?
- Company Formation – What's it Take?
- Current Case Study – Prytime Medical aka "The REBOA Company"
- Seen and Unseen Barriers
  - And How to Overcome Them

My Background Drives My Perspective

- BSEE 1988, Entrepreneur Since 1998
  - Have founded or co-founded 18 companies
    - Software, Banking, Agriculture, Day Care, Medical…

- Angel Investor Since 2000
  - Total Investment to date ~$8.5M
  - 50+ companies, 5 funds

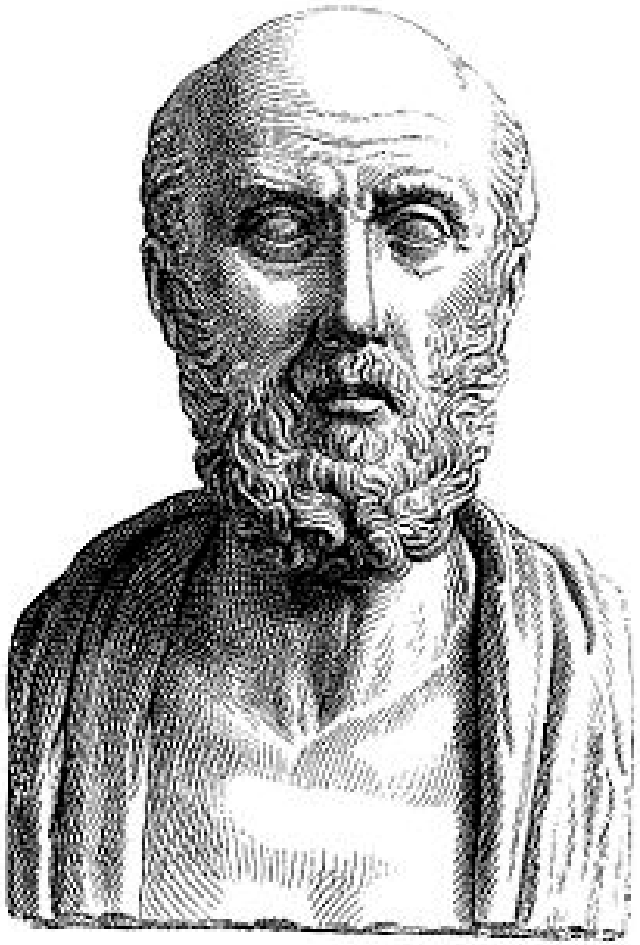
- Venture Capitalist (ish) for 4 Years
  - Texas Emerging Tech Fund Chair 2006-2008
  - $350M Invested
  - Personal Due Diligence on 189 companies

Company Formation – What's It Take?

Only Three Things

1) An Idea (Which better be a strong Clinical Need)
2) A Team
3) Money

Military Medical – An Extraordinary Opportunity?



"The Only Winner in War is Medicine"

- Statue Dude*

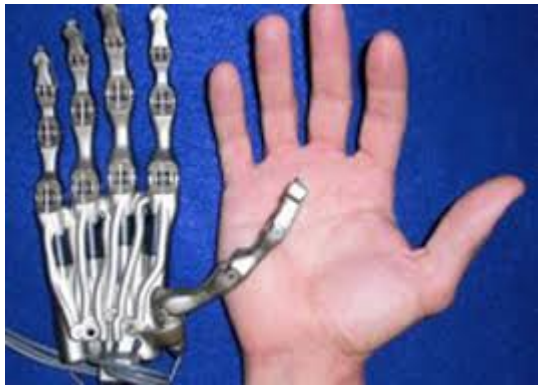
* Hippocrates

SELECTED MILITARY RESEARCH INTERESTS IN SAN ANTONIO

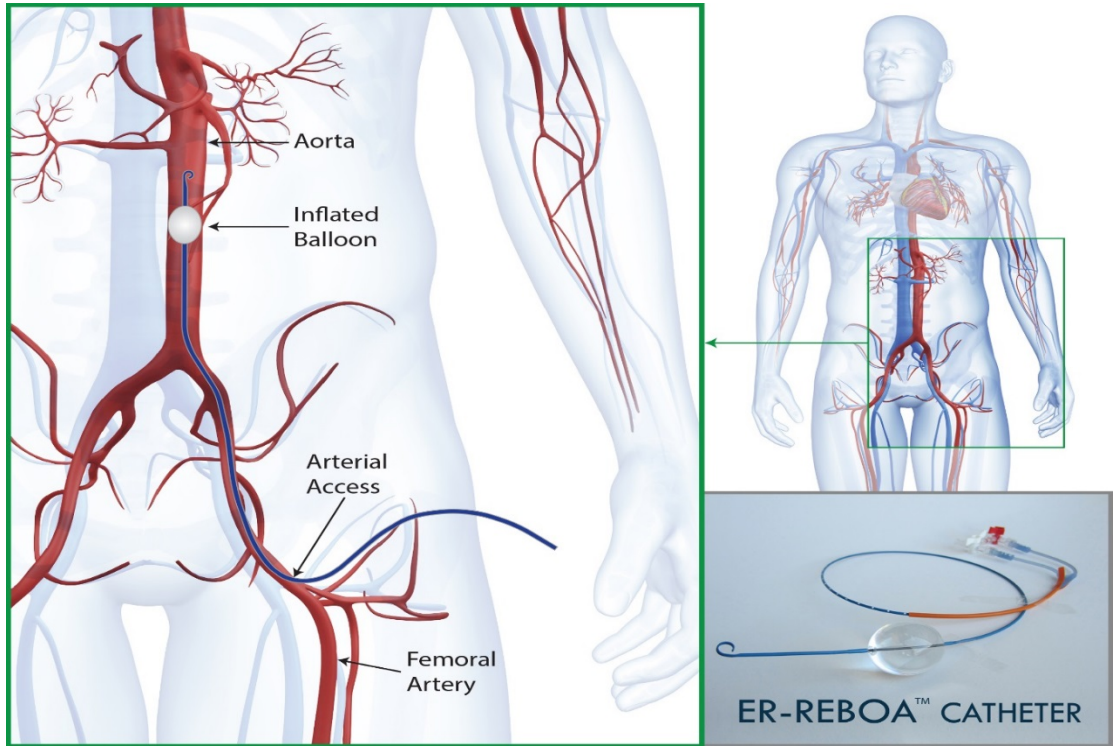
FDA approved Hemostatic Agents

- Cyanoacrylate (2 products)
- Collagen & Thrombin (FloSeal)
- PEG Polymer (FocalSeal & CoSeal)
- Albumin & Gluteraldehyde (Bio Glue)
- Fibrin Sealant (Tisseel)
- Collagen Enhanced FS (CoStasis)
- TachoSil (fibrin sealant patch)
- mRHD (modified Rapid Deployed Hemostat)

USAISR



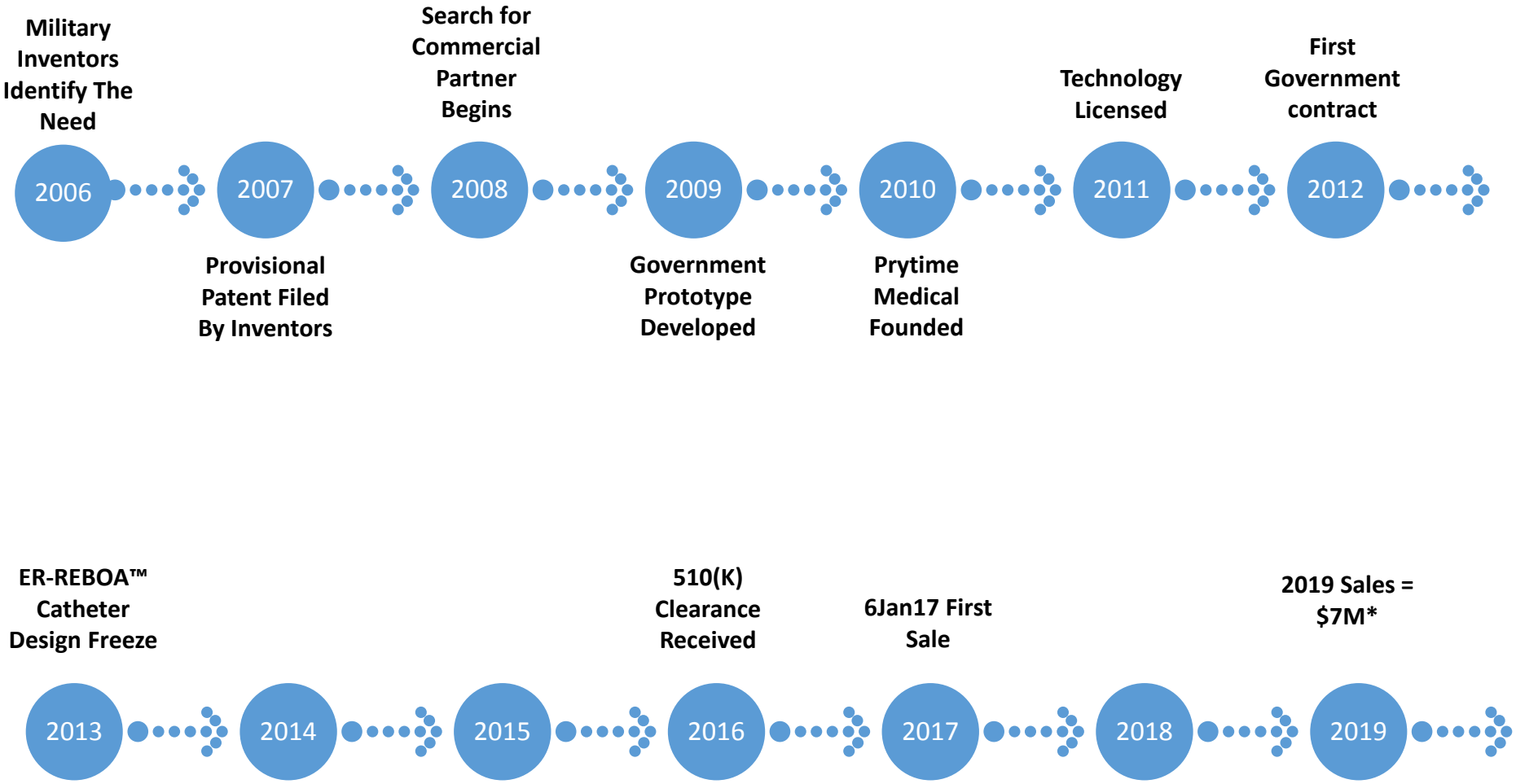
Case Study – Prytime Medical



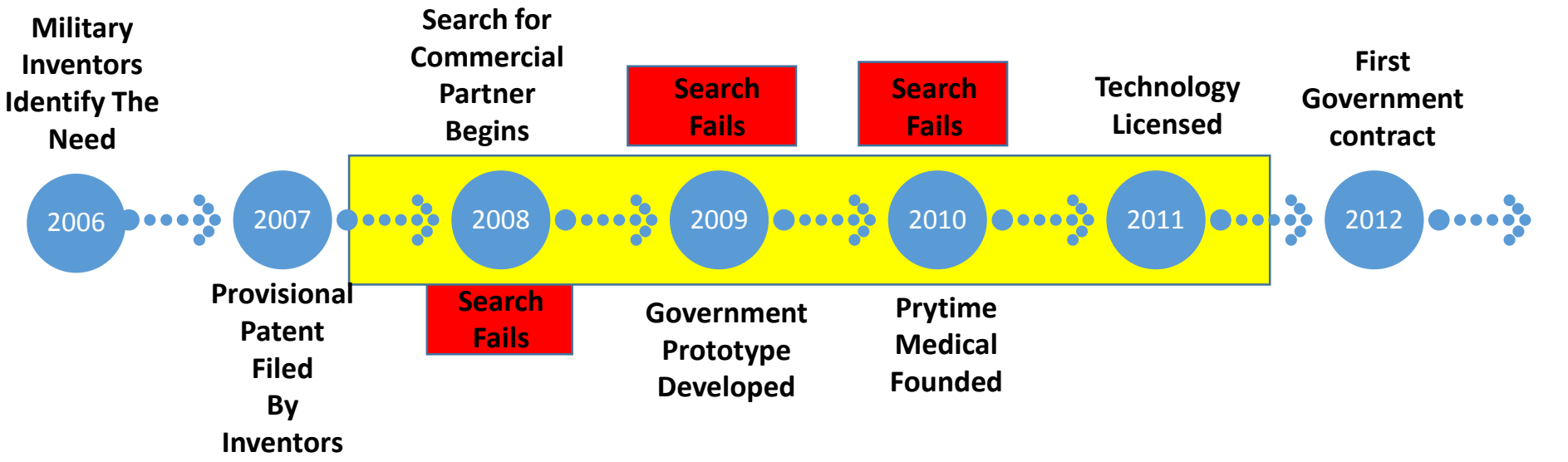
REBOA: Resuscitative Endovascular Balloon Occlusion of The Aorta

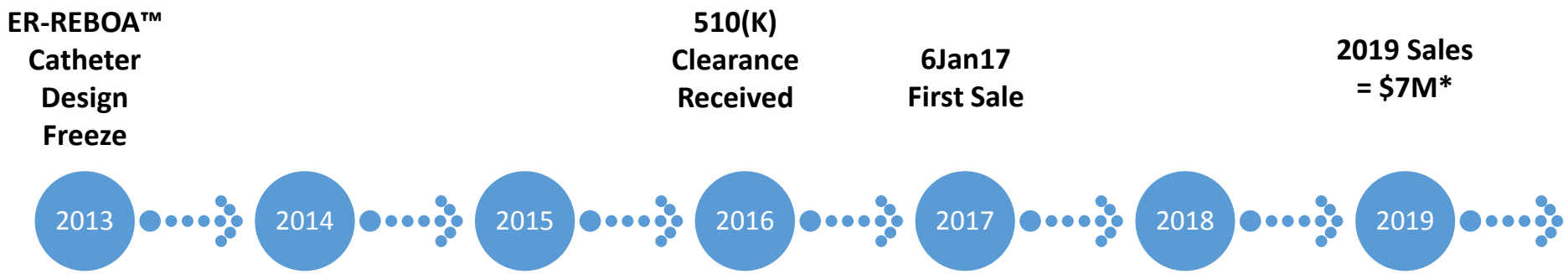
- Temporarily occludes blood flow below balloon
- Goal: Stop bleeding, allow time for definitive repair

Case Study REBOA: An Overnight Success?



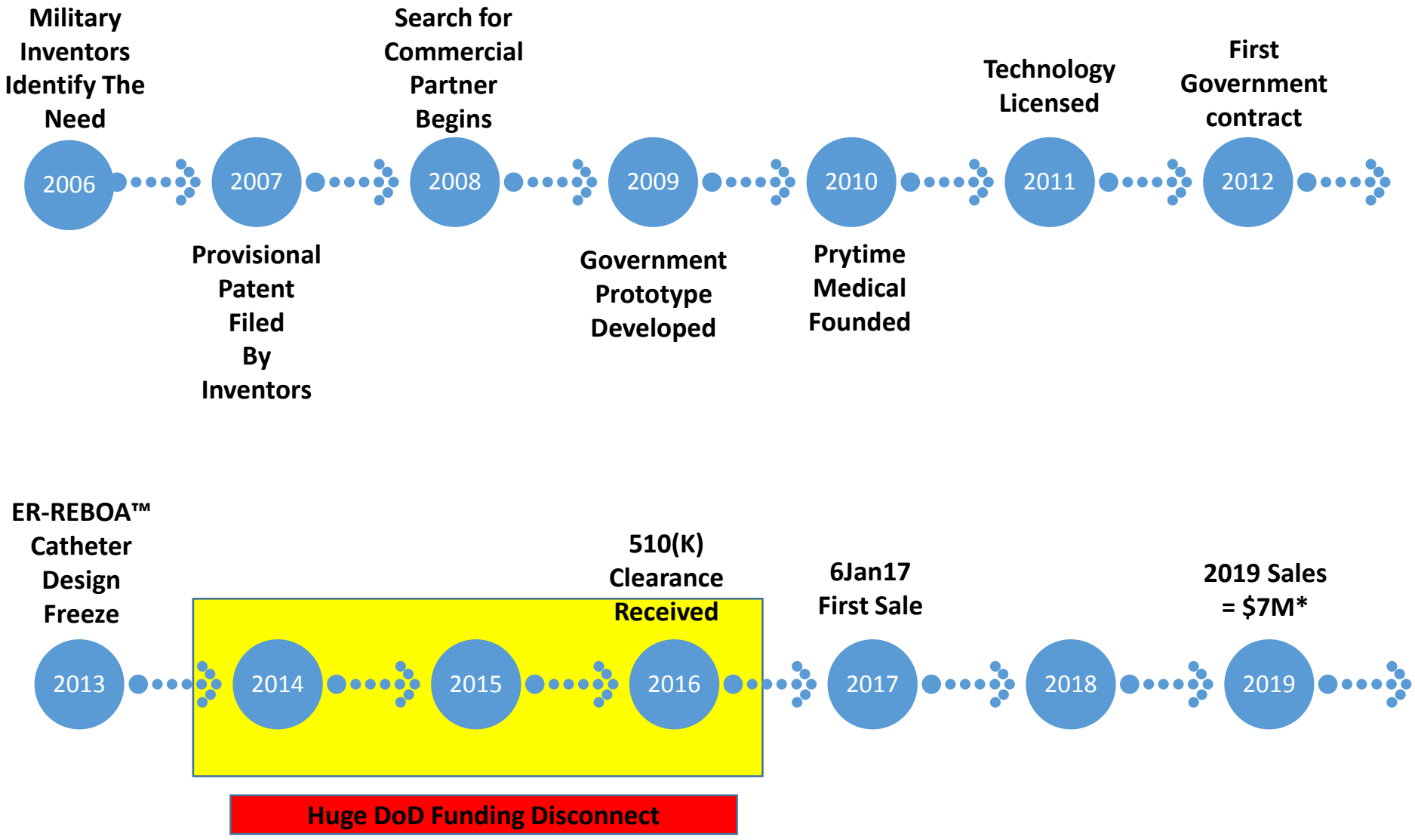
Gap One: Initial Investment



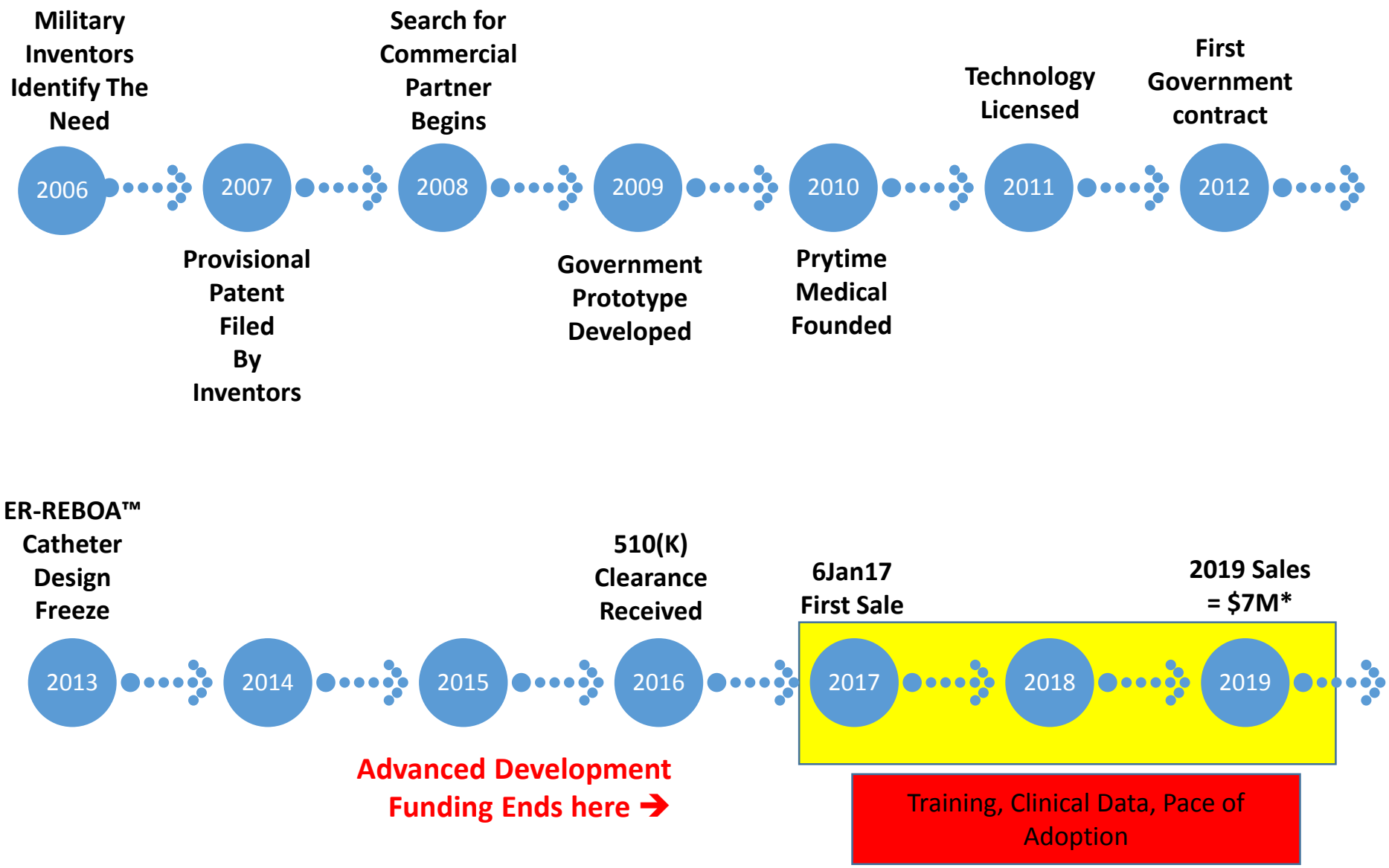


*NOL = $3.5M

Gap Two: The Unsexy Work is Expensive



Gap Three: Generating Sales is Not a Gimme



Can It Be Done?

Of Course

- Intra-Osseus Access
  - VidaCare acquired by Teleflex
- Hemostatic Dressings
  - HemCon, QuickClot, others
- Tourniquets

Does it always work? No

- Shelf Stable Blood Products (Terumo BCT)

Current technologies still in play

- REBOA (No, we are not yet profitable. Sales ≠ Profits!!!)
- Freeze Dried Plasma
- Rescue Foam
- iTClamp
- Others

Does the Military Need to keep on trying?

- You Bet
- (Unless suddenly the world becomes a much safer place)

Challenges, Yet Hope

Tech Transfer Officers

- Startups need help, not expenses! Solve your sunk cost burden
- Trivia: What percentage of the original DoD licensed IP actually made it into Prytime's final commercial product? Answer: ____*

Government Program Managers

- Stop chasing the next greatest thing
- Fund what you have until it is commercially available
  - Connect NOW with your advanced developers
- How are you going to get your technology through Gap Two?

Entrepreneurs

- Start with a credible plan to raise the $20-30M you actually need to commercialize a device. (Biologics = $50M -$60M, Pharma = $100M+)
- Your start up money will be eaten extremely quickly

Angel Investors

- Be ready to re-invest at least 3x your initial investment, just to defend your position

* Zero

Challenges, Yet Hope

City of San Antonio and DoD Leadership – Thank You

Continue to create and underwrite the cost of events like this

We are a several good exits away from critical mass

Creative Collisions Needed!

Events like this provide them

My Question for Everyone:

Where is our Geekdom for Military Medical?

* Zero

PRYTIME MEDICAL™

The REBOA Company™

THANK YOU!

210-340-0116
229 North Main Street
Boerne, TX 78006
WWW.PRYTIMEMEDICAL.COM

Back Up Slides

Barriers

- Gap One: Initial Investment
  - Need must illuminate a 10x return (Not just because investors are greedy)
  - Angels don't have sufficient pockets to cross Gap Two
  - The last decade has seen dramatically reduced VC Investment in medical startups
  - DoD savvy companies are incented to chase new contracts, not pay to commercialize old ones

- Gap Two: From Design Freeze to FDA Approval
  - There is a major disconnect between Military R&D funding and Advanced Development funding
    - Different Commands, Different Cultures, Different Sales Cycle = It almost never works
  - A prototype does not mean "It's done"
  - Chasing the next thing is more fun (and less risky) than funding the work required to get to FDA approval
    - 'Incremental' vs 'Transformational' Change

- Gap Three: Venture Capital is Predatory to Angel Investors
  - FDA clearance is just a start
  - Who pays for the Clinical Training, Efficacy Data, and Randomized Controlled Trials needed to change practice?

U.S. FOOD & DRUG ADMINISTRATION

FDA and Military Medical Device Development

Heather Agler, PhD
Senior Program Manager
All-Hazards Readiness, Response, and Cybersecurity (ARC)
Office of Strategic Partnerships and Technology Innovation (OST)
CDRH/FDA

October 15, 2019

Today's Theme: What Do You Need to Succeed?

- ✓ Don't wait to think about the regulatory pathway.
- ✓ Don't be afraid to talk to the FDA.
- ✓ Work with your military partner.

Center for Food Safety & Applied Nutrition

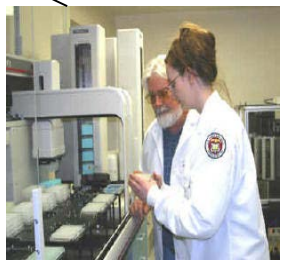
Center for Drug Evaluation & Research

Center for Biologics Evaluation & Research

Center for Tobacco Products

Center for Devices & Radiological Health (CDRH)

Center for Veterinary Medicine



National Center for Toxicological Research

Center for Devices and Radiological Health (CDRH)

- Responsible for regulating firms who manufacture, repackage, relabel, and/or import medical devices and in-vitro diagnostics for sale in the United States.
- Regulates radiation-emitting electronic products (medical and non-medical) such as lasers, x-ray systems, ultrasound equipment, microwave ovens and color televisions

The products we regulate…

133

All Hazards Readiness, Response, and Cybersecurity (ARC) Innovation Program

Supports the development of new innovative medical countermeasure devices and new innovative devices to support the warfighter

- **MCM Devices**: A medical device used in the detection, prevention, and management of a CBRNE, emerging infectious disease, or natural disaster event.

- Work with our federal partners including the military, DoD, BARDA, and others to get new medical countermeasure devices cleared and approved.
  - Outreach
  - Education
  - Collaboration

- Our goal is to shorten time it takes to development safe & effective MCM devices so they are available when needed.

CDRH DoD Collaborations

- DARPA
  - Sepsis, TBI, Prosthetics, Wound Stasis System, Biochronicity
- ONR
  - Automated / Autonomous Critical Care
- ARMY/MRMC
  - TBI, closed-loop control technologies, wearables
- Air Force
  - AFMESA
- DTRA (Defense Threat Reduction Agency)
- Special Operations Command (SOCOM)

Types of Interactions: Medical Device Manufacturers

- Work with small medical device companies that are developing needed medical devices for the warfighter.
  - Often have no prior experience with FDA and need help with understanding our processes and regulations.
  - Provide strategic help by educating companies on the various pathways available. (ex. Breakthrough Devices Program, HDE, De Novo…)
  - Provide information on the various resources FDA has available on our website

Provide a POC to ask questions!!

Classification System and Risk Categorization

Increasing Risk

Classification determines extent of regulatory control (Risk Based)

Class I
- General Controls

Class II
- General controls
- Special controls

Class III
- General controls
- Premarket approval (PMA)

General Controls
- Electronic Establishment Registration
- Electronic Device Listing
- Adulteration / Misbranding
- Premarket Notification [510(k)] (unless exempt)
- Quality Systems
- Labeling
- Medical Device Reporting (MDR)

Special Controls (addressing Risk)
- Guidelines (e.g., Glove Manual)
- Mandatory Performance Standard
- Recommendations or Other Actions
- Special Labeling (e.g., 882.5970, Cranial Orthosis)

Determining Classification and Regulatory Requirements

- Device Regulations
  - 21 CFR parts 800-898
- FDA Web site including
  - Product Classification Database (Classification DB)
  - 510(k) Clearance Database (510k)
  - Device Guidance Documents (Guidance)
- 513(g)
  - Written request for agency's views about the classification and regulatory requirements that may be applicable to your device
  - http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm209841.htm
  - 513(g) submissions are subject to user fees

Public Law 115-92 – Formalizing FDA and DoD Interactions

Public Law 115-92
December 12, 2017

Three Main Components

- **Expands Emergency Use Authorization (EUA) Authority**
  - Allows FDA to issue an EUA for a medical product for a disease/condition caused by an "agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces"
- **Encourages Enhanced Engagement on DoD's Top Priority Products**
  - Authorizes DoD to request and FDA to take actions to ***expedite development and review of medical products*** reasonably likely to diagnose, prevent, treat, or mitigate a specific and life-threatening risk to the U.S. military forces
- **DoD-FDA Required Meetings**
  - Semi-Annual, FDA-DoD to review portfolio & priorities
  - Quarterly, CBER-DoD to discuss CBER priority products

Expedite Development and Review of Military Products

Legislation states that expedited development and review may include the following as appropriate:

- Hold meetings with the sponsor and review team throughout the development of the medical product
- Timely advice and interactive communication to gather clinical and non-clinical information
- Involve senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review
- A cross-disciplinary project lead for the review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor
- Take steps to ensure that the design of the clinical trials is as efficient as practicable
- Apply any applicable FDA program intended to expedite the development and review of a medical product
- In appropriate circumstances, permit expanded access to the medical product during the investigational phase.

FDA-DoD Joint Announcement
Jan 16, 2018

U.S. Department of Health and Human Services

U.S. FOOD & DRUG ADMINISTRATION

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FDA News Release

FDA and DoD launch program to expedite availability of medical products for the emergency care of American military personnel

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For Immediate Release	January 16, 2018
Summary	The U.S. Food and Drug Administration and the Department of Defense launch join program to prioritize the efficient development of safe and effective medical product intended to save the lives of American military personnel.
Release	The U.S. Food and Drug Administration and the Department of Defense's (DoD) Office of Health Affairs announced today the launch of a joint program to prioritize the efficient development of safe and effective medical products intended to save the

- FDA: Blood and Blood Products
- DoD: Military Health System

- Establish a program to prioritize efficient development of medical products for military use
- Describes "partnership" between CBER and DoD, with CBER commitment to key actions
- FDA leadership commits to ensuring these commitments are applied to address aspects of DoD's portfolio in the other medical product centers

https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592581.htm

FDA and DoD Sign MOU to Formalize Agreement

FDA

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FDA News Release

FDA and DoD formalize collaboration to advance medical products in support of American military personnel

New Memorandum of Understanding aligns agency efforts to foster the development and use of safe and effective medical products for members of the U.S. military

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For Immediate Release November 2, 2018

Release

Today, the U.S. Food and Drug Administration and the Department of Defense's (DoD) Office of Health Affairs signed a Memorandum of Understanding regarding medical product development and assessment. This builds upon the work of both agencies to foster and prioritize the efficient development of safe and effective medical products intended to save the lives of American service members.

"We're extremely grateful to the men and women who defend our nation, often at

Inquiries

Media

Megan McSeveney
240-402-4514

Consumers

888-INFO-FDA

Related Information

- MOU
- Emergency Use Authorization - French Freeze-Dried Plasma
- FDA/DoD Collaborations

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First EUA after Public Law 115-92

U.S. Department of Health and Human Services

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FDA News Release

FDA takes action to support American military personnel by granting an authorization for freeze-dried plasma product to enable broader access while the agency works toward approval of the product

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

For Immediate Release July 10, 2018

Release

Today, the U.S Food and Drug Administration announced that an emergency use authorization (EUA) has been granted to the U.S. Department of Defense (DoD) to enable the emergency use of Pathogen-Reduced Leukocyte-Depleted Freeze-Dried Plasma manufactured by the Centre de Transfusion Sanguine des Armées (referred to in the EUA as French FDP).

"Earlier this year, we reaffirmed our commitment to the Department of Defense (DoD)

Inquiries

Media

Megan McSeveney
240-402-4514

Consumers

888-INFO-FDA

Related Information

- Emergency Use Authorization - French FDP
- FDA/DoD Collaborations

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Follow FDA

DoD Priority List

- CDRH is treating devices on the DoD Priority List as if they are in the Breakthrough Devices Program
- For questions regarding the development of the DoD Priority List: https://mrdc.amedd.army.mil/index.cfm/about/jag/pl_115-92

Breakthrough Devices Program History

FDA's EAP Final Guidance
April 13, 2015

21st Century Cures Act
December 13, 2016

Breakthrough Devices Program Final Guidance
December 18, 2018

2015 → 2016 → 2017 → 2018

Expedited Access for Premarket Approval and *De Novo* Medical Devices Intended for Unmet Medical Need for Lif Irreversibly De Co

Guidance for In Drug Adm

Document is

The draft of this docun

"(B) take steps to ensure th of clinical trials is as efficient a practicable, when scientifically app

"(C) facilitate, when scienti priate, expedited and efficient dev review of the device through utiliz ly postmarket data collection with plication for approval under section 515(e); and

Contains Nonbinding Recommendations

Breakthrough Devices Program

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 18, 2018.

The draft of this document was issued on October 25, 2017.

This document supersedes "Expedited Access for Premarket Approval and De Novo Medical Devices Intended for Unmet Medical Need for Life Threatening or Irreversibly Debilitating Diseases or Conditions," issued on April 13, 2015.

For questions about this document regarding CDRH-regulated devices, contact the Office of Device Evaluation (ODE) at 301-796-5550 or BreakthroughDevicesProgram@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

Breakthrough Device Eligibility

Breakthrough devices go through a formal designation process which determines if the device meets the following eligibility criteria:

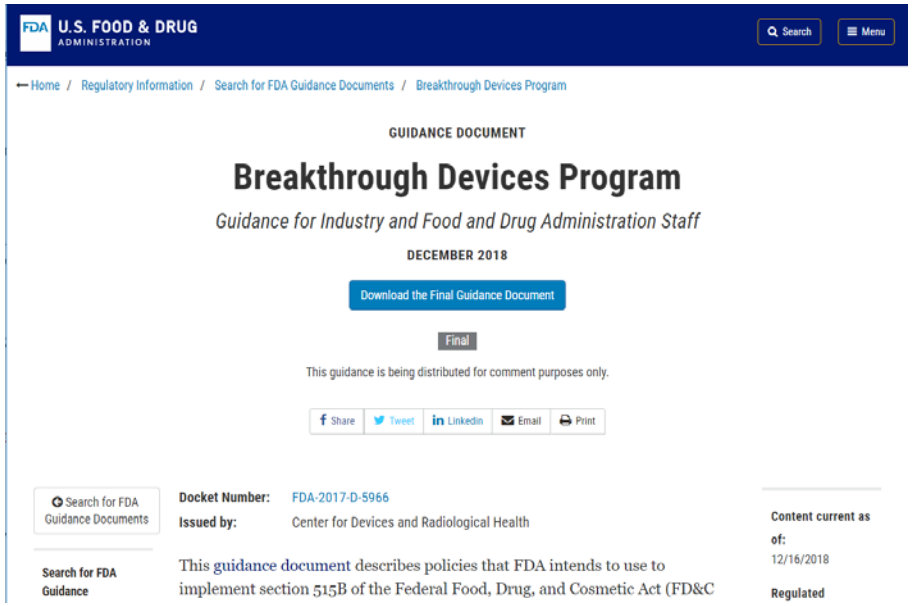
Subject to PMA, De Novo and 510(k) that:

- 1: "provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions; **and**

- 2A: that represent breakthrough technologies; or
- 2B: for which no approved or cleared alternatives exist; or
- 2C: that offer significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies; or
- 2D: the availability of which is in the best interest of patients."

Breakthrough Devices Program Resources

- Breakthrough Devices Program Guidance: https://www.fda.gov/media/108135/download
- More information on the Breakthrough Devices Program: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program



Pre-Submissions

- FDA released a new guidance document on the Q-Submission Program and Meetings with FDA Staff http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf

Contains Nonbinding Recommendations

Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program

Guidance for Industry and Food and Drug Administration Staff

Document issued on May 7, 2019.

This guidance supersedes "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff," dated September 29, 2017.

For questions about this document regarding CDRH-regulated devices, contact ORP: Office of Regulatory Programs/DRP1: Division of Submission Support at 301-796-5640. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010.

Types of Q-submissions

Q-Sub Type	Method of Feedback	Timeframe for Sending Feedback or Scheduling Meeting (from receipt of submission)
Pre-Submission	Meeting (face-to-face or teleconference) with written feedback provided in advance	Written Feedback: 70 days or 5 days prior to scheduled meeting, whichever is sooner Meeting: Date based on mutual agreement (typically at 60-75 days)
	Written Feedback Only	70 days
Submission Issue Request (SIR)	Meeting or Written Feedback	If SIR is received within 60 days of FDA's marketing submission letter: 21 days as resources permit
		If SIR is received more than 60 days after FDA's marketing submission letter: 70 days as resources permit
Study Risk Determination	Formal Letter	90 days
Informational Meeting*	Meeting	90 days

*When used to track requests that do not meet the definition of a Q-Sub type, Informational Meeting timeframe and feedback mechanism can vary. Typically, informational meetings do not include FDA feedback

Involving FDA Early in the Process

- Early collaboration allows you and the reviewers to get on the same page. This in turn can shorten the timeline.

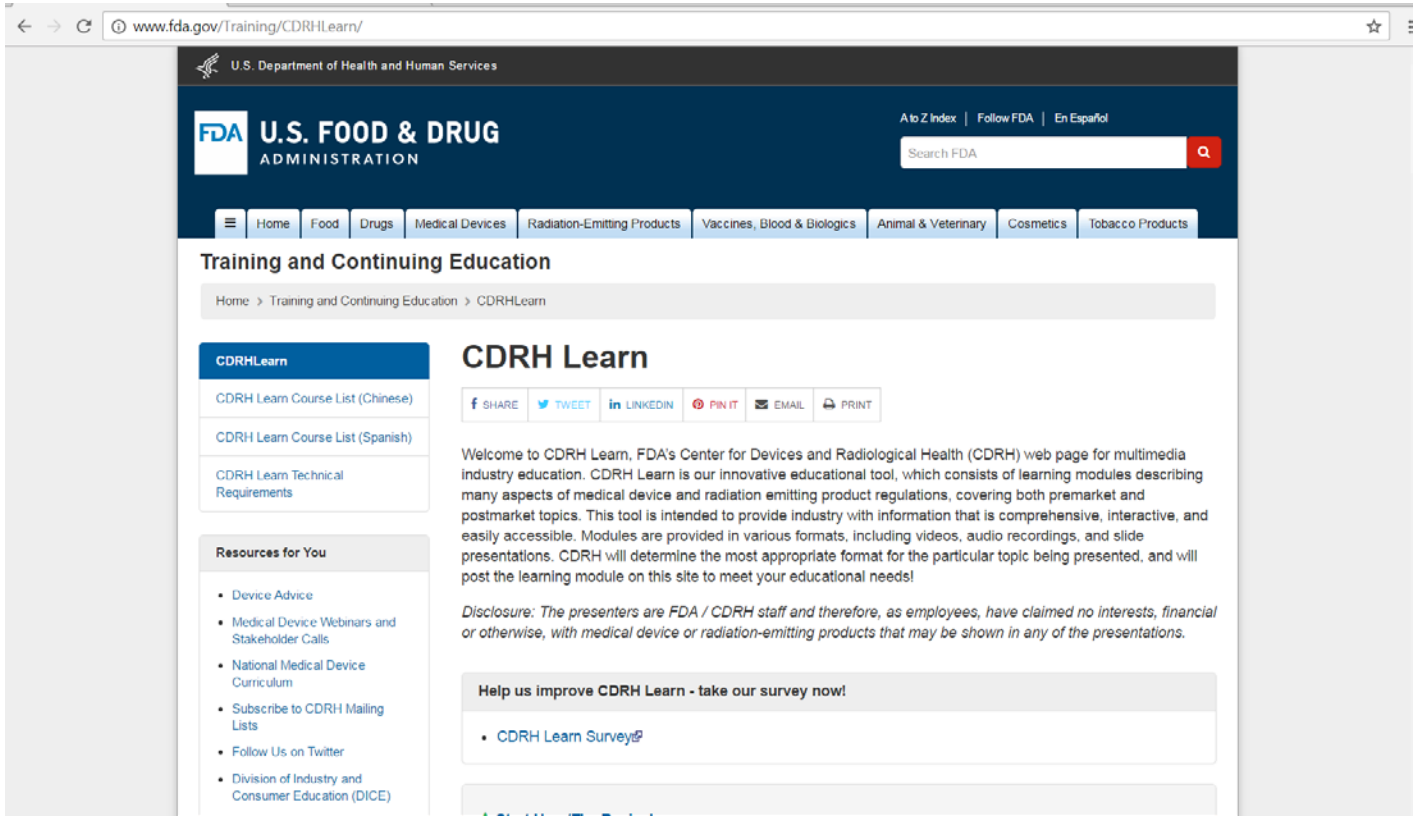
- Provides a way to get feedback early.
  - For example concerns over how an animal study is conducted can be discussed during the planning stage instead of afterwards so that a costly animal study isn't repeated.

- Identify intended patient population early and design appropriate studies to evaluate risk / benefit profiles
  - Usability Studies are becoming increasingly important

Providing Industry Education

CDRH Learn – Multi-Media Industry Education

- Over 80 modules – videos, audio recordings, power point presentations, software-based "how to" modules
- Accessible on your portable devices
  http://www.fda.gov/training/cdrhlearn/default.htm

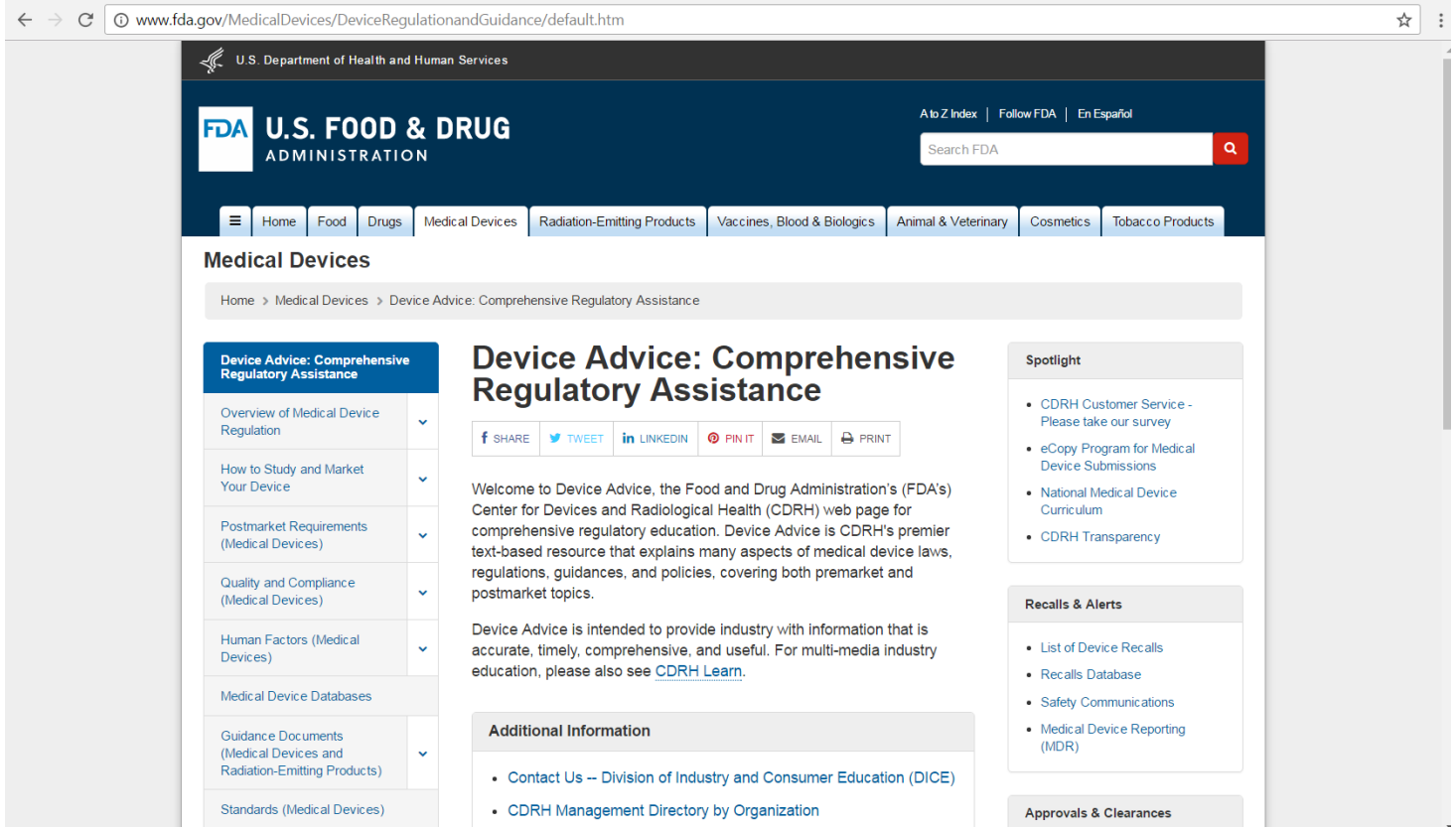


Providing Industry Education

Device Advice – Text-Based Education

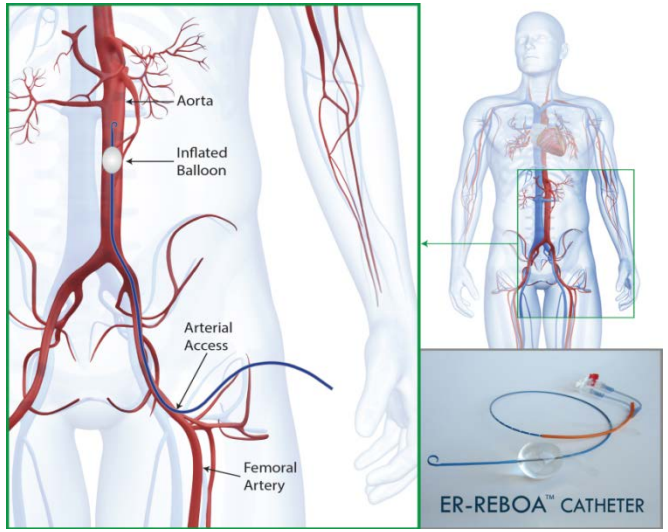
- Comprehensive regulatory information on premarket and post-market topics

http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm



MEDICAL SCOPES LINKED TO
SPREAD OF "SUPERBUG"

ZIKA VIRUS


Aorta
Inflated Balloon
Arterial Access
Femoral Artery
ER-REBOA™ CATHETER

COMBAT READY CLAMP
(CRoC)
CLAMPING DOWN ON HEMORRHAGE

Where to go for help

General Questions:

- FDA Medical Device website (www.fda.gov/medicalDevices/)
  - Guidance Documents
  - Public information on cleared or approved devices
  - Regulations
- Heather.Agler@fda.hhs.gov

Division of Industry and Consumer Education (DICE)

- If you have a question – Email: DICE@fda.hhs.gov
- Phone 1(800) 638-2014 or (301) 796-7100 (Live Agents 9am – 4:30pm EST)

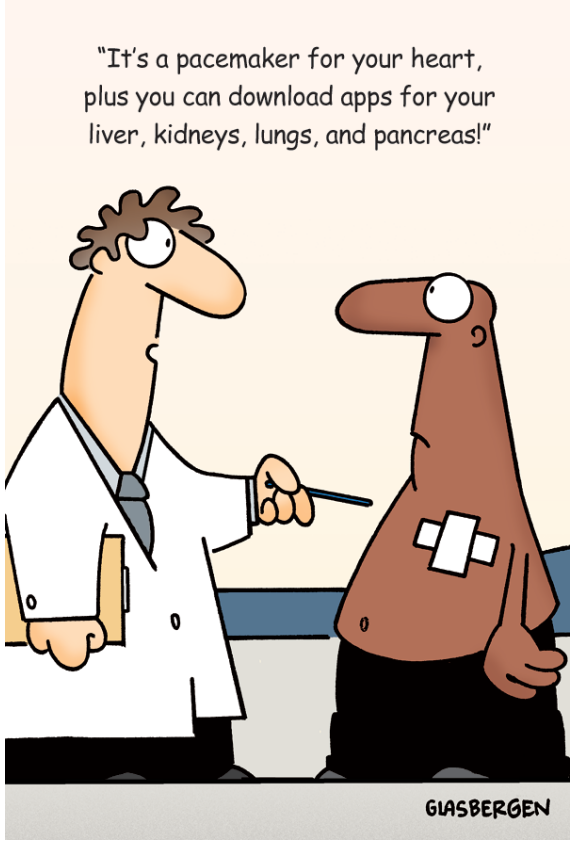
Web Homepage:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm

Digital Health related questions

- DigitalHealth@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

Thank you for your time and attention!



Heather.Agler@fda.hhs.gov
(301) 796-6340

Julia.Marders@fda.hhs.gov
(301) 796-6000

Company+Military Success Briefing

Military Medical Industry Days II

October 15, 2019

Rochal INDUSTRIES LLC

About Rochal

A global leader in commercializing technology innovations in polymer, antimicrobial and biological systems

Rochal Industries, LLC
Ann Salamone, Chairman
absalamone@rochalindustries.com
210-375-9349
www.rochalindustries.com

Rochal
INDUSTRIES LLC

Collaborations

Tissue Regeneration - ARMY

Facial Scar Reduction - ARMY

Transdermal Drug Delivery - NAVY

Wound Biofilm – AIR FORCE

Rochal INDUSTRIES LLC

Development of Flowable Biomaterials that Promote Wound Healing with Infection Control and Prevention
USAMRMC SBIR Phase I: W81XWH-12-C-0033

TEAM: Rochal, ISR, UTAustin, INCELL, Dr. S. Wolf

SCIENCE: Fibrin-based powder → flowable antimicrobial gel

KEY IMPACTS:
Battlefield efficient: lightweight, easy to carry, easy to treat
Promotes healing: flows to cover and protect wound
Infection control: MRSA, *P. aeruginosa*

PRODUCTS:

On battlefield for infection control and wound healing

Post battlefield for skin regeneration therapy

Rochal INDUSTRIES LLC

Injectable Microgel for Soft Tissue RepairPrevention
NIH SBIR Phase I and II: 6R44GM108070-04

TEAM: Rochal, UTAustin, INCELL UTSW, UMiami, QBI, Drs. A Smith M Leong, P Ching, R Salcido

SCIENCE: Collagen powder
→ flowable tissue repair gel

KEY IMPACTS:
Tunneling and undermining wounds: fills irregular defects
Designed residence time: allows cellular and tissue ingrowth

PRODUCTS:

Product market launch in 2021

Rochal INDUSTRIES LLC

Correlation of Surface Free Energy and Cytocompatibility of Amphiphilic Biomaterials
NSF SBIR Phase I and II: IIP-1228399

TEAM: Rochal, UTSA, UTSW
UMIami, INCELL, SwRI, Dr. Wolf

SCIENCE: Siloxysiloxane polymer chemistry and systemic cell biology

KEY IMPACT:
Spray-on silicone film for surgical incision sites

PRODUCT:
FDA cleared, market launch 2020

Rochal INDUSTRIES LLC

Custom Facial Bilayer Neodermis
DOD AFIRM II: SR-11

TEAM: Southwest Research Institute (SwRI)
Rochal, USAISR, Col R. Hale (MD),
Capt G. Grant (WRNMMCB)

SCIENCE: Silicone polymer in
anti-inflammatory solvent

KEY IMPACTS:
Cover and protect dermal graft layer
Serve as membrane for moisture and gas transport
Decrease long term scarring in mobile areas (mouth)

PRODUCT:
Spray-on pseudo-epidermis

Rochal INDUSTRIES LLC

Topical Microparticle Delivery for Burn Pain Control
NIH SBIR Phase I: 1R43GM114857

TEAM: Rochal, Naval Medical Research Unit – San Antonio
UTHealth San Antonio, Dr. S. Wolf

SCIENCE: Sustained release with drug tissue penetration using reverse emulsion

KEY IMPACTS:
Topical treatment of pain associated with dermal burns
Lower usage of systemic opoids
Enhance effectiveness of active agents

PRODUCT:
Spray-on pain-relief burn bandage

Rochal
INDUSTRIES LLC

BIAKŌS Antimicrobial Barrier Film

TEAM: Rochal, Microconsult, cyberDerm

SCIENCE: Reverse emulsion
to incorporate antimicrobials

KEY IMPACTS:
Lower usage of systemic antibiotics
Improved healing time

PRODUCT:
FDA cleared. Market launch 2020

Rochal
INDUSTRIES LLC

BIAKŌS Antimicrobial Wound Cleanser

TEAM: Rochal, INCELL, iFyber, UMiami
Clinical testing: Air Force and NE Baptist Hospital Wound Healing Center

SCIENCE: Multimodal synergistic biofilm disruption and kill

KEY IMPACTS:
Mitigation of sepsis through definitive care
Lower usage of systemic antibiotics
Biofilm remediation

PRODUCT:
FDA cleared. Market launch May 2019

Rochal INDUSTRIES LLC

Key "Take Aways"

Creativity

Observation

Adaptation

Civilian and Military Need

Persistence

Beyond-incremental improvement in patient outcomes

Rochal INDUSTRIES LLC

Welcome

to the

2nd San Antonio Military Medical Industry Day

<u>Wi-Fi Connection</u>: Username is MilMed Industry Day and Password is Bio2020

Thank you to the talented team that made this event possible:

Karen Defee
Ben Rickelman
Cecilie Marchi

Ashley Dory
Olympia Cuellar
Omar Zamora

Michael Mccausland
Erin Nichols
George Wernette

Special Thanks to Mr. Ed Davis:

Executive Director of the San Antonio Economic Development Corporation

Retiring later this year after a dedicated life of service to the City of San Antonio and United States of America:

- **Served as the Executive Director of SAEDC since 2010**
- **Served for 15 years as Assistant Director for the Economic Development Department and retired in February 2013**
- **Served for over 26 years in the United States Air Force retiring as a Colonel in 1998**
- **Consummate professional, leader, visionary, and more!**

Welcome

to the

2nd San Antonio Military Medical Industry Day

<u>Wi-Fi Connection</u>: Username is MilMed Industry Day and Password is Bio2020