



National Defense Industrial Association

**Armed Services Biomedical Research
Evaluation and Management COI**

**Dr Sean Biggerstaff
Interim ASBREM Chair**

13-14 Apr 2016



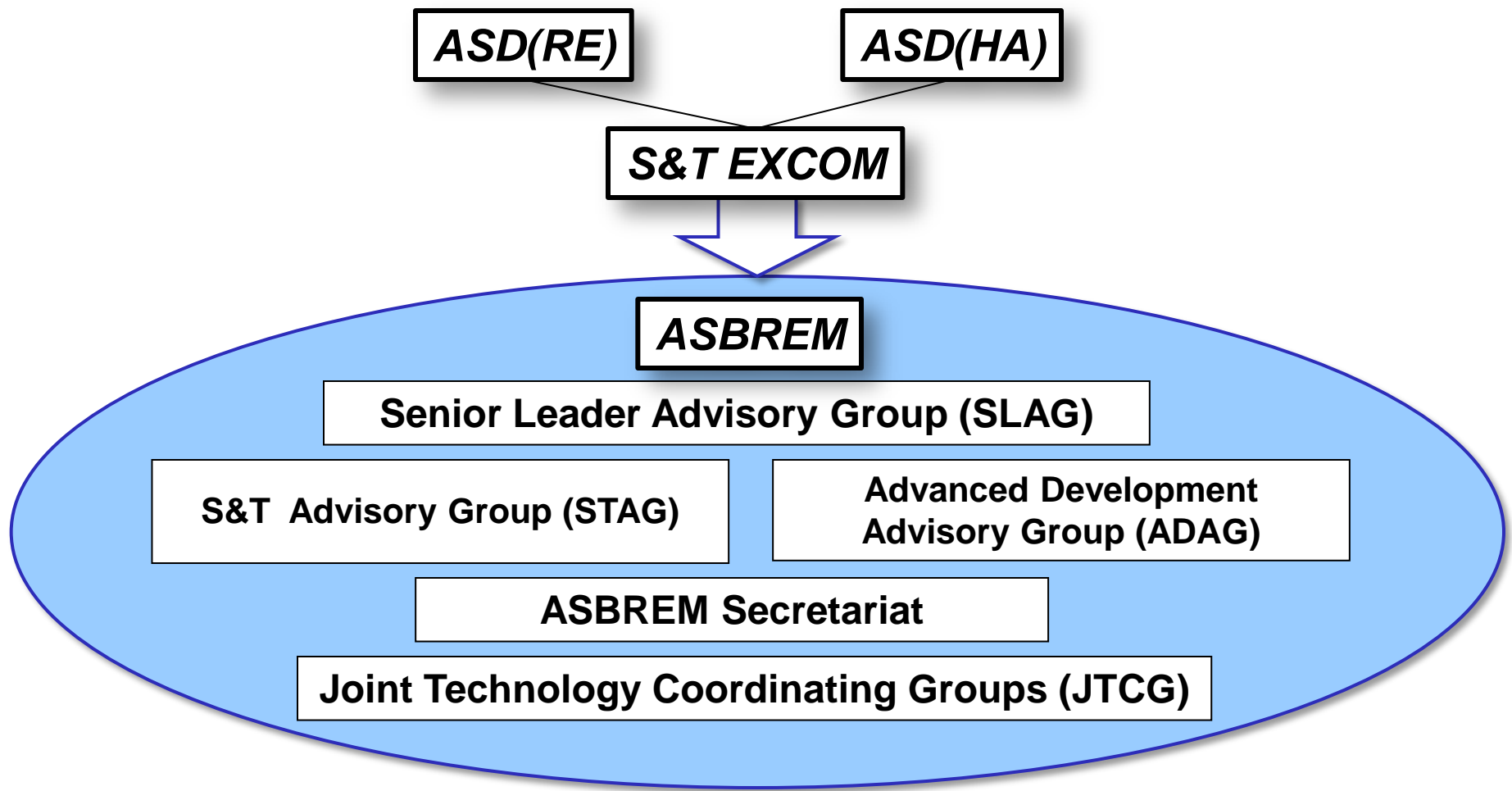
ASBREM Profile



- ASBREM created in 1981 as a model for DoD Reliance 21
- Includes both S&T and Advanced Development enabling streamline transition coordination and planning
- DoD is the lead government agency for trauma research
- DHA IOC October 2013 created RDA Director in April 2014
- RDA Director dual hats as the ASBREM COI Chair
- Aligned with US FDA regulatory processes to develop medical products for the warfighter
- Government / University / Industry collaboration



ASBREM Organization





ASBREM COI Membership



ASBREM COI STEERING LEADERSHIP

Dr Sean Biggerstaff – Interim Chair ASBREM COI and SLAG

Dr. Terry Allard – Chair ASBRAM STAG

Dr. Kenneth Bertram – Chair ASBREM ADAG

JOINT TECHNOLOGY COORDINATING GROUPS (JTCCGs)

JTCCG-1

**Biomedical Informatics
& Health Info Systems
and Technology**
Dr. Jan Harris

JTCCG-2

**Military Infectious
Disease**
COL Michael Kozar

JTCCG-5

**Military Operational
Medicine**
LTC Dennis McGurk

JTCCG-6

Combat Casualty Care
COL Todd Rasmussen

JTCCG-7

**Medical Radiological
Defense**
Dr. Robert Hartzman

JTCCG-8

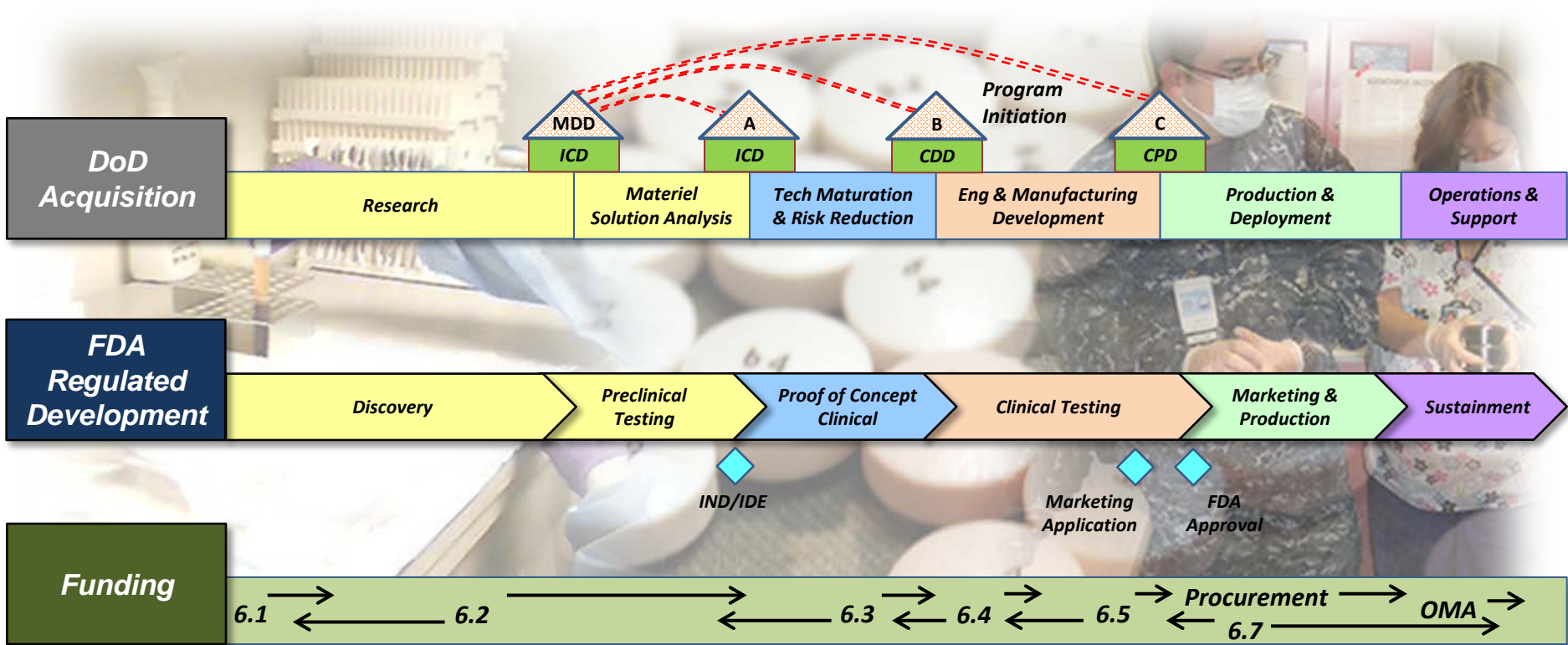
**Clinical Medicine
and Rehabilitation**
LTC Teresa Bringer

JTCCG-9

Medical Chem Bio Defense
Dr Kimberly LeButt

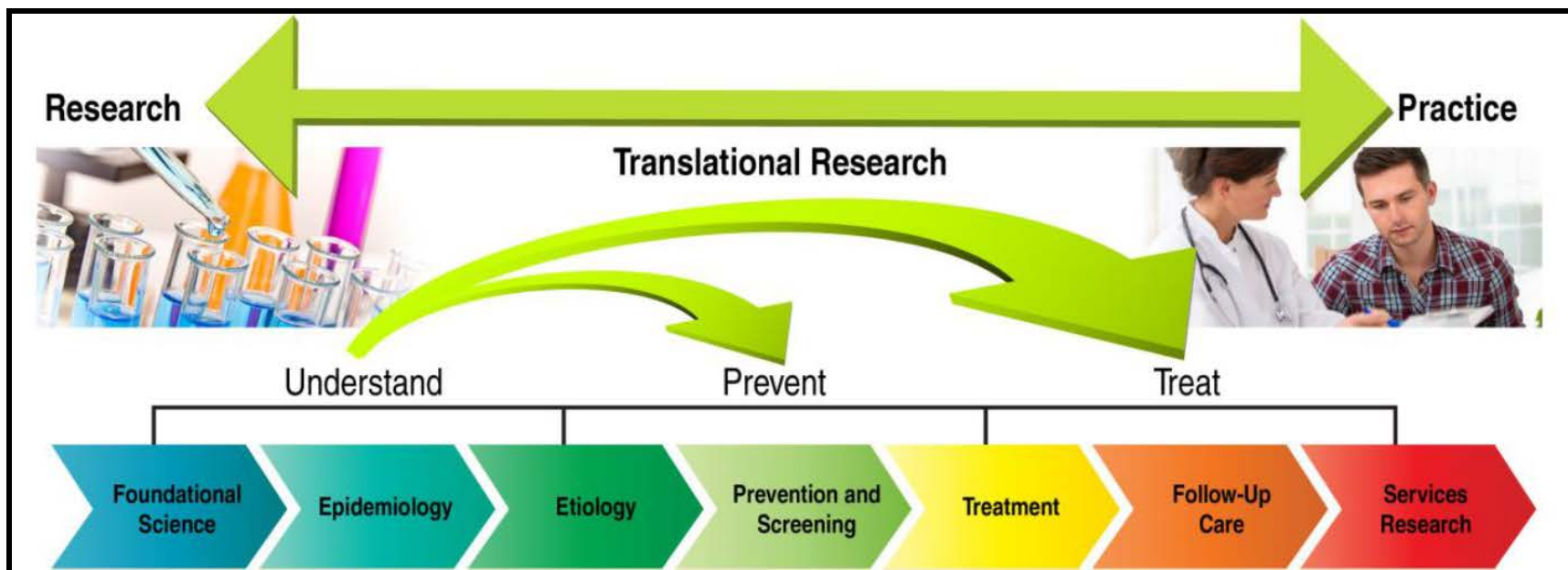


Integration of DoD 5000 and FDA Regulation Process





The Roadmap of Interagency Medical Research Funding





Scope of Military Medical R&D

“Discovery to Delivery”



Diagnosis

Treatment

Rehabilitation

Recovery



JTCG Portfolio Taxonomies (Tier I and II)



<p>JTCG – 1 Biomedical Informatics & Health Info Systems and Technology</p>	<ul style="list-style-type: none"> • Medical Simulation and Training • Health Information Technology and Informatics
<p>JTCG – 2 Military Infectious Disease</p>	<ul style="list-style-type: none"> • Parasitic Infectious Disease • Bacterial and Fungal Infectious Disease • Viral Infectious Disease • Diagnostics, Insect Vectors and Research Support
<p>JTCG – 5 Military Operational Medicine</p>	<ul style="list-style-type: none"> • Injury Prevention and Reduction • Psychological Health and Resilience • Physiological Health and Performance • Environmental Health and Protection
<p>JTCG – 6 Combat Casualty Care</p>	<ul style="list-style-type: none"> • Diagnosis and Treatment of Brain Injury • Devices and Therapeutics for Hemorrhage Control & Resuscitation and Blood Products • Enroute Care • Forward Surgical/Intensive Critical Care (including Advanced Monitoring) • Treatments for Extremity Trauma, Tissue Injury, Cranio-maxillofacial Injury, Lung Injury, and Burns • Military Medical Photonics
<p>JTCG – 7 Medical Radiological Defense</p>	<ul style="list-style-type: none"> • Radiation Countermeasures: Prophylaxis and Therapeutics • Biodosimetry • Low-Level, Delayed, and Chronic Radiation Effects • Radiation Combined Injury • Internal Contamination
<p>JTCG – 8 Clinical and Rehabilitative Medicine</p>	<ul style="list-style-type: none"> • Neuro-musculoskeletal Injury Rehabilitation • Pain Management (Acute/Chronic/Battlefield) • Regenerative Medicine and Transplants • Sensory Systems (Visual, Auditory and Vestibular)
<p>JTCG – 9 Medical Chem Bio Defense</p>	<ul style="list-style-type: none"> • Biological Therapeutics • Chemical Therapeutics • Toxin Therapeutics • Biological Prophylaxis • Chemical Prophylaxis • Toxin Prophylaxis • CB Diagnostics



JTCG-1: Biomedical Informatics/ Health Info Systems Technology



Portfolio Overview

JTCG-1: Level II Taxonomy

- **Medical Simulation & Training**
 - Combat Casualty Training
 - Medical Readiness
- **Health Information Technology & Informatics**
 - Theater/Operational Medicine
 - Military Health Care Services
 - Information Technology Infrastructure and Data Management
 - Medical Resourcing



Medical Simulation & Training

Current Roadmap Goals



- A Platform which allows for scaling a standardized system to a “fidelity appropriate” training tool, utilizing future commercial upgrades, as available
- Appropriate Fidelity Responsive Tissue Behaviors incorporated into Medical Simulation Systems
- Effective Team Training with emphasis on working under stressful scenarios throughout the entire continuum of care
- Evidence-based training methodologies & technologies to accelerate skill acquisition and sustenance



JTCG-2: Military Infectious Disease



Portfolio Overview

JTCG-2: Level II Taxonomy

- **Bacterial and Fungal Infectious Diseases**
- **Viral Infectious Diseases**
- **Parasitic Infectious Diseases**
- **Diagnostics, Insect Vectors and Research Support**



OCONUS Laboratory Presence





Parasitic Infectious Diseases Current Roadmap Goals



- **Drugs for prevention and treatment of malaria**
- **Vaccine for the prevention of malaria**
- **Topical drug to treat cutaneous leishmaniasis**



JTCG-5: Military Operational Medicine



Portfolio Overview

JTCG-5: Level II Taxonomy

• Environmental Health & Protection

- Heat, Cold & Terrestrial Attitude
- Environmental Toxicant Exposure
- Warfighter Physical Performance

• Injury Prevention & Reduction

- Musculoskeletal Injury
- Sensory Performance, Injury & Protection
- Aircrew Health & Performance

• Physiological Health & Performance

- Blunt, Blast & Acceleration Injury
- Brain Health & Performance Risk
- Cognitive Health & Performance
- Nutrition & Weight Balance

• Psychological Health & Resilience

- Psychiatry & Clinical Psychology Disorders
- Behavioral Health, Wellness & Resilience
- Millennium Cohort



Environmental Health & Protection Current Roadmap Goals



- Identify and validate biomarkers for both internal dosimetry and evaluation of Warfighters' exposure to military relevant chemicals
- Develop and validate models for protecting health and performance against combined environmental threats
- Deliver validated medical standards, predictive models, and countermeasures to prevent or mitigate the effects of extreme environments



Injury Prevention & Reduction Current Roadmap Goals



- Deliver validated injury prevention models, musculoskeletal health assessment tools, and published standards
- Deliver validated injury criteria and medical performance standards for devices protecting against hearing loss, and vestibular, ocular and facial injury
- Deliver validated standards for aeromedical support systems; validated hypoxia assessment tools and mitigation systems



Physiological Health & Performance Current Roadmap Goals



- Validate new assessments and interventions for mild to moderate TBI in the operational and training environments
- Prevent or mitigate the effects of fatigue and/or sleep restriction on cognitive performance
- Develop physiological resilience in Service members to prevent/mitigate the negative effects of operational stressors on performance through identification and measurement of biomarkers
- Optimize nutrition-based personalized strategies to maintain physical and mental performance, to promote recovery from injury, and to maintain overall health



Psychological Health & Resilience Current Roadmap Goals



- Deliver validated interventions for the prevention, assessment and treatment of Posttraumatic Stress Disorder (PTSD) and co-morbid mental health disorders
- Assess the impact of military service on acute and chronic physical and mental health across the military lifecycle
- Deliver evidence-based individual and group interventions and tools to build psychological resilience and better prevent, diagnose, and treat mental health issues, such as suicide and substance abuse



JTCG-6: Combat Casualty Care



Portfolio Overview JTCG-6 Level II Taxonomy

- **Diagnosis and Treatment of Brain Injury**
- **Devices and Therapeutics for Hemorrhage Control & Resuscitation and Blood Products**
- **Enroute Care**
- **Forward Surgical/Intensive**
- **Critical Care (incl. Advanced Monitoring)**
- **Treatments for Extremity Trauma, Tissue Injury, Cranio-maxillofacial Injury, Lung Injury, and Burns**
- **Military Medical Photonics**



Hemorrhage & Resuscitation Capability

Current ROADMAP Goals



- Validated Clinical Practice Guidelines for hemorrhage control and resuscitation
- Devices and drugs for control of severe bleeding in the pre-hospital environment
- Improved understanding of the impact of storage time on RBC function
- Improved safety and logistics for life saving blood products stable for use far-forward
- Validated Clinical Practice Guidelines for life-saving interventions by medics in the field using Transemic Acid and Freeze Dried Plasma
- Validated Clinical Practice Guidelines to allow prolonged field and transport care by non-physicians
- Understanding the mechanism of “Acute Coagulopathy of Trauma” and clinical practices which can avoid or treat impaired blood clotting
- Therapeutics which improve survival in casualties with severe blood loss from combat trauma



JTCG-7: Medical Radiological Defense



Portfolio Overview JTCG-7: Level II Taxonomy

- **Radiation Countermeasures: Prophylaxis and Therapeutics**
- **Biodosimetry**
- **Low-Level, Delayed, and Chronic Radiation Effects**
- **Radiation Combined Injury**
- **Internal Contamination**



Radiation Countermeasures Current Roadmap Goals



- Validated treatment systems for complete recovery of each casualty's endogenous hematopoiesis
- Validated replacement based recovery systems of each casualty's endogenous hematopoiesis
- Validated means of replacement of inadequate hematopoietic and non-hematopoietic capacity with modified autologous cells



JTCG-8: Clinical and Rehabilitative Medicine



Portfolio Overview

JTCG-8: Level II Taxonomy

- **NEUROMUSCULOSKELETAL INJURY REHABILITATION**
 - Prosthetics, orthotics, spinal cord injury, and orthopedic injury rehabilitation
- **PAIN MANAGEMENT**
 - Management of pain ranging from the point of injury to chronic pain management
- **REGENERATIVE MEDICINE & TRANSPLANTS**
 - Extremity and craniomaxillofacial injuries, burns and scarless wound healing, hand and face transplants, genitourinary lower abdominal reconstruction
- **SENSORY SYSTEMS**
 - Visual, auditory, and vestibular dysfunction associated with traumatic injury



Neuromusculoskeletal Injury Current Roadmap Goals



- Reintegration and support strategies following NMS injury
- Assistive technologies towards replacement of function following NMS injury
- Predict and mitigate secondary health deficits following NMS injury
- Optimize rehabilitation strategies following NMS injury
- Validated metrics to assess rehabilitation following NMS injury



Pain Management Current Roadmap Goals



- Alternatives to IM Morphine
- Therapeutics to alleviate pain without adverse side effects
- Knowledge products to inform a comprehensive pain management strategy



Regenerative Medicine Current Roadmap Goals



- Regenerate functional vascularization
- Regenerate and integrate functional muscle units
- Regenerate and replace functional and aesthetic skin
- Generate and integrate functional composite tissues
- Regenerate functional neural pathways
- Regenerate functional bone tissue



Sensory Systems Current Roadmap Goals



- Understand vision dysfunction
- Treat, rehabilitate and restore vision
- Diagnostics, treatment and rehabilitation strategies for tinnitus and hearing dysfunction
- Treatment and rehabilitation strategies to restore balance to those with traumatic vestibular dysfunction



Thank you



Questions

