National Defense Industrial Association

Armed Services Biomedical Research Evaluation and Management COI

Dr Sean Biggerstaff

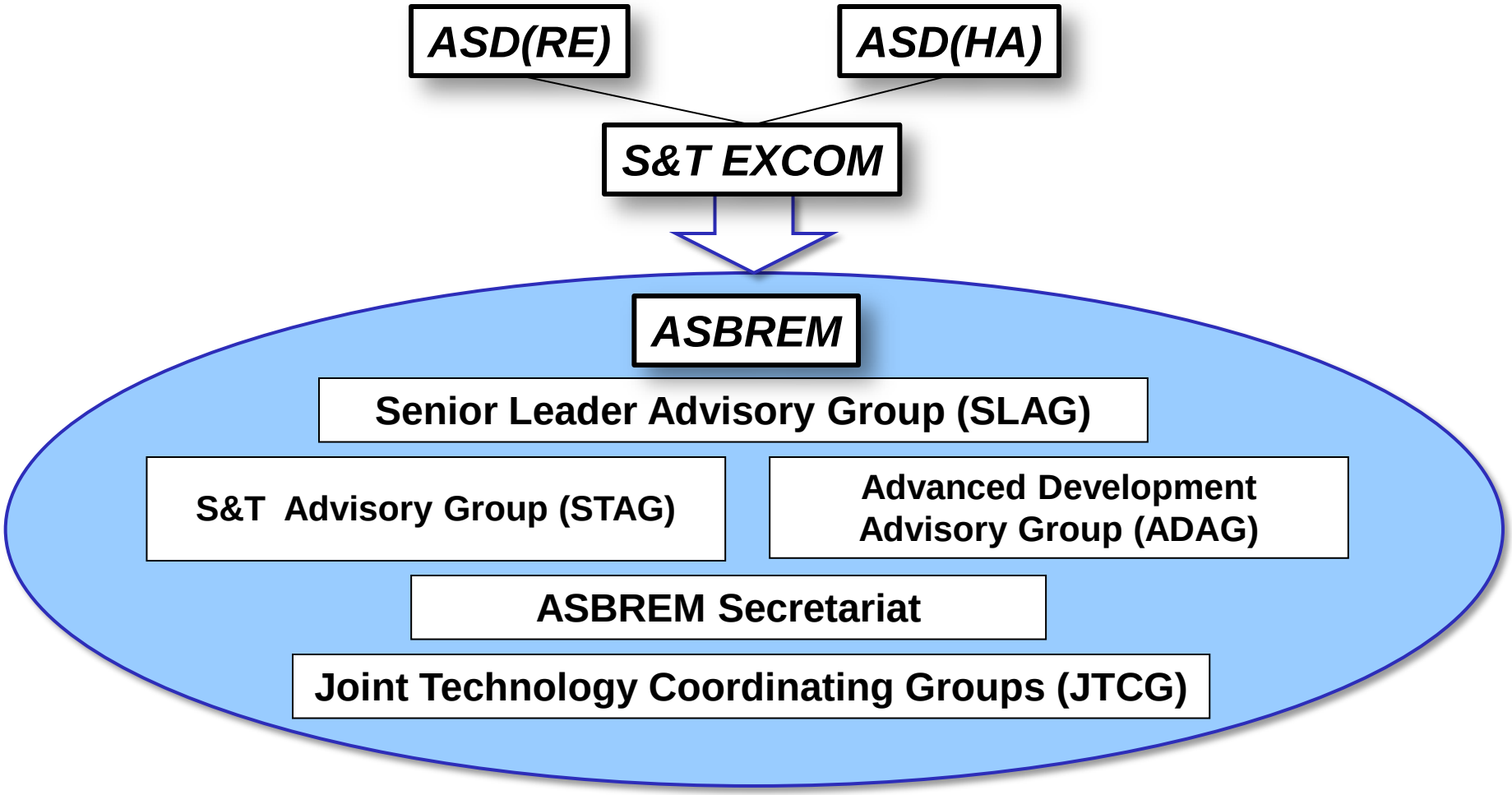
Interim ASBREM Chair

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 (JTCGs)

JTCG-1
Biomedical Informatics & Health Info Systems and Technology
Dr. Jan Harris

JTCG-2
Military Infectious Disease
COL Michael Kozar

JTCG-5
Military Operational Medicine
LTC Dennis McGurk

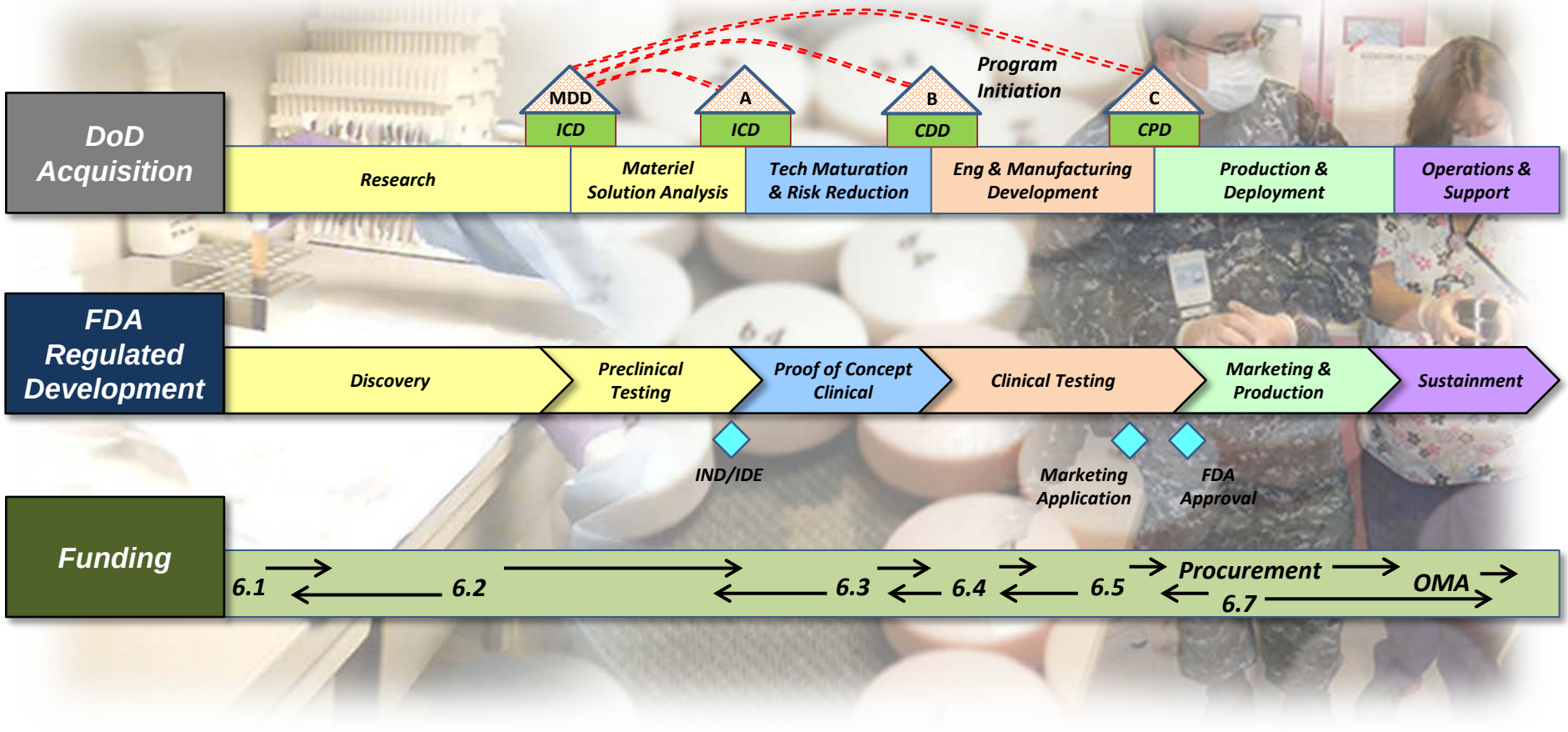
JTCG-6
Combat Casualty Care
COL Todd Rasmussen

JTCG-7
Medical Radiological Defense
Dr. Robert Hartzman

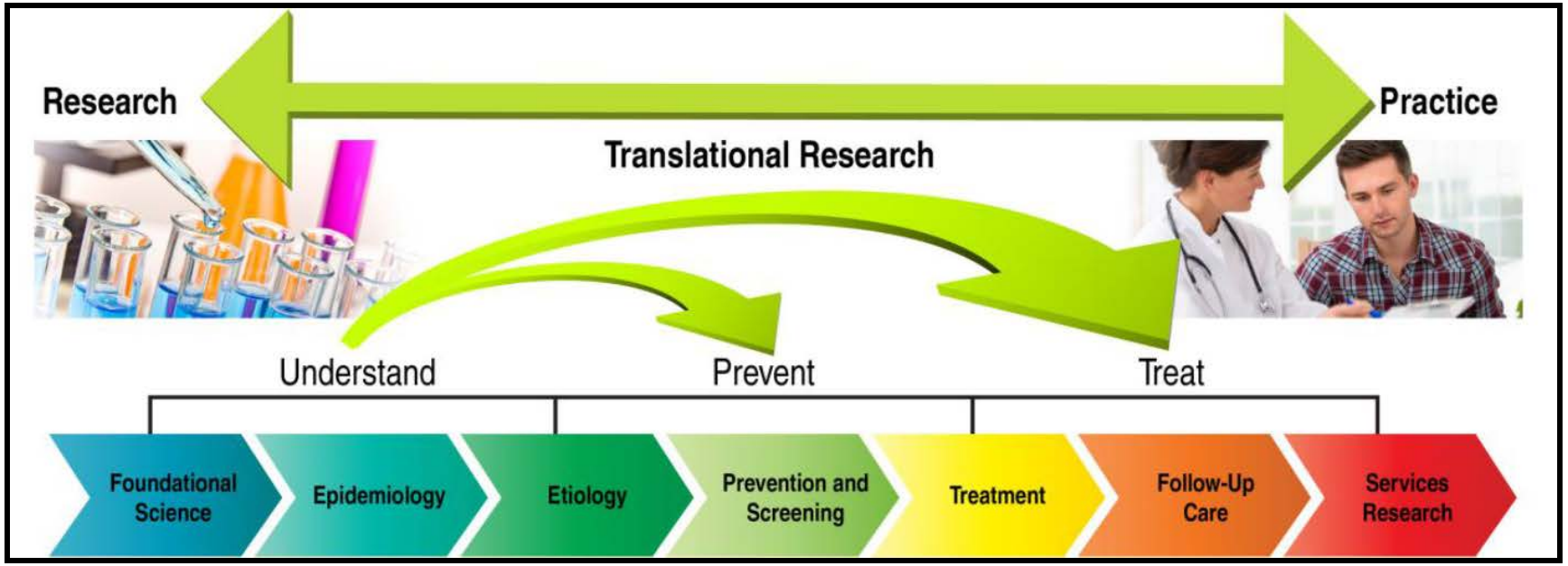
JTCG-8
Clinical Medicine and Rehabilitation
LTC Teresa Brininger

JTCG-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)

JTCG – 1 ***Biomedical Informatics & Health Info Systems and Technology***	• Medical Simulation and Training • Health Information Technology and Informatics
JTCG – 2 ***Military Infectious Disease***	• Parasitic Infectious Disease • Bacterial and Fungal Infectious Disease • Viral Infectious Disease • Diagnostics, Insect Vectors and Research Support
JTCG – 5 ***Military Operational Medicine***	• Injury Prevention and Reduction • Psychological Health and Resilience • Physiological Health and Performance • Environmental Health and Protection
JTCG – 6 ***Combat Casualty Care***	• 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
JTCG – 7 ***Medical Radiological Defense***	• Radiation Countermeasures: Prophylaxis and Therapeutics • Biodosimetry • Low-Level, Delayed, and Chronic Radiation Effects • Radiation Combined Injury • Internal Contamination
JTCG – 8 ***Clinical and Rehabilitative Medicine***	• Neuro-musculoskeletal Injury Rehabilitation • Pain Management (Acute/Chronic/Battlefield) • Regenerative Medicine and Transplants • Sensory Systems (Visual, Auditory and Vestibular)
JTCG – 9 ***Medical Chem Bio Defense***	• 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