Medical Technology Enterprise Consortium (MTEC)

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US Army Medical Research and Materiel Command (USAMRMC)
April 2016

Panel Members

- Dr. J.B. Phillips – Office of the Principal Assistant for Acquisition, USAMRMC
- Dr. Jonathan Miller – Office of the Principal Assistant for Research & Technology, USAMRMC
- Mr. Russ Keller – SCRA Applied R&D
- Mr. Donald Wheatley – US Army Medical Research Acquisition Activity, USAMRMC
- Ms. Sara Langdon - Office of the Principal Assistant for Acquisition, USAMRMC

The US Army Medical Research & Materiel Command

Responsively and responsibly create, develop, deliver, and sustain medical capabilities for the Warfighter

Lead the advancement of military medicine

Current Challenges

- Need for better collaboration with industry, small business, and academic partners
- Acquisition strategies rely on the use of Contracts, Assistance Agreements governed by the Federal Acquisition Regulation (FAR), the Department of Defense Grant and Agreement Regulations (DoDGAR), and Cooperative Research and Development Agreements (CRADA), which have certain limitations & cost impacts
- Future public-sector funding for research and development (R&D) addressing military medical needs is expected to decrease
- Private sector funding is available but largely unreachable

Other Transaction Authority

- Other Transaction (OT) is a special funding vehicle used by federal agencies for obtaining or advancing research and development (R&D) or prototypes
- An OT is not a contract or assistance agreement
- OT is for Small Business and non-traditional contractors but traditional contractors can be funded if certain criteria are met
- Many other DoD offices use the OT Authority

MTEC as a Public-Private Collaboration

A Consortium of industry, academic, and other organizations organized and operated through a 501(c)(3) non-profit corporation and an Other Transaction Agreement (OTA)

- Provides a flexible method to combine public and private resources to focus research, prototype development, and commercialization on specific shared military and civilian medical technology needs
- Facilitates negotiable and flexible operations, collaborations, and competitive research project awards that are not subject to the FAR and DoDGAR acquisition policies and procedures
- Permits streamlined contracting such as lifecycle acquisitions

MTEC as a Public-Private Collaboration

- Limits antitrust liability of Consortium members, promoting collaboration within MTEC
  - National Cooperative Research and Production Act
  - Federal Register posted June 2014

- Expedited transition from development into follow-on production through more typical direct contracting mechanisms via Section 822 of the FY02 National Defense Authorization Act (NDAA)

MTEC with USAMRMC Users*

Operational phase

USAMRMC

USAMRMC Executive Governance Board

USAMRMC AO

MTSC#

USAMRMC Users: Science & Technology, Advanced Development Communities

pOTA^

MTEC

501(c)(3) Corporation

Directors

Management Team

Consortium Member Agreement

Horus Vision Restoration

Regenerative Medicine

Prosthetics

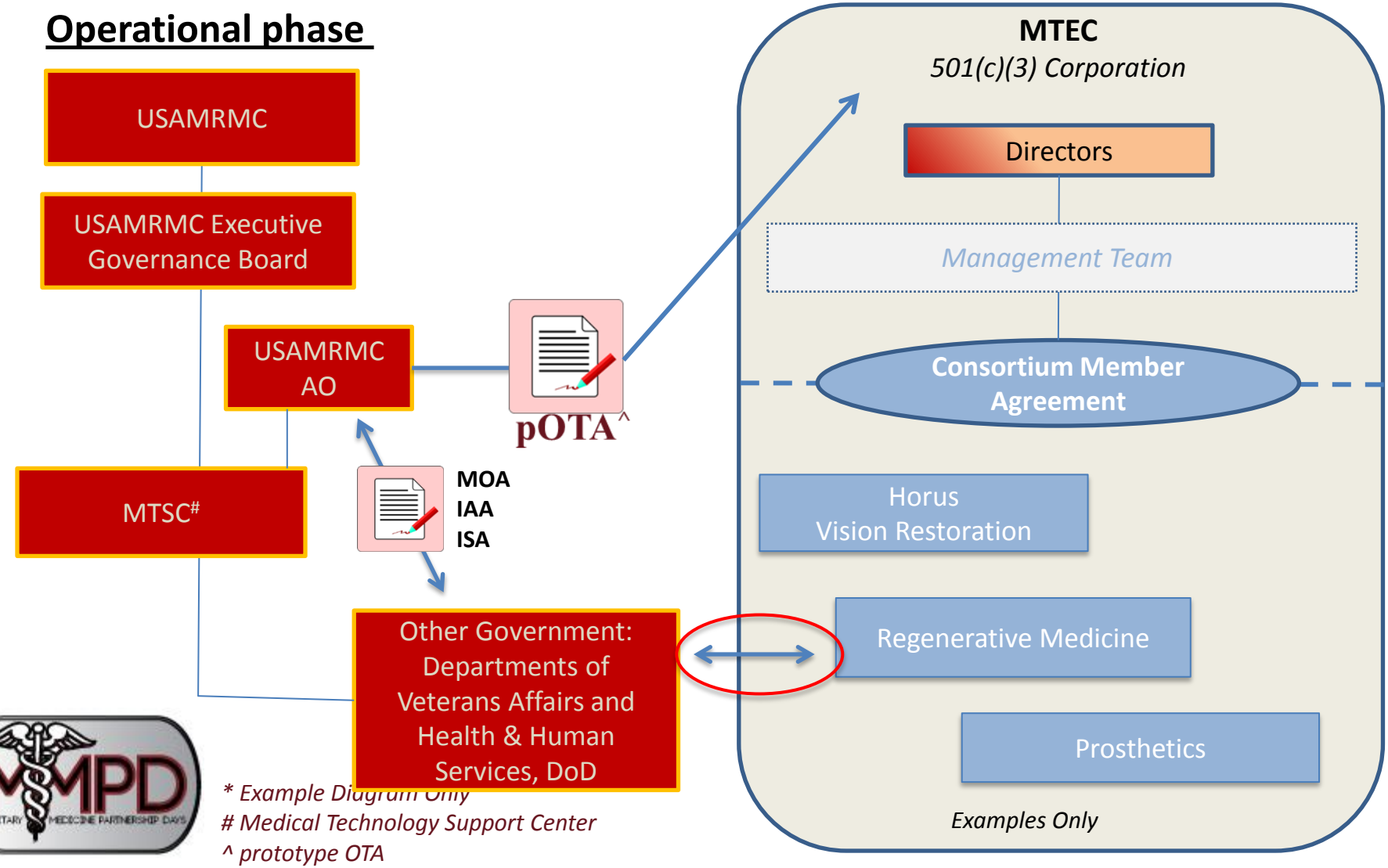
Examples Only

** Example Diagram Only*

 # Medical Technology Support Center

^ prototype OTA

MTEC with Users Outside USAMRMC*



** Example Diagram Only*
 # Medical Technology Support Center
^ prototype OTA

Medical Technology Support Center

- Dr. J.B. Phillips
  - Office of the Principal Assistant for Acquisition
- Dr. Jonathan Miller
  - Office of the Principal Assistant for Research & Technology
- Ms. Sara Langdon
  - Office of the Principal Assistant for Acquisition
- Mr. Don Wheatley & Ms. Jennifer Brown
  - US Army Medical Research Acquisition Activity

Available Intellectual Property & Collaboration Opportunities

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Sara B. Langdon, MBA
Medical Technology Support Center
US Army Medical Research and Materiel Command (USAMRMC)

Threats to Service Member Health and Performance

Endemic Disease Threats
- Parasitic Diseases
- Bacterial Diseases
- Viral Diseases

Chemical/Biological Warfare Threats
- Bacterial Threats
- Viral Threats
- Toxin Threats
- Nerve Agents
- Vesicant Agents
- Blood Agents

Environmental Hazards
- Heat and Cold
- Altitude
- Toxic Industrial Chemicals & Materials

Battle Sequelae
- Loss of limbs
- Loss of tissue
- Loss of vision
- Pain

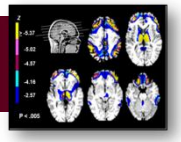
Combat Injuries
- Hemorrhage
- Head Trauma
- Blast Injury

Operational Stressors
- Sleep Deprivation
- Traumatic Stress and Situational Stressors
- Physical Work Load
- Cognitive Burden & Operational Complexity

Systems Hazards
- Laser
- Blast
- Biomechanical Insults and Stresses
- Noise

Laboratory Competencies

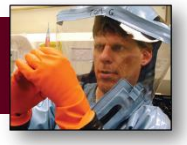
WRAIR
Forest Glen, MD



Walter Reed Army Institute of Research

- Infectious Diseases: Parasitic, Bacterial, Viral
- Vector Control
- TBI Neurotrauma & Brain Dysfunction
- Psychiatry & Clinical Psychology Disorders
- Cognitive Health & Performance
- Behavioral Health, Wellness, & Resilience

USAMRIID
Ft. Detrick, MD



U.S. Army Medical Research Institute of Infectious Diseases

- Bacterial Diseases
- Viral Diseases
- Biological Toxins

USARIEM
Natick, MA

U.S. Army Research Institute of Environmental Medicine

- Brain Health & Performance Risk
- Heat, Cold, & Terrestrial Altitude
- Musculoskeletal Injury
- Nutrition & Weight Balance
- Warfighter Physical Performance
- Biophysics and Biomedical Modeling

TATRC
Ft. Detrick, MD

Telemedicine and Advanced Technology Research Center

- TeleHealth
- Health Information Technology
- Medical Simulation & Training Systems
- Medical Intelligent Systems

USAISR
Ft. Sam Houston, TX

U.S. Army Institute of Surgical Research

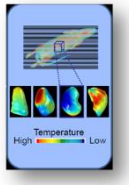
- Maxillofacial Trauma & Combat Dentistry
- Extremity Trauma
- Ocular Trauma
- Burn Injury
- Hemorrhage, Shock, & Coagulopathy of Trauma
- Pain
- Pre-Hospital Tactical Combat Casualty Care
- Critical Care Delivery

USAMRICD
Aberdeen PG, MD

U.S. Army Medical Research Institute of Chemical Defense

- Traditional & Emerging Chemical Threats
- Biological Toxins

USACEHR
Ft. Detrick, MD



U.S. Army Center for Environmental Health Research

- Environmental Toxicant Exposure

USAARL
Ft. Rucker, AL

U.S. Army Aeromedical Research Laboratory

- Aircrew Health & Performance
- Sensory Performance, Injury & Protection
- En Route Care Environment
- Crew Survival in Military Helicopters & Combat Vehicles

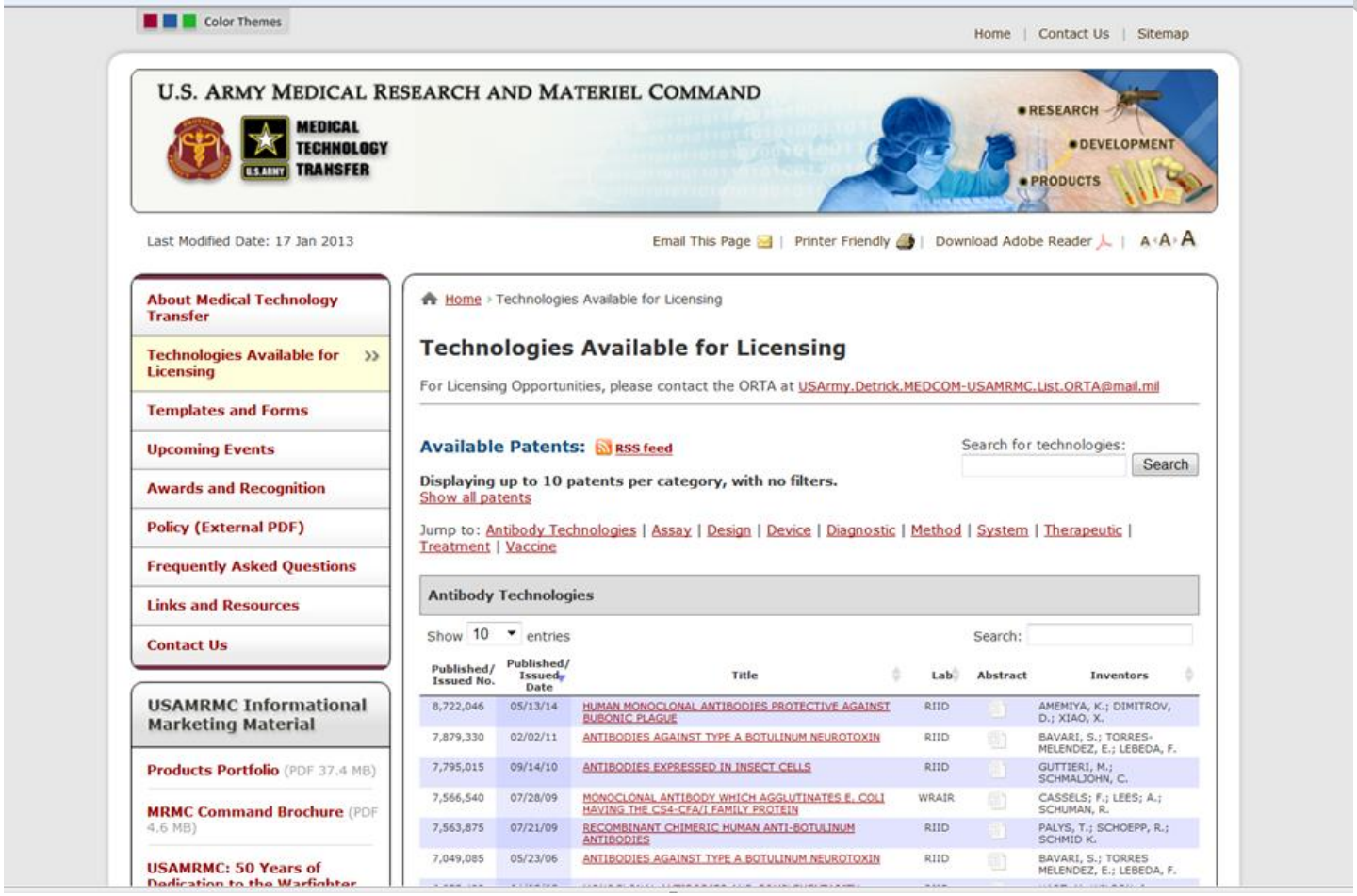
MMPD
MILITARY MEDICINE PARTNERSHIP DAYS

What is a CRADA?

- Cooperative Research and Development Agreement
  - Contract to do an R&D collaboration
  - We have a boilerplate and flexibility
  - CRADA partners have the right to license inventions stemming from the collaboration

USAMRMC Available IP

http://technologytransfer.amedd.army.mil



Conclusion

- At every project level, we have an opportunity to negotiate terms
- There is flexibility in the MTEC IP Plan provisions to be presented to negotiate terms that are favorable to both parties
- We want to work with our partners, as our goal is to have solutions for the warfighter fulfilled.
- MTEC members have the option to leverage Army Medical lab capabilities and existing intellectual property.

MTEC Overview

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Russ Keller

Senior Vice President

SCRA

20 April 2016

Overview

- **SCRA background and experience with OT-Consortia**
- **The OT-Consortium Business Model**
- **The specific MTEC application of the Model**
- **Questions**

SCRA Applied R&D

- Our core competency is building customized collaborations among government and industry participants that are responsive to their objectives, and managing those collaborations to deliver the right mix of skills at the right place and time.
  - We do not ***do*** the technical work; we facilitate the ***processes*** by which the technical work gets done.
- We are 30 years up the collaboration management learning curve, and have incorporated those three decades of experience in approaching the challenges presented by each new collaboration business opportunity we pursue.
  - No two collaborations are the same, either in organization or in operation.
  - We do not pre-ordain organizational or operational structures, but have experience in many of the options.
- MTEC presents several new challenges, so we look forward to working with our partners and sponsors to craft the best possible solutions for this unique initiative

DoD-Sponsored OT-Consortia

Consortium Name	Year Chartered	DoD Sponsor
National Shipbuilding Research Program (NSRP)	1998	NAVSEA (Note 1)
National Armaments Consortium (NAC)	2002	OSD AT&L (Note 2)
System of Systems Security Consortium (SOSSEC)	2004	U.S. Army ARDEC
National Advanced Mobility Consortium (NAMC)	2008	OSD AT&L (Note 3)
Vertical Lift Consortium (VLC)	2010	OSD AT&L
Consortium for Command, Control, Communications and Computer Technologies (C5T)	2014	U.S. Army ARDEC
Consortium for Energy, Environment and Demilitarization (CEED)	(Note 4)	U.S. Army ARDEC
National Spectrum Consortium (NSC)	2015	OSD DR&E
Medical Technology Enterprise Consortium (MTEC)	2015	U.S. Army Medical Research & Materiel Command

Note 1: OT for Research

Note 2: Formed as the National Warheads & Energetics Consortium; merged with National Small Arms Technology Consortium in 2013 to form the National Armaments Consortium

Note 3: Formed as the Robotics Technology Consortium in 2008 by OSD AT&L and transitioned to U.S. Army TARDEC in 2012; re-branded as the National Advanced Mobility Consortium in 2014 with an expanded scope to address all manned and unmanned ground vehicle system technologies

Note 4: Sponsored originally by Department of the Interior; new OTA issued by U.S. Army ARDEC in 2014

The OT-Consortium Business Model

- An **"enterprise partnership"** between the Government and a consortium of technology developers/providers in a specific domain where….
  - The **"Government"** partner can be a single sponsor (program executive officer) or multiple sponsors coordinated through a lead agency
  - The **"Consortium"** partner is a group of for-profit, not-for-profit and/or non-profit companies, universities and other academic research organizations having competence in the technical domain of interest
- The parties are connected through a binding "contract-like" instrument called an **"Other Transaction"** that operates outside the normal Federal Acquisition Regulations (FAR)
- Government – Consortium discussions are protected from penalties under U.S. anti-trust law

Acquisition Benefits of the Model

Unique Acquisition Process:

- ***Competitive yet Flexible***: Membership is open and competitive. Awards can be made to any member of the consortium. White paper process enables DoD to provide guidance to industry on the proposals to be submitted

- ***Basket Provision***: If funding is not available, DoD has the option of placing a source-selection-approved proposal in a "basket" with the option of funding it within two years of proposal submission should funds subsequently become available

- ***Single Point Contracting***: Consortium Manager facilitates and manages DoD's engagement with all members of the consortium (e.g., cost analyses and Subcontractor agreement verifications will be conducted by the Consortium Manager)

Shorter Time to Award:

- First time award (funding / approved Statement of Work received to award): ***Less than 90 days***

- Incremental award: If an approved Statement of Work was incrementally-funded, and an additional increment of funding subsequently is made available, it can be awarded and available to the awardee: ***Less than 45 days***

- Basket provision ("Basket" proposal pulled out for award): ***60-80 days***

"The Basket"

- A "holding zone" for proposals that are recommended for award, but for which Government funding is not available at the time the source selection decision is made.

- Proposals can remain in the Basket and be eligible for project award for up to two years after the original Request for Project Proposal due date.

- When selecting project proposals from the Basket, the Government reserves the right to select the Basket proposal that best matches the customer's requirements.

Mutual Benefits from Using the Model

U.S. Government

- Reduced Acquisition lead time
- One-stop technology shopping
- Access to broad spectrum of traditional and non-traditional contractors
- Full and open competition throughout
- Source selection integrity preserved
- Full control over use of sponsor's funds
- Ability to fund projects incrementally
- Open dialogue with Contractor is permitted up until proposal submittal
- Technically acceptable proposals placed in basket awaiting funding for 2 years

Industry and Academia

- Relief from FAR provisions
- Enables industry/academia planning for technology development and/or Internal R&D (IRAD) investments
- Enhanced collaboration between the Government, Industry and Academia during white paper and proposal preparation processes
- Higher visibility into USG requirements
- Open dialogue with the Government is permitted up until proposal submittal
- Technically acceptable proposals placed in basket awaiting funding for 2 years

MTEC Mission and Scope of Activities

- **MTEC Mission:** Assist the U.S. Army Medical Research and Materiel Command by providing cutting-edge technologies and effective materiel life cycle management to transition medical solutions to industry that protect, treat, and optimize Service Members' health and performance across the full spectrum of military operations.

- **Scope of activities anticipated: Stand up and operate a 501c3 organization (MTEC) that will engage in**
  - biomedical research and prototyping;
  - **capitalization of private sector technology opportunities;**
  - **technology transfer;**
  - **commercialization of Government intellectual property; and**
  - follow-on production for the U.S. Army Medical Research and Materiel Command

- **This opportunity represents a "first of its kind" construct that combines the "traditional" Government-funded prototype project work with requirements to raise and execute private sector funding streams that could support not only the individual projects, but also the *companies* who will execute those projects**

Technology Areas of Interest

The following biomedical technology domains will constitute the "playing field" for the collaborative efforts between the MTEC Members and the Government sponsors:

a) **Military Infectious Diseases –** Discover disease causing microorganisms and develop vaccines/drugs to prevent and treat infectious diseases rapidly.

b) **Combat Casualty Care –** Reduce killed-in-action rate of warfighters, reduce the morbidity of combat injuries and reduce the medical footprint on the battlefield by providing biologics, pharmaceuticals, and devices that enhance the capability of the medical staff to effectively treat causalities as close to the location and time of injury.

c) **Military Operational Medicine –** Develop effective countermeasures against stressors and to maximize health, performance, and fitness. This includes injury prevention and reduction, psychological health and resilience, and environmental health and protection.

d) **Clinical and Rehabilitative Medicine –** Develop technologies and products to replace or regenerate human cells, tissues, or organs to restore or establish normal functions such as tissue regeneration, bone scaffolding, and stem cell enabled treatments to severely injured Service members.

Technology Areas of Interest, Cont'd

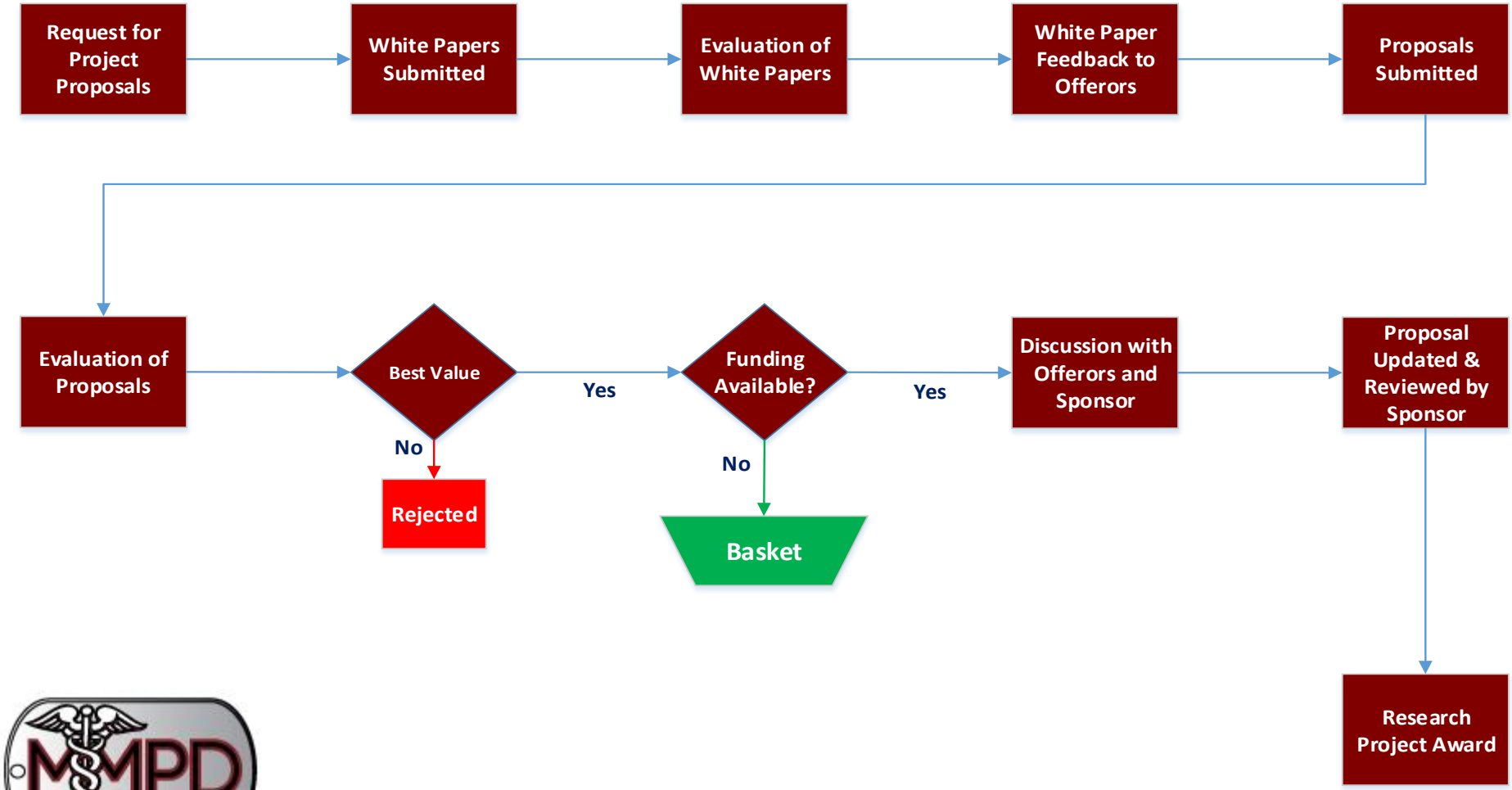
e) **Medical Chemical, Biological, and Radiological Defense –** Develop medical countermeasures in response to joint chemical, biological, and radiological warfare defense. Vaccines, pretreatment drugs, skin lotions, and diagnostic tests are being developed to protect the warfighter.

f) **Advanced Medical Technologies –** Develop initiatives and products that will increase medical mobility while ensuring access to essential medical expertise and support regardless of the operating environment. Efforts include e-health, digital warrior, hospital of the future integrative medicine, advanced orthopedic devices and treatments, advanced medical imaging technologies, robotic technologies to treat and rescue battlefield casualties, nanotechnology and biomaterials for diagnosis and therapy, technologies for treating neurological injuries, and regenerative medicine.

g) **Medical Training and Health Information Sciences –** Develop products and processes that increase patient safety and quality of care through simulation-based technologies and health informatics systems to include the development of products and processes that implement or improve medical simulation and training, health informatics and mobile health, and decision support tools and physiological models.

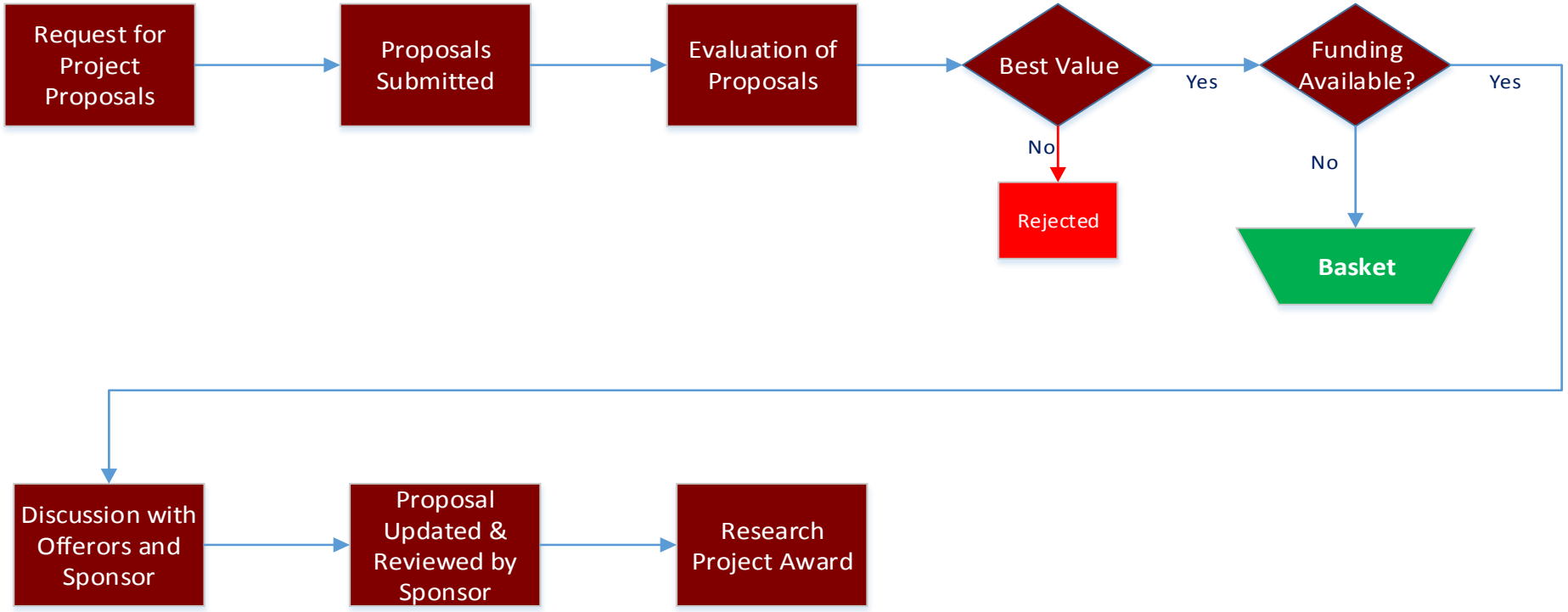
Solicitation-to-Award Process

with White Papers

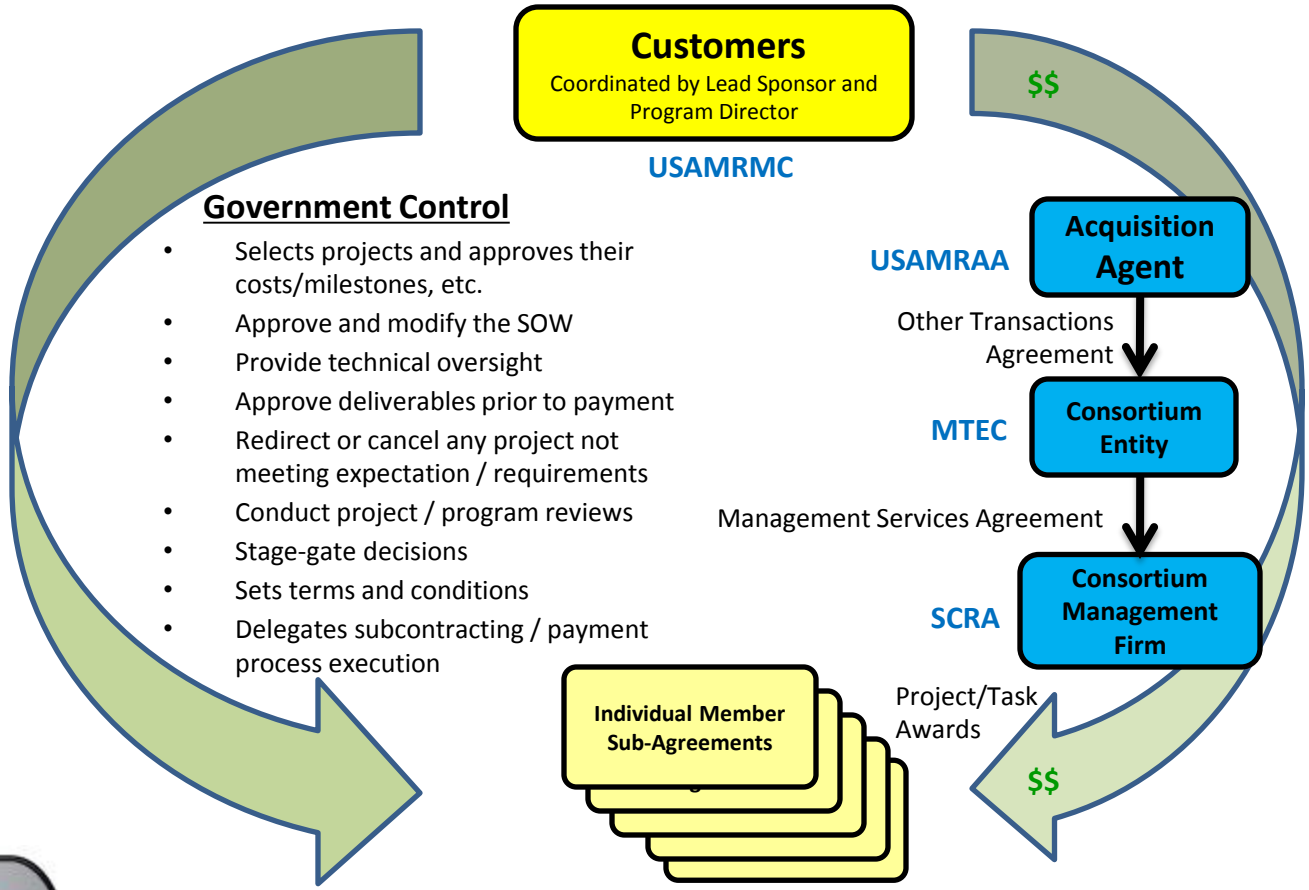


Solicitation-to-Award Process

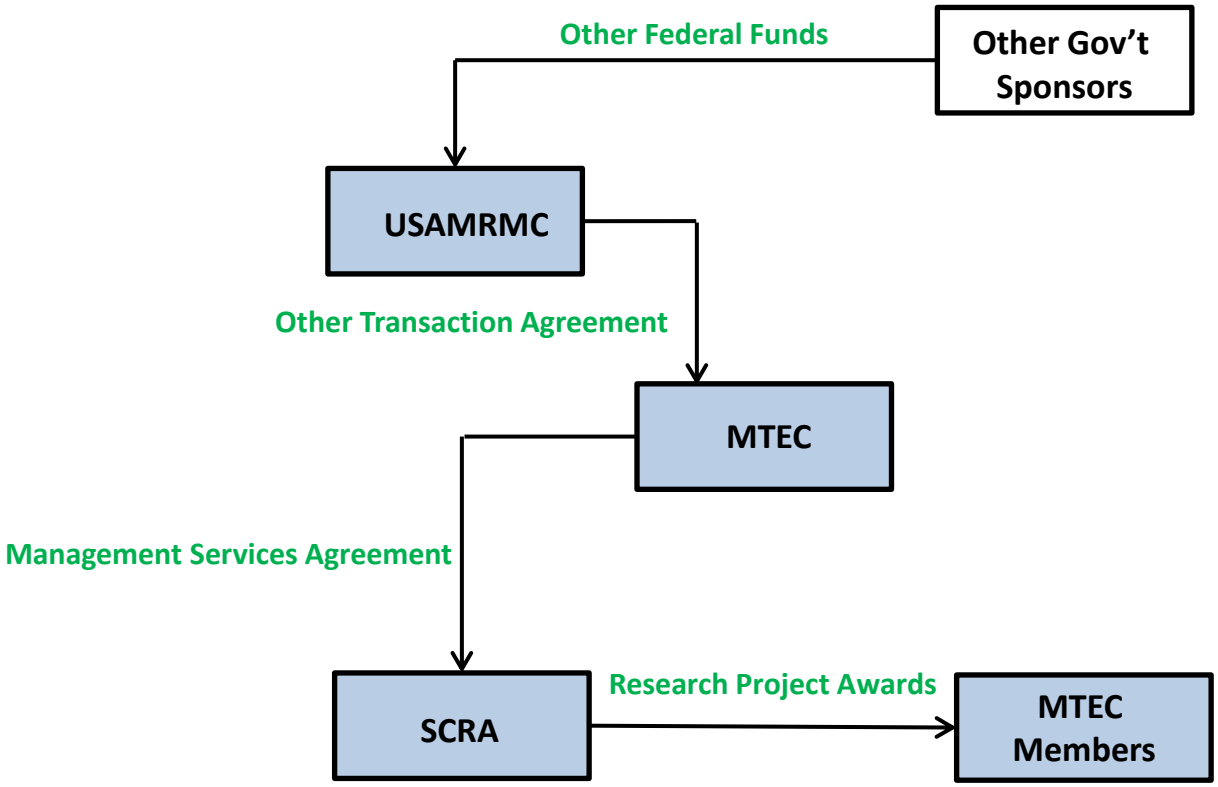
without White Papers



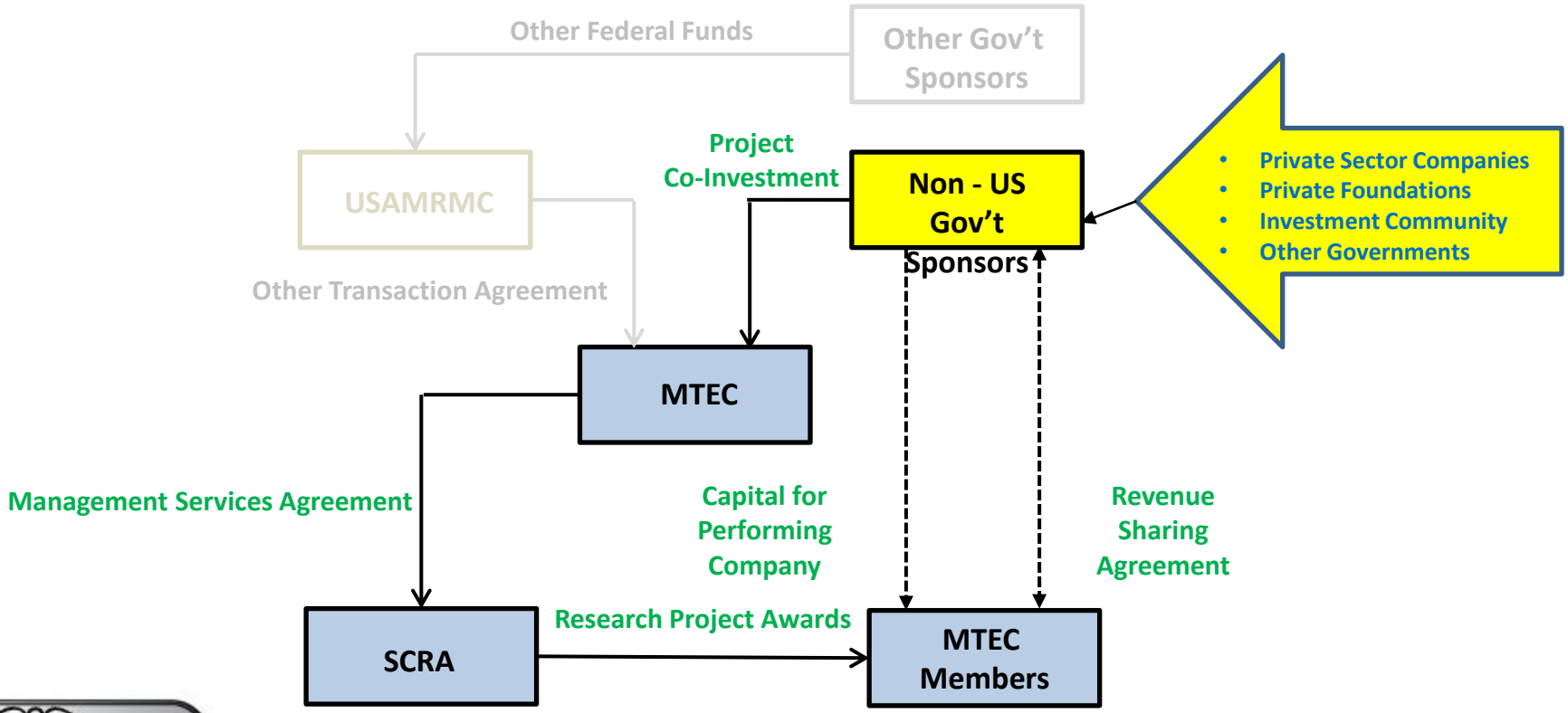
Technical & Financial Management



Funding Flows – "Traditional" Research Ops



Additional Funding Flows – the MTEC Model



Benefits of MTEC Membership

MTEC has been organized to provide the following benefits to member organizations:

- USAMRMC, other federal agencies ***and various private sector entities*** may use the OTA vehicle to fund certain research and development programs. **Only consortium members will be eligible to bid and receive awards for such programs funded through the OTA.** ***Awards result in non-dilutive funding.***

- **Access to information concerning Government technology requirements** which may not be available to non-members. In addition to promoting information exchange with Government attendees at MTEC general membership meetings, MTEC officers and staff will work to foster discussions between the Government and consortium members on a case basis.

- **A forum for conducting emerging technology discussions among member organizations,** and reporting the results of such discussions back to the Government to help shape the requirements the Government may publish in a subsequent research announcement.

- **Opportunity for an executive from member organizations to serve on the MTEC Board of Directors, or committees/subcommittees the Board may establish.**

Benefits of MTEC Membership, Cont'd

The MTEC Management Team will provide the following:

- **Facilitate interactions between and among consortium members so that proposals can be more collaborative and more closely aligned with specific Government requirements.** Such collaboration should increase the potential for an award.
- **Engage industry to gain a better understanding of their metrics for the technology areas being funded,** thereby presenting a research target for consortium members that would facilitate greater technology transfer opportunities.
- **Maintain access to regulatory and clinical specialties that can assist start-up members in their research program development.**
- **Maintain access to intellectual property rights professionals who could assist in licensing agreements and royalty valuation as desired by consortium members.**

Our Perspective

Questions?

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