MTEC WEBINAR AGENDA

2:00-2:05pm  Welcome and Introductions
Stacey Lindbergh, MTEC Executive Director

2:05-2:15pm  MTEC as a Public-Private Collaboration
JB Phillips, Ph.D., Projects Officer, Principal Assistant for Acquisition Army SBIR, Technology Area Chief (Medical) U.S. Army Medical Research & Materiel Command, and Jonathan S. Miller, Ph.D., J.D. Office of the Principal Assistant for Research and Technology, MCMR-RT

2:15-2:30pm  The OT Consortium Business Model & Benefits of MTEC Membership
Russ Keller, Senior Vice President, SCRA

2:30-2:40pm  Philanthropy Overview for MTEC
Michael Hutchinson, Managing Director, Changing Our World

2:40-2:45pm  Research Operations
Lauren Macri-Palestrini, Ph.D., Director of Research Programs

2:45-2:50pm  Commercialization Support
Rick Satcher, Director of Commercialization

2:50-2:55pm  Project Solicitations
Polly Graham, MTEC Program Manager

2:55-3pm  Next Steps
Stacey Lindbergh, MTEC Executive Director
Questions & Answers

- Email Questions to mtec-sc@mtec-sc.org
  - Questions & Answers will be posted on the MTEC website the week of December 14th under the FAQ section, www.mtec-sc.org.
- The webinar will be repeated on Friday, December 11th at 2 PM – 3 PM EST. Link to register on home page of MTEC website.
- The webinar, including video and audio will be posted on the MTEC website the week of December 14th.
- Contact Info
  - Stacey Lindbergh, MTEC Executive Director at 843.760.3566
    - stacey.Lindbergh@scra.org
  - Allison Moody, MTEC Program Assistant at 843.760.3344
    - allison.moody@scra.org
The OT-Consortium Business Model and Benefits of MTEC Membership

Russ Keller
Senior Vice President, SCRA

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)
**Rationale for Using an OT**

- Generally, the reason for using OT authority is that the Government needs to obtain leading edge R&D (and prototypes) from commercial sources, but some companies (and other entities/non-traditionals) are unwilling or unable to comply with the Government’s procurement regulations.
  - The Government’s procurement regulations and certain procurement statutes do not apply to OTs, and, accordingly, other transaction authority gives agencies the flexibility necessary to develop agreements tailored to a particular transaction.

- By using an OT instead of a contract, an agency and its partners are able to develop a flexible arrangement tailored to the project and the needs of the participants:
  - “Other Transactions are meant to present the Government and contractor with a ‘blank page’ from which to begin when negotiating such instruments.”
  - Additionally, OTs promote “a more collaborative working relationship,” which can be more conducive to R&D than the type of relationship established by a contract.

  **Source:** L. Elaine Halchin - CRS Report to Congress, July 2011

**Types of OT Agreements**

- Two distinct partnership models exist, depending on the maturity of the R&D efforts being contemplated:
  - OT for **Research**: for performing basic, applied, advanced research and development tasks
  - OT for **Prototypes**: for prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, weapons or weapon systems, components and/or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, weapons or weapon systems, components and/or materials in use by the Armed Forces.
Technical and Financial Management

Customers Coordinated by Lead Sponsor and Program Director

Government Control
- Selects projects and approves their continuation, etc.
- Approves and modifies the BOPW
- Provides technical oversight
- Approves deliverables prior to payment
- Redirects or cancels any project not meeting expectation/requirements
- Conducts project/program reviews
- Stage-gate decisions
- Sets terms and conditions
- Delegates subcontracting/payment process execution

Acquisition Agent

Other Transactions Agreement

Consortium Entity

Management Services Agreement

Consortium Management Firm

Individual Member Sub-Agreements

Project/Phase Awards

DoD-Sponsored OT-Consortia

<table>
<thead>
<tr>
<th>CONSORTIUM NAME</th>
<th>YEAR CHARTED</th>
<th>DOD SPONSOR</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Shipbuilding Research Program (NSRP)</td>
<td>1998</td>
<td>NAVSEA (Note 1)</td>
</tr>
<tr>
<td>National Armaments Consortium (NAC)</td>
<td>2002</td>
<td>OSD AT&amp;L (Note 2)</td>
</tr>
<tr>
<td>System of Systems Security Consortium (SOSSC)</td>
<td>2004</td>
<td>U.S. Army ARDEC</td>
</tr>
<tr>
<td>National Advanced Mobility Consortium (NAMC)</td>
<td>2008</td>
<td>OSD AT&amp;L (Note 3)</td>
</tr>
<tr>
<td>Vertical Lift Consortium (VLC)</td>
<td>2010</td>
<td>OSD AT&amp;L</td>
</tr>
<tr>
<td>Consortium for Command, Control, Communications and Computer Technologies (C3T)</td>
<td>2014</td>
<td>U.S. Army ARDEC</td>
</tr>
<tr>
<td>Consortium for Energy, Environment and Environmetal Mitigation (CEED)</td>
<td>(Note 4)</td>
<td>U.S. Army ARDEC</td>
</tr>
<tr>
<td>National Spectrum Consortium (NSC)</td>
<td>2015</td>
<td>OSD DMEA</td>
</tr>
<tr>
<td>Medical Technology Enterprise Consortium (MTEC)</td>
<td>2015</td>
<td>U.S. Army Medical Research &amp; Materiel Command</td>
</tr>
</tbody>
</table>

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
• **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.

• **Requirement:** 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 that would support not only the individual projects, but also the **companies** who will execute those projects

---

**MTEC Leadership**

**Board of Directors**

- **Mark D. Breyen**
  Device Manufacturer Board Representative

- **Dr. Anthony Atala**
  University/Non-for-Profit Board Representative

- **Dr. Lester Martinez Lopez, MPH**
  Major General (Ret), U.S. Army
  MTEC President and Chairman of MTEC Board

- **Leslie H. Sherman**
  Small Business Board Representative

- **Dr. Kent Kester, FACP, FIDSA, FASTMH**
  Vice President and Head, Translational Science & Biomarkers
The following biomedical technology domains will constitute the “playing field” for the collaborative efforts between the MTEC Members and the Government:

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.
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.

Funding Flows – the “Traditional” OT Model

Other Federal Funds

Other Gov’t Sponsors

Lead Gov’t Sponsor

Other Transaction Agreement

Consortium Entity

Management Services Agreement

Consortium Manager

Research Project Awards

Consortium Members
Additional Funding Flows – the MTEC Model

Benefits of MTEC Membership

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

• **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.

• USAMRMC and other federal agencies 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.**

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

Michael Hutchinson
Managing Director, Changing Our World
Changing Our World is a philanthropy firm that knows management and a management firm that knows philanthropy.

- Designing, building and managing the implementation of strategic initiatives that enable nonprofits and corporations to achieve their philanthropic goals

- Four primary service areas:
  - fundraising
  - corporate social engagement
  - research and analytics
  - digital

- Collaborating across all four service areas to deliver results – organizational, programmatic and financial – for our clients
What have we been asked to do?

- Determine whether, and if so how, private philanthropy might become part of the **funding base** for MTEC and its research support
  - Specifically for research areas
  - Generally for the long-term

- Recommend how private resource mobilization should be **structured** within MTEC for the next two years.

- Provide a plan for **market entry** in those two years, including critical tactics

- Develop a private voluntary **leadership structure** for resource mobilization that, over time, will open philanthropic doors for the work.

**Changing Models of Philanthropy**
Key Components for Fundraising Success

- The framework for any successful fundraising program includes these four (4) elements:
  - A strong **case for support**
  - Committed **leadership** with the ability to open doors and influence philanthropy
  - A sufficient number of cultivated **prospects** necessary to achieve the campaign goal
  - A comprehensive and well thought-out **plan**

For “public-private partnerships” the fundraising success elements are the same. But the philanthropist needs to see a clear distinction in roles. No philanthropist is interested in doing the government’s job. Hence,

- the case must pay particular attention to value propositions and roles; and,
- governance must ensure a role for private funders in decision making.
The Arc of Innovation in Philanthropy

What Changes?
The Money: Grants vs loans vs equity vs bonds
Results Expectations: Demonstrating the outcomes and their scalability
Timeframes: From short to long
Funder Role: From passive to engaged
Expected Nonprofit Consequences: Scale

Traditional resource transfers
Charitable grants

Traditional philanthropic resources at efficiency and scale

Traditional philanthropic resources demanding market-like results

Philanthropic resources moving in new ways onto the societal commons

Entirely new kinds of resources moving onto the societal commons

Collaboratives Interactive hubs Multiple-funder partnerships

Venture philanthropy

PRIs Micro-insurance pools Embedded transfers

Social stock exchanges Impact investing MRIs Equity-like flows Bond-like flows Social business Blended investments

Our Approach to the Work and Progress to Date
This project requires us to **plan and execute** strategy that is **BOTH** Traditional **AND** Innovative

- **We need to develop strategy** in terms of
  - Support for MTEC in general
  - Support for issues or constituencies
  - Support for specific research projects
  - Long-term continuous flows for a pipeline of research and technology development
- **And we need tactics** that are
  - Focused on institutions
  - Focused on philanthropic leaders
  - Focused on new technologies and crowdfunding

There are Four Market Segments

- **Foundations**
  - Family
  - Private Independent
- **Corporations**
  - Foundations
  - Corporate Giving
  - R&D Departments
  - Employees Matching
- **Individuals**
  - Major Gifts
  - Small gifts
  - Donor Advised Funds
- **Nonprofits**
  - Disease NPs
  - Associations

Leadership: Institutional and Individual Networks
Progress to Date

Management
- Establish entire workplan and deliverables schedule
- Establish a prospect tracker for capturing all information on all prospects identified which will be the base for MTEC identification-cultivation-solicitation process going forward

Case for Support
- Drafted a General Case and two specific mini-cases, one for vision, one for veterans

Prospect Research and Testing
- Compiled a list of 100+ Foundations and Corporations with overlapping interests; currently prioritizing and sorting list
- Compiled list of 100+ potential individual prospects; developing profiles for those identified as the top 20 individuals
- Have begun testing the opportunity with traditional philanthropies, nonprofits with resource capacity, and high net worth individuals for traditional and venture philanthropy interest

Systems and Templates
- Research, prospect and leadership tracking templates for future use

Leadership
- Identifying and profiling initial private leaders and developing structural options

Preliminary Reactions
- Traditional funders interested in intersection with their own portfolios
- Innovation funders intrigued with concept, but much more thought and work are needed to determine how the flow of funds would work.
- Much more exploration is needed.

Lauren Macri-Palestrini, Ph.D.
Director of Research Programs
MTEC’s model of development relies heavily on external collaboration and seeks to engage the external environment earlier than other investors.

Rick Satcher
Director of Commercialization
Guidance for commercialization plan component of proposals

12/15/2015

12/15/2015 MTEC

Proprietary

MTEC

Commercialization Support

Assess Commercial Opportunities
- IP status
- Technology readiness and state of the art
- Commercial market needs
- Ability to produce

Market research on key prioritized technology objectives for MTEC

Analyze Market Sectors
- Technology benefits to various markets
- Market players/level of competition
- Available distribution channels
- Cost of entry/initial drivers
- Alternate solutions

Negotiation License/Sec

Consider Value to Licensee/Partner
- Economic (revenue, saving, etc.)
- Strategic (competition, market timing, etc.)
- Emotional (human “gotta have,” momentum, etc.)

Attract Qualified Partners
- Value proposition
- Ability to succeed in market
- Assets of value
- Investment required
- Need for exclusivity

Valuation

Develop Negotiation Strategy
- Develop Agreement Terms
- Exclusivity (e.g., time, region, limitations, etc.)
- Up-front fees/royalty, milestones, non-mandatory performance milestones

Negotiation/License/Sec

Polly Graham
MTEC Program Manager
### MTEC Solicitation Process

1. **Government/Industry Requirement and Funding Identified**
2. **MTEC Issues Request for Proposals (RFP) to Consortium Members**
3. **Workshop/Webinar/Industry Day for Government and Consortium Members**
4. **Consortium Members Develop Teams and Submit Responses**
5. **MTEC and Government Review and Evaluate Submissions**
   - **Award Decision:** Yes → **Execution of Research Project Award**
   - **Funding Available:** Yes
   - **No** → **Rejected**

*Notional process subject to change

---

### Government and Industry Collaboration

- **Government/Industry Interface**
  - Technology Specific Workshops/Industry Days/Webinars at cycle kickoff
    - Early engagement of industry, academia and government facilitates mutual understanding and refinement of customer requirements
  - Continued collaboration permitted until proposal submission
    - Improves the fidelity of proposals that better meet the Customers’ needs
Anticipated Schedule GFY16

• Vision Restoration:
  • Release solicitation mid-January 2016
  • Conduct Industry Day/Webinar late January 2016
  • Proposals due to MTEC early March 2016
  • Source selection decision communicated to MTEC early June 2016
  • Award recipient(s) on contract early August 2016

• Regenerative Medicine:
  • Release solicitation mid-February 2016
  • Conduct Industry Day/Webinar late February 2016
  • Proposals due to MTEC early April 2016
  • Source selection decision communicated to MTEC early July 2016
  • Award recipient(s) on contract early September 2016

Joining The Consortium

- Who Should Join? Any company, university, or research organization is eligible to join the consortium that operates in the technology objective areas of the U.S. Army Medical Research & Materiel Command
- How to Join. The Consortium Member Agreement and Application are available at www.mtec-sc.org. Completed applications can be emailed to mtec-sc@mtec-sc.org.
- Annual Membership Dues
  - Annual dues: $1000 for small business, academic research institutions and not-for-profits
  - $5000 for large businesses
  - Payable once an applicant company has been approved for membership by the consortium’s governance body
Medical Technology Enterprise Consortium℠

Industry Day/MTEC Membership Day
February – Washington, DC

More information:
www.mtec-sc.org; email mtec-sc@mtec-sc.org
Stacey Lindbergh – 843.760.3566
Allison Moody – 843.760.3344

Who should be in the spotlight?

wounded warriors

government sponsors
MTEC member solution providers

consortium management staff