

U.S. Army Medical Research and Materiel Command



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UNCLASSIFIED



Why is Army Medicine Involved?

We select, modify and procure commercial medical materiel solutions when appropriate, or we partner to develop.

We take the lead in Research & Development when:

- The issue is unique to the Military
 - » Blast injuries
- Industry/academia lack interest
 - » Endemic diseases in specific area of responsibility
- Military needs a timely solution
- Directed by Congress



To: Increase Warfighter readiness; improve fitness, health, protection, and resilience; improve downrange health delivery; and enhance recovery, rehabilitation or reintegration





Current Hurdles

- Acquisition strategies that rely on Contracts and Assistance Agreements have restrictive legal/regulatory requirements that discourage non traditional companies from engaging with the Government.
- We need more and better communication with contractors to accomplish the mission
- Government funding for R&D addressing military medical needs is decreasing
- Private sector funding is available but largely unreachable





Other Transaction Authority

- Other Transaction (OT) is another funding vehicle used by federal agencies for obtaining or advancing research and development (R&D) or prototypes
- 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
- MRMC is using a prototype OT





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 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 instrument called an “**Other Transaction**” that is not subject to the FAR or DoDGAR

Government ↔ OTA ↔ Consortium





Medical Technology Enterprise Consortium (MTEC)

A Consortium of industry, academic, and other organizations operating through a 501(c)(3) non-profit corporation and an OT

- 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
- Expedited transition from development into follow-on production
- Attracts Small Business and non-traditional contractors



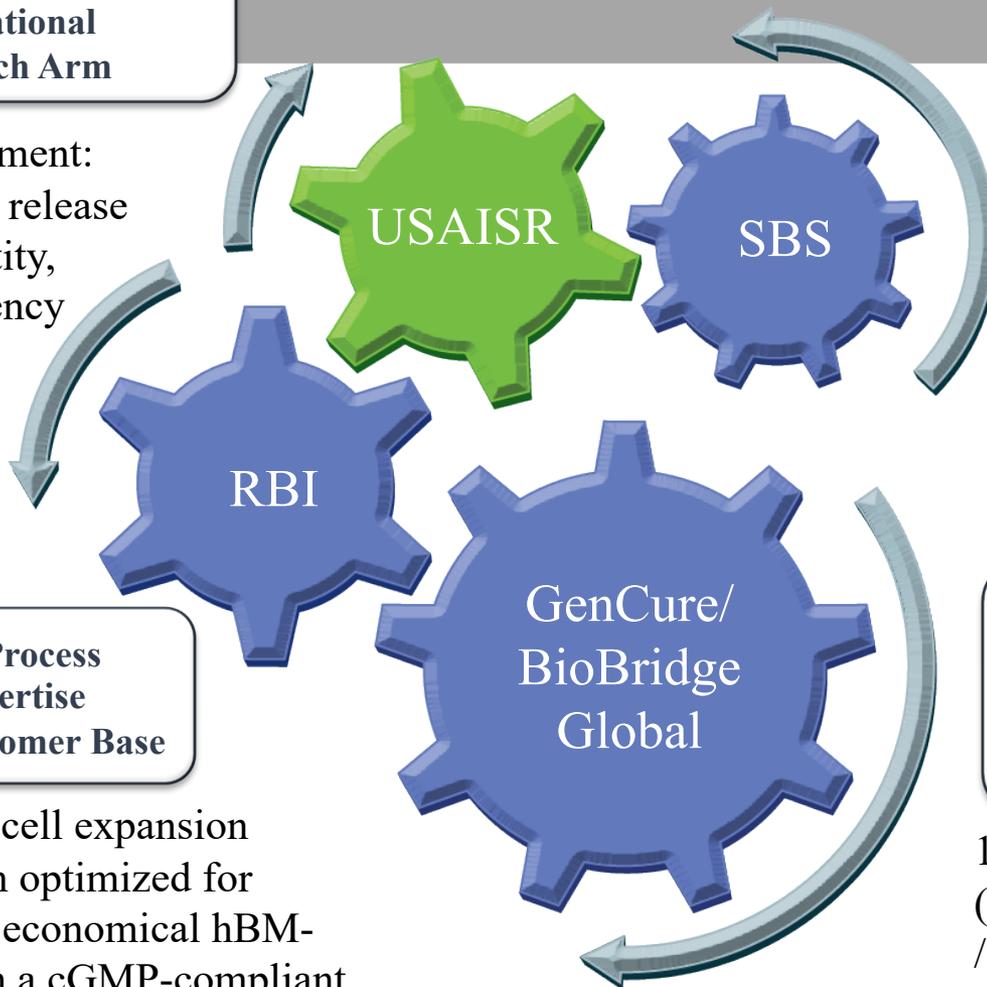


- Bench Research
- End Users
- Translational Research Arm

Collaboration Example

- Manufacturing Tool Production
- Customer
- Co-Developer of Source Materials

Assay Development:
hBM-MSC QC release assays for identity, safety, and potency



Xeno-Free High Performance Microenvironment (XF-HPME) optimized for microcarrier-suspension bioreactor use

- Manufacturing Process Engineering Expertise
- Established Customer Base

- cGMP manufacturing
- Quality Assurance
- Regulatory
- Demonstrated Capability
- Physical Facility

1. Xeno-free stem cell expansion
2. Media & system optimized for scalable, rapid and economical hBM-MSCs expansion in a cGMP-compliant system
3. Transfer developed technologies to GenCure/BBG

1. Human umbilical cord blood (hUCB)-derived platelet lysate / releasate for XF media / booster
2. Manufacture cGMP-grade hBM-MSCs at a 10B-30B cell lot (40-80 liter batch)

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Questions



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Backup Slides





What's Different about OTs?

- » What does not apply under an OT?
 - » Grants and Agreements Regulations (DODGARS)
 - » Cost Accounting Standards for Award Recipients
 - » Bayh-Dole and Rights in Technical Data
 - » Procurement Protest System
 - » Competition in Contracting Act
 - » Truth in Negotiations Act
 - » Contract Disputes Act
 - » Procurement Integrity Act

- » **Relief from FAR and supplemental regulations**
 - » Not required to comply with all of the FAR, DFAR, AFAR – **but** Agreements Officer “should consider FAR procedures and clauses” along with commercial practices

- » **Flexibility to use “best practices”**
 - » Costs reasonable, but still requires due diligence to award federal dollars
 - » Schedule and other requirements are enforceable
 - » Payment arrangements promote on-time performance





Definition of Prototype Project

According to the most recent DoD OT Guide for Prototype Projects:

- » A prototype project can be a preliminary pilot, test, evaluation, demonstration or agile development activity.
 - » It may include systems or subsystems, components or materials, methodology or processes and technology
 - » It can be used to evaluate the feasibility of a particular technology, process, concept, end item, effect, or other discrete feature
- » Prototype projects may involve proof of concept, pilot, novel application of a commercial technology for a defense application, and/or creation, design, development, demonstration of technical or operational utility as related to a prototype.
- » **Prototype projects are NOT: basic research, services, maintenance, production (including LRIP) and construction**

