

**MTEC**  
Medical Technology  
Enterprise Consortium

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Newsletter**

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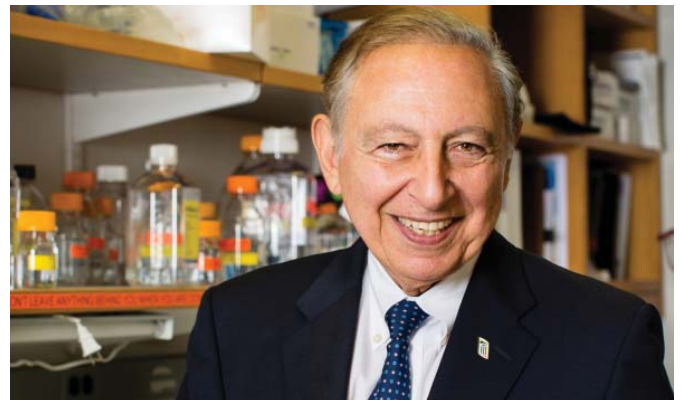
## **New Member Spotlight:**

### ***MTEC Welcomes Dr. Robert Gallo and The Institute of Human Virology***

The Institute of Human Virology (IHV) at the University of Maryland School of Medicine is the first center in the United States - perhaps the world - to combine the disciplines of basic science, epidemiology and clinical research in a concerted effort to speed the discovery of diagnostics and therapeutics for a wide variety of chronic and deadly viral and immune disorders - most notably HIV, the cause of AIDS.

Formed in 1996 as a partnership between the State of Maryland, the City of Baltimore, the University System of Maryland and the University of Maryland Medical System, IHV is an institute of the University of Maryland School of Medicine and is home to some of the most globally-recognized and world-renowned experts in the field of human virology. IHV was co-founded by Robert Gallo, MD, director of the of the IHV and co-founder and scientific Director of the Global Virus Network (GVN), William Blattner, MD, retired since 2016 and formerly associate director of the IHV and formerly director of IHV's Division of Epidemiology and Prevention and Robert Redfield, MD, associate director of the IHV and director of IHV's Division of Clinical Care and Research. IHV is also comprised of an Animal Models Division, Basic Science Division and Vaccine Research Division.

The Institute, with its various laboratory and patient care facilities, is uniquely housed in a 250,000-square-foot building located in the center of Baltimore and our nation's HIV/AIDS pandemic. IHV creates an environment where multidisciplinary research, education and clinical programs work closely together



*Robert Gallo, MD*

to expedite the scientific understanding of HIV/AIDS pathogenesis and to develop therapeutic interventions to make AIDS and virally-caused cancers manageable, if not curable, diseases.

A particular focus of IHV includes learning how to utilize the body's natural chemistry for its own therapeutic potential and pursuing biologically-based treatment approaches that are less toxic to the body and, often, less costly to the patient and public. IHV also pursues the development of effective therapeutic and preventative vaccines, science's greatest hope in putting an end to the AIDS pandemic.

IHV's more than 300 employees include 70 faculty whose research efforts are focused in the area of chronic human viral infection and disease. At present, more than 75 percent of the Institute's clinical and research effort is targeted at HIV infection, but also includes hepatitis C virus, human T cell leukemia viruses 1 and 2, human papillomavirus, herpes viruses and cancer research. Under the leadership of Dr. Robert Redfield (formerly at the Walter Reed Medical Center), IHV's patient base has grown from just 200 patients to approximately 6,000 in Baltimore and well over 1,000,000 in 6 African and 1 Caribbean nation.

Many may recognize Dr. Robert Gallo from his thirty year career at the National Cancer Institute in Bethesda, MD. His long interest has followed themes including the study of the basic biology of human blood cells, their normal and abnormal growth, and the causes of abnormal growth whether excessive, e.g., leukemias or insufficient, e.g., immune deficiencies and the involvement of viruses in these abnormalities.



*The Institute of Human Virology*

## New Member Spotlight Continued

Dr. Gallo and his co-workers opened and pioneered the field of human retrovirology when in 1980 they discovered the first human retrovirus (HTLV-1) and with others showed it was a cause of a particular form of human leukemia. (This was the first, and to date, the only known human leukemia virus and one of the few known viruses shown to cause a human cancer). A year later he and his group discovered the second known human retrovirus (HTLV-2). Dr. Gallo and his colleagues also independently discovered HIV (the 3rd known human retrovirus), and provided the first results to show that HIV was the cause of AIDS. They also developed the lifesaving HIV blood test (1983-1984). Earlier (1978) Gallo discovered a variant of gibbon ape leukemia virus (Hall's Island strain) which causes T-cell leukemia.



**Robert Redfield, MD**

The discoveries of all human retroviruses, including HIV, were to a great extent dependent on being able to grow human T-cells (lymphocytes) in the laboratory, and this was achieved by the use of a growth factor called Interleukin-2 or IL-2. Dr. Gallo and his co-workers discovered Interleukin-2 in 1976, thus setting the stage for all groups to culture human T-cells. Today IL-2 is used not only in laboratory experiments, but also in some therapies for cancer and AIDS. Gallo and co-workers also spent several years in the 1970's working out detailed biochemical and immunological characteristics of human cellular DNA polymerases alpha, beta, and gamma as well as reverse transcriptase (RT) from several retroviruses in order to use RT as a sensitive and specific surrogate marker for retroviruses. It was particularly essential to distinguish the mitochondrial DNA polymerase (DNA pol. gamma) from RT because of their similar biochemical characteristics which led to many prior false claims for detecting human retroviruses.

"My colleagues and I at IHV look forward to working with MTEC and exploring ways in which we can collaborate and advance the human condition," said Dr. Gallo.

## A Message on Philanthropy from Dr. Susan Raymond, MTEC Director of Strategic Funding

In March 2016, MTEC received 501(c)(3) status and officially became operational as a nonprofit. As a start-up organization, we faced the same natural challenges of most new organizations. MTEC had no market or brand recognition, no pre-existing supporters, and no fundraising infrastructure. Through our philanthropic objectives, we aimed to address these issues by lifting the awareness of MTEC and its work among sources of private support, attracting funding for research initiatives in collaboration or coordination with public funders, and developing opportunities for social finance that can bridge between traditional philanthropy and new mechanisms for social investing. As a founding partner of the fundraising and philanthropy management firm, Changing Our World, Inc., I knew from experience that meeting these objectives would require, but extend well beyond, finding private funds to meet the needs of a particular research initiative. Above all, we seek to utilize philanthropy to drive and establish MTEC's long-term capacity and sustainability to continuously leverage between public and private resources in the interests of continued and sustained medical support for our warfighters and veterans, and to do so in ways that will bring those innovations to the general public.

Seven months later, MTEC has hit the ground running, attracting corporations, foundations, and individuals for partnership. We have a fully functioning fundraising infrastructure, including a newly redesigned website and online giving capabilities. There are multiple co-funding discussions in process, and MTEC continues to attract significant interest in its mission to improve warfighter's health from potential partners as well as from the 90 plus organizations that have become members. We continue to identify funding partners and are currently growing our research domains in scope in order to maximize the number of projects funded and provide added value to the interests of funders. At the end of the day, our philanthropic efforts have one end goal in mind: to bring breakthrough medical solutions to reality and return our warfighters to independent, fully functional lives.

## Giving Back: MTEC Receives Early Gift From Veteran

MTEC is one of many worthy veterans-related nonprofits to support. However, when Colin Raymond (to the left, completing the 2015 Best Ranger Competition), former Army infantry captain and veteran of Operation Enduring Freedom, heard about our innovative approach and how our medical breakthroughs will impact the lives of many warfighters, he felt compelled



**Captain Colin Raymond completing the 2015 Best Ranger Competition**

## Giving Back Continued

to make a personal gift. Captain Raymond said, “It is important to me to help those who were so seriously injured while standing side-by-side with me – in duty if not in person – in protecting freedom. And to be sure that the technology is available to prevent those injuries for future soldiers.” Captain Raymond also noted a differentiating factor in supporting our nonprofit, “MTEC is focused not on theory, but on practical solutions, on getting the job done and getting it done soon.” MTEC needs individuals, corporations, and foundations to join people like Captain Raymond to make a gift in support of our efforts to bring medical solutions to our warfighters.

## A Call to Action: Your Opportunity to Support MTEC

You can make your own positive impact on the lives of our warfighters by making a charitable gift to MTEC. With the opportunity to support specific cause areas – like vision restoration or regenerative medicine – or simply making a gift to where needed most, you can help push forward breakthroughs to help others.

Give hope and the promise of better lives for our veterans by making your tax-deductible gift today at: [www.mtec-sc.org/donations](http://www.mtec-sc.org/donations).

## Zero to \$30 Million: Reflecting on MTEC's First Year of Operations

On 4 November 2016 Advanced Technology International (ATI) placed the final two research projects on contract that were selected during the initial solicitation cycle conducted through the enterprise partnership between the US Army Medical Research and Materiel Command (USAMRMC) and the Medical Technology Enterprise Consortium (MTEC). In all, four projects totaling nearly \$30 million in contract value were awarded from proposals submitted during this cycle. These results demonstrate the speed, agility and flexibility of the Other Transactions (OT) – Consortium business model compared with traditional, Federal Acquisition Regulations (FAR) – based models. Significant outcomes from this cycle include:

- The time from release of the final solicitation to last project on contract was 249 days (just over 8 months);
- Collectively, \$19 million in federal funding was supplemented by \$11 million in non-federal funding across the four awarded projects;
- One project team includes direct participation by a federal lab in the work to be conducted.

With a second round of projects currently in source selection, and with an eye toward the immediate future in which multiple solicitations spanning several medical technology domains are being prepared for release over the next 2-4 months, the potential is great for the USAMRMC - MTEC enterprise partnership to accelerate getting more sponsors and more research dollars into play in support of our warfighters, their families and the

broader civilian population. This article recaps MTEC's development trajectory to date, and provides insights into the future direction for this innovative public – private partnership. It is sub-divided into the following four sections:

1. Launching the Enterprise Partnership: a Smooth and Successful Start-up
2. Institutionalizing the Enterprise Partnership: Crawl, Walk, Run
3. The 2017 Crystal Ball: Be on the Lookout for.....
4. Benefits of MTEC Membership: Maximizing the Value of Participation

### 1. Launching the Enterprise Partnership: a Smooth and Successful Start-up

On 17 August 2015 USAMRMC issued an award to ATI to create the MTEC entity as a tax-exempt non-profit corporation, develop its governance, recruit a broad membership of qualified medical technology providers, and prepare the MTEC entity to begin research operations – all within six months. A subsequent agreement envisioned transitioning the “consortium formation” activities into a ten-year period of performance, during which USAMRMC and other federal sponsors could access the MTEC membership to conduct research and development activities authorized under the OT Agreement between USAMRMC and MTEC.

During the pre-proposal phase, ATI recruited four key partners having complementary skill sets critical to addressing the full range of capabilities required to execute the vision for MTEC as developed by USAMRMC:

- Tunnell Government Services (for its understanding of, and experience providing support services to USAMRMC);
- Research Triangle Institute, International (for its proven expertise in technology transfer and commercialization of medical technologies);
- Changing Our World, Inc. (for its skills and capabilities in establishing successful philanthropic fundraising strategies for non-profit corporations); and
- Innovation Financing Roundtable (for its novel approaches toward engaging private sector investors in support of public sector initiatives).

In the 15 months since the initial award, ATI and its execution partners met the ambitious timeline established by USAMRMC for organizing the MTEC entity and transitioning that entity into funded research operations on behalf of the Government. Key milestones achieved during this period include the following:

- 17 Aug 2015: Initial agreement awarded to ATI
- Aug 2015: MTEC incorporated as a non-profit corporation in South Carolina
- Oct 2015: MTEC Board of Directors seated and approved all key governance documents
- Oct 2015: MTEC begins recruiting members (50 join by the time the initial solicitation was released)



## Zero to \$30 Million Continued

- Jan 2016: MTEC applies to the IRS for tax-exempt status
- Jan 2016: All consortium formation requirements are met (one month early); USAMRMC issues OT to begin research operations; MTEC and USAMRMC develop initial solicitation for regenerative medicine requirements
- Feb 2016: MTEC issues first solicitation (Regenerative Medicine)
- Apr 2016: IRS approves MTEC tax exempt status
- Jun 2016: MTEC issues second solicitation (Brain – Machine Interface for Vision Restoration)
- Aug 2016: Regenerative Medicine award recipients announced at Military Health System Research Symposium
- Oct 2016: First Regenerative Medicine award recipients on contract
- Nov 2016: Final Regenerative Medicine award recipients on contract

### 2. Institutionalizing the Enterprise Partnership: *Crawl, Walk, Run*

Prior to issuing its solicitation to create and operate the MTEC entity, USAMRMC had no prior direct experience with the OT – Consortium business model. Prior to responding to the USAMRMC solicitation to create and operate the MTEC entity, ATI had experience managing several other OT – Consortium partnerships, but none of those partnerships required the significant emphasis USAMRMC placed on identifying and recruiting non-federal funding to join with federal funding for the research activities being contemplated.

Because of the “first-of-its-kind” charter envisioned for MTEC, the challenge for the Government and for the Consortium was to overlay “learn” and “do” cycles in a way that maximizes progress in the former without causing missteps in the latter. Clearly such an approach requires an iterative process across successive solicitation cycles, with the hope that small successes will lead to larger successes as USAMRMC and MTEC work their way up the process learning curves.

By every metric, that iterative learning curve is off to a good start.

By January 2017, the first anniversary of the launch of research operations, MTEC will have awarded multiple research projects across two different solicitation cycles. This initial year can be associated with the first stage of the crawl-walk-run process, where USAMRMC and MTEC will have administered two “test” solicitation cycles, neither of which included a precursor “white paper” phase, and both of which were drawn from a single research area among the six potential domains where MTEC plans to operate in the future.

Moving into the next program year, MTEC members can expect to see the “crawl” stage grow into a “walk” stage. MTEC expect to release multiple solicitations across several technology domains within USAMRMC’s mission focus, thereby opening

opportunities for more MTEC members to be able to propose against requirements aligned with their respective qualifications and capabilities. Moreover, the MTEC staff believes that this broader engagement of medical technology domains also will increase the likelihood MTEC can attract additional private sector interest in the devices and treatment protocols that will be solicited.

Looking further downstream, the long term goal for what a fully-developed enterprise partnership can accomplish – the “run” stage – would be characterized by a single, all-encompassing annual solicitation cycle that also could accommodate several one-off / out-of-cycle emergent requirements. This fully developed process would include the following activities:

- MTEC and USAMRMC will engage in the late spring / early summer to identify the slate of potential research topics to be solicited in the upcoming Government fiscal year. This process will leverage several key inputs:
  - Components of the Government’s Program Objective Memorandum (POM) process that address key USAMRMC research and development activities that are anticipated to be funded in the upcoming fiscal year;
  - Inputs from MTEC member organizations that can be used to inform the Government’s medical research and development sponsors regarding the “state-of-the-art” on medical technologies that may be of interest to the Government;
  - Results from initial market and technology assessments regarding the commercial market potential for the medical technologies that may be of interest to the Government; and
  - Inputs from other potential federal Government funding sponsors whose medical research and development portfolios align/overlap with the USAMRMC portfolio. Enabling multiple Government sponsors to fund medical research projects via the USAMRMC-MTEC OT Agreement is an additional advantage provided by the OT-Consortium business model, and the MTEC staff already is actively reaching out to these other potential funding sponsors to educate them regarding how they can use the USAMRMC-MTEC OT vehicle to fund their own medical research and development projects.
- Once the slate of candidate research topics has been developed, the MTEC staff will take that slate and engage private sector organizations (corporate, philanthropic, etc.) to determine areas of potential mutual interest (Government and private sector). Information from this private sector vetting process will provide the final input into the smooth solicitation that gets released to MTEC members.
- The solicitation cycle envisions a two-step process. The first step will focus on a call for white papers, in which MTEC members will submit non-proprietary 3-5 page “concept papers” that are germane to the research topics/requirements being solicited, and include a rough order of magnitude cost estimate.
- The MTEC staff will review the white papers to identify

## Zero to \$30 Million Continued

potential teaming opportunities with other MTEC members, “shop” the project concepts with private sector sponsors to assess their level of interest, and then prepare comments recommendations for discussion with the USAMRMC sponsor.

- The USAMRMC sponsor will evaluate the white papers. The MTEC staff will participate in this review to provide input from potential private sector sponsors contacted during the outreach, with a focus on those concept papers that attract both Government and private sector interest.
- The MTEC staff will provide feedback on the white papers to all the Offerors. This feedback will include suggestions for teaming/partnering with one or more other MTEC members (if applicable) and comments from both Government and private sector reviewers regarding how the white paper may be improved when preparing the full proposal.
- Armed with feedback from the white paper process, the solicitation cycle will transition into the second step. MTEC members will develop and submit full technical and cost proposals based upon feedback gained from the white paper process.
- From this point onward, the process will look similar to the “traditional” FAR-based process (although certain support activities will be accomplished by ATI in its role as the MTEC Consortium Manager to accelerate the time from technical evaluation to project award):
  - The Government sponsor(s) will convene a Technical Evaluation Panel to evaluate the technical proposals (joined by representatives from the private sector if there is interest in co-funding the project), and will identify those projects conditionally selected for award;
  - ATI will conduct a full cost analysis on all proposals recommended for award by the Technical Evaluation Panel, seek clarifying information from the Offeror(s) as necessary, and will forward its completed analysis to the Government for review;
  - Should the Government have any remaining technical or cost questions, ATI will work with the Offeror(s) to update the Statement of Work and/or cost proposal to resolve these questions;
  - The Government will execute its final source selection decision and will direct ATI to place the awardee(s) on contract.
- One significant departure from the “norm” of FAR-based source selection involves incorporating a “basket provision.” In conducting its proposal reviews, the Technical Evaluation Panel is charged with identifying *all* proposals that satisfy the requisite technical merit criteria and a “cost reasonability” threshold. The most highly-rated proposals are selected for immediate funding as described above. However, if funding is not available from the original sponsor at the time of the Government’s source selection decision to fund all of the otherwise eligible proposals, that

sponsor has the option of placing one or more source-selection-approved proposals in a “basket” with the option of funding those proposals within two years of the date of the original solicitation. Should funds subsequently become available, the original proposal may receive funding from:

- The same funding sponsor at a later time when additional funds become available (up to two years from the original solicitation);
- A different federal funding sponsor (this is a significant opportunity, and can leverage the relationships the MTEC staff has developed with these non-USAMRMC funding sponsors during the pre-proposal phase as described above);
- A private sector funding sponsor (philanthropic, foundation, venture, etc.)

This flexibility in holding qualified proposals for future award enables both the sponsor(s) and the Offerors to realize a significant value proposition – in effect providing both groups multiple opportunities to fund / receive funding for projects that can replace poor-performing projects, expand the portfolio of projects that can be accomplished should additional / end-of-year funds become available, or contribute to the research goals of other funding sponsors who may or may not have been actively involved in the solicitation cycle that generated the proposal of interest.

Going forward, MTEC’s immediate priorities are to execute the second program year (more solicitations across more technology domains) and position the enterprise partnership to begin “running” with a comprehensive annual process as soon as that transition can be accomplished.

### 3. The 2017 Crystal Ball: Be on the Lookout for...

Given what the MTEC staff knows today, our planning horizon for the next 9-12 months includes the following prospective milestones and key events:

- Multiple project awards from the current vision restoration solicitation cycle (estimated award date in January 2017)
- Multiple (3-5) new solicitations for research projects in technology domains including, but not limited to:
  - Follow-on solicitations in the regenerative medicine and vision restoration domains;
  - Infectious disease (one or two new topics);
  - Combat casualty care (one new topic);
  - Combination medical device (one new topic);
  - Medical simulation / health information technology (one or more new topics);
  - Perhaps one or two others yet to be identified

In preparation for the anticipated solicitations highlighted

## Zero to \$30 Million Continued

above, the MTEC staff encourages all MTEC members to submit one-page “quad charts” for those technology initiatives MTEC Members believe may be of interest to Government and/or private foundation sponsors conducting medical R&D. For directions regarding quad chart development and submission, see the MTEC website at <https://private.mtec-sc.org/membership-capabilities>.

Finally, MTEC Members should “be on the lookout for” information announcing the MTEC annual membership meeting, which is being planned for the February-March 2017 timeframe in San Antonio, TX. Watch the MTEC website for the formal announcement and agenda. Attending these annual meetings provides MTEC member organizations another source of value for their membership dues. Continue reading for the full list of membership benefits available to MTEC member organizations.

### 4. Benefits of MTEC Membership: Maximizing the Value of Participation

Article II, Section 2.5 of the MTEC Consortium Member Agreement highlights several of the benefits of membership MTEC is organized to provide. These include:

- MTEC members will have 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 staff will work to foster discussions between the Government and consortium members on a case-by-case basis.
- One method for facilitating such interaction involves MTEC member organizations developing and submitting project “quad charts” that describe a technology initiative that can improve Government and/or private sector funding sponsors’ awareness of the “state-of-the-art” in a particular technology domain.
- The MTEC staff will provide a forum for conducting emerging technology discussions among member organizations, and report the results of such discussions back to the Government to help shape the requirements the Government may publish in a subsequent research announcement.
  - This objective currently is being advanced through MTEC-sponsored “speed networking” events, where individual MTEC members can share a quick overview of their technology capabilities and partnering interests with all other MTEC member organizations participating in the event.
- 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.
- The MTEC management team will 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.

- The “white paper” step within the overall two-step solicitation cycle is intended to accomplish this objective, as part of the intended feedback to all Offerors will be suggestions for potential teaming partners as the process moves from white papers to full proposal submission.
- The MTEC management team will engage industry to gain a better understanding of their metrics for the technology areas to be solicited, thereby presenting a research target for consortium members that would facilitate greater technology transfer opportunities.
- MTEC staff already has engaged more than 20 private sector and philanthropic organizations during the first two solicitation cycles. These discussions have led to several promising partnership opportunities that currently are under development.
- The MTEC staff will maintain access to regulatory and clinical specialties that can assist start-up members in their research program development should such assistance be desired.
- The MTEC staff will maintain access to intellectual property rights professionals who could assist in licensing agreements and royalty valuation as desired by consortium members.

Finally, as described in Section 2 above, the “basket” provision within the solicitation cycle essentially provides MTEC proposal Offerors an opportunity for multiple “bites at the apple” in securing project funding for the program of work being proposed. Upon completion of a solicitation cycle, the MTEC staff will “shop” basket proposals to other Government funding sponsors **and** to private sector sponsors who may have interest in funding the work being proposed.



**Optimizing the Health  
and Performance of  
Our Nation's Warfighters**

## **What is MTEC?**

The Medical Enterprise Technology Consortium (MTEC) is a new, tax-exempt, nonprofit corporation consisting of industry, academia and nonprofit organizations committed to realizing USAMRMC's vision. MTEC's main focus is to develop medical tools that better manage, treat, and rehabilitate those suffering from traumatic injury on the battlefield. The MTEC Board of Directors is chaired by Major General Lester Martinez-Lopez, MD MPH (Ret.), and is comprised of academic leaders and corporate executives with deep experience in medical technology development. Business and management services are provided by Advanced Technology International (ATI), a nonprofit corporation whose core competency is building and leading complex collaborations. Membership includes the top biomedical R&D organizations from across the nation, and from international organizations.

MTEC's initial focus will be the development of technologies that can improve or restore lost vision - the fourth leading result of combat actions - and on regenerative technology for tissue destroyed by trauma and burns.

## **MTEC's Technology Focus Areas**

- Prevention, Diagnosis, and Treatment of Infectious Diseases
- Care of Combat Casualties
- Support for Military Operational Medicine
- Support for Clinical and Rehabilitative Medicine
- Support for Advanced Medical Technologies

**For information and assistance with making a donation or forming a partnership with MTEC, please contact:**

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