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Interoperability Standards and Technology Leadership"

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<b>14. ABSTRACT</b> This award provides core program support to develop key capabilities of the Medical Device "Plug-and-Play" (MD PnP) Interoperability Program to lead medical device interoperability to support clinical solutions for improving patient safety and healthcare efficiency. Under MD PnP program leadership during the past year, we have convened working and writing groups for ICE standard Parts II and III (for the ICE network controller and device models), such as the Medical Device Interoperability Safety (MDIS) Working Group and the AAMI / UL2800 joint committee standard for certifiable safety of medical device interfaces, and to manage their work to produce draft standards for submission to ASTM Committee F29. We have also organized requirements that will facilitate adoption by the DoD, the VA, and device manufacturers. We continued collaborating with FDA, NIST, NSF, ONC, DocBox, UMass, Penn, and others for work on smart alarms initiatives, smart dynamic checklists, certifiable safety of medical device interfaces, and the updated Pre-IDE regulatory submission to FDA. We leveraged our work to provide leadership and program artifacts and results to related federal initiatives such as the FCC Consumer Advisory Committee and the White House sponsored SmartAmerica NSF Challenge.					
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**Annual Report: Medical Device Plug-and-Play Interoperability  
Standards and Technology Leadership  
Award Number W81XWH-09-1-0705  
Principal Investigator: Julian M. Goldman, MD  
Period of Performance: 21 September 2013 – 20 September 2014**

## **Introduction**

A May 2004 symposium jointly sponsored by TATRC and CIMIT kicked off what became the Medical Device “Plug-and-Play” (MD PnP) interoperability program. Initially focused on creating a standardization framework for interoperability of medical devices in the Operating Room of the Future (ORF), the program collected clinical requirements from anesthesiologists, surgeons, and clinical engineers, and began to define an agenda for standards development. Within a year, we acknowledged that the need for interoperability encompasses the full continuum of healthcare environments, and we developed a strategy to accelerate the development of interoperability technologies, as well as standards. This strategy addressed the need for a “sandbox” laboratory environment to facilitate the testing of devices and technologies with proposed standards; the development of a “plug-and-play” system architecture; collaboration with regulatory agencies; leveraging standards and technology to address vendors’ legal concerns; and assuring the clinical relevance of all proposed interoperability solutions.

TATRC support, through a prior BAA and conference grants, has enabled the MD PnP interoperability program to develop key capabilities, to identify and access numerous available resources, and to build collaborations to achieve MD PnP objectives. TATRC’s commitment has enabled us to attract additional program funding from Partners Information Systems, CIMIT, NSF, NIST, and NIH. We have created a medical device interoperability laboratory in Cambridge, MA as a multi-institutional, interdisciplinary shared resource. We have developed clinical use cases demonstrating the capability of medical device interoperability to improve patient safety and exhibited these demonstrations at national meetings. In 2007, we held our first international conference on “Improving Patient Safety through Medical Device Interoperability and High Confidence Software”, jointly sponsored by TATRC and NSF.

Significantly, core program support from TATRC enabled us to write the first medical device integration system standard – the Integrated Clinical Environment (ICE) standard, ASTM F2761—Part 1, which includes functional architecture and risk mitigation strategies for networked, patient-centric interoperable medical devices. In addition, we led a successful collaborative effort involving three major healthcare providers to develop and adopt sharable interoperability contracting language for use in the procurement of medical devices and related equipment. We facilitated the endorsement of medical device interoperability for improving patient safety by seven medical societies (including the American Medical Association). We additionally worked with three companies on DoD SBIR projects to develop a first-responder ICE Supervisor. TATRC BAA support has been instrumental in providing “program glue” to effectively leverage these highly interdependent and synergistic activities to realize program objectives.

With the FDA and Continua Health Alliance, MD PnP planned and co-sponsored a three-day workshop on Medical Device Interoperability in January 2010. The workshop was attended by over 200 participants from industry, health care, and federal agencies. There has since been a follow-on working group, which meets regularly under MD PnP leadership, to address safety and regulatory concerns for integrated medical device systems. The FDA organized another meeting on device interoperability with AAMI in 2011, and, in January 2012, the FDA formed a

Medical Device Interoperability Coordinating Council to bring together various groups working on different aspects of interoperability. MD PnP has continued to play a leadership role in this activity.

## **Body of Report**

The MD PnP Program has become a recognized leader in developing clinical solutions for improving patient safety and healthcare efficiency through medical device interoperability. Interoperability will enable the creation of complete electronic health records and will introduce error resistance into networked medical device systems. We are producing a standardization framework consisting of a functional architecture and requirements for implementing standards in a manner that will support interoperability for effective clinical deployment. This requires critical evaluation (or “gap analysis”) of potentially suitable candidate standards, as well as the modification of existing standards and the development of new standards for implementation in the MD PnP standardization framework. By leveraging available standards, we expect to accelerate the MD PnP standards framework development so that useful candidate standards can be vetted and demonstrated. This includes partnering with industry and the FDA to define interoperability-related hazards and mitigation thereof to help inform a regulatory pathway for networked medical device systems. This will also involve developing the MD PnP Laboratory as a “sandbox” populated with medical devices and test equipment to serve as a vendor-neutral environment to devalue proposed standards through interoperability testing and conformance testing. Building on our accomplishments to date, we have sought to leverage areas of traction around five key themes identified for this work:

- Standards Development
- Clinical and Engineering Requirements for Safe Medical Device Interoperability
- Interoperability & Security Requirements for Medical Device Procurement
- Regulatory Science for Safe Medical Device Interoperability
- Management of External Collaborations

Since the program’s inception, more than 850 clinical and engineering experts, as well as representatives of more than 120 industrial and academic institutions have participated in our plenary workshops / conferences, working group meetings, and focus groups to contribute to ongoing program activities that helped shape the common goals. Our geographically dispersed, interdisciplinary, multi-institutional team of collaborators has included participants from: Kaiser Permanente, Johns Hopkins Medicine, the VA, FDA, NIST, TATRC, computer and information science groups at University of Pennsylvania, University of Illinois at Urbana-Champaign, Kansas State University, University of New Hampshire, Waterloo University (Canada), Wiener Neustadt (Austria), Draeger Medical Systems, Philips Healthcare, GE Healthcare, Hospira, Intel, DocBox Inc., Moberg Research Inc., Linea Research Inc., Anakena Solutions Inc., LiveData Inc., MITRE Corporation, Lockheed Martin Corporation, IXXAT, Draper Laboratory, NSF/CPS (Cyber Physical Systems), Geisinger Health System, and the Partners HealthCare System community (MGH Anesthesia, Biomedical Engineering at MGH and Brigham & Women’s Hospital, and Partners HealthCare Information Systems).

These Option-Year 2 activities have built upon all of our MD PnP program work to date and reflect our vision of progressing ICE-related/medical device interoperability standards, development and distribution of these clinical requirements for safe medical device interoperability, helping healthcare delivery organizations, particularly the DoD, with strategies for the procurement of interoperable medical devices, working with the FDA to develop the regulatory science related to integrated medical device systems, and continuing to build the

community of interest that will lead to widespread availability and adoption of medical device interoperability for the improvement of patient safety and clinical workflow efficiency. Our work has reached a level of federal interest, national recognition, and resource development that underscores our ability to provide strong clinical leadership in all of these areas.

For Option-Year 2 of this grant, this updated set of aims has been agreed on with TATRC:

### **Standards Development**

- **Aim 1:** Work on development of the following: AAMI/UL2800, which will help with device interface certification; the AAMI standard for Integrated Clinical System for PCA (for implementation of PCA safety); and the AAMI Working Group on Interoperability, which is developing interoperability standards strategy and overseeing standards development in that domain. (Dr. Goldman co-chairs each of the last two groups.)
- **Aim 2:** Develop foundational content for a standard for an ICE-compliant clinical Data Logger.
- **Aim 3:** Based on experience with our open ICE platform in our MD PnP Interoperability Lab, provide expertise to other standards development organizations, e.g. IEEE, AAMI, IEEE, UL, ISO, ASTM, HL7, IHE (Integrating the Healthcare Enterprise), and OMG (Object Management Group).

### **Clinical and Engineering Requirements for Safe Medical Device Interoperability**

- **Aim 4:** Create a database of the clinical requirements we have been developing through various projects, and explore ways of making these requirements useful for the broader community.
- **Aim 5:** Enhance our requirements gathering process through (1) the evaluation of collaborators' prototype research implementations based on our OpenICE platform and tools, and (2) bringing subject matter experts to our lab as part of a Visiting Scholars program.

### **Interoperability & Security Requirements for Medical Device Procurement**

- **Aim 6:** Identify requirements that are central to meet near-term and long-term needs of DoD and Healthcare Delivery Organizations (HDOs) for medical device procurement, including an adoption pathway roadmap that is reasonably aligned with expectations for industry adoption and that can serve as a basis for procurement strategy.
- **Aim 7:** Continue to update MD FIRE procurement language to reflect new information.

### **Regulatory Science for Safe Medical Device Interoperability**

- **Aim 8:** Submit the supplement to the pre-IDE document to the FDA, and provide new relevant information as needed and available.
- **Aim 9:** Once pre-IDE supplement has been submitted, release those documents into the public domain.

### **Management of External Collaborations**

- **Aim 10:** Support and facilitate use of the MD PnP program artifacts and tools (including our Interoperability Lab/Test Bed) for interoperability R&D projects (including mobile applications and Visiting Scholars), "plug-fests", and evolving clinical system integration activities.
- **Aim 11:** Leverage our work to provide leadership and program artifacts and results to related federal initiatives such as the FCC Consumer Advisory Committee and the White House sponsored SmartAmerica NSF Challenge.

- **Aim 12:** Coordinate our work under this award with standards development activities and device-related academic and industry initiatives.

## Research Accomplishments

For standards development in the first half-year, we aimed to continue to convene working and writing groups for subsequent ICE standard parts (Parts II and III for the ICE network controller and device models) such as the Medical Device Interoperability Safety (MDIS) Working Group and the AAMI / UL2800 joint committee standard for certifiable safety of medical device interfaces, and to manage their work to produce draft standards for submission to ASTM Committee F29. This is ongoing work, and we continue our interoperability standards leadership work supporting ICE and related standards through participating in these multi-organizational working groups. They provide a forum for sharing the findings from our TATRC work and from our NIH Quantum work relative to the gaps in existing standards and recommendations on how they can be improved. We are currently in discussions with the IEEE Standards Administration group about developing a Memorandum of Understanding to under-pin our collaboration efforts. By the third quarter of this year, we transitioned to the following updated standards-related aims for Option-Year 2.

**Standards Development, Aim 1:** Work to develop the following: AAMI/UL2800, which will help with device interface certification; the AAMI standard for Integrated Clinical System for PCA (for implementation of PCA safety); and the AAMI Working Group on Interoperability, which is developing interoperability standards strategy and overseeing standards development in that domain. (Dr. Goldman co-chairs each of the last two groups.)

We continue our leadership with standards development groups: the AAMI/UL JC2800 standard for certification of safe medical device interoperability, the AAMI Interoperability Working Group, the AAMI Task Group on Patient-Controlled Analgesic (PCA) Integrated Clinical System, and IEEE 11073, which are all building on our foundational work or using it.

Engineers within the IEEE 11073 standards community have been analyzing clinical requirements from the Serena MD PnP requirements database to extend the IEEE 11073 medical device communication standard Domain Information Model. We are collaborating to develop a semi-automated approach to ensure that new or updated device communication standards will include QMDI-identified clinical system requirements.

In collaboration with DocBox and other members of the UL2800 standard committee we have prepared the first draft of the “Systems requirement from clinical user perspective” document. This along with a list of Clinical Requirements and Hazard analysis has been submitted for comments from the UL and AAMI committees.

AAMI/UL 2800 version 1 was published internally and is architecture- and use case-agnostic. JC 2800 1-1 is currently being developed (with input from MD PnP) to include ICE architecture-specific parts. The JC 2800 committee is beginning formal verification of MD PnP Serena RM requirements and developing a reference model based on that work.

**Standards Development, Aim 2:** Develop foundational content for a standard for an ICE-compliant clinical Data Logger.

We have collected requirements for an ICE Data Logger and will refine this content based on feedback from our collaborators. This will serve as the basis of the draft standard for an ICE-

compliant clinical Data Logger. A preliminary ICE Data Logger draft has been written in the ISO/IEC template and will be shared with NIST and key collaborators in the next period.

**Standards Development, Aim 3:** Based on experience with our open ICE platform in our MD PnP Interoperability Lab, provide expertise to other standards development organizations, e.g. IEEE, AAMI, IEEE, UL, ISO, ASTM, HL7, IHE (Integrating the Healthcare Enterprise), and OMG (Object Management Group).

The IEEE 11073 committee meeting requested a presentation on OpenICE (which uses IEEE 11073, OMG DDS, and ASTM F2761), and this was delivered by collaborator Tracy Rausch of DocBox (composed with the help of Dr. Goldman) during the third quarter. DocBox is working on commercializing OpenICE, so their insights were quite useful and well-accepted by the committee. The ongoing assessment of OpenICE by the IEEE 11073 committee is a very useful step towards broader adoption. The initial presentation resulted in several follow up meetings and an IEEE activity to evaluate how OpenICE requirements should influence updates to IEEE 11073. We have ongoing discussions of these requirements for connectivity and interface capabilities with medical device manufacturers, most recently with DDS providers RTI and PrismTech.

During the final quarter, our work progress toward developing standards using OpenICE as a prototype platform for interconnectivity engineering, research, and technology has been presented to Open Group, Military Health System Research Symposium (MHSRS), IEEE standards Association, UL, and AAMI.

### **Platform Development**

Prior to the transition to Option-Year 2 aims, we completed several objectives related to platform development. We expanded the gap analysis work of the ICE-PAC group to include additional medical devices and clinical scenarios, and continued ongoing work to refine the attributes of device models, including the association (or set-up time) protocol, the real-time communication protocol, and the information or data model. This work is being done with our Device Models working group for the NIH project, in collaboration with NIST. We have ongoing discussions of these requirements for connectivity and interface capabilities with medical device manufacturers, such as Draeger and DDS providers RTI and PrismTech. The work of coordinating outputs of collaborative projects with NIST, FDA, universities, CIMIT investigators, and industry partners to further open platform development is ongoing, as we continue to leverage synergies among our projects and our collaborative relationships to ensure that all efforts contribute to the overarching goal of furthering medical device interoperability. This gives us a current understanding of stakeholder needs and requirements, and facilitates project planning. This specific work has transitioned into the open-source code dissemination environment that we are developing under TATRC award W81XWH-12-C-0154.

### **Clinical and Engineering Requirements**

While we have transitioned into new requirements-centered aims for the purposes of this award, our early objectives of continued analysis of clinical scenarios to define detailed workflows, clinical requirements, and related engineering requirements; and identifying appropriate use cases to include in subsequent ICE parts are supported by ongoing work. We continue to identify and refine high-level clinical scenarios, as a foundation for developing technical specifications for medical device interoperability. With TATRC support, we have been able to organize requirements across multiple projects and sources – NIH, FDA, ONC, NSF, etc. – to pull together and vet information that will facilitate adoption by the DoD, the VA, and device manufacturers. We have expanded our work on use cases from the ASTM ICE standard to

include ISO, AAMI, AAMI UL, and ONC FDASIA Workgroup (Food and Drug Administration Safety Innovation Act) work.

The web-based repository of clinical scenarios was transitioned to TATRC award W81XWH-12-C-0154, where we are building a more robust web-based implementation of the use case repository that can be tested and deployed.

**Clinical and Engineering Requirements for Safe Medical Device Interoperability, Aim 4:** Create a database of the clinical requirements we have been developing through various projects, and explore ways of making these requirements useful for the broader community.

In the third quarter, we began implementing Serena RM, a commercially available requirements management database designed to support collaboration. We began implementing Serena in May, and have used it to import and upload from Excel the requirements we have developed under our NIH grant – including generic ICE requirements and PCA Safety clinical requirements and associated attributes, along with collaborator comments. We then used Serena to export these requirements and comments, and presented them to AAMI/UL JC2800 during the AAMI Standards Meeting in June – we are using these requirements to establish the scope of the exemplar used for AAMI/UL JC2800, based on our design documentation (requirements and hazard identification). Since then, we have continued to develop our implementation of Serena RM to support our work and that of the AAMI/UL JC2800 committee by contributing standardization artifacts, such as clinical requirements and safety algorithms.

Within the MD PnP Program, our focus over the last quarter has been on refining the requirements schema to support a production version of our PCA Safety requirements set. We are targeting October for release. We are continuing to refine and elaborate upon the set via weekly requirements reviews with the members of the development team. Serena groups related sets of requirements into a database it terms a “project”; one Serena implementation may contain many projects. We recently created a copy of our PCA Safety project for use and development by AAMI/UL JC2800, enabling our and their work to continue in parallel.

The implementation of requirements in Serena is very powerful, because of the capability to export Excel documents and re-import them with full tracking of all edits to requirements. This is enabling a pathway of “open sourcing” requirements for use by the extended community of researchers and manufacturers – an exciting enabler of innovation. The response to initial sharing of Serena requirements output at standards meetings has been very positive.

**Clinical and Engineering Requirements for Safe Medical Device Interoperability, Aim 5:** Enhance our requirements gathering process through (1) the evaluation of collaborators’ prototype research implementations based on our OpenICE platform and tools, and (2) bringing subject matter experts to our lab as part of a Visiting Scholars program.

Victoria L. Danhaki, MD, a physician at New York Presbyterian - Columbia University, served as an MD PnP program Clinical Visiting Scholar for one month, during which she documented clinical workflow for cardiac surgery and intensive care.

The lab continues to receive visitors such as Shawn Forrest, a biomedical engineer from the FDA. We are moving forward with receiving and training post-docs, visiting scholars, (e.g. David Gregorczyk of the University of Lübeck), and with anesthesia residents and fellows at MGH (e.g. Stesha Doku, MD) and other institutions, such as Katharine White, MD of UCSF. We are currently working with Georgetown University to plan for several graduate students in

Technology Management to complete their capstone projects in the MD PnP Lab.

**Interoperability & Security Requirements for Medical Device Procurement, Aim 6:**

Identify requirements that are central to meet near-term and long-term needs of DoD and Healthcare Delivery Organizations (HDOs) for medical device procurement, including an adoption pathway roadmap that is reasonably aligned with expectations for industry adoption and that can serve as a basis for procurement strategy.

The ISO TC 121 International Standardization Committee for Anesthetic and Respiratory Equipment, chaired by Dr. Goldman, oversees worldwide standards for devices such as ventilators, blood pressure monitors, and pulse oximeters. The committee met in Incheon, Korea in June 2014 and supported a unanimous resolution to require that medical devices perform to interoperability standards.

The implementation and analysis in the lab, coupled with the FDA Pre-IDE submission, standards work, MD FIRE updates, and OpenICE software development, is helping to define an adoption roadmap that considers the state of legacy technology, market influences, emerging technology capabilities, and standards convergence.

**Interoperability & Security Requirements for Medical Device Procurement, Aim 7:**

Continue to update MD FIRE procurement language to reflect new information.

There has been recent increased interest in MD FIRE, including from the US Army ISR.

We are in the process of identifying and collating specific requirements that could be added to MD FIRE from our experience with OpenICE development. This activity is being performed in conjunction with the Association for Healthcare Resource & Materials Management (AHRMM) of the American Hospital Association and USAMMA.

**Regulatory Science for Safe Medical Device Interoperability, Aim 8:**

Submit the supplement to the pre-IDE document to the FDA, and provide new relevant information as needed and available.

The multi-institutional Medical Device Interoperability Safety Working Group (MDISWG) submitted the Pre-IDE supplement to FDA in March 2014, and held a follow-up meeting with FDA in May to discuss questions. It is now well documented that FDA is supportive of the component-level testing approach (rather than pair-wise) for interoperability, which will ensure safety and appropriate risk mitigation through architecture and system design. Manufacturers will be able to submit products for component-level regulatory clearance. FDA is eager for MD PnP and its collaborators to provide artifacts to support that approach. MD PnP regulatory work will continue; the program will release more guidelines as they become available. This work is interwoven with the technical and scientific work being done in the program.

The FDA has formally responded to our minutes, so the results of the last Pre-IDE meeting are now final. MDISWG submitted an important follow-up Pre-IDE submission, which includes 1) questions that could not be included in the Pre-IDE submission 2) Follow-up questions based on the final FDA response from the Pre-IDE meeting and 3) deeper and expanded issues on Medical device interoperability, partially based on ICE, partially based on the progress made by JC 2800 (i.e. use of conformity assessment standards), and partially based on the interoperability aim of this grant. We expect this cycle to be finalized by December 2014.

Dr. Goldman and Michael Robkin of Anakena Solutions have led this effort for the past four years, and other MD PnP collaborators have participated. MD PnP team members created much of the content describing our proposed regulatory approach and the desired regulatory concepts that are necessary for the industry to achieve regulatory cleared plug-and-play interoperability in an ICE (ASTM 2761)-compliant architecture. Our program's approach to clinical scenario analysis (e.g. identification of clinical requirements and hazardous situations mitigated by or attributable to interoperability) was used for the Pre-IDE Supplement Submission. See [http://mdpnp.org/MD\\_PnP\\_Program\\_MDISWG.html](http://mdpnp.org/MD_PnP_Program_MDISWG.html) for the history of this effort.

### **Regulatory Science for Safe Medical Device Interoperability, Aim 9:**

Once pre-IDE supplement has been submitted, release those documents into the public domain.

We published the Pre-IDE materials in May 2014 on the mdpnp.org web site: [http://mdpnp.org/uploads/MDISWG\\_Cover\\_letter\\_and\\_FDA\\_Pre-Submission\\_I120162\\_Supplement.pdf](http://mdpnp.org/uploads/MDISWG_Cover_letter_and_FDA_Pre-Submission_I120162_Supplement.pdf)

### **Management of External Collaborations, Aim 10:**

Support and facilitate use of the MD PnP program artifacts and tools (including our Interoperability Lab/Test Bed) for interoperability R&D projects (including mobile applications and Visiting Scholars), “plug-fests”, and evolving clinical system integration activities.

As part of the Presidential Innovation Fellows SmartAmerica Challenge initiated in December 2013, Dr. Goldman helped to form a healthcare-related challenge group called Closed Loop Healthcare: From Home to Hospital to Home, comprised of collaborators from academia, industry, and government, which he co-chairs with Marge Skubic from the University of Missouri. SmartAmerica has provided a unique opportunity to involve a broader community in the use of our lab and open source resources. We hosted the Closed Loop HealthCare team (46 people from 16 organizations) for a three-day meeting and “hackathon” in the MD PnP Lab on March 18-20, 2014, to work on a collaborative demonstration that used our lab test bed capabilities, for the June 2014 White House-hosted SmartAmerica Expo. We introduced the participants from academic research, industry, and federal agencies to our OpenICE platform and tools as a means for connecting their individual test beds or research artifacts for the collaborative demonstration we developed, and we provided direct support for their access of medical data from devices in the Lab.

Following the success of the SmartAmerica CPS Challenge, and its focus on the Internet of Things (IoT) concept, the IEEE Standards Association held an IoT Workshop in September. Dr. Goldman was invited to speak on a panel about “IoT Activities and IEEE Standards.” MD PnP medical device interoperability requirements are helping to create the foundation for a Medical Internet of Things (MIoT), enabling the next generation of connectivity – beyond the internet – for the healthcare industry.

At the NSF-sponsored CPS Week in April in Berlin, Germany, two of our engineers gave several talks and poster presentations to inform the Medical CPS research community about our lab resources and open source artifacts and tools.

Dr. Goldman and the MD PnP team's lead software engineer represented the program at the Smart Monitoring meeting held in conjunction with the Military Health System Research Symposium (MHSRS) in August, Dr Goldman served on the Regulatory panel, At MHSRS, the

MD PnP team presented two posters, one on Web-Based Clinical Scenario Repository (CSRTM) and one on OpenICE as a Platform for Clinical, Engineering, and Technology Research, and App Deployment. MD PnP's work on safe interoperability, data logging, and identifying device and data integration improvement opportunities was of great interest to many parties at the Military Health Symposium, and potential partnerships are evolving as a result of this event. A Military Health visit to the MD PnP interoperability lab to continue discussion about possible collaboration is scheduled for next quarter.

### **Management of External Collaborations, Aim 11:**

Leverage our work to provide leadership and program artifacts and results to related federal initiatives such as the FCC Consumer Advisory Committee and the White House sponsored SmartAmerica NSF Challenge.

At the SmartAmerica Expo held on June 11, 2014 in Washington DC, the Closed Loop HealthCare team demonstrated their technology to display the functionality illustrated in the scenario above – the exhibit was viewed as a great success and provided valuable feedback to the collaborating organizations. MD PnP provided an ICE network for feeding data into ICE applications, and most of the demonstrations were integrated with at least one other organization's technology. Our PCA scenario was an element of the larger Closed Loop HealthCare demonstration; the ICE patient network data was consumed by the MD PnP PCA Safety application and by multiple other applications in the booth, including the data logger built and run by NIST.

Dr. Goldman announced our new SmartAmerica / MD PnP Healthcare App Challenge (SAMHAC), jointly sponsored with SmartAmerica and funded with \$30,000 in prize money, funded by a gift to the program from the Gordon and Betty Moore Foundation. We showed a demonstration in our App Challenge booth of an “app” running in several different web browsers and on several types of devices streaming physiological data from medical devices in our lab in Cambridge, MA (available at <http://bit.ly/samhac>). This was an excellent opportunity to show the capabilities of our Interoperability Lab/Test Bed (see **Aim 10**).

One of the Presidential Innovation Fellows responsible for the SmartAmerica CPS Challenge has been appointed to a NIST position to plan a “Global City Teams Challenge: SmartAmerica Round 2,” and have asked the MD PnP team to be involved. The team's leadership and expertise (including the MD PnP lab as an open test bed) in the SmartAmerica initiative was viewed as a great success.

MD PnP leadership in the SmartAmerica Challenge Closed-Loop Healthcare team at Expo and White House demonstration sparked further government interest in our work. The Congressional Medical Technology Caucus invited Dr. Goldman to speak at a July congressional briefing on “Medical Device Interoperability and Safe Medical Integration.” Dr. Goldman shared the program's expertise in emerging medical technologies like integrated medical devices, as well as regulatory processes and current gaps in Health IT.

In September, Dr. Goldman was invited meet with various leaders of the medical devices industry, senior officials from the FDA, and other experts at the National Academies' Innovation Policy Forum Workshop on Medical Devices Innovation: Opportunities, Threats, and Challenges. The group presented challenges facing the industry in areas such as interoperability, cybersecurity, data stewardship, and system reliability, and policies needed to accelerate medical device innovation and the time to market for safe and effective medical devices. Dr. Goldman moderated a panel on “Challenges: The Digital Health Platform (System of Systems).”

Dr. Goldman's invited participation in the FDASIA working group during 2013 facilitated the group's foundational concepts being influenced by the MD PnP program's work. As a result, MD PnP expertise was sought for a May 2014 FDA workshop, scheduled after the April 2014 release of FDASIA recommendations related to the regulatory oversight of Health IT systems: <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf>. Dr. Goldman spoke in multiple panels at this workshop, and referenced what has been learned through the course of our MD PnP program's work, from our collaborators' guidance and insight, and from the experiments performed in our Interoperability Lab. He announced the availability of the second phase of the Pre-IDE document to support a regulatory pathway for safe interoperability (see **Aim 9**). The second phase was well accepted by the community, who are eager to see this work address a key aspect of interoperability – the market pathway.

#### **Management of External Collaborations, Aim 12:**

Coordinate our work under this award with standards development activities and device-related academic and industry initiatives.

Our leadership and participation in standards efforts like AAMI/UL JC2800 (see **Aim 1**) enables the coordination of our MD PnP program work with those activities. Numerous manufacturers are involved in this standardization activity.

#### **Program Development:**

Before transitioning to Option-Year 2 aims, we met our earlier goals of finding a way for the MD PnP collaborators group to publicly share information (using SourceForge and GitHub to host source code, binary distributions designed for easy deployment, and issue tracking) and publishing a second iteration of MD FIRE contracting language.

#### **Key Research Accomplishments**

- **Standards work related to medical device interoperability.** We have leveraged our foundational work on the ICE standard (ASTM F2761) to bring those concepts into other related standards work. We have been actively involved in the AAMI / UL2800 joint committee standard for certifiable safety of medical device interfaces, and the new AAMI standards task groups on PCA safety. We have drawn on requirements and architecture material from our TATRC and NIH work to assist the efforts of these groups, which provide a forum for sharing learnings from our projects relative to the gaps in existing standards and recommendations on how they can be improved. This year the ISO TC 121 International Standardization Committee for Anesthetic and Respiratory Equipment, chaired by Dr. Goldman supported a unanimous resolution to require that medical devices perform to interoperability standards.
- **Interoperability procurement language.** In June 2012 the VA signed onto the MD FIRE (Medical Device Free Interoperability Requirements for the Enterprise) interoperability procurement guide, joining the original contributing institutions – Kaiser Permanente, MGH/Partners HealthCare, and Johns Hopkins Medicine – that under MD PnP leadership issued a call for action in October 2008 to improve patient safety by recommending that medical device interoperability requirements be included as an essential element in vendor selection criteria and procurement processes. This sample procurement language has been shared with many organizations and is currently being

reviewed by several groups for potential adoption. The second version was recently published, which reflects input from the VA and is available on the MD PnP website (<http://mdpnp.org/mdfire.php>).

- **Clinical and Engineering Requirements for Safe Medical Device Interoperability.** We have begun implementing Serena RM, a commercially available requirements management database designed to support collaboration, and using it collect the requirements we have developed under our NIH grant – including generic ICE requirements and PCA Safety clinical requirements and associated attributes, along with collaborator comments. Using Serena, we have presented requirements to AAMI/UL JC2800 to establish the scope of the exemplar used for AAMI/UL JC2800, based on our design documentation (requirements and hazard identification). We have continued to develop our implementation of Serena RM to support our work and that of the AAMI/UL JC2800 committee by contributing standardization artifacts, such as clinical requirements and safety algorithms. The implementation of requirements in Serena is very powerful and enables a pathway of “open sourcing” requirements for use by the extended community of researchers and manufacturers – an exciting enabler of innovation.
- **Regulatory Science for Safe Medical Device Interoperability.** The MD PnP program has from its inception worked closely with the U.S. FDA to identify a regulatory pathway that will support the MD PnP concept – one which will not require re-validation or re-clearance of an entire networked system as each new independently validated device is added to the medical network. Over the past seven years we have studied and elaborated the issues and solutions surfaced by medical device interoperability stakeholders. An important step towards FDA buy-in was the three-day workshop on medical device interoperability planned by the MD PnP program in conjunction with the Continua Health Alliance and the FDA and held at the FDA in January 2010. This workshop brought together over 200 participants from stakeholder communities to explore the issues and roadmap potential solutions ([http://mdpnp.org/FDA\\_Workshop.html](http://mdpnp.org/FDA_Workshop.html)).

As follow-up to the workshop, a working group comprised of companies, standards organizations, clinical and legal participants, and the FDA has met weekly to work on the development of a prototype regulatory submission of an interoperable medical device system. This group handed off its work products to the FDA in Spring 2011, for further internal development at FDA, and has continued to meet under Dr. Goldman’s leadership as the Medical Device Interoperability Safety (MDIS) working group. The MDIS further developed these concepts and completed a pre-IDE document, followed by a supplement based on FDA response, submitted to the agency in the past year. It is now well document that the FDA is supportive of the component-level testing approach (rather than pair-wise) for interoperability, which will ensure safety and appropriate risk mitigation through architecture and system design.

- **MD PnP Lab at Massachusetts General Hospital.** The MD PnP Interoperability Lab opened in May 2006 to provide a vendor-neutral “sandbox” to evaluate the ability of candidate interoperability solutions to solve clinical problems, to model clinical use cases (in a simulation environment), to develop and test related network safety and security systems, and to support interoperability and standards conformance testing. The Lab has been used by our university collaborators to further develop demonstrations of interoperability-based patient safety improvements (improving the safety and quality of portable x-rays and of patient-controlled analgesia systems that are used for pain

management). We have ongoing work in the Lab on our NIH project as well as collaborative work with NIST, Intel, and others. We hold regular open house demonstrations to share our work with interested parties. The lab has hosted inter-institutional 'hackathons' for groups such as the SmartAmerica Closed-Loop Healthcare Group, and visiting scholars from various institutions.

- **Relationships with federal agencies.** This year, the MD PnP program took on a team leadership role in the new Presidential Innovation Fellows' SmartAmerica Challenge initiative, where Dr. Goldman gave a presentation on the White House Stage. Our work there sparked further interest in Washington, leading to invited participation in a congressional briefing on medical device interoperability and safe integration this past July. We have continued to work collaboratively with NIST, the FDA, NSF, the Office of the National Coordinator for Health IT, and the Office of Science & Technology Policy (OSTP) at the White House, and Dr. Goldman serves on the FDA Safety Innovation Act (FDASIA) Workgroup of the Health IT Policy Committee (HITPC), and the FCC's Consumer Advisory Committee (CAC) under the Federal Advisory Committee Act (FACA). Under FDASIA, he serves as co-chair on the Regulations Subcommittee and provides expert input on issues and concepts identified by the FDA, ONC, and the FCC to inform the development of a report on an appropriate, risk-based regulatory framework pertaining to health information technology including mobile medical applications that promotes innovation, protects patient safety, and avoids regulatory duplication. As a voting member representing Partners Healthcare on the FCC CAC, he helps to facilitate the participation of consumers in the regulatory process, ensuring that all Americans have access to modern communications services.

In addition to the specific achievements above, the MD PnP program has continued to gain increasing traction through our collaborative relationships. The web of connections among people in our community of interest continues to generate new connections to supportive individuals in government agencies, healthcare institutions, and other organizations who are helping to further the aims of the program.

## **Reportable Outcomes**

### **200+ Meetings:**

Recurring meetings and demonstrations all year:

- Weekly teleconference calls of the Medical Device Interoperability Safety (MDIS) working group to refine the Pre-IDE submission to FDA
- Regular teleconference calls (weekly starting April) of the AAMI / UL Joint Committee working on the 2800 standard
- 24 MD PnP lab demonstrations for device manufacturers and standards groups
- Regular teleconference calls of the FCC Consumer Advisory Committee
- Regular teleconference calls (starting January) of the SmartAmerica Challenge working group on "Closed Loop Solutions"
- Regular teleconference calls (weekly starting April) of the AAMI / UL Joint Committee working on the 2800 standard

Quarter 1, September 21 2013 – December 20 2013:

- Hosted series of Open Houses in MD PnP Interoperability Lab, Cambridge, MA

- Face-to-face meetings of Open Health Tools (OHT) and the OHT Board of Directors, hosted by MD PnP in Cambridge, MA
- Week-long meeting of ISO TC121 SC2 Standards Committee for Airways and Related Equipment, hosted by MD PnP in Cambridge, MA
- AAMI Standards Week, Las Vegas, NV
- Teleconference meeting of DICOM Standards Development Workgroup, WG-24-Surgery
- FCC Town Hall at mHealth Summit, Washington, DC
- White House SmartAmerica Challenge meeting, Washington, DC
- Plenary meeting of the FCC Consumer Advisory Committee, Washington, DC
- Teleconference meeting of the HTSI Alarm Steering Committee

Quarter 2, December 21 2013 – March 20 2014:

- Smart Monitoring meeting, San Francisco, CA
- Sentinel Initiative Public Workshop, Washington, DC
- Meeting of US TAG for TC121 and ASTM F29 Standards Committees, Cambridge, MA
- Meeting with group at NIH Clinical Center, to further adoption of our work, Bethesda, MD
- 2<sup>nd</sup> White House SmartAmerica Challenge meeting, at NIST, Washington, DC
- MD PnP demo in ONC area of Interoperability Showcase at HIMSS14, Orlando, FL
- Joint Committee AAMI/UL2800 Web/Teleconference Meeting, Standard for Medical Device Interoperability
- Meeting with UL regarding test bed capabilities of MD PnP Lab, Cambridge, MA
- Collaborative demo development by SmartAmerica working group on “Closed Loop Solutions” in MD PnP Lab, Cambridge, MA

Quarter 3, March 21 2014 – June 20 2014:

- NSF Workshop on CPS Reference Architectures, Washington, DC
- AAMI meeting on standards, Washington, DC
- Meeting on EHR & medical device integration for the VA & DoD, Washington, DC
- FCC Consumer Advisory Committee meeting, Washington, DC
- Telcons and a one-day web-based meeting of the standards committee working on US TAG ISO TC 121 on Anesthetic and Respiratory Equipment and the transition of ICE from ASTM to AAMI
- Meetings of the AAMI Alarms Coalition, Washington, DC
- Meetings of the UL Health Council, Chicago, IL
- AAMI Standards Week meetings, Philadelphia, PA
- Technology demonstrations at SmartAmerica Expo in Washington, DC
- Dr. Goldman chaired 43rd Plenary Meeting of ISO/TC121 and Subgroups, Incheon, Republic of Korea

Quarter 4, June 21 2014 – September 20 2014

- Meeting with the Open Group, Boston, MA
- Meeting with IDL, Inc. medical device company, Cambridge, MA
- Meeting of the FCC Consumer Advisory Committee, Washington, DC
- Meeting of the US TAG ISO TC 121 on Anesthetic and Respiratory Equipment and the transition of ICE from ASTM to AAMI, Washington, DC
- Meeting with ViTel Net, telemedicine company, Cambridge, MA to collaborate on ICE-based data access solutions for an App Challenge
- Panel at Military Health Smart Monitoring 2014, Fort Lauderdale, FL.

- Anesthesia Patient Safety Foundation (APSF) Consensus Conference: Patient Safety and the Perioperative Surgical Home, Phoenix, AZ

### **34 Presentations on Medical Device Interoperability Topics:**

Dr. Goldman delivered invited presentations on topics related to medical device interoperability for improving patient safety and healthcare efficiency to the following groups during the past year:

Quarter 1, September 21 2013 – December 20 2013:

- Plenary lecture at American Society of Anesthesiologists (ASA) Annual Meeting, San Francisco, CA
- MD PnP Research updates at annual ASA meeting to Scientific & Educational Exhibits Committee; Committee on Technology; Equipment, Monitoring & Engineering Technology Committee; Equipment & Facilities Committee; and Electronic Media & Information Technology Committee, San Francisco, CA
- “CPS Testbeds: Medical Devices.” Lecture at Cyber-Physical Systems Pls meeting, Washington, DC
- “The SHARP Program and the Next Generation of Health Information Technology.” Plenary panel with SHARP grantees at American Medical Informatics Association (AMIA) Meeting, Washington, DC
- “The Regulatory Future for Health IT, Mobile Applications, and Interoperability,” “Introduction to an Open-Source Integrated Clinical (ICE) Environment Platform,” and “Interoperability Standards: How Far Can They Take Us?” Keynotes and plenary panels at Medical Device Connectivity Conference, Herndon, VA
- “MD Plug-and-Play Lab.” Lecture at Mass General Hospital NeuroICU Conference
- Research presentation at the White House SmartAmerica Challenge meeting, Washington, DC
- “QR Code Demonstration for Anesthesia Professionals and the Use of Advanced Medical Technologies: Recommendations for Education, Training, and Documentation.” Lecture and technology demonstration at the Anesthesia Patient Safety Foundation (APSF) and the Committee on Technology Meeting, New York, NY

Quarter 2, December 21 2013 – March 20 2014:

- “Interoperability: A Cornerstone of Systems Integration.” Lecture at panel on “Improving the Safety & Quality of Patient Care by Systems Engineering” at the Society for Critical Care Medicine meeting, San Francisco, CA
- “A New, Open, Interoperable Medical Device Clinical Research Platform,” and “Medical Device Interoperability – Are We Approaching the Tipping Point?” Presentations at workshop on OpenICE Research Platform and poster sessions on Clinical Scenario Repository and ICE standard at annual meeting of Society for Technology in Anesthesia, Orlando, FL
- Research presentation at NSF Workshop on Medical CPS, Washington, DC
- Lecture at Draeger Medical regarding adoption, Andover, MA
- “Safe Interoperability: What are the Challenges?” Lecture at Interoperability Showcase at HIMSS14, Orlando, FL
- “Real-Time Blue Button™ for Patients & Families.” Technology Demonstration in ONC area of Interoperability Showcase at HIMSS14, Orlando, FL.

- Lecture on OpenICE at meeting of the Electronic Media Information Technology Committee of the American Society of Anesthesiologists, Chicago, IL
- Data logger poster presentation at NIST Data Science Symposium 2014, Washington, DC
- Lecture at VA meeting on time-stamping and time synchronization of medical devices, Washington, DC

Quarter 3, March 21 2014 – June 20 2014:

- “Enabling Innovation Through Medical Device Interoperability: from architecture to analytics.” Lecture at the Children’s Hospital of Philadelphia, April 1 2014, Philadelphia, PA.
- “Towards Better Critical Care: From data to information to decision to action” Lecture at Society of Critical Care Medicine Research Summit, April 10 2014, Emory Conference Center, Atlanta, GA.
- “Conformity assessment – Role in assuring safety and innovation.” Panel at NIST/FDASIA Public Workshop: Proposed Risk-Based Regulatory Framework and Strategy for Health Information Technology May 14 2014, Washington, DC.
- “Standards and Interoperability.” Panel at NIST/FDASIA Public Workshop: Proposed Risk-Based Regulatory Framework and Strategy for Health Information Technology May 14 2014, Washington, DC.
- “Health IT Safety Center.” Panel at NIST/FDASIA Public Workshop: Proposed Risk-Based Regulatory Framework and Strategy for Health Information Technology May 15 2014, Washington, DC.
- “Closed-Loop Healthcare: From Home to Hospital to Home.” Lecture and technology demonstrations at White House SmartAmerica Expo, June 10-11 2014, Washington, DC.

Quarter 4, June 21 2014 – September 20 2014:

- “Medical Device Interoperability and Safe Medical Integration.” Congressional briefing at U.S. Congress, Washington, DC.
- MD PnP Research Demonstrations at Lab Open House, Cambridge MA.
- “Setting the Stage for the Next Generation of Clinical Care Through the Procurement of Interoperable Medical Devices and Health IT Systems.” Keynote at Association for Healthcare Resource & Materials Management (AHRMM) Annual Conference, Orlando, FL.
- “Interoperability,” Panel at Military Health Smart Monitoring 2014, Fort Lauderdale, FL.
- “Web-Based Clinical Scenario Repository (CSR™).” Poster Presentation at Military Health System Research Symposium (MHSRS), Fort Lauderdale, FL.
- “Health Cyber-Physical Systems: Present Status and Future Directions, Parts I and II.” Panels at 36<sup>th</sup> Annual International Conference of the IEEE Engineering in Medicine and Biology Society, Chicago, IL.
- “Challenges: The Digital Health Platform (System of Systems).” Panel moderator at the National Academies’ Innovation Policy Forum Workshop on Medical Devices Innovation: Opportunities, Threats, and Challenges, Washington, DC.
- “IoT Activities and IEEE Standards.” Panel at IEEE Standards Association Internet of Things (IoT) Workshop 2014, Mountain View, CA.

Engineers from the MD PnP research team delivered the following presentation on medical device interoperability topics during the past year:

- Lecture by Dave Arney at CERIST International Autumn School on Cyber-Physical Systems, Algiers, Algeria
- Technology presentation by Dave Arney and Jeff Plourde at the FCC mHealth Innovation Summit, Washington, DC
- Presentations by Dave Arney and Jeff Plourde at workshop on OpenICE Research Platform and poster sessions on Clinical Scenario Repository and ICE standard at annual meeting of Society for Technology in Anesthesia, Orlando, FL
- “Web-Based Clinical Scenario Repository to Improve Patient Safety” Poster presentation by Diego Alonso at Mass General Hospital Scientific Advisory Council poster sessions, Boston, MA.
- “OpenICE: An Open, Interoperable Platform for Medical Cyber-Physical Systems.” Poster and talk by Dave Arney and Jeff Plourde at the International Conference on Cyber-Physical Systems (ICCPS), Berlin, Germany.
- “Potential Advantages of Applying Assurance Case Modeling to Requirements Engineering for Interoperable Medical Device Systems.” Poster presentation by Dave Arney and Jeff Plourde at Medical CPS Workshop, Berlin, Germany.
- “Design Pillars for Medical Cyber-Physical System Middleware.” Lecture by Dave Arney and Jeff Plourde at Medical CPS Workshop, Berlin, Germany.
- “OpenICE: An Open, Interoperable Medical Device Integration Platform for Clinical, Engineering, and Technology Research, and App Deployment.” Poster Presentation by Jeff Plourde at Military Health System Research Symposium (MHSRS), Fort Lauderdale, FL.

#### Web Site:

- [www.mdppnp.org](http://www.mdppnp.org) is maintained as a major communication vehicle for the program and had a major redesign this past year – provides access to ICE standard, MD FIRE contracting language, publications, posters, links to streaming video of talks from plenary meetings and from the FDA Workshop, and downloads of sharable documents and code – receives about 1,000 visits per week

#### Manuscripts/Publications:

- Draft report from UL of the UL “STPA/STAMP” hazard analysis
- Food and Drug Administration Safety Innovation Act (FDASIA) Workgroup. FDASIA Health IT Report: Proposed Strategy and Recommendations for a Risk-Based Framework. Published April 2014. [Contributions by Dr. Goldman as part of Workgroup] Available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM391521.pdf>
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Funding Applications Facilitated by this BAA to Date (total costs shown):

- Funded: CIMIT: \$51K for FY10 program leader support
- Funded: CIMIT: \$51K for FY11 program leader support
- Funded: CIMIT: \$98K for FY11 support for development of a pre-clinical PCA closed-loop control application
- Funded: CIMIT: \$98K for FY11 support for interoperability of portable x-ray devices with ventilators in an ICU at a VA hospital (collaboration with VA Boston)
- Funded: CIMIT: \$98K for FY11 support for development of a clinical algorithm-driven interoperable smart ventilator (collaboration with Boston University)
- Funded: CIMIT: \$98K for FY12 support for prototype demonstration of veterans health data exchange between 3 EHR systems (collaboration with VA HITIDE, TATRC, and NwHIN)
- Funded: CIMIT/DoD: \$815K for building “Warfighter OpenICE”
- Funded: TATRC: \$70K for MD PnP subcontract on Moberg Research SBIR Phase II award
- Funded: TATRC: \$100K for MD PnP subcontract on DocBox Inc. award
- Funded: TATRC: \$785K contract for enabling medical device interoperability for the Integrated Clinical Environment
- Funded: NIST: \$100K for evaluation of ICE functional requirements for medical device interoperability (standards gap analysis)
- Funded: NSF: \$620K for MGH subcontract on University of Pennsylvania 5-year award for assuring safety, security, and reliability of medical device systems
- Funded: NSF: \$500K for MD PnP subcontract on University of Massachusetts CPS collaborative research award
- Funded: NSF: \$49K conference grant for CPS Workshop Planning Meeting
- Funded: NIH/NIBIB: \$9.9M for 5-year development of prototype healthcare intranet, an open ICE platform
- Not Funded: Office of Naval Research: \$11.6M for 5-year development of prototype acute critical care system of integrated medical devices for safer, monitored transport of wounded warriors from battlefield to care facility

Other: In-kind engineering support and/or contribution of equipment for the lab from Draeger Medical, Philips Healthcare, FDA, Draper Laboratory, Kaiser Permanente, University of Pennsylvania, LiveData Inc., and DocBox Inc. (valued at approximately \$500,000 to date).

## Conclusions

As with prior TATRC BAA support, this BAA has provided core program support that enables the Medical Device “Plug-and-Play” (MD PnP) Interoperability Program to provide important clinically focused leadership of the growing move towards open standards and related technologies for networking medical devices to support clinical solutions for improving patient safety and healthcare efficiency. The majority of this BAA has been used for core personnel salary support, which provides the foundation to identify and access other available resources, to lead relevant standards work, and to build collaborations to achieve device interoperability objectives. These collaborations include activities and relationships with federal agencies and the White House; clinical, engineering, and IT societies; clinicians in the US, Canada, Europe, and Japan; and integrated healthcare delivery organizations like Kaiser Permanente, Johns Hopkins, Partners HealthCare, and the Veterans Health Administration.

Although we have been successful in past years in attracting funding from several federal agencies (NIH, NSF, NIST), as well as CIMIT, all of this funding is project-specific and does not support the standards work, convening, and program infrastructure that the TATRC funding has so greatly enhanced.

Notable achievements enabled or facilitated by this TATRC support include:

- We led the development of an international standard for the Integrated Clinical Environment (ICE) and saw it through to adoption and publication by ASTM International;
- Three major healthcare delivery systems collaborated on shared interoperability contracting language under MD PnP program leadership, and a second iteration of this language was signed this year by the VA;
- Sixteen medical societies (including the AMA) have endorsed the need for medical device interoperability;
- Strong collaborations have been established with the VA and with federal agencies, including the Office of the National Coordinator for Health IT and the White House, putting medical device interoperability on the national healthcare agenda;
- The FDA held a jointly sponsored Workshop on Medical Device Interoperability, worked with an MD PnP/industry working group on defining components of a prototype regulatory submission of a system of integrated medical devices, and is reviewing the pre-IDE produced by that working group.

These activities are highly interdependent and synergistic, and TATRC support has been instrumental in providing the “program glue” to effectively leverage these synergies to realize our mutual program objectives.

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**Other relevant documents are linked to from the text of the report.**