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ACTION ON INTEROPERABILITY OF MEDICAL DEVICES, DATA, AND PLATFORMS TO ENHANCE PATIENT CARE

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RFI Response: Action on Interoperability of Medical Devices, Data, and Platforms To Enhance Patient Care

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Purpose: There is ongoing recognition that medical device interoperability is an issue and has a documented impact on patient care and safety. These issues persist despite previous government efforts by the Food and Drug Administration, the Department of Defense, the Veterans Administration, the National Institute of Standards and Technology, the National Institutes of Health, and the National Science Foundation. The goal of this effort is to determine whether a vision of sustained interoperability in the hospital and into the community is feasible and, if so, what it will take to realize it. In addition, this RFI looks to examine how users might leverage the existing tools and processes for implementing this shared future vision.

Executive Summary

The goal is simple: deliver a fully automated digital health solution that will dramatically improve patient care and drive down costs. Achieving that goal requires adding connectivity to clinical-grade medical devices inside and outside the hospital, layering on analytics or artificial intelligence (AI) for clinical-decision support, then topping it off with application software that automatically implements those decisions. Since the early 2000s, healthcare professionals and system developers have shared this vision for a modern, highly efficient, cost-effective and life-saving digital health structure. However, while the concept seems easy enough, executing on it is extremely challenging.

The Industrial Internet of Things (IIoT) presents an opportunity to bring the concept of a fully automated digital health system to fruition. The IIoT has the potential to transform the healthcare industry in the same way that the consumer-focused IoT is already revolutionizing the retail, music, publishing and transportation markets. But to take full advantage of the IIoT for healthcare/medical applications, developers must meet the industry's particularly rigorous requirements for connectivity, interoperability, real-time communications and analysis, and security.

The most significant of these challenges is interoperability, the ability to share information across multiple technologies, from medical devices at the point of care, to EHR's, and throughout the entire healthcare ecosystem. This level of syntactic and semantic interoperability across technologies is essential to realizing the benefits of a connected healthcare system. Interoperability in healthcare has the ability to save more than $30B in cost due to inefficiencies and has the ability to reduce the number of preventable medical errors which has risen to >400k per year. (West Health and Journal of Patient Safety[1])

There are a variety of factors that have contributed to this lack of interoperability: misaligned incentives, proprietary equipment and solutions, and most importantly the limited adoption of modern standards based technology. We believe that taking a standards based approach to develop an healthcare IIoT platform, or Integrated Clinical Environment (ICE), will provide a foundation from which all devices, applications, and systems are able to interoperate, leading to a reduction in preventable medical errors, improved patient care, and overall lower healthcare system costs.

In response to this request we will discuss the approach and work of Real-Time Innovations, the ICE Alliance, and the Industrial Internet Consortia (IIC) to drive interoperability within the healthcare ecosystem through the adoption of modern, standards based, data-centric technologies. Following this, we provide RTI's answers to the RFI Questions, provide references, and finally provide some background about RTI.

RTI's Integrated Clinical Environment (ICE) Vision

Healthcare IIoT customers are focused on creating a network of physical healthcare devices embedded with electronics, software, sensors and network connectivity, which enables these devices/objects to collect and exchange data, and provide valuable insights via AI. Their impact on medicine will be perhaps the most important, and personal of the "digital revolution". By 2020, it is estimated that 40% of IoT-related technology will be health-related.

The fundamental goal of ICE is to interconnect medical devices into a distributed smart system. As an integrated environment, devices will cooperate to better analyze patient status, accurately record and thus improve medical practice, and make clinical

[1] https://www.informationweek.com/interoperability/medical-device-ehr-integration-could-save-$30b-study/d/d-id/1109208

https://www.hospitalsafetygrade.org/newsroom/display/hospitalerrors-thirdleading-causeofdeathinus-improvementstooslow

environments safer for patients. The medicine is compelling; this could be the most important revolution in patient care of the 21st century.

However, realizing this vision requires more than medicine. It requires reliable, scalable, interoperable technology that can connect varied vendor products, implement advanced algorithms and analytics, and execute in the complex hospital IT environment. Most importantly, it will require broad support and cooperation in an industry accustomed to a strictly-proprietary culture.

The Industrial Internet of Things (IIoT) offers a chance to change this culture. The Internet of Things (IoT) is the term used to describe the next wave of network connectivity, and thus the most important economic trend of our time. Connected consumer devices, like smart thermostats and wearable devices, will change daily life. However, the advent of the Industrial Internet of Things (IIoT) is much more economically profound. According to the 2015 World Economic Forum report, the IIoT will impact two thirds of the world's economy in essentially every industry. We are truly on the cusp of a third industrial revolution.

The ICE Alliance is an organization of the world's leading medical professionals and companies. It is not a standards organization; rather its goal is to recommend architectural guidelines and standards to hospitals and device manufacturers.

The Industrial Internet Consortium (IIC) is "ground zero" of the IIoT. Global industrial leaders founded the IIC: GE, Intel, Cisco, AT&T, and IBM. In less than a year, the IIC exploded; it now includes over 150 members (iiconsortium.org). The IIC has the full attention of the highest levels of government and worldwide industry. No organization on the planet approaches its respect or potential to drive the next industrial revolution.

Similar to the ICE Alliance, the IIC's goal is to recommend architecture and standards for the development of an interconnected future. However, the IIC targets a much broader range of industries and an architecture that can span those industries. Common architecture is the enabler of the IIoT. Immediately, it enables a practical connection between operational systems and cloud analytics. Longer term, it enables connection between applications, between vendors, and between industries. In the medical industry, for instance, such an architecture would enable a third-party market for software and mobile phone apps that can access patient data and connects care teams. Long term, it could connect home healthcare with emergency response, speed ambulance transport through traffic flow control, and help ambulance personnel communicate with care teams to prepare the hospital reception.

Together, the IIC and ICE can deliver this interoperable, practical, revolutionary technical and business vision.

On the technical front, the IIC will develop generic architectural, security, and implementation guidelines. The ICE alliance will build on the IIC architecture to solve the targeted medical-device connectivity problem. This includes device and physiological model definition, nomenclature, "quality of service" requirements, and clinical supervisory services. The resulting design will address the immediate clinical challenge in an ICU. It will also address the practical issues of integrating that ICU into the larger hospital IT systems. It will enable the promise of cloud-based analytics to optimize care and device maintenance. And, it will pave the way to the future power of the IIoT to connect disparate applications.

On the business front, the ICE Alliance message of safety and cross-vendor interoperability appeals strongly to the government and hospital buyers. Progressive vendors, too, may see the value of the medical and technical support and decide to compete in a more ICE-compliant open environment. However, the proposed ICE-IIC alliance will combine the ICE design with the IIC's impressive collective strength in technology vendors, large and small, governmental support, and systems engineering research.

The very premise of the IIoT is broad-scale interoperability. Thus, the IIC also brings together focused industry and governmental cover to press interoperation. For instance, an IIC "approved" testbed based on the ICE framework would be strongly indicative of market direction for many vendors. The IIC's IIoT market pull will encourage, support, and de-risk the business-model change for medical vendors.

Thus, the ICE Alliance's medical expertise, combined with the IIC's business and technology leadership, can greatly accelerate transition to open architecture. This liaison has potential to transform the medical landscape. Together, these organizations address the most critical technical and business barriers. Together, we can improve patient outcome at lower cost.

The ICE business value proposition (besides saving lives) is to enable vendor interoperability. While that's obviously of huge benefit to the "customer" (hospitals and government), it directly threatens the current business structure of the big medical device manufacturers. Today, their businesses are structured around the objective of landing exclusive relationships with hospital chains. Their sales model is to compete

only once for each chain, and thereafter to rely on the lack of interoperability to hold an essentially captive audience.

This restricted competition, on the surface, is in their interest. While the initial high-stakes competition is expensive, sales costs are lower for subsequent business.

However, we have seen this movie before in many contexts; the first was the "Navy Open Architecture" (NavyOA) initiative. In the Navy, the big prime contractors like Lockheed and Northrop were loath to adopt standards that would break their stovepipes; they liked competing for entire ship systems. All their bidding process, team strategy, and even sales compensation plans depended on this model. Breaking ships into independently-competed units was hugely threatening. The NavyOA program battle raged for years, with the DDS standard at its core. Eventually, a few players who were not dominant and therefore willing to sacrifice stovepipes to seek market share helped the market turn. Navy OA is now the mantra for all new projects. Adopted DoD-wide as Open Systems Architecture, the DoD now claims that 75% of all programs are open[1].

RTI is a real veteran of this, and other similar fights in avionics, vehicle architecture, consumer electronics, power grids, manufacturing, and more. Our lessons:

a) System interoperability is about the data. In particular, the system must understand and control interfaces and quality of service (the "data model") for each data flow. Overall, the system must establish a common data model. This is the key technical barrier.

b) Adopting *data centricity* is key to exposing those concepts, but it is a necessary-but-not-sufficient step. Even if the business value is compelling, changing established products to a new data model is expensive and risky. It is much easier to adopt the data-centric principles (notably DDS) than it is to adopt an external data model.

   Data centricity is when data is a first-class citizen on the network – it's a migration away from treating data as opaque network payloads. By precisely defining, declaring, *and enforcing/validating* the structure of the data that is flowing over the network, we inherently facilitate interoperability.

c) Ownership of the data model is hugely significant. It is the essence of openness.

d) Ownership of the source code IP is insignificant. In fact, *the sole imperative to control software costs is to establish a stable team working on a single code base*. This is obvious to any software manager, but ignored by payer after payer. One consequence: expecting a community-led open-source development strategy to work is naïve. Open source works only for very established code bases that can evolve slowly and with markets large enough to afford split "distributions". Prematurely forcing IP capture or open source sucks the money out of the software business, cutting investment and eventually dooming the code base. Surprisingly, it's more cost effective to have many stable teams each with its own code base than it is to have a "free" common code base. Open standards that enable competition are critical. Open source is a primrose path to doom.

e) The payers have business motivation for an open data model. But, when the vendors own success, *the payers lose*. An open architecture makes the ecosystem more competitive and efficient. It eventually floats all boats, but that is not obvious to incumbent market-share leaders. <u>This is the key business barrier</u>.

f) The brute-force approaches: dictating an architecture, or forcing a data model, or trying to build a complex "semantic" data model, may eventually work, but they at best result in a decades-long fight.

We propose that the ICE and IIC together consider a different approach. Rather than try to force vendor cooperation on an interoperable data model, we will request only sufficient openness to join into a common data model on a core databus. Each vendor will not have to face the difficult prospect of adopting an alien data model for its product lines. Instead, we will leverage adaptation technology. The vendor data models only need to be exposed to the extent required by the core ICE services. In fact, it may not even require vendors to expose their data models at all; they need only maintain their own adapters.

This approach, in fact, already underlies the current CIMIT lab implementation (https://cimit.org/). CIMIT installed small, smart translator modules (on BeagleBone boards) for each device. Those translators connected to each device's maintenance port to access data. They then normalized the data to ICE's 11073-based model and exported it over the DDS bus. This has the advantage of backwards compatibility, but the big disadvantages include: 1) difficulty in getting the right data, 2) dealing with many different devices, and 3) possibly tracking changing maintenance-port interfaces. It is hard to see this as a long-term strategy to enable (or force) compliance, although it is the easiest immediate path.

We suggest replacing the process of accessing maintenance port interfaces with a requirement for vendors to offer minimum device openness via any convenient transport. To be ICE compliant, each vendor would only have to offer some sort of intentional access to data. The standard would require open data exchange, rather than requiring any particular format. In fact, if each vendor is able to install DDS-based data-model adaptation technology on their devices, they may not have to expose their internal models at all. Alternatively, third parties like DocBox (www.DocBoxInc.com) could provide off-device adaptation.

The standard must still specify a "core" data model. This approach will decouple it from the vendor products. Long term, there is an advantage to vendors who can natively adopt the standard core data model. But, that process can take decades while saving lives and lowering costs *today*.

If this approach works, it will minimize disruption to each device-vendor's product architecture. Conversely, it will speed disruption to the device-vendor business model. That threat will create a barrier to adoption.

However, even to incumbent device vendors, that threat is nothing compared to the huge benefit of opening the entire industry to a common data model and a common architecture. The common architecture extends beyond the ICU and the clinical environment. The common architecture will enable much simpler hospital IT integration. With a common architecture, a new class of cloud-based applications can access the data, and use it to optimize workflow, predict maintenance issues, and even change billing models. Enabled by access to information, new generations of applications will track patients, integrate patient data with EHRs, and coordinate care teams. Long term, it can even enable the IIoT vision of integrating healthcare into other industries.

The technology is available to drive this change. The team is here to drive this change. The time is now to drive this change. Let's work together to drive medical practice into the 21st century.

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[1] http://www.defense.gov/news/newsarticle.aspx?id=123565

RTI's Answers to the Specific Questions

(1) What is your vision for addressing interoperability issues between medical devices, data, and platforms? How would this plan to create interoperable systems address your key use cases and pain points?

The future of the healthcare industry is connected. Systems of interoperable medical devices communicating seamlessly and securely have the opportunity to improve patient outcomes, reduce medical errors and lower the cost to our healthcare system. To realize its full potential, the healthcare industry will need to transport and analyze unprecedented amounts of data in real time. RTI believes that to make that vision a reality is through enabling the development of data-aware products and systems based on standards-based *data centric* connectivity technology.

For a connectivity standard to be viable, it must be considered medical grade and satisfy the following requirements: enable true plug and play interoperability, maintain 100% reliability, meet the security requirements as defined by the FDA, provide secure and seamless data flows, provide interfaces to external systems, provide interfaces to legacy systems, support all healthcare/medical related data types, provide the ability to scale to millions of nodes, be completely open and vendor neutral, and provide a future proof architecture that can be used in on-prem or cloud-based systems today, and near patient distributed edge computing based systems in the future.

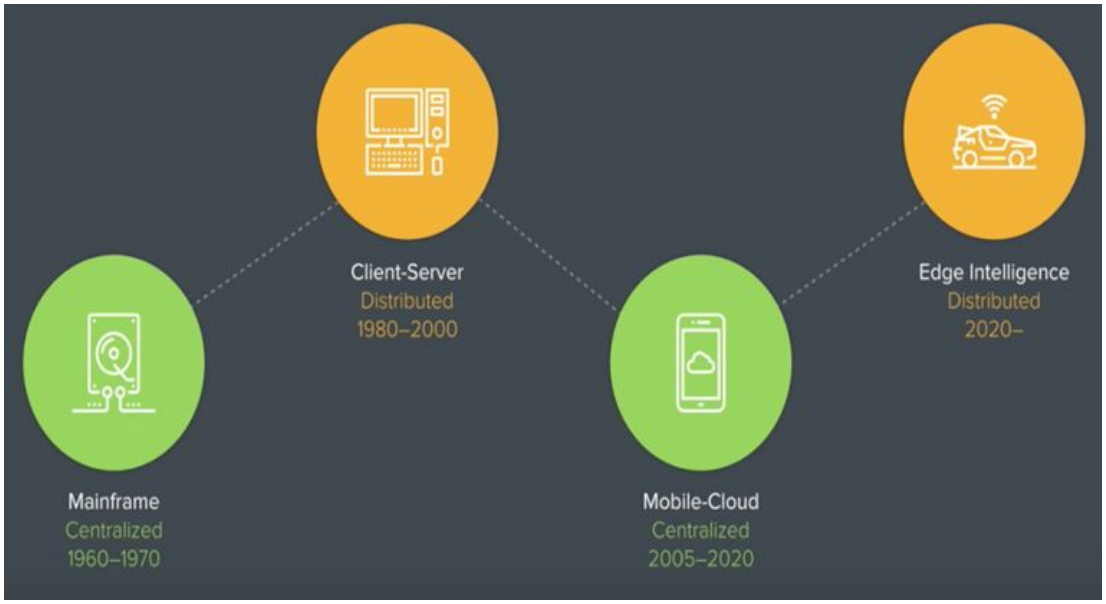

Figure 1: Timing of Distributed Edge Computing Solutions

OMG's Data Distribution Service (DDS) standard is the only standards based technology that can meet ALL of these requirements which is why we believe it provides a foundational element to the developers of a connected healthcare platform. DDS technology is what allows all of the connected components of an IIoT system to work as a single integrated solution. It enables sharing real-time (<ms and deterministic) data reliably, securely, and in a syntactically interoperable format. A DDS-based solution, paired with a complete, comprehensive, and widely adopted data model provides the interoperability needed to develop a near patient real-time connected health platform consisting of medical devices regardless of vendor. Below is a graphic developed by the Center for Medical Interoperability modified to show the notional placement of DDS as the standards-based connectivity architecture.

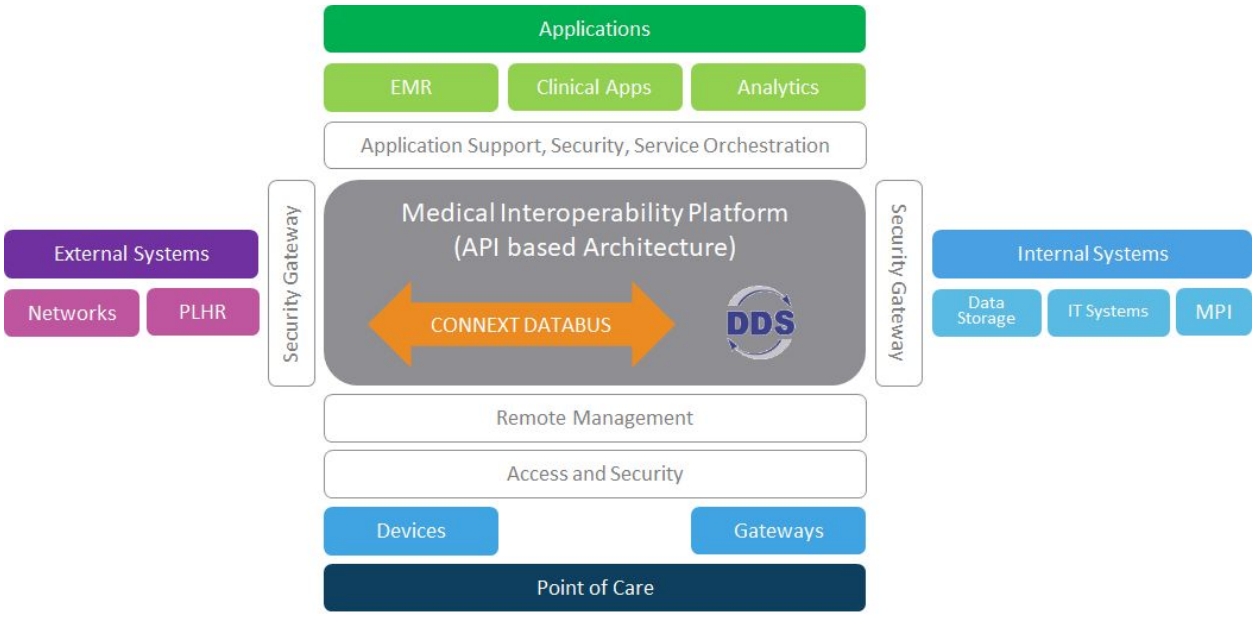

Figure 2: Medical Interoperability Vision containing OMG's Data Distribution Service (DDS)

The DDS open standard implements a shared databus that is language, device and transport independent. It understands data types and communicates them to all participants. The technology scales across millions of data paths, enforces millisecond timing, ensures reliability, supports redundancy and selectively filters information. Each path can be unicast, multicast, open data or fully secure. DDS was designed from the ground up to provide syntactic interoperability between single-vendor devices as well as across devices from multiple vendors.

In order to make this vision a reality, a data centric standards based technology is the first component to achieving the goal of interoperability.

The second component that is required is a complete, comprehensive, and widely adopted data model. This is an area where government intervention could help speed up the process for widespread interoperability and open the door to innovation throughout the ecosystem, by defining and requiring the use of a single complete and comprehensive data model.

However, a more realistic/pragmatic view would be that healthcare will follow the lead of many other commercial industries – where, over time, platforms and ecosystems develop and evolve around a specific data model. A market that starts out with 100's of platforms over time consolidates down to less than 5, generally owned by the largest players in their respective industries. We see this as being a much longer path, but a more likely scenario for achieving interoperability in healthcare. With this scenario you never truly achieve plug and play interoperability, but you would have a scenario like you have today in mobile phones with Apple and Android.

The road to achieving a truly interoperable healthcare system is not going to be easy, but by looking at other industries and available technology, we can do far better than we have been so far. Putting a plan in place that focuses on the adoption of open, data centric, standards based connectivity technology (like DDS) will put us on a path to success. The timing of that success will then be dictated by the adoption of data models, which could take many years depending on the approach taken.

(2) Who are the relevant parties and their contributions to your interoperability solution?

In order to make the vision we have outlined come true we need the support of key standards organizations and other influential groups throughout the healthcare ecosystem. We have listed each of these groups, why they are relevant and how they contribute to the mission of providing interoperable healthcare.

- Influencers
    - Standards Organizations (CMI, AAMI, IEEE, etc.)
        - **We believe that a single standards organization working in the best interest of the industry is exceptionally important**. We are now working with a variety of standards organizations, none of which we believe have the power to influence the entire market. But it is important that we evangelize to each and all organizations working on the challenge of interoperability that the technology is available to begin driving towards an interoperable future today.
    - Providers (VA, Kaiser, HCA, Ascension, etc)
        - We are working with a number for provider organizations to educate them on the power of data centric standards based technology. We work with them hoping they will influence the device manufacturers, EHR vendors, and others in the ecosystem to embrace data centric standards based technology.
- Interoperability Platform Providers
    - EHR Vendors (Cerner, Epic, etc)
        - An EHR provider would utilize a standards based approach to develop a near patient real time interoperability platform.
        - We believe the EHR vendors are uniquely positioned as the current data aggregation location.
        - An EHR vendor would adopt a data centric standards based connectivity framework and continue to use its proprietary data model. This would allow them to create a semi-interoperable connected healthcare solution. This solution would still be proprietary, but it would provide each healthcare system the interoperable real-time edge computing system it needs to lower costs.

- Medical Device Vendors (GE Healthcare, Philips Healthcare, etc.)
    - A medical device vendor would utilize a standards based approach to develop a near patient real time interoperability platform.
    - We believe the Medical Device vendors are uniquely positioned in this market as they have existing relationships with providers.
    - They see that interoperable connectivity will commoditize their current capital equipment business, forcing them to begin their development of a near patient real time interoperability platform.
- Medical Device Data Integration Platforms (ex. Capsule, Nant Health, Ellkay, Redox, etc)
    - A medical device data integration platform would utilize a standards based approach to develop a near patient real time interoperability platform.
    - We believe that these companies have a unique opportunity to disrupt the healthcare market by providing healthcare providers an interoperable near patient real time edge computing platform more quickly than the EHR vendors or the medical device companies.
    - These companies already have a history of providing cloud based interoperability solutions, but are much smaller and agile, giving them a time to market advantage over the current large players.
    - Additionally, they don't have the burden of hardware to begin moving to a services company.

(3) What are the challenges and impediments to making interoperability happen? How might these issues be addressed and by whom?

The three biggest challenges we see to achieving the future vision of interoperability in healthcare (as defined in this RFI) are: the lack of standards, technology, the relative position of the medical device and EHR vendors to the providers, and finally the business model of the medical device and EHR vendors.

- Lack of Standards - Single Biggest Impact
    - Minimally, this includes data models & wire protocols. If the industry all implement different wire/networking protocols, then true interoperability would not be achieved. For example, without ubiquitous HTTP adoption, the internet would not function. Because of its critical role, the protocol needs to be robust, scalable, secure, extensible, open, and proven.
    - You cannot align a market without them.
    - Healthcare does not have any standards that are pervasive.
    - Every other mission critical industry solving a problem this complex has used standards.
        - Example: Airlines
- Market Position of the Device Companies vs Providers – and the lack of motivation to adopt standards.
- Business Model
    - The business models of the medical device manufactures and EHR vendors do not incent them to implement interoperable or semi-interoperable (invite only ecosystems) solutions.
    - Because of this, corporate representation (lobbyists) will resist such efforts.

While it will be an uphill battle, the only viable approach is the creation of a single standards body that will work with industry to create a viable solution.

(4) Is the federal vision for a medical device, data, and platform interoperability end state outlined in this RFI viable? Please explain why you have reached the conclusion that you have.

We believe that the federal vision outlined in the RFI is viable (though not without its challenges). Over the past few years, many of the technical challenges that inhibited progress in this space have been removed. The increase in CPU performance and general availability of medical grade off the shelf standards based software has opened the door to the development of open real time edge computing systems. These standards based open platforms provide a foundational capability from which we can build complex distributed systems.

As we have stated many times, the key to success is alignment throughout the healthcare ecosystem, and that comes through the adoption of standards. If you look at any other mission critical industry that has tried to manage this level of complexity, they have all relied on standards. The tools to make this happen are available, the next step is building critical mass around a single set of standards.

Supporting Material and Documents

RTI's Presentation from HIMSS19 - Embracing the IoT: Ideas are Easy, Execution is Hard

Healthcare delivery is in need of a technological transformation. Many of the challenges facing our healthcare system today can be remedied by applying the principles of an IIoT system and combining it with AI and ML, creating a highly reliable automated system for real time decision support. This session will take you on a journey starting with the current state of the IIoT in healthcare and highlighting the gaps that exist. The speakers will paint a futuristic picture of healthcare, utilizing a standards-based, edge-computing IIoT architecture and discuss the benefits and challenges of implementation. Finally, you will be provided with the tools (reference architectures from the IIC and MD PnP) necessary to help the healthcare industry begin developing products and creating an ecosystem for a next-generation of connected healthcare products.

RTI Whitepaper on Healthcare IIoT - A Data-Centric Approach to Developing Digital Health Solutions within the IIoT

"DDS is the only data-centric standard that allows communication directly with the data. The DDS transport and framework standard was architected from the bottom up to address the challenges of interoperability, real-time data transfer/analysis and security unique to industrial grade healthcare applications."

Frost and Sullivan: 2019 Best Practices Award - Industrial Internet of Things Connectivity in Healthcare

Frost & Sullivan believes that RTI's market and technology leadership is a result of aligning its remarkable capabilities and resources to create integrated system solutions. RTI's goal is to provide competitive, tailored solutions that get to the heart of problems and generate sustainable business value for its customers. The company prioritizes mutually beneficial partnerships. For instance, RTI's partnership with GE Healthcare CLEARLY exemplifies this effective cooperation, as GE leverages Connext DDS as a common connectivity platform across many classes of intelligent machines — from simple oximeters to large CT imaging systems. The collaboration enables both performance and functionality, while making GE's connected care vision a reality.

> "GE Healthcare is leveraging the RTI Connext DDS-based architecture to connect medical devices, edge-based analytics as well as mobile and wearable instruments."
>
> — Matt Grubis, Chief Engineer for Mobile Digital Health Solutions, GE Healthcare

This customer-oriented approach adds incredible value to the user's operations and contributes to their effective and sustained success. The company continues its vital growth and heavily invests in research and development to meet emerging demands. With a remarkable can-do attitude, the company faces even the most pressing challenges in the industry when providing custom-tailored solutions built under the highest standards.

Notably, RTI partnered with DocBox, who develops an innovative clinical process management solution for hospitals to help clinicians eliminate medical mistakes and improve overall clinical processes. RTI's Connext DDS supports DocBox with secure, interoperable device connectivity, allowing the point of care consolidation of device alarms, health, and status. Additionally, it enables decision support to utilize data streams from various medical devices.

> "RTI Connext DDS met all our initial needs, and continues to grow with us — whether we're handling expanding amounts of data for 12 patients, or 200."
>
> —Tracy Rausch, DocBox Founder

About Real-Time Innovations, Inc.

Real-Time Innovations (RTI) is the Industrial Internet of Things (IIoT) connectivity company. RTI Connext® databus, our communications framework, is running in numerous critical infrastructure systems around the world. It is a secure, mature, proven technology.

RTI Connext is a software framework that shares information in real time, making applications work together as one, integrated system. It connects across field, fog and cloud. Its reliability, security, performance and scalability are proven in the most demanding industrial systems. Deployed systems include medical devices and imaging; wind, hydro and solar power; autonomous planes, trains and cars; traffic control; Oil and Gas; robotics, ships and defense.

RTI Connext DDS streamlines connectivity across a complex system of systems. Developers can build and link healthcare applications, regardless of architecture or operating system. From surgical robots to medical imaging to connected care, Connext DDS dynamically connects systems and data in real-time.

Committed to open standards, open community source and open architecture, RTI provides the leading implementation of the Object Management Group (OMG) Data Distribution Service (DDS) standard. Our customers are in aerospace and defense, process automation, financial services, energy, automotive, health sciences and transportation. RTI is privately held and headquartered in Sunnyvale, California.

Public-private partnership Interactions

- RTI has been funded by Army Defense Health Agency (JPC-1) to build and mature technology that will provide a robust, secure, scalable, and open standards-based solution for medical device communications. We are completing the third year of funding in March 2019.
- RTI has been working for 4+ years with MDPnP.org to develop and promote the Integrated Clinical Environment standard OpenICE (https://www.openice.info/), and ASTM 2761-09(2013).