WHITEPAPER

How Dataflow is Transforming Connected Medical Devices

EXECUTIVE SUMMARY

For MedTech, the goal is simple: deliver digital health solutions that will dramatically improve patient care and drive down costs. Achieving that goal requires adding connectivity to 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. Healthcare professionals and the MedTech industry share 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 digital disruption in healthcare is underway, and MedTech must pivot to a new era where the Industrial Internet of Things (IIoT) has progressed to the Internet of Medical Things, the Internet of Surgical Things and the Internet of Medical Robotic Things. In this evolving landscape, one core theme persists: Medical Devices must address the challenges of delivering next-generation solutions that rely on increasingly complex, interoperable and secure devices. To remain relevant, MedTech must traverse a platform-shift from designing siloed devices, to architecting intelligent and real-time clinical applications based on software, and leverage the latest data-driven technologies and a connected device ecosystem.

This paper describes how the Real-Time Innovations (RTI) software connectivity framework, based on the Data Distribution Service (DDS™) standard, helps address these challenges, and drives the digital software architectures needed for the development of next-generation connected medical devices and systems. RTI Connext® helps software product teams develop intelligent and real-time medical applications by:

- Providing a real-time, data-connectivity framework that abstracts the software communication infrastructure across devices and networks — enabling software teams to focus on application development instead of middleware
- Providing a fine-grained security framework for data-in-motion to support regulatory requirements and zero-trust architectures
- Enabling interoperable dataflow across heterogeneous devices and data (including sensors, robotic components, monitoring systems, imaging and AR/VR systems)
- Enabling modular, future-proof applications with compatibility for legacy and next-generation communication interfaces across devices and platforms
- Enabling highly reliable software communications with a decentralized architecture and Quality of Service (QoS) features
- Enabling a reference architecture for real-time intelligence through scalable data capture and distribution to AI processing engines

A FLEXIBLE DATA CONNECTIVITY FRAMEWORK TO MEET DEMANDING PERFORMANCE, SECURITY, AND RELIABILITY REQUIREMENTS

RTI's software connectivity framework enables modular and flexible software architectures that rely on interoperable, secure, and real-time dataflow. Intelligent digital system architectures may be decomposed into subsystems that have differing data connectivity requirements to perform image acquisition, robotic control, monitoring, AI/processing and therapy. Some subsystems also need to integrate with different robotic or other high-speed electromechanical systems.

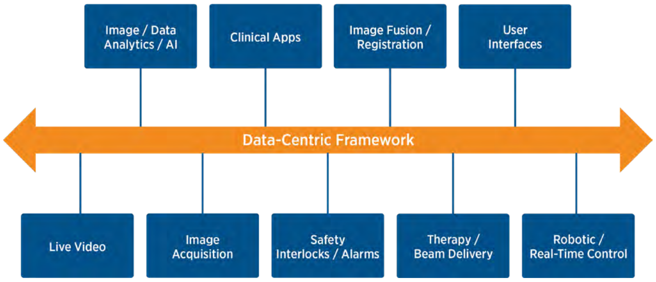

Figure 1: Data Centricity Enables Interoperability

This connectivity framework enables syntactic interoperability across internal and external device ecosystems and provides a global, shared data space that is independent of programming language, platform or network transport. The framework is defined by user-defined data types and manages distributed dataflow across applications, components, devices and networks. This is achieved through an abstraction of the messaging between applications, thereby enabling modular architectures and eliminating the need for communication infrastructure software in application code. As a result, device manufacturers are able to design scalable and software-upgradeable applications that leverage RTI's software connectivity framework of libraries, tools and partner integrations.

RTI's technology is powering highly reliable, secure and intelligent dataflow across safety-critical industries. What is driving the need for this technology in healthcare?

THE DIGITAL HEALTHCARE TRANSFORMATION

Today's healthcare systems are faced with numerous challenges to address high costs, staffing shortages and expand access to high quality patient care. These issues have accelerated the need for health systems to leverage digital technologies and connected medical devices to address clinical efficiencies and deliver increasingly minimally invasive and targeted treatments.

To address these needs, healthcare systems require innovative solutions from medical device manufacturers that provide:

- Automated, assisted and efficient clinical workflows across the patient care cycle
- Adaptable and multi-functional devices that support diverse applications/procedures
- Increasingly precise, patient-centric treatments that improve care delivery, clinical workflows and lower costs
- Ability to monitor and treat patients in dynamic and remote clinical environments

These solutions are made possible by leveraging the latest advancements in medical technologies, not as standalone devices, but as integrated solutions that unlock the potential of real-time processing, intelligent device and patient monitoring, and system control.

The future of MedTech innovation relies on intelligent connectivity — seamless and real-time dataflow across integrated components, devices and systems.

THE RISE OF CONNECTED MEDICAL DEVICES

For MedTech, the call to action is clear: medical devices need to be better, smarter and more agile. Because on a practical level, innovation is not found in a list of specs or features. Instead, meaningful innovation resides in clinical solutions that deliver measurable value to patients, clinical teams and hospitals. Therefore, to achieve true innovation, medical devices must reliably leverage the right data to the right patient — not only at the right time, but every time.

In the case of patient monitoring systems for example, solutions require capturing physiological data from hundreds or even thousands of disparate sensors and devices — and this data must then be continuously monitored, fused and processed in dynamic clinical environments. Similarly, for minimally invasive procedures, the convergence of sensor data, imaging, robotics and real-time intelligence promises to transform how patients are diagnosed, treated and monitored.

The technologies driving minimally invasive and precision healthcare require the integration of robotics, imaging, sensors, and data-driven technologies. MedTech is evolving from siloed products and devices to increasingly multi-functional and integrated digital ecosystems. In fact, **one study estimated that the global market for connected medical devices is expected to nearly quadruple from $26.5 billion in 2021 to $94.2 billion by 2026**[1].

Now more than ever, device manufacturers are faced with significant challenges in bringing these connected solutions to market. What are the reasons? The increasing complexity and connectivity of these solutions present new challenges for product teams to design and manage distributed dataflow for evolving use cases. As a result, development lifecycles are slow and expensive, device architectures are complex and inflexible, and the need to address the cybersecurity and regulatory hurdles pose significant business and technical risks.

Companies and product development teams must evolve to address these challenges or risk being left behind. The solution lies in a new generation of devices powered by intelligent software dataflow.

THE NEW CHALLENGE OF INTELLIGENT DATAFLOW AND SOFTWARE-DEFINED ARCHITECTURES

With significant advances in AI, data analytics and robotics devices, manufacturers are challenged with developing new solutions and business models based on software and data-driven technologies. Innovative solutions must integrate and process data from diverse data sources and distributed applications and systems. The design of these products must also provide for continuous evolution and interoperability either by upgrading the product already in service, or releasing a new version or a derivative.

Based on these key challenges imposed on product development, this paper presents a technology that enables device manufacturers to:

- Simplify the complexity and accelerate development of interoperable devices, components and systems of systems
- Develop highly reliable solutions that require high-speed data sharing and secure connectivity across distributed devices, applications and networks
- Design for adaptable and upgradeable systems that incorporate varied technologies, algorithms and platforms

We present a "data-centric" software connectivity infrastructure that accelerates the development of intelligent and connected medical devices and solutions.

HOW DATA-CENTRICITY ENABLES A SCALABLE SOFTWARE CONNECTIVITY ARCHITECTURE

The traditional approach to software communication architecture is message-centric, where messages are simply passed between applications. A message-centric architecture (typically point-to-point, or server-based) is typically not scalable or flexible for increasingly distributed and complex systems.

In a data-centric approach, data is the central aspect — distributed applications may come and go and communicate on a peer-to-peer basis. In a data-centric system, a shared data model precedes and outlives the implementation of any given application. A data-centric architecture abstracts communications from the application logic, thereby the data model, instead of application logic, is the communication interface. Applications are able to remotely access data anywhere in the system, on-demand, through a virtual databus (Figure 2).

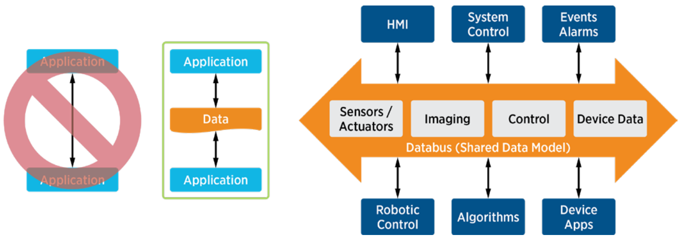

Figure 2: With a data-centric databus, modular applications can remotely access the data they need on demand at the rate they need it, with messaging abstracted from application logic

A data-centric communication architecture provides the ability for distributed applications to "share state" instead of simply exchanging messages. Message exchange becomes a means to an end. With data-centric communications, it's possible to notify applications of relevant changes to the shared state, including changes to data values, the presence of new data-objects, and even the availability and liveliness of other applications accessing the shared state.

A data-centric architecture is modular and decentralized, with no central broker or server. This enables high reliability, scalability, low-latency performance for real-time and intelligent connected medical devices. Data-centric communications can also provide stronger consistency models to applications (e.g., eventual consistency), which greatly facilitates building robust and highly-available applications.

The data-centric model also provides a mechanism for applications to be decoupled in time. For example, a late-joining application can just observe the current state in order to "catch up" with the rest of the system. It does not need to process all the intermediate messages that caused the past state changes — rather, it only needs to focus on the end result.

DATA-CENTRIC CYBERSECURITY — A ZERO-TRUST APPROACH TO COMMUNICATIONS

The need for data sharing across complex subsystems, devices and networks contribute to increased cybersecurity risk as a matter of design.

Cybersecurity architecture must be considered early in the design stage to ensure effective and robust security controls. One approach that is discussed across industries, and shared by Health-ISAC (HISAC), is the **"zero-trust" concept**[2]. This approach emphasizes the need for the granularity to grant only the minimal permissions needed for each application to access data.

Data-centric software communication frameworks enable zero-trust principles by enabling device manufacturers to secure the actual data in motion — independent of transport or network location. Because the communication framework is "data-aware" by design, known data structures may only be shared with authorized applications that need the data. **Through the fine-grained configurability of security controls applied to dataflow, "deny-by-default" security architectures may be established and optimized for system performance**[3].

A zero-trust architecture supports requirements for best-practice cybersecurity threat models and effective implementation of secure communications across internal and external interfaces of the system. This design approach should be applied at the beginning stages of the system development. Figure 3 shows an example of dataflows across several applications, illustrating that different levels of security may be applied to data types, enabling least-privilege and optimization of bandwidth and CPU cycles.

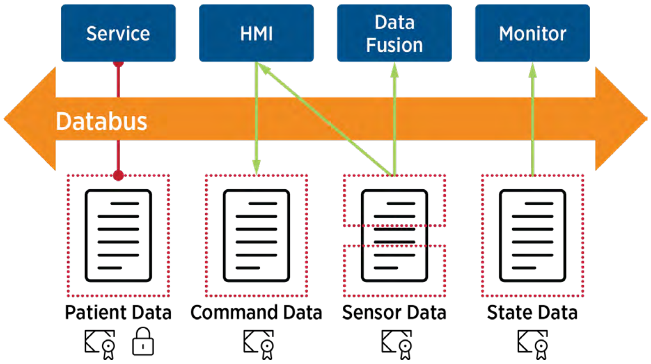

Figure 3: Data-centric cybersecurity provides the ability to design systems that restrict access control (e.g., authentication, encryption) for data in motion based on least privilege

RTI CONNEXT: A DATA-CENTRIC FRAMEWORK FOR INTELLIGENT REAL-TIME MONITORING AND CONTROL

RTI Connext is a data-centric framework for distributing and managing real-time dataflow. The Connext databus allows applications and devices to work together as a single integrated system, and provides the robust interoperability, security and real-time functionality essential for healthcare applications. Based on data-centricity, the framework offers the benefits of decoupled applications and data (separation of concerns) — enabling modular and scalable architectures with no single point of failure.

To develop clinical solutions consisting of devices and applications capable of assisting clinical decisions, workflows and delivering therapy — not just providing data — devices must be able to communicate in real time. In general, that means delivering microsecond or millisecond response times to support thousands of control decisions per second. Connext enables exactly that by allowing devices to publish and subscribe to data directly on the databus. Unlike a database or other client/server architectures which require a query and response protocol structure that must send a message requesting data and then return the data, Connext makes the data itself the message, enabling real-time device control. The DDS Data Model distributes the real-time data samples (the what) to the subscribed endpoints (the where) at the time they need to arrive (the when).

RTI is a leader in IIoT connectivity software with more than 2,000 commercial designs developed on RTI Connext platforms. RTI serves on the Object Management Group® (OMG®) Board of Directors and is actively engaged in more than 20 other standards efforts, including OpenICE, an implementation of the Integrated Clinical Environment standard for medical device communication.

RTI Connext addresses the development challenges of next-generation medical systems by enabling:

- **Flexible and Efficient Development:**
    - Flexible and modular architecture supports dataflow interoperability and upgradeable platforms, with multi-platform/programming language support
    - Reference software architectures across platforms and product lines
    - Enables product teams to focus on clinical application development instead of infrastructure
- **Reliability and Performance:**
    - Low-latency software communications for real-time monitoring and control
    - Decentralized communication architecture with no servers or brokers
    - Scalable connectivity to thousands of applications and dataflows
    - Proven framework across safety-critical industries, standards-based
    - QoS features to specify non-functional characteristics of dataflow, such as reliability, durability, lifespan, ownership, liveliness
- **Cybersecurity By Design**
    - Fine-grained security controls for least-privilege software communication
    - Dataflows are separately isolated and protected cryptographically
    - Enables regulatory and industry expectations for secure communication architecture across interfaces and operational states

RTI's software connectivity framework is based on DDS, the open international standard for distributed data connectivity.

WHAT IS DDS?

DDS is a family of standards that specify the API, protocol and security mechanisms that can be used by distributed applications to exchange real-time data (Figure 4A). The software application programming interface (API) used by applications is based on a secure, QoS-aware "Data-Centric Publish-Subscribe" (DCPS) model. This means that applications need only be concerned with the data that they wish to produce or consume, as well as the desired QoS. The DDS communication infrastructure takes care of the rest. Since DDS is a transport-agnostic and cross-platform solution, it can be added as the communication interface for any software application. DDS manages data communications over local area networks, mobile and wide area networks, or even the same machine (shared memory).

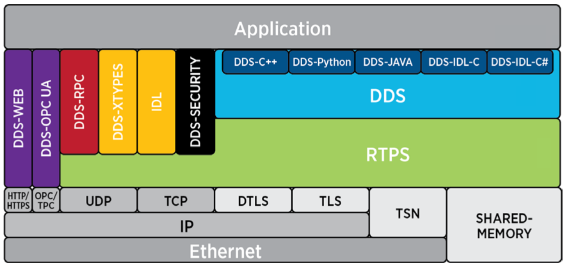

Figure 4A: The Connext Interface Stack

DDS is a data-centric middleware communication standard maintained by the OMG. The infrastructure abstracts messaging functions and sender-receiver dependencies from the application logic, thereby simplifying the system development and evolution of connected applications, and enabling software developers to focus on application development instead of messaging infrastructure (Figure 4B).

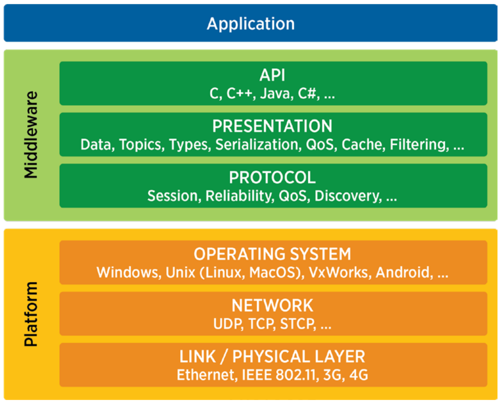

Figure 4B: The DDS Middleware abstracts the application from the messaging infrastructure, along with network, and platform dependencies. Advanced communication features are also provided by DDS to reliably manage distributed data across the system. Source: OMG DDS Foundation

DDS provides unique flexibility and robust functionality to meet very specific application parameters. Via the QoS mechanism, an application designer can choose from a variety of well engineered solutions to common communications issues, such as a slow client, bursty traffic throttling, sample batching and even primary/secondary/tertiary data sourcing. The technology makes it possible to share different data types at whatever data rate is required by the application that needs to receive and process that data. Enabling one or more QoS features is done by configuration, not code, and so the application-level testing is greatly simplified.

DATA-CENTRIC PUBLISH-SUBSCRIBE INTERFACE

In data-centric communications, instead of simply sending messages, the communication infrastructure is defined by a shared data model that manages the dataflows and data types of the system. This enables Publish-Subscribe (pub-sub) applications to be built as a composition of modules that communicate with each other by sending (publishing) data and receiving (subscribing) data anonymously. Usually, the only thing a publisher needs in order to communicate with a subscriber is the **Topic** name (this identifies the flow) and the associated **Data-Types** (this defines the application-level APIs to read/write the data and the mechanisms to convert application data to or from a network representation). The publisher does not need any information about the subscribers, while subscribers only need to know the Topic name.

The DDS pub-sub infrastructure (Figure 5) is capable of delivering that data to the appropriate nodes — without having to manually set up individual connections. Publishers are responsible for gathering the appropriate data and sending it out to currently registered or future subscribers. Subscribers are responsible for receiving data from the appropriate publishers and presenting the data to the interested user application.

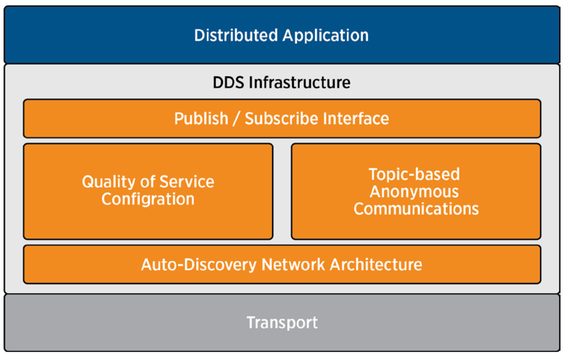

Figure 5: The DDS Infrastructure

Solutions for using a pub-sub communication mechanism have typically been accomplished with proprietary solutions. DDS formalizes the QoS-aware data-dentric Publish-Subscribe communication paradigm by providing a standardized interface and the necessary protocols for achieving the required functionality.

THE RTI CONNEXT FRAMEWORK

RTI provides DDS-based connectivity technology, as well as a full suite of tools, services and software development kits (SDKs). Connext language bindings to the OMG DDS API now include C/C++, Java, C# and Python with Connector for JavaScript.

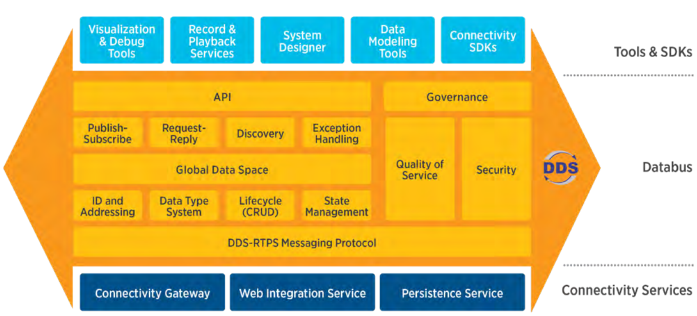

Figure 6: Elements of the Connext Connectivity Framework

RTI's development tools are a game-changer for software teams. The Admin Console provides a real-time view of all endpoints, where one can drill into the details by Topic or Endpoint. It also provides data visualization. One can interactively plot multiple values from multiple topics and share this data graphically. This feature can be used to debug the system, keep a record of known, good state, or help craft a better application algorithm.

Dataflows may be saved to a database using the Connext record and playback service. Data may be modified to create test cases and played back (via the playback service) at faster or slower speeds as needed to exercise the system for functional testing, validation, stress-testing, etc.

The Web Integration Service provides both a REST and WebSocket interface to any Connext Databus, enabling connectivity to mobile devices and/or web pages with a very small amount of coding.

The Connext Code Generator ingests datatype descriptions in IDL (or XML) and emits functional serialization code for the target language and platform. This generated code implements the RTPS protocol, freeing developers to focus on application-specific coding. Connext handles the "plumbing."

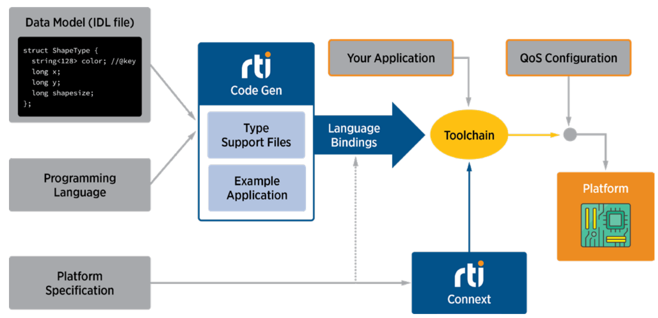

Figure 7: Connext Application Development

The code generator translates the IDL to Support Files, which implement the RTPS protocol. The existing toolchain links application code with the Connext libraries. The QoS configuration is consulted when the application starts on the target hardware.

RTI Connext enables open architectures for dataflow across internal and external interfaces. For developers designing next-generation healthcare systems, the RTI Connext Databus effectively addresses the traditional challenges of data connectivity, plug-and-play interoperability, real-time analytics and fine-grained security to enable the vision of fully automated systems built on the IIoT. Additionally, by partnering with an industry leader, developers can benefit from RTI's expertise, experience and success in helping healthcare and other industrial organizations deliver truly transformational systems and solutions.

RTI partners with the industry's leading technology providers to deliver a broad set of hardware and software solutions that are optimized for the RTI Connext platform. These assets help our customers to facilitate and optimize development of their complex distributed systems. RTI partners include experts in areas that include semiconductors, embedded software, operating systems, programming languages, development environments, design and visualization tools, and cybersecurity.

CYBERSECURITY FOR MEDICAL CONNECTIVITY

While secure communications is only part of an overall secure device architecture, recent FDA cybersecurity guidance highlights the need for manufacturers to assess the security risks of communication interfaces across the device ecosystem.

To address some of these concerns, RTI Connext® Secure provides the ability to configure access control (least privilege) to the data in motion based on consideration of the intended use cases and/or operating environments of the dataflows. Connext Secure enables data-centric, fine-grained security of dataflows — meaning that security can be set per role and per topic. This capability allows security configuration, at both system and network transport boundaries, to provide complete protection of critical data.

Regulatory guidance also calls for systems to be designed to be resilient to network attacks. The inherently decentralized architecture of the Connext framework along with the redundant communication patterns provided by the QoS help to ensure the availability of data access, thereby enabling resilient and recoverable dataflows.

Connext Secure provides plugins for Authentication, Cryptography, Access Control, Data Tagging and Security Logging. Configuring Connext Secure requires no code changes, since the QoS manages each DDS Entity's security posture.

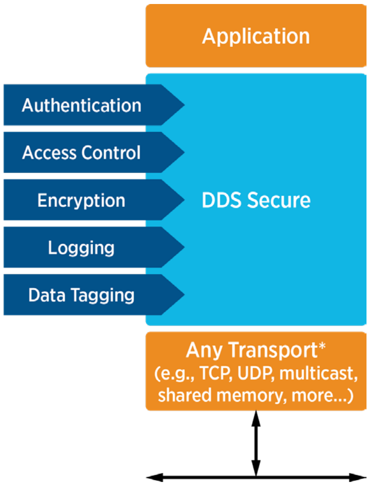

Figure 8: Connext Secure Plugins: Built-in support for Authentication, Access Control, Encryption, Security Logging and Data Tagging, all configurable by QoS

Connext Secure also provides plugins for future encryption algorithms and interfaces with other security solutions providers (such as WolfSSL). Recent enhancements to Connext Secure allow for the banishment of a node with invalid or expired credentials without having to restart the node, which is key for long-running SaaS applications.

ENABLING FASTER DEVELOPMENT OF REAL-TIME INTELLIGENCE IN THE INTERNET OF MEDICAL THINGS (IoMT)

Figure 9 depicts the three levels of IIoT use cases: monitoring, optimization and autonomy. Relating these stages to healthcare, an application at the monitoring level might collect continuous data from a number of data sources to accurately capture the state of the patient and devices. Optimized systems could be providing automation, control, and clinical decision support to help eliminate the alarm fatigue in critical care environments.

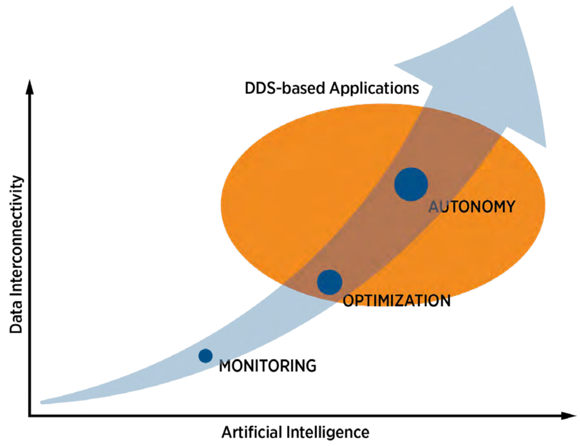

Figure 9: The Evolution of the IIoT

At full automation, data might be collected from one device and transmitted to another that uses machine learning (ML) (or AI) that confirms a clinical decision, and then initiates the recommended therapy. Similar advances are underway in surgical robotics, imaging and across minimally invasive, diagnostic and therapeutic applications.

In healthcare and across industries, this technical evolution is rapidly accelerating. Intelligent and connected devices along with edge computing are unlocking new capabilities at the point of care. RTI is enabling the digital transformation of healthcare by powering this next-generation of intelligent and connected systems across life-saving applications.

ACHIEVING REAL WORLD OBJECTIVES

Connext offers a software connectivity framework that is both "data-aware" and transport-agnostic. This enables device manufacturers to efficiently adapt to future dataflow requirements and user needs. New programs can support a variety of computing platforms across networks while also integrating legacy and third-party applications. Software teams can focus development and maintenance for clinical applications instead of infrastructure. Connext is therefore able to help customers optimize software development resources, costs and life cycles.

In the MedTech space, RTI has successfully helped its customers solve a variety of diverse challenges, such as:

- Integrating next-generation intelligent systems including robotics, imaging, device telemetry, video and therapy devices for enterprise device companies
- Enabling distributed and real-time connectivity for the leading surgical robotic systems
- Sharing, monitoring and controlling clinical applications from any location in real-time
- Achieving critical uptime, performance and secure communication requirements for continuous patient monitoring with scalability to thousands of connected machines

CONCLUSION

As the healthcare industry pursues innovation with new technologies, we are seeing the expansion of surgical robotics, along with the demand for connected solutions in operating rooms. Next-generation critical care systems are enabling intelligent and continuous patient monitoring from anywhere. RTI is proud to be a trusted technology advisor for the innovative companies that are transforming healthcare across robotics, imaging, monitoring and other evolving forms of connected healthcare.

FOR MORE INFORMATION

To learn more about the use of RTI Connext in healthcare applications, we suggest the following:

- **Visit >** Our **Connecting Healthcare Applications** page to view some of our customer success stories and learn about connecting healthcare with RTI Connext.
- **Read >** The RTI in Healthcare datasheet offering a short summary of how RTI is enabling the future for connected healthcare (**English**) (**Japanese**).
- **Learn >** Understand how our comprehensive **product suite** enriches our healthcare solutions and find a helpful overview of the DDS standard upon which our technology is based.

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ABOUT RTI

Real-Time Innovations (RTI) is the largest software framework company for autonomous systems. RTI Connext® is the world's leading architecture for developing intelligent distributed systems. Uniquely, Connext shares data directly, connecting AI algorithms to real-time networks of devices to build autonomous systems.

RTI is the best in the world at ensuring our customers' success in deploying production systems. With over 2,000 designs, RTI software runs over 250 autonomous vehicle programs, controls the largest power plants in North America, coordinates combat management on U.S. Navy ships, drives a new generation of medical robotics, enables flying cars, and provides 24/7 intelligence for hospital and emergency medicine. RTI runs a smarter world.

RTI is the leading vendor of products compliant with the Object Management Group® (OMG®) Data Distribution Service (DDS™) standard. RTI is privately held and headquartered in Sunnyvale, California with regional offices in Colorado, Spain and Singapore.

Download a free 30-day trial of the latest, fully-functional Connext software today: www.rti.com/downloads.

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Working as one.

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