



Addressing Real-World Data and Evidence Challenges with InterSystems IRIS for Health

The use of data and machine learning to improve business and clinical outcomes is about to take an exponential leap for medical technology (MedTech) companies. With the widespread adoption of HL7 FHIR,[®] the Web-based healthcare data sharing standard, MedTech gains faster, more efficient access to clinical data in electronic medical records (EMRs). Data sets created from clinical data plus the diverse information collected from medical devices, social media, formal complaints, email chains, regulatory filings, and in spreadsheets can be used to accelerate innovation and optimize product lifecycles. The question is, how can you efficiently work with all this data?

EMR data is complex and diverse, with structured and unstructured elements. It's often challenging to link data across different EMRs to the same patient. Even the same data elements may be identified and stored differently in different systems. Making the most of this data requires advanced interoperability and database technology, as well as partnerships with clinical data experts such as InterSystems. The combination of InterSystems technology and domain knowledge can improve:

- Post-market surveillance
- The extraction of insights from data
- Success in value-based care arrangements

InterSystems IRIS for Health[®] Data Platform Unlocks the Potential of Your Data

InterSystems IRIS for Health is an advanced data and development platform for building MedTech applications, and for developing complementary digital solutions and services around medical devices. It includes deep support for FHIR and other standards, plus advanced interoperability, data management, natural language processing, analytics, and out-of-the-box machine learning technology to unlock the value of medical records and related clinical and device data.

“**INTEROPERABILITY IS ARGUABLY THE BIGGEST CHALLENGE FOR MEDTECH, INCLUDING COMPLYING WITH VARIOUS NATIONAL AND INTERNATIONAL STANDARDS AND PROTOCOLS AROUND THE EXCHANGE AND USE OF DATA.**”

Deloitte Centre for Health Solutions report, “MedTech and the Internet of Medical Things.” July 2018.

InterSystems IRIS for Health supports the entire cycle of data acquisition, analysis, and reporting including:

- Aggregating device and clinical data, from clinical systems or IoT (Internet of Things)
- Driving analytics-based insights to improve products and clinical care, identify patient cohorts for marketing, and enhance research and development
- Decreasing the time, effort, and cost of post-market surveillance and other real-world data activities, and preventing adverse clinical events
- Capturing device, patient survey, and clinical outcome metrics to demonstrate the value of devices and therapies in value-based care contracts

Easier Post-Market Surveillance

Humans are complex systems, so without a complete understanding of the patient population it's easy to under or over represent the risks associated with use of a given medical device. A robust device monitoring program with early detection of problems is critical for the introduction of new technology. It will limit any long-term effects of a device or therapy not foreseen in pre-market assessments. And it simplifies post-market clinical follow-up for accurately assessing the real-world clinical use of the device.

InterSystems IRIS for Health enables you to address medical regulations and monitor devices on the market with proactive post-market surveillance, and analytics for creating dashboards and reports. For example, you could use InterSystems IRIS for Health to combine device information with data pulled from EMRs or laboratory information systems, and show that your device is safe with limited adverse reactions.

Leverage More Data to Improve Quality, Identify Cohorts, and Drive Innovation

You can derive greater value from your data with InterSystems IRIS for Health interoperability and built-in natural language processing, analytics, and machine learning capabilities. For example, you could use natural language processing and rules to monitor each patient's clinical status and laboratory values, or unstructured data such as social media or customer complaints. The system could flag signs that indicate device issues or other problems requiring corrective action to avoid serious and costly adverse events. Analyzing device and clinical data together with proactive and reactive post-market surveillance information enables a range of other benefits, including:

- Discovering trends in device performance and patient-specific responses
- Patient-specific device optimizations
- Easier documentation of safety and regulatory compliance
- Identification of patient cohorts most likely to have the best outcomes and lowest costs with your solutions
- Trending that helps providers manage population health
- Tracking device performance to enable predictive maintenance
- Developing real-world evidence, faster, to demonstrate the value of your products



Success in Value-Based Contracts

Organizations entering into value-based care models want help to demonstrate a device's clinical and economic benefits to the healthcare system. According to a study published in MedTech Strategist, progressive healthcare systems are seeking partnerships with their MedTech vendors to deliver value-based care. InterSystems IRIS for Health provides complementary digital solutions and services around your medical devices to deliver what your customers need. Such solutions and services include the ability to:

- Lower costs and increase value through collaboration
- Share accountability for outcomes
- Access diverse data sources
- Provide insights into methods and conditions that lead, in a repeatable way, to the best outcomes
- Deliver the right intervention to the right patients at the right time

InterSystems IRIS for Health Key Features for MedTech

Industry Standards are the Foundation of Interoperability

To simplify access to and use of clinical data, InterSystems IRIS for Health offers development tooling for most healthcare interoperability standards and document-based health information exchange, including:

- HL7 FHIR® (STU3, R4)
- HL7 V2 and HL7 V3
- X12
- CDA
- DICOM

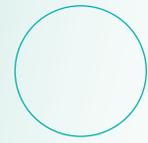
Advanced FHIR Capabilities and Transformations Between Standards

FHIR is the latest standard from the HL7® organization for exchanging patient data. The U.S. government Office of the National Coordinator has mandated use of FHIR Release 4 as the application programming interface (API) for accessing patient data. InterSystems IRIS for Health provides MedTech companies a platform that communicates easily with all versions of FHIR, and a FHIR Resource Repository to store FHIR data. For example, under new U.S. government regulations, with patient consent an insulin pump vendor could use FHIR for access to the patient's hemoglobin A1c data in an electronic medical record. No business relationship with the patient's provider organization would be necessary. Additional InterSystems IRIS for Health advanced FHIR capabilities include:

- Analytics on FHIR data
- Support for apps based on FHIR data standards which can operate within EMR environments
- Secure data exchange without VPNs (virtual private networks)

InterSystems IRIS for Health can transform messaging standards such as HL7 v2 and CDA into FHIR, giving other developers access to any type of healthcare data when building solutions. InterSystems IRIS for Health pre-built and extensible transformations between modern and legacy data representations include:

- Transforming an HL7 V2 message from one schema version to another
- Producing HL7 V2 messages from a CDA document
- Transforming a portion of a CDA document out as FHIR resources



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ONE BILLION
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“**INTERSYSTEMS HAS DEVELOPED SIGNIFICANT HEALTHCARE DOMAIN EXPERTISE IN DATA INTEGRATION FROM DIVERSE SOURCES. IT HAS SIGNIFICANT KNOWLEDGE OF THE NUANCES REQUIRED TO CREATE HIGH QUALITY AND RELIABLE INTEROPERABILITY CHANNELS, TOGETHER WITH THE HEALTHCARE EXPERTISE TO DELIVER ALL KEY ANALYTICS USE CASES.**”

*IDC Marketscape Report
March, 2020.*



Unified Development Environment

InterSystems IRIS for Health includes a unified graphical and code-based environment that simplifies and accelerates development and maintenance of real-time, data-rich solutions. It supports a variety of development languages, including a native API for Java, .NET, and Python, full life-cycle API management, and a choice of data models. The InterSystems IRIS for Health trace capability enables you to track and see the behavior of messages to and from your application, simplifying debugging and diagnosis, lowering development costs, and accelerating time to market.

Embedded and Open Analytics

InterSystems IRIS for Health provides embedded, state-of-the-art analytics capabilities, distributed SQL, business intelligence, and natural language processing in data-intensive, real-time applications. It can easily incorporate a wide range of third-party tools, such as Microsoft Power BI, and open source analytics packages, such as Apache Spark.

AI, and Machine Learning for SQL Developers

IntegratedML, a component of InterSystems IRIS for Health, brings the power of machine learning to SQL developers. With three simple SQL statements, users can create and train machine learning models on their data, and then use those models to make predictions on new data from SQL-based applications. This turnkey tool dramatically increases the productivity of data teams and enables data scientists to focus on the most complex problems, without having to worry about data access or model deployment.

InterSystems IRIS for Health also supports connection to machine learning and AI automation environments like DataRobot, H2O, Apache Spark and KNIME, and its own machine learning toolkit for embedding Python or R code into applications and business processes.

Scalability to Support Your Success

The combination of device, sensor, software, clinical data, and ubiquitous Internet connectivity presents an opportunity with tremendous value for innovative MedTech organizations. InterSystems IRIS for Health, with its unified database, interoperability, natural language processing, analytics, and machine learning technology simplifies creation of applications tied to medical devices. These new solutions require less code and fewer resources in operation. InterSystems IRIS for Health scales effortlessly, cost-effectively, and reliably to support your operations and success at any level.

In the Cloud or On Premises

InterSystems IRIS for Health provides a simple, intuitive way to provision and deploy your solutions in the cloud or on-premises. Using Inter Systems Cloud Manager, InterSystems IRIS for Health delivers the benefits of infrastructure as code, immutable infrastructure, and containerized deployment of applications. InterSystems IRIS for Health runs on AWS, Google Cloud Platform, Azure, Tencent Cloud, or a private cloud, but is not tied to any one platform. You have freedom of choice and the flexibility to change cloud providers as needed.

MedTech Company Tests InterSystems IRIS for Health Scalability, Performance, Efficiency

A global supplier of smart intravenous patient-controlled analgesia infusion pumps conducted a head-to-head performance evaluation of InterSystems IRIS for Health vs. its current SQL Server-based cloud platform.

InterSystems IRIS for Health was challenged with:

- Connecting over 20,000 IoT devices to monitor the status and safety of analgesia patients
- Storing more than 200 million device records
- Reducing technology costs

InterSystems IRIS for Health exceeded the company's requirements and provided ample headroom for growth. Results of the evaluation showed:

- Increased sensor data throughput, from 300/second to 19,600/second
- Improved SQL query performance by 6,500%
- Reduced hardware footprint (4GB memory vs 10 GB)
- Consumed 55.5% less disk space
- Made analytics easier to use

“THIS PARTNERSHIP WILL STRENGTHEN OUR DIGITAL STRATEGY, WHICH IS DESIGNED TO SIMPLIFY DECISION-MAKING FOR HEALTHCARE PROFESSIONALS.”

Adan Martin, Head of Digital Solutions, Guerbet

“A CRITICAL PIECE OF THE VALUE DELIVERED BY OUR SOLUTIONS RESTS ON THE INTEROPERABILITY WITH OTHER HEALTHCARE INFORMATION SYSTEMS ENABLED BY INTERSYSTEMS.”

Gabi Daniely, Vice President Products, Solutions and Marketing, STANLEY Healthcare

InterSystems and its Customers Extend Access to Clinical Data

Over one billion health records worldwide are managed by solutions built on InterSystems technology. No other vendor has more experience accessing, managing, and using clinical data than InterSystems. Clients using our technology in their products or services include:

- MedTech vendors such as Roche Diagnostics, Guerbet, Medtronic, Canon Medical, Olympus, and Arthrex California Technology
- Healthcare IT firms such as Epic and 3M Healthcare
- Leading health information networks such as Healthix and Manifest MedEx, which aggregate clinical data for nearly 40 million people in New York and California
- Healthcare organizations such as Northwell Health, Mass General Brigham, Providence Saint Joseph Health, Bumrungrad International Hospital, NHS Scotland, and Mediclinic Middle East

Guerbet Uses Clinical Data to Expand Capabilities, Enhance Workflow, Increase Safety and Value

Guerbet manufactures contrast agents and related software used in medical imaging worldwide.

The company uses InterSystems IRIS for Health as the foundation for Contrast&Care®, its contrast agent injection management solution, to:

- Integrate faster with CT/MRI devices, electronic health records, and other IT systems used in hospitals and medical imaging centers
- Present a unified view of the patient record and injection history
- Customize contrast dosing based on the patient's laboratory and clinical profile
- Increase safety and support decision-making by collecting, analyzing, archiving, and sharing data on contrast products, adverse events, injector activity, estimated glomerular filtration rate (eGFR), and other risk factors before an imaging study
- Improve radiologist workflow with advanced connectivity and analytics
- Support development of its next generation applications powered by real-time analytics and machine learning

STANLEY Healthcare Integrates Devices and Clinical Information to Improve Staff Efficiency and Patient Care

STANLEY Healthcare developed a suite of applications and devices that make it easier to locate patients, staff, and equipment for improved workflow efficiency and enhanced patient experience. The company relies on InterSystems technology for:

- Critical integrations to electronic health records
- Enabling automatic admission, update and discharge of patients in STANLEY's AeroScout solution
- Providing context for and automating patient flow processes by enhancing location data with EHR-generated demographic and clinical information
- Documenting the patient journey to inform staff workflow and room utilization analytics

Try InterSystems IRIS for Health for Free

You can try InterSystems IRIS for Health for free by downloading it from Docker Hub (capacity constraints apply) at <http://bit.ly/IHdocker>

To learn more about InterSystems IRIS for Health, call us at +1 800.753.2571 or see InterSystems.com/IRISforHealth. For local InterSystems office contact information, see InterSystems.com/offices.

About InterSystems

No data management vendor has a greater commitment to healthcare or more relevant experience than InterSystems. From the earliest days of healthcare IT, the industry has relied on and grown with InterSystems data platforms. And our interoperability solutions have been at or near the top of KLAS Research rankings for over a decade. Globally, more than one billion health records are managed by solutions built on InterSystems technology. Laboratories running on InterSystems-based software process nearly half the specimens in the U.S. every day. The most sophisticated private and government healthcare providers depend upon devices, records, and IT powered by InterSystems.

¹ MedTech Strategist, June 27, 2018, Vol 5, No 9. Good News, Bad News, Hospitals want to Partner. Jonas Funk, Monish Rajpal, and Ilya Trakhtenberg, LEK Consulting.

² IDC MarketScape: European Electronic Healthcare Records, 2020 Vendor Assessment. March 2020, IDC #EUR146131320e