



ACCELERATE **-HEALTH**



White Paper

Fundamentals of Medical Grade Data Exchange

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1 Introduction

HIMSS is a global thought leader for eHealth interoperability, reaching out to the community of governments and health care organizations and ministries with whom to explore how healthcare obligations may be met through the open exchange of health data. HIMSS Accelerate Health, the innovation hub of HIMSS, works with the community of healthcare providers and system integrators to define the care models and workflows required for the practical application of Remote Patient Monitoring (RPM). Within the Accelerate Health initiative, the Personal Connected Health Alliance (PCHAlliance) sponsors the development of standards, including those in the IEEE, Bluetooth SIG, and IHE.

The world's largest technology companies have made great strides in connecting healthcare apps, devices and electronic health record systems but they are all based on proprietary interfaces (APIs) that must be custom managed company to company, and device to device, by each system integrator. This is called *connectivity* and has allowed each of those companies to move quickly into the healthcare IT space, but it is costly to scale and problematic to maintain and support. The U.S. Department of Health and Human Services Proposed Rule to Improve the interoperability of Electronic Health Information calls for open APIs. This is an important and very practical step, but it only improves *connectivity*, which is still costly to scale.

The PCHAlliance promotes **one open API** to provide *interoperability* that enables *any* device to securely and automatically connect to *any* health record system and provide universally understood health data essential to clinical decisions. To help overcome economic barriers, the PCHAlliance has taken this one step further and developed a cost-effective standards-based software implementation creating one open API. This dramatically reduces the cost to maintain compatibility across innumerable platforms that employ proprietary APIs, or even open APIs.

This one open API empowers:

- Governments to help meet their social obligations to citizens in providing healthcare,
- Healthcare providers to reduce clinical burden when using Patient-Generated Health Data (PGHD),
- Remote care service companies to reduce system integration and maintenance costs across innumerable platforms,
- Device companies to provide meaningful observations in a commoditized market,
- Patients to make choices and use their own interoperable devices,
- Pharmaceutical companies to improve accuracy of drug trials, and
- Payers to provide healthcare at lower cost.

No other organization offers this combination of open standards implementation guidance, software and product assurance procedures. This dramatically reduces product integration to days instead of months freeing engineers to focus on applications that provide value add and differentiate their offering in the market.

2 Purpose & Scope

The purpose of this white paper is to provide a basic description of the medical-grade data that is being exchanged between sensors, gateways, and end services and value-add that the profiles and conformance testing provide beyond the referenced standards to make implementations truly interoperable.

Within the context of this white paper, medical-grade data is defined as "the use of IEEE nomenclature to precisely describe the 'when, where and how' of a patient's vital signs were measured so that this critical information is universally understood and not lost as it is transported from the sensor, to the gateway, and ultimately to the electronic medical record system."

This white paper:

- Outlines for healthcare informaticists an architecture that empowers *any* device to *securely and automatically* connect to *any* health record system,
- Provides medical systems developers with overviews of implementations to collect and share RPM data and introduce tools to rapidly integrate these solutions into devices, and
- Promotes methods for test engineers to help ensure products meet customer expectations.

3 Architecture in Brief

The architecture developed by the PCHAlliance provides an open standards-based, secure flexible framework by which data of known provenance from personal health devices can be ingested by the existing health IT ecosystem.

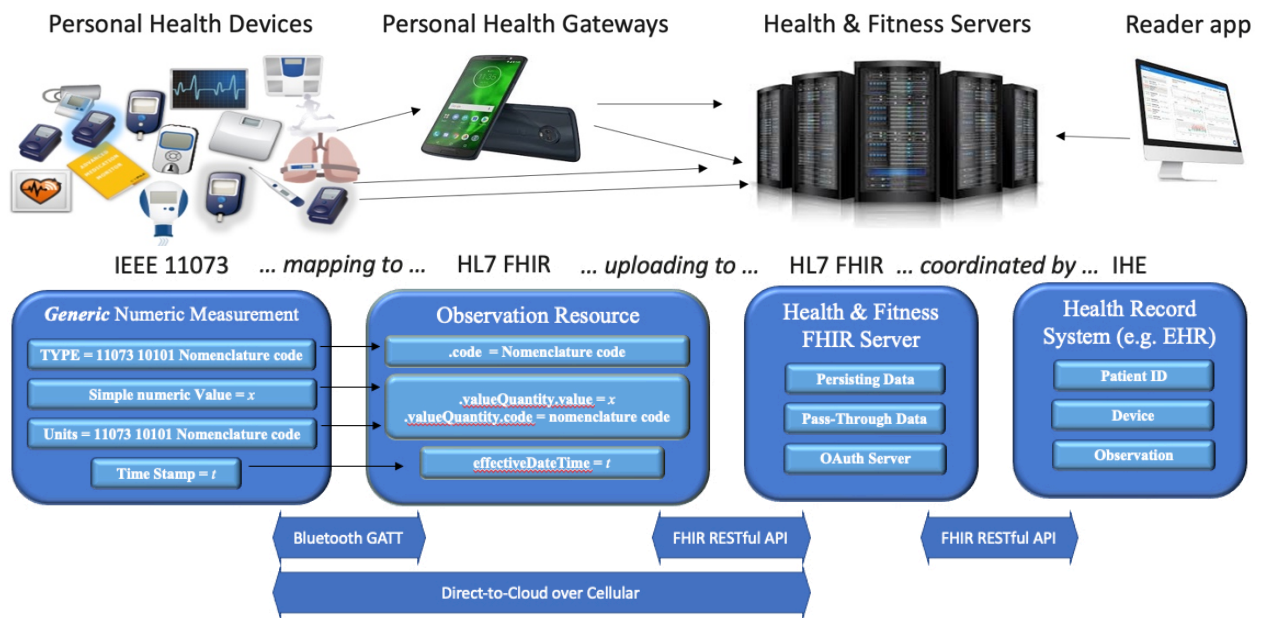


Figure 1: High Level Architecture

Open standards are essential but not sufficient to ensure that *any* compliant device can automatically and securely communicate with *any* compliant health record system. Standards, by design, have mandatory and optional features and functions. The IHE profiles provide uniform implementations of the standards and test processes that enables this automatic secure exchange of health data among sensors, gateways and end services.

As illustrated in Figure 1, ensuring that health data is universally understood starts with the IEEE 11073 Personal Health Devices family of open standards which define the precise, clinically understood, content of devices and the measurements they generate. These IEEE 11073 specifications enable the interoperable exchange of the medical information between a personal health device that generates the measurement and a Personal Health Gateway (PHG). The PHG maps the received measurements and supporting data into FHIR resources, then uploads them to a FHIR server within a Health & Fitness Service (HFS). This information can then be made available from the HFS to a traditional Electronic Health Record (EHR) system as well as applications that link remote patient monitoring and well-designed software to meet specific needs of the patient and care team (e.g. disease management solutions) resulting in improved patient outcomes.

4 Personal Health Devices Interface to Collect Quality Health Data

To ensure the quality and provenance of RPM essential to support clinical decisions, the IEEE 11073 Personal Health Devices family of standards provides a device information model and Bluetooth provides a mechanism for its secure transport to a gateway. To avoid the expense of developing the expertise to digest and implement these standards and profiles, a library of commercial ready software is being developed to rapidly integrate these features into devices providing remote patient monitoring.

4.1 Ensuring Health is Data Clearly Understood

Remote care services can benefit greatly by contextualizing multiple data inputs – both device and manual inputs for clinical decision support for both patients and healthcare professionals. However, as more sensor data (i.e. vital signs from blood pressure and glucose monitors, pulse oximeters, weight scales, thermometers or other remote monitoring devices) come online, the integration of these devices is difficult to scale unless a consistent nomenclature describing the data is established.

PCHalliance provides the only multi-measurement solution that includes a comprehensive nomenclature coding system allowing an authentic and holistic view and understanding of the data for RPM and Clinical Decision Support (CDS) solutions developers. This enables the evolution of remote care from simple observations to creating insights and effective CDS that enables a person/patient to play a more active role in their health and care and live a more active and quality life and leads to a more efficient and effective provision of care by the healthcare providers

4.2 Modeling Health Data and Transport

To this end, the PCHalliance works closely with the IEEE to develop the *IEEE 11073 Personal Health Device* family of standards to specifically address the consistency and quality of personal health device data (e.g. temperature, blood pressure) with an emphasis on addressing the needs of simple devices that are proliferating the market. This family of standards ensures that the user of the data knows exactly what was measured where and how, and that this critical information is not lost as it is transported from the sensor, to the gateway, and ultimately to the electronic health record system.

Unlike any other standard, an observation from a device using the 11073 standards provides metadata that captures supporting information such as the measurement technique being used, device characteristics and setting that may impact the data reported, how timestamps are to be understood, and status events critical to supporting clinical decisions.

By way of example, a message from a blood pressure monitor could communicate use of the oscillometric technique, up to 18 common device attributes (e.g. model, manufacturer), 25 or more device specific attributes (e.g. measurement units, status, time), and 7 events (e.g. configuration, update). The protocol to communicate these makes sure that only changed data needs to be sent. In the example below in Figure 2 the units of blood pressure are not sent as they are already known by the receiver. See IEEE 11073-10407 Device Specialization – Blood Pressure Monitor for more detail. Time order of measurements is preserved regardless of poor connectivity conditions that occur from time to time and the individual moving between time zones (and possibly switching between home and travel measurement devices).

0xE7 0x00	APDU CHOICE Type (PrstApdu)
0x00 0x3E	CHOICE.length = 62
0x00 0x3C	OCTET STRING.length = 60
0x00 0x54	invoke-id
0x01 0x01	CHOICE (Remote Operation Invoke Confirmed Event Report)
0x00 0x36	CHOICE.length = 5
0x00 0x00	obj-handle = 0 (MDS object)
0x00 0x49 0x00 0x50	event-time (set to 0xFFFFFFFF if RelativeTime is not supported)
0x0D 0x1D	event-type = MDC_NOTI_SCAN_REPORT_FIXED
0x00 0x2C	event-info.length = 44
0xF0 0x00	ScanReportInfoFixed.data-req-id = 0xF000
0x00 0x00	ScanReportInfoFixed.scan-report-no = 0
0x00 0x02	ScanReportInfoFixed.obs-scan-fixed.count = 2
0x00 0x24	ScanReportInfoFixed.obs-scan-fixed.length = 36
0x00 0x01	ScanReportInfoFixed.obs-scan-fixed.value[0].obj-handle = 1
0x00 0x12	ScanReportInfoFixed.obs-scan-fixed.value[0].obs-val-data.length = 18
0x00 0x03	Compound Object count (3 entries)
0x00 0x06	Compound Object length (6 bytes)
0x00 0x78	Systolic = 120
0x00 0x50	Diastolic = 80
0x00 0x64	MAP = 100
0x20 0x07 0x12 0x06	Absolute-Time-Stamp = 2007-12-06T12:10:0000
0x12 0x10 0x00 0x00	
0x00 0x02	ScanReportInfoFixed.obs-scan-fixed.value[1].obj-handle = 2
0x00 0x0A	ScanReportInfoFixed.obs-scan-fixed.value[1].obs-val-data.length = 10
0xF2 0x58	Basic-Nu-Observed-Value = 60.0 (BPM)
0x20 0x07 0x12 0x06	Absolute-Time-Stamp = 2007-12-06T12:10:0000
0x12 0x10 0x00 0x00	

Figure 2: Sample IEEE 11073 Message

Communicating such an exhaustive set of attributes may not be necessary or practical in all healthcare monitoring applications. Therefore, the PCHalliance works within the healthcare community to agree on a subset of attributes that are sufficient for consumer-friendly medical-grade healthcare monitoring solutions. The PCHalliance is working with the [IEEE 11073 Personal Health Devices](#) to define a simplified information model independent of transport. Members are active within the [Bluetooth SIG Medical Devices](#) Workgroup to create a Generic Health Sensor (GHS) service and profile based on this model that enables communication of a wide range of health-related observations from sensor devices to collectors. And, as part of the PCH program, the participants are defining a uniform implementation profile following this model to deliver sensor data over cellular Direct-to-Cloud.

5 Services Interface to Ease Sharing of Patient Health Data

The ability to share health data with *any* health record system is made possible through the uniform implementation of FHIR standards and IHE profiles to upload observations to a server to be accessed by applications performing analytics, the results of which are displayed for the clinician. Again, to avoid the expense of developing the expertise to digest and implement these standards, a library of commercial ready software is available to rapidly integrate the observation upload feature into devices providing remote patient monitoring.

The IHE Personal Health Devices Observation Upload (POU) Profile describes a standardized means of reporting as FHIR resources measurements taken by Personal Health Devices (e.g. pulse oximeters, glucose monitors). It leverages the HL7 Personal Health Devices Implementation Guide which specifies how to map ISO-IEEE 11073-20601 attributes received from a sensor into FHIR resources.

The POU profile defines a Device Observation Reporter that generates and transfers a complete FHIR bundle to a Device Observation Consumer. A complete FHIR bundle contains all the resources pertinent to the measurements and all resources in the bundle only have references to resources within the bundle. A Device Observation Consumer receives the complete FHIR bundle from the Device Observation Reporter. In the POU profile, the Device Observation Consumer is typically grouped with a Device Observation Reporter that uploads the FHIR data from the complete FHIR bundle to a RESTful FHIR server.

The POU profile also defines two transactions:

- Communicate FHIR PHD Data [PCH-01] transaction communicates a complete FHIR Bundle to the appropriate consumer over RESTful POST transports, secured using TLS, and authenticated using OAuth2 bearer tokens.
- Communicate RESTful FHIR PHD Data [PCH-02] transaction delivers FHIR resources to a FHIR server using the RESTful FHIR API, is secured using TLS, and authenticated using OAuth2 bearer tokens.

A sample transaction bundle containing an Observation resource is shown in Figure 3.

```
{
  "resourceType": "Bundle",
  "id": "2017-03-06T16:30:12.436-05:00",
  "type": "transaction",
  "entry": [
    {
      "fullUrl": "urn:oid:1.0.0.1",
      "resource": {
        "resourceType": "Observation",
        "identifier": [
          {
            "value": "sisansarahld-urn:oid:1.2.3.4.5.6.7.8.10~1234567800000033~160368~20170306163009.000~95"
          }
        ],
        "status": "final",
        "code": {
          "coding": [
            {
              "system": "urn:iso:std:iso:11073:10101",
              "code": "160368",
              "display": "MDC_CONC_GLU_UNDETERMINED_PLASMA"
            }
          ]
        },
        "subject": {
          "reference": "Patient/PatientId-sisansarahld"
        },
        "effectiveDateTime": "2017-03-06T16:30:10.245-05:00",
        "performer": [
          {
            "reference": "Patient/PatientId-sisansarahld"
          }
        ],
        "valueQuantity": {
          "value": 95,
          "unit": "mg/dl",
          "system": "urn:iso:std:iso:11073:10101",
          "code": "264274"
        },
        "device": {
          "reference": "Device/SysId-1234567800000033"
        },
        "related": [
          {
            "type": "qualified-by",
            "target": {
              "reference": "urn:oid:3.14159.20170306163008.245"
            }
          }
        ]
      }
    },
    {
      "fullUrl": "urn:oid:3.14159.20170306163008.245",
      "resource": {
        "resourceType": "Observation",
        "text": {
          "status": "additional",
          "div": "<div xmlns='http://www.w3.org/1999/xhtml'>CoincidentTimeStamp-20170306163008.245-0500</div>"
        },
        "status": "final",
        "code": {
          "coding": [
            {
              "system": "urn:iso:std:iso:11073:10101",
              "code": "67975",
              "display": "MDC_ATTR_TIME_ABS"
            }
          ]
        },
        "subject": {
          "reference": "Patient/PatientId-sisansarahld"
        },
        "effectiveDateTime": "2017-03-06T16:30:08.245-05:00",
        "valueDateTime": "2017-03-06T16:30:07.000-05:00",
        "device": {
          "reference": "Device/SysId-1234567800000033"
        }
      }
    }
  ],
  "request": {
    "method": "POST",
    "url": "Observation",
    "ifNoneExist": "identifier=sisansarahld-urn:oid:1.2.3.4.5.6.7.8.10~1234567800000033~160368~20170306163009.000~95"
  }
}
```

Figure 3: Sample FHIR Message

6 Commercial Ready Implementation Software

The PCHAlliance is developing a cost-effective standards-based software implementation to dramatically reduce the cost to maintain compatibility across innumerable platforms that employ proprietary APIs, or even open APIs.

Bluetooth LE Manager software collects vital signs observations employing profiles and services with data types compatible with the IEEE 11073-20601 Personal Health Devices family of standards. It maintains semantic content of observation data for both standards compliant and proprietary devices. To support proprietary devices, the interface allows sensor manufacturers to create independent drivers for their devices on gateway platforms that link their products into the standards-based health ecosystem. The Bluetooth LE Manager implementation also resolves common interoperability issues such as device connection, user notification and authentication.

FHIR Observation Uploader software performs the translation and upload. Specifically, it enables vital signs data from a variety of sensors to be uploaded separately or combined as a multi-measurement to help medical system developers integrate and analyze the data presenting a more holistic perspective for the user/patient and healthcare provider. To help collect and provide a universal understanding of RPM from proprietary devices, this software creates industry standard semantic content by mapping proprietary or standard device data into FHIR resources and then uploads those observations to a FHIR server.

FHIR Observation Server software understands and maintains the semantic content to ensure that users of that data clearly understand what was measured where, how, and when. It includes a complete suite of components for the reception and processing of the FHIR observations from a Personal Health Gateway. For resource constrained devices (i.e. small sensors with limited compute capability and battery life) requiring greater efficiency, the software supports uploading individual resources (Patient Resource, Device Resource, or Observation Resource) employing the HL7 FHIR data model.

By way of example, this combination of software collects temperature (e.g. oral readings in °F) from vendor A, heart rate in BPM from vendor B, and weight in pounds from vendor C. These universally understood observations are stored together in a computer file (i.e. FHIR resource) which is then uploaded to a health information system (e.g. FHIR Server) using secure internet protocols. Applications can then access these observations, perform analytics designed to meet the specific needs of the care team, and display on a monitor the right information at the right time.

7 Product Development Tools

The PCHAlliance employs a suite of popular integration and test tools to simplify and accelerate the integration of health data collection and upload software. This helps developers to rapidly evaluate and ensure software modifications produce the intended result throughout the build and test process.

7.1 Integration Tools

To help ensure the software has been properly implemented in your products, PCHAlliance provides a validation framework that supports continuous integration testing, including tests that employ the use of the physical Bluetooth interface and the cloud interface. Continuous integration allows developers to rapidly evaluate and ensure software modifications produce the intended result throughout the build and test process. A [test tool](#) is freely available to demonstrate conformance to industry standards.

7.2 Test Tools

The test infrastructure is intended to support detailed automated testing in a continuous integration environment that involves the Bluetooth interface of the Personal Health Gateway. A dongle-based Bluetooth Low Energy Simulator is employed to simplify Bluetooth testing by providing control over the test environment that is often not possible using physical devices. Using the low-level Bluetooth hardware enables the test system to control the characteristic table that is presented to the PHG, the timing of disconnects, the duration and frequency of advertisements and a number of other specific behaviors that are not possible when sitting on top of a Bluetooth stack or OS Bluetooth interface.

A *mock FHIR server* implements a subset of the HFS allowing it to take the place of a full HFS for testing. It also notifies the tester of created FHIR resources. The mock FHIR server provides a controlled way for the test developer to get results from the content of the FHIR message sent by the PHG.

7.3 Developer Support

Support of the developer starts with a [Confluence space](#) for accessing software including documentation for building, running and programming of the Personal Health Gateway. A development environment provides the technical and social infrastructures and fundamental software development and release processes to help ensure productive engagement by a community of experts to improve and deploy successful remote patient monitoring products. Connectathons provide a collaboration environment with industry leaders.

7.4 Conformity Assessment

While standards are essential, they are not sufficient to ensure interoperability between devices from multiple vendors. Going beyond the implementation guidance, the PCHAlliance works closely with IHE International to provide for product assurance by maintaining a compliance and interoperability assessment program. This includes all the tools, processes and procedures necessary to ensure buyer requirements are clearly communicated and products can demonstrate conformance to required standards essential to interoperability.

The [IHE International Conformity Assessment Scheme](#) focuses on assessing compliance of in-clinic medical systems. Part 1: Requirements for IHE Authorized Testing Laboratories describes the management and technical requirements necessary for a Testing Laboratory involved in the IHE conformity assessment program. Part 2 describes the baseline set of IHE profiles and procedures to be used for Conformity Assessment and Testing Laboratory accreditation.

The [PCHAlliance Conformity Assessment Scheme](#) focuses on assessing compliance of devices used primarily outside the hospital. It achieves that delicate balance between a comprehensive and rigorous method for ensuring devices meet stated functional requirements yet demonstrated in an affordable time and cost that allows vendors to be profitable in a highly competitive market. This scheme goes beyond assessment of compliance by defining high value objective methods and criteria for 3rd party certification of test results that are recognized worldwide. Certified products may sport the certification logo and be listed on the [Certified Products Showcase](#). For more price sensitive markets, this scheme also outlines a more affordable yet disciplined process, and [freely available test tool](#), by which device vendors can self-declare compliance to the profiles directly to their customer. They do not sport the certification logo but are posted on the [PCHAlliance Compliant Listing](#).

8 Foundational Specifications & Standards

IEEE drives the functionality, capabilities and interoperability of a wide range of products and services that transform the way people live, work and communicate. The *IEEE 11073 Personal Health Devices* family of standards enables communication between medical, health care and wellness devices and with external computer systems. It includes the *IEEE 11073-10101 Nomenclature*, *11073-10201 Domain Information Model*, *11073-20601 Optimized Exchange Protocol*, and the device specializations in the *IEEE 11073-10400-series*. The Nomenclature standard defines the overall architecture of the organization and relationships among nomenclature components along with specific semantics and syntaxes. The Domain Information Model standard addresses the definition and structuring of information that is communicated or referred to in communication between devices. The Optimized Exchange Protocol standard defines a common framework for making an abstract model of personal health data available in transport independent syntax. Device Specializations standards define communications between compute engines (e.g. personal health gateway) and specific personal health tele-health devices.

Integrating the Healthcare Enterprise is an initiative by care providers and vendors to improve the way information systems communicate to support patient care. Integration profiles describe clinical requirements for systems integration and well-defined and highly constrained solutions to address them. Transactions are used to specify in careful detail the roles for each component in the system and are based on standards such as IEEE 11073 and HL7.

The *Bluetooth Special Interest Group* expands Bluetooth technology by fostering member collaboration to create new and improved specifications, drive global Bluetooth interoperability through a world class product qualification program, and grow the Bluetooth brand by increasing the awareness, understanding, and adoption of Bluetooth technology.

HL7 is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services.

9 References

[IHE Personal Health Devices Observation Upload Trial Implementation](#)
[Bluetooth SIG's GATT services for Medical Devices](#)
[IEEE 11073-10101 Nomenclature and subsequent amendments](#)
[IEEE 11073-10201 Domain Information Model](#)
[IEEE 11073-20601 Optimized Exchange Protocol and subsequent corrigenda](#)
[IEEE 11073-10407 Device Specialization – Blood Pressure Monitor](#)
[ITU-T H.810 Interoperability Design Guidelines for Personal Health Systems](#)
[PCHAlliance Certification Process](#)
[HL7 Personal Health Device Implementation Guide](#)

10 Acronyms

API	Application Programming Interface
BLE	Bluetooth Low Energy
CAS	Conformity Assessment Scheme
CDS	Clinical Decision Support
D2C	Direct-to-Cloud
FHIR	Fast Healthcare Interoperability Resources
GHS	Generic Health Sensor
HFS	Health & Fitness Server
HIMSS	Healthcare Information Management Systems Society
HL7	Health Level 7 International
IEEE	Institute of Electrical and Electronic Engineers
IHE	Integrating the Healthcare Enterprise
IT	Information Technology
ITU	International Telecommunications Union
PCHA	Personal Connected Health Alliance
PGHD	Patient-Generated Health Data
PHD	Personal Health Devices
POU	Personal Health Devices Observation Upload
RPM	Remote Patient Monitoring
TLS	Transport Layer Security

11 About HIMSS

[Healthcare Information and Management Systems Society](#), Inc. (HIMSS) is a global advisor and thought leader supporting the transformation of the health ecosystem through information and technology. As a mission-driven non-profit, HIMSS offers a unique depth and breadth of expertise in health innovation, public policy, workforce development, research and analytics to advise global leaders, stakeholders and influencers on best practices in health information and technology. Through our innovation engine, HIMSS delivers key insights, education and engaging events to healthcare providers, governments and market suppliers, ensuring they have the right information at the point of decision.

Headquartered in Chicago, Illinois, HIMSS serves the global health information and technology communities with focused operations across North America, Europe, the United Kingdom, the Middle East and Asia Pacific.

12 For More Information

HIMSS Accelerate Health Personal Connected Health Alliance

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