WHITE PAPER

# Achieving Interoperability as Healthcare Embraces Mobility

Personal Connected Health Alliance

*The Personal Connected Health Alliance publishes the Continua Design Guidelines, an open interoperability framework that helps manufacturers, providers and consumers get the most out of personal health devices*

## Executive Summary

As technology continues to become a part of everyday life, the use of mobile devices to manage healthcare is gaining considerable momentum. Getting beyond the novelty of these devices to truly manage health, however, requires the collection and integration of personal health data. The Continua Health Alliance was established more than a decade ago to address this interoperability challenge in the healthcare industry — and has specifically tackled the issue with its Continua Design Guidelines.

The Continua Health Alliance then partnered with the mHealth Summit (now the Connected Health Conference) and HIMSS to launch the Personal Connected Health Alliance (PCHAlliance) in April 2014. Now operating under the auspices of the PCHAlliance, the group continues to lead the industry toward the interoperability that is needed to capitalize on the potential inherent in personal healthcare devices. This white paper provides a look at the group's history, industry challenges and its value to the industry as it continues to push the interoperability cause in the years ahead.

THE CONTINUA DESIGN GUIDELINES

## A Decade of Progress

*Mary Smith is 72 years old, in fair health, and lives alone. After she experienced a couple of random falls at night a few years ago, her adult children insisted that she start using a personal emergency response device. Although she was able to immediately get up after these falls, she determined that since she lives by herself she might as well use the gadget just in case she tumbles again and actually needs assistance.*

*Last year, Mary was feeling fatigued on a daily basis. After being diagnosed with sleep apnea, she started using an oral device that treats sleep-related diseases by positive airway pressure and measures the performance of the sleep therapy. And, just a few months ago, Mary decided to purchase a fitness tracker. She uses the wristwatch-like device to track her steps — and often good naturedly competes with a few of her neighborhood friends who have formed a walking group.*

## Key Attributes of the Continua Design Guidelines

- Not for profit
- Not proprietary (no ties to a particular vendor, device or system)
- Based on open standards developed by recognized industry groups and standards development organizations (SDOs)
- Flexible – provide maximum choice to developers, tech buyers, clinicians and consumers
- Save money along the value chain
- Reduce time to market – benefit for manufacturers, clinician and consumers
- Offer simple cross-vendor connectivity for end-users
- Leverages medical standards and specifications to transport medical grade data and clinical utility
- Adopted by the International Telecommunications Union (ITU) as ITU-T H.810-series

*Each of these devices provides value to Mary, helping her to manage her health to some extent. However, imagine what would happen if these three devices could share information. It might be possible to identify a correlation between the amount of walking and the quality of sleep at night. Or, it might be possible to tell if the quality of sleep has an impact on the probability of a fall. Indeed, the data would be much more valuable — and could help Mary take care of herself much better. Now, imagine if the data could be shared with other family members, caregivers or medical professionals — and they could also use it to identify patterns. The information would be exponentially more valuable once again.*

Therein lies the promise of data sharing — and interoperability between fitness, health and medical devices and information systems. The need for interoperability is what prompted the formation of the Continua Health Alliance. On June 6, 2006, the international nonprofit organization was founded in San Francisco by a distinguished group of leading technology, medical-device and healthcare companies, launching a collaborative effort aimed at transforming the delivery of personal healthcare through the application of technology. More specifically, the group came together to establish an ecosystem of connected personal health and fitness products and services, making it possible for patients, caregivers and healthcare providers to share data and more proactively address ongoing healthcare needs.

Founding members of the PCHAlliance included BodyMedia, Cisco Systems, GE Healthcare, IBM, Intel, Kaiser Permanente, Medtronic, Motorola, Nonin Medical, Omron Healthcare, Panasonic, Partners HealthCare, Polar Electro, Royal Philips Electronics, RMD Networks, Samsung Electronics, Sharp, The Tunstall Group, Welch Allyn and Zensys.

"When the group first came together about a decade ago, there were three siloed verticals — fitness, aging in place and chronic disease management — out there. And, there were different companies in each of these verticals offering different products that weren't talking to one another," said Rick Cronssen, global director health and life sciences at Intel. "Someone who is aging in place, an elderly person could have multiple chronic conditions and might also be participating in fitness activities. So, that's a case where you have a person that has all three of those verticals come into play. The vision was to provide a common framework to combine data from devices in each of those three verticals in creative and innovative ways. That was the main challenge we were trying to solve when the Continua group was first established."

Indeed, when data is integrated, it transforms from information to actionable intelligence, according to Joyce Sensmeier, MS, RN-BC, vice president of informatics at the Healthcare Information and Management Systems Society (HIMSS), a global, cause-based, not-for-profit organization focused on better health through information technology (IT).

"When devices contain an individual's data, that's great. But if you want to see the whole picture, you need to be able to see the data across multiple siloed devices. That's what will really give you an understanding of what's going on with that person," Sensmeier said. "For example, a fitness tracker will provide information about steps and pulse and that's good data. But if you add another device such as a pulse oximeter, that will allow you to build on the data.

## Continua: 10 Highlights from 10 Years

1. Continua Health Alliance is founded in San Francisco by a distinguished group of leading technology, medical device and healthcare companies, launching "a collaborative effort aimed at transforming the delivery of personal healthcare through the application of technology" (June 6, 2006)
2. First Continua Design Guidelines are publically published (2008). In February 2009, Continua announced the release of its Version One Design Guidelines. Continua has released updated versions of the Guidelines since. The current Design Guidelines are available here. Additional capabilities will be added to the Continua ecosystem through the release of future versions of the guidelines.
3. First Bluetooth device receives Continua Certification (2009)
4. First Continua-certified mobile phone launches in Japan (2010)
5. First Continua-certified Apple mobile device (2011)
6. Denmark adopts Continua Design Guidelines (2012)
7. Continua Guidelines are first made available free to the public, following member release (2012)
8. ITU ratifies Continua Design Guidelines as the international standard for personal health systems, making the Guidelines a global standard freely available in six different languages (2013)
9. Continua Health Alliance joins with mHealth Summit and HIMSS to establish the Personal Connected Health Alliance (PCHAlliance) (2014)
10. Technical achievements include: the world's first demonstration of Continua-compliant data transmitted via HL7's FHIR specifications; Continua's Remote Patient Monitoring (RPM) profile was approved by IHE; and Continua's Personal Health Monitoring Report (PHMR) was approved by HL7 (2015)

You might discover that the pulse is normal but you're not oxygenating your blood. So, that interconnected data enables you to make better decisions about your health."

The goal of Continua was — and still is — to make personal health solutions interoperable, which would then contribute toward improved health management. Not a standards body per se, Continua was established to write guidelines on how to use standards to achieve true interoperability across many companies and many devices. Indeed, the group recognized that limited interoperability is not caused by a lack of standards, but rather by the limited use of standards.

"When we started back in 2006, it was very, very challenging to get any sort of information out of many devices at any level to use in a healthcare delivery system because the standards were simply not used at all or they were implemented differently by different vendors and often not supported or maintained," said Michael Robkin, president and founder of How Many Engineers, Inc., former IT leader at Kaiser Permanente, and a founding board member of Continua.

"Plus, the vendors were not providing the capability to users because the customers weren't asking for it or there wasn't a cost-effective way to provide it," he said. "So, it was a chicken-and-egg problem in that the providers and patients didn't ask for it because it wasn't available and the medical device vendors didn't provide it because it was expensive and difficult, and they didn't see enough customer demand."

As a matter of fact, when the group was formed, interoperability was at a standstill, as standards — while perhaps plentiful — were largely unused. As such, the adoption and consistent use of existing open standards loomed as the main challenge to realizing interoperability and has remained as the main focus of the Continua Design Guidelines (CDG) from its beginnings about a decade ago through today (see sidebar, "10 Highlights"). Indeed, this challenge remains a daunting one today, as vendors continue to wait for providers and patients to demand interoperability — and providers and patients continue to wait for vendors to provide it.

To move beyond the inertia, the design guidelines support and advance interoperability by referencing industry standards and specifications, providing clarity around implementing these specifications and ensuring consistent implementation through product certification. Over the past decade, the Continua Design Guidelines have been honed to address the interoperability challenge. In the process, the guidelines have emerged as the only open implementation framework for authentic, end-to-end interoperability of personal connected health devices and systems.

This emerging interoperability, in turn, is now poised to bring far-reaching benefits to a variety of constituents. "Continua was formed to create solutions that are based on standards good for individual users but also for institutional users like clinics, hospitals and government organizations that can benefit from data being captured in a consistent and interoperable way," said Simão Campos, counsellor, International Telecommunications Union, Study Group 16 "Multimedia."

THE CONTINUA DESIGN GUIDELINES

## Secrets of Interoperability Success

To successfully fulfill the group's interoperability mission, the Continua Design Guidelines have been developed based on four key principles:

1. **AUTHENTIC INTEROPERABILITY**
   Connectivity requiring minimal effort on the part of the end-user, as products easily work together

2. **OPEN-SOURCE DEVELOPMENT MODEL**
   The Continua Design Guidelines are universally accessible, non-proprietary and not for profit

3. **FLEXIBILITY**
   Designed to provide maximum choice for developers and end-users (healthcare buyers, individual clinicians and consumers)

4. **WISDOM OF THE MARKET**
   The market in aggregate has more wisdom than any individual stakeholder; thus, the Continua Design Guidelines are developed through a consensus process

With these principles in place, Continua has achieved many milestones over the past 10 years (see sidebar, "Key Attributes"). What's more, the organization has pushed its agenda — and become increasingly relevant by partnering with other industry groups in an effort to have a profound impact on interoperability in the international healthcare market. Continua Health Alliance partnered with the mHealth Summit (now the Connected Health Conference) and HIMSS to launch the Personal Connected Health Alliance (PCHAlliance) in April 2014. PCHAlliance now publishes the Continua Design Guidelines, promoting open, interoperable personal health solutions as part of its mission to achieve personal connected health for all.

In fact, to achieve its interoperability goals, PCHAlliance, a global, nonprofit organization, brings together technical leadership with Continua's plug-and-play interoperability design guidelines and product certification program; education with the mHealth Summit's international ecosystem of networking events, industry education and thought leadership; and advocacy through HIMSS' worldwide presence creating locally based advocacy for standardization and market development to enable the free exchange of healthcare data across systems. As such, PCHAlliance continues to work to generate greater awareness of, and access to, plug-and-play, consumer-friendly personal health technologies that will empower individuals to manage their health and wellness anywhere, anytime.

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## Achieving the Interoperability Vision

According to the International Telecommunication Union, devices such as wireless blood pressure cuffs, weight scales and a wide range of activity trackers can play a critical role in the prevention and improved management of chronic conditions such as diabetes, hypertension and heart disease. The value of these devices, however, increases when they are capable of connecting.

Interoperability can play a huge role in creating this value. In fact, establishing global interoperability standards will stimulate innovation and nourish the personal connected health ecosystem. For manufacturers, standards will decrease time-to-market, reduce development costs and increase efficiencies. In particular, they will enable quicker, less expensive integration to electronic health records (EHR) or health information exchange (HIE) platforms.[1]

To this end, the Continua Design Guidelines define the interfaces that enable the secure flow of medical data among sensors, gateways, and end services, removing ambiguity in underlying healthcare standards and ensuring consistent implementation through product certification. Based on the use of a variety of established standards (see chart below, "A Sampling of Standards Included in the Continua Design Guidelines"), the guidelines have been designed to actually make interoperability something that can be achieved with ease.

## A Sampling of Standards Included in the Continua Design Guidelines

### THE IEEE 11073 PERSONAL HEALTH DEVICE STANDARDS

These Standards specifically address the interoperability of personal health devices (e.g., thermometer, blood pressure monitor) with an emphasis on personal use and a simpler communication model. 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 EHR system.

### HL7 STANDARDS

These Standards offer 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.

### FAST HEALTHCARE INTEROPERABILITY RESOURCES (FHIR)

FHIR is a draft standard developed by HL7. As a standard for exchanging healthcare information electronically, FHIR defines a set of "Resources" that represent granular clinical concepts. The resources can be managed in isolation, or aggregated into complex documents. The benefit of FHIR then, is that it can make development and implementation of products based on HL7 standards faster and more efficient.

### W3C STANDARDS

These Standards define an Open Web Platform for application development that has the unprecedented potential to enable developers to build rich interactive experiences, powered by vast data stores that are available on any device.

### INTEGRATING THE HEALTHCARE ENTERPRISE (IHE)

IHE promotes the coordinated use of established standards such as DICOM and HL7 to address specific clinical needs in support of optimal patient care.

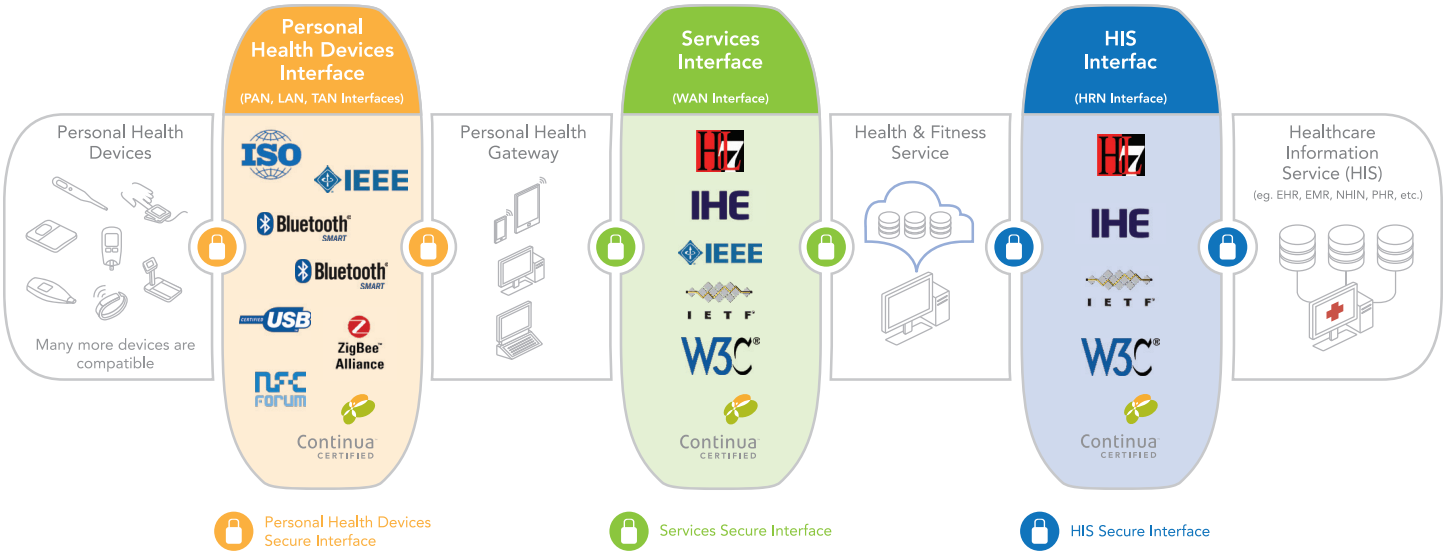
THE CONTINUA DESIGN GUIDELINES

## The Four Components

The notion was never that we were going to start with a clean slate and rewrite everything. What we really wanted to do was identify the best standards that were out there and then [use] them as appropriate to make sure interoperability is more straightforward, simplifying the standards to make it possible for small- and medium-sized companies to understand and handle the development of products with the standards," said Cnossen.

In addition, the Continua Design Guidelines recognize that the use of standards alone does not guarantee interoperability. For example, a device or system using HL7 v3.0 might not interoperate with another HL7 v2.0 or HL 7 v3.0 system or device. To address these situations, the Continua Design Guidelines specify exact parameters for the variable elements inevitably present in any standard, to ensure consistent application throughout a connected health system.

Working with these standards, the Continua Design Guidelines have grown into an interoperability framework that includes the four components below.




### PERSONAL HEALTH DEVICES

These devices (owned or operated by the Individual) capture health and wellness data, and have some means of interacting with the end-user.

### PERSONAL HEALTH GATEWAY

The link between any device, service or app that is used by the individual to access the health services with which he or she engages.

### PROFESSIONAL SERVICES

A professional service that uses health and fitness data on a continuous basis to support individuals in making healthy lifestyle choices to support their wellness goals, manage or prevent chronic disease, all in alignment with their health and wellness needs and aspirations.

### HEALTHCARE INFORMATION SERVICES

This data is kept in the institutional healthcare system to document diagnosis and therapeutic interventions for review and facilitate clinical decision making.

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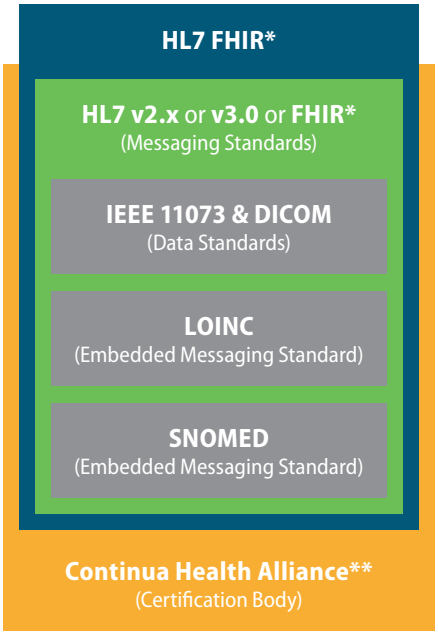
## IHE (Interoperability Integration Profile)




Source: GSMA

* FHIR could currently serve as a translation between HL7 v2.x and HL7 v3.0. However, it is migrating to become a standalone messaging standard in its own right.

** HL7 FHIR not currently captured in Continua Design Guidelines.

## Development Done Right

The key to making these guidelines successful, however, always has hinged on developing them in a manner that makes them useful to consumers, providers, healthcare organizations and nations. As such, the guidelines have been developed with the following attributes:

**REQUIRE CONSENSUS FROM ALL CONSTITUENTS.** The American National Standards Institute (ANSI) holds consensus as a hallmark of any reliable and successful standards-setting process. According to ANSI, "consensus must be reached by representatives from materially affected and interested parties."[2]

Indeed, the Continua Design Guidelines follow suit and are built in a consensus-based environment. "For the guidelines to be widely accepted, we have always realized that they needed to be developed by consensus. There have been over 240 companies from many industry sectors involved in Continua over the last 10 years. These are all very different industries. There are also a lot of competitors in the same room, as well," Cnossen said. "So, for these guidelines to work, it has to be consensus based. You can't have companies prescribing what needs to be done based on their own personal market objectives. It just wouldn't be supported or adopted."

Achieving consensus, however, isn't an easy exercise. According to Sensmeier, who has been an active leader of the Integrating the Healthcare Enterprise (IHE) initiative, the process of creating guidelines or standards in a consensus-based manner becomes fairly involved. Typically, a consensus-based process requires:

- Convening experts in a neutral setting or manner
- Encouraging and enabling volunteers to commit their time to the initiative
- Ensuring that the volunteers have a technical understanding of the issues
- Providing a meeting space
- Implementing and monitoring a public-review process
- Offering a validation or certification process (see sidebar, "Continua's Certification")

And, while this consensus process is involved, the extra effort is worthwhile. "When you get standards or guidelines implemented, you want to be assured that they are going to work," Sensmeier said. "So, the process is very rigorous and time-consuming, but essential."

**RELY ON ESTABLISHED STANDARDS.** Instead of reinventing the wheel with new standards, the Continua Design Guidelines are based on common, international technology standards defined by recognized industry groups and standards development organizations such as IEEE's 11073 Personal Health Device Standards, Integrating the Healthcare Enterprise (IHE) Patient Care Device PCD-01 Transaction and the Health Level Seven International (HL7) Personal Health Monitoring Report (PHMR), Systematized Nomenclature of Medicine (SNOMED) and Logical Observation Identifiers Names and Codes (LOINC). The chart below illustrates how various architectural components, standards and profiles are not mutually exclusive and therefore might overlap and be used simultaneously.

## Advancing the Connectivity Cause

With these unique development practices in place, the Continua Design Guidelines have advanced personal connected health in a variety of ways over the past decade:

- Regularly updated Guidelines facilitate a one-stop solution to interoperable health data exchange for personal devices and solutions
- Product-certification program and Continua logo signify readiness for authentic, user-friendly data exchange with all other certified devices and solutions
- Standardized medical-grade data, including consumer-generated data from personal health devices, can easily be integrated into EHRs and other clinical information systems
- Device manufacturers have achieved reduced development costs and time to market for products
- Adoption by national and regional health ministries supports large-scale public healthcare
- The public availability of free guidelines

**LEVERAGE OPEN STANDARDS.** Standards need to be available to all end-users to be effective. "With the Continua Design Guidelines, the whole idea is to allow any party to join the ecosystem of interoperable devices," said Paul Coebergh van den Braak, standardization manager, Intellectual Property & Standards, Philips Group Innovation. "The guidelines would hopefully result in a market where system components for personal connected health can be freely mixed and matched. This way there are not any burdens for any player, large or small, to contribute to innovation — such as limitations of use or license fees that are often associated with closed eco-systems defined by one or a few leading players. With a truly open standard, there can't be any roadblocks; the standards need to be easily acquired by every player in the marketplace."

**ADDRESS SECURITY.** The guidelines address end-to-end security and privacy through a combination of identity management; consent management and enforcement; entity authentication; confidentiality; integrity and authentication; non-repudiation of origin; and auditing.

**DELIVER EASILY UNDERSTOOD DATA.** In contrast to many standards and solutions, the Continua Design Guidelines enable a scalable, seamless and secure end-to-end flow of data in formats that can be readily understood and used throughout the continuum of care. This is both unique to Continua and essential to creating high-value health management opportunities, which rely on breaking down the barrier between the consumer and professional healthcare domains.

**OFFER PROOF OF CONCEPT.** Continua's Test and Certification program ensures interoperability by verifying that products conform to the Continua Design Guidelines and its underlying standards. For example, certification of sensor devices ensures that IEEE 11073-conformant data is securely received at the gateway; certification of the Services interface ensures that each field of every segment in the PCD-01 message contains a valid value; and certification of the Health Information Service interface ensures the syntax and semantics of the XML message.

"It's not sufficient to just have specifications, you also need to have a way to check that the implementations are done well. Otherwise, interoperability is impossible," Campos said. "So, conformity testing of any standard is paramount, and in the health area it's even more important because you are dealing with something very sensitive, your health. So, you want to make sure that devices are conformed properly — and the certification process that Continua has put in place is a key component of making this happen."

The Continua-certification process involves a very well-structured sequence of testing that manufacturers must follow. Indeed, the process, itself, often brings about the changes needed to achieve interoperability. "Many times in the first round, it might not work very well. So, in that process of trying to make it work, the manufacturer then identifies the problem and solves the issue — and then retests interoperability until it works properly," Campos explained. "In the final analysis, the certification process provides a greater level of assurance devices from different brands will interoperate."

CONTINUA CERTIFICATION

## The Details

The Continua Certification Program certifies personal connected health devices and systems according to the Continua Design Guidelines. The program is only open to manufacturers that are members of the PCHAlliance.

## The Process

The certification process consists of the following four steps:

1. **PREPARE.** Member completes product, studies the certification process, and starts pre-testing using transport and Continua Test Tools.
2. **APPLY.** When member is ready, they submit the Continua application. The test lab provides testing date to member.
3. **TEST.** Personal area network (PAN) or wide area network (WAN) certification testing begins at test lab. Testing typically completes within a few days. HRN testing is completed by the member.
4. **CERTIFY.** Certification received when all tests receive a passing verdict, payment has been received and legal documentation is signed.

## The Support

Test tools, test labs, plugfests and experts are in place to support certifying companies throughout the process. In fact, the Continua Certification Expert (CCE) program is specifically designed primarily to support members planning to certify a Continua device. CCEs are involved daily in supporting Continua's Test and Certification program, ensuring the quality of Continua Certified products. CCEs are recognized as experts in the Continua Design Guidelines, relevant supporting technologies, certification process and policies. CCEs are available to provide services for Continua members and members may contract directly with a CCE for certification services.

All CCEs are proficient in the Continua Certification Process, Continua Design Guidelines, have experience using the Continua Enabling Software Library (CESL) and Continua Certification Test Tools. Additionally, each are recognized to be experts in a subset of Continua transport technologies and interface.

## The Benefits for Device Manufacturers

With the Continua program, once products are certified, they carry a recognizable logo signifying interoperability with other Continua certified products. Products that carry the Continua Certified™ logo enjoy strong competitive advantages:

- Protection from premature obsolescence through authentic interoperability
- User friendly
- Less labor-intensive for developers
- Eliminates inefficient technology duplication

## The Benefits for Customers

Whether a healthcare provider organization or a patient, customers are likely to seek interoperability, regardless of whether they understand interoperability on a technical level. Indeed, providers and patients alike simply want to know that their medical and fitness devices will be able to work together and share data. Certification can act as the representation of this "plug-and-play" ability.

The Continua Matchmaking program makes it even easier for customers to identify and purchase needed interoperable solutions. Through this program, member companies can receive notices of trials, pilots and significant Requests for Proposals (RFPs). Web conferences, teleconferences, the Continua Web site and the members-only Continua newsletter are several ways Continua can help a provider find companies to respond to a trial or help a vendor find a large request for proposal (RFP).

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## Value to Stakeholders

Perhaps most important, the Continua Design Guidelines offer a framework that will result in the interoperability that will truly benefit a variety of constituents such as:

**PATIENTS/CONSUMERS.** With Continua-certified devices, patients and consumers have the freedom to choose the solutions that fit their lifestyle and preferences, free from concerns about connectivity. Authentic interoperability supports health self-management and connection to healthcare providers, and eliminates cost and complications due to incompatible devices or outmoded technologies.

"The fact that you can switch from one device to the other and not lose your precious data is a huge advantage for consumers," Campos said. "So, you can be monitoring your glucose level. You can be measuring your weight. You could be measuring your heart rate. You could be monitoring how much you walk. All of these parameters create your history. If you have a set of data that is interoperable — then you can reuse the data and move it from one device to another without worrying about losing it. Interoperability frees you from that. Interoperability also frees users to choose devices based on features and price — because you don't have to worry about whether or not your devices will work with one another."

**DEVICE MANUFACTURERS.** The Continua Design Guidelines are proven to reduce development costs and time to market. Additionally, with the efficiency gained from standardization, developers can focus on value-added functionality while pipeline resources can be devoted to product differentiation and higher value solutions in the analytics and information management segments.

"Continua was created to make it possible for manufacturers to go from creating devices that can be used in a proprietary way to creating devices that can be used in an interoperable way," Campos said.

Cnossen added that the guidelines, for example, make it possible "for a company that provides the best pulse oximeters in the world to manufacture those pulse oximeters so that they will plug and play with other devices and even make the data available to electronic health record systems. In fact, the guidelines go so far as to say that if you want it to map to an electronic health record, here is exactly what you need to put in your device."

**HEALTHCARE PROVIDERS.** Adopting Continua for personal health devices at the medical practice-level represents an opportunity to cost-effectively invest in personal health technology to engage and motivate individual patients, as well as to implement population health management programs that target high-risk patients. Continua-certified devices have forward- and backward-compatibility and a guarantee of authentic interoperability, offering medical practices the dual assurances of enduring value and maximum choice while freeing individual clinicians to focus on practicing medicine.

**HEALTH SYSTEMS AND HOSPITALS.** For health systems and hospitals, big data represents a big return: reduced costs resulting from new capability to deliver individual and population health insights, predictive analytics to drive the shift to preventive health, and better resource management. Health systems and hospitals stand to benefit enormously from integrating consumer-generated data from personal health devices into EHRs and other clinical information systems. The Continua Design Guidelines make this possible through the secure, interoperable exchange of medical-grade data, which unlocks new capability to monitor patients in high-cost, high-touch and high-risk areas of medicine such as chronic disease, acute/post-operative care, and mental and behavioral health.

The installed base of hospital information systems and the variety of healthcare information services are complex and represent substantial past investments. Therefore, information must be available in representations and formats these systems recognize. The Continua Design Guidelines provide a vendor-neutral solution for simplified data exchange in personal connected health, so that devices are interchangeable and easily added or removed from the existing ecosystem.

"For the institutional user, interoperability allows them to have more choice of device provider so they can get a better deal when they do procurement," Campos said. "It also gives them more confidence when going from one device to another, from one brand to another, the data that winds up in the servers will be compatible."

**NATIONS.** National and regional health ministers, responsible for administering healthcare systems that serve populations in the millions, were among the first stakeholders to recognize the potential to cost-effectively scale connected healthcare through authentic interoperability. With Continua in place, nations can offer the convenience of mobility to their citizens, reduce disparities in healthcare access and realize new value in preventive health at scale. The early adopters of the Continua Design Guidelines also benefit reduced system complexity and long-term costs.

"Internationally, healthcare systems have communicated to us that there is a great need for more supply of compliant, interoperable devices. The supply is not really that large yet, and it is needed to create a connected healthcare system," said Coebergh van den Braak, who also serves as the vice chairman of the PCHAlliance board and Continua Council.

The fact that interconnected personal devices can simultaneously improve population health and reduce costs has not gone unnoticed by many leaders.

"Healthcare is a sector that affects each and every one of us on the globe. It is a growing part of the national product because healthcare is needed by every individual sooner or later. Doing things that help healthcare create better results at lower budgets is always in the public interest," Coebergh van den Braak said.

Indeed, many health systems already see the value of achieving interoperability through the Continua Design Guidelines. Denmark, for example, was the first government in 2012 to declare its intent to base its telehealth services on the Continua Design Guidelines for collecting health data from citizens, and will make them mandatory for public procurers as of 2017. Austria, Finland, Norway, and Sweden have similarly expressed endorsements of the Continua Design Guidelines for their respective frameworks for healthcare IT. These countries serve as national examples of connected health at scale.

Further, the International Telecommunications Union (ITU), the standards-setting body within the United Nations, ratified the Continua Design Guidelines as a worldwide standard, and they are available in six languages on the ITU website. Mandated adoption of the Continua Design Guidelines offers a route to addressing widespread and costly public health challenges such as diabetes; cardiovascular, respiratory and other chronic diseases; obesity; aging; rural populations; and provider shortages.

"The fact that the Continua Design Guidelines came from a private-led entity, which has recognition by some but not all, used to bring to certain users such as government entities in organizations like the World Health Organization a pause," Campos pointed out. "In fact, the moment that the Continua Design Guidelines were adopted by the ITU as one of its global standards, immediate recognition was brought to the quality of the specification in the guidelines, erasing all previous doubts."

## Value to Three Markets

The Continua Design Guidelines can produce the interoperability that results in a variety of cost savings and benefits. The following use cases illustrate how these benefits can be achieved:

### HEALTH AND WELLNESS

Obesity is rising rapidly with an estimate of more than 1 billion clinically obese individuals worldwide. Obesity leads to all of the major chronic diseases (diabetes and heart-related diseases) and these diseases account for 75 percent to 85 percent of the total healthcare costs. Continua is developing connectivity and interoperability Guidelines for fitness equipment, heart-rate monitors, pedometers, weight scales, internet diet services, internet fitness coaching services and dozens of other devices and services yet to be thought of. These tools will help individuals to manage their weight and general health, thereby warding off costly chronic diseases.

### CHRONIC DISEASE MANAGEMENT

Chronic diseases account for 75 percent to 85 percent of the total healthcare spend in total healthcare costs. One of the ways to mitigate some of the costs associated with chronic disease is to help the patient maintain stable vitals, stick to the medication regime and quickly respond to any changes in vital signs before they result in a costly emergency or trauma. Better monitoring supports a higher quality of life for the patient and their loved ones.

### HEALTHY LONGEVITY

Population aging is rapidly becoming a shared global experience as the percentage of older adults is increasing while falling birth rates are resulting in fewer young people. To meet this new challenge, societies around the world are exploring how to help older adults live longer, healthier and more productive lives. One particularly important response has been to help elders to remain in their home and close to their caregivers and health providers through connecting technologies such as remote monitoring and sensors as well as stronger social links to community and caregivers. The goal is healthy longevity — a longer, healthier life with more opportunities to contribute and remain productive.

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## Navigating Interoperability Opportunities and Challenges

The need for an ecosystem of connected personal health products and services, making it possible for patients, caregivers and healthcare providers to more proactively manage health is expected to continue to escalate in coming years. Indeed, as information has become the currency of 21st century healthcare, the exchange of personal health data is critical to deriving the health insights that drive engagement, clinical decisions, population health management and public health. What's more, the aggregation and analysis of data — whether it is sensor data from a single patient or massive storehouses of consumer and patient information ("big data") — further rely on standardization and validation of data from disparate sources.

What is feeding this demand for connectivity and interoperability through data standardization? To start, the rise of chronic conditions and the rapid aging of the population are driving a need to shift healthcare from traditional institutional settings to everyday environments such as the home. In fact, spurred on by the growth of the geriatric population, the rising prevalence of chronic conditions and the persistent need for cost-effective care, the global home healthcare market is expected to reach USD $349.8 billion by 2020 from USD $227.5 billion in 2015, at a CAGR of 9 percent during the forecast period, according to a report from MarketsandMarkets.[3]

At the same time, consumers are flocking to mobile devices and wearables to stay healthy. According to a report from research firm IHS Technology, the wearable technology market is expected to grow form $8.5 billion in revenues in 2012, with 96 million devices shipped to $34 billion in revenue by 2019, when some 230 million devices will be sold.[4]

In fact, according to the McKinsey Institute, consumers could buy as many as 1.3 billion connected fitness monitors by 2025, some of which might be embedded in other products, such as smart watches.[5] What's more, rapid growth in devices and systems for in-home monitoring of patients, particularly those with chronic conditions such as diabetes, also is on the rise. In fact, wearables, smart devices, implantables and a slew of patient-monitoring devices in the hospital and the home are likely to push the healthcare Internet of Things (IoT) ecosystem to a $409.9 billion in value by 2022, according to a report from Grand View Research.[6]

All this growth is expected to occur as the value of these devices continues to become more apparent. Consider the following: IoT can "improve patient adherence to prescribed therapies, avoid hospitalizations (and post-hospitalization complications), and improve the quality of life for hundreds of millions of patients," according to a report from the McKinsey Institute. In fact, the report proclaims that the devices could be used to monitor and treat illness, extending life spans for people with chronic illnesses and reducing cost of treatment, and by providing data generated by wearables to improve wellness through diet and exercise.[5]

The benefits, however, extend beyond the feel-good. In fact, another study estimates that these improvements could have a global economic impact of between $170 billion to $1.6 trillion per year by 2025.[7]

Changing healthcare delivery models could also bring about a spike in the demand for connected healthcare devices. As value-based care takes hold in the United States, for example, consumers are expected to become more responsible for their healthcare from both a clinical and financial perspective. Indeed, consumers will increasingly be called upon to become partners in their care, instead of merely receiving services from providers. And, the use of mobile devices could help consumers get skin in the game.

"A patient might have been in the hospital for breathing-related issues. Once the patient is out of the hospital, she could start monitoring her fitness tracker and pulse oximeter to see if there are any changes that might mean she needs to change her follow-up care or go back in the hospital," Sensmeier said. "So, it's going to enable the patient to manage her health better as an individual and that's where we want to head in healthcare. We want each person to have ownership of their health, to understand what's going on and to stay out of the hospital. That's where healthcare is going with new regulations emanating from the Affordable Care Act. So, that's a big driver."

Even in European and other health systems with a guarantee of universal coverage and access to services, individuals are becoming agents and "co-producers" of their health. There prevails the notion of "empowerment" of individuals, citizens and patients to make informed decisions based on data that is available to them in real time. Some insurers have introduced incentive programs to entice individuals to adopt more healthy habits. And with smartphones becoming ubiquitous, innovative apps, games and services are applying learnings from behavioral sciences to "nudge" users everywhere to adapt their lifestyles.

The need to leverage mobile devices to involve consumers in their care is not lost on healthcare leaders. In fact, IoT also made the ECRI Institute's 2016 watch list for hospital executives in January. "Wearable sensors hold promise for both outpatient and inpatient monitoring as they continuously monitor health status less obtrusively, capture and provide more data to clinicians, and possibly enable patients to leave the hospital sooner and prevent readmissions," the report said. "Wearable sensors have potential to cut the cord for inpatient physiologic monitoring and can potentially provide continuous, unobtrusive monitoring pre-, intra- and post-surgery."

In fact, ECRI suggests that IoT devices may have applications for monitoring Alzheimer's and dementia patients, managing patients with Parkinson's disease or those who have experienced strokes, and even predicting epileptic seizures. And, these capabilities will become increasingly important as the American population ages and the healthcare system continues to seek innovative strategies to cut spending across the care continuum.[8]

Using the data to improve the health of entire populations also looms as a significant opportunity. "If you look at the Precision Medicine Initiative that the U.S. government has, they're trying to assess a million people's worth of data and looking at all sorts of data including environmental data that can be picked up by your cell phone. For example, environmental data that shows where you were on a particular day, it might say what the smog level was, and you could determine if you were in a smoggy area that might have precipitated your cough," Cnossen said. "To use this data, though, it has to be integrated, clean and analyzed. And, to do that, it has to be collected and used in some standardized way."

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## The Future: Navigating the Interoperability Journey

Fulfilling the promise associated with personal connected devices, however, is not proving to be as easy as it looks. To start, the healthcare industry is simply averse to change.

"When Continua was first started, healthcare was going through a tremendous innovation surge because of these new technologies. And, many companies saw this as 20 percent of the economy and immediately concluded that they were going to make a ton of money because of the digital transformation of healthcare," said Christopher Wasden, executive director of the Sorenson Center for Discovery and Innovation at the University of Utah and a former member of the Continua board of directors. "However, the expectation was that they were going to turn this new healthcare digital opportunity into a billion-dollar business in five to 10 years but most of these companies were very naïve about the rate of change of healthcare, the challenges associated with healthcare transformation. Healthcare organizations simply do not change on a whim."

The lack of interoperability in the healthcare market, of course, has emerged as a major barrier to the more widespread adoption of connected health devices, according to Ian Hay, head of emerging ecosystems at Orange, a mobile device provider. "To be honest, our first foray into the healthcare market back in 2008 was an eye opener. Everything's proprietary. Nothing connects to each other. Everything needs specific development to make anything work with each other," Hay said. "There's a shocking lack of interoperability."

This lack of interoperability stems from the fact that many companies want to continue to offer proprietary devices. "Companies tend to want to do proprietary things. They want to sell their own products," Sensmeier said. "They want their products to be the only ones that people use. Interoperability opens the door to using multiple products that can connect."

As such, the demand for products with interoperability has to warrant the effort that is required to make said products capable of exchanging data. "Companies that are providing the mobile solutions need to be motivated and incented to adopt the standards," Cnossen said. "And, that's going to come from demand-side pull. Sometimes it's more expensive to incorporate the guidelines and sometimes it's against a company's business model. That's why there has to be demand-side pull."

Campos agreed. "It's a chicken-and-egg situation. There are not many standardized devices available. I personally have yet to find one on the shelves — and that's very frustrating. Manufacturers are looking at the bottom-line and are choosing to continue to make devices that are cheaper and quicker to produce. Plus, there is not demand from the user side, so the manufacturers say, 'Why should I invest money in producing standardized, interoperable devices when the user are not asking for it?'" he said. "So, that's the one point that needs to be worked on. Users need to recognize the value of interoperability and start to demand that it be a feature of their personal health devices."

Indeed, consumers and provider organizations need to recognize the need for standardized interoperable devices before manufacturers make them available. "Think back to the 1980s when CD players first came out. The early buyers paid a lot of money for expensive devices to play a handful of discs. But those pioneers proved the value of the new technology and eventually more demand was created. So, music companies started to release music on CDs and the prices of CD players came down," Coebergh van den Braak said.

Sensmeier agreed and pointed to the fact that this ground-up demand will start to prompt more manufacturers to develop standardized, interoperable devices. "The customer is really the driver," she said. "Once they realize the value of these devices being connected, then the manufacturers will start to respond to meet demand."

Provider organizations also need to recognize the value of interoperability and create demand for connected personal devices. While a report from Accenture shows that 85 percent of doctors acknowledge that the use of wearable health devices could help patients become more engaged in their own health,[7] a variety of factors could be keeping providers at bay.

"Clinicians are not necessarily ready to accept data from personal connected devices," Cnossen said. "One time, I testified in front of Congress and one of the congressmen was a doctor. I was talking about the need for increased rural connectivity so that we could send in personal health data. He kind of slammed his fist on the table and said, 'You expect me to be liable for hundreds of pieces of data coming in from each of my patients?'"

Indeed, doctors and other clinicians want to be able to verify that any data coming for a connected device is validated and reliable. "They don't want to be working with bogus data. Did a dog step on the scale and that's why there was a weight drop? They don't want those situations," Cnossen said.

What's more, physicians need to be trained to use the data that is coming out of personal connected devices, according to Wasden.

"No doctor in the United States has ever been trained in medical school to believe that measuring activity is important or valuable and that it will make a difference in their patients' life. Even though the research that is coming out about physical activity is very positive, it has not yet made it into the practice of physicians. For example, even if a physician believed that activity is good for patients, which most would in principle, they are not trained in medical school to prescribe certain exercise routines or programs to patients," Wasden said. "Typically, they will just tell their patients to be more active. They don't say, 'You need to do interval training three days and week and get your heart rate up to 160 beats per minute for three minutes.' They just don't understand it well enough to prescribe it as a therapy even though scientific research shows that it is the best therapy you can have for anything that ails you."

Clinicians are also concerned about liability with information that makes it into the EHR. "They are concerned that data might get into the record that could be an indicator of a problem that they didn't consider, and therefore, they could be held liable because they technically have the data," Wasden said.

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## Moving Forward

Many of the barriers to adopting interconnected devices, however, can be overcome. To move forward, it's important to:

**MAKE ADOPTION OF STANDARDS EASY FOR DEVICE MANUFACTURERS.** To start, standards and guidelines could become much easier to actually leverage if an open-source reference implementation of the Continua Guidelines was available.

"There is work on an open-source reference implementation of the Continua Design Guidelines. This is an essential part of the process to lower the barrier to entry for manufacturers," Campos said. "It would be much easier to develop a prototype and a final product because manufacturers would have something practical that they could base their efforts on — and this could lower development time and costs considerably."

Currently, it's easy for device manufacturers to develop their own proprietary products, as they simply develop an app and decide what data to collect. But if they venture into the data-sharing realm, developers need to understand how to leverage a certain set of specifications and comply with certain rules — and that adds time and cost to the equation.

"Developers concentrate on designing something that is attractive, very well done, very sleek, or consumers will not adopt it," Campos said. "But if developers want to add interoperability, they have to understand standards. Then, they often experience the trial and error with implementing these standards. When you have an open-source reference code, you just start developing the product and the learning curve is reduced because you see how someone else did it."

**ENSURE END-USERS UNDERSTAND THE VALUE OF CONNECTIVITY AND CERTIFICATION.** Consumers, providers, and health systems need to fully understand the value of interoperability — before they start to demand interconnected devices from manufacturers.

"Consumers are really going to be the driver of the market demand. Once they start buying a number of mobile devices and then realize that they have to do the data aggregation themselves, they will realize the value of interconnectivity and start demanding it," Sensmeier said.

What's more, consumers and care providers will also drive the demand for interoperability "done right" when they realize the value of certification. "The customer, whether it is an individual consumer or provider organization, is not going to understand the deep technical level of standards, nor should they need to," Sensmeier said. "They should just know that if they are buying a certified product that they will be able to plug it in and start using it. It will be a lot easier."

What's more, when purchasing a Continua Design Guidelines certified product, consumers and providers will rest assured that the device complies with security specifications — a concern that is likely to grow in importance as data security continues to dominate the headlines.

## Meet the Experts

**Simão Campos**
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Study Group 16 "Multimedia"

**Rick Cronssen**
*Global Director Health and Life Sciences*
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**Paul Coebergh van den Braak**
*Standardization Manager, Intellectual Property & Standards*
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**Ian Hay**
*Head of Emerging Ecosystems*
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**Michael Robkin**
*President and Founder*
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**Joyce Sensmeier, MS, RN-BC**
*Vice President*
HIMSS

**Christopher Wasden**
*Executive Director of the Sorenson Center for Discovery and Innovation*
University of Utah

"Data security has become a big conversation in our country," Sensmeier noted. "The breaches that can compromise patient care, confidentiality and privacy are becoming important concerns for consumers. So, they will be more likely buy a certified device that has used standards to build protocols for security into the device. If they know the information is not going to be compromised, they will be more comfortable. If people can hack your pacemaker and start to compromise your data, that's not a good thing."

**SECURE BUY-IN FROM GOVERNMENTAL ORGANIZATIONS.** Getting more governmental bodies to support the Continua Design Guidelines, of course, will move interoperability efforts forward as well.

Fortunately, a number of national health ministries are taking up the cause. Health ministries and their agencies responsible for ICT systems from Austria, Catalonia, Denmark, Finland, Norway and Sweden recently delivered a joint letter to the eHealth Network endorsing large-scale deployment of telehealth systems, outlining challenges to implementation and requesting support to address telehealth challenges related to enabling technology and interoperability. All have made a commitment to open standards and interoperability, and to use the Continua Design Guidelines (CDGs) as part of advanced planning or deployment of their telehealth programs. The signers acknowledged the design guidelines, as published by the PCHAlliance, as "the leading open framework for many technical interoperability aspects of personal connected health."

The letter was signed by officials from the Austrian Ministry of Health; the Danish Health Data Authority; the Finnish Ministry of Social Affairs and Health; The Norwegian Directorate of eHealth; and the Inera/Swedish Association of Local Authorities and Regions in Sweden.

"Telehealth has demonstrated considerable potential as an approach for empowering citizens with timely personalized health data and improving health and quality of life for our people," said Sara Meunier, chief technology officer of Inera/SALAR, the agency responsible for coordinating the joint eHealth activities across Sweden's county councils and municipalities, and a member of PCHAlliance. "Our letter appeals to the eHealth Network and its Member States to help us overcome gridlock in the industry and advance the adoption of open standards for interoperable personal connected health."

Increased governmental support would help to create the demand that is needed to push manufacturers to invest in interoperability. "If we can get governments to demand interoperability, then that might provide the push that is needed to move the market for interconnected devices forward. It would help to create the market that would make interoperability worthwhile for developers," Hay said. "Otherwise, manufacturers may be reluctant to adopt interoperability as they perceive that it will require extra development money."

**ENCOURAGE PROVIDERS AND DEVICE MAKERS TO JUMP ON THE INTEROPERABILITY BANDWAGON.** Getting involved with organizations such as PCHAlliance can also help to move interoperability forward. By taking part in PCHAlliance activities, for example, provider organizations could have a voice in how the Continua Design Guidelines are developed and utilized. "Because providers are the consumers of data, they can provide better care for their patients. So, they should want to have a voice in how the guidelines are created because they are the consumers of the data," Robkin said.

Manufacturers also have a large stake in interoperability — and should insert themselves into the standardization conversation as well. "Manufacturers can help to create more useful and easy-to-use guidelines by providing their input into the development," Robkin said. "Without becoming involved with groups such as PCHAlliance, manufacturers don't have any input into the design guidelines and they hear about it when the rest of the industry hears about it, but they don't have insight into the development process as it happens. They can see the public documents. Everyone can see them. So, it is much more valuable for them to actually get involved in the guideline development as it unfolds."

## Getting Involved

Indeed, getting involved with organizations such as PCHAlliance can enable providers and manufacturers to become more involved with interoperability efforts — and could help to move the industry toward the interconnectedness required to fully take advantage of mobile technologies.

Personal Connected Health Alliance

## About PCHAlliance

The PCHAlliance works collaboratively with health, technology and life sciences, public policy, research and advocacy groups to support a new norm of personal health engagement, positive behavior change and improved wellbeing and health outcomes. PCHAlliance is focused on driving the agenda, creating an evidence base and mobilizing collective action to achieve personal connected health for all. PCHAlliance hosts the annual Connected Health Conference, an international forum and expo for networking and showcasing advancements in research, innovations and opportunities in personal connected health. PCHAlliance is a division of HIMSS and home to Continua, which publishes the Continua Design Guidelines. Continua is recognized as the international standard for user friendly end-to-end interoperability of personal connected health devices and systems.

For more information on PCHAlliance, including information about the development of the Continua Design Guidelines as well as information about how to become more involved in the healthcare industry's interoperability efforts, go to **pchalliance.org**

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