New Continua Design Guidelines & HL7 FHIR Webinar
January 24, 2018
8:00am ET/ 14.00 CET

Presented by
Personal Connected Health Alliance
Webinar
The new Continua Design Guidelines with HL7 FHIR

Wednesday, 24 January 2018, 14.00-15.00 CET
Welcome

- Presenters
Presenters

Horst Merkle
Roche Diabetes Care and Chair, PCHAlliance

Ariadna Rius Soler
TicSalut Social Foundation (an agency of the Catalan Ministry of Health)

Ian Hay
Orange and Chair, PCHAlliance Global Technical Committee

Asim Mohammed
Philips and Vice Chair, PCHAlliance Global Technical Committee

Michael Kirwan
PCHAlliance Vice President for Continua

Michael Strübin
European Programme Director, PCHAlliance

(Moderator)
Welcome

- Presenters
- Agenda
The new Continua Design Guidelines with HL7 FHIR

Welcome

About the PCHAlliance and Continua Adoption case: CDGs in Catalonia

The new version of the Continua Design Guidelines, with Q&A

Next steps for CGDs, Continua test tools, “Continua-compliant”

Closing
Welcome

• Presenters
• Agenda
• Ground rules
  • During presentation all listeners are muted
  • (You may put questions in the chat box)
  • The Q&A will be moderated
  • For questions please raise hands
  • Michael will unmute
• A recording and the presentations will be made available.
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About the PCHAlliance and Continua

Horst Merkle
Roche Diabetes Care and Chair, PCHAlliance
PCHAlliance’s flagship event, the Connected Health Conference, is the premier international conference and expo for the exchange of research, evidence, ideas, innovations and opportunities in connected health. Formerly the mHealth Summit, and now in its ninth year, the event features industry-leading keynote presentations, dynamic programming, poster presentations, an interactive exhibit floor, and high-value networking sessions. [www.ConnectedHealthConf.org](http://www.ConnectedHealthConf.org)

Published annually, PCHAlliance’s Continua Design Guidelines define a flexible framework for user friendly end-to-end interoperability of personal connected health devices and systems. Continua certified products bear the globally recognized Continua logo, which signals market-readiness for 21st century health data exchange. The Guidelines are recognized as an international standard by the United Nations’ International Telecommunication Union (ITU-T) and available free in six languages.
PCHAlliance membership

GLOBAL MEMBERS

AT&T  CSIRO  Eli Lilly and Company

intel  Ipsos

PHILIPS  QUALCOMM LIFE  SAMSUNG

ResMed  Roche

STRATEGIC MEMBERS

AND  BD  HP

Helsedirektoratet  Medtronic

MIDMARK  Orange

teva Connected Respiratory breathing technology

verizon

Personal Connected Health Alliance
Continua Design Guidelines

- Continua Health Alliance founded in 2006
- Brings together industry, research, technology and users
- Works from use cases and end-to-end interoperability
- Takes existing standards (ISO/IEEE, IEC, HL7...), makes them fit for purpose
- Maintains & publishes the Continua Design Guidelines (CDGs)
- Offers robust certification program to assess and certify Continua compliance
- Since 2013:
  - CDGs available for free (download on the website)
  - Recognised as formal ITU Standard (ITU Recommendation ITU-T H.810)
- Offer to members: source code, test tools, technical support...
Continua Guidelines for Personal Health Interoperability

Flexible & Future Oriented Architecture

- Supports flow of medical grade data end-to-end
- Extensible to integrate new technologies e.g. FHIR, IoT (2017 CDG)
Opportunity in Europe

- Public health systems
  - universal coverage
  - trusted by citizens
- ... under pressure
  - to make healthcare delivery more efficient and effective
  - to enable citizens and patients to connect
- ... invest in eHealth and telehealth
  - Build EHRs and personal health records

→ Interoperability identified as key prerequisite by all governmental organizations
→ Require open standards
Towards demand push in Europe

**Norway:** (Dec 2014) MoH announced Continua standards as the framework for new national remote health and social care program

**Sweden** (June 2016) Inera signed letter from six governments asking eHealth Network to work towards EU interoperability framework

**Denmark:** (2012) National health IT strategy sets out reliance on (Continua); roll out of national COPD services in 2018.

**European Commission:** (2013) Continua referenced alongside IHE in European eHealth Interoperability Framework

**Catalonia** (July 2017) MoH mandates Continua compliance for glucose meters to connect with personal health record

**Finland:** (Oct 2017) MoH launches personal health record in Dec 2017, expressed interest in diabetes pilot with Continua in 2018.

**eHealth Network:** (May 2017) Invited six governments to present at Malta meeting; new MWP being prepared, led by SPMS

**Austria:** (Oct 2017) MoH published technical framework directive for telemonitoring with Continua

**Portugal:** (Aug 2017) SPMS (division of MoH) joined PCHAlliance, is exploring Continua compliance for devices

**EE Presidency/Digital Health Society:** (Oct 2017) PCHAlliance joins DHS Task Force on interoperability led by Dutch MoH
Evolution of diabetes management

- Advanced analytics requires access to multiple data sources
- Enabling formal and informal partnering is critically important
- Free & secure flow of consistent data via standards is key

**Device & Strip Manufacturer Model**
- **Value Prop:** Meter & Strip Technology
- **Pros:**
  - DMS free of charge
- **Cons:**
  - User confusion, inefficiency

**Third Party DMS Provider Model:**
- **Value Prop:** Connectivity
- **Pros:**
  - Solves connectivity, user issues, population management, improves practice efficiencies, ...
- **Cons:**
  - Adds cost, locks user in, scalability of proprietary connectivity & business

**Integrators Model:**
- **Value Prop:** Content, Context, Analytics
- **Pros:**
  - Freedom of choice, interoperable, extendable, scalable, supports pay for performance
- **Cons:**
  - Slow adoption of techn. Standards

**Inclusion Model:**
- **Value Prop:** Insights, Prediction, Action
- **Pros:**
  - Interoperable across ecosystems, IoHT
- **Cons:**
  - Slow adoption due to competing business models
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Adoption case: CDGs in Catalonia

Ariadna Rius Soler
TicSalut Social Foundation
(an agency of the Catalan Ministry of Health)
• Created in **2006**.
• Public agency within the **MoH of Catalonia**.
• Focus on the deployment of digital health in the Catalan Health System ("Sistema sanitari integral d'utilització pública de Catalunya", SISCAT).
• Includes the Catalan Office of Standards and Interoperability.
• Serves around 7,500,000 citizens.
• More than 100,000 healthcare professionals.
• 70 Hospitals.
• 421 Primary Care centres.
• 240 Mental Health centres.
• 140 Social & Health centres.
• 3,151 Pharmacies.
An adoption case - Glucometers

Promoter needs

Catalan Health Institute (ICS)

State of the art

PCHAlliance - CDG

Approval process

Six companies undergoing
OFSTI has published the new interoperability approval domain for Glucometers

The Office of Standards and Interoperability (OFSTI) of TicSalut Foundation has defined a new domain for the approval of glucometers, with the Catalan Institute of Health (ICS) as a promoter. The defined requirements are based on Continua Design Guidelines of the international organization PCHA (Personal Connected Health Alliance). These guidelines define an interoperability framework to ensure that the information recorded by personal devices can be exchange in a coherent way.

As part of the domain, the following documents have been published:

- Functional requirements for the approval of Glucometers.
- Interoperability requirements for the approval of Glucometers.
- Conformity criteria for the approval of Glucometers.
Next steps

• Finalize the **glucose meter** approval process.

• Work on other device categories (domains).

• Create a **new integration interface** (based on **FHIR**) for Portal AppSalut.

• Define a model to directly **integrate devices** to Portal AppSalut based on **CDG** and **FHIR**.
Ariadna Rius
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Personal Connected Health Alliance

Continua FHIR Observation Upload
Continua e2e architecture
Continua e2e architecture

- Personal Health Devices Interface
  - 11073 Device
  - Bluetooth LE Device
  - Personal Health Device

- Personal Health Gateway (PHG)
  - BLE-IF
  - ZigBee
  - Bluetooth

- Services Interface
  - HL7 FHIR
  - HL7 FHIR added in 2017

- Health & Fitness Service (HFS)
  - IHE
  - OASIS
  - IETF
  - W3C

- HIS Interface
  - IHE
  - OASIS
  - IETF
  - W3C

Direct to Cloud will be added in 2018

Focus of this webinar
Healthcare interoperability standards
Value of the data model

Specs for payload data represent **decades of experts work** on **modelling clinical concepts** and **data models to represent** them.

Clinical concepts evolve, but smoothly and slowly.
The models are being re-used across standards and over time.

The **ICT vehicles** to capture, move, store, manage and access health data **keep changing rapidly**.
- Quite strongly driven by “consumer markets” driven technology changes
- In institutional healthcare, slowed down by regulations and legacy IB
Continua Observation Upload Evolution

- Reuse of 11073 data model in all Phases
- Keep up with evolving technologies and guidelines relevance for the market
- Our life cycle process is designed to extend, recently introduced more agile development approach
Why FHIR based observation upload?

• Many developers (at least the new generation) find it difficult to work with PCD-01
• These new generation of developers feel at ease with web technologies such as JSON, OAuth and HTTP REST.
• FHIR as key enabler for Health 2.0, building an ecosystem of apps and cloud enabled services.
• Easy to develop & test applications due to the availability of open source libraries and FHIR servers
• FHIR as data model for other use cases in the remote patient monitoring domain e.g. patient reported outcomes measures
Continua FHIR based observation upload

- Continua sees two real world scenarios for using FHIR on the Services Interface in the Continua e2e architecture

**Scenario 1:** Observation Server is a standard FHIR Server
  - Client uploads resources in an optimized manner
  - Server is expected to store FHIR resources

**Scenario 2:** Observation Server may not be a standard FHIR Server
  - Uses FHIR as a data model only
  - Client uploads resources as complete bundle that contains the full context information
  - Server is NOT expected to store FHIR resources
Overview of Continua Requirements

• Gateway should map 11073 or Bluetooth LE data to the following FHIR Resources
  • Patient resource
  • DeviceComponent resource
  • Observation resource
• Gateway is expected to use either JSON or XML when uploading a measurement while the server shall support both
• Server shall expose FHIR capabilities via Capability Exchange
• Security
  • OAuth 2.0 is mandatory
  • Gateway shall use either Client Credentials or Resource Owner Credentials as grant type, while Server shall support both
  • Other grant types such as “Authorization Code” are optional
  • Measurements must be uploaded using a secure TLS section using a valid OAuth Bearer Token
What’s next

• FHIR Retrieval API
• Continua FHIR profiles for Patient Reported Outcomes Measures
• Direct to Cloud Use Case
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Michael Kirwan
PCHAlliance Vice President for Continua
NEW CONTINUA DESIGN GUIDELINES ENABLE INTEGRATION OF PATIENT GENERATED DATA INTO ELECTRONIC HEALTH RECORDS TO SUPPORT CHRONIC DISEASE MANAGEMENT BUILT ON HL7 FHIR SPECIFICATIONS


We’ve completed coverage for all use-cases initially targeted. We are now in a new period where, with several new PCHAlliance initiatives, we can now focus on new use-cases, new stakeholder needs and in improving what we’ve built.
Next Steps for the CDG: A Better Developer Implementation Experience

2017 Device-side Expansion
1. Power Status Monitor
2. Drop-in Commercial Ready Code

2017 Bluetooth low energy Fixes
1. Current Time Service & Time-stamping (Sensor disconnect, inconsistent setting of time)
2. Handling of duplicate data
3. Pairing issues
4. Uploads to servers that either do or do not store data
5. ASN.1 Bits

2018 Device-side Expansion
1. Enabling any Transport Technology
2. BTLE Physical Activity Monitor
3. Urine Analyzer
4. Device Cyber-Security
5. Command and Control
6. Updates for many device specializations/Profiles
   - for better time stamping and synchronization, better error reporting, cybersecurity, errata, etc.
7. Updates for the IoT & Healthy Longevity Initiatives

2017 Service-side Expansion
1. FHIR H.821.5 Observation Upload
2. Drop-in Commercial Ready Code
3. Errata updates

2018 Service-side Expansion
1. Direct-to-Cloud
2. Commercial Ready Drop-in Code
3. PHD over IP Connectivity project
4. E2E Cyber-security integration
5. Command and Control
6. IoT (Cellular and IP based development)

2018 Architecture Improvements
1. Better Alignment with ITU
2. Full Open-Source of Continua
3. Improving our key SDO’s RPM standardization for Continua
4. Redundant pathways
5. Decentralization of information
Committed to Complete Device Certifications by 2020

Continua Certification now Fully Open

1. **Continua Design Guidelines freely available.**
   - Members may certify to them immediately.

2. **Adopter members can join for only $1500 level and Certify**
   - And are allowed to certify.
   - And all Certification listing fees are now only $1000 USD.
   - Certifications will be heavily marketed to governments, health ministries and other large organizations via PCHAlliance Match-making program (matching buyers to sellers) as well as accessible via the new Certified Product Showcase (CPS).
   - The CPS is search engine optimized, shows all commercially available products, is mobile format ready and includes the ability to download as a .CSV any filtered searches.

3. **If not ready to certify**, we have also created a new program called Continua Compliant.
   - This program allows any vendor to self-declare that they are compliant if you’re not ready to become a member and get fully certified.
   - We will give away the test tool for free. Vendors need only share their completed summary test report with PCHAlliance to be listed on the Continua Compliant listing (at no cost).

We’ve completed coverage for all use-cases initially targeted. We are now in a new period where, with several new PCHAlliance initiatives, we can now focus on new use-cases.
Sponsors Needed: Help us catalyze a technology movement

https://members.pchalliance.org/document/dl/1166
Our biggest challenge
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• Next PCHAlliance events:
  • HIMSS Annual Conference, 5-9 March, Las Vegas, NV
  • PCHAlliance Plugfest, 17/18 April 2018, The Hague/NL (side event of the IHE Europe Connectathon)
  • PCHAlliance Open House and Member Summit, 29-31 May 2018, Sitges, Spain

• Would you like to contribute? For membership information go to
  • www.pchalliance.org > membership

• Questions? Issues? Contact:
  • Michael Strübin, European Programme Director: mstrubin@pchalliance.org
  • Michael Kirwan, Continua Vice President: mkirwan@pchalliance.org
Thank You!

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