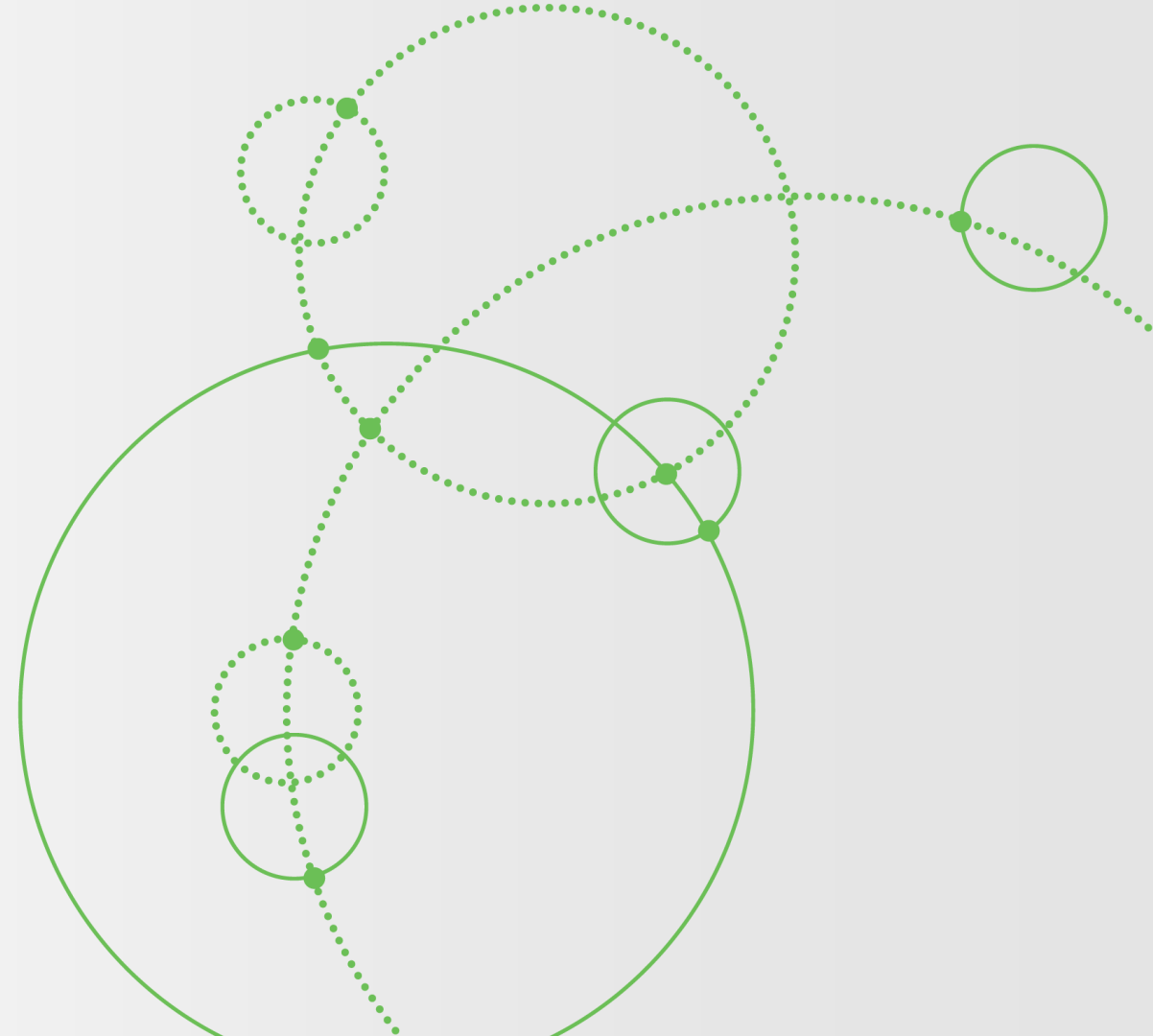




**Personal  
Connected  
Health  
Alliance**

Continua Compliant Webinar

*June 28<sup>th</sup>, 2018*



# Continua Compliant Webinar



This 1-Hour Webinar is for Bluetooth and HL7 FHIR developers and engineers involved in medtech, government, associations, educational institutions, start-ups, research, integrators, etc., who would like to learn how to ensure that their PGHD health, medical or fitness products (hardware and/or software) are compliant with the Continua Design Guidelines.

This Webinar will be recorded and viewable from [PCHAlliance.org](http://PCHAlliance.org).

# Continua Compliant Webinar

Significant membership growth, global confidence in the CDGs and the attainment of a worldwide ecosystem of Continua Compliant Products.


1. PCHAlliance & Continua
2. Continua Compliant
3. Continua Test Tool



**Continua**<sup>®</sup>  
CERTIFIED



**Continua Design Guidelines**  
Deploying Interoperable Connected Health in Your Health System





**Continua**  
DESIGN GUIDELINES

*Secure Medical Data Exchange*

**Problem**  
Improving outcomes at lower cost is being stymied by lack of interoperability between vital signs sensors and population management platforms.

Today's solutions are limited in scope (e.g., using blood sugar level as the sole input to manage only diabetes) while sensor and platform vendors consume precious development resources repeatedly integrating a multitude of sensors.

They should be developing care support functions that can be unleashed by a free flow of health data.




**Continua Design Guidelines**


**Solution**

- Healthcare providers and insurance companies focus on achieving outcomes at lower costs through outsourced population management services.
- Remote care service companies integrate the personal connected health technology systems essential to realizing these lower costs.
- Device and sensor companies furnish the meaningful observations that enable these ICT systems to deliver vital signs data captured from multiple sources by people at home and on the move.

These opportunities converge on Continua, which provides the only multi-measurement solution crucial to unleashing the massive amounts of data that enables a more holistic perspective, empowering people and clinicians with better insight to deliver better health services.



Download the CDG!  
Scan here or visit  
<http://www.pchalliance.org/continua-design-guidelines>



*CDG's foster integration to enable medical-grade health/sensor data to flow from a multitude of vital signs devices used by consumers to health services, all the way into local, regional or national EHRs and data lakes in a safe and secure manner.*



**What We're Aiming For**

# Panelists

**Diego Bartolomé Arquillo**

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**CTT Project Manager and CCE at  
DEKRA**

**[diego.bartolome@dekra.com](mailto:diego.bartolome@dekra.com)**

**Thom Erickson**

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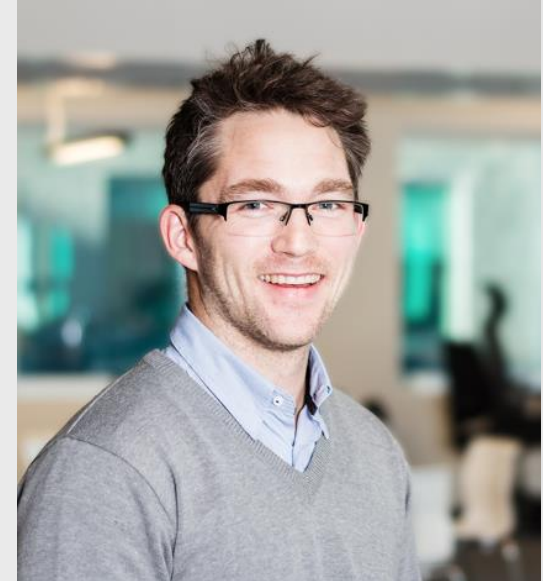


**Director, Technical Operations at  
PCHalliance**

**[terickson@pchalliance.org](mailto:terickson@pchalliance.org)**

**Bjørnar Henriksen**

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**Senior Consultant and CCE at  
Egde Consulting**

**[bjornarh@egdeconsulting.no](mailto:bjornarh@egdeconsulting.no)**



# Personal Connected Health Alliance (PCHAlliance)

- A Non-Profit organization formed 2014 under the leadership of HIMSS
- A merger of:
  - Continua Health Alliance
  - mHealth Summit
  - HIMSS
- Leading the field of Personal Connected Health



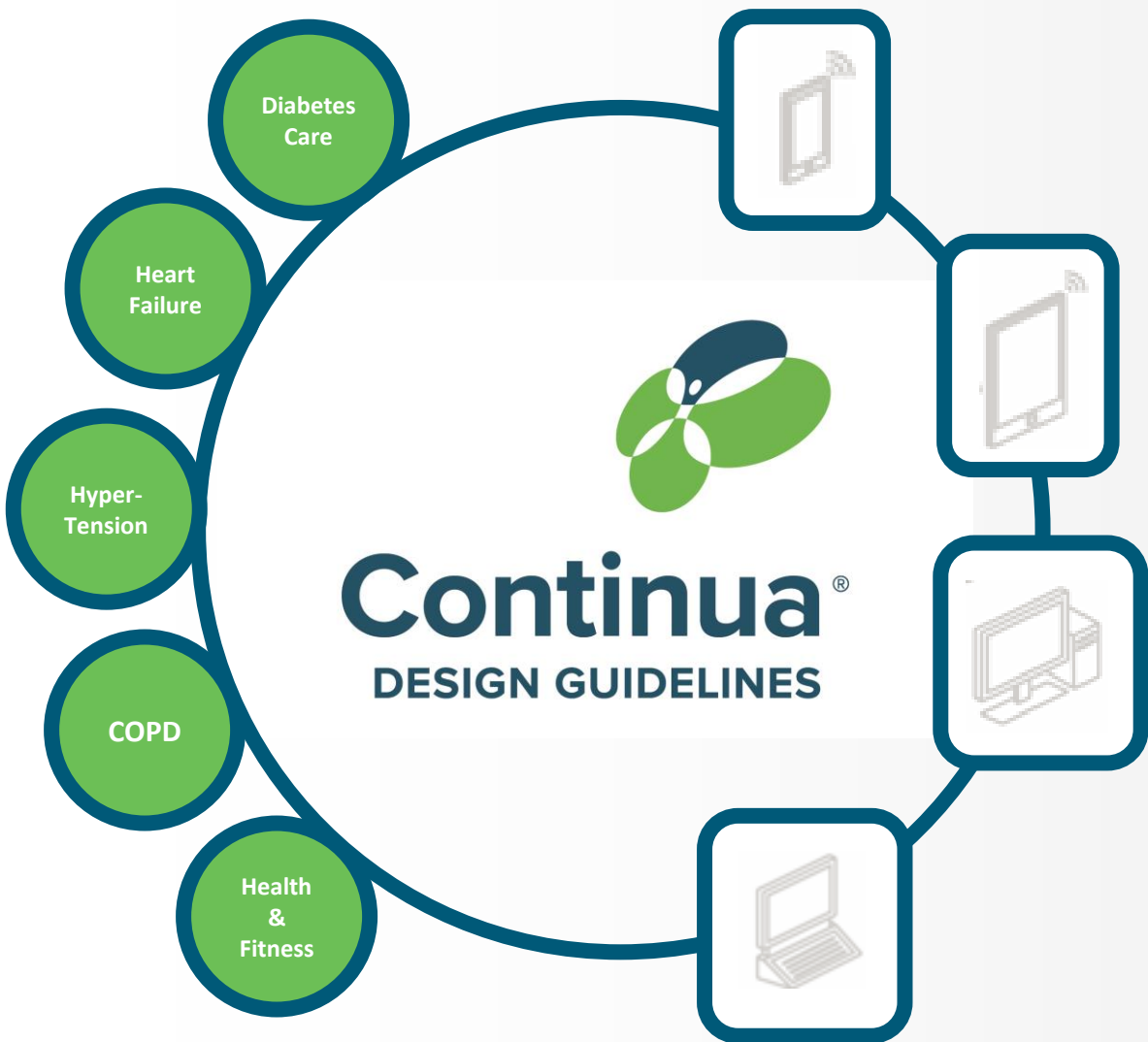
Our Vision:

*Help people make health and wellness an effortless part of daily life*

**We Put The Person in Connected Health**



# Personal Connected Health Alliance



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)

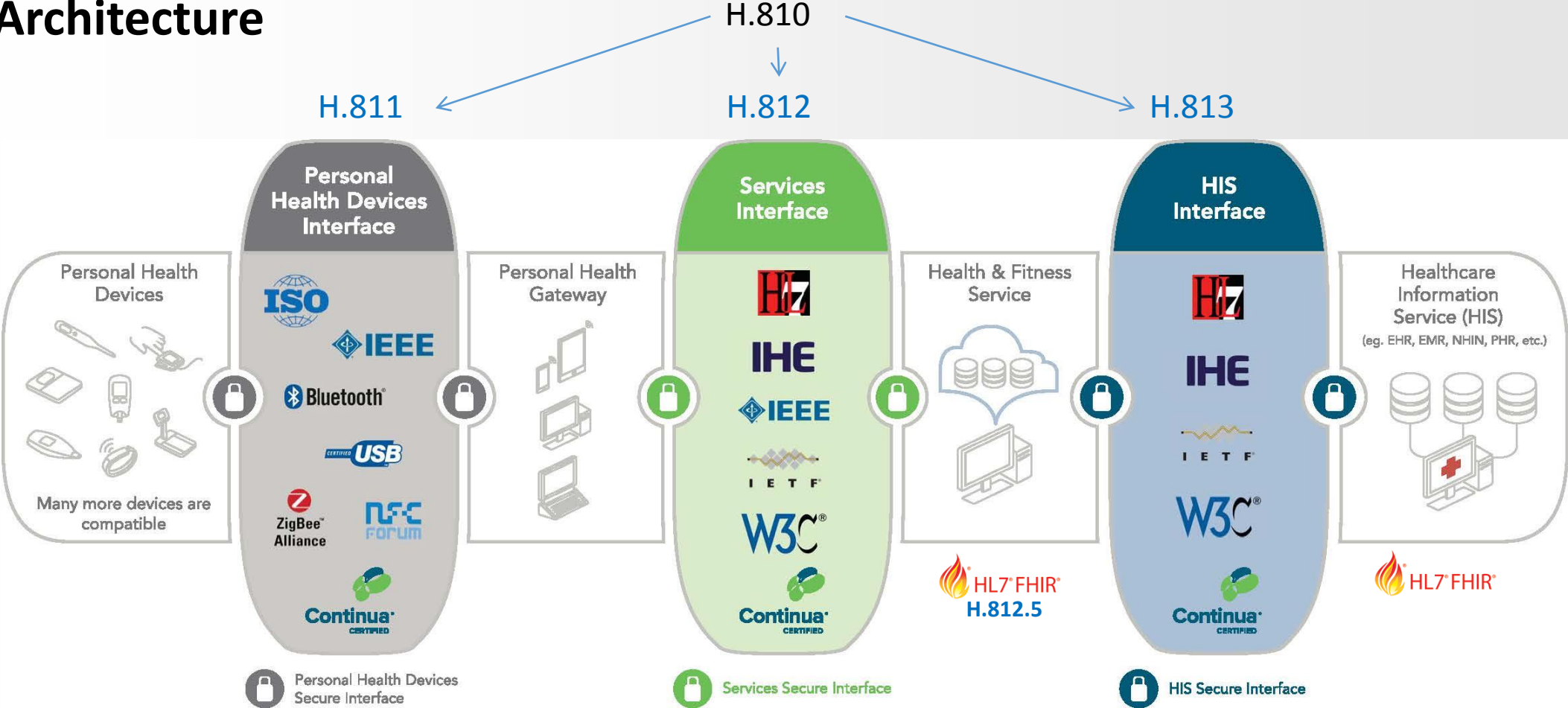


## Continua®

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.

# ITU Global Standard = Continua Design Guidelines

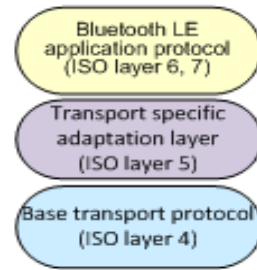
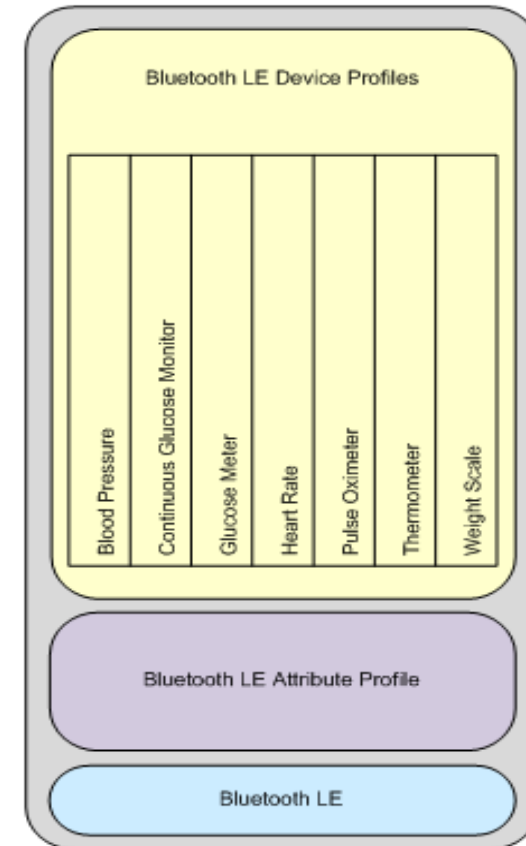
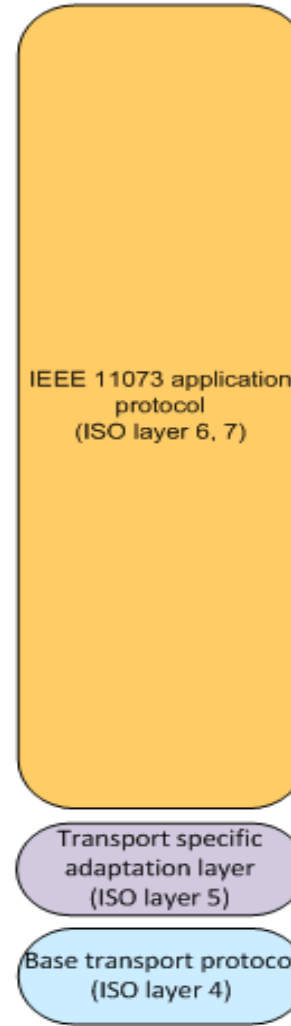
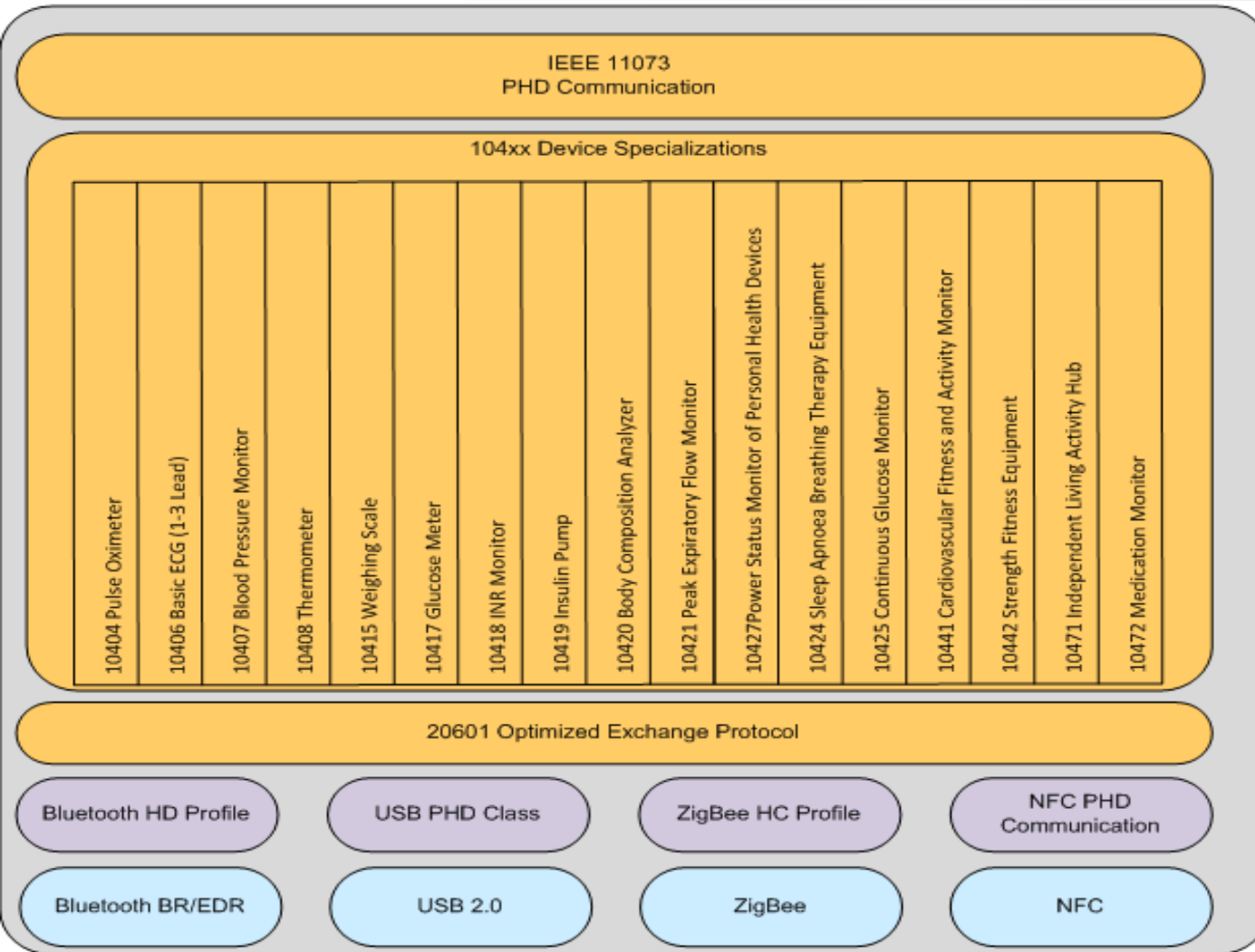
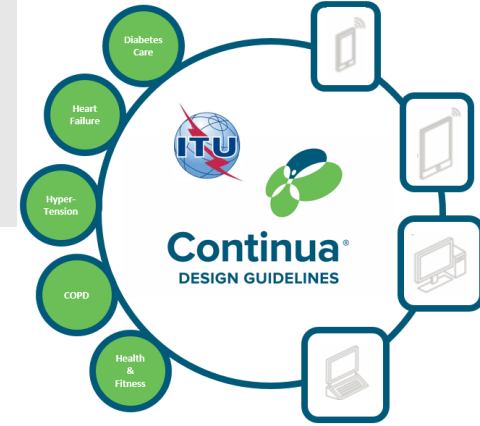
## CDG Architecture



<http://www.itu.int/rec/T-REC-H.810-201312-I>



# Continua Technical Foundation



# PCHAlliance Membership Structure (Governance)

**PCHAlliance Board of Managers**

**PCHAlliance Advisory Council**

**Rich Scarfo**  
Vice President  
PCHAlliance

**Continua Council**

**Michael J. Kirwan**  
Vice President,  
Continua

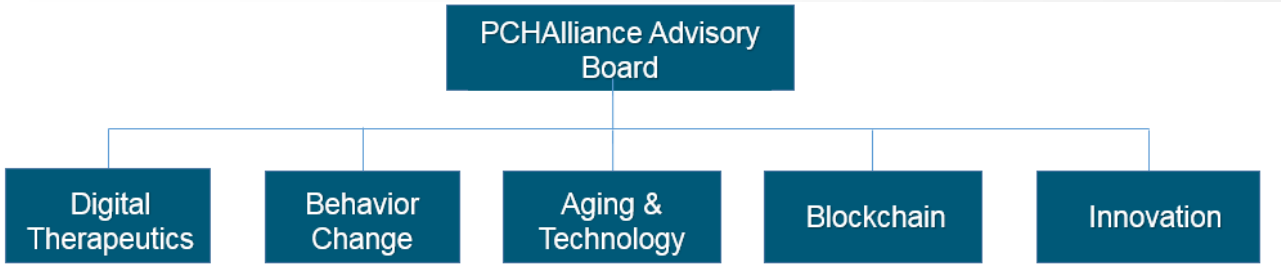
**Committees**



**Standing Work Groups (SWG)**



**Task Forces**



# Committed to Complete Device Certifications by 2020

## Continua Certification now Fully Open

### 1. Continua Design Guidelines freely available.

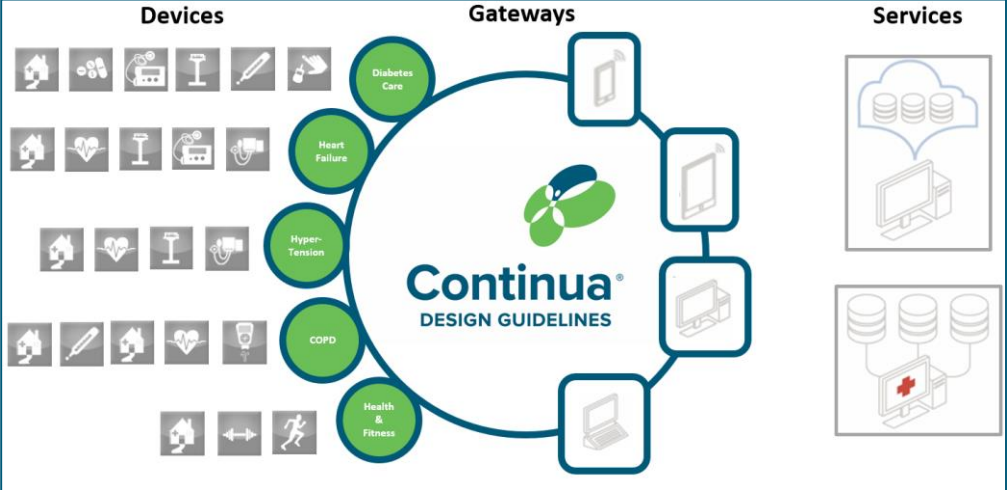
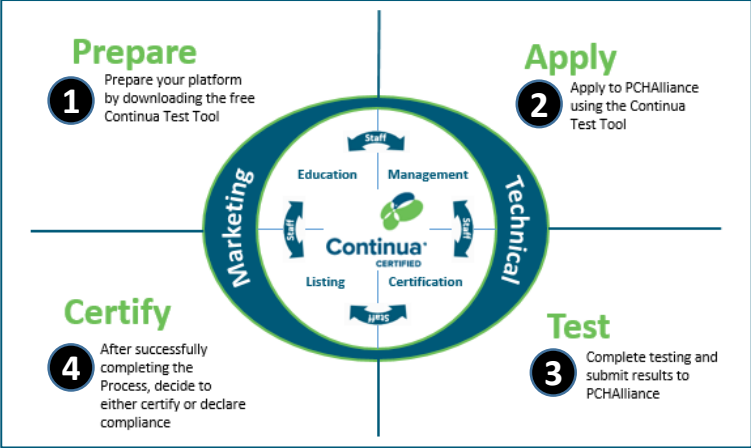
- Members may certify to them immediately.

### 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.

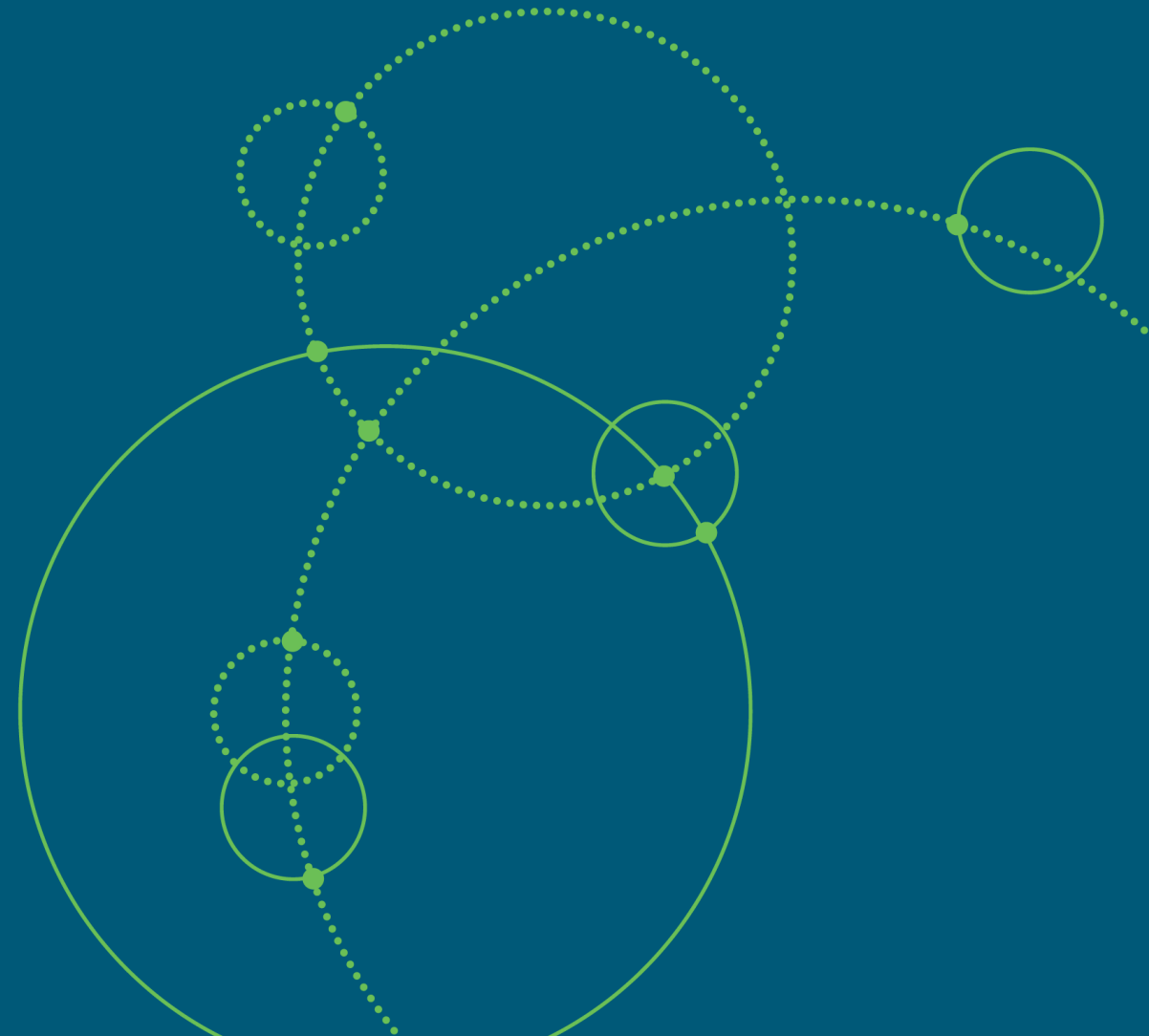
### 3. If not ready to certify, we have also created a new program called Continua Compliant.

- 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. Venders need only share their completed summary test report with PCHAlliance to be listed on the Continua Compliant listing (at no cost).



# Continua Compliant

Bjørnar Henriksen



# Continua Conformity Assessment

**CTT**  
Continua Test Tool

**CLI**

All Organizations who want to be listed are required to test their product with the CTT

Organizations who successfully pass the CTT may be listed.

A "Continua Compliant" Product may use the wordmark only (no Continua logo).

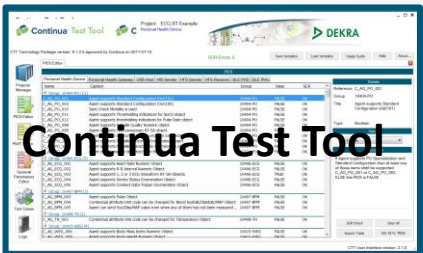
A member who has certified may use the Continua Certified logo.

**1** Continua Compliant



Free Listing

**"Continua Compliant"**



Continua Test Tool

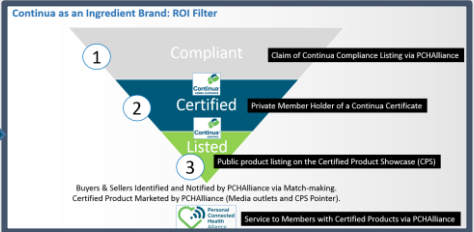
**2** Continua Certified



Member Only Listing



PCHAlliance Markets Member's Product

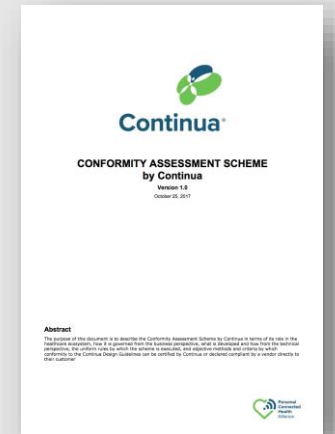


PCHAlliance Match-making (matching buyers to sellers)

**Any Product Can Be Compliant**

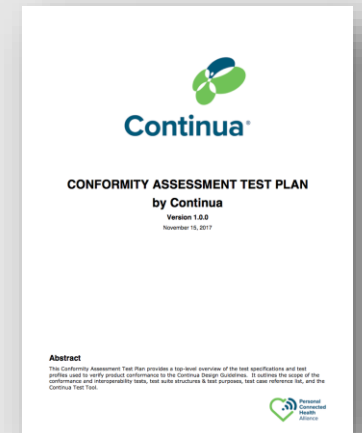
# Conformity Assessment Scheme (CAS) by Continua

- Ensure products conform to the Continua Design Guidelines and underlying standards and demonstrate interoperability between conforming products.
- Defines Uniform Processes & Procedures for
  - Developing and maintaining test cases, test plans, and test platforms.
  - Operation of and access to recognized test facilities.
  - Common assessment criteria, approved lab configurations, uniform standards-based test method selection based on product features, standardized test reports, and declaration statements.
- 3<sup>rd</sup> Party Certification
  - High value, transparent and objective methods and criteria for certification of test results that are recognized worldwide
- Continua Compliant Self-Declaration



# Conformity Assessment Test Plan (CATP) by Continua

- Conformance and interoperability testing that is performed to ensure products conform to the Continua Design Guidelines and its underlying standards and demonstrate interoperability between conforming products.
- Test Descriptions are written in the form of Test Suite Structure & Test Procedures documents to guide execution of conformance tests using the Continua Test Tool (CTT).
- Conformance testing verifies compliance with:
  - PHD IF requirements for transports, exchange protocols, certified capability classes, and device specializations;
  - Services IF requirements for Web Services Interoperability, SOAP/ATNA, PCD-01 HL7 messages, consent management, hData observation upload, and questionnaires;
  - HIS IF sender and receiver.
- Interoperability testing verifies basic PHD and Services functionality of typical use cases for a device specialization against a test bed of Continua certified devices



# Product Assurance by Continua

- Standards essential but not sufficient to ensure multi-measurement interoperability.
- Conformity Assessment provides a common framework for buyers to articulate product requirements and vendors to demonstrate compliance to those requirements.
- Proper integration of conformity assessment into the product development life cycle can reduce overall time to market.
- Vendors may:
  - Use the Continua Test Tool in their own lab to self-declare compliance.
  - Work with 3<sup>rd</sup> party labs to enjoy benefits of Continua Certification
- Demonstrating interoperability is key to resolving root causes of regulatory challenges.



# Continua Compliant Process

- The objective is to provide a freely available uniform pre-approval process enabling any vendor the ability to declare that its products are compliant to the Continua Design Guidelines.
- It is important to note that self-declaration of compliance is governed by the business arrangements between the product vendor and the customer requesting the testing in order to self-declare compliance.
- It is recommended, but not required, that laboratories conducting conformity assessment testing for the express purpose of self-declaration of compliance to the CDG be accredited to ISO 17025.
- All compliance assessment criteria appropriate for the features supported by the product under test are the same regardless of pursuing certification or self-declaration.

# Continua Compliant Procedure

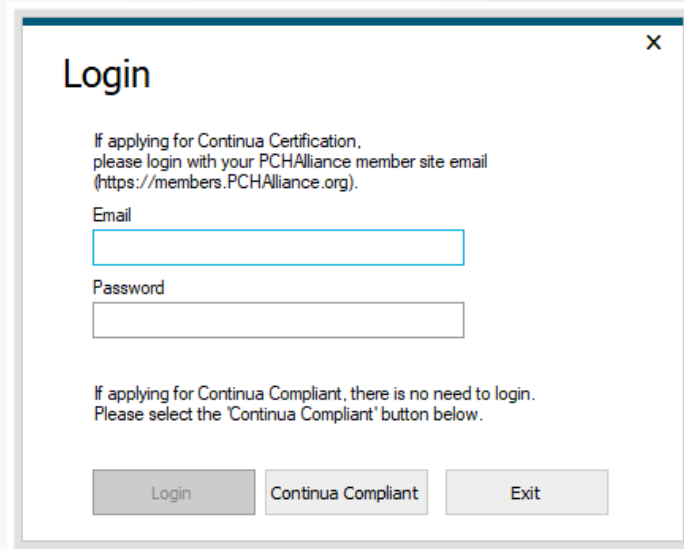
- Continua provides a series of procedures in sufficient detail for vendors to navigate the test and self-declaration process. Continua Certified Experts are available for assistance.
  1. Download the Continua Test Tool
  2. Execute Compliance Testing
  3. Execute Interoperability Testing (Optional)
  4. Generate Statement of Compliance
  5. Post to Continua Compliant Products Listing
- It is recommended that the vendor familiarize themselves with the following documentation prior to testing:
  - [Conformity Assessment Scheme by Continua](#)
  - [Conformity Assessment Test Plan by Continua](#)

# Continua Test Tool for Continua Compliant

Diego Bartolomé Arquillo



# CTT for Continua Compliant: Login procedure



The screenshot shows a 'Login' dialog box with the following content:

**Login**

If applying for Continua Certification, please login with your PCHAlliance member site email (<https://members.PCHAlliance.org>).

Email

Password

If applying for Continua Compliant, there is no need to login. Please select the 'Continua Compliant' button below.

- If the user is a PCHAlliance member, he/she must use his/her PCHAlliance member site email and password and press the “Login” button. Once verified, the Continua Test Tool – Continua Certification version will start.

NOTE: an Internet connection is required to use the Continua Test Tool – Continua Certification version.

- If the user is not a PCHA member, he/she shall use the “Continua Compliant” button to access the Continua Test Tool – Continua Compliant version.

# CTT for Continua Compliant: Submit test results

The screenshot displays the Continua Test Tool interface. The top bar shows the project name "New Project Personal Health Device" and the DEKRA logo. The main window is titled "Logs" and contains several sections:

- Test Cases Execution:** A table listing test cases with columns for ID and GroupName. The selected test case is TP\_PLT\_PHD\_OXP\_COM\_BV\_007, which belongs to GroupName 20601.
- Test Case ID:** A field containing the selected test case ID: TP\_PLT\_PHD\_OXP\_COM\_BV\_007.
- Verdict:** A dropdown menu set to "ALL".
- Date:** A date selector set to "19/02/2018".
- Logs Table:** A table showing execution logs for the selected test case. The table has columns for Date, Time, and Verdict. Two entries are shown, both with a "PASS" verdict.
- TestConfig.cfg:** A text area showing configuration details for the test case, including ID, position, group, date, and SCR Errors (0).
- Result TestCase.html:** A preview of the test report, which includes the Continua and DEKRA logos, the test case ID, verdict (PASS), and date (Mon Feb 19 16:11:21 2018).

At the bottom of the interface, there are two buttons: "Continua Compliant Self-Declaration Statement" and "Continua Certification Application". The status bar at the bottom right indicates "CTT User Interface version: 3.0.0 - Continua Certification Version ...".

- “Continua Compliant Self-Declaration Statement” button: it starts the Continua Compliant Self-Declaration Statement wizard. This wizard requires that all applicable test cases have been run.

# CTT for Continua Compliant: Self-Declaration

Continua Compliant Self Declaration Statement Wizard  
Section 1 - Product Overview

Company Name	A Company
Product Name	Insulin Pump A
Model Number	A23
Hardware Version	1.2
Software Version	2.0
Product Role	PHD
Transport Type	USB
Declaration Date	martes .20 de febrero de 2018
Guidelines Version	DG2017
Continua Test Tool Version	7.0.0.0
Company URL	http://companyurl.org
Product URL	http://insulinpumpa1.org

Do you wish to upload the self-declaration to the PCHA web site?

Not to be publically displayed by PCHAAlliance before (enter date) martes .20 de febrero de 2018

Next  
Previous  
Save

Continua Compliant Self Declaration Statement Wizard  
Final Step

Required materials have been generated and zipped in  
[C:\Program Files \(x86\)\dekra\ContinuaTestTool\SDDecl\New Project\\_self\\_decl\\_package.zip](C:\Program Files (x86)\dekra\ContinuaTestTool\SDDecl\New Project_self_decl_package.zip)

You must submit the Continua Compliant Self-Declaration Statement to PCHAAlliance (CertAdmin@members.pchalliance.org) to have your product listed on the Continua Compliant Product Listing.

Open Folder

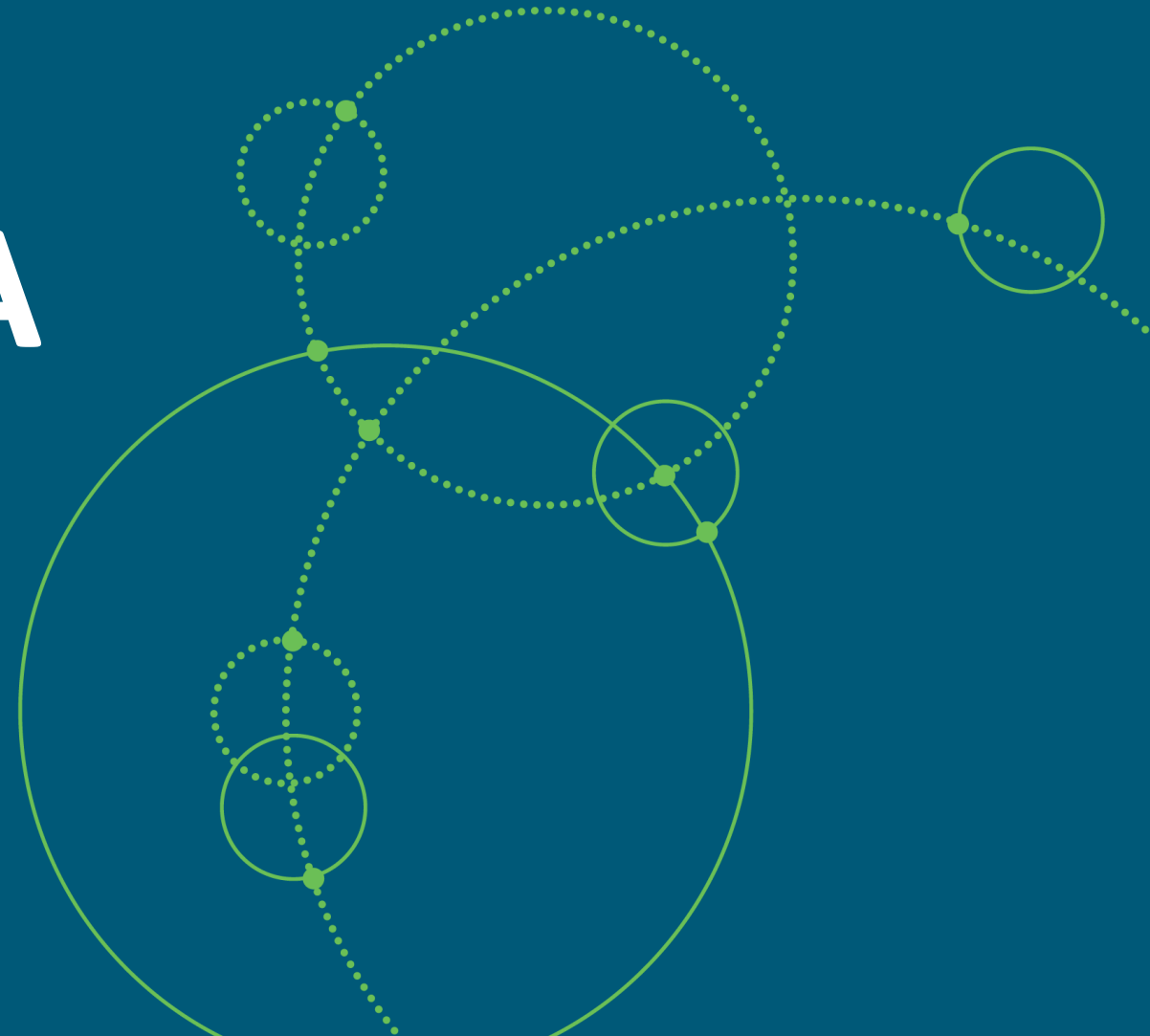
Finish  
Previous  
Save

- When user has completed the execution of all applicable test cases according to project configuration, the Continua Compliant Self-Declaration Statement Wizard can help him/her to generate and send the required self-declaration documentation files to Continua.

# Tool Demonstration



# Q&A







**Thank You**

