
Connectivity Industry Consortium (CIC)

The Universal Standard for Point of Care Connectivity

CIC EI MEDICA 2007 Meeting Summary

November 15th, 2007 Düsseldorf, Germany



This memo summarizes the essential details of the Point of Care Connectivity Industry Consortium - European Initiative MEDICA 2007 Meeting, held November 15th on the Roche boat "MS Viking Pride" in Düsseldorf.

1. EXECUTIVE SUMMARY

The European Initiative (EI) of the formerly US Connectivity Industry Consortium (CIC) held its eighth major briefing meeting for Point-of-Care and related organizations during Medica 2007 trade fair on November 15, 2007 in Düsseldorf, Germany. Traditionally the annual meeting was held in conjunction with the MEDICA conference and again it took place on one of the boats chartered by Roche Diagnostics. Our special thanks goes to Roche Diagnostics for this arrangement.

More than forty individuals indicated their interest in participating at the workshop or receiving information about the content of the meeting 2007. The event was a great success providing very informative and interesting presentations by top-class referents. This year the congress focused on the two aspects of POCT - the professional and the personal point of care testing. Besides the presentation of the present status of POCT1-A2 two healthcare information technology partners presented their organizations and activities: Continua Health Alliance (CHA) and IHE. In spring 2007 IHE had performed a "Connectathon" - its unique connectivity testing platform for interoperability profile implementations - in conjunction with the eHealth Week 2007 congress in Berlin, Germany. CHA as the leading industrial consortium in the field of emerging Personal Health technology presented their vision of future personalized health care connectivity.

BRIEF HISTORY

At MEDICA 2000, the CIC had launched the European Round Table (ERT) with the goal of involving European users and vendors into the related standardization and dissemination efforts and to internationalize the standard. One of the European key activities was to support and drive the process of adopting NCCLS/CLSI POCT1-A, which was further developed into today's POCT1-A2, as a formal international standard.

In 2001 the ERT was renamed to "CIC European Initiative" (CIC EI). By the end of that year the Connectivity Industry Consortium (CIC) achieved its goal of developing a standard for point-of-care (POC) connectivity based on existing IEEE and HL7 standards and on specifications developed by the CIC. The CLSI1 (formerly NCCLS) updated and approved the originally proposed AUTO6-P draft standard. This standard was later published as 'POCT1-A'. Relevant HL7 and IEEE standard specifications correspond to POCT1-A.

The standard is also embedded in the CEN / ISO / IEEE 11073 family of standards which was enabled by the 2002 ISO/IEEE pilot process agreement. Results from POCT1-A-related CLSI modification and extension efforts are reflected in the recent standard edition POCT1-A2 published in March 2005.

The CIC European Initiative supported the process of promoting POCT1-A - and ongoing POCT1-A2 - as a formal joint international standard. In September 2006 the CIC EI reached the first important step towards its target: ISO adopted POCT1-A as Draft International Standard ISO 11073-90101. Ongoing CIC EI revision work contributed to the recent POCT1-A2 edited by CLSI, further aiming at its adoption on international level and future revisions to align it with recent developments in HL7 and CEN / ISO / IEEE 11073 standard systems.

Our efforts as well as complimentary activities of our technology partners from Continua Health Alliance (CHA) and "Integrating the Healthcare Enterprise" (IHE) are jointly contributing to a common international system of open interoperability standards for integrated professional and

¹ As of January 2005, the NCCLS changed its name to the "Clinical Laboratory and Standards Institute", CLSI.

personal health-related infrastructures. Accordingly, POCT1-A2 is embedded in the ISO 11073 family of standards, which is also giving direction to the CHA standards development. IHE with its work on interoperability profiles and related "Connectathon" activities is an established link between standardization and related user communities.

CIC EI MEETING 2007

The eight CIC EI meeting received excellent feedback. This year we focused mainly on activities around the international system of open interoperability standards for integrated professional and personal health-related infrastructures.

Particular attention was raised by the presentations of our partner organizations. While the efforts and activities of the CIC EI as well as of IHE relate to the professional health care sector, the CHA is representing the personal health sector. Both focus on the same objective for the health care market - the user's respectively the customer's barrier-free data access utilizing functional and semantic interoperability standards.

We updated the audience on the status of the POCT1-A2 standard, its acceptance and internationalization. Two diagnostics companies presented their perspectives of the main topic: Roche Diagnostics as a former core member of the CIC and present member of CHA, and GE HealthCare as a former supporting vendor of the CIC and member of both IHE and CHA. Intel as initiator of the CHA introduced the Alliance to the participants.

Christina Rode-Schubert, CIC Secretary General, opened the meeting welcoming the attendees and introducing the main topic. She gave a brief history of CIC EI and the development and updates of the standard which was latest issued in March 2005 as POCT1-A2 by the CLSI. The long history of communication and cooperation between CIC EI and its technology partners IHE and CHA as well as their complimentary activities were focussed second in this speech.

Thomas Norgall, Fraunhofer-Institut für Integrierte Schaltungen, Erlangen, Chair of the CIC EI, then updated attendees on the recent progress regarding formal approval of the standard by DIN, CEN and ISO (see above), industrial and user acceptance as well as related activities from a CIC European Initiative perspective. The institute offers not only general support and services for POCT1-A interface development, but particularly an independent service and related protocol simulator tools for POCT1-A compliance and interoperability testing. These were successfully used by several industrial partners in their product development processes, most recently in a cooperation with Roche.

Robert Hughes from Intel Corporation, Santa Clara, USA, is chair of the Bluetooth Medical Device WG closely collaborating with Continua Health Alliance. He introduced the Continua Health Alliance (CHA): Continua Health Alliance is an industry consortium targeting the telehealth and remote monitoring markets with the stated intent of bringing together standards and diverse technology to enable better personal health care for people worldwide. The alliance is active in IEEE 11073. Mr. Hughes presented the vision of the alliance and drew a picture of a future personal health ecosystem. The video he was supposed to show is available on the CHA website http://www.continuaalliance.org/about/vision_video/

Horst Merkle, Roche Diagnostics, Indianapolis USA, presented a Diagnostics company member perspective of Continua Health Alliance. Roche Diabetes Care is participating as a founding member to drive and support the development of emerging markets for interoperability, remote monitoring / telehealth. Roche's broad diabetes care expertise motivates their concern to ensure that the requirements of end customers are adequately addressed in the Continua guidelines. They are also

leveraging technical resources to ensure that Continua specifications reflect the requirements of devices / applications and enable the product portfolio to be Continua compliant. Roche is contributing regulatory knowledge with the goal to achieve endorsement of the Continua standard by regulatory bodies. Mr. Merkle presented expected benefits from their participation in the CHA. He also expressed a couple of questions for relevant issues of EHR/meter integration.

Andreas Kumbroich, managing director of Vision4Health Germany, presented a new, visionary company profile to address the diagnostic market providing the vision of a new generation of diagnostic software. He described the role of POCT Standards at Vision4Health. The founders and the employees have a long-term experience in laboratory and healthcare markets. The company is a participating manufacturer at the IHE Oxford 2008 conference to support POCT with IHE-Profiles.

It was a great pleasure having Charles Parisot, GE Healthcare France, at our conference. GE is promoting member of CHA. His speech was entitled "GE Healthcare - Health Care Companies striving for Standardization in IHE and CHE". As a co-chair of the IHE IT Infrastructure Committee he gave an overview of IHE as framework for interoperability and provided general information about the IHE, impressions of the connectathon and an introduction to the IHE laboratory domain where also POCT is located.

Fabrizio Mastrantonio, A. Menarini Diagnostics, Florence, Italy, presented "e-POCT - A paradigm-shift in POCT Connectivity". Mr. Mastrantonio gave an overview of NetCare 2.0, the A.Menarini system that allows decentralised laboratory tests, taking the organisation, control and management of diagnostic tests outside the traditional central laboratory. He presented the EolieNet project aiming at the development of a Telemedicine platform for the Eolian Archipelago and focused on special customizing of NetCare 2.0 for the project. He further introduced the Chr.I.S.T.I.N.A. Project (with ISS) addressing treatment of post-acute cardiovascular patients via home telehealth.

Bernd Blobel - University Hospital Regensburg Germany, Head of eHealth Competence Center Regensburg: Personal Health Requirements and the Framework of Standardization

Finally Thomas Norgall, CIC Europe Initiative Chairperson, led the meeting discussion. He reviewed, summarized and closed the CIC EI MEDICA 2007 meeting.

Please find all presentations as attached and soon on our CIC EI website (www.poct.fraunhofer.de).

In this year's discussion the attendees agreed that, regardless of global trends towards "e-health", there is still a lot of work left to be done at European and international levels to educate users in particular on how implementation of the POCT1-A2 standard can establish cost-effective multi-vendor connectivity. This issue was already part of the CIC sunset strategy and is recorded in the "Sunset Transition Plan". Funds are set aside to continue supporting the CIC EI.

The CIC EI continues to be actively involved in the further development of global POCT standards. In this regard, its mission is to articulate in particular the European users' perspective. Emphasis is on motivating the different players in the POCT arena to bring in their expertise and resources and to co-ordinate their work towards common standards that fit well into the emerging system of international interoperability standards and frameworks. Hence CIC EI does not completely restrict its focus to "pure" POCT device interoperability issues only, but also has to take into account the whole domain of medical device communication including ongoing "e-health" and emerging "personal health" activities and related infrastructure deployment. Therefore, in 2007 we focused on CIC EI relationships with CHA and IHE and we will proceed with this strategy in 2008.

Furthermore, the EI endorses POCT1-A2 conformance and interoperability testing activities, e.g. at the Fraunhofer Institute IIS. Since 2005 the institute offers an independent implementation support and evaluation service that enables companies to provide interoperability-test-proofed standard-compliant implementations. The task of the CIC EI will be to promote the standard and to support and communicate related services among the diagnostics industry.

2. PRESENTATIONS

The following presentations will be available on the CIC EI website or websites named

- Christina Rode-Schubert - BE Consulting Heidelberg Germany, Secretary' General CIC Europe: A Brief CIC EI History - and Personal Health as a New Driver for Near Patient Testing Standardization
- Thomas Norgall - Fraunhofer-Institut für Integrierte Schaltungen IIS-A Erlangen Germany, CIC Europe Chairperson: Status Quo and Ongoing Work. The way to NCCLS POCT1-A as a formal international standard
- Robert Hughes - Intel Corporation Santa Clara USA, Bluetooth Medical Device Profile Chair
Continua Health Alliance: Continua Health Alliance (CHA) - An Alliance Focusing on Personal Health
- Horst Merkle - Roche Diagnostics Indianapolis USA, Roche Diagnostics - Information Management Program Diabetes Care, Continua Health Alliance Member: Continua Health Alliance - A Members Perspective
- Andreas Kumbroch - Vision4Health Germany: POCT Standardization at Vision4Health
- Charles Parisot - GE Healthcare Buc France, IHE IT Infrastructure Technical Committee Co-chair: GE Healthcare - Health Care Companies striving for Standardization in IHE and CH
- Fabrizio Mastrantonio - A. Menarini Diagnostics Florence Italy: "Case study" - A Paradigm Shift in the Point-of-Care Testing Connectivity
- Bernd Blobel - University Hospital Regensburg Germany, Head of eHealth Competence Center Regensburg: Personal Health Requirements and the Framework of Standardization

3. PARTICIPANTS

Thirty-five individuals representing twenty-four different organizations attended the meeting, as summarized in the following two tables.

Table 1: Attendance, by Country

COUNTRY	ATTENDEES
Belgium	1
Denmark	2
Finnland	1

France	2
Germany	23
Netherlands	1
Spain	2
Swiss	2
UK	1
USA	7
Total	42

Participants represented the in-vitro diagnostics industry, information technology vendors, point-of-care users, universities and research institutes, healthcare consultancies, and other point-of-care-related organizations. The following table summarizes the attendance by the type of organization represented.

Table 2: Attendance and Content Providing, by Organization Type

	PARTICIPANTS	ORGANIZATIONS
Diagnostics	16	9
Information Technology	9	7
User	5	4
Consultant	5	5
University & Institute	6	6
Others	1	1
Total	42	32

4. NEXT STEPS EUROPE

The former CIC website, taken over by the EI in 2003, is maintained by the Fraunhofer-Institut für Integrierte Schaltungen, Erlangen, as a resource for meeting documentation and presentations. It is intended to be supplemented by functionalities for information updates, implementation aids, best practice information and related contacts (www.poct.fraunhofer.de).

Information about POCT1-A-related services initiated by the CIC EI provided by the Fraunhofer IIS and piloted in cooperation with Roche Diagnostics is available via a link from the CIC EI Internet page to the website of the Fraunhofer IIS (www.iis.fraunhofer.de/EN/bf/med/telematik/std/poctsim.jsp).

The CIC EI intends to maintain regular contact to the European diagnostic industry and to utilize it for up-to-date information on available POCT1-A devices, developer and user experiences,

available services and the status of standardization. In addition, technical questions arising from standard implementation efforts shall be documented and discussed - and hopefully sufficiently answered.

The CIC EI website is currently reorganized. To set up the information exchange and the discussion platform for the POCT1-A community, the Fraunhofer Institute will invite registered CIC EI participants to register.

Representatives of the CIC EI continue to participate in international initiatives aiming at Common POCT1-A2 test and verification tools and possibly a related global certification infrastructure.

The CIC EI continuously works on further development, increasing awareness and application of POCT1-A2 by continuous national and international standardization as well as marketing and outreach activities (e.g. press articles, trade shows).

The CIC EI focuses on current and future trends in POCT technologies in general with comprehensive presentations at the annual highlight event in conjunction with MEDICA. The CIC EI will again present innovative POCT development activities and incentives during MEDICA 2008.

The CIC EI strives for POCT to become and remain a main topic at MEDICA in Düsseldorf, and is therefore utilizing cooperations with different partner organizations to support the POCT topic. The first step towards this goal was the valuable cooperation between the CIC EI and the POCT Working Group of the German Society of Clinical Chemistry and Laboratory Medicine (DGKL) during MEDICA 2005. In 2006 and 2007 we focused on our cooperation with technology partners IHE and CHA.

5. THE CIC EI NETWORK

A mailing list has been established to facilitate communication between individuals interested in European point-of-care connectivity standardization issues. If you are interested in being added to this mailing list, or would like to distribute information to the list, please contact the CIC European Initiative General Secretary, Christina Rode-Schubert, at the following e-mail address: christina.rode-schubert@MBE.unisg.ch

6. SOURCE OF SUPPLY FOR THE STANDARD

POCT1-A2 is an approved standard of the CLSI (former NCCLS - National Committee of Clinical Standards) and can be ordered as follows:

Document name: POCT1-A Point-of-Care Connectivity; Approved Standard (2001)
Note: The standard is distributed either on CD-ROM or (via web) as electronic document (PDF)

Order by mail: Clinical and Laboratory Standards Institute
940 West Valley Road, Suite 1400
Wayne, PA 19087-1898, United States

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