



CIC-EI Medica Meeting 2004

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A New Incentive 2003

The German Medical Association (Bundesärztekammer) has triggered renewed incentives for the topic connectivity in Germany.

In 2003 the German Medical Association ("GMA") issued a new Quality Assurance Guideline focusing on high quality control for point-of-care testing (POCT):

"Quality Assurance Guideline for Clinical Laboratory Testing by the German Medical Association"



A New Incentive 2003

The Guideline issued on November 14, 2003 and published in December 2003 provides:

Each organization unit within an hospital which uses POCT must regularly partake in external QA (Ringversuche/Proficiency Testing)

EXCEPT where the hospital's central laboratory acts as an internal quality manager ("QM") and is in charge of the quality control for POCT devices.



A New Incentive 2003

The Guideline requires that a physical and/or electronic standard be used for the quality control, as well as comprehensive documentation (see pages 11 and 12 of the Guideline).

It is obvious that an open standard would be the most price efficient solution for POCT quality control.



“Imposing the obligation
to implement quality
control forces the
Connectivity issue” ...



QA forces Connectivity

.... was the headline of an article by Prof. Lupp, University Hospital Munich, published in the hospital magazine "Trillium Report" in 2003.

The University Hospital Munich connected approx. 100 POCT devices to the HIS and controls them from its central laboratory.



The POCT1-A is
the only available
open standard
for connecting POCT devices
with Database Management
Systems (HIS/LIS)
worldwide.



A Brief POCT1-A History

... from a Concept at AACCC'98,
to the Standard Launch in Feb 2001,
to the CIC Sunset in Jan. 2002
and the Tasks of the EI ...



Foundation

- CIC was launched in 1999
- as a not-for-profit organization
- from initiative within the AACC
(American Association for Clinical Chemistry)



Target

- The Consortium's target was to develop an open standard.
- The standard should enable seamless connectivity between POC devices and HIS/LIS (Hospital / Lab Information Systems)



Addressed User Requirements

The POC connectivity standards were developed to address the following essential user requirements:

- Bi-directionality
- Standardized device connection
- Compatibility with standard software
- Data security according to national law
- Support for quality management



Timeline

The CLIC's timeline in 1999 allowed

- for one year
- to develop connectivity specifications
- and the subsequent transition of these specifications
- to the selected standards organizations (NCCLS, HL7 and IEEE) for approval.



History

- The CIC reached that first goal.
- The CIC specification was presented to the standard organizations on time.
- The procedure of approving the specification within the standard organizations started.



History Europe

- During Medica 2000, the CIC launched the European Round Table ("ERT") which was renamed the "European Initiative" ("CIC-EI") in 2001.
- The goal was to involve European users and vendors in the efforts and to internationalize the standard.
- In June 2001 representatives from Europe met in Prague for a workshop to realize the goal.

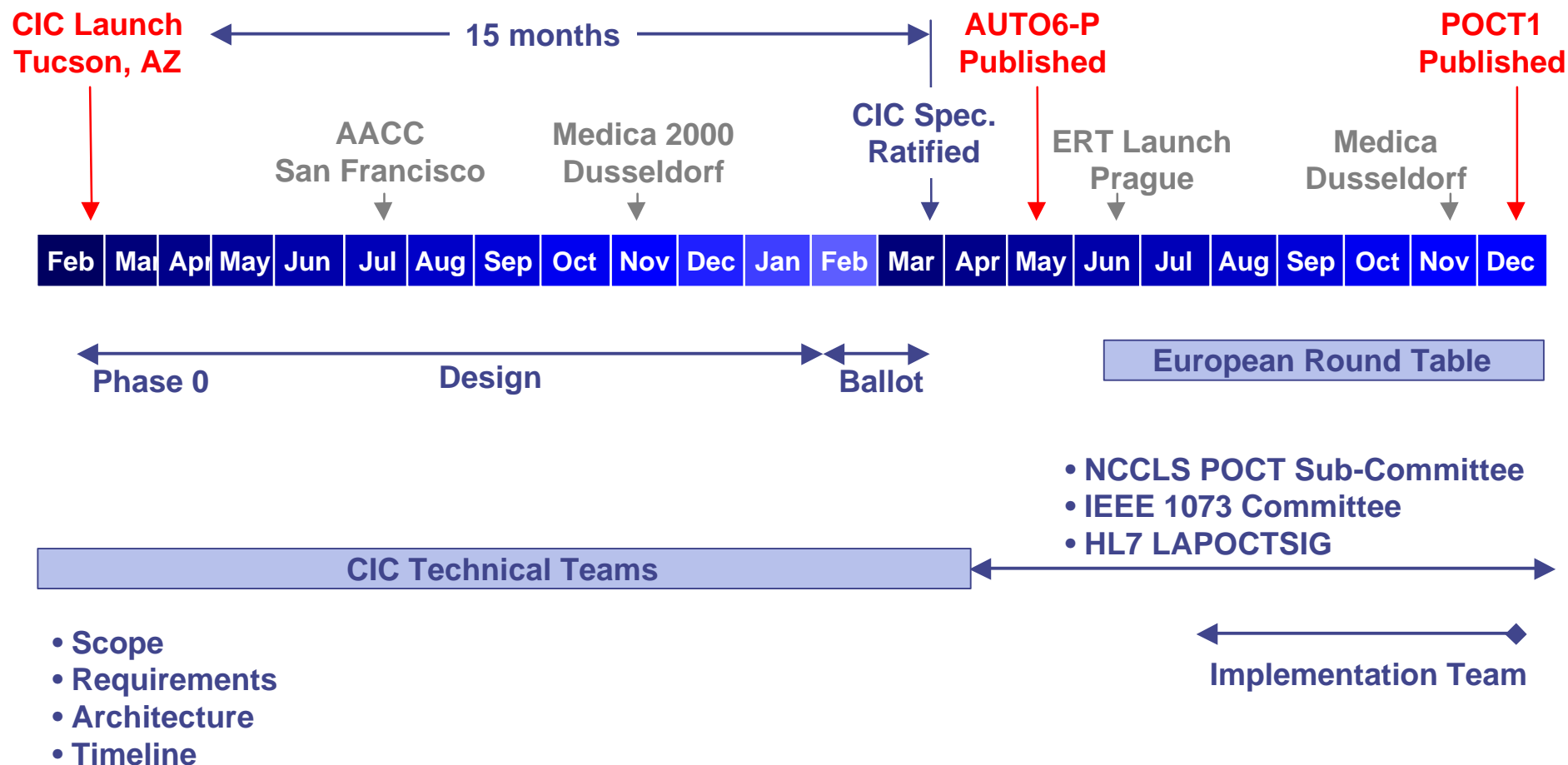


History

- In the meantime the NCCLS refined, renamed and ratified the CIC specification as "POCT1-A".
- The NCCLS published the POCT1-A specification at the end of 2001.



CIC Timeline: Feb '00 to Dec '01





Sunset

- By summer 2001, the CIC workgroups had generated the specification
- After transferring their work to registered standards bodies, the consortium closed down
- The EI tasks were announced in the sunset transition plan.



What is the POCT1-A Now?



POCT1-A

- Today the POCT1-A is a complete standard for multi-vendor point-of-care connectivity.
- It is a standard for point-of-care connectivity based on existing IEEE and HL7 standards and on specifications developed by the CIC and approved by the NCCLS.
- HL7 and IEEE have published relevant components of the POCT1-A specification in their own norms.
- The ongoing process of adopting the POCT1-A as a formal international ISO and CEN standard is now nearing first results.



Task of the European Initiative



Sunset Transition Plan (2002)

Plan: Remaining funds transfer to the AACCC to continue work to develop and promote the standard:

1. Continue the internationalization push through the European Round Table effort - today EI
2. Maintain the CIC website as a resource for implementation aids and best practices (FHI)
3. Develop an open source 'reference implementation' code that vendors and customers can use for testing (FHI)
4. Continue some world-wide marketing and outreach activities (e.g. coordinate articles, trade shows)



The future of the EI



Today

The CIC's European Initiative meets today for the fifth time with the following topics:

- information about the new projects at NCCLS
- AACC and ILC (the CIC's successor) proposed joint activities with NCCLS (JD)
- an update on the internationalization and standardization process (TN)
- the POCT1-A standard implementation activities in the industry presented by Roche Diagnostics (AS)



Today

- An introduction of the economic benefits of a POCT connectivity standard



Today and Tomorrow

And two presentations leading us into tomorrow's world

- The POCT Working Group of the German United Society of Clinical Chemistry and Laboratory Medicine ("DGKL") will be presented by H. Ziervogel
- POCT Communication Standard - The first step towards the fourth generation of Laboratory Systems (GH) brings us back to the introductory topic, "Incentives".



Tomorrow

- Continue with the tasks announced in the Sunset Transition Plan
- We plan to build up a strategic cooperation with the DGKL's POCT working group
- And consider holding a POCT event in cooperation with DGKL at Medica 2005



Agenda

Today's Agenda

1:00	05 min	Opening, Welcome, Agenda	Christina Rode-Schubert - Heidelberg, BE Consult, <u>Secretary'General</u> CIC Europe
1:05	10 min	A Brief CIC History - the US and European movement	Christina Rode-Schubert - Heidelberg, BE Consult, <u>Secretary'General</u> CIC Europe
1:15	20 min	POCT in the US - NCCLS - New Projects/ Activities and AACC ILC Proposed Joint Activities with NCCLS	Jeff DuBois - Nova Biomedical and NCCLS Representative USA
1:35	20 min	CIC Europe - Status Quo of the Standard Approval in DIN, CEN and ISO	Thomas Norgall - Erlangen Fraunhofer-Institut für Integrierte Schaltungen, <u>Chair</u> CIC Europe
1:55	20 min	POCT-1A Implementation Activities at Roche <u>Diagnostics</u>	Andreas <u>Staubert</u> - Mannheim Roche Diagnostics GmbH
2:15	20 min	POC In Europe - The Perspective of the Working group POCT of the German Society of Clinical Chemistry (DGKL)"	Heiko Ziervogel - Berlin, <u>HCx Consulting</u>
2:35	20 min	<i>Economical benefits of a POCT standard</i>	Gunter von <u>Leoprechting</u> - Berlin <u>LEO-IMPACT CONSULTING GmbH</u>
2:55	20 min	POCT Communication Standard - The first step towards the fourth generation of laboratory systems	Georg Hoffmann - Grafrath Trillium GmbH
3:15	10 min	<u>Discussion, Q&A</u>	Thomas Norgall - Erlangen Fraunhofer-Institut für Integrierte Schaltungen, <u>Chair</u> CIC Europe
3:25	05 min	Next Steps Europe and Closing	Thomas Norgall - Erlangen Fraunhofer-Institut für Integrierte Schaltungen, <u>Chair</u> CIC Europe



More information:

- Presentations will be available:
 - E-mail to all attendees who leave business cards
 - On the CIC website
www.poccic.org
- Contact Christina.Rode-Schubert@mbe.unisg.ch