

Agenda

| Start | Length | Topic | Presenter |
|-------|--------|--|---|
| 1:30 | 15 min | Opening, Welcome, Agenda A Brief CIC EI History - And CIC EI meets CHA and IHE | Christina Rode-Schubert - Germany, BE Consulting Heidelberg, Secretary-General CIC Europe |
| 1:45 | 15 min | Status Quo and Ongoing Work: The way to NCCLS POCT1-A as a formal international standard. | Thomas Norgall - Germany, Fraunhofer-Institut für Integrierte Schaltungen Erlangen, Chair CIC Europe |
| 2:00 | 15 min | Continua Health Alliance (CHA) - An Alliance Focusing on Personal Health | Robert Hughes - USA Intel Corporation Santa Clara, Bluetooth Medical Device Profile Chair Continua Health Alliance |
| 2:15 | 15 min | Roche Diagnostics - Information Management Program Diabetes Care Continua Health Alliance - A Members Perspective | Horst Merkle - USA Roche Diagnostics Indianapolis |
| 2:30 | 15 min | POCT Standardization at Vision4Health | Andreas Kumbroch - Germany Vision4Health Bochum |
| 2:45 | 15 min | GE Healthcare - Health Care Companies striving for Standardization in IHE and CHA | Charles Parisot - France GE Healthcare Buc |
| 3:00 | 15 min | "Case study" - A Paradigm Shift in the Point-of-Care Testing Connectivity | Fabrizio Maitrantonio - Italy A. Menarini Diagnostics Florence |
| 3:15 | 15 min | Personal Health Requirements and the Framework of Standardization | Peter Pharow - Germany University Hospital Regensburg |
| 3:30 | 15 min | IHE Germany - Technical Communities | Tim Becker - Germany (inquired) University Hospital Kiel |
| 3:45 | 15 min | Discussion / Q&A, Further Demands & Requirements, Next Steps Europe and Closing | Thomas Norgall - Germany, Fraunhofer-Institut für Integrierte Schaltungen Erlangen Chair CIC Europe |



Connectivity Industry Consortium European Initiative

“CIC EI meets IHE and CHA”

Christina Rode-Schubert eMBA HSG
CIC European Initiative



Connectivity Industry Consortium European Initiative

Towards international standards
for Point-of-Care testing - A brief History



The 1st CIC Meeting RC CA 1999

- At the request of the POC division of the AACC, Hewlett-Packard (Agilent Technologies) organized an open meeting attended by the POC/IVD industry, LIS/HIS suppliers, health care providers and consultants.
- The meeting was held in Redwood City, California, October 20 1999, and attended by more than 120 people, representing 60 organizations.
- The intent of this meeting was to assemble an open, industry-wide forum to address problems and outline practical solutions for POC connectivity.
- At this meeting, the objectives, organizational structure, and timeline for a new Connectivity Industry Consortium (CIC) were presented.



The 1st CIC Meeting RC CA 1999

- Over the next 12-15 months, the CIC should prepare a base-level standard for POC connectivity and transfer the results to an established industry standards-setting organization.
- The goal of this standard is to provide a technical solution for POC connectivity that meets worldwide user community requirements, while enabling vendors to build differentiating features, functions, and applications.
- The Consortium will utilize existing standards and commercial implementations where possible.
- Both a multi-vendor connectivity demonstration and preliminary pilot study results were planned for late fall 2000.



The History of the History

- The Andover Working Group, consisting of over 300 member organizations, was founded by Hewlett Packard in 1996 with the objective "To accelerate and broadly deliver standards-based solutions for healthcare which feature plug & play interoperability across the continuum of care."
- Hewlett-Packard and the Andover Working Group believe that heterogeneity is a fact of life in the healthcare information infrastructure today and for the foreseeable future.
- Independent of whether heterogeneity is the result of a "best of breed" architecture, consolidation of formerly independent organizations, or of government mandates for electronic communication of healthcare information, interoperability of healthcare information in a heterogeneous environment is a top priority of healthcare information technology executives.

Jack Harrington

Principal Systems Architect, HP Medical Products Group

Technical Chair, Andover Working Group

Chair, IEEE 1157 Medical Data Interchange (MEDIX)

Vice-Chair, IEEE 1073 Medical Information Bus (MIB)

Co-Chair, HL7 Special Interest Group - Conformance

Connectivity Industry Consortium



1st CIC Meeting - Business Plan
October 20, 1999 Redwood City, California

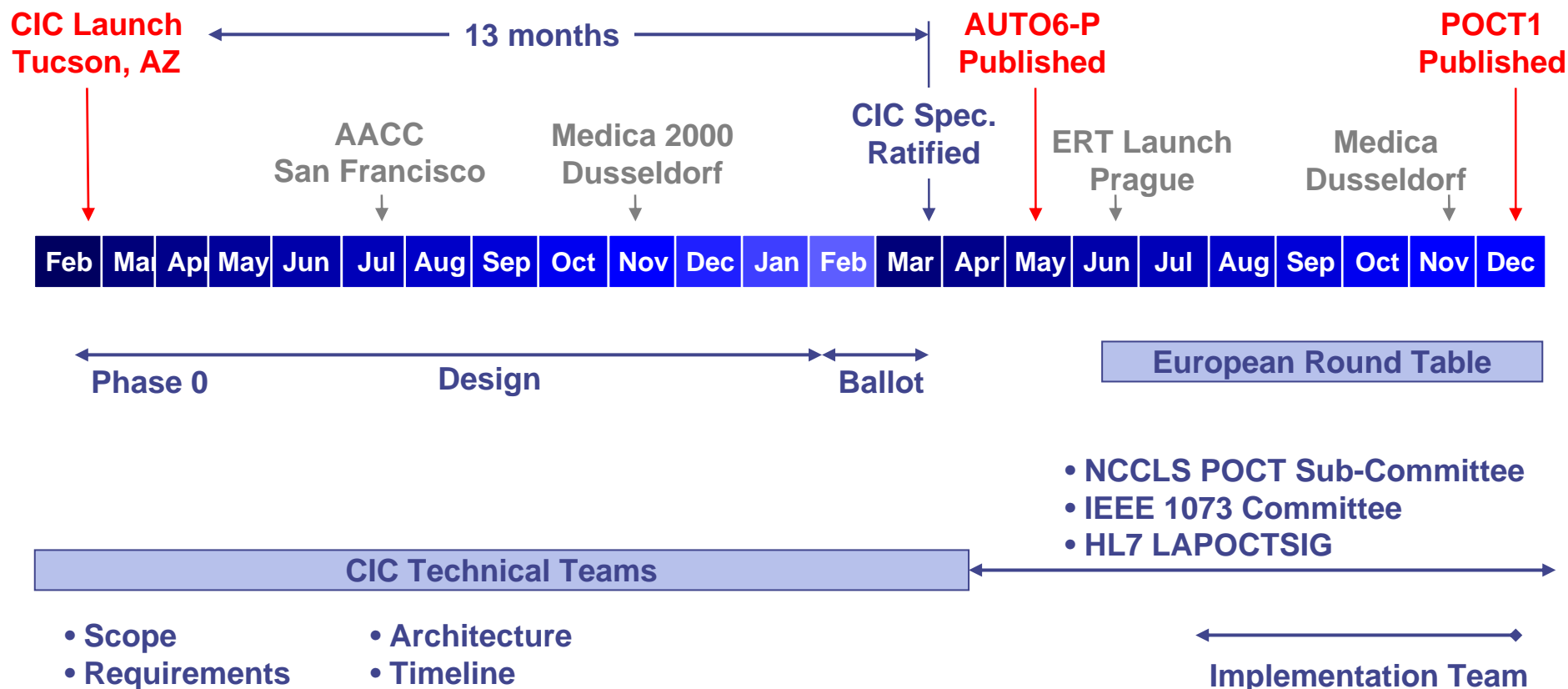


...connecting the industry



CIC Timeline: Feb '00 to Dec '01

From a Concept at AACC'98, to Launch in Feb 2000, to Sunset by Jan. 2002





Membership Status 2001

Core VENDOR

Abbott Diagnostics
Agilent Technologies
Bayer Diagnostics
BD
Instrumentation Laboratory
LifeScan/Johnson & Johnson
Medical Automation Systems
Radiometer Medical
Roche Diagnostics
Sunquest

Banner Health System

Core PROVIDER

Bradford Royal Infirmary
Geisinger Health System
Hospital Costa del Sol
John Hopkins Medical Institutions
Kaiser-Permanente
Mayo Clinic
The Mount Sinai Hospital
St. Vincent Mercy Medical Center
University of Iowa

Supporting VENDOR

Abaxis
Avocet Medical
Cerner
Citation Computer Systems
Clarinet Systems
Control
GE Medical Systems
HemoCue
HemoSense
IGEN International
InterComponentWare
International Technidyne Corp. (ITC)
i-STAT
Lantronix
Medtronic
Motorola
Pharmacia & Upjohn
Profil GmbH
Shared Medical Systems (SMS)
Sigma Diagnostics
STC Technologies
Telcor
VIA Medical

Liaisons

AACC
CAP
COLA
IFCC Scientific Division
Medical Devices Agency

Individual

Neil Halpern, MD
Georg Hoffman, MD
LTC Forrest Kneisel
Gerald Kost, MD PhD
Petrie Rainey, MD, PhD
Maurice Green, PhD



The European Mandate to BE Consulting

- BEC was mandated to organize the setup of the CIC in European
- by inviting representatives from various CIC resources and external health care market contributors to discuss the European involvement and user requirements in a workshop in conjunction with the Medica 2000
- by promoting the standard throughout the EU
- and by initiating the procedure of adopting the standard i.p. as national (e.g. DIN) and European (CEN) standard
- fortunately Thomas Norgall, who is familiar with European and international standards for communication and interoperability joined the European movement of the CIC
- we launched the European Initiative (former ERT) in Prague in Mai 2001

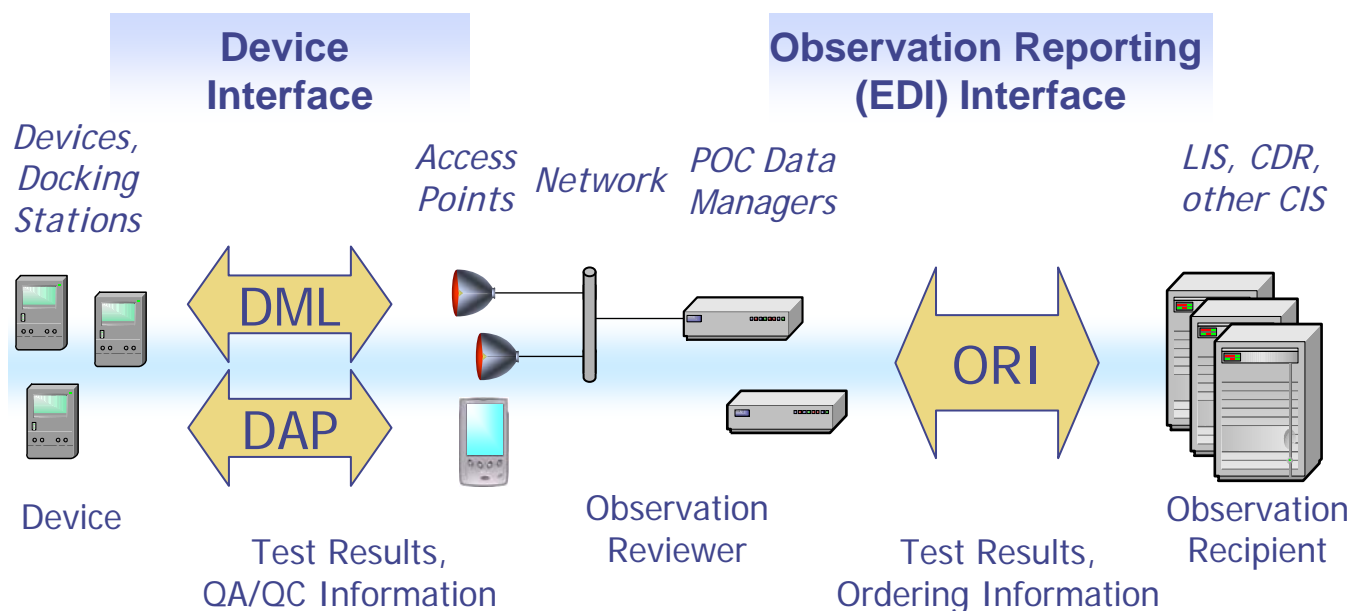
El starting point:

CIC European (Round Table) Initiative Kickoff (Prague, 29.5.2001)

| # | ACTION | RESP. | DoD | COMMENT |
|----|--|---|-------|---------|
| 4 | <p>A team was formed to define the strategic direction of the European Round Table, according:</p> <ul style="list-style-type: none">• Ensure that NCCLS AUTO6-P POCT standard is reflected in national mirror norm organizations.• Ensure that NCCLS AUTO6-P POCT standard is reflected in CEN TC251 | <p>T.Norgall, S.Field, A.St.John, J.Perry, P.Schmitz R.Ruiz, R.Jones,</p> | 11/01 | |
| 12 | <p>Introduce “work item” for ISO-certification of “AUTO6” to ISO TC215WG2</p> | <p>T.Norgall</p> | 12/01 | |

NCCLS (CLSI) POCT1-A Standard – what it is about

- developed 1999-2001 (as AUTO6-P) by POCCIC Industry Consortium using IEEE and HL7 components
- defines 2 Interfaces: – Device Interface: DAP: IEEE 1073,
DML: HL7 V2.3 + XML-Syntax
– Observation Reporting Interface: ORI: TCP / IP + HL7 V2.3





Where we are now:

CLSI* POCT1-A2 (March 2005) replaces POCT1-A

Changes and extensions:

- Device Identifier: 3 Options
 - EUI-64 (preferred)
 - Concatenation of vendor_id, model_id, and serial_id fields from the device object of the DML using the ^ as a delimiter
 - A legacy identifier string, distinguishable from EUI-64 and vendor_id
- Naming of vendor-specific directive messages
 - Identification
 - Use of Coded Vendor Identifier
- Error corrections & minor textual improvements etc.
- Enhanced accessibility and readability

*(Clinical & Laboratory Standards Institute, former NCCLS)

Adoption of POCT1-A by ISO TC 215

- “... Resolved that ISO/TC 215 accepts the **POCCIC/NCCLS AUTO6-A** POCT standard “Health informatics - Analytical instruments - Point-of-care test” as a **fast track DIS ballot** with a designation of **11073-90100....**”
(Resolution 13 of ISO/TC 215: 30 August 2001, London / England)
- ⇒ CLSI POCT1-A will be issued as ISO DIS11073-90100 as soon as copyright problems between ISO and CLSI (NCCLS) are solved
- This process was finished by early 2006
- Ballot for **ISO DIS 11073-90100** started 07 April 2006, ended 07 September 2006
- Result: Approval / 14 P-Members in favour out of 17 = 82,35% (required 66,66%)
- Apart from 3 negative votings, there was a number of comments
- Next step: adoption of ISO DIS11073-90100 as a CEN standard
(thus overriding national standards in EU)



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CIC EI and IHE

Evolution of IHE Domains

IHE Global Developments

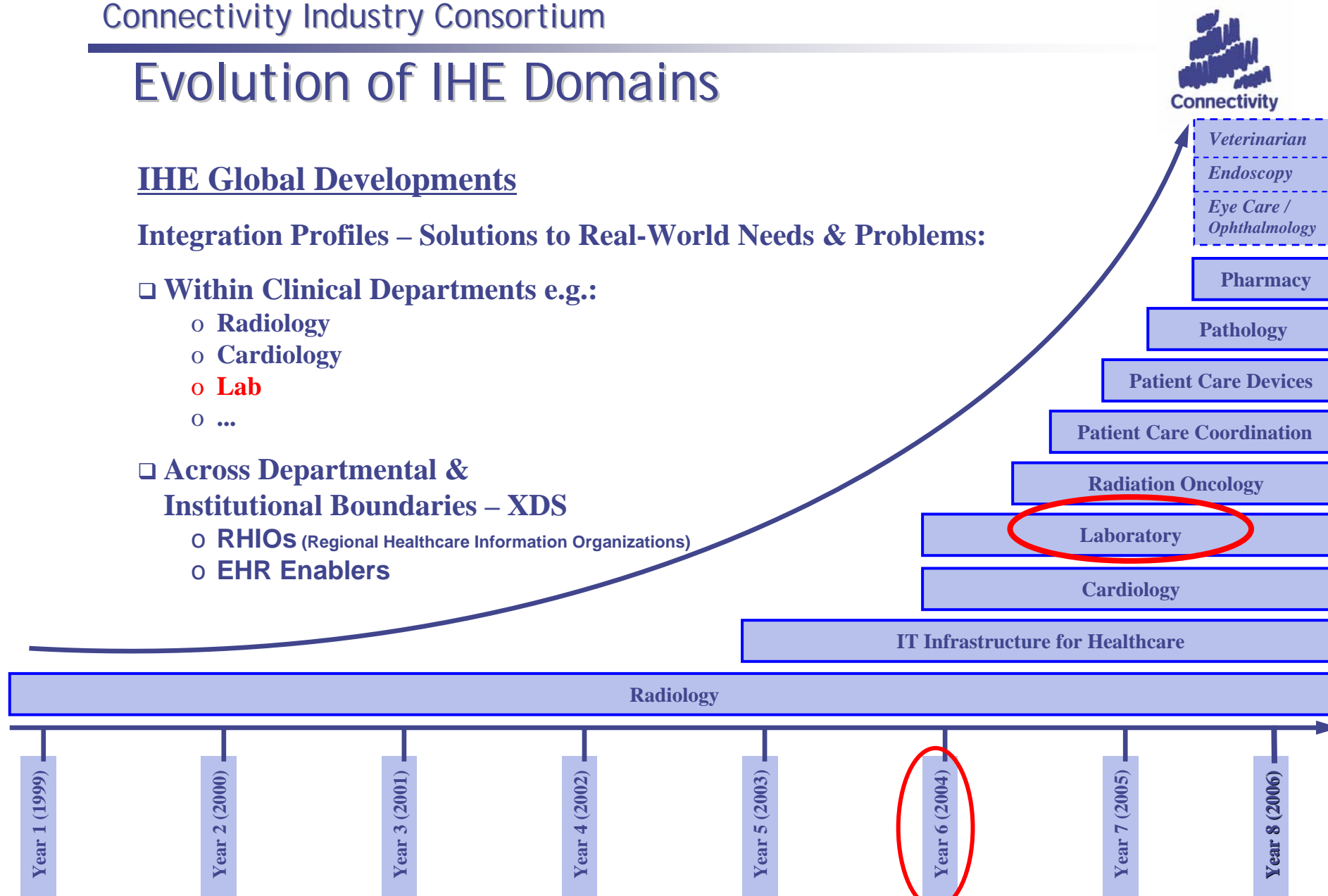
Integration Profiles – Solutions to Real-World Needs & Problems:

□ Within Clinical Departments e.g.:

- Radiology
- Cardiology
- **Lab**
- ...

□ Across Departmental & Institutional Boundaries – XDS

- RHIOs (Regional Healthcare Information Organizations)
- EHR Enablers





Role of IHE in CIC EI

CIC EI tracking of IHE Point Of Care Activities

- 2002 MEDICA CIC EI Status Report mentions IHE (... "Point-of-Care/Lab potential field for IHE or similar activities ? ")
- 2003 MEDICA CIC EI Status Report updates on current IHE work (... Point-of-Care/Lab "next field for IHE activities")
- 2004 MEDICA CIC EI Status Report outlines IHE Laboratory Point Of Care Testing profile proposal
- 2005 MEDICA CIC EI Status Report gives a detailed update on IHE activities
- 2006 MEDICA CIC EI Status Report mentions expected 2007 IHE Point Of Care Testing Showcase and Conncetathon events
- 2007 CIC EI representatives visit IHE Connectathon and participate in IHE-Europe Interim Steering Committee meeting during eHealth Week in Berlin
- 2007 Charles Parisot, representative of the IHE, as speaker in Düsseldorf



Connectivity Industry Consortium European Initiative

CIC EI and CHA

Connectivity





Role of CHA in CIC EI

CIC EI tracking of CHA Activities

- 2006: CHA was founded and former CIC members as Jeff Perry, CTO of the CIC, and Horst Merkle, CIC Board Member, are CHA contributors
- March 2007: BEC met David Whitlinger, CEO of the Continua Health Alliance, at Cebit in Hannover
- Mai 2007: Teleconference scheduled by David Whitlinger (DW) on “ ... we can discuss ways that our organizations can work more closely together. There is an opportunity rapidly approaching with the Seventh Framework” (EU).
- September 2007: CIC EI tried to publish an article on “Personal Health” in a German Health Care Market Magazine in cooperation with the CHA
- November 2007: Due to business constraints in travel DW asked Bob Hughes (Intel /CHA Bluetooth Medical Device Profile Chair) to represent the Continua Health Alliance in stead of him to the POCT members
- 2008: CHA plans to have a booth and a substantial presence next year at the Medica



Thank you for your attention

Christina Rode-Schubert

Exec. MBA in Business Engineering HSG
Secretary General CIC European Initiative

BE Consulting Heidelberg



More information:

- Presentations will be available:
 - E-mail to all attendees who leave business cards
 - On the CIC EI website:
www.poct.fraunhofer.de
- Contact:
Christina.Rode-Schubert@MBE.UNISG.CH



Why it worked...

Russ Mock, Bayer Diagnostics * Imre Trefil, Lifescan, Inc. * Greg Menke, Medical Automation Systems, Inc. * Leslie Leonard, Agilent Technologies * Nonato Bautista, Lifescan, Inc. * Becky Clarke, Telcor Inc. * Jeff Sutherland, IDX * Sidney Goldblatt, Sunquest Information Systems * John Low, Instrumentation Laboratory * Taia Ergueta, Agilent Technologies * Marcia Zucker, International Technidyne Corporation * Gerald Kost, University of California - Davis Medical Center * Vladimir Ostoich, Abaxis * Rorie Morgan, Lifescan, Inc. * Kevin Callahan, Spectrx * Larry Cohen, HemoSense Inc. * Jeffrey Perry, Agilent Technologies * James E. Robinson, Lifescan, Inc. * Petrie Rainey, University of Washington * Dan Nowicki, GE Marquette Medical Systems * Joachim Koeninger, Agilent Technologies * Rodney Kugizaki, Lifescan, Inc. * Thomas Bluethner, Roche Diagnostics Corporation * Dominique Freeman, Agilent Technologies * Charles Schindler, POC Consultant * Jacqueline Baker, Roche Diagnostics Corporation * Ken Gary, Abbott Diagnostics * Mike Higgins, Agilent Technologies * Christopher Fetters, Medical Automation Systems, Inc. * Miguel Blanc, Motorola * Borzu Sohrab, Lifescan, Inc. * Stephen Kellet, Agilent Technologies * Christian Kargl, AVL Scientific * Ellis Jacobs, Mount Sinai Medical Center * Syrous Parsay, Lifescan, Inc. * Rick Hrabe, Medical Automation Systems, Inc. * Jon Kitahara, Lifescan, Inc. * Gerhard Pross, Agilent Technologies * Bryan Allen, Bayer Diagnostics * Matthias Essenpreis, Roche Diagnostics Corporation * Deepak Narsipur, Lifescan, Inc. * Jack Harrington, Agilent Technologies * Tom Braithwaite, Medical Automation Systems, Inc. * Stephen Lee, Medical Devices Agency * Dirk Boecker, Agilent Technologies * Paula Santrach, Mayo Medical Center * Kendra Whittier, Agilent Technologies * Wayne Mullins, Medical Automation Systems, Inc. * Bob Anders, Agilent Technologies * Andrew St. John, AVL Scientific * Roger D. Hughes, SCC Clinical Information Systems * Craig Robinson, SMS * Allan Soerensen, Radiometer Medical * Chris Melo, Agilent Technologies * Thomas Downey, Avocet Medical, Incorporated * Gerd Grenner, Roche Diagnostics Corporation * Daniel Trainor, Agilent Technologies * Steve Lundy, AVL Scientific * Michael Vock, IGEN International, Inc. * Paul Chirico, Avocet Medical, Incorporated * William J. Fannon, Instrumentation Laboratory * Jody Tirinato, i-STAT Corporation * Horst Merkle, AVL Scientific * Kent Lewandrowski, Massachusetts General Hospital * Alan Greenburg, Roche Diagnostics Corporation * David Frey, Agilent Technologies * James LaFrance, Bayer Diagnostics * Roger Kaltefleiter, Cerner Corporation * Kevin Bryan, Citation Computer Systems, Inc. * Bill Lesar, Telcor Inc. * Sean Field, AVL Scientific * Jim Terrano, Telcor Inc. * Rick Lebo, Geisinger Medical Center * Forrest Kneisel, Department of Defense Office of Clinical Laboratory Affairs * Mike Gavin, International Technidyne Corporation * Jared Monaco, AVL Scientific * Billie Keller, Medical Automation Systems * Candi Barker, Citation Computer Systems, Inc. * Jim Macemon, VIA Medical Corp * Bruce Noon, Sunquest Information Systems * Suzanne Cross, Lifescan/OCD * Louis J. Dunka, Lifescan, Inc. * Wolfgang Janschitz, AVL Scientific * Heiko Ziervogel, Agilent Technologies * Kenneth Powell, BD * Stephanie Higgins, Kaiser-Permanente * Stephen Zweig, Avocet Medical, Incorporated * Paul Schluter, GE Marquette Medical Systems * Sharon Sampson, Agilent Technologies * Anwar Azer, Instrumentation Laboratory * John Quigley, Chiron Diagnostics Corporation * Robin Zimmerman, Kaiser-Permanente * Klaus Kjoller, Radiometer Medical * Kendra Whittier, Agilent Technologies * Joe Rodgers, i-STAT Corporation * Teresa Prego, Bayer Diagnostics * Dana Landry, Instrumentation Laboratory * Barry Willis, Agilent Technologies * Charles Balas, International Technidyne Corporation * Marcy Anderson, Medical Automation Systems, Inc. * Mary Audette, Medtronic * Charles Laughinghouse, AVL Scientific * Fabienne Sebiere, FluorRX, Inc. * Nancy Newton, Mayo Medical Center * Robert Uleski, FluorRX, Inc. * Robert J. Knorr, Lifescan, Inc. * Daniel Cheek, Medtronic * Kamran Rastgooy, Roche Diagnostics Corporation * Jay B. Jones, Geisinger Medical Center * Kenneth Levy, Roche Diagnostics Corporation * Jason Ratcliffe, AVL Scientific * Mark Maund, i-STAT Corporation * Gerhard Krammer, Agilent Technologies * Brent Lowensohn, Kaiser-Permanente * Jim Lindauer, Agilent Technologies * Anne LeBlanc, Bayer Diagnostics * Paul Fernandes, CompuCyte Corporation * Tony Nugent, Cholestech Corp * Paul Fingerman, Kaiser-Permanente * Jim Nichols, Johns Hopkins Hospital Department of Pathology * Gert Fendesak, Roche Diagnostics Corporation * Mark Cederdahl, Telcor Inc. * Rick Pittaro, Agilent Technologies * Per Matsonn, Pharmacia & Upjohn * Emery Stephans, Enterprise Analysis Corporation * Thomas Norgall, Frauenhofer Institut * Horst Merkle, Roche Diagnostics * Christina Rode-Schubert, CHROSC Consulting *