

# Connectivity Industry Consortium - European Initiative



Start	Length	Topic	Presenter
1:30	15 min	Opening, Welcome, Agenda A Brief CIC EI History - and a New Incentive for the POCT1-A in Europe	Christina Rode-Schubert - Germany, BE Consulting Heidelberg, Secretary General CIC Europe
1:45	15 min	Status Quo and Ongoing Work. The ongoing and successful European process of adopting NCCLS POCT1-A as a formal international standard.	Thomas Norgall - Germany, Fraunhofer-Institut für Integrierte Schaltungen Erlangen, Chair CIC Europe
2:00	15 min	The Continua Health Alliance - POCT1-A and broader health and wellness standards	Jeff Perry - USA Philips Consumer Healthcare Solutions Milpitas, CA
2:15	15 min	POCT QM in perception of the Industry	Karl-Heinz Pick - Germany <u>Abbott Wiesbaden</u>
2:30	15 min	Industrial Experience I: Implementing the POCT1-A communication standard - Roche Diagnostics Mannheim	Jürgen Richter - Germany, Roche Diagnostics Mannheim
2:45	15 min	Industrial Experience II: Experiences connecting POCT devices with a POCT Data Manager - Conworx Berlin	Roman Rosenkranz - Germany Conworx Berlin
3:00	15 min	POCT1-A @ Connetathron Berlin 2007	Andreas Kassner - Germany VHitG e.V. Berlin
3:15	15 min	User Requirements - Laboratories	Andreas Kumbroch - Germany iSOFT Mannheim
3:30	15 min	Diagnostic Pathways	Georg Hoffmann - Germany, Trillium GmbH Grafrath
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

Medica Düsseldorf - November 15, 2006



“POCT1-A” - Worldwide the only available open  
POCT Communication Standard

Christina Rode-Schubert  
BE Consulting Heidelberg  
Secretary-General CIC Europe

Medica 2006, Germany  
November 15, 2006



# The Connectivity Industry Consortium

From a Vision to a Success Story

Medica 2006, Germany  
November 15, 2006



## VISION

"The vision of the CIC is to *develop*, pilot and transfer the foundation for *a set of seamless 'plug and play' POC communication standards*, ensuring fulfillment of the critical user requirements of bi-directionality, device connection commonality, commercial software interoperability, security, and QC/regulatory compliance."



## STRUCTURE

The CIC was

- an open, non-profit, industry-driven consortium
- comprised of device manufacturers, information system vendors and health care providers
- chartered to address impediments to POC device connectivity

with the objective of enabling seamless information exchange between POC devices and electronic medical records and laboratory information systems



# LAUNCH

## The Connectivity Industry Consortium

was launched in February 2000,  
after the point-of-care industry  
had wrestled with trying to find  
solutions  
to the connectivity problem.



## PRE-HISTORY

### SUMMARY OF THE EVENTS – directly leading to the formation of the CIC:

- AACC 1998: AACC POC Division determines that connectivity is its most important and pressing problem
- 1998-1999: POC Division studies options to address the connectivity problem, and asks Agilent Laboratories to propose an approach to solve the problem (Experience: Andover Working Group)
- AACC 1999: Agilent Laboratories' plan to address connectivity problems via an industry consortium (CIC) gets overwhelming support
- Aug-Sep1999: Dirk Boecker, Jeff Perry (Agilent) and Emery Stephans (AACC) visit key core members to present CIC mission and for fundraising.
- Oct 2, 1999: Leading healthcare provider institutions meet in Palo Alto to prioritize POC connectivity user requirements.



# HISTORY

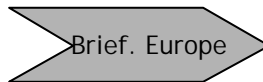
## MILESTONES AND DELIVERABLES CIC

Oct 20, 1999: Consortium Kick-Off Meeting - Redwood City, CA



- hosted by Agilent Technologies
- Member buy-in and commitment
- Structure of the Consortium
- IVD Vendors, IS companies, and Providers in alignment on structure, objectives and timeline

Nov 1999: Briefing for European Companies



- Held at Medica, November 17-20 - Duesseldorf, Germany
- Introduce consortium concept, objectives, structure and process

Feb 2000: Consortium Launch Event - Tucson, AZ

- Elect Consortium Board and Officers
- First organizational and planning meeting





# HISTORY

## MILESTONES AND DELIVERABLES CIC

Apr 2000: Milestone #1 - HIMSS, Dallas, Texas

- Preliminary architecture
- Presentation of concept

Jul 2000: Milestone #2 - AACC, San Francisco, CA

- Demonstrate preliminary interoperability solution
- Certification of concept
- Detailed architecture
- Start pilots

Nov 2000: Milestone #3 - Medica, Dusseldorf, Germany

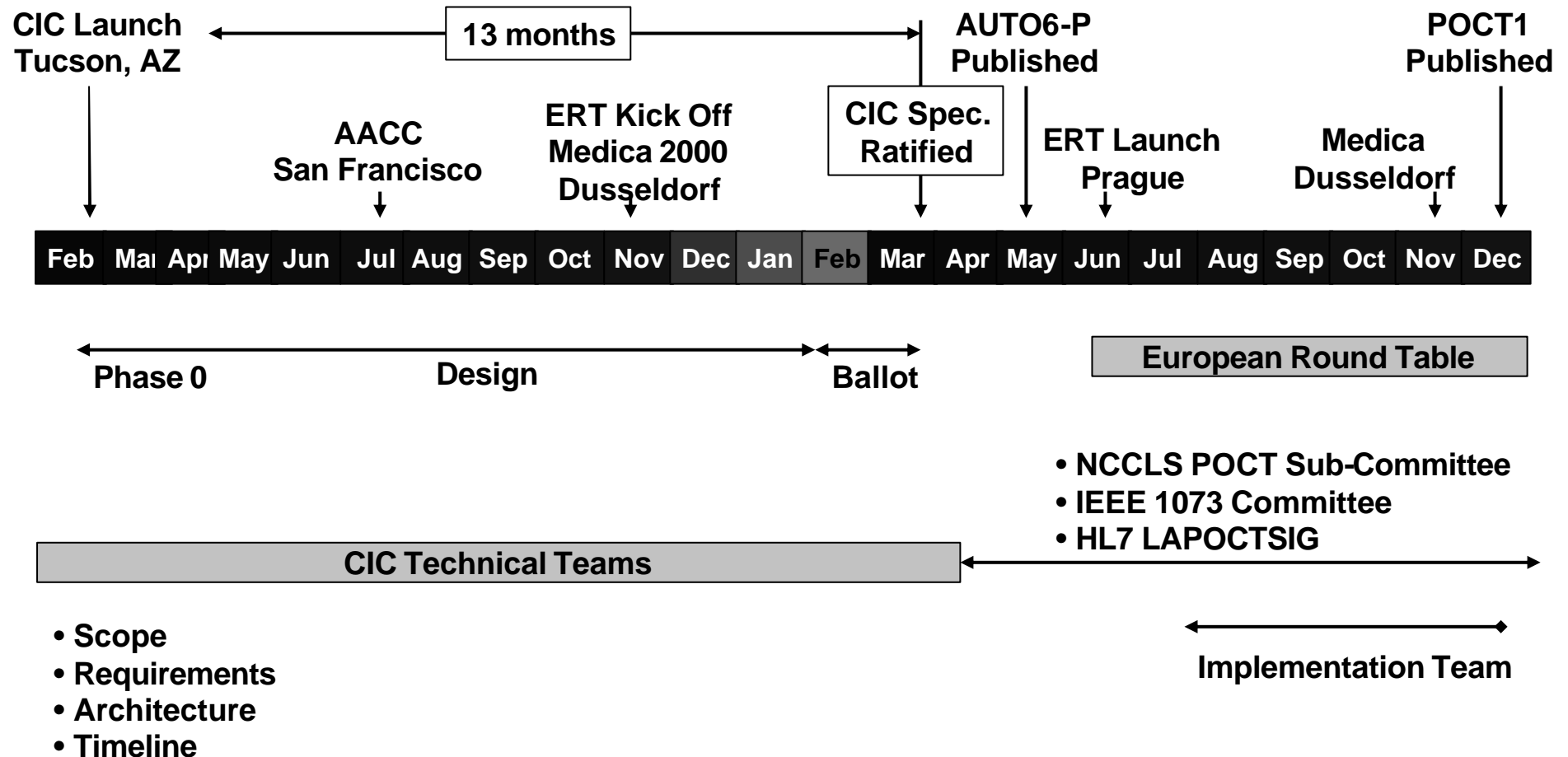


- Operating multi-vendor demo
- Product announcements
- Show first results from pilots



# THE TIMELINE - Feb '00 to Dec '01

The Consortium's bylaws dictated a one-year lifespan for the organization





## SUCCESS STORY

- The CIC reached the first goal -  
and during a period of only one year the connectivity specifications were developed.
- By summer 2001, the CIC workgroups had generated the specification.
- And the specification was presented to the first selected standards organizations for approval: CLSI (former NCCLS), HL7 and IEEE

The diagram illustrates the relationship between three main entities: CEN TC251, ISO TC215, and the International National Standards Organization (ISO).

- CEN TC251** (European Committee for Standardization) is shown on the left, containing:
  - WG1
  - WG2
  - WG3
  - WG4: Technology for Interoperability** (highlighted with a dashed border)
- ISO TC215** (International Organization of Standardization) is shown on the right, containing:
  - WG1
  - WG2: Messages and Communication (highlighted with a dashed border)
  - WG3
  - WG4
  - WG5
- International National Standards Organization** (ISO) is shown at the bottom, containing:
  - Europe
    - Other NR
    - DIN** (highlighted with a dashed border)
  - USA (ANSI)
    - NCCLS\* (highlighted with a dashed border)
    - HL7 (highlighted with a dashed border)
    - IEEE (highlighted with a dashed border)
    - DICOM (highlighted with a dashed border)
    - ASTM (highlighted with a dashed border)

Connections are shown between the highlighted workgroups (WG4 in CEN TC251 and WG2 in ISO TC215) and the corresponding national standards organizations (DIN in Europe and NCCLS/HL7/IEEE in the USA) within the International National Standards Organization.

\*C I S I

\*CLSI



## THE SUCCESS STORY

- The procedure of approving the specification within the standard organizations started.
- The CLSI (NCCLS) refined, renamed and ratified the CIC specification as "POCT1-A".
- The specification was published at the end of 2001.



# MEMBERSHIP Status 2001: > 50 Members

## 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 SUNSET

- After transferring their work to registered standards bodies the consortium closed down.
- The EI tasks were announced in the 'Sunset Transition Plan'



# The CIC European Initiative

## History, Tasks & Activities

Medica 2006, Germany  
November 15, 2006





## EUROPEAN INITIATIVE - HISTORY

November 1999: Roche sponsors the CIC update for European companies at Medica in Duesseldorf/ Briefing

November 2000: Kick Off of European Round Table during Medica in Dusseldorf (renamed in 2001: "European Initiative) with the goal:

- ♦ to involve European users and vendors in the efforts to customize and to internationalize the standard
- ♦ to ensure that POC suppliers and users in Europe be kept informed about and have an opportunity to contribute to international POC standardization after the CIC sunset in 2002.



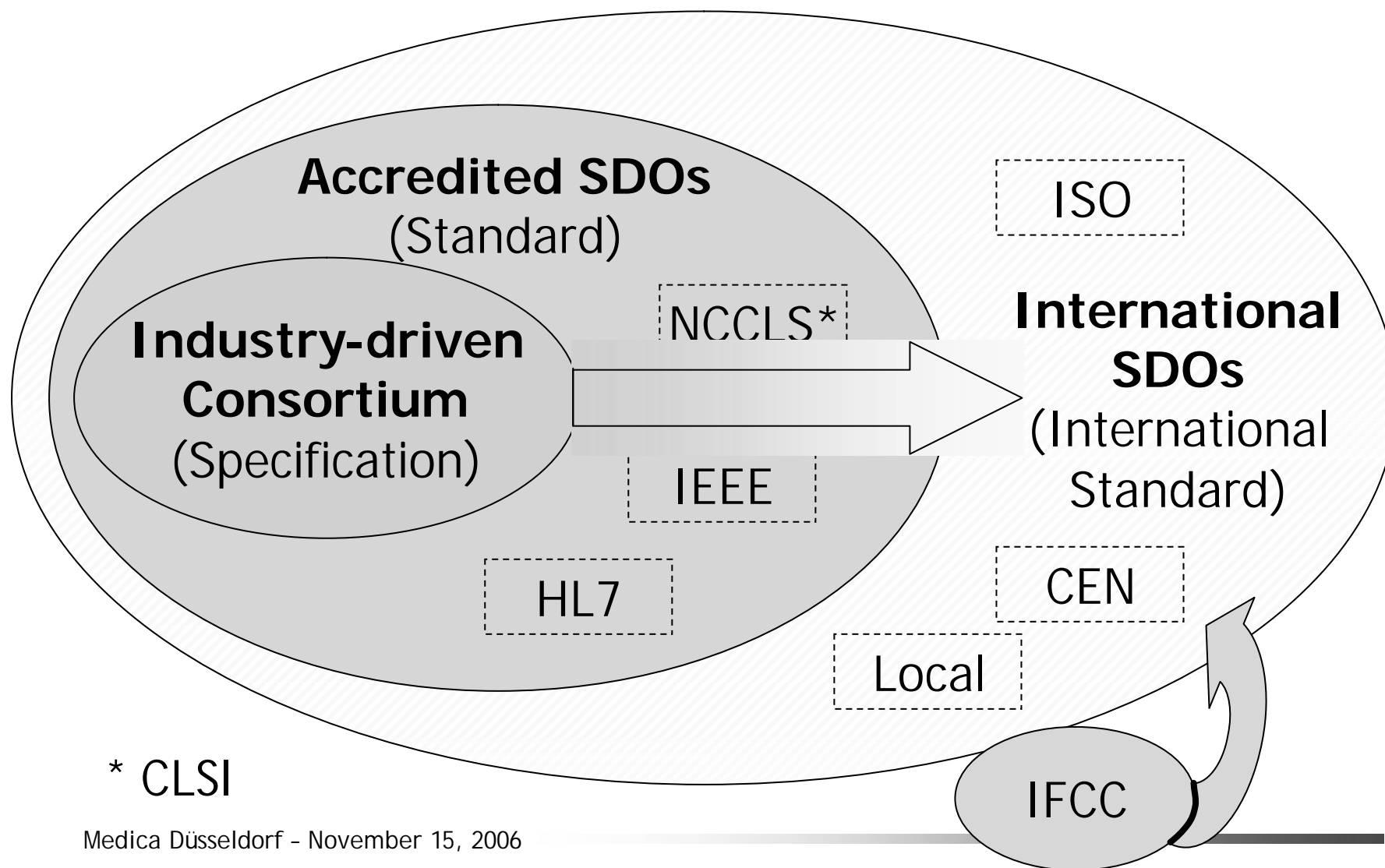
## EUROPEAN INITIATIVE - HISTORY

May 29, 2001: European Round Table (ERT) in Prague  
Launch of the ERT - Representatives from Europe met in Prague for a workshop to realize the goal

### Main Outcome:

- Formation of a European Work Group (self sustaining)
- Standard Development Organizations (CEN/ISO/DIN) / Forcing Standardization
  - o Fast-tracking the NCCLS document as an ISO TC 215 "Work Item"
  - o Status of a DIS (Draft International Standard)
  - o CEN and ISO cooperate in the internationalization (Vienna Agreement)
  - o DIN asked for participation of Roche in their committee for Medical Informatics
- Publication (user involvement) - IFCC
  - o White paper and various articles about the CIC standard
  - o Acts as user-liaison to SDO's e.g. review of standard document

# Standard Implementation



\* CLSI



## EUROPEAN INITIATIVE - HISTORY

November 2001: 2. EI Medica Meeting in Duesseldorf

Outcome: "The CIC will dedicate funds and resources to continue the European outreach initiative begun by the ERT."



Sunset Transition Plan 2002



## Sunset Transition Plan (2002)

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

1. Continue the internationalization push through the European Round Table ("EI") effort
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 EUROPEAN INITIATIVE - Content

- November 2002: 3. EI Medica Meeting in Duesseldorf  
Special: The presentation of a POCT1-A demonstrator
- November 2003: 4. EI Medica Meeting in Duesseldorf  
Outcome: "The discussion showed that most important is to step into the future and mirror the next horizon for POC standard development."
- July 2003: Publication "Worldwide Harmonization of Electronic Communication for Patient near Diagnostics"  
An Article in Trillium-Report 07/2003-06-27



## THE EUROPEAN INITIATIVE - Content

November 2004: 5. EI Medica Meeting in Duesseldorf  
Special: The presentation of the new horizons: AACC and ILC (the CIC's successor for a wireless solution) proposed joint activities with NCCLS.

December 2004: Publication "The POCT1-A Communication Standard. A path breaking Innovation"  
An Article in Trillium-Report 2004;2(4):101

November 2005: 6. EI Medica Meeting in Duesseldorf  
Special: The presentation by the Diagnostic companies Radiometer & Hemocue demonstrating interoperability among their devices using POCT1-A connectivity exchanging data between the two devices.



# THE EUROPEAN INITIATIVE - Content

August 2006: Publication "Market Survey: Status quo of POCT in Germany"  
An Article in Trillium-Report Trillium-Report  
2006 4(1):42-43

September 2006: ISO adopted POCT1-A as Draft International  
Agenda Standard ISO 11073-90101

November 2006: 7. El Medica Meeting in Duesseldorf



## EUROPEAN INITIATIVE - Activities

### 1. Continue the internationalization push through the European Round Table ("EI") effort - examples:

- Annual CIC EI Meeting during Medica in Duesseldorf
- ISO / CEN / DIN - national, pan-European and international activities:
  - ♦ The CIC European Initiative (EI) supported the process of promoting POCT1-A as a formal joint international (ISO / CEN / IEEE) standard.
  - ♦ The EI recently reached the first important step towards this target:
  - ♦ ISO adopted POCT1-A as Draft International Standard ISO 11073-90101 in September 2006.
  - ♦ The EI further contributes to the ongoing revision to result in version POCT1-A2 by CLSI.
- Participation in relevant congresses & organizations





## THE EUROPEAN INITIATIVE - Activities

2. Maintain the CIC website as a resource for implementation aids and best practices:
  - The "Fraunhofer-Institut für Integrierte Schaltungen in Erlangen" is owner of CIC website since 2003
  - The URL was taken over and in 2005 renamed: [www.poct.fraunhofer.de](http://www.poct.fraunhofer.de)
  - The website is well maintained and provides the CIC history documentation, information upon the ongoing activities of the EI and a POCT1-A community chat option



## THE EUROPEAN INITIATIVE - Activities

3. Develop an open source 'reference implementation' code that vendors and customers can use for testing:
  - The "Fraunhofer-Institut für Integrierte Schaltungen Erlangen" presented during Medica 2002 a POCT-1A Simulator (POCT-Device / POCT Observation Reviewer).
  - In cooperation with the industry the POCT1-A demonstrator was enhanced and
  - Since 2005 the simulator is utilized to provide standard compliance test and certification services for POCT1-A equipped devices.
  - The CIC EI intends to participate in the connectathon event 2007 in Berlin to demonstrate the open source ability of the POCT1-A.

Agenda



## THE EUROPEAN INITIATIVE - Activities

4. Continue some world-wide marketing and outreach activities (e.g. coordinate articles, trade shows):
  - The CIC European Initiative publishes articles on the topic POCT.
  - The publications focus on the development, availability and internationalization progress of the POCT1-A communication standard.
  - CIC EI representatives participate in various roles and functions as multipliers.
  - The CIC EI establishes cooperations with further leading POCT related organizations (e.g. DGKL, IHE /VHitG)
  - CIC EI intends a cooperation with the "Continua Health Alliance" WG (JP/HM)

Agenda

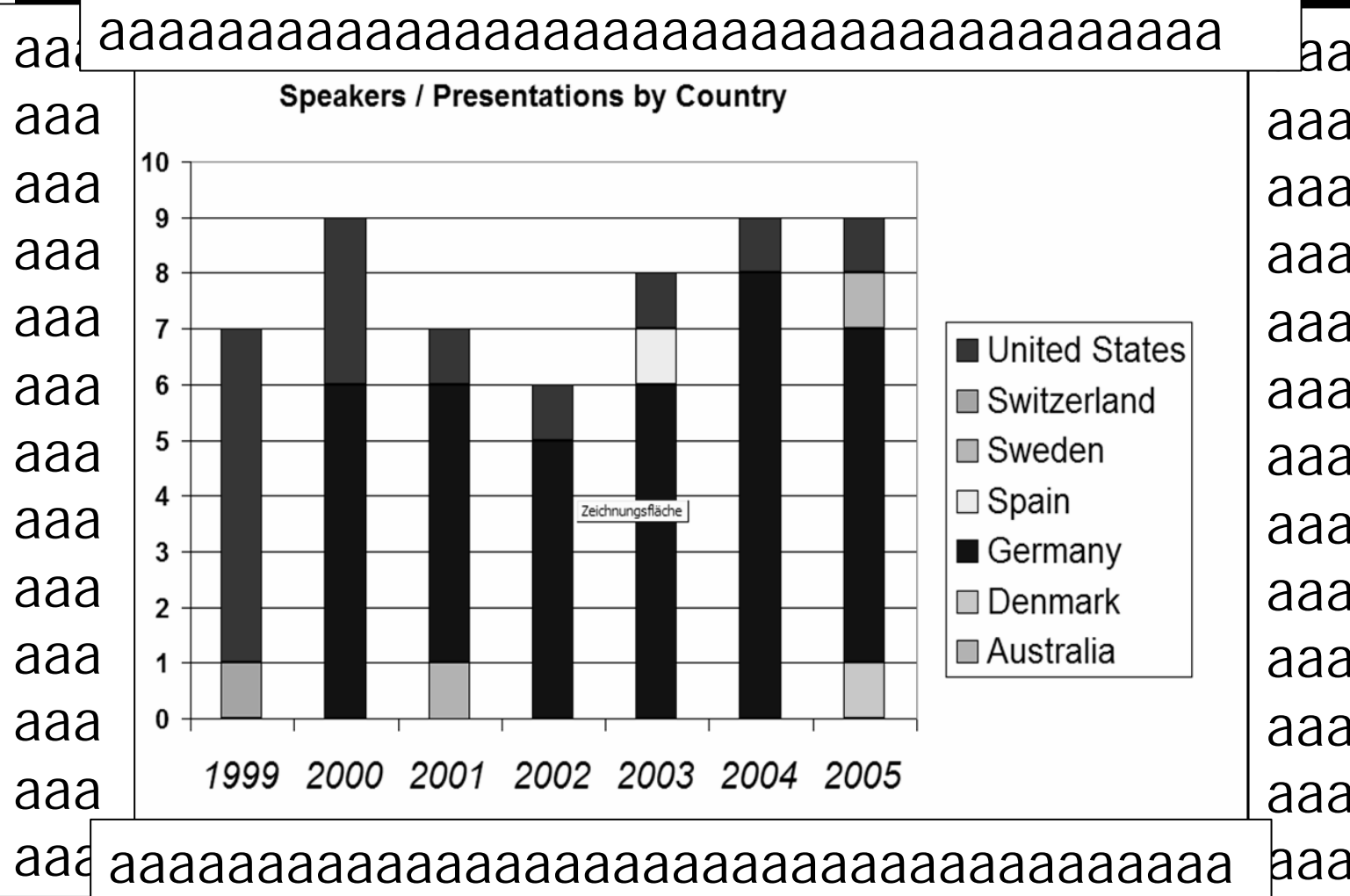


# The European Initiative - by numbers

Speakers/Presentations and Attendance

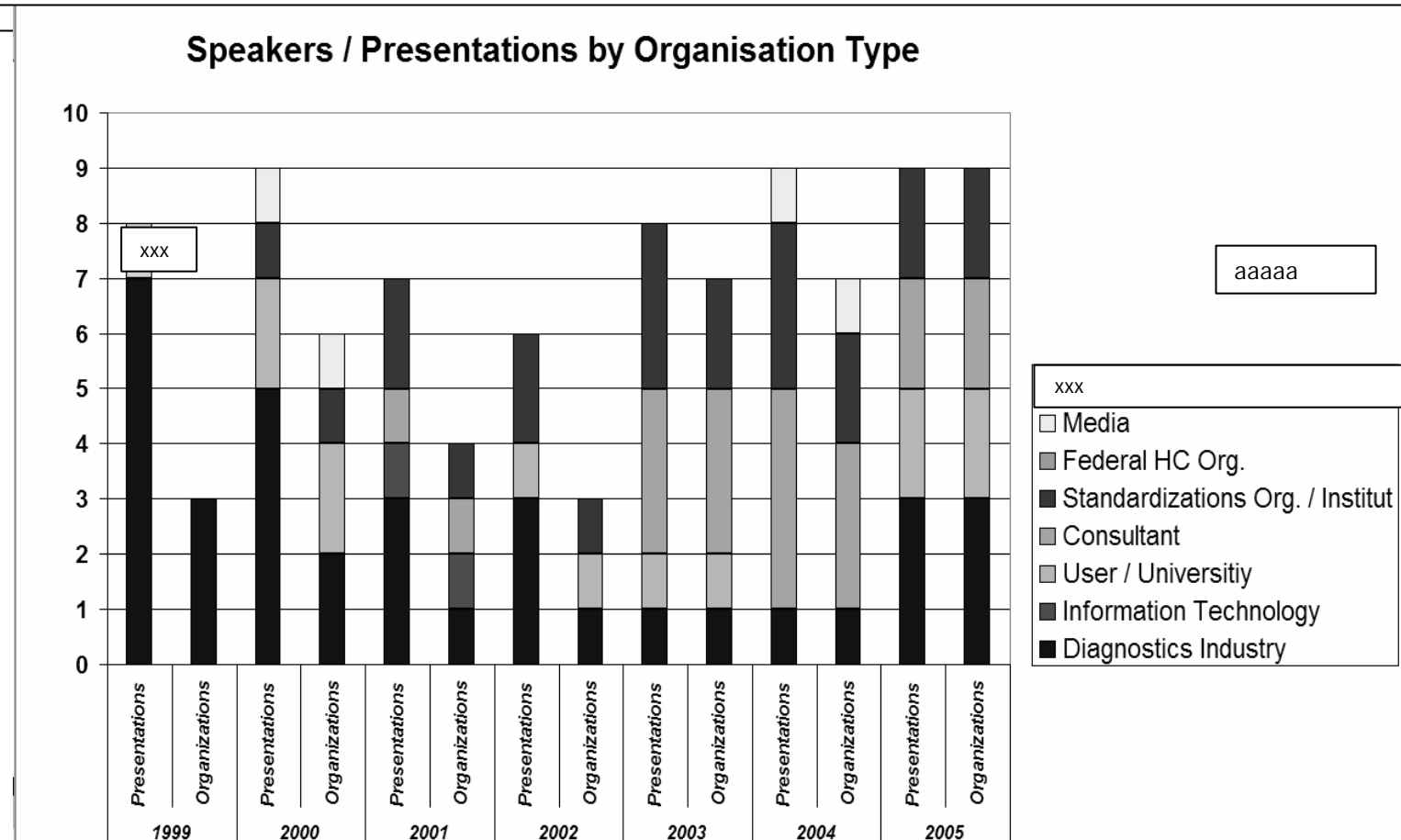
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## THE PRESENTATIONS - by Country



# THE PRESENTATIONS - by Org. Type

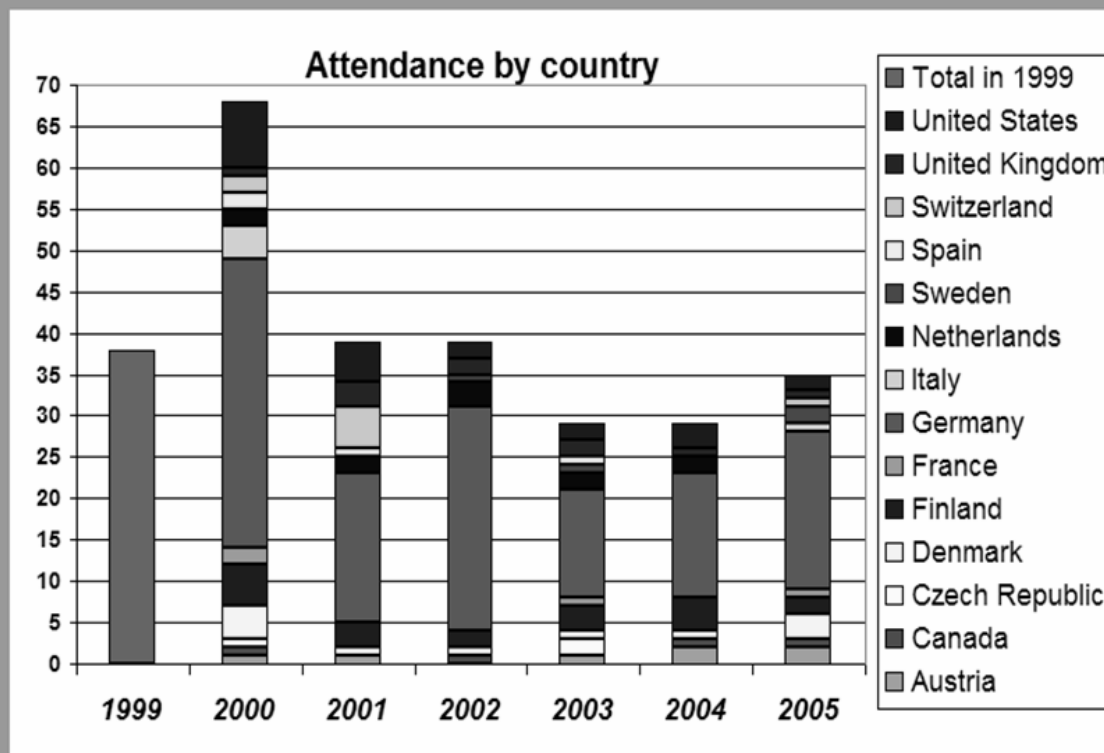
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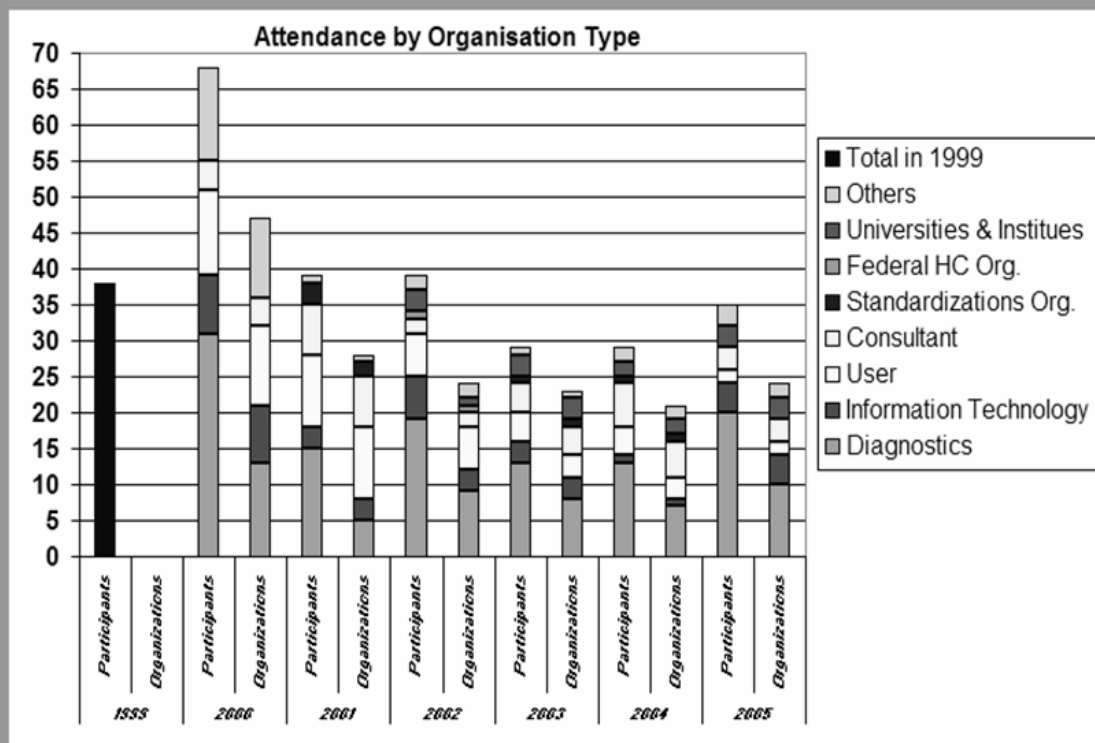
## THE ATTENDANCE - by Country

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## THE ATTENDANCE - by Org. Type





# The POCT1-A

What is the POCT1-A Now?

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## POCT1-A

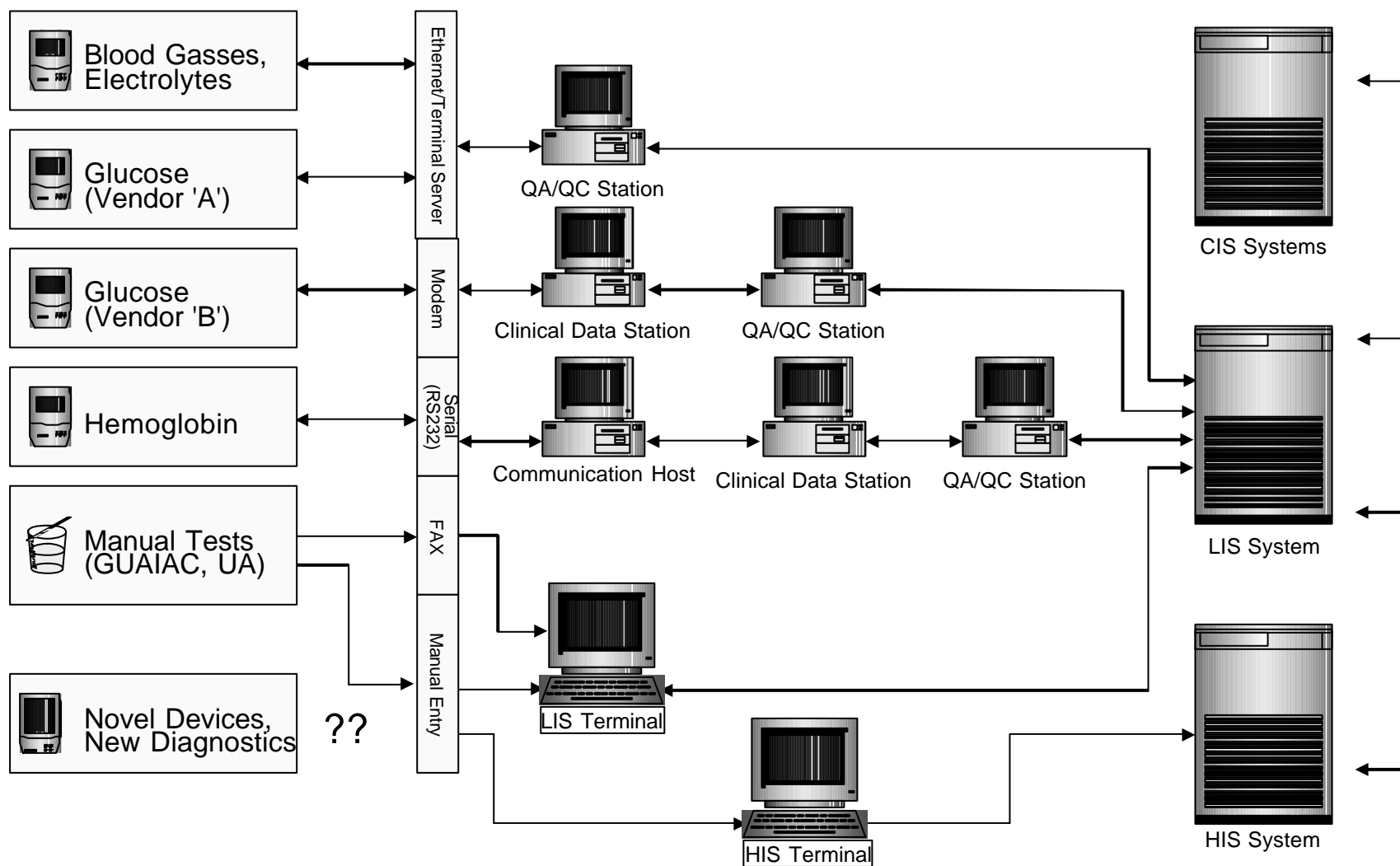
- Today the POCT1-A is a complete standard for multi-vendor point-of-care connectivity
- based on existing IEEE and HL7 standards and on specifications developed by the CIC.
- It is approved by the CLSI (former NCCLS) and
- ISO adopted as Draft International Standard ISO 11073-90101 and
- relevant components of the POCT1-A specification have been published by HL7 and IEEE in their own norms.



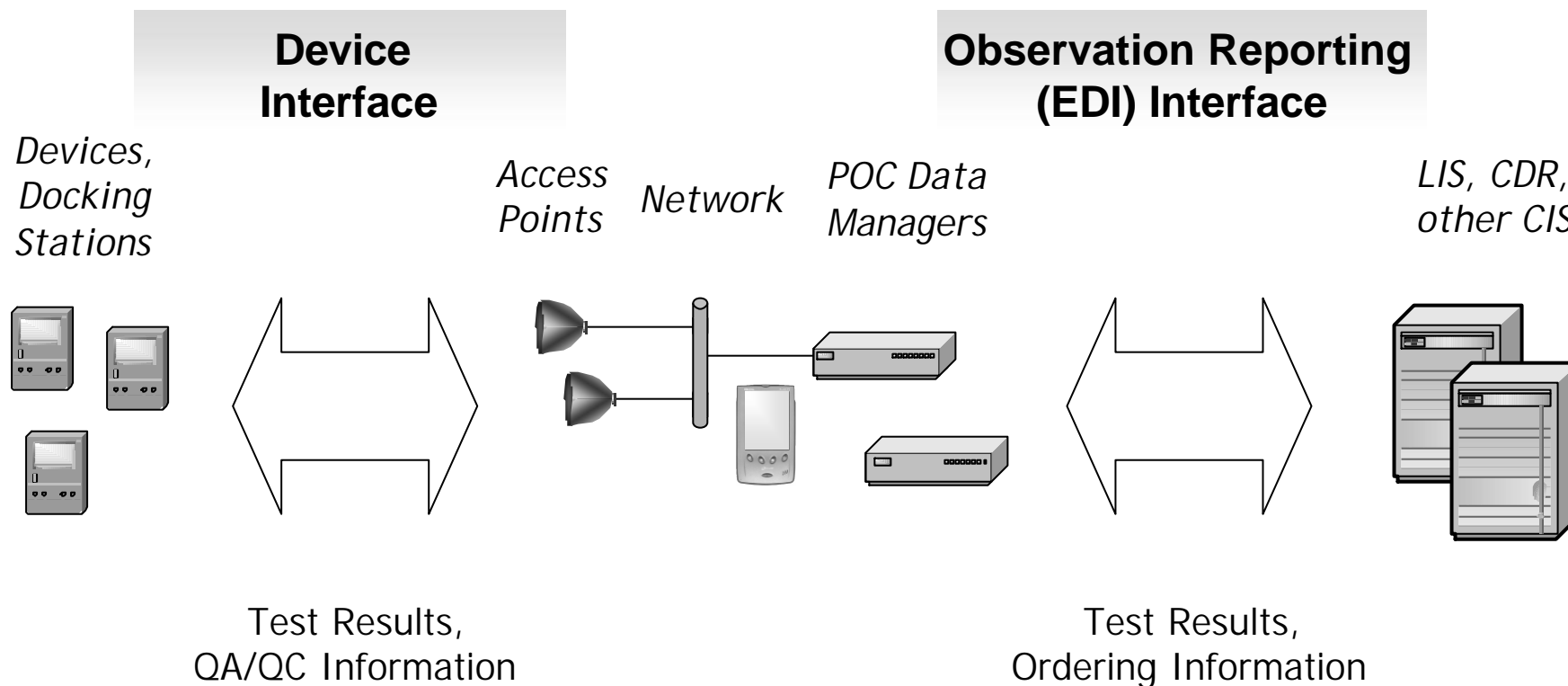
## POCT1-A

- The process of adopting POCT1-A as a formal international joint ISO and CEN standard (CEN ISO/IEEE 11073-90100) was supported by the CIC European Initiative (EI).
- The ongoing revision to result in version POCT1-A2 by CLSI is contributed by the European Initiative.

## Before the CIC...



# The CIC Solution





## POCT1-A in the HCM

- A survey among POC device manufacturers by Enterprise Analysis Corporation / USA in 2003 summarized:
  - 2 companies implemented the POCT1-A in their devices (Abbott and Nova)
  - 5 companies provide a DBMS which is compatible with the POCT1-A standard
  - 20 companies announced to launch a compatible POCT1-A device during the next two years

## POCT1-A in the HCM

Hersteller	Datenmanager
Abbott Diagnostics	QC Manager 3.0 Web Services
Med. Autom. Systems	RALS Plus
Nova Biomedical	Patient Data Management
Roche Diagnostics	Data Care POC, Data Care GM
Telcor	QML

***DBMS compatible with the communication standard POCT1-A***

*Quelle: Paula Byrde (EAC): Progress in Compliance. Point of Care 2003;2:39-48*





## POCT1-A in the HCM

- A survey among the members and partners of the CIC EI in 2005/06 summarized:

Agenda

- 3 companies implemented the POCT1-A in one of their devices (Roche, Radiometer, Hemocue)
- 1 company expressed strong interest to implement the standard in their POC devices contemporary (Bayer/Siemens)

Agenda

- Roche announced to launch two further POCT1-A equipped devices in 2007

Agenda

- Conworx and I-Soft are going to present their experiences with the POCT1-A during this meeting

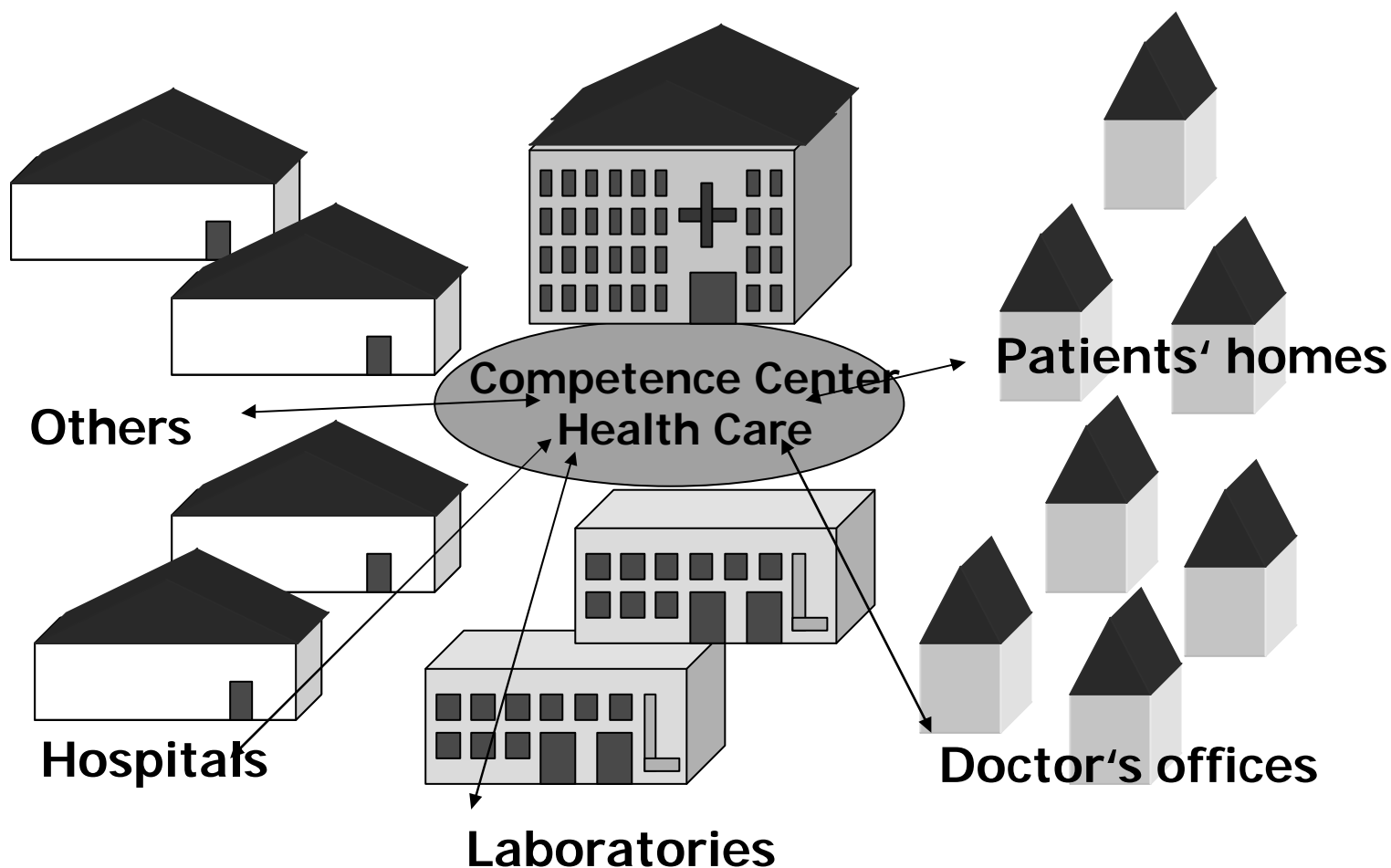


# POCT Connectivity in Europe

Incentives In Progress:

Integration Issue of the Health Care  
Reformation and the Medical Record

# Integration forces Connectivity - CCHC





# Telematics pushes Connectivity - PDC

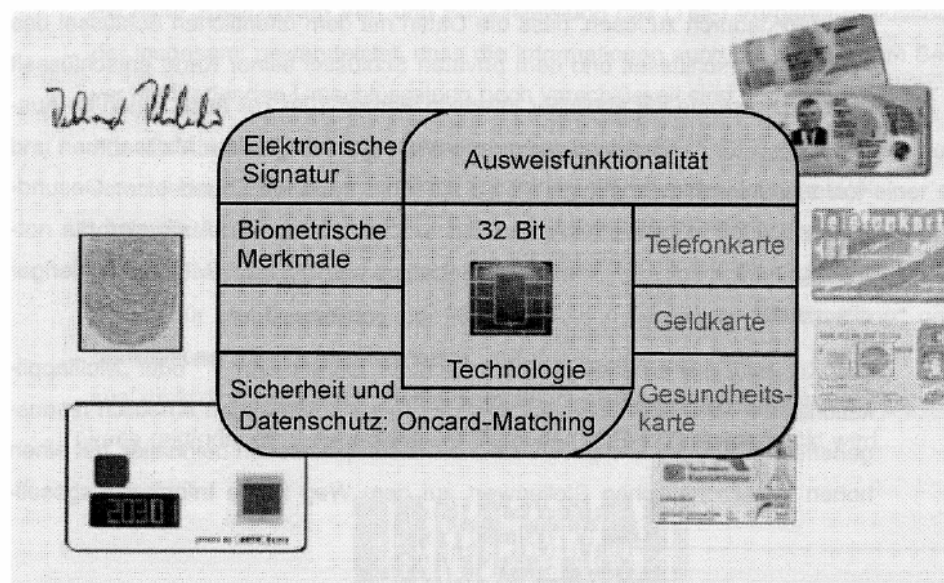
The German Federal Ministry of Health and Social Security announced to introduce a 'Patient Data Card' or 'Electronic Health Card' (eGK) in Test Areas in 2006. (Austria Jan 2005)

The implementation of the Electronic Health Card will be smartcard and server based.

The utilization of this resource requires a telematics platform.

# Telematics forces Connectivity - PDC

## PDC – Patient Data Card



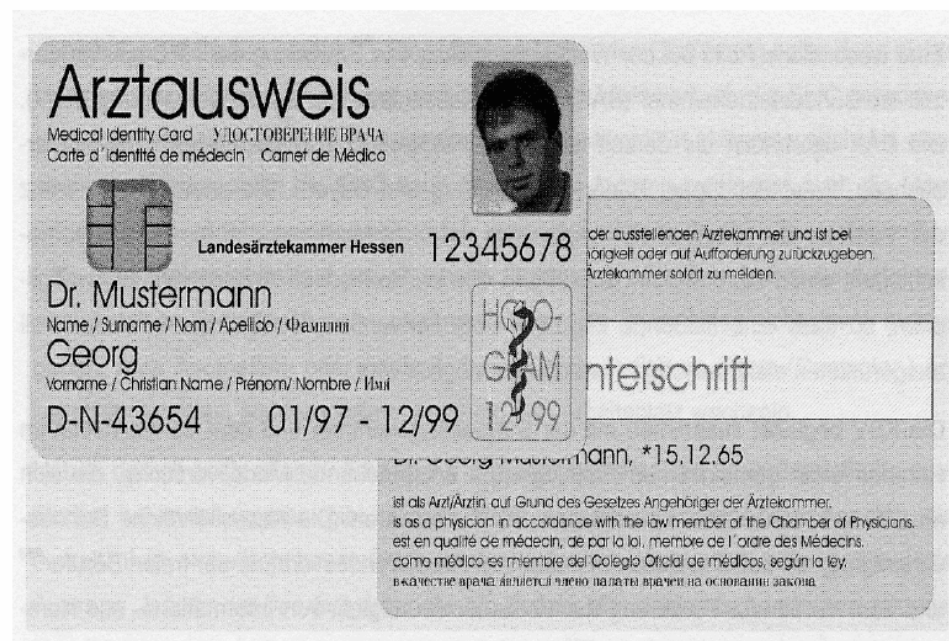
13. April 2005

Elektronische Gesundheitskarten und Gesundheitsakten

Prof. Dr. Paul Schmücker

# Telematics forces Connectivity - HPC

## Arztausweis – Health Professional Card



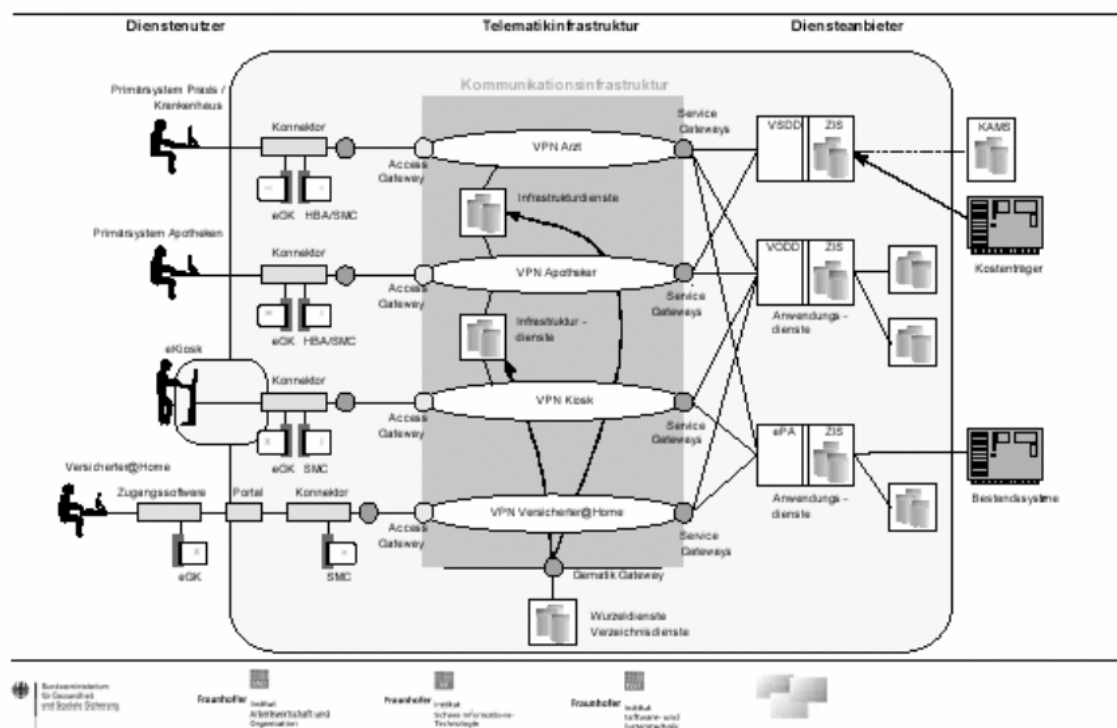
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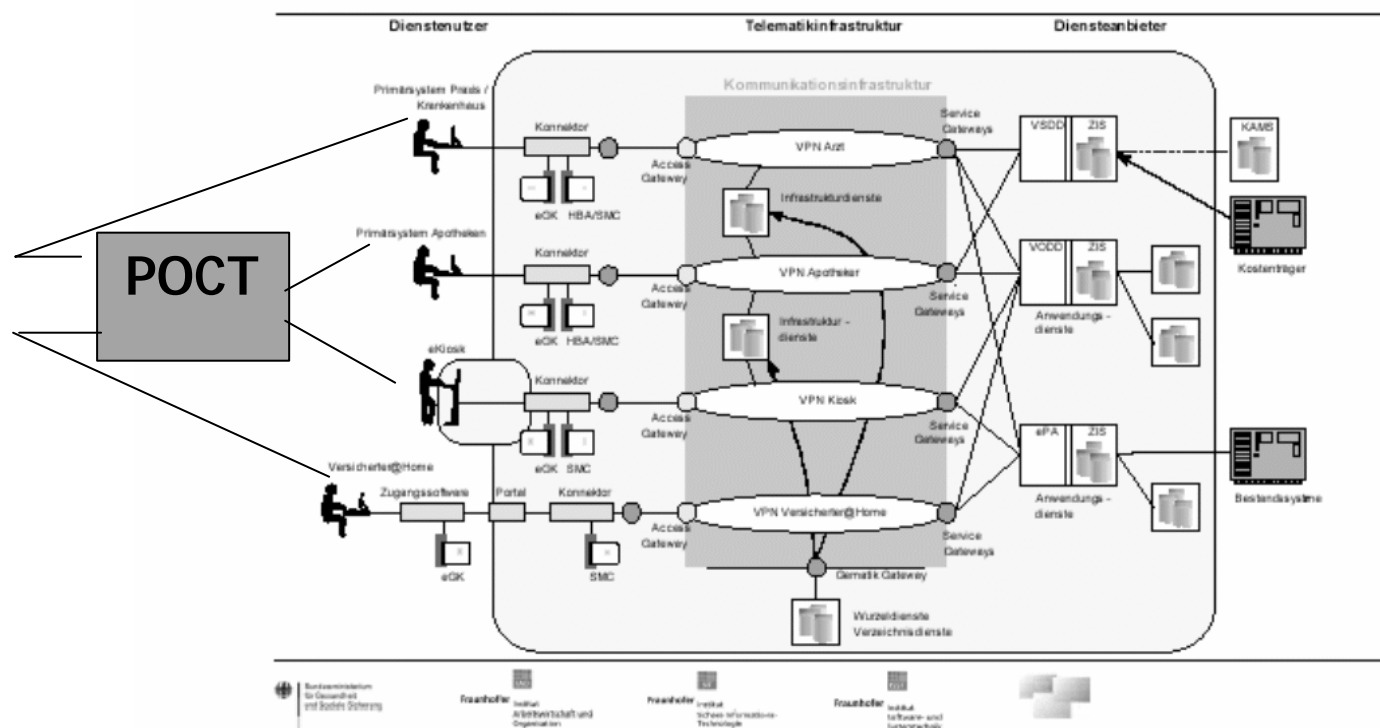
# Telematics forces Connectivity - POCT

## Grobarchitektur



# Telematics forces Connectivity - POCT

## Grobarchitektur







# POCT Connectivity in Europe

New Incentives:

„RiliBÄK“ 2006/07

Diagnostic Pathways



## QA/QC forces Connectivity - RiliBÄK 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"



## QA/QC forces Connectivity - RiliBÄK 2003

The Guideline 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.



## QA/QC forces Connectivity - RiliBÄK 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.

# From QC to QM - RiLiBÄK 2006/07

## Agenda

The new RiLiBÄK (Draft 2006) leads from  
Quality Control (QC) to Quality Management (QM)

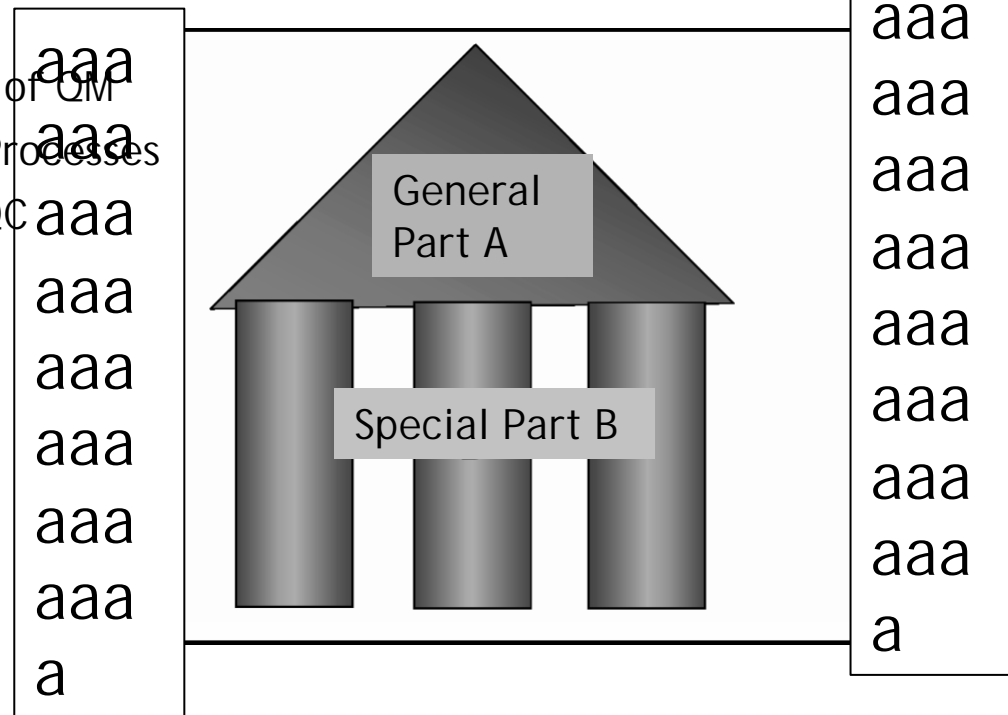
General Part (A):

- Laboratory relevant elements of QM
- Quality of Lab Structure and Processes
- QMS / external and internal QC

Special Part (B) -

Three Pillars - B1 POCT :

- POCT Connectivity Hospital
  - POCT devices and LIS
  - Responsibilities
- POCT not Hospital





## QA/QM 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.

# Diagnostic Pathways forces Connectivity

“Clinical Pathways - Diagnostic Pathways - Dia Lab Pathways”

Agenda





## Further Information @

- ✓ Website

[www.poct.fraunhofer.de](http://www.poct.fraunhofer.de)

- ✓ Contact

[Christina.Rode-Schubert@mbe.unisg.ch](mailto:Christina.Rode-Schubert@mbe.unisg.ch)