

# Connectivity Industry Consortium – European Initiative



Start	Length	Topic	Presenter
1:15	05 min	Opening, Welcome, Agenda	Christina Rode-Schubert – Germany, BE Consult Heidelberg, Secretary-General CIC Europe
1:20	10 min	A Brief CIC EI History – and a New Incentive for the POCT1-A in Europe	Christina Rode-Schubert – Germany,
1:30	15 min	Status Quo and Ongoing Work. The ongoing and successful European process of adopting NCCLS POCT1-A as a formal international ISO and CEN standard.	Thomas Norgall – Germany, Fraunhofer-Institut für Integrierte Schaltungen Erlangen, Chair CIC Europe
1:45	10 min	The ongoing development of the POCT1-A in the US. The CIC EI cooperation with the ILC.	Bob Uleski – USA, Diamedix
1:55	10 min	Industrial Experience Implementing the POCT1-A communication standard I: Roche Diagnostics Mannheim	Andreas Staubert – Germany, Roche Diagnostics Mannheim
2:05	10 min	Industrial Experience Implementing the POCT1-A communication standard II: Hemocue Sweden	Andreas Moe – Sweden, HemoCue AB
2:15	10 min	Industrial Experience Implementing the POCT1-A communication standard III: Radiometer Denmark	Allan Soerensen – Denmark Radiometer
2:25	05 min	Industrial Experience Implementing the POCT1-A communication standard IV: Bayer Germany	Tronka - Germany Bayer Leverkusen
2:30	15 min	Introduction on the mission of the POCT WG of the German Association of Clinical Chemistry and Laboratory Medicine (GACL)  Quality Assurance as incentive for a POCT communication standard. The POCT1-A as a solution to comply with legal requirements.	H.G. Wahl – Germany, Märkische Kliniken GmbH, Klinikum Lüdenscheid Chair POCT WG GACL (DGKL)
2:45	15 min	The Benefit of a communication standard as the POCT1-A for a central laboratory in a University hospital. Experiences connecting POCT devices with a central Laboratory.	Peter Lupp – Germany, University Hospital Munich
3:00	15 min	Market survey in 250 German hospitals. Successful point-of-care testing requires connectivity	Heiko Ziervogel – Germany, HCx Consulting Berlin
3:15	10 min	Discussion, Further Demands & Requirements, Q&A	Thomas Norgall – Germany,
3:25	10 min	Next Steps Europe and Closing	Thomas Norgall – Germany,



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

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

Medica 2005, Germany  
November 16, 2005



# The Connectivity Industry Consortium

From a Vision to a Success Story

Medica 2005, Germany  
November 16, 2005



## THE 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."



## THE 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



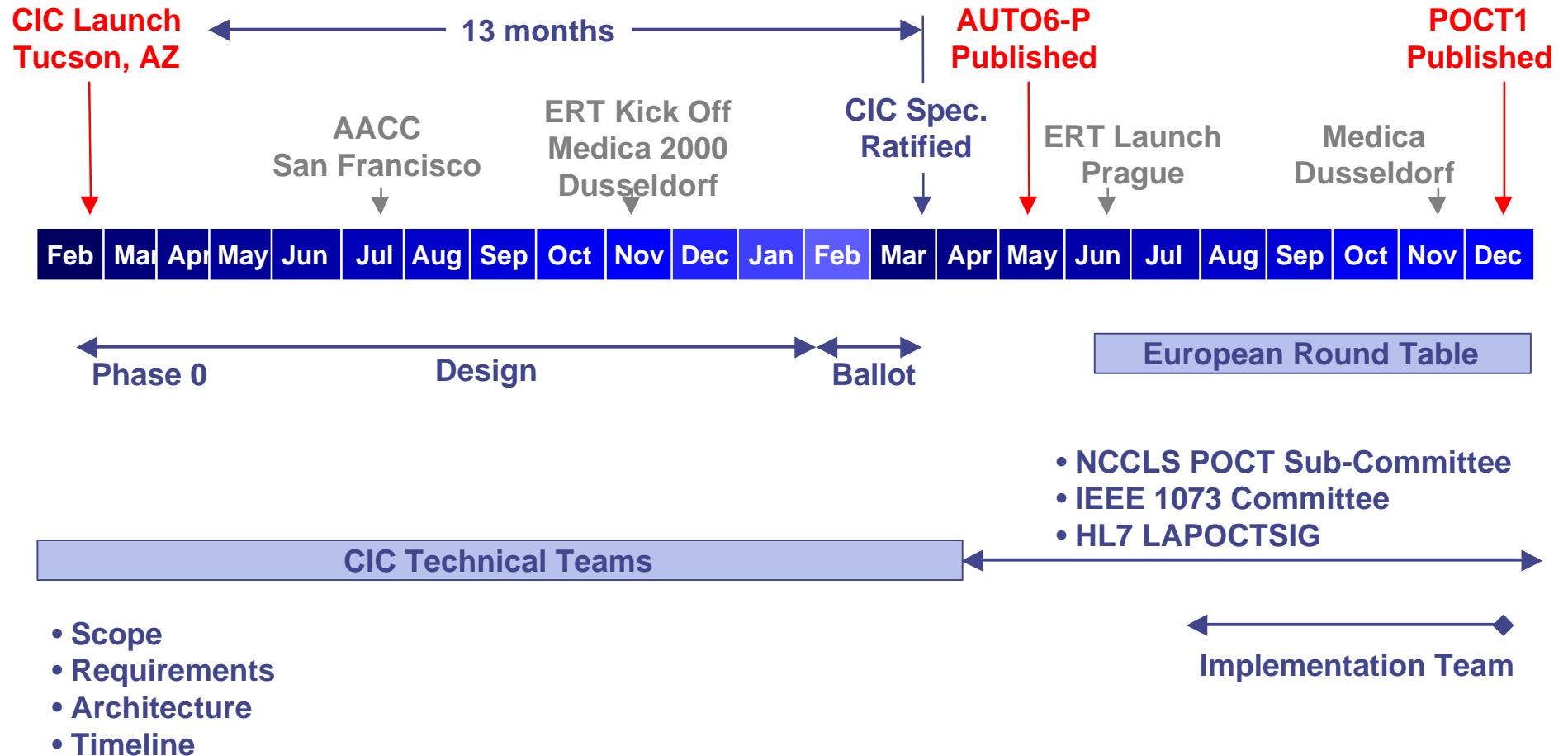
## THE LAUNCH

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.



# THE TIMELINE - Feb '00 to Dec '01

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





## THE 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.
- Oct 20, 1999: Agilent Technologies hosts a meeting to discuss and refine the proposal for the Connectivity Industry Consortium. 122 individuals from the point-of-care industry attend this meeting in Redwood City, CA:





# THE HISTORY

## MILESTONES AND DELIVERABLES

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

- Member buy-in and commitment
- Structure of the Consortium
- IVD Vendors, IS companies, and Providers in agreement on structure, objectives and timeline

*European Round Table*

**ERT DECISION**

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



# THE HISTORY

## MILESTONES AND DELIVERABLES

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

*European Round Table*  
***ERT Kick Off***



## THE 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.
- The CIC specification was presented to to the  
selected standards organizations for approval:  
CLSI (former NCCLS), HL7 and IEEE



## THE SUCCESS STORY

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



## THE COVER

- Substantial contributions from a great number of individuals from the point-of-care industry directly accounted for the Consortium's progress and success to date.
- The CIC's very existence is a tribute to the dedication and vision of the individuals, who believe that standardization of point-of-care testing connectivity will benefit the industry, healthcare providers, and patients.
- The cover is a tribute to the dedication and commitment of these individuals & organizations.



## 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

### Core PROVIDER

Banner Health System  
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

From Duesseldorf to Praque and back  
to Duesseldorf

Medica 2005, Germany  
November 16, 2005





# THE EUROPEAN INITIATIVE HISTORY

- November 1999: Roche sponsors a CIC update for European companies at Medica in Duesseldorf
- 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.
- June 2001: Launch of the ERT - Representatives from Europe met in Prague for a workshop to realize the goal:



## THE PRAQUE MEETING

- The POC European Connectivity Industry Consortium (CIC) Initiative Meeting was held May 29, 2001 during the EuroMedLab Congress in Prague.
- Twenty-eight attendees from throughout Europe joined the meeting on POC Connectivity.
- European Key Members:
  - Dr. Fratermann, G.Hoffmann, T.Norgall, G.Schmitz,  
H. Ziervogel ... - Germany
  - P. Mocarelly - Italy
  - R. Riuz - Spain
  - D.Hirst - U.K.



# THE PRAQUE MEETING OBJECTIVE

## Meeting objective

- Catalyze the formation of a 'network' of principal individuals from health care providers, regulatory bodies and industry who are committed to advancing POC connectivity standardization in Europe

## Proposed objectives for this network

- Advocate for POC Connectivity Standardization throughout Europe
- Provide European Perspective and Requirements to the CIC's POC Standardization Effort:



## THE OUTCOME I - Differences Europe & USA

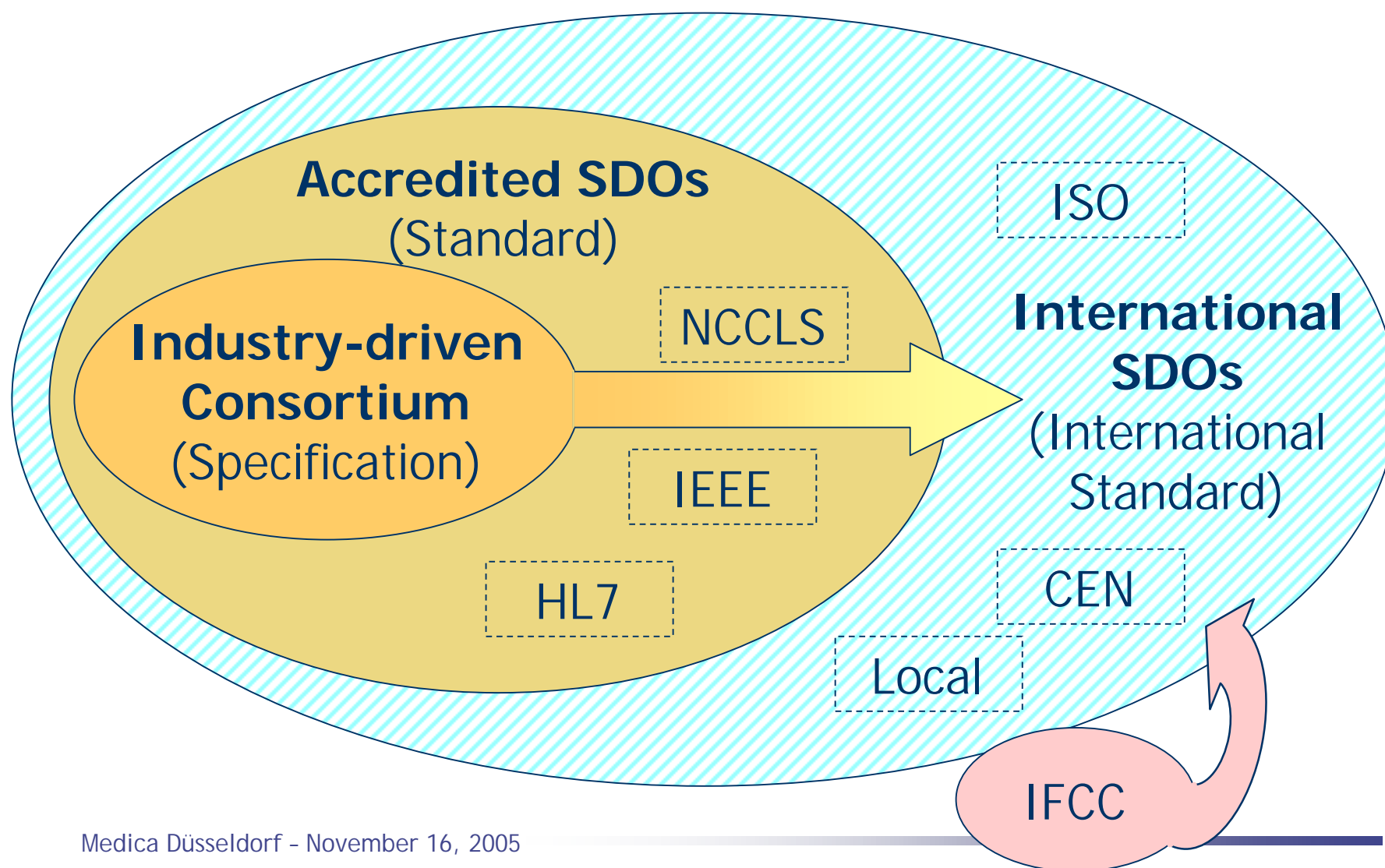
- Standardized patient and operator identification is becoming very important in Europe (positive, relative to the US)
  - Starting in 2002, Germany will implement a requirement to link test results to the patient and operator
  - One significant 'enabling' issue is standardization of Patient identification ("CliniCard")
  - A "health professional" card is expected to be ready and available by end of 2001
- In Europe, there is a lack of a standard certification process or regulatory bodies (like CLIA, CAP in the US)
- There is a wide diversity of skill set, organization level, expertise and experience in the European POC world regarding how to implement POCT successfully
  - In general centralized POCT committees are lacking, and there are conflicts of interest and control between clinicians and laboratorians
  - The decision power still rests in the hand of a few individuals, rather than a committee
- There is a lack of awareness regarding how connectivity can improve the usefulness and effectiveness of POCT (Changed '04)



## THE OUTCOME II - European Initiative Task

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

# Standard Implementation



The diagram illustrates the relationship between various standards organizations and their working groups. It features three main colored ovals representing different organizational structures:

- CEN TC251 (Yellow Oval):** Contains four working groups: WG1, WG2, WG3, and **WG4: Technology for Interoperability**.
- ISO TC215 (Blue Oval):** Contains five working groups: WG1, **WG2: Messages and Communication**, WG3, WG4, and WG5.
- International National Standards Organization (Green Oval):** Contains two regional/national bodies:
  - Europe:** Includes "Other NR" and **DIN**.
  - USA (ANSI):** Includes NCCLS, DICOM, ASTM, and IEEE.

A separate white oval labeled **Consortia** contains **CIC**. Dotted lines indicate connections from WG4 in CEN TC251, WG2 in ISO TC215, and DIN in Europe to the USA (ANSI) section of the International National Standards Organization.



# The CIC European Initiative

## Sunset Transition Plan & European Activities

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## 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 ("ET") 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 - 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
  - eHealthCare.com - an annual autumn congress in Zürich/Swiss
  - GMDS Project Group Mobil Computing in Medicine (MOCOMED) - a national German project with international co-operations
  - 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 renamed in 2005: [www.poct.fraunhofer.de](http://www.poct.fraunhofer.de)
  - The website is well maintained and provides the CIC history documentation as well as information upon the ongoing activities of the EI.
  - A POCT1-A community chat will be established on the site.



## 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 Demonstrator/Simulator.
  - An impressive demonstration of a communication between a POCT-Device and a POCT Observation Reviewer utilizing the POCT-1a standard.
  - Meantime the Fraunhofer-Institute in cooperation with the industry has enhanced its POCT1-A demonstrator and utilizes the simulator since 2005 to provide standard compliance test and certification services for POCT1-A equipped devices.



## THE EUROPEAN INITIATIVE - Activities

4. Continue some world-wide marketing and outreach activities (e.g. coordinate articles, trade shows):
  - The CIC European Initiative published articles on the POCT1-A development, availability and internationalization progress in a hospital magazine.
  - CIC EI representatives participate/act in various roles as multipliers.



## THE EUROPEAN INITIATIVE - Content

- May 29, 2001: European Round Table (EI) in Prague
- 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."
- 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."



## THE EUROPEAN INITIATIVE - Content

- July 2003: Publication "Worldwide Harmonization of Electronic Communication for Patient near Diagnostics"  
An Article in Trillium-Report 07/2003-06-27
- 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.  
Outcome: A POCT1-A community chat will be established on the website.
- 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



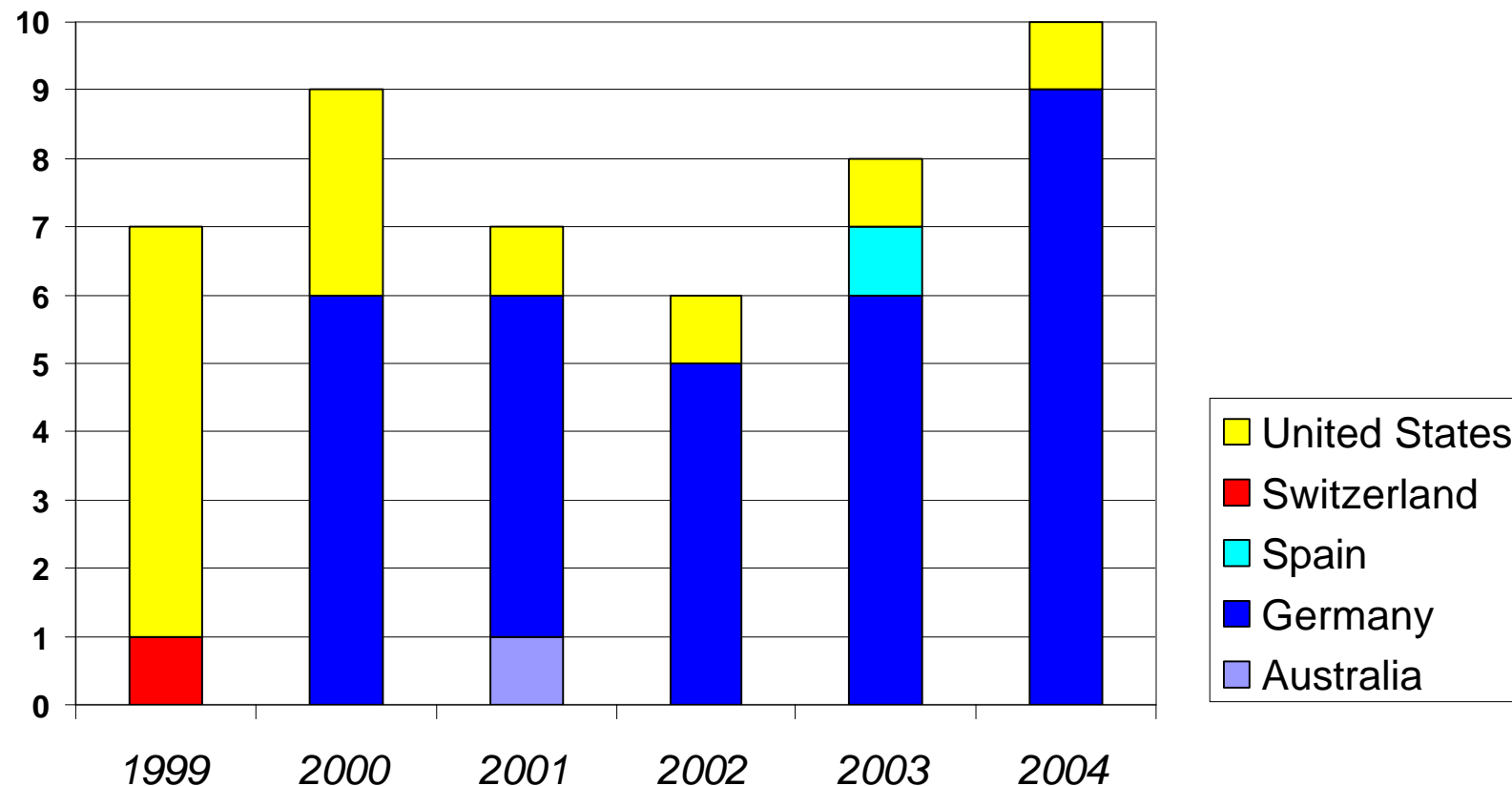
# The European Initiative – by numbers

Speakers/Presentations and Attendance

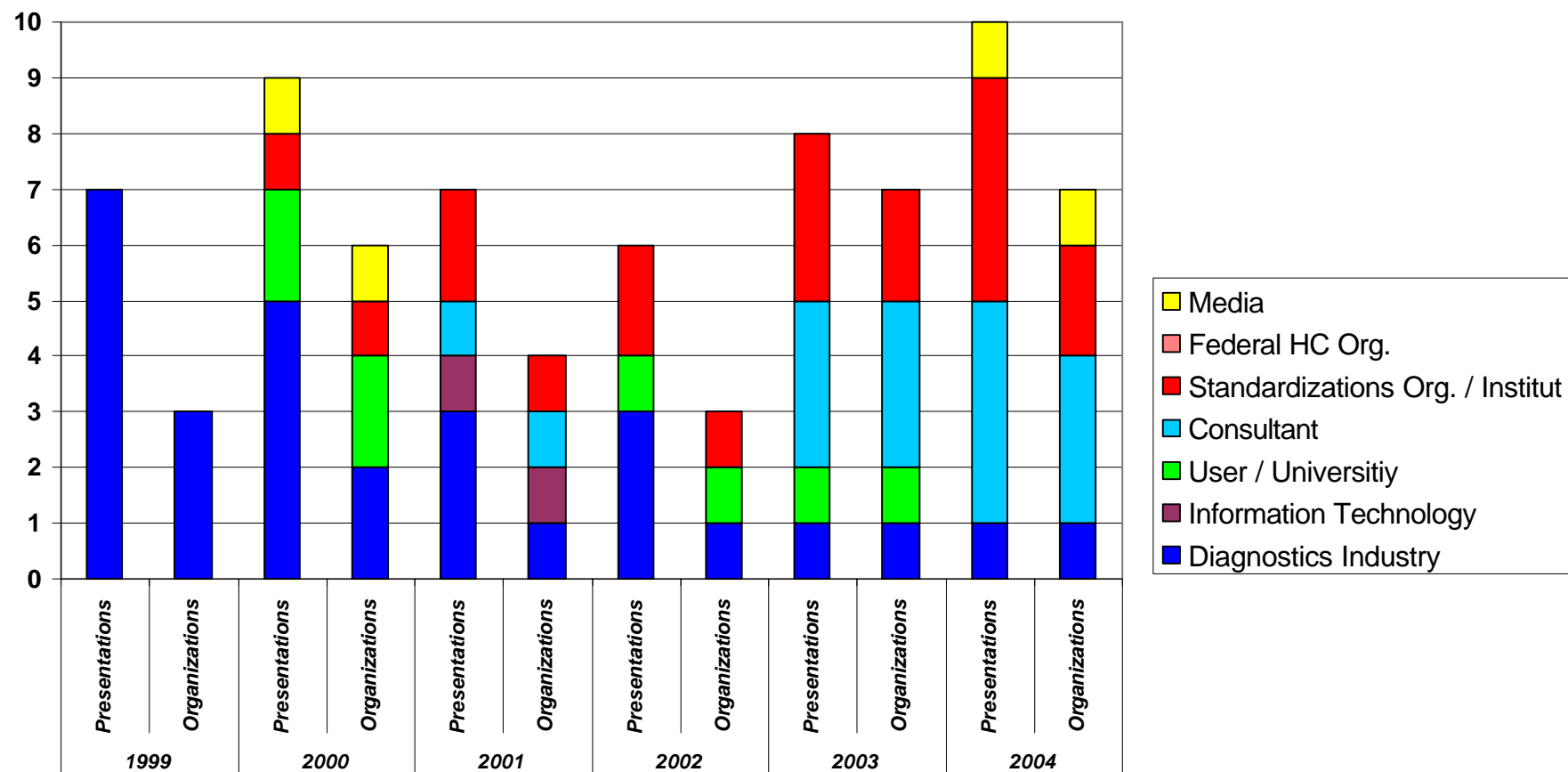
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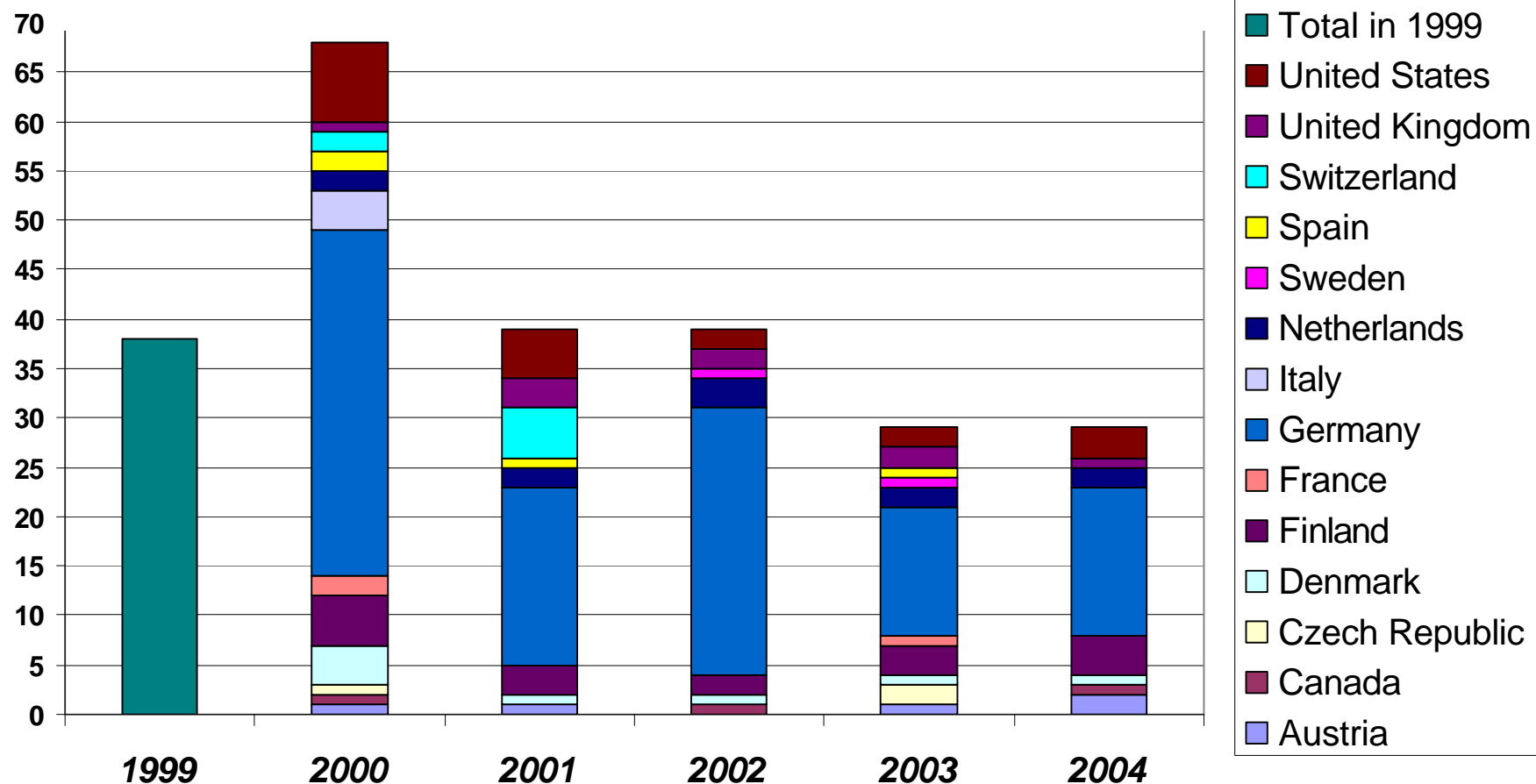
## THE PRESENTATIONS - by Country



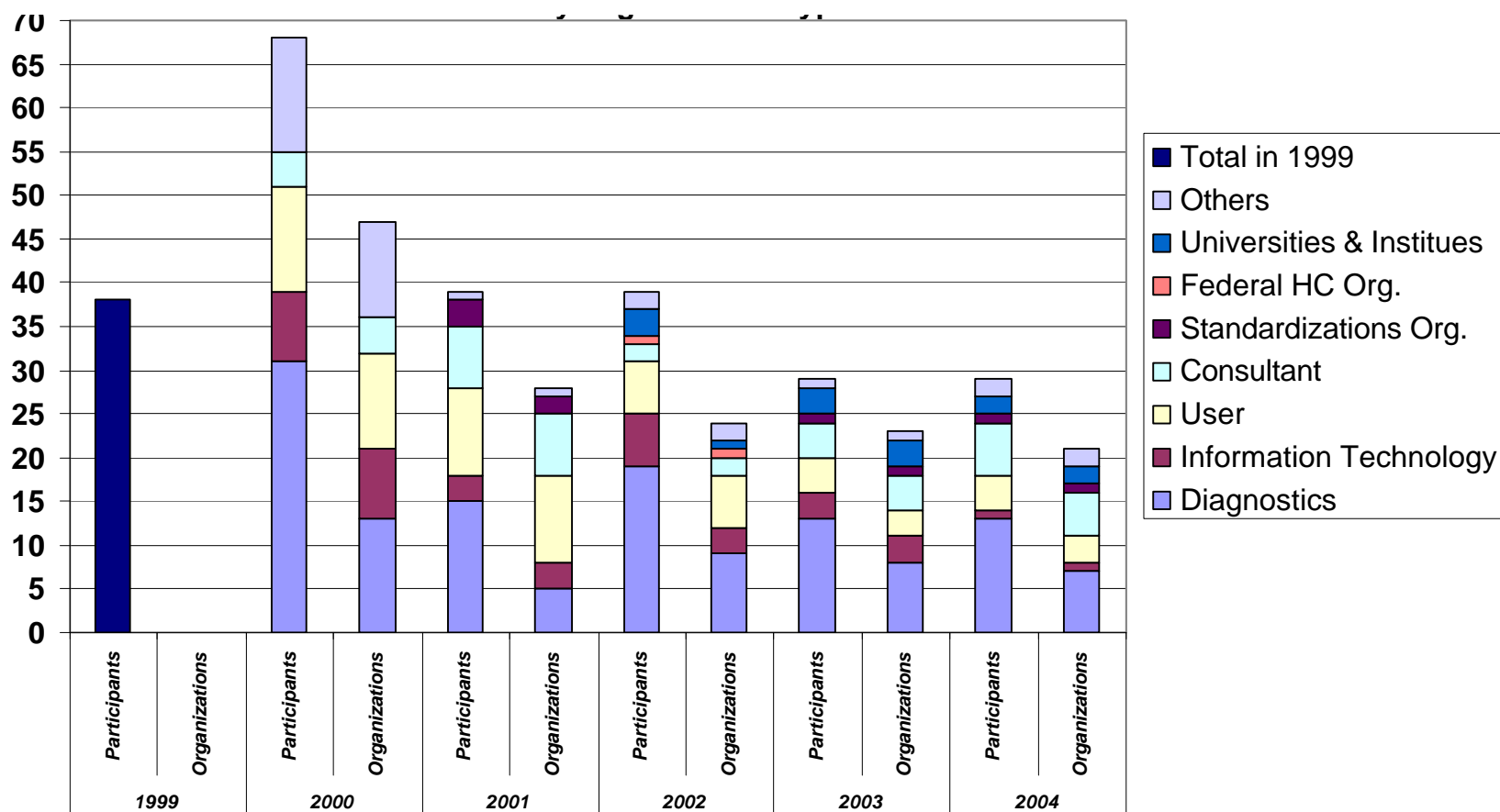
# THE PRESENTATIONS - by Org.Type



## THE ATTENDANCE - by Country



## THE ATTENDANCE - by Org. Type





# The POCT1-A

What is the POCT1-A Now?

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## POCT1-A

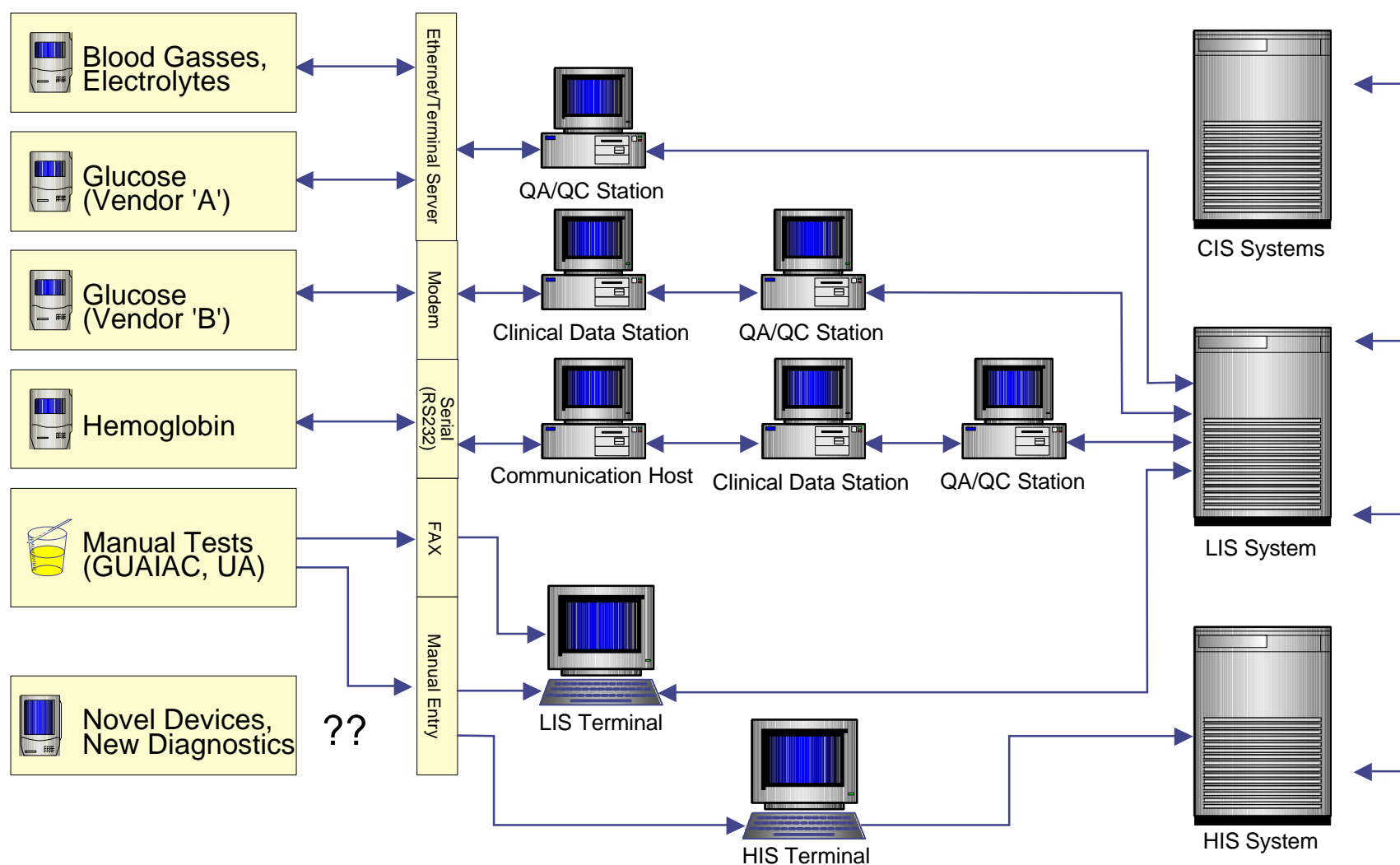
- Today the POCT1-A is a complete standard for multi-vendor point-of-care connectivity.
- It is a standard for point-of-care connectivity based on existing IEEE and HL7 standards and on specifications developed by the CIC and approved by the CLSI (former NCCLS).
- HL7 and IEEE have published relevant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



## POCT1-A

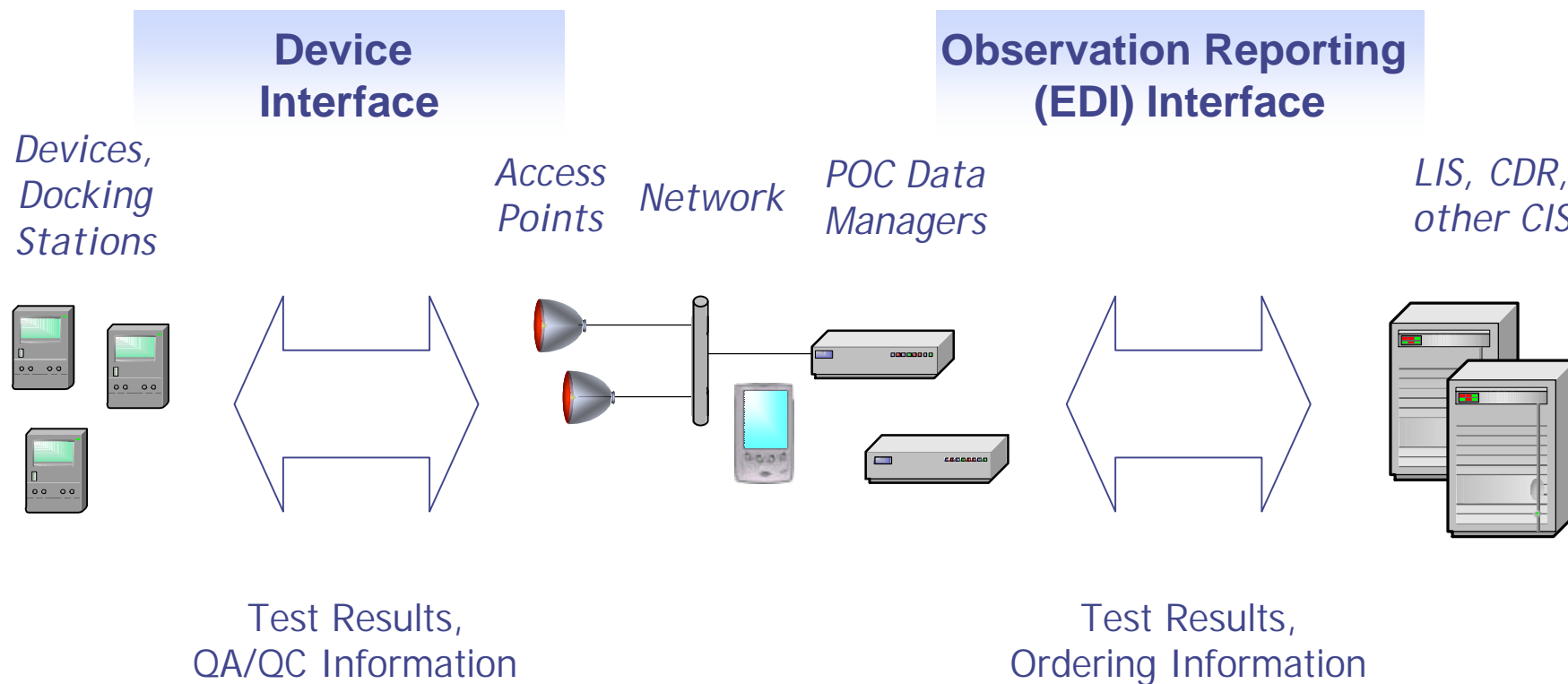
- The process of adopting POCT1-A as a formal international joint ISO and CEN standard (CEN ISO/IEEE 11073-90100) is supported by the CIC European Initiative (EI).
- The EI also contributes to the ongoing revision of POCT1-A by CLSI.

## 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 Byrdy (EAC): Progress in Compliance. Point of Care 2003;2:39-48*



# POCT Connectivity in Europe

Incentives: The „RiliBÄK“, the  
Integration Issue of the Health Care  
Reformation and the Medical Record

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November 16, 2005



## QA forces Connectivity - RiliBÄK

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 forces Connectivity - RiLiBÄK

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.



## QA forces Connectivity - RiliBÄK

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” ...



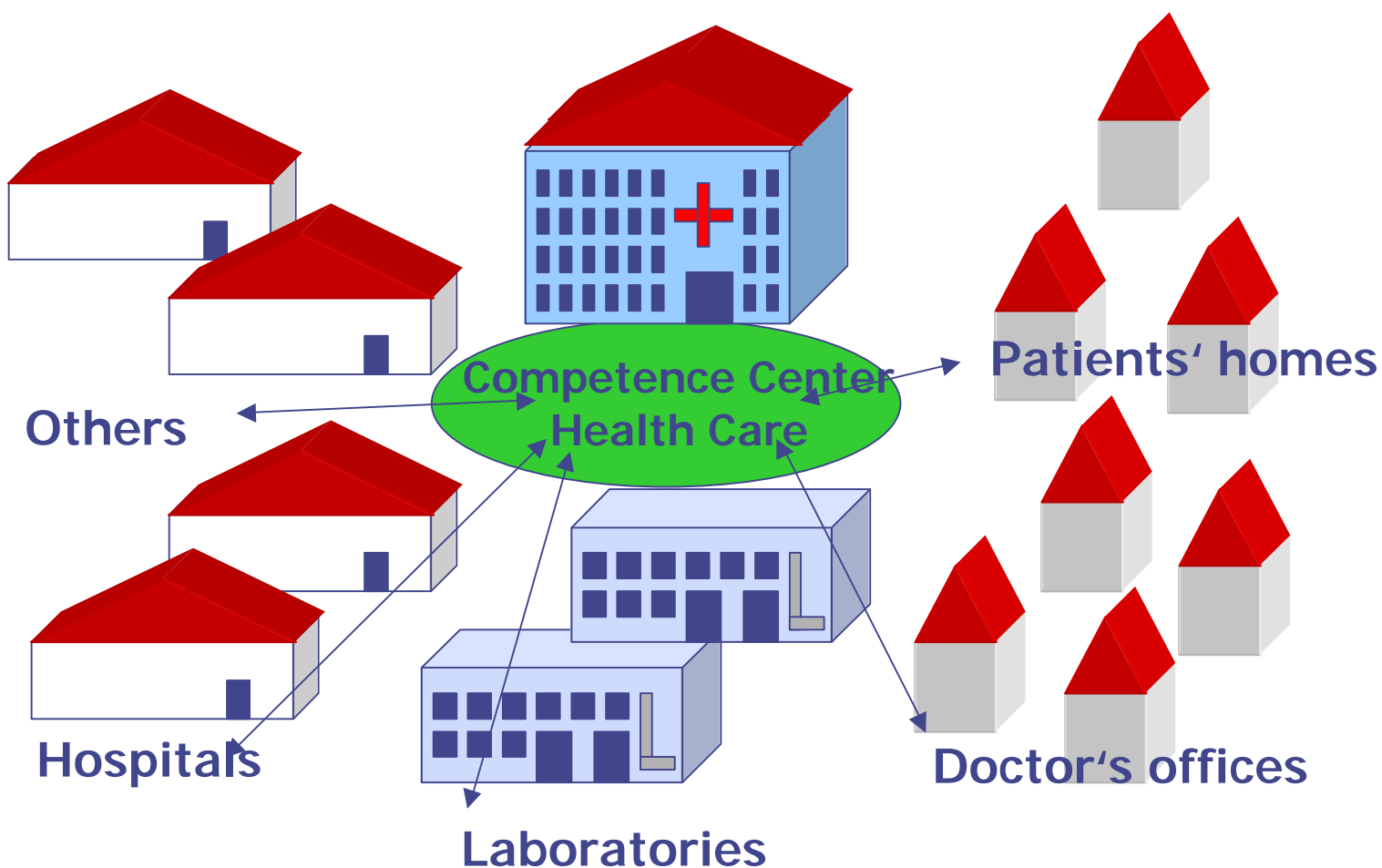


## QA forces Connectivity

.... 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.

# Integration forces Connectivity - CCHC





## Telematics forces Connectivity - PDC

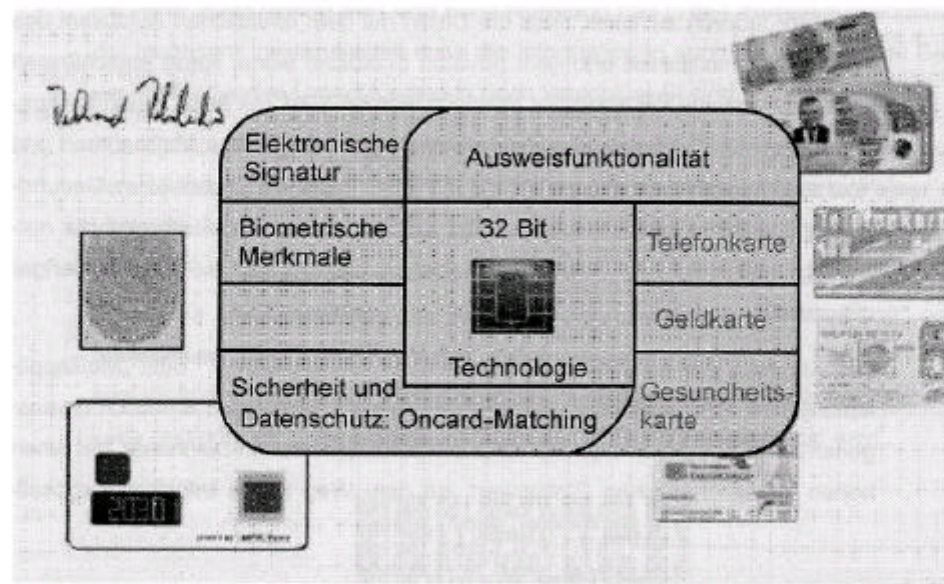
The German Federal Ministry of Health and Social Security announced that they will introduce a 'Patient Data Card' or 'Electronic Health Card' (eGK) in January 2006. (Austria Jan 2005)

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



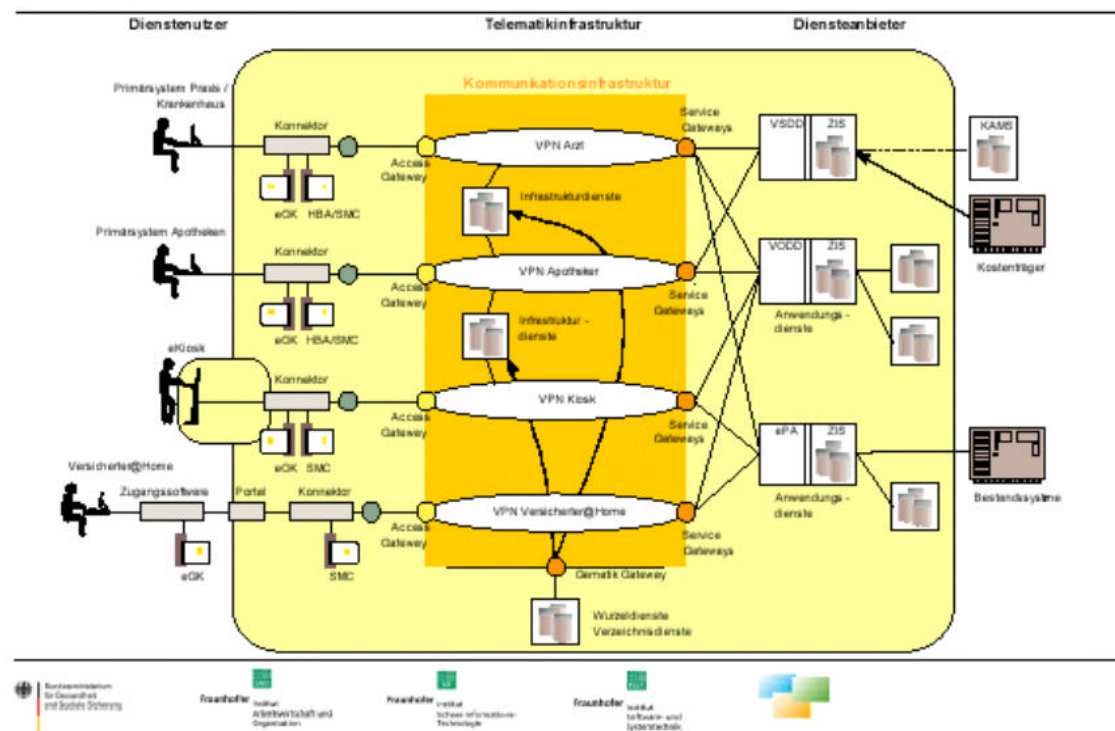
13. April 2005

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# Telematics forces Connectivity - POCT

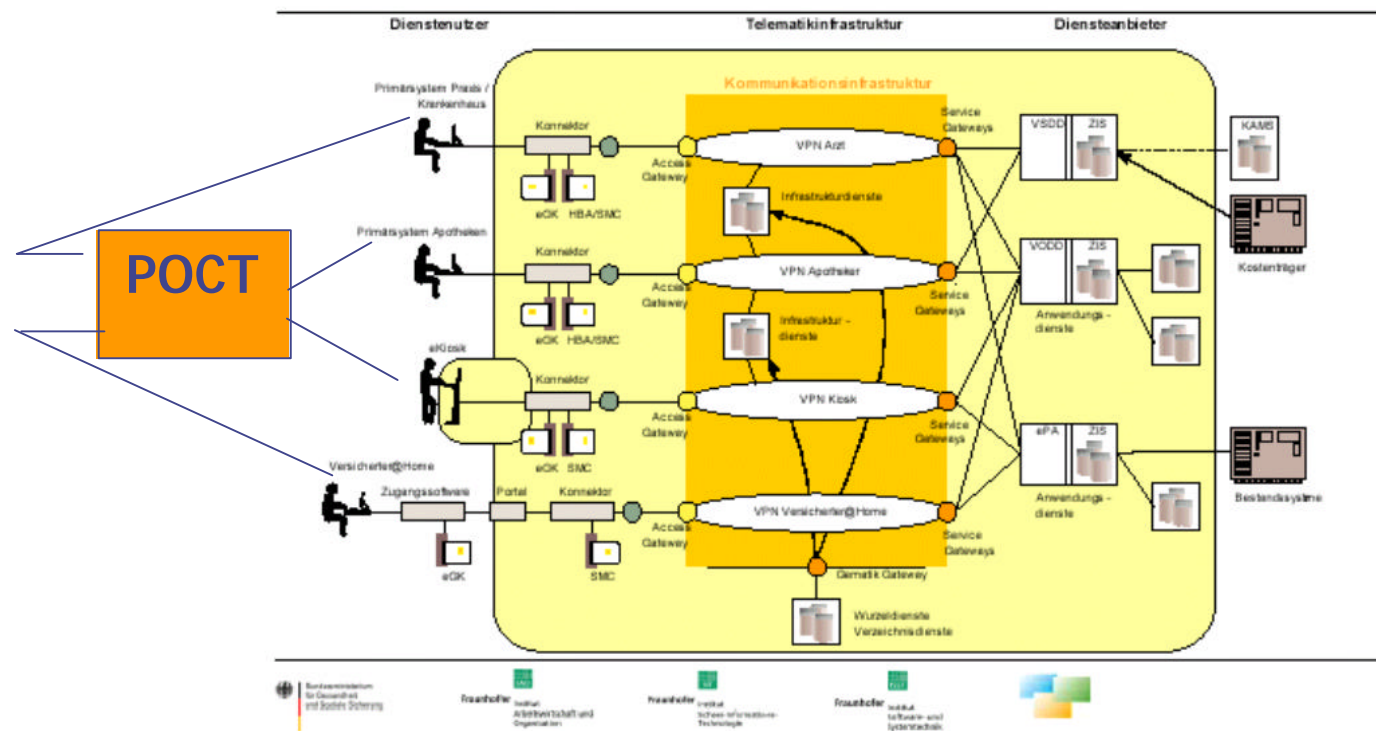
## Grobarchitektur





# Telematics forces Connectivity - POCT

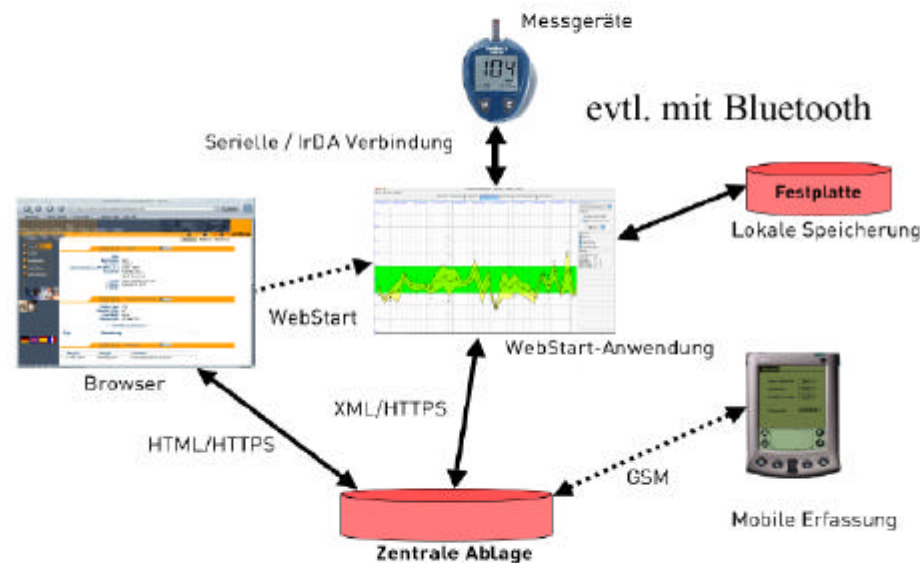
## Grobarchitektur



# Instance of Application - Diabetes Care

by Paul Schmücker - Professor for Informatics/Computer Science University Mannheim

## Diabetes als chronische Behandlung



13. April 2005

Elektronische Gesundheitskarten und Gesundheitsakten

Prof. Dr. Paul Schmücker



# Instance of Application - Diabetes Care

by Paul Schmücker - Professor for Informatics/Computer Science University Mannheim

## **Funktionalität Diabetesakte:**

1. Dokumentationswerkzeuge für Ärzte
2. Dokumentationswerkzeuge für Eigenbeobachtungen
3. Therapieplanung
4. Schulung
5. Anbindung von Blutzucker-Messgeräten
6. Auswertewerkzeuge
7. Reminderfunktionen
8. Bereitstellung von Wissen

13. April 2005

Elektronische Gesundheitskarten und Gesundheitsakten

Prof. Dr. Paul Schmücker

# Patient Healthcard Data ISO

Besonders relevant sind die Standards ISO/DIS 21549-1 bis -7 (Patient Healthcard Data). In diesen Entwürfen werden die Datenstrukturen für eine elektronische Gesundheitskarte beschrieben (siehe Abbildung 14).

Von den Teilen 1-3 existieren Entwürfe, die sich derzeit im Abstimmungsstadium befinden, die übrigen Teile befinden sich noch in früheren Phasen.

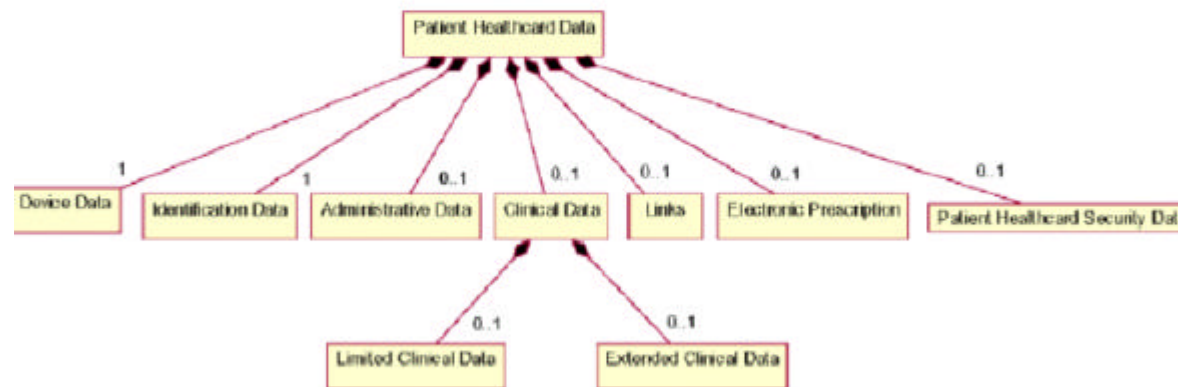


Abbildung 14: ISO Patient Healthcard Data - Überblick

Source: [http://www.dimdi.de/static/de/ehealth/karte/download/b4h\\_standards\\_v1-1.pdf](http://www.dimdi.de/static/de/ehealth/karte/download/b4h_standards_v1-1.pdf)



## More information:

- ✓ Website

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