

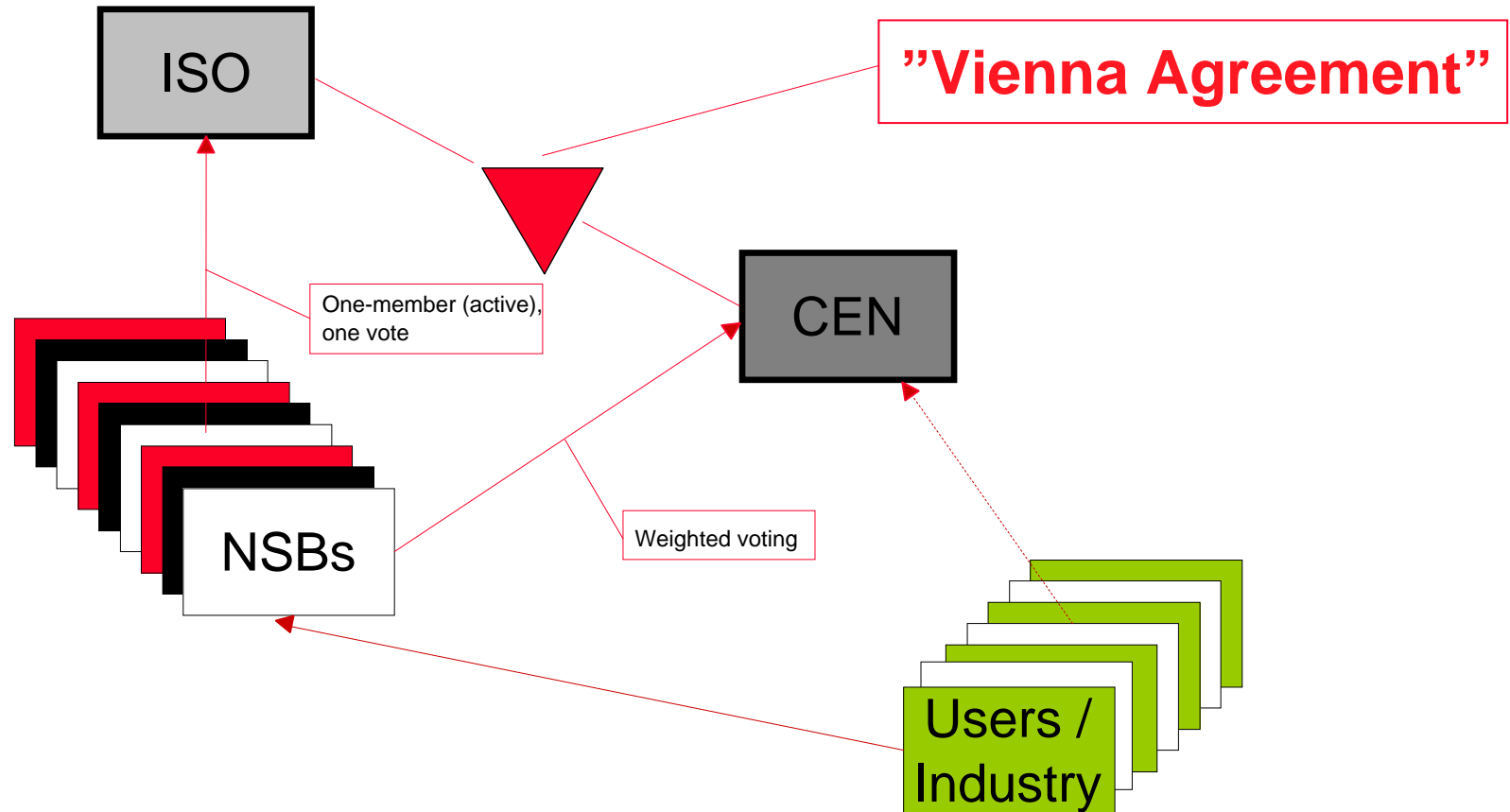
Connectivity Industry Consortium
European Initiative Meeting 2004

POCT1-A Approval in ISO, CEN, DIN Status Quo - *Obstacles and Drivers*

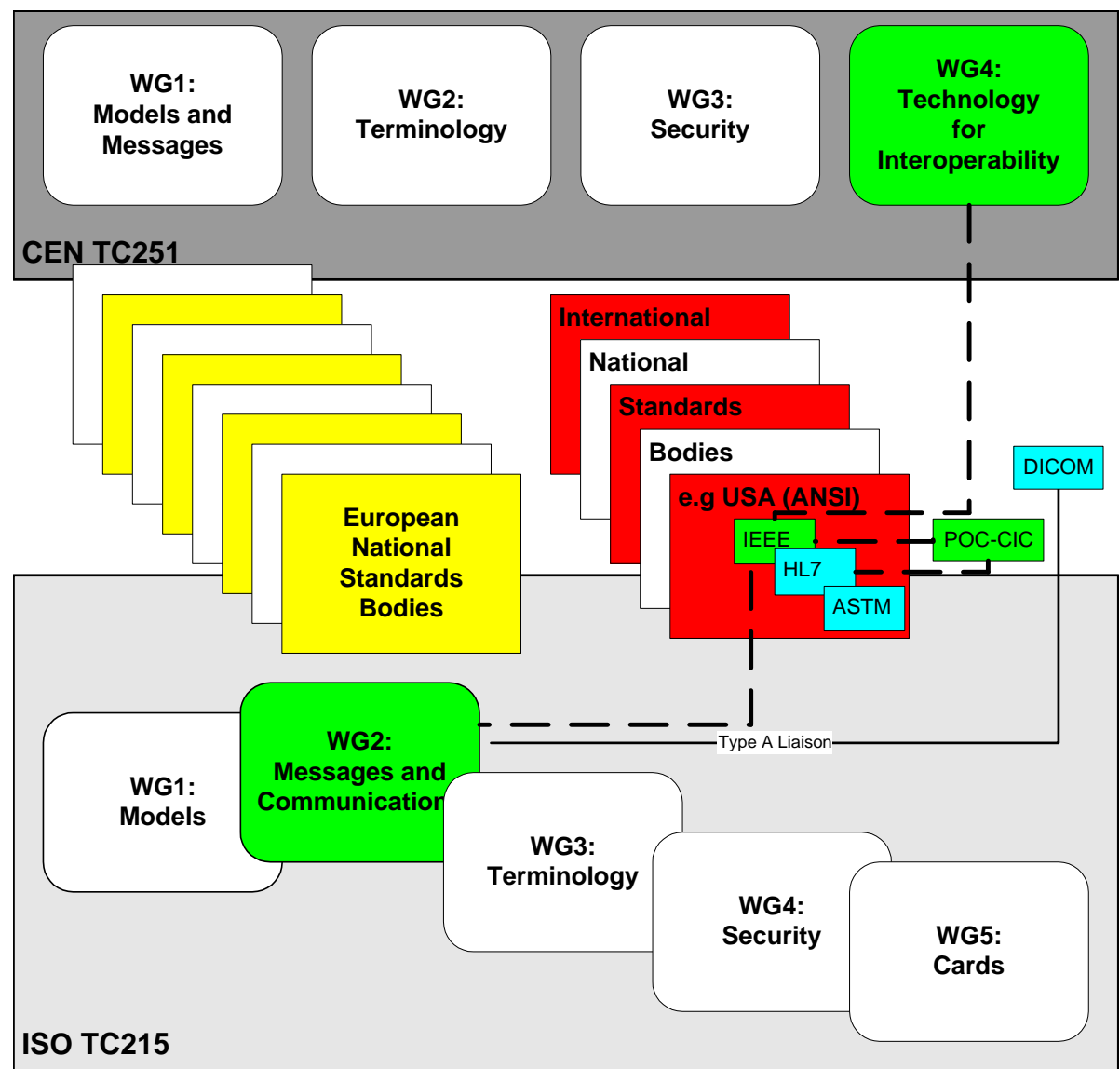
MEDICA, Düsseldorf, 25 Nov. 2004

Thomas Norgall
Fraunhofer-Institut für Integrierte Schaltungen
Erlangen, Germany
Email: nor@iis.fraunhofer.de
Internet: www.poccic.org

International Standardization: How it works



International Health Informatics Standardization



History of NCCLS POCT1-A in ISO TC 215 (2001/02)

- "... 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)
- Health informatics – Analytical instruments – Point-of-care test, **ISO 11073-90100**:
 - "... key problem that has been hindering the submission of the standard is the **lack of a copyright agreement between NCCLS and ISO**. ...(NCCLS and ISO) are working on resolving this problem as soon as possible..."
 - "... (ISO TC215 WG 2.1) has offered support to NCCLS in this regard (based on our experience with the IEEE and the HL7 pilot projects); ... (it) will also continue to follow-up on this effort, to ensure that it is progressing"

(Draft Minutes of ISO/TC 215 Meeting August **2002**, Melbourne/Australia)

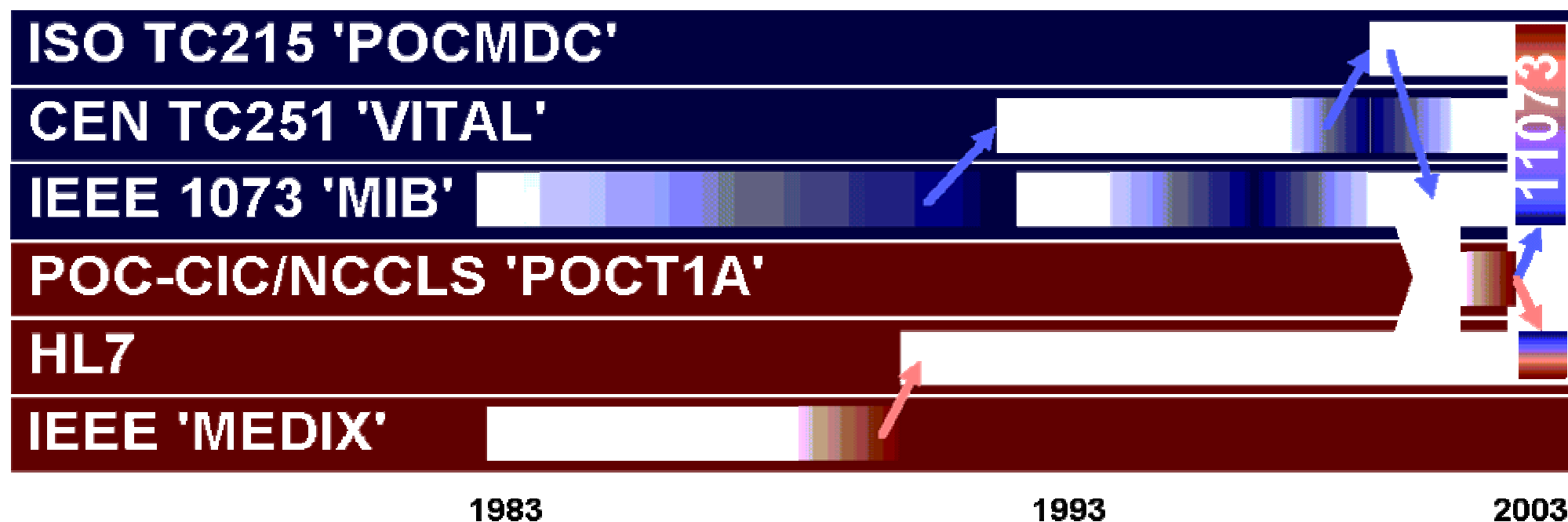
⇒ **NCCLS POCT1-A will be issued as ISO DIS11073-90100 as soon as copyright problems between ISO and NCCLS are solved**

History of POCT-1A in CEN TC 251 (2001)

- “CEN/TC 251/WGIV resolves that the Convenor prepare the Point-of-Care for Medical Device Communication new Work Item drafts and issue these to the CEN/TC 251 and ISO/TC 215 Secretariats.....”
(Resolution 5 of CEN/TC 251/WG IV: 16 October **2001**, Stockholm/ Sweden)
 - The ISO/IEEE pilot process ... (will) allow more countries to participate in the IEEE ballots than were permitted in either CEN or ISO. (...). At the ballot stage, **parallel work items would be raised in ISO and CEN, with ISO to take the lead** on the WI. There would also be parallel voting in the IEEE/ISO and CEN, with all comments raised to noted by the international experts and resolved.
This co-operative process (will) result in IEEE/ISO standards and CEN ENs...
(CEN TC251 WG IV Minutes of CEN/TC 251/WGIV Meeting October 2001, Stockholm/Sweden)
- ⇒ **Future ISO DIS 11073-90100 (POCT-1A) will be issued in parallel as CEN standard (thus overriding national standards in EU!)**

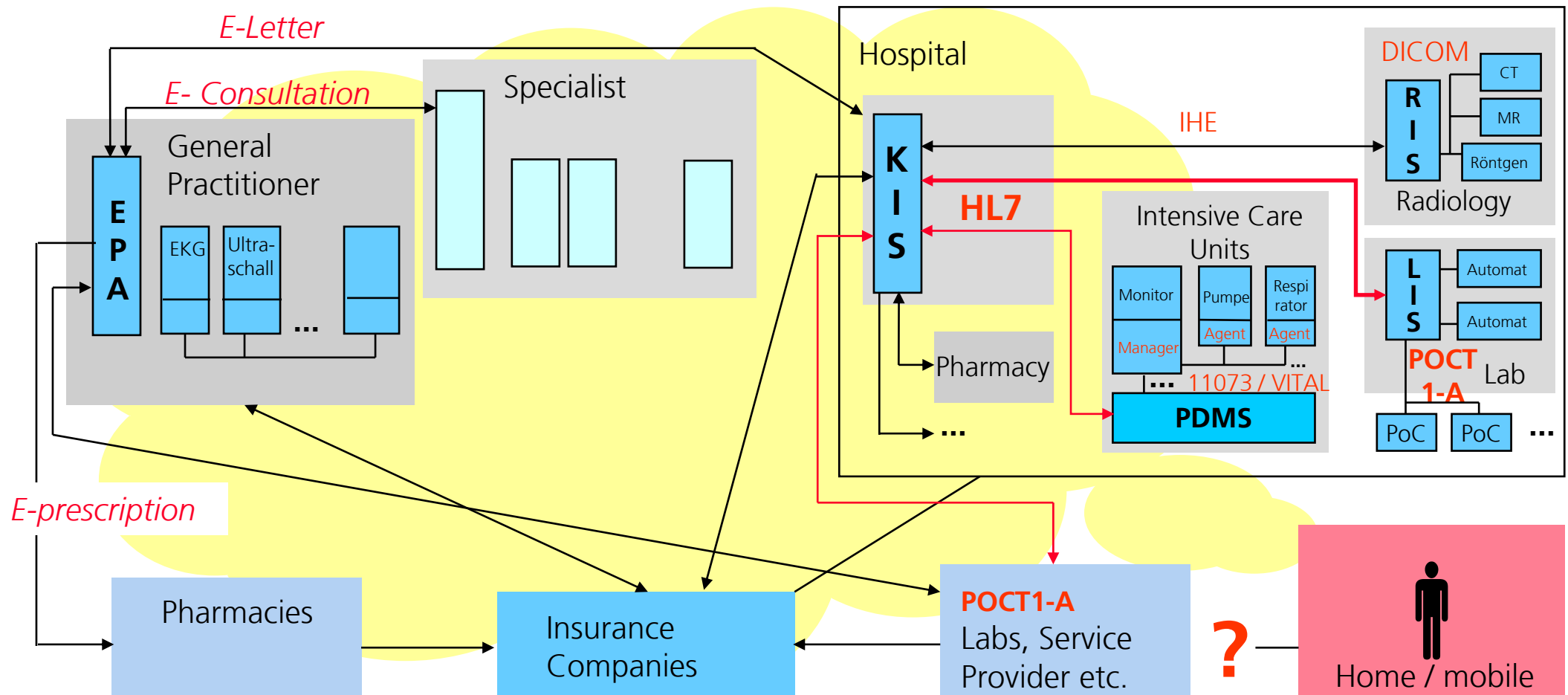
CEN ISO/IEEE11073 Standards history :

Development towards co-operative and complementary work:



Arrows indicate effective transfer of development and/or maintenance responsibility.

"E-Health" - Interoperability / Integration Needs



Interoperability

Interoperability:

ability of two or more systems or components

- to exchange information

(“**functional interoperability**”:

Shared Communication Architectures, Methods, Frameworks)

and

- to use the information that has been exchanged

(“**semantic interoperability**”

Shared Data types, Terminologies, Coding Schemes)

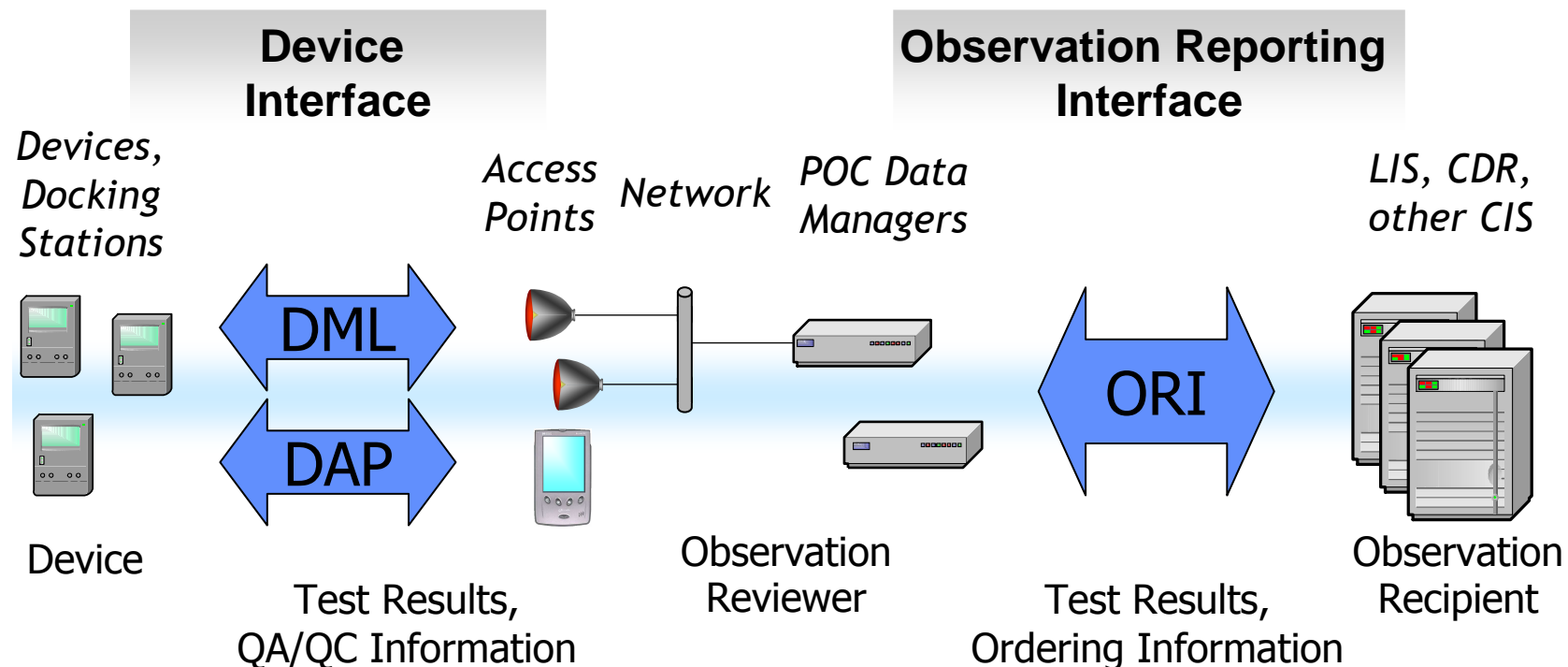
(without further need for user interaction)

source: IEEE Standard Computer Dictionary -

A Compilation of IEEE Standard Computer Glossaries, IEEE, 1990

NCCLS POCT1-A Standard

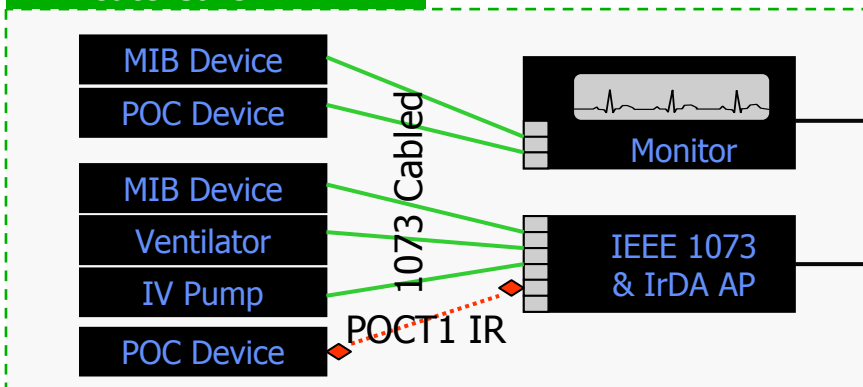
- developed 1999-2001 by POCCIC Industry Consortium using IEEE und HL7 components
- defines 2 Interfaces:
 - **Device Interface** (DAP: IEEE 1073, DML: HL7 V2.3 + XML)
 - **Observation Reporting Interface** (ORI: TCP / IP + HL7 V.2.3)



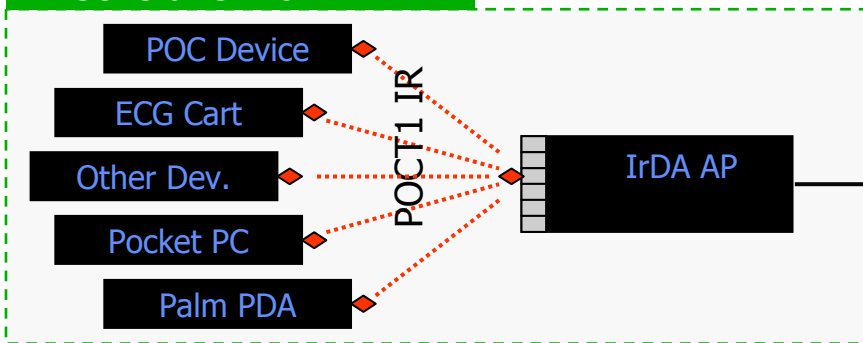


POCMDC / POCT Devices Co-Existence

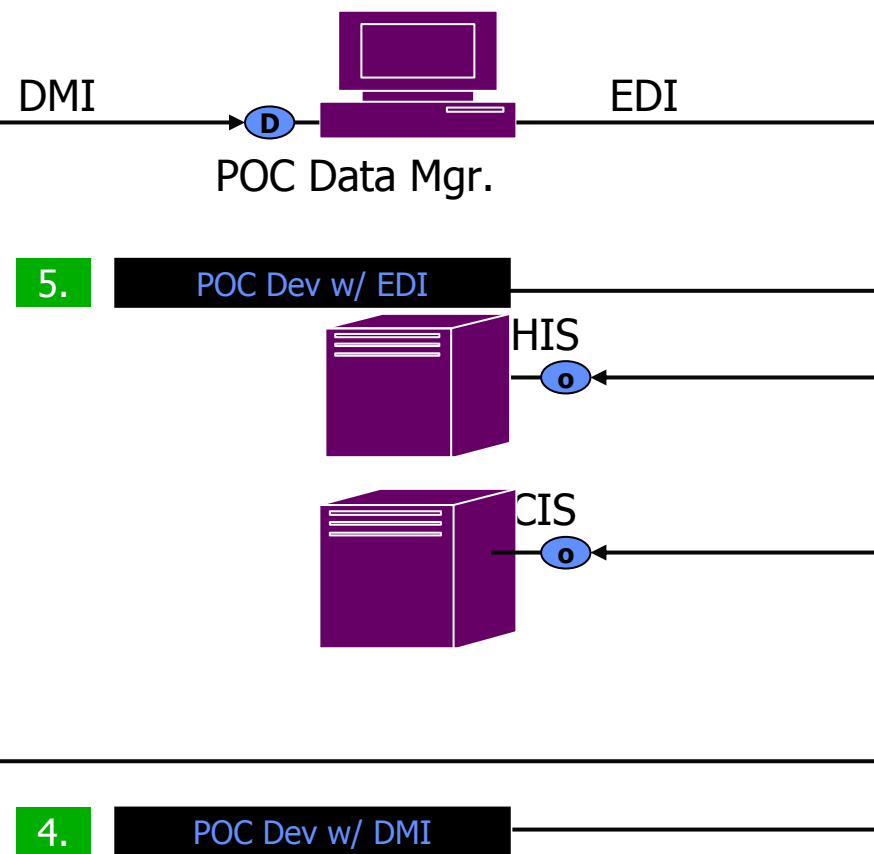
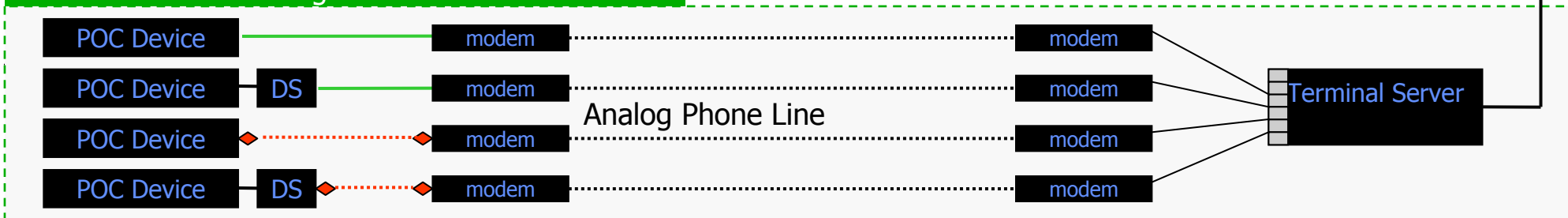
1. Acute Care



2. General Clinic



3. Remote Device using Modem



CEN ISO/IEEE 11073 HL7 Application Gateway



Interoperability among Application Protocols

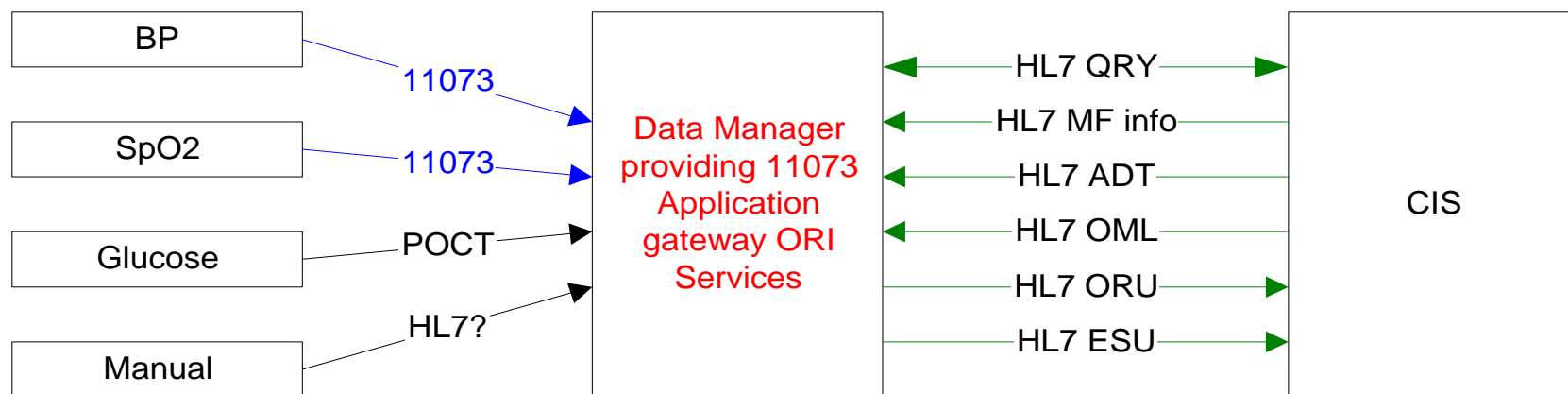
Objective: **HL7 / 11073** Gateway (CEN ISO-IEEE 11073-60101) -
"HL7 Observation Reporting Interface":
enables Device-to-HIS-level interoperability.

(11073 Coding Scheme Registered HL7 Coding Scheme in 2003.)

Preparatory work: CEN SSS-HIDE (2001) : Health Informatics-Strategies for harmonization and integration of device-level and enterprise-wide methodologies for communication as applied to HL7, LOINC and ENV 13734)

11073-60101 HL7 - Observation Reporting Interface

Objective: To ensure that ... information ... from devices using ... 11073 standards is conveyed with appropriate ... identification of source device system, medical device, channel and metric (... with required annotation ...). For traceability the 11073... nomenclature is retained ... payload of the HL7 message/document that carries the information to the target information system.



History of POCT1-A and CEN ISO/IEEE 11073-60101 in ISO TC 215 (2003)

CEN/IEEE/ISO Standards Editorial Plan 2003				
ISO/IEEE #	ISO/IEEE Title	Editor(s)	Status	Description / Comments
ISO 11073-60101 IEEE 11073.6.1.1	Health informatics – Point-of-care medical device communication – Application gateway – HL7, Observation reporting interface (ORI)	Melvin Reynolds	IEEE PAR approved 2003- 08; project must be completed Dec' 2007.	This is the first work of the collaborative Point-of-Care Joint Working Group including representatives from HL7's LAPOCT and CBHS SIGs, as well as IEEE 1073, CEN TC251, and ISO TC215. CEN/ISO NWIPs to be raised when first draft available.
ISO 11073-90101	Health informatics – Analytical instruments – Point-of-care test		Standard was published by NCCLS in 2002 Feb/Mar. To be submitted by NCCLS to ISO (TC215) - when?	NCCLS POCT1 standard; based on specifications from the Point of Care Connectivity Industry Consortium (POC CIC). CEN to raise NWIP for EN using Vienna Agreement when notice of ANSI submission to ISO received. NCCLS must first finalize an agreement with ISO similar to the ISO/IEEE Pilot Project agreement. This should be accomplished via the new ANSI/ISO Council 2003 Q1 - NCCLS chairs that group.

1. PAR = IEEE Project Authorization Request; must have an authorized project before most "official" IEEE standards development activities can be engaged.
2. NWIP = ISO/CEN New Work Item Proposal which must still be approved in both bodies if the item is to be jointly approved under the Vienna Agreement. See Flowcharts for detail of the joint IEEE/ISO development process.

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Role of DIN NaMed Fachbereich G

Part of Normenausschuss Medizin (NaMed)

- Fachbereich G “Medizinische Informatik” (since 3/2000) with Arbeitsausschüssen:
 - AA G 1 “Modellierung”
 - AA G 2 “Kommunikation”
 - AA G 3 “Terminologie”
 - AA G 4 “Sicherheit”
 - AA G 5 “Karten”
- Substantial contributions to standardization work, dissemination and application of standards
- “Mirroring” of equivalent Working Groups in CEN TC251 and ISO TC215
 - Information and discussion about ongoing standardization activities
 - Identification and articulation of national interests, **e.g. RiliBÄK**

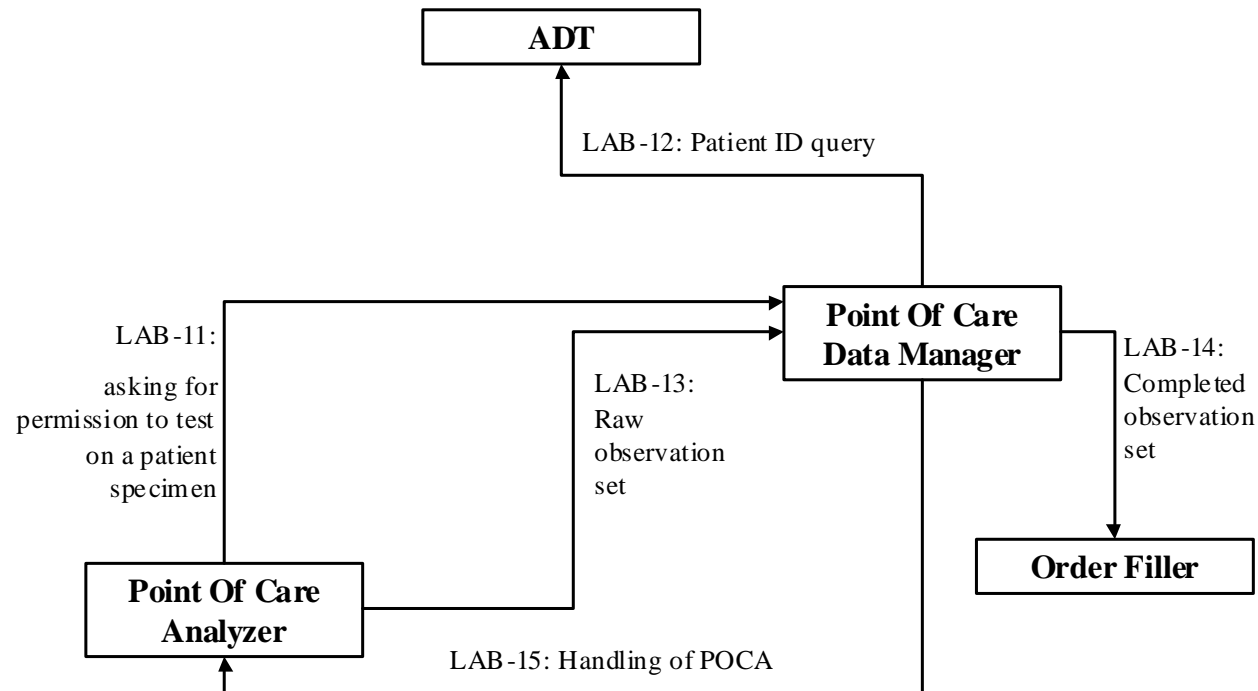


-“Integrating the Healthcare Enterprise” 2004

- Initiative initiated in 1998 by HIMSS (Healthcare Information and Management Systems Society) & RSNA (Radiological Society of North America) to “promote and support the integration of systems in a healthcare enterprise (hospital)”
- Motivation: Lack of interoperability among HIS / RIS / PACS systems
- **Clinical Workflow Optimization:** Definition of 7 (HL7 / DICOM) “Integration Profiles” to
 - provide continuity & integrity of patient information
 - foster communication among information systems from different vendors
 - avoid repeating tasks (like typing patient name)
 - eliminate data redundancy
 - eliminate rigid & costly proprietary solutions
- Paradigm: Specify the **use of existing standards** wherever possible
- **IHE Profile Proposal for Laboratory Technical Framework: Laboratory Point Of Care Testing**
- **“Candidate standards to cover this new LPOCT profile are:**
 - HL7 v2.5 or higher (version 3 is to be considered if it is ready for this need)
 - **NCCLS “Point Of Care Connectivity; Approved Standard” POCT1-A which also uses HL7 messages.”**



-“Laboratory Point Of Care Testing” Profile



Actors and Transactions



POCT1-A-related Activities

- Initiative aiming at revision and update of POCT1-A document. (2004)
- Announcement (2004) - NCCLS is evaluating two new projects:
 1. Implementation Guide of POCT1 for Healthcare Providers
Description: This guideline will provide
 - Information what features to expect in a connectivity-compliant device
 - practical advice on how to optimally apply these features...
 - explanations in non-technical language of terms used in POCT1-A.
 2. Implementation Guide of POCT1 for Manufacturers
Description: This guideline will provide the framework for IVD manufacturers to implement POCT1-A into their device software.
It is intended to be used by the project manager or engineer
...to better understand the components of a POCT1-A interface and
how to break down the interface writing project into manageable tasks....

European / German PoC Quality Control Guidelines

- EU Guideline 98/79/EG (27 October 1998) requirements::
Traceability of measurement results for calibration and /or quality control material has to be maintained by application of reference measurement procedures and / or reference materials.
- Corresponding Guideline („Richtlinie“) of German Bundesärztekammer („RiliBäk“ 2001):
...Every organizational unit (e.g.intensive care ward) which performs ad-hoc near-patient (point-of-care) diagnostics has to participate in mutual / circular trials for external quality control. This requirement ca be replaced by internal quality control of ad-hoc near-patient diagnostics performed under responsibility of the clinical central laboratory...
(„Jede, die patientennahe Sofortdiagnostik durchführende Organisationseinheit (z.B. Intensivstation) muss an Ringversuchen entsprechend 3.2 dieser Richtlinien zur externen Qualitätskontrolle teilnehmen. Diese Verpflichtung entfällt, wenn die interne Qualitätssicherung für die patientennahe Sofortdiagnostik in der Verantwortung des Zentrallabors durchgeführt wird“)

⇒ **Urgent need for Point-of-Care Connectivity! / Standard?**

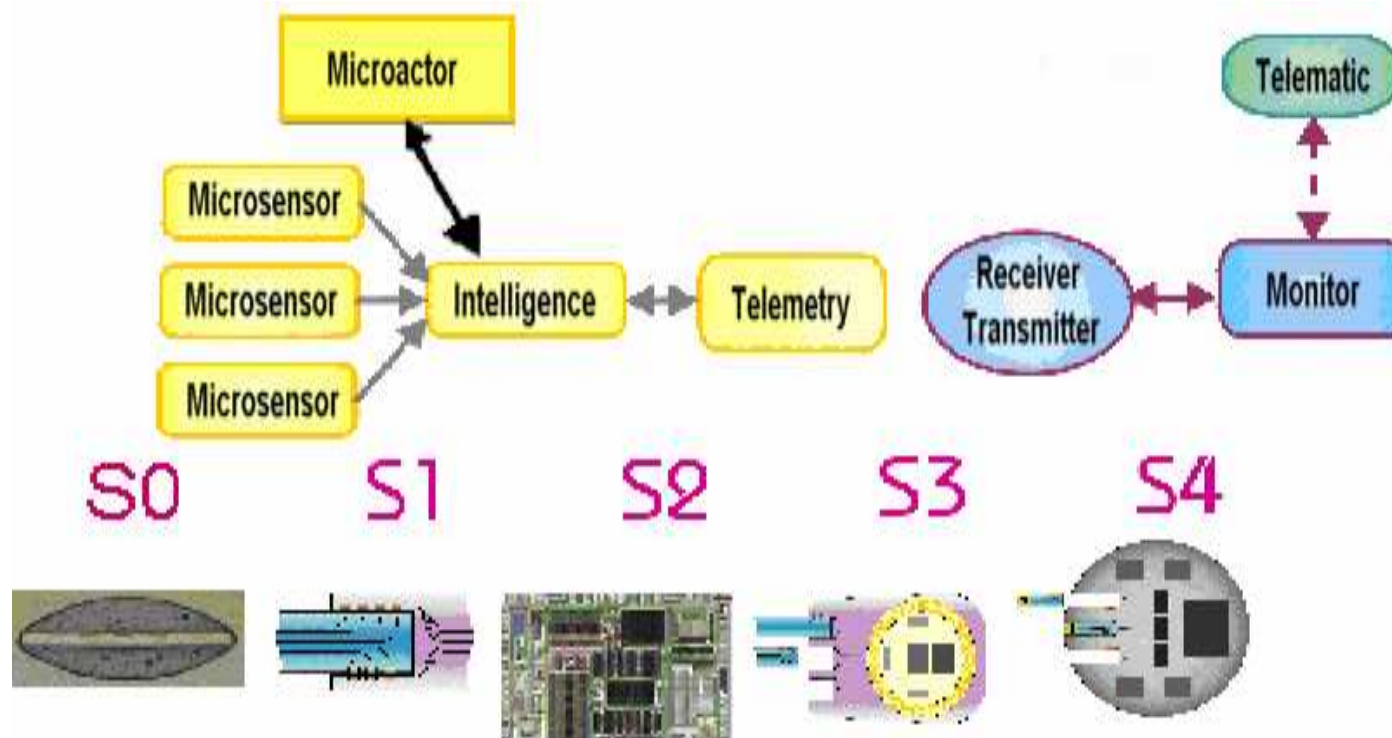
German Health Telematics Activities (BMGS/GMG)



Legislation (2003) aims at replacement of paper mail by electronic communication between healthcare stakeholders:

- Introduction of Electronic Health Card for
 - Authentication (electronic identity check),
 - Encryption and
 - Electronic Signature
 - enabling electronic prescription and other applications
 - optional Drug / Application Documentation, Patient Emergency Data, Patient Private Health Data
 - Preparation of Electronic Health Record
 - Preparation of corresponding Health Telematics Infrastructure
- ⇒ **need for inclusion of PoC / Medical Devices**

IMEX* Project: Micro-System Interoperability



⇒ **IMEX IEC standard draft for cross-vendor data format extends interoperability chain to micro-system level**

*VDE/BMBF IMEX: „ Implantierbare und extrakorporale modulare Mikrosystemtechnikplattform“

Conclusions: ?

Thomas Norgall
Fraunhofer IIS
Erlangen, Germany
Email: norl@iis.fraunhofer.de

 **Fraunhofer**
Institut
Integrierte Schaltungen



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What next? : (Potential) Directions / Action Items

- Promoting / User and vendor awareness
- Implementing (new developments vs. legacy devices)
- Profiling for Use Cases (IHE?) and Interoperability Demos
- (Application) Integration
- Conformance Specifications and Tests

Thank you for your attention

Thomas Norgall

Chair CIC European Initiative

Contact:

Fraunhofer-Institut für Integrierte Schaltungen (FhG-IIS)

Am Wolfsmantel 33

D-91058 Erlangen, Germany

Email: nor@iis.fraunhofer.de

www.iis.fraunhofer.de

Thomas Norgall
Fraunhofer IIS
Erlangen, Germany
Email: nor@iis.fraunhofer.de

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