

Connectivity Industry Consortium
European Initiative Meeting 2005

Status Quo and Ongoing Work

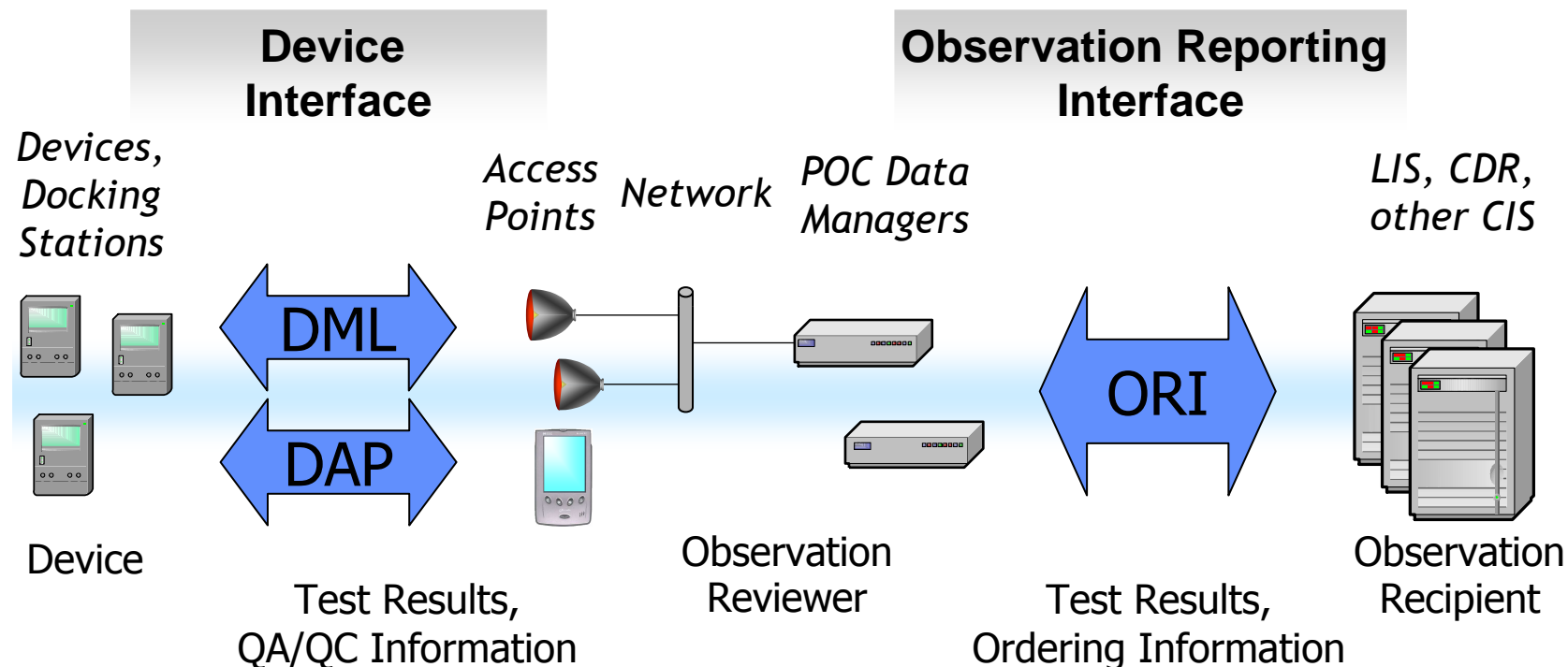
*The successful process of adopting POCT1-A
as a formal international standard*

MEDICA, Düsseldorf, 15 Nov. 2006

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

- 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)



Where we are now:

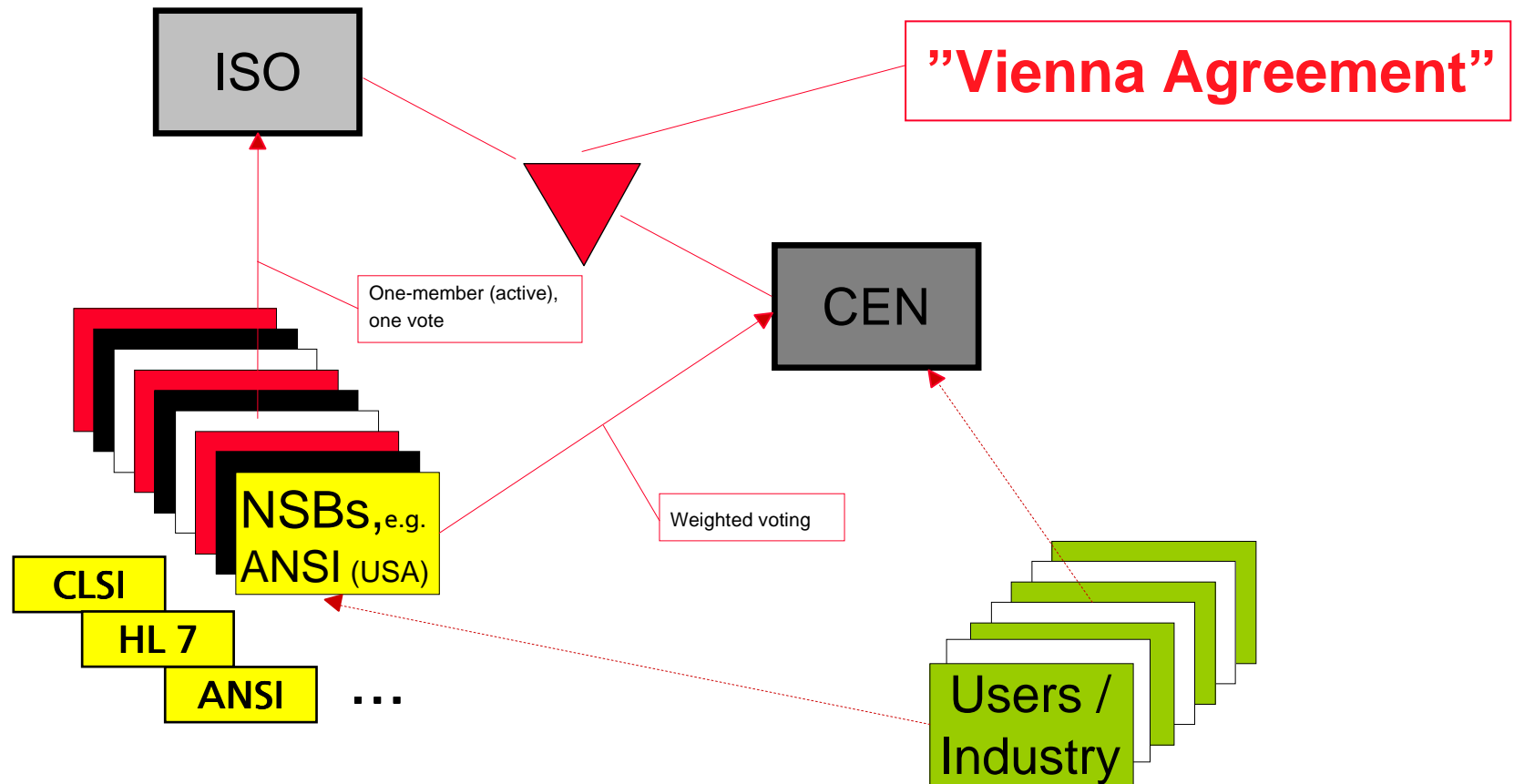
CLSI* POCT1-A2 (March 2005) replaces POCT1-A

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)

International Standardization: How it works



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)

Ballot comments on ISO DIS 11073-90101

- “We are much in favour of this standard, and we would very much like to see it published. However, we perceive that there is a newer version: POCT1-A2, and we suggest to publish this instead.”
 - ⇒ *Integrate the latest developments due to the new available version POCT1-A2*
- “The UK is very supportive of the long-awaited submission of this CLSI standard in the ISO 11073 series. as an international he version of the HL7 V3 datatypes referenced is outdated. However, we are aware that since the submission was started an amended version of the POCT1-A (2001) standard has been balloted. This contains some important clarifications plus some minor corrections based on experience in use. For this reason, the UK is of the opinion that the published international standard should be the test of the revised version (...) It is for this reason, and this reason only, that the UK is submitting a negative ballot on DIS 11073-90101.(...)”
 - ⇒ *Replace the balloted text (...) with the text of POCT1-A2 (...)*

Adoption of POCT1-A by CEN TC 251

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...**

(Minutes of CEN/TC 251/WGIV Meeting October 2001, Stockholm / Sweden)

⇒ **Next step: adoption of ISO DIS11073-90100 as a CEN standard (thus overriding national standards in EU!)**

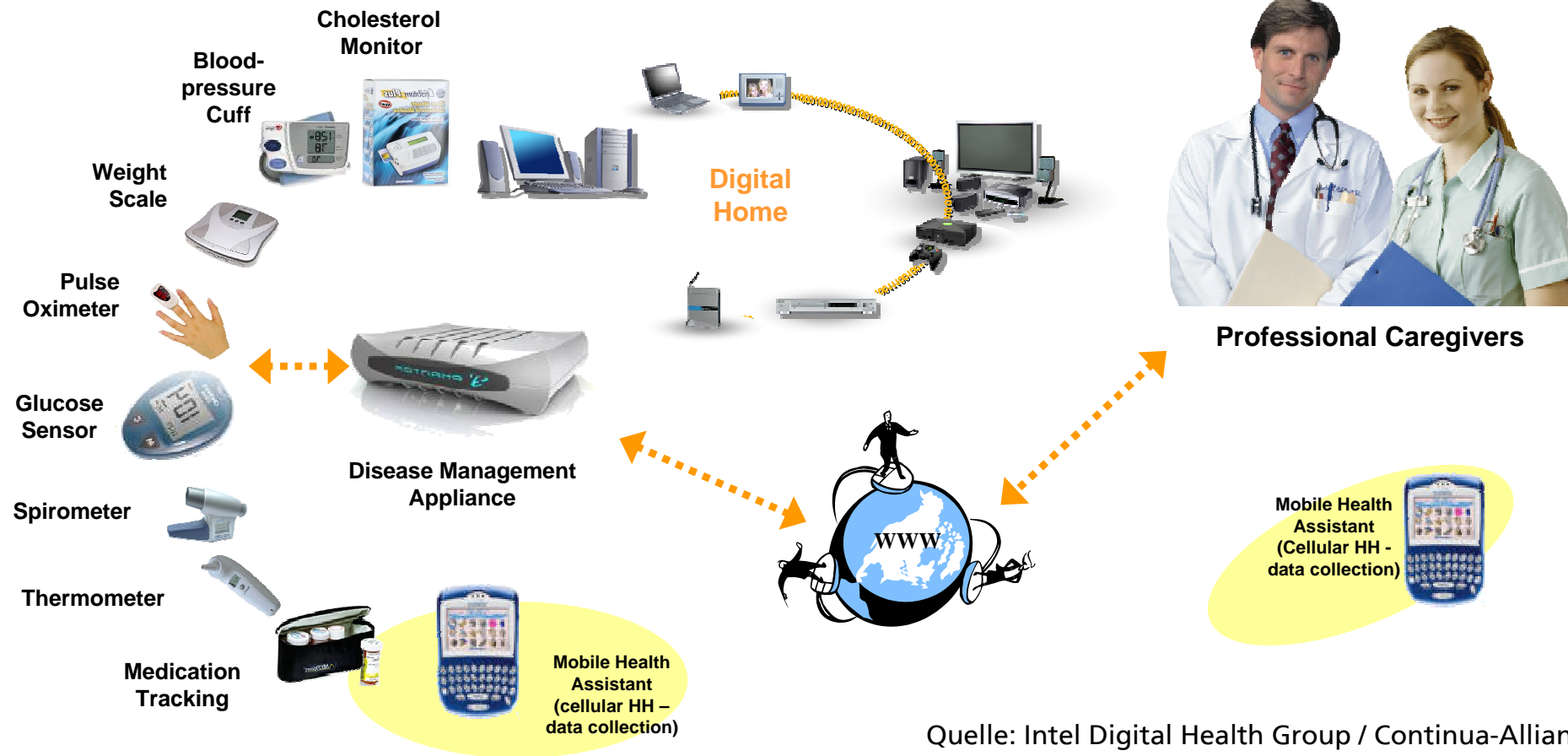


-“Integrating the Healthcare Enterprise”

- 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 > Definition of “**Integration Profiles**”
- Paradigm: Specify the **use of existing standards** wherever possible
- IHE **Profile for Laboratory Point Of Care Testing** leverages CLSI POCT1-A
- IHE European events expected for 2007 to include Point Of Care Testing:
 - **Connectathon** (17 April 2006 in conjunction with ITEG 2007 in Berlin?)
 - **Interoperability Showcase** (Vienna 23-26 October 2007?)
- Planning started with Kickoff Meeting 12 October 2006 in Geneva during “The World of Health IT”
- Preparatory communication and workshop expected soon (early 2007?)

See IHE presentation

Evaluation of POCT1-A for "Personal Health" use



Quelle: Intel Digital Health Group / Continua-Alliance for
IEEE11073 Personal Health Data Workgroup



Continua
HEALTH ALLIANCE

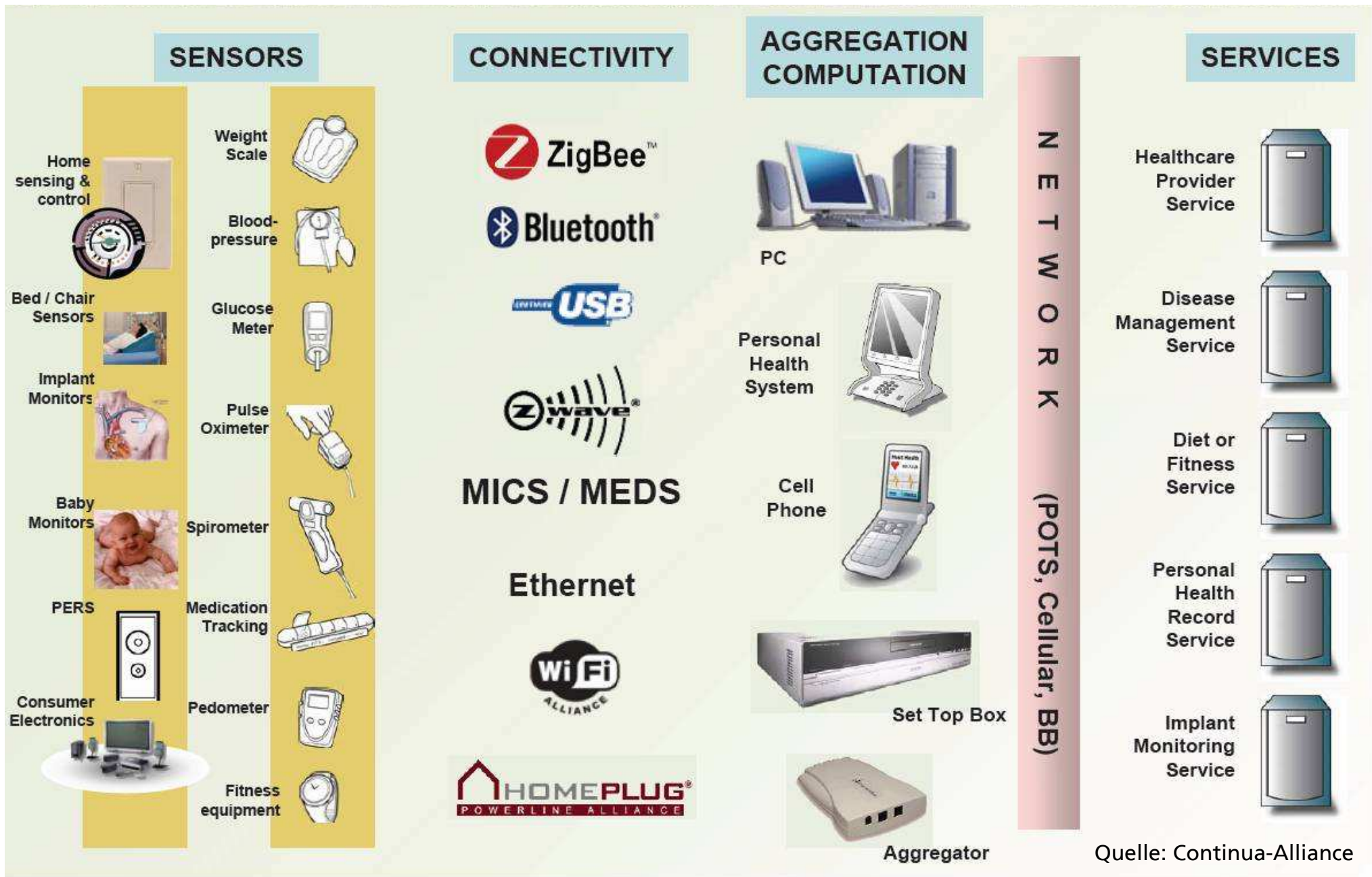
Founding Promoters (37)



Over 55 companies are now part of Continua!


See Continua presentation

Quelle: Continua-Alliance

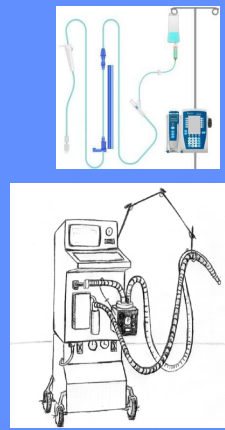


Quelle: Continua-Alliance

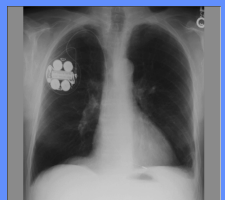
Body worn sensors



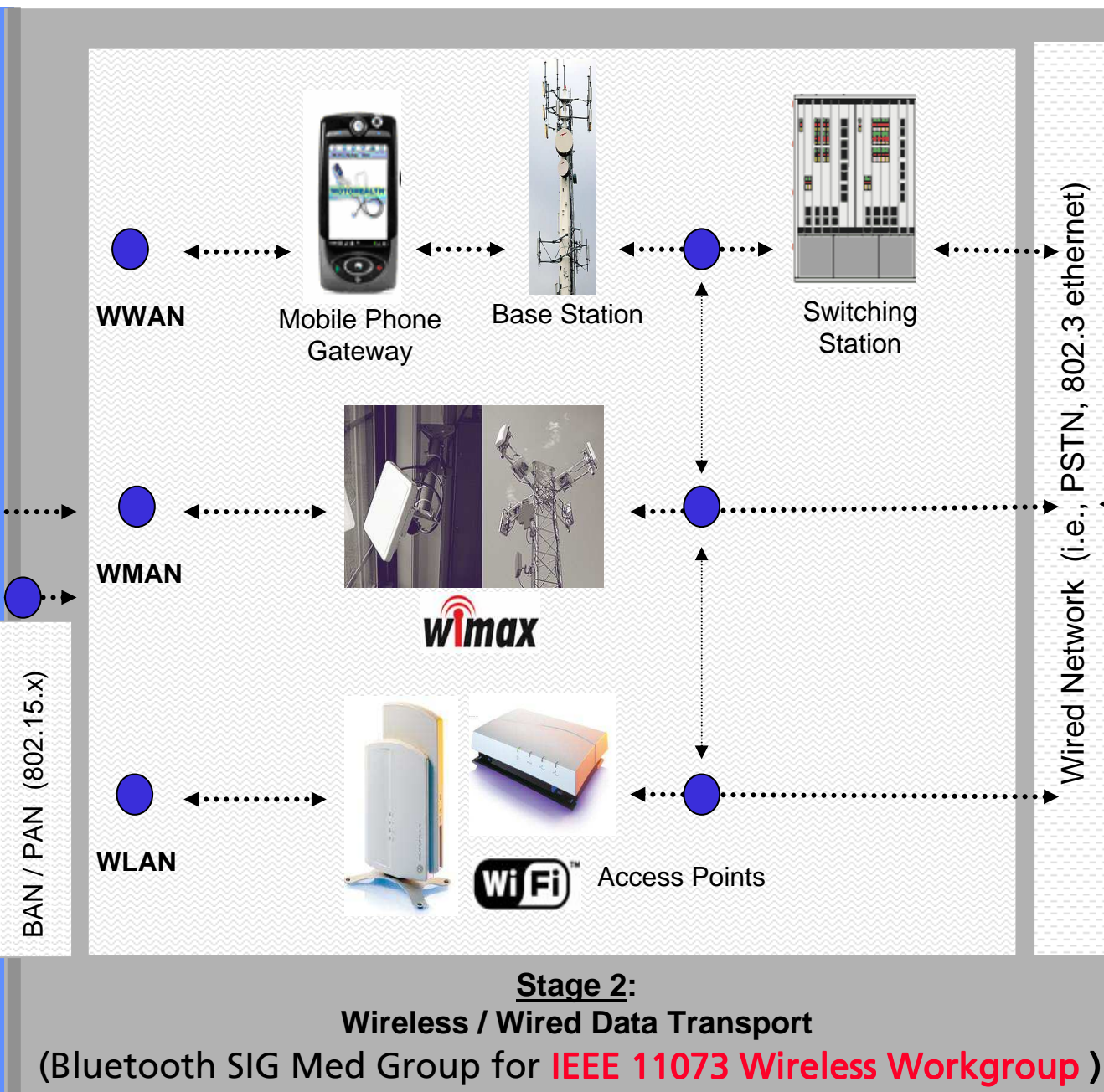
External MDs



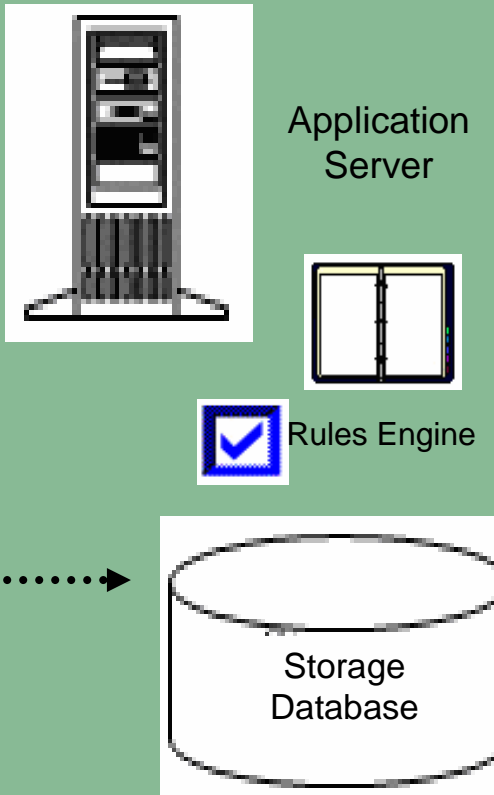
Implantable MDs




Stage 1: Medical Device



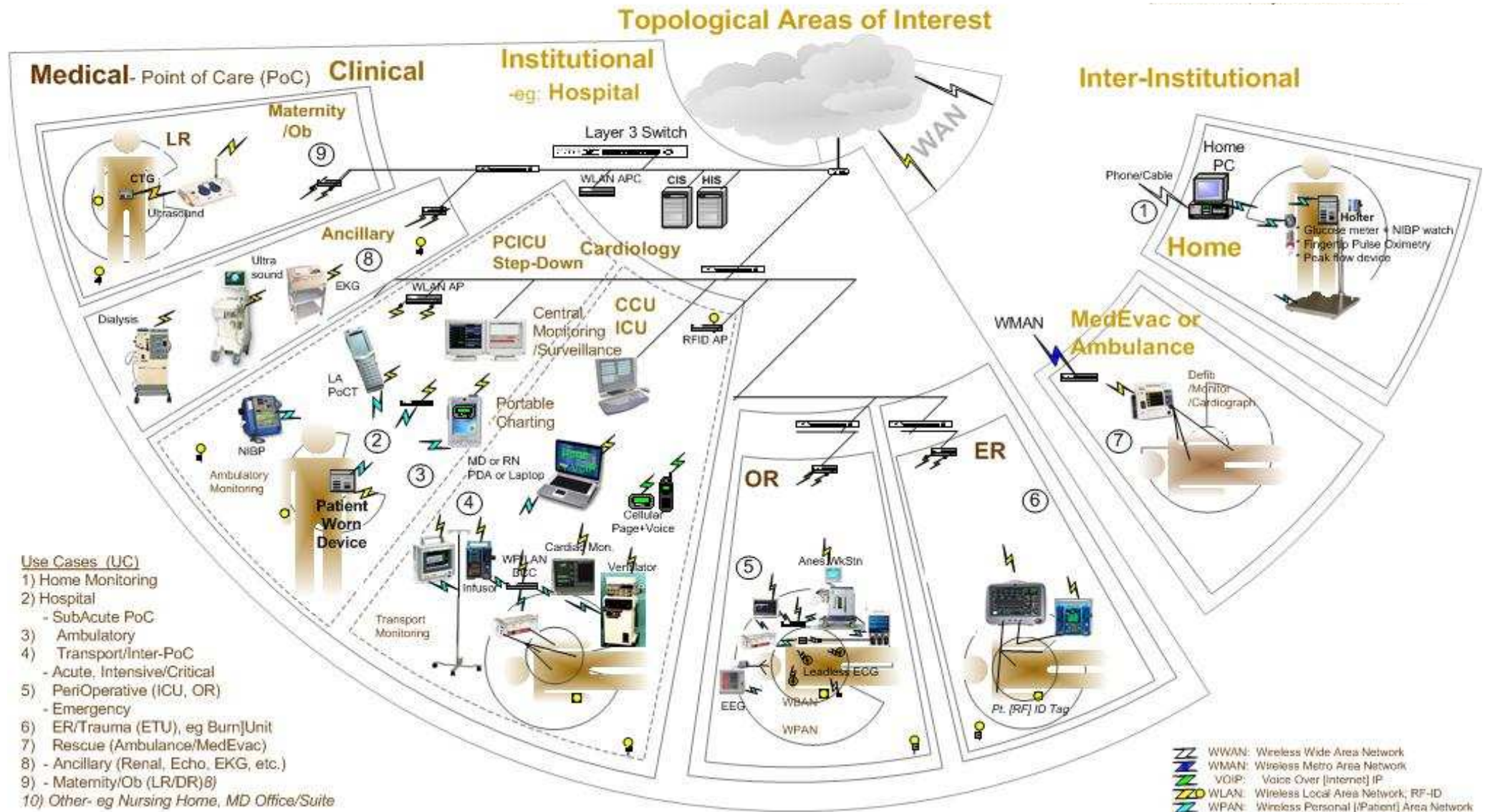
Stage 3: Data Collection



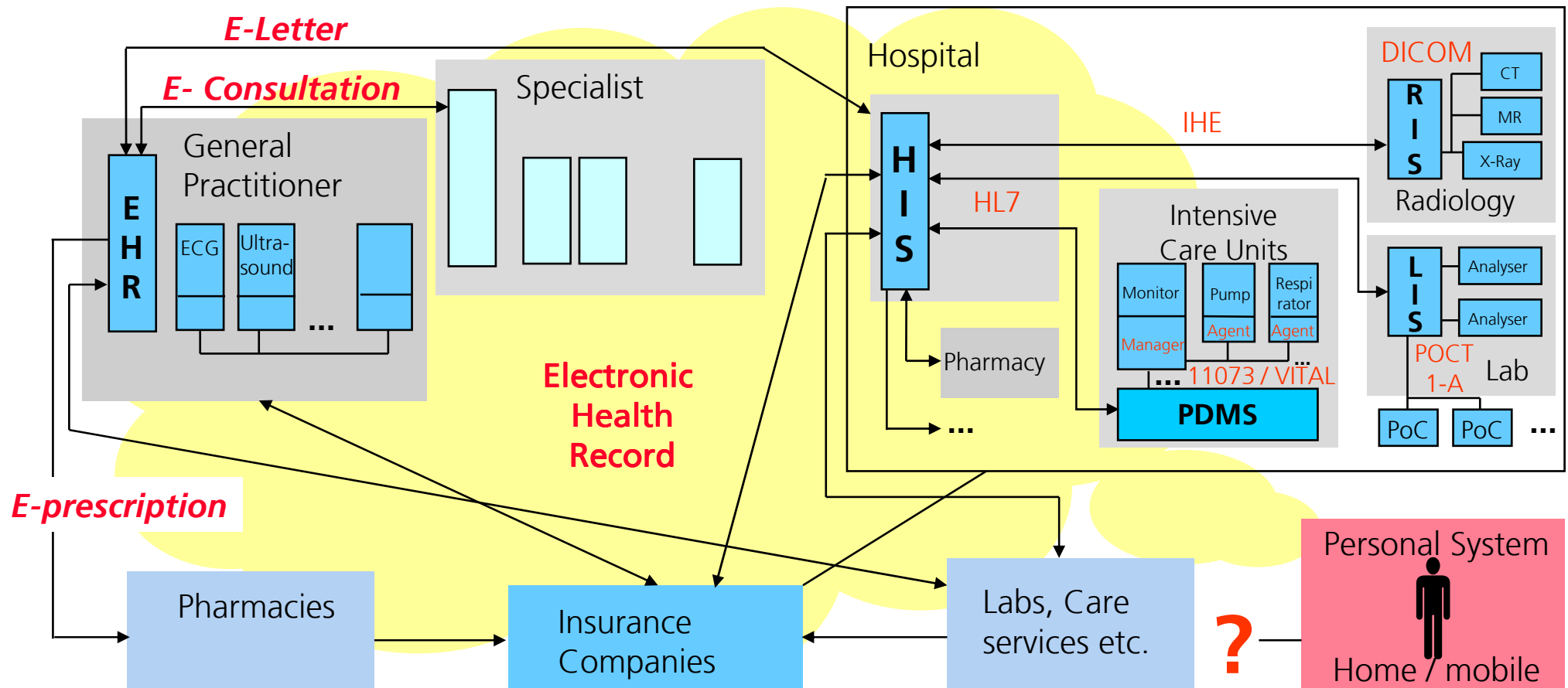
Stage 4: Data Evaluation



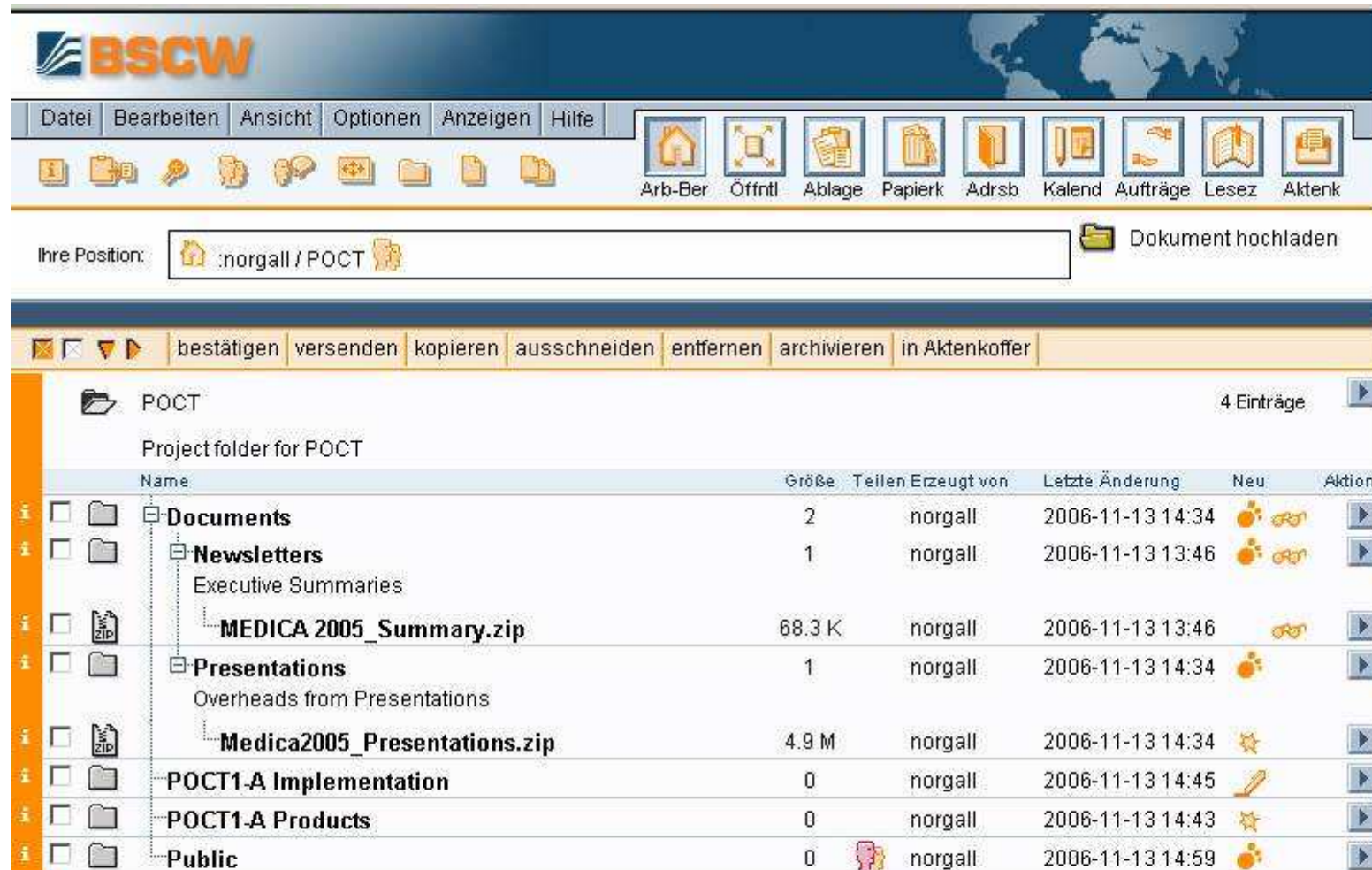
ISO/IEEE 11073 | IHE PCD | HL7 Dev SIG Wireless Use Cases



e-Health / Personal Health Interactions & Integration Paths



CIC EI Communication Platform: BSCW-Server



The screenshot displays the BSCW web interface. At the top, there is a navigation bar with the BSCW logo and a menu with options: Datei, Bearbeiten, Ansicht, Optionen, Anzeigen, and Hilfe. Below this is a toolbar with icons for various functions: Arb-Ber, Öffntl, Ablage, Papierk, Adrsb, Kalend, Aufträge, Lesez, and Aktenk. A status bar indicates the current position: :norgall / POCT. A button labeled 'Dokument hochladen' is visible. Below the status bar is a toolbar with actions: bestätigen, versenden, kopieren, ausschneiden, entfernen, archivieren, and in Aktenkoffer. The main content area shows a folder named 'POCT' with 4 entries. Below the folder name is the text 'Project folder for POCT'. A table lists the contents of the folder:

Name	Größe	Teilen	Erzeugt von	Letzte Änderung	Neu	Aktion
<input type="checkbox"/> Documents	2		norgall	2006-11-13 14:34		
<input type="checkbox"/> Newsletters	1		norgall	2006-11-13 13:46		
Executive Summaries						
<input type="checkbox"/> MEDICA 2005_Summary.zip	68.3 K		norgall	2006-11-13 13:46		
<input type="checkbox"/> Presentations	1		norgall	2006-11-13 14:34		
Overheads from Presentations						
<input type="checkbox"/> Medica2005_Presentations.zip	4.9 M		norgall	2006-11-13 14:34		
<input type="checkbox"/> POCT1-A Implementation	0		norgall	2006-11-13 14:45		
<input type="checkbox"/> POCT1-A Products	0		norgall	2006-11-13 14:43		
<input type="checkbox"/> Public	0		norgall	2006-11-13 14:59		

Thank you for your attention

Thomas Norgall

Chair CIC European Initiative

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What next? : (Potential) Directions / Action Items



Conclusions: ?

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