

Connectivity Industry Consortium
European Initiative Meeting 2007

Status Quo and Ongoing Work

Point-of-Care Testing and Personal Health International Standardization

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Adoption by ISO TC 215: *Where we are now*

- "... 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. (Content is completely identical with CLSI POCT1-A.)
- 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, mainly aiming at updating 11073-90101 to POCT1-A2 and HL7 V2.6 / V3.0 level.

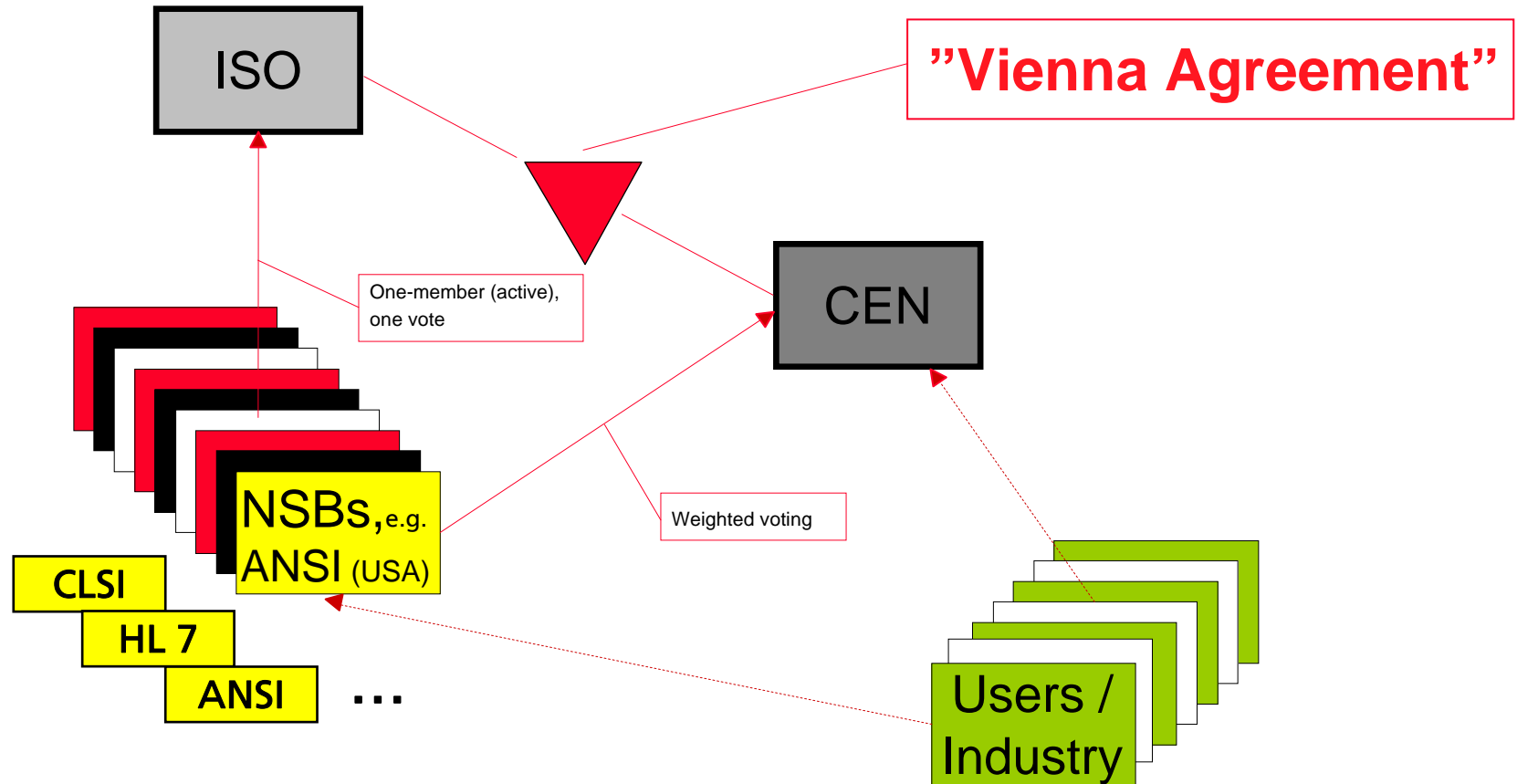
Adoption of POCT1-A by CEN TC 251

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)

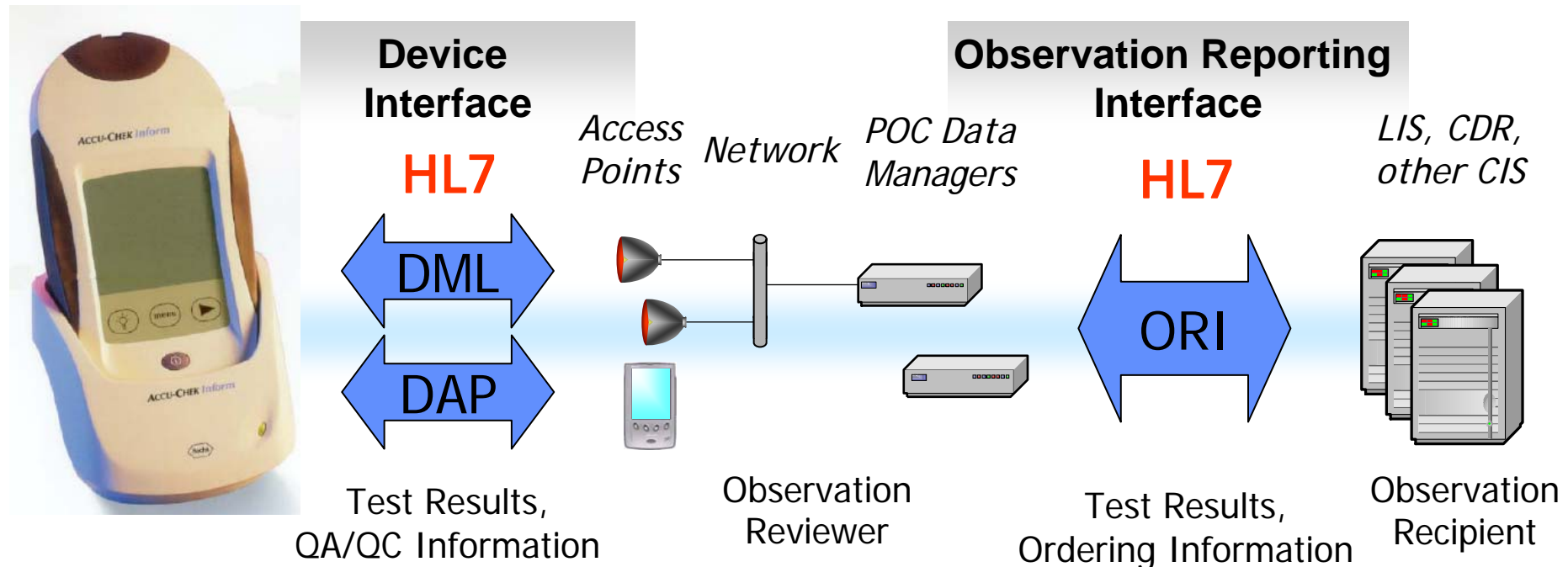
⇒ **Adoption of ISO DIS11073-90100 as a CEN standard
(thus becoming mandatory in the EU)
requires finalization of ISO/TC 215 work.**

International Standardization: Vienna Agreement



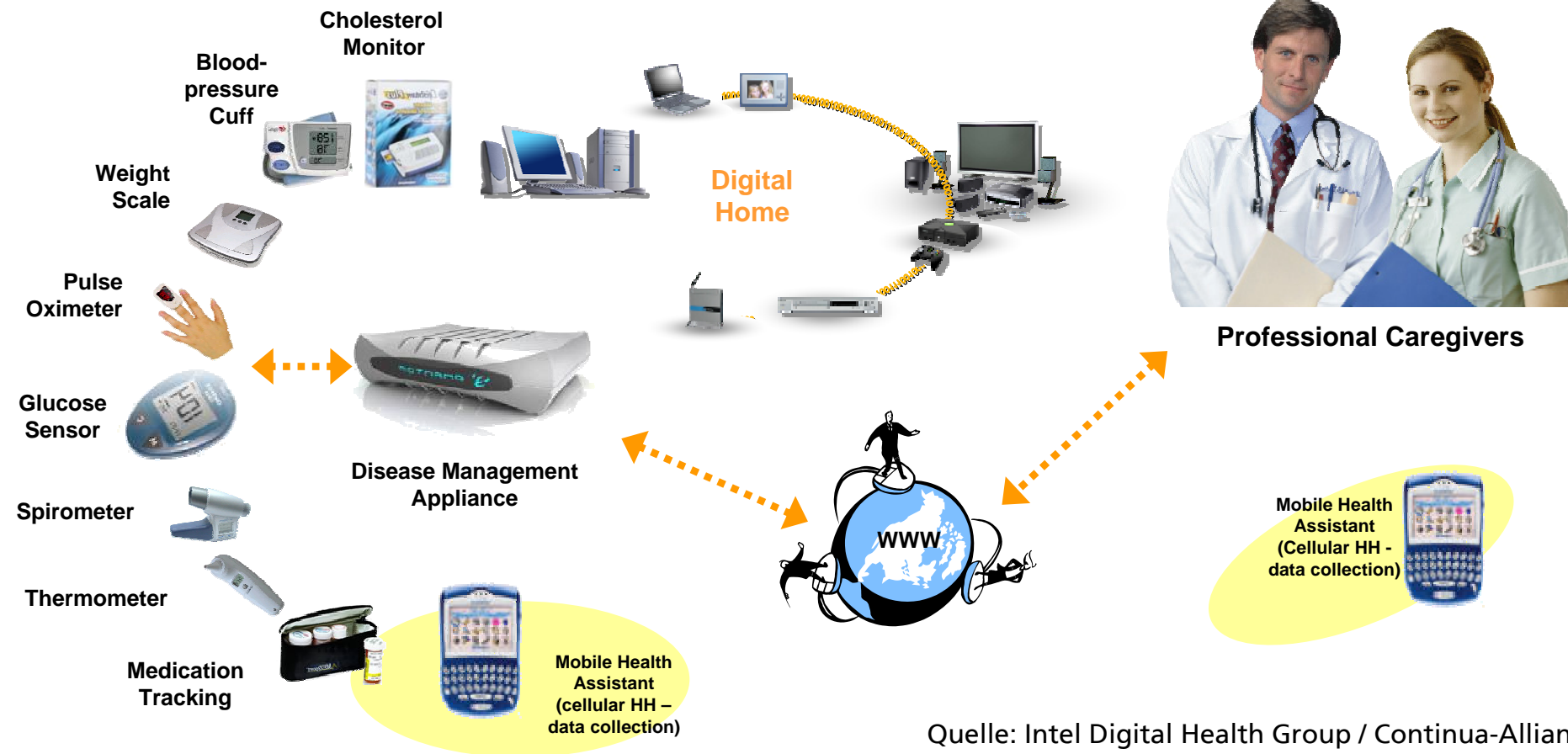
Evaluation of POCT1-A for “Personal Health” use

- motivated by Korean request for ISO/TC 251 New Work Item Proposal (2006)
- use case: data acquisition, storage and quality control by external service provider
- connection via docking station or wireless (Zigbee)



Scope of IEEE 11073 Personal Health Data Workgroup

(coordinating 11073, Continua Alliance and BT SIG Personal Health Work)



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

Activities / Directions / Action Items

- IHE POCT Profile Connectathon
- Promotion / User Awareness
- Monitoring Market Acceptance / Products
- Networking / Communication Platform

Thank you for your attention

Thomas Norgall

Chair CIC European Initiative

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