



BUSINESS AREA ROCHE NEAR PATIENT TESTING

## **Industrial Experience Implementing the POCT1-A Standard I:**

### **Roche Diagnostics**

Dr. Andreas Staubert

Director Software Development  
Platform Management RNP Instrumentation, Mannheim

**Düsseldorf, November 16, 2005**

## Status - Historic



- Roche, as a core member of the CIC, recognizes the **value** of the POCT1-A standard.
- Roche intends to implement the POCT1-A standard on its **POCT devices**
- Roche intends to implement the POCT1-A standard on its **POCT IT solutions**
- **Restrictions**: implementation of standard requires significant SW changes and increased HW resources
- **Consequence**: Roche had to wait for new instrument generations in order to implement POCT1-A

## New Developments

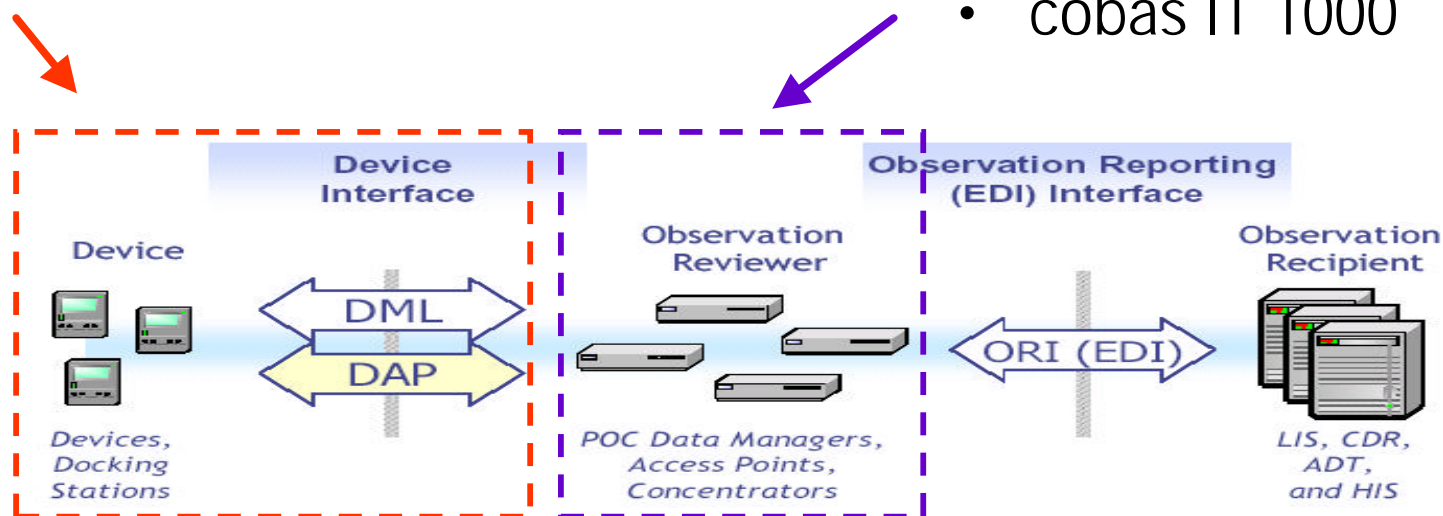
### Instruments:

- Coagulation Monitoring
- Cardiac Panel
- Professional Glucose
- Blood Gas / Electrolytes

- “IrDA devices in general clinical care areas” + DS
- “Mobile devices using RF LAN or cellular”

### POC Data Manager:

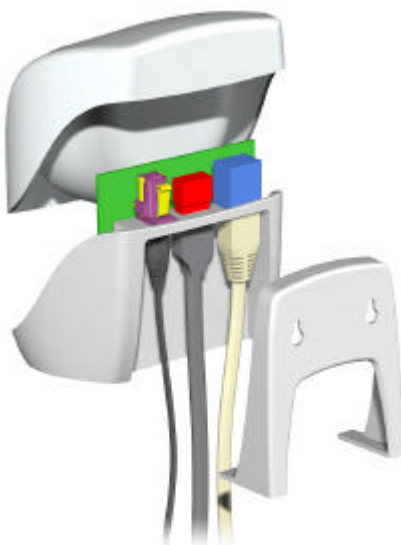
- cobas IT 1000



# 1<sup>st</sup> Instrument – CoaguChek XSPlus (planned for Q1/06)



The DML allows for bidirectional data exchange on the following topics:



- |       |                               |   |
|-------|-------------------------------|---|
| 1     | Device Status                 | ✓ |
| 2     | Observations                  |   |
| 2.1   | Patient Tests                 | ✓ |
| 2.2   | Calibration Tests             |   |
| 2.3   | Quality Tests                 |   |
| 2.3.1 | Liquid QC                     | ✓ |
| 2.3.2 | Electronic QC                 |   |
| 2.3.3 | Calibration Verification      |   |
| 2.3.4 | Proficiency Test              |   |
| 3     | Device Events                 |   |
| 3.1   | Test Denied                   |   |
| 3.2   | Uncertified Operator          |   |
| 3.3   | Vendor-specific               | ✓ |
| 4     | Update Lists                  |   |
| 4.1   | Operator List                 | ✓ |
| 4.2   | Patient List                  | ✓ |
| 5     | Directives                    |   |
| 5.1   | Set Time                      | ✓ |
| 5.2   | Lockout (with explanation)    | ✓ |
| 5.3   | Remove Lockout                | ✓ |
| 5.4   | Vendor-specific               | ✓ |
| 6     | Vendor-specific Data Exchange | ✓ |

- remote SW-upload  
- instrument setup

## Experience

### Positive:

- Experienced development Partner  
Fraunhofer IIS provides Host-Simulator
- Discussion of weak points in standard with Fraunhofer IIS
- Successful reference-check of implementation against 2nd simulator – provided by Bob Uleski  
=> **POCT1-A is “a” standard**
- Successful implementation of complex vendor specific message for remote-software-update

### Negative:

- Development effort larger than expected (10 month instead of 6)
- Debugging tools complex the establish an maintain
- “Shalls” in standard – no reference communication specifications available from other vendors, e.g.
  - vendor\_id (use of EUI-64)
  - observation\_id (use of LOINC codes)

## Whish list



- **Exchange** of experience between manufacturers (instruments & IT-solutions)
- **Public availability** of POCT1-A communication specifications for released products
- **Certification** of POCT1-A implementations by independent 3<sup>rd</sup> party (voluntary)

June 2005

CAP TODAY / 33

whole blood collection tubes (heparin) or precentrifuged plasma (heparin); onboard centrifugation; unit-dose test packs; color-coded calibrators packaged on Calpaks; diluent packs for dilutions; self-contained system (no waste lines, water, etc.); closed container sampling; electronic QC; POCT1-A compliant when interfaced to Telcor or MAS Data Managers