Integration of EHRs with CDISC, CDASH and ODM – A European Initiative

Budapest, Hungary
22nd – 23rd April 2009

Session 2 11:00- 12:30
European perspective of EHR integration
Chair: Udo Siegmann (Parexel)

CDISC
Setting the Global Standard for Medical Research

CLINICAL DATA INTERCHANGE STANDARDS CONSORTIUM

Integration of EHRs with CDISC, CDASH and ODM A European Initiative

Jozef Aerts
XML4Pharma

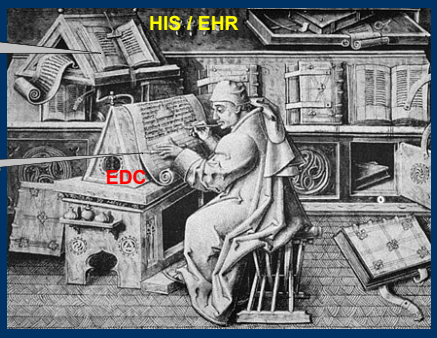
The problem

- EDC system and Hospital Information Systems (HIS) are two completely separated systems
- Investigators need to re-enter information into EDC that was already entered into the HIS, or is available in EHRs
- Investigators need to use a different computer for EDC

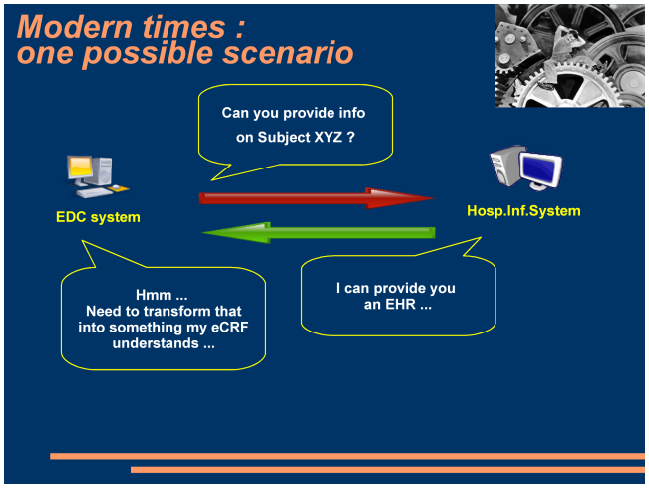
The current process

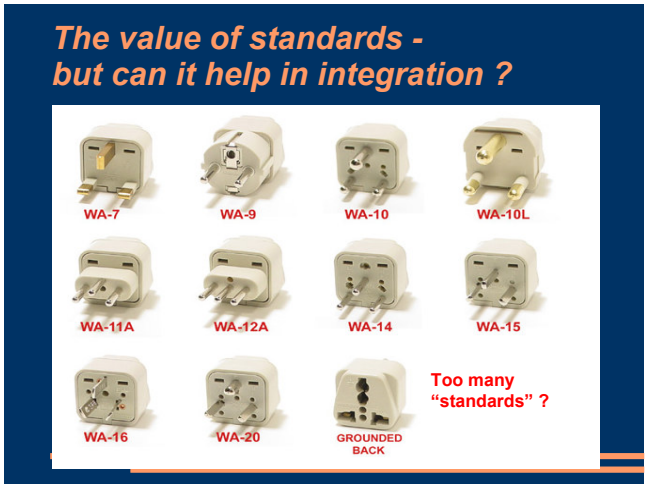
Data source

Data entry



From the year 584 A.D.





Standards and Integration

- Standards for clinical research information exchange:

  CDISC ODM

- *"Standards"* for Electronic Health Records ???
  - (C)EN 13606
  - HL7-v3-XML
  - VistA (Veterans Affairs)
  - OpenEHR, OpenEMR

Towards a worldwide standard for EHRs ?

- ISO, CEN, HL7 and CDISC ... talk to each other
- HL7-v3-XML datatypes unacceptable for CEN
- Compromise: ISO-21090 datatypes

  "Grudging acceptance" (G.Grieve)

  Metadata Open Forum 22-05-2008
  metadataopenforum.org/download.php?1aaeb486434ef7b142363ef8c3dc0b07
- Acceptance can take many many years
- ISO-21090 is still full of compromise
  - Non-ideal at all, making implementation expensive

Another approach - transformations

intermediate formats using XSLT – Prepopulation data

- Must be easy to generate from the EHR
- EDC system must be able to ask for it
- EDC system must be able to read it
- Independent from EHR "standard"
  - As there is not a single one
- Uncomplicated, easy (costs!) to implement

IHE = Integrating the Healthcare Enterprise

IHE changing the way healthcare connects www.ihe.net

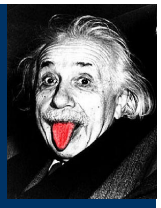
An IHE – CDASH – ODM initiative

- Implementing the IHE profiles
  - Retrieve Form for Data Capture (RFD)
  - Clinical Research Data Capture (CRD)
- Project: can we extract information from an HL7 "Continuity of Care Document" and feed it into an EDC system with CDASH forms ?

Yes, we can !

Integration of EHRs with CDISC, CDASH and ODM – A European Initiative

The team



- The "Godfather": Landen Bain
- IHE / EHR:
  - Kevin Power and John Gedeon (Cerner)
  - Jason Colquitt and Daemon Whittenburg (Greenway Medical)
- CDASH:
  - Rhonda Facile (CDISC) and Gary Walker (Quintiles)
- ODM:
  - Andrew Fowler (XClinical) and Jozef Aerts (XML4Pharma)

The task

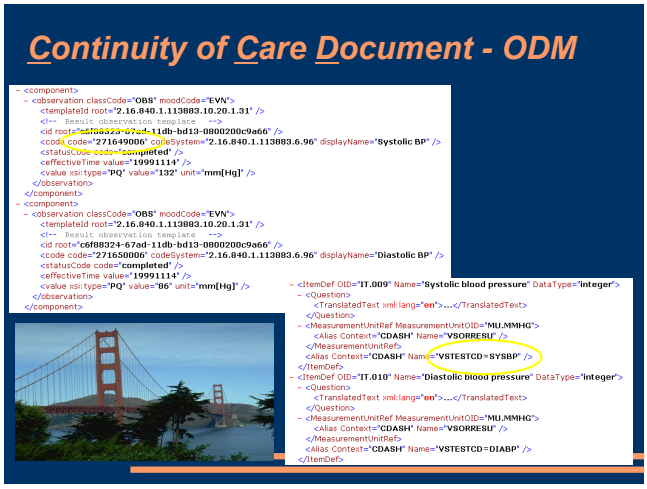
- Design a format that
  - Can easily be generated from the EHR
  - Can be read by the EDC system
  - In order to prepopulate the CDASH form
- So that EHR system and EDC system do not need to know about each others details
  - Generic solution
- Vendor neutral format
- EHR system neutral format
- Develop the XSLT transformation stylesheets to go from HL7-v3-XML CCD to the new format

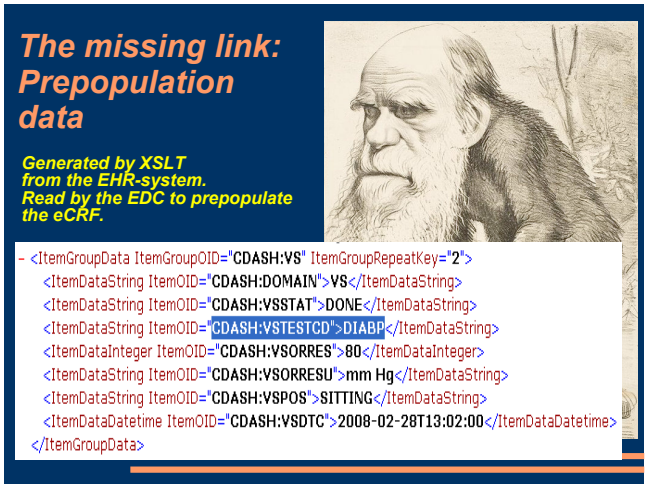
CDISC ODM Annotation for EHR-integration

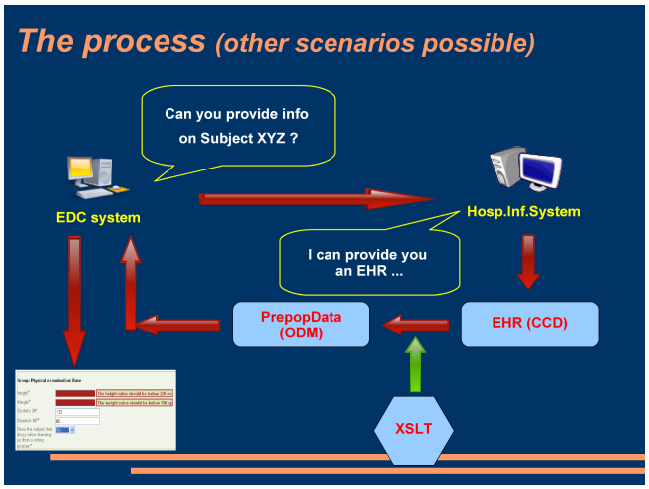
```
- <ItemDef OID="IT.010" Name="Diastolic blood pressure" DataType="integer">
  + <Question>
  + <MeasurementUnitRef MeasurementUnitOID="MU.MMHG">
    <Alias Context="CDASH" Name="VSTESTCD=DIABP" />
  </ItemDef>
</ODM>
```

CDASH Initiative

Integration of EHRs with CDISC, CDASH and ODM – A European Initiative

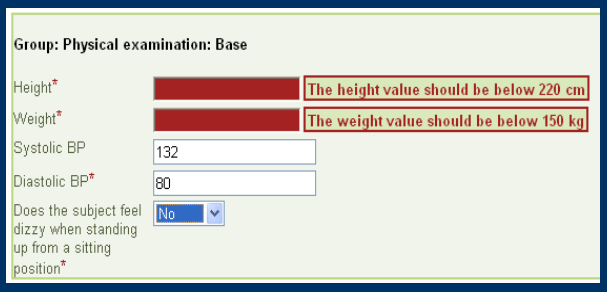






Jozef Aerts – XML4Pharma
CDISC European Interchange 2009

The result – prepopulated eCRF



Results so far

- Defined the PrepopData format (and conventions for OIDs) based on ODM 1.3 ClinicalData
- Constructed XSLT to transform Continuity of Care Document (HL7) to PrepopData.xml
- Constructed XSLT to transform OpenEHR extract to PrepopData.xml
- Demo at Chicago Connectathon 2009

Advantages of this approach

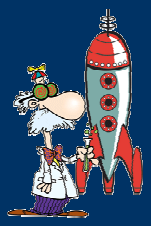
- Many EDC systems can read & write ODM
- XSLT can easily be generated for different HIS / EHR systems
- Approach is generic
- Easy to implement (costs!)
- Needed: SNOMED to CDISC CT mapping

A European initiative

- Mostly US based companies are currently involved
- But Europe is far ahead in implementation of EHR
- Start integration projects in Europe
- Proove genericity of concept
- Develop the first commercial implementations !

This is not rocket science !

- So we should start implementing !



Es ist nicht genug zu wissen, man muss auch anwenden.
Es ist nicht genug zu wollen, man muss auch tun.

Il ne suffit pas de savoir, il faut aussi appliquer.
Il ne suffit pas de vouloir, il faut aussi agir.

Knowing is not enough; we must apply.
Willing is not enough, we must do.

Johann Wolfgang vom Goethe

Thank you for your attention

Extra slides

What's the Political Discord?

- HL7 V3 Data Types highly controversial
  - Improper UML diagrams
  - Modeling by constraint
  - Gap between specification and implementation
  - Open war about null flavors
- CEN rejected V3 Data types
  - Strong input from OpenEHR
  - Several candidate standards proposed
- ISO: Several candidate standards proposed
- A mess: personal, and a disaster

G.Grieve, Metadata Open Forum 22-05-2008