The REUSE project: EHR as single datasource for biomedical research

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AP-HP Patient care

ASSISTANCE PUBLIQUE HÔPITAUX DE PARIS

- Most important French University Hospital Organization with
  - 38 hospitals : 1,000,000 hospitalized patients, 23,000 beds, 1500 day care and 850 home care capacity
  - 69,000 employees including 15,300 physicians
- G.Pompidou university hospital (HEGP = Hôpital Européen Georges Pompidou) (853 beds)
  - **EHR : DxCare® (Medasys©)**

CDISC

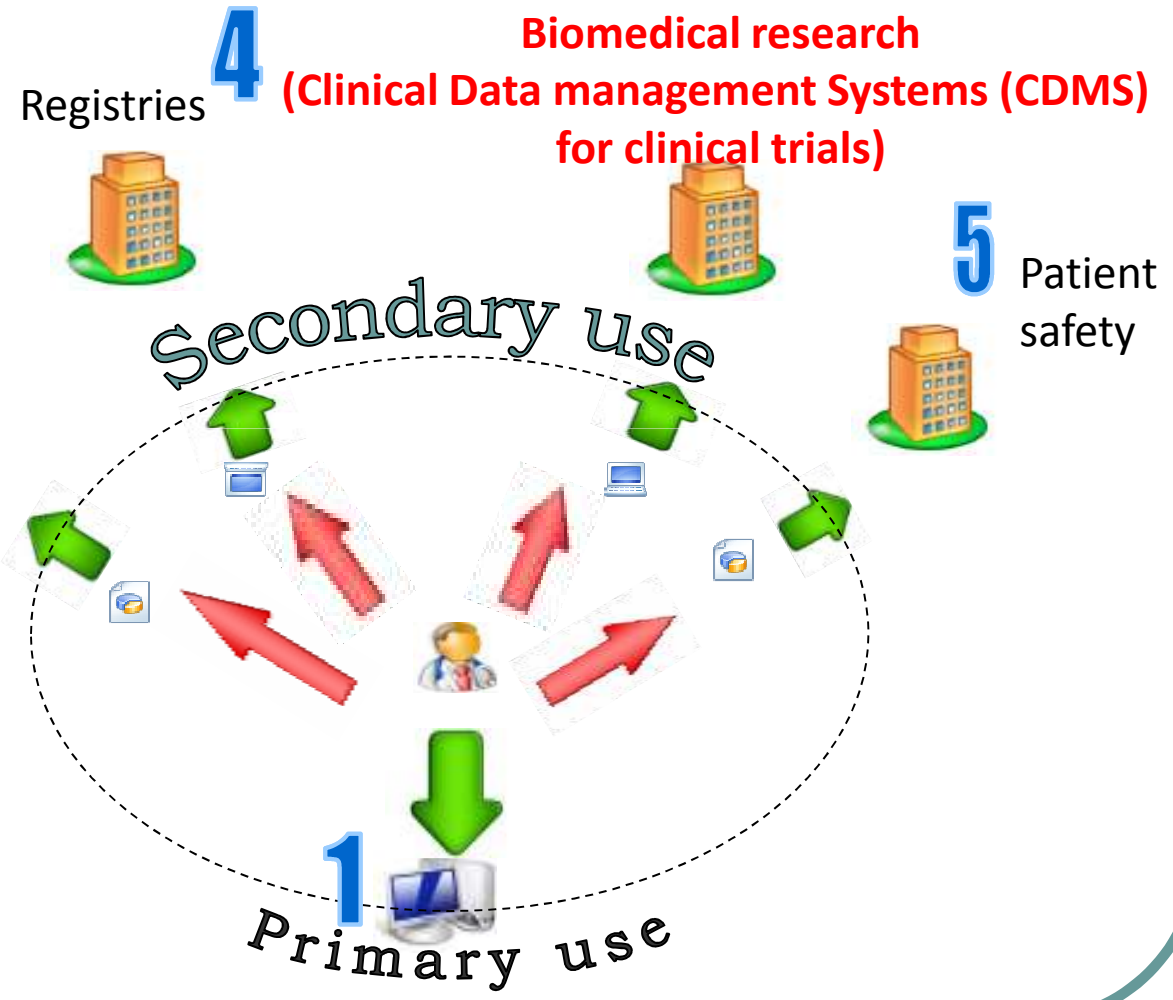
AP-HP clinical research

- First research center about human beings in Europe
  - 354 active research projects et 35 000 enrolled patients
  - Sponsors: AP-HP, pharma industry, public institutions
  - Research structures
    - 18 federated research institutes, 7 Clinical Investigation Centers, 12 bio-medical research centers, 8 Clinical Research Unit
    - 112 INSERM (French National Institute for Health and Medical Research) teams, 30 CNRS (French National Institute for Scientific Research)
- HEGP, Necker, Cochin (GHU Ouest) : half of the institutional research conducted at AP-HP
  - **HEGP : pilot studies of eCRF using MARVIN® (XClinical ©)**

http://www.aphp.fr/site/recherche_innovations/presentation1.htm

http://www.aphp.fr/site/connaitre/chiffres_recherche.htm

One patient, how many records?



Landen Bain. How the CDISC Standard can be used to Integrate Healthcare and Therapeutic Product Safety

Integrating Patient Care & Biomedical Research

- Improve patient recruitment
  - Only 7% of eligible patients enroll in a clinical trial
  - 86% of all trials fail to enroll on time
  - Women, minorities, children and special populations are under-represented
- Improve data capture and submission to regulatory agencies
  - EHR contains 30% to 50% of items of research forms
- Improve reporting of drug adverse events
  - Only few % of Adverse Events are spontaneously reported

Kahn M.G; Kaplan D. Implementing Translational Research Policies in Electronic Medical Records. Academic Medicine. 82(7):661-669, July 2007.

The eClinical Forum and PhRMA EDC. The Future Vision of Electronic Health Records as eSource for Clinical Research. Draft version 0.1, March 3, 2006

Kush, R.D., Helton E. Electronic Health Records, Medical Research and the Tower of Babel. The new england journal of medicine. 1738-40. april 2008

Why is it so difficult?

	Electronic Healthcare Record (EHR)	**Clinical Data Management System (CDMS)**
Different business processes and information systems	HL7 EHR-S Functional Model, Release 1 (HL7)	BRIDG business models FDA guideline (« Computerized Systems Used in Clinical Investigations »(CSUCI))
Different regulatory constraints	IHE integration profiles ("Audit Trail and Node Authentication", "Consistent Time" and "Document Digital Signature")	Directive 2001/20/EC of the European parliament Committee for the Protection of Persons (CPP)
Different data standards	HL7, CDA	CDISC, ODM

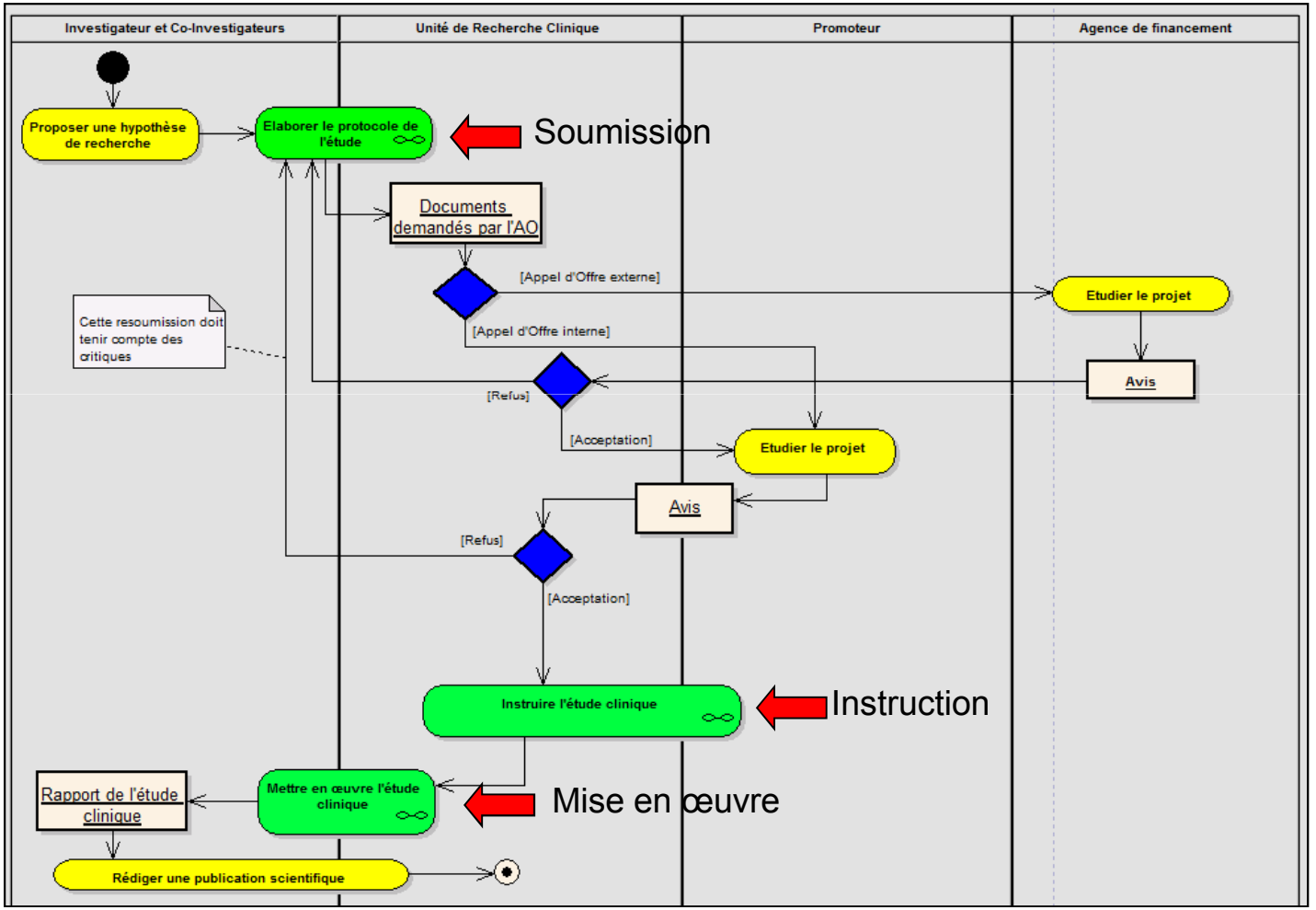
Objectives

- To conceive, implement and assess an integrated solution for both clinicians and researchers
  - using EHR and CDMS
  - taking into consideration recent standardization and integration efforts by IHE (Integrating Healthcare Enterprise)
- To evaluate this solution in real settings of AP-HP

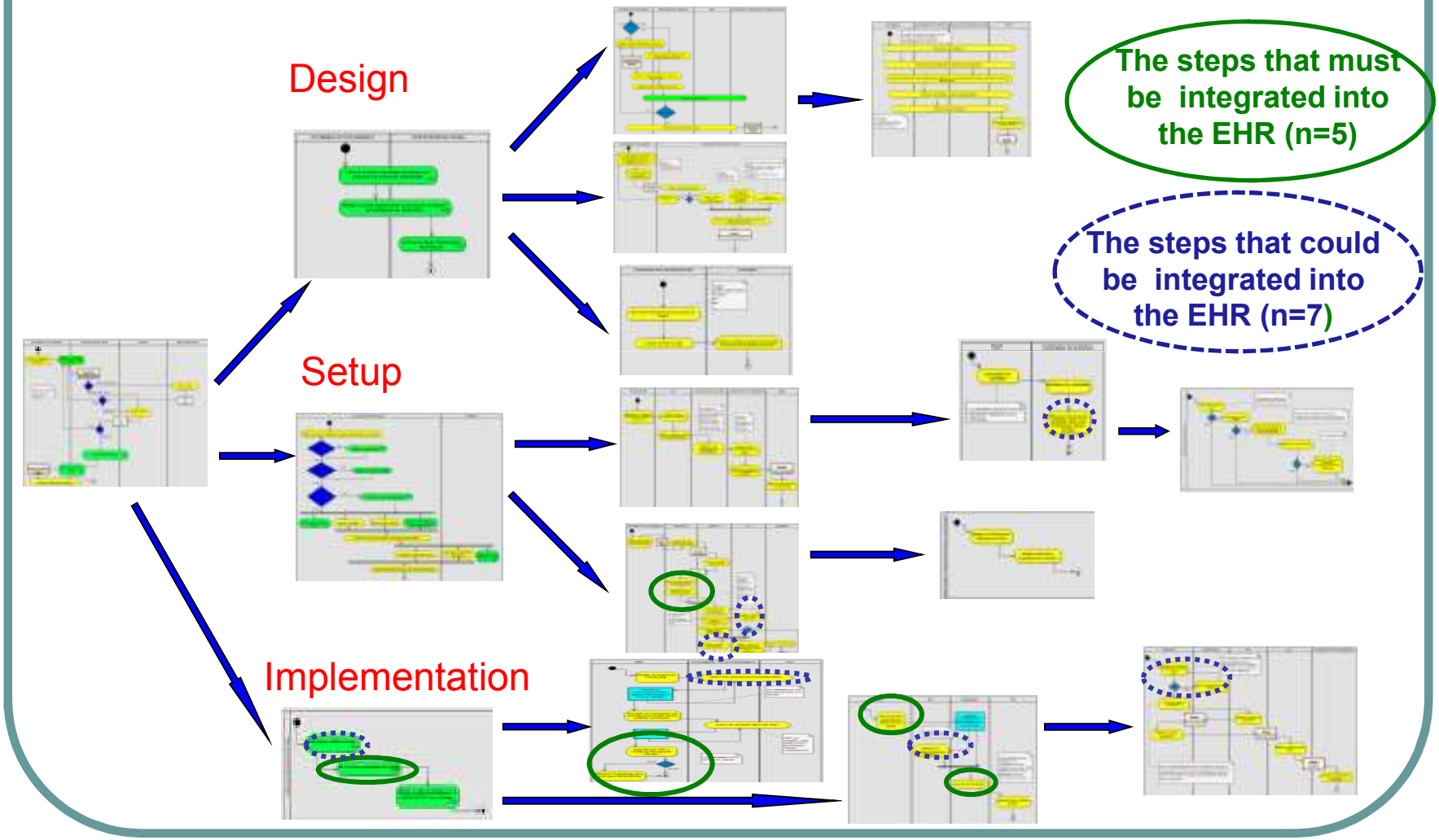
Methods

- Modelization
  - Business models of biomedical research
  - UML models and architecture of the REUSE project
    - Derived from the IHE integration profile RFD (Retrieve Form for Data Capture)
- Implementation et experiment in real settings
  - Biomedical study « Dyspnea »

Results:
High Level Interaction Diagram



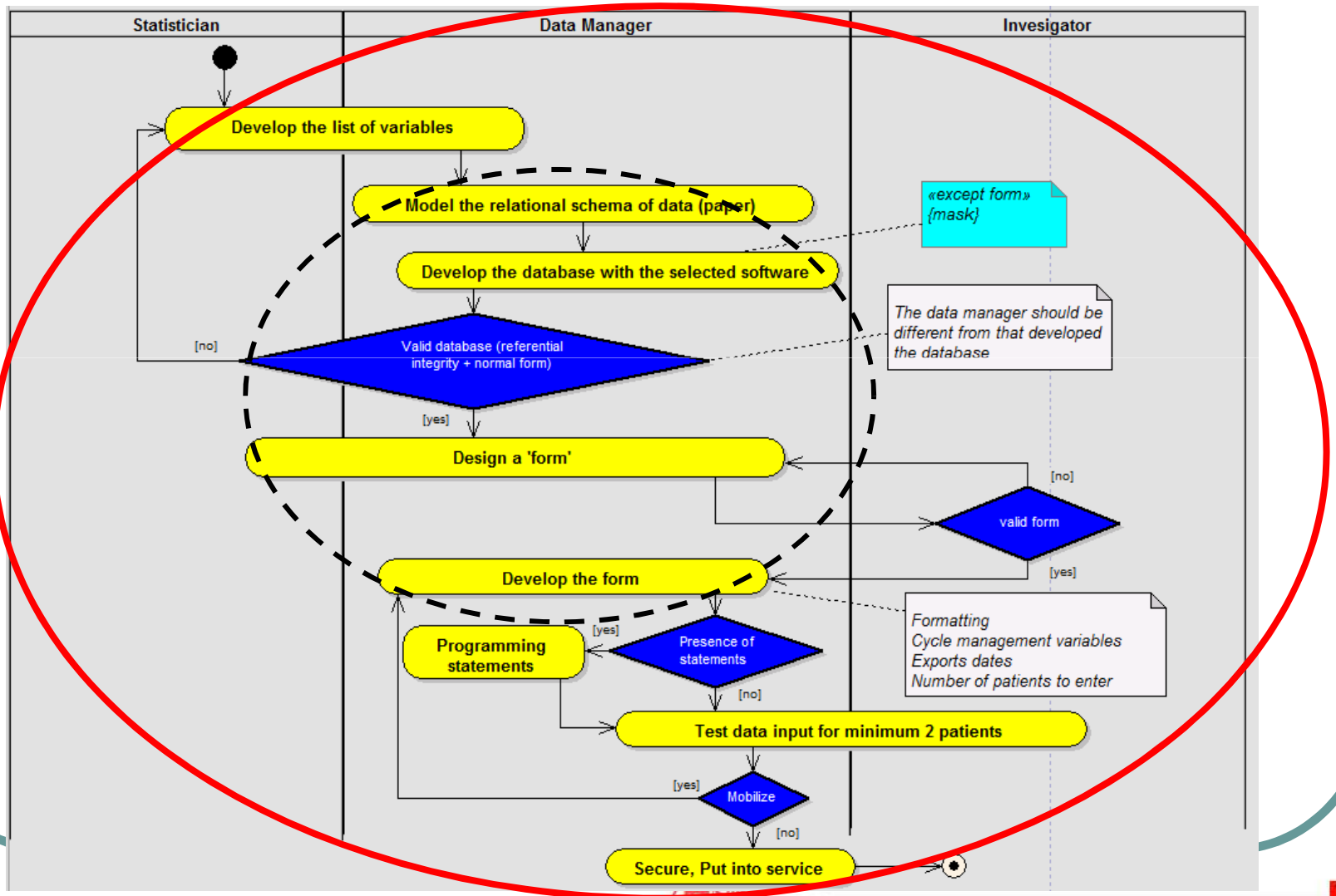
Results:
12 2nd Level Interaction Diagrams



Results

- The steps that must be integrated into the EHR (n=5)
  - Designing eCRF
  - Designing the data management program
  - Pre-populating eCRF with clinical data
  - Updating administartive or clinical data during the study
  - Data monitoring

Results:
Database Management



Results:
RE-USE architecture (1/2)

Clinical Research Unit
Marvin (XClinical©)
CDISC

Form Manager

CDMS

Retrieve Forms
(Metadata)

export

eCRF

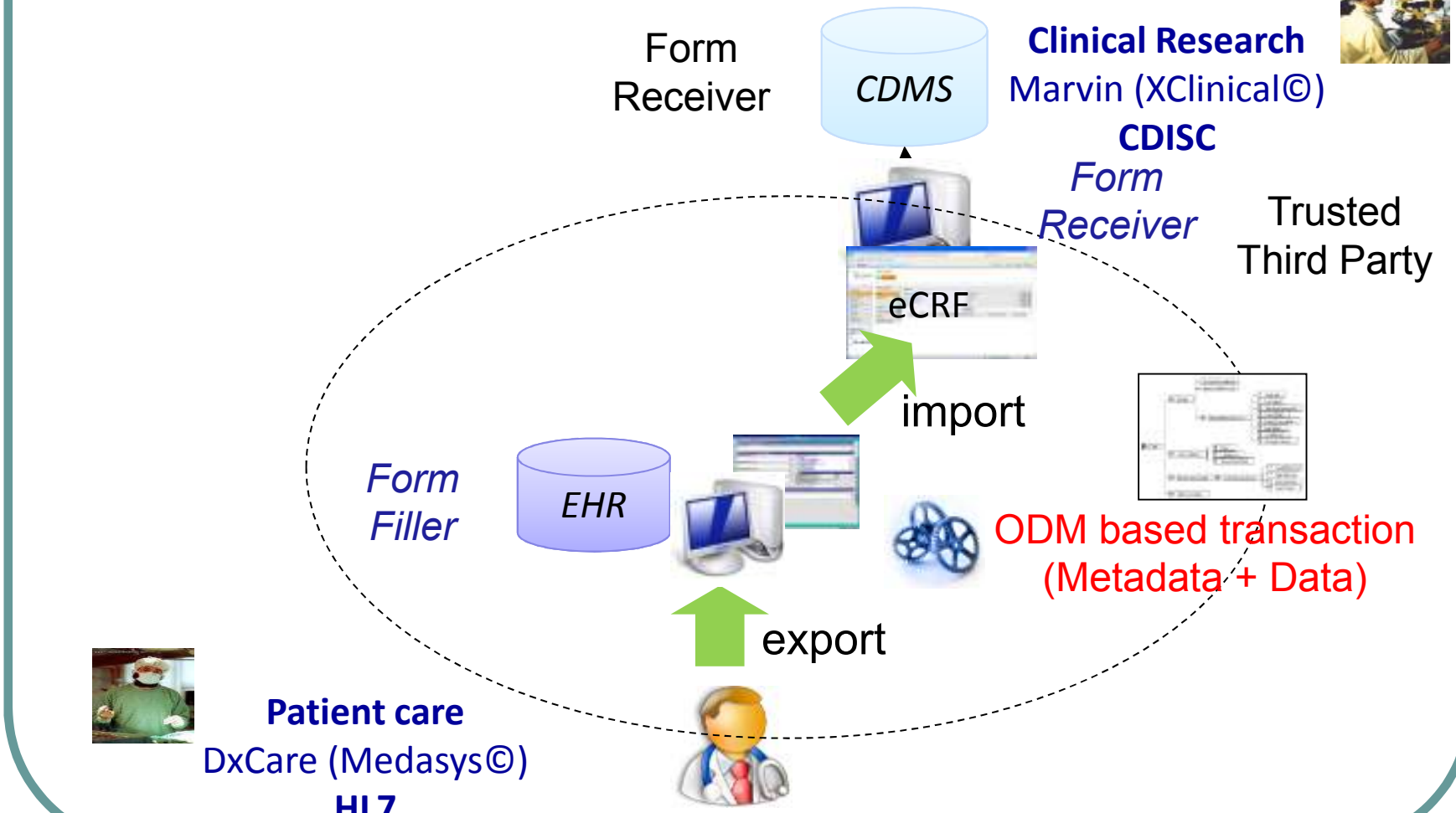
Import &
integration

Form Mapper/Filler

EHR

Patient care
DxCare (Medasys ©)
HL7

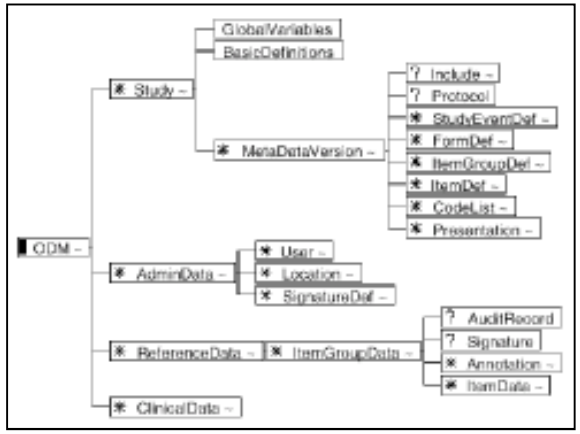
Results:
RE-USE architecture (2/2)



Results : REUSE experiment Clinical study “Dyspnea”

CDMS
MARVIN
(XClinical)

EHR
DxCare® (Medasys)



ODM (MetaData + Data)

Results : REUSE architecture
On going development

Template

Retrieve & Integrate Forms
Transaction
based on an HL7 CDA template
(Metadata)

Form
Manager

SGDC

Clinical research
Marvin (XClinical©)
CDISC

Form
Receiver

eCRF

DPI

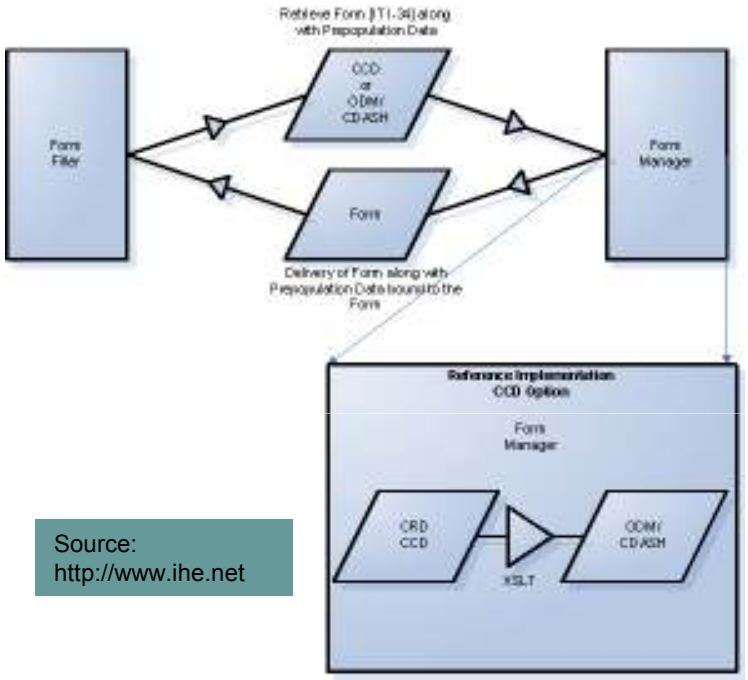
Submit Form
HL7 CDA/ ODM mediator
(Metadata + Data)

Form
Mapper/Filler

Patient care
DxCare (Medasys©)
HL7

HL7 CDA/CDISC ODM mediator

Based on alignment between CCD content modules and CDASH domains



Source: http://www.ihe.net

(QRPH domain)

Clinical Research Data Capture Data Elements	
CDASH Domains	**CCD Reference**
Demography	CCD Header Information
Medical History	Active Problems, Past Medical History, and Procedures and Interventions
Concomitant Medication	Current Medications
Substance Use	Social History
Vital Signs	Vital Signs
Physical Exam	Physical Exam
Adverse Events	Allergies
Lab Test Results	Coded Results
ECG Test Results	Coded Results

Source: http://www.ihe.net

HL7 CDA/CDISC ODM mediator

Based on alignment between CCD content modules and CDASH domains

CR: CDASH Domains	EHR: CCD Référence	Template CDA
Exposure		New content module
Concomitant Medication	Current Medications	Medications. Medications Administered
Substance Use	Social History	History of Tobacco Use Current Alcohol/Substance Abuse
Adverse Event	Allergies	Allergies and Other Adverse Reactions
Disposition		New content module
Medical History	Active Problems, Procedures and Interventions, Past Medical History	Active Problems. History of Present Illness Family Medical History.
Deviations		New content module
Lab Test Results	Coded Results	Coded Results
ECG Test Results	Coded Results	Coded Results
Vital Signs	Vital Signs	Vital Signs
Physical Examination	Physical Exam	Physical Exam
Inclusion / Exclusion Criteria		New content module
Subject Characteristics		New content module
Drug Accountability		New content module
Demographics	CCD Header Information	CDA Header templates (Patient Contacts, Spouse,..)
Comments		Comments

Discussion - Conclusion

- REUSE project
  - Integrated solution for both clinicians and researchers between EHR and CDMS
  - Differs from IHE RFD integration profile since EHR is the single source of data
- Benefits
  - For healthcare providers: avoiding double data entry
  - For patients : in our approach, considering the EHR as the single source of data may improve patient safety as ALL data collected in a biomedical research setting is kept in the EHR, which is currently not the case for most research studies
- Limits
  - Ongoing implementation of the transaction « Retrieve and integrate form »
  - Current transaction « Submit form » is specific to the HEGP DPI; a new version will be implemented (HL7 CDA/CDISC ODM mediator)