KING'S HEALTH PARTNERS

Pioneering better health for all

Practical and informatics challenges of using data from the electronic health record: From ePCRN to TRANSFoRm

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www.transformproject.eu

History

ePCRN

- Funder NIH (US) 2005-8 Pilot for NIH Roadmap
- University of Minnesota, University of Birmingham, UCSF.
- Additional funds 2008-9 from NIHR NSPCR (Bham)

TRANSFoRm

- Funder EU FP7 ICT, €7m integrated project 2010-15
- 16 partner universities in 9 EU countries led by KCL
- Builds on and links to ePCRN

Aims of ePCRN

Data linkage between eHRs and clinical research

- To identify eligible subjects

A standards-based system for generating web-based data capture for RCTs

- To control data items via a meta-data repository
- For re-use of data elements
- To generate forms and databases from the meta data

ePCRN brings the technologies of the NCI cancer Bioinformatics Grid (CaBIG) into the Primary Care setting

- Extends the BRIDG data model
- Integrates the Enterprise Vocabulary Service
- Enables the creation and reuse of data elements and forms via the Data Standards Repository

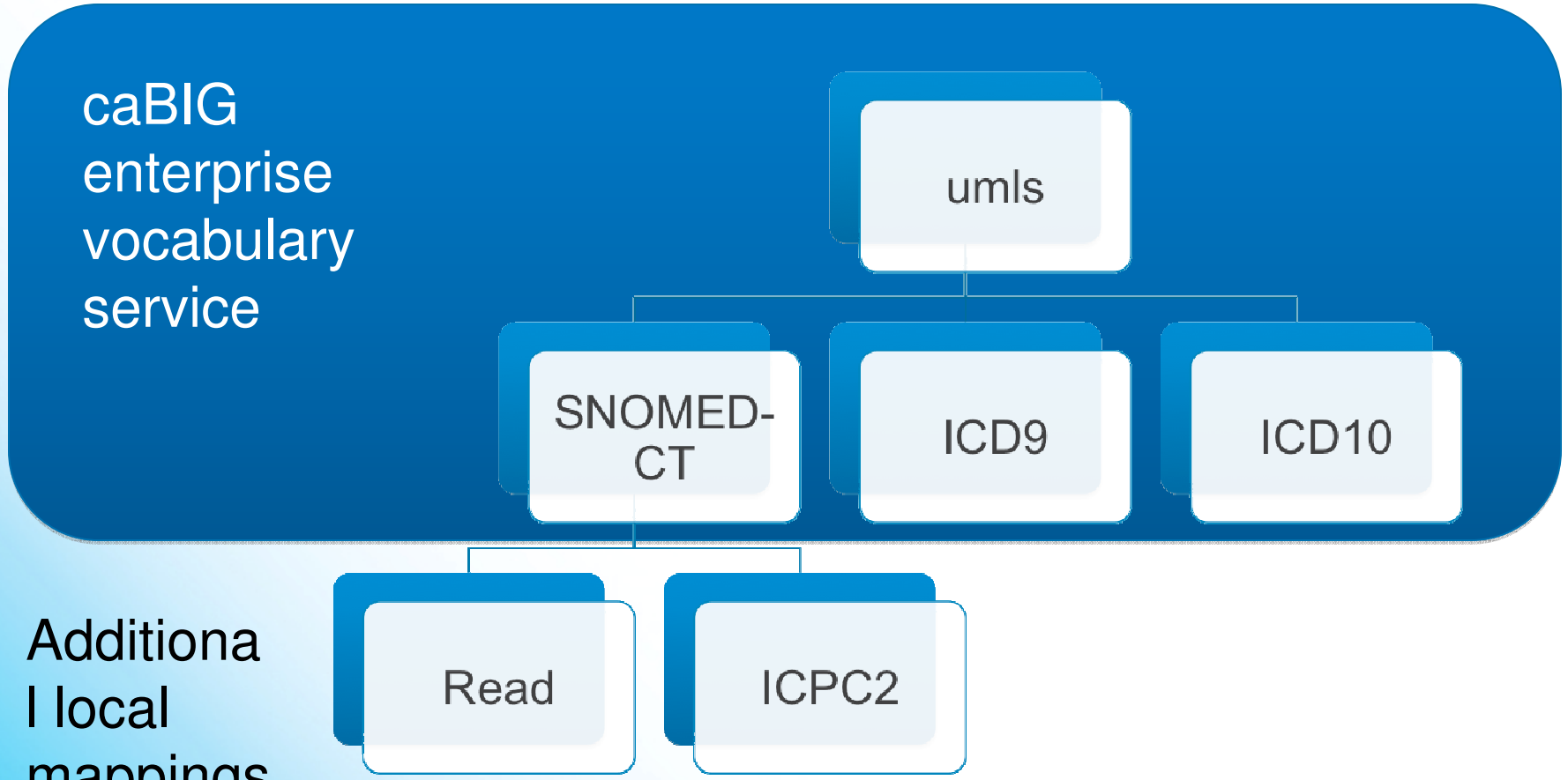
Confidentiality and data security

- **Confidentiality - for subjects not having consented to use of their data for research**
  - Search reports only ‘counts’ - NO DATA is extracted
  - Subjects are flagged locally
- **Security**
  - OGSA-DAI & GTK4(certificates and authorisation)

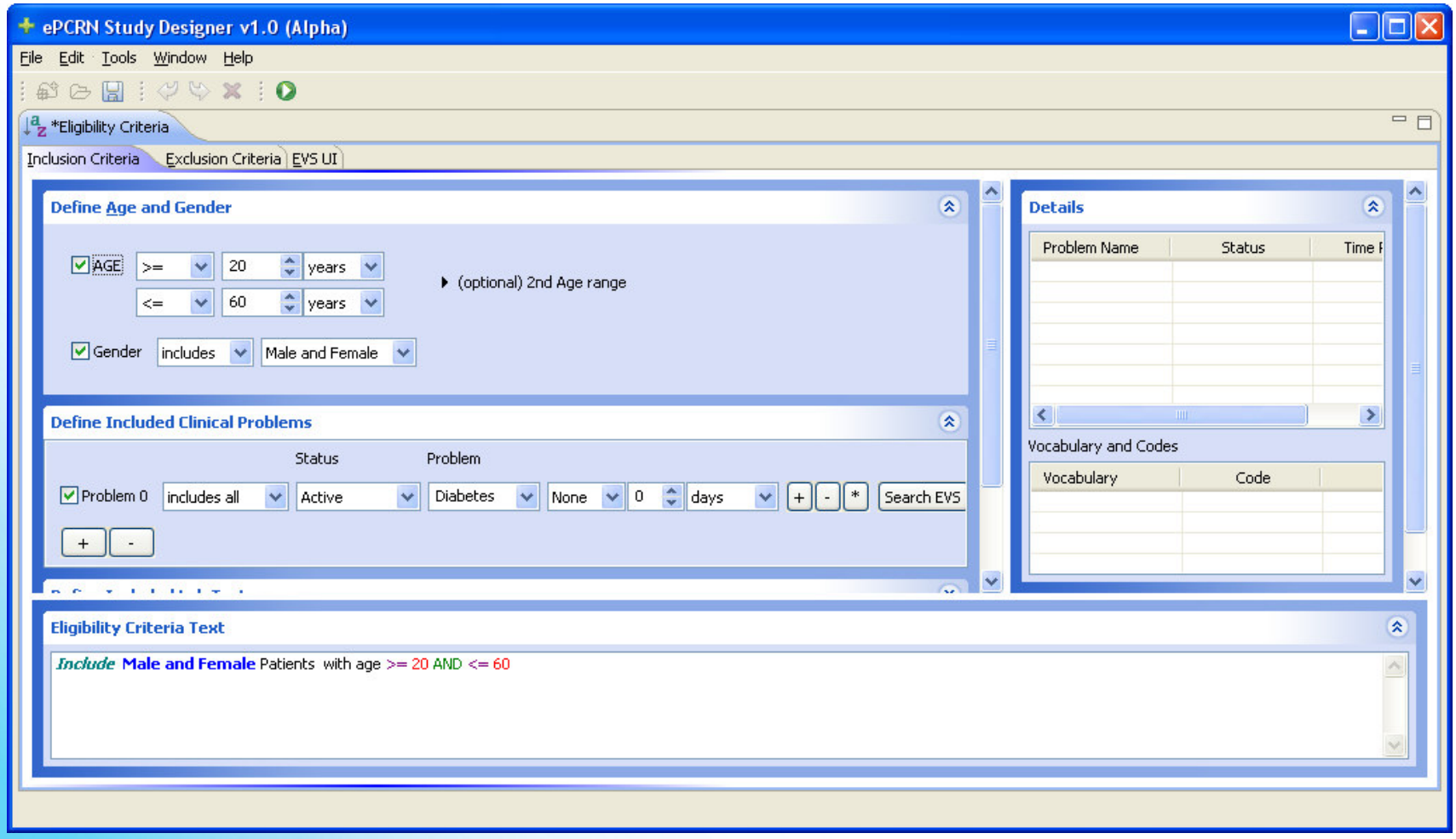
ePCRN: Recruitment

1. Capture protocol definition
2. Drill down to capture eligibility criteria via ‘semantic workbench’
3. Browse CaBIG Enterprise Vocabulary Service
4. Construct query in selected vocabulary
5. Authorise and run

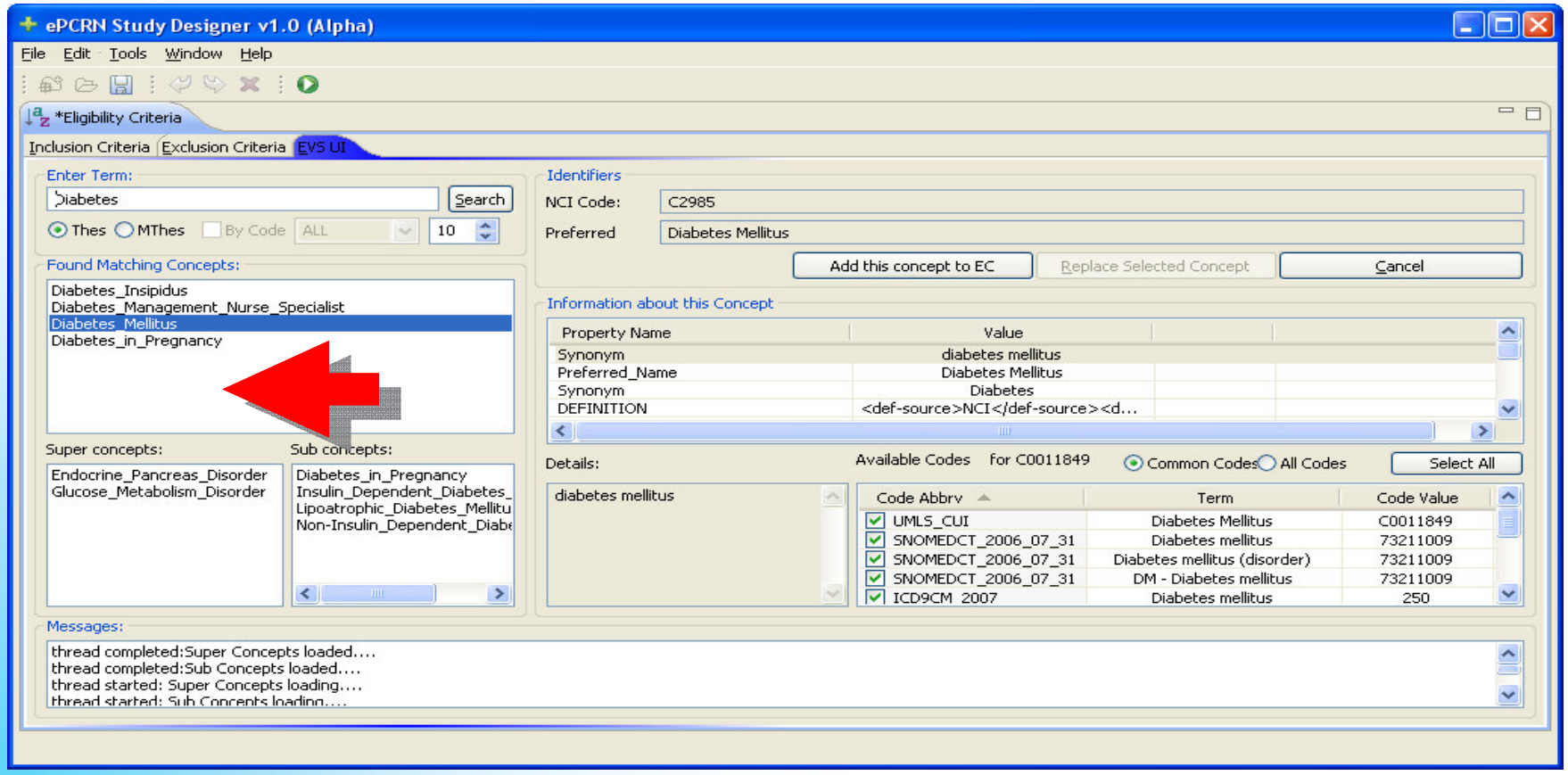
Controlled vocabulary



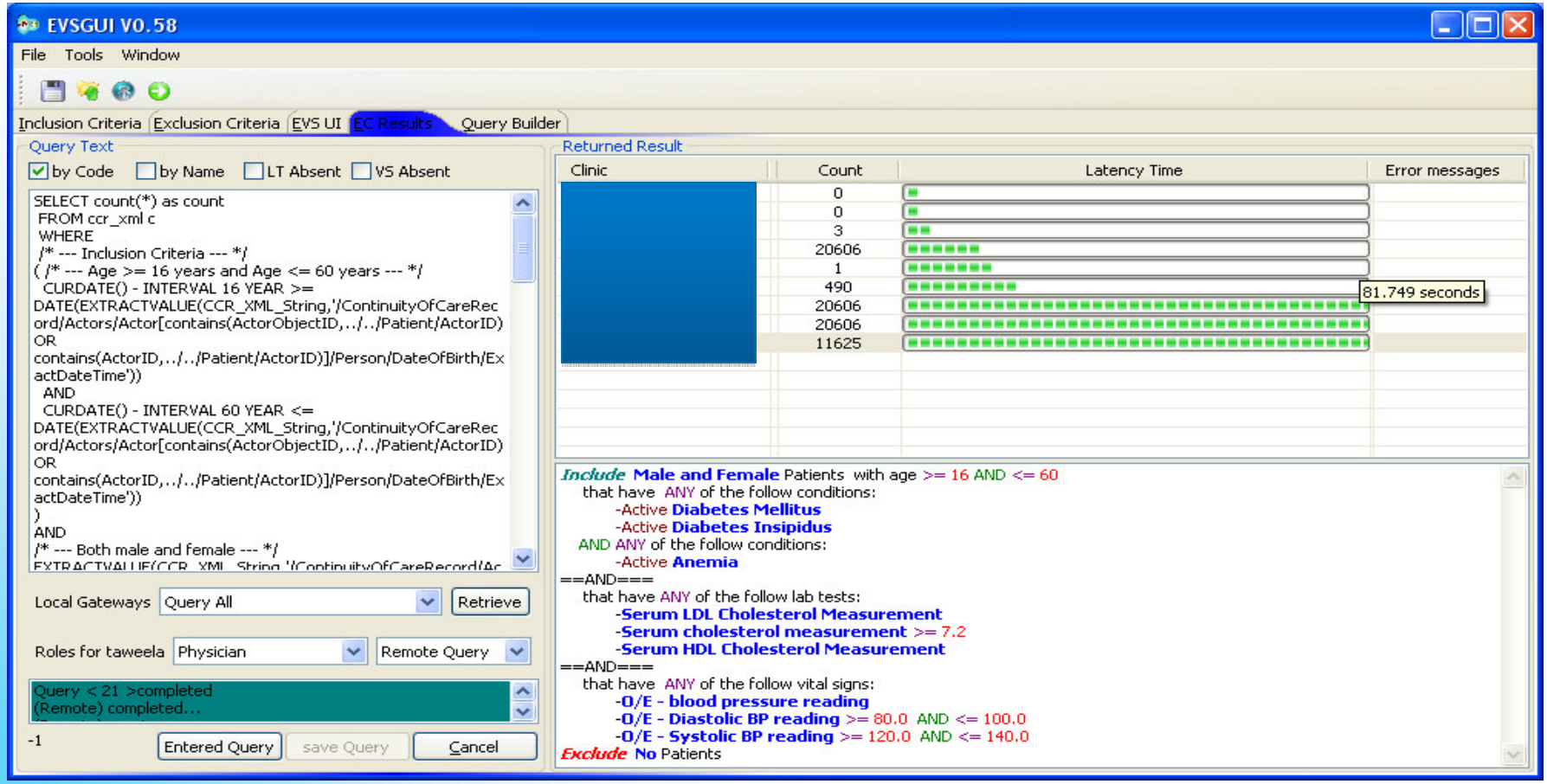
Define eligibility criteria



Define the problem semantically



Count eligible community subjects



Clinical Trial Data management Systems

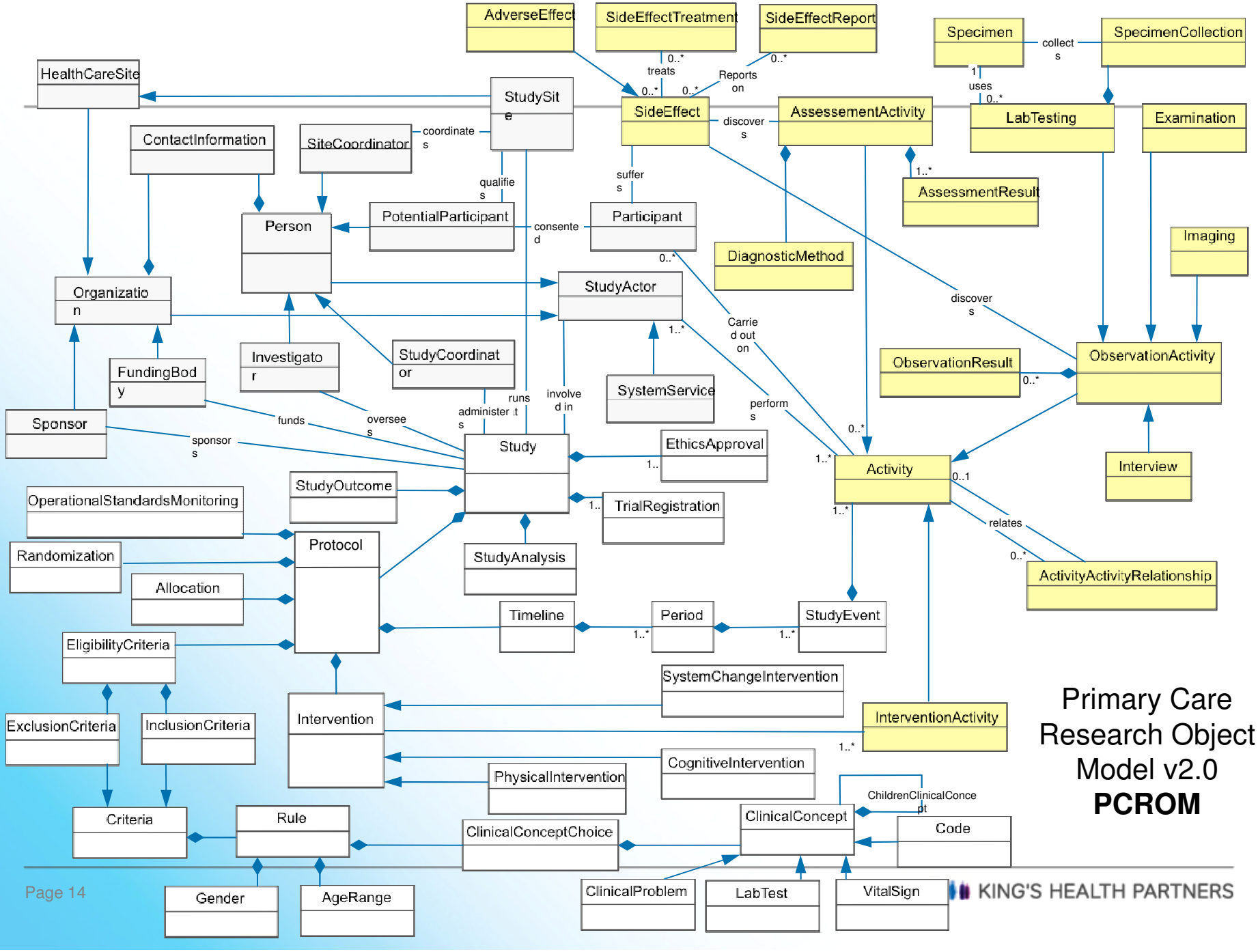
- Proprietary hell
- Numerous partial solutions, open source forms are often quite basic in functionality
- Little standardisation in spite of CDISC
- Like buying a new CD player for every album
- No ‘one system’ for every domain

The solution

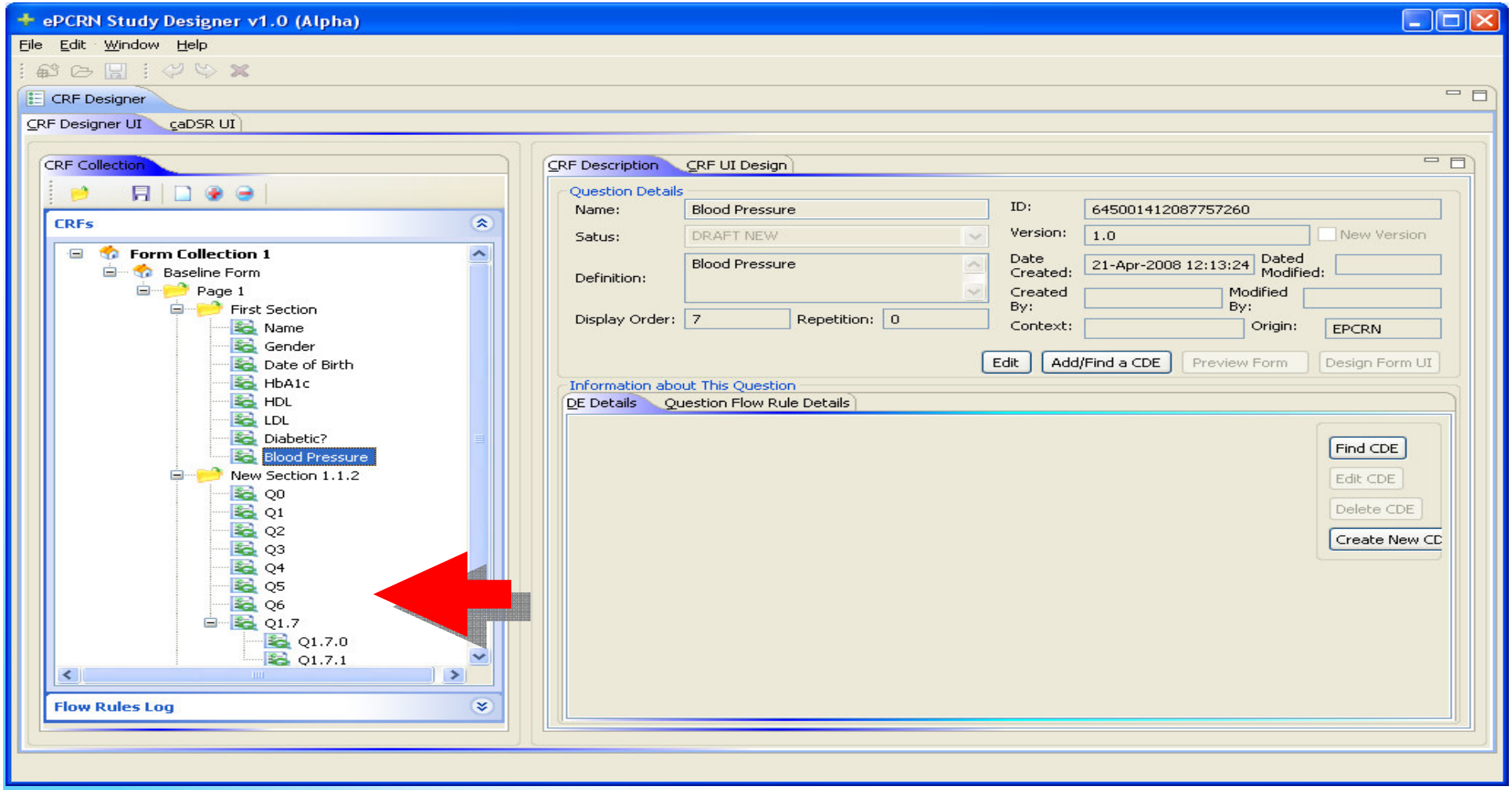
Separate domain semantics from the system implementation……

Requirements

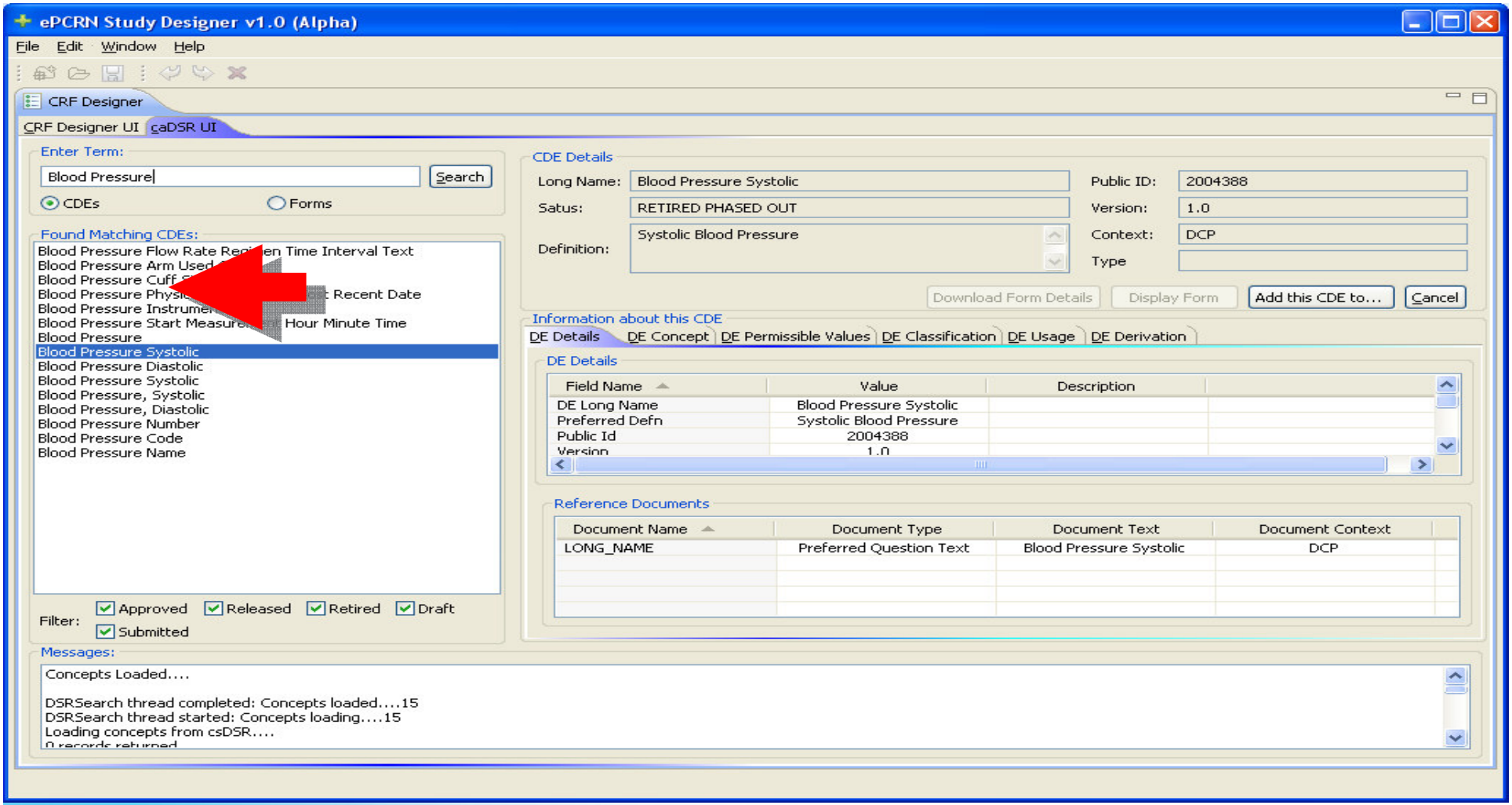
- A domain object model
- A system that can author specific (xml) documents as an instance of the domain model for a specific study
- A system to write the xml representation into a set of forms and a database


AdverseEffect
SideEffectTreatment
SideEffectReport
Specimen
collect s
SpecimenCollection
HealthCareSite
StudySit e
treats
Reports on
SideEffect
discover s
AssessementActivity
uses
LabTesting
Examination
ContactInformation
SiteCoordinator
coordinate s
qualifie s
suffer s
AssessmentResult
Person
PotentialParticipant
consente d
Participant
DiagnosticMethod
Imaging
Organizatio n
StudyActor
discover s
Carrie d out on
ObservationResult
ObservationActivity
FundingBod y
Investigato r
StudyCoordinat or
SystemService
Sponsor
funds
oversee s
runs
administer s
involve d in
perform s
Study
EthicsApproval
Activity
Interview
sponsor s
StudyOutcome
TrialRegistration
OperationalStandardsMonitoring
relates
Protocol
Randomization
StudyAnalysis
ActivityActivityRelationship
Allocation
Timeline
Period
StudyEvent
EligibilityCriteria
SystemChangeIntervention
Intervention
InterventionActivity
ExclusionCriteria
InclusionCriteria
CognitiveIntervention
PhysicalIntervention
ChildrenClinicalConcept
Criteria
Rule
ClinicalConceptChoice
ClinicalConcept
Code
ClinicalProblem
LabTest
VitalSign
Gender
AgeRange
Primary Care Research Object Model v2.0
PCROM

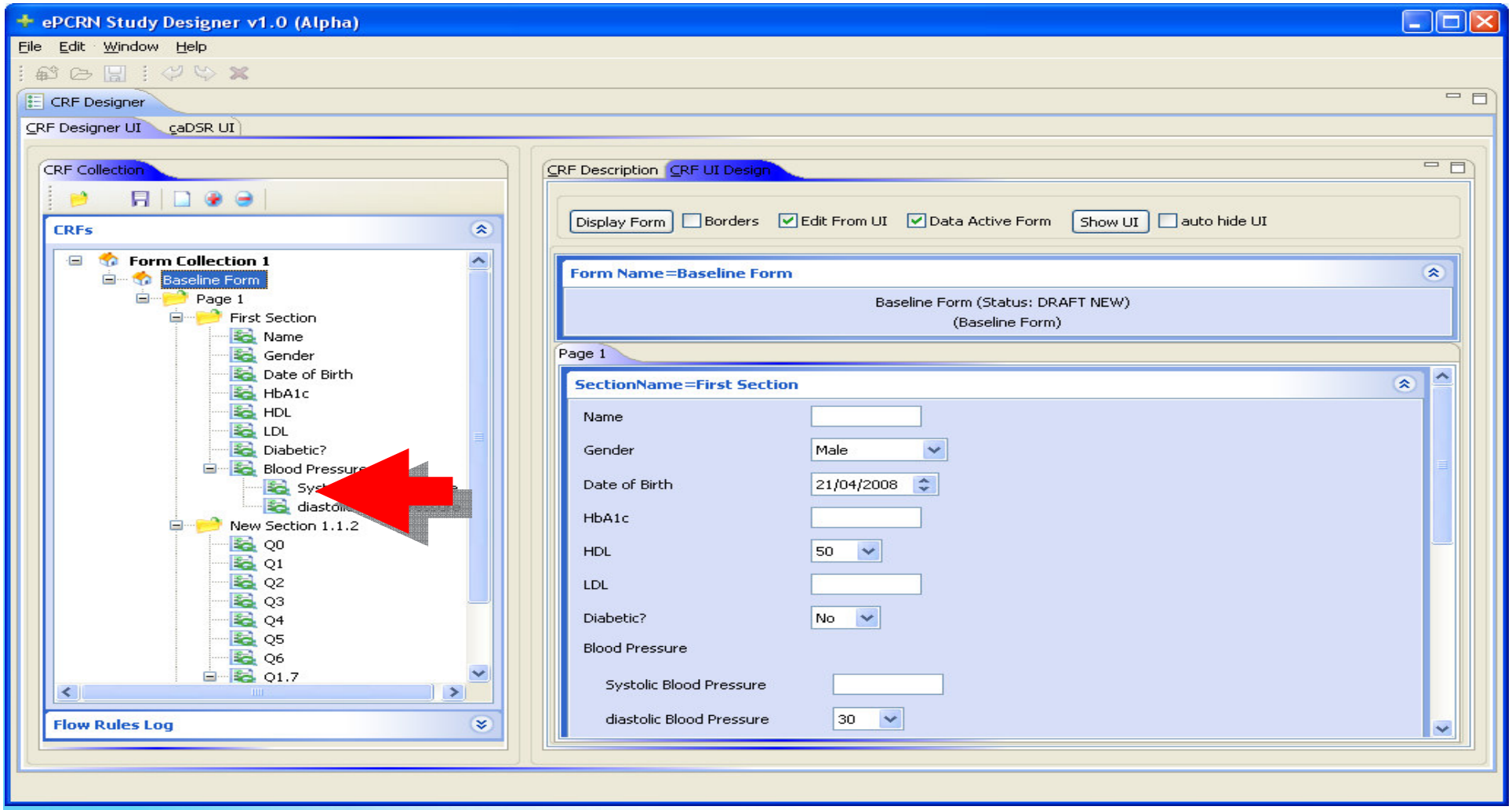
Define a new data element



Use a data standards repository



Create your own form design



PCROM and ISO11179

ISO 11179 is a six part international standard for meta data registries where each data element is

- Registered
- Uniquely identified
- Named
- Defined –for which a domain model is useful
- May be classified – for which a domain model is essential

Progress planned from 2010

ePCRN is an open source project

€7M of funding from the European Commission via the TRANSFoRm project (www.transformproject.eu)

Plans for widely usable tools for:

- Authoring searches using controlled vocabulary
- Working with metadata and forms
- Writing computable protocols

Where does the future lie?

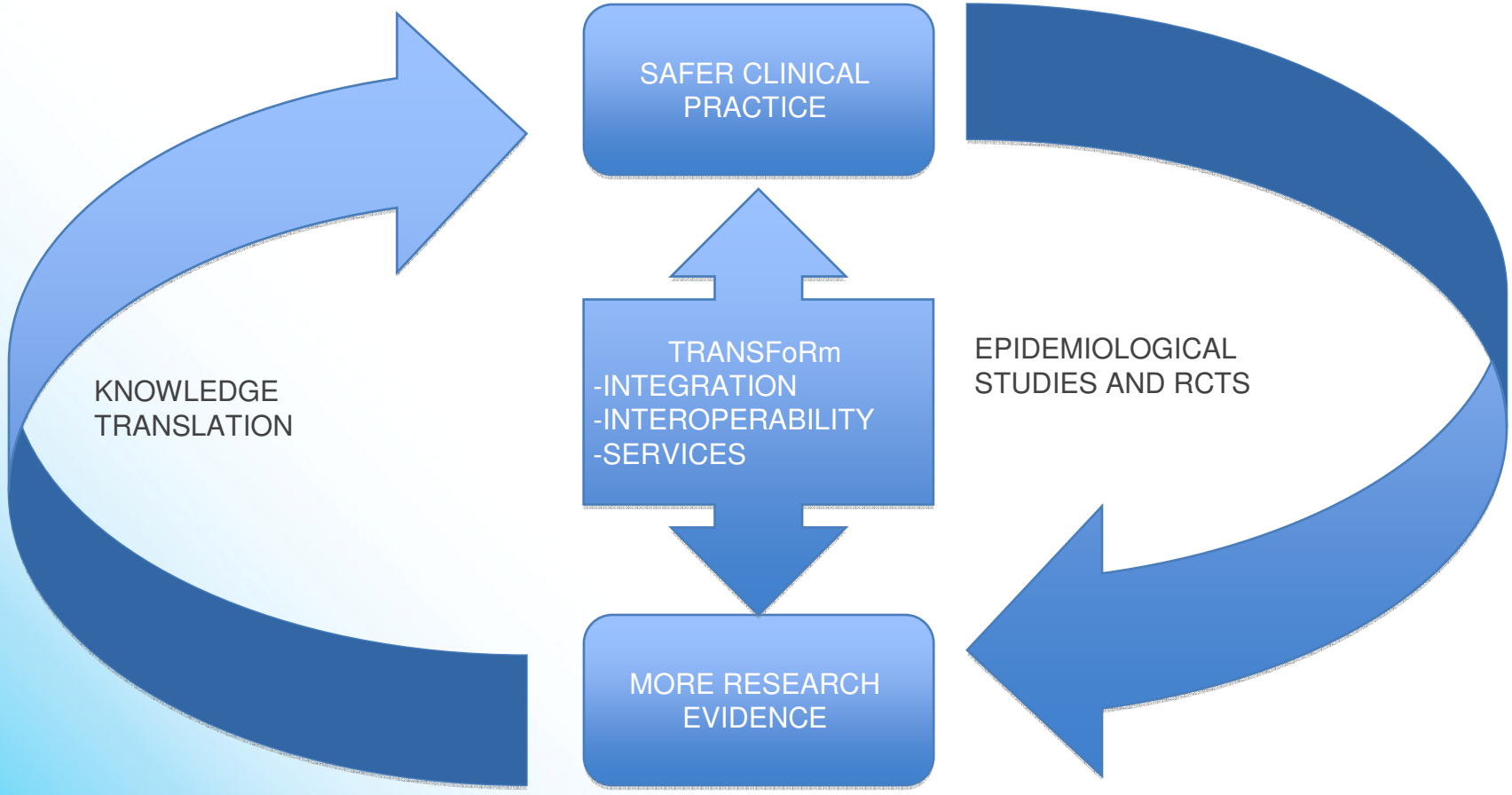
Open systems

Standards

Standardized computable trial protocols

Ability deploy studies in a variety of different software systems

TRANSFoRm


SAFER CLINICAL PRACTICE
TRANSFoRm
-INTEGRATION
-INTEROPERABILITY
-SERVICES
MORE RESEARCH EVIDENCE
KNOWLEDGE TRANSLATION
EPIDEMIOLOGICAL STUDIES AND RCTS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of Primary Care


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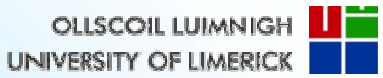

OLLSCOIL LUIMNIGH
UNIVERSITY OF LIMERICK


TRINITY COLLEGE DUBLIN
COLÁISTE NA TRÍONÓIDE, BAILE ÁTHA CLIATH
THE
UNIVERSITY
OF DUBLIN


Universiteit
Antwerpen


St George's
University of London


UNIVERSITY OF
BIRMINGHAM

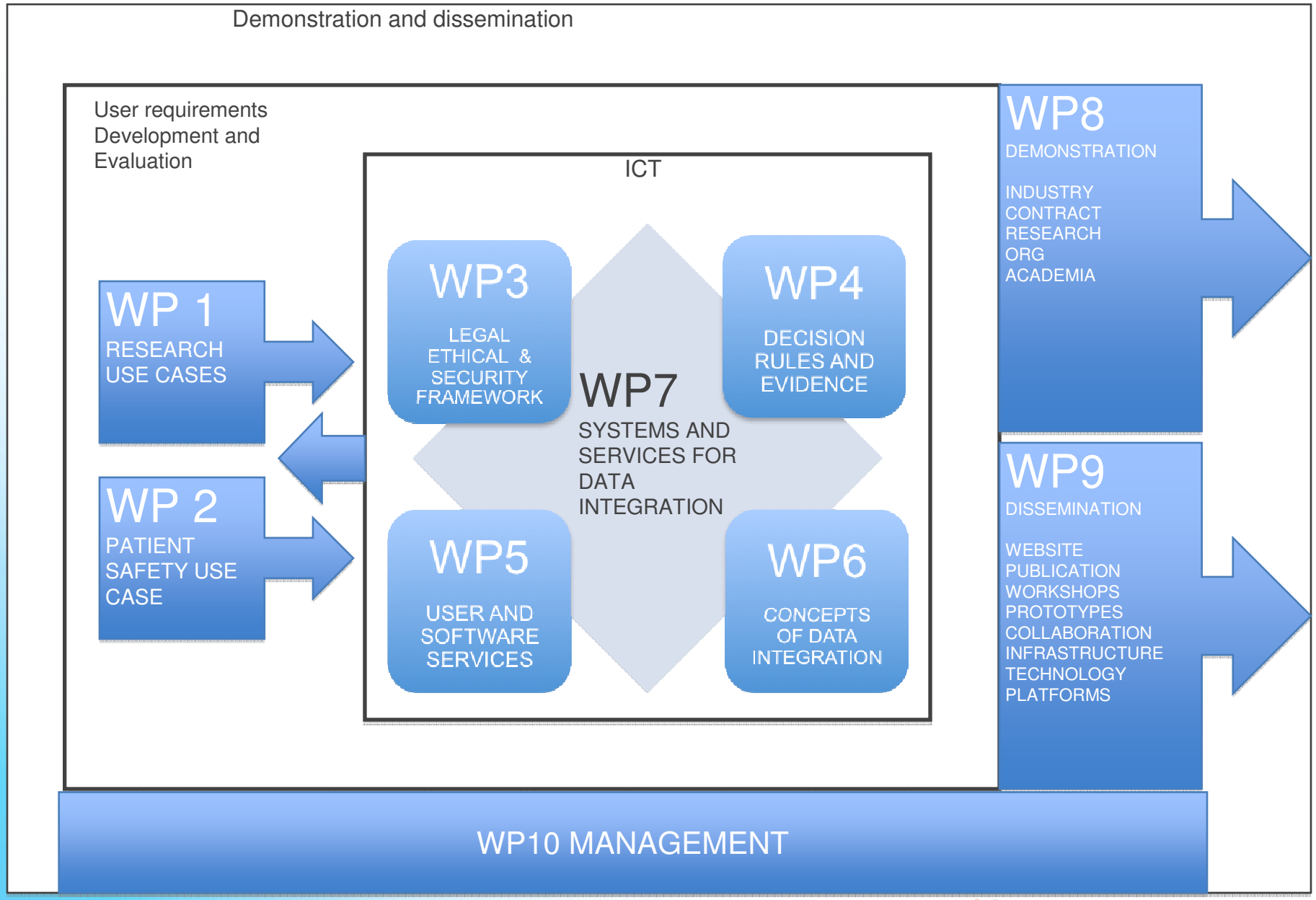

Imperial College
London


University of Crete


University of Dundee


HEINRICH HEINE
UNIVERSITÄT
DÜSSELDORF


GPRD


Demonstration and dissemination
User requirements
Development and
Evaluation
ICT
WP 1
RESEARCH
USE CASES
WP 2
PATIENT
SAFETY USE
CASE
WP3
LEGAL
ETHICAL &
SECURITY
FRAMEWORK
WP4
DECISION
RULES AND
EVIDENCE
WP7
SYSTEMS AND
SERVICES FOR
DATA
INTEGRATION
WP5
USER AND
SOFTWARE
SERVICES
WP6
CONCEPTS
OF DATA
INTEGRATION
WP8
DEMONSTRATION
INDUSTRY
CONTRACT
RESEARCH
ORG
ACADEMIA
WP9
DISSEMINATION
WEBSITE
PUBLICATION
WORKSHOPS
PROTOTYPES
COLLABORATION
INFRASTRUCTURE
TECHNOLOGY
PLATFORMS
WP10 MANAGEMENT

System Integration

Using the models, based on use cases to inform the development of a system that has shared concepts:

- Provenance model
- Protect the data via provenance and common security model
- Consent model
- Middleware based on open source and standards (and building on ePCRN)

Workflow Integration

For research

- Seamless prompts, reminders and data collection

For clinical practice

- DSS have failed
- Strong emphasis on development from MDM experimental approach

- Prompting v Alerting
- Data entry interface and design

Knowledge translation

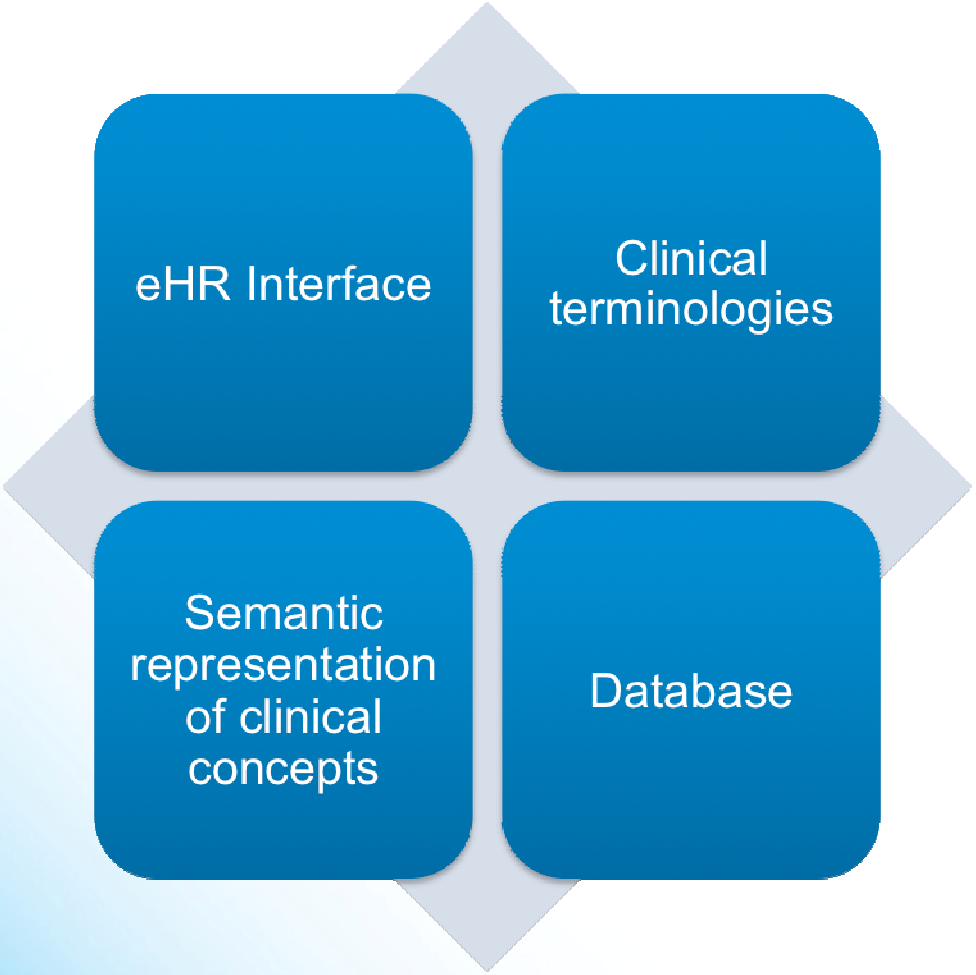
Understand how systems work with human judgment

Need to enable a much finer granularity of interaction between the eHR and research systems

Use the openEHR standard

- Observations, archetypes, templates
- User interface design

CEN 13606: independence of semantic representation.



Archetypes

A computable expression of a domain content model in the form of structured constraint statement based on a reference information model.

Often encapsulated together in Templates.

Sit between lower level knowledge resources and production systems

Independent of interface and system

Interoperability of research data

Model based

- CDISC ODM
- BRIDG
- PCROM

ISO/IEC 11179 Metadata Registry standard

Integrate Vocabulary service, Metadata registry and core interoperability model as a seamless service.

Current progress

Use case development

Experimental background to DSS

Survey of network capacity and IT resource

Model of data comparability

Legal and ethical survey

Provenance framework

Security Framework

QA Framework

Potential areas for co-operation

Standards

- Clinical data representation/ archetypes
- Standard computable representation of clinical research / trial data

Common Implementation

- eHR interface
- Middleware / system integration

Common Business Models

- Open but exploitable
- epSOS and EHR4CR projects

Overcoming the barriers

Funding for research

- FP7, ARRA, CTSA inhibit ‘ePCRN style’ collaborative research

Funding for networking and collaboration

- Goes beyond individual projects and needs LONG TERM investment

Involvement of standards bodies

- Cannot be a short term aim

Agile and open

- Should encompass all those working in the area