

TRANSFoRm: TRANSFoRming health care research and its implementation

Frank Sullivan, on behalf of the TRANSFoRm Consortium.

Health Informatics Centre Dundee

www.transformproject.eu

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247787)

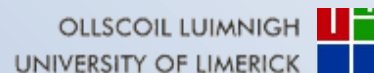


TRANSFoRm Vision

The European Commission is funding the TRANSFoRm project (€7M) as part of its efforts to advance information and computer science to address these market challenges in a European context.

TRANSFoRm will develop a digital infrastructure that facilitates the reuse of Primary Care Real World electronic Health Records (eHR) data to improve both patient safety and the conduct and volume of Clinical Research in Europe

TRANSFoRm Consortium



Content

What TRANSFoRm is

Need

Benefits

Technologies

Tools

Knowledge In Healthcare



The GP Electronic Medical Record

- Demographics
- Prescriptions
- Diagnoses
- Test Results
- Free Text

G GPASS 57Y - 01/01/1955 (F) (CHI No:) Top Of The Law., D Ndee, Dundee - [Practice View]

Consultation Summary Guidelines Add List Tasks View Window Help

Clinical Portal Appointments Guidelines Patient Select Patient Details Consultations Journal Priority Diagnosis Tests Therapy

Initial Filter

- 20 Problems
- 1997 Consultation
- 10 Drug Allergies & Adverse F
- 48 Recalls and Reviews
- Patient Preference
- 563 Medical History
- 550 Therapy
- 65 Lifestyle
- 59 Examination Findings
- 74 Immunisations
- 116 Miscellaneous
- 115 All Test Results
- 1 New Registration Exam
- 5 Child Health Surveillance
- 4 Maternity
- Well Person Clinic
- 13 HP Interventions
- 2 Elderly

Incomplete Registration

Health promotion

Interventions not recorded
Health Promotion out of date

Current Recalls

Immunisations Due in Next ...

- Influenza 26/02/2011 o/d
- Meningococcal ++ 27/11/2006 o/d
- Influenza 2nd 21/12/2009 o/d
- Influenza 2nd 09/12/2009 o/d
- Influenza 2nd 24/12/2009 o/d
- Diphtheria/Tet/Polio/Haemop...

Evidence of existing CVD

Palliative Care Plan Review...

Review was due on 08/03/2012.

Date	Description	6	3	3	3	3	3	3
30/04/12	H _i Referral to pharmacist							
25/04/12	H _a Referred by pharmacist fluticasone pMDI for EoE							
20/04/12	H _a Referred by pharmacist - rivaroxaban							
12/04/12	MUMPS Stage: 1 Given Routine Measure							
	RUBELLA Stage: 1 Given Routine Measure							
	MEASLES Stage: 1 Given Routine Measure							
	PNEUMOCOONJ13 Stage: 1 Given Routine Measure							
	HIB Stage: 1 Given Routine Measure Due: 10/05/2012							
	POLIO Stage: 1 Given Routine Measure Due: 10/05/2012							
	PERTUSSIS Stage: 1 Given Routine Measure Due: 10/05/2012							
	TETANUS Stage: 1 Given Routine Measure Due: 10/05/2012							
	DIPHTHERIA Stage: 1 Given Routine Measure Due: 10/05/2012							
	Paediatric surveillance checks Clinician: Mrs Carolyn Burnett							
	Keep well programme							
03/04/12	H _a Referred by pharmacist - lot search							MCARS
23/03/12	H _a Referred by pharmacist - mycophenolate							
13/03/12	H _i Referral to pharmacist - rosex cream and S/E's							
12/03/12	H _a Referred by pharmacist - Onbreeze							
09/03/12	Refer for Intermenstrual bleeding - irregular Action: 30/03/2012							SCREA
02/03/12	H _a Referred by pharmacist - vit k							MCARS
08/02/12	Palliative Care Plan: Clinician: Mrs Sam Creamer Date of agreement: 08/02/2012 GP to sign death certificate: No Review date: 08/03/2012							SCREA
	Repeat CHLORAMPHENICOL caps 250mg [ESSENTIAL] maximum 1 allowed Supply (1) capsule **** HOSPITAL ONLY. DO NOT PRESCRIBE ****							DGEMM
	Repeat CHLORAMPHENICOL caps 250mg maximum 1 allowed Supply (1) capsule **** HOSPITAL ONLY. DO NOT PRESCRIBE ****							
	H _a Referred by pharmacist - chloramphenicol message							MCARS
06/02/12	Recall on 06/02/2014 for Patient "call" admin. NDS with Mrs Sam Creamer Status: Outstanding							SCREA

Read Term - Add [OK] [Cancel]

Community Partner Links Patient Documents Workflow Intry Dr F Sullivan Surgery 03/05/12 13:12 | 13:12



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COPD Quality Indicators v20.0.00

Quality and Outcomes Framework COPD Quality Indicators v20.0.00

Chronic Obstructive Pulmonary Disease (COPD) Register

NEWLY DIAGNOSED COPD: Confirmation by post bronchodilator spirometry

FeV1

Quality and Outcomes Framework Smoking Quality Indicators v20.0.00

Current Smoking Status

Smoking Cessation Advice

Annual Review

Flu Vaccination Indicated for Vulnerable Patients

COPD Recall

Respiratory Recall for COPD Nurses

Non COPD Recall - screening review for DFG

References...

Last Updated - July 2011

Medicines

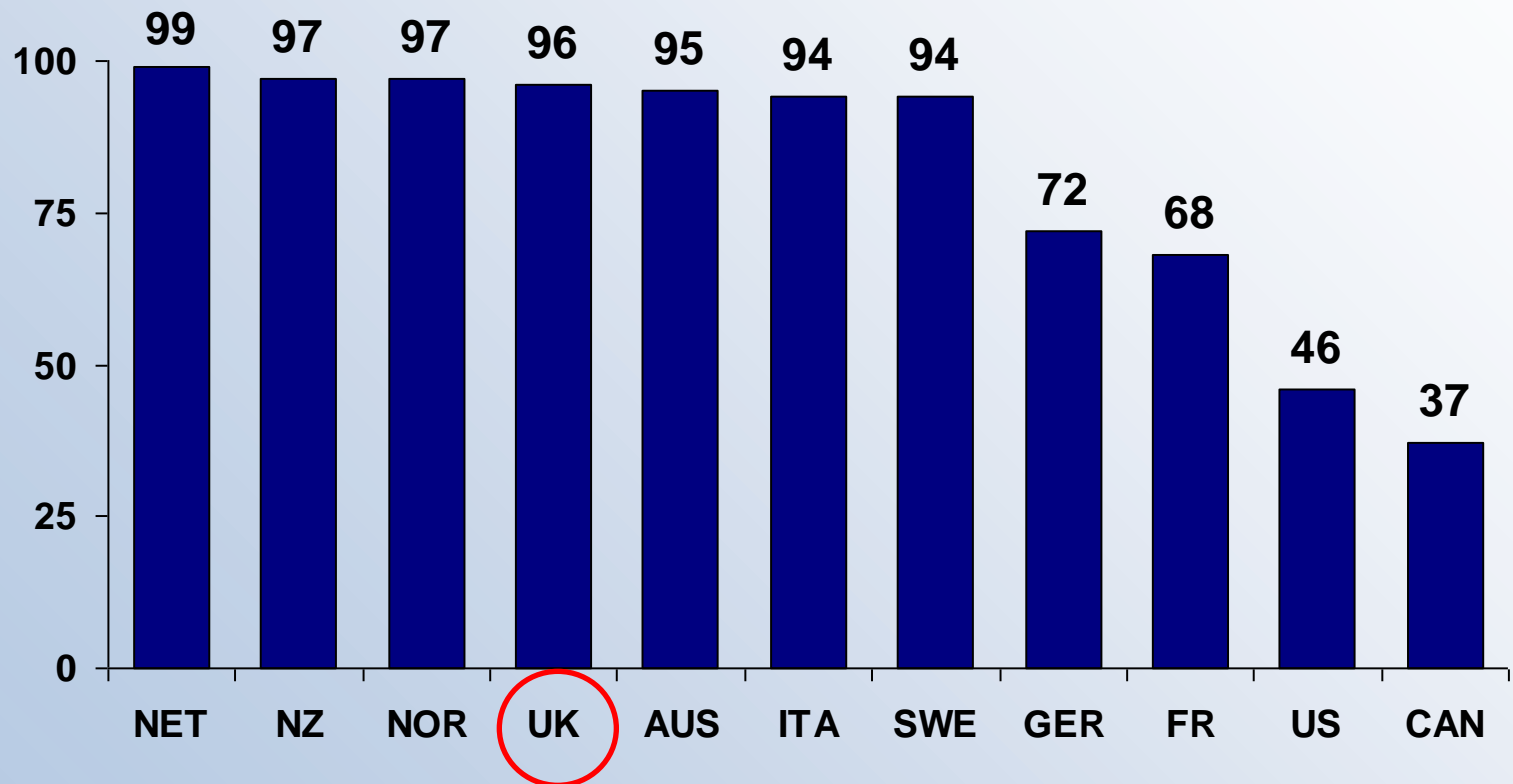
Education
patient leaflets

Professional
information & articles

Services ^{medical}

GP Use Electronic Medical Records*

Percent



* Not including billing systems.

Source: 2009 Commonwealth Fund International Health Policy Survey of Primary Care Physicians.

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Healthcare Challenges

The EU has a longstanding strategy to promote greater safety and productivity for EU healthcare via advanced Information Communication Technologies (ICT).

- Clinical Research In Crisis
 - Subjects hard to identify
 - Complex, costly CRFs with duplicate data entry
 - Research not cost-effective in EU
- Diagnostic Error
 - 60% of litigation claims against GPs*
 - Failure of Decision Support Systems for Diagnosis

TRANSFoRm's Objectives

The project will drive the advanced integration of clinical practice and research data to:

- Support clinical care on diagnosis and monitoring of patients
- Support clinical research with participant identification and evaluation of outcomes
- Support epidemiological research with large scale phenotype-genotype association studies and follow-up on trials

TRANSFoRm Use Cases

To support TRANSFoRm benefit realisation, we will partner with eHR vendors to validate 3 well-defined use cases.

- **Shape and inform the development of the ICT tools**
- **Support the realisation of TRANSFoRm vision by :**
 - Demonstrating the feasibility of conducting very large and long-term studies at low cost
 - Demonstrating the DSS prototype's ability to improve diagnostic accuracy and patient safety

Type II Diabetes

Research Question: Are well selected SNPs in T2D patients associated with variations in drug response to oral antidiabetics?

Tool: Data federation tools for epidemiological analysis & follow-up

GORD

Research Question: What gives the best symptom relief and improvement of quality of life (QoL): continuous or on demand PPI use?

Tool: Electronic CRF embedded in the eHR

Decision Support

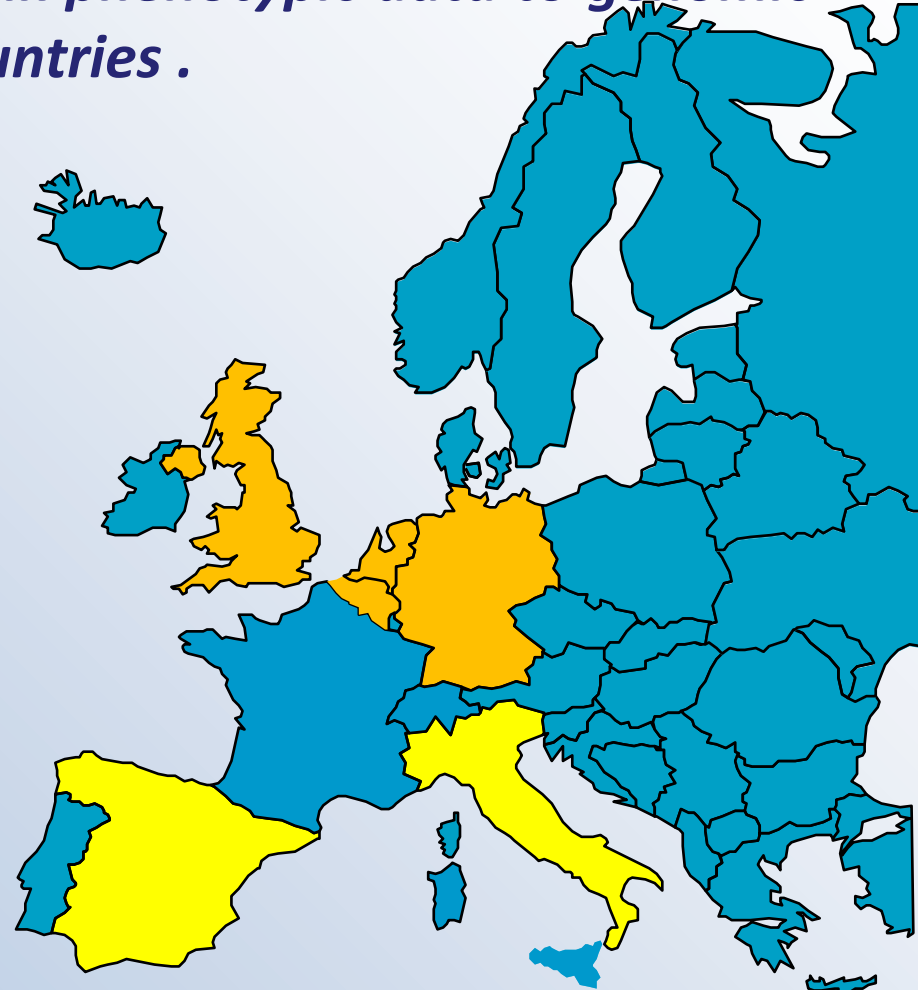
Experimental Study: Comparing approaches to diagnostic support: 'Suggesting' vs. 'Alerting' vs. Control

Tool: Decision Support System (DSS)

Group 1 – Use Case 1

Group 1 will be actively engaged with the validation of the Type 2 Diabetes Use Case which will link phenotypic data to genomic data (genetic databases) in 5 countries .

Research Database	Country
Go-Darts Tayside – Scottish Health Information Programme	Scotland
GPRD	UK
Nivel	Netherlands
Institute of Primary Care at the Medical School Hannover	Germany
Intego	Belgium
SNAMID NAzionale and Gruppo Cure Primiare of Valmadrera *	Italy
SIDIAP – Institut Catala de la Salut *	Spain



* Participation depending on their readiness

Demonstrations

In addition to the use cases, we will also partner with the Pharmaceutical Industry to deploy the project tools in the context of a clinical trial as a demonstration and proof of concept.

We will run two demonstrations:

1. Test TRANSFoRm ability to support the identification of eligible patients in primary care records
2. Test TRANSFoRm interoperability with clinical trial data management software allowing clinical data capture

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TRANSFoRm Anticipated Benefits

Support quicker and more economic recruitment and follow-up of Randomised Clinical Trials...

...with an integrated eHR interface that enables the **rich capture of clinical data, including symptoms and signs** and a **query workbench that supports the identification of patient eligible to participate in clinical trials**

Improve patient safety...

...by providing not only a **diagnosis support tool** but also a **Adverse Event (AE) management tool**

Support large scale phenotype-genotype association studies and follow-up on trials...

... through **interoperability of distributed eHR data and clinical data repositories** that maintain provenance, confidentiality and security

Drive the integration and re-use of clinical data stored in different eHR systems...

... with software tools and web-services that support clinical research by enabling **use of controlled vocabulary and standardised data elements**

Enhance uptake of eHR systems that offer support for clinical care and research...

... by allowing eHR vendors and data integrators **to reach more customers**

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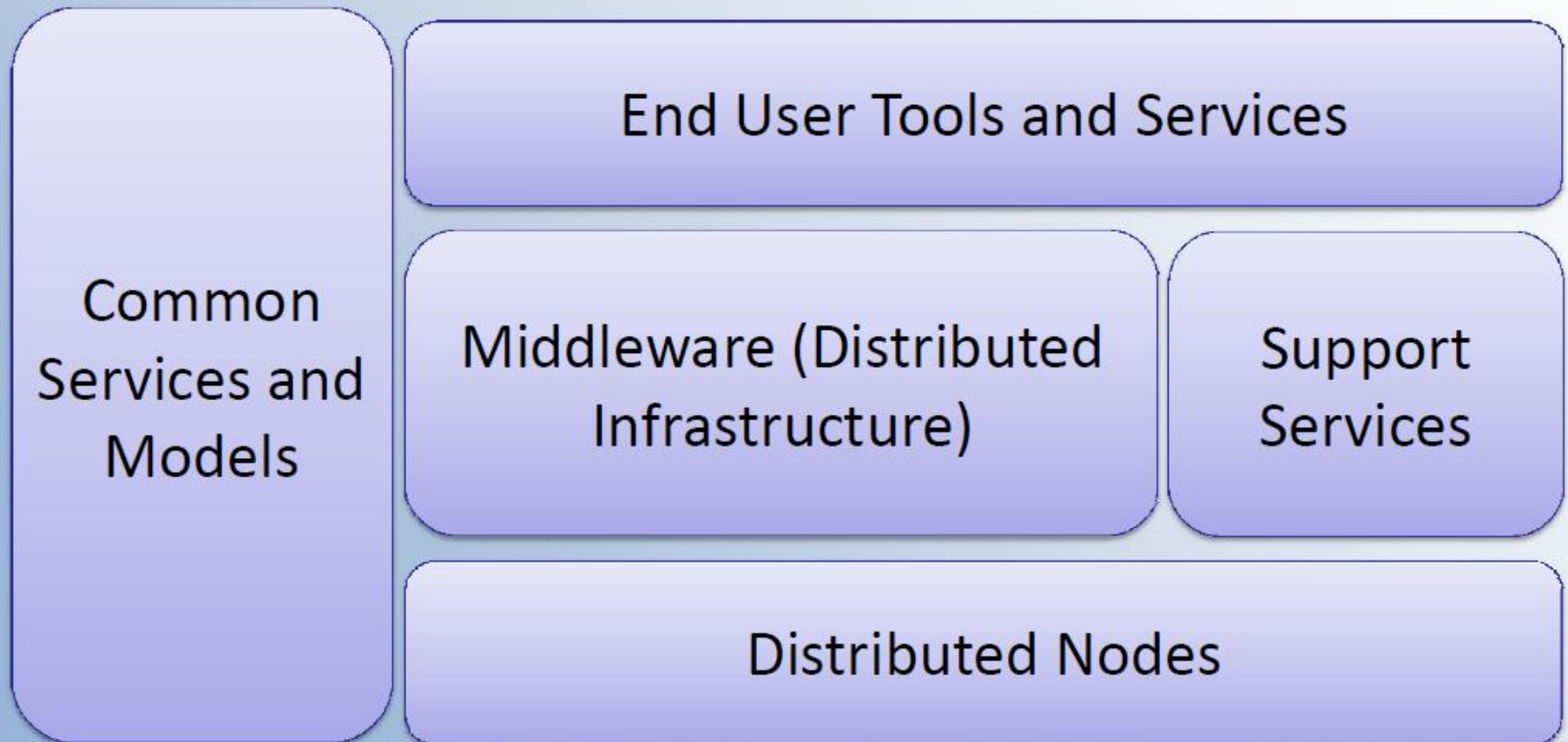
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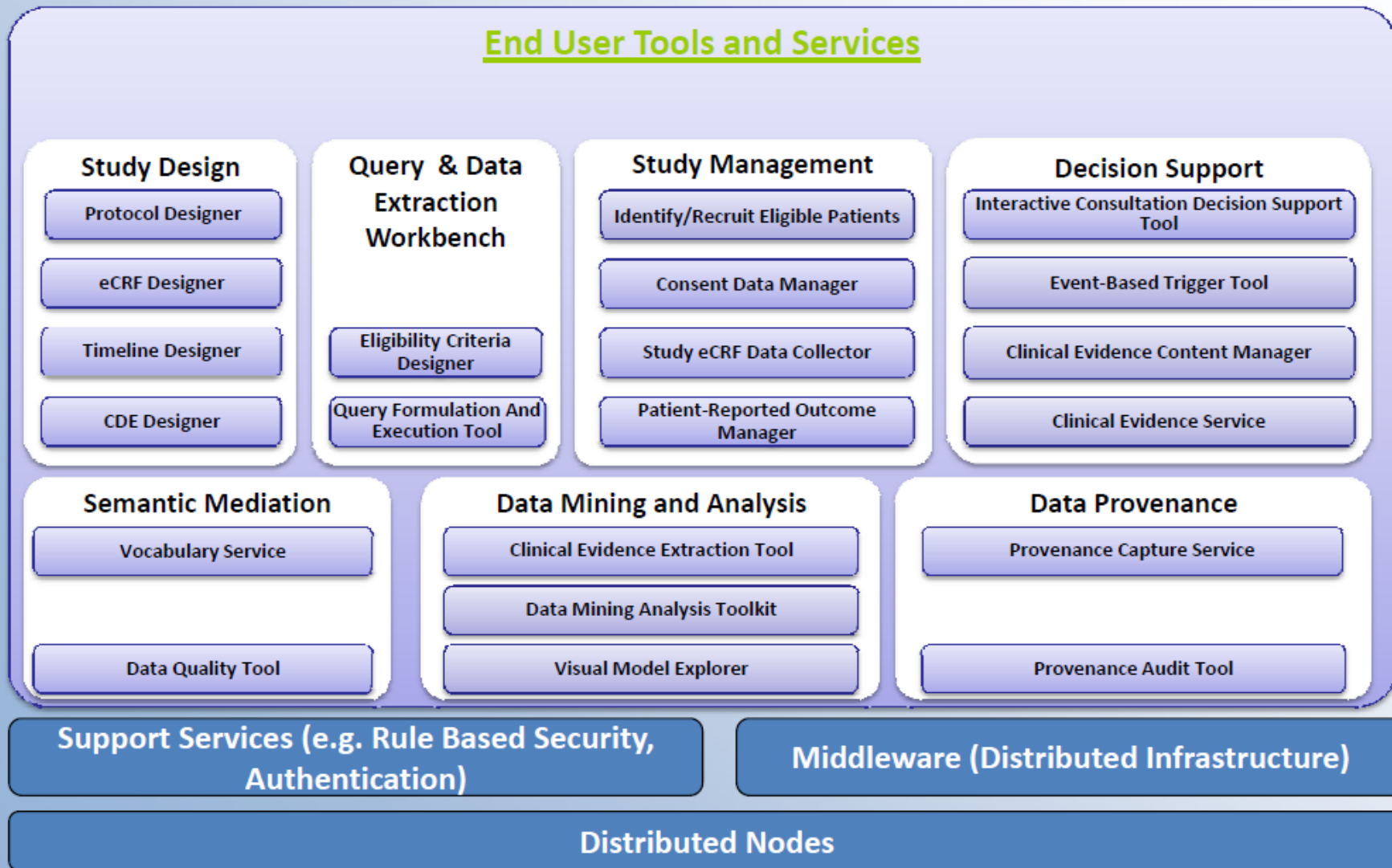
Tools

Overall Architecture 1/2



Overall Architecture 2/2

End User Tools and Services

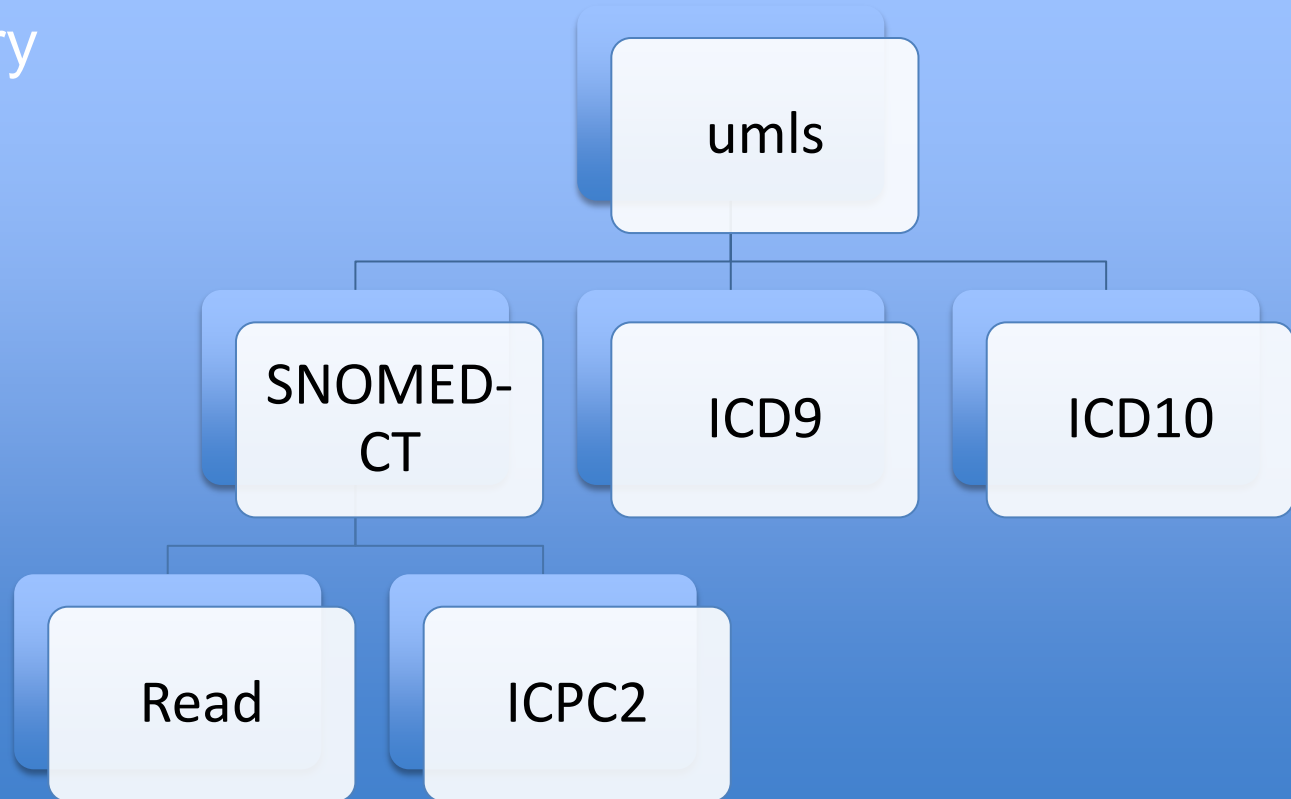


Interoperability

- Of concepts
 - Development of PCROM and map to BRIDG 3
 - Detailed Clinical Models/Archetypes
- Of Terminology
 - LexGRID 5.0 for vocabulary services
- Of Language
 - Essential in an EU context

Controlled vocabulary

vocabulary
service



Semantic Interoperability Approach

TRANSFoRm aims to establish semantic interoperability between eHR datasets and clinical research data requirements, including linkage to other data such as genomic data. This will be achieved through:

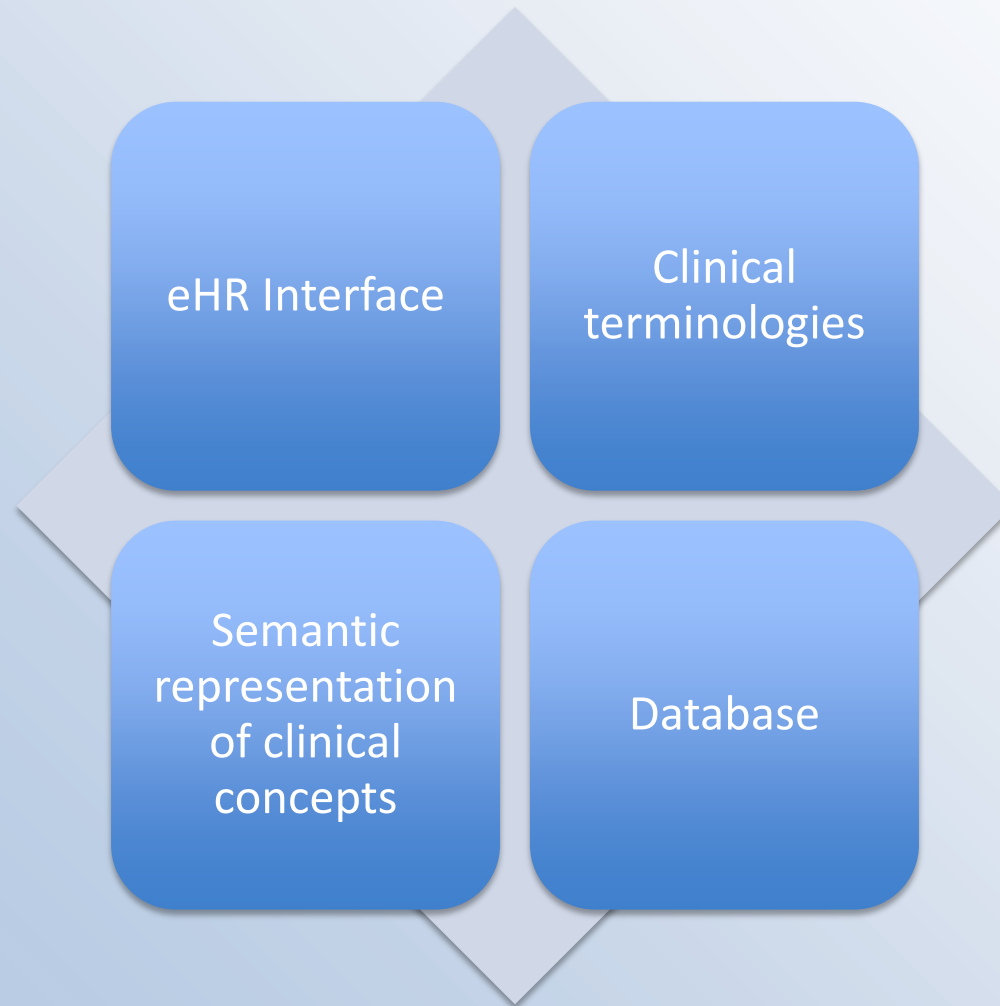
- Combination of models AND terminology mapping to a reference terminology via a core terminology service
- Mapping of clinical data from eHR or data repository through a Clinical Data Integration Model (CDIM)
- Representation of research Data via Clinical Research Information Model (CRIM)

Adoption Of Standards

The approach taken by TRANSFoRm is to utilise relevant open-source software and standards and to use a modular approach to provide maximum integration with existing (but incomplete) solutions at both EU and International level.

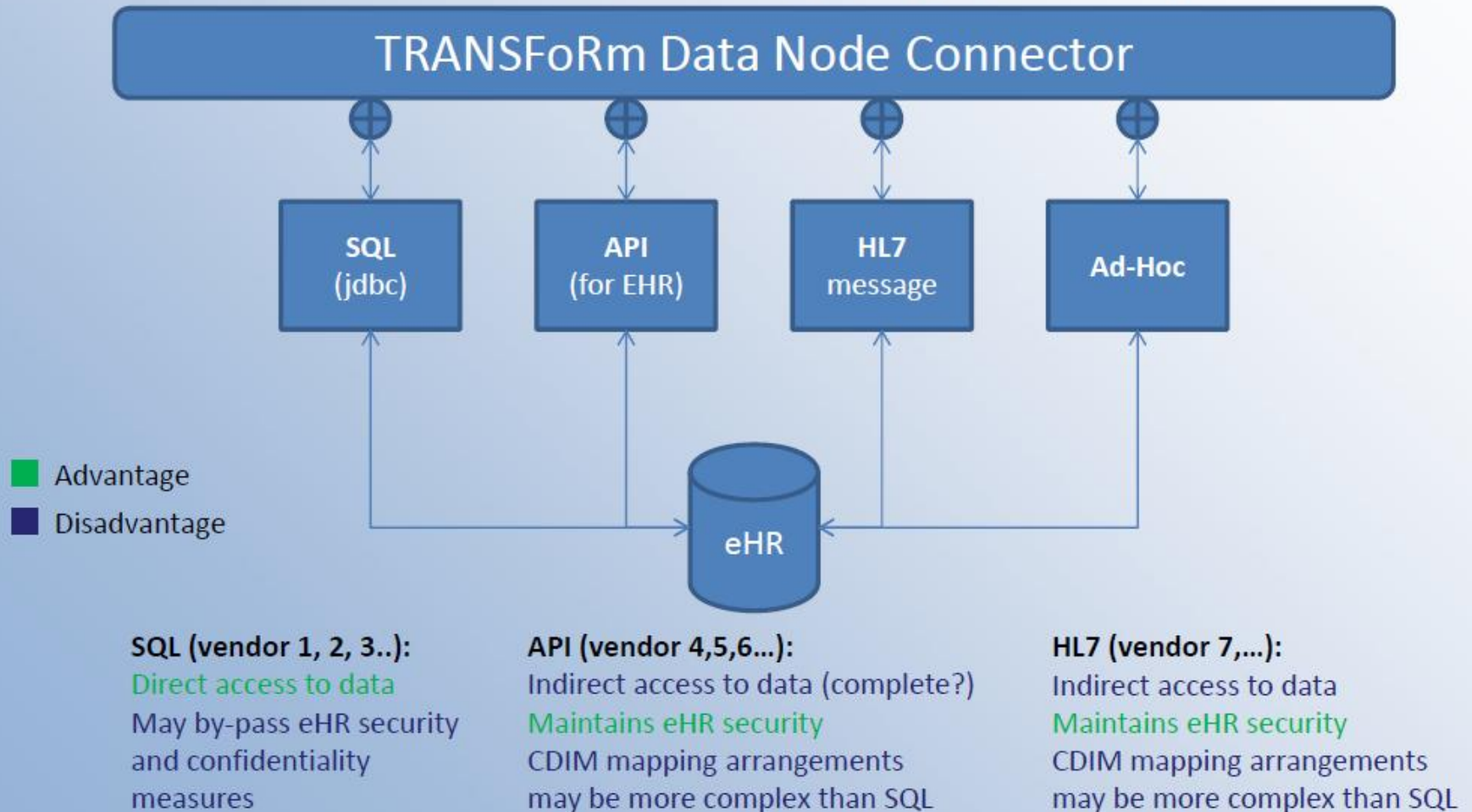
- **Reference Information Models And Terminologies:**
 - Clinical Research Information Model (PCROM v3)
 - Clinical Data Integration Model - subset of HL7, EPSOS, i2b2, comparison underway
- **Standard Terminology Services:**
 - Lex EVS 6 referencing to UML-S
 - ICD, SNOMED-CT, [Read, ICPC2 added via project]

CEN/ISO 13606: a rigorous and stable information architecture.



Compatibility with eHR Systems

Different models of data integrations are being proposed with direct access to the database being the preferred option.



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Web-Based Interface

TRANSFoRm EVS

147.188.87.176:8080/evs/

TRANSFoRm EVS

Type II diabetes UMLS ReadCodes2

Diabetes Mellitus, Non-Insulin-Dependent

Diabetes Type II (non-insulin-dependent) associated with renal failure

Type II diabetes mellitus uncontrolled

Insulin-treated non-insulin-dependent diabetes mellitus

Diabetes mellitus autosomal dominant type II (disorder)

Ketoacidosis in type II diabetes mellitus

Non-insulin-dependent diabetes mellitus with renal complications

Diabetic oculopathy associated with type II diabetes mellitus

Non-insulin-dependent diabetes mellitus with neurological complications

Type II diabetes mellitus with multiple complications

Type II diabetes mellitus without complication

Type II diabetes mellitus with ulcer

Type II diabetes mellitus with gangrene

Non-insulin-dependent diabetes mellitus with retinopathy

Type II diabetes mellitus - poor control

Super concepts: Sub concepts:

Diabetes Mellitus Diabetes mellitus type 2 in obese

Disorder of endocrine pancreas NIDDM with peripheral circulatory disorder

DISEASES OF THE ENDOCRINE PANCREAS INCLUDING DIABETES Diabetes mellitus type 2 in nonobese

Duplicate concept Insulin-resistant diabetes mellitus AND acanthosis nigricans

Ambiguous concept Insulin-treated non-insulin-dependent diabetes mellitus

Diseases Component Diabetes mellitus, adult onset, with hyperosmolar

UMLS Code (CUI): C0011860

Semantic Type: Disease or Syndrome

Definition: A type of diabetes mellitus that is characterized by insulin resistance or desensitization and increased blood glucose levels. This is a chronic disease that can develop gradually over the life of a patient and can be linked to both environmental factors and heredity.

Source vocabularies: Language:

Source	Language	Code	Text
ICD10	ENG	E11	Non-insulin-dependent diabetes mellitus
ICPC2EENG	ENG	T90	Diabetes non-insulin dependent
ICPC2ICD10ENG	ENG	MTHU003788	adult-onset; diabetes
ICPC2ICD10ENG	ENG	MTHU022756	diabetes
ICPC2ICD10ENG	ENG	MTHU022756	diabetes; adult-onset
ICPC2ICD10ENG	ENG	MTHU022796	diabetes; maturity-onset
ICPC2ICD10ENG	ENG	MTHU022815	diabetes; NIDDM
ICPC2ICD10ENG	ENG	MTHU022816	diabetes; non-insulin-dependent
ICPC2ICD10ENG	ENG	MTHU022817	diabetes; nonketotic
ICPC2ICD10ENG	ENG	MTHU022833	diabetes; type II
ICPC2ICD10ENG	ENG	MTHU047774	maturity-onset; diabetes
ICPC2ICD10ENG	ENG	MTHU052916	NIDDM; diabetes
ICPC2ICD10ENG	ENG	MTHU063298	non-insulin-dependent; diabetes
ICPC2ICD10ENG	ENG	MTHU053299	nonketotic; diabetes
ICPC2ICD10ENG	ENG	MTHU077306	type II; diabetes
ICPC2P	ENG	T90005	non insulin dependent diabetes
ICPC2P	ENG	T90007	adult onset diabetes



Query & Data Extraction Workbench

Below is an example screenshot of a prototype of the Query Workbench with TRANSFoRM Vocabulary Service integration.

The screenshot displays the EPCRN Study Designer v1.0 (Alpha) interface. The main window is titled "SQL Query" and contains the following SQL code:

```
SELECT COUNT(DISTINCT C.ANON_ID)
FROM CCR_XML C, CCR_PROBLEMS P
WHERE
C.ANON_ID = P.ANON_ID
AND
/* --- Inclusion Criteria --- */
( /* --- Age >= 16 years and Age <= 60 years --- */
  CURDATE() - INTERVAL 16 YEAR >= DATE(EXTRACTVALUE(C.CCR_XML_STRING, 'XPATH:CCRXI'))
  AND
  CURDATE() - INTERVAL 60 YEAR <= DATE(EXTRACTVALUE(C.CCR_XML_STRING, 'XPATH:CCRXI'))
)
AND
/* --- Both male and female --- */
EXTRACTVALUE(C.CCR_XML_STRING, 'XPATH:CCRXI') = 'M' OR EXTRACTVALUE(C.CCR_XML_STRING, 'XPATH:CCRXI') = 'F'
AND
/* --- Problem Diabetes Mellitus --- */
EXTRACTVALUE(P.CCR_XML_STRING, 'XPATH:CCRXI') = 'Diabetes Mellitus'
/* --- Exclusion Criteria ---
```

A "Criteria Text" window is open, showing the following text:

```
Include Male and Female Patients with age >= 16 AND <= 60
that have ANY of the following conditions:
-Active Diabetes Mellitus, Non-Insulin-Dependent
AND
Exclude No Patients
```

A "Count Subject Result" table is displayed, showing the following data:

Research Network	Found Subject Count	Status	Total Time
<input type="checkbox"/> Bham	227		00:01:28
<input type="checkbox"/> LSP-Gateway	227		00:01:28

A "Finished" dialog box is open, displaying the message: "Total 1 query has finished." with an "OK" button.



Decision Support Tool

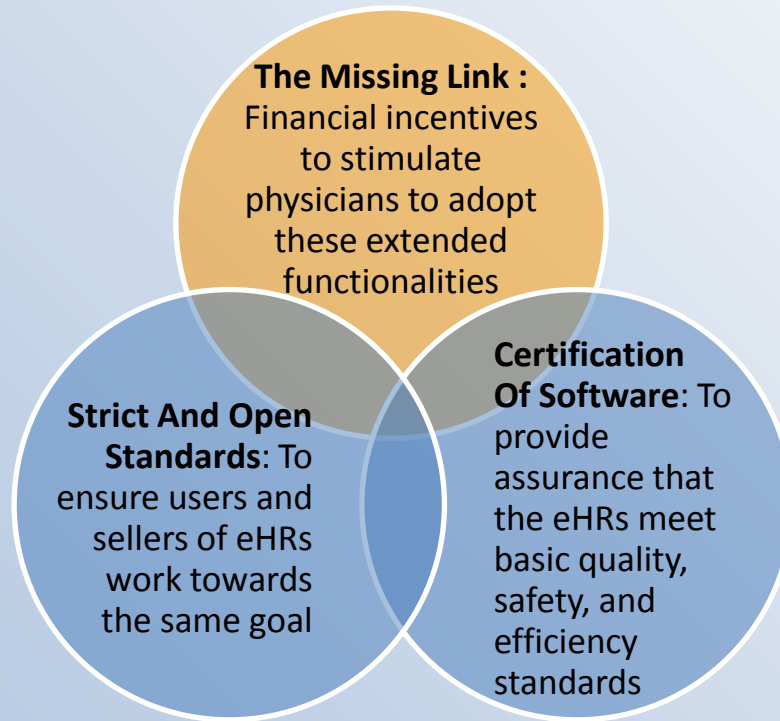
The DDS uses Sesame which provides an application platform to host the ontology of evidence which can be queried via a web based service.

Query Repository	Query Result (
Query Language: SPARQL ▾	Limit results: 100 ▾											
Query: <pre>PREFIX rdf:<http://www.w3.org/1999/02 PREFIX swrlb:<http://www.w3.org/2003/ PREFIX owl:<http://www.w3.org/2002/07 PREFIX foaf:<http://xmlns.com/foaf/0. PREFIX dcterms:<http://purl.org/dc/te PREFIX xsd:<http://www.w3.org/2001/XM PREFIX evd:<http://www.semanticweb.or PREFIX dctype:<http://purl.org/dc/dcm PREFIX swrl:<http://www.w3.org/2003/1 PREFIX rdfs:<http://www.w3.org/2000/0 PREFIX dc:<http://purl.org/dc/element SELECT ?anyEvidenceCue WHERE {?anyEvidenceCue evd:isCueOf evd:UrinaryTractInfection.}</pre>	<table border="1"> <tr><td>AnyEvidenceCue</td></tr> <tr><td>ClinicalEvidence:Fever</td></tr> <tr><td>ClinicalEvidence:UrineCloudiness</td></tr> <tr><td>ClinicalEvidence:Dysuria</td></tr> <tr><td>ClinicalEvidence:NewSexualPartner</td></tr> <tr><td>ClinicalEvidence:Nocturia</td></tr> <tr><td>ClinicalEvidence:DipstickUrinalysis</td></tr> <tr><td>ClinicalEvidence:PregnancyTest</td></tr> <tr><td>ClinicalEvidence:PreviousUTI</td></tr> <tr><td>ClinicalEvidence:SexualActivity</td></tr> <tr><td>ClinicalEvidence:UrineSmell</td></tr> </table>	AnyEvidenceCue	ClinicalEvidence:Fever	ClinicalEvidence:UrineCloudiness	ClinicalEvidence:Dysuria	ClinicalEvidence:NewSexualPartner	ClinicalEvidence:Nocturia	ClinicalEvidence:DipstickUrinalysis	ClinicalEvidence:PregnancyTest	ClinicalEvidence:PreviousUTI	ClinicalEvidence:SexualActivity	ClinicalEvidence:UrineSmell
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ClinicalEvidence:Dysuria												
ClinicalEvidence:NewSexualPartner												
ClinicalEvidence:Nocturia												
ClinicalEvidence:DipstickUrinalysis												
ClinicalEvidence:PregnancyTest												
ClinicalEvidence:PreviousUTI												
ClinicalEvidence:SexualActivity												
ClinicalEvidence:UrineSmell												
Limit results: 100 ▾ <input checked="" type="checkbox"/> Include inferred statements <input type="button" value="Execute"/>												



Critical Success Factors

In addition to the current efforts on standards and certification, we believe it would be critical to define incentives to stimulate physicians to adopt extended eHR functionalities such as these provided by TRANSFoRm.



eHR Adoption in US

The Obama Administration's Health IT program intends to use federal investments to stimulate the market of electronic health records.



TRANSFoRm Stakeholders

...to key healthcare stakeholders.

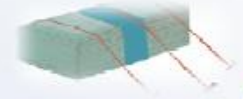
Pharmaceutical Industry

- Improve targeting the right patient population & indication
- Increase number effective sites, enrollment rate, shorten trial time & cost
- Enhance patient safety



Healthcare Representatives

- Address wellness, disease prevention, & disease management
- Prevent illness & promote adherence to treatment regimens



... And for patients, faster drug to market, enhanced access to drug information and improved personalized treatment capability

eHR System Providers

- Enhance the adoption of eHR systems by providing an easier, more accurate, and faster means of entering data



Data Providers / Research Facilitators

- Support of community-based studies
- Extend reach to supranational level
- Build stronger scientific evidence base for primary care



eHR Providers & Data Integrators

We have started to engage with eHR providers & data integrators.

