

*TMF-Workshop Register-Toolbox 20.01.2014 Frankfurt am Main*

# **i2b2/SHRINE**

## **Eine alternative Registerplattform**

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## "Klassische" Registerplattformen

- Zentralistischer Ansatz
  - Daten werden in einem gemeinsamen, zentral betriebenen System erhoben
  - Web-basierte Eingabe bei den teilnehmenden Kliniken
- Vorteile
  - mit jedem Remote Data Entry-System umsetzbar
  - differenzierte Plausibilitätskontrollen schon während der Eingabe möglich
  - alle Detaildaten (MDAT) sind direkt in der Registerstelle verfügbar
- Nachteile
  - aktive Neueingabe von Daten nötig (ggf. redundant zum Routineprozess)
  - teilnehmende Kliniken haben keine direkte Kontrolle über die weitere Nutzung der von ihnen eingegebenen Daten

## Alternative: Verteilte Registerplattform

- **Föderierter Ansatz**
  - Daten werden lokal im Routineprozess erhoben
  - Aufbereitung der Daten in einem lokalen Datamart
  - Bereitstellung für einen begrenzten (aggregierten) Zugriff von außen
  - Ergebnis: "virtuelles" Register mit Abfrage der lokal vorhandenen Daten
- **Vorteile**
  - einmalige Erhebung der Daten direkt im Routineprozess
  - ggf. auch Zugriff auf bereits vorhandene historische Datenbestände
  - Datenhoheit verbleibt bei den teilnehmenden Kliniken
- **Nachteile**
  - benötigte Datenelemente müssen im Routineprozess auch erfasst werden
  - eingeschränkte Plausibilitätskontrollen bei der Eingabe
  - Zugriff auf Detaildaten erfordert separate Rückfrage bei den beteiligten Kliniken

## i2b2/SHRINE

- Plattform für die Abfrage biomedizinischer Daten
  - Ziel: intuitive Nutzung für klinische Anwender
  - Konzepthierarchie und Faktendaten
  - einfache Konstruktion von Abfragen per Drag & Drop
  - einfaches, generisches Datenmodell
  - Vernetzung mehrerer i2b2-Instanzen mit SHRINE
- Herkunft
  - NIH-Förderung von 2004-2015
  - Entwicklung an der Harvard University
  - Bereitstellung als Open Source Software
- Verbreitung
  - große internationale Community, organisiert in Academic User Groups
  - zunehmende Nennung in Publikationen (PubMed 01/2014: 164 Citations)

# Demo (Video/Screenshots)

**i2b2 Query & Analysis Tool** Project: i2b2 Demo User: i2b2 User Find Patients | Analysis Tools | Message Log | Help | Logout

**Navigate Terms** Find Terms

- Clinical Trials
- Custom Metadata
- Demographics
- Diagnoses
- Expression Profiles Data
- Laboratory Tests
- Medications
- Procedures
  - ICD9 (Inpatient) - 102
    - Diagnostic and nonsurgical procedures - 60
      - Obstetrical procedures - 7
      - Operations on cardiovascular system - 15
      - Operations on digestive system - 20
      - Operations on ear - 1
      - Operations on endocrine system - 5
      - [Operations on eye - 0]
      - Operations on female genital system - 10
      - Operations on hemic and lymphatic system - 9
      - Operations on integument - 17
      - Operations on male genital organs - 16
      - Operations on musculoskeletal system - 29
      - Operations on nervous system - 11
      - Operations on nose, mouth and pharynx - 8
      - Operations on respiratory system - 7
      - Operations on urinary system - 3
      - [Procedures and interventions, NEC - 0]
- Providers
- Reports
- Visit Details

**Query Tool**

Query Name: \_\_\_\_\_

Temporal Constraint: Treat all groups independently

Group 1			Group 2			Group 3		
Dates	Occurs > 0x	Exclude	Dates	Occurs > 0x	Exclude	Dates	Occurs > 0x	Exclude
Treat Independently			Treat Independently			Treat Independently		
Circulatory system - 66			35-44 years old - 29 45-54 years old - 11 55-64 years old - 7			Operations on cardiovascul		

one or more of these AND one or more of these AND one or more of these

Run Query Clear Print Query 3 Groups New Group

**Query Status**

Navigate Terms | Find Terms

- Clinical Trials
- Custom Metadata
- Demographics
- Diagnoses
  - Circulatory system - 66
    - Admit Diagnosis
    - Principal Diagnosis
    - Secondary Diagnosis
  - [Acute Rheumatic fever - 0]
  - Arterial vascular disease - 6
  - [Cerebrovascular disease - 0]
  - Chronic Rheumatic heart disease - 5

Workplace

- SHARED
- demo

Previous Queries

- Hypertensive di@10:17:44 [6-17-2013] [demo]
- Hyper-Antih-Chemi@10:05:04 [6-17-2013] [demo]
- Hyperte-Antihyp@10:04:16 [6-17-2013] [demo]
- Hypertensive di@10:02:05 [6-17-2013] [demo]
- Female- 18-34@10:57:18 [6-14-2013] [demo]
- Laboratory\_Test@10:52:05 [6-12-2013] [demo]

Query Tool

Query Name: Hypertensive di@10:17:44

Temporal Constraint: Treat all groups independently

Group 1			Group 2			Group 3		
Dates	Occurs > 0x	Exclude	Dates	Occurs > 0x	Exclude	Dates	Occurs > 0x	Exclude
Treat Independently			Treat Independently			Treat Independently		
Hypertensive disease - 60								

one or more of these    AND    drop a term on here

Run Query | Clear | Print Query | 1 Group | New Group

Query Status

**Finished Query: "Hypertensive di@10:17:44"** [17.2 secs]  
 Compute Time: 12 secs

**Patient Set for "Hypertensive di@10:17:44"**

**Number of patients for "Hypertensive di@10:17:44"**  
 patient\_count: 40

**Navigate Terms** | Find Terms

- Clinical Trials
- Custom Metadata
- Demographics
- Diagnoses
  - Circulatory system - 66
    - Admit Diagnosis
    - Principal Diagnosis
    - Secondary Diagnosis
  - [Acute Rheumatic fever - 0]
  - Arterial vascular disease - 6
  - [Cerebrovascular disease - 0]
  - Chronic Rheumatic heart disease - 5
  - Disease of capillaries - 1
  - [Diseases of pulmonary circulation - 0]
  - Hypertensive disease - 40
  - Ischemic heart disease - 17
  - Other forms of heart disease - 35

**Workplace**

- SHARED
- demo

**Previous Queries**

- Hypertensive di@10:17:44 [6-17-2013] [demo]
- Results of Hypertensive di@10:17:44 [6-17-2013] [demo]
  - Patient Set for "Hypertensive di@10:17:44" - FINISHED
  - Number of patients for "Hypertensive di@10:17:44" - FINISHED
- Hyper-Antih-Chemi@10:05:04 [6-17-2013] [demo]
- Hyper-Antih-Chemi@10:04:16 [6-17-2013] [demo]

**Demographics**

Specify Data | View Results | Plugin Help

**Patient Count:** 40

**Age in Years**

10-20	3	
20-30	4	
30-40	5	
40-50	8	
50-60	4	
60-70	10	
70-80	3	
80-90	3	

**Sex**

F	17	
M	23	

**Race**

asian	7	
black	16	
hispanic	10	
indian	3	
white	4	

**Language**

english	14	
german	17	
spanish	9	

**Plugins**

Detailed List View | Category: ALL

- ExportXLS**  
This plugin populates a table of selectable concepts/observations and provides the possibility to download the result as a file.
- Demographics (1 Patient Set) - Simple Counts**  
This plugin displays a demographic break-down of a Patient Set.

**Navigate Terms**

**Find Terms**

- Rx Sig
- [Alternative medicines - 0]
- Anti-infectives - 78
- Antihyperlipidemic agents - 7
- Antineoplastics - 3
- [Biologicals - 0]
- Cardiovascular agents - 19
- Central nervous system agents - 78
- Coagulation modifiers - 11
- Gastrointestinal agents - 43
- Hormones - 49
- Immunologic agents - 3
- Miscellaneous agents - 13

**Workplace**

- SHARED
- demo

**Previous Queries**

- Hyperte-Antihyp@10:20:29 [6-17-2013] [demo]
- Hypertensive di@10:17:44 [6-17-2013] [demo]
- Hyper-Antih-Chemi@10:05:04 [6-17-2013] [demo]
- Hyperte-Antihyp@10:04:16 [6-17-2013] [demo]
- Hypertensive di@10:02:05 [6-17-2013] [demo]
- Female-18-34@10:57:18 [6-14-2013] [demo]

**Query Tool**

Query Name:

Temporal Constraint:

Group 1			Group 2			Group 3		
Dates	Occurs > 0x	Exclude	Dates	Occurs > 0x	Exclude	Dates	Occurs > 0x	Exclude
Treat Independently			Treat Independently			Treat Independently		
Hypertensive disease - 40			Antihyperlipidemic agents -					
one or more of these			AND			one or more of these		
			AND			drop a term on here		

**Run Query** | **Clear** | **Print Query** | 2 Groups | **New Group**

**Query Status**

**Finished Query: "Hyperte-Antihyp@10:20:29"** [13.4 secs]  
 Compute Time: 11 secs

**Patient Set for "Hyperte-Antihyp@10:20:29"**

**Number of patients for "Hyperte-Antihyp@10:20:29"**  
 patient\_count: 6



### Navigate Terms

### Find Terms

- ⊕ Blood Gases/Oximetry - 2
- ⊕ CSF Chemistries - 6
- ⊕ Cardiac Tests - 64
- ⊕ Endocrine Studies - 40
- ⊕ [Fetal Lung Maturity - 0]
- ⊕ Fluid Chemistries - 3
- ⊕ General Chemistries - 124
- ⊕ Hemoglobin - 15
- ⊕ Lipid Tests - 96
- ⊕ Liver Function Tests - 113
- ⊕ Lytes/Renal/Glucose - 123
- ⊕ Thyroid Studies - 81
- ⊕ Urine Chemistries Random - 8

### Workplace

- ⊕ SHARED
- ⊕ demo

### Previous Queries

- ⊕ Hyper-Antih-Lipid@10:21:37 [6-17-2013] [demo]
- ⊕ Hyperte-Antihyp@10:20:29 [6-17-2013] [demo]
- ⊕ Hypertensive di@10:17:44 [6-17-2013] [demo]
- ⊕ Hyper-Antih-Chemi@10:05:04 [6-17-2013] [demo]
- ⊕ Hyperte-Antihyp@10:04:16 [6-17-2013] [demo]
- ⊕ Hypertensive di@10:02:05 [6-17-2013] [demo]

### Query Tool

Query Name: Hyper-Antih-Lipid@10:21:37

Temporal Constraint: Treat all groups independently

Group 1			Group 2			Group 3		
Dates	Occurs > 0x	Exclude	Dates	Occurs > 0x	Exclude	Dates	Occurs > 0x	Exclude
Treat Independently			Treat Independently			Treat Independently		
Hypertensive disease - 40			Antihyperlipidemic agents -			Lipid Tests - 96		
one or more of these			AND			one or more of these		
AND			one or more of these			AND		
one or more of these			AND			one or more of these		

Run Query | Clear | Print Query | 3 Groups | New Group

### Query Status

**Finished Query: "Hyper-Antih-Lipid@10:21:37"** [5.4 secs]  
 Compute Time: 3 secs

**Patient Set for "Hyper-Antih-Lipid@10:21:37"**

**Number of patients for "Hyper-Antih-Lipid@10:21:37"**  
 patient\_count: 6

**Navigate Terms** Find Terms

- Clinical Trials
- Custom Metadata
- Demographics
- Diagnoses
- Expression Profiles Data
- Laboratory Tests
- Medications
- Procedures
- Providers
- Reports
- Visit Details

**Workplace**

- SHARED
  - demo

**Previous Queries**

- Hyper-Antih-Lipid@10:21:37 [6-17-2013] [demo]
- Hyperte-Antihyp@10:20:29 [6-17-2013] [demo]
- Hypertensive di@10:17:44 [6-17-2013] [demo]
- Hyper-Antih-Chemi@10:05:04 [6-17-2013] [demo]
- Hyperte-Antihyp@10:04:16 [6-17-2013] [demo]
- Hypertensive di@10:02:05 [6-17-2013] [demo]

**Timeline**

Specify Data View Results Plugin Help

Drop a Patient Set and one or more Concepts (Ontology Terms) into the input boxes below, and then click the "View Results" tab to view a timeline showing when those concepts were observed in the selected patient set.

**Patient Set:** Hyper-Antih-Lipid@10:21:37 [6-17-2013] [demo] [PATIENT]

**Concept(s):**

Diagnoses
Expression Profiles Data
Laboratory Tests
Medications
Procedures
Reports

Click a concept to remove it from the list.

**Plugins**

Detailed List View Category: ALL

- Timeline**  
This plugin creates a visual representation of when selected observations occur within a given patient set.
- Project Request**  
This plugin is used to generate a request for a new project based on concepts, patients and sets..

### Navigate Terms

Find Terms

- Clinical Trials
- Custom Metadata
- Demographics
- Diagnoses
- Expression Profiles Data
- Laboratory Tests
- Medications
- Procedures
- Providers
- Reports
- Visit Details

### Workplace

- SHARED
- demo

### Previous Queries

- Hyper-Antih-Lipid@10:21:37 [6-17-2013] [demo]
- Hyperte-Antihyp@10:20:29 [6-17-2013] [demo]
- Hypertensive di@10:17:44 [6-17-2013] [demo]
- Hyper-Antih-Chemi@10:05:04 [6-17-2013] [demo]
- Hyperte-Antihyp@10:04:16 [6-17-2013] [demo]
- Hypertensive di@10:02:05 [6-17-2013] [demo]

### Timeline

Specify Data | View Results | Plugin Help

<<< start: 1 size: 10 go >>> zoom: - + pan: < >

4/3/1997 11/11/2003 6/22/2010

**Person\_#1000000025\_\_Female\_\_76yroid\_\_Hispanic**

- Diagnoses
- Expression Profiles Data
- Laboratory Tests
- Medications
- Procedures
- Reports

**Person\_#1000000031\_\_Male\_\_50yroid\_\_Hispanic**

- Diagnoses
- Expression Profiles Data
- Laboratory Tests
- Medications
- Procedures
- Reports

**Person\_#1000000054\_\_Female\_\_66yroid\_\_Asian**

- Diagnoses
- Expression Profiles Data
- Laboratory Tests
- Medications
- Procedures
- Reports

**Person\_#1000000083\_\_Female\_\_65yroid\_\_Black**

- Diagnoses
- Expression Profiles Data
- Laboratory Tests
- Medications
- Procedures
- Reports

### Plugins

Detailed List View | Category: ALL

- Timeline**  
This plugin creates a visual representation of when selected observations occur within a given patient set.
- Project Request**  
This plugin is used to generate a request for a new project based on concepts, patients and sets..

**Navigate Terms** Find Terms

- Clinical Trials
- Custom Metadata
- Demographics
- Diagnoses
- Expression Profiles Data
- Laboratory Tests
- Medications
- Procedures
- Providers
- Reports
- Visit Details

**Workplace**

- SHARED
- demo

**Previous Queries**

- Hyper-Antih-Lipid@10:21:37 [6-17-2013] [demo]
- Hyperte-Antihyp@10:20:29 [6-17-2013] [demo]
- Hypertensive di@10:17:44 [6-17-2013] [demo]
- Hyper-Antih-Chemi@10:05:04 [6-17-2013] [demo]
- Hyperte-Antihyp@10:04:16 [6-17-2013] [demo]
- Hypertensive di@10:02:05 [6-17-2013] [demo]

**Timeline**

Specify Data View Results Plugin Help

<<< start: 1 size: 10 go >>> zoom: - + pan: < >

4/3/1997 2/2010

**Person\_#1000000025\_Female\_\_76yroid\_\_Hispa**

Diagnoses  
Expression Profiles Data  
Laboratory Tests  
Medications  
Procedures  
Reports

**Person\_#1000000031\_Male\_\_50yroid\_\_Hispani**

Diagnoses  
Expression Profiles Data  
Laboratory Tests  
Medications  
Procedures  
Reports

**Person\_#1000000054\_Female\_\_66yroid\_\_Asian**

Diagnoses  
Expression Profiles Data  
Laboratory Tests  
Medications  
Procedures  
Reports

**Person\_#1000000083\_Female\_\_65yroid\_\_Black**

Diagnoses  
Expression Profiles Data  
Laboratory Tests  
Medications  
Procedures  
Reports

**Observation Details**

event\_id: 473200  
patient\_id: 1000000031  
concept\_id: LCS-I2B2:XR\_RPT\_DID  
observer\_id: LCS-I2B2:D000109064  
start\_date: 2000-07-14T00:00:00.000+02:00

Radiology: X-Ray

Report Status: Final  
Exam: Hand, > 2 views  
Ordering Provider: Kildare, James M.D.

HISTORY:  
Rheumatoid arthritis; Question of erosions.

REPORT:  
TECHNIQUE: Two views of both hands.

COMPARISON: There are no prior studies available for comparison.

FINDINGS:  
There are no significant degenerative changes. There are no bony erosions. There is no evidence of fracture or joint malalignment. There is normal mineralization.

IMPRESSION:  
Unremarkable examinations.

[report\_end]

**Plugins**

Detailed List View

**Timeline**  
This plugin creates a visual representation of wher

**Project Request**  
This plugin is used to generate a request for a new project based on concepts, patients and sets..

### Navigate Terms

Find Terms

- Clinical Trials
- Custom Metadata
- Demographics
- Diagnoses
- Expression Profiles Data
- Laboratory Tests
- Medications
- Procedures
- Providers
- Reports
- Visit Details

### Workplace

- SHARED
- demo

### Previous Queries

- Hyper-Antih-Lipid@10:21:37 [6-17-2013] [demo]
- Hyperte-Antihyp@10:20:29 [6-17-2013] [demo]
- Hypertensive di@10:17:44 [6-17-2013] [demo]
- Hyper-Antih-Chemi@10:05:04 [6-17-2013] [demo]
- Hyperte-Antihyp@10:04:16 [6-17-2013] [demo]
- Hypertensive di@10:02:05 [6-17-2013] [demo]

### ExportXLS

Specify Data | View Results | Plugin Help | Settings

Drop a patient set and at least one concept (ontology term) onto the appropriate input boxes below, then click the "View Results" tab to retrieve the respective observations in the selected patient set.

For more info refer to the "Plugin Help" tab.

Patient Set:

Concept(s):

- Diagnoses
- Laboratory Tests
- Medications
- Procedures

Click a Concept to remove it from the list.

Output Options:

Formatting:

Replace Patient IDs with Ascending Numbers starting at 1

Include Patient Demographic Data:

- Sex
- Age
- Birth Date
- Birth Year
- Vital Status
- Language
- Race
- Religion
- Income
- State/City/ZIP

### Plugins

Detailed List View | Category: ALL

- ExportXLS**  
This plugin populates a table of selectable concepts/observations and provides the possibility to download the result as a file.
- Demographics (1 Patient Set) - Simple Counts**  
This plugin displays a demographic break-down of a Patient Set.

### Navigate Terms

- Clinical Trials
- Custom Metadata
- Demographics
- Diagnoses
- Expression Profiles Data
- Laboratory Tests
- Medications
- Procedures
- Providers
- Reports
- Visit Details

### Workplace

- SHARED
- demo

### Previous Queries

- Hyper-Antih-Lipid@10:21:37 [6-17-2013] [demo]
- Results of Hyper-Antih-Lipid@10:21:37 [6-17-2013] [demo]
- Patient Set for "Hyper-Antih-Lipid@10:21:37" - FINISH
- Number of patients for "Hyper-Antih-Lipid@10:21:37" -
- Results of Hyper-Antih-Lipid@10:21:37 [6-17-2013] [demo]
- Results of Hyper-Antih-Lipid@10:21:37 [6-17-2013] [demo]

### ExportXLS

Specify Data | View Results | Plugin Help | Settings

Click the one of the buttons on the right to download the following table in the appropriate format. [CSV Export](#) [HTML/XLS Export](#)

**Patient Information**  
for Patient Set 'Hyper-Antih-Lipid@10:21:37 [6-17-2013] [demo] [PATIENTSET\_14]'

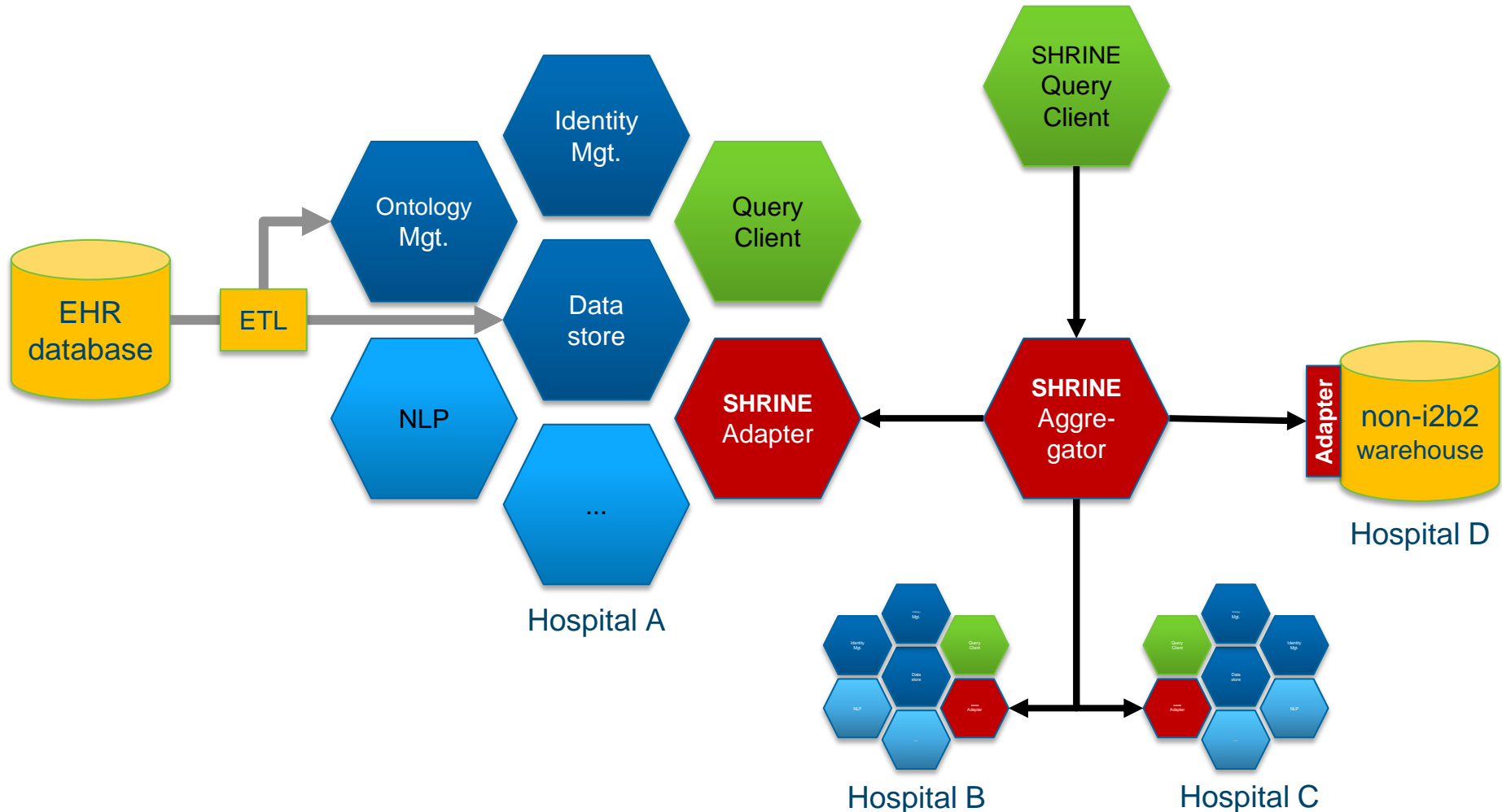
	Patient ID	Sex	Age in Years	Timestamp Start	Timestamp End	Observation Set	Observation Concept Code	Observation Value	Observation Unit
1	1000000025	F	76	2001-12-05	2001-12-05	Diagnoses	ICD9:786.50		
2	1000000025	F	76	2001-12-07	2001-12-07	Diagnoses	ICD9:493.90		
3	1000000025	F	76	2001-12-07	2001-12-07	Diagnoses	ICD9:780.8		
4	1000000025	F	76	2001-12-07	2001-12-07	Diagnoses	ICD9:782.0		
5	1000000025	F	76	2001-12-07	2001-12-07	Diagnoses	ICD9:786.59		
6	1000000025	F	76	2001-12-10	2001-12-10	Diagnoses	ICD9:354.0		
7	1000000025	F	76	2001-12-10	2001-12-10	Diagnoses	ICD9:493.90		
8	1000000025	F	76	2001-12-10	2001-12-10	Diagnoses	ICD9:723.4		
9	1000000025	F	76	2001-12-10	2001-12-10	Diagnoses	ICD9:786.50		
10	1000000025	F	76	2001-12-10	2001-12-10	Diagnoses	ICD9:786.59		
11	1000000025	F	76	2001-12-11	2001-12-11	Diagnoses	ICD9:786.59		
12	1000000025	F	76	2003-07-15	2003-07-15	Diagnoses	ICD9:494		
13	1000000025	F	76	2003-07-16	2003-07-16	Diagnoses	ICD9:273.2		
14	1000000025	F	76	2003-07-16	2003-07-16	Diagnoses	ICD9:493.90		
15	1000000025	F	76	2003-12-23	2003-12-23	Diagnoses	ICD9:V16.0		

### Plugins

Detailed List View | Category: ALL

- ExportXLS**  
This plugin populates a table of selectable concepts/observations and provides the possibility to download the result as a file.
- Demographics (1 Patient Set) - Simple Counts**  
This plugin displays a demographic break-down of a Patient Set.

## Föderierte Architektur



## EuroSHRINE Pilot im EHR4CR-Projekt





## Research and applications



**OPEN ACCESS**

### An i2b2-based, generalizable, open source, self-scaling chronic disease registry

Marc D Natter,<sup>1</sup> Justin Quan,<sup>2</sup> David M Ortiz,<sup>1</sup> Athos Bousvaros,<sup>3</sup> Norman T Ilowite,<sup>4</sup> Christi J Inman,<sup>5</sup> Keith Marsolo,<sup>6</sup> Andrew J McMurry,<sup>7</sup> Christy I Sandborg,<sup>8</sup> Laura E Schanberg,<sup>9</sup> Carol A Wallace,<sup>10</sup> Robert W Warren,<sup>11</sup> Griffin M Weber,<sup>12</sup> Kenneth D Mandl<sup>1,7</sup>

*J Am Med Inform Assoc* 2013;**20**:172–179.

- Erfolgreiche Nutzung von i2b2/SHRINE in 2 Disease Registries in den USA
  - CARRAnet: Register für kindliche rheumatoide Arthritis
    - 56 Standorte
    - >6.000 Patienten
  - Harvard Inflammatory Bowel Disease Registry
    - 3 Standorte (Harvard-Kliniken)
  - i2b2/SHRINE als Basis
  - Erweiterung um projektspezifische Funktionen ("i2b2 Self-Scaling Registry")

- Potential
  - verteilte Register mit lokaler Datenhoheit
- Hürden
  - Etablierung der lokalen Datamarts
  - Semantisches Mapping der lokalen Datenelemente
  - für retrospektive Daten: Aspekte von Einwilligung und Datenschutz
- Unterstützung
  - IDRT-Projekt der TMF
    - Wizard für die Installation und Administration der Plattform
    - Komponenten für Aufbereitung und Import von Rohdaten ("ETL-Strecke")
    - Werkzeuge für die Bearbeitung der Konzepthierarchie & das Mapping
    - Anbindung des TMF Metadata Repository (MDR)
    - Anbindung von Biobanken
    - ...
  - i2b2-SSR-Erweiterungen

# **Vielen Dank für Ihre Aufmerksamkeit!**