



I2b2 - SHRINE support for Clinical Trails and the Substitutable Medical Applications and Reusable Technologies (SMART) project

Shawn Murphy MD, Ph.D. Nich Wattanasin MS Alyssa Porter Stella Ubaha Kenneth Mandl MD, MPH Isaac Kohane MD, Ph.D.

I2b2 to support specific use case: Recruiting Patients for Clinical Trials

- At an institution, sets of patients that result from queries can be reviewed after appropriate permissions are obtained to be recruited for clinical trials.
- SHINE will allow a federated query to be performed across i2b2 SHINE databases, and the resulting patient population can be reviewed and recruited for clinical trials with the involvement of a coordinating center.





| 🥹 i2b2 Web Client - Mozilla Firefox | | | | _ 8 × |
|---|--|---|---|-----------------------------|
| Eile Edit View History Bookmarks Too | ols <u>H</u> elp | | | |
| C X 🟠 http://smarti2b2.org/webclient2/# | | | 🖒 👻 🚼 - Google | P |
| 🔎 Most Visited 📄 Getting Started 脑 Latest | Headlines 📄 Customize Links 📄 Free | Hotmail 📋 Windows Marketplace 🛷 Windows Media ಿ Windows | | |
| i2b2 Web Client | + | | | - |
| i2b2 Query & Analysis Too | bl | | Find Patients View Patient Analysis Tools | Message Log Help Logout |
| Navigate Terms Find Terms | View Patient | | 1000000 | 096 (76 y/o F black) |
| 🖻 🔂 Ischemic heart dise 🛋 | SMART EMR View | | Patient Number: 100000096 | |
| Acute myocardial Angina pectoris Cold myocardial ir Cold myocardial ir Colder acute and Cother forms of cr | Yolande Ond MRN: PHS:100000096 Sex: Female Born: 1934-05-01 (Age: 77) | ersma 10 MAIN ST Boston, Massachusetts 02228 USA | | Customize EMR View |
| Workplace 🔂 📮 | | | | |
| 🗄 📇 i2b2 Patients | Select View | Problem List | 1000 00 00 100 100 100 100 100 100 100 | |
| | Problem List | Hypothyroidism (disorder) | | |
| | Default View | Hypothyroidism (disorder) | 2003-04-15 2005-04-1 | 5 |
| | Medications | Malignant tumor of thyroid gland (disorder) | | |
| | Alleray Treatments | Malignant tumor of thyroid gland (disorder) | 1999-06-03 2001-06-0 | 13 |
| Previous Queries 🛛 🔂 🖻 🚽 | Anergy Treatments | Old myocardial infarction (disorder) | | |
| 🖻 🔚 Old myocardial @00:03:2:🛋 | | Old myocardial infarction (disorder) | 1997-10-30 1999-10-3 | |
| ⊡-100 Results of Old myocar | | Osteoarthritis (disorder) | 2000 02 45 | |
| 1000000096 [7 € | | Osteopartinitis (disorder) | 2006-03-15 2008-03-1 | 9 |
| 📲 Patient Count - 1 pc | | | | |
| | | | | |
| Transferring data from smarti2b2.org | | | | |







Privacy assumptions:

- I An IRB has been approved at that site (or across sites) for a study and that IRB is attached to specific project. DUA's (or the equivalent) have been signed by all project members.
- 2 At the site where the patients have signed the HIPAA notification, the PHI of specific sets of patients can be made available to the investigators. The specific set of patients will be defined by a patient list created in (1) and "promoted" to the level of PHI by transferring the list to a well defined access control place. Accesses to the PHI of these patients will be reported on all HIPAA audits for the patients.

In keeping with the above, components for development are:

- I. Regulatory i2b2 infrastructure to support management of permissions across institutions to enable clinicians and support staff to participate in a multicenter trial
 - A. The authorization that ultimately leads to the creation of a patient-set and the ability to review the patients that make up the set will be administered by creating a similarly identified project at each institution's local i2b2 that is tied to specific local and global authorizations (such as IRB protocols).
 - B. All (including multisite) investigators in the project will be authorized to use the entire project data set as Limited Data Set Users (LDS user). The creation of patient sets will be enabled in this fashion.

- 2. Detailed patient data is available to the members of the project. This will allow the review and sorting of the patient sets and initial screening of patients using tools in i2b2 that allow viewing of Limited Data.
 - A. The creation and definition of patient sets at the LDS level will be possible through the i2b2 workplace.
 - B. A patient set that is created in the workplace can be requested for identification by the Investigators at the local site. Activity up to this point is leading up to this designation. The patients in the set are available to HIPAA audits, labeled with those users that had access to the PHI.

- 3. The patients that are on the specific lists with access by local users in the specific project will have PHI revealed. [There may be a configurable switch in the local hive will determine if a coordinating center has access to the PHI.]
 - A. Patients who are approved to have their identified data displayed will clearly appear in the workplace and be available to drag to the SMART lookup. The SMART lookup will allow a display of the EMR view for a patient..

What is the SMART project about?



Substitutable Medical Apps, reusable technologies

- Provides a unified mechanism for diverse apps to interact with medical record data – An iPad kind of App that fits into AJAX model of web browsing
- Enables SMART Apps built against a SMART API to be embedded within any SMART Container
- A SMART Container can be an EMR system used by physicians, or a PHR system used by patients...or a dataanalytics platform such as i2b2 used by researchers

SMART apps can be used to review detailed patient data, as LDS and as PHI (if part of authorized patient set)?



SMART Container in i2b2

| C n Status C Status Status Status | |
|--|---------------|
| Elab Query & Analysis Tools Message Log Ind Patients Analysis Tools Message Log Ind Patient Record here Ind Patient Record here <th< td=""><td>☆ 👧 ٩</td></th<> | ☆ 👧 ٩ |
| Navigate Terms Image: Similar Control of Contr | lelp Logout |
| Workplace 😡 🗐 | À ₽ ↓ |
| | |
| Previous Queries Plugins | <u>_</u> |
| Buth radianagos.so. to [3-4-2011] [12b2] Category: ALL Detailed List View Category: ALL SMArt Dashboard Fins plugin enables you to run SMArt (Substitutable Medical Apps, reusuable technologies) applications within the 12b2 web client. Example #1 - Hello World Fins plugin demonstrates how to register a plugin within the 12b2 web client framework. | |

SMART Container in i2b2

| 🗅 i2b2 Web Client × + | | |
|--|---|---------------------------------------|
| ← → C f Smarti2b2.org/webclient/# | | x 🔎 🔺 |
| i2b2 Query & Analysis Tool | Find Patients Analysi | s Tools Message Log Help Logout |
| Navigate Terms Find Terms Image: Second state | Step 1. Drag a patient to box below: Step 2. Choose a SMArt App below: PATIENT:1000000008 Image: Colored Colore | ar Medication |
| | Name Start Date Est. End Date Instructions | E . |
| Workplace 🔛 🕒 | 100 ACTUAT Beclomethasone Dipropionate 0.08 MG/ACTUAT Metered Thu Apr 04 2002 Sun Apr 04 2004 Dose Inhaler [Qvar] | |
| - S PATIENT:1000000001 E - S PATIENT:1000000002 - - S PATIENT:100000003 - - S PATIENT:1000000003 - | 200 ACTUAT Ipratropium Bromide 0.018 MG/ACTUAT Metered Dose Inhaler Thu Apr 04 2002 Sun Apr 04 2004 [Atrovent] | |
| - PATIENT:100000005 - PATIENT:100000006 - PATIENT:100000007 - PATIENT:100000008 | 200 ACTUAT Ipratropium Bromide 0.018 MG/ACTUAT Metered Dose Inhaler Wed Jul 17 2002 Sat Jul 17 2004 [Atrovent] | |
| - PATIENT:100000009 - PATIENT:100000010 - PATIENT:100000011 | Acetaminophen 24 MG/ML / Codeine Phosphate 2.4 MG/ML Oral Solution Thu Aug 27 2009 Sat Aug 27 2011 | |
| PATIENT:100000012 PATIENT:100000013 | Cyclobenzaprine hydrochloride 10 MG | - |
| Previous Queries Image: Constraint of the second seco | Plugins Detailed List View SMArt Dashboard | |
| Herbal products@02:29:26 [3-4-2011] [i2b2] Image: Second state in the second stat | This plugin enables you to run SMArt (Substitutable Medical Apps, reusuable technologies) applications within the i2b2 web client. Example #1 - Hello World This plugin demonstrates how to register a plugin within the i2b2 web client framework. | |

Message Architecture: SMART i2b2 Cell (REST & OAuth)



i2b2 Query & Analysis Tool



Client can be optimized for EMR-View of patient



Layout of editable EMR-Screen



Layout of locked EMR Screen



Flow for conversion of patient_num to MDR



IM Cell

Main functions

- Converts MRNs to i2b2 patient nums
- Holds demographics in tables which do not contain clinical data
- Links to enterprise services and converts custom enterprise output to i2b2 standards
- Lists of patients with real identifiers are managed and linked to a project

Contact data through IM Cell

- Links to enterprise services and converts custom enterprise output to i2b2 standards
 - Request for demographics is sent to IM cell
 - If using i2b2 number converts to MRN
 - Depending on implementation
 - Demographics requested from services = most uptodate
 - Demographics requested from database
 - Demographics sent back in PDO

Flow for getting demographics



Mapper Cell



Messages

1. An individual's problems as represented in an i2b2 XML message:

- <ns2:concept_set>

- <concept>

```
<concept_path>\i2b2\Diagnoses\Circulatory system (390-459)\Hypertensive disease (401-405)\(401)
     Essential hypertension (401-9) Unspecified essential hype 
   <concept_cd>ICD9:401.9</concept_cd>
   <name_char>Huchard's disease</name_char>
  </concept>
- <concept>
   <concept_path>\i2b2\Diagnoses\Digestive system (520-579)\Oral cavity diseases (520-529)\(523)
     Gingival and periodontal di~(523-6) Accretions on teeth </ concept path>
   <concept_cd>ICD9:523.6</concept_cd>
   <name char>Dental plague</name char>
  </concept>
- <concept>
   <concept_path>\i2b2\Diagnoses\Digestive system (520-579)\Oral cavity diseases (520-529)\(523)
     Gingival and periodontal di\sim (523-9) Unspecified gingival and \sim (concept path)
   <concept cd>ICD9:523.9</concept cd>
   <name char>Unspecified gingival and periodontal disease</name char>
  </concept>
- <concept>
   <concept_path>\i2b2\Diagnoses\Genitourinary system (580-629)\Nephritis, nephrotic syndrome, and
     nephrosis (580-589)\(585) Chronic renal failure\</concept_path>
   <concept_cd>ICD9:585</concept_cd>
   <name char>Chronic renal failure</name char>
                                                                                                    Ontology
  </concept>
```

<u>**Case</u>**: We require diagnoses to be coded in SNOMED, but we only have ICD9 codes.</u>

Cell

Action: Send an XML request to the Mapping Cell with the desired ICD9's (above) to be mapped to SNOMED (e.g. ICD9: 401.9)

2. Response from Mapping Cell contains SNOMED codes and names:

- <mapped_concept_set>

| - <mapping></mapping> | |
|---|----------|
| <source_coding_s<u>vstem>ICD9</source_coding_s<u> | |
| <source_basecode>401.9</source_basecode> | |
| <destination_coding_system>SNO</destination_coding_system> | |
| <destination_basecod<mark>e>38341003<destination_basecode></destination_basecod<mark> | |
| <pre><destination_name>Hypertensive disorder, systemic arterial (disorder)</destination_name></pre> | ame> |
| | |
| - <mapping></mapping> | |
| <source_coding_system>ICD9</source_coding_system> | |
| <source_basecode>523.6</source_basecode> | |
| <destination_coding_system>SNO</destination_coding_system> | |
| <pre><destination_basecode>17552000</destination_basecode></pre> | |
| <destination_name>Dental calculus (disorder)</destination_name> | |
| | |
| - <mapping></mapping> | |
| <source_coding_system>ICD9</source_coding_system> | |
| <source_basecode>523.9</source_basecode> | |
| <destination_coding_system>SNO</destination_coding_system> | |
| <pre><destination_basecode>2556008</destination_basecode></pre> | |
| <pre><destination_name>Periodontal disease (disorder)</destination_name></pre> | |
| | |
| - <mapping></mapping> | |
| <source_coding_system>ICD9</source_coding_system> | |
| <source_basecode>585</source_basecode> | |
| <destination_coding_system>SNO</destination_coding_system> | |
| <pre><destination_basecode>90688005</destination_basecode></pre> | |
| <pre><destination_name>Chronic renal failure syndrome (disorder)</destination_name></pre> | |
| | / Mappir |

Cell

The mapping cell returned the mappings for the ICD9's sent from the previous slide (e.g. SNOMED of **38341003** mapped to ICD9: 401.9)

3. i2b2 "Mapped PDO" is transformed into RDF in SMArt Cell

- <sp:Problem>
 - <sp:problemName>
 - <sp:CodedValue>
 - <sp:code rdf:resource="http://www.ihtsdo.org/snomed-ct/concepts/38341003/" />
 - <dcterms:title>Hypertensive disorder, systemic arterial (disorder)</dcterms:title>
 - <sp:codeProvenance>
 - <sp:CodeProvenance>
 - <sp:sourceCode rdf:resource="http://smart.i2b2.org/concepts/code#ICD9:401.9" />
 - <dcterms:title>Huchard's disease</dcterms:title>
 - <sp:translationFidelity rdf:resource="http://smartplatforms.org/terms/code/fidelity#automated" />
 </sp:CodeProvenance>
 - </sp:codeProvenance>
 - </sp:CodedValue>
 - </sp:problemName>
 - <sp:onset>2005-10-31</sp:onset>
 - <sp:resolution>2007-10-31</sp:resolution>
 - </sp:Problem>

SMArt Cell

Work to be done on Components



THANK YOU - URL's

http://smarti2b2.org/webclient/

[HTML5 = IE8+, Firefox3+, Chrome]

http://wiki.chip.org/smart-project/index.php/Main_Page

<u>http://www.smartplatforms.org/</u>