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

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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.
Privacy assumptions:

1 – 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:

1. 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 data-analytics 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
SMART Container in i2b2
Message Architecture: SMART i2b2 Cell (REST & OAuth)

1. SMART Connect
   - A SMART app can run inside the new web client plugin and access the SMART API via SMART Connect

2. SMART REST
   - A SMART app can also access the SMART API directly via REST calls
The job of the SMART cell is to do most of the heavy lifting to convert SMART queries into serviceable i2b2 queries and convert i2b2 responses to SMART RDF responses that can be consumed by the SMART apps.
Layout of editable EMR-Screen
Layout of locked EMR Screen
Flow for conversion of patient_num to MDR

1. P_num 001
2. P_num 001
3. eMGH-fheu
eBWH-djifs
4. eMGH-fheu
eBWH-djifs
5. MGH MRN#3234567
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 up-todate
    - Demographics requested from database
  - Demographics sent back in PDO
Demographics are in IM database, but for most current may need to use Enterprise Service.
Mapper Cell

1. Sends **request** to i2b2 hive to get problems on patient 1000000012
   - Receives **response** as an i2b2 PDO

2. For concepts in PDO, **request** local codes to be mapped to needed code (ICD9 → SNOMED)
   - Receives **response** as i2b2 message containing mapped code in SNOMED

3. **Transforms i2b2 message into SMArt RDF**
   - XML Transformation

RDF
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 hypertension\</concept_path>
    - `<concept_cd>` ICD9:401.9</concept_cd>
    - `<name_char>`Hypertension\</name_char>
  </concept>
- `<concept>`
  - `<concept_path>`
    - i2b2\Diagnoses\Digestive system (520-579)\Oral cavity diseases (520-529)\(523) Gingival and periodontal disease\(523-6) Accretions on teeth\</concept_path>
  - `<concept_cd>` ICD9:523.6</concept_cd>
  - `<name_char>`Dental plaque\</name_char>
</concept>
- `<concept>`
  - `<concept_path>`
    - i2b2\Diagnoses\Digestive system (520-579)\Oral cavity diseases (520-529)\(523) Gingival and periodontal disease\(523-9) Unspecified gingival and periodontal disease\</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>
</concept>

Case: We require diagnoses to be coded in SNOMED, but we only have ICD9 codes.

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>
    - <source_coding_system>ICD9</source_coding_system>
    - <source_basecode>401.9</source_basecode>
    - <destination_coding_system>SNOMED</destination_coding_system>
    - <destination_basecode>38341003</destination_basecode>
    - <destination_name>Hypertensive disorder, systemic arterial (disorder)</destination_name>
  </mapping>
  - <mapping>
    - <source_coding_system>ICD9</source_coding_system>
    - <source_basecode>523.6</source_basecode>
    - <destination_coding_system>SNOMED</destination_coding_system>
    - <destination_basecode>17552000</destination_basecode>
    - <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>SNOMED</destination_coding_system>
    - <destination_basecode>2556008</destination_basecode>
    - <destination_name>Periodontal disease (disorder)</destination_name>
  </mapping>
  - <mapping>
    - <source_coding_system>ICD9</source_coding_system>
    - <source_basecode>585</source_basecode>
    - <destination_coding_system>SNOMED</destination_coding_system>
    - <destination_basecode>90688005</destination_basecode>
    - <destination_name>Chronic renal failure syndrome (disorder)</destination_name>
  </mapping>

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>`
      `<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>`
      `<onset>2005-10-31</onset>`
      `<resolution>2007-10-31</resolution>`
    - `<sp:Problem>`
Work to be done on Components

CRC
ONT
PM
IM
SMART
<Mapper
Adpt
Agg

Enterprise Services
THANK YOU - URL’s

- http://smarti2b2.org/webclient/
  - [HTML5 = IE8+, Firefox3+, Chrome]


- http://www.smartplatforms.org/