



Introduction to i2b2 Software Platform

Shawn Murphy MD, Ph.D. Griffin Weber MD, Ph.D. Michael Mendis Vivian Gainer MS Andrew McMurry MS Lori Phillips MS Rajesh Kuttan Wensong Pan MS Nick Benik Janice Donahue Susanne Churchill Ph.D. John Glaser Ph.D. Isaac Kohane MD, Ph.D.

Agenda

- 8:30 i2b2 Overview (Zak Kohane)
- 8:35 Introduction to i2b2 Software Platform (Shawn Murphy, Mike Mendis, Vivian Gainer, Griffin Weber)
- 9:35 SHRINE Regulatory Issues ("How One Multipart System Agreed to Share Data") (Susanne Churchill)
- 10:05 Break
- **10:35** Introduction to SHRINE (Andy McMurry)
- 11:05 i2b2 Planned Applications for Cool Science (Zak Kohane)
- 11:30 i2b2 Plans for New Software Enhancements and Incorporating Contributions from the Community (Shawn Murphy)

The National Center for Biomedical Computing entitled Informatics for Integrating Biology and the Bedside (i2b2) Clinical Research Chart, what is it?

- Explicitly organized and transformed person-oriented clinical data optimized for clinical genomics research
- An architecture that allows different studies to come together seamlessly
- An integration of clinical data, trials data, genotypic data, and knowledge annotation
- A portable and extensible application framework

i2b2 Cell: Canonical Hive Unit







Set of patients is selected through Enterprise Repository and data is gathered into a data mart



Research Silos



Project data can be added back to the ESD



Enterprise-wide repurposing and distribution of medical record data for research



- Enable high performance collection of medical record data for querying and distribution
 - Enterprise web client
- Enable discovery within data on enterprise wide scale
 - Relationship networks
 - Pharmacovigilance

Enterprise web client



Repurpose medical record information for research studies

- I2b2 Workbench
- Natural language processing
- Enable genomic studies
 - Tissue/blood selection
 - Data integration



Use of medical record data in clinical studies focused upon genomics and pharmacology

I2b2 Workbench carries hive activity into a detailed patient view for Investigator

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Natural Language Processing Cell

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asthma	
PRINCIPAL DISCHARGE DIAGNOSIS (Responsible After Study for Causing Admission) Asthma exacerbation	
OTHER DIAGNOSIS;Conditions,Infections,Complications,affecting Treatment/Stay	
SEASONAL ALLERGIES; CLUSTER HA; ANEMIA WALDENSTROM'S MACROGLOBULINEMIA OPERATIONS AND PROCEDURES:	
OTHER TREATMENTS/PROCEDURES (NOT IN O.R.)	
cardiac MIBI exercise tolerance test BRIEF RESUME OF HOSPITAL COURSE:	
xx y F c h/o asthma, HTN p/w SOB x 1 day	
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were stable until day of admission when she developed worsening	
wheezing and SOB. No CP, orthopnea, edema, PND. In ED: peak flow 190.	
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ST depressions in anterolateral leads in the setting of HR >	
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free; subsequent sets of enzymes were nl. Echocardiogram showed no wall	
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NLP Cell Architecture



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Data integration – Genotype / Phenotype



Query by values

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Query by values

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Workplace Interface



Selecting and Reviewing Patients for Studies

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Integration of several data export and analysis tools in i2b2 Workbench





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	25 HIVE	100000007	Sagittal	2003-05-03 00:00:00	2003-05-03 00:00	HIVE	1000000001	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00:00	0AS1_0003	_MR1/RAW/OAS1_00	01_MR1_mpr-2_ar	non.img		
	26 HIVE	100000007	Sagittal	2003-05-03 00:00:00	2003-05-03 00:00	HIVE	1000000001 1000000001	Sagittal Sagittal	2003-05-03_00:00:00 2003-05-03_00:00:00	2003-05-03_00:00:00 2003-05-03_00:00:00	OAS1_0003 OAS1_0003	1_MR1/RAW/OAS1_00 1_MR1/RAW/OAS1_00	01_MR1_mpr-3_ar 001_MR1_mpr-4_a	non.img		
2 2	27 HIVE	100000007	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00	HIVE	1000000002	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00:00	0151_0002	NR1/RAW/OAS1_0	/02_MR1_mpr-1_ar	non.img		
2	28 HIVE	100000008	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00	HIVE	1000000002	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00:00	0481_0003	_MR1/RAW/OAS1_00)02_MR1_mpr-3_ar	non.img		
1 2	29 HIVE	100000008	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00	HIVE	1000000002	Sagittal Sagittal	2003-05-03_00:00:00 2003-05-03_00:00:00	2003-05-03_00:00:00 2003-05-03_00:00:00	0AS1_0003 0AS1_0003	<pre>L_NR1/RAW/OAS1_00 NR1/RAW/OAS1_00</pre>	02_MR1_mpr-4_ar 003 MR1 mpr-1 a	non.img non.img		
3 3	30 HIVE	100000008	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00	HIVE	1000000003	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00:00	0481_0003	MR1/RAW/OAS1_00	/03_MR1_mpr-2_ar	non.img		
1 3	31 HIVE	100000008	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00	HIVE	1000000003	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00:00	0451_0003	MR1/RAW/OAS1_00	JO3_MR1_mpr-4_a	non.img		
3	32 HIVE	100000009	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00	HIVE	1000000004 1000000004	Sagittal Sagittal	2003-05-03_00:00:00 2003-05-03_00:00:00	2003-05-03_00:00:00 2003-05-03_00:00:00	0131_0004 0151_0004	<pre>4_MR1/RAW/OAS1_00 4_MR1/RAW/OAS1_00</pre>	04_MR1_mpr=1_ar 004_MR1_mpr=2_a	non.img non.img		
i 3	33 HIVE	100000009	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00	HIVE	1000000004	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00:00	0481_0004	MR1/RAW/OAS1_00	04 MR1 mpr-3 ar	non.img		
3 3	34 HIVE	100000009	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00	HIVE	1000000005	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00:00	0151_0005	5_MR1/RAW/OAS1_00	JO5_MR1_mpr=1_ar	non.img		
3	35 HIVE	100000009	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00	HIVE	1000000005 1000000005	Sagittal Sagittal	2003-05-03_00:00:00 2003-05-03_00:00:00	2003-05-03_00:00:00 2003-05-03_00:00:00	0AS1_0005 0AS1_0005	5_MR1/RAW/OAS1_00 5 MR1/RAW/OAS1_00	05_HR1_mpr-2_ar 305 MR1 mpr-3 a	non.img non.img		
3	36 HIVE	100000010	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00	HIVE	1000000005	Sagittal	2003-05-03 00:00:00	2003-05-03 00:00:00	0151_0005	MR1/RAW/OAS1 00	05 MR1 mpr-4 ar	non.img		
ί 3 [°]	37 HIVE	100000010	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00	HIVE	1000000006	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00:00	0431_0000	6_MR1/RAW/OAS1_00	J06_MR1_mpr-2_ar	non.img		
3	38 HIVE	100000010	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00	HIVE	1000000006	Sagittal Sagittal	2003-05-03_00:00:00 2003-05-03_00:00:00	2003-05-03_00:00:00 2003-05-03_00:00:00	0AS1_0000 0AS1_0000	5_NR1/RAW/OAS1_00 5_MR1/RAW/OAS1_00	06_HR1_mpr=3_ar 006_HR1_mpr=4_a	non.img non.img		
3	39 HIVE	1000000010	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00	HIVE	1000000007	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00:00	0151 0007	MR1/RAW/OAS1_00	07 MR1 mpr-1 ar	non.img		
4	10 HIVE	100000011	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00	HIVE	1000000007	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00:00	0481_000	7_MR1/RAW/OAS1_00	J07_MR1_mpr-3_a	non.img		
	•					HIVE	1000000008 1000000008	Sagittal Sagittal	2003-05-03_00:00:00 2003-05-03_00:00:00	2003-05-03_00:00:00 2003-05-03_00:00:00	0AS1_0009 0AS1_0009	9_MR1/RAW/OAS1_00 9 MR1/RAW/OAS1_00	09_MR1_mpr-1_ar 309 MR1 mpr-2 a	non.img		
)						HIVE	100000008	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00:00	0481_0005	MR1/RAW/OAS1_0	09 MR1 mpr-3 a	non.img		
🖁 Imag	ges@02:57:0	33 [01-03-200)8] [wp066]			HIVE	1000000009	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00:00	OAS1_0005 OAS1_0010	NR1/RAW/OAS1_00	J10_MR1_mpr-1_a	non.img		
i Imac		54 [01-03-200	18 1 [wp066]			HIVE	1000000009	Sagittal Sagittal	2003-05-03_00:00:00 2003-05-03_00:00:00	2003-05-03_00:00:00 2003-05-03_00:00:00	0AS1_0010 0AS1_0010	D_MR1/RAW/OAS1_00 D_MR1/RAW/OAS1_00	10_MR1_mpr-2_ar 010 MR1 mpr-3 a	non.img		
a nudê	905602.01.		~][mpooo]			HIVE	1000000009	Sagittal	2003-05-03 00:00:00	2003-05-03_00:00:00	0451_0010	MR1/RAW/OAS1_00	10_MR1_mpr-4_a	non.img		
						HIVE	1000000010	Sagittal Sagittal	2003-05-03_00:00:00	2003-05-03_00:00:00	0AS1_0013 0AS1_0013	L_HR1/RAW/OAS1_00 L_MR1/RAW/OAS1_00)11_MR1_mpr-1_ar)11_MR1_mpr-2_a	non.img		
						HIVE	1000000010	Sagittal Sagittal	2003-05-03 00:00:00	2003-05-03_00:00:00 2003-05-03_00:00:00	0451_0011 0451_0011	MR1/RAW/OAS1_00	11_MR1_mpr-3_ar	non.img		
						HIVE	1000000011	Sagittal	2003-05-03_00:00:00	2003-05-03_00:00:00	0AS1_0012	MR1/RAW/OAS1_00	12 MR1 mpr-1 a	non.img -		



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Working Assumptions of i2b2 Data

Shawn Murphy Vivian Gainer

Data Model: Data Requirements

- Integration of data from distributed and differently structured databases in order to perform comprehensive analyses.
- Separation of data used for research from daily operational or transactional data.
- **Standardization** of a model across systems.
- **Ease** of use by end-users.

Dimensional Modeling

- 1. **FACTS** the quantitative or factual data being queried.
- 2. **DIMENSIONS** groups of hierarchies and descriptors that define the facts.

Star Schema

One fact table surrounded radially by numerous dimension tables.

i2b2 Star Schema



i2b2 Fact Table

- In i2b2, a fact is an observation on a patient.
- Examples of FACTS:
 - Diagnoses
 - Procedures
 - Health History
 - Genetic Data
 - Lab Data
 - Provider Data
 - Demographics Data
- An observation is not necessarily the same thing as an event

i2b2 Dimension Tables

- Dimension tables contain descriptive information about facts.
- In i2b2 there are four dimension tables

concept_dimension provider_dimension visit_dimension patient_dimension

Indexes

- Very large data warehouses and marts require many indexes for good performance. Use as many indexes as necessary for covering virtually any query
- Consider adding a clustered index (SQL Server) to any table in a data warehouse that needs to produce sorted results.

Values

Valtype_cd	either N for numeric or T for text	
Tval_char	if valtype_cd = 'T', then the text value goes here.	
for greater	if valtype_cd = 'N', then tval_char can be 'E' for than, L for less than	equals, G
Nval_num	if valtype_cd = 'N', then the text value goes here	
Valueflag_cd	Flag (for high or low values, for example)	

Example: Lab Test Values

select o.concept_cd, name_char, valtype_cd, tval_char, nval_num, valueflag_cd, units_cd from observation_fact o join concept_dimension c on o.concept_cd = c.concept_cd where valtype_cd = 'N'

concept	name_char	valtype_cd	tval_char	nval_num	valueflag_cd	units_cd
BC1-20	Alt/gpt (Test:bc1-20)	N	E	6.00000	L	u/l
BC1-21	Ast/got (Test:bc1-21)	N	E	16.00000	0	u/l
BC1-24	Alk phos (Test:bc1-24)	N	E	107.00000	0	u/l
BC1-39	Albumin (Test:bc1-39)	N	E	4.20000	0	g/dl
BC1-7	Creatinine (Test:bc1-7)	N	E	0.70000	0	mg/dl
BC1-10	Chloride (Test:bc1-10)	N	E	106.00000	0	mmol/l
BC1-106	B12 (Test:bc1-106)	N	E	409.00000	0	pg/ml
BC1-11	Total co2 (Test:bc1-11)	N	E	26.00000	@	mmol/l
BC1-110	Ferritin (Test:bc1-110)	N	E	42.00000	0	ug/l
BC1-136	VIdI (Test:bc1-136)	N	E	12.00000	0	mg/dl
BC1-19	Anion gap (Test:bc1-19)	N	E	10.00000	0	mmol/l
BC1-20	Alt/gpt (Test:bc1-20)	N	E	9.00000	0	u/l

Relationship of Metadata to Star Schema

- Star Schema contains one fact and many dimension tables.
- Concepts in these tables are defined in a separate metadata table or tables.
- The structure of the metadata is integral to the visualization of concepts as well as for querying the data.
- All metadata tables have the same basic structure.
Typical i2b2 Metadata Categories

- Diagnoses
- Procedures
- Demographics
- Lab Tests
- Encounters (visits or observations)
- Providers (observers)
- Health History (physical findings and vital signs)
- Transfusion
- Microbiology

Structure of Metadata Table

 METAI	ΔΑΤΑ	
C_HLEVEL	INT NULL	
C_FULLNAME	VARCHAR(900) NULL	
C_NAME	VARCHAR(2000) NULL	
C_SYNONYM_CD	CHAR(1) NULL	
C_VISUALATTRIBUTES	CHAR(3) NULL	
C_TOTALNUM	INT NULL	
C_BASECODE	VARCHAR(450) NULL	
C_METADATAXML	TEXT NULL	
C_FACTTABLECOLUMN	VARCHAR(50) NULL	
C_TABLENAME	VARCHAR(50) NULL	
C_COLUMNNAME	VARCHAR(50) NULL	
C_COLUMNDATATYPE	VARCHAR(50) NULL	
C_OPERATOR	VARCHAR(10) NULL	
C_DIMCODE	VARCHAR(900) NULL	
C_COMMENT	TEXT NULL	
C_TOOLTIP	VARCHAR(900) NULL	
UPDATE_DATE	DATETIME NULL	
DOWNLOAD_DATE	DATETIME NULL	
IMPORT_DATE	DATETIME NULL	
SOURCESYSTEM_CD	VARCHAR(50) NULL	
VALUETYPE_CD	VARCHAR(50) NULL	

c_hlevel = 1



select c_hlevel, c_fullname, c_name,c_visualattributes from testrpdr where c_hlevel=1

🛄 F	🧾 Results 📑 Messages					
	c_hlevel	c_fullname	c_name	c_visualattributes		
1	1		Microbiology	FA		
2	1	\RPDR\Procedures	Procedures	FA		
3	1	\RPDR\Labtests	Laboratory Tests	FA		
4	1	\RPDR\Medications	Medications	FA		
5	1	\RPDR\Transfusions	Transfusion Services	FA		
6	1	\RPDR\HealthHistory	Health History	FA		
7	1	\RPDR\HPCGG	Molecular Medicine	FA		
8	1	\RPDR\Diagnoses	Diagnoses	FA		
9	1	\RPDR\Demographics	Demographics	FA		

c_hlevel = 2



c_hlevel = 3



c_fullname and c_name

c_fullname is the hierarchical path that leads to the term	
\RPDR	
\Diagnoses	
\Musculoskeletal and connective tissue (710-739)	
\Arthropathies (710-719)	
\(714) Rheumatoid arthritis and other arthrop	oathies
\(714-0) Rheumatoid arthritis	
c_name is the actual term	
Rheumatoid arthritis	
Atrophic arthritis	
RA [Rheumatoid arthritis]	
Chronic rheumatic arthritis	
c_fullname	c_name
\RPDR\Diagnoses\Musculoskeletal and connective tissue (710-739)\Arthropathies (710-719)\(714) Rheumatoid arthritis and ot ~\(714-0) Rheumatoid arthritis	Rheumatoid arthritis
\RPDR\Diagnoses\Musculoskeletal and connective tissue (710-739)\Arthropathies (710-719)\(714) Rheumatoid arthritis and ot ~\(714-0) Rheumatoid arthritis	Atrophic arthritis
\RPDR\Diagnoses\Musculoskeletal and connective tissue (710-739)\Arthropathies (710-719)\(714) Rheumatoid arthritis and ot~\(714-0) Rheumatoid arthritis	RA [Rheumatoid arthritis]

\RPDR\Diagnoses\Musculoskeletal and connective tissue (710-739)\Arthropathies (710-719)\(714) Rheumatoid arthritis and ot ~\(714-0) Rheumatoid arthritis Chronic rheumatic arthritis

c_visualattributes



C_HLEVEL	C_NAME	C_SYNONYM_CD	C_VISUALATTRIBUTES	C_BASECOD)E
5 5	Other specified inflammatory polyarthropathies Other specified inflammatory polyarthropathies	N Y	FA FH	7148 7148	(non-specific code)
6	Other specified inflammatory polyarthropathies	N	LÀ	71489	(specific code)

c_basecode

The basecode is the coded value for the term.

c_hlevel	c_fullname	c_name	c_visualattributes	c_basecode	c_operator
2	\RPDR\Demographics\Gender	Gender	FA	NULL	LIKE
3	\RPDR\Demographics\Gender\Female	Female	LA	DEM[SEX:f	LIKE
3	\RPDR\Demographics\Gender\Male	Male	LA	DEM SEX:m	LIKE
3	\RPDR\Demographics\Gender\Unknown	Unknown	MA	NULL	LIKE
4	\RPDR\Demographics\Gender\Unknown\Unknown@	Unknown-@	LH	DEMISEX:@	LIKE
4	\RPDR\Demographics\Gender\Unknown\Unknown-U	Unknown-U	LH	DEM[SEX:u	LIKE

It maps to the concept_cd in the star schema tables.

c_facttablecolumn,c_tablename,c_columnname,

c_columndatatype,c_operator,c_dimcode

TADATA
INT NULL
VARCHAR(900) NULL
VARCHAR(2000) NULL
CHAR(1) NULL
CHAR(3) NULL
INT NULL
VARCHAR(450) NULL
TEXT NULL
VARCHAR(50) NULL
VARCHAR(50) NULL
VARCHAR(50) NULL
VARCHAR(50) NULL
VARCHAR(10) NULL
VARCHAR(900) NULL
TEXT NULL
VARCHAR(900) NULL
DATETIME NULL
DATETIME NULL
DATETIME NULL
VARCHAR(50) NULL
VARCHAR(50) NULL

Fields used to construct queries

c_facttablecolumn	c_tablename	c_columnname	c_columndatatype	c_operator	c_dimcode
concept_cd	concept_dimension	concept_path	Т	LIKE	\RPDR\Demographics\Gender
concept_cd	concept_dimension	concept_path	Т	LIKE	\RPDR\Demographics\Gender\Female
concept_cd	concept_dimension	concept_path	Т	LIKE	\RPDR\Demographics\Gender\Male
concept_cd	concept_dimension	concept_path	Т	LIKE	\RPDR\Demographics\Gender\Unknown
concept_cd	concept_dimension	concept_path	Т	LIKE	\RPDR\Demographics\Gender\Unknown\Unknown-@
concept_cd	concept_dimension	concept_path	Т	LIKE	\RPDR\Demographics\Gender\Unknown\Unknown-U

Select * from observation_fact where c_facttablecolumn in

(select concept_cd from c_tablename where c_columname c_operator 'c_dimcode%')

Select * from observation_fact where concept_cd in (select concept_cd from concept_dimension where concept_path like '\RPDR\Demographics\Gender%')

c_metadataxml

stores values and information about the concept such as high and low indicators

Navigating concept_dimension

Except for diagnoses, which do not have a standard prefix, the prefix of the location_path identifies the type of concept:

LAB\	is for Laboratory data
TRS \	is for Transfusion data
MIC\	is for Microbiology data
MCP\	is for CPT medications
	MUL\ is for hospital medications
	PRC\ is for procedures

So, if looking for a list of all possible labs, the query to run is select * from concept_dimension where concept_path like 'lab\%'

concept_cd can be joined to concept_cd in the Observation_Fact table.

Visit_dimension

- Encounter number
- In/out code
- Hospital of service
- Clinic

Encounter_num can be joined to encounter_num in the Observation_Fact table.

Patient_num can be joined to patient_num in the Observation_Fact and Visit_Dimension tables.

Example 1: Query based on a diagnosis

To find all the patients diagnosed with migraines, use this query:

Select p.patient_num From patient_dimension p join observation_fact f On p.patient_num = f.patient_num And f.concept_cd in (select concept_cd from concept_dimension where concept_path like 'Neurologic Disorders (320-389)\(346) Migraine\%') To find the ages of all patients diagnosed with migraines, use this query:

Select p.age_in_years_num From patient_dimension p, observation_fact f Where p.patient_num = f.patient_num And f.concept_cd in (select concept_cd from concept_dimension where concept_path like 'Neurologic Disorders (320-389)\(346) Migraine\%') To limit the query to only those patients seen at MGH, add the Visit table.

Select p.patient_num,p.age_in_years_num From patient_dimension p join observation_fact f on p.patient_num = f.patient_num join visit_dimension v on v.encounter_num = f.encounter_num And v.location_cd = 'MGH' And f.concept_cd in (select concept_cd from concept_dimension where concept_path like 'Neurologic Disorders (320-389)\(346) Migraine\%')

Multiple paths

select distinct(patient_num) into BoneMarrowTransplants from observation_fact where

concept_cd in

(Select concept_cd

From concept_dimension

Where concept_path LIKE

- 'PRC\ICD9 (Inpatient)\(40-41) Operations on hemic and lymphatic system\(p41) Operations on bone marrow a~\(p41-0) Bone marrow or hematopoie~\%'
- or concept_path LIKE 'PRC\CPT\(10021-69990) Surgery\(38100-38999) Hemic and Lymphatic Systems\(38204-38242) Bone Marrow or Stem Cell\(38242) Bone marrow or blood-deri~\%'
- or concept_path LIKE 'PRC\CPT\(10021-69990) Surgery\(38100-38999) Hemic and Lymphatic Systems\(38204-38242) Bone Marrow or Stem Cell\(38240) Bone marrow or blood-deri~\%'
- or concept_path LIKE 'PRC\CPT\(10021-69990) Surgery\(38100-38999) Hemic and Lymphatic Systems\(38204-38242) Bone Marrow or Stem Cell\(38241) Bone marrow or blood-deri~\%'
- or concept_path LIKE '(Pre) Transplants and Tracheostomy\Surgical\(481) Bone Marrow Transplant\%'
- or concept_path LIKE 'zz V-codes\Conditions influencing health status (V40-V49)\(V42) Organ or tissue replaced by~\(V42-8) Other specified organ or ~\(V42-81) Bone marrow replaced by ~\%'
- or concept_path LIKE 'PRC\LMR\(LPA547) bone marrow transplant\%'
- or concept_path LIKE 'Injury and poisoning (800-999)\Complications of medical care (996-999)\(996) Complications peculiar to c~\(996-8) Complications of transpla~\(996-85) Complications of bone ma~\%')

Find CCP lab codes

select c_hlevel,c_fullname,c_name,c_basecode into CCPCodes from labtests where c_fullname like '%ACCP%' or c_fullname like '%ANTCCP%'

c_hlevel	c_fullname	c_name	c_basecode
3	LAB\(LLB63) DBNull\(LLB64) DBNull\ACCP	CCP Ab (Group:ACCP)	ACCP
4	LAB\(LLB63) DBNull\(LLB64) DBNull\ACCP\BC1-1318	A-CCP (Test:bc1-1318)	BC1-1318
4	LAB\(LLB63) DBNull\(LLB64) DBNull\ACCP\WC890.0334	CYCLIC CITRULLINATED PEPTIDE (Test:wc890.0334)	WC890.0334
3	LAB\(LLB63) DBNull\(LLB64) DBNull\ANTCCP	CCP Ab, IgG (Group:ANTCCP)	ANTCCP
4	LAB\(LLB63) DBNull\(LLB64) DBNull\ANTCCP\FC50.05	ANTI CYCLIC CITRULLINE PEPTIDE (Test:fc50.05)	FC50.05
4	LAB\(LLB63) DBNull\(LLB64) DBNull\ANTCCP\LC6138	CCP IgG Antibodies (Test:lc6138)	LC6138
4	LAB\(LLB63) DBNull\(LLB64) DBNull\ANTCCP\MCSQ-AN	Anti CCP (Test:mcsq-antccp)	MCSQ-ANTCCP
4	LAB\(LLB63) DBNull\(LLB64) DBNull\ANTCCP\MISQ-CCPT	anti-CCP IgG (Test:misq-ccpt)	MISQ-CCPT
4	LAB\(LLB63) DBNull\(LLB64) DBNull\ANTCCP\NCCCPG	ANTI CCP IGG (Testinocopg)	NCCCPG

Determine which patients have a CCP titer >40 and have been seen in either the BWH Arthritis center or MGH Arthritis Associates.

select distinct(patient_num)
from observation_fact
where concept_cd in
(select c_basecode from CCPcodes) and nval_num >40
and patient_num in
(select patient_num from vg_ravisitsbypatient)
and patient_num in
(select distinct(patient_num)
from visit_dimension
where location_path like '%arthritis%')

Tips

- Look at the tables
- Bear in mind that you won't need to concentrate on every field in every table, but can drill down into the particular fields of interest as needed.
- Figure out how the dimension tables tie into the fact table.
- Check out the mapping tables that are included if you need to further identify the data.
- Try running one of the sample queries.
- Think about what questions you want answered, then try to frame them based on the data in the data mart.
- Write the SQL to perform your queries. Start slowly and gradually build up the complexity of each query.



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Principles of Creating an i2b2 Cell

Shawn Murphy Michael Mendis

i2b2 Hive - Architecture

- Formed as a collection of interoperable services provided by i2b2 Cells
- Loosely coupled
- Makes no assumptions about proximity
- Connected by Web services
- Activity can be directed manually or automatically

i2b2 Cell Architecture

- Leverage existing software
- Use Web services as basic form of interaction
- Provide tools to help developers distill complexity into basic automation for clinical investigators
- Emphasize usable open protocols

i2b2 Cell: Canonical Hive Unit



Exposing Cells

- At a low level for integrators; ie, bioinformaticians & software engineers
- At a functional level for investigators
- i2b2 toolkits to allow integrators to expose controlled functionality to investigators so it may be used in workflows.

i2b2 Environment



i2b2 Cell:



(Minimize this approach)

Traversing the i2b2 Hive





🕼 i2b2 Workbench		
<u>File Window Help</u>		
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FEV1 % of Predicted		
FEV1 % of Predicted Post BD		
FEV1 Observed		
EVC 9/ Change in Deck PD from Dro Pi		
EVC % of Predicted		
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E Past smoker		
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Acute Astma [04-04-2007 01:13:15]		
H GuteNacal-Rulmo [04-04-2007 01:537]		
Diagn [04-04-2007 01:58:08]		
H A Cromo-Hormo [04-04-2007 02:23:49]		
⊞ A Diagn [04-04-2007 03:41:19]		
E Acute [04-09-2007 02:32:08]		
🕀 🔐 Murph [04-14-2007 01:52:32]	Templates Additional Items Delete From List Delete All Put In Order	
Male-Acute [04-19-2007 04:56:47]	E Ninka ananta sita a data 🖾 Diada antiat dan anakira	
H Frenc-Acute [04-19-2007/04:59:31]	Display concepts with no data. I Display patient demographics	
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H Age 10-17 [04-27-2007 01:05:04]		
H Acute [04-30-2007 03:12:17]	Definet Setu All	
🖈 🖓 Acute-Male [05-01-2007 09:38:33]	radin see 174	🖷 All Topics 💥 Search 👊 Bookmarks





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E - Acute-Male [05-01-2007 09:38:33]	▼ Person_#4Female70yroldBlack	
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🕀 🚰 Male-Acute [05-01-2007 10:34:43]	▼ PFT_Report	
E Asthm-Acute [05-01-2007 10:35:39]		
E H LMR N-Medic [05-01-2007 04:52:24]	▼ FEV1%Pred	
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Rheum [05-02-2007 10:05:57] Dearm Mala [05-02-2007 10:07:17]	11000100	
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H-ABRODC [05-07-2007 11:46:07]	↔ /89 90 0 ↔	
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⊕ Â Acute-35-44 [05-09-2007 03:48:43]	Patient Set: Patient Set: 4034 Patients	Go To:
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Cells perform services



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FVC	(L)	2.58	2.12	82				
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4								►
Get Pulmonary F	Data Clear Te	wt						
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PFT Cell


i2b2 Message Format



🕼 i2b2 Workbench _ 8 × File Window Help i2b2 Workbench for Demo demo Status: PFT 🗙 Report Results Request XML Response XML <ns4:request xmlns:ns4="http://www.i2b2.org/xsd/hive/msg/1.1/" xmlns:ns3="http://www.i2b2.org/xsd/hive/plugin/" xmlns:ns5= 🔺 <message header> <i2b2 version compatible>1.1</i2b2 version compatible> <hl7_version_compatible>2.4</hl7_version_compatible> <sending application> <application_name>i2b2 Workbench</application_name> <application version>1.2</application version> </sending application> <sending facility> <facility name>i2b2 Hive</facility name> </sending facility> <receiving application> <application name>PFT Cell</application name> <application version>1.0</application version> </receiving application> <receiving facility> <facility name>i2b2 Hive</facility name> </receiving facility> <datetime_of_message>2008-04-04T13:46:46.528-04:00</datetime of message> <message control id> <message num>ApBChwo8XZellLRps69k</message num> <instance_num>O</instance_num> </message control id> <processing id> <processing_id>P</processing_id> <processing mode>I</processing mode> </processing_id> <accept acknowledgement type>AL</accept acknowledgement type> <application acknowledgement type>AL</application acknowledgement type> <country code>US</country code> <project id>Demo</project id> </message header> <request header> <result waittime ms>120000</result waittime ms> </request header>

e <u>Window H</u> elp i2b2 V PFT × teport Results <message <ms< th=""><th>Norkben Request XML e_body> 2:patient</th><th>ch for Demo</th><th></th><th></th><th></th><th>demo</th><th>Status: 🕚</th><th>Wiki</th></ms<></message 	Norkben Request XML e_body> 2:patient	ch for Demo				demo	Status: 🕚	Wiki
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		<pre><concept_cd>L <concept_data>2</concept_data></concept_cd></pre>	008_04_02T1	<pre>4.43.10 043-04</pre>	•00//etert data	~		
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Stop Listen Po	t: 8080 Host	webservices.i2b2 Port: 80	Proxy			
State	lime	Request Host	Target Host	Request	Elapsed Time	
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	(<u> </u>	1				
Remove belected	Remove All					
POST /PM/rest/	PFTService/o	etPulmonaryData HTT	TP/1.1		<u> </u>	
Connection: Ke	ep-Alive					
User-Agent: Ax	is2					
Host: webservi	ces.i2b2.org	:8080				
Transfer-Encod	ing: chunked					
Content-Type:	text/xml; cr	arset=UTF-8				
e54						
<pre></pre>						
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PFT Cell



Admin Sender Port 8080						
Scop Listen Port: 8080 Host:	webservices.izba Port: 180					
State Time	Request Host	Target Host	Request	Elapsed Time		
Most Recent Reg 2008-04-04 13:46:46	 localbost	 webservices.i2b2.org	 POST /PM/rest/PETService/getPulmoparyData H.			
		hobsel hebbling				
Remove Selected Bernove All	1					
Kellove Scietted						
▲						
HTTP/1.1 200 OK				<u> </u>		
Date: Fri, 04 Apr 2008 17:	45:43 GMT					
Server: Apache/2.2.6 (Unix) mod_ss1/2.2.6 Opens	3SL/0.9.8c mod_jk/1.2	2.25 PHP/5.2.5 mod_per1/2.0.3 Per	1/v5.8.8		
Keep-Alive: timeout=15, ma	x=100					
Connection: Keep-Alive						
Transfer-Encoding: chunked	l					
Content-Type: application/xml;charset=UTF-8						
1084						
<pre></pre>						
<message header=""></message>						
<i2b2 comp<="" td="" version=""><th>atible>1.1</th></i2b2> <th>sion compatible></th> <th></th> <th></th>	atible>1.1	sion compatible>				
<hl7 compa<="" td="" version=""><th>tible>2.4<th>on compatible></th><th></th><th></th></th></hl7>	tible>2.4 <th>on compatible></th> <th></th> <th></th>	on compatible>				
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<receiving application=""></receiving>						
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    🔀 i2b2 Workbench for Demo
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 Report Results Request XML Response XML
 xmlns:ns2="http://www.i2b2.org/xsd/hive/pdo/1.1/">
                                                                                                      ٠
     <message header>
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          <h17_version_compatible>2.4</h17_version_compatible>
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              <application version>1.0</application version>
          </sending application>
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          </sending facility>
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              <application version>1.2</application version>
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          <message control id>
              <message num>wXafFCOubatSgusosiZn</message num>
              <instance num>1</instance num>
          </message control id>
          <processing_id>
              <processing id>P</processing id>
              <processing mode>I</processing mode>
          </processing id>
          <accept acknowledgement type>AL</accept acknowledgement type>
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          <country code>US</country code>
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     </message_header>
     <response header>
          <result status>
              <status type="DONE">PFT processing completed</status>
          </result status>
     </response header>
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eport Results Request XML Response XML			
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<pre><event id="">1000001</event></pre>			
<pre><patient id="">1234567</patient></pre>			
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<nval num="">1.51</nval>			
<pre><units cd="">liter</units></pre>			
<pre></pre>			
<pre><cvent id="">1000001</cvent></pre>			
<pre><nation1000001(<nation1="" cvcmo_10)="" id="">1000001(/cvcmo_10)</nation1000001(></pre>			
<pre></pre>			
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<units_cd>percent</units_cd>			
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Name	Value/Units	Code	
Height	63.0 inch	LCS-I2B2:pulheight	
Weight	105.0 pound	LCS-I2B2:pulweight	
FEV1 Observed	1.51 liter	LCS-I2B2:pulfev1obs	
FEV1 % of Predicted	76 percent	LCS-I2B2:pulfev1pred	
FVC Observed	2.12 liter	LCS-I2B2:pulfvcobs	
FVC % of Predicted	82 percent	LCS-I2B2:pulfvcpred	
d			



A National Center for Biomedical Computing



i2b2 Web Client

Griffin Weber, MD, PhD weber@hms.harvard.edu Chief Technology Officer Harvard Medical School Assistant Professor of Medicine Beth Israel Deaconess Medical Center

Nicholas Benik nick_benik@hms.harvard.edu Senior Software Architect

Find Patients

🖉 i2b2 Web Client	
i2b2 Query & Analysis Tool	Find Patients Analysis Tools Message Log Help Logout 🤷
Navigate Terms Find Terms	Query Tool
Image: Clinical Trials Image: Clinit Image: Clinical Trials	Group 1 X Group 2 X Group 3 X Dates Occurs > 0x Exclude Dates Occurs > 0x Exclude Regional enteritis Male Male Reoplasms
Image: Vital Status Workplace Image: SHARED Image: Generative Share Sha	One or more of these AND One or more of these AND One or these AND One or
Previous Queries Image: Constraint of the second seco	Query Status Executing query Elapsed time (seconds): 1.2 Query Finished Matching patients: 27
Circulatory sys@23:49:33 [3-9-2009] [demo] Ane-Cender@23:48:28 [3-9-2009] [demo]	↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓ ↓

Drag-and-drop query design interface

Demographics Plugin

🖉 i2b2 Web Client		
i2b2 Query & Analysis Tool	Find Patients Analysis Tools Message Log Help	o Logout 🧧
Navigate Terms 🕴 💐 🖳	Demographics 0	V I
Dinical Trials	Specify Data View Results Plugin Help	
E Contology	Below are the demographic details for the selected patient set. For each demographic category, the values, number of patients, and a histogram are shown. Patient Set: Digesti-Endocri@23:50:30 [3-9-2009] [demo] [PATIENTSET_10743]	~
	Patient Count: 27	-
	Age in Years	- 2
	10.20 6	
	20-30 3	
Workplace	30-40 5	-
	40-50 2	
🔁 🚍 demo	50-60 1	
	60-70 5	
	70-80 2	
	80-90 2	
	Sex	
	F 14	
	M 13	
		<u>~</u>
Previous Queries	Plugins	
Eircula-Hematol@23:55:07 [3-9-2009] [demo]	Detailed List View Category: ALL	~
Grading Strength Strengt Strength Strength Strength Strength Strength Strength Strength	Demographics (1 Patient Set) - Simple Counts This plugin displays a demographic break-down of a Patient Set.	^
Patient Count - 27 patients	Demographics (2 Patient Sets) - Simple Counts This plugin compares the demographic break-down of two Patient Sets.	~
	🐻 😜 Internet	€ 100% ·

Analysis of a saved patient set using a "plugin"

Two Patient List Plugin

🖉 i2b2 Web Client		
i2b2 Query & Analysis Tool	Find Patients Analysis Tools Message Log Help	Logout 🧖
i2b2 Query & Analysis Tool	Demographics Image: Constraint of the selected patient sets. For each demographic category, the values, number of patients, and a histogram are shown. The pink bar and first patient count for each category value corresponds to Patient Set 1. The green bar and second patient count for each category value corresponds to Patient Set 2. Patient Set 1: Digesti-Endocri@23:50:30 [3-9-2009] [demo] [PATIENTSET_10743] Patient Set 2: Demographics@04:34:26 [3-10-2009] [demo] [PATIENTSET_10746] Patient Count 1: 27 Patient Count 2: 133 Age in Years 0.10 0 0.10 0 0 0.10 0 0 0.20 0 0 0.10 0 0 0.10 0 0 0.10 0 0 0.20 0 0 0.10 0 0 0.10 0 0 0.10 0 0 0.10 0 0 0.10 0 0 0.10 0 0 0.10 0 0 0 0.10 0 0 0 0.10 0	Logout
Previous Queries Circula-Hematol@23:55:07 [3-9-2009] [demo] Circula-Hematol@23:55:07 [3-9-2009] [demo] Circula-Hematol@23:50:30 [3-9-2009] [demo] Circulation: sus @23:40:23:12:92:0091 [demo] Circulation: sus @23:40:23:12:92:0091 [demo]	60-70 6 70-80 2 80-90 2 80-90 3 Sex F F 51 M 13 B2 Category: ALL Demographics (1 Patient Set) - Simple Counts This plugin displays a demographic break-down of a Patient Set. Image: Demographics (2 Patient Sets) - Simple Counts This plugin compares the demographic break-down of two Patient Sets.	
	🕞 😝 Internet	€ 100% ▼

Compare multiple patient sets

Timeline Plugin

🖉 i2b2 Web Client	
i2b2 Query & Analysis Tool	Find Patients Analysis Tools Message Log Help Logout
Navigate Terms 🛛 🐻 🖳	Timeline 🕈 🖉 🖳
Ontology Ontology Ontology Onemographics Onem	Specify Data View Results Plugin Help <<
Workplace	Laboratory Tests Medications Person_#100000003_Male_38yrold_Asian
	Person_#100000007_Male_25yrold_Asian Disgnoses
	Person_#100000009_Female_18yrold_Hispanic Diagnoses Diagnoses I I I I I I I I Diagnoses I I I Person #1000000010 Female 30yrold Hispanic
Previous Queries	Plugins
Circulatory sys@03:14:22 [11-2-2008] [demo]	Detailed List View Category: ALL Category: This plugin displays a demographic break-down of a Patient Set. Demographics (2 Patient Sets) - Simple Counts This plugin compares the demographic break-down of two Patient Sets.
(+) & ne @04:02:53 111-2-2008Lidemol	

An example of visualization of patient data

Debugging Tools

🖉 Message Log - Windows Internet Explo	orer	
WORK:Workplace 👻 All Cells	All Actions	<u>A</u>
sent getFoldersByUserId WORK gcvd called by WORK:Workplace @ T+00:00.00 sent getChildren WORK gcvd called by WORK:Workplace @ T+02:55.32 sent getChildren WORK	<pre><?xml version="1.0" encoding="UTF-8" standalon <ns3:request xmlns:ns3="http://www.i2b2.org/xs
<message_header></td><td>e=" yes"?=""> d/hive/ms .org/i2b2</ns3:request></pre>	
sent getChildren WORK:Workplace @ T+03:19.84 sent getChildren WORK rcvd called by WORK:Workplace @ T+03:21.57 sent getChildren WORK rcvd called by WORK:Workplace @ T+03:24.81	<i2b2_version_compatible>1.1<!-- <sending_application--> <application_name>i2b2</application_name></i2b2_version_compatible>	i2b2_vers Ontology
sent getChildren WORK rcvd called by WORK:Workplace @ T+03:26.62	<application_version>1 <sending_facility> <facility_name>i2b2 Hi</facility_name></sending_facility></application_version>	.1ve
sent deleteChild WORK rcvd called by WORK:Workplace @ T+03:52.67	 <receiving_application_name>1.1<</receiving_application_name>	/applicat
sent getChildren WORK scvd called by WORK:Workplace @ T+03:54.99 Sent getChildren sent getChildren WORK WORK	<application_version>1 <receiving_facility> <facility name="">i2b2 Hi</facility></receiving_facility></application_version>	.1
Refresh	<pre> 2008-08-20 HarvardDemo<!--/d </username-->demo</pre>	OT16:08:4 omain> me>
Done	🕡 🍚 Internet	🔍 100% 🔹 💡

View all client-server i2b2 communication

Enterprise vs. Project

Enterprise

- All investigators, no IRB needed
- All patients, aggregate only
- Exploratory analysis, preliminary data
- Web client

Project

- Small group with IRB protocol number
- Selected patients, limited or identified data
- Detailed data analysis
- Web client or desktop client



Web Client vs. Desktop Client

Web Client

- Written entirely in JavaScript, HTML, CSS
- Same code runs on Windows IIS, Linux, etc
- Easy to deploy and update
- Designed for enterprise-based use
- Desktop Client
 - Written in Java, Eclipse plugin framework
 - Good for heavy client-side processing
 - Can use other Java/Eclipse plugins
 - Designed for project-based use

i2b2 Platforms

Client	Desktop App	Web Client
Web Services	Java	C# .NET
Database	Oracle	SQL Server

Traditional Web Application





Traditional Single Domain Website



https://harvard.edu

Cross Domain AJAX (Not Possible)



Cross Domain AJAX (With a Proxy)



Cross Domain AJAX (With a Proxy)



Cross Domain AJAX (With a Proxy)



i2b2 Messaging with the Proxy Cell

POST to https://i2b2/ontology

<request>

<message_header>

<security>

<username>demo</username>

<password>demouser</password>

</security>

<project_id>demo</project_id>

</message_header>

<request_header />

<message_body /> </request>



i2b2 Messaging with the Proxy Cell

POST to https://localserver/Proxy

<request>

<message_header>

<proxy>

<redirect_url>https://i2b2/ontology</redirect_url>

</proxy>

<security>

<username>demo</usernar

<password>demouser</pas

</security>

<project_id>demo</project_id>

</message_header>

<request_header />

<message_body /> </request>



Client Architecture

Online Help HTML & Graphics		
Core Cells PM ONT CRC WORK	Plugin Manager Plugin Plugin	
Messaging Web Client Framev	vork Utilities	
View ControllerGlobal ObjectsSDX System	K External Em Libraries	

Framework Components

- Messaging AJAX calls to server, debugging
- View Controller Common GUI elements
- Global Objects Shared variables
- SDX System Standard data exchange (drag-drop)
- Utilities XML parsing, browser compatibility
- External Libraries YUI, Prototype, Firebug

Model-View-Controller



Directory Structure



i2b2_config_data.js

```
{
  urlProxy: "index.php",
  urlFramework: "js-i2b2/",
  //-----
                       _____
                                      _____
  // THESE ARE ALL THE DOMAINS A USER CAN LOGIN TO
  lstDomains: [
        { name: "localhost",
          domain: "demo",
          debug: true,
          urlCellPM: "http://127.0.0.1:9090/axis2/rest/PMService/"
        },
         { name: "i2b2.org (1.3)",
          domain: "HarvardDemo",
          debug: true,
          urlCellPM: "http://services.i2b2.org/PM/rest/PMService/"
        }
  1
  1/-
            }
```

i2b2_loader.js

```
i2b2.hive.tempCellsList = [
          { code: "PM",
            forceLoading: true <--- Must be true for PM cell
          },
          { code: "ONT"
                                },
          { code: "CRC"
                                },
          { code: "WORK"
                                },
          { code: "PLUGINMGR",
             forceLoading: true,
          },
           { code: "Dem1Set",
             forceLoading: true,
             forceDir: "cells/plugins/standard"
          },
           { code:
                     "Timeline",
             forceLoading: true,
             forceConfigMsg: { params: [] },
             forceDir: "cells/plugins/standard"
          }
  ];
```

cell_config_data.js

```
{
  files:[
           "Dem1Set ctrlr.js"
  ],
  css:[
           "vwDem1Set.css"
  ],
  config: { // additional configuration variables
           short name: "Demographics",
           name: "Demographics (1 Patient Set) - Simple Counts",
           description: "Demographics of a Patient Set.",
           category: ["celless", "plugin", "standard", "demographics"],
           plugin: {
                      isolateHtml: false, // do not use an IFRAME
                      isolateComm: false, // use built-in communicator
                      standardTabs: true, // use default tabs
                      html: {
                                 source: 'injected_screens.html',
                                 mainDivId: 'Dem1Set-mainDiv'
                      }
           }
  }
}
```

Regulatory Issues for Sharing EHR Data across Institutional Boundaries

A Survival Guide Based on Our Experience at Harvard's CTSA

Susanne Churchill, PhD
OUR MODEL

- Four + Major Teaching Hospitals
- Fiscally/Administratively Independent
- Historical Competitors
- Married at Gunpoint
- Concerned about Inappropriate Use of Data

MAJOR CONCERNS

Protecting the Patients

Protecting the Institutions

Enabling the Investigators

****Inherent Conflicts****

Protecting the Patients

IRB Review – Depends on Data Type

HIPAA Authorization – Implied Consent....

Trust

Protecting the Institution

- Patient Data = Proprietary Property?
 - View from Management
 - View from Clinicians
- Competitive Mischief
- Patient Backlash/Public Perception

Enabling the Investigator

Easy to Use System

- Minimize the Bureaucracy
 - Registration
 - Oversight
 - Number of steps
- Support?

BIG QUESTIONS

- Who are the key institutional stakeholders and what is the process for gaining their support and approval?
- What kind(s) of data will you provide?
- How will you manage
 - Access to Data?
 - Limitations on Use of Data?
 - Insuring Integrity of Data Use?

Institutional Stakeholders

- Go wide and deep
- Go wide and deep
- Go wide and deep

.....

E.g., IRBs, Privacy Officers/Committees, General Counsel, Sr. Research Officers, Sr. Management, PR offices, Key Faculty, Curmudgeons, Skeptics – Think "Shuttle Diplomacy" – SINGLE MOST IMPORTANT STEP

What Kind of Data to Share?

Aggregate Totals

Limited Data Sets

Identified Data

Access to Data

- Who can use the system to access data?
- What about secondary faculty appointees?
- What about non-clinically based investigators within your system?
- What about investigators who wish to collaborate with industry? With other academic health centers?
- Should query topics be reviewed and approved?

Limitations on Data Access and Use

- Should any type of data be reserved?
- Same rules for everyone?
- Should access be limited in time?
- Small samples?
- Harmonize available time spans?
- At what level do you authenticate users (institution vs central)?

Insuring Integrity of Data Use

- Should you seek personal assurances of integrity?
- Should you review requests for "ethical" appropriateness?
- Should you archive and review all queries?
- Should each institution review use of name in publications?
- What are the penalties for violating rules?
- Reporting?
- How do you manage new policy issues?
- How will you handle patient concerns?

Etc.

- Intellectual Property
- Linking to Biospecimens
- Consent
- Governance for discipline-specific Networks
- Scaling from Local to National Networks

i2b2/SHRINE Team

Zak Kohane, Andy McMurry, Griffin Weber, Shawn Murphy, Susanne Churchill

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schurchill@partners.org



A National Center for Biomedical Computing



Shared Health Research Information Network

Andrew McMurry, MS Informatics Team Lead and Architect, Harvard Medical School Center for BioMedical Informatics

SHRINE: Obtaining Samples for Research

Sufficient cohort sizes

 Often cited concern for biomedical research is obtaining cohorts of sufficient size. Often requires aggregating across locations where patients receive care or where investigators do research.

Reproducible study results

 Many papers raise alarms that even in studies with sufficient sample sizes they may still have strong "population sampling" biases.

Sampling Bias Example 1



http://www.boston.com/news/special/politics/2010/senate/results.html

i2b2/shrine National Participation (growing rapidly)



SHRINE: Current Status

- Can we capitalize on the critical mass of i2b2 deployments? YES
- Simply being able to search for patient populations across hospitals is a major first step
 - Demographics : HITSP C32 / HL7
 - Diagnoses : ICD9-CM
 - Medications : RxNorm
 - Lab Procedures : LOINC

Selecting national standards that reflect the reality of data collected at the point of care

East Coast SHRINE: Harvard Deployment

- 5.6M+ Patients
- 890M+ Facts
- Ontology Categories, 18k+ Terms
- 7,500+ Potential Users
- <u>4 IRBs</u>
- 4 major competing hospitals, 3 sites
- Partners Health Care (BWH, MGH)
- Children's Hospital Boston
- Beth Israel Deaconess Medical Center











West Coast SHRINE: Cross-Institutional Clinical Translational Research

3 CTSAs in demonstration network

- University of Washington
- UC Davis
- UC San Francisco
- Primary focus is diabetes
- IRB approvals secured for all sites
- Nick Anderson et all with support from Recombinant Corp

National SHRINE: Pediatric Registry

- 60 sites!
- Grand Opportunity (GO) Stimulus Award
- National registry of rare pediatric disorders
- Childhood Arthritis & Rheumatology Research Alliance http://www.carragroup.org/

- OBTAIN Institutional buy-in
- ETL into your locally controlled i2b2 Data Repository
- MAP your local terminology codes (software provided)
- LINK your local user authentication system
- DEPLOY shrine on a locally controlled server

- ETL into your locally controlled i2b2 Data Repository (Or use your existing i2b2 instance)
 - Review the STAR schema
 - Patient (very basic)
 - □ Concept (ICD, Medication, etc)
 - □ Encounter (hospital visit)
 - Observation Fact (any recorded fact and value)
 - □ "Dimension" tables

- MAP your local terminology codes (software provided)
 - SHRINE concept = Local concept
 - Think "Male = M" instead of complex XML/RDF models
 - A single SHRINE concept can relate to multiple local concepts
 - Demographics mappings can be done in a day
 - Diagnosis are easy (ICD9-CM)
 - Medications are harder (ingredients)
 - Labs are hardest due to lab values

- LINK your local user authentication system
 - Local user auth stays OFF the public internet
 - Your webclient asks "username and password valid" and is returned a list of URLs or invalid logon
 - Probably easiest to "wrap" an existing service at your hospital than doing a daily copy

- DEPLOY shrine on a locally controlled server
 - Can deploy the broadcaster-aggregator and adapter on the same machine or on separate machines. Your preference.
 - SHRINE components served up from cheap commodity hardware

How SHRINE works

- 1. Broadcast queries across a network of i2b2 clinical databases
- 2. Aggregate query results across all sites in near-real time
- 3. Each site maintains an autonomous database
- 4. Patients remain de-identified

SHRINE : how it works



SHRINE plugs into an existing i2b2 hive

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Previous work leading up to SHRINE

- i2b2 \rightarrow Clinical Data Repository
 - Zak Kohane, Shawn Murphy et all
 - Turning everyday clinical encounters into huge research cohorts
 - Star-schema database with associated ontology
- SPIN \rightarrow cross hospital query model
 - Federated query of autonomous/independent hospitals
 - Abstracted away the differences of each data repository enabling on the fly query translation

Overly simplified : i2b2 clinical database + spin federated query = shrine

I2b2 features leveraged for SHRINE

Webclient, Project Management, Ontology, Data Repository



I2b2 features leveraged for SHRINE: <u>Webclient</u>

- 1. Webclient speaks to the broadcaster aggregator as if it were another i2b2 Clinical Data Repository
- 2. Minor enhancements to support additional auditing/monitoring of SHRINE queries

Griffin Weber, Nicholas Benik

I2b2 features leveraged for SHRINE: <u>Project Management</u> Cell

1. Authenticate local investigators

2. Pointers to "Cells in the Hive"
➢ Location for the Ontology
➢ Location of the Data Repository
➢ URLs for all i2b2 cells

I2b2 features leveraged for SHRINE: Ontology Cell

Handles deep "nested" hierarchies like **Diagnoses\Neoplasms\Cancer of breast**

- 1. Demographics
 - Age

- Gender
- Language

- ISO 639-1
- Marital Status
- HL7 Marital Status

Religion

- HL7 Religious Affiliation

- HL7 Administrative Gender

- Race and Ethnicity CDC Race & Ethnicity Code Sets
- 2. Diagnoses ICD-9-CM and CCS hierarchy
- 3. Medications RxNorm and NDF-RT hierarchy
- 4. Lab Tests (demo) LOINC

I2b2 features leveraged for SHRINE: Data Repository Cell

 ✓ Star Schema design concurrently supports multiple ontologies (local ontology and SHRINE ontology)

✓ SHRINE works with CRC v1.3 and v1.4

✓Use your existing i2b2 deployment, no code or data changes required!

Shawn Murphy et all.

<u>SPIN</u> features leveraged for SHRINE

- Local database control to engender participation
- Query Broadcaster-Aggregator
- p2p Trust Model with De-Identification
- Coming in 2010: Limited Data Sets
- Coming in 2010: Search for Biospecimens

SPIN features leveraged for SHRINE <u>Model of Autonomy</u>

SPIN had already proven successful for linking up de-identified pathology reports across independent HIPAA covered entities

Brigham & Women's Hospital* Beth Israel Deaconess Medical Center* Cedars-Sinai Medical Center Dana-Farber Cancer Institute* Children's Hospital Boston* Harvard Medical School* Massachusetts General Hospital* National Institutes of Health National Cancer Institute Olive View Medical Center Regenstrief Institute University of California at Los Angeles Medical Center University of Pittsburgh Medical Center VA Greater LA Healthcare System
SPIN features leveraged for SHRINE: Query Broadcaster-Aggregator



SPIN features leveraged for SHRINE: p2p Trust Model with De-Identification

W3c standard security with patient de-identification

- Well beyond SSL alone
- W3C official libraries for digital signatures
- Encryption of result concents
- IP restricted firewalls
- Anonymize patient counts



SHRINE queries (Actual Patient Counts)

- Comorbidity of Breast and Cervical Cancers
- Acute Myocardial Infarction with Gender Breakdown
- Pediatric Rhematoid Arthritis (rare)
- Countless more secondary uses of electronic medical records...

Common: Breast Cancer

SHRINE Find Find Terms 6) 💙 🗖 Query Tool **Navigate Terms** Query Name: Search by Names Search by Codes contains + cancer Group 1 Group 2 Occurs > 0x Dates Exclude Dates Occurs > 0x Any Category Find Cancer of breast Female E Cancer of bladder Cancer of bone and connective tissue E Cancer of brain and nervous system Cancer of breast - arcinoma in situ of breast Malignant neoplasm of axillary tail of female breast Malignant neoplasm of breast (female), unspecified Malignant neoplasm of central portion of female breast Malignant neoplasm of lower-inner quadrant of female breast Malignant neoplasm of lower-outer quadrant of female breast one or one or AND more of more of Malignant neoplasm of nipple and areola of female breast these these Malignant neoplasm of nipple and areola of male breast Malignant neoplasm of other and unspecified sites of male breast Malignant neoplasm of other specified sites of female breast Malignant neoplasm of upper-inner guadrant of female breast Breast Cancer Comorbidity Malignant neoplasm of upper-outer guadrant of female breast 2 Groups Run Query **New Query** Personal history of malignant neoplasm of breast E Cancer of bronchus, lung + Cancer of cervix **Query Status** E Cancer of colon Finished Query: "Cancer -Female@04:38:02" E Cancer of esophagus BIDMC - 11516±3 patients + Cancer of head and neck CHB - 60±3 patients E Cancer of kidney and renal pelvis Partners - 73629±3 patients Cancer of liver and intrahepatic bile duct AGGREGATED - 85205±3 patients E Cancer of lymphatic and hematopoietic tissue

Comorbidity: Breast and Cervical Cancer

Find					
Navigate Terms Find Terms	Query Tool				
Search by Names Search by Codes	Query Name:				
contains cancer Find Any Category	Group 1 Image: Construction of the second seco				
 Cancer of bladder Cancer of bone and connective tissue Cancer of brain and nervous system Cancer of breast Cancer of breast Carcinoma in situ of breast Malignant neoplasm of axillary tail of female breast Malignant neoplasm of breast (female), unspecified Malignant neoplasm of central portion of female breast Malignant neoplasm of lower-inner quadrant of female breast Malignant neoplasm of lower-outer quadrant of female breast Malignant neoplasm of nipple and areola of female breast Malignant neoplasm of other and unspecified sites of male breast 	One or more of these One or more of these				
Malignant neoplasm of upper-inner quadrant of female breast Malignant neoplasm of upper-outer quadrant of female breast Personal history of malignant neoplasm of breast	Breast Cancer Comorbidity Run Query New Query 2 Groups				
 Cancer of bronchus, lung Cancer of cervix Carcinoma in situ of cervix uteri Malignant neoplasm of cervix uteri, unspecified Malignant neoplasm of endocervix Malignant neoplasm of exocervix Malignant neoplasm of other specified sites of cervix Malignant neoplasm of cervix with cytologic evidence of malignancy Personal history of malignant neoplasm of cervix uteri 	Query Status Finished Query: "Cancer -Cancer @04:44:50" BIDMC - 111±3 patients CHB - 10 patients or fewer Partners - 1291±3 patients AGGREGATED - 1401±3 patients				

Relative counts by gender (Male Acute MI)

IRINE										1
avigate Terms	Find Terms			5 0	_	Query T	ool			
arch hu Namaa	Search by Codes	1		Chipped Chipped Chi		Query Na	me:			
earch by Names	Search by Codes	1			-1				2	
contains 😫	infarct					10 50	Group 1	X	-	Group 2
Find	Any Category					Dates	Occurs > 0x	Exclude	Dates	Occurs > (
Acute myoca	ardial infarction			5		Acute	e myocardia	I infarction	D Male	в
Acute my	ocardial infarction	of anterolateral	wall episode of	care unspecif						
- Acute my	ocardial infarction,	of anterolateral	wall, initial episo	de of care						
Acute my	ocardial infarction	of anterolateral	wall, subsequen	t episode of c						
Acute my	ocardial infarction.	of inferolateral	wall, episode of c	care unspecifie						
- 6 Acute my	ocardial infarction.	of inferolateral	wall, initial episod	de of care						
- 6 Acute my	ocardial infarction.	of inferolateral	wall, subsequent	episode of ca						
Acute my	ocardial infarction.	of inferoposteri	or wall, episode o	of care unspec						
Acute my	ocardial infarction.	of inferoposteri	or wall, initial epis	sode of care						
- 6 Acute my	ocardial infarction,	of inferoposteri	or wall, subseque	ent episode of						
- 6 Acute my	ocardial infarction,	of other anterio	r wall, episode of	f care unspeci						
- Acute my	ocardial infarction,	of other anterio	r wall, initial epis	ode of care						
Acute my	ocardial infarction,	of other anterio	r wall, subseque	nt episode of (one or			one o
- 6 Acute my	ocardial infarction,	of other inferior	wall, episode of	care unspecif			more of	A	ND	these
- 6 Acute my	ocardial infarction,	of other inferior	wall, initial episo	de of care			linese	-		
- Acute my	ocardial infarction,	of other inferior	wall, subsequen	t episode of c						
- Acute my	ocardial infarction,	of other lateral	wall, episode of o	care unspecific						
- 6 Acute my	ocardial infarction,	of other lateral	wall, initial episor	de of care		Breast C	ancer Como	orbidity		
- Acute my	ocardial infarction,	of other lateral	wall, subsequent	episode of ca		-				
- Acute my	ocardial infarction,	of other specifi	ed sites, episode	of care unspe		Run Que	ary New	Query		2 Groups
- Acute my	ocardial infarction,	of other specifi	ed sites, initial ep	isode of care						
- Acute my	ocardial infarction,	of other specifi	ed sites, subsequ	uent episode c		Query S	tatus			
- Acute my	ocardial infarction,	subendocardia	I infarction, episo	de of care uns		Fisishes	0			
- Acute my	ocardial infarction,	subendocardia	I infarction, initial	episode of ca		FINISNEO	AC - 5730+3	cute m-Ma	ale@04:	55:19
- Acute my	ocardial infarction,	subendocardia	l infarction, subse	equent episod		CHB	- 92+3 patie	ents		
Acute my	ocardial infarction,	true posterior v	vall infarction, epi	isode of care u		Partr	ners - 32606	5±3 patients	5	
- Acute my	ocardial infarction,	true posterior v	vall infarction, init	ial episode of		AGG	REGATED	- 38428±3	patients	
- Acute my	ocardial infarction,	true posterior v	vall infarction, sub	bsequent epis		100,000-0				
- D Acute my	ocardial infarction,	unspecified site	e, episode of care	e unspecified	4					
- 6 Acute my	ocardial infarction,	unspecified site	e, initial episode o	of care	+					

Relative counts by gender (Female Acute MI)

HRINE	Fir
Navigate Terms Find Terms	🐼 💟 📃 Query Tool
SHRINE Age Age O-9 years old O-9 years old O-9 years old O-9 years old O-10-17 years old O-11-17 years O-1	Query Name: Group 1 X Dates Occurs > 0x Exclude Dates Occurs > 0x Exclude Dates Occurs > 0x Acute myocardial infarction Pemale One or AND more of AND these AND Breast Cancer Comorbidity Run Query New Query 2 Groups Query Status Finished Query: "Acute m-Female@05:00:22" BIDMC - 3793±3 patients CHB - 62±3 patients Partners - 25135±3 patients AGGREGATED - 28990±3 patients

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Rare: Children with Rheumatoid Arthritis

HRINE			Fi
Navigato Torme	Find Torres		Owen Test
Navigate remis			
Search by Names	Search by Codes		Query Name:
contains 🛟	Rheum		Group 1 🔣 Group 2
Find	Any Category		Dates Occurs > 0x Exclude Dates Occurs > 0x
	RIALS.ANTIRHEUMATIC	6	Rheumatoid arthritis
	MATICS		
- 6 ANTIMA	ALARIALS ANTIRHEUMATIC		
	EUMATICS OTHER		
- A CYTOT	OXICS ANTIRHEUMATIC		
F GOLD C	COMPOUNDS ANTIRHEUMATIC		
	LICYLATE NSAIS ANTIRHEUMATIC		
T SALICY	LATES ANTIRHEUMATIC		
ANTIRHEU	MATICS OTHER		
- Accidental	poisoning by antirheumatics (antiphlogistics)		
- 6 Acute rheur	matic endocarditis		
Acute rheur	matic heart disease, unspecified		one or one or
- 6 Acute rheur	matic myocarditis		more of AND more of
Acute rheur	matic pericarditis		these these
- 6 Antirheuma	tics (antiphlogistics) causing adverse effects in therapeutic	use	
- D CYTOTOX	CS ANTIRHEUMATIC		
- 6 Chronic pos	strheumatic arthropathy		Broast Cancer Comercidity
Chronic rhe	sumatic disease of the heart valves		Breast Cancer Comorbidity
- 6 Chronic rhe	aumatic pericarditis		Run Query New Query 2 Groups
GOLD CON	POUNDS, ANTIRHEUMATIC		
- 6 Monoarticu	lar juvenile rheumatoid arthritis		In the second se
NONSALIC	YLATE NSAIS, ANTIRHEUMATIC		Query Status
Nonrheuma	atic aortic valve disorders		Finished Query: "Rheumat-0-9 yea@05:10:04"
Nonrheuma	atic mitral valve disorders		BIDMC - 10 patients or fewer
Other acute	e rheumatic heart disease		CHB - 96±3 patients
Other and u	unspecified rheumatic aortic diseases		Partners - 31±3 patients
			AGGREGATED - 127±3 patients

SHRINE: Current Work

- Making SHRINE rapidly deployable to 60 sites
- Training new developers
- Documentation and source code refactoring
- Launching SHRINE Open Source effort

SUMMARY

- Rapid deployment of i2b2 technology across the country
- SHRINE enables federated searches of existing i2b2 deployments without modifying the software or databases
- SHRINE "sub-networks" exist both at Harvard and the west coast with major new efforts underway per Recovery Act funds
- Even simple searches can power many translational studies
- Current work focus = rapid deployment and open source
- Headed towards supporting Limited Data Set and Biospecimen exchange in 2010

Acknowledgements: Core SHRINE team

Zak Kohane	(SHRINE PI / HMS)
Joanna Brownstein	(Project Manager, HMS)
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Shaun Kelly	(QA, HMS)
Doug Macfadden	(HMS CBMI IT Director)
Charles McGow	(Developer, Children's)
Andrew McMurry	(Architect / HMS)
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