Informatics Resources for Clinical Research

Jim Cimino, Geoff Gordon, Matt Wyatt and James Willig
UAB Informatics Institute
April 6, 2016
Today’s Take-Home Messages

- Overview of the clinical informatics systems and services available through CCTS Research Commons
- Understand how you can use i2b2 to get patient data
- Find your way around the Clinical Informatics pages on the Research Commons Website
Clinical Informatics Systems

- IMPACT: UAB Health System’s electronic health record
- Clinical trial support systems (including data capture)
- UAB Enterprise Clinical Data Warehouse
- i2b2 clinical research data repository
Clinical Trials Support Systems

- OnCore – Clinical Trials Management System
  - Cancer Center currently using
  - Being expanded to the UAB Campus
- PowerTrials – Clinical orderables for Study participants
  - Integrated with IMPACT for Orders and Charges
  - Being tested; planned go-live in May
  - Also integrated with OnCore
CTMS Environment - Future State

- Clinical Trials Management
- OnCore
- IRB
- IRAP
Study creation begins in OnCore, our clinical trials management system. Once the information is in OnCore, the clinical trial data is sent to PowerTrials (IMPACT) through an interface.

When IMPACT is aware of a trial, participants can be registered, trial information can be made available, and research PowerPlans can be developed.

As patients are registered to trials in OnCore, they will also be registered in PowerTrials and their charts will be updated to reflect their participation.
OnCore: Clinical Trial Management

- Protocol and Subject Lifecycle Management
- Calendar and Schedule of Events
- Financial Management – Budget Negotiation and Sponsor Invoicing
- Reporting
- Effort Tracking
- Study Information Portal
OnCore: Electronic Data Capture

- Integrated with CTMS functionality
- Forms library
- Easy to use eCRF designer
- Query management
- Data export & reporting
OnCore Case Report Form

1. Patient Study ID #

2. First Dose Date

3. Last Dose Date

4. Con Med Ongoing

Search

5. Medication

6. Total Daily Dose

7. Dose Unit

Search

8. Schedule

Search

9. Dose

Search

10. Dose Units

Search

11. Reason

Search

12. Baseline Med

Search
PowerTrials: A Component of the EHR

[Diagram showing components of PowerTrials]

- Decision Support
- Charge Delineation
- Orders
- Screening and Recruitment
- Enrollment Tracking
- Study Management

[PowerChart, PowerTrials, Lab, Pharmacy, Radiology, etc.]

IMPACT
Screening Referral
Patient Enrolled: Banner Bar indicator in PowerChart

- Note the On Study indicator in the banner bar and the Clinical Research tab in the left menu.
- Opening the tab will display more information about the trial.
Ordering View of Research PowerPlan
Access to EHR Data at UAB

IMPACT

PowerTrials

OnCore

Case Report Forms

UAB Enterprise Clinical Data Warehouse

i2b2
Access to Clinical Data

- Use of i2b2 repository to obtain de-identified summary data is deemed to “Not Involved Human Subjects”
- Use of i2b2 for detailed, de-identified data is considered exempt from IRB oversight
- Bottom line: with the right authorizations, you can access our data in real time without IRB approval.
Access to Clinical Data – i2b2
(Informatics for Integrating Biology & the Bedside)

- Self service tool for UAB faculty and Staff
  - Access and download data related to UAB Patients
    - Feasibility assessment
    - Hypotheses exploration
- Easy to use
  - Drag and drop user interface for determining the number of patients meeting research criteria
- Expandable to include more data, different tools, etc.
- Available at: https://i2b2-uab.hs.uab.edu
Access to EHR Data at UAB

IMPACT

UAB Enterprise Clinical Data Warehouse

i2b2

Cohort Feasibility

Summary Data

Researcher

Analyst
Detailed Questions

Constrain Group by Date Range

From: 12/01/2015
To: 01/31/2016

Choose value of BMI Range (Test:BMI)

Searches by Lab values can be constrained by the high/low flag set by the performing laboratory, or by the values themselves.

- No Value
- By Value

Please select operator:
- LESS THAN (<)

Please enter a value:

Units = kg/m²

* No Known Allergies - 383613

none of these
Detailed Questions

Searches by Lab values can be constrained by the high/low flag set by the performing laboratory, or by the values themselves.

- No Value
- By Value

Please select operator: GREATER THAN (>)

Please enter a value: 7

Units: PERCENT
Access to EHR Data at UAB

IMPACT

UAB Enterprise Clinical Data Warehouse

Data sets for analysis

i2b2

Detailed Data

Analyst

Researcher
## Downloading a Dataset

### Patient Data Download and Consultation Request

This plugin is used to request extraction of patient details from a query's patient set.

<table>
<thead>
<tr>
<th>Limit Fact Type</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Labs</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diagnosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vitals</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Limit Date Range**

From: MMDDYYYY To: MMDDYYYY

**Limit Details**

- Download all data rows
- Download a summary (get patient counts for each concept)

**Information Recorded with this Download**

Displaying your most recently recorded project information; you may sort this information for each download request.

- **Title of Research Project**: testing
- **Description of the Research Project**: testing
- **List Blazer IDs of Others Who Will View/Use This Data (comma separated)**: blazer1, blazer2, blazer3...

**Select at Least One Data Set**

Only completed queries that return patient sets are displayed below. Most recent is first.

- **Patient Set for Black-FEMALE** (ID@12:43:39)
  - Patients in Set: 7524
  - Patients in Set: 229
  - Patients in Set: 277
  - Created: 04/05/2016 12:43:46 PM
  - Created: 04/04/2016 01:40:19 PM
  - Created: 04/04/2016 01:42:53 PM

- **Patient Set for *Myopia* (ID@13:46:17)
- **Patient Set for *Sjoca syndrome* (ID@13:42:61)**
## Downloading a Dataset

### Summary or Detailed

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong></td>
<td><strong>B</strong></td>
<td><strong>C</strong></td>
<td><strong>D</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Patient Count</strong></td>
<td><strong>Percentage</strong></td>
<td><strong>Concept Code</strong></td>
<td><strong>Concept Name</strong></td>
<td></td>
</tr>
<tr>
<td>69</td>
<td>87.34</td>
<td>ICD9:204.10</td>
<td>Chronic lymphoid leukemia without mention of remission (ICD9:204.10)</td>
<td></td>
</tr>
<tr>
<td>33</td>
<td>41.77</td>
<td>ICD9:401.9</td>
<td>Unspecified essential hypertension (ICD9:401.9)</td>
<td></td>
</tr>
<tr>
<td>23</td>
<td>29.11</td>
<td>ICD10-CM:C91.10</td>
<td>Chronic lymphocytic leukemia of b-cell type not having achieved remission (ICD10:C91.10)</td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>25.32</td>
<td>ICD9:204.11</td>
<td>Chronic lymphoid leukemia in remission (ICD9:204.11)</td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>22.76</td>
<td>ICD9:V58.69</td>
<td>Encounter for long-term (current) use of other medications (ICD9:V58.69)</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>20.25</td>
<td>ICD9:202.80</td>
<td>Other malignant lymphomas, unspecified site, extranodal and solid organ sites (ICD9:202.80)</td>
<td></td>
</tr>
<tr>
<td>16</td>
<td>20.25</td>
<td>ICD9:272.4</td>
<td>Other and unspecified hyperlipidemia (ICD9:272.4)</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>16.46</td>
<td>ICD9:785.50</td>
<td>Unspecified chest pain (ICD9:785.50)</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>16.46</td>
<td>ICD9:V76.12</td>
<td>Other screening mammogram (ICD9:V76.12)</td>
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</tr>
<tr>
<td>13</td>
<td>16.46</td>
<td>ICD9:401.1</td>
<td>Benign essential hypertension (ICD9:401.1)</td>
<td></td>
</tr>
</tbody>
</table>
Access to EHR Data at UAB

Cohort Identification (Enrollment)

Request for Additional Data

i2b2

UAB Enterprise Clinical Data Warehouse

IMPACT

Analyst

Researcher

UAB SCHOOL OF MEDICINE

INFORMATICS INSTITUTE
Request Additional Data or Consultation

**UAB-i2b2 Data Request/Consultation Request**

Please select the best description of your data needs.

- I have a patient set that I built in i2b2 and I need more data about those patients than is available in i2b2.
- My patient set is too large to download to Excel using your website. Please send me that data.
- There is data I would like to see added to i2b2 in the near future so I can build queries that include that data.

Tell us something about your project and its data.

<table>
<thead>
<tr>
<th>Your Blazer ID</th>
<th>Your Role on the Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>mcwyatt</td>
<td>PI, coordinator, data manager, etc</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Blazer ID of PI (if not you)</th>
<th>PI Name</th>
<th>PI Email Address</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>UAB School/Department/Division/Center/Institute behind this Project</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>* Project Title/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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</table>

<table>
<thead>
<tr>
<th>IRB Number</th>
<th>IRB Title</th>
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<tbody>
<tr>
<td></td>
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</tbody>
</table>
Access to EHR Data at UAB

IMPACT

UAB Enterprise Clinical Data Warehouse

Cohort Identification (Enrollment)
Data sets for analysis
Cohort Feasibility
Summary Data
Detailed Data
Request for Additional Data

Analyst

Researcher

i2b2
## i2b2 Data

### Current i2b2 Data

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>~883K</td>
</tr>
<tr>
<td>Visits</td>
<td>~10M</td>
</tr>
<tr>
<td>Labs</td>
<td>~123M</td>
</tr>
<tr>
<td>BMI &amp; Waist circ.</td>
<td>~502K</td>
</tr>
<tr>
<td>Allergies</td>
<td>~1.2M</td>
</tr>
<tr>
<td>Diagnoses</td>
<td>~23M</td>
</tr>
<tr>
<td>Medications</td>
<td>~22M</td>
</tr>
<tr>
<td>Inpt Procedures</td>
<td>~36K</td>
</tr>
</tbody>
</table>

### Planned i2b2 Data

<table>
<thead>
<tr>
<th>Category</th>
<th>Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outpatient Procedures</td>
<td></td>
</tr>
<tr>
<td>Blood Pressure</td>
<td></td>
</tr>
<tr>
<td>Social History</td>
<td></td>
</tr>
<tr>
<td>UAB Surgical Procedures</td>
<td></td>
</tr>
<tr>
<td>Pregnancy</td>
<td></td>
</tr>
<tr>
<td>Cancer Registry Data</td>
<td></td>
</tr>
<tr>
<td>Other: Based on Needs</td>
<td></td>
</tr>
</tbody>
</table>
Access to EHR Data at UAB

IMPACT
  PowerTrials

UAB Enterprise Clinical Data Warehouse

OnCore
  Case Report Forms

i2b2

REDCap

Research Electronic Data Capture
Capturing Clinical Research Data - REDCap

- REsearch Data Capture
- Collects Case Report Forms for research studies or surveys completed by participants
- Configurable to collect virtually any data
- Supports longitudinal studies, multi-arm, branching logic, field validation, etc.
Capturing Clinical Research Data - REDCap

- Multi-user ability with control of privileges
- Exports data:
  - Excel, PDF, SAS, R, SPSS, Stata
- Supported in partnership with the Dpt. Of Medicine, and CCTS
  - https://www.uab.edu/medicine/department-of-medicine/services/137-it/152-redcap
Access to EHR Data at UAB

IMPACT

PowerTrials

UAB Enterprise Clinical Data Warehouse

i2b2

OnCore

Case Report Forms

PRO

REDCap
Capturing Clinical Data

- Capturing Patient Reported Data
  - At the Point of Care → PRO System
  - At home → RheumPRO System
Capturing Clinical Data – PRO System

- Web-based platform to implement capture of patient reported outcomes in care settings

- Expandable instrument library, currently > 40
  - Examples: GAD-7 (anxiety), PHQ-9 (depression), MOS-4 (social support), Substance abuse, BPI (Brief pain inventory)

- Build practice specific panels from library
## General Overview

### Settings Sessions

<table>
<thead>
<tr>
<th>Settings</th>
<th>Sessions</th>
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</thead>
<tbody>
<tr>
<td>Social Services&lt;sup&gt;1&lt;/sup&gt;</td>
<td>2,610</td>
</tr>
<tr>
<td>Palliative&lt;sup&gt;1&lt;/sup&gt;</td>
<td>1,208</td>
</tr>
<tr>
<td>Signs &amp; Symptoms&lt;sup&gt;1&lt;/sup&gt;</td>
<td>52,249</td>
</tr>
<tr>
<td>Viral Hepatitis&lt;sup&gt;1&lt;/sup&gt;</td>
<td>1,213</td>
</tr>
<tr>
<td>Supportive Care&lt;sup&gt;2&lt;/sup&gt;</td>
<td>1,376</td>
</tr>
<tr>
<td>Breast Health&lt;sup&gt;2&lt;/sup&gt;</td>
<td>106</td>
</tr>
<tr>
<td>iEngage&lt;sup&gt;3&lt;/sup&gt;</td>
<td>217</td>
</tr>
<tr>
<td>BA2C&lt;sup&gt;3&lt;/sup&gt;</td>
<td>256</td>
</tr>
<tr>
<td>Pediatric Neurosurgery</td>
<td>65</td>
</tr>
</tbody>
</table>

(1) 1917 Clinic; (2) TKC; (3) Research
1917 Palliative Care Clinic

**Symptoms**
- Pain
- Anxiety
- QOL
- Depression

**Improved Pain**

**PRO Implementation**
- Selection of instruments
- Sequence
- Internal logic
- Frequency
- Alerts

**Notification Triggered**
- Clinical: SI, IPV (starts clinic response protocol)
- Study enrollment
Pediatric Implementation #1 Spina Bifida

- **PRO Implementation**
  - Selection of instruments
  - Sequence
  - Internal logic
  - Frequency
  - Alerts
  - One session, multiple users

**Next Partner Clinics?**
Capturing Clinical Data at home – RheumPRO

Design Pillars:
1. Empower user to capture their data
2. Empower user to share/manipulate/own data
3. Empower user to fight chronic illness via research
4. Educate and connect to community
## Capturing Clinical Data at home – RheumPRO

### Your Assessments

<table>
<thead>
<tr>
<th>Assessment</th>
<th>Current Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alcohol Use</td>
<td>65</td>
</tr>
<tr>
<td>Pain Interference</td>
<td>69</td>
</tr>
<tr>
<td>Physical Function</td>
<td>20</td>
</tr>
<tr>
<td>Sleep Disturbance</td>
<td>56</td>
</tr>
<tr>
<td>Appraised Cognition Abilities</td>
<td>54</td>
</tr>
<tr>
<td>Fatigue</td>
<td>69</td>
</tr>
<tr>
<td>Upper Extremity</td>
<td>17</td>
</tr>
<tr>
<td>Sleep-Related Impairment</td>
<td>66</td>
</tr>
<tr>
<td>Informational Support</td>
<td>50</td>
</tr>
<tr>
<td>Anger</td>
<td>75</td>
</tr>
</tbody>
</table>

**Physical Function**

![Graph showing physical function over time](image)

- **Past Month**: Your current score is 20.
Capturing Clinical Data at home – RheumPRO

KNOW YOUR RA SCORE

Enroll in this advanced blood test that helps you and your doctor better understand your rheumatoid arthritis disease activity with a single score.

This is a label

This is a label

This is a label

This is a label

This is a label
Access to EHR Data at UAB

IMPACT

PowerTrials

UAB Enterprise Clinical Data Warehouse

OnCore

Case Report Forms

i2b2

SHRINE

TriNetx

REDCap

PRO

Informatics Institute
Access to non-UAB Data

- SHRINE – network of i2b2 instances for distributed queries
- TriNetX – the commercial version of SHRINE
Access to EHR Data at UAB

IMPACT

PowerTrials

UAB Enterprise Clinical Data Warehouse

OnCore

Case Report Forms

i2b2

REDCap

SHRINE

TriNetx

PRO
If you want to...

...estimate potential cohort: i2b2 and Data Warehouse
...find subjects for a study: i2b2 and Data Warehouse
...set up a clinical trial: OnCore and PowerTrials
...enroll subjects: PowerTrials
...capture data: IMPACT, OnCore, REDCap, PRO
...pull data from your trial: i2b2 and Data Warehouse
...reuse data for new questions: i2b2, SHRINE, TriNetX
Today’s Take-Home Messages

- Get some sense of all the clinical informatics systems and services available through Research Commons
- Understand how you can use i2b2 to get patient data
- Find your way around the Clinical Informatics pages on the Research Commons Website
CCTS Research Commons

The UAB Center for Clinical and Translational Science (CCTS) is your connection to tools, technology, research, and inter-institutional resources. Whether a trainee, full professor or somewhere in between, we facilitate processes and direct you to appropriate services, and help identify related opportunities at UAB or within our partner network.

For any internal or external funding application:
- Take advantage of CCTS expertise in study design, methods and biostatistics to optimize your proposal.
- Meet with a project panel, which is a team of scientific experts who have perused your application as a first level of peer review.
- You write the science, let CCTS facilitate the process.
- Get assistance with grant development. Council of Center Administrators (COCA) SWAT Team.

If you need additional guidance and / or extended assistance in assembling grant proposals or contracts, please contact:

CCTS Research Commons
1924 7th Avenue South
PCAMS Building