Informatics Tools for Clinical Research

Cohort Finding, Accessing Patient Data and Recruitment

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Outline

• **Obtaining Counts Preparatory for Research**
  – UC-Research Exchange (UC-ReX)
  – Los Angeles Data Resource (LADR)
  – Informatics for Integrating Biology & the Bedside (i2b2)

• **Obtaining Medical Record Data to Conduct Your Research**
  – Studies with Direct Patient Contact
  – Studies with No Direct Patient Contact
## Obtaining Counts: UC-ReX

### Sites
- UCLA
- UCSF
- UCD
- UCI
- UCSD

### What You Can Search On:
- Demographics
- Laboratory Tests
- ICD-9 Codes
- Medications
- Vital Signs
- Vital Status

<table>
<thead>
<tr>
<th>Sites</th>
<th>Distinct Patient Records</th>
<th>Diagnoses</th>
<th>Labs</th>
<th>Medications</th>
<th>Procedures</th>
<th>Vital Signs</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCD</td>
<td><strong>2,361,467</strong></td>
<td>46,735,705</td>
<td>117,944,810</td>
<td>27,952,027</td>
<td>1,052,211</td>
<td>46,048,977</td>
<td><strong>256,343,183</strong></td>
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<tr>
<td>UCI</td>
<td><strong>1,585,160</strong></td>
<td>14,875,209</td>
<td>43,571,225</td>
<td>9,130,634</td>
<td>918,705</td>
<td>7,424,967</td>
<td><strong>68,510,973</strong></td>
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<tr>
<td>UCLA</td>
<td><strong>4,537,355</strong></td>
<td>37,968,248</td>
<td>128,805,690</td>
<td>5,373,547</td>
<td>1,460,767</td>
<td>19,227,267</td>
<td><strong>224,643,847</strong></td>
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<tr>
<td>UCSD</td>
<td><strong>2,361,398</strong></td>
<td>18,189,436</td>
<td>85,614,364</td>
<td>29,953,062</td>
<td>119,148</td>
<td>25,104,772</td>
<td><strong>171,003,400</strong></td>
</tr>
<tr>
<td>UCSF</td>
<td><strong>3,277,988</strong></td>
<td>8,831,305</td>
<td>94,559,761</td>
<td>9,504,694</td>
<td>433,422</td>
<td>21,536,651</td>
<td><strong>127,468,273</strong></td>
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<tr>
<td>Total</td>
<td><strong>14,123,368</strong></td>
<td>126,599,903</td>
<td>470,495,850</td>
<td>81,913,964</td>
<td>3,984,253</td>
<td>119,342,634</td>
<td><strong>847,969,676</strong></td>
</tr>
</tbody>
</table>
## Obtaining Counts: LADR

### Sites

- UCLA
- Cedars Sinai

**Forthcoming by Fall 2015:**
- University of Southern California
- Children’s Hospital Los Angeles
- City of Hope
- Community clinics affiliated with Charles R. Drew University

### What You Can Search On:

- Demographics
- ICD-9 Codes
- Medications
- Vital Signs
- Vital Status

<table>
<thead>
<tr>
<th>Sites</th>
<th>Distinct Patients</th>
<th>Total Facts</th>
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<tbody>
<tr>
<td>Cedars</td>
<td>2,599,282</td>
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</tr>
<tr>
<td>UCLA</td>
<td>4,395,293</td>
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Obtaining Counts: UC-ReX
Obtaining Counts: LADR
Obtaining Counts: i2b2
Getting Access to UC-ReX/LADR/i2b2

Requirements:
• Affiliation with a participating institution
• Completion of a training
• Submission of signed user agreements for UC-ReX and/or LADR and/or i2b2

Contact Information
ucrex@ctsi.ucla.edu or ladr@ctsi.ucla.edu
Ruby Wan: ywan@mednet.ucla.edu
Obtaining Medical Record Data to Conduct Your Research

Obtain a Data Consult - Talk to us first

Obtain IRB Approval

Obtain Compliance Approval

Data extraction and delivery

We will review your IRB application

We will draft needed forms

We will help you define your data request
Types of Studies

Direct Patient Contact
- Screening
- Consented Patients

No Direct Patient Contact
- De-identified
- Limited
- Identified
- Chart Review

Protected Health Information (PHI):
- HIPAA Waiver
- HIPAA Release Authorization

Excludes all 18 identifiers
Excludes 16 identifiers
Data Elements

### Imaging Orders and Results

<table>
<thead>
<tr>
<th>Variable</th>
<th>Include Field</th>
<th>Selection Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Order Procedure Id</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Order Time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result Time</td>
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<td></td>
</tr>
<tr>
<td>Procedure Code</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedure Name</td>
<td></td>
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</tr>
<tr>
<td>Accession Number</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Impression</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Narrative</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Footnotes: Counts of orders by Type can be pulled first for review and to allow for more detailed selection. Result Text can potentially be searched for specific terms or string patterns (regular expressions). Narrative and Impression will each be sent as a separate table with order procedure id, line, and text fields.*

### Microbiology

<table>
<thead>
<tr>
<th>Order Type</th>
<th>Include Orders</th>
<th>Selection Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Order Procedure Id</td>
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<tr>
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<tr>
<td>Procedure Name</td>
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<td></td>
</tr>
<tr>
<td>Specimen Source</td>
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<tr>
<td>Specimen Type</td>
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<tr>
<td>Organism Name</td>
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</tr>
<tr>
<td>Susceptibility</td>
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</tr>
<tr>
<td>Sensitivity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antibiotic</td>
<td></td>
<td></td>
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</tbody>
</table>

*Footnotes: Counts of orders by Type can be pulled first for review and to allow for more detailed selection. Results prior to 3/1/2013 will have similar layout to the pathology & cytology table above.*

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**Step 1: Generate cohort**

**Step 2: Extract variables**
Compliance

- We will help draft UCLA Compliance forms
  - Request to Interface or Download Restricted Information (RI) Form*
  - Data Use Agreement (DUA)

* Requires PI and CAO signatures
Obtaining Medical Record Data: Data Delivery

- Password-protected Excel files
- REDCap (Research Electronic Data Capture)
How to Request Our Services

• Submit a service request at http://intranet.ctsi.ucla.edu/
How to Request Our Services

CLINICAL DATA REQUESTS

The Biomedical Informatics Program (BIP) of the UCLA CTSI provides researchers with access to data derived from patient care activities. Investigators can access patient count data using one of our self-service systems. If accessing individual-level data is desired, a consult from BIP is required. More information can be found below.

Obtaining Counts Preparatory for Research

UCLA participates in two networks that you can use to assess how many patients would meet different study inclusion criteria that are being considered. The systems also help you choose which other institutions to approach for participation if you need a larger sample size. Once your criteria is set, you can also obtain patient counts by gender, race and ethnicity to facilitate the completion of NIH planned enrollment tables.

> Click here for more information about these systems and how you can obtain access.

Obtaining Medical Record Data to Conduct your Research

BIP acts as the storefront for provisioning healthcare-related datasets for research projects at UCLA. As part of our data provisioning service, BIP supports investigators through the whole process of obtaining patient data. BIP reviews IRB applications and suggests modifications to the investigator in order to ensure IRB approval. If needed, BIP collaborates with the Biostatistics Program to integrate electronic health record (EHR) data with other kinds of data and analytic efforts. BIP also assists investigators with data security review by the UCLA Office of Compliance Services. BIP is delegated the authority to grant approval on behalf of the Compliance office in routine cases. Once BIP ensures all approvals have been secured, our programmers extract the requested data and securely deliver the data set to the investigator via our internal instance of REDCap (HIPAA compliant) or as an encrypted file via University email. You can receive data for studies involving direct patient contact or studies with no direct patient contact.

> Click here to find more information on the process for receiving data for your study.
How to Request Our Services

**RESEARCHER RESOURCES**

**OBTAINING COUNTS PREPARATORY FOR RESEARCH**

We have a variety of informatics tools to assess the feasibility of your research idea or complete NIH planned enrollment tables.

**UC Research eXchange (UC-ReX)**

UC-ReX currently contains data from over 13.5 million patients seen across the 5 UC medical centers. More information on UC-ReX can be found [here](#).

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<td></td>
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**Los Angeles Data Resource (LADR)**

LADR is a collaborative effort of major Los Angeles healthcare organizations. More information on LADR can be found [here](#).

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**Getting Access to UC-ReX/LADR**

**Requirements:**

1. Affiliation with a participating institution
2. Completion of an in-person training
3. Submission of signed user agreements for UC-ReX and/or LADR

*For UC-ReX, you must be affiliated with UCLA. If you are affiliated with another UC please contact the appropriate site.
For LADR, you must be affiliated with one of the sites currently contributing data (UCLA or Cedars Sinai Medical Center).

**If you are not a faculty member, you must have an affiliated faculty member’s signature on both of your user agreements.**

**NOTE:** If estimating your population size requires data not available in either tool, it may be possible for the SID team to run the query for you. If this is the case, please note we will need at least 2 weeks notice prior to the desired deadline.

**Contact Information**

ucrex@ctsi.ucla.edu or ladr@ctsi.ucla.edu
How to Request Our Services

RESEARCHER RESOURCES

OBTAINING MEDICAL RECORD DATA TO CONDUCT YOUR RESEARCH

To receive data derived from patient care at UCLA you will need IRB approval and Compliance approval, unless the data is de-identified. The specific requirements for different types of studies are provided in the tabs below. However, in general, we recommend the following steps:

1. Obtain a Data Consult - Talk to us first. We help with all aspects of data requests for research purposes. Click here to request a consult online at intranet.ctsi.ucla.edu.

2. Obtain IRB approval - To ensure that IRB-approved procedures are followed, we will need copies of your IRB approval letter, and your complete, currently-approved IRB application.

3. Obtain Compliance approval - Unless you are using de-identified data (as defined below), UCLA Compliance will need to approve your data security plans, after the plans are signed by your department’s chair or chief administrative officer. We’ll draft the Compliance review forms based on your IRB application, which you can then take for signatures.

4. Data extraction and delivery - Data can be delivered securely in a variety of ways. Populating a REDCap database is a preferred method, but we can also deliver data in Excel files and by other means.

Additional requirements depend on whether your study involves direct patient contact. For studies involving direct patient contact, requirements differ based on whether patients involved have given consent for use of their medical record data. For studies that do not involve direct patient contact, an important distinction is whether chart review is required. Find the tab for your study type below and follow the specific instructions. If your study involves activities in more than one category, please follow the instructions for all applicable categories.

Studies with Direct Patient Contact

Studies with No Direct Patient Contact

There are two major study categories that involve direct patient contact: screening health record data for possibly-eligible patients vs. obtaining health record data for patients already consented and enrolled in a study.

Screening UCLA Health Record Data for Purposes of Recruiting Eligible Patients

Find the tab for your study type below and follow the specific instructions.
References

- UCLA CTSI: [http://ctsi.ucla.edu/](http://ctsi.ucla.edu/)
- Clinical Data Requests: [http://ctsi.ucla.edu/researcher-resources/pages/clinicaldata](http://ctsi.ucla.edu/researcher-resources/pages/clinicaldata)

Questions? Contact Us

- Marianne Zachariah: mzachariah@mednet.ucla.edu
- Ruby Wan: ywan@mednet.ucla.edu
- Amanda Do: aldo@mednet.ucla.edu