

**UAMS**

UNIVERSITY OF ARKANSAS  
FOR MEDICAL SCIENCES

**UAMS**

WINTHROP P. ROCKEFELLER  
CANCER INSTITUTE

UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES



**caBIG<sup>®</sup>**

cancer Biomedical  
Informatics Grid<sup>™</sup>

# An Open Source Clinical Research Infrastructure powered by caBIG

Umit Topaloglu Ph.D.  
Information Technology

# Agenda



- **Our Clinical Research Infrastructure (CRI) goal**
- **Implementations employing caBIG tools and standards**
  - Participant
    - Registry
    - Calendar
  - Clinical Data Management
  - Lab values
  - Semantic Infrastructure and CDEs
- **Next steps**
- **Conclusion and Questions**

# Our CRI goal



## Where were we?

- No standards and tools in place,
- Many paper, MS Access, MS Excel based systems,
- Bioinformaticians and other researchers are/were spending 75-80% of their time to just locate data they need,
- It was a challenge to find who is in what study, what consent etc.
- No data integrity and quality measures in place

## Our CRI goal-II

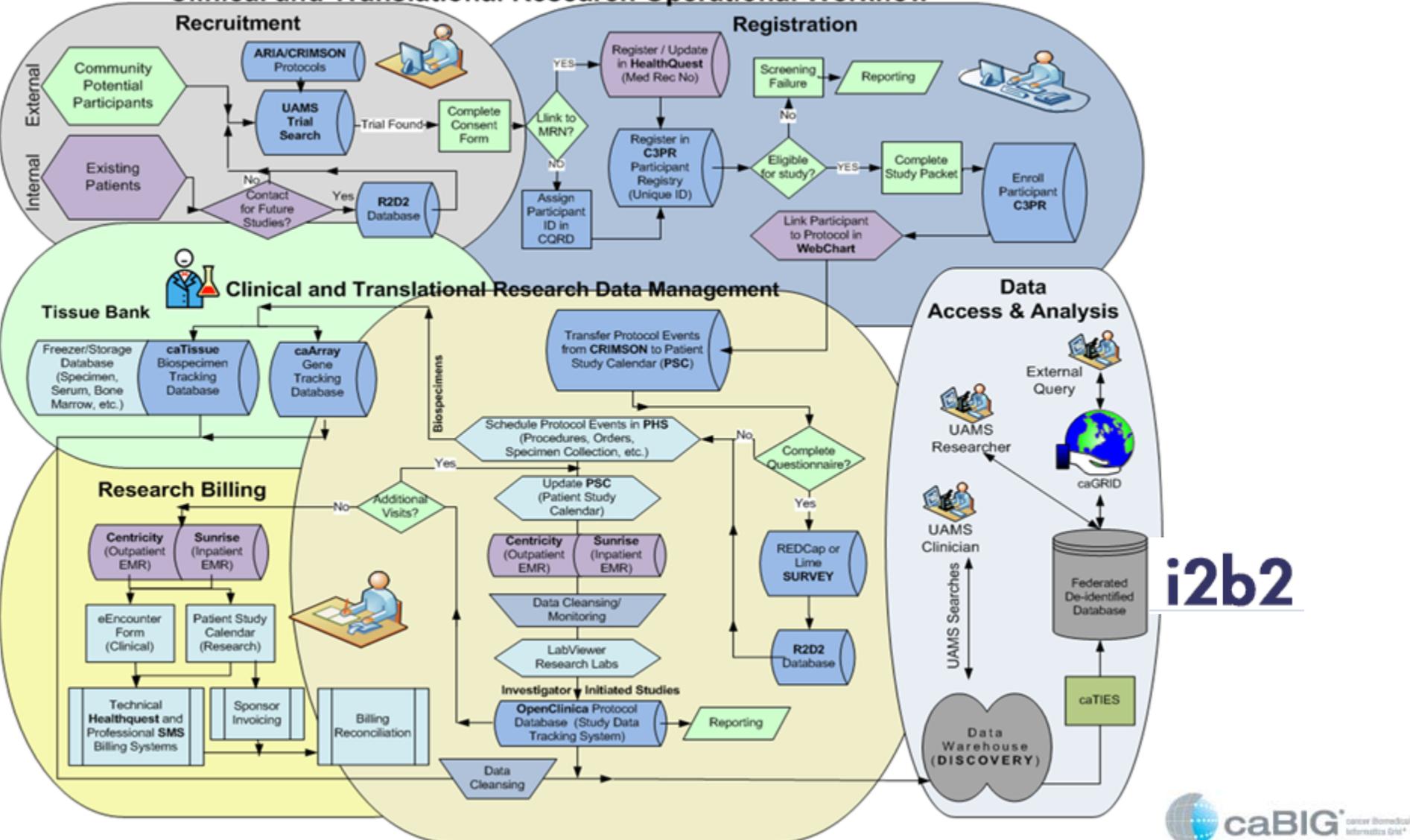


- **We want to create an open and interoperable clinical research infrastructure**
- **Challenges;**
  - *Must be a cost effective solution...*
  - *Very little additional funding (in house development will take too much time)*
  - *No Vendor(buying an app is not an option)*
  - *It should work.*
- ***What is left?***
  - Collaborate and reuse standards and open source initiatives

# Our TRI dream- a food web



## Clinical and Translational Research Operational Workflow



i2b2

# *The Catalyst...*



- **Champions from the Winthrop P. Rockefeller Cancer Institute**
- **Some institutional funding**
- **Having a centralized IT and a dedicated team**
- **caBIG**

NATIONAL CANCER INSTITUTE National Cancer Institute

caBIG<sup>®</sup> cancer Biomedical Informatics Grid<sup>™</sup>

caBIG™: Power of Connection caBIG™ and Molecular Medicine

ACCELERATING BIOMEDICAL RESEARCH WITH caBIG<sup>®</sup>

Check out the video case studies, Q&A's, and more in our caBIG™ In Action part of the site

[Click here to learn more](#)

# Clinical Trials Management



- **Subject Management**
- **Calendar**
- **Adverse Event Reporting**
- **Lab Values**
- **Toxicity Grading**
- **Clinical Data Management**

## The caBIG Suite

-C3PR

-Patient Study Calendar

-CAAERS

-Labviewer

## Other

-CALAEGS

-OpenClinica

# The Suite at UAMS



## Cancer Central Clinical Participant Registry (C3PR v2)



*Eligibility is verified and patient is registered to a study*

## Patient Study Calendar (PSC)



*Tracks the patient schedule throughout the study*

## Lab Viewer



*Identifies labs, loads them into the CDMS and AE system*

**CALAEGS  
CTCAE v3**

caBIG Hub

## Cancer Adverse Event Reporting System (caAERS)



*Identifies and tracks adverse events and any associated schedule changes*

## OpenClinica



*Clinical data is captured*

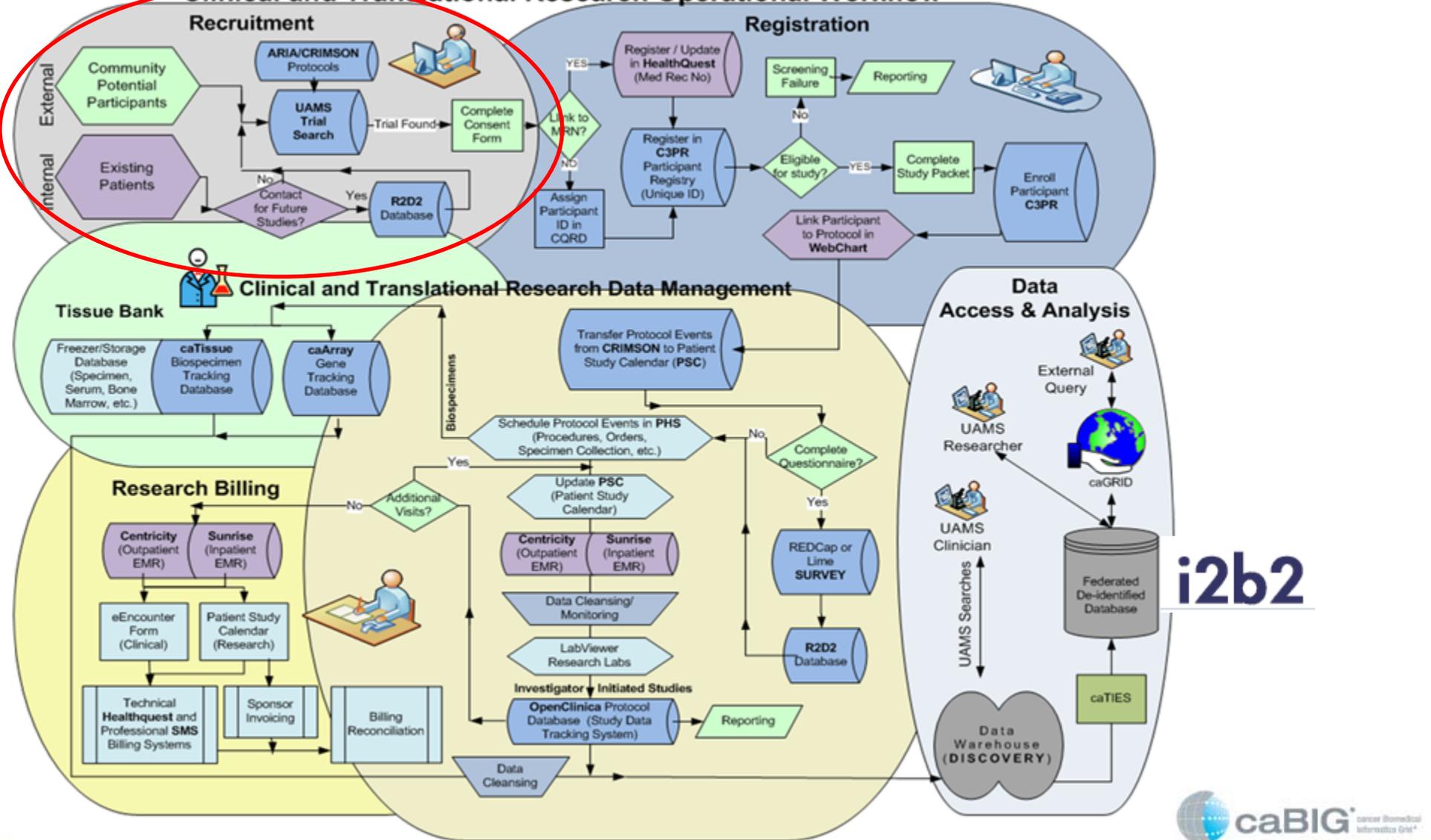


*Patient visits the Physician*

# Our Dream: Recruitment



## Clinical and Translational Research Operational Workflow



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# UAMS Trial Search- Recruitment



**UAMS** | Clinical Trials Management Welcome Gail Douglas!

Dashboard | ARIA | CRIMSON | C3PR | Study Calendar | OpenClinica | ET | **TrialSearch**

## UAMS TrialSearch

Search  for

Browse trials by [Disease](#) | [Investigator](#) | [Treatment](#) | [Sponsor](#) | [Cancer](#)

### Choose a disease site / subsite

- [Adolescent Health](#) (2 studies)
- [Aging](#) (3 studies)
- [Bacterial and Fungal Diseases](#) (1 studies)
- [Bacterial and Fungal Diseases](#) >> [Blastomycosis](#) (1 studies)
- [Behaviors and Mental Disorders](#) >> [Amphetamine-Related Disorders](#) (3 studies)
- [Behaviors and Mental Disorders](#) >> [Cocaine-Related Disorders](#) (1 studies)
- [Behaviors and Mental Disorders](#) >> [Marijuana Abuse](#) (1 studies)
- [Behaviors and Mental Disorders](#) >> [Substance-Related Disorders](#) (3 studies)
- [Biobehavioral Health](#) (9 studies)
- [Bioterrorism](#) (1 studies)
- [Blood and Lymph Conditions](#) >> [Anemia\\_Neonatal](#) (1 studies)
- [Blood and Lymph Conditions](#) >> [Blood Coagulation Disorders\\_Inherited](#) (1 studies)
- [Blood and Lymph Conditions](#) >> [Vascular Hemostatic Disorders](#) (1 studies)
- [Cancers and other Neoplasms](#) >> [Adenocarcinoma](#) (1 studies)
- [Cancers and other Neoplasms](#) >> [Bladder Neoplasms](#) (1 studies)
- [Cancers and other Neoplasms](#) >> [Bone Neoplasms](#) (4 studies)
- [Cancers and other Neoplasms](#) >> [Brain Neoplasms](#) (1 studies)
- [Cancers and other Neoplasms](#) >> [Breast Neoplasms](#) (5 studies)
- [Cancers and other Neoplasms](#) >> [Carcinoma](#) (2 studies)
- [Cancers and other Neoplasms](#) >> [Carcinoma\\_Lobular](#) (1 studies)
- [Cancers and other Neoplasms](#) >> [Carcinoma\\_Renal Cell](#) (1 studies)
- [Cancers and other Neoplasms](#) >> [Carcinoma\\_Small Cell](#) (1 studies)
- [Cancers and other Neoplasms](#) >> [Carcinoma\\_Squamous Cell](#) (1 studies)
- [Cancers and other Neoplasms](#) >> [Gastrointestinal Neoplasms](#) (1 studies)
- [Cancers and other Neoplasms](#) >> [Head and Neck Neoplasms](#) (2 studies)
- [Cancers and other Neoplasms](#) >> [Lung Neoplasms](#) (1 studies)

## UAMS TrialSearch

Search  for

Browse trials by [Disease](#) | [Investigator](#) | [Treatment](#) | [Sponsor](#) | [Cancer Specific](#)

Welcome [topalogluimit](#) | [Logout](#)

[<< Back to your search results](#)

IRB Number: 109709

### A Prospective, Non-Intervention, Observational Assessment of the Correlation between Circulating Biomarkers of Fungal Bioburden and Clinical Outcome in the Setting of Invasive Aspergillosis

#### Principal Investigator

**Elias J Anaissie**  
College of Medicine  
5016868250

#### Contact Information (internal)

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#### Contact Information (external)

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501-296-1503 ext 1411

#### Protocol Summary

This study will take place at 15 hospitals in the United States. About 100 research participants, male or female, ages 18-75, regardless of race or ethnicity, will take part in this study. Approximately 15 participants will be enrolled at UAMS. Participants will be in the study for about 12 weeks. Participants will have about 1-2 tablespoons (7-27 ml) of blood taken each time blood is drawn as part of standard care. No genetic or human DNA testing will be done on their blood.

In addition to having the above done at their study visits, at Week 6 and Week 12, the study doctor will review the results of a recent CT or MRI scan.

#### Study Objectives and Outcomes

In patients with proven or probable invasive aspergillosis, the average of the z-scores of the time weighted averages of the serial serum measurements of (1,3)- $\beta$ -D-glucan and galactomannan during the initial two weeks of anti-fungal therapy will be lower in patients with a successful clinical outcome compared to patients with a failed clinical outcome. Successful clinical outcome is defined as complete (or partial) cure at 6 weeks from the initiation of anti-fungal therapy.

#### Eligibility Criteria

# Research participant DB-Recruitment



- **We are in process of developing an IRB protocol to create a system in which we can store**

- Potential participants
- re-contact allowed?
- Collect Biospecimens
- Questionnaires

Apps we will use

-C3PR

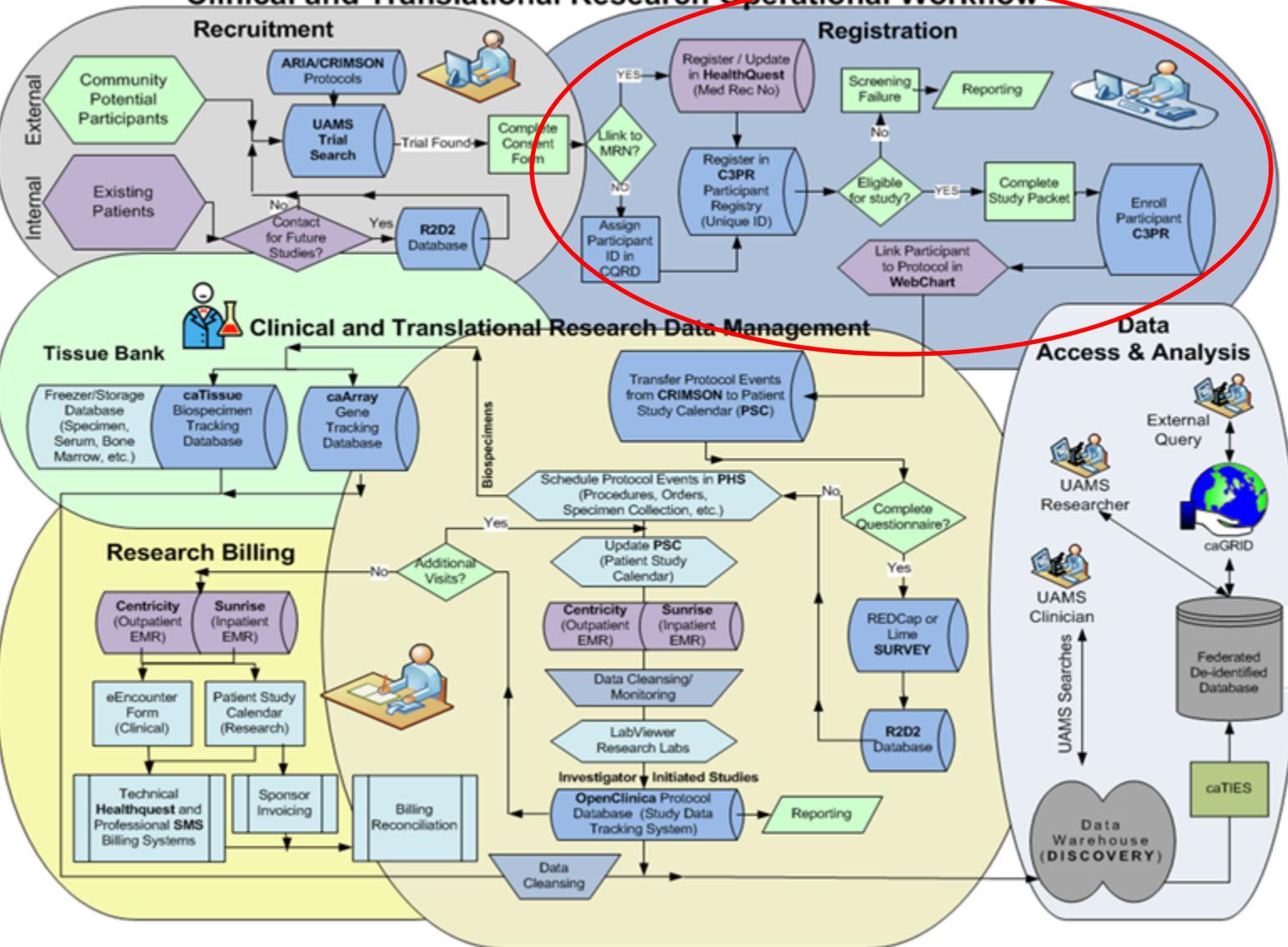
-caTissue

-LimeSurvey

# Our Dream: Registration



## Clinical and Translational Research Operational Workflow



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- **Participant registry**
  - It manages study, randomization, amendments etc.
  - Tracks subjects during screening, treatment, follow up
- **We have added some additional functionality**
  - Web service to import patient demographics
  - Integration with other systems
- **There are 59 studies and 319 subjects in one of our instance**

# UAMS Event Tracker (ET)



UAMS | Clinical Trials Management

Welcome Umit Topaloglu!

Dashboard

ARIA

CRIMSON

C3PR

Study Calendar

OpenClinica

▶ ET

TrialSearch

Reports

User Guides

Support Request

## EventTracker

Search by IRB or title

Protocol # 99075

Days to activation: 167

### A Preliminary Study Utilizing a Flexible Endoscope for Pelvic Culdoscopy

Basic Details

Submissions

Disease Sites

Activated (Open to Enrollment) on Feb. 18, 2008

[Change status](#) [View status history](#)

#### CRIMSON

Created on Jan. 22, 2008

Completed on Feb. 21, 2008

#### IRB

Submitted on Feb. 22, 2008

Approved on Jun. 10, 2008

#### Continuing Reviews

Last CR on Apr. 27, 2009

Next CR on Apr. 27, 2010

#### Protocol Committee Approvals

08/24/2009 Institutional Review Board:Sent

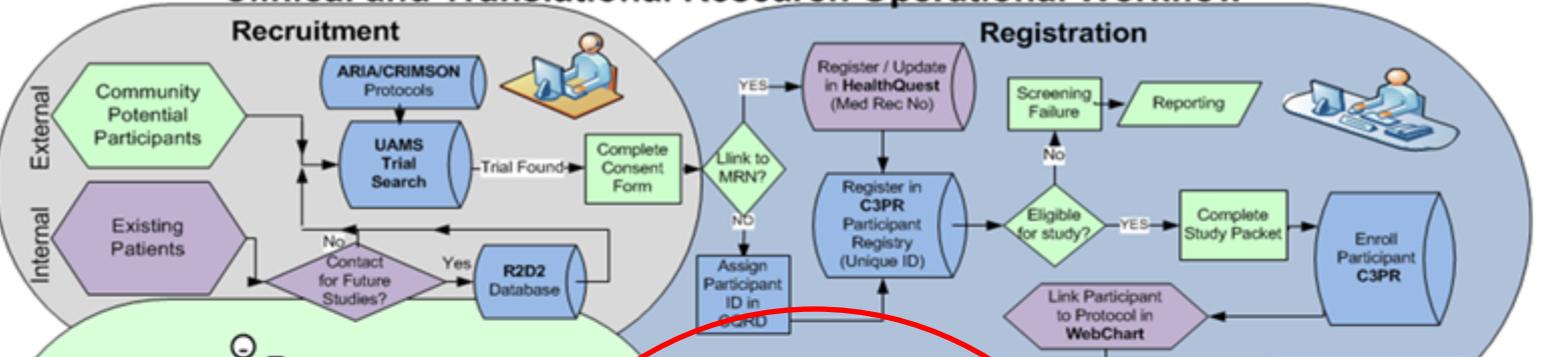
09/13/2009 Institutional Review Board:Approved

Days to approval: 20

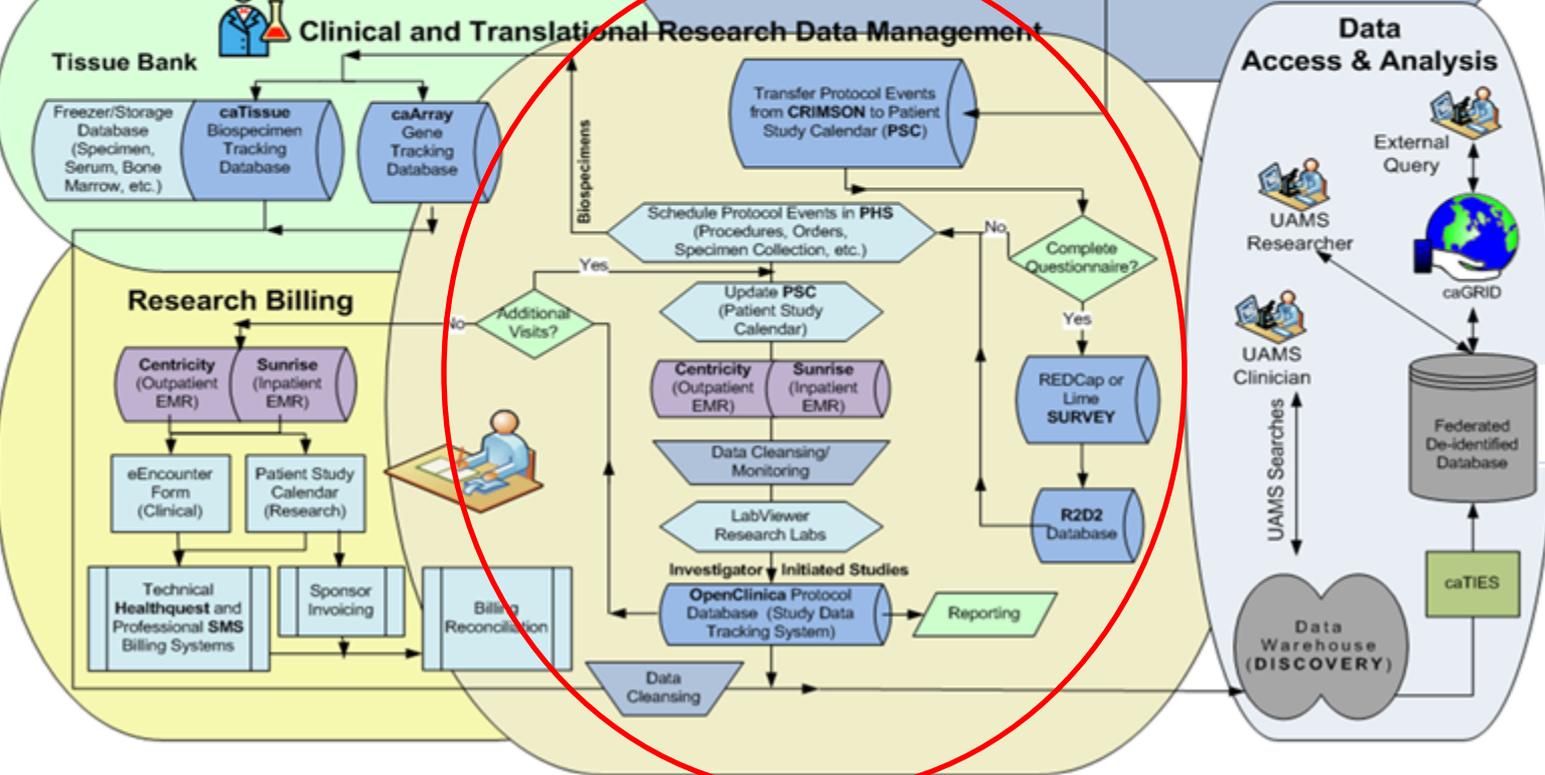
# Data Management



## Clinical and Translational Research Operational Workflow



## Clinical and Translational Research Data Management



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# caBIG's Patient Study Calendar



- **Detailed study calendar**
- **It can manage;**
  - all the study related activities
  - The same study structure with C3PR screening, treatment, follow up
  - Activities imported from our IRB system with “R”, “C”, “I” to represent what account the activity should be charged.

# OpenClinica

## Open Source Clinical Data Management



**OpenClinica**  
Open Source for Clinical Research

A Preliminary Study Utilizi... (99075) | Change Study/Site

topalogluumit (Data Manager) | Log Out

Home | Subject Matrix | Notes & Discrepancies | Study Audit Log | Tasks

Report Issue | Support | Study Subject Id

**Alerts & Messages** ▾

**Instructions** ▾

**Info** -

**Study:** A Preliminary Study Utilizing a Flexible Endoscope for Pelvic Culdoscopy

**Start Date:** 19-Mar-2009

**End Date:** N/A

**PI:** Alexander Burnett

**Protocol Verification/IRB Approval Date:** 06-Jul-2006

### Welcome to A Preliminary Study Utilizing a Flexible Endoscope for Pelvic Culdoscopy

You are logged in as a Data Manager

0 Notes & Discrepancies Assigned to Me.

Site	Enrolled	Expected Enrollment	Percentage
A Preliminary Study Utilizing a Flexible Endoscope for Pelvic Culdoscopy	2	20	10%

Event Status	# of Events	Percentage
scheduled	0	0%
data entry started	3	100%
completed	0	0%
signed	0	0%
locked	0	0%
skipped	0	0%
stopped	0	0%

Study Subject Status	# of Study Subjects	Percentage
available	2	100%
signed	0	0%
removed	0	0%

# caBIG's Labviewer

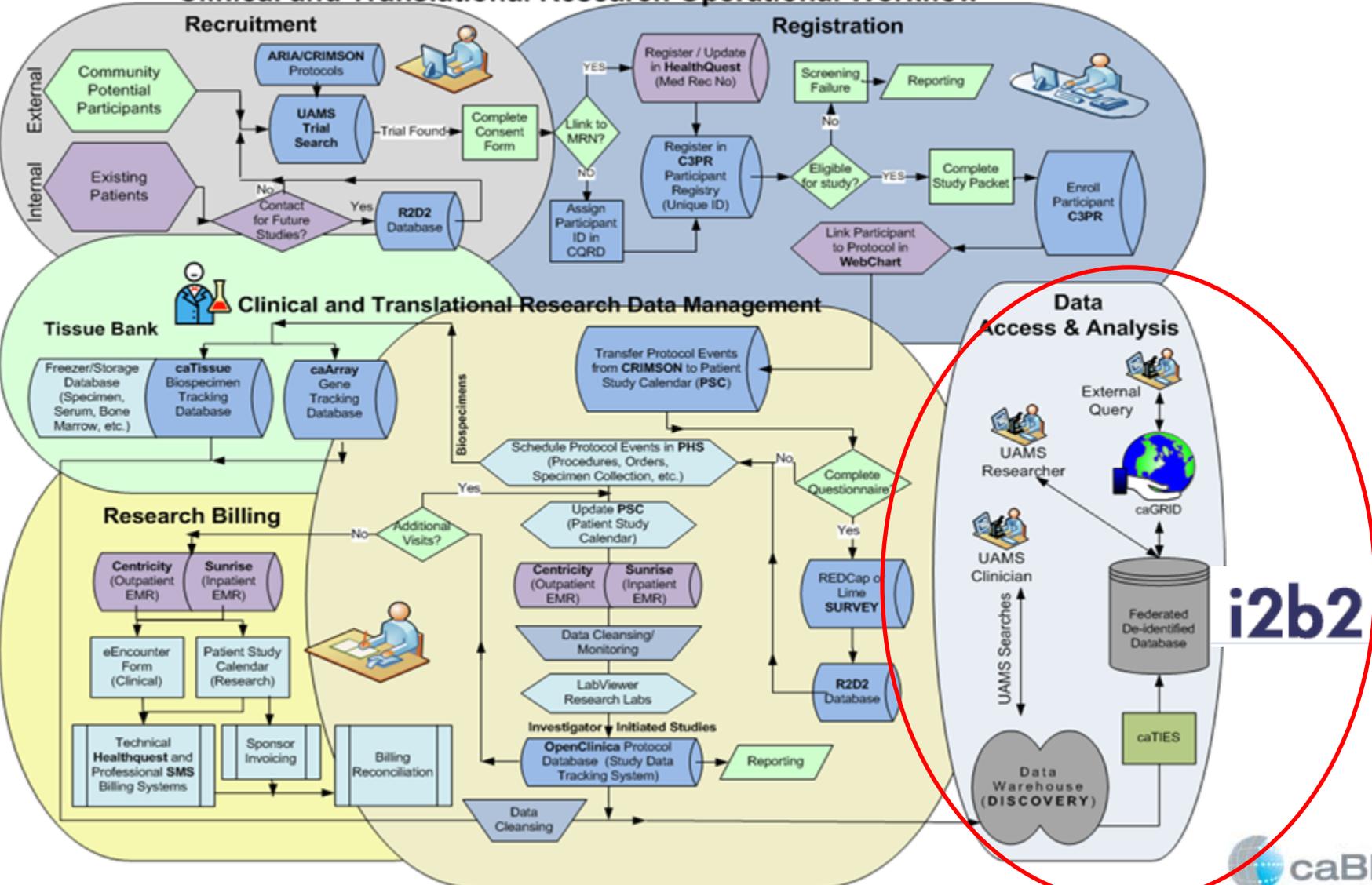


- It is a tool to display lab results of a participant
- It can push the selected values to **CDMS** and/or CAAERS
- We have developed an interface to query CALAEGS for CTCAE V3 toxicity grading
  - It displays next to the lab result
- We are pilot testing

# Our Dream: Data sharing and access



## Clinical and Translational Research Operational Workflow



# Data Access and Sharing-tech issues



- **As we talk and trying to achieve semantic interoperability,**
  - We need to identify terminologies and map to our data
  - Data sources should be identified
  - Common Data Elements (CDEs) are needed
  - Data warehouse may be a solution
  - ...

# Common Data Elements from caDSR



- It is an Cancer Institute mandate that all the data collections should be harmonized with CDEs
  - Case Report Forms (CRFs)
  - And Cancer Control Questionnaires
- It is a time consuming commitment.
- We have local curator in training to facilitate the process.

# Creating a rules engine



- **A request**
  - “I want to set up an alert systems it should alert me when there is/are **X** adverse event with the severity of **Y**
- **You can pull from adverse event or adverse effect CRFs.**

# What have we done so far?

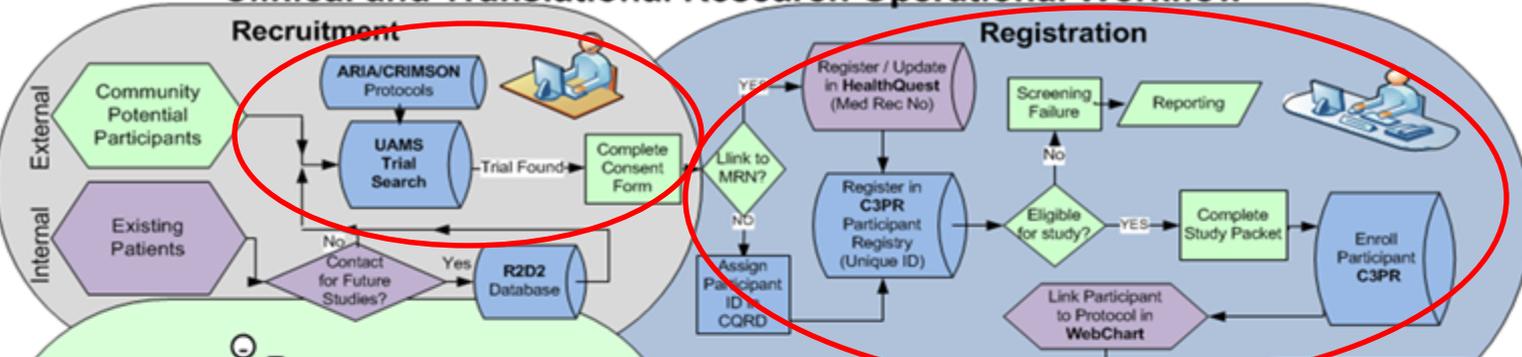


- **We are testing I2B2 with different cell options**
  - Using LexEVS as terminology server
  - caTIES being NLP cell
- **We have caBIG LexEVS in place with ICD9 and NCI thesaurus loaded.**
  - Web service was implemented
- **Trying to identify the use case openMDR for local metadata registry and reuse of models**

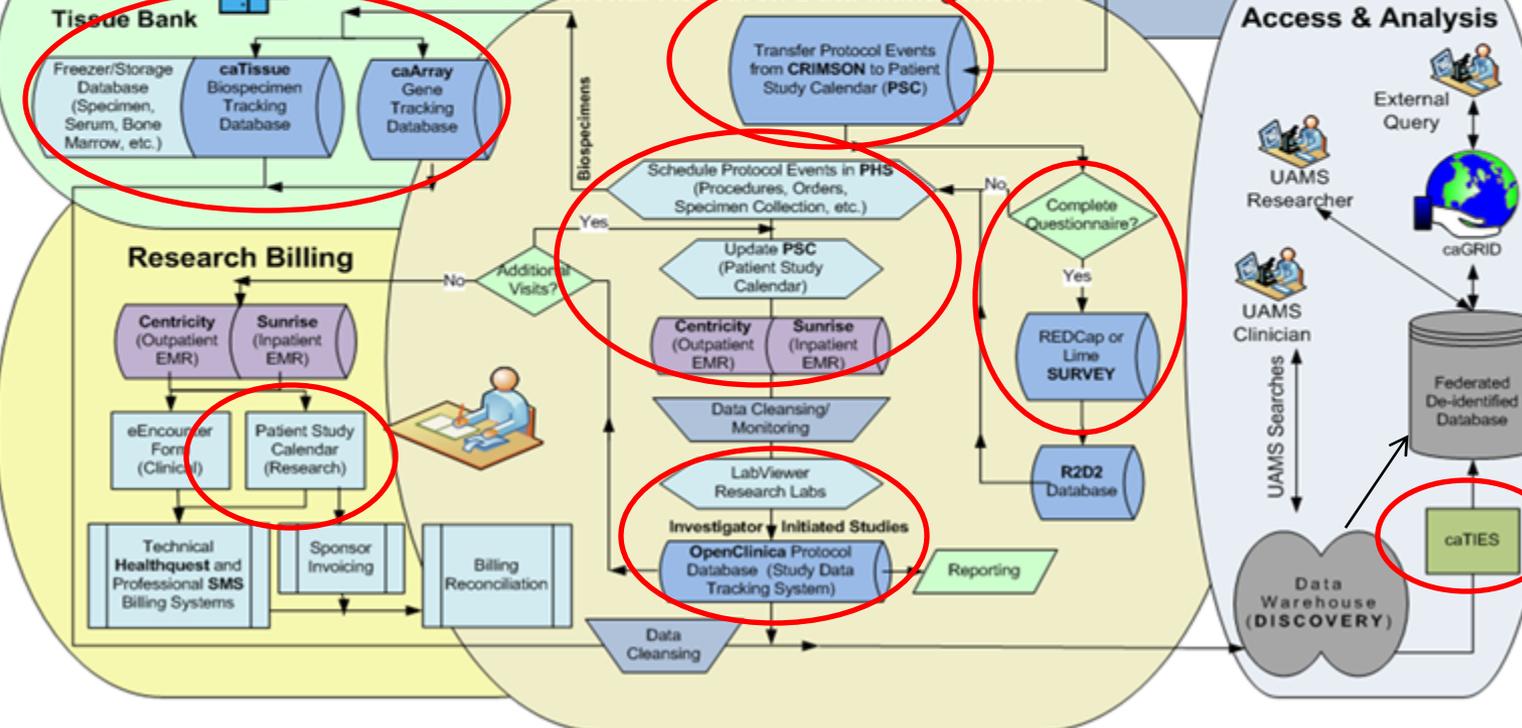
# Our Dream: where are we?



## Clinical and Translational Research Operational Workflow



## Clinical and Translational Research Data Management



**i2b2**

# Future work



- **Completing the remaining items in our vision picture**
- **Use of these tools to help in clinics during the clinical trial**
  - Such as PSC
  - Sharing data on caGRID

# Thanks for listening



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# Research Portal with caTIES



- Ability to do web search on
  - deidentified free text reports, Deidentified demographics, Biospecimen search, Tumor registry

