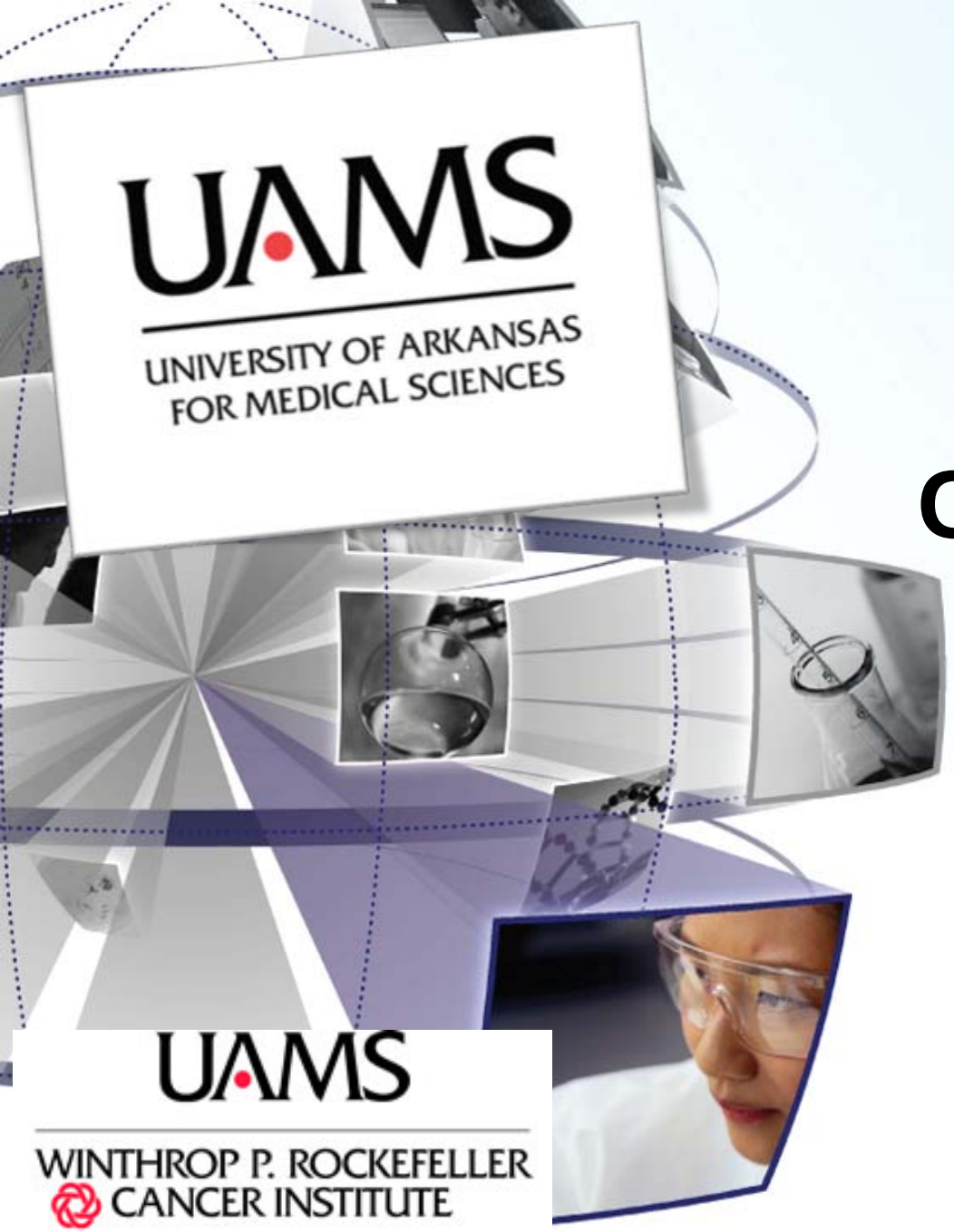


caBIG®
cancer Biomedical
Informatics Grid®

An Open Source Clinical Research Infrastructure powered by caBIG

Umit Topaloglu Ph.D.
Information Technology

UAMS
WINTHROP P. ROCKEFELLER
CANCER INSTITUTE
UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES

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

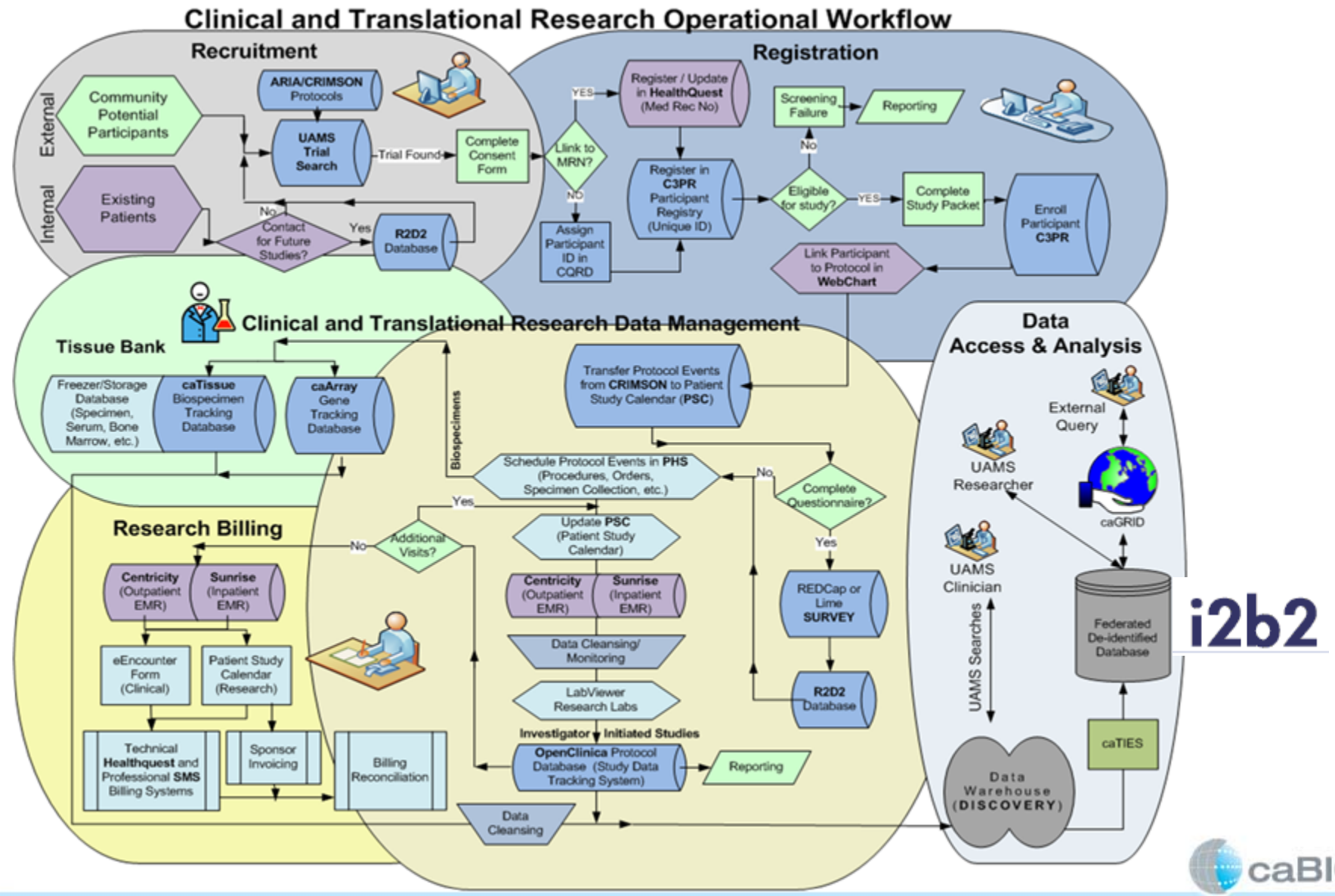
Where were we?

- 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



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The Catalyst…

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

caBIG

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

Patient visits the Physician

caBIG Hub

OpenClinica

Clinical data is captured

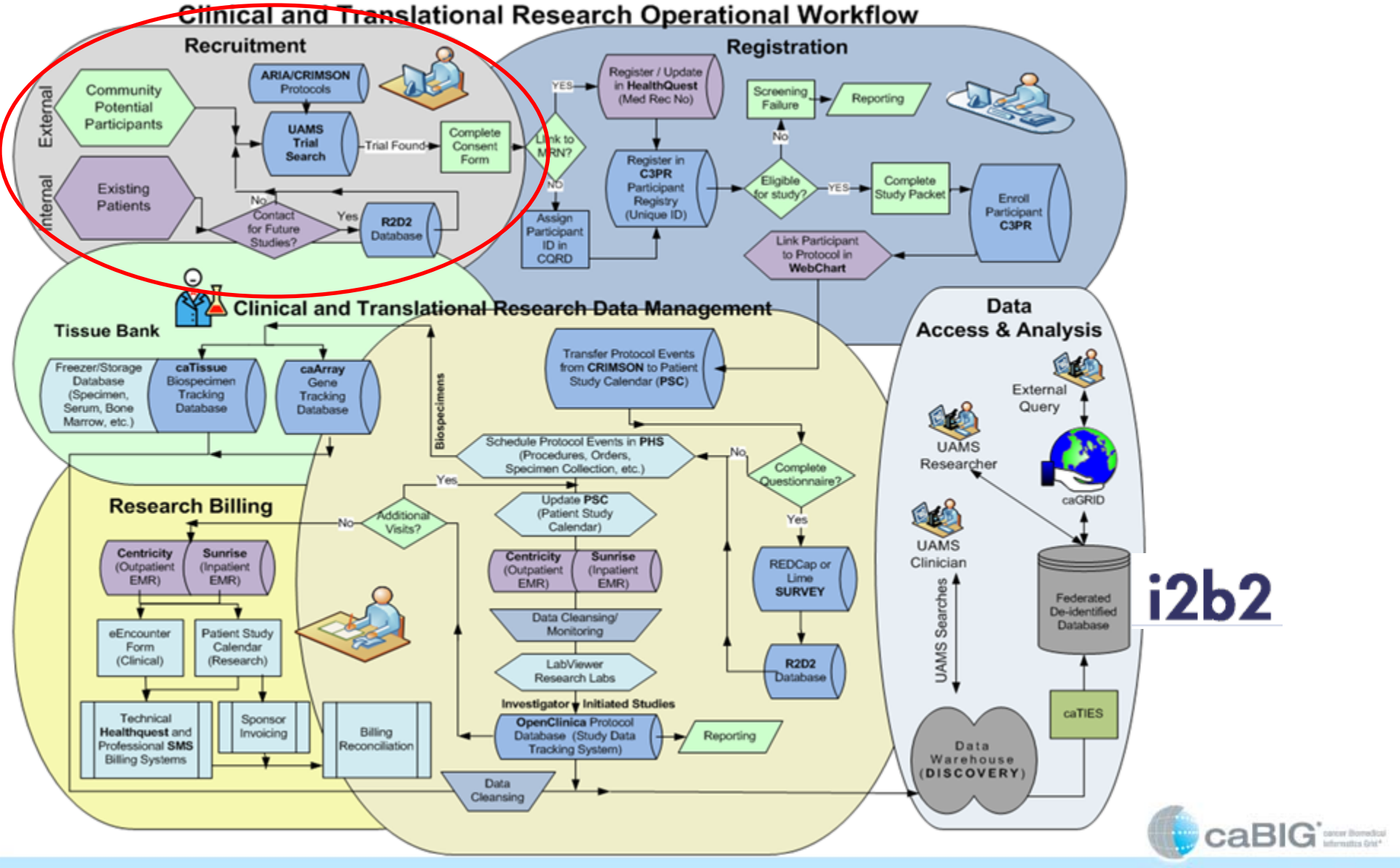
Cancer Adverse Event Reporting System (caAERS)

Identifies and tracks adverse events and any associated schedule changes

CALAEGS
CTCAE v3

caBIG

Our Dream: Recruitment



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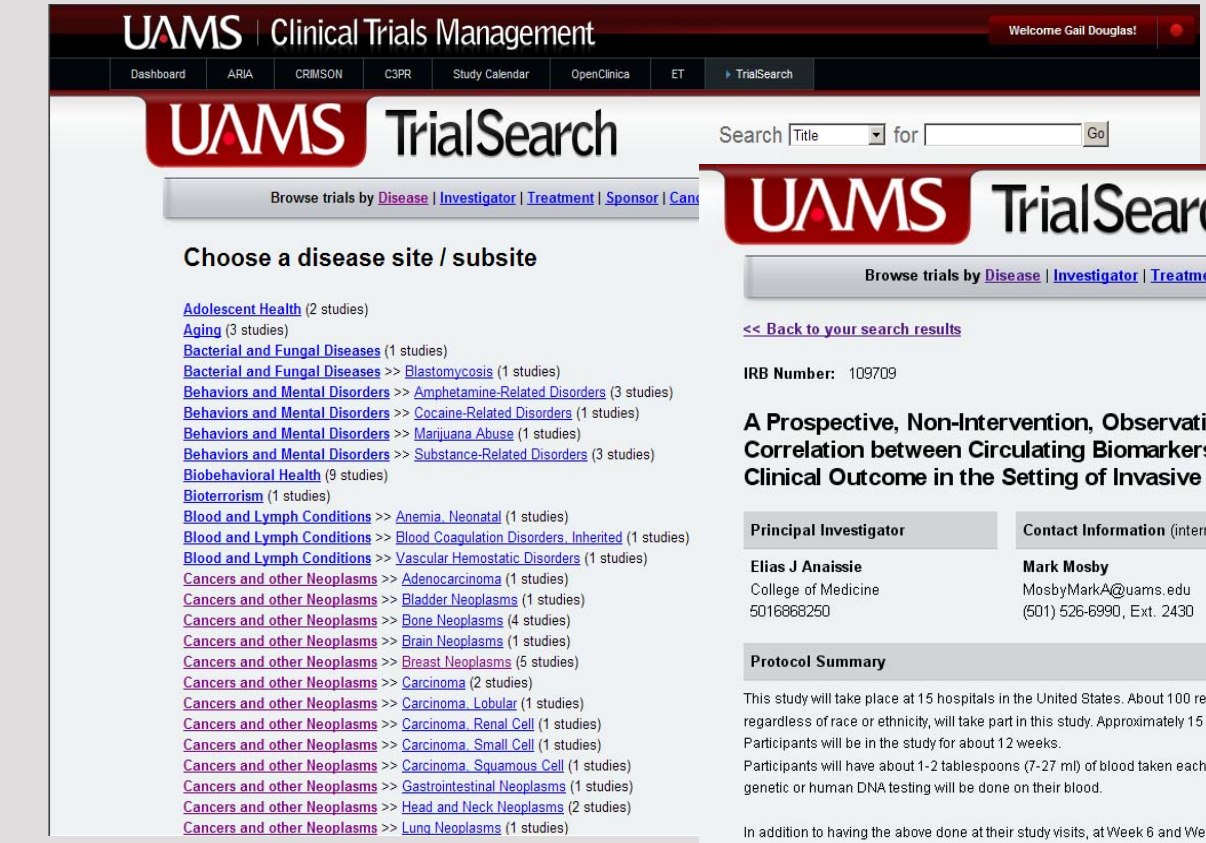
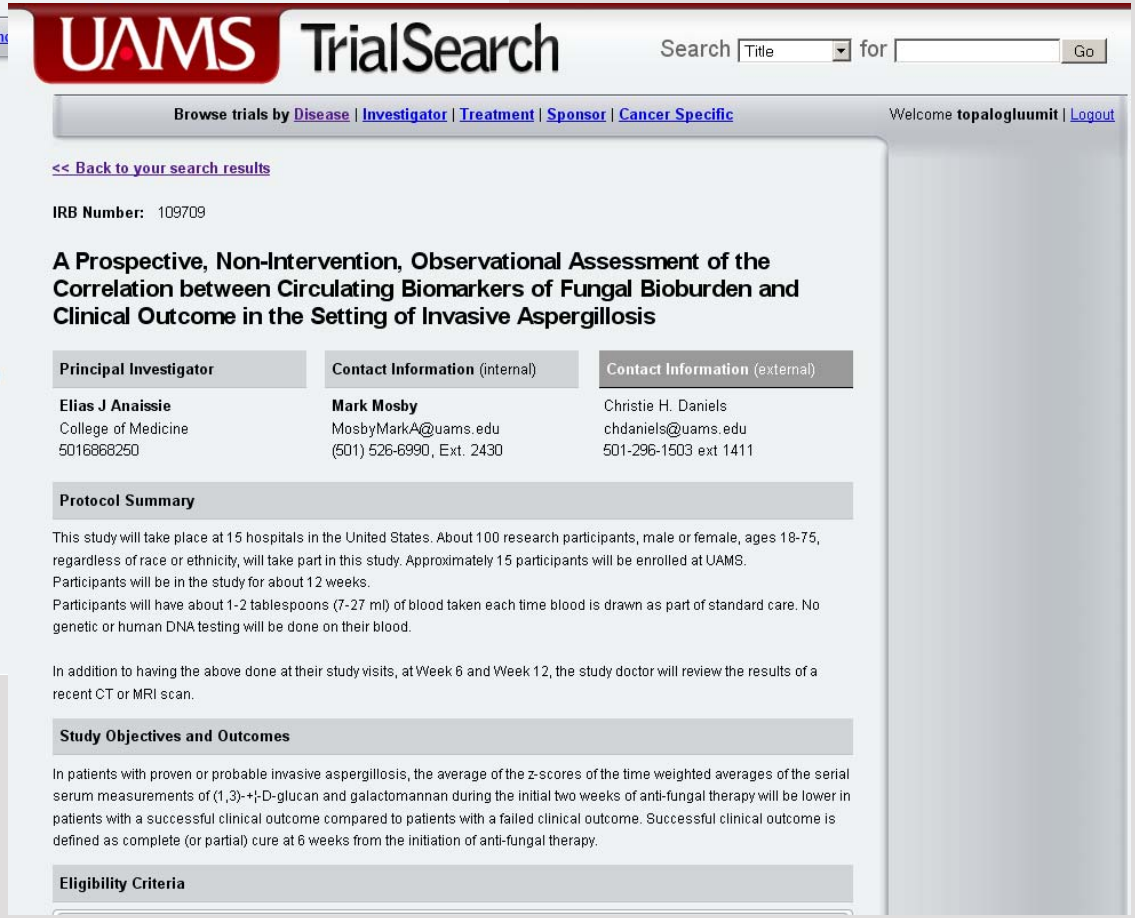
UAMS Trial Search- Recruitment





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

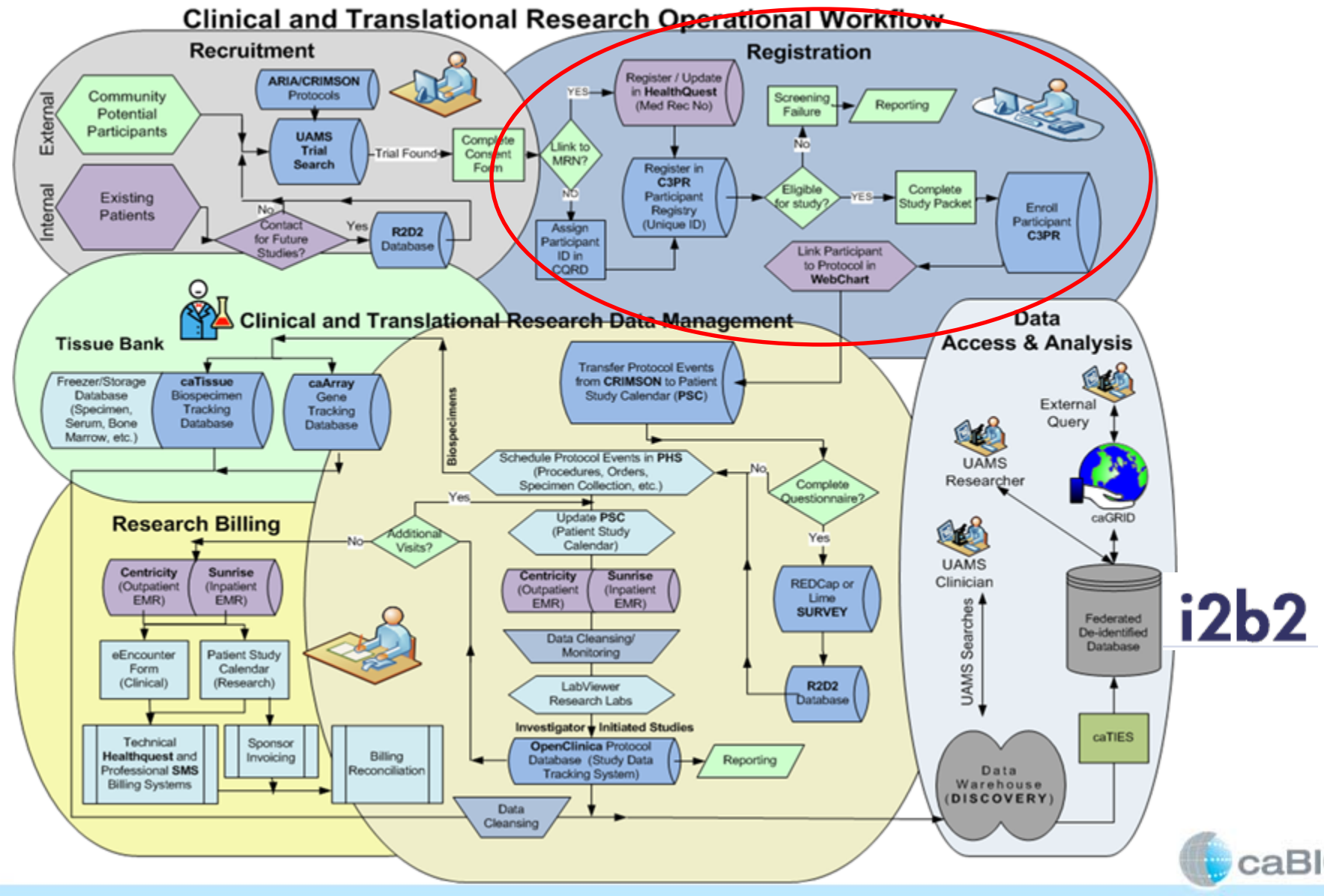
Apps we will use

-C3PR

-caTissue

-LimeSurvey

Our Dream: Registration



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caBIG's C3PR-

- **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	IRB	Continuing Reviews
Created on Jan. 22, 2008	**Submitted** on Feb. 22, 2008	**Last CR** on Apr. 27, 2009
Completed on Feb. 21, 2008	**Approved** on Jun. 10, 2008	**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

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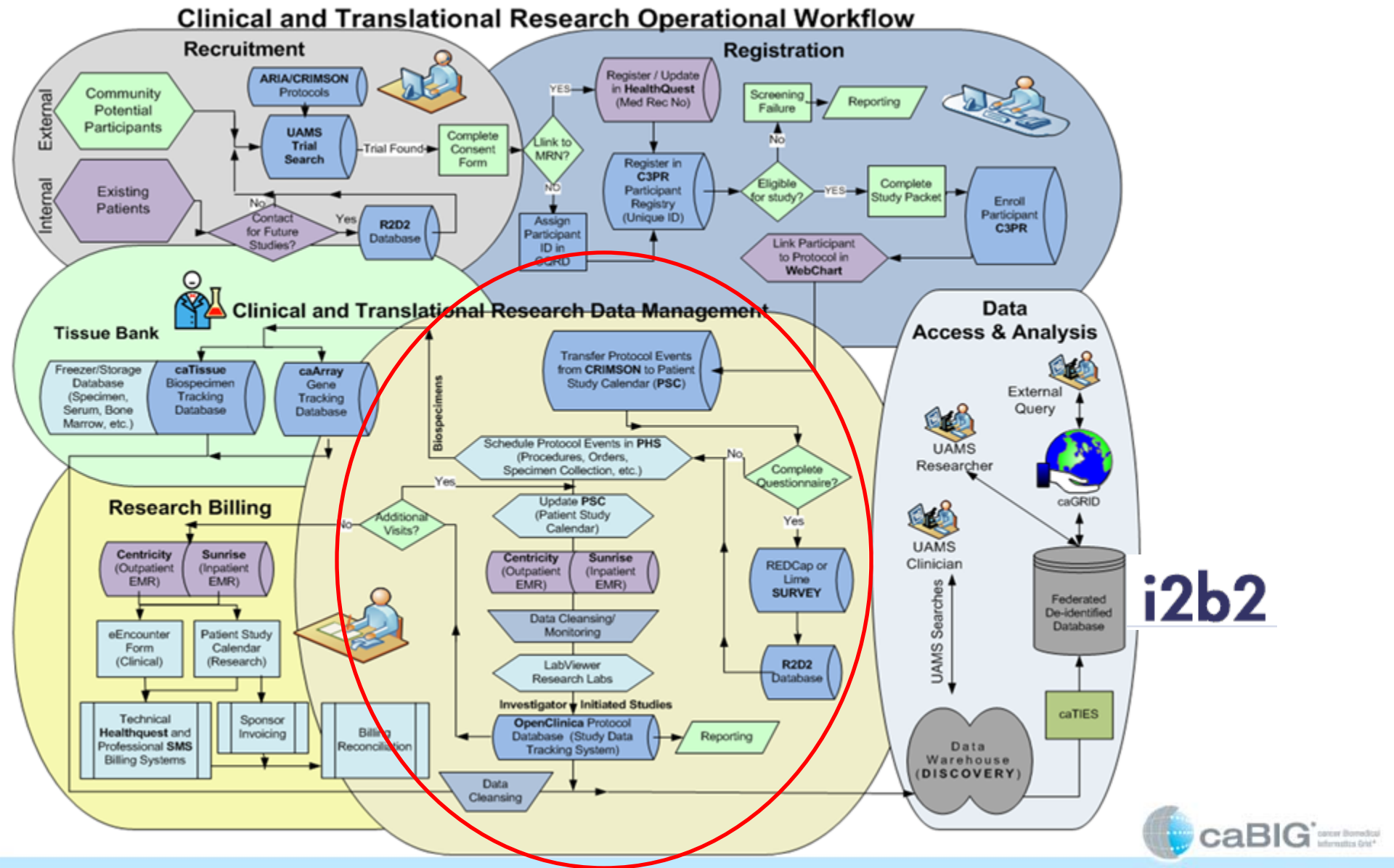
Data Management



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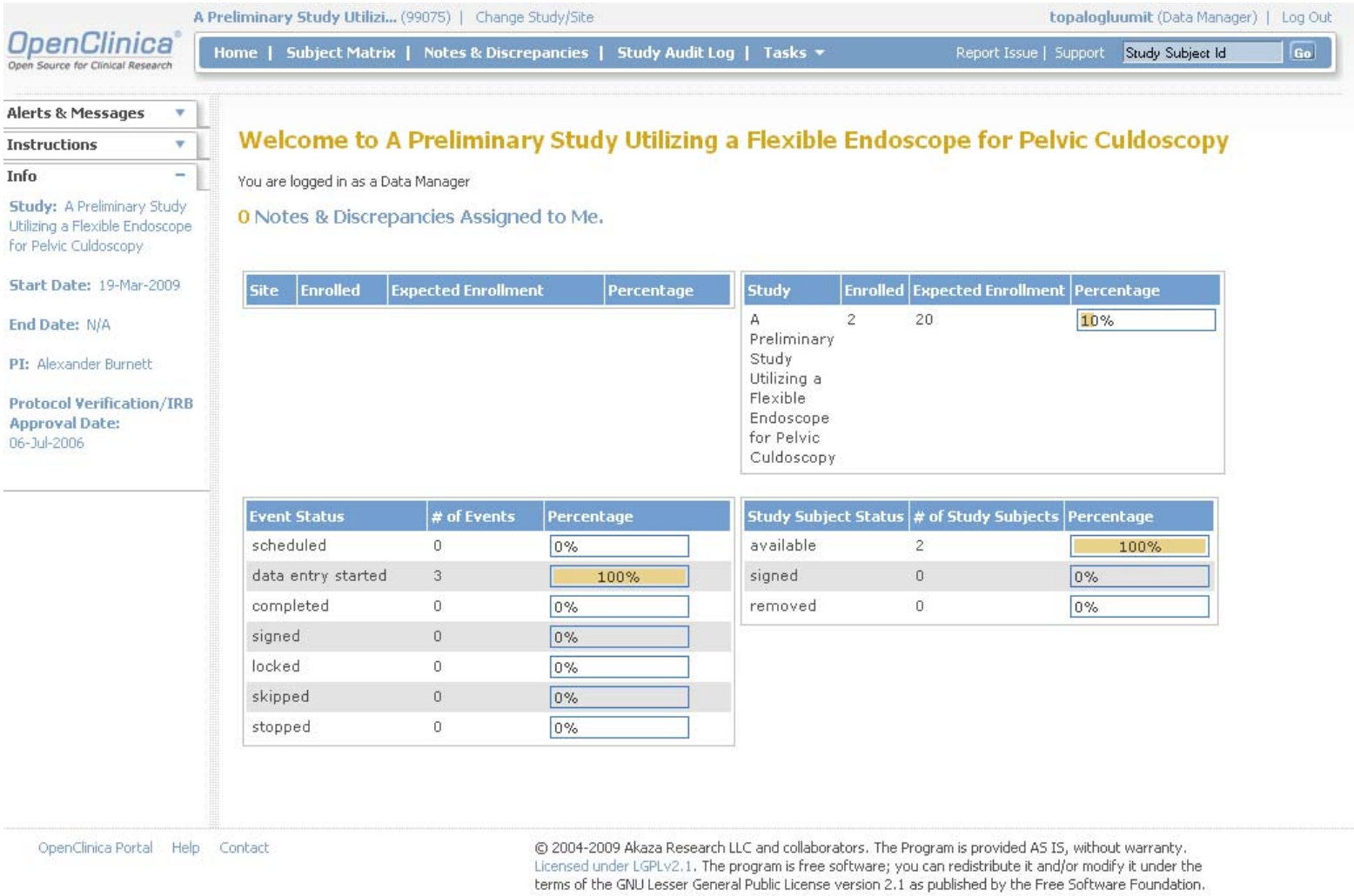
caBIG's Patient Study Calendar

- **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



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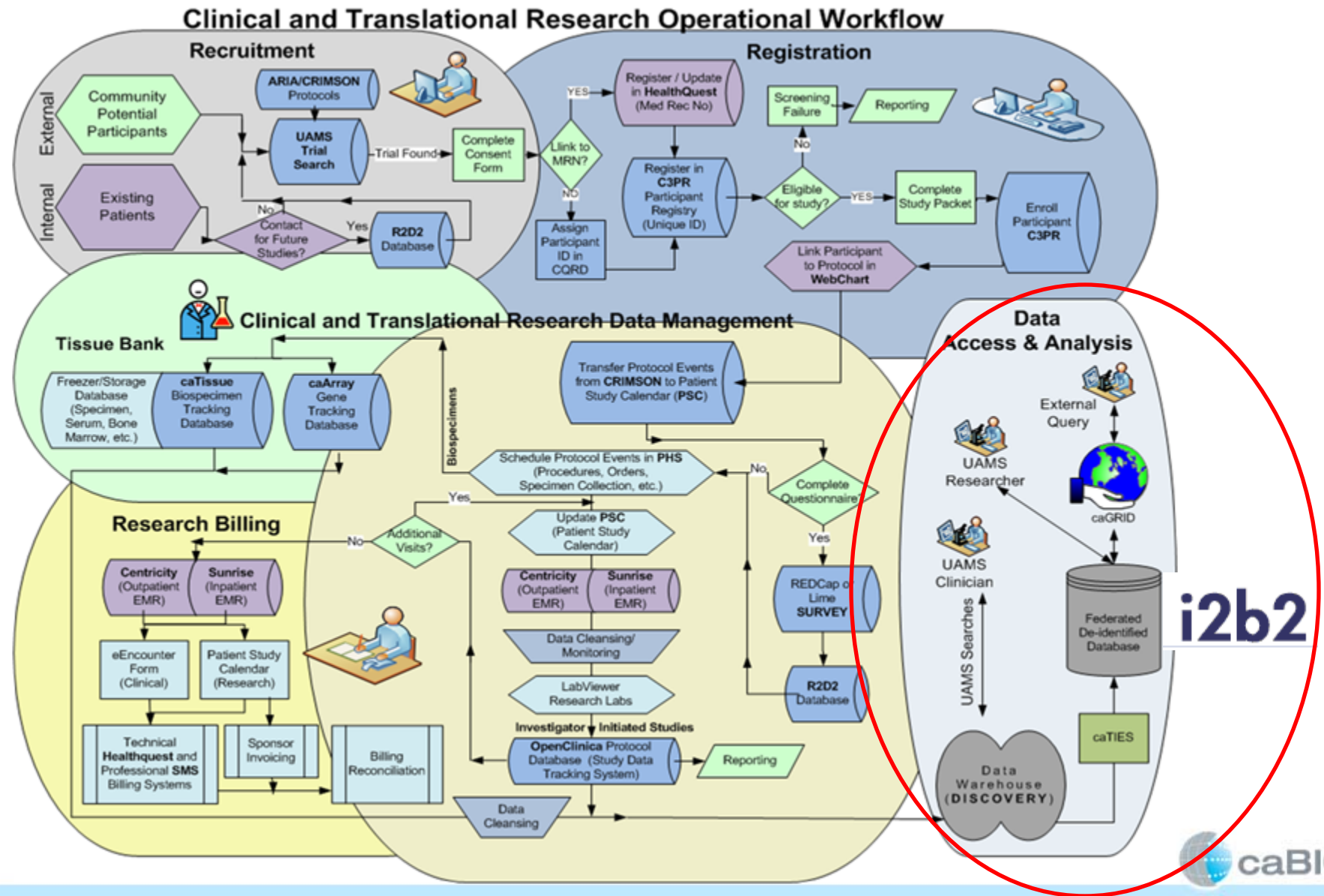
caBIG's Labviewer

- **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 and 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



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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

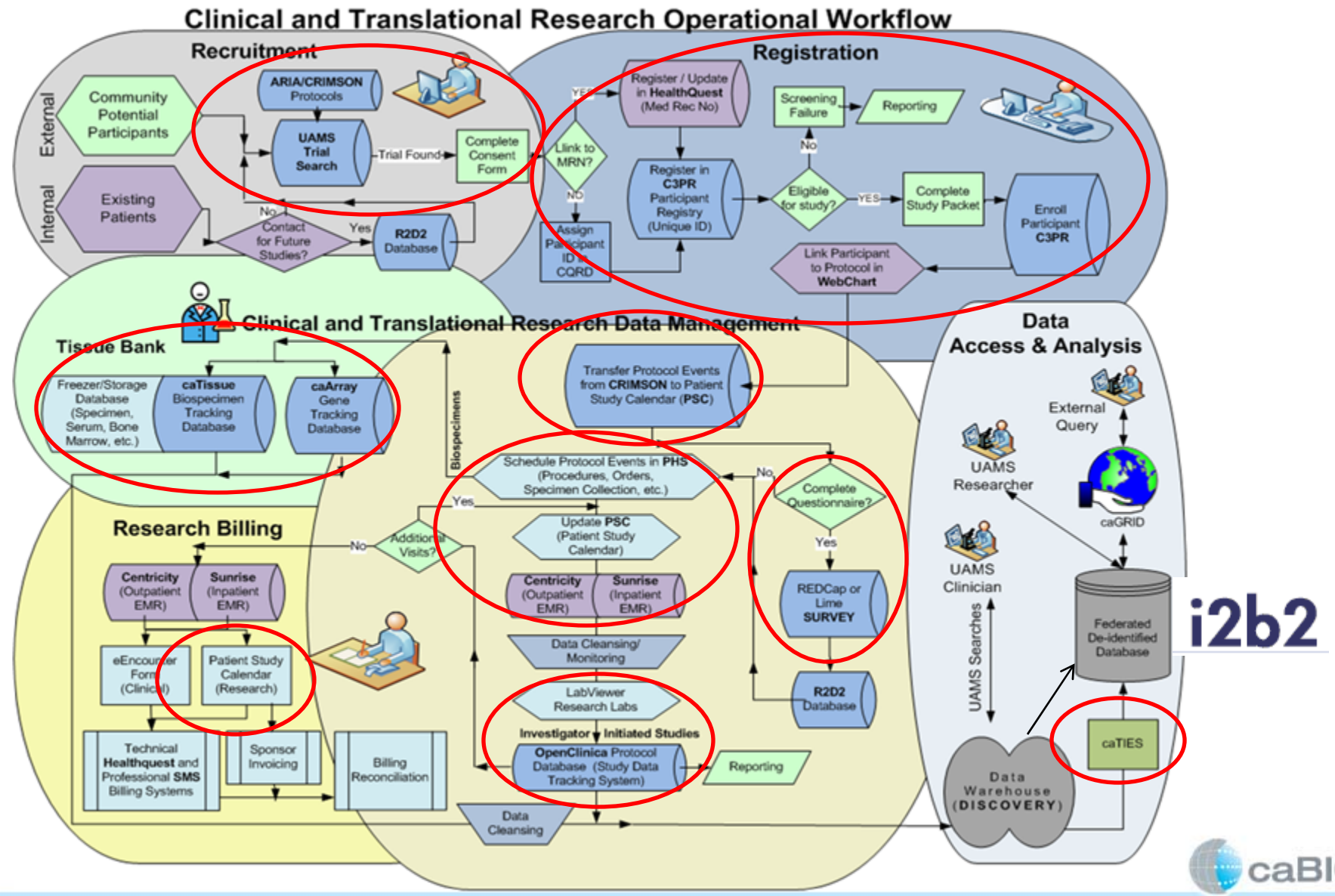
    alert me when there is/are X adverse event

    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?



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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