An Open Source Clinical Research Infrastructure powered by caBIG

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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

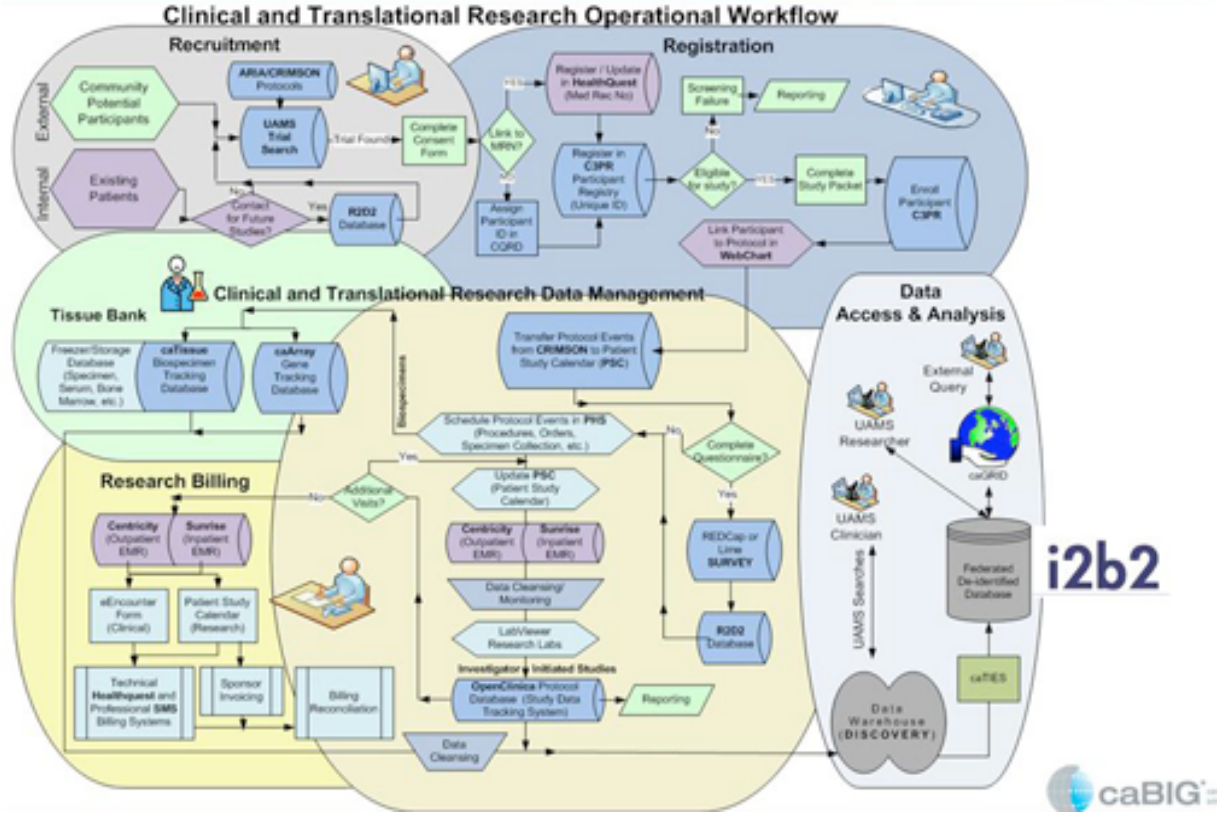
Where were we?

- 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



The Catalyst…

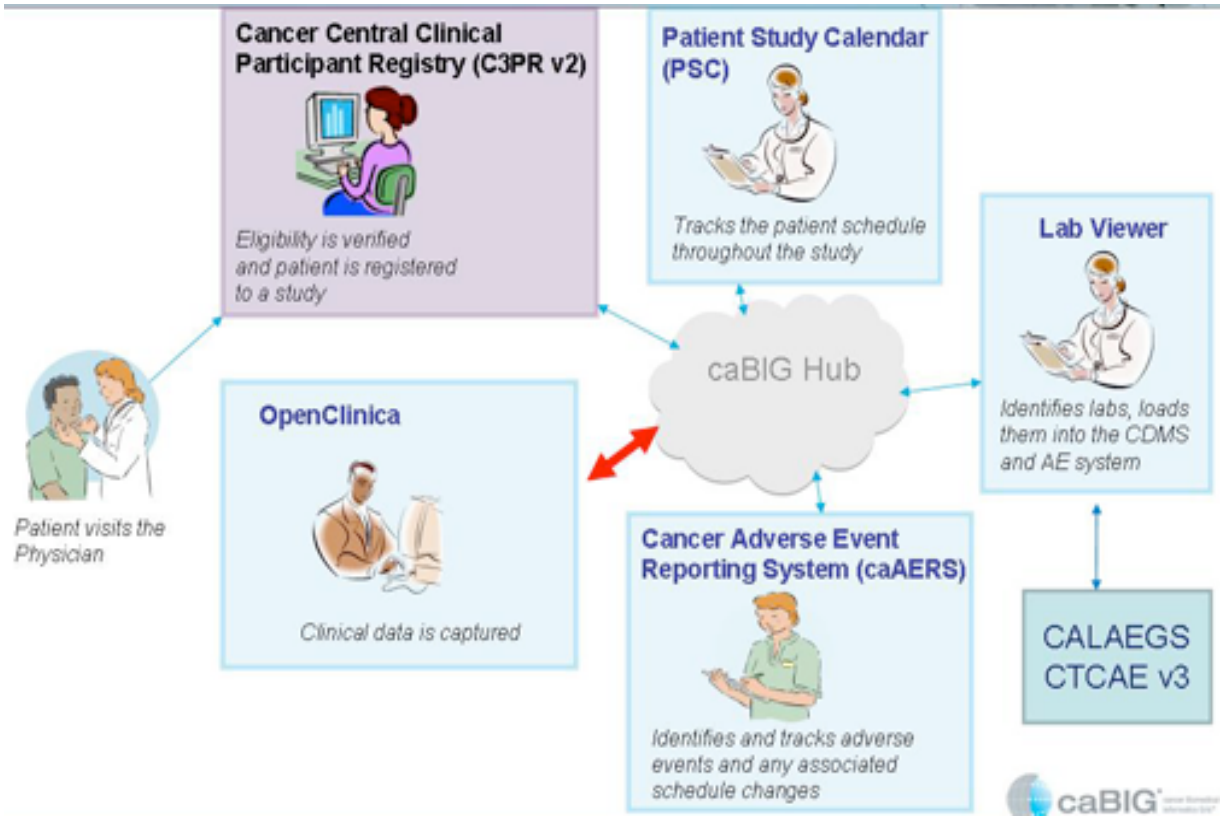
- Champions from the Winthrop P. Rockefeller Cancer Institute
- Some institutional funding
- Having a centralized IT and a dedicated team
- caBIG

Clinical Trials Management

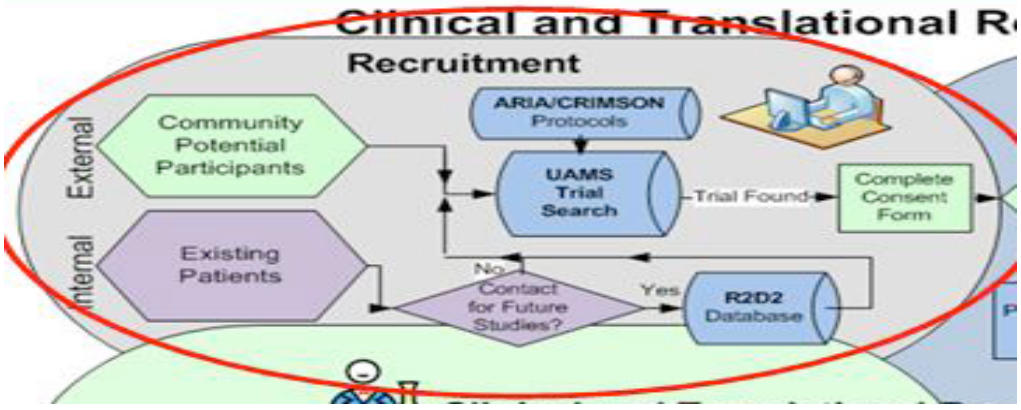
- Subject Management
  - The caBIG Suite
    - C3PR
- Calendar
  - Patient Study Calendar
- Adverse Event Reporting
  - CAAERS
- Lab Values
  - Labviewer
- Toxicity Grading
  - Other
    - CALAEGS
- Clinical Data Management

- OpenClinica

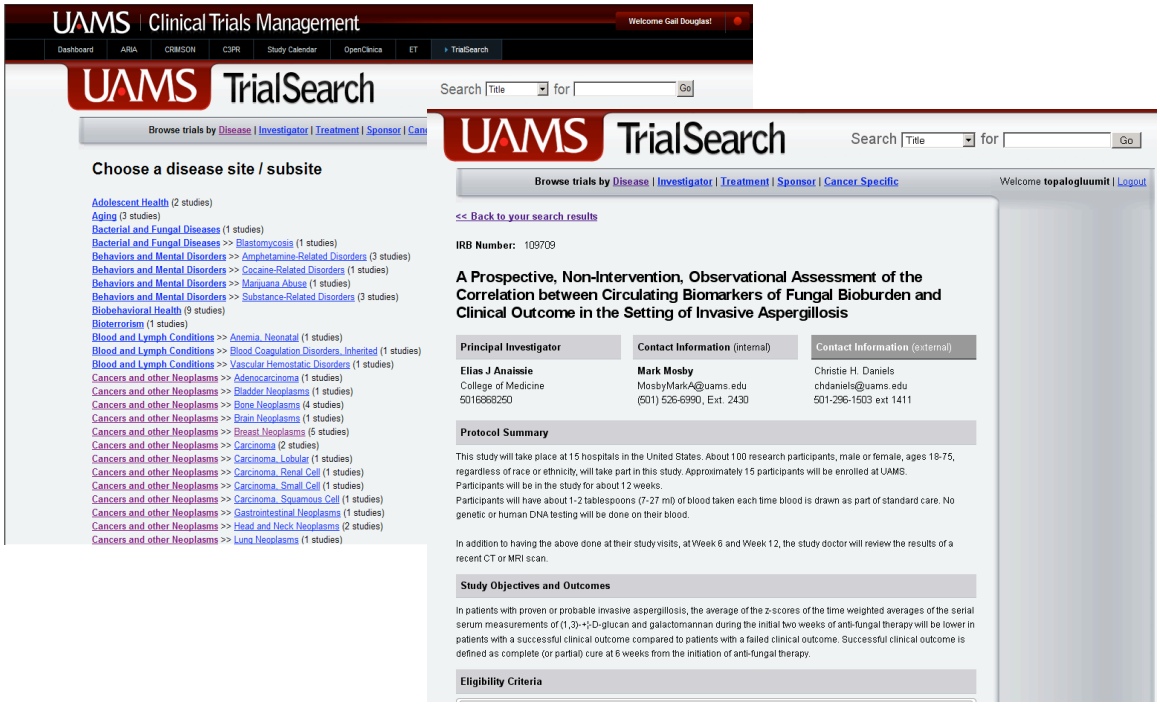
The Suite at UAMS



Our Dream: Recruitment



UAMS Trial Search- Recruitment



Research participant DB-Recruitment

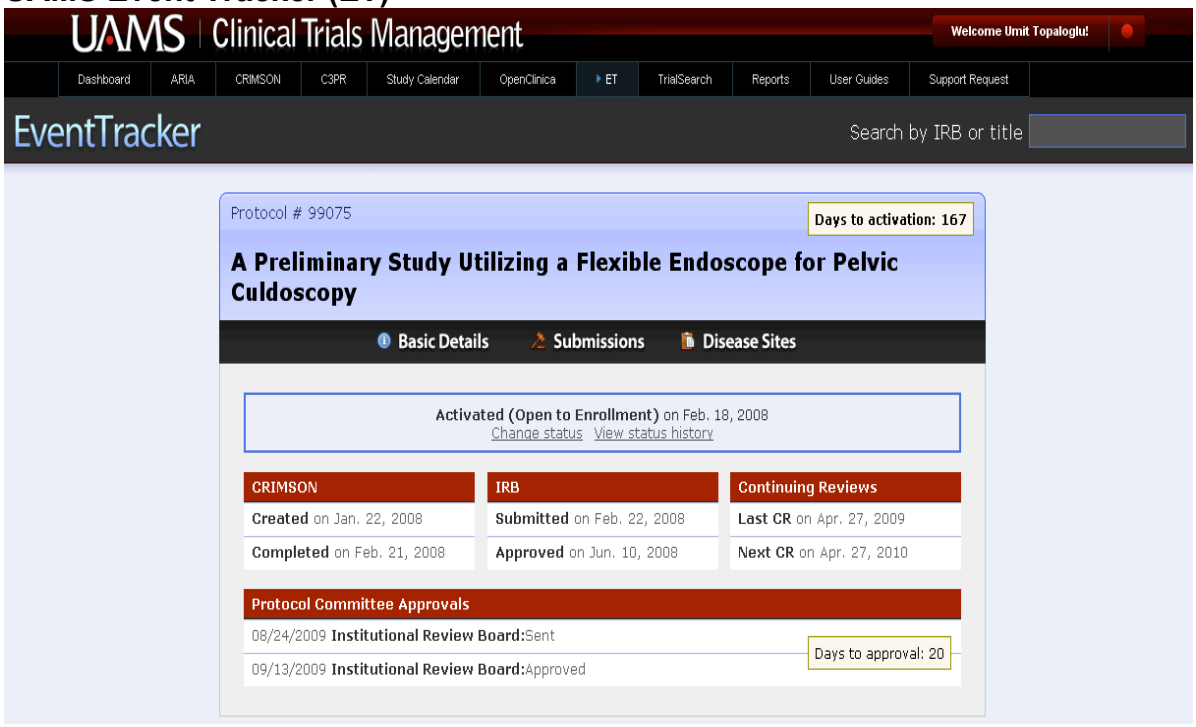
- We are in process of developing an IRB protocol to create a system in which we can store
  - Potential participants
    - Apps we will use
  - re-contact allowed?
  - Collect Biospecimens
  - Questionnaires

Our Dream: Registration

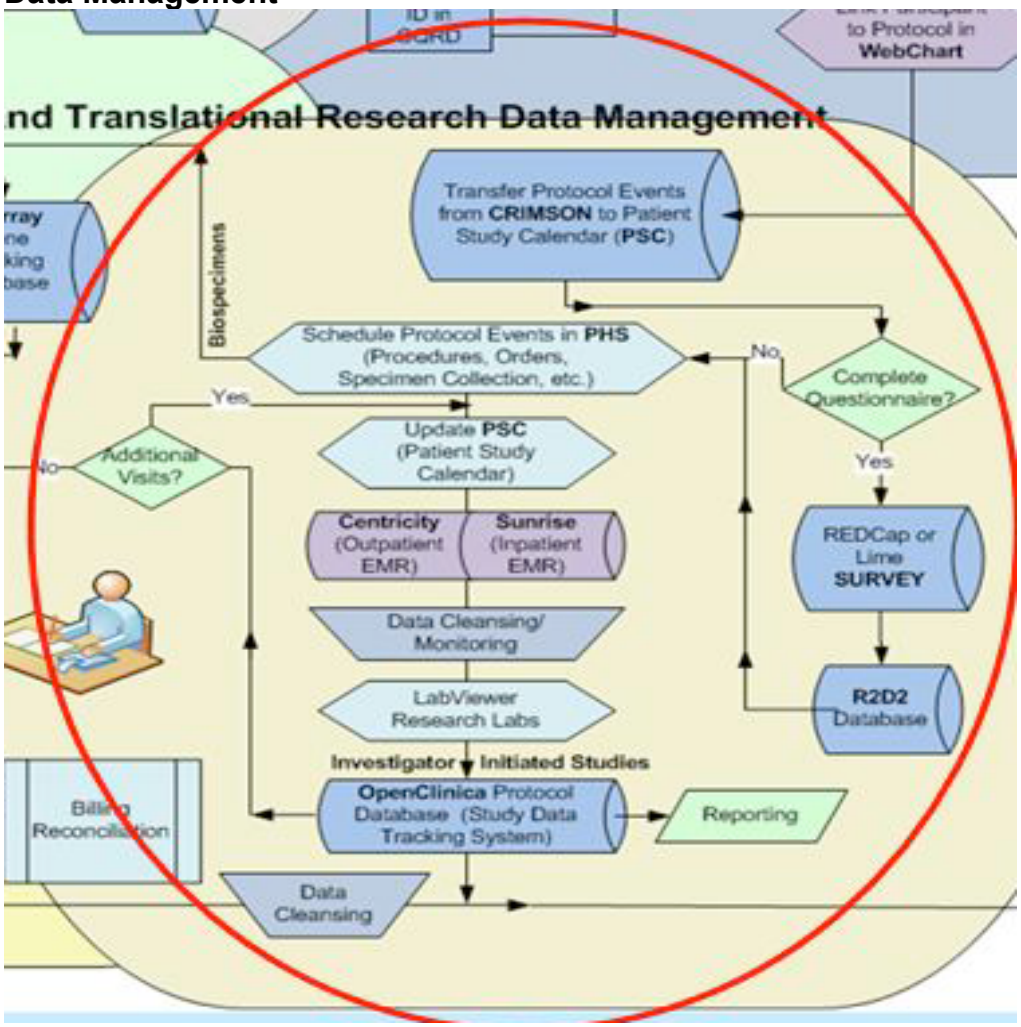
caBIG's C3PR-

- 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)



Data Management

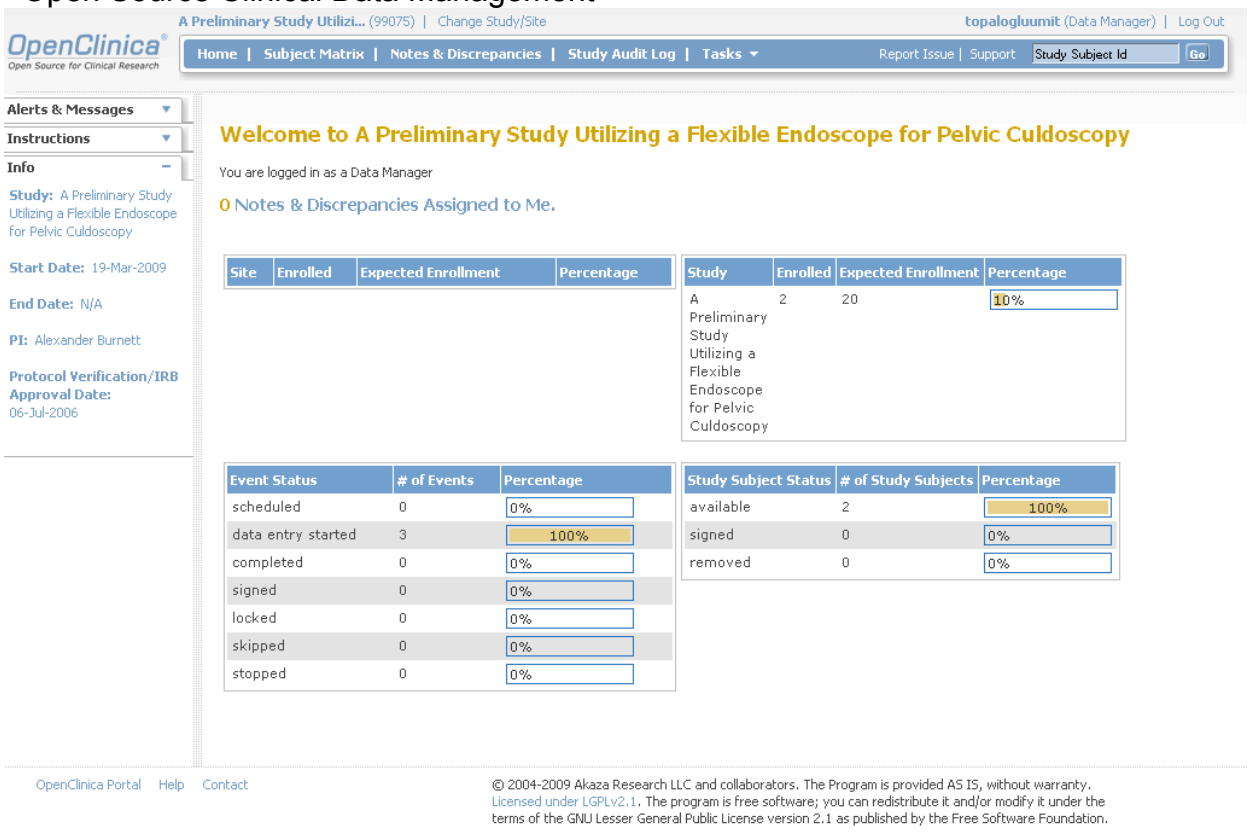


caBIG's Patient Study Calendar

- 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

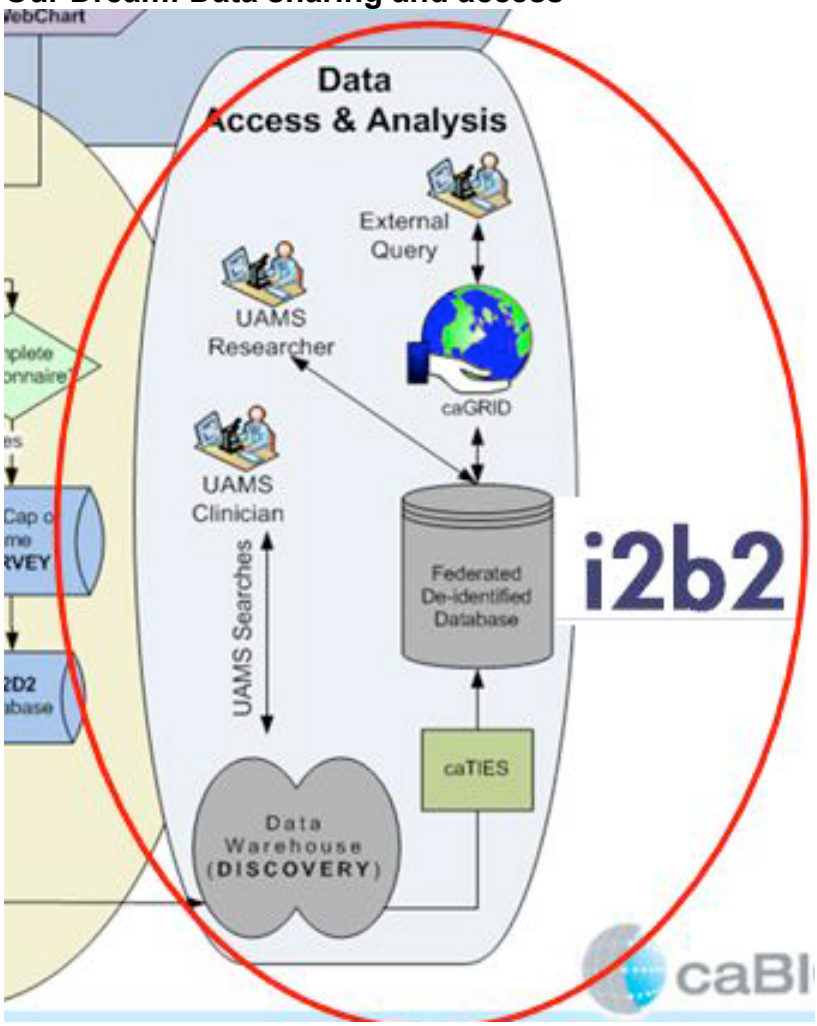
Open Source Clinical Data Management



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



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.

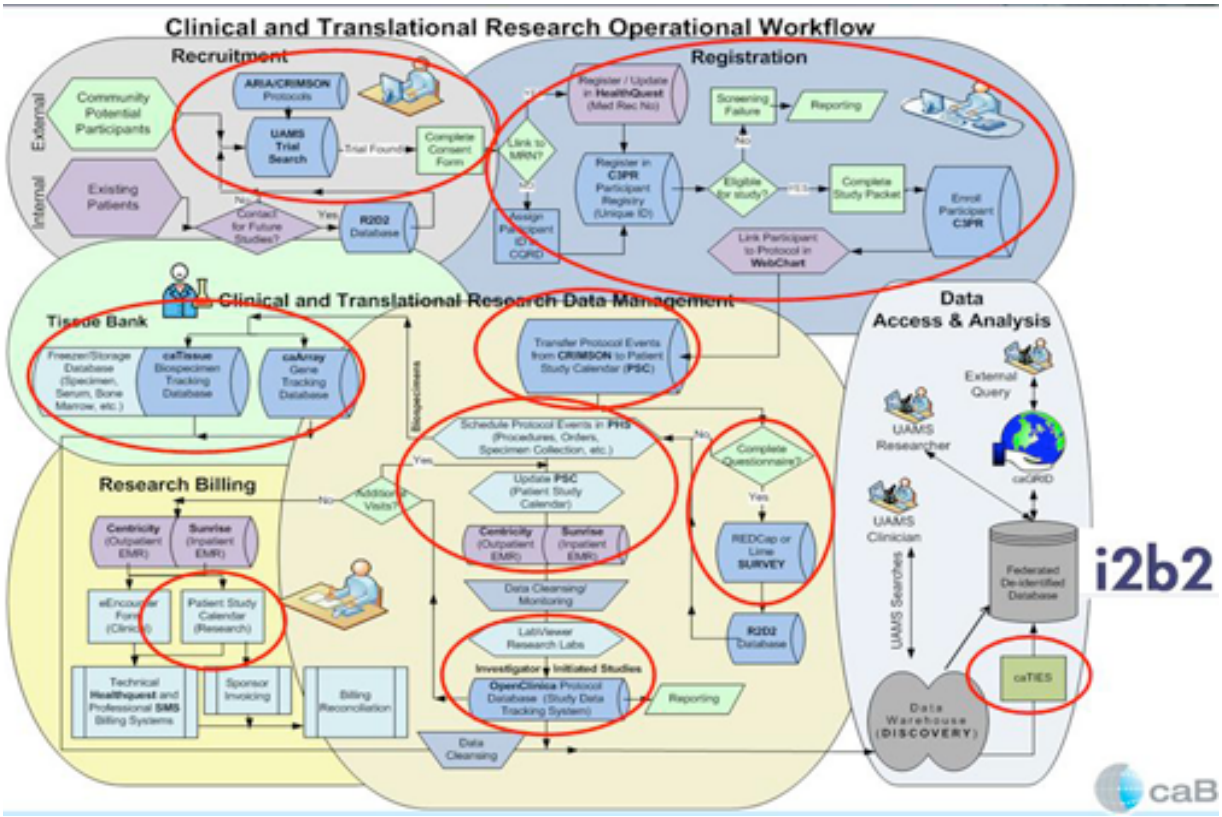
Creating a rules engine

- 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?



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

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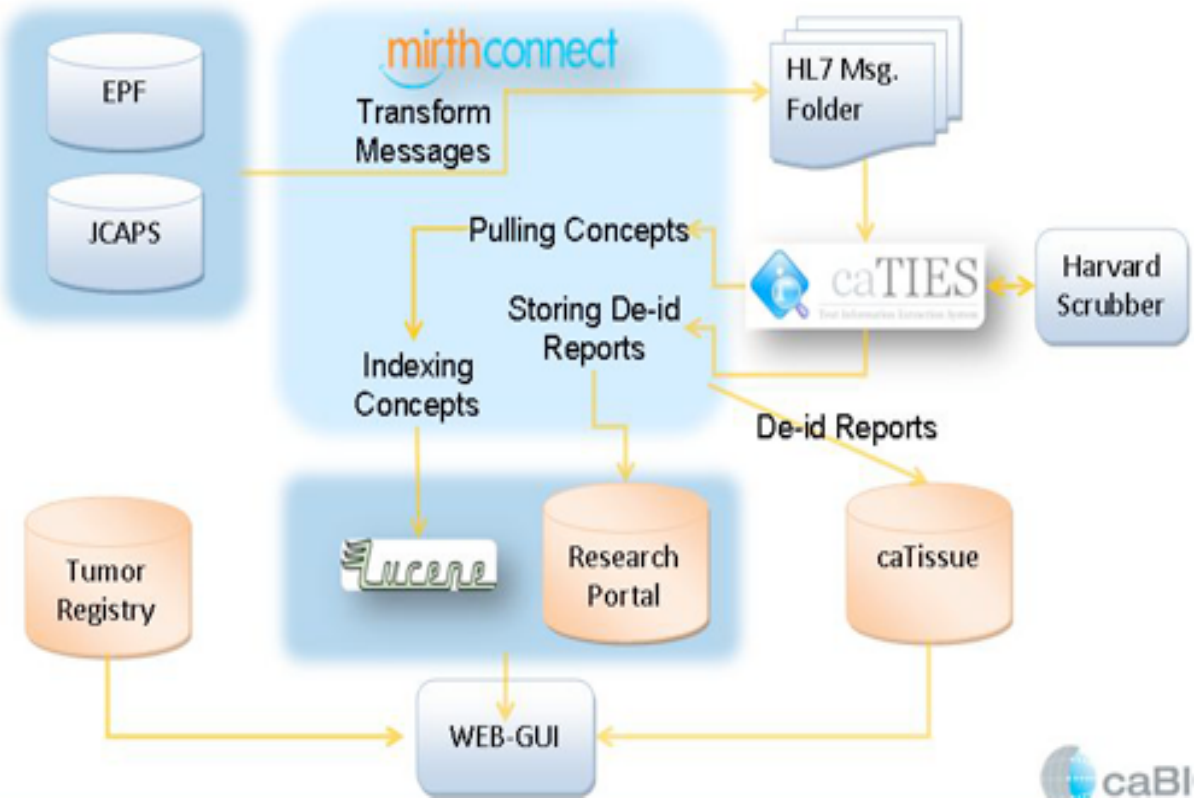
Research Portal with caTIES

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


EPF
JCAPS
mirthconnect
Transform Messages
HL7 Msg. Folder
Pulling Concepts
caTIES
Harvard Scrubber
Storing De-id Reports
Indexing Concepts
De-id Reports
Tumor Registry
Lucene
Research Portal
caTissue
WEB-GUI
caBI