



# Centers of Excellence in Regulatory Science and Innovation (CERSI)

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FDA, Office of the Chief Scientist



# CERSI

Centers for Excellence in Regulatory Science  
and Innovation

Address priority areas of the Strategic Plan



## Research

Innovative and  
Collaborative  
Research Projects

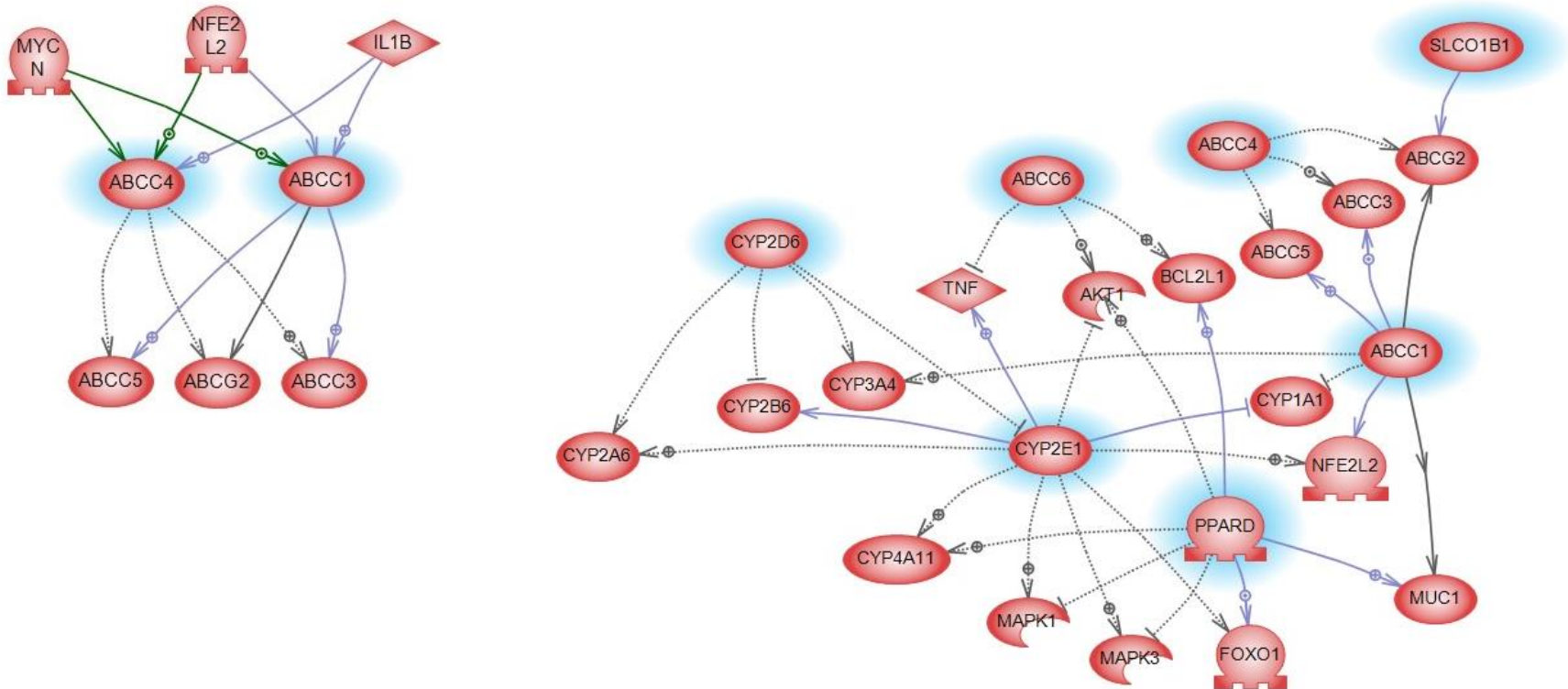


## Education/Training

Lectures, Courses,  
Seminars, Teaching,  
Professional  
Development,  
Masters Programs

# Georgetown CERSI

## Genes involved in gemcitabine response



## Pathway Modeling of Autoimmune Diseases

Fig. a: Common Pathways

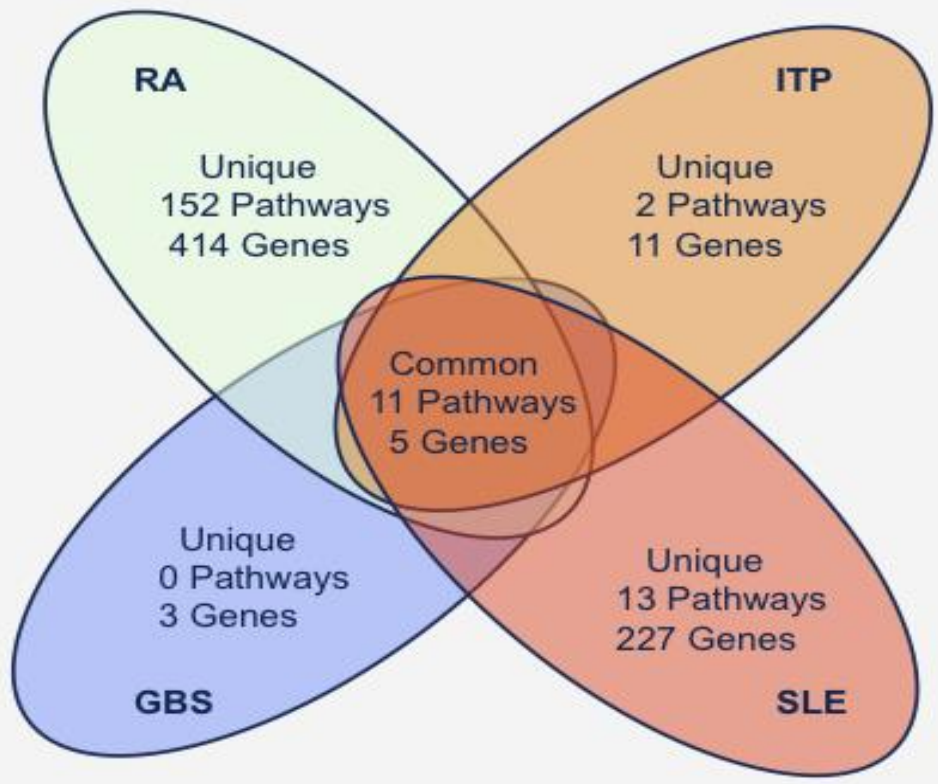
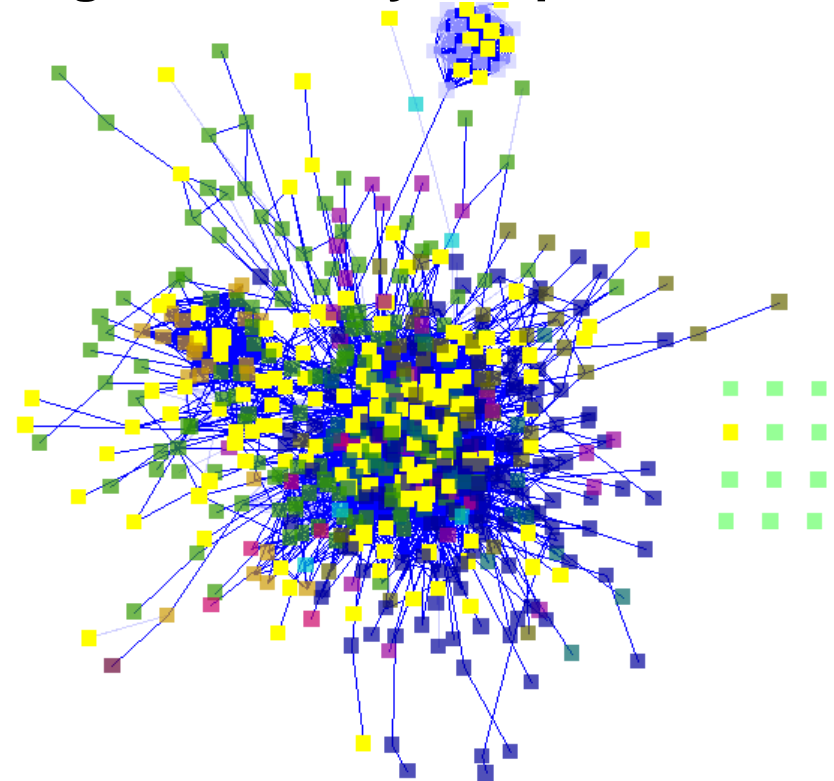
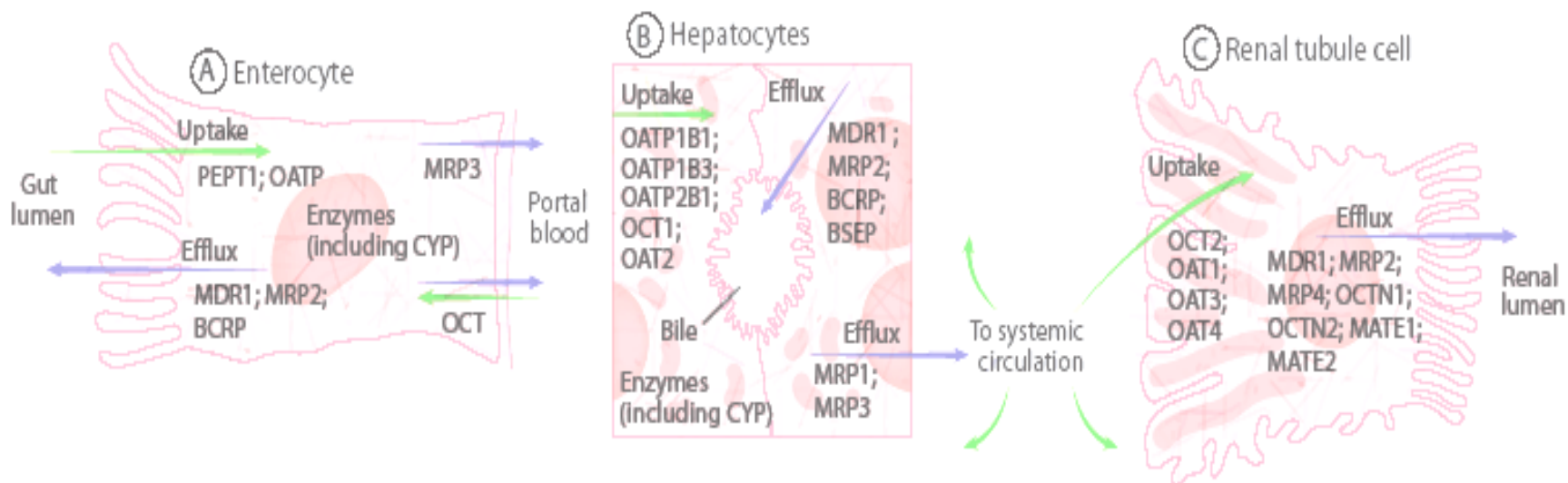
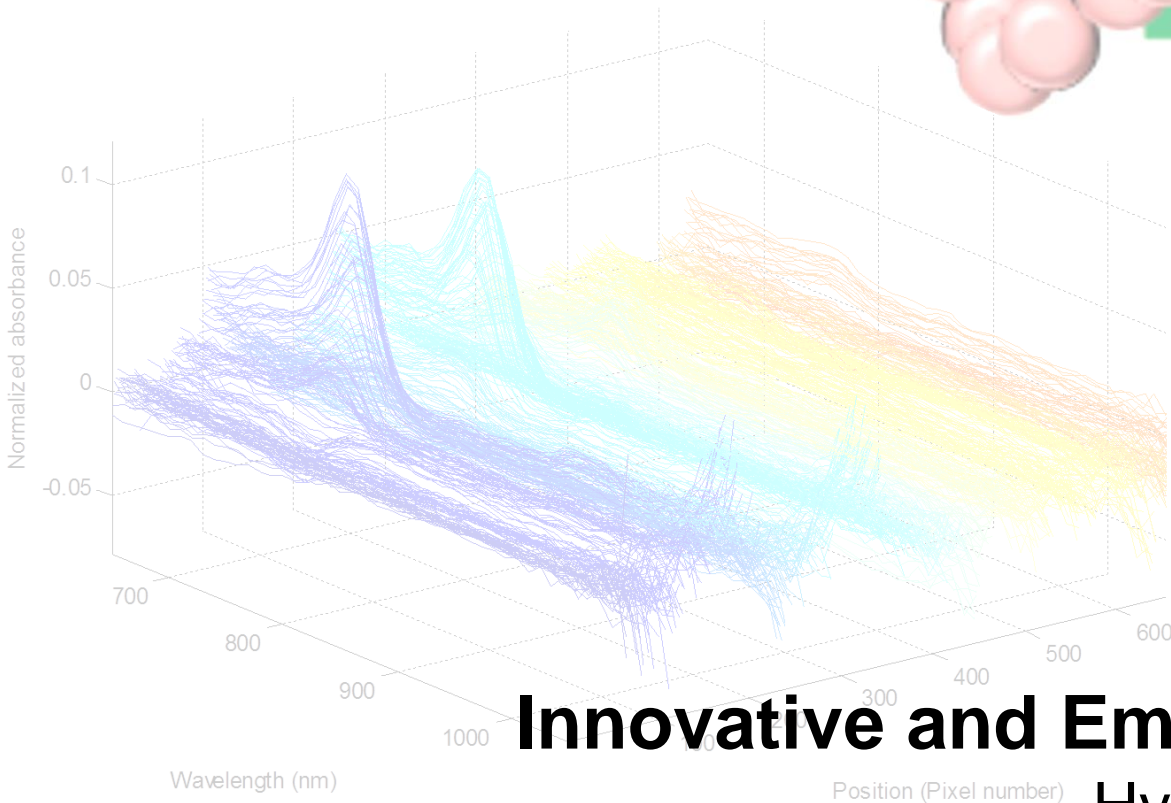


Fig. b: Pathways Map of RA





**Regulatory science collaborative research Project 1:  
Modernize Toxicology to Enhance Product Safety**  
Membrane Transporters in Mediating Drug-Drug Interactions



## **Innovative and Emerging Technologies**

Hyperspectral Imaging (HSI)

Advanced Tissue Engineering Scaffolds

# SECOND ANNUAL M-CERSI DAY

THURSDAY, SEPT. 5, 2013 • 8:30 A.M. - 1 P.M.

UNIVERSITY OF MARYLAND SCHOOL OF PHARMACY  
PHARMACY HALL • 20 N. PINE STREET, BALTIMORE, MD



**Georgetown University CERSI Research Day 2013**

Friday, March 1, 2013 – 1:00-4:30pm

U.S. Food & Drug Administration – White Oak Campus – Bldg. 2, Room 2045

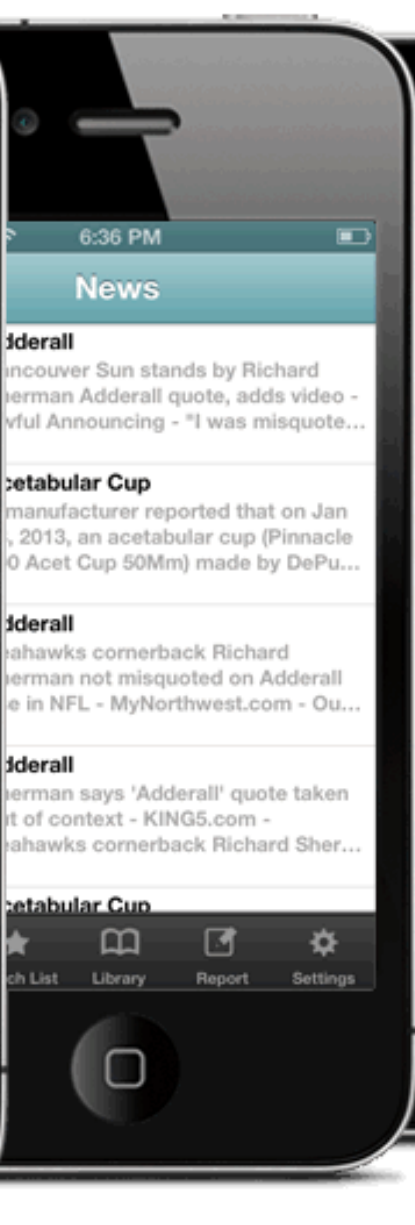
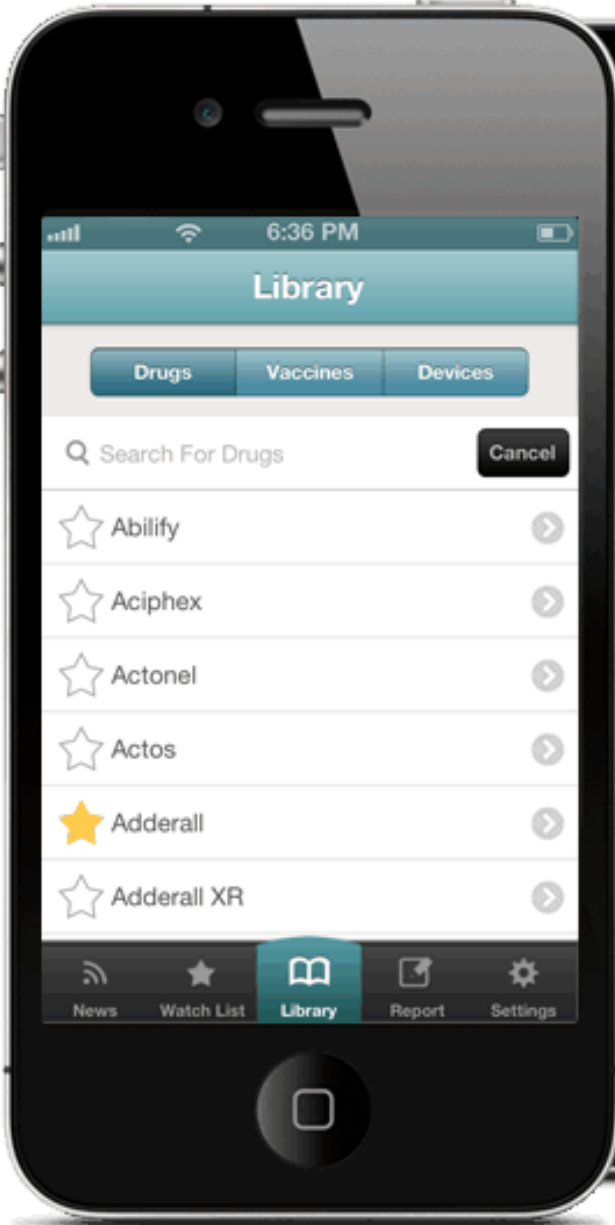
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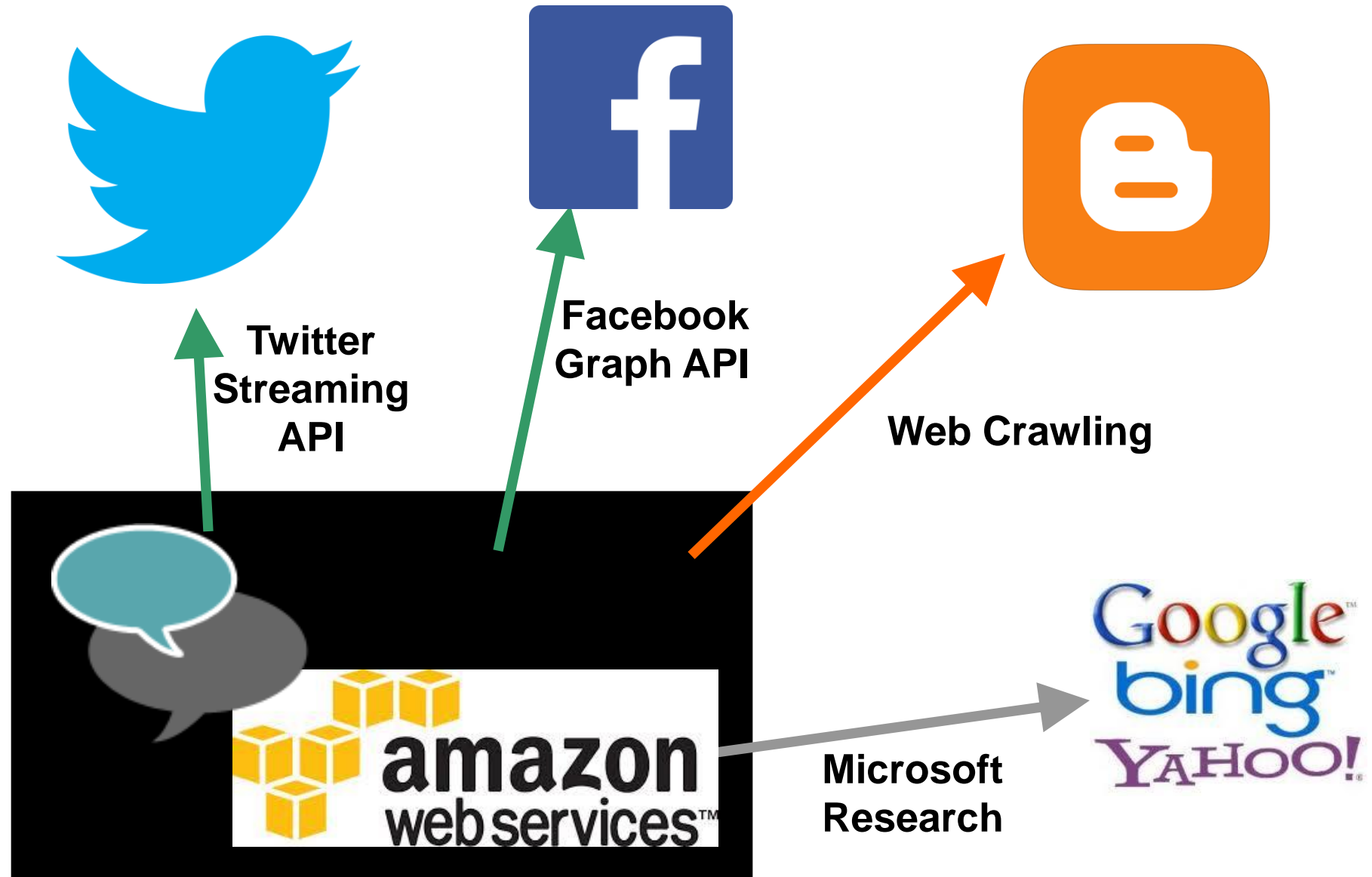
Adobe Connect: <https://collaboration.fda.gov/georgetown/>

## Department of Health and Human Services

### Part 1. Overview Information

<b>Participating Organization(s)</b>	U.S. Food and Drug Administration ( <a href="#">FDA</a> )  The FDA does not follow the NIH Page Limitation Guidelines or the Enhanced Peer Review Scoring Criteria. Applicants are encouraged to consult with FDA <a href="#">Agency Contacts</a> for additional information regarding page limits and the FDA Peer Review Process.
<b>Components of Participating Organizations</b>	Office of the Commissioner-Office of the Chief Scientist
<b>Funding Opportunity Title</b>	<b>Collaborating Centers of Excellence in Regulatory Science and Innovation (U01)</b>
<b>Activity Code</b>	<a href="#">U01</a> Research Project – Cooperative Agreements
<b>Announcement Type</b>	New
<b>Related Notices</b>	<ul style="list-style-type: none"><li>• August 21, 2013: Removed reference to ASSIST in section IV.3, since ASSIST is currently only available for multi-project applications.</li><li>• <a href="#">June 24, 2013</a> - See Notice NOT-FD-13-017. Notice of Change to Foreign Institutions Eligibility Information.</li></ul>
<b>Funding Opportunity Announcement (FOA) Number</b>	<b>RFA-FD-13-034</b>
<b>Companion Funding Opportunity</b>	None
<b>Number of Applications</b>	See <a href="#">Section III. 3. Additional Information on Eligibility</a> .
<b>Catalog of Federal Domestic Assistance (CFDA) Number(s)</b>	93.103
<b>Funding Opportunity Purpose</b>	<p>As part of the FDA's Advancing Regulatory Science Initiative, the Office of Chief Scientist supports innovation to improve the development of new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products.</p> <p>This Funding Opportunity Announcement (FOA) will provide support for one or more Collaborating Centers of Excellence in Regulatory Science and Innovation (CERSI). The CERSI's will be established to foster an innovative and thematically coherent approach to advance the field of regulatory science (including laboratory, population, behavioral, and manufacturing sciences) and the Critical Path Initiative toward more effective and efficient product development and evaluation.</p>





**Medwatcher Social platform (built using Amazon Web Services) queries multiple sources for publicly available raw data.**

**→ :active**

**→ :initiated**

**→ :planned**

**500M**

Streaming API filtered on  
product names

**30K**

## Daily Dose of Tweets

**500**

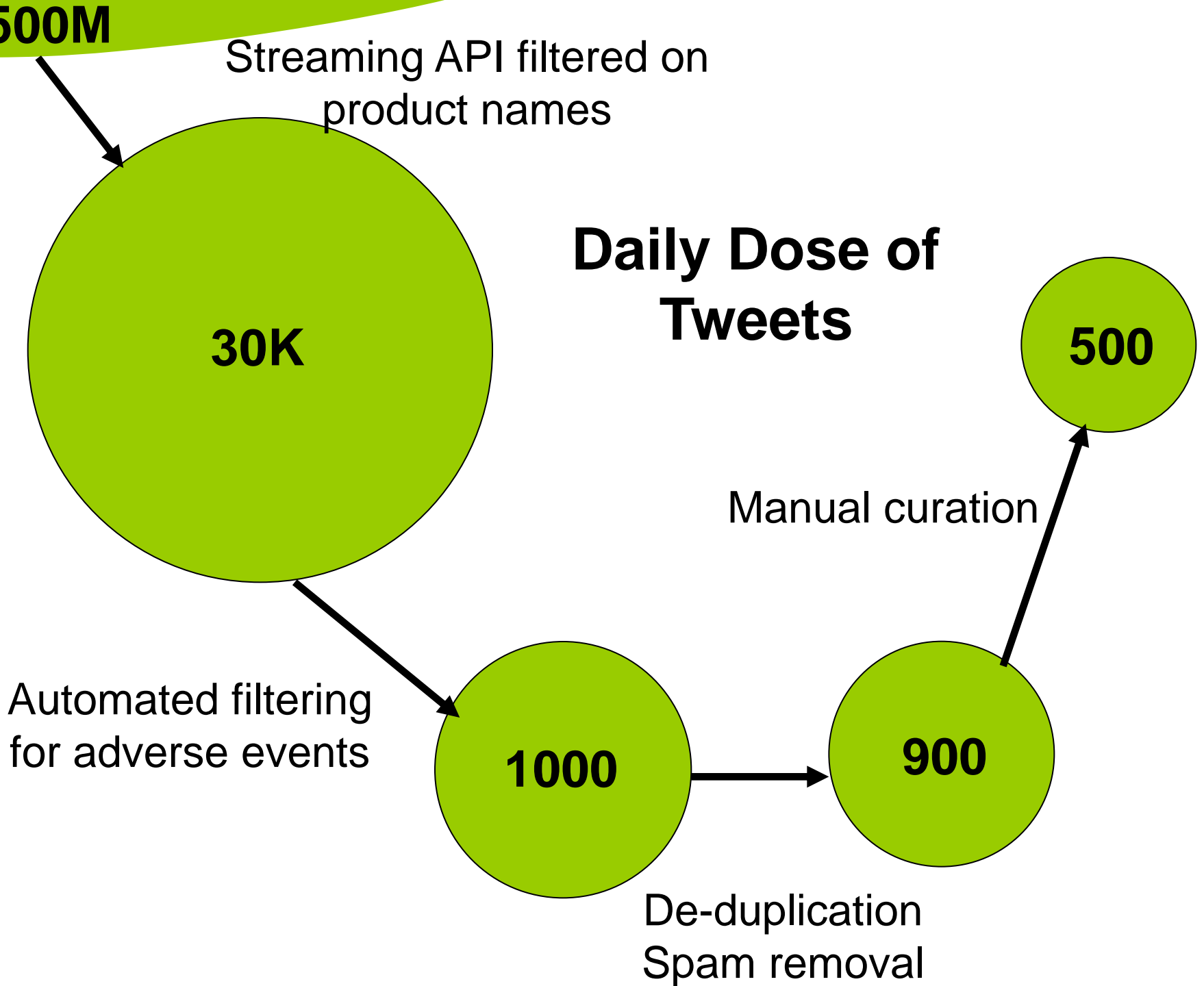
Manual curation

Automated filtering  
for adverse events

**1000**

**900**

De-duplication  
Spam removal



# Severity

Did any of the following happen? (*Check all that apply*)

- Hospitalization – admitted or stayed longer
- Required help to prevent permanent harm (*for medical devices only*)
- Disability or health problem
- Birth defect
- Life-threatening
- Death (*Include date*): \_\_\_\_\_
- Other serious/important medical incident (*Please describe below*)

# Labeled

*Body as a whole:* Weakness.

*Cardiovascular:* Hypotension including orthostatic Hypotension (may be aggravated by alcohol, barbiturates, narcotics or antihypertensive drugs).

*Digestive:* Pancreatitis, jaundice (intrahepatic cholestatic jaundice), diarrhea, vomiting, sialadenitis, cramping, constipation, gastric irritation, nausea, anorexia.

*Hematologic:* Aplastic anemia, agranulocytosis, leukopenia, hemolytic anemia, thrombo-cytopenia.

*Hypersensitivity:* Anaphylactic reactions, necrotizing angitis (vasculitis and cutaneous vasculitis), respiratory distress including pneumonitis and pulmonary edema, photosensitivity, fever, urticaria, rash, purpura.

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