

# **AMIA 2012 Summit in CRI CRI Year-In-Review**

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San Francisco, California  
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# Approach to this presentation

- Mix of Dan Masys' and Russ Altman's approaches
  - Started with structured approach
    - (akin to ACP "update" sessions)
  - Quickly moved to augment with "what seemed interesting" approach
- Learned a lot from doing this last year
  - Tracked manuscripts throughout the year
  - (still worked down to the wire)
- So, what was my approach...

# Source of Content for Session

- Literature review:
  - Initial search by MESH terms:
    - ("Biomedical Research"[Mesh] NOT "Genetic Research"[Mesh]) NOT "Translational Research"[Mesh]) AND "Informatics"[Mesh] AND "2011/01/01"[Pdat] : "2013/02/01"[Pdat]
    - Resulted in 77 articles; 41 were CRI relevant
  - Additional 63 relevant articles through:
    - Recommendations from colleagues
    - Other keyword searches using terms like:
      - Clinical Trials, Clinical Research, Informatics, Translational, Data Warehouse, Recruitment
  - Result = 104 total CRI relevant to choose from
  - I then selected 33 papers that I'll present here (*briefly*)

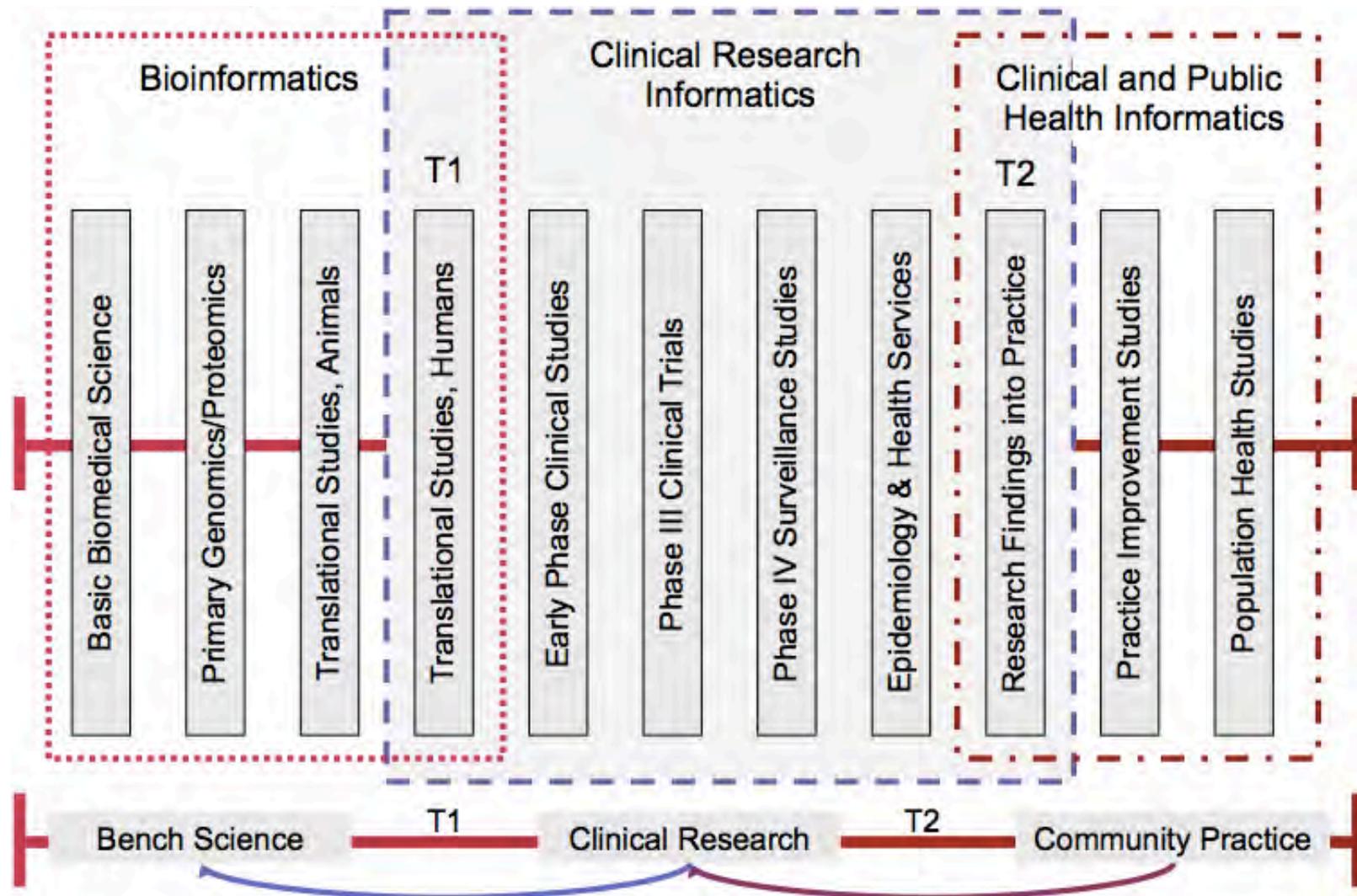
Note: If from early 2011 but discussed last year, not selected to avoid repetition

# Session caveats

- What this is not...
  - A systematic review of the literature
  - An exhaustive review
- What this is...
  - My best attempt at *briefly* covering *some* of the representative CRI literature from the past year
  - A snap-shot of CRI activity over past year
  - What I thought was notable

# Clinical and Translational Research & Informatics: T1, T2, and Areas of Overlap for Informatics

Shaded CRI Region is Main Area of Focus



# Topics

- Grouped 33 articles into several CRI categories (admittedly, not *all* CRI areas)
  - Clinical Data Re-Use for Research
  - Data/Knowledge Management & Discovery
  - Researcher Support & Resources
  - Participant Recruitment
  - Patients/Consumers & Research Informatics
  - Policy & Fiscal
- In each category, I'll emphasize a few key articles and then given a “shout out” to a few others
- Conclude with notable events from the past year

# Apologies up front

- I'm CERTAIN I've missed a lot of great work
- I'm REALLY SORRY about that

# Clinical Data Re-Use for Research



## “Portability of an algorithm to identify rheumatoid arthritis in electronic health records” (Carroll WK et al, JAMIA, 2012)

- **Goal:** Test ability to identify a patient cohort from other institutions' EHR databases using a published phenotype algorithm demonstrated effective one site.
- **Methods:** Charts reviewed by physicians at three sites to find patients with RA. NLP approaches used against EHR derived data from each site.
- **Results:** Northwestern and Vanderbilt's data performed nearly as well as Partner's (AUC 92% and 95% vs. 97%, respectively). Retraining the logistic regression models improved results, and all were better than billing code count thresholds.
- **Conclusion:** Electronic phenotyping algorithms allow rapid identification of case populations across sites with different EHRs, NLP systems, with little retraining.

## “Validity of electronic health record-derived quality measurement for performance monitoring” (Parsons A. et al, JAMIA, 2012)

- **Goal:** NYC primary care practices taught to adjust workflows and use EHR’s built-in population health monitoring tools (quality measures, registries, CDSS), with technical assistance.
- **Methods:** Charts for 4081 pts reviewed across 57 practices to determine validity of documented measures and preventive services.
- **Results:** Automated, EHR-derived quality measures underestimated actual performance. Documentation varied between sites and with some exceptions did not reflect numbers of patients who actually got preventive measures.
- **Conclusion:** This study confirms that caution is required when determining performance based on EHR documentation. Implications for data re-use.

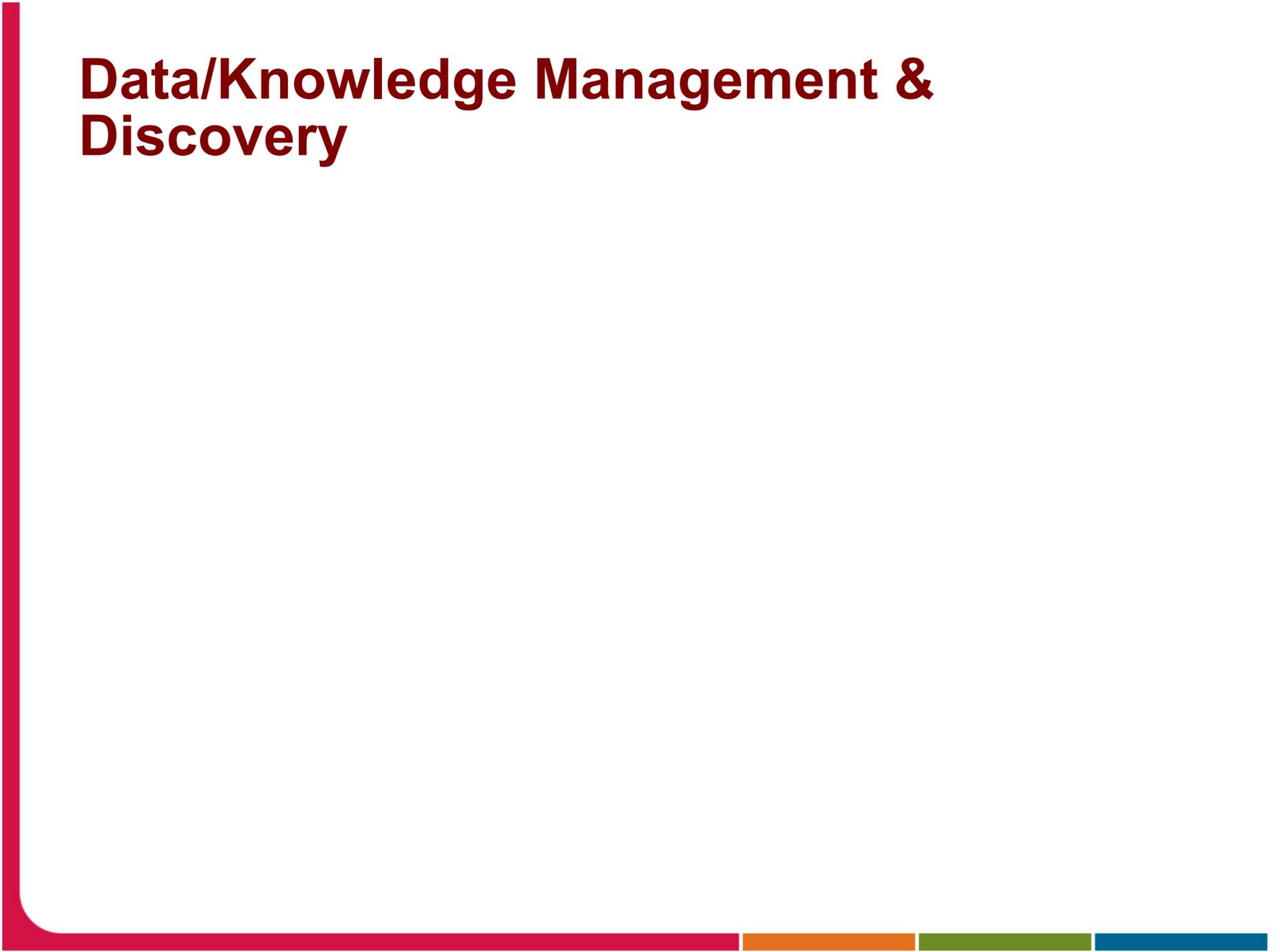
## “Improving completeness of electronic problem lists through clinical decision support: a randomized, controlled trial” (Wright A. et al, JAMIA, 2012)

- **Goal:** To determine whether a clinical alert system using inference rules to notify providers of undocumented problems improves problem list documentation.
- **Methods:** Inference rules for 17 conditions implemented. Cluster, randomized trial of 28 primary care areas (14 intervention, 14 control). Alerts suggested provider add missing problem to list. Acceptance of alert main outcome.
- **Results:** 17,043 alerts presented, 41.1% accepted. Intervention providers documented more problems (OR=3.4,  $p < 0.0001$ ), with 70.4% of all problems added via alerts. Significant increases noted for 13 of 17 conditions.
- **Conclusion:** Problem inference alerts significantly increased important problem documentation. Can improve quality and research that re-uses EHR data.

## Other notable papers in this category:

- **“Concept and implementation of a computer-based reminder system to increase completeness in clinical documentation.”** (Herzberg S. et al. Int J Med Inform. 2011)
- **“Utility of electronic patient records in primary care for stroke secondary prevention trials.”** (Dregan A. et al. BMC Public Health, 2011)
- **“Quality of data collection in a large HIV observational clinic database in sub-Saharan Africa: implications for clinical research and audit of care”** (Kiragga A.N. et al. J. Int AIDS Soc. 2011)
- **“Mapping clinical phenotype data elements to standardized metadata repositories: the eMERGE Network experience”** (Pathak J. et al. JAMIA. 2011)
- **“Never too old for anonymity: a statistical standard for demographic data sharing via the HIPAA Privacy Rule”** (Malin B. et al. JAMIA. 2011)

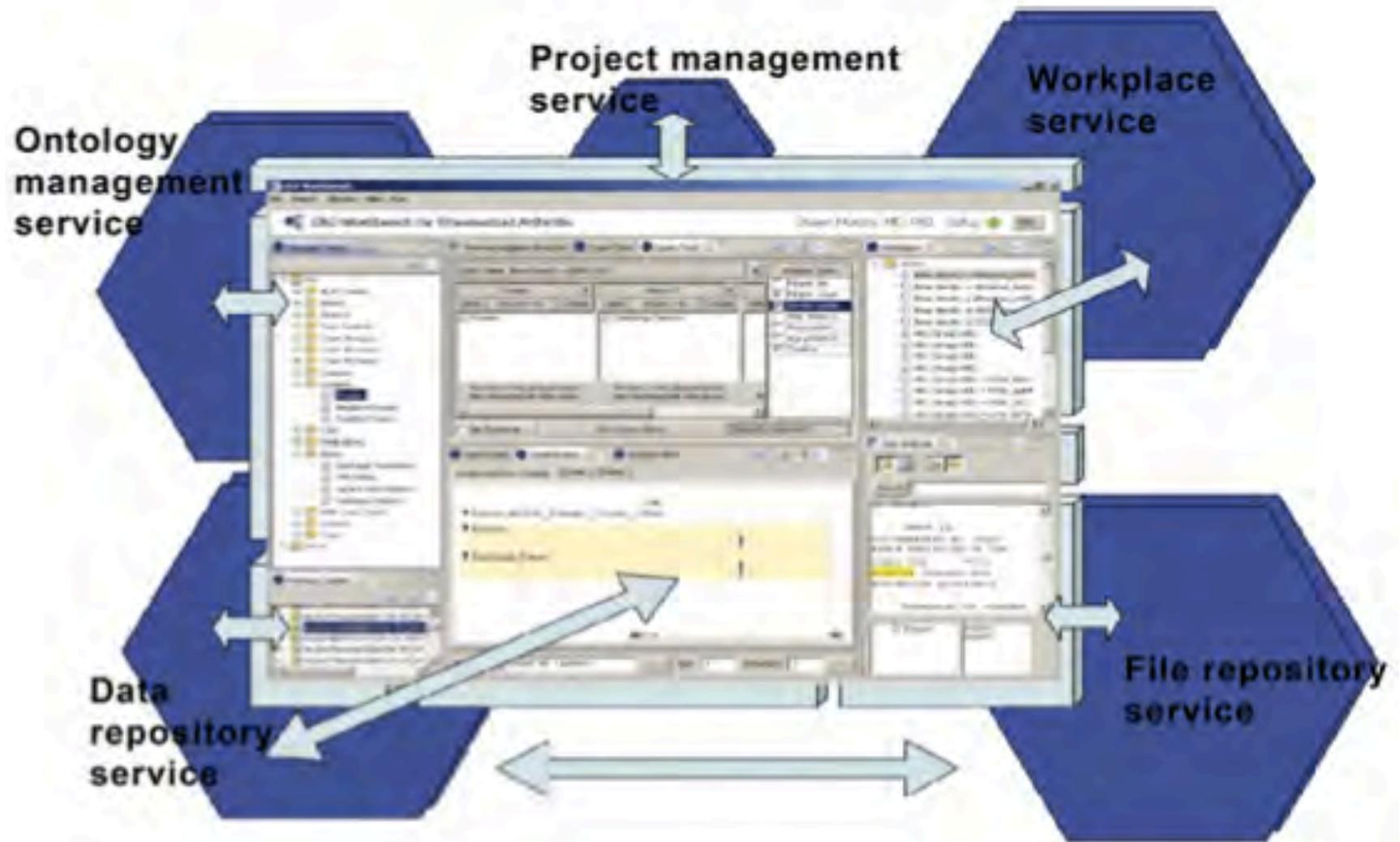
# Data/Knowledge Management & Discovery



# “A translational engine at the national scale: informatics for integrating biology and the bedside” (i2b2) (Kohane et al, JAMIA, 2012)

- **Goal:** Brief communication, update on tools designed to integrate medical record and biological data for research.
- **Methods:** Description of NIH-supported i2b2 software for cohort finding and query.
- **Results:** Now implemented at >60 centers inter-nationally. Query capability across instances via SHRINE. Multiple partner sites contributing to collaborative development.
- **Conclusion:** i2b2 has become a valued and widespread resource for clinical and translational science.

# i2b2 toolkit software components (cells), organized into collections (hives)



# Map of sites that have adopted i2b2



-  CTSAs\* Adopting i2b2
-  CTSAs\* Evaluating i2b2 platform
-  Academic Medical Centers Adopting i2b2 Platform
-  Foreign Medical Centers Adopting i2b2 Platform

Geographical distribution of over 60 academic health centers (50 in the USA). Some locations (eg, San Francisco and Boston) have more sites than can be shown at the map's resolution.

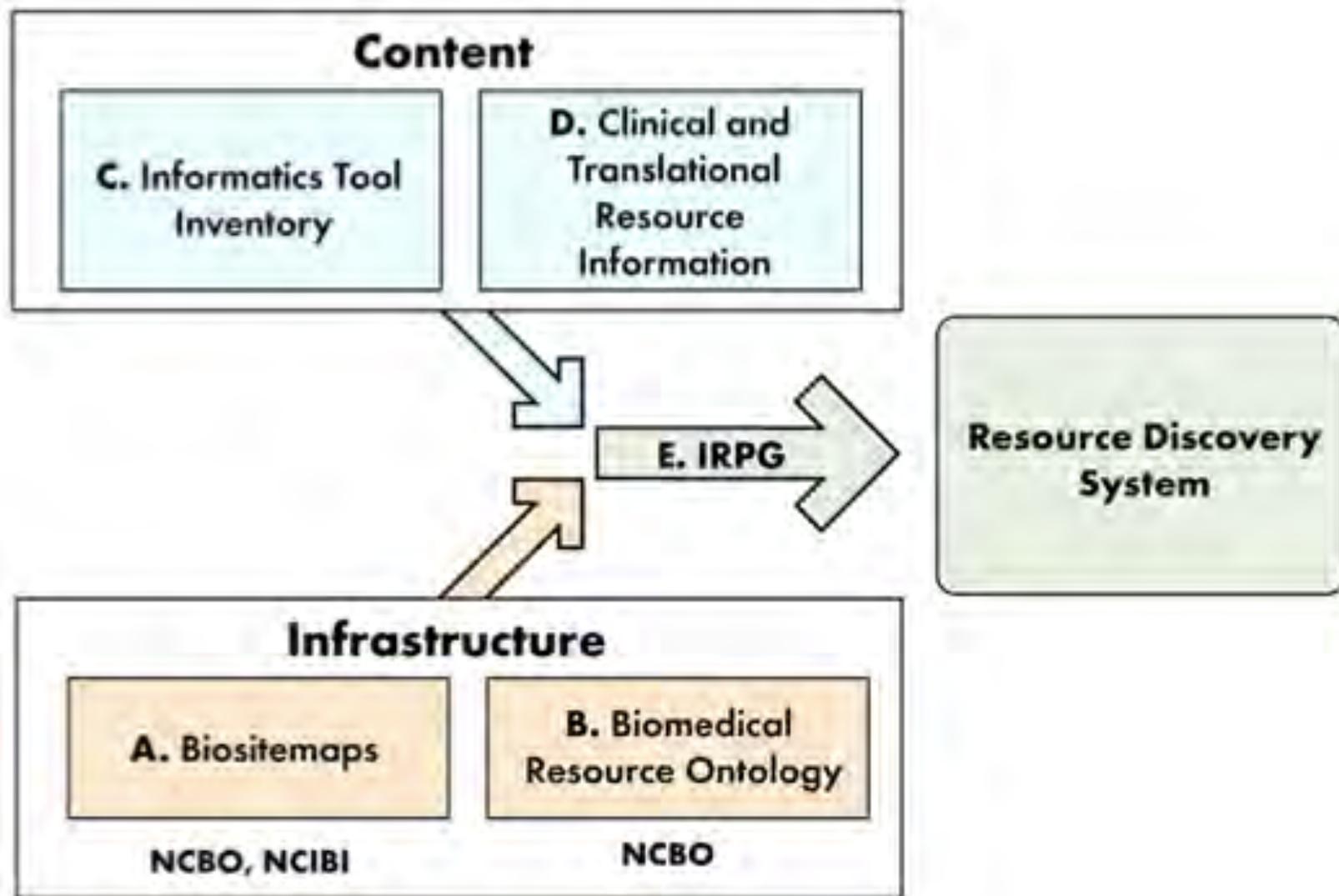
# “The Biomedical Resource Ontology (BRO) to Enable Resource Discovery in Clinical and Translational Research”

(Tenenbaum J, et al. J Biomed Inform, 2011)

- **Goal:** To enable semantic annotation and discovery of biomedical resources across sites to facilitate their discovery among investigators.
- **Methods:** Development and use of Biomedical Resource Ontology (BRO) as well as the Resource Discovery System (RDS).
- **Results:** Through study of the RDS framework (the federated, inter-institutional pilot project that uses BRO to facilitate resource discovery over the Internet) and its associated Biositemaps infrastructure, the BRO facilitated semantic search and discovery of biomedical resources.
- Some key elements...

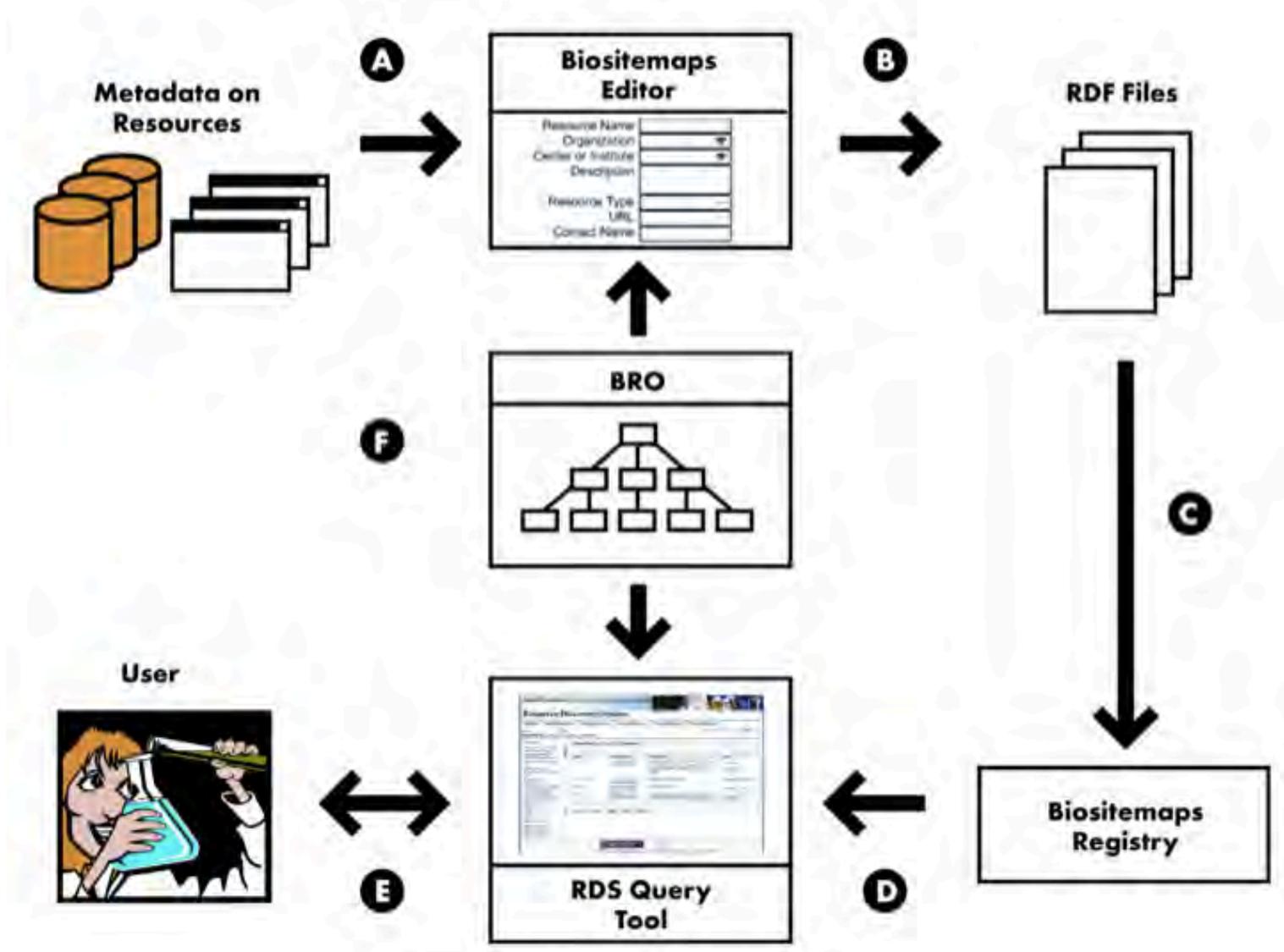
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*Scientific explorer*



## Resource Discovery System

[Software](#)
[Material Resources](#)
[Funding Resources](#)
[Service Resources](#)
[Training Resources](#)
[People Resources](#)

Search   [Advanced Search](#) | [Map](#) | [FAQ](#) | [About](#)

**Organization**

- Aberystwyth University (2)
- Argonne National Laboratory (1)
- Auckland Bioengineering Institute (1)
- Boston University (3)
- Broad Institute (1)
- Carnegie Mellon (2)
- Cleveland Clinic (1)
- Cleveland Clinic, Lerner Research Institute (3)
- Columbia University (57)
- Compendia Bioscience (1)
- Computer Human Interaction & Software Engineering Lab (CHISEL) (1)
- Creare, Inc. (1)
- Drexel University (1)
- Drexel University College of Medicine (1)
- Center
- Research Program
- Resource Type
- Related Activities
- Areas of Research

1,553 **Resources** found, displaying 1 to 25.

1 • 2 • 3 • 4 • 5 • 6 • 7 • 8 ▶▶

Name	Organization	Description	Links
2007BioE215 Fox	Stanford University	Submitted coursework for BIOE215 Spring 2007	Home page Contact: Melanie Fox
2D Difference Gel Electrophoresis	University of Florida	1D and 2D SDS PAGE Native gel electrophoresis 2D DIGE (Cy2, Cy3, and Cy5 fluorescent dye labeling) 2D gel-based PTM...	Home page Contact: Marjorie Chow
3d Brain Atlas Reconstructor		3d Brain Atlas Reconstructor 3dBAR <a href="httpwww.3dbar.org">httpwww.3dbar.org</a> is a software package for reconstructing three-dimensional models of brain structures from 2-D delineations...	Home page Contact: Piotr Majka
3D RNA Modeling & Simulation Workshop, UIC Chicago, March 2010	Stanford University	The structure and dynamics of molecules is central to understanding biological function, and yet most experimentalists find existing structural modeling...	Home page Contact: Blanca Pineda, Joy Ku
3D RNA Modeling and Simulation Workshop, June 19, 2009	Stanford University	The structure and dynamics of molecules is central to understanding biological function, and yet most experimentalists find existing structural modeling...	Home page Contact: Blanca Pineda, Joy Ku
454 Sequencing	University of Florida	Services Include: Library construction and titration Sample preparation for titration for samples that need no library construction Production sequencing using...	Home page Contact: David Moraga, PhD
A Coarse-Grained Physical Model for RNA	University of Texas at Austin	This project aims to develop a coarse-grained (CG) model for RNA at the functional group, residue as well as secondary...	Home page Contact: Johnny Wu, Pengyu Ren, Pavel Golubkov

# “The Biomedical Resource Ontology (BRO) to Enable Resource Discovery in Clinical and Translational Research”

(Tenenbaum J, et al. J Biomed Inform, 2011)

- **Conclusion:** This approach/resource shows promise to help investigators discovery resources otherwise not visible to them, thereby potentially streamlining research.

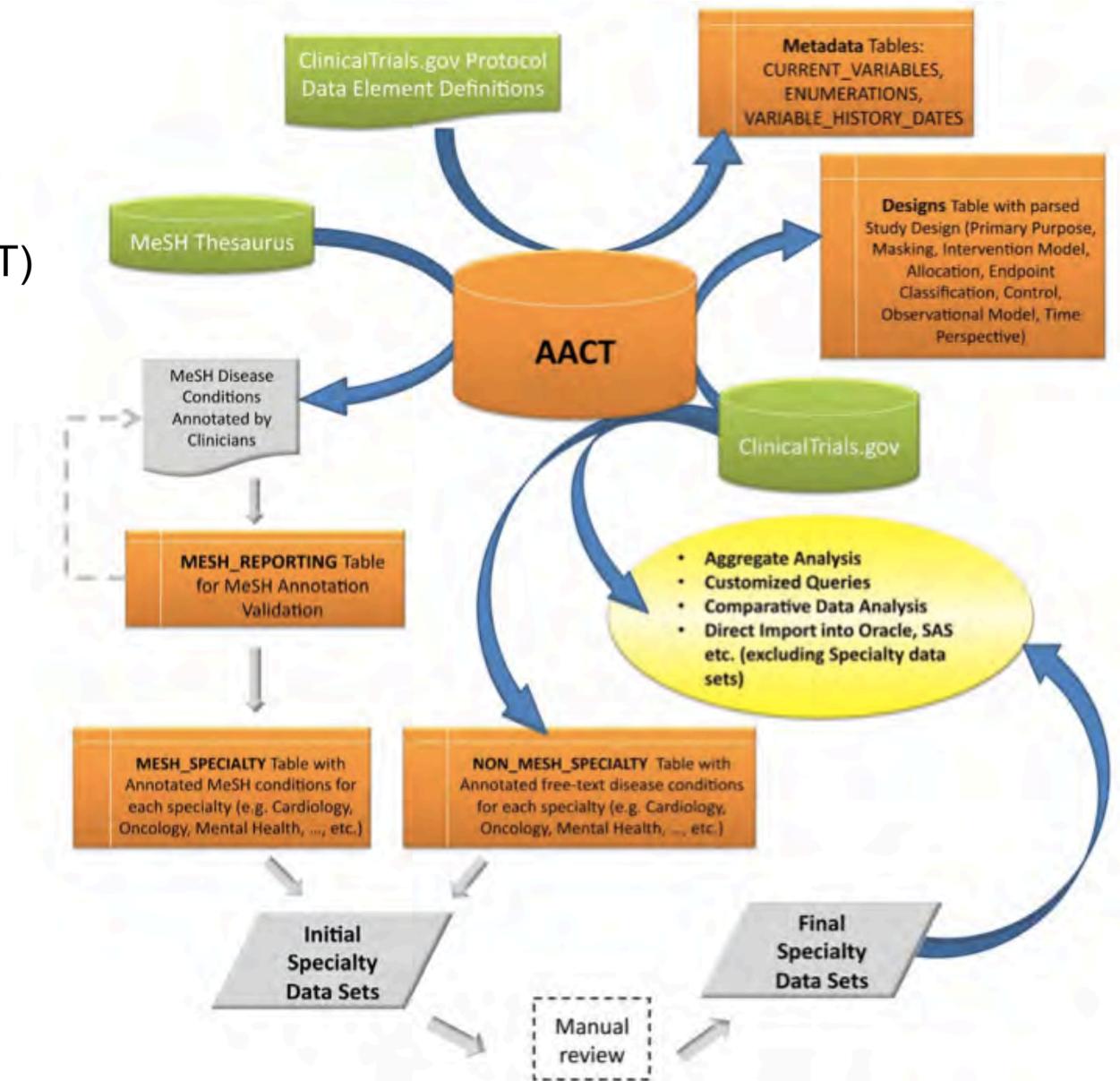
# “The Database for Aggregate Analysis of ClinicalTrials.gov (AACT) and Subsequent Regrouping by Clinical Specialty”

(Tasneem A, et al. PLoS One, 2012)

- **Goals:** Enhance utility of clinicaltrials.gov as a research resource by creating a database for aggregate analyses of registered content, and annotate by clinical specialty.
- **Methods/Results:** Consumed clinicaltrials.gov XML for all 96,346 trials in at that time. Also developed methodology involving experts for annotating studies by clinical specialty. Clinical experts reviewed and annotated MeSH and non-MeSH disease condition terms and algorithm was developed. Ability to extend dataset, link additional data sources, and integrate metadata are planned.

# AACT – PLoS 2012

- **Figure:** A schematic representation of the database for Aggregate Analysis of ClinicalTrials.gov (AACT) with its key enhancements.



# AACT – PLoS 2012

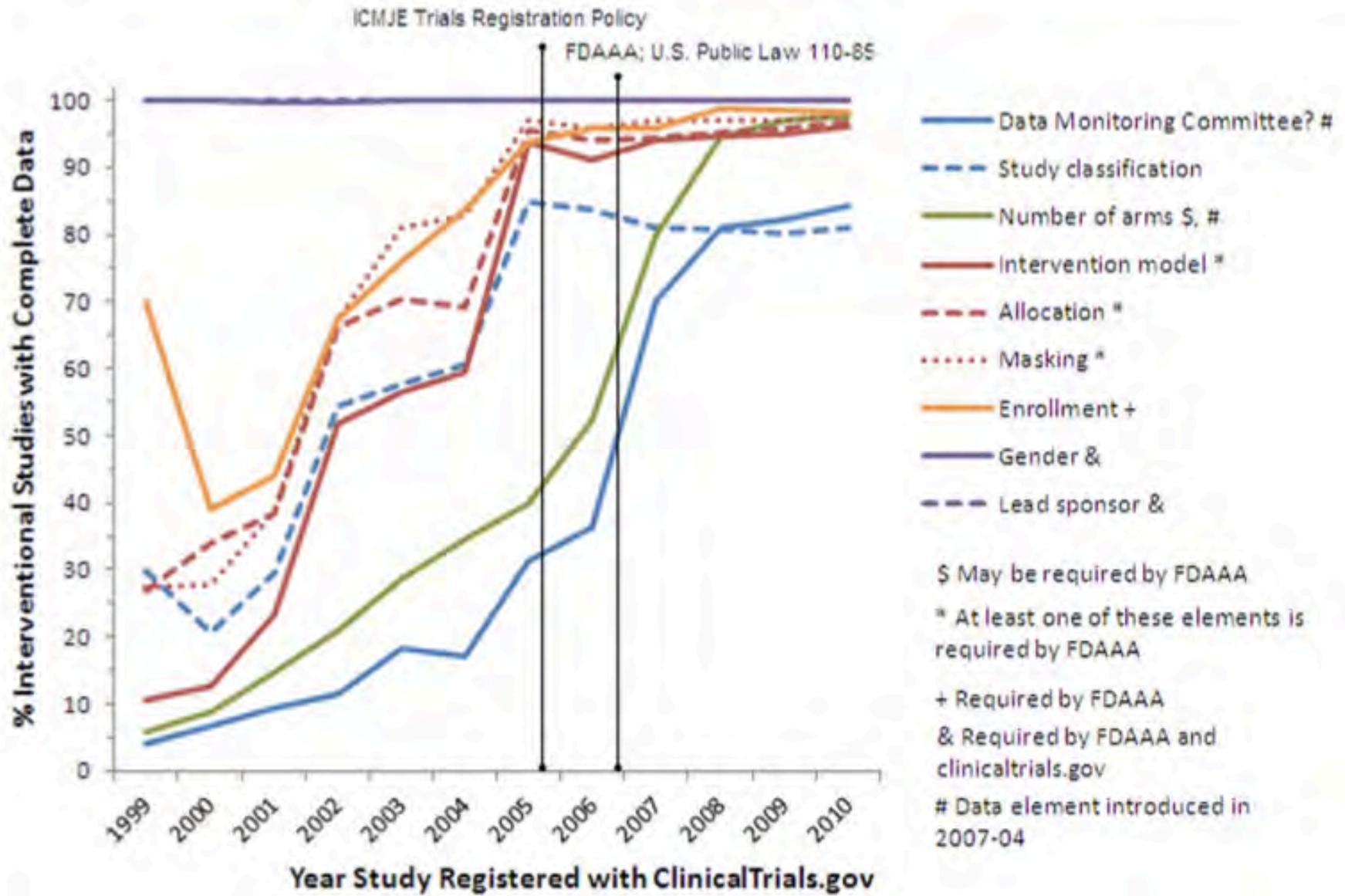


Figure 3. Percentage of interventional studies with complete data by registration year for selected data elements.  
 doi:10.1371/journal.pone.0033677.g003

# “The Database for Aggregate Analysis of ClinicalTrials.gov (AACT) and Subsequent Regrouping by Clinical Specialty”

(Tasneem A, et al. PLoS One, 2012)

- **Conclusions:** This database of ClinicalTrials.gov content organized for aggregate analysis and public should enable analyses of historical data previously not possible or very time-consuming. It represents a resource for those interested in the content of clinicaltrials.gov.

-

## Other notable papers in this category:

- **“The TOKEn project: knowledge synthesis for in silico science”** (Payne PRO, et al. J Biomed Inform, 2011)
- **“Data standards for clinical research data collection forms: current status and challenges”** (Richesson RL, et al. JAMIA, 2011)
- **“Toward and ontology-based framework for clinical research databases”** (Kong YM, et al. J Biomed Inform, 2011)
- **vSPARQL: a view definition language for the semantic web”** (Shaw M. et al. J Biomed Inform, 2011)

# Researcher Support & Resources



# “Enabling distributed electronic research data collection for a rural Appalachian tobacco cessation study”

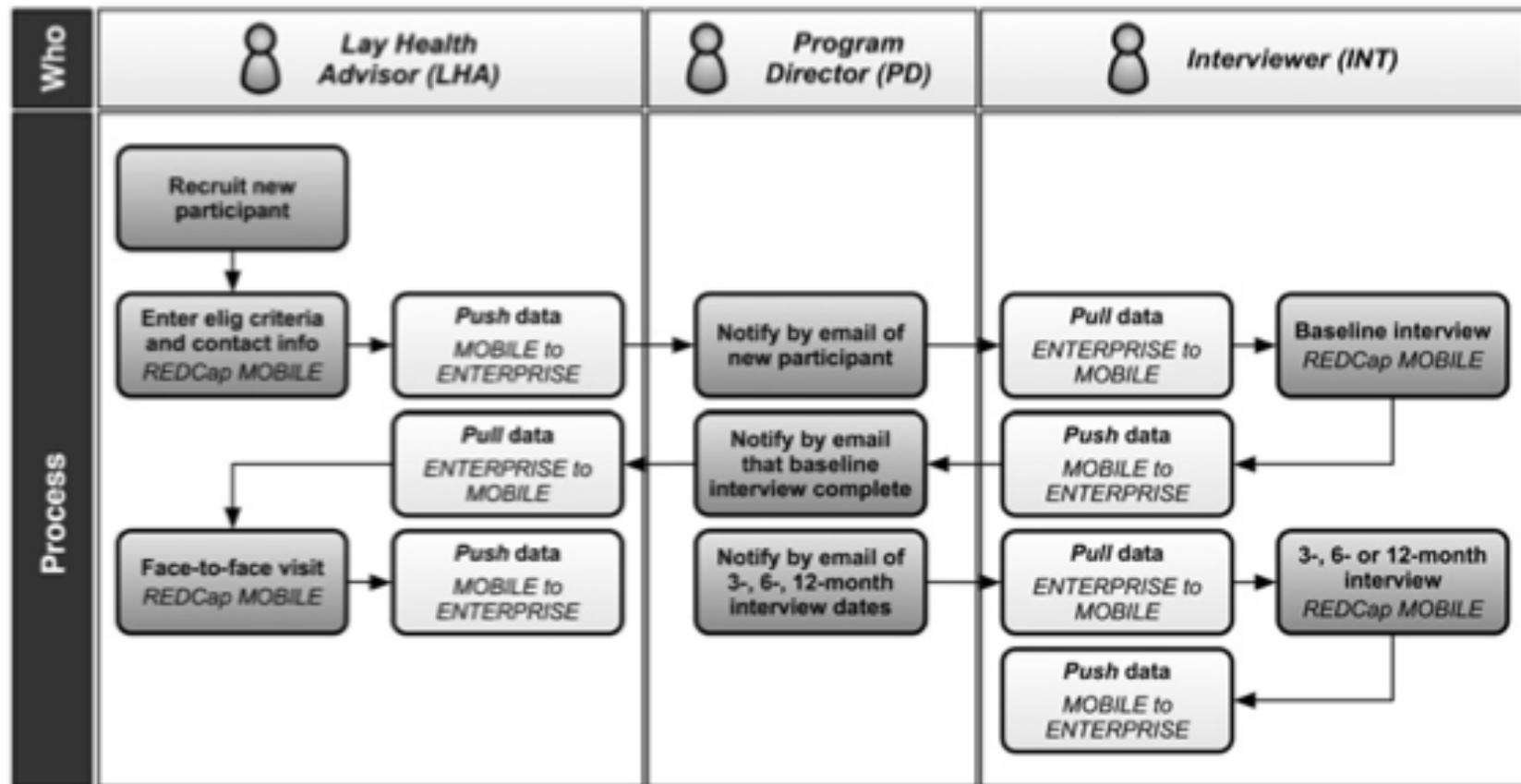
(Borlawsky T, et al. JAMIA, 2011)

- **Goals:** Enable secure, systematic electronic data capture in remote community-based research sites with limited Internet connectivity.
- **Methods:** Integration of the REDCap data collection application with a customized synchronization tool to enable encrypted data exchange with laptop-based when connection next established.
- **Results:** System functioned as intended, allowing users to easily adopt and use the system in a secure manner even with limited internet connectivity.

# “Enabling distributed electronic research data collection for a rural Appalachian tobacco cessation study”

(Borlawsky T, et al. JAMIA, 2011)

- Overview of synchronization workflow:



# “Enabling distributed electronic research data collection for a rural Appalachian tobacco cessation study” (Borlawsky T, et al. JAMIA, 2011)

- Synchronization tool interface, with discrepancy reconciliation, if needed

The screenshot shows the RedCap Sync Tool interface. It has two tabs: "Mobile To Enterprise" (selected) and "Enterprise To Mobile". Below the tabs is an "Input Panel" with a "Participant:" dropdown menu containing "Mouse , Minnie , TEST456" and an "Event Name:" dropdown menu containing "Contact information". A "Start Synchronization" button is centered below these fields.

Below the input panel is a "Discrepancy Table" with the following data:

Field Name	Enterprise Value	Mobile Value
tele	(222) 222-2222	(555) 555-5555
first_name	Donald	Minnie
last_name	Duck	Mouse

Below the table is a "Commit Panel" with the text "1 new data items and 4 saved data items to be committed to the 'Enterprise' database." and two buttons: "Save" and "Cancel".

# “Enabling distributed electronic research data collection for a rural Appalachian tobacco cessation study”

(Borlawsky T, et al. JAMIA, 2011)

- **Conclusions:** Combination of off-the-shelf EDC tools and a custom data synchronization application can facilitate the central coordination of distributed research studies conducted in communities with limited internet access, as well as provide near-real-time exchange among field project staff members and the study coordinator.

# “Current State of Information Technologies for the Clinical Research Enterprise across Academic Medical Centers”

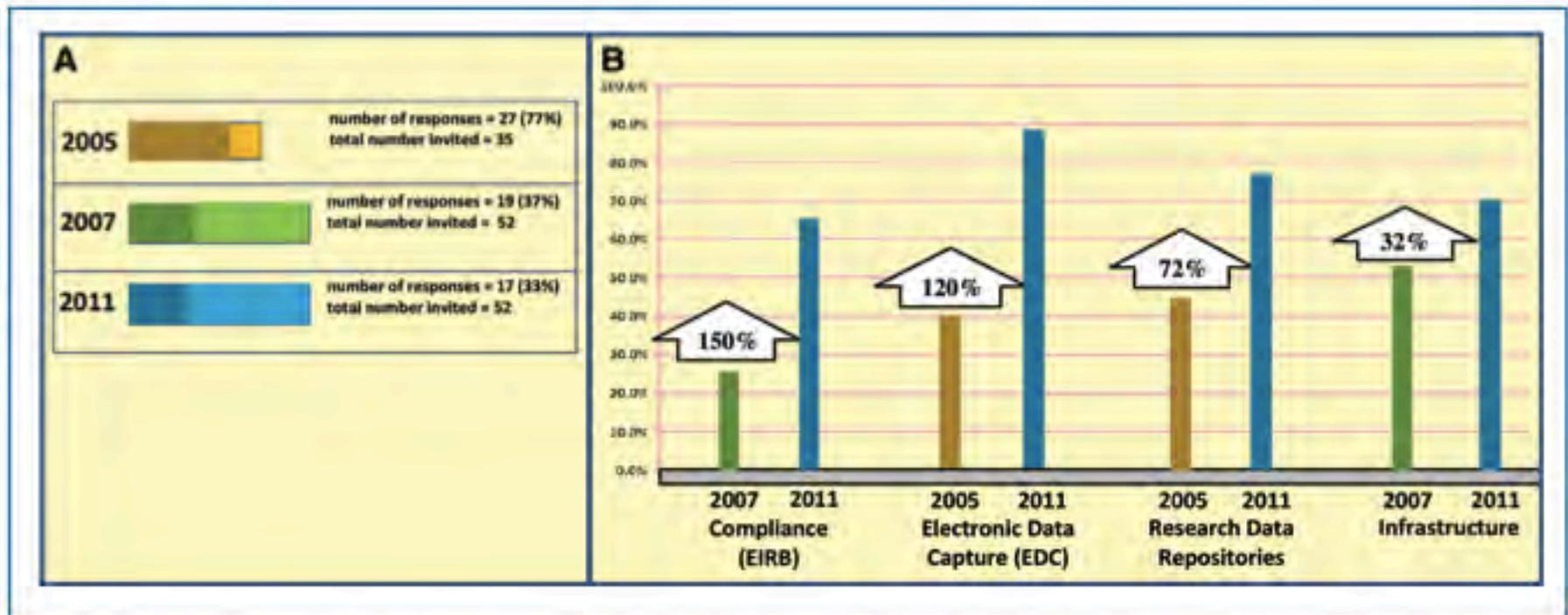
(Murphy SN, et al. Clin Trans Sci. 2012)

- **Goals:** Clinical Research Forum IT Roundtable group surveyed member organizations to assess current state, changes in Research IT infrastructure since prior surveys in 2005 and 2007.
- **Methods:** Survey to all member sites. Four main areas:
  - The use of IT in research compliance, such as conflicts of interest, research budgeting, and reporting to the Institutional Review Board (IRB);
  - The use of IT for electronic data capture (EDC) requirements related to clinical studies and trials of different size;
  - The use of data repositories for the repurposing of clinical care data for research; and,
  - The IT infrastructure needs and support for research collaboration and communication.

# “Current State of Information Technologies for the Clinical Research Enterprise across Academic Medical Centers”

(Murphy SN, et al. Clin Trans Sci. 2012)

- **Results:** 17/51 responded (33% response rate)



**Figure 1.** Comparison of response rates and responses regarding adoption of major categories of research IT infrastructure between the current (2011) and previous (2005 and 2007) surveys. **(A)** It demonstrates the response rate difference. **(B)** It depicts percentage increases for each category.

# “Current State of Information Technologies for the Clinical Research Enterprise across Academic Medical Centers” (Murphy SN, et al. Clin Trans Sci. 2012)

	% Respondents with completed installations	Open source solution(s)	Most frequent solution used	
<b>Research Compliance</b>	Conflict of Interest	76.5%	CoBig	Click Commerce
	Clinical Research Budgeting	35.3%	None	Click Commerce
	Electronic IRB	64.7%	Atlassian JIRA, caBIG	Click Commerce
<b>Electronic Data Capture (EDC)</b>	Investigator-initiated studies	87.5%	RED Cap	RED Cap
	Multi-center studies EDC- less than 1000 participants	81.3%	RED Cap	RED Cap
	Large Studies EDC- greater than 1000 participants	68.8%	RED Cap	Informa/Phase Forward
<b>Research Repositories</b>	Identify patients for clinical trials	70.6%	i2B2	i2B2
	Aggregate clinical research data	62.5%	i2B2	i2B2, Microsoft Amalga
	Advanced searching and analytics	50.0%	i2B2	i2B2, SAS, SPSS, R
<b>Infrastructure</b>	Content collaboration (e.g. Wikis; Content Management solutions)	76.5%	Confluence	Sharepoint
	Communication/social networking (e.g. Listserv, discussion boards)	88.2%	Listserve	Listserve

**Figure 2.** Percentage of respondents with completed installations, open-source solutions cited by respondents, and most commonly cited solution cited by respondents (commercial or open source) for key elements of functionality in the categories of research compliance, electronic data capture, research repositories, and infrastructure.

# “Current State of Information Technologies for the Clinical Research Enterprise across Academic Medical Centers”

(Murphy SN, et al. Clin Trans Sci. 2012)

- **Conclusions:** Research IS adoption across respondent sites has increased over past 7 years. The availability of more robust and available vendor-based and “open-source” solutions, coupled with new research initiatives (e.g., CTSA) and regulatory requirements, appear to be contributing to these advances.

# “Temporal evolution of biomedical research grant collaborations across multiple scales – a CTSA baseline study”

(Nagarajan R, et al. AMIA Ann Symp Proc, 2011)

- **Goals:** To understand the properties of biomedical research grant collaboration networks as a function of scale (Staff, Department) and time (2006, 2009), with onset of CTSA.
- **Methods:** Data derived from internally developed grants management system and analyzed using Network analysis approach.

# “Temporal evolution of biomedical research grant collaborations across multiple scales – a CTSA baseline study”

(Nagarajan R, et al. AMIA Ann Symp Proc, 2011)

- **Results:** BRGC networks appeared disconnected with mutually exclusive research clusters. Coefficient of the dominant weakly-connected cluster was noted to increase with more time in the Staff and Department network, suggesting increasing collaboration over time.
- While the Staff network captured the collaborations between the principal investigators and co-investigators in a grant, the Department network specifically targeted inter-departmental collaborations with multiple Staff belonging to a given Department.

(a) Staff (2006)



(b) Staff (2009)



(c) Department (2006)



(d) Department (2009)



# “Temporal evolution of biomedical research grant collaborations across multiple scales – a CTSA baseline study”

(Nagarajan R, et al. AMIA Ann Symp Proc, 2011)

- **Conclusions:** Network analysis approaches like this are preliminary, but could provide insights into:
  - Effects of investments into services and resources designed to enhance collaboration over time
  - Enable identification of isolated or perhaps influential group nodes that might be worthy of targeting with research informatics interventions to encourage collaboration
  - Would need to be studied in different settings... interesting...

## Other notable papers in this category:

- **“Enabling collaborative research using the Biomedical Informatics Research Networks (BIRN)”** (Helmer, KG, et al. JAMIA. 2011)
- **“A CTSA-sponsored program for clinical research coordination: networking, education, and mentoring”** (Brandt, D.S. et al. Clin Transl Sci. 2011)

# Recruitment Informatics



## “A novel method to enhance informed consent: a prospective and randomised trial of form-based vs electronic assisted informed consent in paediatric endoscopy”

(Friedlander JA, et al. J Medical Ethics. 2011)

- **Goals:** To evaluate the ability to augment informed consent via supplemental computer-based module.
- **Methods:** Parents were randomized to either form-based or form-based plus interactive learning module (electronic assisted) consent. Anxiety, satisfaction, number of questions asked, and attainment of informed consent were measured and analyzed.
- **Results:** Ability to achieve informed consent was 10% in control and 33% in intervention group ( $p < 0.0001$ ). Electronic assisted consent did not alter satisfaction, anxiety or number of questions asked of endoscopist.

## “A novel method to enhance informed consent: a prospective and randomised trial of form-based vs electronic assisted informed consent in paediatric endoscopy”

(Friedlander JA, et al. J Medical Ethics. 2011)

- **Conclusions:** Form-based consents is limited, at least for studies like this one. Supplemental information via electronic form was helpful, but still consent rates were sub-optimal. Further study is needed.

# Recruitment: Researchmatch.org



[ main menu ]

- REGISTER NOW
- RESEARCHER INTEREST FORM
- VOLUNTEER FAQ
- RESEARCHER FAQ
- TELL A FRIEND

Interested in a specific medical condition?

Please enter your city:

Please enter your state:

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Advancing knowledge **today**  
for our health **tomorrow.**

have you seen this?

13762 volunteers  
635 researchers  
264 active studies  
56 institutions

[ [see more](#) ]

## what is researchmatch?

It is a registry of volunteers willing to learn more about research studies. Research needs both volunteers and researchers. ResearchMatch helps bring these two groups together in a secure and convenient way. [ [more](#) ]

## how do I get involved?

Signing up is free and anyone can join. Learn more about ResearchMatch and join the registry today!

## what's new?

[YouTube Video - Participating in Research](#)

[Baystate Medical Center joins volunteer clinical trial match \(ResearchMatch\)](#)

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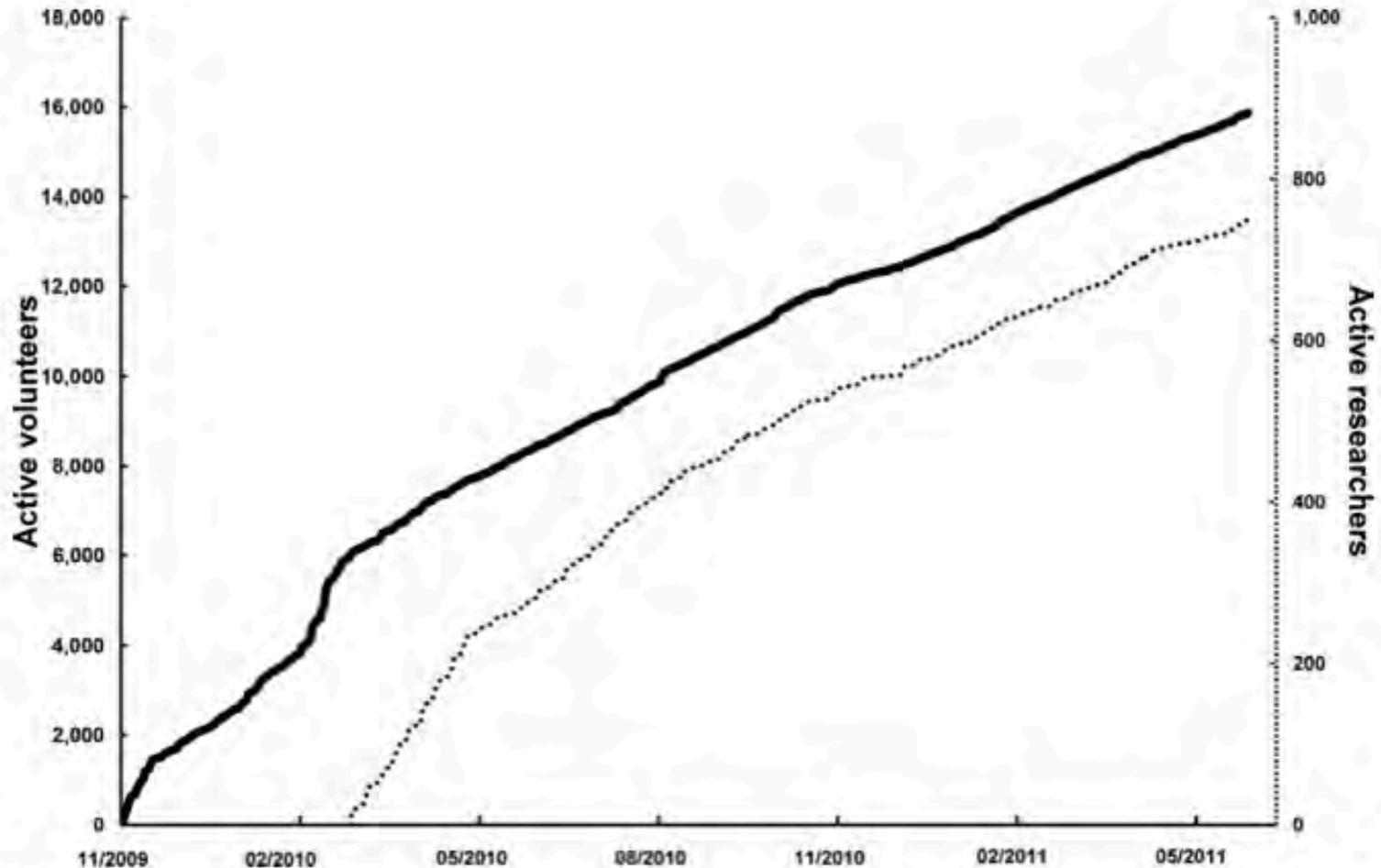
# “ResearchMatch: A National Registry to Recruit Volunteers for Clinical Research”

(Harris PA, et al. Acad Med. 2012)

- **Goals:** To establish a registry for public who are interested in volunteering for research studies.
- **Methods:** A CTSA-consortium resource that originated at Vanderbilt University. Disease neutral by design. Volunteers register and are then contacted by investigators.
- **Results:** Over 15,800 volunteers from all 50 US states, though 75% from 10 states. Registration growing steadily. About 20% acceptance rate by registrants upon being contacted for a study. Over-representation by whites (81.2% vs. 75.1% in population), and women (72.7% vs. 50.9% in population).

# “ResearchMatch: A National Registry to Recruit Volunteers for Clinical Research”

(Harris PA, et al. Acad Med. 2012)



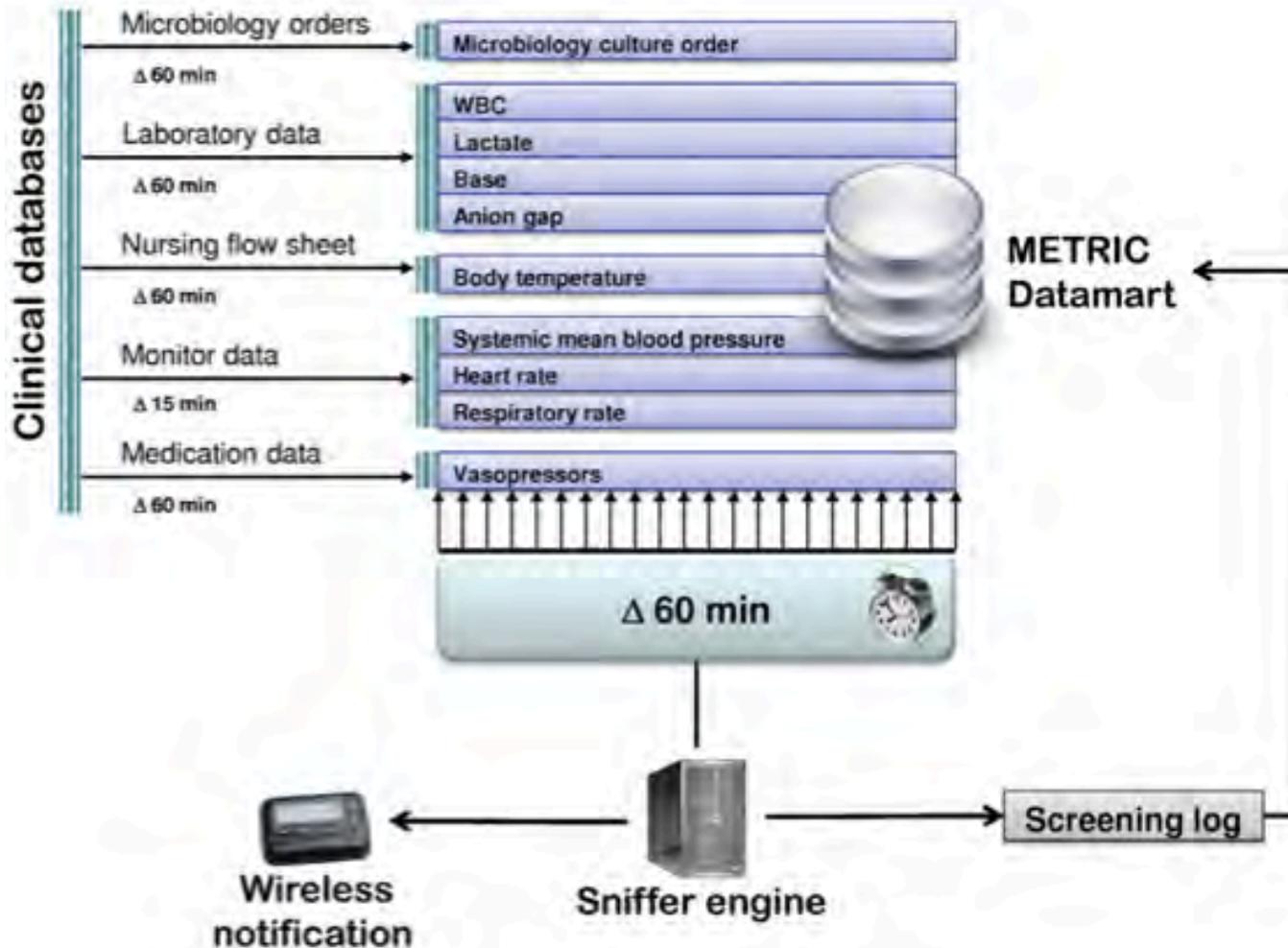
**Figure 1** Growth in the populations of volunteers (thick line) and researchers (dotted line) who registered with ResearchMatch during its first 19 months of operation (November 2009 to June 2011). ResearchMatch did not start registering researchers until about four months after starting to register volunteers in order to first build a pool of volunteers who might fit researchers search criteria.

## “Enrollment into a time sensitive clinical study in the critical care setting: results from computerized septic shock sniffer implementation”

(Herasevich V, et al. JAMIA. 2011)

- **Goals:** To improve recruitment of patients with recent-onset (24hrs) septic shock into a trial using automated alerts.
- **Methods:** A sniffer program monitored EHR for parameters indicating shock, then paged research coordinator on-call to recruit patient. Before-after study assessing recruitment rates.

# “Enrollment into a time sensitive clinical study in the critical care setting: results from computerized septic shock sniffer implementation” (Herasevich V, et al. JAMIA. 2011)



- Schematic of information flow in the notification system.
- METRIC = Multidisciplinary Epidemiology and Translational Research in Intensive Care

## “Enrollment into a time sensitive clinical study in the critical care setting: results from computerized septic shock sniffer implementation”

(Herasevich V, et al. JAMIA. 2011)

- **Results:** Sniffer had positive predictive value of 34%. Electronic screening doubled enrollment, from 37 before to 68 enrolled during period after implementation ( $p < 0.05$ ).
- **Conclusions:** Automated screening and paging to recruit to trials for acute, time-sensitive conditions appears effective.

## Other notable papers for this section:

- **“The design and implementation of an open-source, data-driven cohort recruitment system: the Duke Integrated Subject Cohort and Enrollment Research Network (DISCERN)”** (Ferranti JM, et al. JAMIA. 2011)
- **“Implementation of a deidentified federated data network for population-based cohort discovery”** (Anderson N. et al. JAMIA. 2011.)
- **“EliXR: an approach to eligibility criteria extraction and representation”** (Weng C. et al. JAMIA. 2011.)

# CRI and Patients/Consumers



# “Spontaneous Coronary Artery Dissection: A Disease-Specific Social Networking Community-initiated Study”

(Tweet MS, et al., Mayo Clin Proc. 2011)

- **Goal:** To improve identification, recruitment and evaluation of patients with rare conditions.
- **Methods:** Members of a disease-specific support group contacted investigators via social-networking site. Then, investigators used the social networking site to identify and recruit participants who had been diagnosed with at least 1 episode condition. Medical records were reviewed and original diagnosis was independently confirmed via imaging studies. Health status was assessed via questionnaires and validated assessment tools.
- **Results:** Recruitment of all 12 participants was completed in 1 week of IRB approval. Data collection was completed within 8 months. All completed the study questionnaires and provided needed records and tests results.
- **Conclusions:** Successful example of patient-initiated research. Demonstrates feasibility of social media to recruit for rare diseases.

# “Patient-driven online survey on Granulomatosis with Polyangiitis”

(Hall A, et al., Arthritis & Rheumatism. Suppl. 2011)

- **Goal:** Patient-driven survey of fellow patients with rare form of vasculitis.
- **Methods:** Patient developed and posted survey-monkey questionnaire on her blog to solicit responses from others with this condition. The survey targeted patients with GPA, as a self-reported diagnosis, and included 10 questions to anonymously assess country of residence, gender, age at diagnosis, selected comorbidities, presenting symptoms, specialty of the physician who eventually provided the diagnosis, diagnostic delay and initial treatments.
- **Results:** within 7.5 mos, 369 had completed survey, with 345 remaining in study after some exclusions. 75% were from US, and responses were consistent with that expected for patients with GPA.
- **Conclusions:** Another example of successful patient-initiated research using Web technologies.

# “Osteoarthritis Index delivered by mobile phone (m-WOMAC) is valid, reliable, and responsive” (Bellamy N, et al., J. Clin Epidemiol. 2011)

- **Goal:** Evaluate the validity, reliability, responsiveness, and mode preference of electronic data capture (EDC) using WOMAC on mobile phones.
- **Methods:** Patients with OA undergoing hip or knee replacement were randomly assigned to paper-based vs. electronic WOMAC. They completed survey pre- and post-surgery.
- **Results:** No clinically important or statistically significant between-method differences were noted.
- **Conclusions:** There was close agreement and no differences between paper and mobile delivered WOMAC.

# Policy and Fiscal



## **Commentaries related to CRI Policy & Fiscal:**

- **“A historical perspective on clinical trials innovation and leadership: where have the academics gone?”**  
(DeMets, DL, & Califf, RM. JAMA, 2011)
  - A call to action
- **“The relative research unit: providing incentives for clinician participation in research activities.”**  
(Embi PJ & Tsevat J. Acad Med. 2012).
  - Incentivizing clinician participation in research
- **“Translational informatics: an industry perspective.”**  
(Cantor, MN. JAMIA, 2012)
  - Tools, standards, and effective delivery

# Notable CRI-Related Events in Past Year



# Approval of ABMS clinical informatics subspecialty

**Home** About us Online Services Getting Certified Staying Certified Verifications and Searches Resources and Publications



**Welcome to the American Board of Preventive Medicine**

The American Board of Preventive Medicine (ABPM) provides this web site as a service to our clients - our Diplomates, applicants, residents, residency program directors, and the general public. The look and enhanced functionality of our web site is designed to meet the needs of our clients in a more efficient and comprehensive way. The information presented here is also available from the Board office, but generally the most up-to-date information will be accessible here more quickly than through the mail from the Board Office. Documents downloaded from this web site are identical to and current with the paper copy documents from the Board office. Most documents are available in [Adobe® Reader®](#) (pdf) format for downloading. Virtually all the interactions between our clients and the Board staff can be conducted through the various features of the web site. However, we are available for telephone calls between 8:30 AM and 4:30 PM, Monday through Friday at (312) 939-ABPM [2276] if we can be of further assistance.

**New Clinical Informatics Subspecialty Certification**

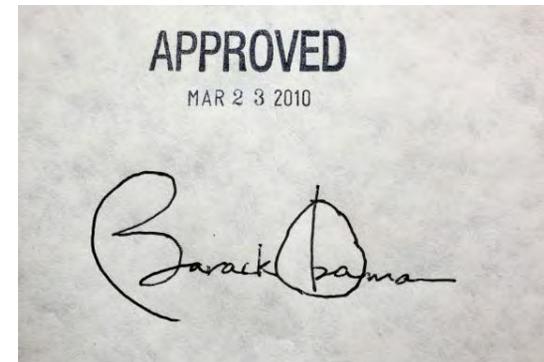
The ABPM is pleased to announce that the American Board of Medical Specialties (ABMS) has recently approved its application for subspecialty certification in Clinical Informatics. Clinical Informatics is co-sponsored by the American Board of Pathology (ABPath) and certification in this new subspecialty will be available to diplomates of all ABMS Member Boards. The ABPM and ABPath have started the process of creating a certification examination in the subspecialty of Clinical Informatics, but the first offering is yet to be determined. Further information will be on the ABPM website as it becomes available. If you would like to be added to our Clinical Informatics email list, please send an email to [kdh@theabpm.org](mailto:kdh@theabpm.org)

# **Establishment of new NIH Center: *National Center for Advancing Translational Sciences (NCATS)***

- Established December 23, 2011
  - As part of FY12 omnibus appropriations bill
  - Budget of \$575M for FY2012
- Includes CTSA program among others
- Major implications for CRI efforts
  
- **“Reengineering translational science: the time is right.”** (Collins, FS. Sci Transl Med. 2011).

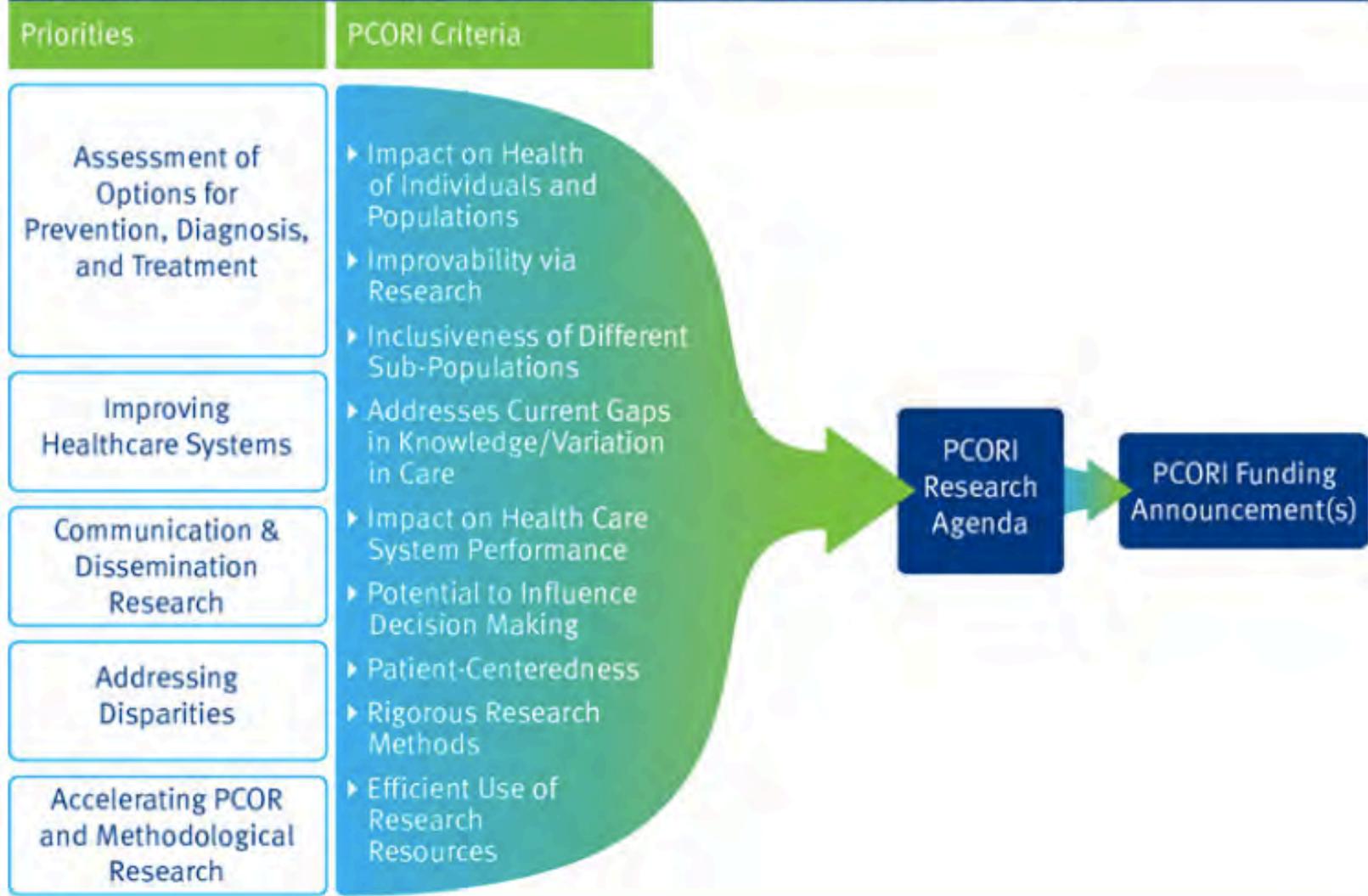
# Patient Centered Outcomes Research Institute (PCORI)

- Established in the Patient Protection and Affordable Care Act of 2010
  - 2<sup>nd</sup> Anniversary Today
- PCORI funding opportunities already under way
- Draft National Priorities for Research and Research Agenda released in January



# PCORI: Proposed Priorities and Research Agenda

Figure 1: Framework for Translation of PCORI National Priorities into the Research Agenda



## HITECH Act

- ARRA allocated ~\$27B billion to the Office of the National Coordinator for Health IT (ONC)
  - For incentives for “meaningful use” of health information technology through
- Continuation of HITECH
  - Stage 2 meaningful use rules announced – Feb '12
  - Include registry reporting

## Common Rule: Advanced Notice of Proposed Rule Making announced July 2011

- “Seven possible regulatory reforms are envisioned and described in the ANPRM:
  1. Revising the existing risk-based framework to more accurately calibrate the level of review to the level of risk.
  2. Using a single Institutional Review Board review for all domestic sites of multi-site studies.
  3. Updating the forms and processes used for informed consent.
  4. Establishing mandatory data security and information protection standards for all studies involving identifiable or potentially identifiable data.
  5. Implementing a systematic approach to the collection and analysis of data on unanticipated problems and adverse events across all trials to harmonize the complicated array of definitions and reporting requirements, and to make the collection of data more efficient.
  6. Extending federal regulatory protections to apply to all research conducted at U.S. institutions receiving funding from the Common Rule agencies.
  7. Providing uniform guidance on federal regulations.”

# AMIA Strategic Plan Update – Featuring CRI

- Published in February 2011
- Calls out and acknowledges the importance of CRI and TBI key domains our profession and hence for AMIA

## Messages from AMIA

### AMIA's realigned strategic plan

It is an honor to serve as the Chair of the Board of Directors of such a vibrant and member-focused organization.

Before beginning my term as chair, I met with the AMIA staff. One of the questions I was asked was "What is your vision for AMIA and what do you want your legacy to be?" As I learned during my 1-year term as chair-elect, it is nearly impossible for one person to understand the sheer volume and depth of our programs and activities. AMIA's board, committees, working



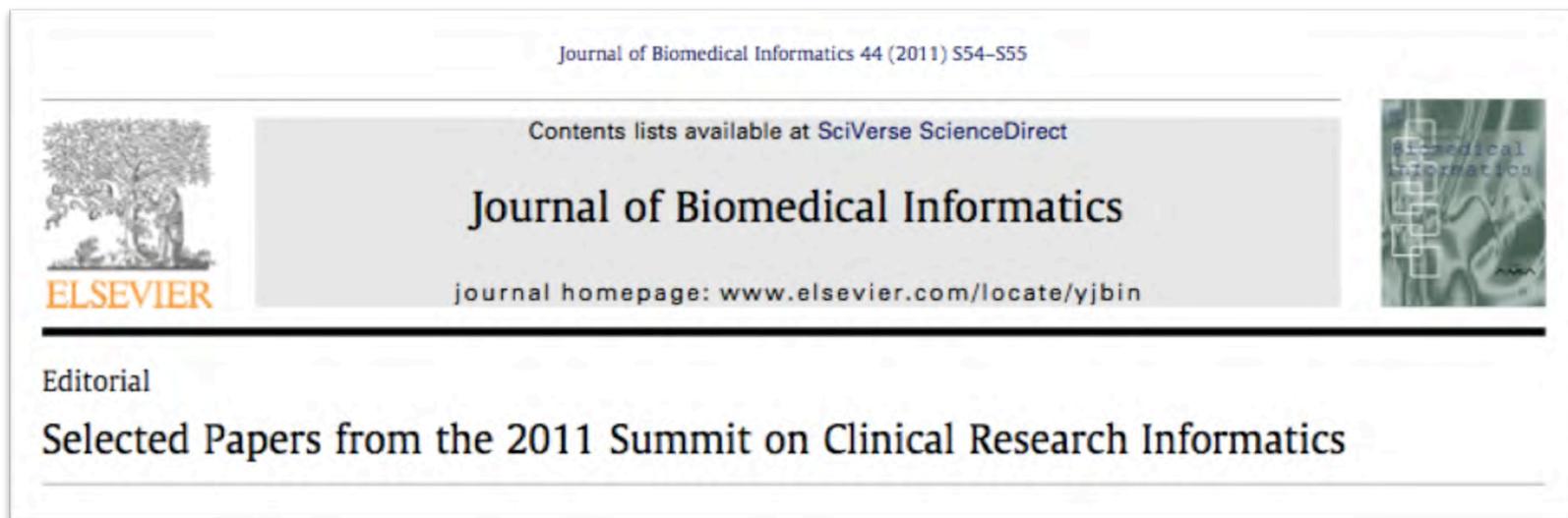
were shared with the board for comment and refinement and we are excited to share this report, which contains the organizational goals and selected objectives, with our members.

#### MISSION

AMIA and its members aim to transform healthcare through trusted science, education, and practice in biomedical and health informatics.

## JBI CRI Special Issue

- Highlight selected papers from the 2011 CRI Summit



Journal of Biomedical Informatics 44 (2011) S54-S55

Contents lists available at SciVerse ScienceDirect

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**Journal of Biomedical Informatics**

journal homepage: [www.elsevier.com/locate/yjbin](http://www.elsevier.com/locate/yjbin)



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Editorial

**Selected Papers from the 2011 Summit on Clinical Research Informatics**

## JAMIA Special Issue highlighting articles on clinical research informatics

- Several CRI papers, along with related topics
- Inspired by events related to PCORI, NCATS, etc.
- Preview of upcoming CRI-dedicated special issue scheduled for 2012

Highlights

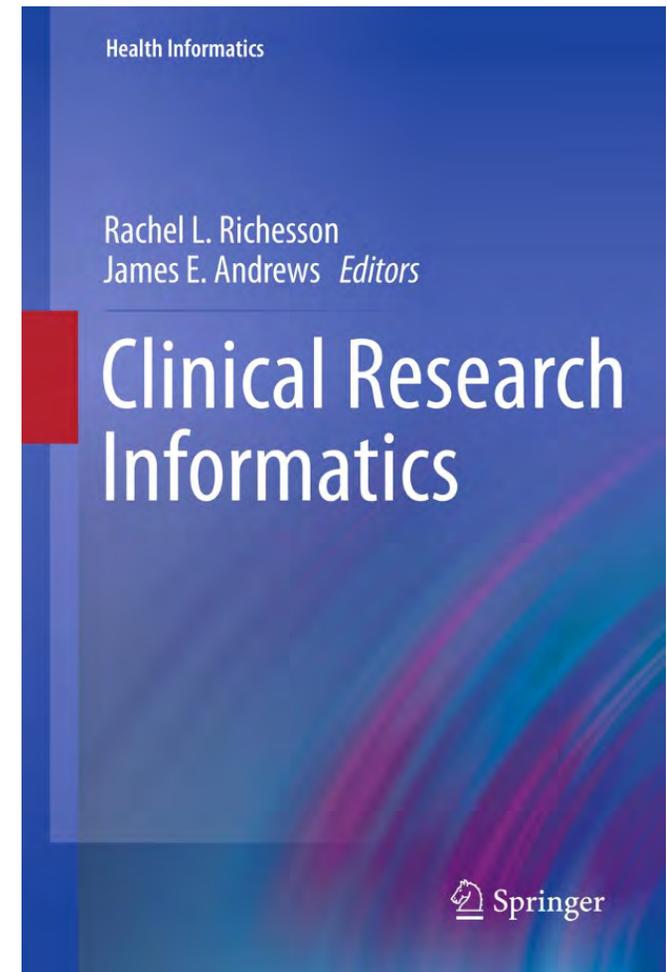
**Innovative approaches to support patient decision making, improve safety, and enable large-scale clinical research**

doi:10.1136/amiajnl-2011-000707

Lucila Ohno-Machado, *Editor-in-Chief*

# First of its kind textbook dedicated to CRI

- Editors: Richesson & Andrews
- Contributing authors from across our community
- A major achievement
- More evidence of CRI as established domain



- <http://www.springer.com/public+health/book/978-1-84882-447-8>
- <http://www.amazon.com/Clinical-Research-Informatics-Health/dp/1848824475>

## In Summary...

- Maturing data infrastructure and sharing capabilities
- Advances toward accelerating and improving science
- Some (too few) randomized, controlled studies
- Poised to deploy and test our approaches to realize the “*learning health system*”
  
- Exciting time to be in CRI!

# Thanks!

Special thanks to:

- Michael Kahn
- Philip Payne
- Eta Berner
- Rachel Richesson
- Joyce Niland
- Adam Wilcox

# Thanks!

[Peter.Embi@osumc.edu](mailto:Peter.Embi@osumc.edu)

Slides will be posted on AMIA Website & on <http://www.embi.net/> (click on “Informatics”)

