



Staying up-to-date on methods in drug safety: CARMA(IC) insight

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World Series







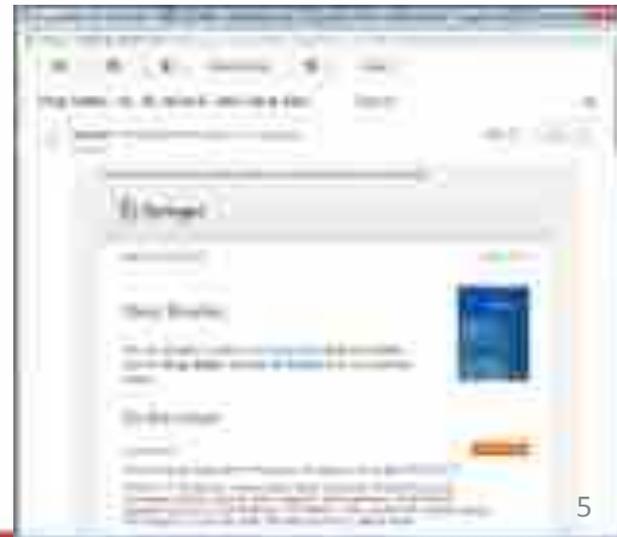
Funding

- UIC Center for Annotating Research Methods and Analyses (CARMA): Focused on New Approaches in Utilizing 'Real World' Data
- Funded by Reagan Udall Foundation IMEDS Methods Program
- RUF-IMEDS-FP_0003



Keeping Current with Rapidly Evolving Field

- Subscribe to and read journals
 - Ever expanding number of journals makes this increasingly difficult
- Sign up for electronic tables of contents
 - Identify articles of interest
 - Still difficult to keep pace
- Saved topic searches



Other Strategies

- Review Articles
 - Doesn't help in terms of timeliness with current literature
- Literature Scans A yellow circular emoji with a winking eye, a smiling mouth, and a small red heart next to it, representing a kiss or affection.
- Identify 'relevant' literature
- Provide regular updates
 - DOPE – Monthly Methods Literature Scan
 - Mini-Sentinel / Sentinel Literature Updates

RUF IMEDS RFP

- Fund a ‘Center of Excellence’ for annually collating and summarizing research relevant to the IMEDS-Methods program mission
- Specifically interested in research “at the intersection of data analysis and medical data generation, particularly as these pertain to the evaluation of safety and effectiveness”

CARMA Goals



AP Photo/Matt Slocum

1. Complete regular literature searches focused on the development and use of new 'real world' data sources for safety and effectiveness analyses
2. Develop annotated summaries of key articles identified in literature searches
3. Post annotated summaries to publically available website
4. Complete a detailed review of important area(s) of development
5. Provide graduate-level seminar for students participating in the above activities

The How?

- Identifying relevant literature
 - Core Journal List
 - Starting List
 - TOC Reviewed
 - Core List Modifications
 - Literature Searches
 - Search terms
 - Lots of false positives
 - Focused on current issues
 - Each new issue reviewed for relevant articles

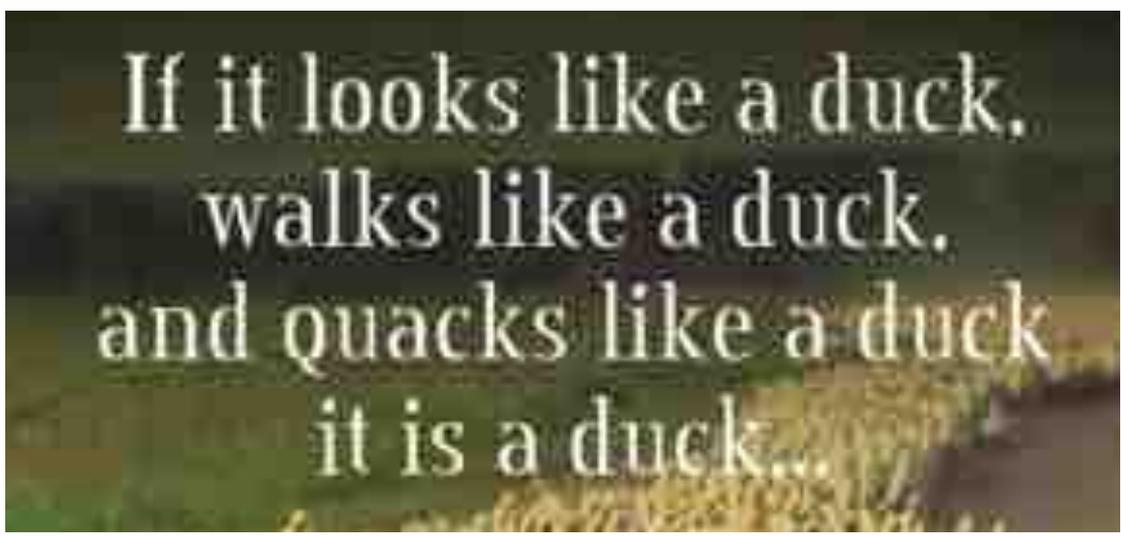
Table 1. List of Target Journals for Routine Searches

Journals
American Journal of Epidemiology
American Journal of Managed Care
American Journal of Public Health
Annals of Epidemiology
BMC Medical Research Methodology
BMC Public Health
Clinical Epidemiology
Drug Safety
Emerging Themes in Epidemiology
Epidemiologic Perspectives and Innovations
Epidemiology
Epidemiology Reviews
European Journal of Epidemiology
Health Informatics Journal
International Journal of Database Management Systems
International Journal of Epidemiology
Journal of the American Medical Informatics Association
Journal of the American Statistical Association
Journal of Clinical Epidemiology
Journal of Epidemiology
Medical Care
Medical Care Research and Review
Pharmacoepidemiology and Drug Safety
Statistics in Medicine
Statistical Methods in Medical Research
Value in Health



'Relevant' Literature

- Early challenges



If it walks like a duck
talks like a duck
then it could be
a dragon doing
a duck impersonation.



- Group process of evaluating TOC for assigned journals
- Identified articles reviewed by senior grad student

Annotations

- Goal was to provide more information than contained in abstract
 - “Super” abstract
 - Don’t repeat information in the abstract
- Give those reviewing annotated articles enough information to know if the article was relevant / interesting
- Include implications to field if possible
- General rules of thumb
 - Brief paragraph (5-8 sentences)
 - Include 1-2 sentences on each of the following:
 - Background and why important
 - Methods
 - Results
 - Conclusions and Implications



Annotations Posted

- Annotations periodically posted to website
 - Not entirely user-friendly
- Also use public access version of group library in Zotero
 - Better search capabilities
 - Can use key-words, etc. to identify specific types of articles

Data

- Journals contributing at least 1 article
 - 29
- Annotated articles on website
 - 128

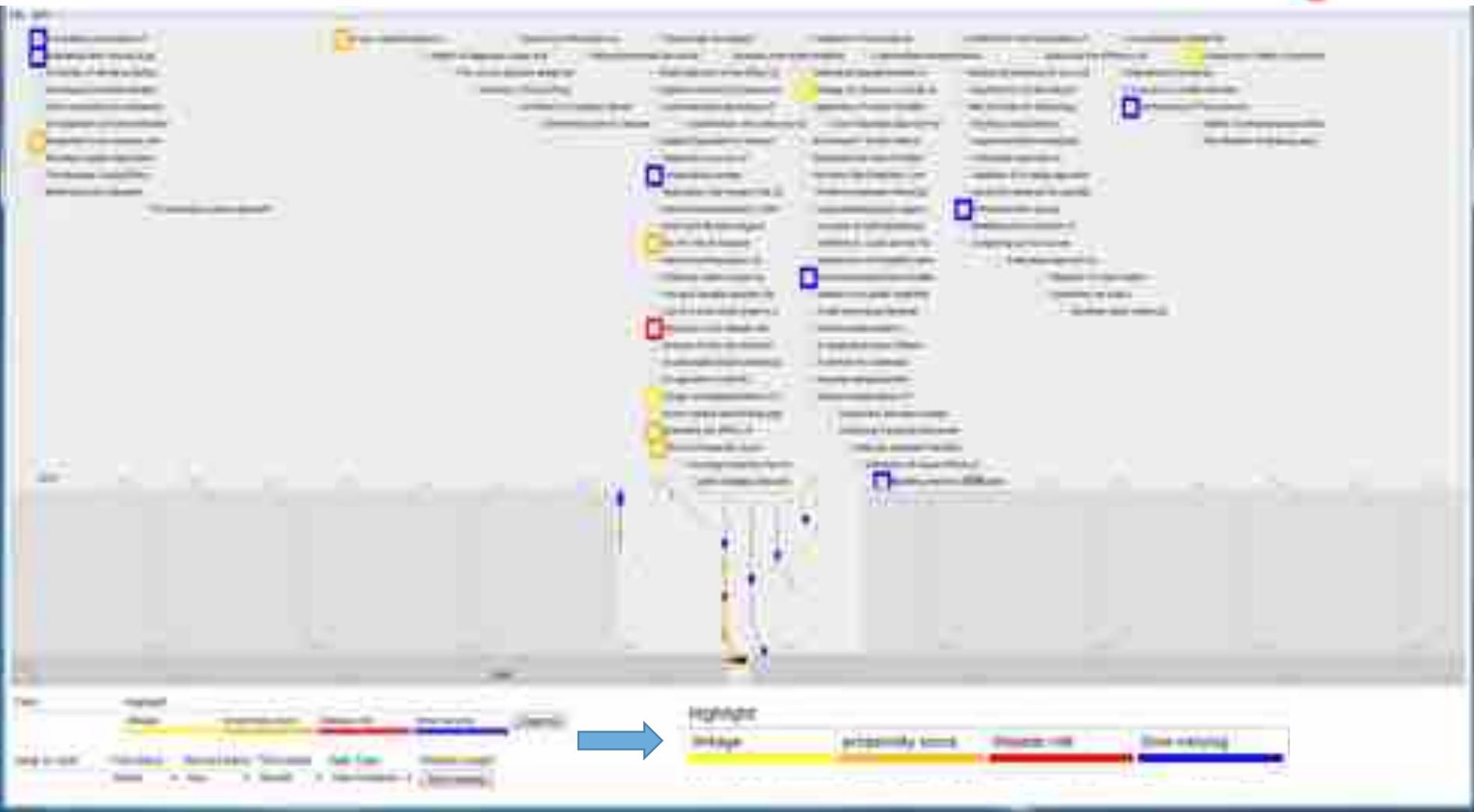
Articles by Journal

Journal	Count
Pharmacoepidemiology and Drug Safety	4
Statistical Methods in Medical Research	3
Statistics in Medicine	3
Journal of the American Medical Association	2
Epidemiology	2
Biometrical Journal	2
Drug Safety	2
BMC Medical Research Methodology	2
American Journal of Epidemiology	1
Medical Care	1
Journal of the American Statistical Association	1
Journal of Clinical Epidemiology	1
Psychological Methods	1
Journal of Statistical Planning and Inference	1
Journal of Biomedical Informatics	4
Journal of Causal Inference	3
Biostatistics	3
Pharmaceutical Statistics	2
Lifetime Data Analysis	2
Journal of The Royal Statistical Society	2
Journal of Biometrics and Biostatistics	2
Annals of Epidemiology	2
The International Journal of Biostatistics	1
Multivariate Behavioral Research	1
Health Services Research	1
Epidemiology, Biostatistics and Public Health	1
Clinical Epidemiology	1
BMC Medical Informatics and Decision Making	1
American Journal of Public Health	1



Keyword	Freq.	Percent	Cum.
Pharmacoepidemiology	15	2.66	2.66
survival analysis	9	1.6	4.26
propensity score	8	1.42	5.67
Natural Language Processing	7	1.24	6.91
Bias	6	1.06	7.98
Pharmacology/Toxicology	6	1.06	9.04
multiple imputation	6	1.06	10.11
Drug Safety and Pharmacovigilance	5	0.89	10.99
missing data	5	0.89	11.88
Epidemiologic methods	4	0.71	12.59
JASA	4	0.71	13.3
Modeling techniques	4	0.71	14.01
Signal Detection Methods	4	0.71	14.72
electronic health records	4	0.71	15.43
Longitudinal data	3	0.53	15.96
Missing data	3	0.53	16.49
Monte Carlo simulations	3	0.53	17.02
epidemiologic methods	3	0.53	17.55
logistic regression	3	0.53	18.09
marginal structural models	3	0.53	18.62





Focused Review

- Data Source Development
 - Data Linkage
 - Data Pooling
 - Novel Data Sources / Uses
- Identified 10 papers



	Author	Article Summary	Topic Area
Pharmacovigilance (EHR or Claims Data + SRS)			
1	Winnenburg et al	Development of an algorithm for the identification and extraction of adverse drug events in the biomedical literature using MEDLINE indexing	Biomedical literature surveillance for pharmacovigilance
2	Pacurariu et al	Evaluate the use of EHR data to supplement spontaneous reporting systems to detect important adverse events (myocardial infarction (AMI), bullous eruption, hip fracture, acute pancreatitis, and upper gastrointestinal bleeding (UGIB)).	EHR+SRS for pharmacovigilance
3	Li et al	Develop and test the performance of a framework of using EHR and/or claims data to FAERS for detection of adverse events.	EHR+SRS and/or Claims + SRS for pharmacovigilance



	Author	Article Summary	Topic Area
Novel Data Sources for Epidemiologic Disease and ADE Surveillance			
4	Jonge et al	Linkage of 5 European congenital anomaly registries to administrative prescription databases to assess the quality of data linkage and maternal medication exposure for several common prescription drug classes.	Registry + Claims data (birth defects)
5	Hammil et al	Linkage of laboratory data to Medicare claims data using the Medicare Health Insurance Claim (HIC) number and/or Social Security number (SSN), date of birth, and sex.	Laboratory + Claims data
6	Lee et al	Use of ER surveillance data to measure local disease prevalence	ER data for disease surveillance
7	Nyberg et al	Use of multiple, coordinated disease registries to contextualize AE rates observed in clinical trial programs and make more accurate comparisons between clinical trial and observational data	Observational disease registry data to contextualize clinical trial AE rates

	Author	Article Summary	Topic Area
Technology-Based Solutions for Data Pooling and Distributed Data Networks			
8	Yoon et al	Development of subgroup-adjusted normalization (SAN) software, which can be used to standardize lab values from different sources (e.g. distributed research networks)	Software to standardize lab data from different sources – improve interoperability
9	Kho et al	Describe designing and implementation of a privacy preserving EHR linkage tool in the Chicago area using a secure encryption algorithm.	Linkage of different EHR systems
10	Lu et al	Develop a web-based system (WebDISCO) that allows distributed survival analyses via a Cox model without patient-level data. Proof of concept paper.	Web system to conduct survival analysis without patient-level data

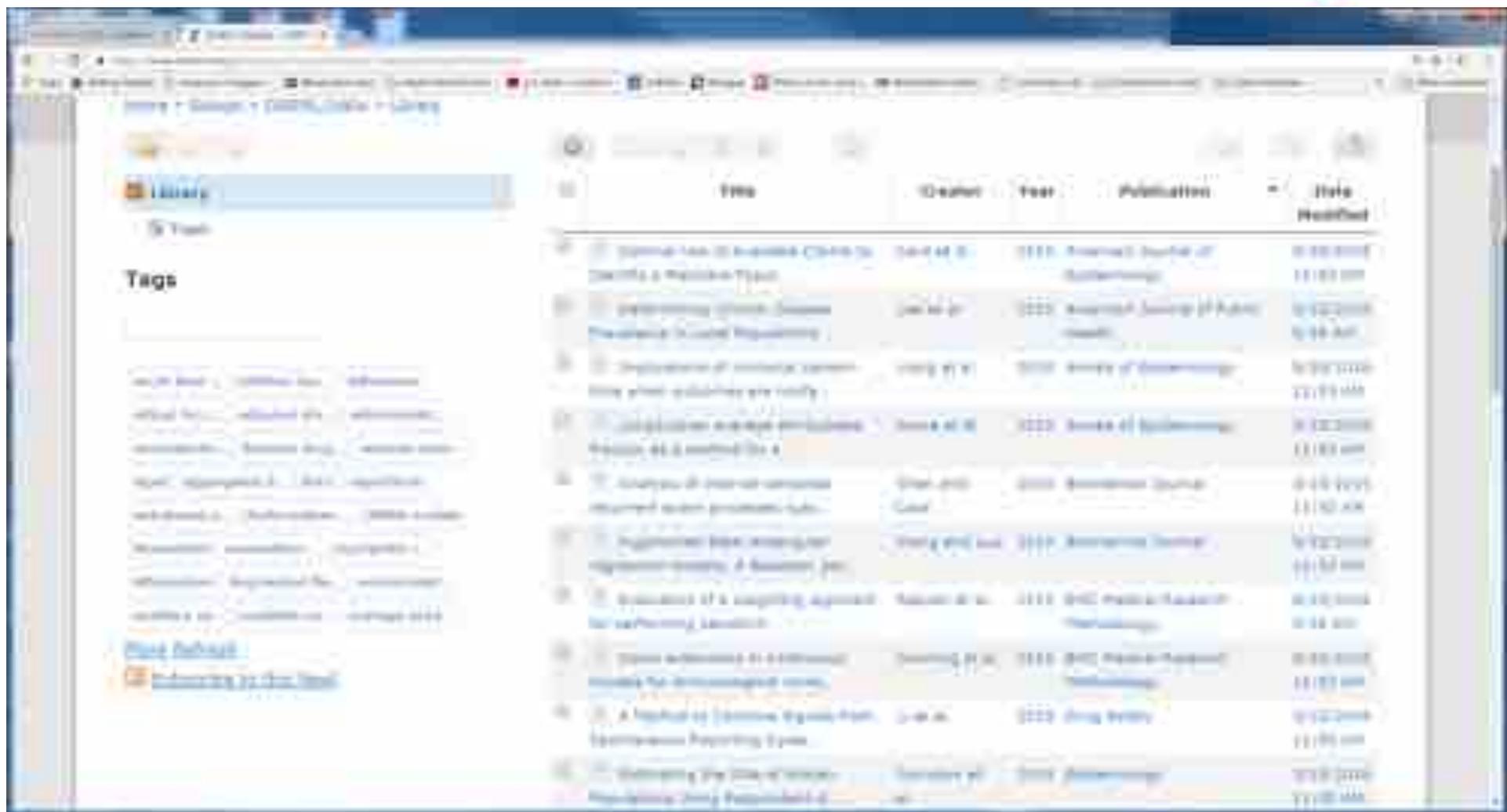


Website and Public Library

<https://pharmacy.uic.edu/departments/pharmacy-systems-outcomes-policy/research-and-scholarship/research-programs/carma>

https://www.zotero.org/groups/carma_public



ID	Title	Author	Year	Publication	Date Modified
1	Journal of Pharmacy Practice and Research	2011	2011	Journal of Pharmacy Practice and Research	11/01/2011
2	Journal of Pharmacy Practice and Research	2011	2011	Journal of Pharmacy Practice and Research	11/01/2011
3	Journal of Pharmacy Practice and Research	2011	2011	Journal of Pharmacy Practice and Research	11/01/2011
4	Journal of Pharmacy Practice and Research	2011	2011	Journal of Pharmacy Practice and Research	11/01/2011
5	Journal of Pharmacy Practice and Research	2011	2011	Journal of Pharmacy Practice and Research	11/01/2011
6	Journal of Pharmacy Practice and Research	2011	2011	Journal of Pharmacy Practice and Research	11/01/2011
7	Journal of Pharmacy Practice and Research	2011	2011	Journal of Pharmacy Practice and Research	11/01/2011
8	Journal of Pharmacy Practice and Research	2011	2011	Journal of Pharmacy Practice and Research	11/01/2011
9	Journal of Pharmacy Practice and Research	2011	2011	Journal of Pharmacy Practice and Research	11/01/2011
10	Journal of Pharmacy Practice and Research	2011	2011	Journal of Pharmacy Practice and Research	11/01/2011
11	Journal of Pharmacy Practice and Research	2011	2011	Journal of Pharmacy Practice and Research	11/01/2011
12	Journal of Pharmacy Practice and Research	2011	2011	Journal of Pharmacy Practice and Research	11/01/2011
13	Journal of Pharmacy Practice and Research	2011	2011	Journal of Pharmacy Practice and Research	11/01/2011
14	Journal of Pharmacy Practice and Research	2011	2011	Journal of Pharmacy Practice and Research	11/01/2011
15	Journal of Pharmacy Practice and Research	2011	2011	Journal of Pharmacy Practice and Research	11/01/2011





Revisiting CARMA Goals



AP Photo/Matt Slocum



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Summary

- Resource available for scientific community that includes annotations of contemporary research articles
- Review article summarizing recent advances

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