Sharing Data through the YODA Project: Early Experience

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Potential Conflicts of Interest

• YODA Project funded by research grant through Yale from Johnson & Johnson, formerly funded by Medtronic, Inc.

• Research grant funding through Yale from:
  • FDA: Center of Excellence in Regulatory Science (CERSI)
  • FDA and Medtronic: medical device post-market surveillance methods
  • CMS: performance measure development
  • Blue Cross Blue Shield Association: medical technology evidence generation
  • Laura & John Arnold Foundation
• ~50% of clinical trials are never published, many after 2 years

• Even when published, limited portion of collected data is reported
  • Particularly secondary endpoints, safety details

• Patients and physicians frequently make treatment decisions based on a fraction of potentially available clinical data

• Need ways to improve publication and reporting of research...
Strengthening Science through Data Sharing

- Ensures all data can be used to inform clinical decisions
- Positions research as a public good
- Respects contributions of participants:
  - maximizing value of collected data, while
  - minimizing duplicative data collection
- Facilitates secondary studies of existing data
- Promotes transparency and reproducibility:
  - sample, design, and analysis
Purpose: To describe early experience with setting up and sharing clinical research data through the Yale Open Data Access (YODA) Project
Principles of the YODA Project

• Promote sharing of clinical research data to advance science and improve public health and healthcare
• Promote responsible conduct of research
• Ensure good stewardship of clinical research data by external investigators
• Protect rights of research participants
Medtronic Partnership

• Initiated in 2011

• Patient-level data for 17 Infuse clinical trials

• Early effort devoted to competitive RFP, 2 independent reviews
  • Both high-quality, conducted in tandem; published simultaneously
  • Provided public assurance via independent review

• Afterwards, established data access policy, required registration, public reporting, publication: 4 requests, 2 completed projects
Johnson & Johnson Partnership

- Initiated in 2014
- Effort focused on promoting, facilitating access to clinical trial data:
  - All pharmaceutical products (including legacy trials)
  - Device and diagnostic products as of 2015
  - Consumer products as of 2017
- Maintained governance structure with formal Steering Committee, engaged experts, stakeholders, and public (via comment)
- Launched YODA Project website to provide trial info, meta-data
• Investigators name, affiliation, 
• Narrative summary 
• Public abstract 
• Detailed research proposal:  
  • Project background  
  • Significance/objectives  
  • Study design  
  • Main outcomes  
  • Statistical analysis plan  
• COI statement 
• Once approved, DUA required 
• Data maintained on secure platform, access via VPN 
• Prevents distribution, protects patient privacy
Number of Data Requests Submitted

*As of September 1, 2017

Median No. Trials Requested: 3 (IQR: 1-9)

*As of September 1, 2017
• Public reporting of approved requests, research proposals, results of project

• Of 78, 71 (91%) approved, 1 (1%) remains under review; 6 (8%) withdrawn/closed (usually data not available)

• Nearly all require some administrative revision, but 28 (36%) required scientific revision after review for clarity

• Most common: new 2⁰ aim (n=44), meta-analysis (n=40), validation (n=21)

• Of 71, 2 completed projects, 4 under peer-review; 7 discontinued ...
This section of the site provides information on study sponsor's criteria for listing studies and other relevant sponsor specific information.

Select the sponsor's logo to view this information.
Challenges Ahead for Data Sharing

• What are best practices among data sharing platforms? What about data analytic servers? What meta-data are needed?
• Who should pay for this?
• Engaging research community to use data (*and knowing it’s complicated*)
• Data Use Agreements ...
• How long should data be available?
• Maintaining public input, transparency
• Large pharma companies are far ahead, what about everyone else?
• What incentives for sharers, users will promote greater success?
YODA Project
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- Cary Gross
- Richard Lehman

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- Karla Childers
- Stephen Bamford

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- YODA Project Steering Committee

http://yoda.yale.edu
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