The Yale Open Data Access (YODA) Project: Lessons Learned in Data Sharing

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Yale

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Open Data, Open Science – Why?

Underreporting Research Is Scientific Misconduct

Iain Chalmers, FRCOG

Substantial numbers of clinical trials are never reported in print, and among those that are, many are not reported in sufficient detail to enable judgments to be made about the validity of their results. Failure to publish an adequate account of a well-designed clinical trial is a form of scientific misconduct that can lead those caring for patients to make inappropriate treatment decisions. Investigators, research ethics committees, funding bodies, and scientific editors all have responsibilities to reduce underreporting of clinical trials. An extended use of prospective registration of trials at inception, as well as benefiting clinical research in other ways, could help people to play their respective roles in reducing underreporting of clinical trials.

Source: Chalmers, JAMA 1990;263:1405-1408.

OPEN ACCESS Freely available online PLoS MEDICINE

Trial Publication after Registration in ClinicalTrials.Gov: A Cross-Sectional Analysis

- **Trials registered at CT.gov in 2000 onwards, completed as of June 2007 (≥ 2 years for all)**
- **46% of trials published**

Trial Funder	Publication, %
Industry	40
Non-government / Non-industry	56
Government (US and non-US)	
US NIH	41
non-NIH, US Government	56
non-US Government	57

Source: Ross et al., PLoS Medicine 2009;6:e1000144.

VIEWPOINT

ONLINE FIRST

Ushering in a New Era of Open Science Through Data Sharing

The Wall Must Come Down

Joseph S. Ross, MD, MHS
Harlan M. Krumholz, MD, SM

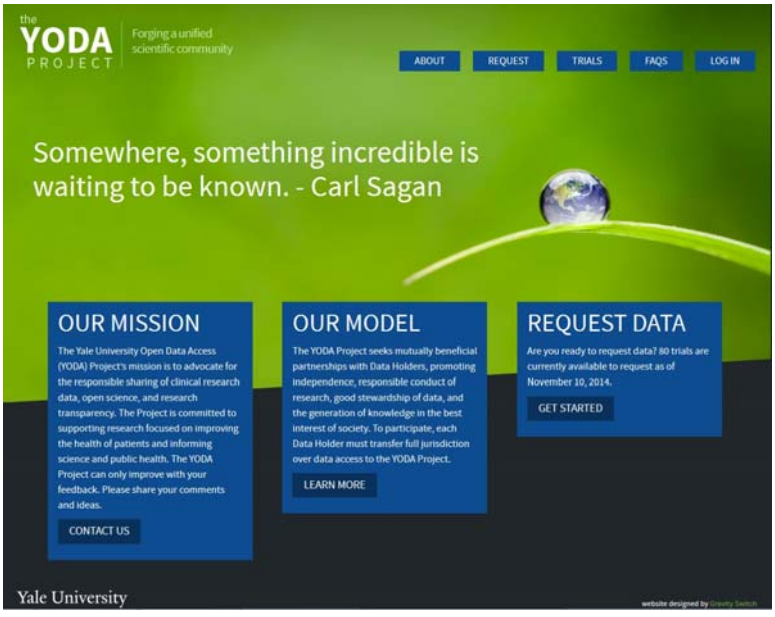
- **~50% of clinical trials are never published**
- **Even when published, limited portion of collected data is reported**
  - **Particularly safety details**
- **Patients and physicians frequently make treatment decisions based on a fraction of potentially available clinical data**

Source: Ross and Krumholz, JAMA 2013;309:1355-1356.

Why Share Data?

- **Promotes data transparency, potential to lead to better informed 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 reproducibility:**
  - **sample, design, and analysis**

the YODA PROJECT Forging a unified scientific community



Source: http://yoda.yale.edu.

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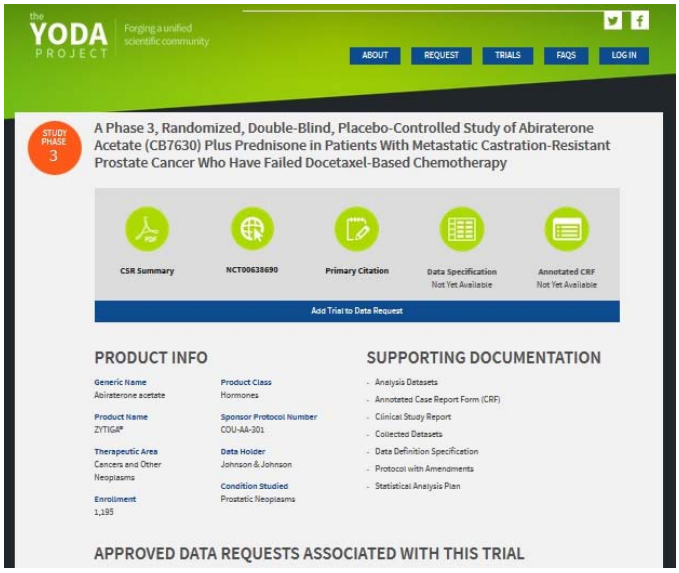
Principles of the YODA Project

- 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

Johnson & Johnson Partnership

- Focused on providing access to clinical trial data:
  - All pharmaceutical products (including historical)
  - Device and diagnostic products from 2014 onward
- Prepared data access policy and established clear procedures with input from Steering Cmte, experts, stakeholders, and public comment
- Require application, registration, public reporting, publication
- YODA Project website provides info on trial and supporting documentation



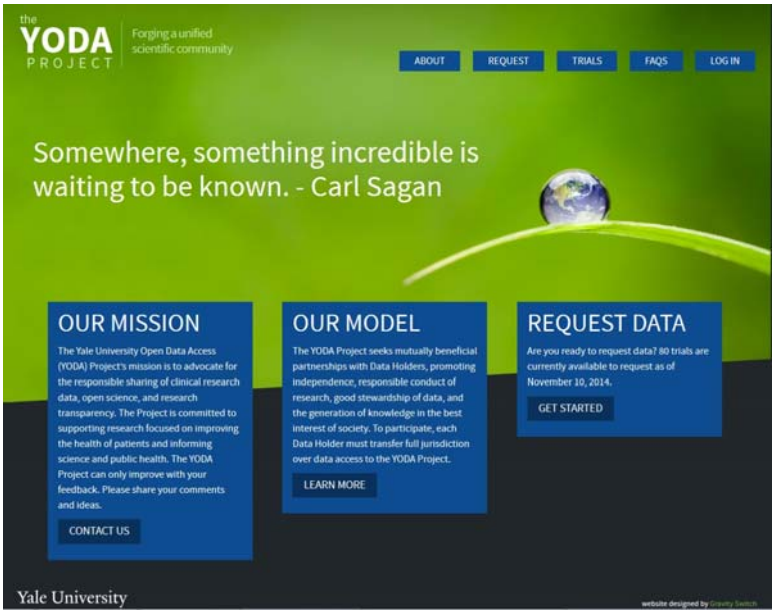
Inquiries Submitted

Total inquiries, No.	**52**
Inquiry led to full data request, No. (%)	**6 (13%)**
Total unique trials requested within inquiries, No.	**104**
Trial data can be made "available", No. (%)	**66 (64%)**
Trial data cannot be made "available", No. (%)	**38 (37%)**

- **Investigator name, affiliation, co-investigators**
- **Research proposal, including background, study design, main outcomes, statistical analysis plan**
- **COI statement**

- **Once approved, require signed DUA**
- **Investigators gain access to data maintained on secure platform, via VPN**
- **Prevents distribution, protects patient privacy**

- **Public reporting of approved requests, submitted proposals, results of project**



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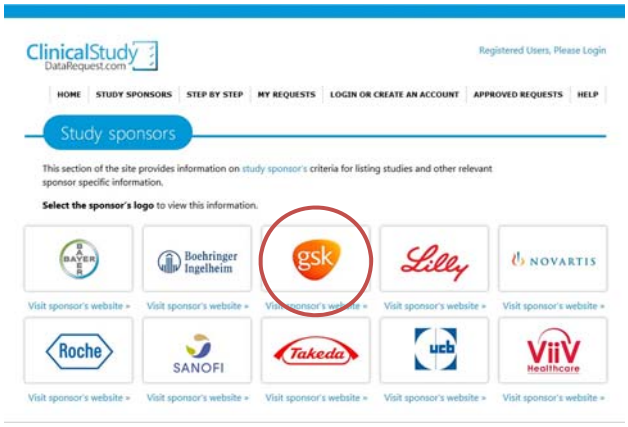

Pfizer

MERCK

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How YODA Project is Different

- **Not our data**
- **Independent third party without interests, removing perception of influence over access**
- **YODA Project has full jurisdiction to make decisions regarding data access**
- **Policies and procedures established via public comment in the best interests of:**
  - **Scientific profession and investigators**
  - **Patients and research subjects**
  - **Data Holders / Partners**

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NHS National Institute for Health Research

NIH National Institutes of Health
Turning Discovery Into Health

PhRMA efpia

ICMJE
INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

ljaf
laura and john arnold foundation

BILL & MELINDA GATES foundation

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"Stakeholders should foster a culture in which data sharing is the expected norm, and should commit to responsible strategies aimed at maximizing benefits, minimizing risks, and overcoming challenges of sharing trial data"

Source: Institute of Medicine report, January 2015.

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Micro Challenges Ahead

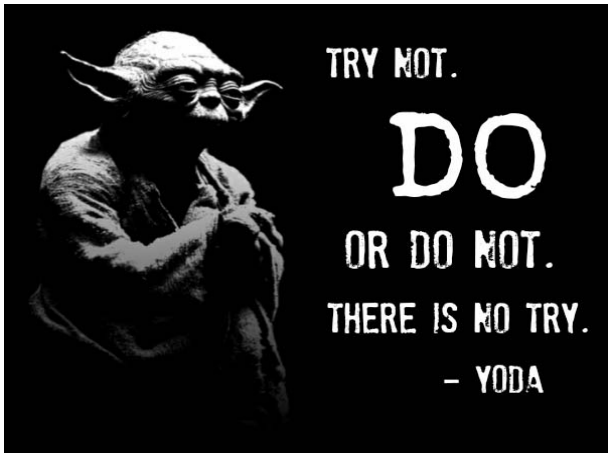
- Creating a platform that facilitates research
  - What trials are or can be made available?
  - What meta-data are needed: CRFs, protocol, SAPs?
- Engaging research community to use data
- Resources are not unlimited – fee?
- Patient privacy, secure data analytic platform – how easy can it be?
- Maintaining public input, transparency
- Scope and intensity of review
- Data Use Agreements

Macro Challenges Ahead

- Large pharmaceutical companies far ahead
  - What about mid-size, small biotech?
  - What about medical device companies?
  - What about academics?
- Linking data sharing platforms
- Dream of automated meta-analyses – will we ever get there?

Objectives Remain Clear

- **Facilitate greater access to clinical trial data, increasing transparency and accelerating generation of new knowledge, while promoting responsible conduct of research**
- **Better inform patients, clinicians, and industry so that decisions can be based on the most comprehensive and contemporary evidence available relevant to benefits and harms of therapies**



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