

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

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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.



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

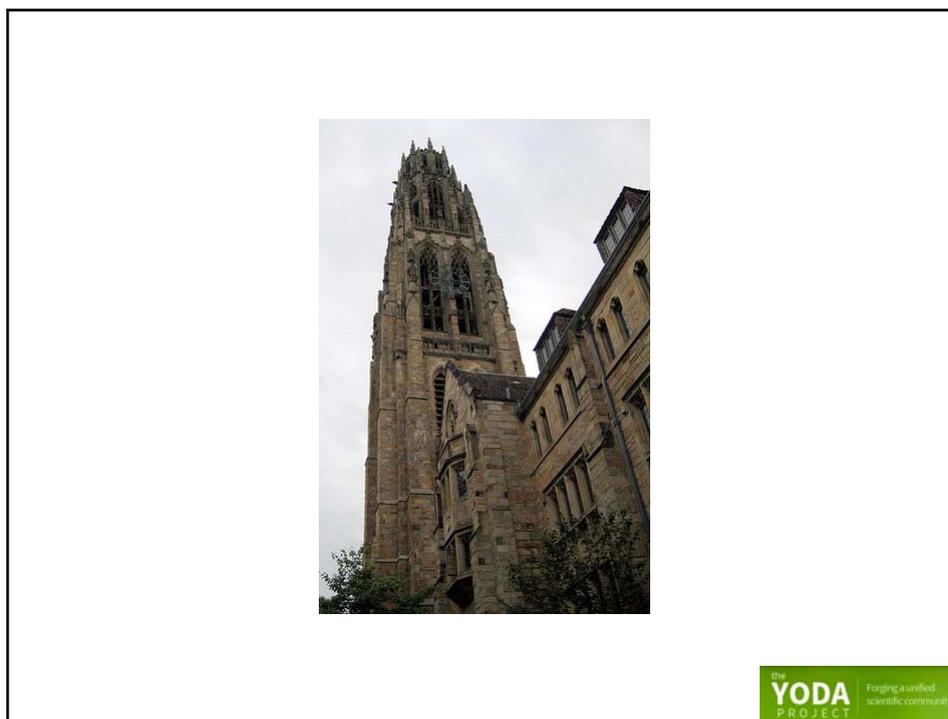
Source: Ross and Krumholz, JAMA 2013;309:1355-1356.



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

ABOUT REQUEST TRIALS FAQS LOG IN

Somewhere, something incredible is waiting to be known. - Carl Sagan

OUR MISSION
The Yale University Open Data Access (YODA) Project's mission is to advocate for the responsible sharing of clinical research data, open science, and research transparency. The Project is committed to supporting research focused on improving the health of patients and informing science and public health. The YODA Project can only improve with your feedback. Please share your comments and ideas.
CONTACT US

OUR MODEL
The YODA Project seeks mutually beneficial partnerships with Data Holders, promoting independence, responsible conduct of research, good stewardship of data, and the generation of knowledge in the best interest of society. To participate, each Data Holder must transfer full jurisdiction over data access to the YODA Project.
LEARN MORE

REQUEST DATA
Are you ready to request data? 80 trials are currently available to request as of November 10, 2014.
GET STARTED

Yale University

website designed by Gravity Search

the YODA PROJECT Forging a unified scientific community

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

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



The screenshot shows the YODA Project website interface. At the top, the logo reads "the YODA PROJECT Forging a unified scientific community" with navigation links for ABOUT, REQUEST, TRIALS, FAQs, and LOGIN. The main content area features a red "STUDY PHASE 3" badge and the title: "A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study of Abiraterone Acetate (CB7630) Plus Prednisone in Patients With Metastatic Castration-Resistant Prostate Cancer Who Have Failed Docetaxel-Based Chemotherapy". Below the title are five icons representing different data types: CSR Summary, NCT00638690, Primary Citation, Data Specification (Not Yet Available), and Annotated CRF (Not Yet Available). A blue button labeled "Add Trial to Data Request" is positioned below these icons. The page is divided into two columns: "PRODUCT INFO" and "SUPPORTING DOCUMENTATION".

PRODUCT INFO		SUPPORTING DOCUMENTATION
Generic Name Abiraterone acetate	Product Class Hormones	- Analysis Datasets
Product Name ZYTIGA®	Sponsor Protocol Number COU-AA-301	- Annotated Case Report Form (CRF)
Therapeutic Area Cancers and Other Neoplasms	Data Holder Johnson & Johnson	- Clinical Study Report
Enrollment 1,185	Condition Studied Prostatic Neoplasms	- Collected Datasets
		- Data Definition Specification
		- Protocol with Amendments
		- Statistical Analysis Plan

APPROVED DATA REQUESTS ASSOCIATED WITH THIS TRIAL

The YODA PROJECT logo is visible in the bottom right corner of the screenshot.

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%)

APPLICATION

Personal Information

Name (Last) _____ (First) _____ (Middle Initial) _____
 Address (Mailing Address) _____
 e-Mail Address _____

Services needed

Current Income

High School Graduate Or General Education (GED) Test Passed? Yes No
 If no, list the highest grade completed _____

Business School, Military (Most recent first)

Date Attended	Credits Earned	Other (Specify)	Graduate	Degree A Year
_____	_____	_____	Yes/No	_____

- 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



The screenshot shows the YODA Project website with a green header and navigation menu. The main content area is titled "Approved J&J Data Requests*" and features a table with two rows of data. To the right of the table is a vertical list of links including "Policies & Procedures", "Project Leadership", "Steering Committee", "Roles & Responsibilities", "Data Holders", "Metronic", "Johnson & Johnson Available Data", "Data Release Pilot Project", and "Summary of Data Inquiries and Requests".

Date of Approval	YODA Project Protocol Number	PI	Affiliation	Project Title	Product(s) of Interest	Research Proposal	Summary of Data Holder Due Diligence Assessment	Link to Journal Article
Nov 18, 2014	2014-0340	Heidi Storgaard, MD, PhD	University of Copenhagen, Center for Diabetes Research	The effects of SGLT-3 inhibitors in patients with type 2 diabetes: a systematic review with meta-analysis of randomised trials	INVOKANA	Click here to view	Click here to view	TBD
Nov 26, 2014	2014-0333	Guru Prasad	University of Minnesota	RECIST response as a prognostic indicator in	ZYTIGA	Click here to view	Click here to view	TBD

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

The screenshot shows the YODA Project website home page with a green background and a central image of the Earth. The page features a quote by Carl Sagan: "Somewhere, something incredible is waiting to be known. - Carl Sagan". Below the quote are three main sections: "OUR MISSION", "OUR MODEL", and "REQUEST DATA". Each section has a brief description and a "LEARN MORE" or "GET STARTED" button. The Yale University logo is in the bottom left, and the YODA Project logo is in the bottom right.

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

ClinicalStudy
DataRequest.com

Registered Users, Please Login

HOME | STUDY SPONSORS | STEP BY STEP | MY REQUESTS | LOGIN OR CREATE AN ACCOUNT | APPROVED REQUESTS | HELP

Study sponsors

This section of the site provides information on study sponsor's criteria for listing studies and other relevant sponsor specific information.

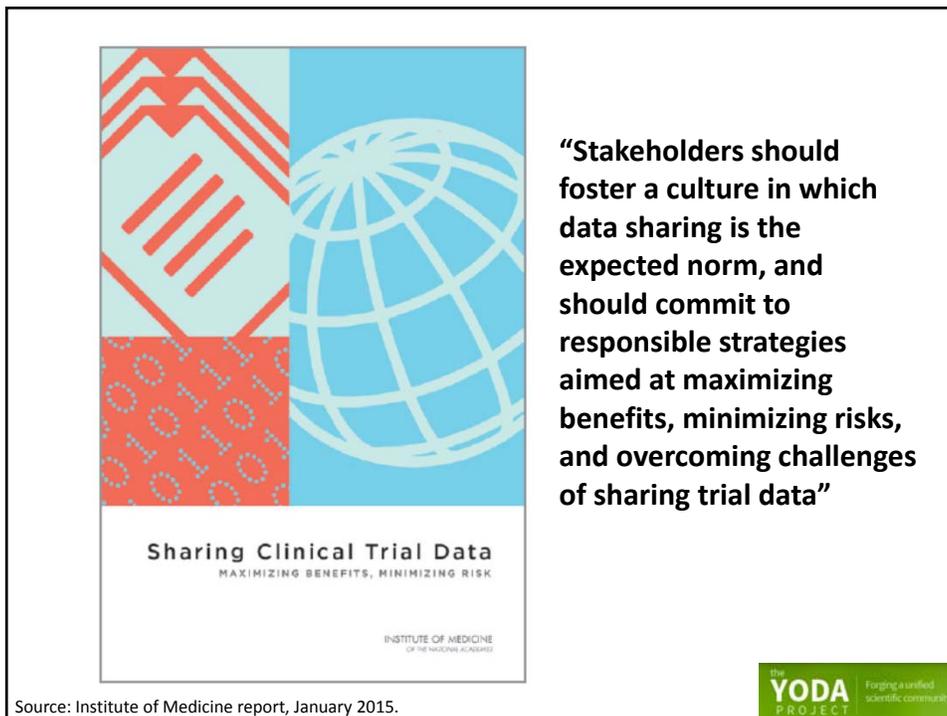
Select the sponsor's logo to view this information.

Visit sponsor's website >				
Visit sponsor's website >				

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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



Source: Institute of Medicine report, January 2015.

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**



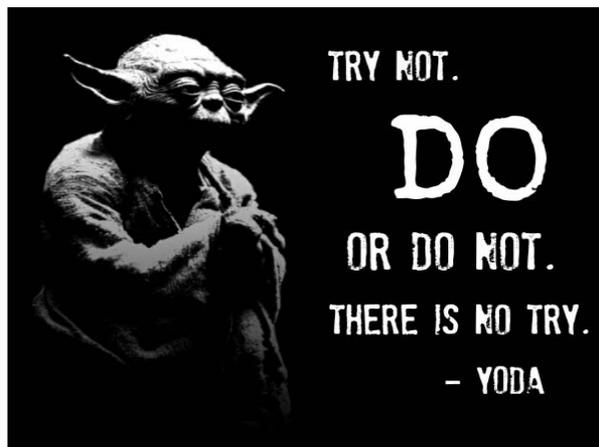
Macro Challenges Ahead

- **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



<http://yoda.yale.edu>
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