The Yale Open Data Access (YODA) Project: Repurposing Data for Researchers

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• ~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

Why Share Data?

• Facilitates secondary studies of existing data
• Promotes data transparency, potential to lead to better informed clinical decisions
• Positions research as a public good
• Respects contributions of participants:
  – Maximize value of collected data
  – Minimize duplicative data collection
• Promotes reproducibility:
  – Sample, design, and analysis
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.
“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.
How to Share Data?
Objectives of the YODA Project

• 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
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
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
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
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

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

PRODUCT INFO
- Generic Name: Abiraterone acetate
- Product Name: ZYTIGA®
- Therapeutic Area: Cancers and Other Neoplasms
- Enrollment: 1,185
- Product Class: Hormones
- Sponsor Protocol Number: COU-AA-301
- Data Holder: Johnson & Johnson
- Condition Studied: Prostatic Neoplasms

SUPPORTING DOCUMENTATION
- Analysis Datasets
- Annotated Case Report Form (CRF)
- Clinical Study Report
- Collected Datasets
- Data Definition Specification
- Protocol with Amendments
- Statistical Analysis Plan

APPROVED DATA REQUESTS ASSOCIATED WITH THIS TRIAL
• Investigator name, affiliation, co-investigators
• Research proposal, including background, study design, main outcomes, statistical analysis plan
• COI statement
• Reviewed by YODA Project
• Once approved, require signed DUA
• Investigators gain access to data maintained on secure platform, via VPN
• Prevents distribution, protects patient privacy
• 165 trials available for sharing
• 46 requests for data received, 42 of which have been approved, 4 are under review
Public reporting of approved requests, submitted proposals, results of project
Challenges Ahead

- Creating a platform that facilitates research
- 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
- Large pharmaceutical companies far ahead
  - What about mid-size, small biotech?
  - What about medical device companies?
  - What about academics?
Data Sharing and Systematic Reviews

• ICMJE proposed rule
• Non-publication of research prohibits the identification and inclusion of all relevant research
• Data sharing can improve the accuracy of systematic reviews
Role of the Librarian

• Increase awareness of data resources
  – Published in ICMJE member journals
  – Controlled vs open access databases
    • YODA Project
    • NIH BioLINCC
    • ClinicalStudyDataRequest.com
    • Dryad
TRY NOT.

DO

OR DO NOT.

THERE IS NO TRY.

- YODA

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