Sharing Patient-Level Clinical Trial Data: The YODA Model

National Brain Tumor Society Research Roundtable
July 20, 2023

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Yale School of Medicine

@cpgYale
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
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.

Our Model
The YODA Project seeks mutually beneficial partnerships with Data Partners, 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 Partner must transfer full jurisdiction over data access to the YODA Project.

Request Data
Are you ready to request data? To date, 445 trials have been identified as available. The YODA Project and Data Partners continue to identify and add more.

CONTACT US
HOW IT WORKS
GET STARTED
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

- Initiated in 2014 – effort focused on promoting and facilitating access to clinical trial data:
  - All pharmaceutical products (including legacy trials)
  - Device and diagnostic products as of 2015
  - Consumer products as of 2017
- Established data access policy and procedures, with input from Steering Committee, experts, stakeholders, and public comment
Trials By Generic Name

Below is a list of trials that have been identified as available. This is not a complete list of the trials that are available for sharing. Before a trial can be shared, Data Partners must confirm data location and availability in an electronic format, and confirm that data availability conforms to any applicable partner agreements. All trials listed below have gone through this process. We continue to add trials to this list on a regular basis.

Next are the trials you are looking for:

- Abiraterone acetate
- Ablation Catheter
- Acetaminophen
- Bedaquiline/TMC207

- Bosentan
- Canagliflozin
- Daratumumab
- Dananavir

- Doxorubicin hydrochloride
- Epoetin alfa
- Ethinyl estradiol
- Etravirine

PRODUCT INFO

- Generic Name: Infliximab
- Product Name: REMICADE
- Disease Area: Musculoskeletal, Bone, and Cartilage Diseases
- Enrolled: 121
- % Female: 41.9%
- % White: 92.4%

SUPPORTING DOCUMENTATION

- Clinical study report
- Collection datasets
- Data definition specification
- Annotated Case report form
- Protocol with Amendments
- Statistical Analysis Plan

APPROVED DATA REQUESTS ASSOCIATED WITH THIS TRIAL

Impact of the dose of immunomodulators on pharmacokinetics of biologics: Patient level meta-analysis of randomized controlled trials.
Requests Submitted Online

- Investigator names, affiliations, funding
- Narrative summary / public abstract
- Detailed research proposal, including:
  - Project background, clear objectives
  - Trials, sample eligibility criteria, variables
  - Primary and secondary endpoints
  - Statistical analysis plan
- Project purpose (meta-analysis, validation ...)
- Timeline and dissemination plan
- Data use agreement training
• Once approved, require signed DUA
• Investigators gain access to data maintained on secure platform via VPN
• Prevents re-distribution, protects patient privacy
Data Requests to Use Johnson and Johnson Data

Requests listing last updated May 1, 2020

All Requests | Approved Requests | Withdrawn/Not Approved Requests

All Requests
The YODA Project posts proposals once data access has been granted or denied.

145 Results

PRODUCT OF INTEREST
- CONCERTA®
- DARZALEX®
- DOXIL®
- EDURANT®
- GETSRT

F1 COUNTRY
- Canada
- United States
- Germany
- United Kingdom
- Singapore

PI AFFILIATION

YODA PROJECT PROTOCOL NUMBER
2018-3121

PRODUCT(s) OF INTEREST
REMICADE® (infliximab), SIMPONI® (Golimumab)

NO. TRIALS PROVIDED
0

Published
Speed of onset of infliximab and golimumab in patients with moderate-severely active ulcerative colitis: A Post-Hoc Analysis of RCTs

PRINCIPAL INVESTIGATOR
Siddharth Singh
Division of Gastroenterology, University of California San Diego

REPORTS & PUBLICATIONS
Clin Gastroenterol Hepatol 2019

YODA PROJECT REVIEW | DUE DILIGENCE ASSESSMENT
If we share it, will they come?
3,255 trials

177 proposals
1 publication

>200 proposals
4 publications

Jan 2014
May 2014
Nov 2015
Mar 2016
Aug 2016

Proposals
234 received
154 approved
1 publication

ClinicalStudy
DataRequest.com

Navar et al. JAMA 2016
Experience so far ...

- Of 445 trials currently available, 86% have thus far been requested.
- Of 346 requests submitted, 331 (95.7%) approved, 5 (1.4%) remain under review; 10 (2.9%) withdrawn/closed, 1 (0.3%) rejected.
  - Usually because data not available/cannot be adequately de-identified.
- Nearly all require some administrative revision, but one-quarter required scientific revision after review for clarity.
- 133 manuscripts have been submitted for publication to peer-reviewed journals, 99 of which have been published.
Specifics of Approved Data Requests

*As of July 1, 2023

Number of Trials Requested

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- **56.6%**  
  - Multiple trials: same product

- **32.7%**  
  - Multiple trials: different products in same disease category

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Most common conditions studied:
- Schizophrenia
- Crohn’s disease
- Diabetes mellitus
- Bipolar disorder
- Ulcerative colitis
Median No. Trials Requested: 3 (IQR: 1-8)
Challenges Remain

• Broadening awareness of data availability
• Fostering expertise in using data from clinical trials
• Making older trial data available in contemporary formats
• Adopt data standards, across sponsors, to enable meta-analyses
• Sustainable model that covers the cost of data sharing
• Data Use Agreements ...
• Establish standards: when should data be available, for how long, how to reward those who share data?
Challenges Ahead for Data Sharing

• Incentives
  • Who should pay for this?
  • Large pharma companies are far ahead, what about everyone else?
  • What incentives for sharers, users will promote greater success?

• Stakeholders
  • Maintaining public input, transparency
  • Engaging research community to use data

• Process
  • What are best practices among data sharing platforms?
  • Giving “credit” where its due
  • Data Use Agreements
Survey of Trial Authors Published in “Pro-Sharing” Journals

89 Trial Manuscripts

35% Received ≥1 Request (n=31)
68 Requests Total
59 Granted
Willingness to Share by Request Type

(6 months post publication)

- Primary efficacy - meta-analysis
- Primary efficacy - replicate primary outcome
- Predictive modeling - NO similar analysis planned
- Predictive modeling - similar analysis planned
- Secondary outcome - NO similar analysis planned
- Secondary outcome - similar analysis planned

Percentage of Respondents Willing to Share

Tannenbaum et al. Annals Intern Med, 2019
Thank You!

YODA Project
- Harlan Krumholz
- Joseph Ross
- Cary Gross
- Richard Lehman

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- Karla Childers
- Stephen Bamford

Additional Thanks
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- Jessica Ritchie
- Maryam Hussain
- Nihar Desai
- Jesse Berlin
- Sandra Morris
- Peter Lins

http://yoda.yale.edu
@YODAProject