

Sharing Patient-Level Clinical Trial Data: The YODA Model

National Brain Tumor Society Research Roundtable
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CONNECTICUT BRAIN
FREEZE



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.

[CONTACT US](#)

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.

[HOW IT WORKS](#)

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.

[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.

Don't see the trial(s) you are looking for?

[Submit an inquiry](#)

GENERIC NAME

PRODUCT CLASS

THERAPEUTIC AREA

CONDITION STUDIED

ADVANCED SEARCH

Abliraterone acetate

[VIEW TRIALS](#)

Ablation Catheter

[VIEW TRIALS](#)

Acetaminophen

[VIEW TRIALS](#)

Bedaquiline/TMC207

[VIEW TRIALS](#)

Bosentan

[VIEW TRIALS](#)

Canagliflozin

[VIEW TRIALS](#)

Daratumumab

[VIEW TRIALS](#)

Darunavir

[VIEW TRIALS](#)

Doxorubicin hydrochloride

[VIEW TRIALS](#)

Epoetin alfa

[VIEW TRIALS](#)

Ethinyl estradiol

[VIEW TRIALS](#)

Etravirine

[VIEW TRIALS](#)STUDY
PHASE
3

A Randomized, Double-Blind Trial of Anti-TNF Chimeric Monoclonal Antibody (Infliximab) in Combination With Methotrexate for the Treatment of Patients With Polyarticular Juvenile Rheumatoid Arthritis

[CSR Summary](#)[NCT0036374](#)[Primary Citation](#)[Data Specification](#)[Annotated CRF](#)
Available upon data
request approval[Add Trial to Data Request](#)

PRODUCT INFO

Generic Name
Infliximab**Product Name**
REMICADE®**Therapeutic Area**
Muscle, Bone, and Cartilage
Diseases**Enrollment**
123**% Female**
85.9%**% White**
92.1%**Product Class**
Antirheumatic Agents - Biologic
Response Modifiers**Sponsor Protocol Number**
C0168T32**Data Partner**
Johnson & Johnson**Condition Studied**
Arthritis, Juvenile**Mean/Median Age (Years)**
11.2

SUPPORTING DOCUMENTATION

- Clinical Study Report
- Collected 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
Impact of Biologic Therapy on the Risk of Arterial and Venous Thromboembolic Events in Chronic Autoimmune Diseases: A Post-Hoc Analysis of RCTs

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



The image shows a close-up of a white application form titled "APPLICATION" in large, bold, black letters. The form is placed on a wooden surface. A blue and silver pen is resting on the form. The form has several sections with labels and checkboxes. The "Personal Information" section includes fields for Name (Last), First, Middle Initial, and Date of Birth. The "Address (Mailing Address)" section includes fields for Address, City, State, and Zip. The "E-Mail Address" section has a field for the email address. The "Services needed" section has a checkbox for "Yes" and a checkbox for "No". The "Current Income" section has a checkbox for "Yes" and a checkbox for "No". The "Education" section includes a checkbox for "High School Graduate Or General Education (GED) Test Passed?" and a checkbox for "Business School, Military (most recent first)". The "Credits Earned" section includes a checkbox for "Quantity or Semester Hours" and a checkbox for "Other (Specify)". The "Graduate" section includes a checkbox for "Yes" and a checkbox for "No". The "Degree & Year" section has a field for the degree and year.



- **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®
- ☐ GETSET

[Show More](#)

PI COUNTRY

- ☐ Canada
- ☐ United States
- ☐ Germany
- ☐ United Kingdom
- ☐ Singapore

[Show More](#)

PI AFFILIATION

YODA PROJECT PROTOCOL NUMBER
2018-3121

PRODUCT(S) OF INTEREST
**REMICADE® (Infliximab),
SIMPONI® (Golimumab)**

NO. TRIALS PROVIDED
6

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](#)

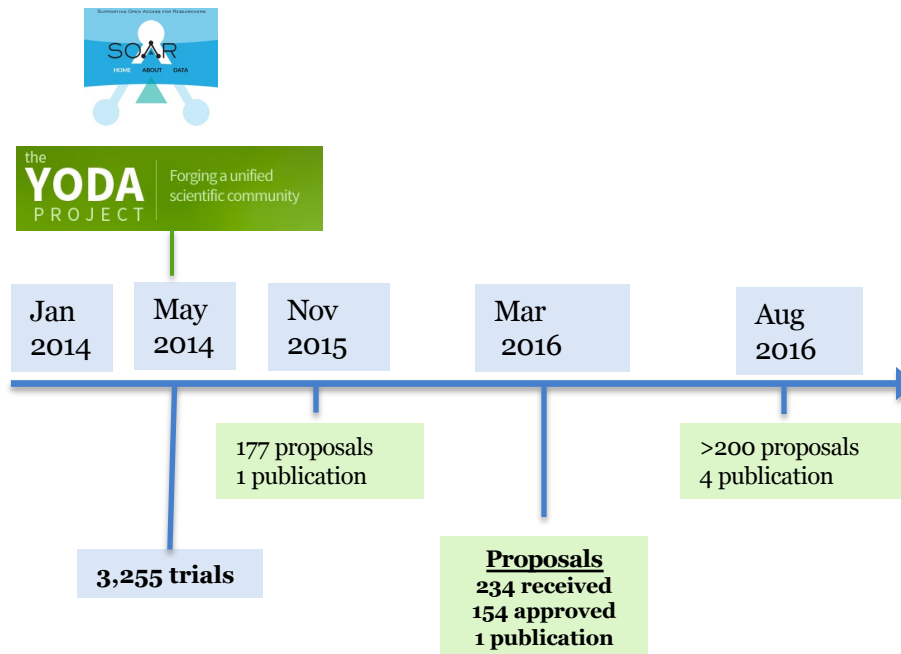
Publication
Available

YODA PROJECT REVIEW

DUE DILIGENCE ASSESSMENT

If we share it, will they come?

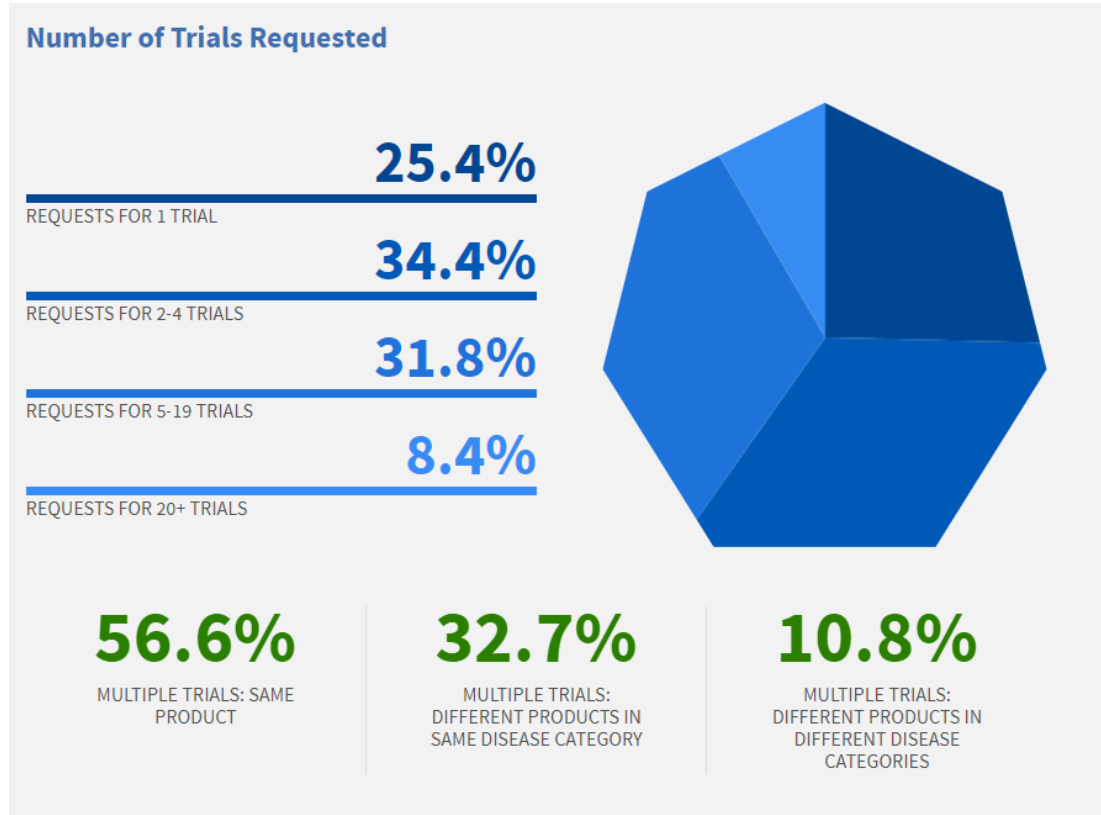




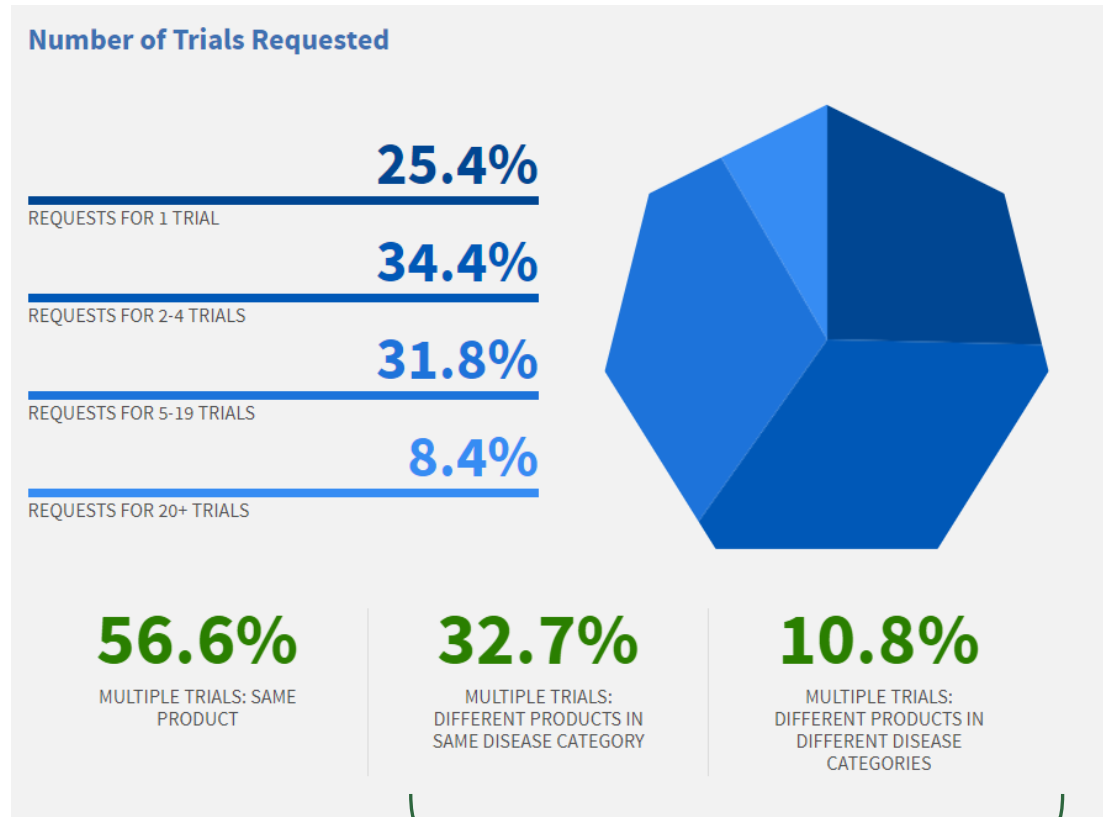
Experience so far ...

- 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 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



Specifics of Approved Data Requests



Most common conditions studied:

- Schizophrenia
- Crohn's disease
- Diabetes mellitus
- Bipolar disorder
- Ulcerative colitis



Not Approved

Withdrawn/Closed

Under Review/Revisions
Requested

Approved (pending signed
DUA or data preparation)

Data access granted
(analyses in progress or
manuscript under review)

Published

Concluded with project
summary

Incomplete without results
reported

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

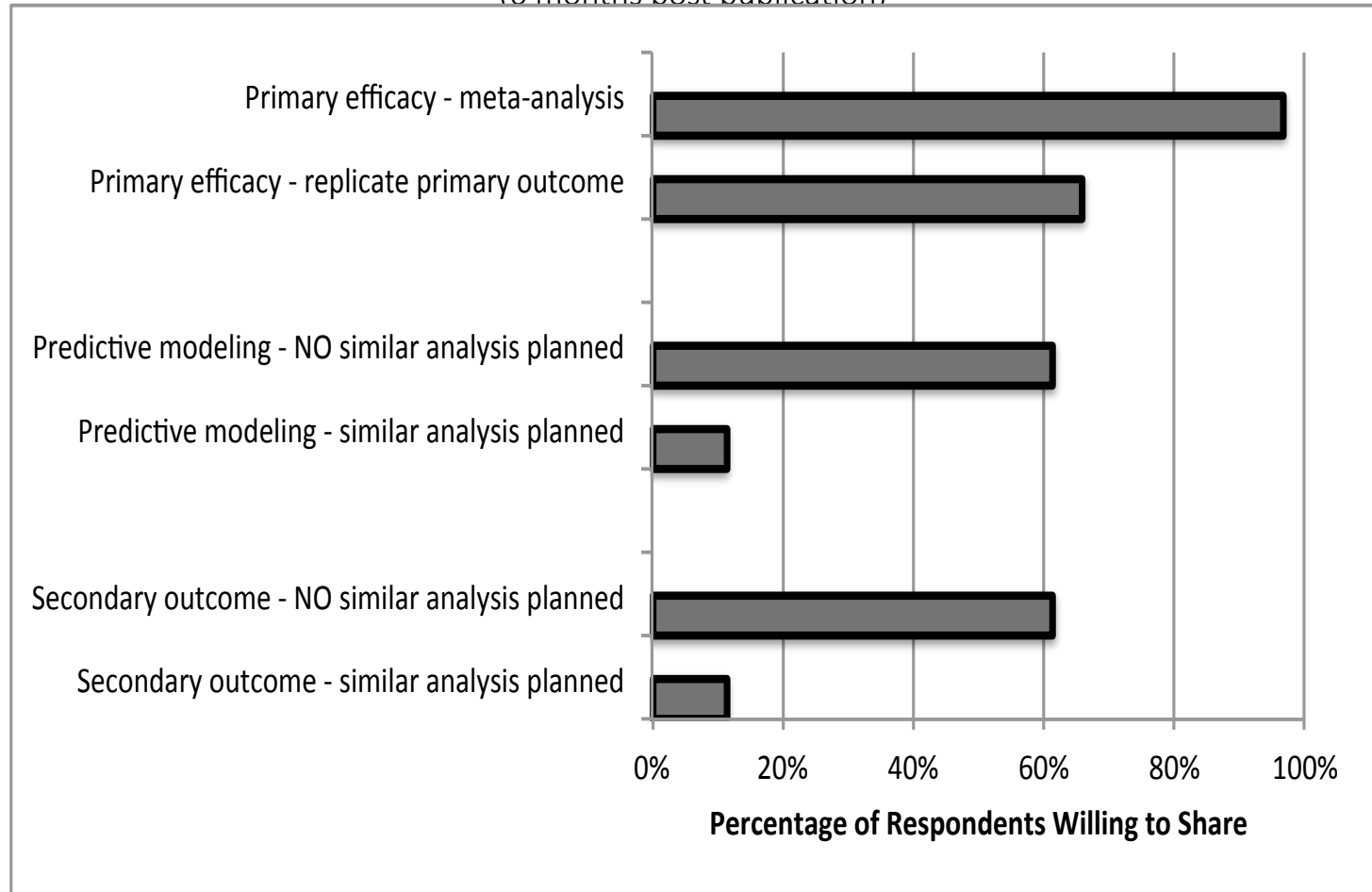


89 Trial
Manuscripts

35% Received ≥ 1 Request (n=31)
68 Requests Total
59 Granted

Willingness to Share by Request Type

(6 months post publication)



Thank You!

YODA Project

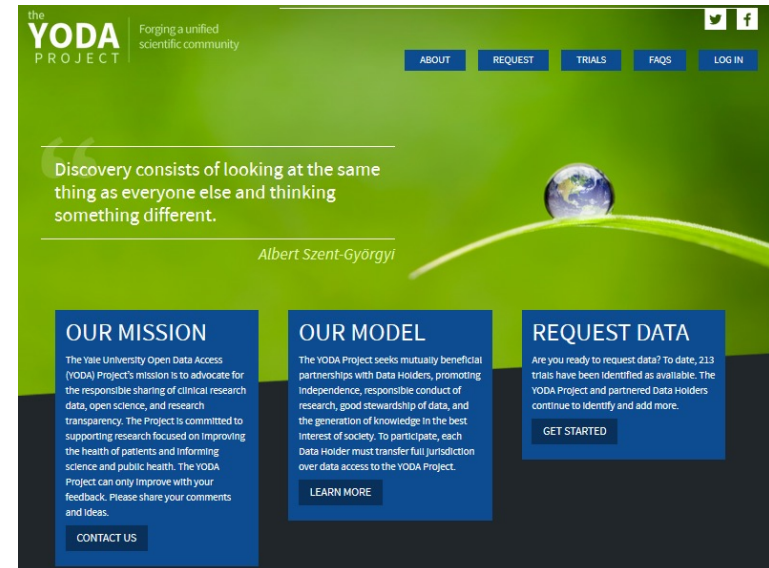
- Harlan Krumholz
- Joseph Ross
- Cary Gross
- Richard Lehman
- Jessica Ritchie
- Maryam Hussain
- Nihar Desai

Johnson & Johnson

- Joanne Waldstreicher
- Karla Childers
- Stephen Bamford
- Jesse Berlin
- Sandra Morris
- Peter Lins

Additional Thanks

- YODA Project Steering Committee



<http://yoda.yale.edu>

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