

The Yale Open Data Access (YODA) Project: 10 Years of Clinical Trial Data Sharing

NIH Collaboratory Grand Rounds
April 19, 2024

Yale



Joseph S. Ross, MD, MHS

Section of General Internal Medicine, School of Medicine
Center for Outcomes Research and Evaluation, Yale-New Haven Hospital



@jsross119



Potential Competing Interests

- **The YODA Project is funded by research grant through Yale from Johnson & Johnson**
- **Research grant funding through Yale from:**
 - **Food and Drug Administration (FDA)**
 - **National Evaluation System for health Technologies (NEST)**
 - **NIH/NHLBI, AHRQ, PCORI**
 - **Arnold Ventures**
- **Deputy Editor at JAMA**

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.

Selective Publication and Selective Reporting

- **~50% of clinical trials are never published**
- **Even when published:**
 - **Many trial publications are delayed > 2 years**
 - **50% of efficacy and 65% of safety data are incompletely reported**
 - **Statistically significant findings more likely to be reported**
 - **62% have ≥ 1 primary outcome that was changed, introduced, or omitted**
- **Patients and physicians frequently make treatment decisions based on only a portion of the potentially available clinical data**
- **Need ways to improve publication and reporting of research ...**

Trial Registration and Results Reporting

- 1997 FDA Modernization Act, section 113, provided public access to information about ongoing clinical trials
- Led to creation of ClinicalTrials.gov

The screenshot shows the ClinicalTrials.gov website. At the top left is the logo "ClinicalTrials.gov" with the tagline "A service of the U.S. National Institutes of Health". To the right are navigation links: "Home", "Search", "Study Topics", and "Glossary". Below these is a search bar with a "Search" button. The main content area is divided into two columns. The left column contains a description of the registry, a "Search for Clinical Trials" section with a sub-description, "Investigator Instructions", and "Background Information". The right column contains "Resources" (with links to "Understanding Clinical Trials", "What's New", and "Glossary"), "Study Topics" (with links to "List studies by Condition", "List studies by Drug Intervention", "List studies by Sponsor", and "List studies by Location"), and a "HONcode" logo with text stating the site complies with the HONcode standard for trustworthy health information.

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

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ClinicalTrials.gov is a registry of federally and privately supported clinical trials conducted in the United States and around the world. ClinicalTrials.gov gives you information about a trial's purpose, who may participate, locations, and phone numbers for more details. This information should be used in conjunction with advice from health care professionals. [Read more...](#)

► [Search for Clinical Trials](#)

Find trials for a specific medical condition or other criteria in the ClinicalTrials.gov registry. ClinicalTrials.gov currently has **80,696 trials** with locations in **170 countries**.

► [Investigator Instructions](#)

Get instructions for clinical trial investigators/sponsors about how to register trials in ClinicalTrials.gov. Learn about mandatory registration and results reporting requirements and US Public Law 110-85 (FDAAA).

► [Background Information](#)

Learn about clinical trials and how to use ClinicalTrials.gov, or access other consumer health information from the US National Institutes of Health.

Resources:

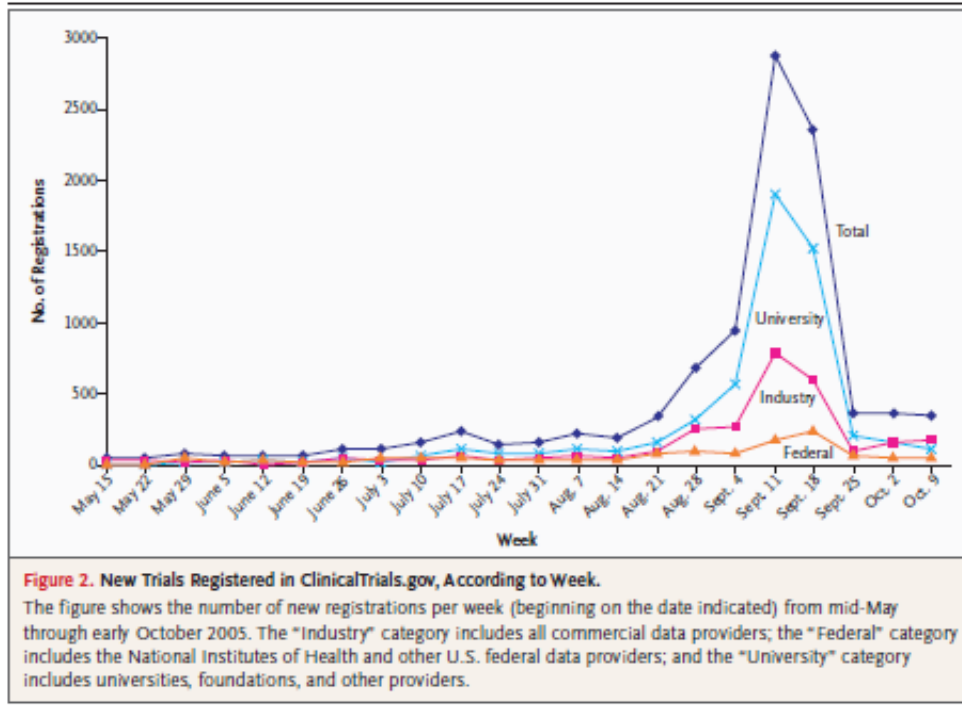
- [Understanding Clinical Trials](#)
- [What's New](#)
- [Glossary](#)

Study Topics:

- [List studies by Condition](#)
- [List studies by Drug Intervention](#)
- [List studies by Sponsor](#)
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**Number of Registered Studies Over Time
and Some Significant Events (as of March 06, 2022)**



Trial Registration and Results Reporting

- 1997 FDA Modernization Act, section 113, provided public access to information about ongoing clinical trials
- Led to creation of ClinicalTrials.gov
- **2007 FDA Amendments Act broadened scope**
 - **Expanded registry**: all studies must be registered at inception
 - **Results database**: trial results uploaded within 12 months of study completion (24 if under review)
 - “Basic results”: baseline characteristics, 1° & 2° outcomes, statistical analyses (overall & by arm)
 - Adverse events (serious & frequent)



FDA A A

stands for

**Food and Drug
Administration Amendments
Act**



Abbreviations.com



P/RMA

efpia*



REVIEW

Open Access

Association of the FDA Amendment Act with trial registration, publication, and outcome reporting

Adam T. Phillips^{1*}, Nihar R. Desai^{2,3}, Harlan M. Krumholz^{2,4,5}, Constance X. Zou⁶, Jennifer and Joseph S. Ross^{3,4,5*}

Abstract

Background: Selective clinical trial publication and outcome reporting on ClinicalTrials.gov, a publicly accessible database, is a concern.

Methods: Using publicly available data from ClinicalTrials.gov, we examined the association between trial registration, publication, and reporting of findings for cardiovascular disease and diabetes between 2005 and 2014. We compared the published interpretation of the findings to the interpretation of the findings.

Results: Between 2005 and 2014, the FDA approved 153 new drugs (n = 15) on the basis of 183 trials (median 10.5 trials per drug). Post-FDAAA studies were more likely to be registered (76 of 78 (97%) vs 93 of 105 (89%), p = 0.03), and to be published (74 of 76 (97%) vs 78 of 93 (84%), p = 0.004). Pre-FDAAA (98%) were published as positive. Post-FDAAA, the FDA approved 153 new drugs (n = 15) on the basis of 183 trials (median 10.5 trials per drug). Post-FDAAA, the FDA approved 153 new drugs (n = 15) on the basis of 183 trials (median 10.5 trials per drug).

Conclusions: FDAAA was associated with increased registration and publication of trials supporting FDA approval of new drugs for cardiovascular disease and diabetes.

Keywords: Clinical trials; Publications; Drug approval; FDA

Background

The US Food and Drug Administration (FDA) approves new drugs based on clinical evidence, requiring "adequate and well-controlled investigations", to demonstrate safety and efficacy [1]. The FDA suggests that drug sponsors provide two or more "pivotal" efficacy trials [2]—typically large, randomized, controlled trials—as well as "non-pivotal" trials that provide additional insights into drug efficacy and safety. These trials provide

* Correspondence: atph1@yale.edu; joseph.ross@yale.edu; ¹Division of Cardiovascular Medicine, Department of Internal Medicine, Yale School of Medicine, 333 Cedar Street, Box 3333, New Haven, CT, USA; ²Center for Outcomes Research and Evaluation, Yale-New Haven Hospital, New Haven, CT, USA

Full list of author information is available at the end of the article



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RESEARCH

Open Access

Registration, results reporting, and publication bias of clinical trials supporting

Open Access



Post-FDAAA, clinical trials more likely to be:

- Registered on CT.gov,
 - Report results on CT.gov,
 - Published, and
 - Published w/o misleading interpretation
- less selective publication and less selective outcome reporting*

* Correspondence: jessie.ming@yale.edu; ¹Department of Health Policy and Management, Yale School of Public Health, New Haven, CT, USA; ²Center for Outcomes Research and Evaluation, Yale-New Haven Hospital, New Haven, CT, USA

Full list of author information is available at the end of the article



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* Correspondence: joseph.ross@yale.edu; ¹Section of General Medicine and the National Clinician Scholars Program, Department of Internal Medicine, Yale School of Medicine, PO Box 208008, New Haven, CT 06520, USA; ²Department of Health Policy and Management, Yale School of Public Health, New Haven, CT, USA

Full list of author information is available at the end of the article

* Correspondence: joseph.ross@yale.edu; ¹Section of General Medicine and the National Clinician Scholars Program, Department of Internal Medicine, Yale School of Medicine, PO Box 208008, New Haven, CT 06520, USA; ²Department of Health Policy and Management, Yale School of Public Health, New Haven, CT, USA

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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



For clinical trials to be considered for publication:

- **Effective July 2018, manuscripts must contain a data sharing statement**
- **Trials that begin enrolling participants on or after January 2019 must include a data sharing plan in the trial's registration**

VIEWPOINT

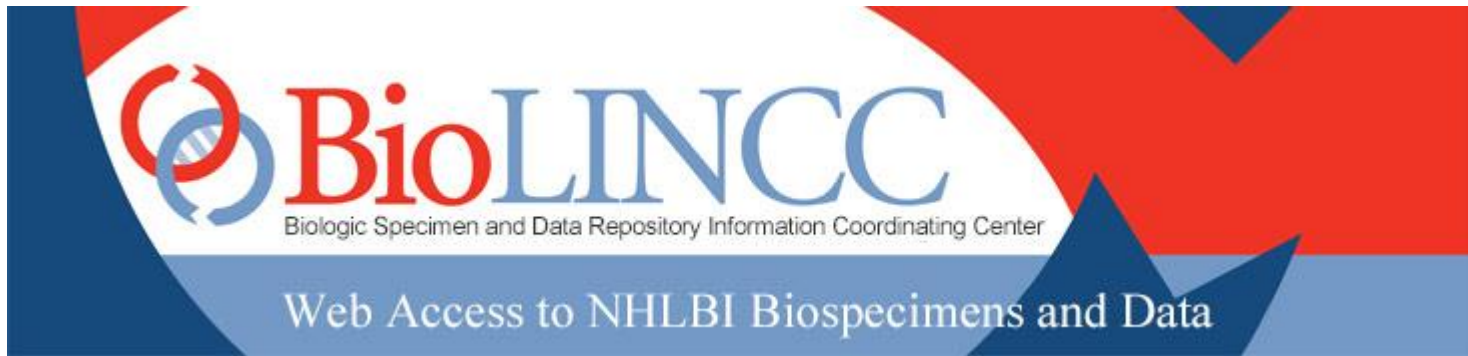
Incentivizing a New Culture of Data Stewardship
The NIH Policy for Data Management and Sharing

For all research, funded or conducted in whole or in part by NIH, that result in the generation of scientific data:

- **Effective Jan 2023, proposals must include plans for management and sharing of all data necessary to validate and replicate research findings**

Elements to Include in a Data Management and Sharing Plan:

- **Data type and amount, as well as metadata**
- **Related tools, software and/or code**
- **Standards (formats, documentation, dictionaries)**
- **Data preservation, access, and associated timelines**
- **Access, distribution, or reuse considerations**
- **Oversight of data management and sharing**
- **Budgets for allowable costs**



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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.

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Visit sponsor's website »	Visit sponsor's website »	Visit sponsor's website »	Visit sponsor's website »	Visit sponsor's website »



Discovery consists of looking at the same thing as everyone else and thinking something different.

Albert Szent-Györgyi



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, 350 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 after proof-of-concept effort with Medtronic**
- **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
Abiraterone acetate	Ablation Catheter	Acetaminophen	Bedaquiline/TMC207	VIEW TRIALS
Bosentan	Canagliflozin	Daratumumab	Darunavir	VIEW TRIALS
Doxorubicin hydrochloride	Epoetin alfa	Ethinyl estradiol	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



NCT00036374



Primary Citation



Data Specification



Annotated CRF
Available upon data
request approval

[Add Trial to Data Request](#)

PRODUCT INFO

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

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



YODA Project Review

The YODA Project reviews proposals to ensure that each proposal has scientific merit, specifically verifying:






- Scientific purpose is clearly described
- Data requested will be used to create or materially enhance generalizable scientific and/or medical knowledge to inform science and public health
- Proposed research can be pursued using the requested data
- Appropriateness of requested data (e.g. CSR vs IPD)

Ensuring Data Stewardship



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

Fostering Collaboration and Responsible Research

YODA Protocol Number 2021-4822	Ongoing Publication Available!
Product(s) of Interest STELARA® (Ustekinumab)	Comparative Efficacy of Ustekinumab and Infliximab on One Year Outcomes Among Biologic-naïve Induction Responders in Crohn's Disease
No. Trials Provided 2	Principal Investigator Neeraj Narula
	Reports & Publications  Inflamm Bowel Dis. 2022
	Cited By  View 1 Citations
	Protocol & Associated Materials  Protocol #2021-4822 Proposal (PDF)  Protocol #2021-4822 Review (PDF)  Protocol #2021-4822 Due Diligence Assessment (PDF)

Experience so far ...

- Of 459 trials currently available, 89.5% have thus far been requested
- Of 385 requests submitted, 368 (95.6%) approved, 4 (1.0%) remain under review; 11 (2.9%) withdrawn/closed, 2 (0.5%) 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
- Median number of trials per request: 3 (IQR, 1-8); 95% for IPD
- 157 manuscripts and 93 abstracts have been submitted, 119 and 89 of which have been published or presented, respectively

scientific data

Check for updates

OPEN
ARTICLE




Clinical trial data sharing: a cross-sectional study of outcomes associated with two U.S. National Institutes of Health models

Anisa Rowhani-Farid¹✉, Mikas Grewal², Steven Solar³, Allen O. Eghrari⁴, Audrey D. Zhang⁵, Cary P. Gross^{2,6,7}, Harlan M. Krumholz^{8,9,10} & Joseph S. Ross^{2,7,8,10}

- **Compared NHLBI centralized to NCI decentralized data sharing models**
- **Identified 2010-2013 trials meeting NIH data sharing criteria, matched on cost or size**
- **77 NHLBI trials, 20 (26%) shared data; 77 NCI trials, 4 (5%) shared data**
- **From the 20 NHLBI trials sharing data, we found 188 secondary internal and 53 shared data publications; for the 4 NCI trials sharing data, we found 65 secondary internal and 2 shared data publications**
- **Centralized model associated with more trials sharing data and more shared data publications**

Characteristics of available studies and dissemination of research using major clinical data sharing platforms

Clinical Trials
1–10
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Enrique Vazquez¹, Henri Gouraud², Florian Naudet² , Cary P Gross^{3,4,5},
Harlan M Krumholz^{6,7,8}, Joseph S Ross^{3,7,8} , and Joshua D Wallach⁹ 

	BioLINCC ^a	CSDR ^c	Project Data Sphere	SOAR-BMS ^d	Vivli ^e	YODA Project
→ Total number of studies listed	219	2897	154	–	(5426) ^e	395
Study design, N (%)						
<i>Clinical trials</i>	164 (74.9)	2876 (99.3)	154 (100.0)	–	–	394 (99.7)
<i>Observational studies</i>	55 (25.1)	21 (0.7)	0 (0.0)	–	–	1 (0.2)
→ Data sets and documents available, N (%)						
<i>IPD (raw or analysis ready)</i>	211 (96.3)	2884 (99.6)	154 (100)	–	–	355 (89.9)
<i>Protocols</i>	157 (71.7)	2773 (95.7)	84 (54.5)	–	–	359 (90.9)
<i>Clinical study reports</i>	4 (1.8)	2785 (96.1)	1 (0.65)	–	–	366 (92.7)
<i>Annotative case report</i>	171 (78.1)	2023 (69.8)	83 (53.9)	–	–	301 (76.2)
<i>Biological specimens</i>	49 (22.4)	0 (0.0)	0 (0.0)	–	–	0 (0.0)
<i>Data specifications</i>	217 (99.1)	2831 (97.7)	149 (96.8)	–	–	281 (71.1)
→ Data requests received, N	–	612	–	202	197	190
Data requests rejected, declined, or out of scope, N (%)	–	105 (17.5)	–	131 (64.8)	10 (5.1)	1 (0.5)
Data requests withdrawn, N (%)	–	144 (23.5)	–	9 (4.4)	24 (12.2)	18 (9.5)
Data requests in progress, N (%)	–	50 (8.2)	–	32 (15.8)	79 (40.1)	12 (6.3)
Data requests approved with contract signature, N (%)	–	313 (51.1)	–	30 (14.9)	84 (42.6)	159 (83.7)
→ Number of approved requests	–	313	–	30	84	159
Ongoing, data access revoked, results not reported, and unclear	–	252 (80.5)	–	24 (80.0)	78 (92.9)	107 (67.3)
→ In peer-reviewed journal	–	61 (19.5)	–	3 (10.0)	4 (4.8)	27 (17.0)
Other (e.g. preprint, conference abstract websites, and platform website only)	–	12 (3.8)	–	3 (10.0)	2 (2.4)	25 (15.7)

How do initially proposed aims compare with published analyses?

Table 3: Concordance between data publications and associated requests across all platforms.

Platform (No. pairs)	Vivli (n=139)	CSDR (n=106)	YODA (n=73)	SOAR-BMS (n=4)
Characteristics	Publication-Request Pairs, No. (%)	Publication-Request Pairs, No. (%)	Publication-Request Pairs, No. (%)	Publication-Request Pairs, No. (%)
Study objective(s)				
Fully concordant	62 (44.6)	40 (37.7)	40 (54.8)	2 (50.0)
Partially concordant	46 (33.1)	36 (34.0)	26 (35.6)	2 (50.0)
Discordant	23 (16.5)	30 (28.3)	7 (9.6)	0 (0.0)
Unclear	8 (5.8)	0 (0.0)	0 (0.0)	0 (0.0)
Trials requested and analyzed				
Fully concordant	76 (54.7)	59 (55.7)	41 (56.1)	3 (75.0)
Discordant	60 (43.2)	24 (22.6)	31 (42.5)	0 (0.0)
	<i>Greater number of trials listed in the data request</i>	60 (43.2)	24 (22.6)	31 (42.5)
	<i>Greater number of trials listed in the publication</i>	0 (0.0)	0 (0.0)	0 (0.0)
Unclear number of trials in the publication	3 (2.1)	23 (21.7)	1 (1.4)	1 (25.0)
Primary endpoint(s)^a				
Undefined primary endpoints	81 (58.3)	-	21 (28.8)	-
	<i>Methods publications</i>	31 (38.3)	21 (100.0)	-
	<i>Unclear or no primary endpoints disclosed</i>	50 (61.7)	0 (0.0)	-
Defined primary endpoints	58 (41.7)	-	52 (71.2)	-
	<i>Fully concordant</i>	23 (39.7)	23 (44.2)	-
	<i>Partially concordant</i>	10 (17.2)	9 (17.3)	-
	<i>Discordant^b</i>	25 (43.1)	20 (38.5)	-
Statistical Methods				
Fully Concordant	63 (45.3)	58 (54.7)	29 (39.7)	3 (75.0)
Partially Concordant	55 (39.6)	28 (26.4)	29 (39.7)	0 (0.0)
Discordant	20 (14.4)	18 (17.0)	12 (16.4)	0 (0.0)
Unclear	1 (0.7)	2 (1.9)	3 (4.2)	1 (25.0)

2 (1.4)

19 (17.9)

3 (4.2)

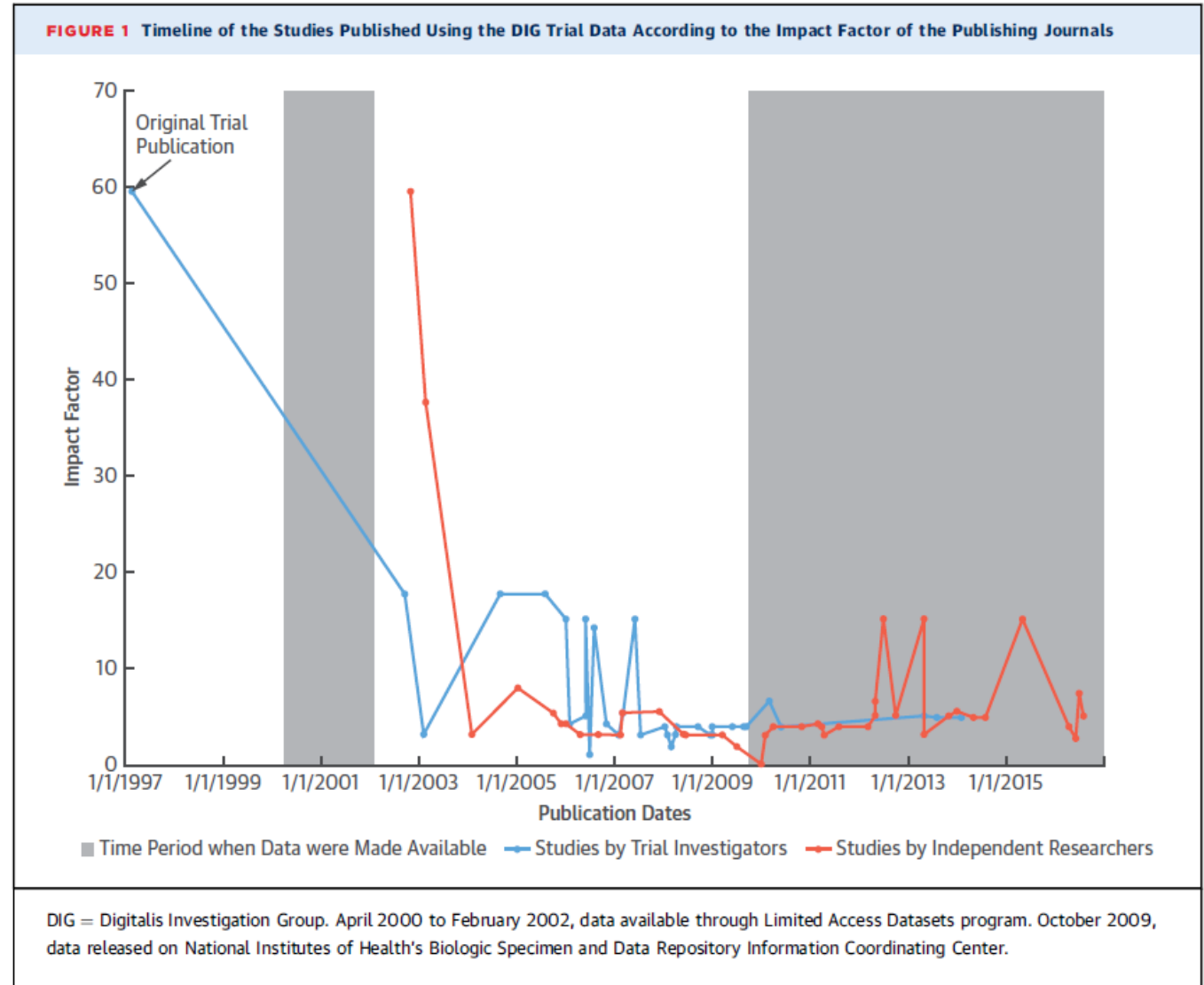
2 (50)

Fully concordant for all reported characteristics

Merits of Data Sharing

The Digitalis Investigation Group Trial

- **Federally funded, run from 1991 through 1995**
- **Trial published in 1997**
- **After which, no publications until 2002**
- **From 2002 through 2016, 75 studies published, 41 (55%) by independent / outside investigators**
 - **34 inside studies: 7 in high-impact, median citations of 6.8**
 - **41 outside studies: 5 in high-impact, median citations of 4.8**
- **230 variables collected, 25% reported in 1st publication, 65% as of 2016**



- **Similar effort under way to evaluate the YODA Project platform**
- **For ~400 trials used at least once:**
 - **When was main trial first published?**
 - **How many total studies published?**
 - **How many by trial teams and how many by independent / outside investigators?**
 - **Among inside and outside studies:**
 - **Proportion published in high-impact journals?**
 - **Median citation number?**
 - **Proportion cited in clinical practice guidelines?**
 - **What else?**

Strengthening Science through Data Sharing

- Numerous studies that might not otherwise have been feasible to pursue, some of which have impacted health policies and guidelines
- Facilitated direct collaborations with original investigators
- Developed efficiencies (J&J now conducts all trials intending to share)
- Replication studies have supported – not undermined – original study
- No instances of patient privacy breaches
- No publications of spurious safety findings that received unwarranted attention or disrupted patient care
- No data have been used for commercial or litigious purposes

Challenges Remain

- **Broadening awareness of data availability**
- **Fostering expertise in using data from clinical trials (*it's complicated*)**
- **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, including centralized platform (especially for NIH)**
- **Data Use Agreements ...**
- **Establish standards: when should data be available, for how long, how to reward those who share data?**
- **Many large pharma sharing, now NIH, what about other sponsors?**

SCIENTIFIC DATA

OPEN

Overview and experience of the YODA Project with clinical trial data sharing after 5 years

Joseph S. Ross^{1,2,3,4}, Joanne Waldstreicher⁵, Stephen Bamford⁶, Jesse A. Berlin⁵, Karla Childers⁵, Nihar R. Desai^{4,7}, Ginger Gamble⁴, Cary P. Gross^{1,2,4,8}, Richard Kuntz⁹, Richard Lehman¹⁰, Peter Lins⁵, Sandra A. Morris⁵, Jessica D. Ritchie⁴ & Harlan M. Krumholz^{2,3,4,7}

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The Yale University Open Data Access (YODA) Project has facilitated access to clinical trial data since 2013. The purpose of this article is to provide an overview of the Project, describe key decisions that were made when establishing data sharing policies, and suggest how our experience and the experiences of our first two data generator partners, Medtronic, Inc. and Johnson & Johnson, can be used to enhance other ongoing or future initiatives.

<http://yoda.yale.edu>

@YODAProject



@jsross119

joseph.ross@yale.edu