ClinicalTrials.gov: Increasing the Transparency of Clinical Research

Presented by Diana Nelson Louden, MLIBR

12:45pm-1:45pm

UW Husky Union Building

Room 145

ITHS | Institute of Translational Health Sciences

ACCELERATING RESEARCH. IMPROVING HEALTH.

ClinicalTrials.gov: Increasing the Transparency of Clinical Research

Diana Nelson Louden
Biomedical & Translational Sciences Librarian
University of Washington Health Sciences Library
July 31, 2019

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Why is a Librarian Talking About Clinical Trials.gov?

- We provide support throughout the biomedical research lifecycle.
- We help people find relevant public biomedical information.
- ClinicalTrials.gov is hosted by the National Library of Medicine.

ARNOLD LIBRARY
a Fred Hutch Shared Resource

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Seattle Children's
HOSPITAL · RESEARCH · FOUNDATION

Action figure from Archie McPhee

Goals for this Session

- Learn about the contents of ClinicalTrials.gov and how this data is used by researchers and the public.
- Describe legal, NIH, and publisher requirements for submitting data.
- Understand the role of ClinicalTrials.gov in increasing the transparency of clinical research.

- Contents
  - Clinical trial registry (starting in 2000)
  - Trial results (starting in 2008)
- Submitters
  - Trial sponsors, both private and public
- Audiences
  - Patients and families
  - Researchers and clinicians
  - Study record managers

Contents of ClinicalTrials.gov

Row	Saved	Status	Study Title	Conditions	Interventions	Locations
2	☐	Recruiting NEW	Veterans Nature Therapy (Vet Hike)	• Posttraumatic Stress Disorders	• Behavioral: Group nature hikes • Behavioral: Group urban hikes	• VA Puget Sound Health Care System Seattle, Washington, United States
3	☐	Not yet recruiting NEW	XperGuide in Sacroiliac Joint Injection	• Sacroiliitis • Sacroiliac Joint Pain	• Other: sacroiliac joint injection	• UW Center for Pain Relief Seattle, Washington, United States
4	☐	Not yet recruiting NEW	Inotuzumab Ozogamicin and Chemotherapy in Treating Patients With Recurrent or Refractory B-cell Acute Lymphoblastic Leukemia	• Blasts 5 Percent or More of Bone Marrow Nucleated Cells • Blasts 5 Percent or More of Peripheral Blood White Cells • CD22 Positive • (and 4 more...)	• Drug: Etoposide • Drug: Doxorubicin • Drug: Doxorubicin Hydrochloride • (and 6 more...)	• Fred Hutch/University of Washington Cancer Consortium Seattle, Washington, United States
5	☐	Not yet recruiting	Developing Low-Cost Universal Malnutrition Screening for Low Income Countries - the MAMMS Trial	• Child Malnutrition	• Other: Maternal Administered Malnutrition Monitoring System (MAMMS)	
6	☐	Recruiting	Harm Reduction for Tobacco Smoking With Support of Tobacco-Replacing Electronic Nicotine Delivery Systems	• Smoking, Tobacco	• Other: HaRTS-TRENDS • Other: Standard Care (SC)	• University of Washington - Harborview Medical Center Seattle, Washington, United States

Thrive, a Computerized Cognitive Behavior Therapy Program to Treat Depression Among Rural Montanans

- > Study design
- > Outcome measures
- > Inclusion & Exclusion criteria
- > Status and relevant dates

ClinicalTrials.gov Identifier: NCT03244878

Study Design

Study Type :	Interventional (Clinical Trial)
Actual Enrollment :	464 participants
Allocation:	Randomized
Intervention Model:	Parallel Assignment
Intervention Model Description:	Participants are randomized to either the wait-list controlled group or intervention group. Intervention period is 8 weeks. Data collection occurs at baseline, 4 weeks, and 8 weeks, with longer-term follow-up assessments.
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	Randomized Controlled Trial of a Culturally-adapted Version of Thrive, a Computerized Cognitive Behavior Therapy (cCBT) Program to Treat Depressive Symptoms, Syndromes, and Disorders Among Rural Montanans
Actual Study Start Date :	May 1, 2017
Actual Primary Completion Date :	January 31, 2018
Actual Study Completion Date :	January 31, 2018

Benefits to the Public

- Meet ethical obligation to human subjects, i.e., that results will be used to help others/inform science
- Enhance patient access to enrollment in clinical trials
- Increased transparency of clinical research being conducted by pharmaceutical companies and with federal funding
- May contribute to increased public trust in clinical research

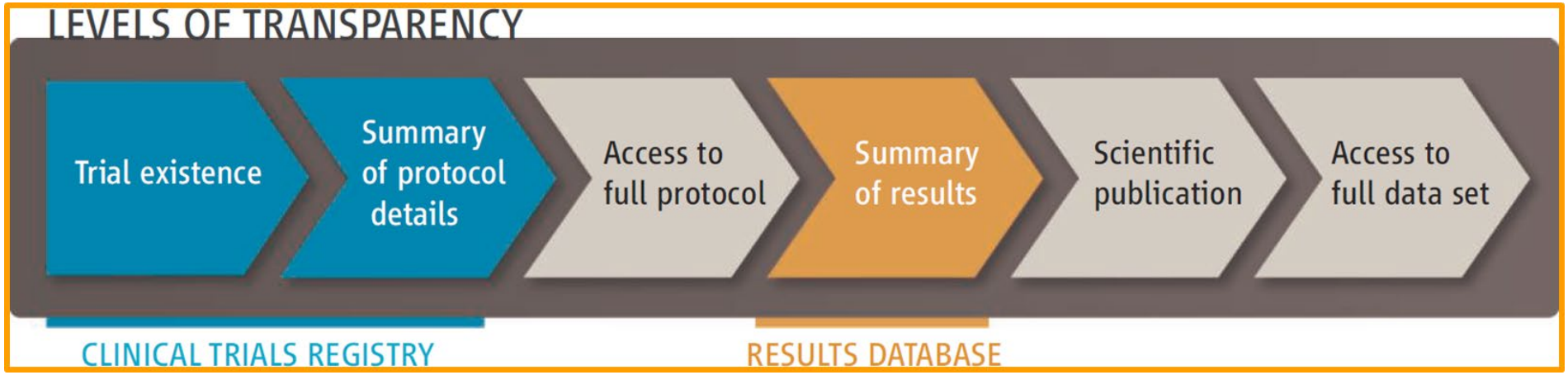
U.S. Air Force photo/Airman 1st Class Kyle Johnson

Benefits to the Clinical Research Process

- Inform future research and research funding decisions
- Mitigate information bias (e.g., non-publication)
- Evaluate research integrity (e.g., adherence to protocol)
- Prevent duplication of trials of unsafe or ineffective interventions
- Provide access to data to support evidence-based medicine

Levels of Transparency

"Transparency exists along a continuum from documentation that a trial exists to full disclosure of the results data set at the end of the trial."



Zarin DA, Tse T. Moving toward transparency of clinical trials. Science. 2008 Mar 7;319(5868):1340-2

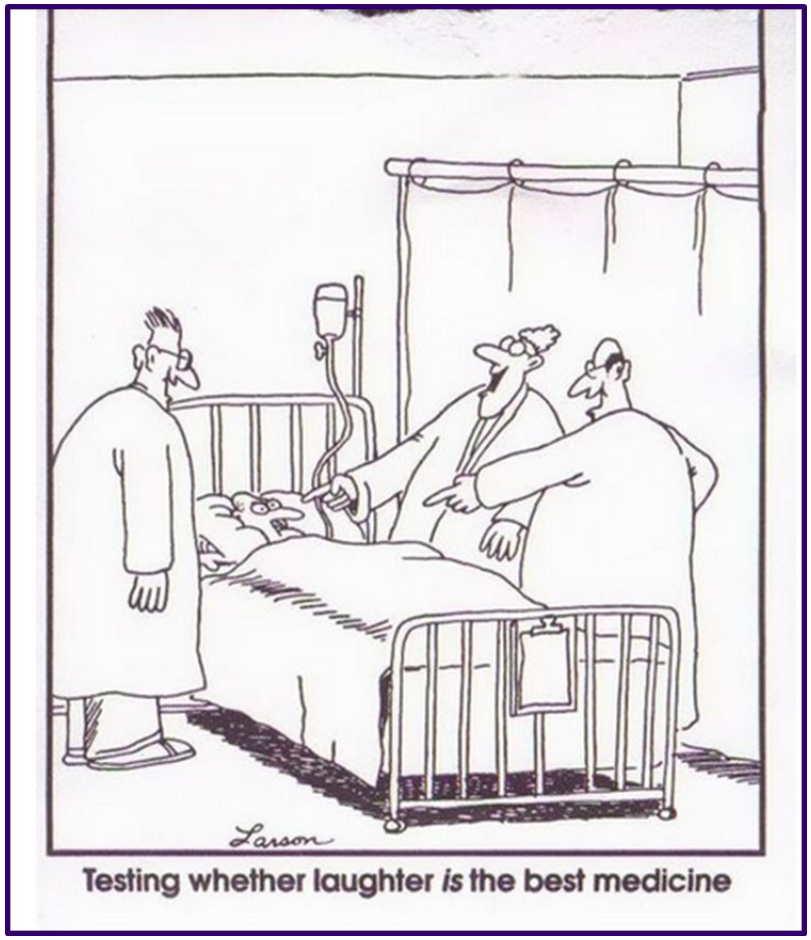
Illustrating the Benefits of a Trial Registry and Results Database

Assuming this is an IRB-Approved, NIH-funded trial involving multiple patients and a control group…

How does registration of this trial benefit the clinical research process?

How does registration of this trial benefit the public?

If this trial shows no benefit to patients, what is the benefit of documenting the results in ClinicalTrials.gov?



Testing whether laughter *is* the best medicine

ClinicalTrials.gov Fulfills its Purpose if the Information is Complete and Discoverable

- Data needs to be high quality.
- Record formats and terminology need to be standardized.

Study Design Go to

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- All relevant studies need to be included.

Who Requires Trial Registration and, in Some Cases, Results Reporting?

ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

- ICMJE policy applies to many scientific journals, such as American Journal of Nursing, Pediatrics, & Transplantation
- Trial registration is a condition of consideration for publication.

FDA

- FDAAA 801 and 42 CFR Part 11 "The Final Rule" require that Applicable Clinical Trial data be submitted no later than 21 days after enrollment of 1st participant.
- Results must be reported no later than 1 year after primary completion date.

NIH National Institutes of Health
Turning Discovery Into Health

- Trial registration and results reporting are requirements for NIH-funded trials, whether or not they are FDA regulated.

BILL & MELINDA GATES foundation

- Organizations such as the Gates Foundation, Wellcome Trust, & PATH require trial registration & results reporting.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

- Trials submitting claims to the Centers for Medicare & Medicaid Services must include the NCT number from ClinicalTrials.gov

ICMJE = International Committee of Medical Journal Editors
FDAAA 801 = Section 801 of the Food and Drug Administration Amendments Act of 2007

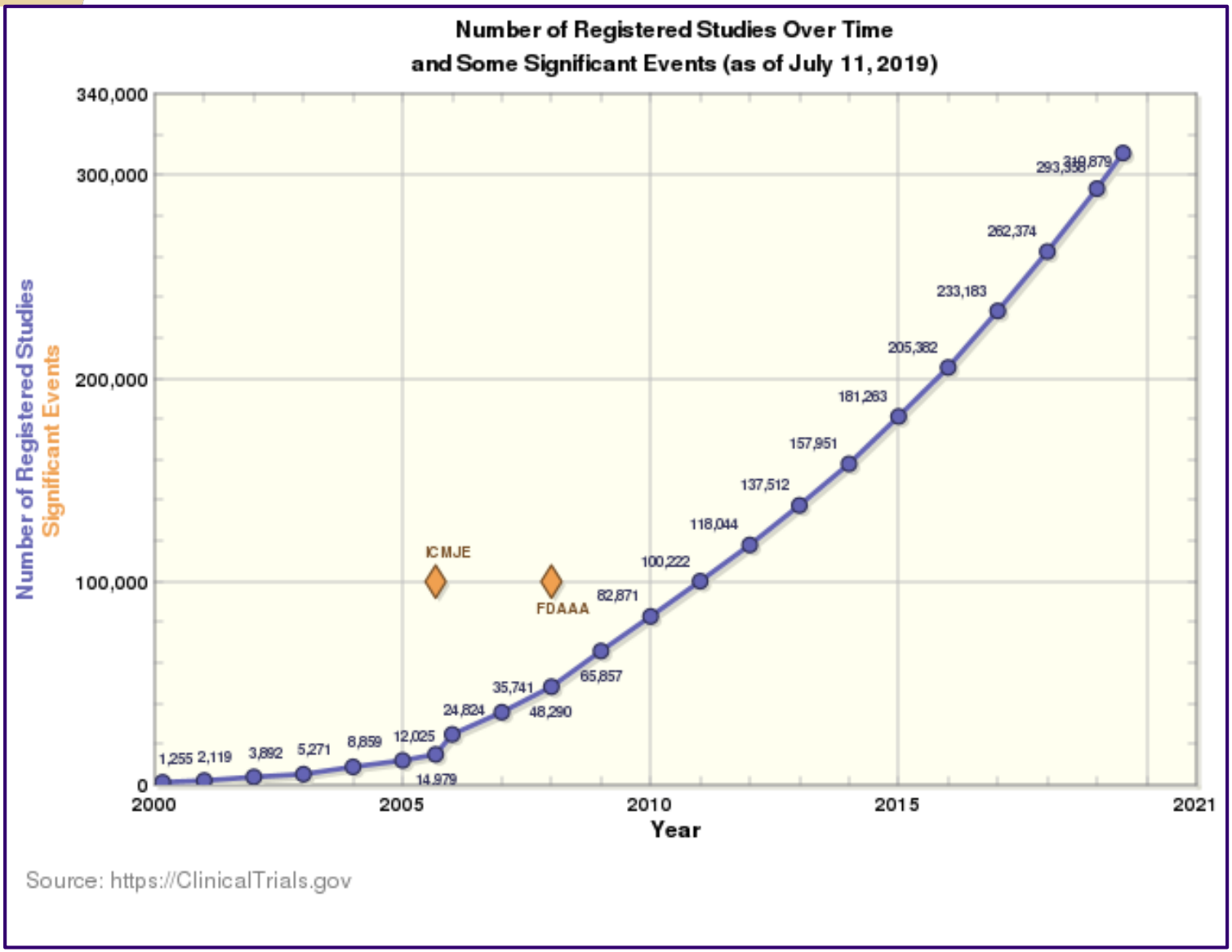
Joint Statement on Public Disclosure of Results from Clinical Trials (2017)

"In addition to the ethical imperative, poor allocation of resources for product development and financing of available interventions, and suboptimal regulatory and public health recommendations may occur where decisions are based on only a subset of all completed clinical trials."

who.int/ictrp/results/jointstatement/en/

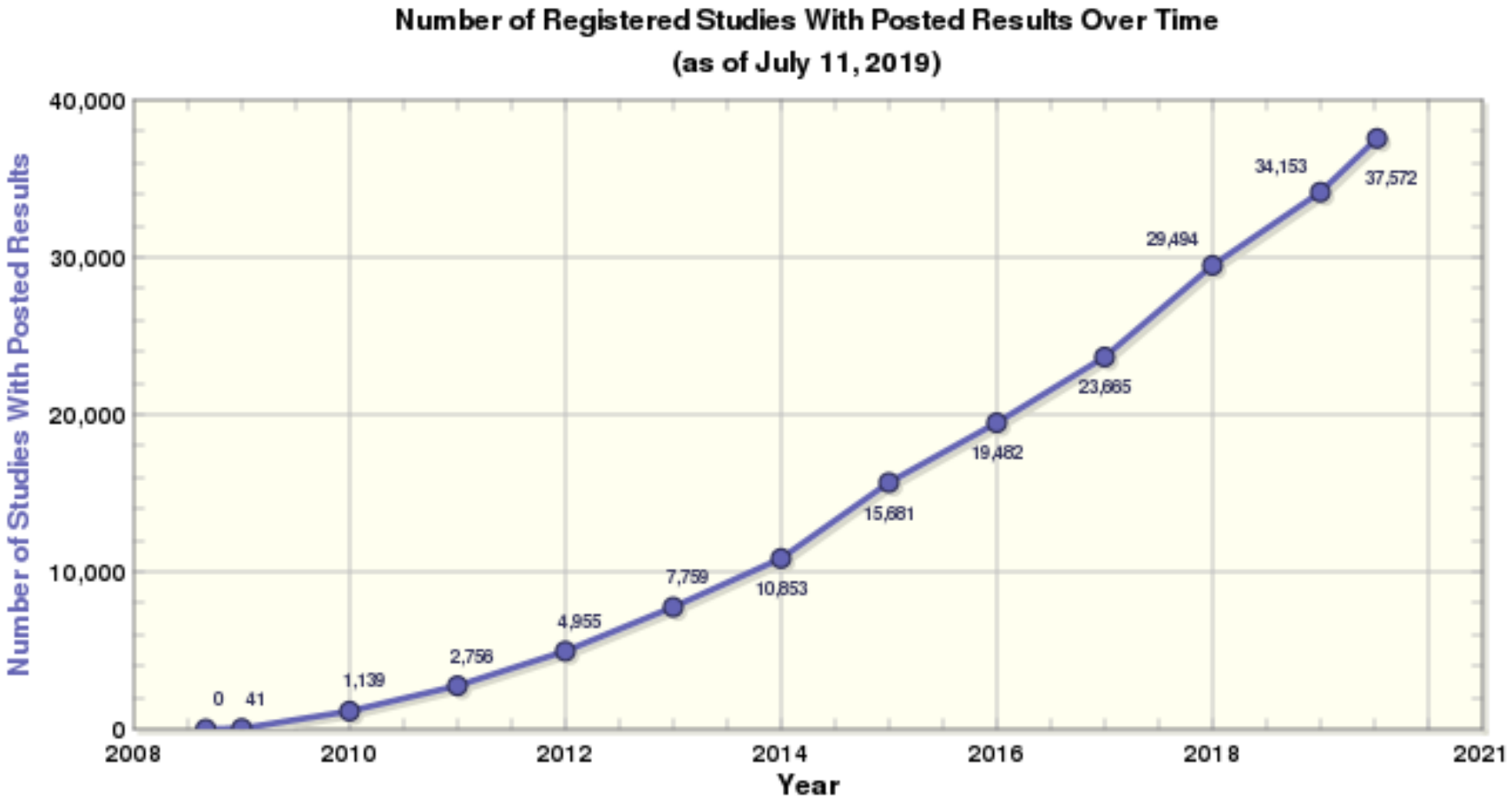
Are 100% of Applicable Clinical Trials Entered in Clinical Trials.gov?

No, but…



Source: https://ClinicalTrials.gov

Trials With Results Data



Source: https://ClinicalTrials.gov

Significant Changes in Trial Registration as of 2017: Expanded FDA Regulation and New NIH Policy

A summary table describes the changes. Three especially noteworthy changes (highlighted by the UW Human Subjects Division) are:

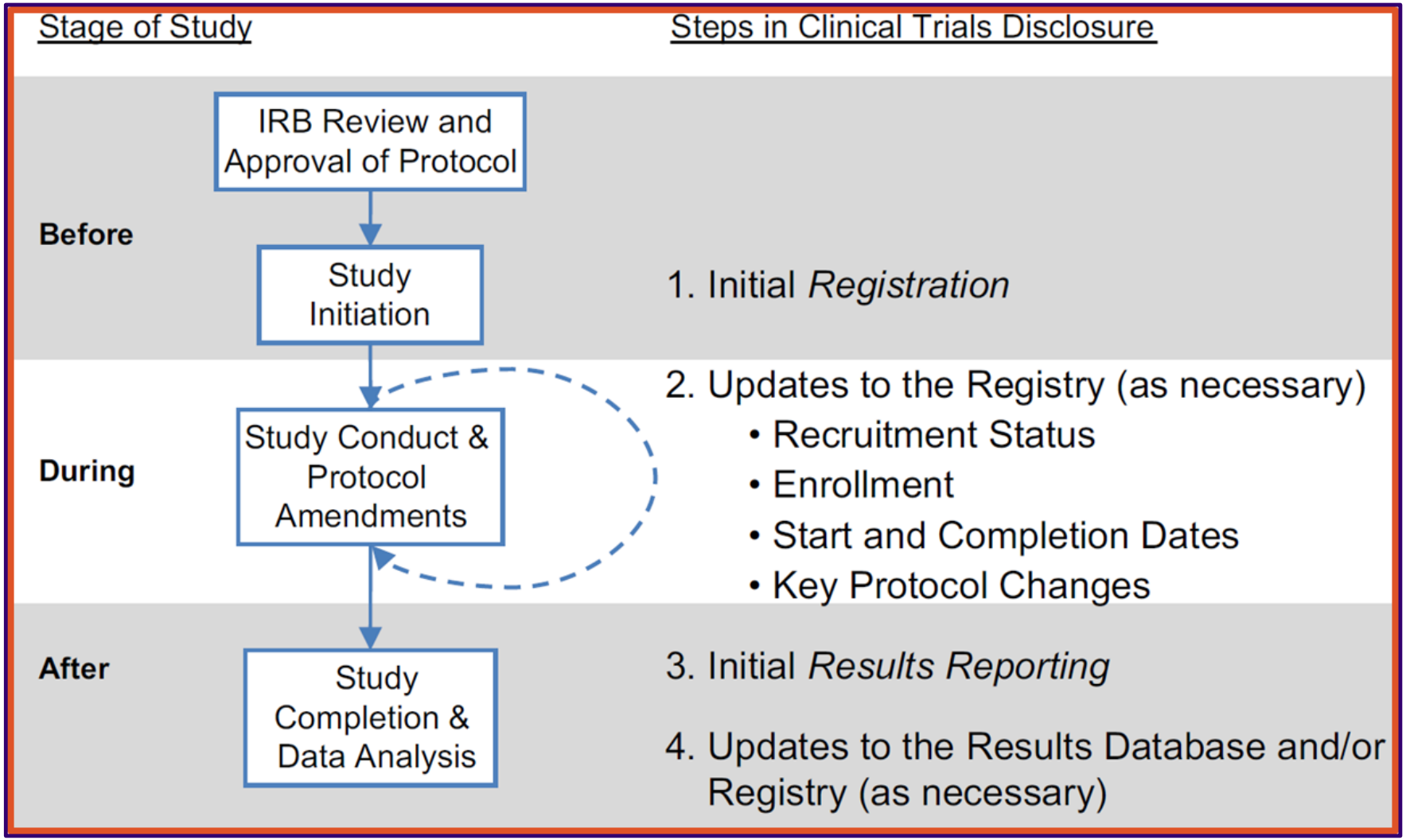
1. All clinical trials funded in whole, or in part, by NIH must be registered, regardless of study phase or type of intervention.
2. Study consent forms must contain a sentence about the trial registration, using the words provided by the FDA and NIH.
3. Penalties for non-compliance may include:
   - Identifying the clinical trial record as non-compliant in ClinicalTrials.gov
   - Suspension or termination of grant or contract funding, if required registration and reporting cannot be verified
   - Consideration of the non-compliance in future funding decisions
   - Civil monetary penalties to the "responsible party" (PI) of up to $10,000/day

Roles & Legal Responsibilities at UW

Who	What	Why
Lead PI	• Register the trial • Update the record • Report the results • Consent statement	42 CFR 11 NIH Policy
Site PI	Consent statement	42 CFR 11 NIH Policy
IRB	Consent form has the statement	21 CFR 50.25(c) 21 CFR 56.111(a)(4,5)
UW ↳ HSD	• Institutional contact for ClinicalTrials.gov • Help with researcher account	ClinicalTrials.gov requirement

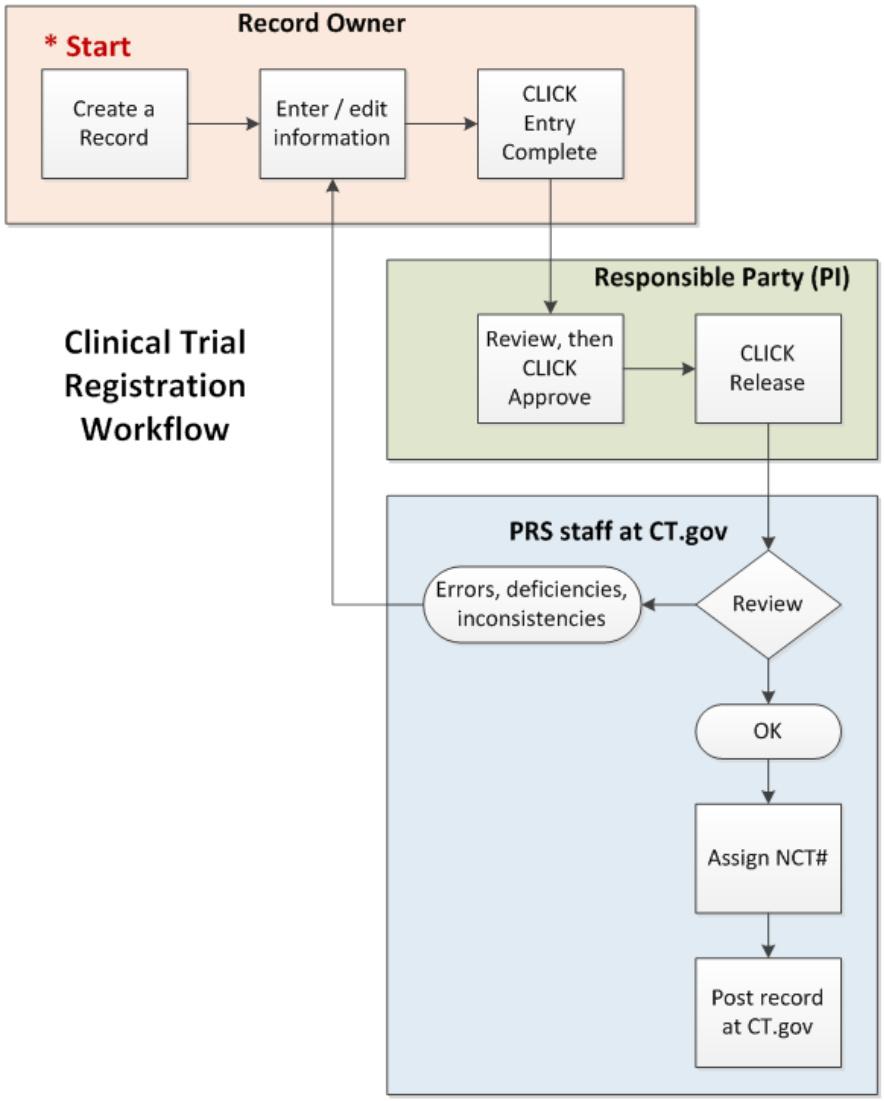
Thank you to the UW Human Subjects Division

When Do Registration & Results Reporting Occur?



Tse T, Zarin DA, Williams RJ, Ide NC. The Role and Importance of Clinical Trial Registries and Results Databases. In: Gallin JI, Ognibene FP, editors. Principles and Practice of Clinical Research. London: Academic Press; c2012. p. 171-181.

Clinical Trial Registration Workflow



Record Owner

Responsible Party (Principal Investigator)

PRS Staff at ClinicalTrials.gov

washington.edu/research/forms-and-templates/clinical-trial-registration-work-flow

Help is Available

- Help from your institution's human subjects department.
- Tools to help you determine if your study is considered a clinical trial under the NIH's revised definition.
- Possible to upload study data to ClinicalTrials.gov from within the NIH's eRA Human Subjects System
- ClinicalTrials.gov user support materials.
  - "How to" information
  - Policies of VA, National Cancer Institute, PCORI, etc.

Submitting High Quality Information: Specificity and Consistency

- > Required Data Elements
- > Internal Consistency
- > Appropriate Level of Specificity
- > Standardized Terminology When Appropriate

Outcome Measure Type *
Definition: The type of outcome measure. Select one.

- Primary
- Secondary
- Other Pre-specified
- Post-Hoc

ClinicalTrials.gov Results Data Element Definitions for Interventional and Observational Studies
prsinfo.clinicaltrials.gov/results_definitions.html

Outcome Measure Title *
Definition: Name of the specific outcome measure.
Limit: 255 characters.

Outcome Measure Description [*]
Definition: Additional information about the outcome measure, including a description of the metric used to characterize the specific outcome measure, if not included in the Outcome Measure Title.
Limit: 999 characters.

Outcome Measure Time Frame *
Definition: Time point(s) at which the measurement was assessed for the specific metric used. The description of the time point(s) of assessment must be specific to the outcome measure and is generally the specific duration of time over which each participant is assessed (not the overall duration of the study).
Limit: 255 characters.

ClinicalTrials.gov Protocol Registration Quality Control Review Criteria - Examples

- Interventions are referred to by the same name throughout the study record.
- If more than one name is used for the same drug (e.g., a generic name and a brand name), the study record clearly indicates that the drugs are the same.
- The Arm Description or Group/Cohort Description include details about the intervention strategies administered (e.g., dosage, dosage form, frequency of administration, duration of administration) or groups evaluated.
- Use, if available, appropriate descriptors from NLM's Medical Subject Headings (MeSH) thesaurus.

*Quality Control Review Criteria for **Registration** and **Results***

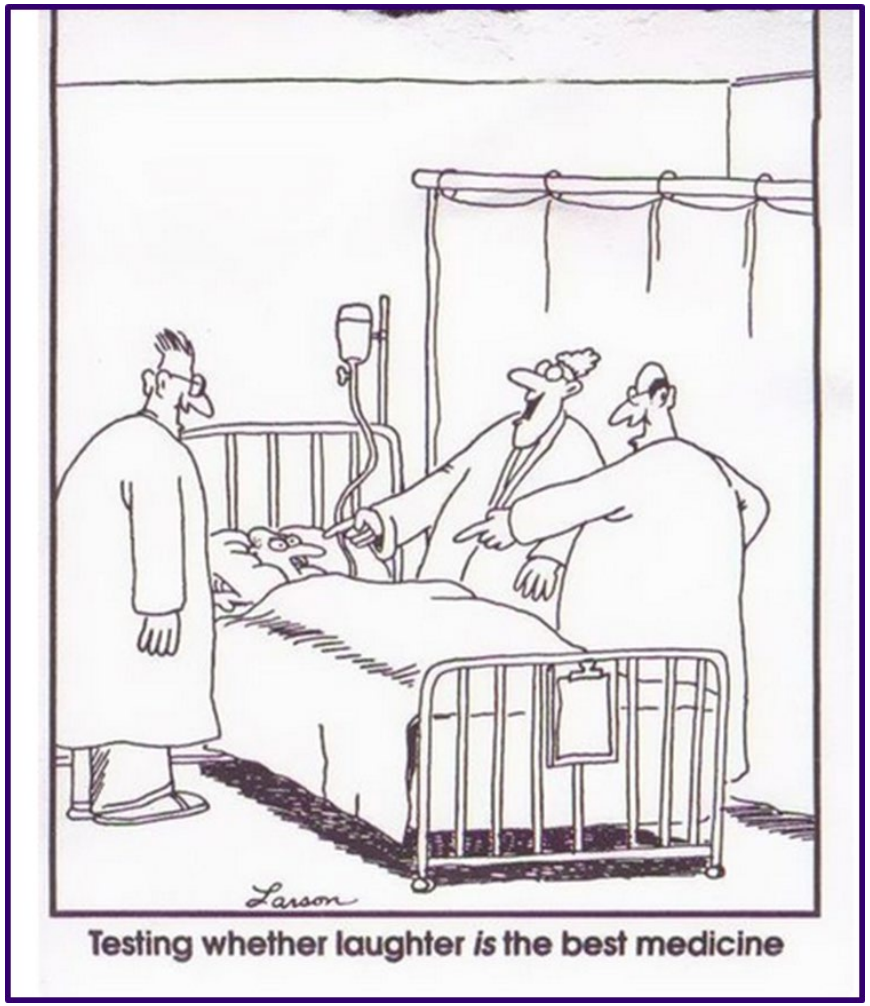
Effectiveness of laughter in alleviating postoperative pain following colorectal resection

Population: hospitalized patients who have undergone colorectal resection for colon cancer.

Study design: 48 patients, randomized to laughter + usual treatment or usual treatment.

Treatment protocol: Laughter administered 3 times a day for 3 days.

Outcomes: Pain measured with the 2010 Revised American Pain Society Patient Outcome Questionnaire



Some Required Data Elements for Trial Registration

Study Description Go to

Brief Summary:

This prospective, randomized, double-blind study will enroll nonsmoking female subjects undergoing laparoscopic bariatric surgery under general anesthesia. The hypothesis of this study is that female nonsmokers who receive nicotine via nasal spray immediately before waking up from anesthesia will need less pain medications 24 hours after the surgery compared to the subjects who receive placebo spray.

Condition or disease	Intervention/treatment	Phase
Pain, Postoperative	Drug: Nasal Nicotine Spray Drug: Nasal Normal Saline Spray	Phase 4

Outcome Measure Title and Time Frame Fields Are Highlighted

Primary Outcome Measures :

1. Postoperative Opioid Use During the Postanesthesia Care Unit (PACU) Stay, and the First 24 Hours Postoperatively [Time Frame: During PACU stay (approximately 94 minutes after operation), 24 hours after operation]

   Opioid use was calculated in intravenous morphine equivalents (iv MEQ) according to the Mayo Clinic Pharmacy opioid conversion calculator based on the recommendations from the American Pain Society. Specifically, the following conversion was used: 10 mg in MEQ=100mcg iv fentanyl=1.5 mg iv hydromorphone=20mg oral oxycodone=30mg oral hydrocodone.

More Suitable Documentation: A or B?

Data Element: Primary Disease or Condition Being Studied in the Trial

A	B
Surgical Pain	Pain, Postoperative [a Medical Subject Heading]

More Suitable Documentation: A or B?

Data Element: Study Description: Brief Summary

A	B
Objective: evaluate the effectiveness of laughter in alleviating postoperative pain following colorectal resection	Objective: evaluate the effectiveness of laughter in alleviating postoperative pain following colorectal resection

Data Element: Arm Title (Used for Interventional Studies)

A	B
Experimental Arm 1: Chuckling administered 3 times/day	Experimental Arm 1: Laughter administered 3 times/day

More Suitable Documentation: A or B?

Data Element: Outcome Measure Title

A	B
Pain	Mean Change from Baseline in Scores on the 2010 Revised American Pain Society Patient Outcome Questionnaire

Data Element: Outcome Measure: Time Frame

A	B
Daily through study completion	2 hours post-surgery; then daily during hospitalization, approximately 3 days.

Improved Access to Information for Researchers & Clinicians

BMC Med Genet. 2013 Jan 11;14:6. doi: 10.1186/1471-2350-14-6.

Effects of smoking on the genetic risk of obesity: the population architecture using genomics and epidemiology study.

Fesinmeyer MD[1], North KE, Lim U, Bůžková P, Crawford DC, Haessler J, Gross MD, Fowke JH, Goodloe R, Love SA, Graff M, Carlson CS, Kuller LH, Matise TC, Hong CP, Henderson BE, Allen M, Rohde RR, Mayo P, Schnetz-Boutaud N, Monroe KR, Ritchie MD, Prentice RL, Kolonel LN, Manson JE, Pankow J, Hindorff LA, Franceschini N, Wilkens LR, Haiman CA, Le Marchand L, Peters U.

Author information

1 Division of Public Health Sciences, Fred Hutchinson Cancer Research Center, Seattle, WA 98109-1024, USA.

Abstract

BACKGROUND: Although smoking behavior is known to affect body mass index (BMI), the potential for smoking to influence genetic associations with BMI is largely unexplored.

METHODS: As part of the 'Population Architecture using Genomics and Epidemiology (PAGE)' Consortium, we investigated interaction between genetic risk factors associated with BMI and smoking for 10 single nucleotide polymorphisms (SNPs) previously identified in genome-wide association studies. We included 6 studies with a total of 56,466 subjects (16,750 African Americans (AA) and 39,716 European Americans (EA)). We assessed effect modification by testing an interaction term for each SNP and smoking (current vs. former/never) in the linear regression and by stratified analyses.

RESULTS: We did not observe strong evidence for interactions and only observed two interactions with p-values <0.1: for rs6548238/TMEM18, the risk allele (C) was associated with BMI only among AA females who were former/never smokers (β = 0.018, p = 0.002), vs. current smokers (β = 0.001, p = 0.95, p(interaction) = 0.10). For rs9939609/FTO, the A allele was more strongly associated with BMI among current smoker EA females (β = 0.017, p = 3.5 x 10(-5)), vs. former/never smokers (β = 0.006, p = 0.05, p(interaction) = 0.08).

CONCLUSIONS: These analyses provide limited evidence that smoking status may modify genetic effects of previously identified genetic risk factors for BMI. Larger studies are needed to follow up our results.

CLINICAL TRIAL REGISTRATION: NCT00000611.

Full text links

Read free full text at BMC | PMC FREE Full text | ClinicalTrials.gov | Check for Full Text W | UW ARTICLE ONLINE

Save items

Add to Favorites

Similar articles

A systematic mapping approach of 16q12.2 and BMI in more than 20,000 [PLoS Genet.

Interaction of FTO and physical activity leve adiposity in African [Obesity (Silver Spring).

BMI loci and longitudinal BMI from adolesce to young adulthood in a [Int J Obes (Lond).

Influence of common variants in FTO and n INSIG2 and MC4R on gro [Eur J Epidemiol.

Review Genetic association studies of obes Africa: a systematic review. [Obes Rev.

See rev

Se

Data for Large-Scale Analysis

Table. Sex Bias in Clinical Studies Determined From Published Articles and Clinical Trial Records[a]

Disease Category	Global Female Prevalence Fraction	Measurement Unit	Published Articles			AACT Records		
			Studies or Participants, No.	Female Participant Fraction	Sex Bias (95% CI)	Studies or Participants, No.	Female Participant Fraction	Sex Bias (95% CI)
Cardiovascular	0.51	Studies	14 371	0.37	−0.14 (−0.14 to −0.13)[b]	2164	0.41	−0.10 (−0.11 to −0.09)[b]
		Participants	540 050 700	0.49	−0.02 (−0.06 to −0.01)	2 229 071	0.39	−0.12 (−0.15 to −0.08)[b]
Diabetes	0.48	Studies	3727	0.45	−0.03 (−0.03 to −0.02)[b]	1420	0.46	−0.03 (−0.03 to −0.02)[b]
		Participants	38 420 434	0.48	0.00 (−0.05 to 0.04)	4 823 058	0.47	−0.01 (−0.08 to 0.02)
Digestive	0.60	Studies	1282	0.49	−0.11 (−0.12 to −0.10)[b]	348	0.54	−0.06 (−0.08 to −0.04)[b]
		Participants	8 519 928	0.51	−0.09 (−0.13 to −0.07)[b]	147 821	0.56	−0.03 (−0.06 to −0.01)
Hepatitis A, B, C, and E	0.44	Studies	1131	0.34	−0.09 (−0.10 to −0.09)[b]	632	0.37	−0.06 (−0.07 to −0.05)[b]
		Participants	1 833 724	0.37	−0.06 (−0.17 to 0.06)	243 846	0.39	−0.05 (−0.07 to −0.03)[b]
HIV/AIDS	0.50	Studies	1741	0.33	−0.17 (−0.18 to −0.16)[b]	387	0.27	−0.23 (−0.25 to −0.21)[b]
		Participants	30 459 386	0.53	0.02 (−0.09 to 0.06)	155 531	0.35	−0.15 (−0.20 to −0.11)[b]
Kidney, chronic	0.57	Studies	2554	0.40	−0.17 (−0.17 to −0.16)[b]	476	0.42	−0.15 (−0.16 to −0.13)[b]
		Participants	18 747 970	0.44	−0.13 (−0.18 to −0.09)[b]	201 763	0.42	−0.15 (−0.17 to −0.12)[b]
Mental	0.48	Studies	3635	0.47	−0.01 (−0.02 to 0.00)[b]	1650	0.44	−0.04 (−0.05 to −0.03)[b]
		Participants	58 097 584	0.48	−0.01 (−0.19 to 0.07)	463 645	0.49	0.00 (−0.01 to 0.02)
Musculoskeletal	0.56	Studies	2418	0.66	0.10 (0.09 to 0.11)[b]	983	0.70	0.14 (0.13 to 0.15)[b]
		Participants	5 898 338	0.60	0.03 (0.00 to 0.08)	438 112	0.65	0.09 (−0.05 to 0.18)
Neoplasms	0.51	Studies	11 121	0.40	−0.11 (−0.11 to −0.11)[b]	3179	0.41	−0.10 (−0.11 to −0.10)[b]
		Participants	54 377 430	0.49	−0.03 (−0.04 to −0.01)[b]	2 946 236	0.50	−0.02 (−0.09 to 0.03)
Neurological	0.59	Studies	3431	0.50	−0.09 (−0.10 to −0.09)[b]	1338	0.52	−0.07 (−0.08 to −0.06)[b]
		Participants	10 576 242	0.53	−0.06 (−0.09 to −0.03)[b]	497 964	0.65	0.06 (−0.01 to 0.12)
Respiratory, chronic	0.48	Studies	2800	0.43	−0.04 (−0.05 to −0.04)[b]	1161	0.44	−0.03 (−0.04 to −0.02)[b]
		Participants	116 410 829	0.48	0.00 (−0.05 to 0.02)	1 231 162	0.47	−0.01 (−0.04 to 0.01)
Total[c]	0.54	Studies	48 211	0.42	−0.12 (−0.12 to −0.11)[b]	13 738	0.45	−0.09 (−0.09 to −0.08)[b]
		Participants	883 392 565	0.49	−0.05 (−0.06 to −0.03)[b]	13 378 210	0.48	−0.06 (−0.09 to −0.03)[b]

Feldman S et al. Quantifying Sex Bias in Clinical Studies at Scale With Automated Data Extraction. *JAMA Netw Open.* July 03, 20192(7):e196700.

Improved Access to Information for Patients & Families

9 Studies found for: **Recruiting, Not yet recruiting Studies | Crohn Disease | Washington, United States | Child**

Applied Filters: ☑ **Recruiting** ☑ **Not yet recruiting** ☑ **Child (birth–17)**

Saved	Status	Study Title	Conditions	Interventions	Locations
☐	Recruiting	Reverse Engineering of Exclusive Enteral Nutrition	• **Crohn Disease**	• Other: Nutritional therapy	• Seattle Children's Hospital Seattle, **Washington**, **United States**
☐	Recruiting	A Study of the Efficacy and Safety of Risankizumab in Subjects With Moderately to Severely Active **Crohn's Disease**	• **Crohn's Disease**	• Drug: placebo for risankizumab • Drug: risankizumab IV • Drug: risankizumab SC	• Phoenix VA Healthcare /ID# 162267 Phoenix, Arizona, **United States** • HonorHealth Research Institute - Shea /ID# 161783 Scottsdale, Arizona, **United States** • Physician's Research Group /ID# 211883 Tempe, Arizona, **United States** • (and 471 more...)

"Access to more information about clinical trials is good for patients, the public and science. The final rule and NIH policy…will help maximize the value of clinical trials…and help us honor our commitments to trial participants, who do so much to help society advance knowledge and improve health."

~NIH Director Francis Collins

nih.gov/news-events/news-releases/hhs-takes-steps-provide-more-information-about-clinical-trials-public

Resources and Further Reading

- PRS User's Guide: Instructions for using the Protocols Registration & Results System (PRS) to submit clinical study information to ClinicalTrials.gov
- Quality Control Review Criteria for Registration and Results. ClinicalTrials.gov.
- Frequently Asked Questions on ClinicalTrials.gov & FDAAA. National Institutes of Health.
- FDAAA 801 and the Final Rule. Summary of Food and Drug Administration (FDA) requirements relating to ClinicalTrials.gov
- Summary Table of HHS/NIH Initiatives to Enhance Availability of Clinical Trial Information. National Institutes of Health.
- NIH Definition of Clinical Trial Case Studies.
- Steps to Compliance for NIH Awardees.
- Clinical Trial Registration Policy. International Committee of Medical Journal Editors
- ClinicalTrials.gov staff email: register@clinicaltrials.gov

Resources and Further Reading, p.2

- University of Washington Human Subjects Division: Clinical Trials Registration and Reporting
- Fred Hutch Clinical Research Support: CTRP & ClinicalTrials.gov
- Seattle Children's Clinical Research Support Office: Registration of Clinical Research Trials on ClinicalTrials.gov
- Friedman, L., Furberg, Curt, DeMets, David L., Reboussin, David, & Granger, Christopher B. (2015). Fundamentals of clinical trials (Fifth ed.). New York: Springer. Chapter 20 "Reporting and Interpreting of Results." [*ebook version available to UW affiliates*]
- FDAAA Trials Tracker. Evidence Based Medicine DataLab, University of Oxford.

Acknowledgements

- Kristina Elliott, MLS, Web Content and Outreach Coordinator, ClinicalTrials.gov
- Elaina Vitale, MLIS, formerly Academic Coordinator at the National Network of Libraries of Medicine, Middle Atlantic Region
- Emily Patridge, MLS, Assistant Director of Clinical Research & Data Services, University of Washington Health Sciences Library
- University of Washington Human Subjects Division Staff