



Introduction to Clinical Research **Boot Camp 2021**

Research Staff

July 19-23

12:00-1:00pm PDT

ITHS

Institute of **Translational** Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.



Thursday, July 22, 2021

Leslie Gascon, MBA, MS(LIS)

**ClinicalTrials.gov:
Increasing the Transparency of
Clinical Research**

Why is a Librarian Talking About This?

- We provide support throughout the research lifecycle.
- We help people find, use, manage, & share information.
- ClinicalTrials.gov is hosted by the National Library of Medicine.



Image credit: Brian Dewey

Learning Objectives

- 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.

ClinicalTrials.gov

Database Contents

- Clinical trial registry (starting in 2000)
- Trial results (starting in 2008)

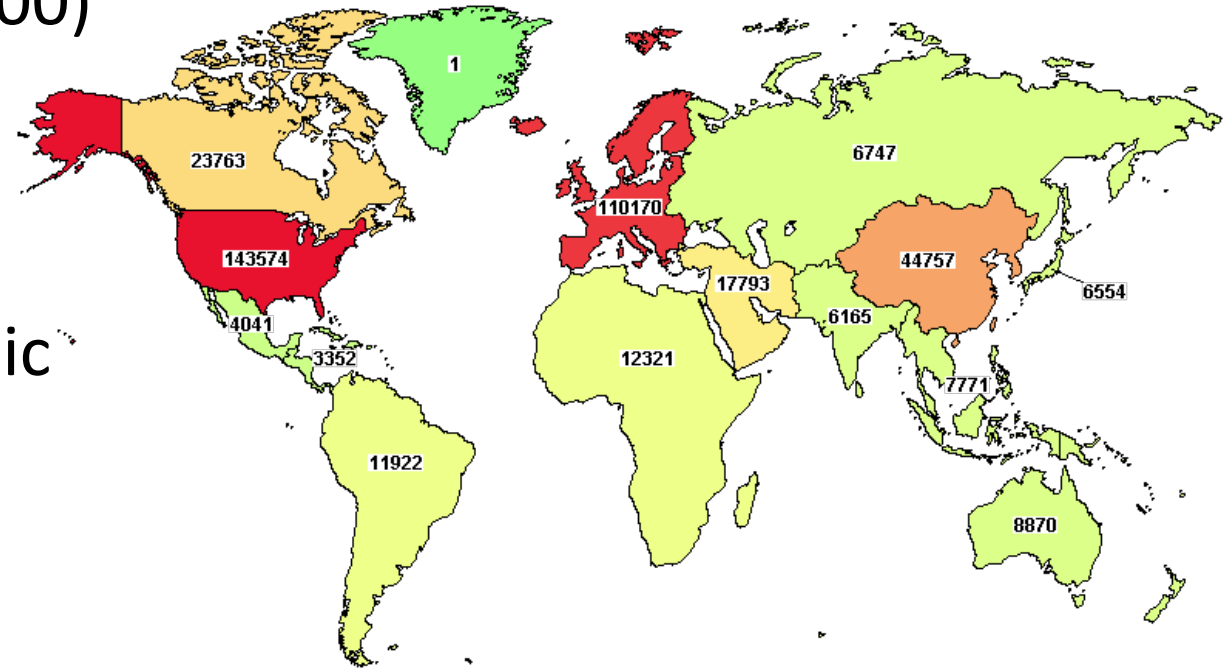
Data Submitters

- Trial sponsors, both private & public

Audiences

- Patients & families
- Researchers & clinicians
- Study record managers

All Studies on ClinicalTrials.gov as of July 5th, 2021



Contents of ClinicalTrials.gov

Status	Study Title	Conditions	Interventions	Locations
Recruiting	Dental Hygiene and Peri-Implant Tissues Homeostasis Ancillary Study	<ul style="list-style-type: none"> • Peri-Implantitis 	<ul style="list-style-type: none"> • Procedure: Peri-implantitis debridement • Other: Dental hygiene procedures 	<ul style="list-style-type: none"> • UTHealth San Antonio San Antonio, Texas, United States • University of Washington School of Dentistry Seattle, Washington, United States
Recruiting	Sequenced Treatment Effectiveness for Posttraumatic Stress	<ul style="list-style-type: none"> • PTSD 	<ul style="list-style-type: none"> • Drug: Selective serotonin reuptake inhibitor • Drug: Serotonin-norepinephrine reuptake inhibitor • Behavioral: Written Exposure Therapy 	<ul style="list-style-type: none"> • Little Rock VA Medical Center North Little Rock, Arkansas, United States • East Arkansas Family Health Center West Memphis, Arkansas, United States • Neighborhood Healthcare San Diego, California, United States • (and 9 more...)
Enrolling by invitation	Life Enhancing Alcohol-management Program	<ul style="list-style-type: none"> • Alcohol Use, Unspecified • Homelessness • Harm Reduction • Community Based Participatory Research 	<ul style="list-style-type: none"> • Behavioral: LEAP 	<ul style="list-style-type: none"> • University of Washington - Harborview Medical Center Seattle, Washington, United States

Trial Details

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



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

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

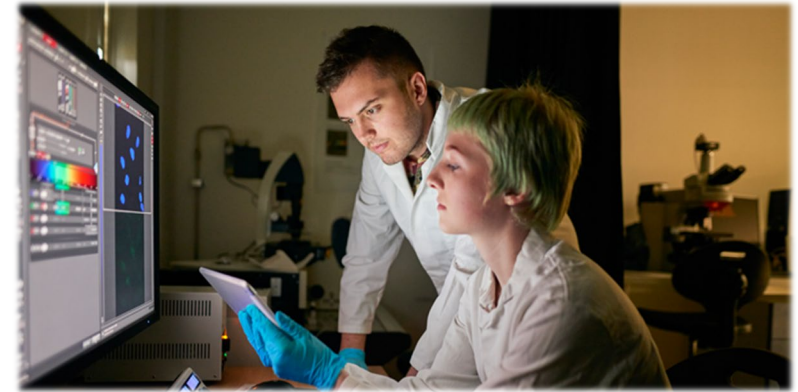
- Meet **ethical obligation to human subjects**, i.e., that results will be used to help others/inform science.
- Enhance **patient access** to enrollment in clinical trials.
- Increased **transparency** of clinical research being conducted by pharmaceutical companies and with federal funding.
- May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



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

Benefits to the Clinical Research Process

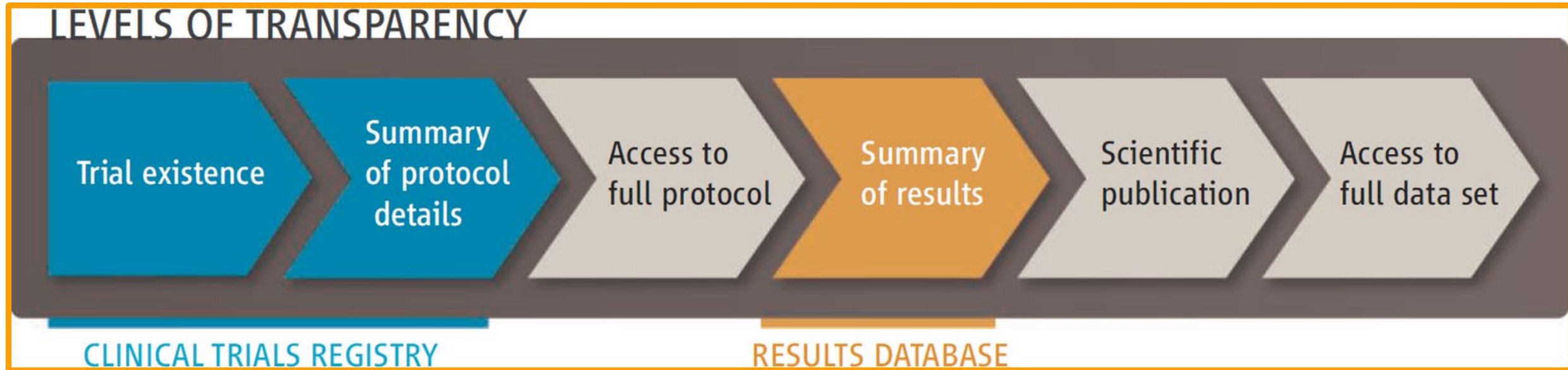
- Inform future research and research funding decisions.
- Mitigate information bias (e.g., non-publication).
- Evaluate research integrity (e.g., adherence to protocol).
- Prevent duplication of trials of unsafe or ineffective interventions.
- Provide access to data to support evidence-based medicine.



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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



Photo by bongkarn thanyakij from Pexels

Diana's imaginary clinical trial:

JAVA

**Java's Association with Virus
Anxiety**

How does drinking coffee affect
anxiety in telecommuting workers
during the COVID-19 pandemic?

What Do You Think?

Assuming this is a well-designed, IRB-Approved, NIH-funded trial...

How does registration of this trial benefit other clinical researchers?

How does registration of this trial benefit the public?

If this trial doesn't demonstrate a clear association between coffee drinking and anxiety during a pandemic, what is the benefit of reporting the results in ClinicalTrials.gov?

JAVA: How does drinking coffee affect anxiety among telecommuting workers during the COVID-19 pandemic?



Photo by bongkarn thanyakij from Pexels

Information Should Be Complete & Discoverable

To fulfill its purpose, the information in ClinicalTrials.gov should be complete and discoverable.

- Consider the **users** of the information.
- Record formats & terminology need to be **standardized**.
- Data needs to be **high quality**.

Study Design

Go to

Study Type ⓘ : Interventional (Clinical Trial)

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Allocation: Randomized

Intervention Model: Parallel Assignment

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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

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Actual Study Completion Date ⓘ : January 31, 2018

Who Requires Trial Registration?



ICMJE = International Committee of Medical Journal Editors

FDAAA 801 = Section 801 of the Food and Drug Administration Amendments Act of 2007

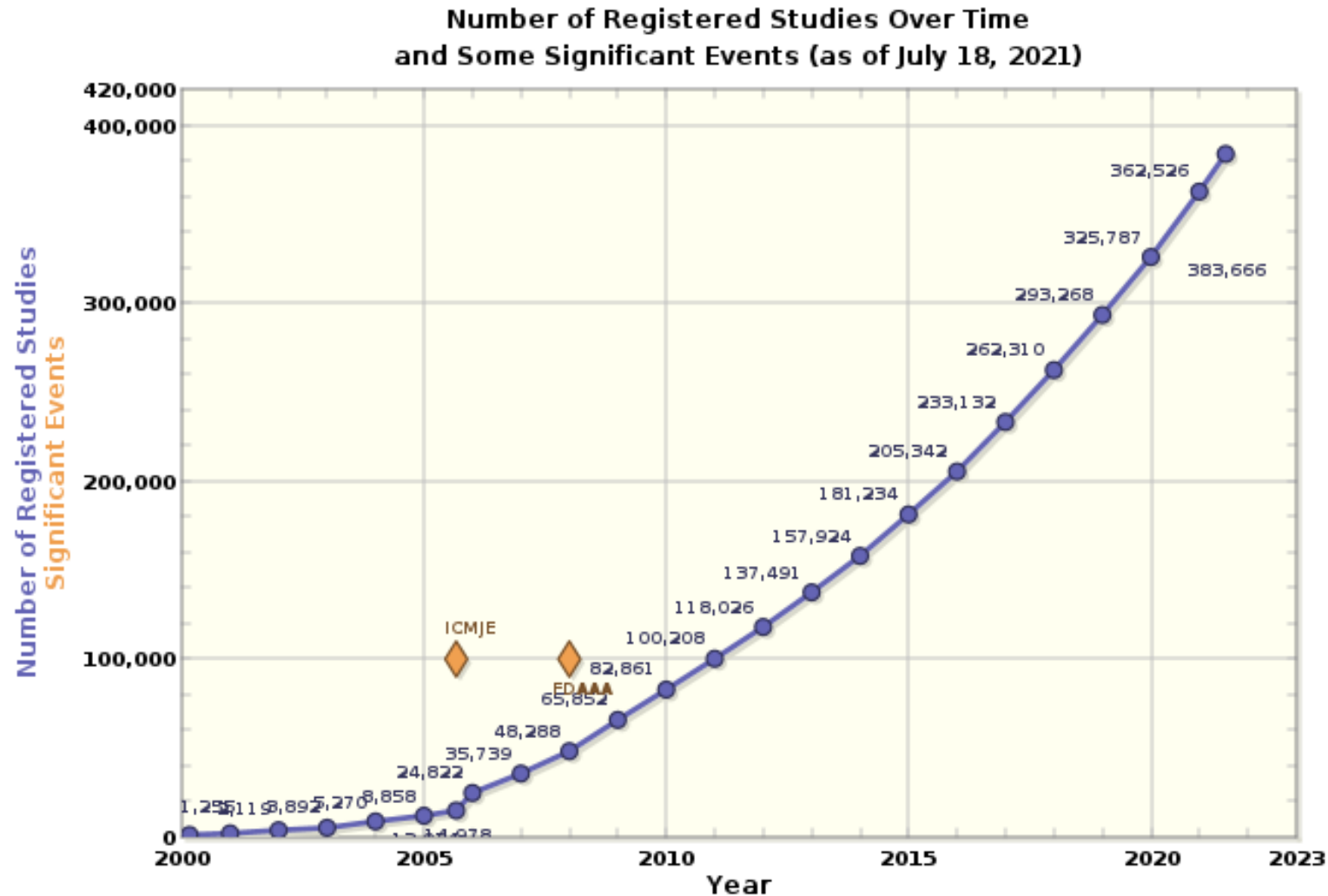
- ICMJE policy applies to many scientific journals, such as American Journal of Nursing, Pediatrics, & Transplantation
- Trial registration is a condition of consideration for publication.
- FDAAA 801 and 42 CFR Part 11 “The Final Rule” require that Applicable Clinical Trial data be submitted no later than 21 days after enrollment of 1st participant.
- Results must be reported no later than 1 year after primary completion date.
- Trial registration and results reporting are requirements for NIH-funded trials, whether or not they are FDA regulated.
- Organizations such as the Gates Foundation, Wellcome Trust, & PATH require trial registration & results reporting.
- Trials submitting claims to the Centers for Medicare & Medicaid Services must include the NCT number from ClinicalTrials.gov.

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.”

<https://www.who.int/news/item/18-05-2017-joint-statement-on-registration>

Are 100% of Applicable Clinical Trials Registered?

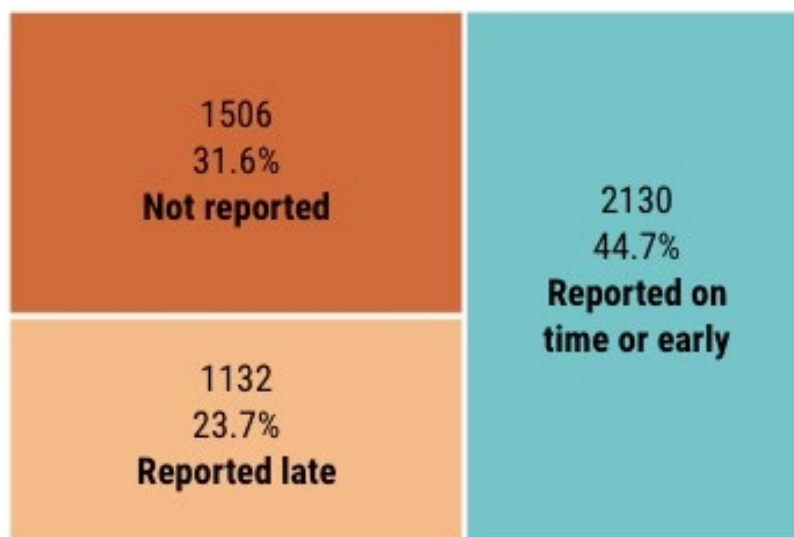


Source: <https://clinicaltrials.gov/ct2/resources/trends#RegisteredStudiesOverTime>

“Missed Deadlines” Reporting Trial Results

Missed deadlines

Among more than 4700 clinical trials examined by *Science*, less than 45% had their results reported early or on time to ClinicalTrials.gov.



(GRAPHIC) N. DESAI/SCIENCE; (DATA) CLINICALTRIALS.GOV, VIA TRIALSTRACKER

“Science analyzed ClinicalTrials.gov records of all clinical trials with results legally required to be reported between 18 January 2018 and 25 September 2019.”

Piller, Charles.
FDA and NIH let clinical trial sponsors keep results secret and break the law.

Science Jan 2020

doi:10.1126/science.aba8123


Expanded FDA Regulation and New NIH Policy

Significant Changes in Trial Registration as of 2017

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

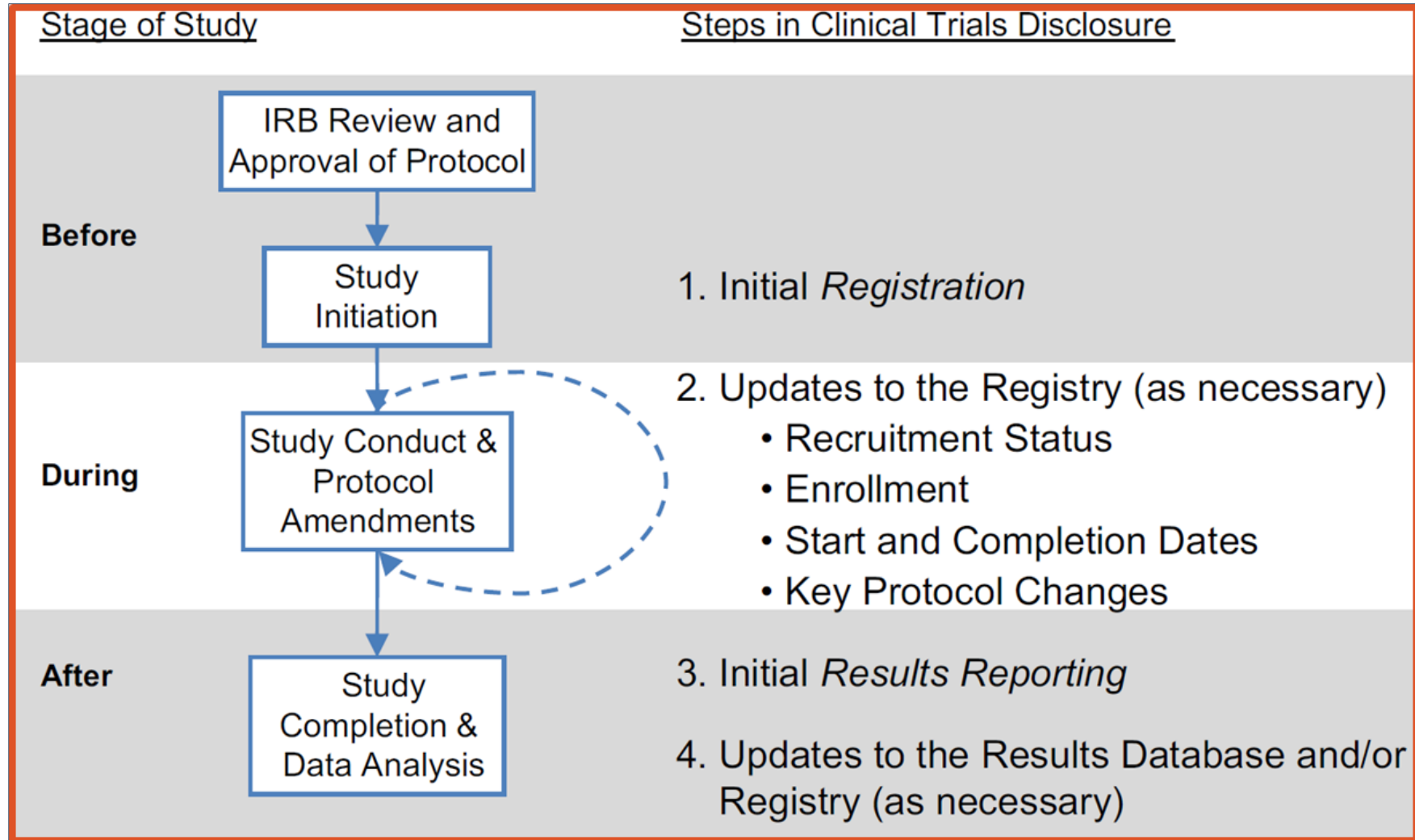
1. All clinical trials funded in whole, or in part, by NIH must be registered, regardless of study phase or type of intervention.
2. Study consent forms must contain a sentence about the trial registration, using the words provided by the FDA and NIH.
3. Penalties for non-compliance may include:
 - Identifying 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

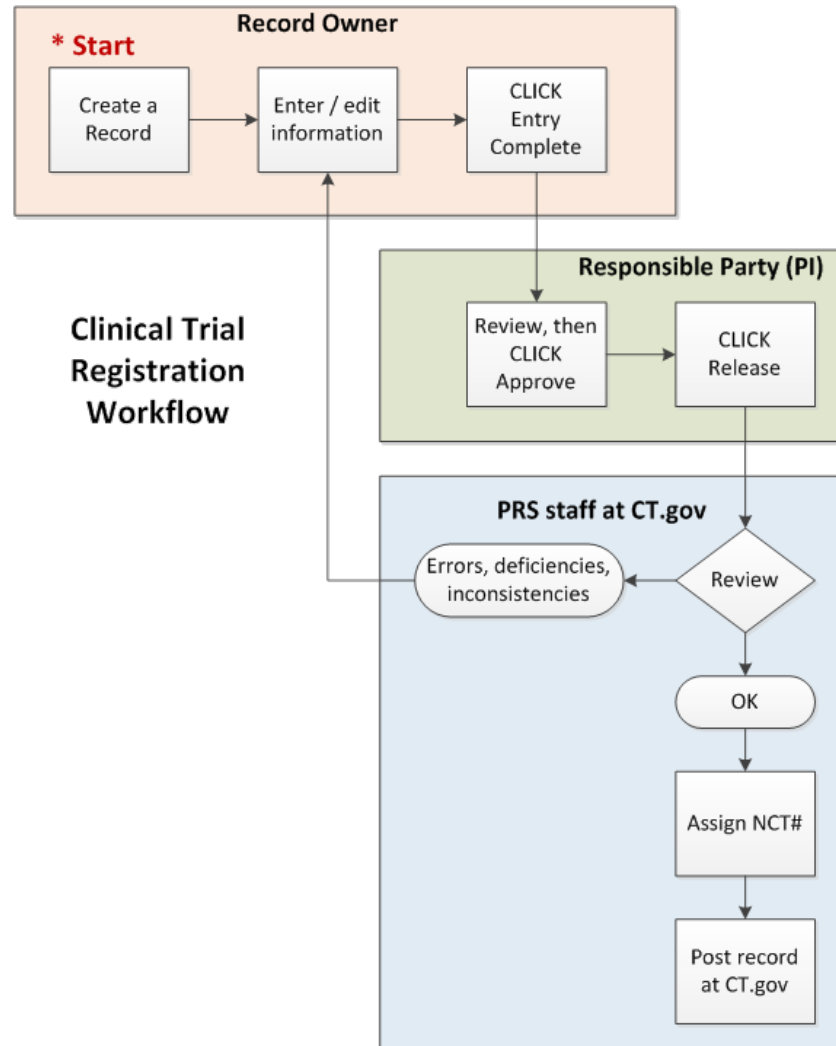
Who	What	Why
Lead PI	<ul style="list-style-type: none"> • Register the trial • Update the record • Report the results • Consent statement 	42 CFR 11 NIH Policy
Site PI	Consent statement	42 CFR 11 NIH Policy
IRB	Consent form has the statement	21 CFR 50.25(c) 21 CFR 56.111(a)(4,5)
UW  HSD	<ul style="list-style-type: none"> • 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?



Clinical Trial Registration Workflow



Record Owner

Responsible Party
(Principal Investigator)

Protocol Registration
& Results System (PRS)
Staff at
ClinicalTrials.gov

Source: <https://www.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

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.

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

ClinicalTrials.gov Protocol Registration Quality Control Review Criteria Examples

- Refer to interventions 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), clearly indicate in the study record that the drugs are the same.
- In 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](#)

JAVA: Java's Association with Virus Anxiety

Population: regular coffee drinkers who are working from home during the COVID-19 pandemic.

Study Design: 360 people, randomized to pre-pandemic level of coffee consumption or increased coffee consumption.

Protocol: Participants drink either their pre-pandemic amount of coffee consumption or consume an additional cup of coffee each day for 60 days.

Outcomes: Anxiety measured with the Generalized Anxiety Disorder (GAD-2) screening measure



Photo by bongkarn thanyakij from Pexels

Some Required Data Elements for Trial Registration

Brief Summary; Condition or Disease; Outcome Measure Title; and Time Frame Fields Are Highlighted

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

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.

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More Suitable Documentation: A or B?

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

A	B
Worrying	Anxiety [a Medical Subject Heading]

Test Searches

Condition or disease ⓘ
Anxiety X

Other terms ⓘ
X

Country ⓘ
X

Worry – 63 studies

Study Title	Conditions
Effects of Duloxetine on Pathological Worry in Patients With Generalized Anxiety Disorder: A fMRI Study	<ul style="list-style-type: none">• Worry• Anxiety
Internet-based Exposure Therapy for Excessive Worry	<ul style="list-style-type: none">• Excessive Worry• Rumination
Training Mental Habits Study	<ul style="list-style-type: none">• Generalized Anxiety• Worry

Anxiety – 4,767 studies

Study Title	Conditions
Anxiety Reduction Treatment for Acute Trauma	<ul style="list-style-type: none">• Anxiety
CHI-907 CBD Extract and Experiences of Test Anxiety	<ul style="list-style-type: none">• Anxiety
School-based Interventions for Test Anxiety in Adolescents	<ul style="list-style-type: none">• Anxiety

More Suitable Documentation: A or B?

Data Element: Study Description: Brief Summary

Objective: study the association between the amount of coffee consumption and level of anxiety

Data Element: Arm Title (Used for Interventional Studies)

A	B
Experimental Arm 1: Pre-pandemic amount of coffee daily	Experimental Arm 1: Pre-pandemic amount of caffeine daily

More Suitable Documentation: A or B?

Data Element: Outcome Measure Title

A	B
Anxiety	Mean change from baseline in scores on the Generalized Anxiety Disorder (GAD-2) screening measure

More Suitable Documentation: A or B?

Data Element: Outcome Measure: Time Frame

A	B
Daily through study completion	Daily for 60 days

Improved Access to Trial Details for Researchers & Clinicians

Pediatrics. 2019 Nov;144(5). pii: e20190802. doi: 10.1542/peds.2019-0802. Epub 2019 Oct 9.

Previsit Screening for Parental Vaccine Hesitancy: A Cluster Randomized Trial.

Opel DJ^{1,2}, Henrikson N³, Lepere K⁴, Hawkes R³, Zhou C^{4,2}, Dunn J³, Taylor JA².

Author information

- 1 Seattle Children's Research Institute, Seattle, Washington; douglas.opel@seattlechildrens.org.
- 2 Department of Pediatrics, School of Medicine, University of Washington, Seattle, Washington; and.
- 3 Kaiser Permanente Washington Health Research Institute, Seattle, Washington.
- 4 Seattle Children's Research Institute, Seattle, Washington.

Abstract

OBJECTIVE: To evaluate the effect of vaccine hesitancy screening on childhood vaccine uptake.

METHODS: We conducted a cluster randomized controlled trial in pediatric primary care clinics in Washington state. Vaccine-hesitant parents (VHPs) with a healthy newborn receiving health supervision at participating clinics were eligible. VHPs were identified by using a 4-item version of the validated Parent Attitudes About Childhood Vaccines Survey (PACV). Before their child's 2- and 6-month health supervision visits, VHPs at intervention clinics completed the 15-item PACV embedded in a survey containing placebo items. Intervention providers received a summary of parents' 15-item PACV responses and interpretation of their PACV score; discretion was given to providers regarding how they acted on this information. VHPs at control clinics completed only the placebo survey items, and their child's provider received a summary of their responses; control providers remained blinded to parent VHP status. Our outcome was child immunization status at 8 months of age expressed as percent of days underimmunized. We compared outcomes in control and intervention participants using *t* test and linear mixed-effects regression.

RESULTS: We enrolled 24 clinics (12 in each arm) and 156 parents (65 in the intervention arm). Parent characteristics were similar across arms except more intervention (versus control) parents had a first-born child (60.9% vs 44%; *P* = .04). No significant difference in outcome was detected between arms (25.2% [95% confidence interval: 16.0% to 34.5%] vs 19.1% [95% confidence interval: 12.0% to 26.3%] mean days underimmunized in the intervention and control arms, respectively).

CONCLUSION: Vaccine hesitancy screening was not significantly associated with days underimmunized.

TRIAL REGISTRATION: ClinicalTrials.gov [NCT02708745](https://clinicaltrials.gov/ct2/show/study/NCT02708745).

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Full text links

PEDIATRICS
FINAL VERSION

[ClinicalTrials.gov](#)

Check for Full Text  [Online Full-text](#)

Save items

☆ Add to Favorites

Similar articles

A randomized trial to increase acceptance of childhood vaccines by vaccir [Acad Pediatr. 2013]

Parent perspectives on childhood vaccination: How to deal with vaccine hesitanc [Vaccine. 2019]

Comparative analysis of the Parent Attitudes about Childhood Vaccines (PACV [Vaccine. 2016]

Review What are the factors that contribute to parental vaccine [Hum Vaccin Immunother. 2014]

Review Addressing vaccine hesitancy: Clinical guidance for primary t [Can Fam Physician. 2019]

[See reviews...](#)

[See all...](#)

Cited by 1 PubMed Central article

A qualitative study examining pediatric clinicians' perceptions of delayed vaccine sc [Vaccine. 2020]

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

Improved Access to Information for Patients & Families

5 Studies found for: **Recruiting, Not yet recruiting, Enrolling by invitation Studies | adhd | Washington, United States | Child**

Applied Filters: ☒ **Recruiting** ☒ **Not yet recruiting** ☒ **Enrolling by invitation** ☒ **Child (birth-17)**

Status	Study Title	Conditions	Interventions	Locations
Recruiting	Lifestyle Enhancement for ADHD Program 2	<ul style="list-style-type: none">• Attention Deficit Hyperactivity Disorder	<ul style="list-style-type: none">• Behavioral: LEAP• Behavioral: Standard BMT	<ul style="list-style-type: none">• Seattle Children's Research Institute Seattle, Washington, United States
Recruiting	Treating Parents With ADHD and Their Young Children Via Telehealth: A Hybrid Type I Effectiveness-Implementation Trial	<ul style="list-style-type: none">• ADHD• Parenting	<ul style="list-style-type: none">• Behavioral: Behavioral Parent Training• Drug: Extended release mixed amphetamine salts (MAS)	<ul style="list-style-type: none">• University of Maryland College Park, Maryland, United States• Seattle Children's Hospital Seattle, Washington, United States
Recruiting	Carboxylesterase 1 Genetic Variation and Methylphenidate in ADHD	<ul style="list-style-type: none">• ADHD• Attention Deficit Hyperactivity Disorder	<ul style="list-style-type: none">• Drug: Methylphenidate	<ul style="list-style-type: none">• University of Florida Gainesville, Florida, United States

“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

<https://www.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, cont.

- 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]
- Piller C. (2020). [FDA and NIH let clinical trial sponsors keep results secret and break the law](#). *Science*. doi:10.1126/science.aba8123
- [FDAAA Trials Tracker](#). Evidence Based Medicine DataLab, University of Oxford.

Acknowledgements

- Diana Loudon, MLS, Life Sciences Librarian, UW Libraries
- 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



Speaker:

Leslie Gascon (she/her/hers), MBA, MS(LIS)

QUESTIONS?

lesj@uw.edu



Introduction to Clinical Research

Boot Camp 2021

THANK YOU!