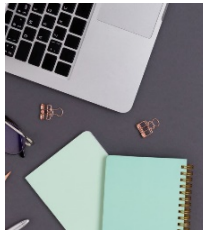

Introduction to Clinical Research
Boot Camp 2020
RESEARCH STAFF TRACK
Day 4
Thursday, July 23, 2020
ITHS
Institute of Translational Health Sciences
ACCELERATING RESEARCH. IMPROVING HEALTH.



Introduction to Clinical Research Boot Camp 2020

ClinicalTrials.gov: Increasing the Transparency of Clinical Research

Diana Nelson Louden, MLib
Life Sciences Librarian
University of Washington

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

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.

ClinicalTrials.gov

Database Contents

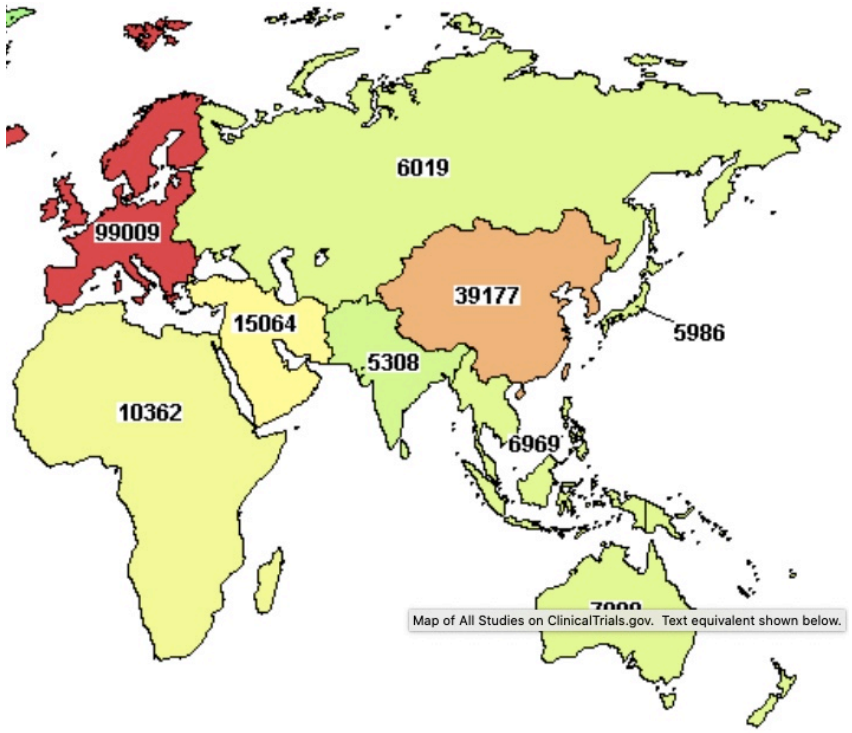
- Clinical trial registry (starting in 2000)
- Trial results (starting in 2008)

Data Submitters

- Trial sponsors, both private & public

Audiences

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



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Contents of ClinicalTrials.gov

Status	Study Title	Conditions	Interventions	Locations
Recruiting	Use of Virtual Reality for Pelvic External Fixator Removal	• Pelvic Fracture Pubic Rami Multiple - Unstable Closed	• Other: Virtual Reality	• University of Washington/Harborview Medical Center Seattle, Washington, United States
Recruiting	Iterative Redesign of a Behavioral Skills Training Program for Use in Educational Settings	• Autism Spectrum Disorder • Disruptive Behavior	• Behavioral: RUBI • Behavioral: RUBIES	• Seattle Public Schools Seattle, Washington, United States
Recruiting	Continuous Infusion Chemotherapy (CI-CLAM) for the Treatment of Relapsed or Refractory Acute Myeloid Leukemia or Other High-Grade Myeloid Neoplasms	• Myeloid Neoplasm • Recurrent Acute Myeloid Leukemia • Refractory Acute Myeloid Leukemia	• Drug: Cladribine • Drug: Cytarabine • Biological: Granulocyte Colony-Stimulating Factor • Drug: Mitoxantrone	• Fred Hutch/University of Washington Cancer Consortium Seattle, Washington, United States
Not yet recruiting	Fluciclovine (FACBC) PET/CT Site-Directed Therapy for Treatment of Prostate Cancer, Flu-BLAST-PC Study	• Prostate Adenocarcinoma • PSA Level Greater Than or Equal to 0.5 • PSA Level Less Than Ten	• Diagnostic Test: fluciclovine-PET/CT scan • Procedure: Lymphadenectomy • Radiation: Radiation Therapy	• Fred Hutch/University of Washington Cancer Consortium 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

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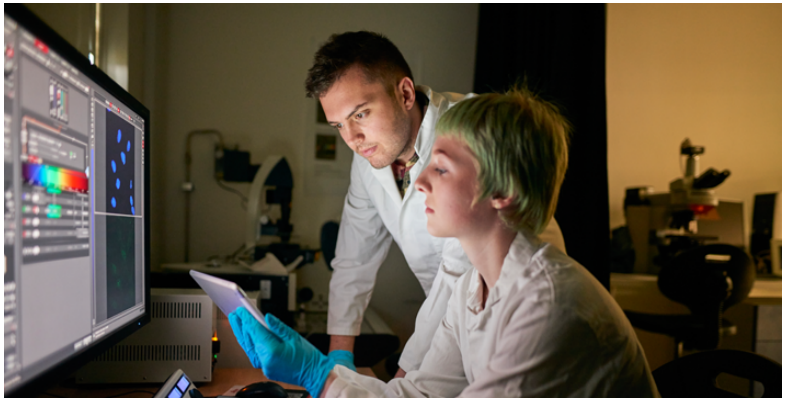
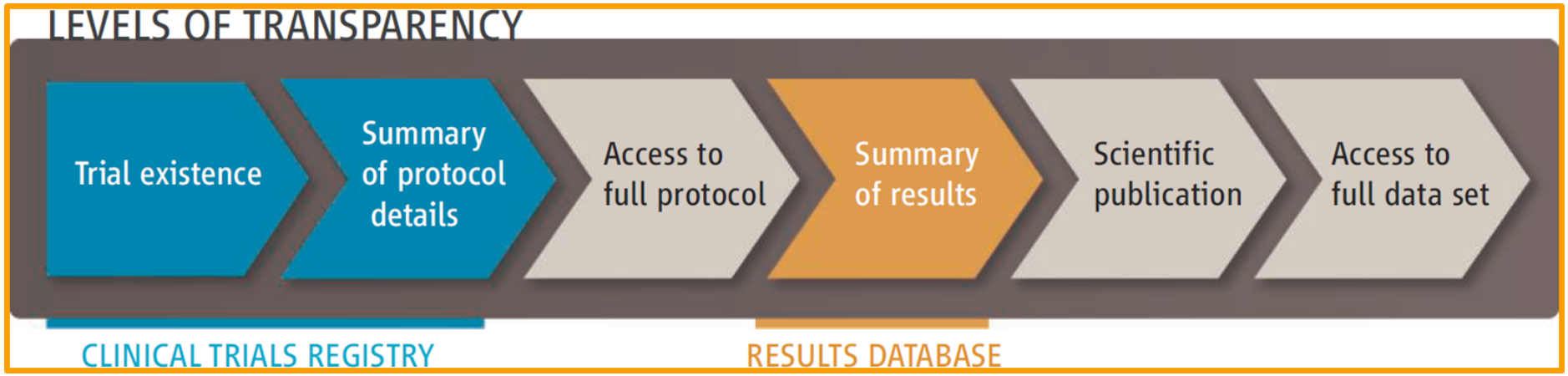
Benefits to the Clinical Research Process

- 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

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Illustrating the Benefits of a Trial Registry and Results Database

Diana's imaginary clinical trial:

JAVA
Java's Association with
Virus **A**nxiety

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

Photo by bongkarn thanyakij from Pexels

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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?

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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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Who Requires Trial Registration?

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

Global Perspective

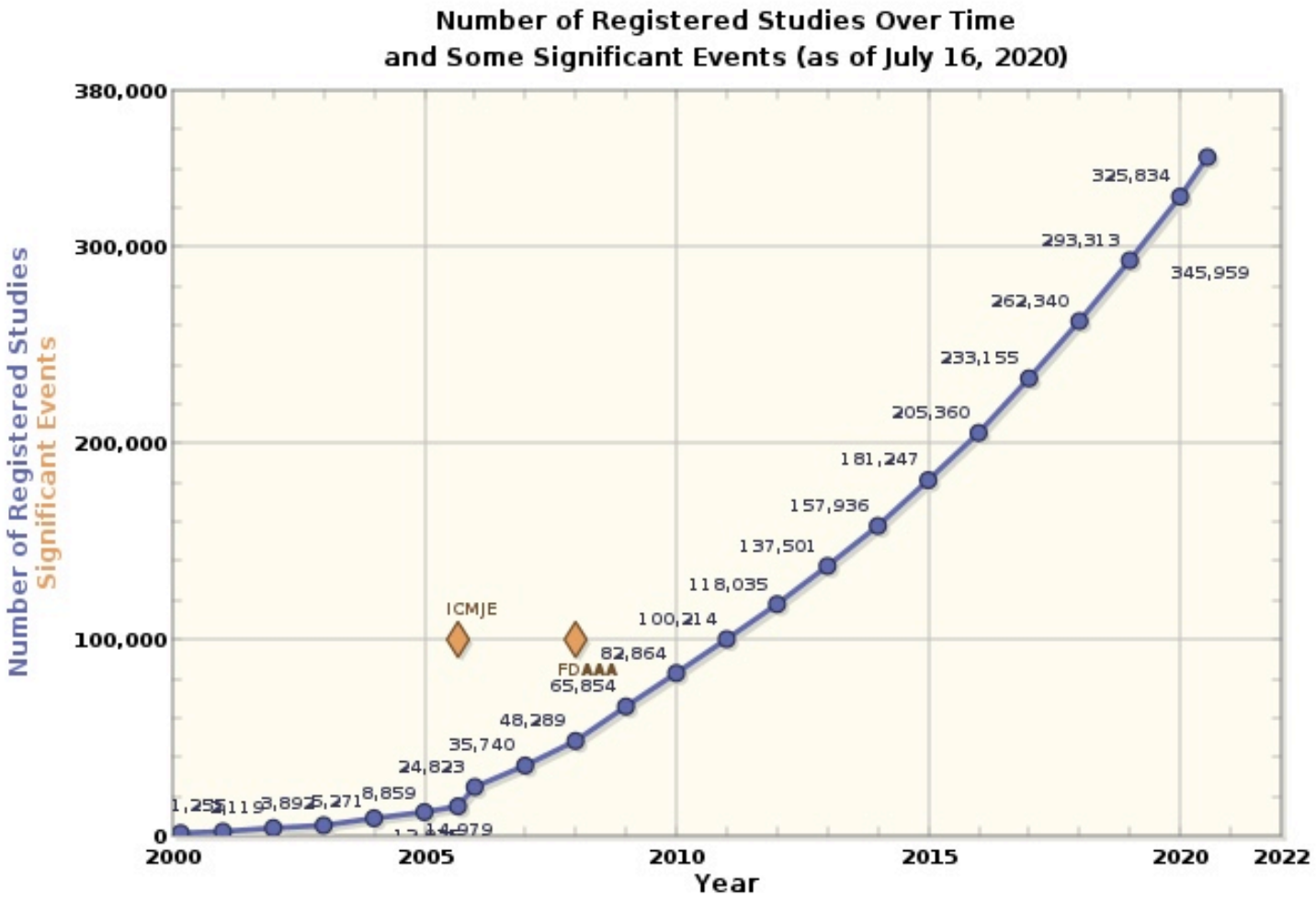
Joint Statement on Public Disclosure of Results from Clinical Trials (2017)

"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/

Are 100% of Applicable Clinical Trials Registered?

No, but…



Source: https://ClinicalTrials.gov

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“Missed Deadlines” Reporting Trial Results

“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

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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

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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.

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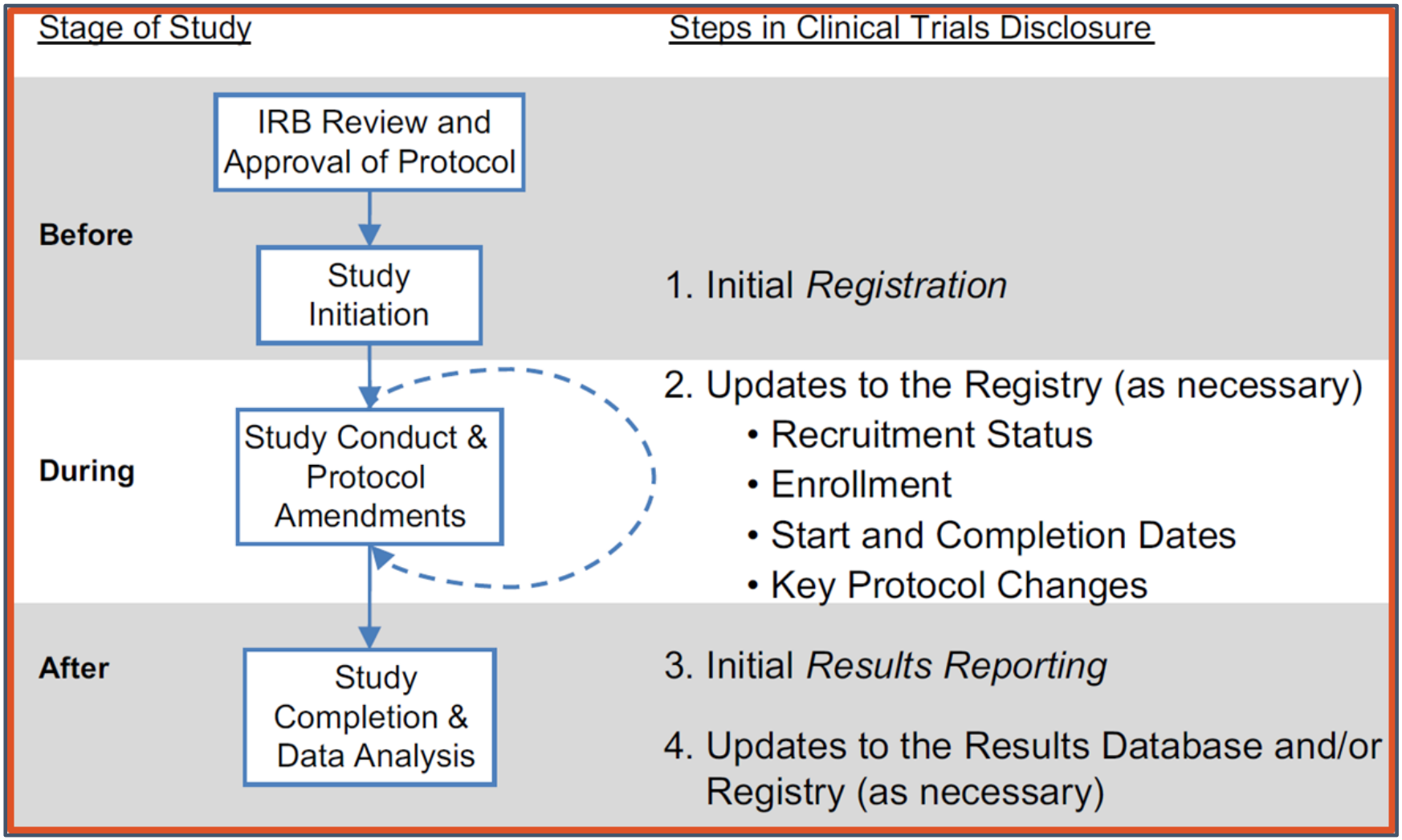
When Do Registration & Results Reporting Occur?



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.

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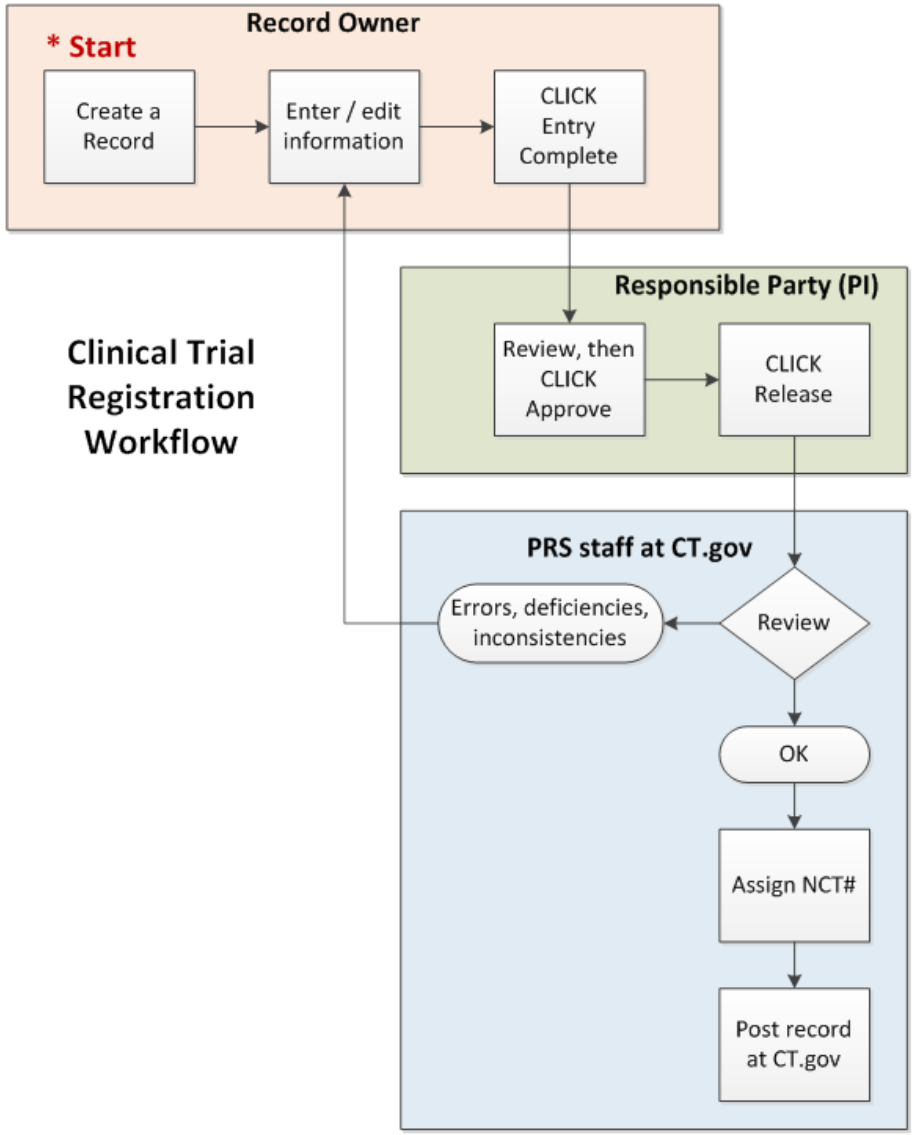
Clinical Trial Registration Workflow



Record Owner

Responsible Party (Principal Investigator)

PRS Staff at ClinicalTrials.gov

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

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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
prsinfo.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.

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

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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]

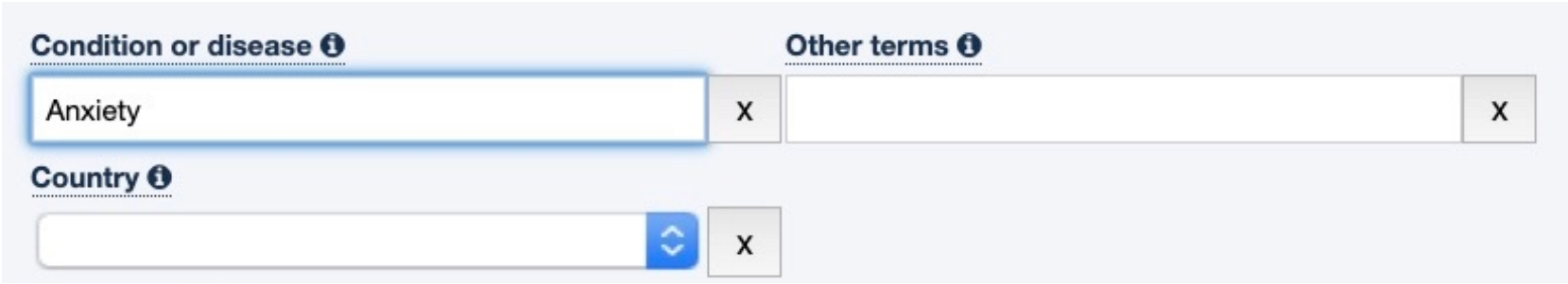
   Opioid use was calculated in intravenous morphine equivalents (iv MEQ) according to the Mayo Clinic Pharmacy opioid conversion calculator based on the recommendations from the American Pain Society. Specifically, the following conversion was used: 10 mg in MEQ=100mcg iv fentanyl=1.5 mg iv hydromorphone=20mg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

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



Worry – 58 studies

Study Title	Conditions
Effects of Duloxetine on Pathological **Worry** in Patients With Generalized Anxiety Disorder: A fMRI Study	• **Worry** • Anxiety
Internet-based Exposure Therapy for Excessive **Worry**	• Excessive **Worry** • Rumination
Training Mental Habits Study	• Generalized Anxiety • **Worry**

Anxiety – 3962 studies

Study Title	Conditions
Anxiety Reduction Treatment for Acute Trauma	• **Anxiety**
CHI-907 CBD Extract and Experiences of Test **Anxiety**	• **Anxiety**
School-based Interventions for Test **Anxiety** in Adolescents	• **Anxiety**

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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?

<u>Data Element</u>: 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 N[3], Lepere K[4], Hawkes R[3], Zhou C[4,2], Dunn J[3], Taylor JA[2].

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.

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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

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

Status	Study Title	Conditions	Interventions	Locations
Recruiting	Lifestyle Enhancement for **ADHD** Program	• **ADHD**	• Behavioral: Lifestyle Enhancement for ADHD Program	• Seattle Children's Research Institute Seattle, **Washington**, **United States**
Recruiting	The Effects of **ADHD** Medication (TEAM) Study	• **ADHD**	• Drug: OROS-Methylphenidate (MPH)	• Children's Hospital Medical Center Cincinnati, Ohio, **United States** • Seattle Children's Hospital Seattle, **Washington**, **United States**

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"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, 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

- 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

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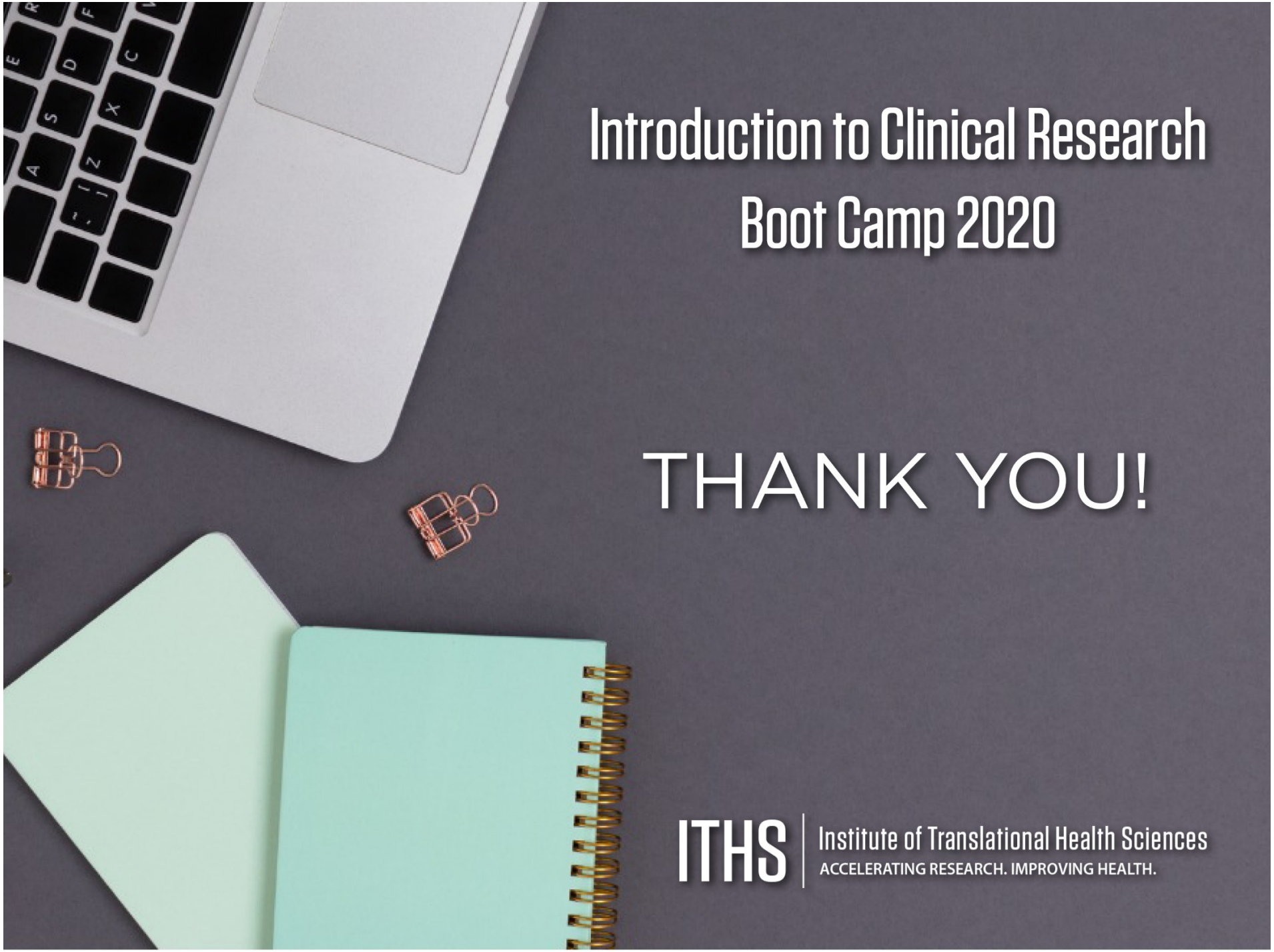
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