



ClinicalTrials.gov: All you need to know

University of Maryland
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ClinicalTrials.gov

U.S. National Library of Medicine
ClinicalTrials.gov

Find Studies ▾ About Studies ▾ Submit Studies ▾ Resources ▾ About ▾

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world.

Explore 273,543 research studies in all 50 states and in 204 countries.

ClinicalTrials.gov is a resource provided by the U.S. National Library of Medicine.

IMPORTANT: Listing a study does not mean it has been evaluated by the U.S. Federal Government. Read our [disclaimer](#) for details.

Before participating in a study, talk to your health care provider and learn about the [risks](#) and [potential benefits](#).

Find a study (all fields optional)

Recruitment status ⓘ

☐ Recruiting and not yet recruiting studies

☒ All studies

Condition or disease ⓘ (For example: breast cancer)

Other terms ⓘ (For example: NCT number, drug name, investigator name)

Country ⓘ

[Advanced Search](#)

[Help](#) [Studies by Topic](#) [Studies on Map](#) [Glossary](#)

Patients and Families
Search for actively recruiting studies that you may be able to participate in or learn about new interventions/treatments that are being considered.

Researchers
Search the database to stay up to date on developments in your field, find collaborators, and identify unmet needs.

Study Record Managers
Learn about registering studies and about submitting their results after study completion.

Public Site

<https://clinicaltrials.gov>

ClinicalTrials.gov PRS
Protocol Registration and Results System

Login

Welcome to the [ClinicalTrials.gov](#) Protocol Registration and Results System (PRS).

Organization:
One-word organization name assigned by PRS (sent via email when account was created)

Username:

Password: [Forgot password](#)

See [Submit Studies](#) on ClinicalTrials.gov for information on how to apply for an account, how to register your study, and how to submit results.

[Send email to ClinicalTrials.gov PRS Administration](#)

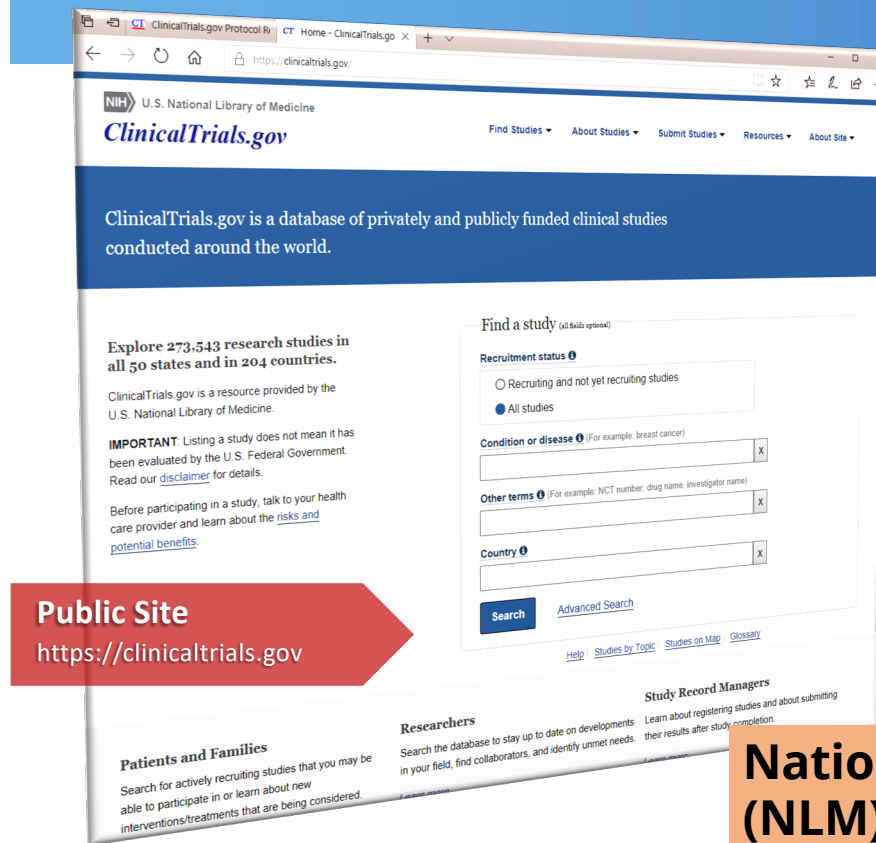
U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

Protocol Registration & Results System (PRS)

<https://register.clinicaltrials.gov>

- **145,000 unique visitors/day**
- **21 million page views/month**

ClinicalTrials.gov



National Library of Medicine (NLM) is looking for feedback

Why is this necessary?

- ✓ Commitment to research participants (including recruitment)
- ✓ Scientific validity/transparency
- ✓ Ethical standards
- ✓ Responsible stewardship of federal funds
- ✓ Help IRB assess value of new studies
- ✓ Required for journal publication (ICMJE)
- ✓ Required by law (FDAAA) and regulations (42 CFR Part 11)
- ✓ Required for all NIH-supported clinical trials (including NCI)
- ✓ Required for CMS
- ✓ Required by WHO
- ✓ Required by Foundations, such as Wellcome Trust

ClinicalTrials.gov Overview

Year	Entity	Event
1997	Congress	1st U.S. law to require trial registration (FDAMA)
2000	NIH	Releases ClinicalTrials.gov website (Results database in 2008)
2005	ICMJE	Requires registration before enrollment
2006	WHO	All clinical trials should be registered
2007	Congress	Expanded registration, submission of results and adverse events, civil penalties (FDAAA)
2015	CMS	Mandatory Reporting of Clinical Trial Number on Claims
2015	NCI	Policy Ensuring Public Availability of Results from NCI-supported Clinical Trials
2016	FDA/NIH	Final Rule and Companion Policy (effective January 18, 2017)
2017	HHS	Final Rule compliance date (April 18, 2017)
2019	HHS	Revised Common Rule requiring informed consent form uploading (effective Jan 21, 2019)

FDAMA: Food and Drug Administration Modernization Act
 NIH: National Institutes of Health
 ICMJE: International Committee of Medical Journal Editors
 HHS: Health and Human Services

WHO: World Health Organization
 FDAAA: Food and Drug Administration Amendments Act
 CMS: Centers for Medicare & Medicaid Services
 NCI: National Cancer Institute

Federal Regulations

“Applicable Clinical Trials” per FDAAA

- **Trials of drugs/biologics:** Controlled clinical investigations, other than Phase 1 trials of drugs/biological products subject to FDA regulations.
- **Trials of devices:**
 - Controlled trials with health outcomes of devices subject to FDA regulation (other than feasibility studies)
 - Pediatric post-market surveillance required by FDA
- **Trial has one or more sites in the U.S.**
- **Trial is conducted under an FDA IND/IDE application**
- **Trial involves a drug, biologic or device that is manufactured in the U.S. or its territories and exported for research**



ACT Wizard: http://grants.nih.gov/clinicaltrials_fdaaa/docs/Flow_chart-ACT_only.pdf
Identifying an ACT under FDAAA http://grants.nih.gov/ClinicalTrials_fdaaa/ACTs_under_FDAAA.htm

Federal Regulations

Trials that meet the NIH Definition of a Clinical Trial

If you answer “yes” to any of the following questions, your study meets the NIH definition of a clinical trial and registration IS required.

- 1. Does the study involve human participants?**
- 2. Are the participants prospectively assigned to an intervention?**
- 3. Is the study designed to evaluate the effect of the intervention on the participants?**
- 4. Is the effect being evaluated, a health-related biomedical or behavioral outcome?**

If you answered YES to all 4 the NIH Criteria (on the left), your study is a clinical trial even if it is one of the following scenarios:

- Studying healthy participants
- Do not have a comparison group
- Only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Behavioral intervention

Uploading the Consent Form

According to the revised Common Rule, effective January 21, 2019...

- ***Important considerations regarding the uploading of the informed consent form (ICF):***
- Applies only to clinical trials conducted or supported by a Federal department or agency using the Common Rule
- The consent form must have been used in enrolling participants
- Should be uploaded **no later than 60 days** after the last study visit by any subject, as required by the protocol
- Must be uploaded to either ClinicalTrials.gov or a docket folder on Regulations.gov

§46.116 [General requirements for informed consent.](#)

Penalties

Penalties outlined in the FDA Final Rule

Final Rule (42 CFR Part 11) ***Released: 09/2016, Effective: 01/2017, Compliance date: 04/2017***

1. Civil or criminal judicial actions
2. Civil monetary penalties up to ~~\$10,000~~ ~~\$12,316~~ \$12,462 per study, per day
3. Withholding of current or future funding to organizations that are out of compliance

These penalties are for any data element FDA determines was, “not submitted as required, or was false or misleading” not just late results

21 U.S.C. 333(f)(3)(A) <https://www.federalregister.gov/documents/2021/11/15/2021-24672/adjustment-of-civil-monetary-penalties-for-inflation-and-the-annual-civil-monetary-penalties>

Publication Recommendations

Trials that meet the clinical trial definition of The International Committee of Medical Journal Editors (ICMJE) that the investigator may wish to publish...

ICMJE journals will consider [for publication] trials beginning on or after July 1, 2005 **only if** registration occurred **before** the first patient was enrolled (“prospective registration”)



Many journals follow the ICMJE criteria for publication.

There have been cases within our institution where a manuscript was rejected for publication simply because the study was not registered on ClinicalTrials.gov before enrolling participants!

<http://www.icmje.org/about-icmje/faqsclinical-trials-registration/>

Summary of Requirements

Entity	Registration	Results Reporting	Penalties
Health and Human Services (HHS)	Within 21 days of enrollment	Within 365 days of primary completion date for ACTs	<ul style="list-style-type: none">• \$12,316/study/day• Criminal proceedings• Loss of grant funding
National Institutes of Health (NIH)	Within 21 days of enrollment	Within 365 days of primary completion date for clinical trials receiving NIH funding	Loss of grant funding (to include the institution)
National Cancer Institute (NCI)	Within 21 days of enrollment	Within 365 days of primary completion date of NCI-supported clinical trials (in a peer-reviewed journal and/or ClinicalTrials.gov)	Loss of grant funding
Veterans Health Administration (VHA)	Prior to release of funding. Prior to enrollment	Within 365 days of primary completion date	Loss of grant funding

Summary of Requirements

Entity	Registration	Results Reporting	Penalties
Centers for Medicare & Medicaid Services (CMS)	All qualifying clinical trials	Study-specific	<ul style="list-style-type: none"> • Coverage denial • Costs and fraud investigations
Patient-Centered Outcomes Research Institute (PCORI)	All Clinical studies (including observational)	Expected of all PCORI Clinical studies – 500 word abstract published on PCORI website	<ul style="list-style-type: none"> • Loss of grant funding
International Committee of Medical Journal Editors (ICMJE)	Prior to enrollment		Ineligibility to publish
Department of Defense (DoD)	Prior to enrollment. Prior to release of funding.	Study-specific	<ul style="list-style-type: none"> • \$12,103/study/day • Withholding or recovery of award funds

Registering and Updating the Record

☐ Register the record within **21 days of enrolment**
(HHS) –OR- **prior to enrolment** (ICMJE)

☐ Update the following data elements no later than
30 calendar days after a change occurs

- Study start date
- Intervention name(s)
- Availability of Expanded Access
- Expanded Access status
- Overall recruitment status
- Explanation for change in status
- Actual enrollment data
- Individual site status
- IRB status
- Completion Date
- Responsible Party
- Official Title
- Contact Information

Responding to Comments

- ❑ Respond to PRS Review Comments
within **15 calendar days** (registration) –
OR- **25 calendar days** (results)

Annual Verification

☐ Verify the record **annually**

IRB Continuing Review will be held for studies that are not verified annually

Entering results

☐ **Report** results within 12 months of the completion dates.

- Estimated time to enter results: **up to 40 hours***
- It may take multiple review cycles to post your results
- Comments must be responded to within **25 calendar days**

Primary Completion Date: the date that the last data point for the primary outcome measure was collected from the last enrolled participant.

Study Completion Date: the date that the last data point for all remaining outcome measures was collected from the last enrolled participant.

*HHS estimated burden statement

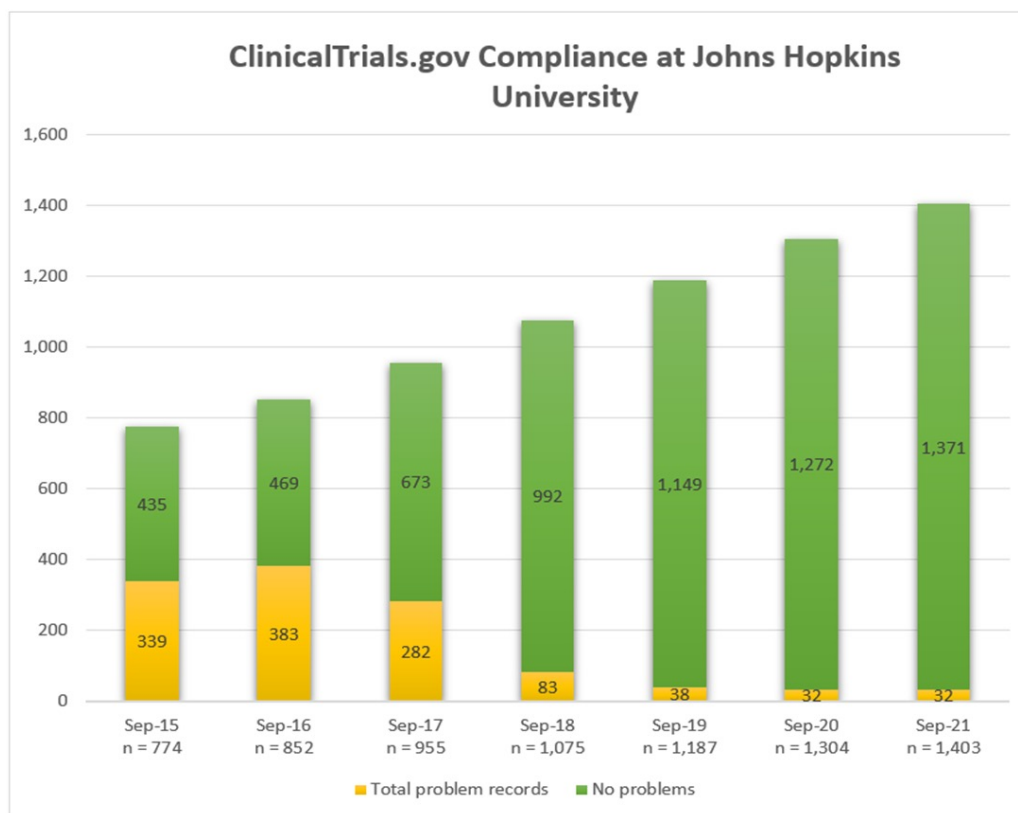
JHU ClinicalTrials.gov Program

Our program is based in the School of Medicine, Institute for Clinical and Translational Research (ICTR)

- “Responsible Party” for over 1,800 records
- Review 150 to 200 records/month
- Use a standardized checklist
- Close collaboration with IRB

[Tetteh, O., Nuamah, P., & Keyes, A. \(2020\). Addressing the quality of submissions to ClinicalTrials.gov for registration and results posting: The use of a checklist. Clinical Trials \(London, England\), doi:10.1177/1740774520942746](#)

Building Compliance



Keyes, Anthony MBA, PMP; Mayo-Wilson, Evan MPA, DPhil; Nuamah, Prince MD, MPH; Lalji, Aliya MD; Tetteh, Oswald MD, MPH; Ford, Daniel E. MD, MPH Creating a Program to Support Registering and Reporting Clinical Trials at Johns Hopkins University, Academic Medicine: April 2021 - Volume 96 - Issue 4 - p 529-533 doi: 10.1097/ACM.0000000000003806



Tips and Tricks for Entering Data

Kim Hill, Clinical Research Compliance Specialist

Registering the Record

ClinicalTrials.gov PRS

Protocol Registration and Results System

Quick Links



[New Record](#)

[Admin Quick Reference](#)

[Lookup Users](#)

[Problem Resolution Guide](#)

Records ▼ Accounts ▼ Help ▼

ClinicalTrials.gov Account set-up

Martina Miller of HRPO

Martina.miller@umaryland.edu



JOHNS HOPKINS
INSTITUTE for CLINICAL &
TRANSLATIONAL RESEARCH

Registering the Record

Module Status:

Study Identification:	✓
Study Status:	✓
Sponsor/Collaborators:	✓
Oversight:	✓
Study Description:	✓
Conditions:	✓
Study Design:	✓
Arms and Interventions:	✓
Outcome Measures:	✓
Eligibility:	✓
Contacts/Locations:	✓
IPD Sharing Statement:	✓
References:	

The System will guide you through each step

[Help](#)

[Definitions](#)

[Spelling](#)

Step-by-step videos

1. Registration
 2. Results Reporting
- YouTube at "[Johns HopkinsCTgov](#)"

Registering the Record at UMB

Study Identification

- **Unique Protocol ID:** IRB number (HP-000XXXXX)
- **Brief title** should be a short-form of the study title in language intended for the lay public
- **Acronym:** if entered it will be seen at the end of the Brief Title when the public sees it. Not a required field.
- **Official Title** should match the title in the IRB
- **Secondary ID:** could be used to enter the NIH grant number or other identifier. Not a required field.

Note: Any **errors** must be addressed so you can continue entering the record. **Warnings** should be addressed to see if you need to make corrections.

Registering the Record

Study Status

This section must be updated at least once a year or within 30 days of any changes

- **Record Verification Date:** the date you're entering the record or the date you're verifying all the information is up to date and correct.
- **Overall Recruitment Status:** use the dropdown list to choose the option that best applies to the current status of the study. *Recruiting, Not yet Recruiting*, etc. (can use Definitions for guidance)
Please note: "Terminated" studies are when participants were enrolled, but the study was closed prematurely; "Withdrawn" studies are when no participants were enrolled.; use "Suspended" if recruitment was stopped but may resume later. You'll need to provide a reason for these statuses.

Registering the Record

Study Status

This section must be updated at least once a year or within 30 days of any changes

- **Study Start Date:** Enter your anticipated/actual start date (month and year)
- **Primary Completion Date:** use drop down to select Anticipated/Actual (month and year)
Date when final data collection for the primary outcome measure will be collected – NOT data analysis.
- **Study Completion Date:** use drop down to select Anticipated/Actual (month and year)
Date when final data collection for all other outcome measures will be collected – NOT data analysis.

Registering the Record

Sponsor/Collaborators

- **Responsible Party:** PI (Sponsor, Principal Investigator Sponsor-Investigator)
- **Sponsor:** is generally the primary organization or individual who initiated the study, not necessarily the funding source.
- **Collaborators:** all sources of support identified in IRB Support Information section

The screenshot displays the 'Edit Sponsor/Collaborators' page within the ClinicalTrials.gov PRS (Protocol Registration and Results System). The page is titled 'PRS TEST SYSTEM' and includes a 'Contact ClinicalTrials.gov PRS' link. The user is logged in as 'Org SKCCC Admin ALalji'. The page shows the following fields:

- Responsible Party:** A dropdown menu with 'Sponsor' selected. A note states: 'Select Sponsor unless the Principal Investigator has been designated as Responsible Party or the Principal Investigator is the Sponsor.'
- Sponsor:** A text field containing 'Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins'. A note states: 'Primary organization conducting study and associated data analysis (not necessarily a funding source).'
- Collaborators:** A text field with a 'Delete' button. A note states: 'Organization(s) providing support: funding, design, implementation, data analysis or reporting. Required by International Committee of Medical Journal Editors (ICMJE) and World Health Organization (WHO). Enter only the organization name.'

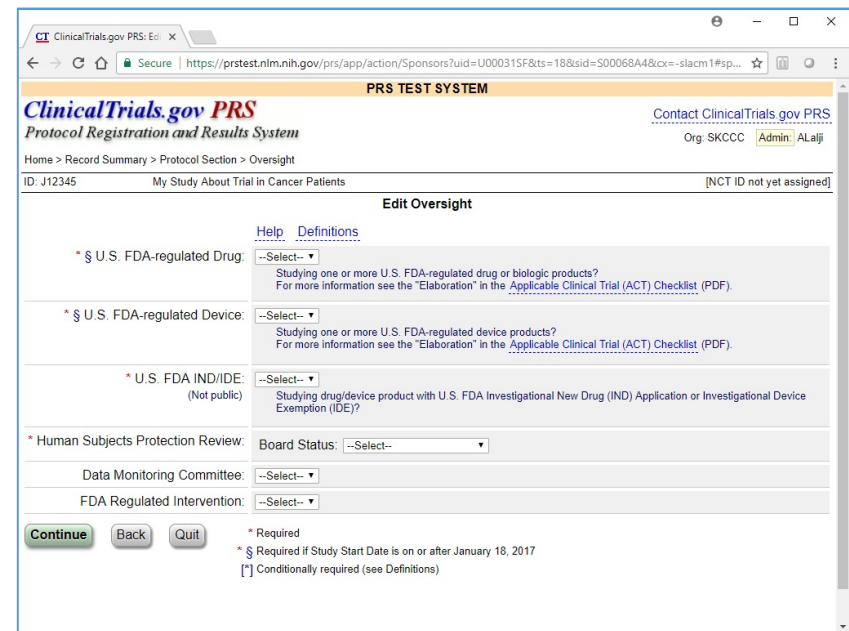
At the bottom, there are three buttons: 'Continue', 'Back', and 'Quit'. A legend indicates that an asterisk (*) denotes a required field and a section symbol (§) denotes a field required if the study start date is on or after January 18, 2017. A footnote (*) indicates that a field is conditionally required (see Definitions).

Registering the Record

Oversight

The oversight section includes information about:

- *If you're studying a FDA regulated drug or biological product*
- *If your studying a FDA regulated device*
- *Human subjects protection (review board status, IRB contact information, and IRB study number)*



The screenshot shows the 'Edit Oversight' page in the ClinicalTrials.gov PRS system. The page is titled 'ClinicalTrials.gov PRS Protocol Registration and Results System' and includes a breadcrumb trail: 'Home > Record Summary > Protocol Section > Oversight'. The study ID is 'J12345' and the study title is 'My Study About Trial in Cancer Patients'. The page contains several dropdown menus for selecting oversight information:

- * § U.S. FDA-regulated Drug: --Select--
- * § U.S. FDA-regulated Device: --Select--
- * U.S. FDA IND/IDE (Not public): --Select--
- * Human Subjects Protection Review: Board Status: --Select--
- Data Monitoring Committee: --Select--
- FDA Regulated Intervention: --Select--

At the bottom, there are 'Continue', 'Back', and 'Quit' buttons. A legend indicates that '*' denotes required fields and '[' denotes conditionally required fields (see Definitions).

Registering the Record

Study Description

- **Brief Summary** states the study's hypothesis or purpose; should be written in complete sentences and in language intended for the general public
- **Detailed Description (optional):** a detailed description of the study that doesn't replicate information found in other sections of the record. You can use the protocol you submitted to the IRB to complete this section. Don't include footnotes, citations, references, or eligibility criteria.

Tips and Tricks for Registering the Record

Formatting:

- Reviewers don't accept personal pronouns "*I, we, my, our, us*" becomes "the investigator(s)" or "the study team"; "*you, your, they, them, their*" becomes "the participant(s)"
- Remove all parenthetical citations (can use reference section which is an optional section)
- Use the spelling feature to check for spelling errors and unexpanded acronyms. All acronyms should be expanded on their first use
- Proof read for grammatical errors.

Registering the Record

Conditions and Keywords

- **Conditions or Focus of Study:** enter name of the disease or condition(s) being studied. As you start typing, the system will suggest conditions you can select.
- **Keywords:** enter associated words or phrases someone might use to search for the study. Key words should be listed one per line.

ClinicalTrials.gov PRS: Edit X

Secure | <https://prstest.nlm.nih.gov/prs/app/action/PopulateStudy?uid=U00031SF&ts=20&sid=500068A4&cx=-9q9p...>

PRS TEST SYSTEM

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: SKCCC Admin: ALalji

Home > Record Summary > Protocol Section > Conditions

ID: J12345 My Study About Trial in Cancer Patients [NCT ID not yet assigned]

Edit Conditions

[Help](#) [Definitions](#)

* Conditions or Focus of Study: [Delete](#)

[Search MeSH](#), the National Library of Medicine's Medical Subject Headings, for valid condition terms.
If there are no conditions under study, enter brief description of focus of study instead.

[Add Condition](#)

Keywords: [Add Keyword](#)

[Continue](#) [Back](#) [Quit](#)

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

Registering the Record

Study Design

- **Study Type:** this is automatically populated
- **Primary Purpose:** select the option from dropdown
- **Study Phase:** select option from dropdown (if this study does not involve any drug or biologic products, select “N/A”)
- **Interventional Study Model:** select the model that applies to this study
- **Number of Arms:** enter the total number of arms/groups for this study
- **Masking:** select who (if any) is being masked in this study
- **Allocation:** select randomization or “N/A” if only a single-arm study
- **Enrollment:** Enter the number of participants anticipated to be consented. Upon completion of the study, change the enrollment type to actual and update the number if necessary)

The screenshot shows the 'Edit Interventional Study Design' form in the ClinicalTrials.gov PRS system. The form is titled 'ClinicalTrials.gov PRS Protocol Registration and Results System' and 'PRS TEST SYSTEM'. It includes a 'Help' and 'Definitions' link circled in red. The form fields are as follows:

- * Study Type: Interventional
- * § Primary Purpose: Treatment
- * Study Phase: Phase 1/Phase 2
- * § Interventional Study Model: Parallel
- * § Number of Arms: 2
- * § Masking: ☒ None (Open Label)
- * § Allocation: Non-randomized
- * § Enrollment: Number of Subjects: 100, Type: Anticipated

Buttons at the bottom include 'Continue', 'Back', and 'Quit'. A legend indicates that asterisks (*) denote required fields and § denotes conditionally required fields.

Registering the Record

Arms

- **Arm Title:** enter a brief descriptive title that will distinguish it from other arms.
(not Arm 1, and Arm 2)
- **Arm Type:** select the option that applies to each arm (experimental, placebo, etc.)
- **Arm Description:** enter a description of the arm(s) such as dosage, method of administration, frequency and duration of the intervention.

Registering the Record

Interventions

- **Intervention Type:** select the intervention type from the dropdown menu (drug, device, behavioral, etc.)
- **Intervention Name:** enter the intervention name using the generic name or assigned drug label name for drugs and devices.
- **Other Intervention Names:** list alternative names for the interventions (i.e.,: brand name for drugs that people might search for)
- **Intervention Description:** provide a description of the intervention to be administered. You do not need to repeat what has already been stated within the Arms Description.

Each intervention must be listed separately.

Registering the Record

Arms/Intervention Cross-Reference

The information you provide about the arms and interventions will populate a grid. Use the checkboxes to match the arm with the appropriate intervention.

Arms	Interventions		
	Drug: Durvalumab	Drug: Tremelimumab 300 mg	Drug: Tremelimumab 75 mg
Experimental: Cohort A - Durvalumab and Single-dose Tremelimumab <div></div>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Experimental: Cohort B - Durvalumab and Weekly-dose Tremelimumab <div></div>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

Check boxes for Interventions associated with each Arm in the study.

Effective Outcome Measures

Entering Outcome Titles

Title: A brief, specific, descriptive title that describes **WHAT** is being measured

INCORRECT:

- Safety
- Adverse Events
- Area Under the Curve
- Blood Pressure
- Stress

CORRECT:

- Safety as assessed by number of participants experiencing serious adverse events
- Number of participants with treatment-related adverse events as assessed by CTCAE v5.0
- Area Under the Plasma Concentration Versus Time Curve (AUC) of [DRUG NAME]
- Change from Baseline in the Mean Seated Trough Cuff Systolic Blood Pressure at 6 Months
- Stress as assessed by the Everyday Stressors index

Effective Outcome Measures

Entering Outcome Descriptions

Description: A detailed description of **HOW** this outcome measure is being assessed. You must make sure to include applicable units of measure. If you're using a scoring scale, you must include the unabbreviated scale title, description of the scale being used including the possible score range, and whether higher scores mean a better or worse outcome.

INCORRECT – “incidence of serious adverse events”

CORRECT – “Number of participants who experience adverse events \geq Grade 3, as defined by Common Terminology Criteria for Adverse Events (CTCAE) v5.0”

INCORRECT: Pain score

CORRECT: The Short Pain Scale-11 is a validated self-reported instrument assessing average pain intensity over the past 24 hour period. Possible scores range from 0 (no pain) to 10 (worst possible pain).

Effective Outcome Measures

Entering Outcome Time Frames

Time Frame:

- Indicate the specific time point when the measurement will be assessed (e.g., 1 week);
- or the duration of time of assessment of the participant (e.g., from admission to discharge, up to 1 week);
- or a change between 2 time points (e.g., baseline and 8 weeks).

INCORRECT – “at time of intervention,” “at start of study,” “Days 1, 28, 60, 90”

CORRECT – “Day 1,” “Day 1 post-intervention,” “Change from baseline to Day 28”

Note: Each specific time point must be entered separately if you’re not assessing a change between time points or assessing pharmacokinetics..

Using the Checklist

CLINICALTRIALS.GOV INTERNAL RECORD REVIEW

DATE RELEASED	COMMENTS DATE	REPLY DATE	DATE PUBLISHED
GENERAL REVIEW ITEMS		NOTES	
<ul style="list-style-type: none"> <input type="checkbox"/> No monetary value (e.g. compensation, food voucher) should be entered anywhere in the protocol <input type="checkbox"/> Record Owner is the PI <input type="checkbox"/> Contact info for Record Owner is up-to-date <input type="checkbox"/> PI on record matches IRB PI: _____ <input type="checkbox"/> NCT# included in IRB "Clinical Trials Information" section <input type="checkbox"/> All Warnings/Errors addressed <input type="checkbox"/> All parenthetical citations have been removed <input type="checkbox"/> All acronyms have been expanded on their first use <input type="checkbox"/> Spell-check complete <input type="checkbox"/> Free-text fields are blank if there is no information to report, and do not contain text such as "TBD," "Pending," "N/A," "None" 			
PROTOCOL SECTION			

Spelling

FDA Enforcement

FDAAA 801 Violations

- Notice is sent to the Responsible Party identified in the ClinicalTrials.gov record
- **Pre-Notice Letters** are **not** identified as an FDAAA 801 Violation and **not** identified in ClinicalTrials.gov
- **Notice of Noncompliance** Letters are identified as an FDAAA 801 Violation in ClinicalTrials.gov

FDAAA 801 Violations

Results Submitted

FDAAA 801 Violations

Disclaimer

How to Read a Study Record

Information on FDAAA 801 Violations ⓘ

More Information: [Notices of Noncompliance \[FDA\]](#)

Available on ClinicalTrials.gov	Issued by FDA	Study Record Submitted	Notice Type	FDAAA 801 Notice
September 3, 2021	August 31, 2021	December 15, 2018	Violation Identified by FDA	Failure to Submit. The entry for this clinical trial was not complete at the time of submission, as required by law. This may or may not have any bearing on the accuracy of the information in the entry.

Responsible Party/Submitter	NCT Number	Notice of Noncompliance
Petrikovets, Andrey M.D.	NCT03052816	8/31/2021
Accutis Inc.	NCT03064438	7/26/2021
Acceleron Pharma, Inc.	NCT01727336	4/27/2021

<https://www.fda.gov/media/151965/download>

FDAAA 801 Violations

Researchers from Yale, Columbia, and Universities Allied for Essential Medicines (UAEM) submitted a Freedom of Information Request

- 58 Preliminary Notice of Noncompliance Letters sent
- 57 for Results, 1 for Registration
- 32 to drug makers
- 0 to Federal Agencies
- 90% reported to ClinicalTrials.gov (median = 3 weeks)
- UAEM released the full text of all 58 letters

Strengthening the FDA's Enforcement of ClinicalTrials.gov Reporting Requirements <https://jamanetwork.com/journals/jama/fullarticle/2786399>
https://www.uaem.org/freedom_of_information_act

Liability

- As a State institution UMB records must comply with records requests under a FOI under state or federal law
- Imperative to maintain public trust through timely, quality submissions

FDAAA TrialsTracker

[Single trials](#)[Ranked sponsors](#)[FAQ](#)[Blog](#)[Fund this work!](#)[@FDAAATracker](#)

an +AllTrials campaign

All individual trials at University of Maryland, Baltimore

Trials reported

24 out of 29



Percent reported

82.8%



US Govt could have imposed fines of at least

\$75,719,105



Fines claimed by US Govt

\$0



Filter trials by status:

☒ On ☐ Overdue ☐ Off ☐ Ongoing ☐ Off ☐ Reported ☐ Off ☐ Reported (late)

<http://fdaaa.trialstracker.net/>

FDAAA TrialsTracker

Filter trials by status:

☒ On Overdue ☐ Off Ongoing ☐ Off Reported ☐ Off Reported (late)

↑↓ Status	↑↓ Trial ID	↑↓ Title	↑↓ Completion date	↑↓ Days overdue
overdue	NCT03220438	Testing TMS Enhancement of Visual Plasticity in Schizophrenia	2019-07-16	533
overdue	NCT02878785	Multicenter Phase 1/2 Study of Combination Therapy w/ DNA Methyltransferase Inhibitor Decitabine & Poly ADP Ribose Polymerase Inhibitor Talazoparib for Untreated AML in Adults Unfit for Cytotoxic Chemotherapy or R/R AML [pACT]	2020-01-05	360
overdue	NCT03840837	Cholinergic Neurotransmission - A Common Underlying Mechanism of Cognitive and Gait Impairment in Parkinson Disease	2020-04-01	274
overdue	NCT04301193	Evaluation of Novel Point of Care Coagulation System in Pregnant Women	2020-07-31	153
overdue	NCT02930044	Prospective Comparison of Early Subcutaneous Insulin Glargine Plus Standard of Care Versus Standard of Care for Treatment of Diabetic Ketoacidosis in the Emergency Department [pACT]	2020-11-30	31

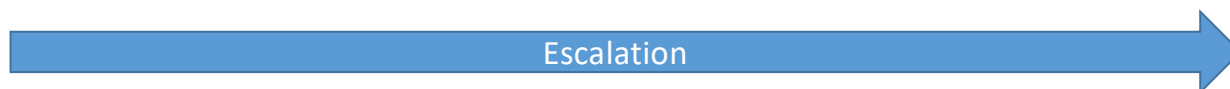
[Download this data](#)

<http://fdaaa.trialstracker.net/>

ClinicalTrials.gov at UMB

Communication Process at UMB

Communication	PI	Auditing and Monitoring (OAC)	Chair/Dean /IO
Email/CICERO	✓		
Email/CICERO #2	✓	✓	
Email/CICERO #3	✓	✓	✓



UMB OAC

- OAC monitors compliance
- OAC will send periodic e-mails to PIs with non-compliant or soon to be non-compliant issues

UMB HRPO

- Problem records will impact future HRPO review
- Continuing Review will be delayed/denied with annual verification
- Appropriate handoff for new PIs (data, reporting obligations)
- Use the checklist to increase quality and decrease time in review

Departing Faculty

- UMB is considering instituting a Checklist for departing faculty
- Each clinical trial needs action
 1. Will the study/grant be transferred to the new institution?
 2. Will the study/grant be transferred to a new PI at UMB?
- Data from clinical trials are property of UMB and not the PI
 - Cannot be taken
 - If taken must be returned immediately
 - Refusal to return may involve legal action

Modernization

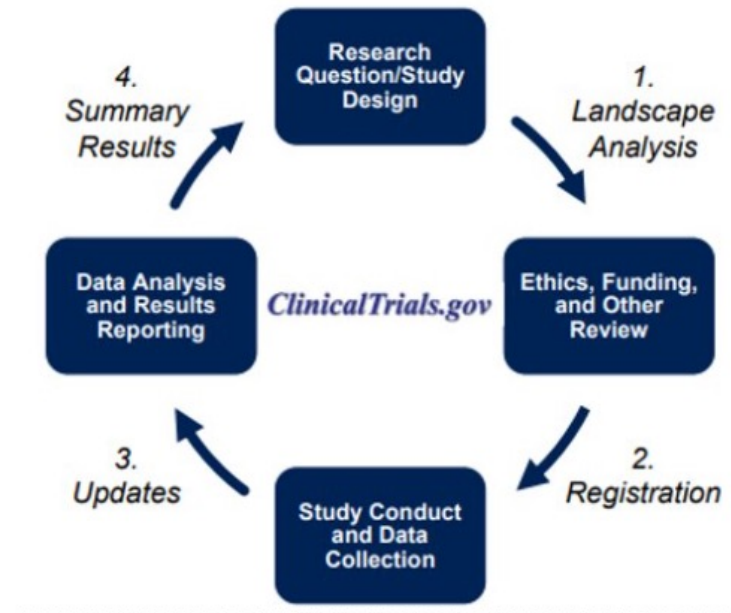
ClinicalTrials.gov Modernization

- NLM: [Public Comments Received in Response to Request for Information \(RFI\): ClinicalTrials.gov Modernization](#) (PDF; April 28, 2020): (268 responses)
- NLM: [ClinicalTrials.gov Summary of Responses to the RFI](#) (PDF; April 28, 2020): This report provides a high-level summary of the responses
- April 30, 2020 Public Meeting
- [Introduction and Overview Session Slides](#) (PDF)
- [Information Submission Panel slides](#) (PDF)
- [Website Functionality Panel slides](#) (PDF)

[ClinicalTrials.gov Modernization](#)

ClinicalTrials.gov Modernization

- Multi-year project entering year 4
- Beta website Launched on December 8, 2021
<https://beta.clinicaltrials.gov/>
- Available in parallel until improvements are made and the current site is retired



Taskforce

The Clinical Trials Registration and Results Reporting Taskforce focuses on the requirements for clinical trials registration and results reporting that affect US academic health centers.

- Understanding and applying the requirements;
- Identifying best practices;
- Developing tools to assist investigators;
- Serving as a communication forum.

<https://ctrtaskforce.org/>

Taskforce

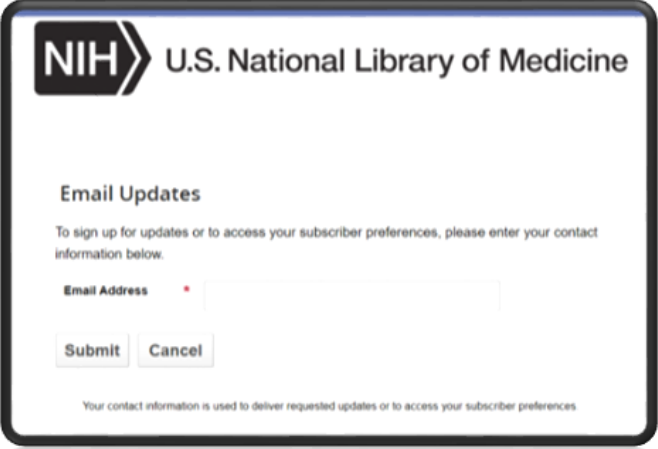
Made up of 200 institutions and 500 members

- Meet monthly to discuss trends, current topics
- Active listserv
- Subcommittees

<https://ctrtaskforce.org/>

Action Items

- Know what records need registration
- Know what records need results reporting
- Keep a close eye on your records
- Listen to the HRPO!
- Join the Taskforce
- [ClinicalTrials.gov](https://clinicaltrials.gov) Hot Off the PRS!



The screenshot shows a web form titled "Email Updates" from the NIH U.S. National Library of Medicine. The form asks for contact information to sign up for updates or access subscriber preferences. It includes a text input field for the email address, a red asterisk indicating a required field, and "Submit" and "Cancel" buttons. A small disclaimer at the bottom states: "Your contact information is used to deliver requested updates or to access your subscriber preferences." Below the form, there is a faint, mirrored version of the form and the Johns Hopkins logo.

NIH U.S. National Library of Medicine

Email Updates

To sign up for updates or to access your subscriber preferences, please enter your contact information below.

Email Address *

Submit Cancel

Your contact information is used to deliver requested updates or to access your subscriber preferences

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TRANSLATIONAL RESEARCH

Questions?

Please visit our website for tutorials and more detailed information:

<https://ictr.johnshopkins.edu/clinicaltrials-gov>

See us on YouTube at "[JohnsHopkinsCTgov](#)"

Email us with any questions at

registerclinicaltrials@jhmi.edu