ClinicalTrials.gov: All you need to know

University of Maryland

January 20, 2022

Presented by: Anthony Keyes, MBA, PMP, *Director, Johns Hopkins Clinical Trials.gov Program*
Kim Hill, Clinical Research Compliance Specialist

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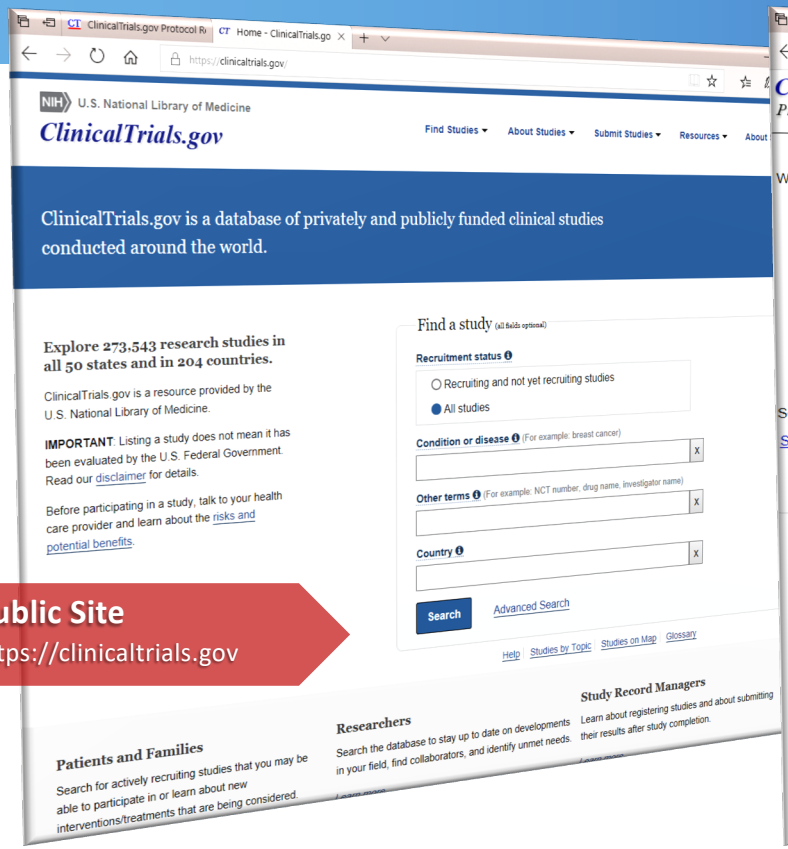
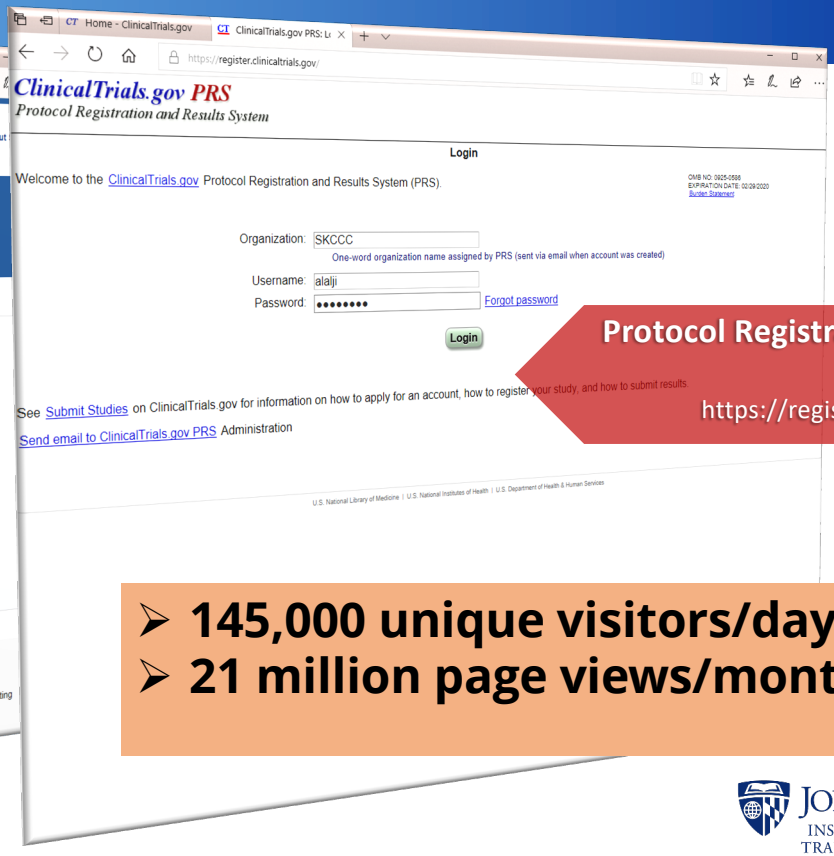
ClinicalTrials.gov





Public Site
https://clinicaltrials.gov

Protocol Registration & Results System (PRS)
https://register.clinicaltrials.gov

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

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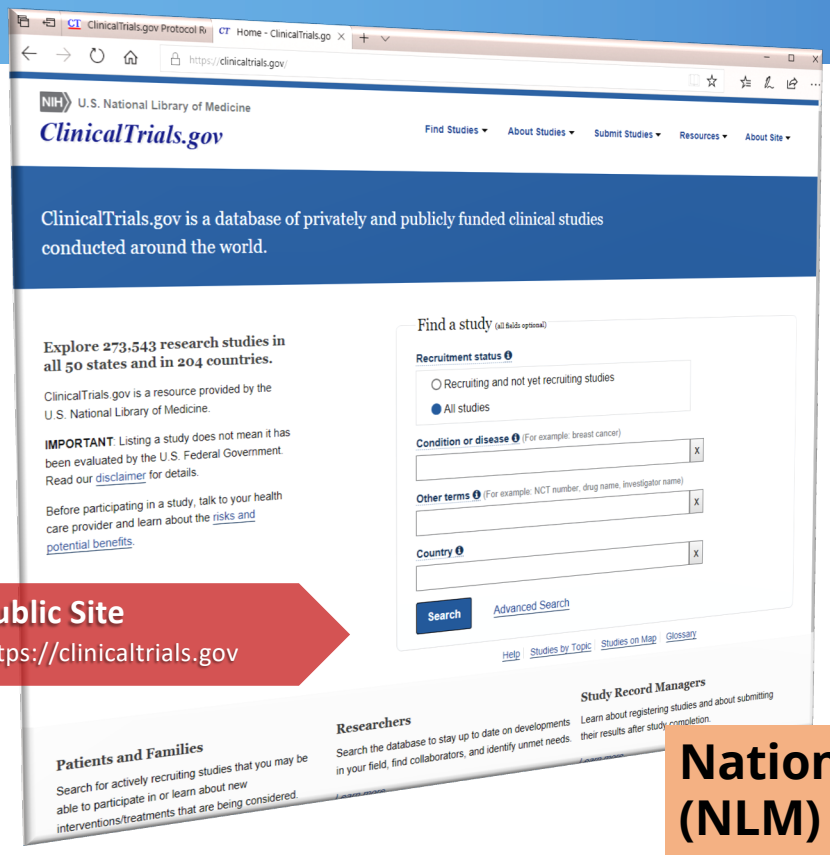
ClinicalTrials.gov



Public Site
https://clinicaltrials.gov

Beta Site
https://beta.clinicaltrials.gov/

National Library of Medicine (NLM) is looking for feedback

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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

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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

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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

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§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	• $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	• 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	• 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	• $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

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Responding to Comments

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

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Annual Verification

- ❑Verify the record **annually**

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

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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.

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*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

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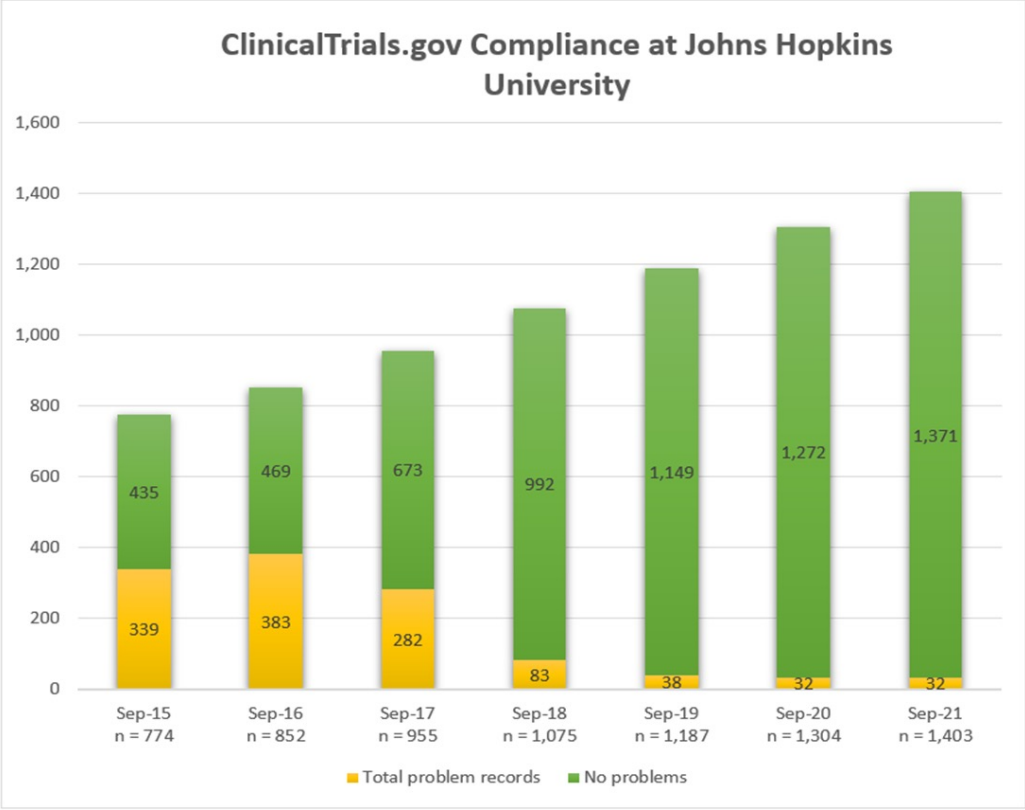
Building Compliance



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

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Tips and Tricks for Entering Data

Kim Hill, Clinical Research Compliance Specialist

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Registering the Record

ClinicalTrials.gov Account set-up
Martina Miller of HRPO
Martina.miller@umaryland.edu

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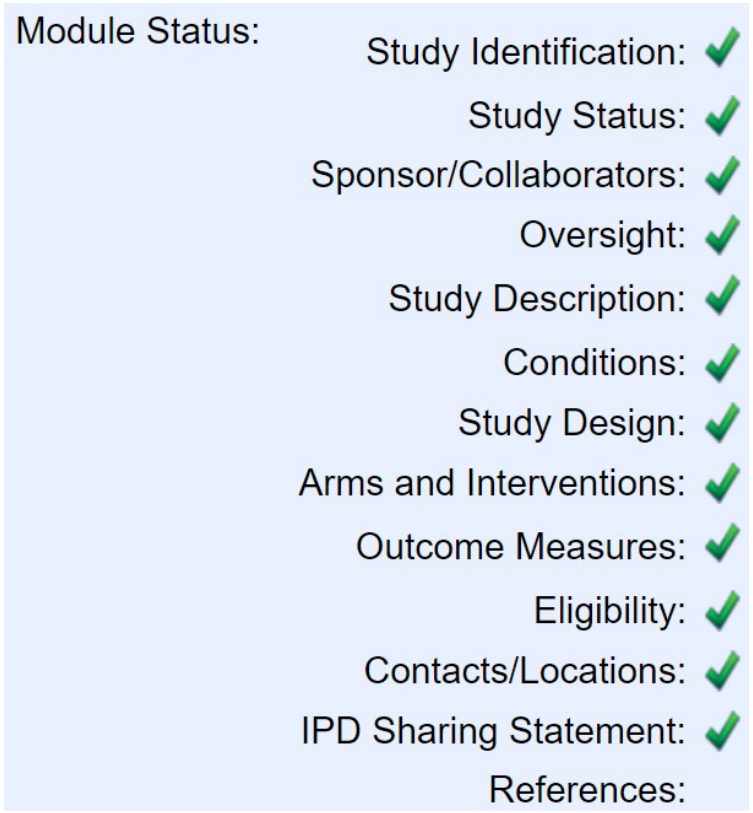
Registering the Record



The System will guide you through each step

Help Definitions Spelling

Step-by-step videos

1. Registration
2. Results Reporting

- YouTube at "Johns HopkinsCTgov"

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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 addressed to see if you need to make corrections.

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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.*

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Registering the Record

Study Status

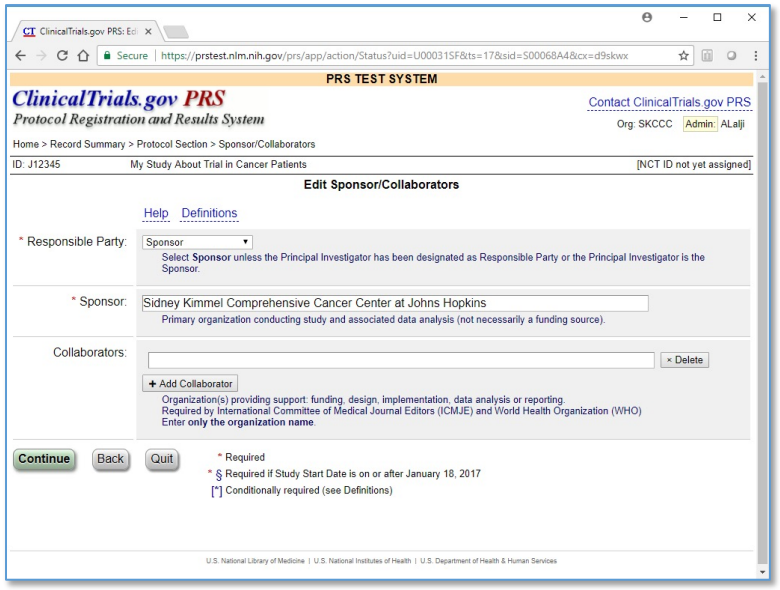
This section must be updated at least once a year or within 30 days of any changes

- **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



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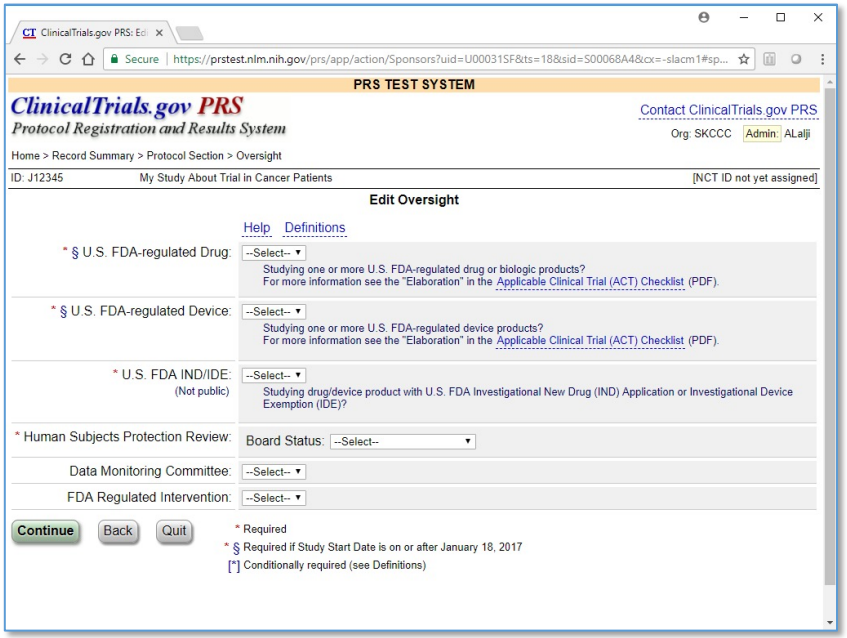
Registering the Record

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)*



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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

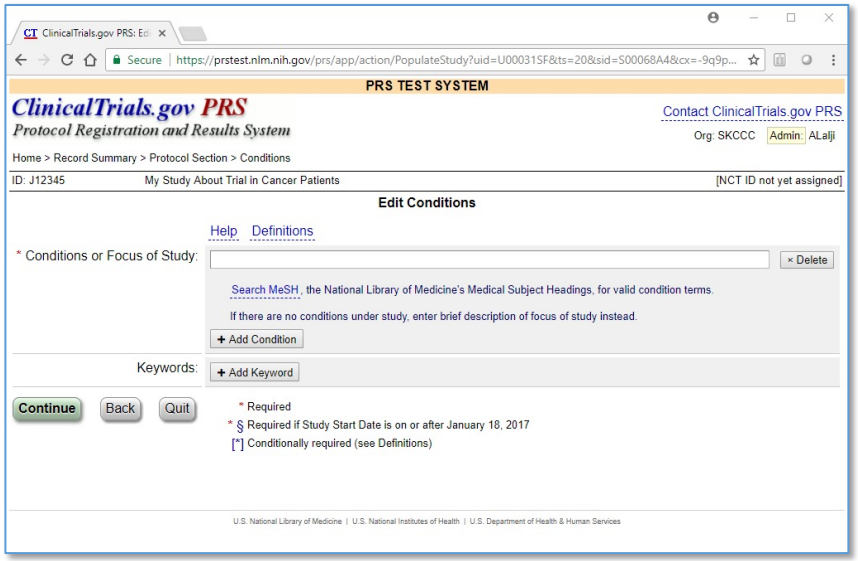
Formatting:

- 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.



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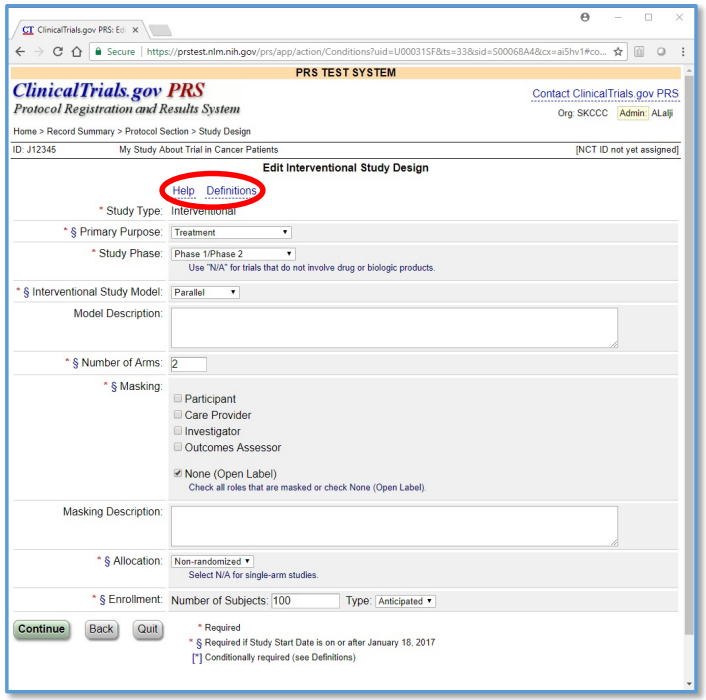
Registering the Record

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)



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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	☑	☑	☐
Experimental: Cohort B - Durvalumab and Weekly-dose Tremelimumab	☑	☐	☑

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

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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 ≥ 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..

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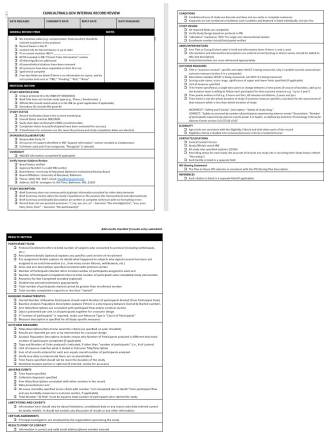
Using the Checklist

CLINICALTRIALS.GOV INTERNAL RECORD REVIEW

DATE RELEASED	COMMENTS DATE	REPLY DATE	DATE PUBLISHED

GENERAL REVIEW ITEMS	NOTES
❑ No monetary value (e.g. compensation, food voucher) should be entered anywhere in the protocol ❑ Record Owner is the PI ❑ Contact info for Record Owner is up-to-date ❑ PI on record matches IRB PI: _____ ❑ NCT# included in IRB "Clinical Trials Information" section ❑ All Warnings/Errors addressed ❑ All parenthetical citations have been removed ❑ All acronyms have been expanded on their first use ❑ Spell-check complete ❑ 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

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FDA Enforcement

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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
Accuitis Inc.	NCT03064438	7/26/2021
Acceleron Pharma, Inc.	NCT01727336	4/27/2021

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

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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

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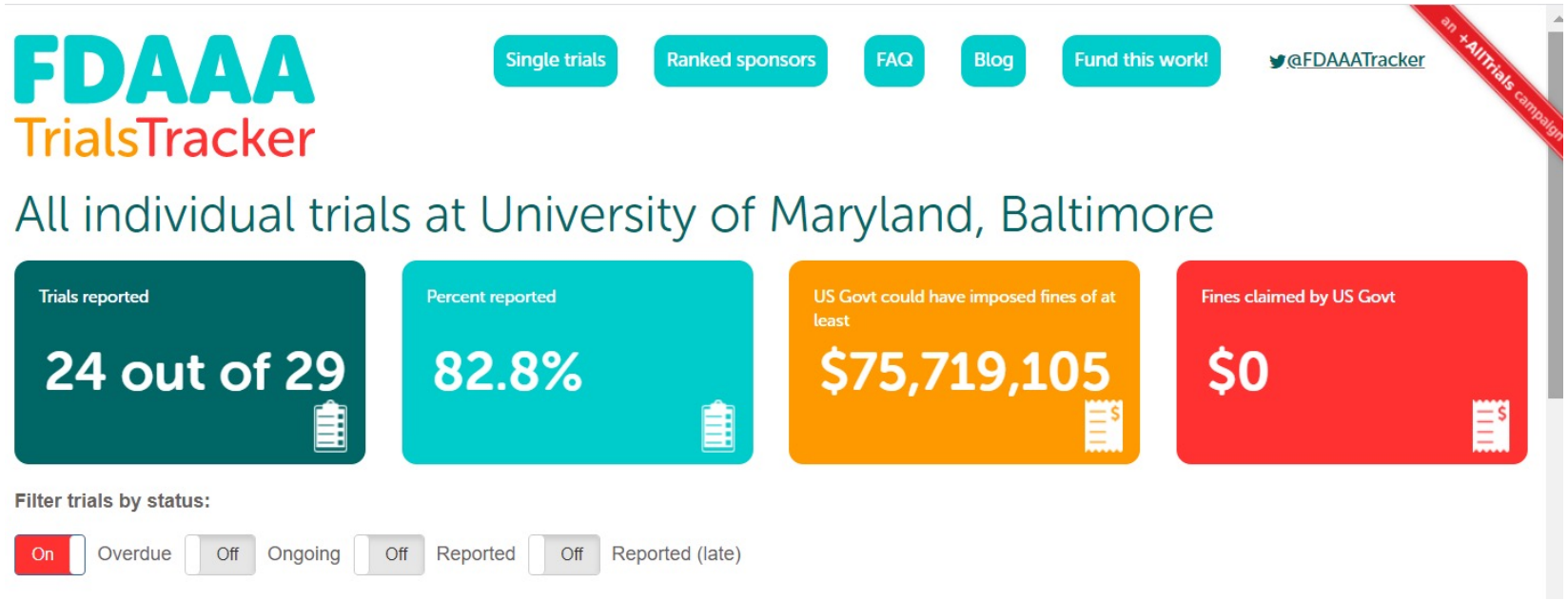
Liability

- 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



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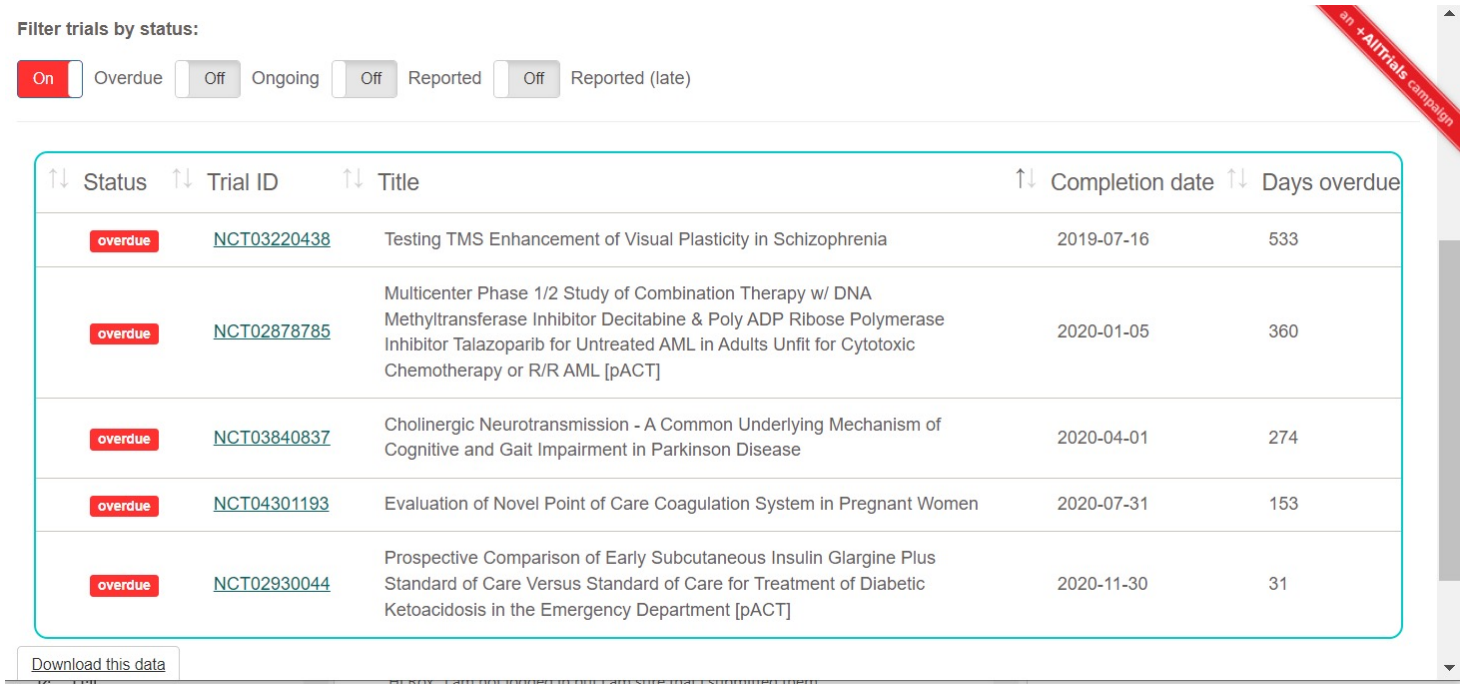
http://fdaaa.trialstracker.net/

FDAAA TrialsTracker



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http://fdaaa.trialstracker.net/

ClinicalTrials.gov at UMB

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Communication Process at UMB

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

Escalation

Escalation

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UMB OAC

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

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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

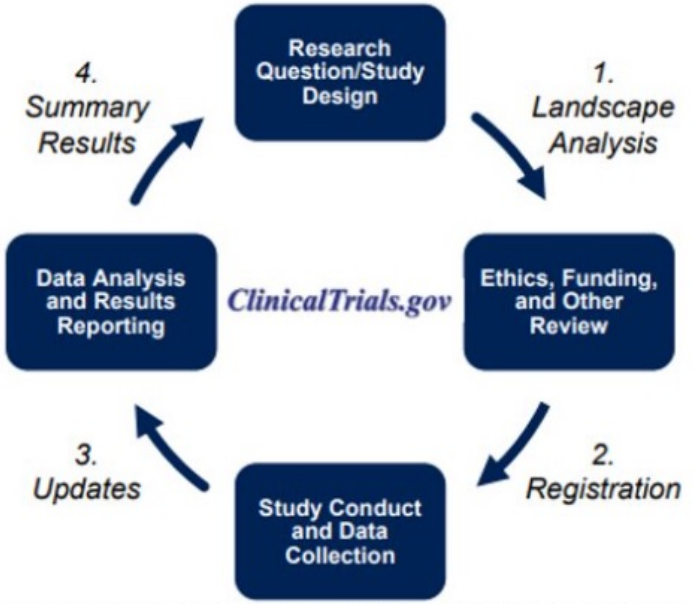
Modernization

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

- 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



ClinicalTrials.gov Modernization

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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://ctrrtaskforce.org/

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Taskforce

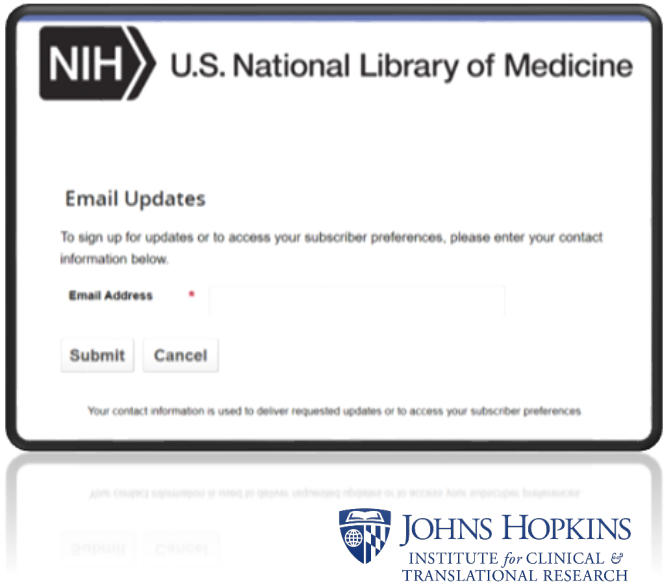
Made up of 200 institutions and 500 members

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

https://ctrrtaskforce.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 Hot Off the PRS!



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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

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