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Overview of ClinicalTrials.gov

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Human Subjects Protections Program

Presentation Objectives

- Conduct an overview and raise awareness of ClinicalTrials.gov's Protocol Registration and Results Reporting Requirements.
- Highlight program centralization as well as new responsibilities and expectations.
- Clarify regulatory requirements for registration and results reporting, including determination of Applicable Clinical Trials (ACTs)
- Provide summary and access to resources and training.

Overview

- What is ClinicalTrials.gov?
- History of ClinicalTrials.gov and Regulatory Requirements
- Why is ClinicalTrials.gov Important?
- Important Terms, Roles and Responsibility
- Process, Requirements and Potential Consequences of Non-Compliance
- Training and Resources

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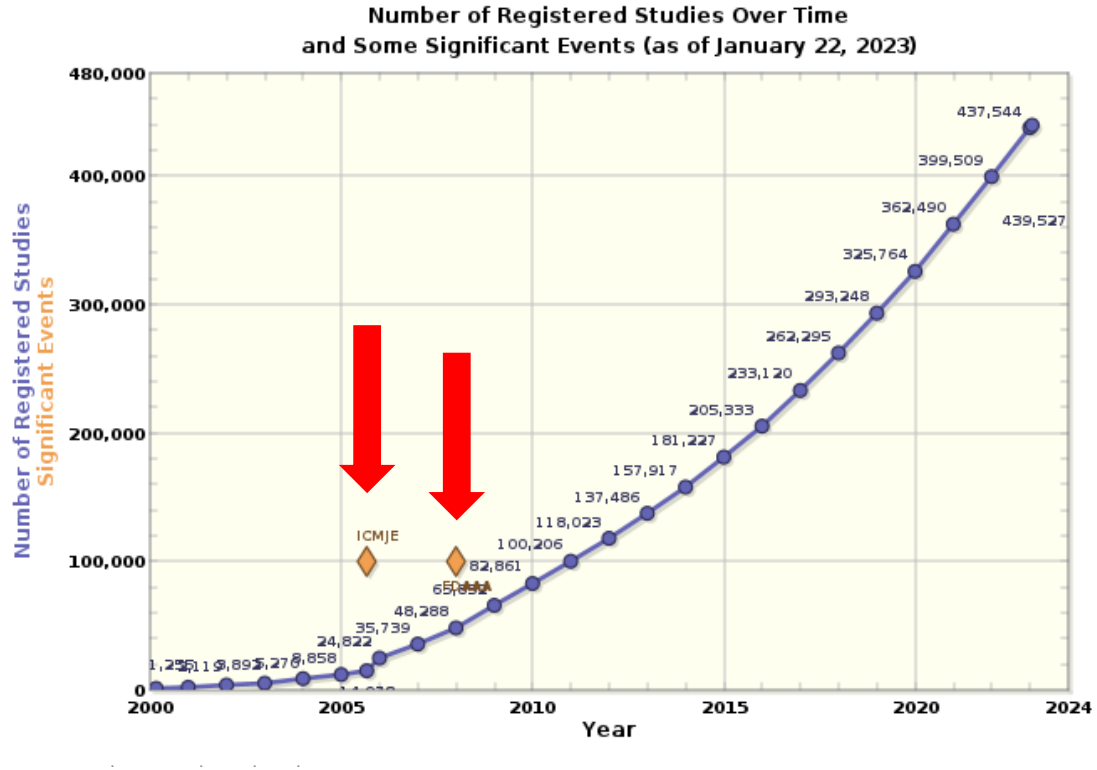
What is ClinicalTrials.gov?

- Clinicaltrials.gov is a publicly accessible database maintained by the National Library of Medicine (NLM) at the National Institutes of Health (NIH).



[1] Number of Registered Studies Over Time. (2023). Clinicaltrials.gov. Retrieved from: https://clinicaltrials.gov/ct2/resources/trends

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What is ClinicalTrials.gov?

- Provides patients, families, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions.
  - Used by patients, families, health care professionals and researchers.
  - It can be used to inform funders and funding decisions.

- ClinicalTrials.gov Basic Functions
  - Registration
  - Results Reporting

- ClinicalTrials.gov Systems
  - Public Site
  - User Site: Protocol Registration and Results System (PRS)

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History of ClinicalTrials.gov and FDAAA 801 and the Final Rule

- History Policies and Laws

- 2020-2023: Current State, ClinicalTrials.gov Beta and Modernization Effort In Progress.

- January 2023: The Final NIH Policy for Data Management and Sharing took effect.

- February 2023: Good Cause Extension

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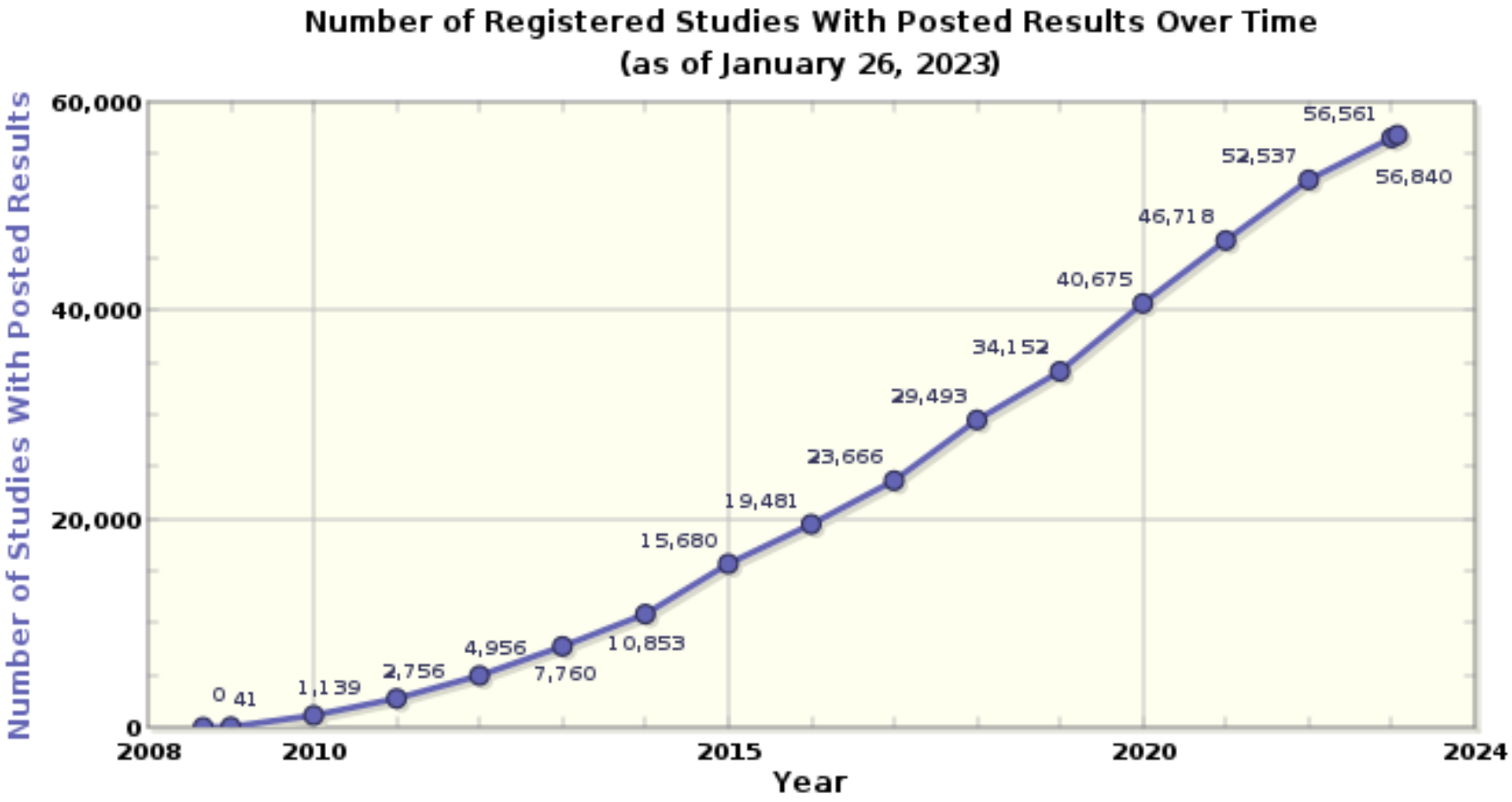
[2] History, Policies and Laws. (2023). ClinicalTrials.gov. Retrieved from: https://clinicaltrials.gov/ct2/about-site/history#CongressPassesLawFDAMA

[1] Number of Registered Studies Over Time. (2023). Clinicaltrials.gov. Retrieved from: https://clinicaltrials.gov/ct2/resources/trends



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[3] Number of Registered Studies with Posted Results Over Time. (2023). ClinicalTrials.gov. Retrieved from: https://clinicaltrials.gov/ct2/resources/trends

History of ClinicalTrials.gov and FDAAA 801 and the Final Rule

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Why is ClinicalTrials.gov Important?

- Public health benefits of access to clinical trials information.
- Publication issues.
- Incomplete disclosure of research results impedes the scientific process.
- Lack of availability of clinical trial results

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[4] Burton, Amanda. (2021, August). History of the Clinical Trial Transparency and Disclosure Landscape [PowerPoint Slides]. NIH National Library of Medicine. Retrieved from: https://www.nlm.nih.gov/oet/ed/ct/2021_prs_ttt/pre-work_ct_landscape/history.html

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Important Terms

Term	Definition
Applicable Clinical Trials (ACT)	The Final Rule states that an "applicable clinical trial means an applicable device clinical trial or an applicable drug clinical trial."
Final Rule	"Final Rule" is short for the Final Rule for Clinical Trials Registration and Results Information Submission, which is the regulation that requires researchers conducting ACTs to register and submit summary results information.
NCT Number	"NCT number means the unique identification code assigned to each record in ClinicalTrials.gov, including a record for an applicable clinical trial, a clinical trial, or an expanded access program"
Principal Investigator	"Principal investigator means the individual who is responsible for the overall scientific and technical direction of the study"
PRS	The Protocol Registration and Results System (PRS) is the interface used by the responsible party (RP) and the RP's associates to enter data into the ClinicalTrials.gov database.
Responsible Party	The RP is the entity or individual who is responsible for registering a clinical investigation and submitting clinical trial information to the clinical trial registry data bank.
Study Start Date	The estimated date on which the clinical study will be open for recruitment of participants, or the actual date on which the first participant was enrolled.
Study Completion Date	Study completion date means, for a clinical trials, the date the final subject was examined or received an intervention for the purposes of final collection of data for the primary and secondary outcome measures and adverse events.

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[5] Protocol Registration and Summary Results Information Submission in ClinicalTrials.gov: Key Terms. (2019). Citi Program. Retrieved from: https://www.citiprogram.org/citidocuments/_001pic/keyterms_MR1.pdf

Roles and Responsibilities

Role	Descriptions of Responsibilities
Sponsor Organization	**A company, university, medical center or other research organization that conducts clinical trials.** Each study record has a sponsor organization, and all PRS accounts associated with that record should be under the sponsor organization. Investigators apply to be users of the sponsor organization's PRS account. If an investigator is conducting trials for more than one sponsor organization, he or she will need an account from each of those organizations to register the studies properly.)
Administrator	**Individual designated by the organization to manage the organization's PRS account, create accounts for users, and serve as the point of contact for PRS Staff**. All PRS organization accounts should have at least one administrator who creates user accounts and oversees the maintenance of the organization's records. Administrators are responsible for releasing records for PRS review and posting to ClinicalTrials.gov
User	**Any PRS account holder who is authorized to enter information into the PRS, including investigators or research assistants**. Users create and modify their own records but cannot access other users' records unless authorized by the Record Owner or by an Administrator.
Record Owner	**PRS account holder who creates a study record in the PRS. Record Owners can maintain the record themselves or give one or more user's access to a record to make changes**. An administrator can change the record owner after the record has been created.
Responsible Party	**Entity or individual responsible for verifying the accuracy of a study record and releasing it to ClinicalTrials.gov.** The responsible part for a particular study may be the sponsor, sponsor-investigator, or principal investigator. When the responsible party is the sponsor, an administrator performs these record functions.

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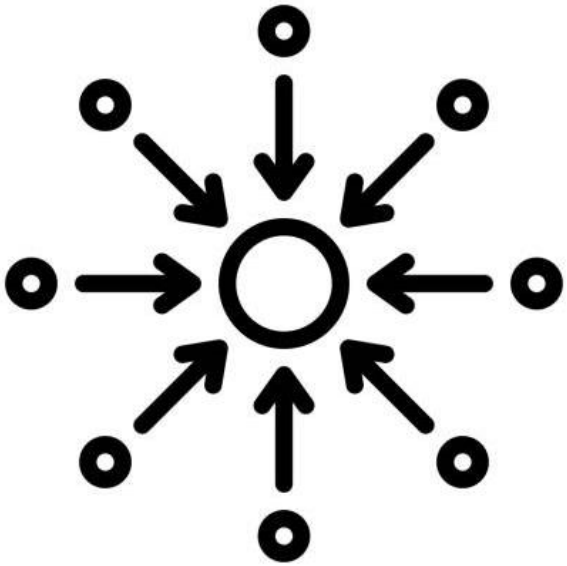
[6] Overview: Roles and Responsibilities. (2023). ClinicalTrials.gov PRS. Retrieved from: https://prsinfo.clinicaltrials.gov/prs-users-guide.html#overviewrolesandresponsibilities

CHLA ClinicalTrials.gov Program Centralization Model



- Reduce risk of non-compliance.
- Reduce administrative burden from PIs and Study Teams.
- Facilitate the registration and results reporting process.
- Provide regulatory expertise and guidance.
- Easier to facilitate and keep momentum on records as they go through the process.

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Overview of Phases and Record Stages

Phase	Record Stage
Registration	New PI/study team member needs ClinicalTrials.gov user account.
	Study is approved by IRB.
	Study needs to be registered
	Study record ready for review and approval.
	ClinicalTrials.gov reviewers identify major issues that need to be addressed before study record can be posted.
Maintenance	Record is posted
	Study has changed (started, completed, amended)
	Study is completed.
Results Reporting	Results need to be reported.
	Results entered and study record marked as entry completed.
	Results are unavailable
	ClinicalTrials.gov reviewers identify major issues in results reporting that need to be addressed.

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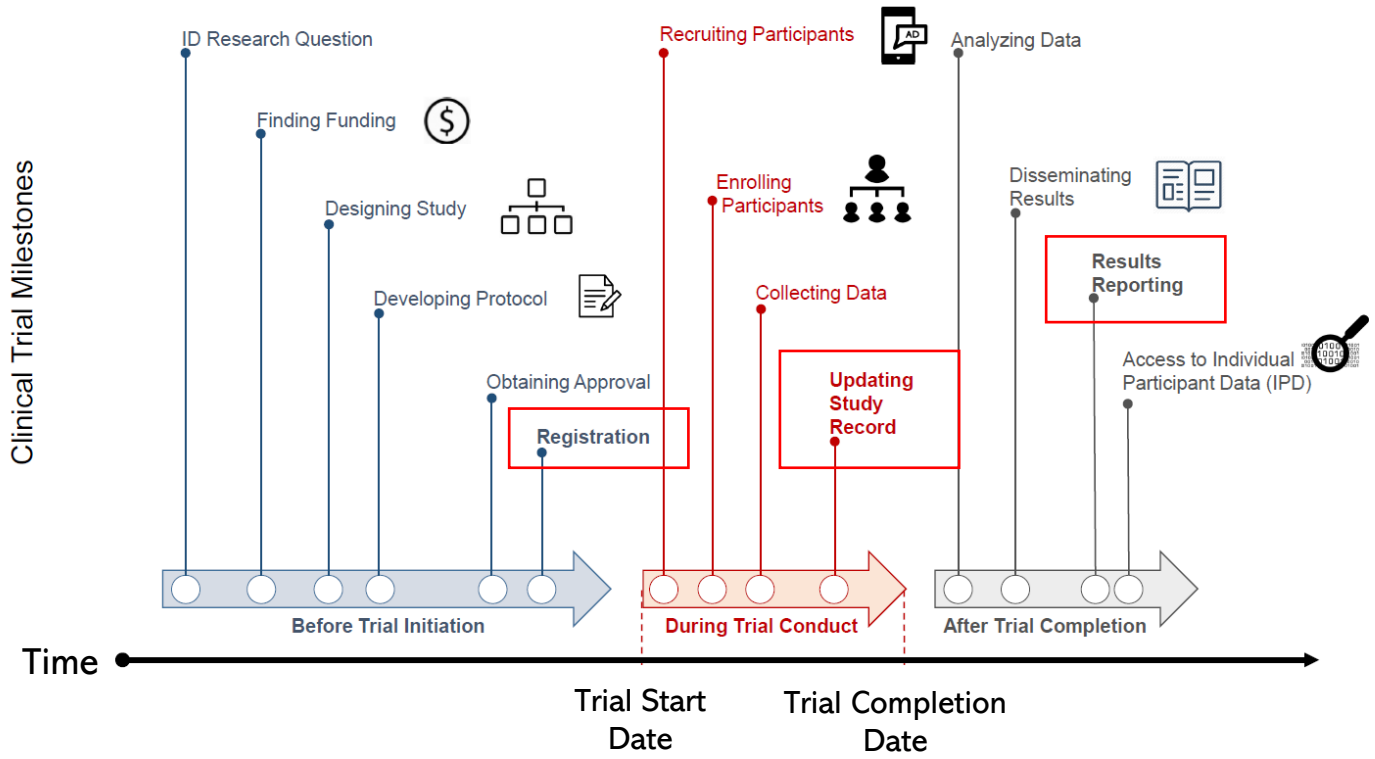
Process



Reporting Requirements	ICMJE Policy	FDAAA 801/FINAL RULE	Final NIH Policy
Initial Registration	Prior to enrollment of first participant.	Not later than 21 days after enrollment of first participant	Not later than 21 days after enrollment of first participant

[8] Williams, Rebecca (2020, January 22) "ClinicalTrials.gov Modernization and How to Provide Your Input". NIH National Library of Medicine. Retrieved from: https://www.nlm.nih.gov/oet/ed/ct/modernization.html

Which trials require registration on ClinicalTrials.gov?

International Committee of Medical Journal Editors (ICMJE): All clinical trials per WHO definition "any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes" require public protocol registration and *Individual Participant Data Sharing Plan* prior to first participant enrolled.

Food and Drug Administration (FDA): Applicable Clinical Trials (ACTs) must register and report results. ACTs (checklist next page, see 'Elaboration' for details) are interventional Phase 2-4 trials that study FDA-Regulated drugs, biologics, or device (with the exception of small feasibility device studies). Trial must have NCT number (be registered) within 21 days of first participant enrolled.

National Institutes of Health (NIH): Applicable to all clinical trials funded by NIH and IRB approved on or after January 18, 2017. NIH Policy requires public protocol registration and results reporting for all trials in which prospectively assigned human participants receive one or more intervention to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. Trial must have NCT number (be registered) within 21 days of first participant enrolled. NIH ASSIST sources CT.gov to pre-populate annual reports due as a condition of funding.

Centers for Medicare and Medicaid Services (CMS): 'Qualifying Trials' of therapeutic intent that enroll participants diagnosed with disease that evaluate an item or service that falls within the Medicare benefit category require study protocols be registered to the public.

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[11] Investigator Guidance to ClinicalTrails.gov (2021). University of Wisconsin. Retrieved from: https://uwclinicaltrials.org/wp-content/uploads/2022/02/Investigator-Guidance-to-CT.gov_vDec2021.pdf

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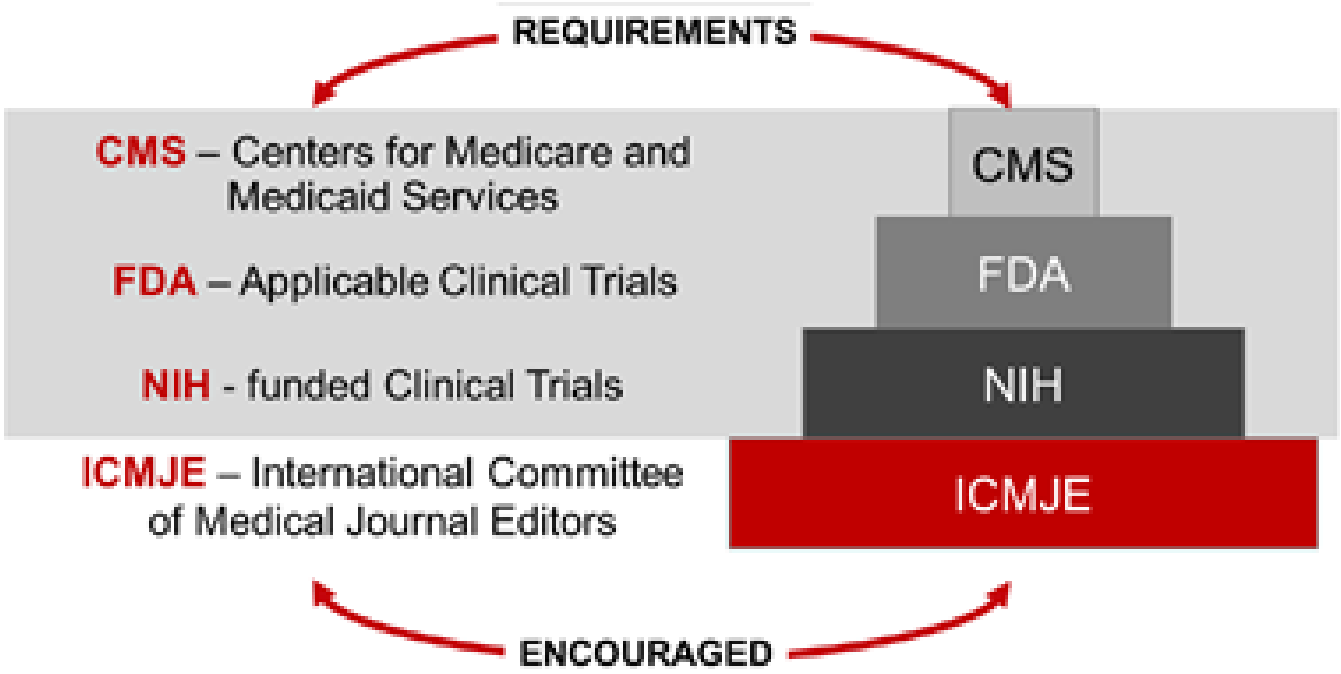
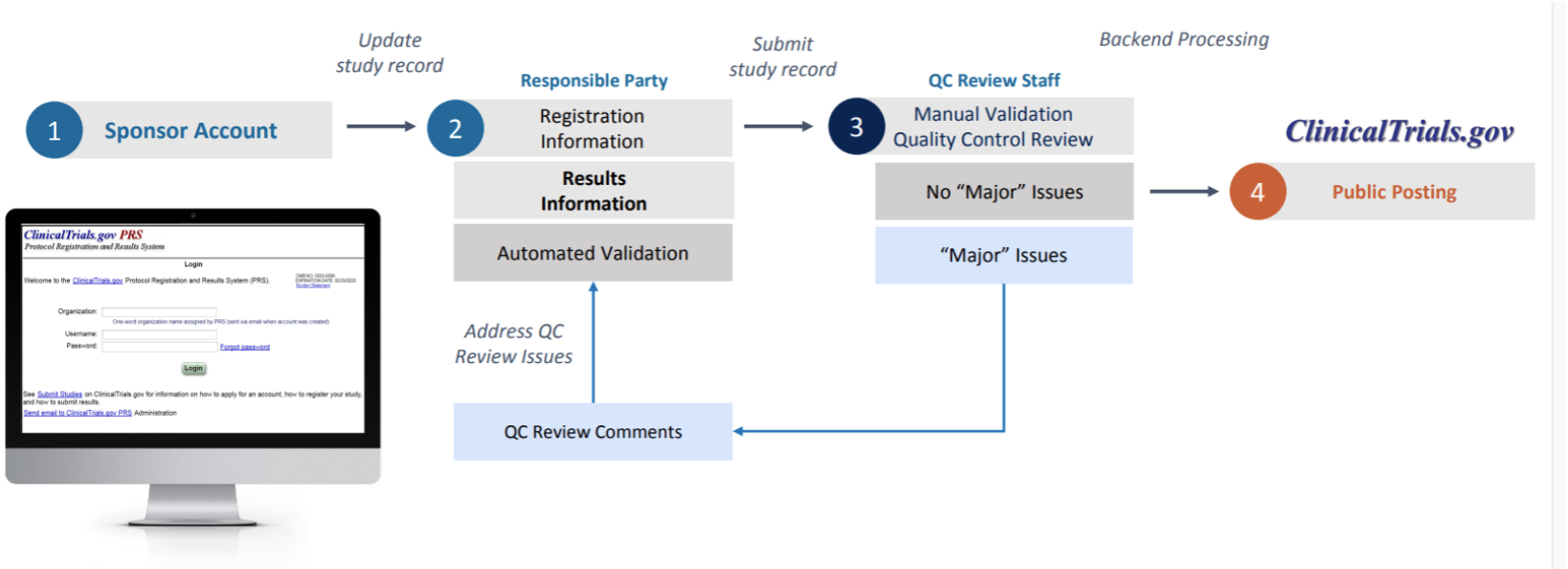


Journals stating that they follow the ICMJE Recommendations

[11] Investigator Guidance to ClinicalTrails.gov (2021). University of Wisconsin. Retrieved from: https://uwclinicaltrials.org/wp-content/uploads/2022/02/Investigator-Guidance-to-CT.gov_vDec2021.pdf



If the investigator would like to designate a member of the study team to make updates to the study record, they can be added to access list.

Contact: nkamel@chla.usc.edu

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Registration	*NCT # assigned prior to first participant enrolled*											
	months											
	1	2	3	4	5	6	7	8	9	10	11	12
Maintenance	*update record within X months of study change*											
Study Status Changes	X											
Protocol Amendments	X											
* Final Enrollment	X											
* Upload Consent Form		X		* *from date upon which all data collection*								
Primary Completion Date	X				*is complete*							
Study Completion Date	X											
Annual Verification												X
Results Reporting	*months from Actual Primary/Study Completion Date*											
Open Results Module						X						
Populate Result Module							X	X	X			
Submit Results Module										X		
PRS Review Process										X	X	
Results Posted												X

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[11] Investigator Guidance to ClinicalTrails.gov (2021). University of Wisconsin. Retrieved from: https://uwclinicaltrials.org/wp-content/uploads/2022/02/Investigator-Guidance-to-CT.gov_vDec2021.pdf

Potential Consequences for Noncompliance

Reporting Requirements	ICMJE Guidance	FDA FDAAA 801/FINAL RULE	NIH Policy	CMS
Scope	Registration for any Clinical Trial	Registration and Results Reporting for Applicable Clinical Trials	Registration and Results Reporting for NIH-Funded Clinical Trials	Registration for any Clinical Trial
Phase	All	Phase II - IV	All	All
Intervention Type	All	Drug, biologic, & device products regulated by the FDA	All (e.g. including behavioral interventions)	"qualifying trial" of therapeutic intent evaluating Medicare benefit & enrolling participants with diagnosed disease
Funding Source	Any	Any	NIH	Any
Individual Participant Data (IPD) Sharing Plan	Required at Registration	N/A	N/A	N/A
Initial Registration	Prior to enrollment of first participant.	Not later than 21 days after enrollment of first participant	Not later than 21 days after enrollment of first participant	N/A
Results Reporting	N/A	Within 12 months of primary completion date	Within 12 months of primary completion date	N/A
Enforcement	Refusal to publish	• Criminal proceedings and civil penalties (up to $12,462/day/study. • Loss of HHS Funding	• Suspension or termination of grant or contract funding • Can be considered in future funding decisions.	• Delayed initiation; Billing delayed or denied

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[11] Investigator Guidance to ClinicalTrails.gov (2021). University of Wisconsin. Retrieved from: https://uwclinicaltrials.org/wp-content/uploads/2022/02/Investigator-Guidance-to-CT.gov_vDec2021.pdf

Emergency Use, Expanded Access Protocols (EAPs) and Compassionate Use

- Emergency Use

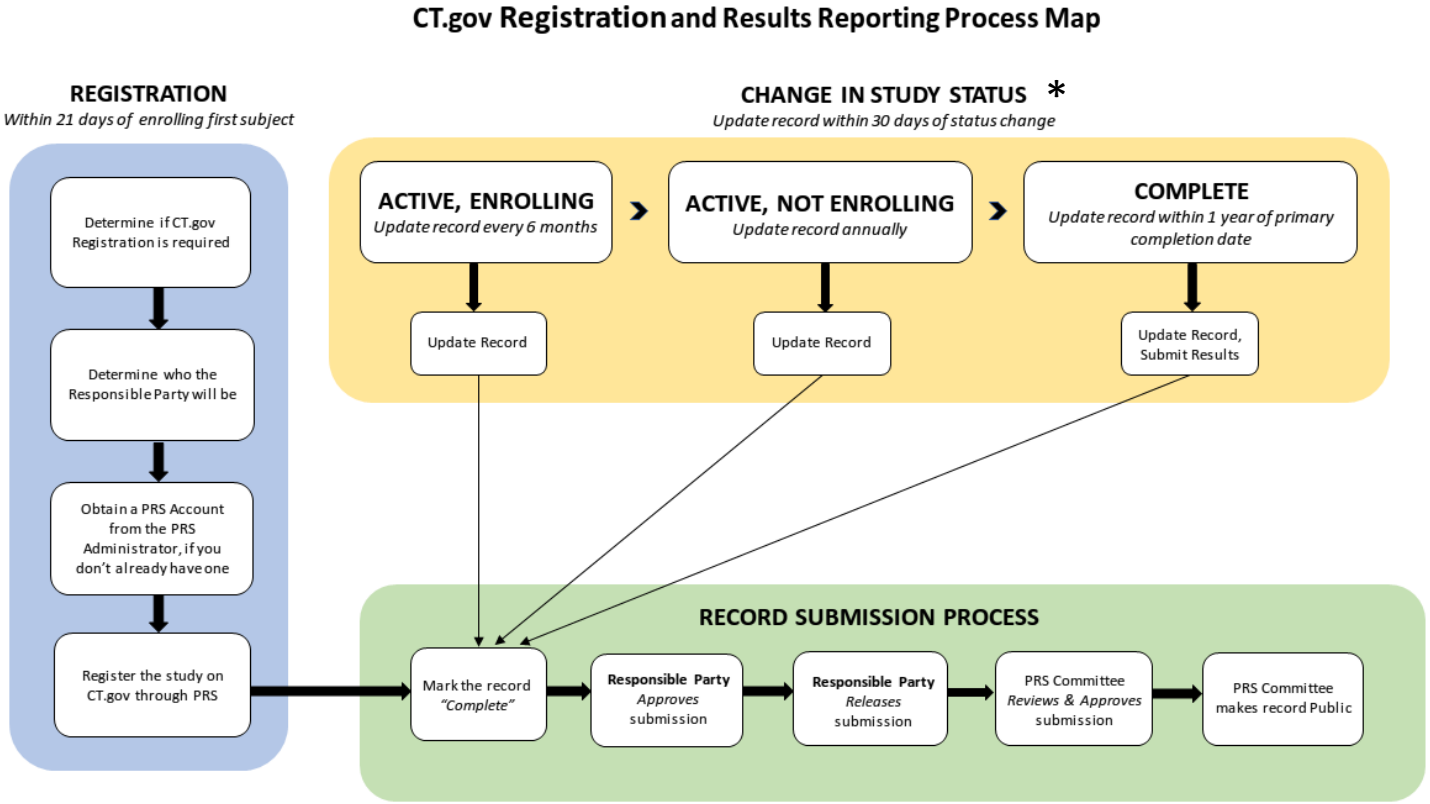
- Expanded Access Protocols (EAPs)/Compassionate Use

Risks of Non-Compliance

- Risks include:
  - Notice of non-compliance.
  - Fined up to $12,462/day/study for any issue of non-compliance (not just late results).
  - NIH can withhold funding.
  - Manuscripts can be refused.

Reporting Requirements	ICMJE Policy	FDAAA 801/FINAL RULE	Final NIH Policy
Enforcement of Non-Compliance	Refusal to publish	• Criminal proceedings and civil penalties (up to $12,462/day/study) • Loss of HHS Funding	• Suspension or termination of grant or contract funding • Can be considered in future funding decisions.

Process, Requirements and Risks of Non-Compliance



*Regarding change in status, device product not approved or cleared by U.S. FDA must be completed within 15 calendar days after a change in approval or clearance status has occurred.

[9] Support for ClinicalTrials.gov Compliance (2023) . The Ohio State University Center for Clinical and Translational Science. Retrieved from: https://ccts.osu.edu/content/support-clinicaltrialsgov-compliance

Registration	*NCT # assigned prior to first participant enrolled*											
	months											
	1	2	3	4	5	6	7	8	9	10	11	12
Maintenance	*update record within X months of study change*											
Study Status Changes	X											
Protocol Amendments	X											
* Final Enrollment	X											
* Upload Consent Form		X		* *from date upon which all data collection*								
Primary Completion Date	X				*is complete*							
Study Completion Date	X											
Annual Verification												X
Results Reporting	*months from Actual Primary/Study Completion Date*											
Open Results Module						X						
Populate Result Module							X	X	X			
Submit Results Module										X		
PRS Review Process										X	X	
Results Posted												X

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Registration Centralization: New Roles and Responsibilities

Phase	Record Stage	Program Manager	PI/ Study Teams
Registration	New PI/study team member needs ClinicalTrials.gov user account.	• Create User Account	• Provide Contact Information for Account
	Study is approved by IRB.	• Look out for IRB Approvals	• Reach out to Program Manager when ready to create a registration record.
	Study needs to be registered	• Facilitate the creation of registration record by gathering all necessary information submitting for review.	• Provide all requested information and verify accuracy and completion of study record.
	Study record ready for review and approval.	• Conduct quality review to ensure all fields are complete and within guidelines.	• Correct any errors and submit completed study record.
	ClinicalTrials.gov reviewers identify major issues that need to be addressed before study record can be posted.	• Provide recommendations for addressing major issues/advisory issues before approving and releasing.	• Address Major Issues/advisory issues.

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Registration

- Study should be registered prior to the first participant is enrolled. It may take up to 2 weeks from the time of registration to when the NCT number is assigned
- **Steps for Registering a Clinical Study** on ClinicalTrials.gov
- Please use the **Protocol Registration Quality Control Review Criteria** when completing your registration record on ClinicalTrials.gov.
- After completing the registration record, PRS admin will review record against the **Protocol Registration Quality Control Review Criteria** and release for PRS review.
  - Reviewer comments may by returned. Once they are addressed, ClinicalTrials.gov will assign the study a NCT Number.
- ClinicalTrials.gov registration has a section for an Individual Participant Data (IPD) sharing statement.
- Share protocol and determine if ultimately the study will require results reporting per FDA FDAAA Law or NIH Policy. Is it an Applicable Clinical Trial?

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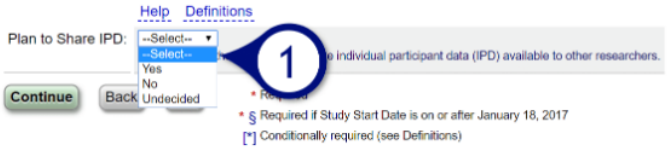
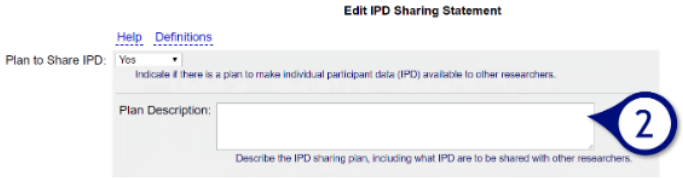
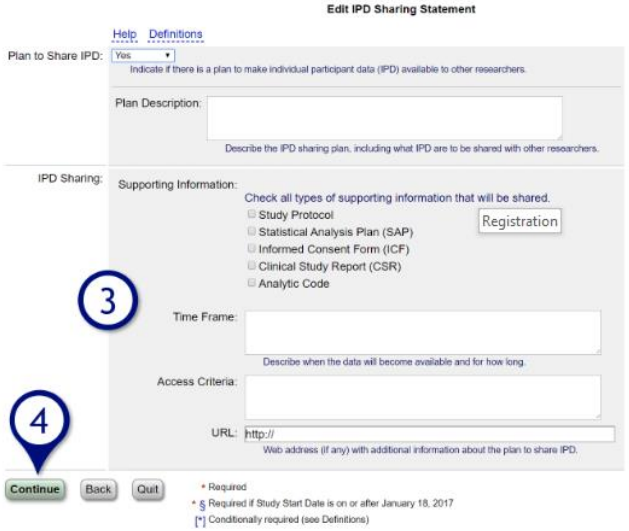
Individual Participant Data (IPD) Sharing Statement

- The guidance for ICMJE is that either “yes” or “no” be selected to the “plan to share IPD” question on ClinicalTrials.gov reg.
- Guidance for [Entering IPD Sharing Statement Information].







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Individual Participant Data (IPD) Sharing Statement Examples

Table. Examples of Data Sharing Statements That Fulfill These ICMJE Requirements*

	Example 1	Example 2	Example 3	Example 4
Will individual participant data be available (including data dictionaries)?	Yes	Yes	Yes	No
What data in particular will be shared?	All of the individual participant data collected during the trial, after deidentification.	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).	Individual participant data that underlie the results reported in this article, after deidentification (text, tables, figures, and appendices).	Not available
What other documents will be available?	Study Protocol, Statistical Analysis Plan, Informed Consent Form, Clinical Study Report, Analytic Code	Study Protocol, Statistical Analysis Plan, Analytic Code	Study Protocol	Not available
When will data be available (start and end dates)?	Immediately following publication. No end date.	Beginning 3 months and ending 5 years following article publication.	Beginning 9 months and ending 36 months following article publication.	Not applicable
With whom?	Anyone who wishes to access the data.	Researchers who provide a methodologically sound proposal.	Investigators whose proposed use of the data has been approved by an independent review committee ("learned intermediary") identified for this purpose.	Not applicable
For what types of analyses?	Any purpose.	To achieve aims in the approved proposal.	For individual participant data meta-analysis.	Not applicable
By what mechanism will data be made available?	Data are available indefinitely at (*Link to be included*).	Proposals should be directed to xxx@yyy. To gain access, data requestors will need to sign a data access agreement. Data are available for 5 years at a third party website (*Link to be included*).	Proposals may be submitted up to 36 months following article publication. After 36 months the data will be available in our University's data warehouse but without investigator support other than deposited metadata. Information regarding submitting proposals and accessing data may be found at (*Link to be provided*).	Not applicable

* These examples are meant to illustrate a range of, but not all, data sharing options.

https://www.icmje.org/news-and-editorials/data_sharing_june_2017.pdf

Criteria for Applicable Clinical Trials

If "Yes" is answered to all 4 questions, and the study was initiated on or after January 18, 2017, the trial would meet the definition of an ACT that is REQUIRED TO BE REGISTERED.

Question	Yes	No
1. Is the study interventional (a clinical trial)? *Study Type* data element is "Interventional"	☐	☐
2. Do ANY of the following apply (is the answer "Yes" to <u>at least one</u> of the following sub-questions: 2a, 2b, OR 2c)?	☐	☐
a. Is at least one study facility located in the United States or a U.S. territory? *Facility Location – Country* data element is "United States," "American Samoa," "Guam," "Northern Mariana Islands," "Puerto Rico," "U.S. Virgin Islands," or other U.S. territory.		
b. Is the study conducted under a U.S. FDA Investigational New Drug application (IND) or Investigational Device Exemption (IDE)? *U.S. Food and Drug Administration IND or IDE Number* data element is "Yes."		
c. Does the study involve a drug, biological, or device product that is manufactured in and exported from the U.S. (or a U.S. territory) for study in another country? *Product Manufactured in and Exported from the U.S.* data element is "Yes."		
3. Does the study evaluate at least one drug, biological, or device product regulated by the United States Food and Drug Administration (U.S. FDA)? *Studies a U.S. FDA-regulated Device Product* data element is "Yes" and/or *Studies a U.S. FDA-regulated Drug Product* data element is "Yes."	☐	☐
4. Is the study <u>other than</u> a Phase 1 trial of a drug and/or biological product or is the study <u>other than</u> a device feasibility study? For drug product trials, *Study Phase* data element is NOT "Phase 1" and for device product trials, *Primary Purpose* is NOT "Device Feasibility."	☐	☐

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[7] Checklist and Elaboration for Evaluating Whether a Clinical Trials of Study is an Applicable Clinical Trial (ACT Checklist). (2018). NIH National Library of Medicine ClinicalTrials.gov. Retrieved from: https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf

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Populate Result Module							X	X	X			
Submit Results Module										X		
PRS Review Process										X	X	
Results Posted												X

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Record Maintenance

- **Status Change:** Update study status within 30 days of change.
  - Actual start date: date on which the first participant is enrolled
  - Federally-funded clinical trials require Informed Consent Form is uploaded to a public database within 60 days of date that all data collection is completed.
  - Upon study completion, relevant manuscripts can be linked to ClinicalTrials.gov record.

- **Protocol Amendments:** Updates to record with every protocol amendment.
  - Release record for PRS Administrator to review before PRS review.

- **Verification:** all ClinicalTrials.gov records should be verified annually.
  - If there were no status changes or protocol amendments, verification involves careful review and relevant update of the public record and verification date.
  - PRS Administrator will reach out to study team to verify the record if deadline is approaching.

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[11] Investigator Guidance to ClinicalTrails.gov (2021). University of Wisconsin. Retrieved from: https://uwclinicaltrials.org/wp-content/uploads/2022/02/Investigator-Guidance-to-CT.gov_vDec2021.pdf

Maintenance Centralization: New Roles and Responsibilities

Phase	Record Stage	Program Manager	PI/ Study Teams
Maintenance	Record is posted	• Reminder PI/Study team that records needs to be updated annually and whenever there is a status change.	• Inform Program Manager of updates annually and when there is a status change.
	Study has changed (started, completed, amended)	• Reminder PI/Study team that records needs to be updated annually and whenever there is a status change.	• Update anticipated study dates with actual study dates within 30 days of a change in status. • Review and update record annually. • Update study record within 30 days of change if study is amended.
	Study is completed.	• Close study record by ensuring that all information is complete, Informed Consent Form and Protocol is uploaded. • Once the Actual Primary Completion Date has been set, Program Manager will email the PI with a deadline of when results are to be submitted.	• Click on "Entry Complete" button after Informed Consent Form is uploaded. • PI will inform Program Manager of the study's Completion Date along with expected dates for results. • Set Actual Primary Completion Date

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Registration	*NCT # assigned prior to first participant enrolled*											
	months											
	1	2	3	4	5	6	7	8	9	10	11	12
Maintenance	*update record within X months of study change*											
Study Status Changes	X											
Protocol Amendments	X											
* Final Enrollment	X											
* Upload Consent Form		X		* *from date upon which all data collection*								
Primary Completion Date	X				*is complete*							
Study Completion Date	X											
Annual Verification												X
Results Reporting	*months from Actual Primary/Study Completion Date*											
Open Results Module						X						
Populate Result Module							X	X	X			
Submit Results Module										X		
PRS Review Process										X	X	
Results Posted												X

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Results Reporting

- PRS Administrator will follow up with study team after the Actual Primary Completion Date regarding results reporting requirnments.

- Results are due for primary outcome measures within 1 year of the Primary Completion Date (the date upon which data collection was complete to answer all primary outcome measures).

- How to Submit Your Results for checklists, examples and templates on submitting:
  - **Participant Flow**
  - **Baseline Characteristics**
  - **Outcome Measure Data**
  - **Adverse Events Data**
  - Full **Study Protocol** and **Statistical Analysis Plan** must be uploaded with results.

- Manuscripts can be linked to ClinicalTrials.gov record.

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Results Reporting Centralization: New Roles and Responsibilities

Phase	Record Stage	Program Manager	PI/ Study Teams
Results Reporting	Results need to be reported.	• Gather results templates, statistical analysis plan and protocol to upload.	• Provide results templates to the Program Manager to enter. • Provide copy of protocol and statistical analysis plan in PDF/a format with cover page to Program Manager to upload.
	Results entered and study record marked as entry completed.	• Review results section to ensure all fields are completed.	• Address any problems identified.
	If Results are unavailable	• Gather rationale and request good cause extension if applicable.	• Inform Program Manager if results will not be available to be reported.
	ClinicalTrials.gov reviewers identify major issues in results reporting that need to be addressed.	• Provide information and guidance related to specific major issues noted by reviewers.	• Correct Major Issues. • Correct Advisory Issues (if desired).

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Results Reporting Requirements

Please use the **Results Quality Control Review Criteria** to help when completing study record with results on ClinicalTrials.gov.

Results Reporting Deadlines	
Change "Overall Study Status" and enter Primary Completion Date	Within **30 days** of study completion, termination, or withdrawal
Enter Results for all primary outcomes	Within **12 months** of the Primary Completion Date
Respond to comments from ClinicalTrials.gov ("PRS Review Comments")	Within **25 days**, as soon as possible to avoid the public posting of information with issues
Enter Results for each secondary outcome measure	Within **12 months** of the date on which the final subject was examined or received an intervention for the purposes of final collection of data for each secondary outcome measure

Good Cause Extension

- Clinical Trials Results Information Submission: Good Cause Extension Request Process and Criteria
- Prior to February 1, 2021, a responsible party may have submitted a late certification for delay. If this occurred, the responsible party should submit results information as soon as possible but no later than the following dates:
  - 30 calendar days after the earliest of the events; OR
  - 2 years after the date that the certification was submitted (i.e., the Results Expected date assigned to the ACT in the PRS).

Overview

- What is ClinicalTrials.gov?
- History of ClinicalTrials.gov and Regulatory Requirements
- Why is ClinicalTrials.gov Important?
- Important Terms, Roles and Responsibility
- Process, Requirements and Potential Consequences of Non-Compliance
- Training and Resources

Training

- **CITI Program Training: Highly Recommended**

Resources

- **CHLA Resources**
  - **Documentation**
    - **SharePoint: ClinicalTrials.gov Resources**
      - **Actively Being Updated: Additional Resources are coming soon.**
  - **ClinicalTrials.gov PRS Administrator**
    - **Monthly ClinicalTrials.gov Update Meetings (to start soon).**
    - **Email Questions for set up an Appointment**
      - **ClinicalTrials.gov: nkamel@chla.usc.edu**
      - **General Regulatory Affairs Questions: regulatoryaffairs@chla.usc.edu**
    - **Office Hours**
      - **Wednesday 3pm-4pm (PST) on Microsoft Teams**

Resources

- **Online Resources**
  - PRS User Guide
  - ClinicalTrials.gov Training Materials
  - Data Element Definition Documents, Templates and Checklists
  - Steps for Registering a Clinical Study
  - Protocol Registration Quality Control Review Criteria
  - How to Submit Your Results
  - Results Reporting Quality Control Review Criteria

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Questions?

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