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Overview of Clinicaltrials.gov Result Posting Requirement

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Why Post Research Results?

- Allows access for patients to innovative clinical trials
- Fulfills ethical obligation to human subjects
- Inform future research through evidence-based
- Mitigates information bias and duplication of trials

Posting Requirements for ClinicalTrials.gov

Reporting Requirement	ICMJE Policy (effective in 2005)	FDAAA& Regulations (2007 and 2017)	Final NIH Policy (Issued in 2016)
Scope	Clinical Trials (any)	Applicable Clinical Trials	Clinical Trials NIH-Funded
What	Registration	Registration & Results Reporting	Registration & Results Reporting
Phase	All	Not Phase 1 or small feasibility device studies	All
Intervention Type	All	Drug, biologic, & device products regulated by the FDA	All (e.g., including behavioral interventions)
Funding Source	Any	Any	NIH
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
Results Reporting	**N/A***	**Within 12 months of primary completion date**	**Within 12 months of primary completion date**
Enforcement	Refusal to publish	• Criminal proceedings and civil penalties (up to $10,000/day) • Loss of HHS funding • Noncompliant records Identified on ClinicalTrials.gov	• Suspension or termination of grant or contract funding • Can be considered in future funding decisions • Noncompliant records Identified on ClinicalTrials.gov

*New ICMJE Requirement: Data Sharing Statement

- As of July 1 2018, manuscripts submitted to ICMJE journals that report results must contain a data sharing statement.

- Clinical trials enrolling participants on/after January 1, 2019 must include a data sharing plan in the trial registration.

- Data sharing statements must indicate:
  - whether individual deidentified participant data in particular will be shared
  - whether additional related documents will be available (protocol, SAP)
  - when data will become available and for how long
  - by what access criteria data will be shared

***While this does not yet mandate data sharing, the ICMJE points out that investigators should be aware that editors may take into consideration data sharing statements when making editorial decisions.**

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What Results Should be Reported?

Data Elements

Participant Flow

Shows how participants were assigned to intervention(s) and how they progressed through the study. Should include dropouts and excluded from analysis.

Baseline Characteristics

Table of demographic and baseline data for the entire trial population and for each arm or comparison group. Age and Gender are required.

Outcome Measures and Statistical Analysis

Summarizes results data for all measures assessed and describes statistical tests (e.g., p-value) or other parameters derived from the outcome data (e.g., odds ratio).

Results Reporting: Adverse Events

- **All-cause Mortality**
  - All deaths due to any cause that occurred during the study.

- **Serious Adverse Events**
  - All SAEs collected during the study, whether or not they were anticipated or considered to be attributed or associated with the intervention.

- **Other (Not Including Serious) Adverse Events**
  - Non-serious adverse events collected during the study, whether or not they were anticipated.

Required During Results Posting: Study Protocol

- Most current version
  - Objectives, design, methods
  - May include relevant scientific background and statistical considerations
  - Needs to include all protocol changes from amendments

- Information that can be redacted
  - Names, addresses, other personally identifiable information (PII)
    - PII should always be redacted unless already disclosed (e.g. PI's name) or appropriate consent is obtained
  - Trade Secrets and/or confidential commercial information
  - Exploratory Endpoints

Other Required Documents During Results Posting

- Statistical Analysis plan (if not included in protocol)
- Blank Informed Consents Forms (optional)

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Posting Results

Reporting Results: Changing Study Status

- Change overall study status log in to http://register.clinicaltrials.gov and enter within 30 days
  - Completed
    - The study has concluded normally; participants are no longer receiving an intervention or being examined (that is, the last participant's last visit has occurred).
  - Terminated
    - Study halted prematurely and will not resume; participants are no longer being examined or receiving intervention.
  - Withdrawn
    - Study halted prematurely, prior to enrollment of first participant
    - Results Not Needed.

Reporting Results: Primary Completion Date

- Primary Completion Date
  - The date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome (if more than one primary outcome, date is when data was collected for **all** primary outcomes).
  - Results for the primary outcome must be submitted within 12 months of the Primary Completion Date.

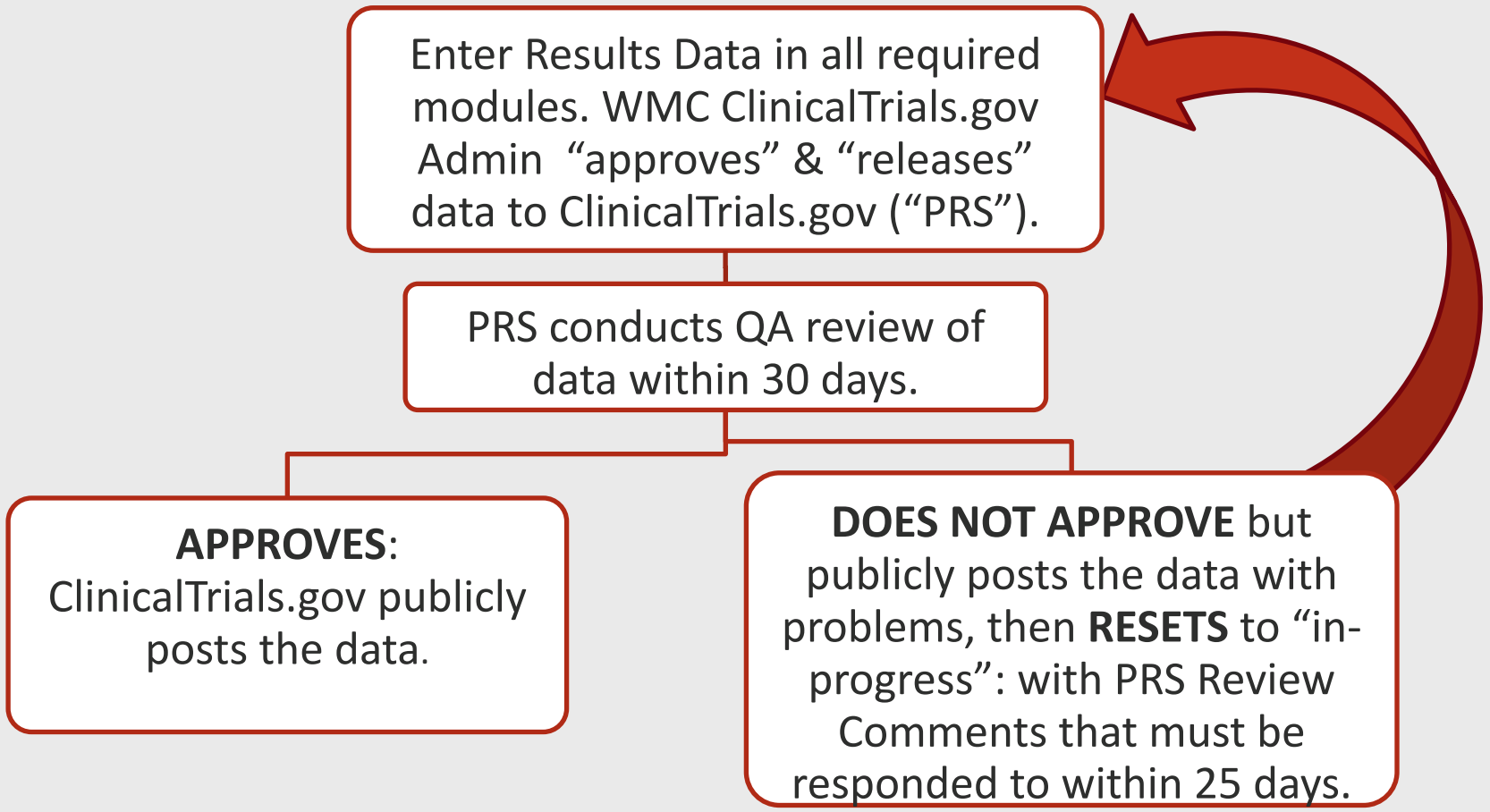
Reporting Results: Secondary Outcomes

- Secondary outcome measures or additional adverse event information must be reported 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 that secondary outcome measure.

- There is no place on ClinicalTrials.gov to enter dates relevant to secondary outcome measures, so it must be tracked externally.

Change of Status

ClinicalTrials.gov PRS Results Data Flow



Responding as soon as possible is in your best interest to stop poor quality information from being publicly posted to ClinicalTrials.gov.

Summary: Results Reporting Timeline

	Timeline
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

For Help: Contact

Clinicaltrials.gov

- Email register@clinicaltrials.gov with your NCT #
  - The PRS Results Team provides detailed assistance in response to targeted questions about filling out the modules
  - Assist in scheduling a WebEx session with the PRS Results Team for assistance in entering results

- Guidance

  The “Help” dropdown for “Results Data Entry” has resources:
  - Results Modules Guidance
  - Definitions for each data element in each section
  - Description of ClinicalTrials.gov review criteria for results
  - Example results entries for parallel, cross-over, factorial, dose escalation, and multiple period study designs

WCM Clinicaltrials.gov Administrator

- registerclinicaltrials@med.cornell.edu or call 646-962-4065

- http://researchintegrity.weill.cornell.edu/clinicaltrialsdotgov.html

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