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ClinicalTrials.gov
Training

Sr. Human Research Compliance Specialist
WCM ClinicalTrials.gov Administrator
Human Research Compliance

February 3, 2022

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Outline

- ClinicalTrials.gov Overview
- Purpose, Impact, and Reputational Implications
- ClinicalTrials.gov Regulations and Definitions
- Registering and Maintaining A ClinicalTrials.gov Record
- Results Modules
- Institutional Resources

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ClinicalTrials.gov Overview

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Overview

NIH U.S. National Library of Medicine
ClinicalTrials.gov

- Service of the NIH National Library of Medicine that acts as a public registry and results database of clinical studies of human participants.
- Requirements to publicly register/post results apply to WCM investigator-initiated studies only.
    - If multi-site, one registration functions as ClinicalTrials.gov registration and results record for all sites.

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Overview

U.S. National Library of Medicine
ClinicalTrials.gov

- Public registration and reporting of clinical trial results on ClinicalTrials.gov is required for:
  - Interventional studies:
    - Evaluating **FDA**-regulated products ("Applicable Clinical Trials"); **or**
    - That are (partially or wholly) **NIH**-funded and meet NIH's clinical trial definition; **or**
    - That meet The International Committee of Medical Journal Editors (**ICMJE**) clinical trial definition (registration only); **or**
    - That are qualifying clinical trials rendering claims for items and services to the Center for Medicare & Medicaid Services (**CMS**)
    - **Note**: Some funding entities require registration and results reporting (e.g., **PCORI; Bill & Melinda Gates Foundation**). Be sure to check the terms of your award!

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Purpose, Impact, and Reputational Implications

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The Importance of ClinicalTrials.gov

HEALTH

The Outcome of My Clinical Trial Is a Mystery

As a kid, I enrolled in a study whose results were never published—meaning I'll live the rest of my life with a heart implant, but may never know how well it actually works.

Yasinski, E. (2016, January 11). The Outcome of My Clinical Trial is a Mystery. *The Atlantic*, pp. Page(s). Retrieved from https://www.theatlantic.com/health/archive/2016/01/clinical-trial-unpublished-results/423540/.

NIH U.S. National Library of Medicine

ClinicalTrials.gov

"…the days of deciding whether or not summary results are worth reporting are over… The time to decide whether a trial is worth doing is before the trial is started, not after participants have been put at risk."

Zarin, Deborah A., Tse, Tony, Williams, Rebecca J &; Carr, Sarah. (2016). Trial Reporting in ClinicalTrials.gov – The Final Rule. *New England Journal of Medicine*, *375*(20), 1998-2004. doi:10.1056/NEJMsr1611785

Q: Isn't it administratively burdensome to have a definition of clinical trial that requires so many studies involving human participants to report their results?

A: Results Reporting should not be considered a burden. Reporting results is an essential part of the scientific process; it is an integral component of the scientific method.

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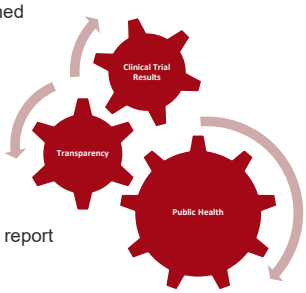
The Importance of ClinicalTrials.gov

- In 1999, GSK received Paxil approval for treating depression in adults.
- After conducting several pediatric trials for Paxil, GSK hired a consulting company to write a journal article selectively presenting results.
- Article:
  - Claimed that Paxil worked better than placebo in treating depression in children and adolescents.
  - De-emphasized side effects like suicidal thoughts and actions.
  - Did not disclose two other studies that did not show Paxil to be efficacious in children and adolescents.
- Doctors prescribed off-label in reliance on this selectively published data.
- In 2015, an article was published in BMJ after researchers re-examined the data concluding Paxil was ineffective and unsafe in the study.
- GSK fined by the government; black box warning put on Paxil.
- ClinicalTrials.gov regulatory requirements remove the "option" to report results selectively.



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Spotlight on Noncompliance

Where Are the Results of These Five Clinical Trials of Antidepressant Drugs?

madinamerica.com/2020/01/missing-clinical-trials-antidepressant-drugs/

By Till Bruckner, PhD — January 28, 2020

AllTrials tracker site names clinical trial non-reporters

PMLiVE - Feb 22, 2018

Organisations that fail to report the results of their clinical trials are to be named on a new website set up by the AllTrials campaign group. The new **FDAAA Trials Tracker** site went live this week and - as its name suggests - seeks to highlight the failings of the FDA Amendments Act 2007 law which required ...

thebmjopinion — Latest — Authors

Introducing unreported clinical trial of the week

March 29, 2018

Every week this new series will uncover an unreported clinical trial

Regulatory Focus

FDA threatens drugmaker with fines for failing to report trial results

Apr 28

More trial results being posted to public database, but data quality lacking

STAT · 13 Nov

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Spotlight on Noncompliance

The Lancet

ARTICLES | VOLUME 395, ISSUE 10221, P361-369, FEBRUARY 01, 2020

Compliance with legal requirement to report clinical trial results on ClinicalTrials.gov: a cohort study

Nicholas J DeVito, MPH • Seb Bacon, BA • Ben Goldacre, MBBS

Published: January 17, 2020 • DOI: https://doi.org/10.1016/S0140-6736(19)33220-9 • Check for updates

Table 3 Reporting performance of large sponsors with more than 30 due trials

	Trials due	Trials with any results (%)	Compliant trials (%)
MD Anderson Cancer Center	85	71 (83·5%)	29 (34·1%)
National Cancer Institute	79	65 (82·3%)	24 (30·4%)
Massachusetts General Hospital	58	46 (79·3%)	32 (55·2%)
Mayo Clinic	47	45 (95·7%)	10 (21·3%)
Novartis Pharmaceuticals	46	46 (100%)	46 (100%)
Gilead Sciences	45	45 (100%)	43 (95·6%)
GlaxoSmithKline	43	43 (100%)	42 (97·7%)
Pfizer	42	42 (100%)	39 (92·9%)
Hoffmann-La Roche	38	38 (100%)	36 (94·7%)
University of California, San Francisco	38	26 (68·4%)	6 (15·8%)

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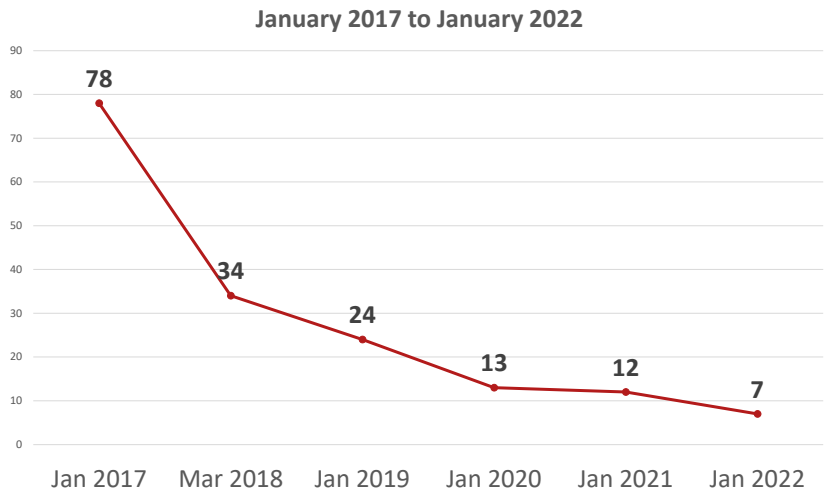
WCM ClinicalTrials.gov Records with Late Results

- **Last 5 Years:** 91% reduction in late results records
- **Last Year**: 41% reduction in late results records



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ClinicalTrials.gov Regulations & Definitions

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ClinicalTrials.gov Reporting Requirement	ICMJE Policy	FDAAA 801 (Applicable to Older Studies)	HHS Final Rule (42CFR11) (Applicable to Newer Studies – Expands on FDAAA 801)	NIH Policy on Dissemination of NIH-Funded Clinical Trial Information (Companion Policy to the Final Rule)
Effective Date	**2005**	**September 27, 2007**	**January 18, 2017**	**January 18, 2017**
Scope	Registration	Registration & Results Reporting		Registration & Results Reporting
Phase	All	Not Phase 0 or Phase 1 studies or small feasibility device studies		All
Intervention Type	All	Approved/licensed/ cleared drug, biologic, & device products regulated by the FDA	Most drug, biologic, & device products regulated by the FDA	All (e.g., including psychological or 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** (for primary outcome measures) Within 12 months of **study completion date** (for secondary outcome measures)		
Document Upload with Results	N/A	N/A	Protocol Document Statistical Analysis Plan	Protocol Document Statistical Analysis Plan
ICF Statement	N/A	Required		Required
Consequences of Noncompliance	• Refusal to publish in ICMJE journals	• Criminal proceedings and/or civil monetary penalties (up to $12,103/day – adjusted for inflation) • Loss of HHS funding		• Suspension or termination of grant or contract funding • Can be considered in future funding decisions

WCM policy requires registration prior to enrollment of the first participant.

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Respond at **PollEv.com/laurenwcm**

Text **LAURENWCM** to **22333** once to join, then **A or B**

Phase 1 studies that are NIH funded don't have to be registered or have results publicly posted on ClinicalTrials.gov.

True **A**

False **B**

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Total Results

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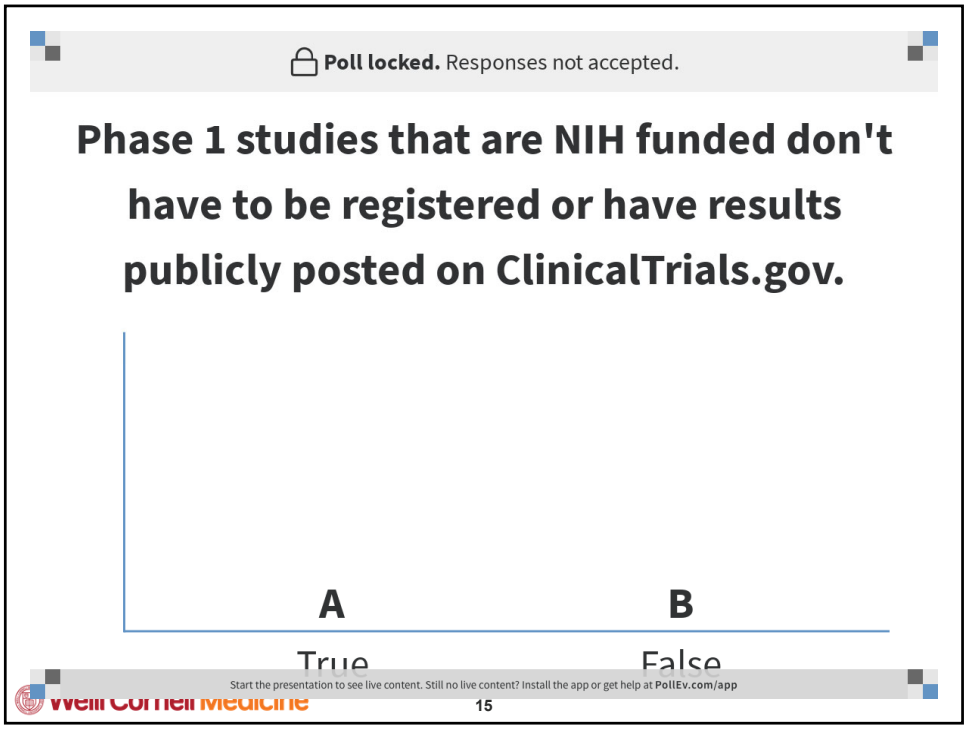
Poll locked. Responses not accepted.
Phase 1 studies that are NIH funded don't have to be registered or have results publicly posted on ClinicalTrials.gov.
A
True
B
False
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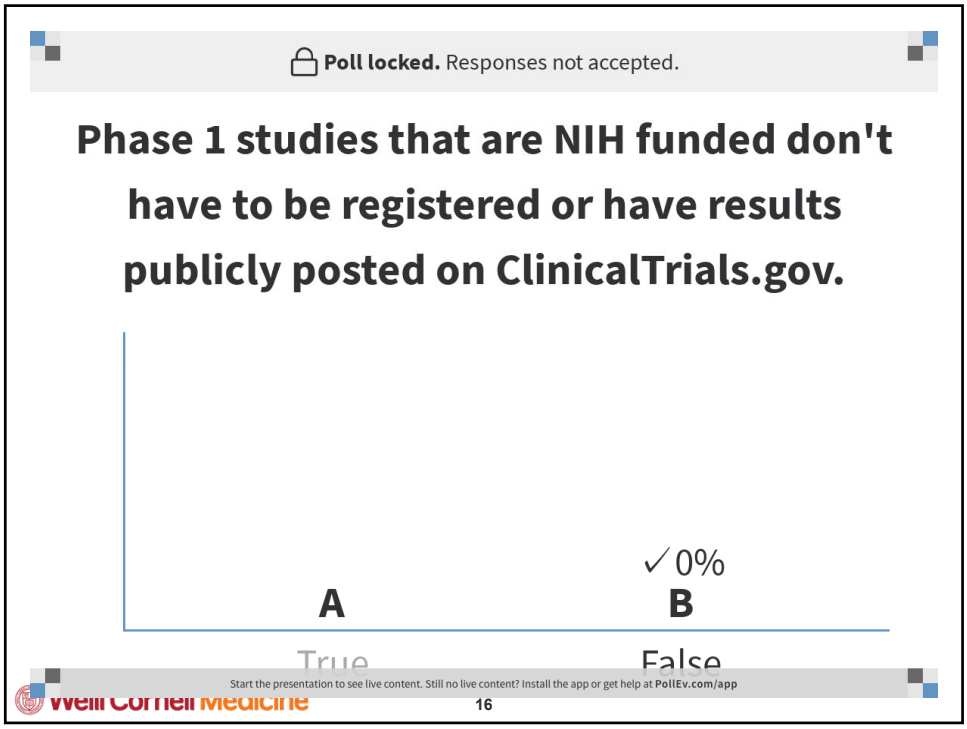
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Phase 1 studies that are NIH funded don't have to be registered or have results publicly posted on ClinicalTrials.gov.
✓0%
A
True
B
False
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When poll is active, respond at **PollEv.com/laurenwcm**
Text **LAURENWCM** to **22333** once to join

A consequence of failing to register on ClinicalTrials.gov prior to enrollment of the first participant is being unable to publish in ICMJE member journals.

True

False

Start the presentation to see live content. Still no live content? Install the app or get help at **PollEv.com/app**

Total Results

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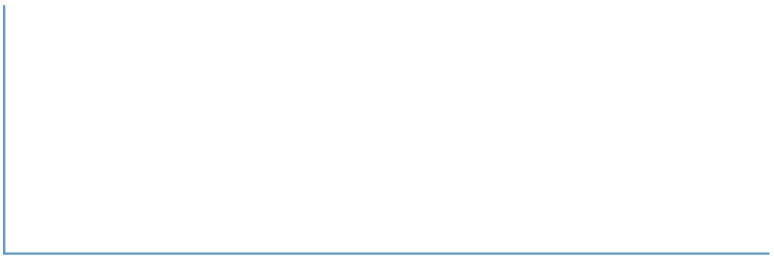
Poll locked. Responses not accepted.

A consequence of failing to register on ClinicalTrials.gov prior to enrollment of the first participant is being unable to publish in ICMJE member journals.



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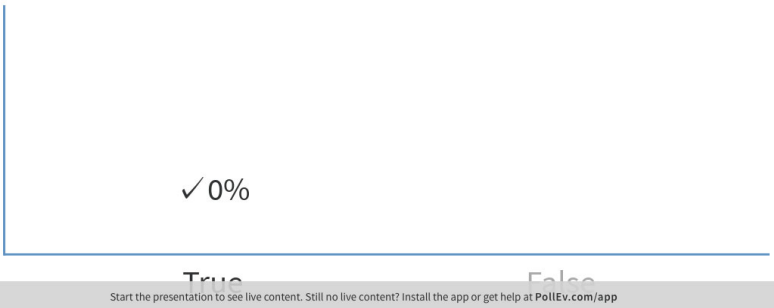

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Publicly Posting the Informed Consent

A Revised Common Rule Requirement Impacting ClinicalTrials.gov for Clinical Trials Conducted or Supported by A Common Rule Agency and Initially Approved on or after January 21, 2019

Common Rule Agencies

- Agency for International Development
- Central Intelligence Agency
- Consumer Product Safety Commission
- Department of Agriculture
- Department of Commerce
- **Department of Defense (DoD)**
- **Department of Education**
- Department of Energy
- **Department of Health & Human Services**
  - **Agency for Healthcare Research and Quality (AHRQ)**
  - **National Institutes of Health (NIH)**
  - **Note:** FDA is not a Common Rule agency; the ICF Posting requirement doesn't apply for FDA conducted or supported clinical trials.
- **Department of Justice**
- Department of Homeland Security
- Department of Housing and Urban Development
- Department of Labor
- Department of Transportation
- Department of Veteran Affairs
- Environmental Protection Agency
- National Aeronautics and Space Administration (NASA)
- National Science Foundation
- Office of the Director of National Intelligence
- Social Security Administration

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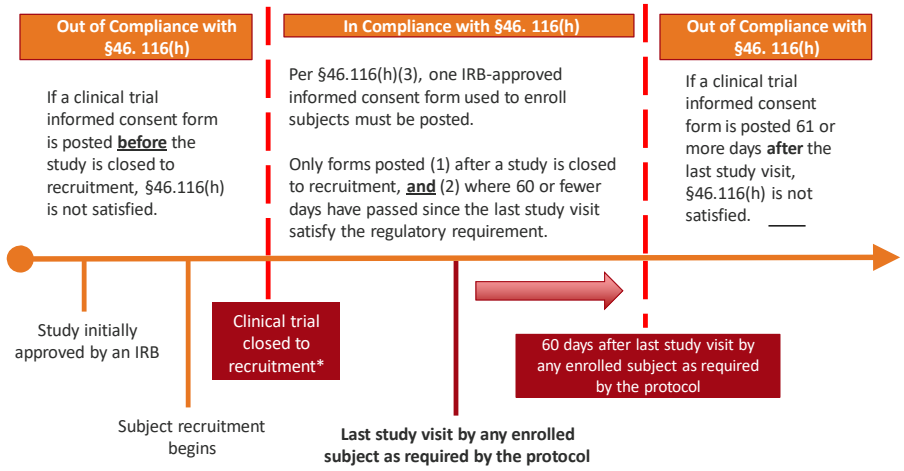

- If clinical trial closes to recruitment 61 or more days after the last study visit by any enrolled subject as required by the protocol, OHRP recommends the ICF be posted within 60 days of when the study is closed to recruitment.

**The clinical trial can be closed to recruitment at any time up to and including 60 days after the last study visit by any enrolled subject as required by the protocol, and this timeline will accurately represent posting requirements.*

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Source: Hartsmith, Lauren. (2019). Clinical Trial Informed Consent Posting for Studies Subject to the Revised Common Rule (i.e., the 2018 Requirements) [Powerpoint Slides] 21

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Required ClinicalTrials.gov Statement in The Informed Consent

ICMJE Clinical Trials	FDAAA 801	HHS Final Rule	NIH-funded Clinical Trials
• N/A – No ClinicalTrials.gov statement is needed in the ICF.	• Requires an exact, unaltered statement in the informed consent form for all sites recruiting subjects. • At WCM, the required statement is already included in the ICF template provided by the WCM IRB. • If multi-site study, coordinate to ensure it's included in ICF at other sites. • "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."		

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Data Sharing Statement

"IPD Sharing Statement"

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- Refers to sharing of de-identified individual participant data with others not affiliated with the research project.
- Applies to all clinical trials enrolling on or after Jan 1, 2019.
- Answer to "IPD Sharing Statement" in initial ClinicalTrials.gov registration must say "No" or "Yes" **<u>at time of initial registration</u>**. (Can be changed later if needed.)
  - "Undecided" is an option in the system, but selecting it doesn't meet the requirement.
- Statement in ClinicalTrials.gov registration **<u>must match</u>** the data sharing statement submitted with the results manuscript at the time of publication.

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Data Sharing Statement

"IPD Sharing Statement" Examples

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	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.

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Dissemination Plan

- Required to be uploaded in NIH FORMS-G.
- Describes how the awardee will ensure:
  - Registration, updates, and results posting will occur as required.
  - ICF statement will be included in the ICF.
- OSRA (grantsandcontracts@med.cornell.edu) provides template text at the following link:
  https://research.weill.cornell.edu/sites/default/files/wcm_clinicaltrials.gov_dissemination_plan_v1.0_4.06.18.docx
- More information:
  https://www.niaid.nih.gov/grants-contracts/take-note-nih-dissemination-plan-does-not-equal-resource-sharing-plan

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Clinical Trial Regulatory Definitions

Knowing When Registration is Required

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Resources

ICMJE Clinical Trial

Registration + Data Sharing: http://www.icmje.org/recommendations/browse/publishing-and-editorial-issues/clinical-trial-registration.html
Definition + FAQ: http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/

Applicable Clinical Trial (ACT) – HHS Final Rule

See the ACT Checklist: https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf

NIH Clinical Trial Definition https://grants.nih.gov/policy/clinical-trials/definition.htm

NIH FAQ: https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm
NIH Case Studies: https://grants.nih.gov/policy/clinical-trials/case-studies.htm

WCM Decision Tool

https://weillcornell.az1.qualtrics.com/jfe/form/SV_9GOTNFgSTCfBfQ9

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Clinical Trial Definition

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- 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.
- Health-related interventions include any intervention used to modify a biomedical or health-related outcome:
  - Examples of health-related interventions: drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes.
  - Health outcomes include any biomedical or health-related measures obtained in patients or participants.

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Clinical Trial Definition

ICMJE
INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

- Unsure of whether the ICMJE clinical trial definition is met?
  - Err on the side of caution and register your study; or
  - Consult the editorial office of the journal you wish to publish the study in.

List of ICMJE member journals:
http://www.icmje.org/journals-following-the-icmje-recommendations/

- Note: ICMJE does not consider the summary results posted on ClinicalTrials.gov to be prior publication.

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Applicable Clinical Trial (ACT)

HHS Final Rule (42CFR11)

ACT if the answer is "Yes" to 1 through 4.
1. Interventional; **AND**
2. ANY of the following applies: ○ At least one study facility in the U.S. or U.S. territory; **OR** ○ Study is conducted under an IND or IDE; **OR** ○ Study involves a drug, device, or biologic manufactured in the U.S. (or U.S. territory) and exported for study in another country; **AND**
3. Evaluates at least one FDA-regulated drug, device, or biological product; **AND**
4. Not a: ○ Phase 0 or Phase 1 study of a drug or biological product; **OR** ○ Device feasibility study

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Clinical Trial Definition

- A research study in which:

1. One or more human subjects are prospectively assigned
   - NIH Clarification: Single arm trials still qualify as prospectively assigned as long as assignment is pre-defined in the protocol.
2. To one or more interventions (which may include placebo or other control)
   - NIH Clarification: Measurements are used to collect data, while interventions are used to modify health-related endpoints.
3. To evaluate the effects of those interventions
4. On health-related biomedical or behavioral outcomes
   - NIH Clarification: Pre-specified goal(s) or condition(s) that reflect the effect of the intervention(s) on subjects' biomedical or behavioral status or quality of life.
     - E.g., Positive or negative changes to psychological or neurodevelopmental parameters (e.g., mood management intervention for smokers; reading comprehension and/or information retention);
     - Positive or negative changes to health behaviors, disease processes, or quality of life.
     - Positive or negative changes to physiological or biological parameters (e.g., improvement of lung capacity, gene expression)

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When poll is active, respond at **PollEv.com/laurenwcm**
Text **LAURENWCM** to **22333** once to join

If an interventional trial evaluating an FDA-regulated product doesn't have an IND or IDE associated with it, then it doesn't have to be registered or have results posted on ClinicalTrials.gov.

True

False

Start the presentation to see live content. Still no live content? Install the app or get help at PollEv.com/app Total Results

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Poll locked. Responses not accepted.

If an interventional trial evaluating an FDA-regulated product doesn't have an IND or IDE associated with it, then it doesn't have to be registered or have results posted on ClinicalTrials.gov.

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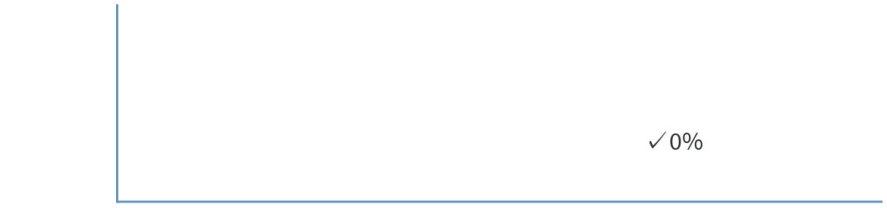

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Preliminary Info on Registration

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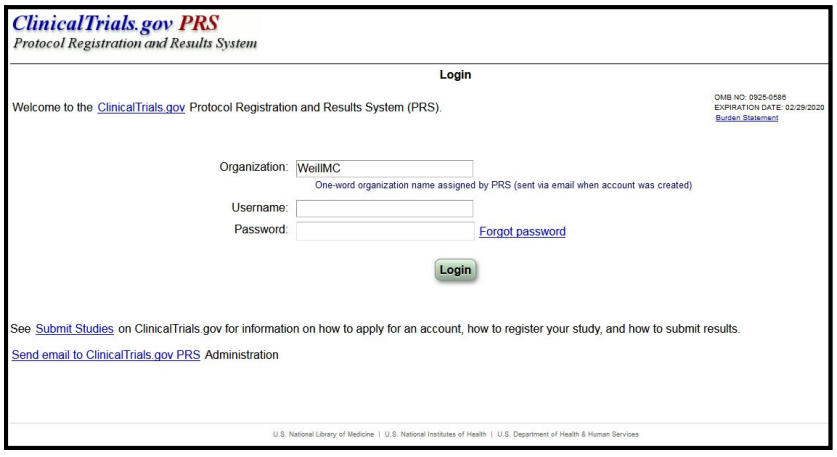
PRS: http://register.clinicaltrials.gov



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Who & When

- WCM PI must be ClinicalTrials.gov record owner or formally name a WCM designee via email at registerclinicaltrials@med.cornell.edu.
- PI and research coordinator receive courtesy "Action Required" notice from Human Research Compliance prompting PI to register on ClinicalTrials.gov.
  - Supplemental to SASP (Study Activation Status Page) in WRG
- Can register to obtain NCT # once an IRB protocol # is assigned to your protocol.
- Receiving a National Clinical Trials (NCT) # means registration has been successful.

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Registering and Maintaining A ClinicalTrials.gov Record

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Staying Compliant

- Courtesy Action Required E-mails from Human Research Compliance:
  - With resources, prompting PI/designee to:
    - **Register** prior to enrollment of the first participant.
    - **Update** the study record at least once every 12 months.
      - Certain elements require proactive updates within 30 days after a change in status.
    - **Enter results** no later than 12 months after the primary completion date (for primary outcome measures) and 12 months after the study completion date (for secondary outcome measures).
      - Internal WCM deadline is earlier to allow for timely completion of internal QC process and statistical analyses entry.
    - **Respond to PRS Review Comments** either in 1 week (if registration) or 2 weeks (if results).
- Noncompliance with associated deadlines for updates, results, and response to PRS trigger hold on IRB approvals for any mid-process submissions by the PI across protocols.

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Deadlines for Proactive Updating

	Study Start Date	30 calendar days after the first subject is enrolled (if the first human subject was not enrolled at the time of registration).
	Intervention Name(s)	30 calendar days after a nonproprietary name is established.
	Availability of Expanded Access	30 calendar days after expanded access becomes available (if available after registration); and 30 calendar days after an NCT number is assigned to a newly created expanded access record. [1]
	Expanded Access Status	30 calendar days after a change in the availability of expanded access.
	Expanded Access Type	30 calendar days after a change in the type(s) of available expanded access.
	Overall Recruitment Status	30 calendar days after a change in overall recruitment status. [2]
	Individual Site Status	30 calendar days after a change in status of any individual site.
	Human Subjects Protection Review Board Status	30 calendar days after a change in status.
*	Primary Completion Date	30 calendar days after the clinical trial reaches its actual primary completion date.
	Enrollment	At the time the primary completion date is changed to "actual," the actual number of participants enrolled must be submitted.
*	Study Completion Date	30 calendar days after the clinical trial reaches its actual study completion date.
	Responsible Party, by Official Title	30 calendar days after a change in the responsible party or the official title of the responsible party.
	Responsible Party Contact Information	30 calendar days after a change in the responsible party or the contact information for the responsible party.
	Device Product Not Approved or Cleared by U.S. FDA	15 calendar days after a change in approval or clearance status has occurred.
	Device Product Not Approved or Cleared by U.S. FDA	15 calendar days after a change in approval or clearance status has occurred.
	Record Verification Date	Any time the responsible party reviews the complete set of submitted clinical trial information for accuracy and not less than every 12 months, even if no other updated information is submitted at that time.

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Overall Recruitment Status in the Study Status Section

- Enter within 30 days of change in status:
  - **Not Yet Recruiting**
    - Participants are not yet being recruited.
  - **Recruiting**
    - Participants are currently being recruited, whether or not any participants have yet been enrolled.
  - **Enrolling by invitation**
    - Participants are being (or will be) selected from a predetermined population.
  - **Active, not recruiting**
    - Study is continuing, meaning participants are receiving an intervention or being examined, but new participants are not currently being recruited or enrolled.

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Overall Recruitment Status in the Study Status Section

- Enter within 30 days of change in status:
  - **Completed**
    - Study has concluded normally; participants no longer receiving intervention or being examined (i.e., last participant's last visit has occurred).
  - **Suspended**
    - Study halted prematurely, but potentially will resume.
  - **Terminated**
    - Study halted prematurely and will not resume; participants no longer receiving intervention or being examined.
  - **Withdrawn**
    - Study halted prematurely, prior to enrollment* of first participant.

*Enrollment definition: see https://clinicaltrials.gov/ct2/manage-recs/faq#fr_28

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Determining the Federal Deadline for Results

Entering the Primary and Study Completion Date in the Study Status Section

PRIMARY COMPLETION DATE Determines results due date for primary outcome measures.	STUDY COMPLETION DATE Determines results due date for secondary outcome measures.
Update from "Anticipated" to "Actual" **within 30 days of occurrence**.	
✓ Date final participant was examined or received intervention for purposes of final data collection for **all primary outcome measures**.	✓ Date final participant was examined or received intervention for purposes of final data collection for all: ✓ (1) primary outcome measures, ✓ (2) **secondary outcome measures**, and ✓ (3) adverse events*.

*Last participant's last visit.

These dates are not:

- ✗ The date the protocol was closed with the IRB.
- ✗ The date of publication.
- ✗ The date of the start of data analysis.

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Example: Study Status Section

Not Yet Recruiting

* Record Verification Date:	Month: December Year: 2016
* Overall Recruitment Status:	Not yet recruiting Before selecting Suspended, Terminated or Withdrawn see the Overall Recruitment Status definition.
	Tip: Day is not required for Anticipated dates.
* § Study Start Date:	Month: January Day: Year: 2017 Type: Anticipated Date study is open for recruitment (Anticipated) or date first participant is enrolled (Actual).
* Primary Completion Date:	Month: October Day: Year: 2019 Type: Anticipated Final data collection date for primary outcome measure.
* § Study Completion Date:	Month: November Day: Year: 2019 Type: Anticipated Final data collection date for study.

- Recruitment status, taking into account all sites, is "Not Yet Recruiting."
- First subject will likely enroll in Jan 2017, so date is set to "anticipated."
- Last subject's last visit for data collection of primary outcome measures is anticipated to occur in Oct 2019.
- Last subject's last visit for data collection of secondary outcome measures is anticipated to occur in Nov 2019.

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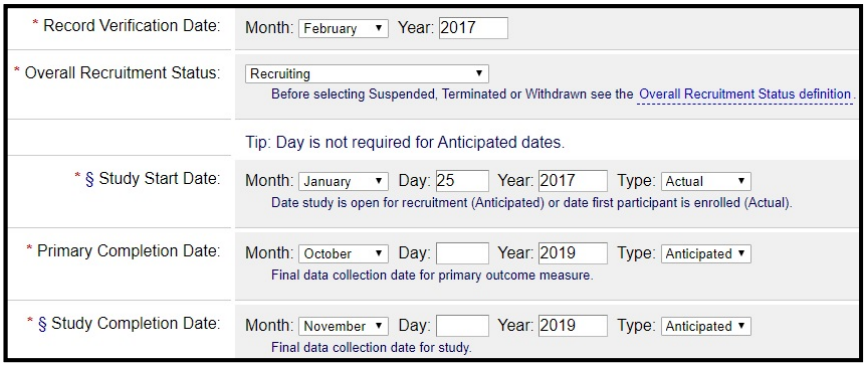
Example: Study Status Section

Recruiting



- Recruitment status, taking into account all sites, is "Recruiting."
- First subject enrolled on Jan 25, 2017, so date is set to actual.
- Last subject's last visit for data collection of primary outcome measures is anticipated to occur in Oct 2019.
- Last subject's last visit for data collection of secondary outcome measures is anticipated to occur in Nov 2019.

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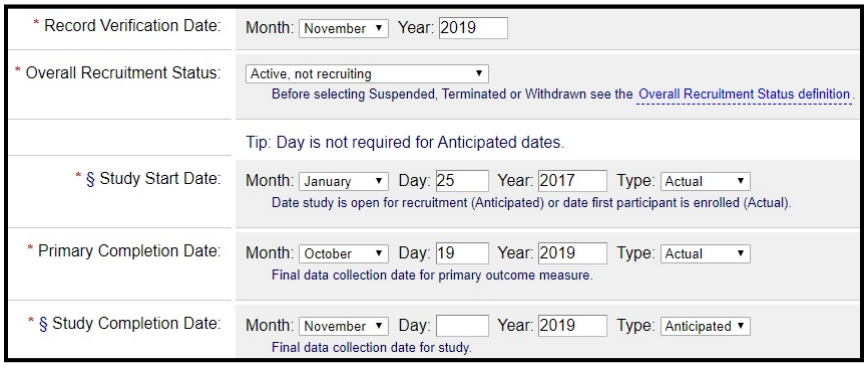
Example: Study Status Section

Active, not recruiting



- Subjects are still receiving intervention or being examined, but the study is no longer recruiting.
- Last subject's last visit for data collection of primary outcome measures occurred on Oct 19, 2019, so the date is set to "actual."
- Last subject's last visit for data collection for secondary outcome measures is anticipated to occur in Nov 2019 so the date is set to "anticipated."

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Example: Study Status Section

Completed

* Record Verification Date:	Month: November Year: 2019
* Overall Recruitment Status:	Completed Before selecting Suspended, Terminated or Withdrawn see the Overall Recruitment Status definition.
	Tip: Day is not required for Anticipated dates.
* § Study Start Date:	Month: January Day: 25 Year: 2017 Type: Actual Date study is open for recruitment (Anticipated) or date first participant is enrolled (Actual).
* Primary Completion Date:	Month: October Day: 19 Year: 2019 Type: Actual Final data collection date for primary outcome measure.
* § Study Completion Date:	Month: November Day: 25 Year: 2019 Type: Actual Final data collection date for study.

- Recruitment status, taking into account all sites, is "Completed." (IRB protocol will still be open while data analysis occurs.)
- Last subject's last visit for data collection of secondary outcome measures occurred Nov 25, 2019, so the date is set to "actual."

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When poll is active, respond at **PollEv.com/laurenwcm**

Text **LAURENWCM** to **22333** once to join

Which of these most accurately explains the meaning of the Primary Completion Date?

- The date the protocol was closed with the IRB.
- The date the last participant's test results are received for analysis of the primary outcome measure(s).
- The date that data analysis for the primary outcome measure(s) is completed.
- The date the last participant was examined or received an intervention for final collection of data for the primary outcome measure(s).
- None of the above

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Total Results

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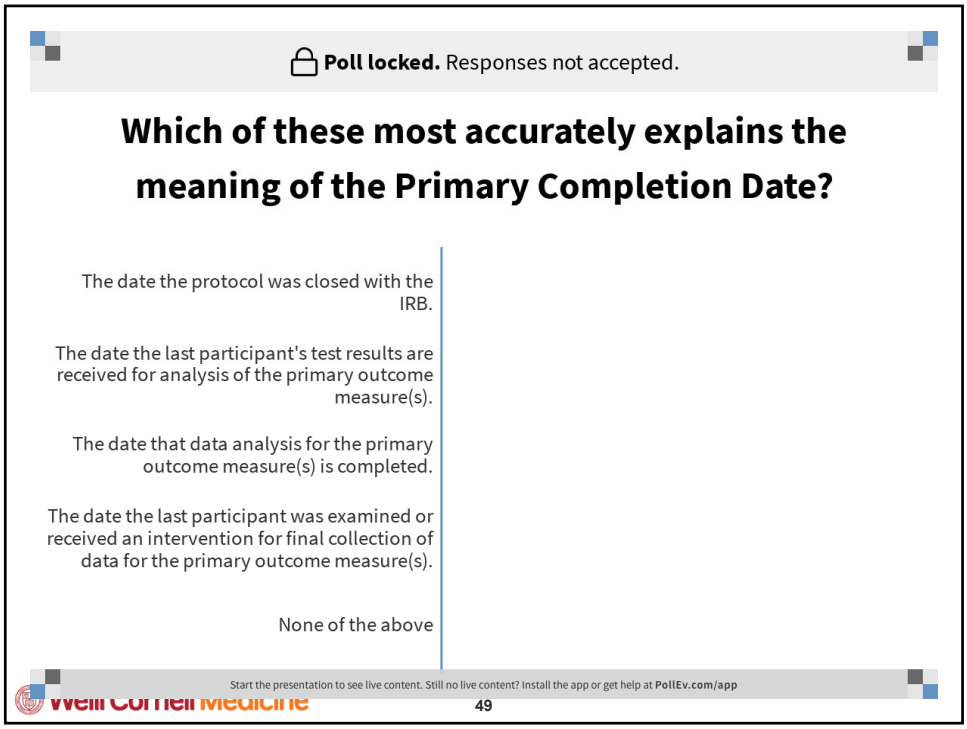
48


Poll locked. Responses not accepted.
Which of these most accurately explains the meaning of the Primary Completion Date?
The date the protocol was closed with the IRB.
The date the last participant's test results are received for analysis of the primary outcome measure(s).
The date that data analysis for the primary outcome measure(s) is completed.
The date the last participant was examined or received an intervention for final collection of data for the primary outcome measure(s).
None of the above
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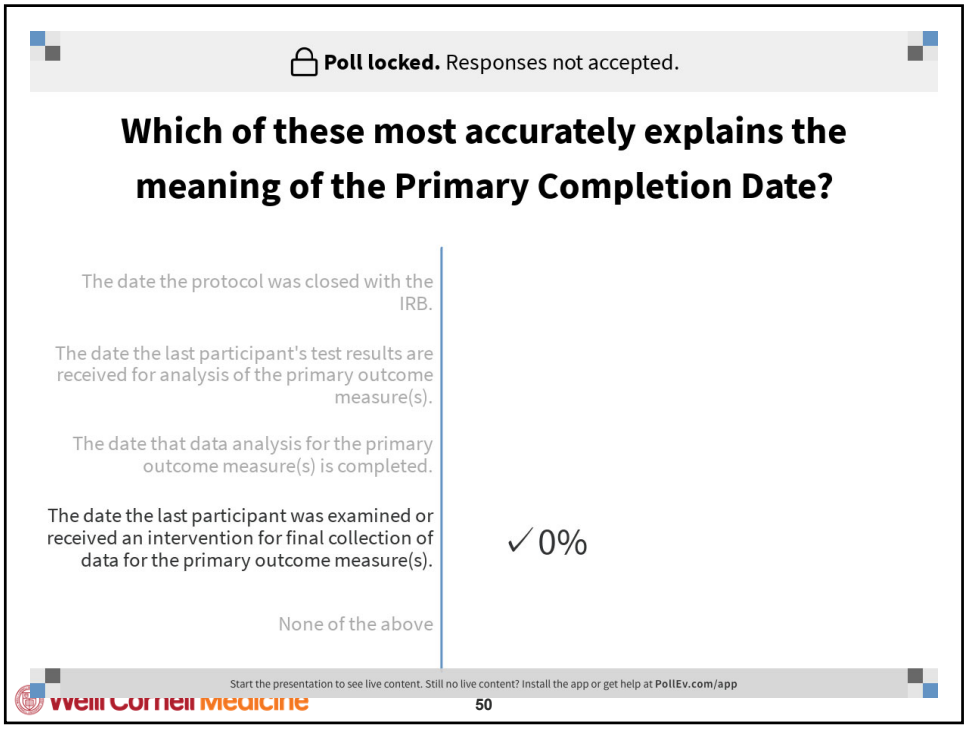
49

49


Poll locked. Responses not accepted.
Which of these most accurately explains the meaning of the Primary Completion Date?
The date the protocol was closed with the IRB.
The date the last participant's test results are received for analysis of the primary outcome measure(s).
The date that data analysis for the primary outcome measure(s) is completed.
The date the last participant was examined or received an intervention for final collection of data for the primary outcome measure(s).
✓0%
None of the above
Start the presentation to see live content. Still no live content? Install the app or get help at PollEv.com/app
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50

50

When poll is active, respond at **PollEv.com/laurenwcm**

Text **LAURENWCM** to **22333** once to join

Which of these most accurately explains the meaning of the Study Completion Date?

- The date of publication.
- The date the last participant was examined or received an intervention for final collection of data for the primary and secondary outcome measures and adverse events. (Last subject's last visit.)
- The date the protocol was closed with the IRB.
- The date the last participant was examined or received an intervention for final collection of data for the primary outcome measure(s).
- None of the above

Start the presentation to see live content. Still no live content? Install the app or get help at **PollEv.com/app**

Total Results

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51

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Poll locked. Responses not accepted.

Which of these most accurately explains the meaning of the Study Completion Date?

- The date of publication.
- The date the last participant was examined or received an intervention for final collection of data for the primary and secondary outcome measures and adverse events. (Last subject's last visit.)
- The date the protocol was closed with the IRB.
- The date the last participant was examined or received an intervention for final collection of data for the primary outcome measure(s).
- None of the above

Start the presentation to see live content. Still no live content? Install the app or get help at **PollEv.com/app**

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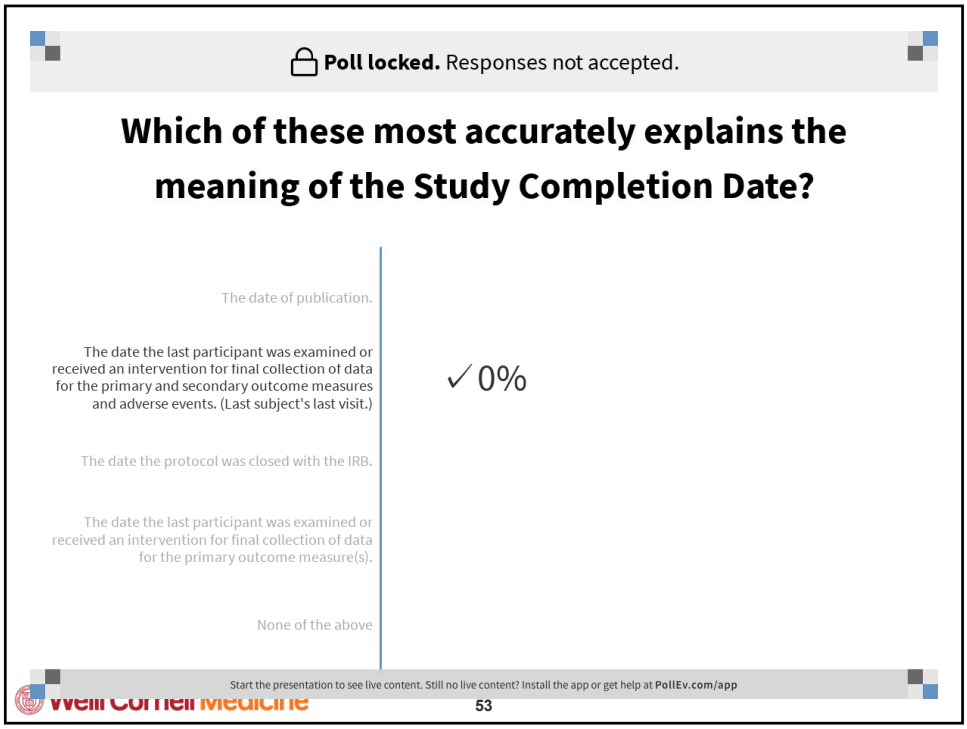


53

Registration Requirements

- Unique Protocol ID must be the IRB protocol number.
- Secondary ID must be the NIH grant number, if applicable.

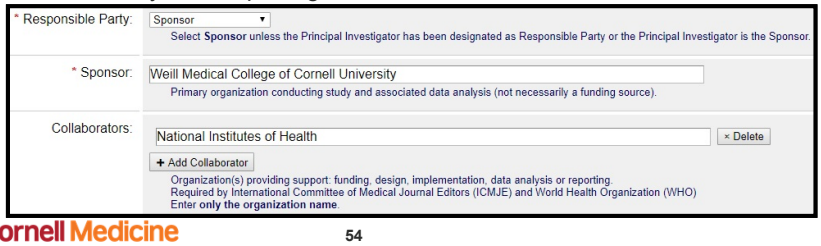
Study Identification

Unique Protocol ID: 19-07020411
Brief Title: Trial to Test the Safety and Effectiveness of SB234 for Asthma
Official Title: A Phase II Trial to Test the Safety and Efficacy of SB234
Secondary IDs: R01GM987654 [U.S. NIH Grant/Contract Award Number]

Brief title=lay language.

Official title=protocol title.

- Sponsor/Collaborators section must:
  - Indicate "Responsible Party" as "Sponsor." WCM account name will auto-populate.
  - List collaborating organizations providing support: funding, design, data analysis or reporting.



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Registration Requirements

- Contacts/Locations section should list:
  - Central Contact w/Backup.
  - WCM Principal Investigator as a Study Official.
  - All sites that will recruit participants w/Site PI and contacts.

Contacts/Locations

Central Contact Person: FirstName1 LastName1, NP
Telephone: 646-962-8200
Email: CWID@med.cornell.edu

Central Contact Backup: FirstName2 LastName2, BS
Telephone: 646-962-8245
Email: CWID@med.cornell.edu

Study Officials: FirstName3 LastName3, MD
Study Principal Investigator
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Locations:

United States, New York

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New York, New York, United States, 10065
Contact: FirstName4 LastName4, BA 646-962-4065 CWID@med.cornell.edu
Contact: FirstName5 LastName5, NP 646-962-7569 CWID@med.cornell.edu
Principal Investigator: FirstName3 LastName3, MD

Brooklyn Methodist Hospital - NewYork-Presbyterian
Brooklyn, New York, United States, 11215
Contact: FirstName6 LastName6, MD 718-780-3542 CWID@nyp.org
Contact: FirstName7 LastName7, MD 718-780-3547 CWID@nyp.org
Principal Investigator: FirstName8 LastName8, MD

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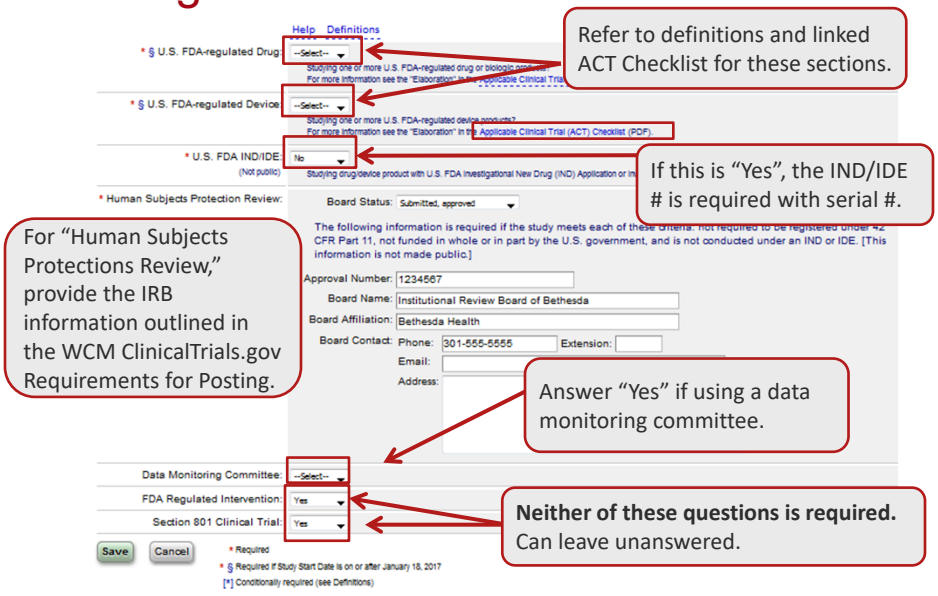
55

55

Oversight Section



Refer to definitions and linked ACT Checklist for these sections.

If this is "Yes", the IND/IDE # is required with serial #.

For "Human Subjects Protections Review," provide the IRB information outlined in the WCM ClinicalTrials.gov Requirements for Posting.

Answer "Yes" if using a data monitoring committee.

Neither of these questions is required. Can leave unanswered.

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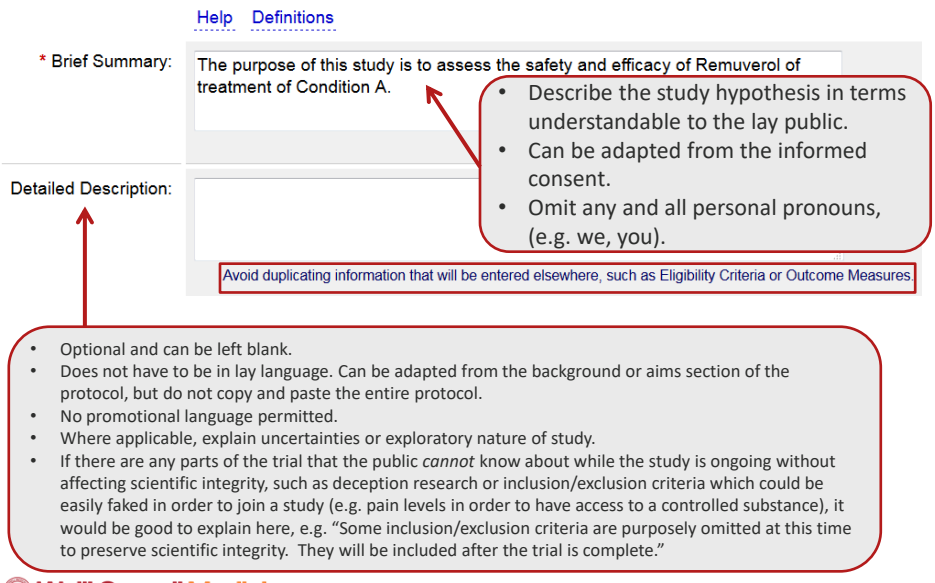
Study Description Section



- Describe the study hypothesis in terms understandable to the lay public.
- Can be adapted from the informed consent.
- Omit any and all personal pronouns, (e.g. we, you).

- Optional and can be left blank.
- Does not have to be in lay language. Can be adapted from the background or aims section of the protocol, but do not copy and paste the entire protocol.
- No promotional language permitted.
- Where applicable, explain uncertainties or exploratory nature of study.
- If there are any parts of the trial that the public *cannot* know about while the study is ongoing without affecting scientific integrity, such as deception research or inclusion/exclusion criteria which could be easily faked in order to join a study (e.g. pain levels in order to have access to a controlled substance), it would be good to explain here, e.g. "Some inclusion/exclusion criteria are purposely omitted at this time to preserve scientific integrity. They will be included after the trial is complete."

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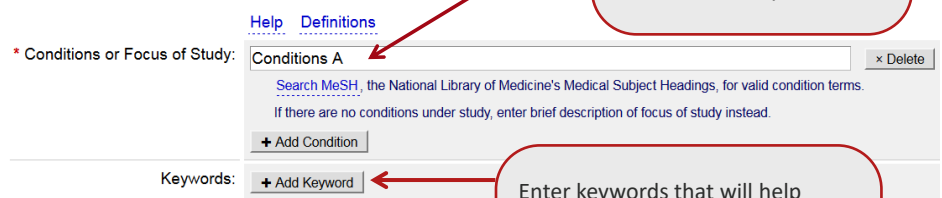
Conditions Section

- Enter each study condition, one per line.
- Use Search MeSH link to verify the correct condition term.
- If no conditions, enter focus of study.



Enter keywords that will help patients find this study when searching at the public ClinicalTrials.gov site.

No need to repeat a Condition or Focus of Study as a Keyword.

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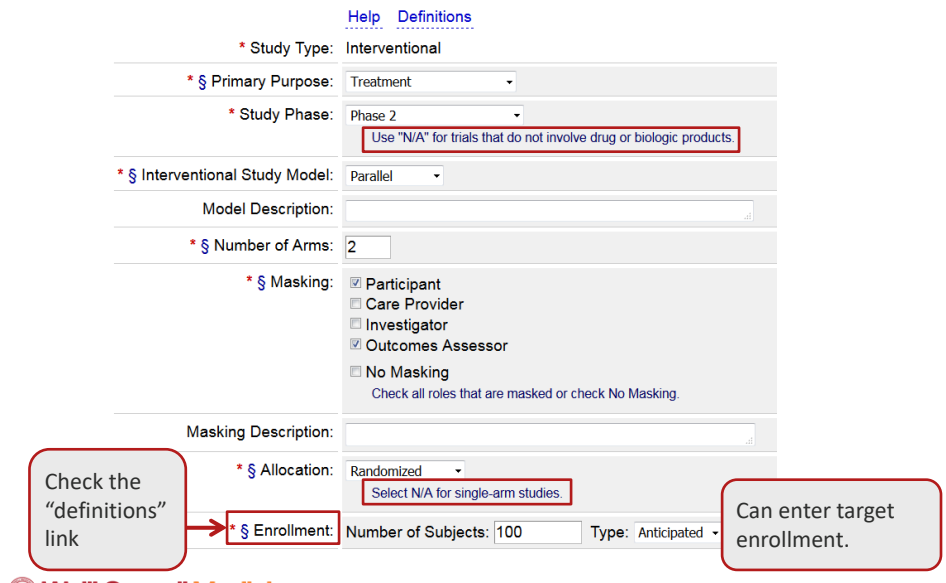
Study Design Section



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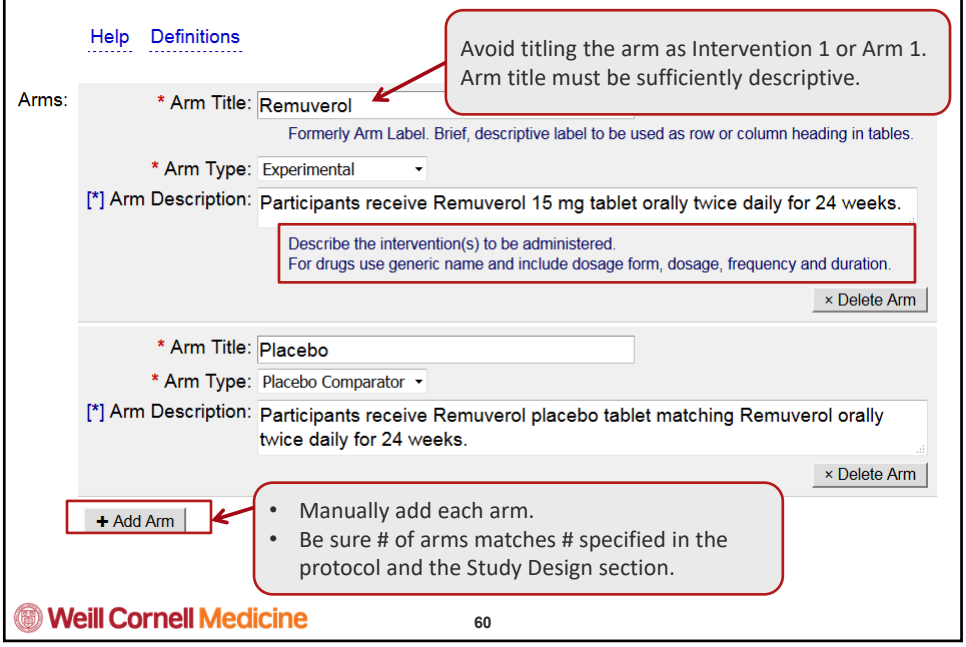
Arms & Interventions Section: Arms



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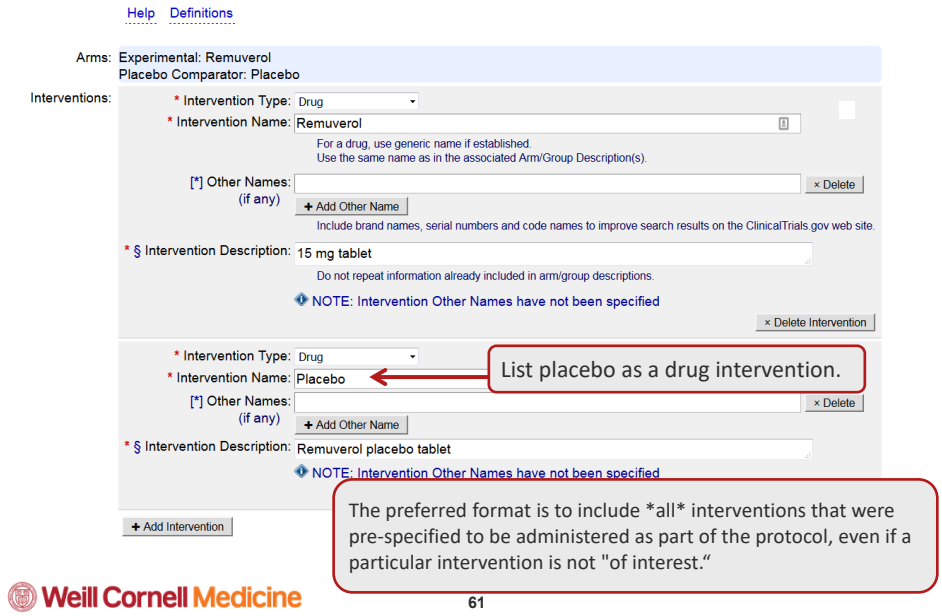
Arms & Interventions Section: Interventions



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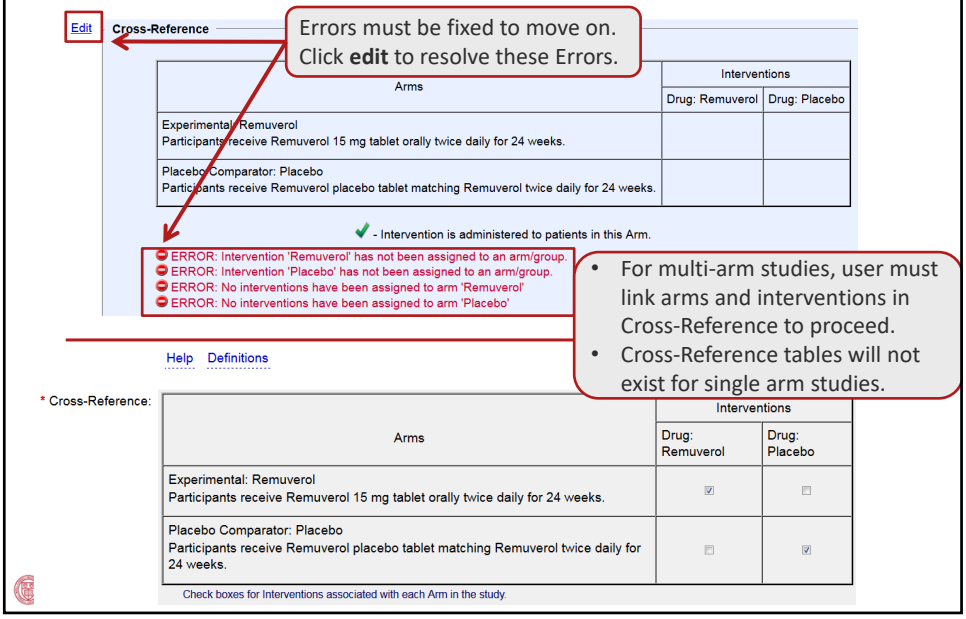
Cross-Reference in Arms & Interventions Section



- For multi-arm studies, user must link arms and interventions in Cross-Reference to proceed.
- Cross-Reference tables will not exist for single arm studies.

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Outcome Measures

- Include **all PRIMARY** and **SECONDARY** outcome measures, as pre-specified in the protocol.
  - Listing tertiary or exploratory outcomes is not required.
- Outcome measures must be specific and indicate what is being measured and how it is being measured.
  - Outcome measure titles, descriptions and time frames should help provide context for the data that will ultimately be publicly posted on the site.

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Outcome Measures: Title

- Include the metric (i.e., scale, score, number, percentage)
  - How can the title be written to explain the meaning of the data in the example data table shown here?

Arm/Group Title	Lexapro		
Arm/Group Description:	escitalopram 10 mg or 20 mg/d Lexapro: Escitalopram will begin at 10mg. a day. Visits will occur biweekly for 12 weeks. Subjects with minimal or no response and minimal or no side effects after 4 weeks will have the dose increased to 20mg. a day. The maximum dose of escitalopram will not exceed the FDA-approved maximum dose of 20 mg per day.		
Overall Number of Participants Analyzed	17		
Measure Type: Count of Participants Unit of Measure: participants	3	17.65%	

    - ✗ Safety
    - ✓ Safety, as measured by number of subjects with at least 1 adverse event
- Be clear and concise; omit verbs
  - How can the title be written to explain the meaning of the data in the example data table shown here?

Arm/Group Title	Cetuximab 250 mg/m2	Cetuximab 375 mg/m2	Cetuximab 500 mg/m2
Arm/Group Description:	Cetuximab 250 mg/m2 IV every two we...	Cetuximab 375 mg/m2 IV every two we...	Cetuximab 500 mg/m2 IV every two we...
Overall Number of Participants Analyzed	3	5	13
Measure Type: Number Unit of Measure: mg/m2	500	500	500

    - ✗ To determine the maximum tolerated dose of Cetuximab in patients with lung adenocarcinoma.
    - ✓ Maximum Tolerated Dose of Cetuximab in patients with lung adenocarcinoma.

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Outcome Measures: Title

- List outcomes separately.
  - ✗ All-cause mortality, hospitalizations, and ER visits.
  - ✓ Number of deaths.
  - ✓ Number of hospitalizations.
  - ✓ Number of ER visits.
- Exception: If a composite score of multiple measures will be used.
  - Example: Count of participants who experience any of the following: All-cause mortality, hospitalizations, or ER visits.

Outcome Measures: Time Frame

- Be specific. E.g., # of minutes, weeks, months a subject is assessed for the outcome measure.
  - Baseline, Week 2
  - During hospitalization, approximately 5 days
  - Post-intervention, Week 12

If protocol can't specify precise time frame, then the following are acceptable:
- average time
- expected average time; or
- max assessment time

- If multiple time points are included:
  - ClinicalTrials.gov assumes change is being assessed. Must include "Change" in the Outcome Measure Title.
    - Example:

Title:	Change in Severity of Depression as Measured by the Hamilton Depression Scale
Description:	Total score of Hamilton Depression Scale ranges from 0 (no depression) to 60 (worst depression possible). If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.
Time Frame:	Baseline, 12 weeks

  - If not measuring change, each time point must be listed as a separate Outcome Measure.

Outcome Measures: Description

- If using a scale as method of measurement for an outcome measure, the description must include:
  - Expanded scale acronym, if acronym is used in title.
  - Low and high scores of the scale with meaning of high score.
    - Example

Title:	Change in Severity of Depression as Measured by the Hamilton Depression Scale
Description:	Total score of Hamilton Depression Scale ranges from 0 (no depression) to 60 (worst depression possible). If reporting a score on a scale, please include the unabbreviated scale title, the minimum and maximum values, and whether higher scores mean a better or worse outcome.
Time Frame:	Baseline, 12 weeks

- If scale isn't linear (e.g., logarithmic), this should be mentioned.

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When poll is active, respond at **PollEv.com/laurenwcm**

Text **LAURENWCM** to **22333** once to join

What's wrong with this example?

Title:	To determine the effect of Remuverol on pain in adults with Condition A
Description:	
Time Frame:	Baseline, 12 weeks

- The title doesn't indicate how pain is being measured.
- The title doesn't omit verbs.
- The title doesn't indicate that change is being assessed.
- The description doesn't include the range of scores for a scale used to measure pain or what the scores mean.
- All of the above.

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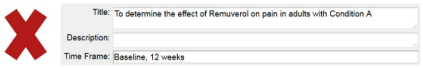
68

Poll locked. Responses not accepted.

What's wrong with this example?



- The title doesn't indicate how pain is being measured.
- The title doesn't omit verbs.
- The title doesn't indicate that change is being assessed.
- The description doesn't include the range of scores for a scale used to measure pain or what the scores mean.
- All of the above.

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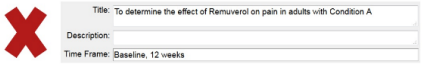
Poll locked. Responses not accepted.

What's wrong with this example?



- The title doesn't indicate how pain is being measured.
- The title doesn't omit verbs.
- The title doesn't indicate that change is being assessed.
- The description doesn't include the range of scores for a scale used to measure pain or what the scores mean.
- All of the above. ✓0%

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Outcome Measures: Example 1

Corrected

Title:	To determine the effect of Remuverol on pain in adults with Condition A
Description:	
Time Frame:	Baseline, 12 weeks

Outcome Measure Title:	Change from baseline in pain, as measured by the Visual Analog Scale (VAS)
Outcome Measure Description:	Scores are measured on a 100 mm VAS. The VAS ranges from 0 to 100 with 0 indicating no pain and higher scores indicating greater pain.
Outcome Measure Time Frame:	Baseline, 12 weeks

Title must omit verbs and include the name of the scale that will be used to assess change in pain.

Since there are 2 time points, the word "change" must be in the corrected title.

The description must include the range of the scale and what the scores mean.

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Text **LAURENWCM** to **22333** once to join

What's wrong with this example?

Title:	To assess the safety of Remuverol
Description:	
Time Frame:	End of study

- The title doesn't omit verbs.
- The title doesn't include the metric by which safety will be measured.
- The time frame isn't specific enough.
- The description doesn't define which adverse events are going to be included in the count.
- All of the above

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Total Results

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72

72

Poll locked. Responses not accepted.

What's wrong with this example?

- The title doesn't omit verbs.
- The title doesn't include the metric by which safety will be measured.
- The time frame isn't specific enough.
- The description doesn't define which adverse events are going to be included in the count.
- All of the above

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Poll locked. Responses not accepted.

What's wrong with this example?

- The title doesn't omit verbs.
- The title doesn't include the metric by which safety will be measured.
- The time frame isn't specific enough.
- The description doesn't define which adverse events are going to be included in the count.
- All of the above ✓ 0%

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Outcome Measures: Example 2

Corrected

Title:	To assess the safety of Remuverol
Description:	
Time Frame:	End of study

Title:	Number of participants with at least one adverse event
Description:	Adverse events will only include those that are determined to be related to the study drug.
Time Frame:	End of study (24 weeks)

The title must omit verbs and include the metric by which adverse events will be measured.

The Time Frame must include the specific point in time at which the outcome measure will be assessed.

The Description must define "adverse events."

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Eligibility Section

Help Definitions

* Sex:	All Biological sex of eligible participants.
[*] Gender Based:	No If applicable, indicate if participant eligibility is based on self-representation of gender identity.
* Age Limits:	Minimum: 18 Years Maximum: N/A (No limit)
* § Accepts Healthy Volunteers:	No
* Eligibility Criteria:	Inclusion Criteria: - Outpatients - At least 18 years old - Diagnosed with Condition A for at least 6 months Exclusion Criteria: - Any cardiovascular, hepatic, or participation, in the opinion of the - Pregnancy - Current use of narcotics

Use Inclusion / Exclusion Criteria **with colon** followed by dashed list format.
No paragraphs.

Make sure that all criteria you post are appropriate for the public to see.
Match informed consent more than protocol, if something might need to be masked from participants.
If necessary, use Detailed Description field to flag that the eligibility criteria are deliberately incomplete to preserve the scientific integrity of the study.

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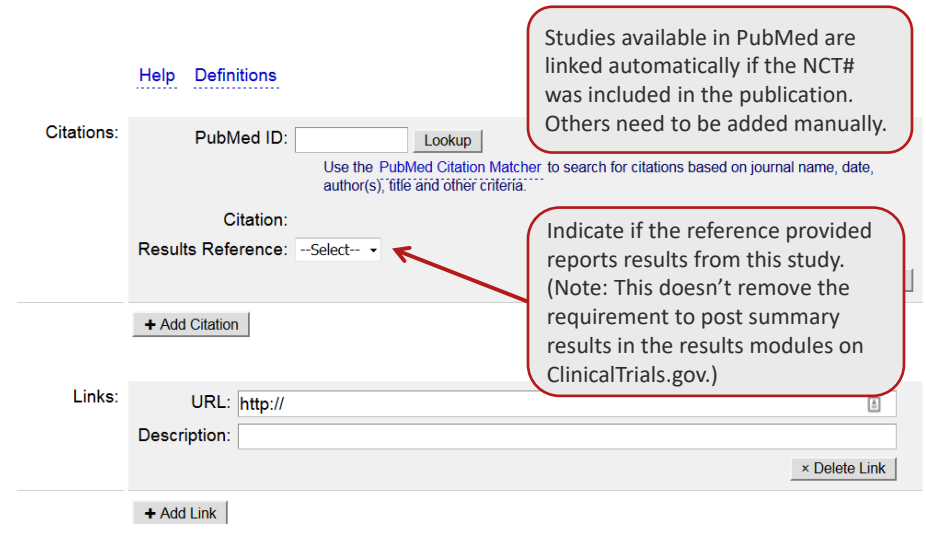
References Section



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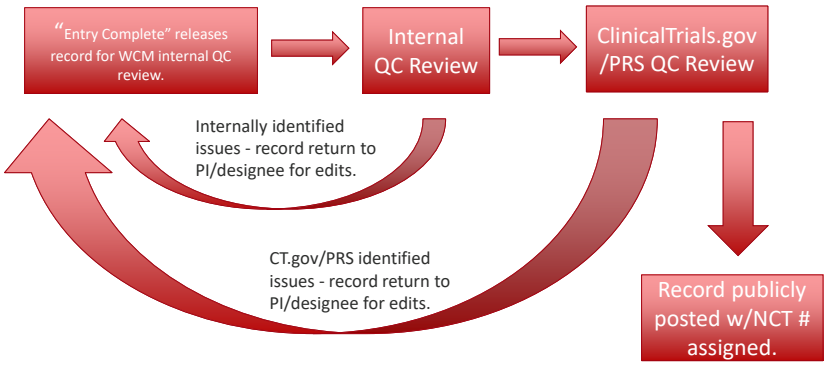
Release to ClinicalTrials.gov

- **After saving any edits to a record:**
  - Update the "Record Verification" date in "Study Status" section to current month and year.
  - Click the green "Entry Complete" button. Entry Complete



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Results Modules

Participant Flow
Baseline Characteristics
Outcome Measures
Adverse Events
Protocol and SAP Document Upload

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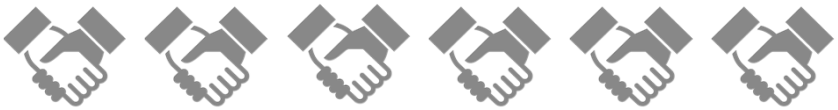
Know Before You Go

- As of January 2020, any ClinicalTrials.gov results record for a study with an FDA-regulated product will be made **permanently public upon first submission**, even if ClinicalTrials.gov identifies major issues during its QC review.
- Once any results record is publicly posted to ClinicalTrials.gov, it's permanently publicly archived along with any subsequent changes made to the record.
- **Partner with the WCM ClinicalTrials.gov Administrator to ensure:**



  - **Consistency**: Make sure one part of the ClinicalTrials.gov record doesn't contradict other parts of the ClinicalTrials.gov record.
  - **Context**: Be sure you're providing information that would effectively communicate the results of the study to someone unfamiliar with the research.
  - **Timeliness:** Federal estimates are 10 – 50 hours for results entry. **Plan ahead** and take advantage of the institutional resources available to you! (E.g., Results sheet, scheduled 1:1 guidance; WebEx call with ClinicalTrials.gov, etc.)

- Human Research Compliance conducts dual-layer internal QC review before a record is publicly released:
  - Review by ClinicalTrials.gov administrator
  - Review by biostatistician with biostatistician entry of statistical analyses.

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Participant Flow

- Shows how participants were assigned to intervention(s) and how they progressed through the study.
  - Arranged by arm/group and according to "period," meaning stages of the clinical study. E.g., Double-Blind Period; Open-Label Period.
    - If only one period, the period title will default to "Overall Study."
    - Each period must include at least 2 milestones to convey key events:
      - MILESTONE: # of subjects who STARTED the period.
        - Should add up across all arms to actual # of subjects enrolled as indicated in Study Design section.
      - MILESTONE: # of subjects who COMPLETED the period.
    - If not all subjects completed the period, indicate # not completed and choose from dropdown list of "Reason Not Completed."
      E.g., AE; physician decision; withdrawal by subject; other.
- Use comments field and footnotes to explain discrepancies.

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Participant Flow

Periods (1) — Protocol Enrollment: 143

* Period Title:	Overall Study			
	AmphoB standard	AmphoB+Fluc400	AmphoB + Fluc800	Total (Not public)
* Started:	47 Edit Comment — 47 subjects randomized; 45 subjects treated	48 Edit Comment — 48 subjects randomized; 47 subjects treated-2 subjects randomized to AmphoB rec'd AmphoB+Fluc400	48 Edit Comment — 48 subjects randomized; 49 treated-3 subjects randomized to AmphoB+Fluc400 rec'd AmphoB+Fluc800	143
+ Add Milestone				
* Completed:	36 Add Comment	33 Add Comment	31 Add Comment	100
Not Completed: (Started - Completed)	11	15	17	
Reason Not Completed				
+ Add Reason Not Completed				

Source: Results: Participants Flow Module, Rebecca J. Williams, PharmD, MPH, Assistant Director, ClinicalTrials.gov, NLM (September 2014)

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Baseline Characteristics

- Table of demographic and baseline data for the overall trial population and for each arm or comparison group. Age, sex, race and ethnicity are required.
  - **Age** can be represented continuously (mean or median), categorically (<=18years; >18 and <65 years; >-65 years), or or customized.
    - Choose only 1. Avoid choosing customized option unless the study design necessitates it.
  - **Sex/Gender** can be displayed using Sex: Female, Male or Sex/Gender, Customized
    - Avoid choosing customized option unless the study design necessitates it.
  - **Race and Ethnicity** entered using:
    - NIH Office of Management and Budget (OMB) Classification Categories; **or**
    - Race and Ethnicity, Customized; **or**
    - Race and Ethnicity Not Collected
  - **Region of Enrollment**

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Baseline Characteristics

- Baseline Measure Title (i.e., name of measure).
- Baseline Measure Type:
  - Count of Participants - Mean
  - Median - Least Squares Mean
  - Geometric Mean - Geometric Least Squares Mean
  - Number - Count of Units
- Measure of Dispersion:
  - N/A (only if measure type is Number, Count of Participants, or Count of Units)
  - Standard Deviation
  - Inter-Quartile Range
  - Full Range
- Unit of Measure – should correspond to Baseline Measure Title (for age, Unit of Measure would be years).
- **Tip 1**: Use "Baseline Analysis Population Description" to explain any discrepancies between number of participants analyzed vs. the number represented in each arm/group.
- **Tip 2**: Don't enter "0" unless the value of a data point is actually "0." Enter "NA" for data "not available" and provide an explanation as to why the data isn't available.
- **Tip 3**: The regulations don't allow researchers to indicate the data was never analyzed. Analyzing available data is required.

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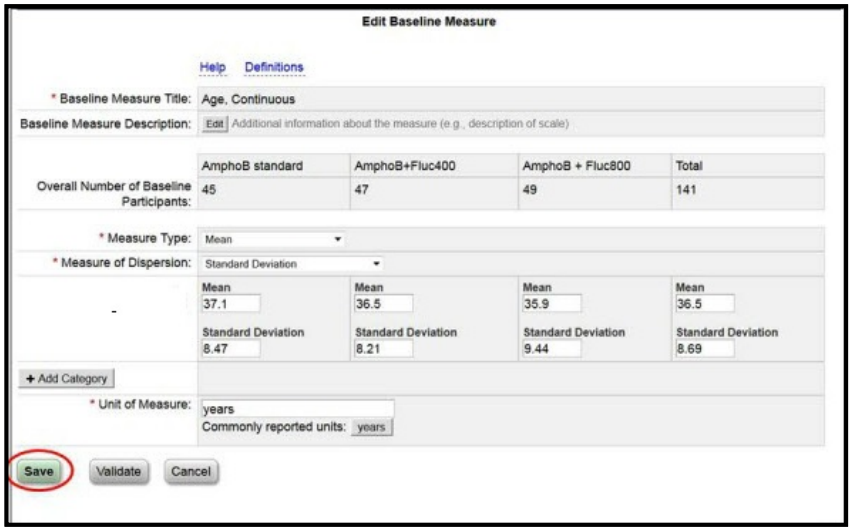
Baseline Characteristics



Source: Results: Baseline Characteristics Module, Rebecca J. Williams, PharmD, MPH, Assistant Director, ClinicalTrials.gov, NLM (September 2014)

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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).

- Arm/Group Title
- Outcome Measure Title
- Measure Type (prim./secondary)
- Measure of Dispersion/Precision (E.g., Standard Deviation)
- Number of Participants Analyzed
- Unit of Measure
- Data

- Statistical analyses are entered by the biostatistician named in the protocol document.
- If no statistician is named in the protocol document, one is assigned at the completion of the internal QC process to enter statistical analyses.

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Outcome Measures for Terminated Studies

If "0" Subjects Analyzed	If Some, but Not All Subjects Analyzed
• Indicate "0" for "Number of Participants Analyzed" in each Arm/Group for which no data were collected. • In "Analysis Population Description" state the specific reason no data were collected, i.e., "No data were collected for this secondary outcome measure because no subjects completed 12 weeks of the study and thus were not assessed."	• Indicate "Number of Participants Analyzed" in each Arm/Group. • In "Analysis Population Description" state the specific reason data were not collected from some subjects, i.e., "No data were collected from x number of subjects because those subjects didn't complete the questionnaire for this outcome measure."
• Submit all available data in Participant Flow, Baseline Characteristics, and Adverse Event Modules. • Note: Analysis is required even for terminated studies. The regulations don't allow for analysis not to be performed because the trial was terminated.	

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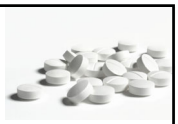
Adverse Events



- Tables showing # of subjects experiencing serious and other adverse events that were collected during the course of the study.
- Need to specify classification system used (e.g., MedDRA 10.0, CTCAE 5.0).
- 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. Option to set frequency threshold to 5% to only report non-serious AEs if exceeded a frequency of 5% within any arm.

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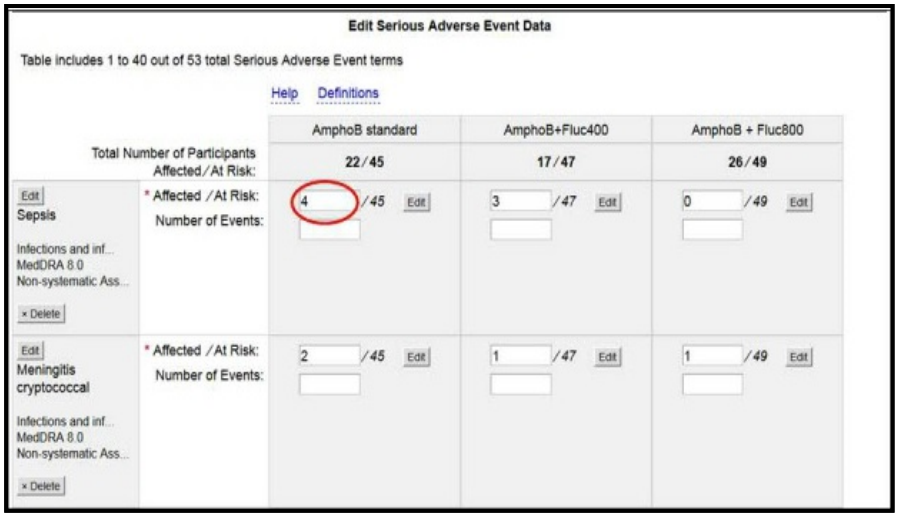
Adverse Events

Organ Systems	**Definition**: High level categories used to group AE terms by body or organ system (If multiple systems affected, select "General Disorders"):
• Blood and Lymphatic System Disorders • Cardiac Disorders • Congenital, Familial and Genetic Disorders • Ear and Labyrinth Disorders • Endocrine Disorders • Eye Disorders • Gastrointestinal Disorders • Hepatobiliary Disorders • Immune System Disorders • Infections and Infestations • Injury, Poisoning and Procedural Complications • Investigations • Metabolism and Nutrition Disorders • Musculoskeletal and Connective Tissue Disorders	• Neoplasm Benign, Malignant and Unspecified (Including Cysts and Polyps) • Nervous System Disorders • Pregnancy, Puerperium and Perinatal Conditions • Product Issues • Psychiatric Disorders • Renal and Urinary Disorders • Reproductive System and Breast Disorders • Respiratory, Thoracic and Mediastinal Disorders • Skin and Subcutaneous Tissue Disorders • Social Circumstances • Surgical and Medical Procedures • Vascular Disorders

Adverse Events for Terminated Studies

- If 0 of subjects "at risk" (i.e., evaluated) for a given adverse event:
  - In "Adverse Event Description" indicate the reason for the difference in # of subjects enrolled vs. # of subjects "at risk."

Adverse Events



Edit Serious Adverse Event Data

Table includes 1 to 40 out of 53 total Serious Adverse Event terms

Help Definitions

		AmphoB standard	AmphoB+Fluc400	AmphoB + Fluc800
Total Number of Participants Affected/At Risk:		22/45	17/47	26/49
Edit Sepsis Infections and inf... MedDRA 8.0 Non-systematic Ass... × Delete	* Affected /At Risk:	4 /45 Edit	3 /47 Edit	0 /49 Edit
	Number of Events:			
Edit Meningitis cryptococcal Infections and inf... MedDRA 8.0 Non-systematic Ass... × Delete	* Affected /At Risk:	2 /45 Edit	1 /47 Edit	1 /49 Edit
	Number of Events:			

Source: Results: Adverse Event Module, Rebecca J. Williams, PharmD, MPH, Assistant Director, ClinicalTrials.gov, NLM (September 2014)

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Protocol and SAP Document Upload

- At time of results posting, upload of a PDF/A required for:
  - IRB-approved protocol document, including:
    - NCT #
    - List of amendments to the document (w/approval dates) affecting all trial sites.
    - Objective(s), design, and methods.
    - Relevant scientific background and statistical considerations.
  - IRB-approved Statistical Analysis Plan (SAP)
    - Can be part of the protocol document.
- Redaction of the following required:
  - Protected Health Information (PHI)
  - Personally Identifiable Information (PII)
  - Trade secrets/confidential commercial information
    - Must not redact info otherwise required to be disclosed by the regulations.
- Cannot upload eIRB application or IRB application as a protocol document to the public site.

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Institutional Resources

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WCM ClinicalTrials.gov Resources

- ✓ CT.gov Institutional Policy
- ✓ CT.gov Decision Tree: Interactive Qualtrics tool that helps investigators determine if study needs to be registered.
- ✓ Registration User Guide: Step-by-step guide for registration (created by CT.gov Taskforce).
- ✓ Requirement for Posting checklist: Checklist to ensure all elements are entered correctly prior to the releasing a record.
- ✓ Registration and Results Resource Guides: 1-pagers with links to help modules, data element definitions etc.
- ✓ Regulatory Resource Guide: 1-pager with all relevant regulatory requirement for registration and posting.
- ✓ When to Update your CT.gov Record: 1-pager with all reasons and timelines to update a record.
- ✓ CT.gov Problem Record Solution guide: A step-by-step guide on how to resolve each problem by type. Includes screenshots of PRS modules.
- ✓ Simplified Result Preparation template: Excel spreadsheet for data gathering prior to posting results. Also, helps facilitate meetings with biostatisticians.
- ✓ Protocol and SAP Upload Guidance: Info on upload of protocol and SAP at time of results entry; includes required format and info, what and how to redact, remove metadata, etc..
- ✓ Tailored WebEx call with CT.gov: Arranged for complicated results entry cases.
- ✓ Dissemination Plan template: Template language to be included in NIH Form F.
- ✓ Biostatistician Results Entry Assistance (statistical analyses)

- ✓ **Guidance and Trainings (Group or 1:1) Available Upon Request**
- ✓ **Website**: https://research.weill.cornell.edu/clinicaltrialsgov
- ✓ **Email**: registerclinicaltrials@med.cornell.edu
- ✓ **Phone**: Available via scheduled Zoom or MS Teams call.

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