Results Requirements for ClinicalTrials.gov

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Contents

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Which Studies Must Submit Results to ClinicalTrials.gov?

Applicable Clinical Trials (ACTs/pACTs)

Applicable Clinical Trials (ACTs) are Federally regulated drug, biologic, or device trials that meet these criteria:

ACT Criteria	Yes	No
1. **The study is interventional (a clinical trial)**	☐	☐
2. **<u>AT LEAST ONE</u> of the following is true:** a. **At least one study facility is located in the United States or a U.S. territory** b. **The study is conducted under an IND or IDE** c. **The study involves 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?**	☐	☐
3. **The study evaluates at least one drug, biological, or device product regulated by the United States Food and Drug Administration (U.S. FDA)?** ***Note: this definition includes both approved and unapproved products.***	☐	☐
4. **The study is NOT a Phase 1 trial of a drug and/or biological product, and is NOT a device feasibility study?** ***Note: A Device Feasibility Study is kind of like a device version of a Phase 1. It involves 10 participants or less, and only studies feasibility, not health outcomes.***	☐	☐

**Per the regulations at 42 CFR 11.22(b)*

IF YOU CHECK "YES" FOR ALL FOUR, THE STUDY IS AN APPLICABLE CLINICAL TRIAL (ACT) AND RESULTS ARE REQUIRED

NIH-Funded Trials

NIH-funded trials that meet the following criteria must report results.

NIH Studies Requiring Reporting	Yes	No
1. **The study meets NIH's definition of a Clinical Trial:** **"A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes."**	☐	☐
2. **The clinical trial is funded in whole or in part by NIH**	☐	☐
3. **The grant application was submitted on or after January 18, 2017**	☐	☐
4. **The funded clinical trial started on or after January 18, 2017.**	☐	☐

* *NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information*

IF YOU CHECK "YES" FOR ALL FOUR, RESULTS ARE REQUIRED

Other Funders

This list includes other notable funders that require results sharing. However, the list is not exhaustive, and policies of funding organizations may change. Be sure to check the policies of your funders and the terms of your grants/contracts. Contact clinicalresearchsupportcenter@ucdenver.edu for help.

Patient-Centered Outcomes Research Institute (PCORI)

PCORI policy requires that:

1) PCORI-funded studies, **including observational comparative effectiveness studies as well as clinical trials**, must be registered on ClinicalTrials.gov before enrollment of the first participant AND
2) Any PCORI-funded studies that are **registered** on ClinicalTrials.gov **must submit results** to ClinicalTrials.gov.
3) PCORI requires results no less than **30 days prior to the draft final research report due date**. This date cannot be later than the 12-month deadline if the study is also an ACT)

Department of Veterans Affairs (VA)

The VA policy requires PIs of VA Office of Research and Development (ORD)-funded clinical trials to register their trials and submit summary results to ClinicalTrials.gov as a condition of funding.

VA ORD defines a Clinical Trial as:

- "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."

Note: this is the same definition used by the WHO and ICMJE.

National Cancer Institute (NCI)

In accordance with its Policy Ensuring Public Availability of Results from NCI-supported Clinical Trials, NCI expects Final Trial Results for all NCI-supported Covered Trials to be reported in a publicly accessible manner.

When do I need to submit results?

If required, results must be posted to ClinicalTrials.gov by the responsible party no later than **12 months** after the Primary Completion Date, even if the study was terminated early. *

** Exception: PCORI results may be required earlier.*

- The **Primary Completion Date** is the last date a participant was examined or received an intervention for the purposes of data collection for the PRIMARY Outcome Measures only.
- The **Study Completion Date** is the last date a participant was examined or received an intervention for the purposes of data collection for the Primary OR Secondary Outcome Measures OR Adverse Events.
- Usually, the dates are both the **last participant's last study visit**, unless you have longer term follow-up for just your Secondary Outcome Measures.

The Completion Dates in ClinicalTrials.gov are often misunderstood. They **are *NOT* connected to**:

- Data analysis
- Manuscript publication
- Enrollment completion
- IRB closure

If you are required to report results to ClinicalTrials.gov and you use the wrong study milestone (e.g., IRB closure) as your completion date, you may have late results!

What data do I need to report?

The results data that need to be reported to ClinicalTrials.gov are probably simpler than you think! Here's what you'll need:

Participant Flow:

- This is how many people started versus finished each period of your study and how many dropped out along the way.
  - Most studies only have one period, but if you're doing something like a crossover study, you may have more (e.g. Period 1: "First Treatment for 3 Weeks", Period 2: "Washout, 1 Week": Period 3: "Second Treatment for 3 Weeks").

Baseline Characteristics:

- Demographics data, like age/sex/ethnicity/race of your participants, and any study-specific baseline measures (e.g. "Participant a1c", etc.) that you collected, if any.

Outcome Measure data:

- These are very basic tables of the data that you collected for each of your Outcome Measures, where the table rows will be the measurement and the columns will be the arms/groups of participants.
  - You can see **sample records with results information here**.

Adverse Events:

- All SAEs, and any AEs that occurred at a frequency over a certain threshold (if any).

Protocol and Statistical Analysis Plan (SAP):

- In most cases you will also need to upload the Protocol and SAP, which are often the same document.

***Note**: You may also need to upload the Informed Consent Form. However, where required, this must be submitted any time after enrollment closes, but within 60 days of the last study visit by any subject, so it should be uploaded before your results are due. Click here for more information about submitting consent forms to ClinicalTrials.gov.*

How do I enter results?

Prepare by gathering the data that you've collected for the modules above and converting your required documents to PDF/A format.

Next, follow the **PRS Guided Tutorials for Entering Results**, which will take you through the process step-by-step.

- ClinicalTrials.gov has sample records with results data entered for a variety of study types.
- Contact clinicalresearchsupportcenter@ucdenver.edu if you get stuck or have questions.

Special Cases

Results Reporting Deadlines for Studies with Different Primary and Study Completion Dates

If required, results must be submitted to ClinicalTrials.gov within 12 months of the Primary Completion Date, but what if your Primary Completion Date occurs before your Study Completion Date, i.e., because you have longer term follow-up for Secondary Outcome Measures and/or Adverse Events?

Does that mean you'll be facing a results time-crunch or even late results because of your longer-term data collection period for Secondary Outcome Measures?

The answer is no. You still must report the results data for which data collection completed at the time of the PRIMARY Completion Date (including, by definition, all Primary Outcome Measures) within 12 months of that Primary Completion Date. *However*, the Outcome Measures for which data collection completed at the time of the STUDY Completion Date will be due within 12 moths of the STUDY Completion Date.

Example:

Sample Record Parameters
Completion Dates: • Primary Completion Date is 8/1/**2021** • Study Completion Date is 8/1/**2023** Primary Outcome Measure: **Title**: Minutes of Daily Exercise at 12 Months **Description:** Average minutes of daily exercise over the past week as measured by wearable fitness device, assessed at the 12 Month visit. **Time Frame**: Month 12 ↑ This time frame defines the *PRIMARY Completion Date*, and results will be due for this Outcome Measure within 12 months of the Primary Completion Date (i.e., by 8/1/2022) Secondary Outcome Measure: **Title**: Minutes of Daily Exercise at 36 Months **Description:** Average minutes of daily exercise over the past week as measured by wearable fitness device, assessed at the 36 Month visit. **Time Frame**: Month 36 ↑ This time frame defines the *STUDY Completion Date*, and results will be due for this Outcome Measure within 12 months of the Study Completion Date (i.e., by 8/1/2024)

Reporting instructions:

Within 12 months of the Primary Completion Date:

1) Report the data available for Participant Flow, Baseline Characteristics, and Adverse Events.
2) Report all Outcome Measures that are due (i.e., within 12 months of the last visit where data was collected for that Outcome Measure).
3) For the Outcome Measures that are not due yet and for which you cannot yet report data:

a. Click on the "Edit" link next to the Outcome Measure.
b. Click "**Save**".
c. Enter an "Anticipated Reporting Date". This must be no later than 12 months after the Study Completion Date.

4) Upload the study protocol & Statistical Analysis Plan, if required.
5) Submit the partial results to ClinicalTrials.gov (don't forget to click the green "Complete" button on the Record Summary page!)

Within 12 months of the Study Completion Date:

6) Go back and report the remaining Outcome Measure(s)
7) Make any final updates or corrections to the other results data (e.g., adverse events).
8) Submit the final, complete results to ClinicalTrials.gov

Extension/ Delay Requests for Good Cause

For Applicable Clinical Trials (ACTs, federally mandated to submit results), requests to delay results reporting for good cause can be submitted to ClinicalTrials.gov (*for non ACTs required to submit results by the funder, you'll need to work directly with the funder on a reporting timeline*).

All delay requests are reviewed by the NIH Director and are accepted if the Director determines that the delay request shows good cause.

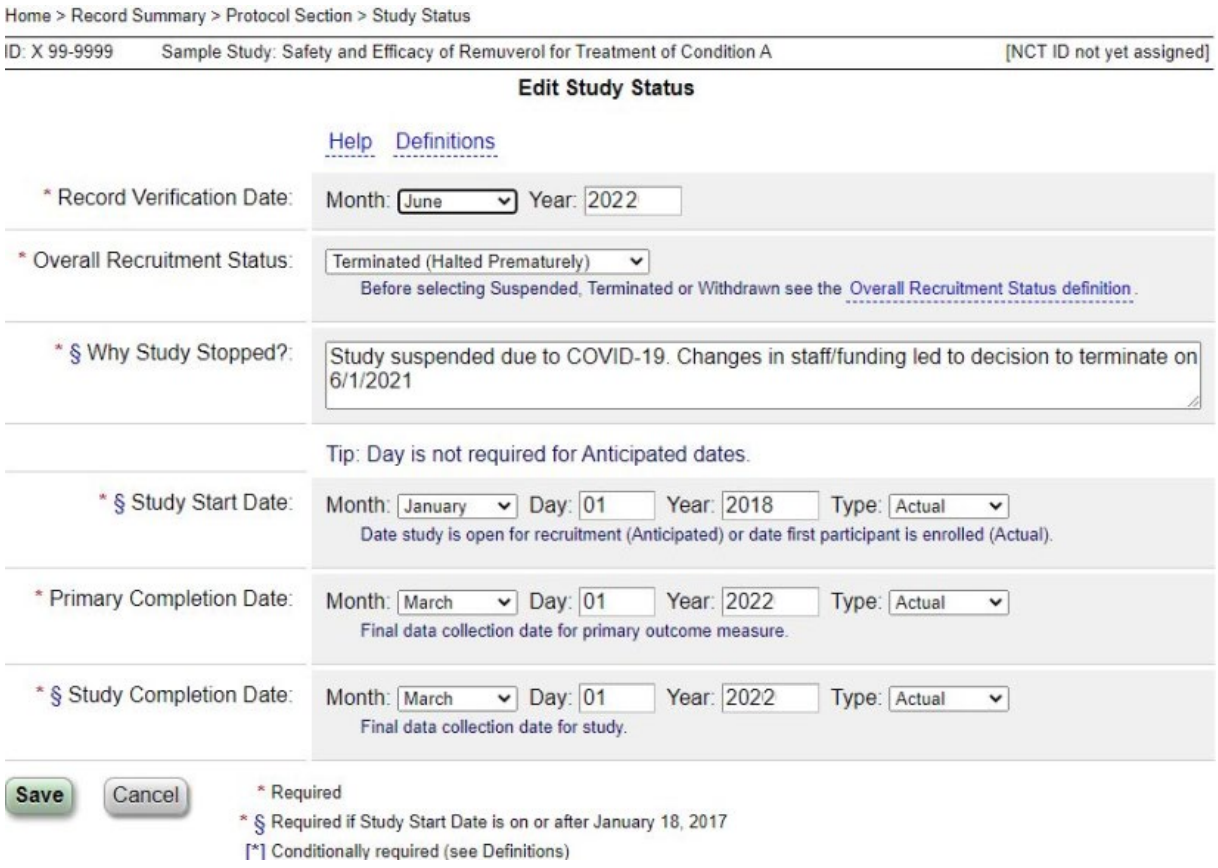
Likely Acceptable Reasons for Delayed Reporting	Unacceptable Reasons for Delayed Results Reporting
➢ Biospecimens to be analyzed were confiscated and held up in Customs ➢ Machine used for analysis broke and is being replaced ➢ Injury, death, or other emergency to PI or data analysts caused delay to study ➢ Lab contracted to do analysis closed and a new vendor is being sought ➢ Study was low-enrolling, and decision to terminate was made too close to the deadline determined by the Primary Completion Date to report on time	➢ Data analysis is taking longer than expected ➢ Not enough personnel/time to complete analysis before the deadline ➢ Researchers are waiting for publication to come out before reporting ➢ Study was terminated and researchers didn't know they still had to report ➢ Researchers were unaware of the deadline ➢ It became clear that endpoints of interest would not be met, and so data analysis was not prioritized

The request to delay results MUST be submitted to ClinicalTrials.gov before the due date for results (*i.e., before 12 months after the last participant's last study visit*). Therefore, it is very important for P.I.s of ACTs that are low-enrolling or suspended to keep a close eye on the length of time since their last study visit, if termination is a possibility.

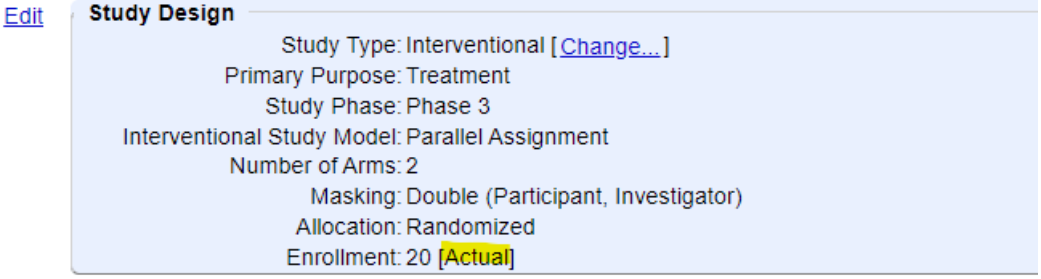
Request instructions

If you need to request delayed results reporting for a terminated study, here is what to do:

1. In the Study Status module in the record, change the "Overall Recruitment Status" to “Completed” *(or "Terminated" and give a reason, if appropriate)*.
2. Enter the Primary and Study completion dates as usual according to the ClinicalTrials.gov definitions:
   - **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 measure(s).
   - **Study Completion Date**: The date the final participant was examined or received an intervention for purposes of final collection of data for the primary and secondary outcome measures and adverse events (usually both are the, last participant’s last visit).



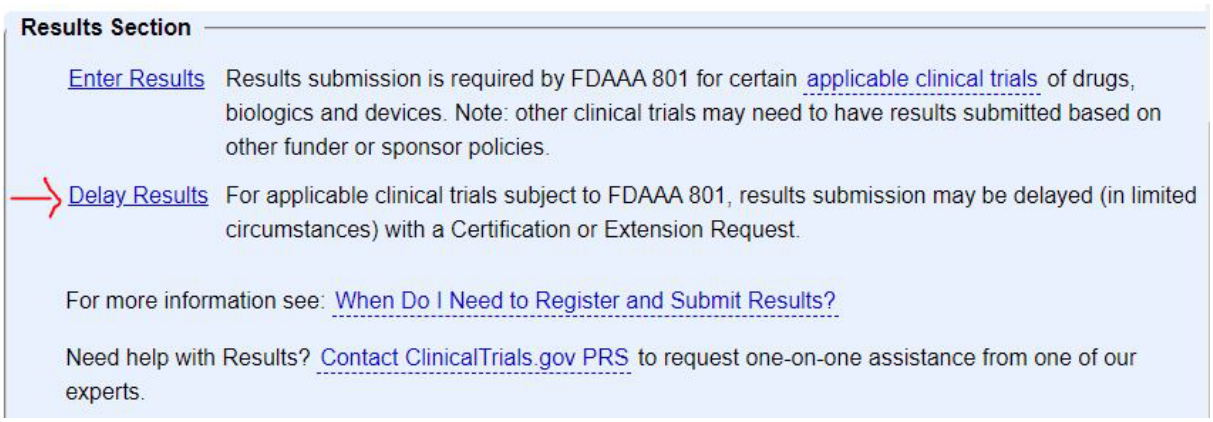
3. Click "Save".
4. Enter the final number of participants enrolled in the Study Design module and change the type to "Actual" *(the system may or may not prompt you to do this)*.



If your study is NOT an Applicable Clinical Trial (ACT), but you are required to submit results because of the funder's policy (e.g., NIH), click the "Complete" button on the record to make it public, and then contact your funder to work with them on a timeline for results submission.

If your study IS an ACT, **continue to step 5**.

5. Go back to the Record Summary page, scroll down to the Results section, and click the "**Delay Results**" link.



6. Enter the reason for the delayed results, and a requested results submission date. If the study was terminated, this date should be no more than one year after the decision to terminate the study.
7. Submit the request and click "Complete" on the Record Summary page to queue the record for release.

Sample Outcome Measure Table and Results Data Entry Exercise

View the outcome measure data, blank data table, and completed data table below to get a sense of the outcome measure data entry process.

Sample Outcome Measure data:

	Experimental arm: Remuverol (n=20)	**Control arm: Placebo** (n = 25)
VAS pain scores (Mean, *Std. Dev*)	55 *(7.3)*	64 *(5.2)*

Sample Outcome Measure results data table (blank):

Outcome Measure 1,

Title	Pain Scores at 2 Weeks
Description	Pain will be assessed via a Visual Analog Scale scores. Possible scores range from 0 to 100, with higher scores indicating more pain and a worse outcome.
Time Frame	2 Weeks

Outcome Measure Data

Analysis Population Description

Arm/Group Title	Remuverol	Placebo
Arm/Group Description:	Participants received Remuverol 15 mg tablet twice daily	Participants received placebo 15 mg tablet twice daily
Overall Number of Participants Analyzed		
Measure Type:		
Unit of Measure		

Sample Outcome Measure results data table (data entered):

Outcome Measure 1

Title	Pain Scores at 2 Weeks
Description	Pain will be assessed via a Visual Analog Scale scores. Possible scores range from 0 to 100, with higher scores indicating more pain and a worse outcome.
Time Frame	2 Weeks

Outcome Measure Data

Analysis Population Description

Arm/Group Title	Remuverol	Placebo
Arm/Group Description:	Participants received Remuverol 15 mg tablet twice daily	Participants received placebo 15 mg tablet twice daily
Overall Number of Participants Analyzed	20	25
Measure Type: Mean (std deviation)	55 (7.3)	64 (5.2)
Unit of Measure: Scores on a scale		

Data entered with color-matched fields:

	Experimental arm: Remuverol (n=20)	**Control arm: Placebo** (n = 25)
VAS pain scores (Mean, *Std. Dev*)	55 *(7.3)*	64 *(5.2)*

Outcome Measure 1

Title	Pain Scores at 2 Weeks
Description	Pain will be assessed via a Visual Analog Scale scores. Possible scores range from 0 to 100, with higher scores indicating more pain and a worse outcome.
Time Frame	2 Weeks

Outcome Measure Data

Analysis Population Description

Arm/Group Title	Remuverol	Placebo
Arm/Group Description:	Participants received Remuverol 15 mg tablet twice daily	Participants received placebo 15 mg tablet twice daily
Overall Number of Participants Analyzed	20	25
Measure Type: Mean (std deviation)	55 (7.3)	64 (5.2)
Unit of Measure: Scores on a scale		

Resources

Need help with ClinicalTrials.gov?

- Contact Clinical Research Support at clinicalresearchsupportcenter@ucdenver.edu for help.
- Visit our ClinicalTrials.gov support page, where you can find an FAQ and helpful ClinicalTrials.gov Tips of the Week.
- Attend a session of CTSA31: ClinicalTrials.gov, a quarterly free lecture which covers registration, regulations, and which touches on results reporting. Upcoming sessions can be found on our Events Calendar.