

UC SAN DIEGO CLINICALTRIALS.GOV QUALITY CONTROL AND POSTING PROCEDURES

ClinicalTrials.gov has updated the procedures for posting results information submitted for applicable clinical trials (ACTs) as of January 2020 (specific date to be announced). ClinicalTrials.gov will post submitted results information publicly within 30 days of submission, regardless of whether the Protocol Registration and Results System (PRS) quality control (QC) review processes are complete. Records will indicate that the QC process has not concluded and include standard QC review comments on the public facing ClinicalTrials.gov website. The following is an overview of the updated QC and posting procedures.

Which studies do the updated procedures apply to?

These procedures apply only to studies that satisfy all of the following criteria:

- Is an ACT *
- Has a study start date that is on or after January 18, 2017 (the effective date of the [Final Rule](#))
- First results are submitted beginning in January 2020

* For more information on identifying ACTs, see [ClinicalTrials.gov Checklist for Evaluating Whether a Clinical Trial or Study is an ACT](#).

What is the regulation?

42 CFR §11.52 *By when will the NIH Director post submitted clinical trial results information?*

No later than 30 calendar days after the date of submission.

Which comments will be posted publicly?

There are two types of comments, “Major” and “Advisory” Comments. Major Comments must be corrected, whereas it is optional to address Advisory Comments. Only the brief, Major Comments identifying relevant sections and data elements will be visible publicly. Additional details that provide explanations and/or suggestions for the Major Comments will not be included on the publicly facing website. Advisory comments will not be publicly visible.

When would comments be posted publicly?

After the QC review comments have been released, the study record will be posted with Major Comments and the Responsible Party will be notified by email. Comments cannot be addressed before the study record is publicly posted.

Do the QC and posting procedures apply if the results are submitted before the submission deadline?

Yes, the procedures apply as long as the study record meets the criteria above.

Resources:

[ClinicalTrials.gov Updated Quality Control and Posting Procedures](#)

[Top Questions About the Updated Quality Control and Posting Procedures for ClinicalTrials.gov](#)