Top Questions About the Updated Quality Control and Posting Procedures for ClinicalTrials.gov

Beginning in January 2020, ClinicalTrials.gov will update the procedures for posting results information submitted for applicable clinical trials (ACTs). Consistent with 42 CFR Part 11, the National Library of Medicine (NLM) will publicly post submitted results information within 30 days of submission, regardless of whether the quality control (QC) review process has been completed.

To help responsible parties understand and prepare for the implementation of these updated procedures, questions and answers are provided below:

1. **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 submitted results information beginning in January 2020 *(specific date will be announced)*

   For more information on identifying ACTs, see Section 8.1.2 of the PRS User’s Guide.

2. **Which comments will be publicly visible? Will advisory comments be shown?**
   *Only* the brief, standard major comments that identify the relevant section will be publicly posted, and a general note that the QC review process has not concluded will be included. Advisory comments will not be publicly posted.

3. **Will I have an opportunity to address a study record with major comments before it’s publicly posted?**
   No, the study record will be posted with major comments after NLM’s QC review. The responsible party will be notified by email when QC review comments, and any further explanations of the issues, are available.

4. **If I submit results before the submission deadline, do these procedures still apply?**
   Yes, the procedures apply as long as the study record meets all the criteria listed in question 1. NLM has an obligation to publicly post submitted results information within 30 days of submission.