

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

In January 2020, ClinicalTrials.gov implemented new procedures for posting results information submitted for applicable clinical trials (ACTs). Consistent with 42 CFR Part 11, the National Library of Medicine (NLM) publicly posts 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 on or after January 1, 2020

For more information on identifying ACTs, see [Section 8.1.2](#) of the PRS User's Guide.

### **2. Which comments are publicly visible? Are advisory comments shown?**

*Only* the brief, standard major comments that identify the relevant section are publicly posted, and a general note that the QC review process has not concluded is included. Advisory comments are not publicly posted.

### **3. Do I have an opportunity to address a study record with major comments before it's publicly posted?**

No, the study record is posted with major comments after NLM's QC review. The responsible party is 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.