Table 3. Data Elements for More Rapid Updating for Clinical Trials Initiated On or After January 18, 2017 (42 CFR 11.64(a)(1)(ii))

For clinical trials initiated on or after January 18, 2017, section 11.64(a)(1)(ii) of the Final Rule specifies update requirements. In general, clinical trial information submitted to ClinicalTrials.gov must be updated not less than once every 12 months. The Final Rule further requires that some data elements be updated more rapidly, as summarized in Table 3 below. In addition, the Final Rule requires that if a protocol is amended in such a manner that changes are communicated to human subjects in the clinical trial, updates to any relevant clinical trial information must be submitted not later than 30 calendar days after the protocol amendment is approved by a human subjects protection review board. See section IV.D.3 of the preamble and 42 CFR 11.64 for a more complete elaboration and specification of these requirements.

Data Element	Deadline for Updating (i.e., not later than the specified date)
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.
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.

Notes:

1. If expanded access to an investigational drug product becomes available after a clinical trial of that drug product has been registered and an expanded access record has not yet been created, a responsible party who is both the manufacturer of the investigational product and the sponsor of the applicable clinical trial must also, not later than 30 calendar days after expanded access becomes available, submit the data elements in accordance with §11.28(c) to create an expanded access record.

2. If Overall Recruitment Status is changed to "suspended," "terminated," or "withdrawn," the Why Study Stopped data element must be submitted at the time the update is made.