Record Update Submission Timelines

For clinical trials initiated on or after January 18, 2017, the regulations at 42 CFR 11.64(a)(1)(ii) specify update requirements. In general, clinical trial registration information should be updated and verified accurate once every 6 months. Regulations require that some data elements be updated more frequently, as summarized in the table below. In addition, if a protocol is amended in such a manner that changes are communicated to human subjects in the clinical trial, the regulations require that updates to any relevant clinical trial information be submitted not later than 30 calendar days after the protocol amendment is approved by a human subjects protection review board. See the Final Rule preamble (81 FR 65109-17) and the regulations at 42 CFR 11.64 for a more complete elaboration and specification of these requirements.

Update ClinicalTrials.gov each time these elements change

Type of Change	*Update ClinicalTrials.gov ≤15 days*	*≤1 mo.*	*≤6 mo.*	*≤12 mo.*
Device Product Not Approved or Cleared by U.S. FDA	15 calendar days after a change in approval or clearance status has occurred.			
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.			
IRB Status Change	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.			
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.			
Study Results	Study results must be submitted within 12 months of Primary Completion Date. If study is withdrawn, suspended, or terminated, results must be submitted within 12 months unless no subjects were enrolled. [2]			

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 42 CFR 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.

Page content adapted from:

Frequently Asked Questions. (n.d.). Retrieved July 3, 2018, from U.S. National Library of Medicine website: https://clinicaltrials.gov/ct2/manage-recs/faq