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42 C.F.R. § 11.64

When must clinical trial information submitted to ClinicalTrials.gov be updated or corrected?

(a) *Updates.* (1) Clinical trial registration information:

(i) The responsible party for an applicable clinical trial for which clinical trial registration information was required to be submitted if the clinical trial was initiated before January 18, 2017, must submit updates in accordance with the following:

(A) In general, changes to the clinical trial registration information specified in section 402(j)(2)(A)(ii) of the Public Health Service Act (42 U.S.C. 282(j)(2)(A)(ii)) that was required at the time of submission must be updated not less than once every 12 months.

(B) Overall Recruitment Status must be updated not later than 30 calendar days after any change in overall recruitment status.

(C) Primary Completion Date must be updated not later than 30 calendar days after the clinical trial reaches its actual primary completion date.

(ii) The responsible party for an applicable clinical trial, or for another clinical trial for which registration information was voluntarily submitted pursuant to § 11.60(c), if the clinical trial was initiated on or after January 18, 2017, must submit updates in accordance with the following:

(A) In general, changes to clinical trial registration information specified in § 11.28 must be updated not less than once every 12 months.

(B) If the first human subject was not enrolled in the clinical trial at the time of registration, the Study Start Date data element must be updated not later than 30 calendar days after the first human subject is enrolled.

(C) Intervention Name(s) must be updated to a non-proprietary name not later than 30 calendar days after a non-proprietary name is established for any intervention included in the Intervention Name(s) data element.

(D) Availability of expanded access:

(*1*) If expanded access to an investigational drug product (including a biological product) becomes available after an applicable clinical trial of that product has been registered, the responsible party, if both the manufacturer of the investigational drug product (including a biological product) and the sponsor of the applicable clinical trial, must, not later than 30 calendar days after expanded access becomes available, update the Availability of Expanded Access data element for that applicable clinical trial and, unless an expanded access record has already been created as required by § 11.28(a)(2)(ii)(H), submit the data elements in accordance with § 11.28(c) to create an expanded access record.

(*2*) No later than 30 calendar days after the date on which the responsible party receives an NCT number for an

expanded access record created as required by § 11.28(a)(2)(ii)(H), the responsible party must update the Availability of Expanded Access data element by entering the NCT number in the clinical trial record for the applicable clinical trial.