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FDA Enforces ClinicalTrials.gov Results Posting Requirements, Including Threats of Financial Penalty

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Clinical trials requiring registration on ClinicalTrials.gov generally must have results submitted no later than one year after the study's primary completion date.[1] In the past, some companies delayed updating a clinical trial record, including by failing to update the primary completion date to reflect delays or failing to submit results within 12 months of that date.

In August 2020, FDA announced its intention to enforce these obligations in a guidance pointedly titled, "Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank."[2] The guidance emphasized the civil penalties for failure to comply with submission requirements, including financial penalties of up to $10,000 for all violations adjudicated in a single proceeding and up to $10,000 per day upon continued violation after the first 30 days following notice.

FDA announced it would identify violations through inspections conducted as part of its Bioresearch Monitoring Program and based on its evaluation of received complaints. FDA said it would send a Preliminary Notice of Noncompliance Letter (Pre-Notice Letter), identifying the noncompliance and giving the party 30 days to respond. The Pre-Notice Letter notifies the recipient that failure to comply may result in further FDA regulatory action, including the issuance of a Notice of Noncompliance (which it posts on its website) and civil penalties. FDA has issued more than 40 Pre-Notice Letters[3] and three Notices of Noncompliance, but it has not yet assessed any penalties.[4]

The new year is a good time to update your clinical trial procedures. We encourage clients to check their records for registered studies and update any primary completion dates that might have changed, consider submitting a certification in support of delayed posting of results if applicable,[5] and submit timely results. Crucially, requests for an extension to post results must be submitted *before* the date on which results would otherwise be due.

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[1] 42 CFR §11.44(a); *see* 42 CFR §11.10(a) (defining primary completion date).

[2] *See* https://www.fda.gov/media/113361/download.

[3] Janet Woodcock, M.D., FDA, FDA Takes Action for Failure to Submit Required Clinical Trial Results

Information to ClinicalTrials.Gov (Apr. 28, 2021), https://www.fda.gov/news-events/press-announcements/fda-takes-action-failure-submit-required-clinical-trial-results-information-clinicaltrialsgov.

[4] FDA, Clinical Trials.Gov – Notices of Noncompliance and Civil Money Penalty Actions (content current as of Dec. 13, 2021), https://www.fda.gov/science-research/fdas-role-clinicaltrialsgov-information/clinicaltrialsgov-notices-noncompliance-and-civil-money-penalty-actions.

[5] For trials with a primary completion date on or after January 18, 2017, the regulations permit delayed submission of results if the responsible party submits a certification before the date on which results would otherwise be due that the product is (1) not yet approved, licensed, or cleared, and the sponsor intends to continue with product development and either is seeking, or may at a future date seek, initial approval, licensure, or clearance for the studied product; or (2) approved, licensed, or cleared by FDA, but is being studied for a new use, and the sponsor of the trial, who is also the manufacturer of the product, is or will be seeking (within one year) FDA approval, licensure, or clearance of the new use. 42 CFR §§11.44(b) and 11.44(c). Certifications are submitted via the ClinicalTrials.gov Protocol Registration and Results System.

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