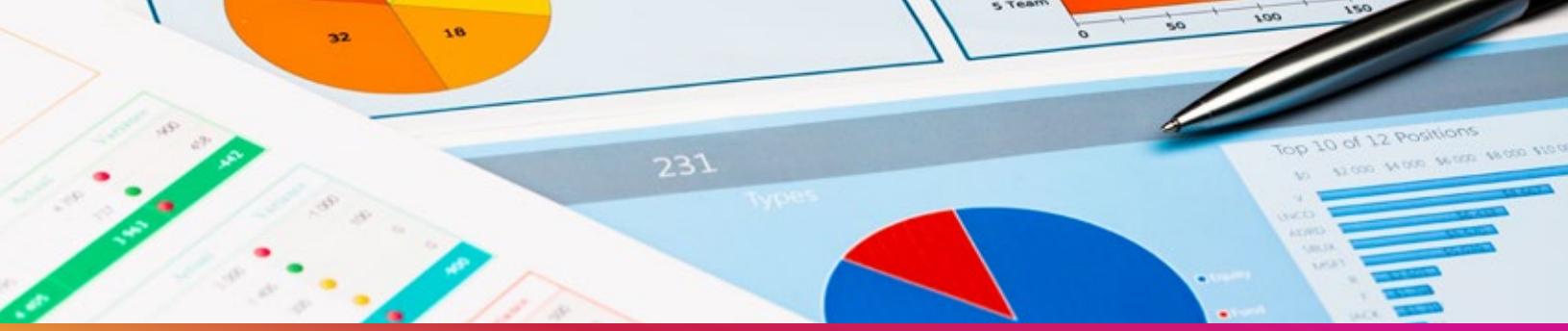

Compliance and Transparency in Clinical Trial Data Reporting

Clinical Trial Data Reporting Guidelines

Transparency is the cornerstone of clinical trials and is vital to enabling genuine advancement of safe and effective medical treatments. Whether an academic institution, an individual, a corporation, a government entity or a combination of these conducts the research, federal law requires that sponsors register the trial on ClinicalTrials.gov within 21 days of the first human subject's enrollment. In addition to reporting the trial itself, sponsors must submit results from the trial—positive or negative, expected or unexpected—no later than one year after the study's completion, unless the sponsor is granted a deadline extension.

ClinicalTrials.gov is a database of clinical trial data that is jointly managed by the National Institutes of Health (NIH) and the National Library of Medicine. However, the burden of determining compliance with reporting to the database lies with the Food and Drug Administration (FDA). The FDA alone has the duty and responsibility to determine legal compliance for clinical trials and act on reports of non-compliance. Section 303(f)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) "authorizes the FDA to assess civil money penalties against responsible parties...who violate applicable FD&C Act prohibitions relating to requirements under section 402(j) of the Public Health Service Act (42 U.S.C. 282(j)), including its implementing regulations in 42 CFR Part 11, to submit registration and/or results information to the ClinicalTrials.gov data bank and/or certain certifications to FDA." Unfortunately, these FDA guidance documents issued in August 2020 do not establish legally enforceable responsibilities; rather, they establish guidance and, per the FDA, should be viewed only as recommendations, unless otherwise specified.

Notices of Noncompliance and Their Impacts

There are many reasons a sponsor may want to omit or not report certain data, from adverse and unplanned side effects, to the rare instance of death in a participant of a trial. But the FDA states that reporting all data is necessary for transparency, ultimately allowing "the broader scientific community to build on the information submitted." The FDA also says that "the submission to and posting of clinical trial information on ClinicalTrials.gov honors volunteers who participate in research to advance medical science and enhances public trust by creating a transparent and robust public record of clinical trials and information about their results."

Reporting all data is necessary for transparency, ultimately allowing "the broader scientific community to build on the information submitted." - FDA

The FDA began sending Pre-Notices of Noncompliance in 2020 and sent more than 40 notices in 2021 to encourage voluntary compliance with the ClinicalTrials.gov reporting requirements. In 2021, a sponsor who previously received a Pre-Notice of Noncompliance and chose not comply with its legal reporting obligations prompted the FDA to issue a formal Notice of Noncompliance. A formal Notice of Noncompliance gives the sponsor 30 days to submit the unreported information and authorizes the FDA to seek civil monetary penalties. If the data is not reported in that timeframe, the FDA is then authorized to seek additional civil money penalties.

More important than a fine, a formal Notice of Noncompliance is posted to the FDA website, as well as on the trial's record on ClinicalTrials.gov. When or if the noncompliance is remedied and the sponsor pays penalties is then subject to public record and could be a reputational death sentence for any legitimate sponsor. These formal sanctions for noncompliance in clinical trials inevitably affect the FDA's approval of therapies and tarnish the general public's vote of confidence in their efficacy, negatively impacting sales. Additionally, certain applications/submissions to the FDA are required to certify that all the above-referenced requirements have been met for applicable clinical trials, otherwise the publications arising from the trials could be excluded from citation.

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Confidence in Clinical Trial Data Reporting Partners

Ensuring compliant and timely data reporting for a clinical trial may seem like the last step in an overwhelmingly long and complex research process, but it is important for an untarnished stamp of approval from the FDA and from the greater scientific community. At Versiti Clinical Trials, our trained project managers are conscious of regulatory requirements and strive to shepherd a trial from conception to final close out so nothing falls through the cracks. Additionally, trial data is available to the sponsor and site professionals in real-time through the GlobeSync platform. Versiti Clinical Trials is your partner in transparency through reporting clinical trial data correctly the first time, on time, every time.

Ready to get started?

Visit versiticlinicaltrials.org/contact-us here

Sources

1. "Notices of Noncompliance and Civil Money Penalty Actions." U.S. Food and Drug Administration, FDA, 13 Dec. 2021, https://www.fda.gov/science-research/fdas-role-clinicaltrialsgov-information/clinicaltrialsgov-notices-noncompliance-and-civil-money-penalty-actions.
2. "FDA Takes Action for Failure to Submit Required Clinical Trial Results Information to Clinicaltrials.gov." U.S. Food and Drug Administration, FDA, 28 Apr. 2021, https://www.fda.gov/news-events/press-announcements/fda-takes-action-failure-submit-required-clinical-trial-results-information-clinicaltrialsgov.
3. "Civil Money Penalties CiinicalTrials.gov Data Bank." U.S. Food and Drug Administration, FDA, 12 Aug. 2021, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/civil-money-penalties-relating-clinicaltrialsgov-data-bank.

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