July 30, 2020

NIH Updates ClinicalTrials.gov Guidance to Address *Seife v. HHS*

On July 28, the National Institutes of Health ("NIH") updated the ClinicalTrials.gov FAQ page, effectively announcing a change of policy with respect to certain clinical trial reporting requirements. The move comes after the government decided not to appeal a February federal court decision, *Seife v. Department of Health and Human Services*,[1] which invalidated NIH's decision to exempt certain clinical trials conducted between 2007 and 2017 from results reporting requirements of the Food and Drug Administration Amendments Act ("FDAAA"). In the new FAQs, NIH signals its acceptance of the *Seife* decision—which Ropes & Gray previously analyzed in an alert available here—and confirms that certain trial results, previously thought to be exempted from FDAAA's reporting requirements, will need to be reported after all.

Seife v. HHS

In *Seife*, the U.S. District Court for the Southern District of New York ruled that the Department of Health and Human Services ("HHS") had, through rulemaking, impermissibly narrowed the scope of clinical trials for which results must be reported, holding that HHS's interpretation of FDAAA ran counter to the unambiguous language of the statute. In relevant part, FDAAA requires that "Responsible Parties"—sponsors or sponsor-designated principal investigators—report "Basic Results" for "each applicable clinical trial [or "ACT"] for a drug that is approved under [21 U.S.C. § 355] or licensed under [42 U.S.C. § 262] or a device that is cleared under [21 U.S.C. § 360(k)] or approved under [21 U.S.C. § 360e or § 360j(m)]."[2] In the *Federal Register* preamble to the 2016 final rulemaking—but not in the final regulatory text—NIH provided its interpretation that "the marketing status of a product will be determined based on its marketing status on the primary completion date [of the ACT]." Consequently, Responsible Parties were not required to report Basic Results for any clinical trial that concluded prior to January 18, 2017 and prior to the studied product's FDA approval or clearance. Because products are typically studied before they receive marketing authorization, this interpretation effectively exempted such results from FDAAA's reporting requirements during this ten-year period.

The *Seife* court rejected the government's interpretation. Judge Naomi Reice Buchwald ruled that the FDAAA results reporting requirements apply to a clinical trial of "a drug or device that is *presently* approved, licensed or cleared" so long as other statutory criteria are satisfied, meaning that Responsible Parties must report Basic Results after marketing authorization is obtained. The government did not appeal the court's decision.

ClinicalTrials.gov FAQs

In its new ClinicalTrials.gov FAQs, NIH expressly adopts the *Seife* holding, confirming that Responsible Parties are required to report certain previously exempted results. (The FAQs are available here, under "Results Information and Submission Deadlines.") Rather than establishing a deadline by which Responsible Parties must "catch up" on delayed results reporting, NIH cites FDAAA and *Seife* as requiring that such results be reported within 30 days of the relevant product's, approval, clearance, or licensure and goes on to state that results impacted by the *Seife* decision should now be submitted "as soon as possible."

Another FAQ indicates that "FDA and NIH may take action against responsible parties if they do not submit required results information for [clinical trials] affected by the Federal Court's decision." While enforcement related to the clinical registration and results reporting requirements of FDAAA has so far been minimal, this FAQ could signal a renewed focus on ClinicalTrials.gov violations. As of July 29, the ClinicalTrials.gov FAQs provide the only articulation of NIH's new results reporting policy. It remains to be seen whether NIH will offer additional, more formal guidance to clinical

[1] *Seife et al v. HHS et al*, 440 F. Supp. 3rd 254 (S.D.N.Y. 2020).
[2] 42 U.S.C. § 282(j)(3)(C).

trial sponsors. For now, Responsible Parties should determine which, if any, of their clinical trials are affected by this change and begin to collect and prepare Basic Results for submission to ClinicalTrials.gov.

If you have questions or would like assistance analyzing the ClinicalTrials.gov reporting requirements, please contact any member of Ropes & Gray's FDA regulatory practice or your usual Ropes & Gray advisor.