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Compliance Today - September 2022
Clinical trial fraud: Mitigating risk with a compliance program framework

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The recent spotlight on the pathway to vaccine development during the COVID-19 pandemic has heightened discussion around science, clinical trial processes, clinical data collection, and the data used to support vaccines and other drug development. Political discussions on the vaccine debate aside, clinical trial conduct may seem secretive and, at times, perhaps not transparent to those unfamiliar. Questioning science and clinical trials hints at underlying implications of fraud or misconduct. However, clinical trial fraud or, more appropriately called, research misconduct, is not a new topic that came with the fury of clinical trial research during the pandemic. In the last few years, clinical trial fraud has been at the forefront of many highly publicized cases brought by the Department of Justice (DOJ).

In December 2021, at the Food and Drug Law Institute Conference, the DOJ announced that clinical trial fraud would be one of four enforcement focus areas for the agency. The announcement delivered by Deputy Assistant Attorney General Arun Rao highlighted the work of the Consumer Protection Branch of the DOJ around the importance of protecting Americans' health, safety, and economic security.[1] The Department of Health & Human Services' Office of Research Integrity (ORI) defines research misconduct as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results."[2] Research misconduct can include omitting, altering, fabricating, or broadly interpreting clinical data. This can happen when a researcher conducts a clinical trial, during the design of the clinical trial by a sponsor, during data recording within a clinical trial, and when someone supervises or reviews the research taking place. An individual can also commit research misconduct when results are reported either to a public registry or a clinical trial sponsor. This article will discuss notable past enforcement actions by the DOJ to highlight the ways in which clinical trial fraud may appear and ways that clinical trial sponsors/pharmaceutical companies can mitigate the risk surrounding clinical trial fraud in their compliance programs.

Notable enforcement actions

In and of itself, clinical trial fraud does not carry criminal penalties or jail sentences; however, it is often the case that defendants in clinical trial fraud cases have also been found to violate the False Claims Act, commit wire fraud when operating across state lines, and violate the Anti-Kickback Statute. In many cases, uncovering fraud within a clinical trial can levy heavy financial fines against individuals, companies, and universities.

In 2019, the Attorney's Office for the Eastern District of Washington brought a case against an individual and the clinical trial centers he owed for falsifying clinical research data in connection with a fraud scheme.[3] The centers conducted trials to treat a wide variety of medical conditions, including mental health conditions, heart disease, and opioid addiction. The case was shocking for several reasons, including the crimes themselves and the fatal outcome for two trial participants.

An immigrant to the US, the trial center owner was unable to obtain the required US license to practice medicine;

instead, he became the owner of several clinical trial sites. According to the DOJ, he made over $6 million from pharmaceutical companies to conduct clinical trials. The compensation the clinical trial centers received were the result of the owner's enrollment of participants who were otherwise ineligible or excluded, falsification of participant medical records, and illegal collection of samples from unwilling or unsuspecting subjects of a trial.

Ultimately, the clinical trial owner received a significant jail sentence and a monetary judgment against him of $1.9 million. However, the harsh reality is that the public was put in considerable danger because of his actions which ultimately led to the deaths of two participants.[4] One participant was a pediatric subject who was misdiagnosed to be included in a clinical trial and the second was a subject who had been enrolled in multiple clinical trials without appropriate monitoring.

In two unconnected cases from Florida, jail sentences for three individuals—a principal investigator, a study coordinator, and a clinical site director—equaled more than 120 months in jail and $2.1 million in restitution after the DOJ uncovered their schemes to defraud pharmaceutical companies financially. Each individual committed clinical trial fraud by falsifying clinical trial data and reporting that participants received study drugs when they had not; however, when they accepted payments—the transmission of which crossed state lines—for fraudulent activities, the DOJ included wire fraud charges.[5][6]

While these cases demonstrate some of the extreme outcomes of clinical trial fraud, other examples highlight that clinical trial fraud is not only found within the private clinical trial sector. For instance, in 2019, a Duke University lab employee reported that another Duke University researcher falsified clinical data and medical research to obtain federal grant money from the National Institutes of Health and the Environmental Protection Agency. The fraud occurred undetected for more than 15 years and resulted in the award of close to $200 million in research grant money to the university. Duke University agreed to pay $112.5 million to settle the False Claims Act allegation by the whistleblower.[7]