



**Department of Justice**

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## **Florida Study Coordinator Sentenced in Scheme to Falsify Clinical Drug Trial Data**

A federal judge sentenced a Florida man to 30 months in prison today in connection with his participation in a conspiracy to falsify clinical drug trial data.

U.S. District Judge Robert N. Scola Jr. of the Southern District of Florida entered the sentence against Duniel Tejeda, 35, of Clewiston. The court also ordered Tejeda to pay \$2.1 million in restitution.

According to court documents, Tejeda worked as a project manager and study manager for a clinical research firm based in Miami called Tellus Clinical Research. As part of his plea agreement, Tejeda admitted that he agreed with others to falsify data in medical records in connection with clinical trials intended to evaluate various medical conditions, including opioid dependency, irritable bowel syndrome and diabetic nephropathy. Among other things, Tejeda falsified data to make it appear as though subjects were participating in the trials when, in truth, they were not.

“Clinical trials help ensure that new drugs are safe and effective for the public,” said Acting Assistant Attorney General Brian M. Boynton of the Justice Department’s Civil Division. “Falsifying clinical trial data undermines a critical component of the drug approval process. The Department of Justice will continue to work with our partners at the Food and Drug Administration (FDA) to investigate and prosecute anyone who puts personal profit over public health by falsifying clinical trial data.”

“Reliable and accurate data from clinical trials is the cornerstone of FDA’s evaluation of a new drug,” said Assistant Commissioner Catherine A. Hermsen for the FDA Office of Criminal Investigations (OCI). “Compromised clinical trial data could impact the agency’s decisions about the safety and effectiveness of the drug under review. We will continue to monitor, investigate and bring to justice those whose actions may subvert the FDA approval process and endanger the public health.”

FDA OCI is investigating the case.

Trial Attorneys Lauren M. Elfner, Joshua D. Rothman and Matthew M. Ryan of the Civil Division’s Consumer Protection Branch are prosecuting the case. The U.S. Attorney’s Office for the Southern District of Florida has provided critical assistance.

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