

News Release
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Vince & Associates Clinical Research Awarded FDA Contract to Conduct Pharmacokinetic Study with Opioids

Overland Park, KS – [Vince & Associates Clinical Research](#) today announced that it has been awarded a contract with the [U.S. Food and Drug Administration \(FDA\) Office of Generic Drugs \(OGD\)](#) to conduct a clinical pharmacology pharmacokinetic (PK) study of opioids manipulated via milling procedures.

In this study-specific contract, Vince & Associates is responsible for conducting the opioid PK study and providing the necessary support services including study design, protocol development, clinical operations, data management, biostatistics, bioanalytical analysis and medical writing.

The objective of this study is to evaluate factors that affect the bioavailability of milled opioid drug products following nasal snorting. The outcome of this study may help in determining critical study design parameters when comparing deterrence of nasal abuse between a generic and its Reference Listed Drug.

“We are eager to partner with the FDA to help address agency concerns about the manipulation of opioid products. Vince & Associates is uniquely qualified to conduct this trial as our Principal Investigators have extensive substance abuse clinical knowledge and are industry leaders in the conduct of [substance abuse trials](#),” said Dr. Brad Vince, CEO and medical director at Vince & Associates Clinical Research.

“This type of study is ideally suited to the technical capabilities of Vince & Associates Clinical Research. Our [state-of-the-art pharmacy](#) with facial recognition security is equipped with a biosafety hood preparation area and controlled substance storage, which are essential for completing complex clinical studies involving opioids,” stated Dr. Lorraine M. Rusch, Vice President, Scientific Development.

This is not the first time Vince & Associates has worked with the U.S. Government on clinical research trials. In 2012, Vince & Associates was awarded a [five year, \\$10 million contract with the National Institute on Drug Abuse](#) as well as a separate [five year, \\$5 million contract with the FDA](#).

The project described in this press release was supported by FDA-RFP-1155964. The content above is solely the responsibility of the authors and does not necessarily represent the official views of the FDA.

About Vince & Associates Clinical Research

[Vince & Associates Clinical Research](#) has provided clinical research services to the biopharmaceutical industry for 15 years. The research professionals at Vince & Associates are proud to be recognized in the industry as a “Center of Research Excellence.”

Vince & Associates currently operates a state-of-the-art, multimillion-dollar, 100-bed clinical pharmacology unit that combines the ultimate in subject safety and luxury. This early development unit has the upscale atmosphere necessary for the recruitment and retention of study volunteers in both short- and long-term clinical trials. From the safety and security of the controlled access unit to the added features of a movie theater and game rooms, no detail has been overlooked.

About Altasciences

[Altasciences](#) is the parent company of wholly-owned subsidiaries Vince & Associates Clinical Research (Kansas, USA), [Algorithme Pharma](#) (Quebec, Canada) and Algorithme Pharma USA (North Dakota, USA). All three organizations provide comprehensive early stage clinical services in Phase I/IIa, including the necessary support services in this critical stage of drug development.

More Information

Additional background materials pertaining to Vince & Associates Clinical Research are located on the corporate website at www.vinceandassociates.com.

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