



Pinnacle 21 Awarded FDA Contract for 5 Years for Software and Services

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Pinnacle 21 Enterprise software expedites regulatory review of all study submission data

PRINCETON, N.J., Oct. 28, 2021 (GLOBE NEWSWIRE) -- Certara, Inc. (Nasdaq: CERT), a global leader in biosimulation, today announced that the U.S. Food and Drug Administration (FDA) has awarded a five-year contract with Pinnacle 21 for ongoing software and related services support for the agency's DataFit program. The DataFit program assesses data quality and performs data validation for standards compliance of all electronic clinical and non-clinical trial study submission data. This agreement is similar to the contracts awarded to Pinnacle 21 in 2015 and 2011 by the FDA. Pinnacle 21 was acquired by Certara in October 2021.

"We are honored by the FDA's continued support of our Pinnacle 21 Enterprise software and partnership," said William F. Feehery, PhD., CEO of Certara. "We are dedicated to making the drug development and submission process more efficient and user-friendly for regulatory agencies and biopharmaceutical companies, helping to get crucial new therapies to patients sooner."

The DataFit custom implementation of Pinnacle 21 Enterprise meets the FDA's data fitness assessment needs. The Pinnacle 21 Enterprise software enables the FDA to perform large-scale data validation and data quality reporting. FDA reviewers can assess and understand the quality of incoming submission data at a summary level in hours instead of the days or weeks required in a manual review.

"Regulatory agencies are embracing change and innovation to streamline the submission process. As the compliance standards are not easy to navigate, our software helps to automate validation and identify issues," said Max Kanevsky, chief technology officer of Certara's Software business unit. "Furthermore, beginning last month, the FDA is enforcing the [technical rejection criteria](#), which are applicable to submissions to the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research."

The contract includes the use of the Pinnacle 21 Enterprise software by the FDA to perform data validation for its DataFit program as well as Operations and Maintenance through IT professional services to the FDA.

About Certara

Certara accelerates medicines using proprietary biosimulation software and technology to transform traditional drug discovery and development. Its clients include more than 1,650 global biopharmaceutical companies, leading academic institutions, and key regulatory agencies across 61 countries.

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