



Certara Announces Release of Pinnacle 21 Enterprise Software

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New metrics and analytics capabilities enable informed decision making for biopharmaceutical clients

PRINCETON, N.J., Dec. 13, 2021 (GLOBE NEWSWIRE) -- Certara, Inc. (Nasdaq: CERT), a global leader in biosimulation, today announced the feature release of Pinnacle 21 Enterprise 5.1.0, which updates the Company's flagship software for preparing clinical trial data for biosimulation and regulatory submission.

"With today's announcement, we are just beginning to realize the compelling opportunities made possible when we welcomed Pinnacle 21 to Certara in October of this year," said William F. Feehery, Ph.D., CEO of Certara. "The release of Pinnacle 21 Enterprise 5.1.0 offers immense value to experts in biostatistics and biometrics, and clinical and statistical programming. We continue to be committed to expanding the quantitative analytics our clients need to achieve clinical and regulatory success and ultimately get critical therapies to patients."

Pinnacle 21 Enterprise validates data quality and compliance with Clinical Data Interchange Standards Consortium (CDISC) standards, enabling a clean data pipeline from worldwide sponsors to health authorities. Pinnacle 21 Enterprise customers include 22 of the top 25 biopharmaceutical companies by R&D spend, as well as the US FDA and Japan's Pharmaceutical and Medical Devices Agency.

"Continued standardization within the CDISC domain is essential to improve decision making in clinical trial and regulatory submission processes around the world," said Daniel R. Matlis, founder and president of Axendia, a leading life science industry analyst firm. "Robust engagement across the biopharmaceutical industry, regulators and standards organizations supports the availability of software, like Pinnacle 21 Enterprise, that optimizes regulatory review and approval cycles to accelerate time to market of medical products that improve patient outcomes."

Pinnacle 21 Enterprise 5.1.0 includes new and advanced capabilities, such as:

- Support for recently released Define-XML 2.1 standard
- New analytics module for portfolio-wide summary statistics and insights, highlighting performance by asset or therapeutic area and identifying frequent unresolved validation issues
- Automation and intuitive capabilities with auto set-up of latest dictionaries, alignment of upload sources over time, simplified roles and assignments, and bulk-actions for user management and company-specific settings

"I am proud of our team for delivering this feature-rich release, all while conducting integration activities," said Max Kanevsky, chief technology officer of Certara Software and founder of Pinnacle 21. "The Define-XML 2.1 standard brings conformance challenges, and we're glad to be proactively supporting the new standard. Thanks to our combined software portfolio and resources, delivering great products is more than ever a part of our DNA."

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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