



## **Certara Launches New Synchrogenix™ Writer Software to Accelerate the Regulatory Submission Process**

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**Cloud-based and validated regulatory software automates and advances quality of patient narratives**

PRINCETON, N.J., Sept. 30, 2021 (GLOBE NEWSWIRE) -- Certara, a global leader in biosimulation, today announced the launch of Synchrogenix™ Writer, a new regulatory SaaS product that expedites the authoring and review of patient narratives. Patient narratives describe adverse events or adverse drug reactions and are critical to clinical study reporting across every therapeutic area throughout the clinical phases.

"In today's automated and standards driven clinical and regulatory processes, authoring patient narratives remains primarily a manual process," said Daniel R. Matlis, Founder and President of Axendia, a leading life science industry analyst firm. "As the number of clinical trials increases globally, this approach is not sustainable. The availability of a product like Synchrogenix Writer provides life science organizations a solution to help automate the writing process, shortening the time to regulatory filing."

The traditional, manual narrative writing process is time consuming and costly due to integration of information from various sources, large authoring teams, and multiple rounds of drafts and reviews. Spearheaded by Certara's regulatory writing experts, Synchrogenix Writer software automates data-mapping and enables earlier drafting before database lock, resulting in increased consistency, reduced risk and expedited time to regulatory filing.

"Managing patient narrative projects with tight timelines is challenging, especially given the complexities that go into preparing important clinical documents to meet regulatory requirements," said Leif E. Pedersen, President of Software at Certara. "With Synchrogenix Writer, organizations can manage thousands of patient narratives in a fraction of the time while ensuring quality, consistency and compliance."

Certara's Regulatory Science team has leveraged Synchrogenix Writer to deliver more than 10,000 patient narratives, through technology-driven services for the life science industry. The team provided expert insight during the product development process to ensure that the software meets high quality standards and evolving global regulatory requirements.

For more information on Synchrogenix Writer, please visit <https://www.certara.com/synchrogenix-writer>.

### **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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