CERTARA®

BACKGROUND

In 2019, Prelude Therapeutics, a small cancer drug discovery company, implemented Certara's GlobalSubmit solution for their electronic common technical document (eCTD) submissions. The regulatory team at Prelude Therapeutics is very lean and responsible for more than 30 submissions annually; therefore, the utmost efficiency in publishing, checking the validation criteria, and reviewing eCTDs is required. The company found that their eCTD publishing process was not agile enough to meet their needs and provided limited review capabilities, resulting in the decision to bring on GlobalSubmit to meet their publishing and submission requirements.

CHALLENGE

Following the initial in-depth training provided by Certara, user acceptance testing (UAT) and validation, the system was implemented into the regular review process. Hyperlinks and bookmarks are seamlessly created, and quality check (QC) is performed quickly and efficiently using the LINK and CROSSCHECK functionality in GlobalSubmit. With VALIDATION, more than 200 error conditions are checked, including more than 40 PDF checks. As a result, the QC process for each submission has been reduced from hours to minutes, saving the team considerable resources.

SOLUTION

The team uses REVIEW to ensure their submissions are properly formatted and that no technical errors remain in the submission, thus eliminating the risk of technical rejection. WEBREVIEW is useful for their stakeholders needing to examine and approve specific submission content. The team appreciates that they can review the backbone of the submission, not just the folder structure, and that updates to eCTD requirements are automatically applied to the software and checked in real-time with live validation, eliminating the inefficiencies of finding technical issues when generating the backbone at the end of the process.

> *"For a small team that has limited time to compile and double check a submission, GlobalSubmit is a really good tool because it is all integrated, including CROSSCHECK and VALIDATION. So, you know when you generate the submission that it is compliant, and you don't need another tool for validation."*
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> *– Jessica Pung, MS, RAC*
> *Associate Director,*
> *Regulatory Operations*
> *Prelude Therapeutics*

About Prelude Therapeutics

Prelude is a clinical-stage biopharmaceutical company designing and developing a pipeline of novel, orally bioavailable, small molecule therapies that target key drivers of cancer cell growth, survival and resistance. For more information, visit www.preludetx.com.

Prelude THERAPEUTICS

About Certara

Certara optimizes R&D productivity, commercial value and patient outcomes through its unique portfolio of model-informed drug development, regulatory science, and market access solutions. In fact, 90+% of all novel drugs approved by the US FDA in the past six years were supported by Certara software or services. Its clients include 1,600 global biopharmaceutical companies, leading academic institutions, and key regulatory agencies across 60 countries. For more information, visit www.certara.com.