Voice of the Customer

Chinese CRO, Zhejiang Longcharm Biomedical Technology, Optimizes Sponsors' Non-clinical & Clinical Regulatory Review Processes with Pinnacle 21 Enterprise

Founded in 2016, Zhejiang Longcharm Biomedicine Technology Co., Ltd. provides one-stop R&D outsourcing services for the Chinese pharmaceutical industry. They can support BA/BE/PK clinical testing and data analysis services that comply with Chinese and American regulatory requirements for both novel and generic drug development programs.

In 2023 July, Zhejiang Longcharm Bio-medical Technology Co., Ltd (Longcharm Bio), a well-known contract research organization (CRO) in China, decided to implement Pinnacle 21 Enterprise to optimize and streamline the internal regulatory review system. Pinnacle 21 Enterprise helps Longcharm Bio to qualify validation data and comply with CDISC standards, providing a high-quality, effective data pipeline from sponsors to regulatory agencies. Improving the efficiency of regulatory document review will also help Longcharm Bio accelerate new product launches.

We interviewed Liming Fang, Deputy General Manager, Longcharm Bio and Philip Johnston, Director of Product at Certara to learn more.

What challenges were you looking to solve within your organization or workflow?

Liming: Our clients were spending too much time on manual data review, and we wanted to be able to strengthen our relationships and build trust with them by providing the best quality service possible. We needed a tool where we could work collaboratively and communicate with customers to review and resolve any issues, something we and they could access from anywhere, without relying on emails and spreadsheets to exchange versions of important documents like define.xml.

P21 Enterprise gave us a way to create efficiency, save time, and improve our communication.

Why did you choose Pinnacle 21 Enterprise?

Liming: Pinnacle 21 Enterprise helps us review the research data from the perspective of regulatory agency review teams. We see what they see – and more – and that helps reduce the risk of technical data rejection. It also gives us the ability to automatically generate define.xml and Reviewers Guide files, reducing our time and labor costs.

Overall, we have seen an improvement in our organization's data quality, and P21E's visual analytics tools keep everyone informed on a projects' delivery status.

What are the biggest benefits of Pinnacle 21 Enterprise for your sponsor clients?

Liming: In non-clinical and clinical research, trial data holds great significance as it is vital information submitted by sponsors to regulatory agencies. The pharmaceutical industry's need for a unified data submission format is clear, whether it is through the mandatory application of the CDISC standard globally or its encouraged use domestically.

Adopting a standardized format streamlines a complex process, fostering efficiency and improving data quality, reducing costs, and ultimately benefiting patients by getting them new medicines faster. Working in a tool like P21 Enterprise has helped us meet the needs of our clients faster, and they can be confident that the data we provide is in a standardized format they can use to drive decisions right away.

Was there anything notable about the deployment and training in your use of P21?

Liming: The onboarding and user training by Certara professionals was highly professional and very thorough. The P21 team guided us through all the setup, deployment, and conducted the training our team needed to get started, and even helped us set up Single Sign-on with our internal system. We were able to learn all the major functions of P21 through the online training videos and articles, and now we're confident in our ability to successfully use this tool.

How do you utilize Pinnacle 21 Enterprise when you support sponsors for their regulatory submission? Is there any feedback from your clients after you implemented Pinnacle 21 Enterprise?

Liming: At present, we mainly use P21E for creating define.XML for UTF-8 type data, generating SDRG (The Study Data Reviewer's Guide) and ADRG (The Analysis Data Review's Guide), as well as validation and FDA declaration for BE projects. However, we are very interested in P21E's integration with Formedix's ryze software to begin validating at the spec creation level, even before data collection begins.

Our decision to use P21E was well received by our customers. They now have more confidence in the quality of our service and data, and since many of them use P21E already, it makes the data delivery process seamless.

What are some of the major benefits working in P21E brings to your team?

Liming: As a CRO partner, we work with multiple sponsors, each with their own preferred methods, formats, issue explanation verbiage, and internal business rules. P21E aids us in context-switching from project to project. A programmer can jump in and pick up where the previous team left off. As living, centralized documentation, it keeps Issue status and task ownership 100% transparent, and makes manual versioning a thing of the past.

We maintain our own environment even when working with sponsors who don't use P21E because we feel much more confident in the quality of what we deliver, and our clients benefit from an accelerated timeline. That said, having access to each sponsor's platform increases our productivity and reduces errors. It helps us establish trust, improve communication, and deliver on commitments promised in Data Transfer Guidelines.

PJ, can you take us through the logistics of CROs and sponsors working together in P21E? For example, whose environment do they use, how do they obtain logins, etc.?

PJ: Sponsor and vendor (CROs, FSPs, etc.) collaboration is increasing as a way to get medicines submitted to agencies and in front of patients faster. There are a number of ways for Sponsors and CROs to collaborate in P21 Enterprise.

The best and most efficient option is for the sponsor to add CRO users to the sponsor's P21E environment to work on specific Projects, Studies, and Data Packages together there. Sponsors are ultimately responsible for ensuring that the final data from CRO partners are clean, i.e., either all Issues are fixed, or each unresolved Issue has a reasonable Explanation for reviewers. Saving everything in the cloud now is an insurance policy against loss of knowledge due to personnel or business changes down the road, especially if questions arise about your data years later once it has been submitted for regulatory review.

P21E's Issue Management module serves as a cloud-based workbench for fixing or explaining noncompliant data. It puts teamwork in one spot, never in a lost email attachment and is your single source of truth for tracking progress, routing communications, delegating tasks, and maintaining oversight. This sharing enables higher quality outputs and maintains a knowledge base that's both living and historical—a stable archive that prevents loss of information during the handoffs.

So, we actively encourage sponsors to share access to their P21 Enterprise environment with their CRO partners. Note that the reverse, sharing access from CRO partners to sponsors, is not permitted under the terms of our service agreement.

Some sponsors, however, prefer that CROs have a separate P21E environment, and sponsor and CRO users do not enter each other's environments. Instead, CRO users work on a Study in their CRO P21E environment, then manually transfer datasets, Validation Report XLSX, define.xml etc. to the Sponsor via sFTP, etc.—outside of P21E.

The sponsor users then revalidate that delivery in the sponsor's P21E environment as part of their QA process. With all parties on P21 Enterprise, everyone uses the same Validator, which eliminates divergent results requiring manual reconciliation. In this case, when the sponsor chooses to not do "environment share," we have options for doing "license share" to enable multiple parties to work in multiple environments on one study in a cost-effective and organized way.

Liming mentioned the integration of ryze with P21Enterprise. How does this new partnership with ryze expand the features available to P21E customers?

PJ: Certara's acquisition of Formedix, together with new P21 products and enhancements from the last year, add several new features for greater control, quality, and time savings to your data management workbench. The union of our two industry-leading applications is a major step towards the long-sought industry goal of end-to-end clinical trial optimization, from study design to submission.

Study teams previously waited until the end of a trial to validate and address issues in the data, and issue management looked more like a fire drill than a strategic approach. P21's validation tools created a way to move validation further upstream so teams could validate and address data issues throughout the study, ensuring that data conforms to more standard metadata earlier.

With the addition of Formedix and P21's new Data Exchange module, validation will begin even earlier, executing rules and checks even for non-CDISC datasets, which then simplifies the mapping of those datasets to SDTM and prevents any unwelcome surprises later in the study. It's best for SDTM datasets to be validated "in stream," even when the datasets are in a partial state. Then, as the study matures, formal validations present a holistic Data Fitness Score and enable final checks needed for submission preparation.

It looks like P21E and ryze will be a partnership that brings Data Management and Biostats together to collaborate on EDC structure and data in the same application early in the workflow, but what can you suggest for organizations with large amounts of non-CRF data?

PJ: The rapidly growing trend of data collection from sources outside the traditional CRF – nearly 70% of all data collected now - is starting to have a significant impact on the time between study close and submission readiness. This is further complicated by having to support data extracted from multiple EDC systems, all with different structure and format requirements, while trying to align data collection formats with SDTM requirements.

And let's face it – all the manual work involved in getting data from all these external non-CRF sources can mean costly delays for the sponsor. Delays in submission, delays in approval, Delays in getting life-changing products to market – all at an estimated cost of $765k per day of delay. Each extra week can cost a sponsor over $5 million. Imagine cutting weeks, or even months, from your end-of-study timeline just by being able to standardize, ingest, and validate data from the very beginning of a study instead of discovering a mass of issues as your submission deadline approaches.

So, in early 2022, P21 debuted an advanced tier module, Data Exchange, designed to bring in non-traditional data from external vendors, establish a central location for data transfer specifications, and standardize external vendor data collected outside of CRF. This module was piloted by a top 10 pharma, who was bringing in 90% of their data from external data sources and reported they were able to automate this process to validate and manage 75% of their data issues simply through use of the combined power of P21's Enterprise and Data Exchange features.

How confident can P21E clients be that agency reviewers see the same results during the review process as the sponsors found prior to submission?

PJ: Pinnacle 21 Enterprise is always up to date with current regulatory agency engines and augments them with a comprehensive P21 engine that combines all rules from major agencies and several more. That way, you can be sure that, regardless of the agency to whom you're submitting, you've performed every check imaginable that could be required – and then checked some more – when it is time for data to be submitted to a specific regulator.

In addition, several major agencies, including the FDA, use their own instances of P21E to perform checks during the review process. This means they see what you saw as datasets are prepared for submission.