Internationalization of Innovative Pharmaceutical Companies Series – How to Manage International Project Trial Master Files (TMF)?

About Guangzhou Lupeng

Guangzhou Lupeng Pharmaceutical Co., Ltd. (hereinafter referred to as "Lupeng")was founded in 2018 by Dr. Fanlai Tan (a Thousand Talents Program expert) and Dr. Yi Chen. The company mainly studies the design and development of new small molecule anti-tumor drugs, with a focus on the most difficult targets. The company is headquartered in Guangzhou and also has an R&D base in Silicon Valley, USA. Following a 170 million RMB Series A+ round of financing led by Lilly Asia Ventures in 2020, LuPeng raised 35 million USD in the Pre-B round of financing in July 2021 to further develop LP-108 (selective BCL-2 inhibitor) and multiple follow-on studies.

Lupeng Pharmaceutical

- International innovative drug development companies
- Multi-site team in China/USA/Europe
- International Multi-site Clinical Study Management
- Core field: anti-tumor

Challenges

How to achieve standardized management of international clinical study TMF?

After the new round of financing, LuPeng continues to invest in internationalization, which is why the number of international clinical trials has increased, with core studies all over the world and multi-site trials conducted in the US, Europe and China. However, as a young innovative drug company, invisible barriers such as cross-country, cross-time zone, cross-language, and cross-custom make it difficult to conduct trials. The international multi-site study environment, the thousands of files involved in the trial process, the different compliance requirements of different countries, the staff management and collaboration barriers across countries and time zones, are undoubtedly the most urgent difficulties for a young innovative drug company to solve. Therefore, whether a suitable clinical research eTMF software can be found and used comprehensively is the key to solving the clinical trial file management problems of Lupeng.

Solutions

TMF file collaboration management solution based on eArchives ®

Taimei team developed the file collaboration management solution based on the "eArchives ®" and conducted a detailed presentation and system demonstration for the Newave team, the U.S. clinical trial implementation company of Lupeng. After repeated evaluation and testing, Lupeng and Taimei formally signed a contract and confirmed the partnership.

After confirming the collaboration, Taimei and Lupeng team determined 4 core goals and requirements for the eTMF solution.

- The system must support FDA reporting program for both China and the U.S.
- Functions must meet the needs of domestic and international teams
- Study outsourcing file management must be convenient and standardized
- The system must support the stable transmission of international multi-sites files

> *I have cooperated with Tai Mei back in 2016 when I was in Betta Pharmaceuticals, and the experience of Taimei's system has always been excellent in terms of interface and functions. Before the supplier was formally determined this time, we consulted with friends and CROs, and surprisingly, the recommended feedback was all from Taimei. Based on the trust of historical cooperation and the recognition of the industry, the cooperation between the two sides also came to fruition in only several communication meetings.*

*-- **Qin Xiong**, Associate Director, Guangzhou Lupeng Medical Department*

Taimei
太美医疗科技

Solution Implementation

Project Management: Development of Global TMF Digital Management Implementation Plan

In the early stage of the project, Taimei formed a team of business experts to communicate with Newave in depth and helped the Newave team sort out TMF management challenges and determine the solution implementation plan.

System Building: Establishment of TMF Global Management System

In response to the issues of multinational sites and diverse regulations, Taimei business experts helped the Newave team build a TMF management system that complies with DIA Reference Model 3.1, adapted it to multiple standards of international compliance, and helped make file structure clear.

To promote collaboration, on the basis of the standard version of eArchives®, Taimei customized the international industry standard template; customized the file naming regulations to distinguish the file language of different countries; arranged overseas accelerators to ensure the smoothness and stability of file management and personnel collaboration in the U.S., Europe and China, which can well solve a series of issues such as easy loss of files and confusion of versions, etc.

Rapid implementation: eArchives® Launched on Schedule in 45 Days

In order to meet the project schedule and operational requirements, Taimei business experts accelerated the customization development and system implementation of eArchives®, completing all the preparation work including administrator environment building, customization development and configuration, UAT testing, pre-launch training and official launch in only 45 days.

Customer Success: Professional After-Sales Continues to Increase the Value of eArchives ®

After the official launch of eArchives® , Taimei business experts assisted administrators in quickly completing the registration of new user invitations and access settings, adding and setting up new site and study processes, consolidating the system foundation, and ensuring the efficient development of clinical trials. For new requirements, Taimei business experts quickly responded to the development and implementation of customized solutions, such as file expiration date reminders.

Assist innovative drug companies to achieve the internationalization strategy

Enabling digital files management at all times

The file collaboration management solution based on "eArchives®" , with standardized configuration + customized development, meets the standardized file management and collaboration needs of international multi-site trials from compliance, completeness, timeliness, confidentiality, and completes the entire digital management of files generation, collection, approval and quality control, which helps the company to carry out international clinical trial projects smoothly.

Enabling efficient file collaboration management

The system is designed to be "convenient and friendly", which is the most intuitive feeling of the clinical trial team. Within a month of the system going live, the number of files uploaded was 1000+ and the team usage rate was 80-90%. It has significantly improved the efficiency of Newave team's file management in international multi-sites projects by 40-60%.

Establishment of an international file management system and smooth operation of the projects

In response to the actual situation that Newave team has multiple sites in multiple countries, Taimei Medical Technology had a professional internationalization team to develop a plan to establish a clear and standardized enterprise file management template (DIA eTMF RM V3.1, ICH-GCP required files, 2020 GCP) to ensure a clear structure of file management at home and abroad, complete and compliant files, and easily cope with audits, which also facilitates the company's subsequent internationalization projects.

	Project Manager	TMF Manager
Interface	4	5
System Functions	4	5
Network Speed	4	5
Guide Documents	4	5
User Training	4	5
Overall	**Slightly** exceeds expectations	**Greatly** exceeds expectations

▪ Client satisfaction feedback

> *Taimei's system solves most problems in our TMF management, and Taimei's service team saves us a lot of time in building up the TMF structures and indexes. The interface is user-friendly and intuitive, and the service team supports us in a flexible and efficient manner, which enhances the coordination of our team members.*

——***Ann G. Vollmer*** , *Senior Clinical Trial Manager*