

Quick Configuration Modification: How does TaiMei CTMS help company quickly update SOP?

About Lepu Biopharma

Lepu Biopharma Co., Ltd. is an innovative biopharmaceutical company with a global focus on oncology therapeutics based in China. It has developed a strong pipeline of oncology drug candidates, including clinical and preclinical ADCs, oncolytic virus drugs and immunotherapies. Through the three rounds model of "independent R&D + strategic cooperation + investment and Merger", LP Bio has built a series of differentiated pipeline platforms, with its strengths in ADC, which is the first tier in China.

Challenges

How to solve the problem of SOP system establishment and update in enterprise management and project execution?

In terms of Enterprise Management:

1. Sloppy enterprise management: lack of a solid systematic process and management framework, non-standard management system, SOP formulation may deviate from the actual situation of the company.
2. SOP processes unclear: there are situations not in line with current industry standards, in considering whether the development of SOPs meets the actual situation of the company.
3. SOP diversity: due to outsourcing different CRO companies, most SOPs used are from CRO companies, no internal accumulation of standard SOP; and commissioning studies to a third party is not reliable. Without certain management tools, it is difficult to be informed that the commissioned parties implement in accordance with the standards; have difficulty managing studies.
4. Multiple teams: nearly 300+ people in Lepu Beijing team, Miracogen team, US team, expert team, and CRO team; mixed experience of internal/external personnel, high cost of personnel training; high mobility of personnel, easy loopholes in the management process, affecting study quality.

In terms of Study Implementation:

1. The system is easy to establish but difficult to implement, with limited acceptance of systematization due to the different professional abilities and work experiences of personnel.
2. SOPs do not run smoothly and need to be revised repeatedly during implementation, and the process is lengthy.
3. SOPs updates are frequent and difficult; GCP is not followed and the quality is low;
4. Although the enterprise SOP system is huge and complex, some SOP files are merged, overlapped, and fuzzy. Some content is difficult to search, some folders include too much content, and some departments have different systems with ambiguous content boundaries.

Client Expectations

- Hope Taimei help achieve enterprise informatization and systematic management
- Through a self-built system, master study outsourcing data and develop control of data accumulation
- Solve SOP uneven management problems through the system, improve standardization performance, improve the enterprise SOP management library, and reduce personnel training costs



Lepu Biopharma

- New Pharmaceutical Company
CRO Outsourcing
Close cooperation with 112+ sites
- Product Area: Product pipeline of oncology drug candidates, including ADCs, oncolytic virus drugs, and immunotherapies.
- Cooperation Projects: CTMS, eTMF
- Cooperation time: 2021.03–2023.03
- Current Online Projects: CTMS: 17, eTMF: 34
- User Counts: CTMS: 280+, eTMF: 340+

Solutions

Taimei provides study operation management solutions based on eCooperate[®]

Professional system consulting services to organize the workflow system

1. We can help enterprises collect and organize the key information in the early stage of SOP update such as MVR templates, PD classified dictionary, visit issue classified dictionary, and approval workflow; Taimei can customize the modules as follows: site feasibility, site screening, site initiation preparation list, visit initiation, visit routine, visit closure, confirmation letter, follow-up letter, PD report, study communication report, study handover report, site communication report, site handover report, PD list, etc.

2. We can provide professional consulting advice to help clients establish management systems and provide rational modifications to the MVR collection, such as common issues, PD classified dictionary, and unified classification which help form subsequent horizontal comparisons of PD/issue report statistics for all company projects.

3. We can provide reasonable suggestions on task warning and reminder, and establish standard reminder rules and warning mechanisms at the enterprise level, such as the time limit settings of visit reports from submission to approval, and the time limit setting of issue processing.

SOP system construction in CTMS system

1. Various SOP template libraries can be established in CTMS to form a library of enterprise SOP templates; when a new SOP is needed, you may just complete the configuration of data fields, forms, dictionaries, etc. in the CTMS system and apply it to the study with one click, and the SOP can be used immediately or any time you want.

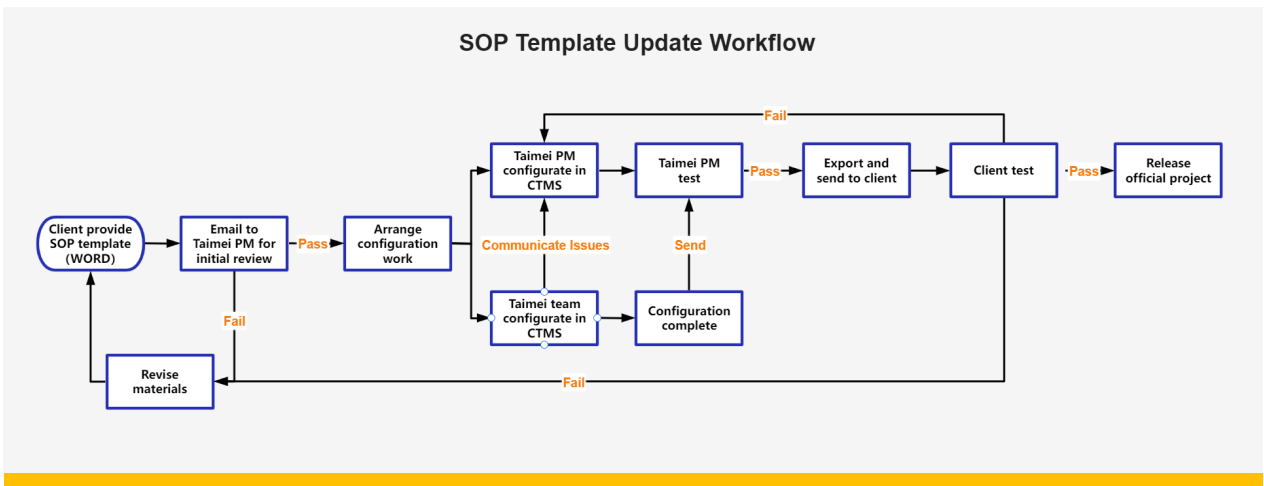
2. CTMS supports the establishment of a standardized auditing workflow, which can be applied to each study with one click, and the processes can also be customized study-by-study to better suit actual business scenarios of studies and outsourcing.

3. CTMS supports setting task warnings and reminders by SOP, task timing/real-time reminders, and automatic calculation of CRA's KPI by AI to ensure the timeliness and timeliness of task completion.

SOP system maintenance and update

1. CTMS supports SOP template update and the quick revision of form, processes, and dictionary to achieve quick SOP revision.

2. CTMS supports SOP template update, one click to switch to the latest version, worry-free switching; fast and high-quality delivery to the sponsors enhances the core competitiveness of Lepu.



Solve SOP system establishment and update issues, help standardize the workflow

The Challenge	Solutions	Effects
<ul style="list-style-type: none"> Support establishing various SOP template libraries in CTMS to form a library of enterprise SOP templates; when a new SOP is needed, the client should just complete the configuration of data fields, forms, dictionaries, etc. in the CTMS system and apply it to the study with one click, and the SOP can be used immediately or any time later; for example, MVR, Communication reports, etc. Support SOP template update, quick revision of form and dictionary 	<ul style="list-style-type: none"> Configure MVR templates within 1 day Create/update a new version of MVR Upload a word file of the new template Complete field and dictionary mapping Test template validation Launch a new version of MVR template within one click Validate right away/as scheduled 	<ul style="list-style-type: none"> Manage SOPs of CRO and establish a library of enterprise SOP templates according to the enterprise situation. Accurate and fast match report templates according to third-party SOPs, effortless office work, AI intelligent capture related information, reduce duplicate work and improve work efficiency Quickly revise forms and dictionaries, with support for customization to better adapt to business. Validate within one click to guarantee the new SOP version to run timely.
<ul style="list-style-type: none"> Support the establishment of standardized online workflow, and customization study-by-study to better suit actual business scenarios of studies and outsourcing 	<ul style="list-style-type: none"> Update the MVR review workflow within 10 minutes Update or create a new MVR audit workflow Validate execution processes Release workflow 	<ul style="list-style-type: none"> Set up the approval workflow within one click according to the enterprise situation. Customize online workflow based on third-party business workflow for quick release and application.
<ul style="list-style-type: none"> Support setting task alerts and reminders according to SOP 	<ul style="list-style-type: none"> Update reminder settings and date intervals within 5 minutes Update or create new reminder settings Save and release settings 	<ul style="list-style-type: none"> Quickly set the file alert length according to KPI requirements to ensure the timeliness of MVR and other submissions/reviews. Timely and diverse task reminders to ensure task processing is on time.

“ Taimei’ s CTMS and eTMF products are highly professional and fit the sponsor’ s needs for unified management of clinical trial studies and files. They regulate the operations of multiple CROs using SOPs, retain data to help statistical analysis and registration, and improve management efficiency and effectiveness.

The project manager and business consultant, Tingting Yao, actively participated in the whole project, wrote SOPs and file templates, and assisted in process importing and dissemination, and made great contributions to the management improvement of Lepu Biopharma.