

Fast and efficient 1-week integration of Taimei RTSM and Medidata Rave EDC

Helping Global Trials Run Smoothly

About Clover Biopharmaceuticals

Founded in 2007, Clover Biopharmaceuticals, Inc. is a global clinical-stage biotechnology company dedicated to developing novel vaccines and biologic therapies to address the world's most life-threatening diseases and public health threats. The company develops innovative vaccines and modern biopharmaceuticals based on the Trimer-Tag™ technology platform. With the Trimer-Tag™ technology platform, Clover has become a COVID-19 vaccine developer and is expected to be one of the first companies in the world to commercialize a recombinant protein COVID vaccine through the COVAX mechanism.

Globally, Trimer-Tag™ is the only trimerization technology platform for designing and producing recombinant, covalently-linked, and trimeric fusion proteins (trimer-tagged proteins) utilizing a human-derived trimerization tag. The trimer-tagged proteins produced by the Trimer-Tag™ technology platform have favorable safety profiles and high potency against trimerization-dependent disease targets. The company has built its product pipeline by employing the Trimer-Tag™ technology platform and leveraging its in-house biologics manufacturing infrastructure and capabilities.

Challenges

It usually takes about 1 month to build a randomization system for a trial, and even more time to meet the integration requirements of external EDC systems; moreover, global trials have other challenges such as system language, risk control, and customer service. The main goal of the Clover Biopharmaceuticals team was to implement a randomization system for global trials that could be quickly set up and easily integrated with an external EDC to ensure fast implementation and minimal disruption to everyday operations.

Solution: Randomization using Taimei Technology RTSM (eBalance) and integration with Medidata Rave

Collection of customer requirements through effective communication:

Through efficient communication with the Clover Biopharmaceuticals team, Taimei Technology summarized the essential information for the randomization system setup according to the trial protocol and customer requirements and completed the RTSM system build accordingly.

Fast and Convenient Database Construction: more than 90% of the database modules could be constructed by ticking boxes, with no additional development needed.

Customized System and Training: precise and tailored RTSM system training according to the clinical trial configuration to ensure users can quickly master the system functions.

Fast and accurate integration with external EDCs: Taimei Technology technical team was able to transfer data between Taimei Technology RTSM (eBalance) and Medidata Rave system efficiently, allowing for complete and error-free data synchronization between the two systems.

Customer Success Story Clover Biopharmaceuticals

*Trial randomization using
Taimei Technology RTSM (eBalance) and
successful integration with Medidata Rave*



Clover Biopharmaceuticals

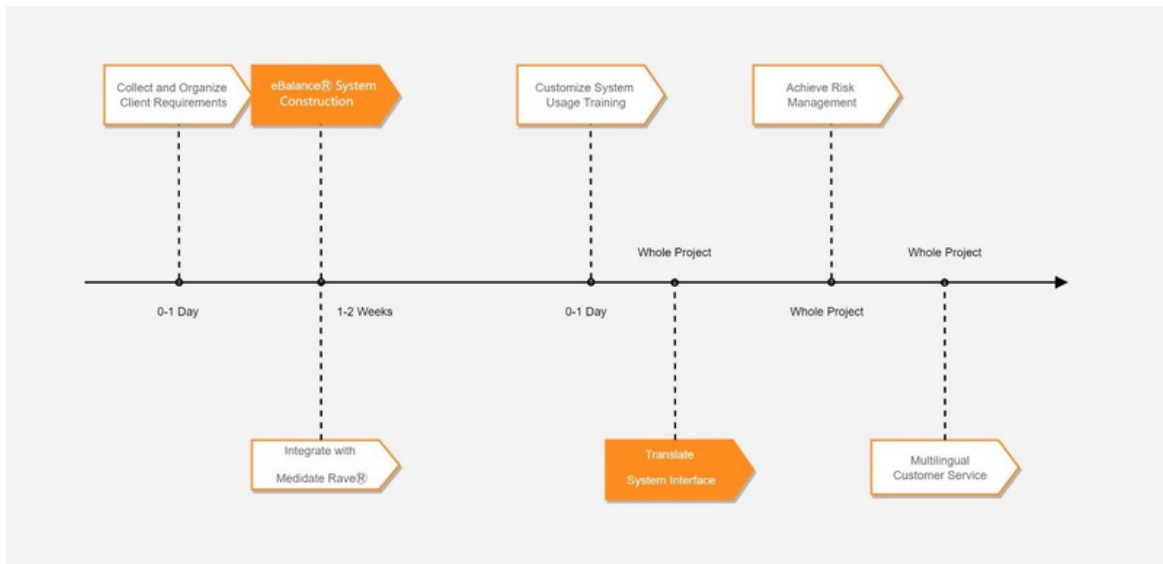
- Novel Vaccines and Biotherapeutics
- Trimer-Tag™ Technology Platform
- Global Business

Taimei Technology

Bilingual System: Taimei Technology RTSM (eBalance) can be used in English and Chinese. The system is built with global studies in mind and is fully functional in those two languages.

Risk Control: When collecting user requirements, Taimei Technology efficiently communicated with the customer to capture the operational requirements and workflow of the study. Through clear communication, alignment on the output, and specific needs, Taimei built the right interface to meet the requirements for the clinical study and trial team, minimizing future risks.

International Customer Service: Taimei's customer success team provided timely responses to the queries received, and provided quick feedback and solutions to the questions from the users, ensuring a smooth execution of global trials.



Rapid integration with external EDC systems to help global clinical trials run smoothly

- **1 week to deliver:** As a result of the joint efforts of Taimei's randomization and technical teams, the RTSM (eBalance) solution only took one week to be set up, go live, and integrate with the Rave EDC system.
- **Trial efficiencies:** The integration with Medidata's Rave system helped to avoid data migration and duplicate entries, improve the efficiency of database creation, avoid potential data migration losses and errors, and reduce clinical data teams' workload.
- **Continued support:** Taimei's customer success team provided comprehensive customer support to users in several locations to effectively reduce potential risks during the execution of the trial.

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*Taimei Technology delivered a randomization solution and integration in less than a week.
Truly amazing job and team! Really proud to contribute as best as I can to this team.*

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Eric Plennevaux, Head of International Operations, Clover Biopharmaceuticals