SimpleTrials

BIOMAPAS
Clinical, Regulatory & Pharmacovigilance

CASE STUDY: Biomapas CRO utilizes SimpleTrials CTMS to Support each Sponsor's Unique Study Needs

Case Study: SimpleTrials CTMS selection and adoption by Biomapas, an international CRO with varied client projects and study needs which require global tracking and oversight of study startup activities, subject recruitment and participation, and monitoring visit activities.

Biomapas is a clinical, regulatory and pharmacovigilance solution provider to the global life science industry. With team members in over 60 countries and clients performing clinical research in diverse scientific areas, Biomapas was seeking to adopt a flexible, innovative and full-featured CTMS to facilitate study management and oversight. Selecting a fully validated CTMS, supported by an experienced team, were fundamental elements to effectively support the Biomapas clinical monitoring and project management elements for their client projects.

Included among the CTMS requirements:

- Built-in **site startup** tracking features with flexibly to efficiently manage activities from confidentiality agreement through subject enrollment by site.
- Straightforward **screening and enrollment** record tracking with **integrated metrics** to facilitate study recruitment progress and subject participation milestones.
- In-app availability for **data imports** of key items such as study sites and contacts, monitor action items, and subject screening, enrollment and visit records.
- Easy to use calendar for company activities and **site monitoring visits** for Sponsored study activities.
- In-app ability to build custom site **visit report templates** and directly manage associations to individual studies for immediate team member use.
- Ability to author and approve 21 CFR Part 11 compliant **electronic visit reports** with attachments, integration to eTMF and workflow alerts.
- Full-featured **study milestone** tracking including chart **visualizations and data exports**.
- Ability to **quickly implement** across different project teams and types of studies.

Finally, the CTMS needed to be flexible enough for future business uses within the Biomapas organization.

"Biomapas greatly appreciates the time and care the SimpleTrials team has dedicated to building an innovative CTMS product with the relevant features and flexibility to meet our needs. Our team has found the application to be very intuitive and the built-in workflows beneficial to organize our team and support our client's studies."

Indre Dryziene
Project Director, Clinical Operations Biomapas

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Results: After a rigorous selection process, SimpleTrials was chosen to address the Biomapas organizational needs. As adoption has progressed, the SimpleTrials product and support team have met and exceeded the client's needs in several specific ways:

- Upon activation of the SimpleTrials workspace, the Biomapas team was able to easily invite users into the system, access training videos and learn from the **included Sandbox study**.
- **New studies** are easily added directly in the application, with no per-study fees.
- The Biomapas team was able to start **study planning** immediately via the pre-populated study plan, making customizations to reflect target dates, durations and dependencies.
- **Sites and contacts** were added and imported using the available import template. Users could easily manage contact details including role for a given study, addresses and contact details.
- Once sites and contacts were associated with studies, the portfolio contacts and organizations area provided **transparency for consistent use** across studies.
- Biomapas team members were easily associated with studies, additional user accounts activated, and site monitor assignments were established.
- **Electronic visit report** templates were built and enabled for study use. The monitors and their managers quickly utilized the authoring and review workflow to finalize electronic visit reports.
- Field monitors with the Biomapas team were able to add site visits to the **calendar**, with integrated **visit report tracking**. Report alerts ensured the visit report drafting and completion were compliant with the monitoring plan timelines.
- **Site start-up** workflow activities were quickly established using the available system columns and **flexible customizations** to manage additional items. Users were able to quickly see selected sites and the status of critical items such as EC submissions, contract status and site activation.
- Subject visit schedules were defined in SimpleTrials to represent the protocol visit schedule and effectively manage **subject visit progress** activities.
- The Biomapas users were able to add or import subject records for screening and enrollment, manage the study participation status of each subject and **oversee global recruitment progress**.
- Using available CTMS Reports, email alerts and in-application notifications, the Biomapas team members were able to successfully **oversee critical study activities** including study milestones, subject enrollment metrics, site startup activities and monitoring report completion metrics.

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