CASE STUDY: Cancer Insight Optimizes Study Management with the SimpleTrials CTMS

Case Study: How the adoption and implementation of SimpleTrials for Cancer Insight, a leading Clinical Research Organization focused on discovering, developing, and testing cutting-edge cancer immunotherapies, provided effective and relevant benefits to their study team and trial management activities.

Cancer Insight's study management portfolio includes a diverse collection of sponsors (from startups to large international pharmaceutical companies) and multiple study phases. Cancer Insight was seeking a robust web-based, easy-to-implement, and cost-effective Clinical Trial Management System (CTMS) to complement their best-in-class study management. Integration of the CTMS with other eClinical systems, namely EDC, was also fundamental to unify and leverage data internally across groups. SimpleTrials CTMS was chosen, offering an intuitive, feature-rich system, backed by an experienced eClinical team, with competitive and transparent pricing that fit their budget.

Included among the CTMS requirements:

- **Integration with the EDC application, providing a snapshot of the critical screening and enrollment efforts by study, site, subject, and visit.**
- **A mechanism to track study startup activities, study milestones and target versus actual enrollment, enabling site selection and ongoing site management.**
- **Provision of a CFR Part 11 compliant electronic Trial Master File (eTMF) utilizing the DIA TMF Reference Model and including document tracking and export features.**
- **CRA monitor visit calendaring and tracking of site visit report progress, which was crucial for resource planning and site trending.**
- **The ability to easily define electronic visit reports (EVRs) per SOPs with the flexibility to accommodate specific Sponsor and/or study needs.**
- **Robust yet flexible exports, dashboards, and reporting tools.**
- **The ability to sign-up and get started quickly, on their schedule.**

Finally, the CTMS needed to be flexible enough to adapt to Sponsor-specific tracking needs within complex oncology programs and across fast-paced study teams.

> **"SimpleTrials was quick and easy to implement, and the well designed and flexible features has allowed us to tailor the system to our CTMS and TMF needs. Integration of the EDC has unified data internally across groups enhancing study management."**

Susie Hargrove
Director of Regulatory Affairs
Cancer Insight

SimpleTrials

CANCER INSIGHT

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RESULTS

SimpleTrials was chosen to address Cancer Insight's study management challenges. The SimpleTrials product and client support team met and exceeded the client's needs in several crucial ways:

- With a **quick implementation** and setup, the Cancer Insight team started seeing the benefits of SimpleTrials immediately, setting up sites, teams, contacts and users.
- Subject **visit schedules** were easily defined in SimpleTrials with mapping of EDC visit names, rules for creation of subject records and visits, and subject status values.
- **EDC integration** was setup directly in the application and Cancer Insight was able to test the integration settings prior to the integration "go live". This step enabled the client team to address any cross-system inconsistencies.
- The Cancer Insight team had the ability to enable the EDC integration directly in SimpleTrials for "go live". This action **automated** the creation and updates to **subject records** based on the latest EDC data.
- With EDC integration enabled, detailed **recruitment and enrollment activities** were managed by site, subject, and visit using the standard screening, enrollment and visit views within SimpleTrials. These records could then be utilized for additional CTMS actions related to electronic visit reports, protocol deviation tracking, and site payments.
- Organizing **essential documents** according to the DIA TMF reference model and uploading them into SimpleTrials was straightforward. SimpleTrials provided a scalable system which allowed Cancer Insight to tailor document tracking based on their needs and SOPs.
- Study metrics and site **startup tracking progress** was able to be managed using target versus actual dates, standard study startup work-flows and Gantt-like visualizations.
- **Electronic visit report templates** could be easily defined at the portfolio level and associated to studies for immediate use directly within SimpleTrials.
- CRAs were able to immediately **create calendar events** in SimpleTrials by CRA, site, visit type, and duration and track the status of development and completion of associated visit reports. Comprehensive calendar entries were viewable by vendor, country, and CRA name for resource planning within and across studies.
- A **"sandbox" study** was setup by the SimpleTrials client support team. This fully built-out, sample study proved to be a valuable resource for the Cancer Insight team members, not only for training, but also to allow ongoing reference and experimentation of the CTMS functionality.
- The SimpleTrials **dashboard visualizations** and out of the box reports provided executive-level roll up of study milestones, site selection, and recruitment activities.

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