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Case Study

Streamlining Safety Review for Immunotherapy Trial through Real-time Data Access & Flexible Study Build



Project Background

Our client is a recently launched, venture-backed biotechnology company developing immunotherapies for oncology, infectious diseases, and immune disorders. The company uses its proprietary platform to develop novel and effective therapies that overcome typical challenges with immunotherapies and meet unmet patient needs.

The Challenge

Our client planned a phase 1 dose escalation and expansion study investigating safety and PK/PD (pharmacokinetics and pharmacodynamics) for an immunotherapy treating advanced solid tumors. They chose to partner with eClinical Solutions as their biometrics services provider and benefit from the capabilities of the elluminate platform to accommodate the complex data collection requirements for the study. The services encompassed clinical data acquisition, clinical data management, and statistical programming.

As part of this delivery, our client sought a solution to support their pharmacovigilance processing and serious adverse event (SAE) reporting requirements. They were keen to leverage the study's existing technologies—Medidata Rave and elluminate—to fulfill the requirements.

SAEs must usually be reported within 24 hours or less, to the appropriate regulatory authorities, institutional review boards (IRBs), ethics committees, and the sponsor. Therefore, ensuring real-time data access was crucial to assure patient safety and timely interventions, early signal detection and insight into emerging patterns of adverse events, and accurate reporting and detailed documentation of events.

Company Profile

- Emerging biotechnology company
- Headquartered in United States
- Approx. 30 employees

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Products Utilized

→ Biometrics Services

→ elluminate Clinical Data Cloud

The Approach

The client needed a robust approach for allowing stakeholders to gain visibility into serious adverse events, in the context of their early phase, complex oncology trial. As an emerging biotechnology company with limited resources, they were keen to simplify the approach, using the available technologies they had at their disposal. They also wanted a solution which could be used by their clinical CRO as well as by eClinical Solutions as the biometrics services provider.

Given the 24-hour reporting window for SAEs, the critical factor was ensuring data was accessible in near real time, and available for review across stakeholders.

eClinical Solutions created a solution encompassing flexible design of the client's Medidata Rave database, alongside the capabilities of the elluminate Clinical Data Cloud®:

- The eClinical Solutions' clinical data acquisition team designed a casebook approach that brought across derived subject information from other database fields into the Serious Adverse Event report form. This approach meant that all background information about the subject was available within a single form eliminating the need for the study team to cross-reference across different fields.
- Once the serious adverse event data was captured within the electronic data capture system, it was ingested into elluminate. The client used this process, and the capabilities of elluminate, to drive ongoing review of the SAE.
- Within the electronic data capture (EDC) system, if a record was modified in any way, including initial submission, email notifications were built to notify the team immediately enabling swift action.
- The sponsor's clinical CRO used the bi-directional capabilities of elluminate to review safety data and generate queries about the adverse events directly from elluminate to Rave.
- The client was able to access existing visualizations and reports such as adverse event dashboards and patient profiles within elluminate CDA (Clinical Data Analytics) to support clinical safety and efficacy signal detection.
- As part of the solution, the eClinical Solutions team also created customized dashboards within elluminate including SAE and AESI (adverse event of special interest) data as well as peripheral data needed to perform their review.

Success Factors

The eClinical Solutions team applied creativity and flexibility to create an innovative solution that could meet the client's needs.

Deep expertise in the Medidata platform enabled the team to customize the database build to create a practical and streamlined solution.

The Biometrics Services team brought a strong understanding of the data collection challenges for immuno-oncology and oncology trials to the project.

Results

The client and the clinical CRO gained access to their critical SAE data in real time through elluminate, enabling faster decision-making.

The evaluation of SAEs requires significant input from various roles, including investigators, pharmacovigilance scientists, biostatisticians, and medical monitors. The solution, using elluminate, facilitated effective collaboration across stakeholders to ensure a comprehensive assessment of SAEs. Importantly, this could take place without the need for users to log into multiple systems.

The client benefited from a streamlined and simplified approach, avoiding the need for supplementary technologies and additional study costs.

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