Best Practices in Data Management:

Bioforum Simplifies Complexity and Successfully Delivers Quality EDC for First-in-Human Clinical Trial Sponsored by Dren Bio, Inc.

Bioforum and Dren Bio, Inc. ("Dren") joined forces to focus on Dren's first clinical trial evaluating DR-01 in patients with large granular lymphocytic leukemia or cytotoxic lymphomas in January 2022.

Prior to engaging Bioforum, Dren had already delivered robust preclinical data for DR-01 and was well positioned to rapidly advance DR-01 towards clinical studies. With an eye towards the study's upcoming FPI ("first patient in"), Dren selected Bioforum as its clinical trial data management partner to ensure the operational readiness of the clinical database without delaying enrollment timelines.

DR-01, the California-based biotech's first asset to enter clinical studies, is a monoclonal antibody designed to bind to a receptor selectively expressed on cytotoxic cells involved in a variety of hematologic malignancies and autoimmune disorders.

CHALLENGES

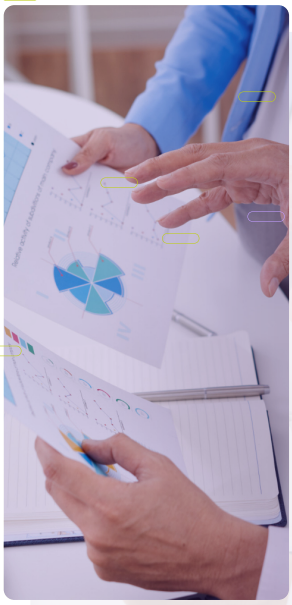
With first-in-human clinical trials, there is typically minimal literature to reference. This was further amplified by the ultra-rare nature of the indications and highly complex response assessments associated with cytotoxic lymphomas. Importantly, the study was the first in this subset of aggressive t-cell lymphomas. With this, the Bioforum team had to navigate frequently changing clinical requirements and protocol amendments as the study evolved. And as new information emerged, the electronic data capture (EDC) system needed to be adjusted to meet changing requirements and scenarios, while never delaying study enrollment or critical data cuts for data and safety monitoring boards (DSMBs) and development safety update reports (DSURs).

GET IN TOUCH:

Website: bioforumgroup.com Email: info@bioforumgroup.com

USA South Africa Israel Australia

During this process, Bioforum also provided support with real-time data visualization to optimize decision-making processes, identify anomalies, spot trends, and inform practices, as well as clinical trial-related IT support, such as with secure File Transfer Protocols (sFTPs).



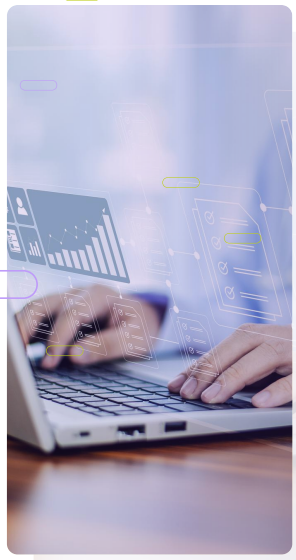
SOLUTIONS

Bioforum used a combination of clinical, data management, and technical EDC expertise to create a streamlined system to simplify the complexities of the study design.

A cross-functional team of Bioforum experts delivered an EDC system that was easy to use despite the complexity of the study. They removed redundancies and adjusted the study flow to accommodate participating patients throughout the trial. During this iterative process, Bioforum coordinated with clinical operations, data management, and medical monitoring at Dren to ensure all study aspects ran smoothly. The Bioforum team closely and continually monitored data quality and proactively raised concerns to ensure that the data met the highest standards.

OUTCOMES

Bioforum achieved impressive results despite a tight deadline. Initially, Bioforum delivered the EDC in May 2022, just four months after beginning to work with Dren in January 2022. However, as the trial progressed, the EDC required changes to reflect the study's evolution. Bioforum planned the EDC updates in December 2022 and implemented them in January 2023. By March 2023, the EDC system updates were available at all the clinical trial sites.



Based on this success, Bioforum is now Dren's long-term, preferred data management CRO partner with additional studies across additional Dren platforms already underway.

Interested in learning more about Bioforum's data management offerings and other capabilities?

Reach out here.