

Partnership Success Story

International biopharma sponsor and partner CRO maximize flexibility of **Judi in DSMB** for Phase 2 multinational clinical program with over 100 patients and 60 sites

Maintaining Integrity

Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) oversight is pivotal for ensuring the safety and credibility of clinical trials. These committees play a crucial role in protecting the interests of study participants and maintaining trial integrity. It is imperative for DSMBs and DMCs to maintain independence to effectively carry out their mission. To overcome the challenges that arise, innovative and streamlined approaches are required. Furthermore, it is essential to provide prospective DSMB/DMC members with enhanced training to excel in their roles.

The Problem

An international biopharma company required a unique solution for a clinical study to test the safety and efficacy of a novel therapy designed to improve outcomes of patients with **Myasthenia Gravis**—an auto-immune condition marked by chronic weakness in the voluntary muscles, which may cause blurred vision and impaired speech, among other symptoms, and affects an estimated 30 million people globally. The success of the sponsor's trial will provide a potentially life-altering treatment for patients with Myasthenia Gravis worldwide.

The Situation

The trial sponsor and CRO selected **Judi in DSMB** for its secure and globally compliant collection and transport of blinded and unblinded data, real-time transparency, complete audit reporting, and best-in-class management of DMC/DSMB processes—**over 100 patients, 60 Sites**. Also, the sponsor and CRO expressed a need for unique, dynamic workflows for each trial, including customized notifications, permissions, and reports based on individual roles, with real-time scheduling and communication for blinded and unblinded biostatisticians, and medical committee specialists. Moreover, the CRO and sponsor required the capability to supplement user training at the onset of each trial.



Enhanced Collaboration

Employing AG Mednet's **CORE principals**—Client Centricity, Orchestrated Collaboration, Robust Simplicity, and Efficient and Secure Workflows, the AG Mednet Team leveraged the flexibility of the entirely configurable Judi Platform to help the trial team to seamlessly manage complex global interactions and insights, allowing them to do their best work, faster.

Along with unique, secure, and dynamic DMC/DSMB workflows, the Judi Collaboration Platform provided an efficient way for the biopharma sponsor and CRO to distribute and store compliant reports, source documents, and forms, and remotely manage permissions of members through role-based data behaviors. In addition, before the trial was live, the sponsor and CRO requested an expanded ability to securely conduct and audit training for specific users. Because the Judi Collaboration Platform is fully configured to meet the needs of the sponsor's workflows, the training and questionnaire were integrated without delay, with potential for expansion through **Judi for Site and User Qualification**. Judi saved the CRO and sponsor significant time and ensured trial integrity and effective DSMB/DMC reporting.

“The sponsor and CRO required several unique workflow solutions to manage and automate complex DMC processes, and simultaneously ensure user training. We worked closely to ascertain all their needs were met. Judi offers a fully-configured platform that nothing else can match.”

—Megan Golding, Project Manager, AG Mednet



Megan Golding, Project Manager,
AG Mednet, Trial Delivery

About AG Mednet

AG Mednet is revolutionizing the clinical trial process through Judi, the innovative and **award-winning** clinical trial collaboration platform. Designed to empower the ecosystems that drive clinical research, Judi streamlines workflows, facilitates communication, and accelerates the development of novel therapies for patients. The proven Judi platform is trusted by 19 of the top 20 global biopharmaceutical sponsors and 5 of the top 6 global CROs. Additionally, the Judi platform enables clinical teams worldwide to come together and seamlessly manage complex workflows in endpoint adjudication, eligibility, data safety monitoring, medical imaging, and other mission-critical areas of clinical development.

To learn more about Judi, visit www.judi.io or please contact the company at info@agmednet.com.

Request a demo

Contact us to learn how Judi accelerates and improves all your clinical trial journeys.