Judi
by AG Mednet

Partnership Success Story

United States-based medical device sponsor and partner CRO leverage flexibility of Judi for DSMB for novel cardiovascular implant trial with over 100 patients and 25 sites

Crucial Oversight

Data Safety Monitoring Board (DSMB) or Data Monitoring Committee (DMC) oversight is crucial for safeguarding the interests of study participants and assuring the integrity and credibility of clinical trials. **FDA guidance** strongly advises the use of an independent DSMB/DMC to effectively monitor safety in clinical trials, especially when studying a population at high risk of severe outcomes. To seamlessly manage DSMB/DMC workflows in real-time, it is essential to eliminate obstacles that hinder clinical team efficiency, transparency, and automation while mitigating the risk of non-compliance.

The Problem

A United States-based medical device company required a unique solution for a clinical study to test the safety and efficacy of a novel implant designed to improve outcomes of patients who have experienced **Acute Aortic Dissection Type A (AADA)**—a life-threatening condition marked by significantly high morbidity and mortality rates, which affects approximately 50,000 people annually. The success of the sponsor's trial will provide a potentially life-saving treatment for patients with AADA worldwide.

The Situation

The CRO and trial sponsor selected **Judi for DSMB** for its best-in-class management of Data Safety Monitoring Board and Data Monitoring Committee activities and processes, the secure and compliant collection and transport of blinded and unblinded data, real-time data transparency and review, and full audit reporting—**over 100 patients, 25 Sites**. Also, the sponsor and CRO expressed a need for customized permissions and notifications based on specific roles. This includes medical committee specialists, blinded and unblinded biostatisticians, as well as members participating in both open and closed meetings. Moreover, they required the capability to create ad hoc auditable and compliant meetings within these parameters.

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

Click here to read why Frost & Sullivan selected AG Mednet as winner of the Global Customer Value Leadership Award for 2023.

95% of Help Desk inquires are resolved during the initial inbound call by AG Mednet's 24x7x365 in-house support team.

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Enhanced Collaboration

Employing AG Mednet's **CORE principals**—**C**lient Centricity, **O**rchestrated Collaboration, **R**obust Simplicity, and **E**fficient 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 a secure and nimble DSMB/DMC workflow, the Judi Collaboration Platform provided an efficient way for the medical device sponsor and partner CRO to remotely manage permissions of clinical team members through role-based data management, and distribute compliant biostatistics reports appropriately. In addition, before the trial was live, the sponsor and CRO requested an expanded ability to securely conduct ad-hoc real-time meetings for specific committee members. Because the Judi Collaboration Platform is fully configured to meet the needs of the sponsor's workflows, the ad-hoc meeting workflow was deployed without delay. Judi saved the sponsor significant time and ensured trial integrity and effective DSMB/DMC reporting.

> *"The CRO and sponsor needed a comprehensive solution that could effectively monitor patient safety through automated, compliant reporting, real-time transparency, and flexible data management. Judi offers a unique and fully-configured platform that no one else can provide."*
>
> –Jennifer Wiley, Senior Project Manager, AG Mednet

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.

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Request a demo

Contact us to learn how the Judi Collaboration Platform can speed and improve all your workflows.