Judi
by AG Mednet

Partnership Success Story

European-based biopharma and partner CRO employ dynamic controls of **Judi in Adjudication** and **Site & User Qualification** for rare disease immunotherapy trial with over 250 endpoints

Best Clinical Practices

Both 21 CFR Part 11 and GCP require the maintenance of accurate and complete records. Training users in these regulations helps maintain audit readiness. If users are qualified and trained to handle electronic records and systems in accordance with regulatory standards, audits are more likely to go smoothly, and the organization can avoid costly findings and penalties.

While compliance with regulations is a priority, the efficient operation of clinical trials is equally important. Properly trained and qualified users are more likely to work efficiently within the framework of GCP and 21 CFR Part 11, avoiding unnecessary delays and errors that can affect trial timelines and budgets.

The Problem

A European-based biopharma company required a unique solution for a global clinical study to test the safety and efficacy of a novel immunotherapy designed to treat **Systemic Lupus Erythematosus (SLE)**. More than five million people have some form of Lupus. This incurable autoimmune disease can cause complications that lead to premature death. The success of the sponsor's trial will provide a new treatment for patients with SLE worldwide. The CRO and biopharma also required an integrated solution to centrally manage and monitor clinical site qualification and global user training.

The Situation

The CRO and trial sponsor selected **Judi in Adjudication** for its best-in-class adjudication of clinical endpoint data, query generation, document collection, event tracking, and de-identification of DICOM data; and organized reporting—over **250 Endpoints, Multiple Sites**. The sponsor and CRO added **Judi in Site & User Qualification** to centrally manage global site and user qualification processes, including training, data collection, and reporting, **ensuring every step is followed by every site and user**—as the trial needed a solution that could manage qualification and adjudication processes within an integrated platform.

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 fast and secure adjudication workflow, the Judi Collaboration Platform provided an efficient way for the biopharma sponsor to remotely manage site and user qualification through role-based training and certification within Judi for the global trial. Moreover, before the trial was live, the sponsor and CRO requested additional ad-hoc interactive training exams for end users. Because the Judi Collaboration Platform is fully configured to meet the needs of the sponsor's workflows, the training review was adjusted and deployed without delay to the trial conduct. Judi saved the sponsor significant time and served as a regulatory safeguard to ensure only qualified users had the ability to operate within the platform – ultimately ensuring the trial integrity would never be jeopardized.

> *"The CRO and sponsor required the ability to qualify site users, and implement, manage, and store user training and compliance records, while also powering the adjudication of a global rare disease trial where patient retention is mission-critical…all within the same platform. To my knowledge, these capabilities didn't exist together before Judi. No platform could offer a truly unified solution like Judi."*
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> –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.

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.