

Certifications & Compliance Posture

AG Mednet · Client-facing summary · July 2026

Judi is a clinical trial optimization platform operating as a data processor / business associate on behalf of sponsors and CROs. Our assurance posture is built for that role: independently verified security and privacy credentials, alignment to the recognized frameworks our clients audit against, and clearly documented boundaries.

1 CERTIFIED independently verified, evidence available

CREDENTIAL	WHAT IT VERIFIES	EVIDENCE WE CAN SHARE
SOC 2 Type 2 (AICPA Trust Services — Security)	Annual independent CPA examination of the design and operating effectiveness of our security controls, performed every year since 2021. Latest report (2025): no exceptions noted.	Full report available under NDA (standard practice)
EU–U.S. Data Privacy Framework, incl. UK Extension & Swiss–U.S. DPF	Active certification administered by the U.S. Department of Commerce and enforceable by the FTC; lawful transfer mechanism for EEA/UK/Swiss personal data.	Publicly verifiable: dataprivacyframework.gov/list

2 COMPLIES / ALIGNED frameworks with no standalone certificate (or none held)

FRAMEWORK	OUR POSTURE	EVIDENCE WE CAN SHARE
EU GDPR	Processes personal data solely as processor on documented controller instructions, under Art. 28 data processing agreements and the 2021 EU Standard Contractual Clauses; Art. 32 security measures independently examined via SOC 2. (No GDPR certificate exists for processors.)	DPA/SCCs executed per client; privacy policy; DPF listing
HIPAA / HITECH	Operates as a business associate; administrative, physical, and technical safeguards evidenced through the SOC 2 examination.	Business Associate Agreements executed per client
21 CFR Part 11	Judi is designed and validated to support clients' Part 11 compliance (electronic records/signatures, audit trails, access controls). No "Part 11 certification" exists for any vendor.	Part 11 Compliance Assessment & traceability matrix
ISO/IEC 27001	Information security management program aligned to the ISO/IEC 27000 series; control effectiveness independently verified within the annual SOC 2 examination. Certificate not held.	Alignment demonstrable via SOC 2 report & security white paper
ISO 9001	Quality Management System modeled on ISO 9001 principles — documented SOPs, management review, internal audits, CAPA. Certificate not held.	Quality Manual overview on request
GAMP 5	Judi is validated as a GAMP 5 Category 4 configured product; computer systems validation follows GAMP methodology. (A methodology, not a certification.)	Validation documentation summary on request
AWS infrastructure (inherited)	Judi is hosted on AWS, which holds ISO 27001, SOC 1/2/3, and HIPAA-eligible attestations for the infrastructure layer. These are AWS's credentials, inherited for infrastructure only — always presented as such.	AWS Artifact reports; shared-responsibility summary

3 NOT APPLICABLE BY DESIGN deliberately not held

CREDENTIAL	WHY IT DOES NOT APPLY
FDA QMSR (21 CFR Part 820) / ISO 13485	Judi is not a medical device and AG Mednet is not a device manufacturer. Our QMS references these principles as best practice, but holding device-QMS certification would misrepresent the platform's intended use.
EU MDR / IVDR / CE marking	Judi has no medical intended purpose (per MDCG 2019-11): it manages trial process, data transfer, de-identification, and adjudication workflow — it does not diagnose, treat, or drive patient care.
FDA establishment registration / device listing	No device and no marketing authorization: no registration requirement applies to a clinical-trials SaaS. Regulatory scrutiny appropriately arrives through sponsor audits and inspections — which we support.

The documented "not applicable — and here's why" position is itself part of our compliance posture: it is maintained in writing, reviewed by QRC, and available to client auditors.

EVIDENCE REQUESTS

compliance@agmednet.com · Quality & Regulatory Compliance (QRC). AG Mednet supports client security questionnaires, vendor assessments, and audits as part of standard engagement.

AG Mednet, makers of Judi, delivers the clinical trial optimization platform built for the AI era. Judi is where the work of your trial gets done – faster and better – orchestrated across sponsors, CROs, AROs, core labs and sites. It governs all your AI models, so every output is traceable and every decision defensible.

[Talk to our team](#)



Judi
by AG Mednet