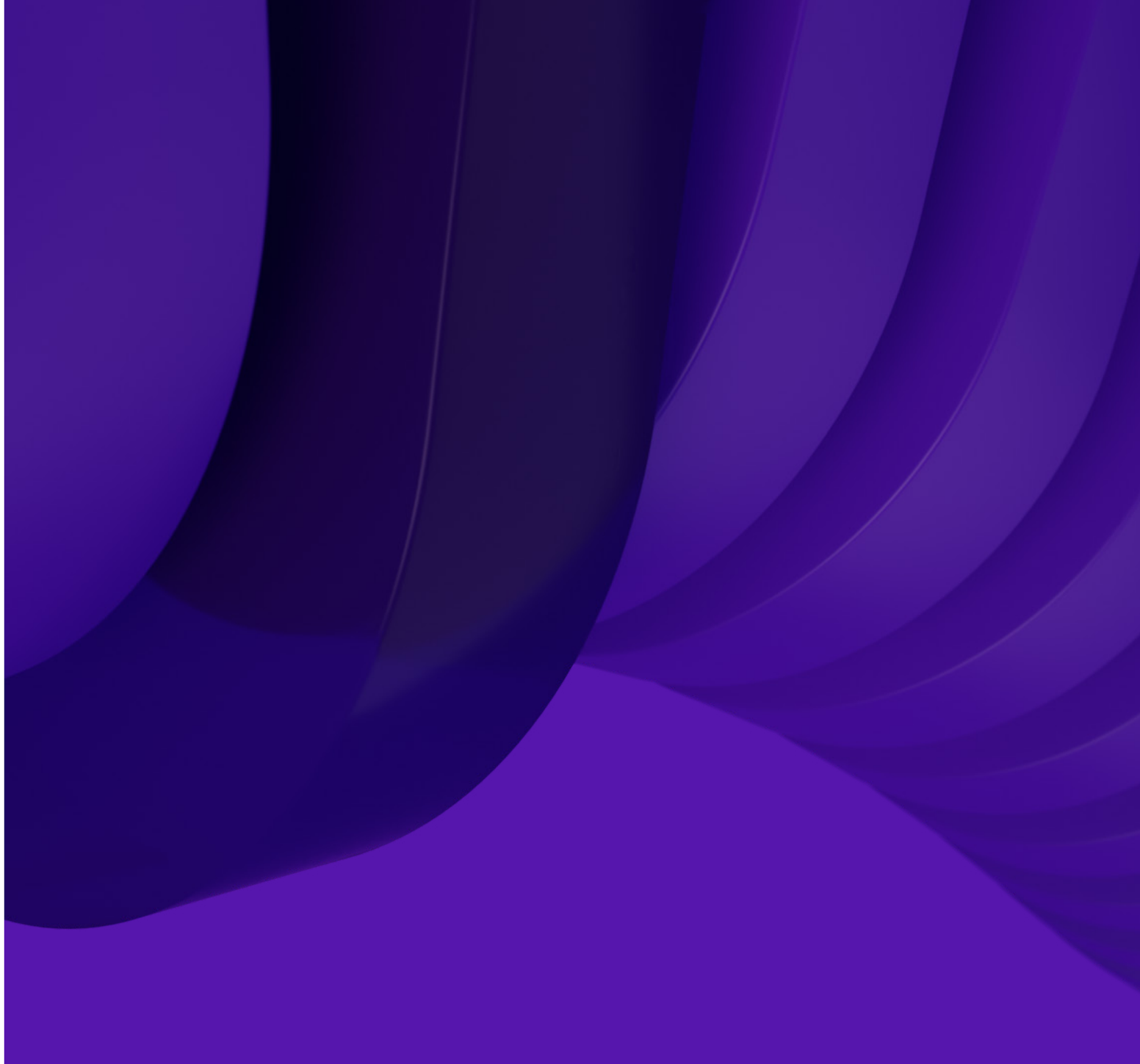
Putting the flow into workflows while staying compliant with regulations

Judi
by AG Mednet



The regulations involved in global clinical trials are exceedingly complex.

The official version of the General Data Protection Regulation (GDPR) is 261 pages long. Likewise, the U.S. Food and Drug Administration's 21 CFR Part 11 is as intricate as it sounds, with a guidance document that alone is 12 pages.

GDPR and 21 CFR Part 11 are only two of the regulations that clinical trial stakeholders must navigate. To prevent costly delays, fines, or even outright rejection, you need significant resources and effort to ensure compliance. Adding to the regulatory rigor, trials based in multiple countries are subject to increased data standards and rules regarding localization and retention.

The trend toward decentralized clinical trials adds another layer of technological and systematic uncertainties. As a result, it is best practice for sponsors, contract research organizations (CROs), and committees to use a customized workflow to mitigate regulatory entanglements.[1]

[1] https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/no-place-like-home-stepping-up-the-decentralization-of-clinical-trials

21 CFR Part 11

Title 21 of the Code of Federal Regulations (CFR) Part 11 pertains to electronic records and signatures, specifically "records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted under any records requirements set forth in Agency regulations.[2]"

GDPR

The GDPR applies to European Union and foreign companies (including most U.S.-based organizations) and other stakeholders who process personal data. According to the GDPR, health-related information is considered sensitive data, so its processing is forbidden.[3] Therefore, organizations involved in global clinical trials need to gain explicit consent from participants or determine whether they qualify for an exception to this ban3. In effect, the GDPR requires healthcare professionals, companies, and other contributors processing the healthcare data of subjects residing in the EU to adhere to the regulations even if individuals do not invoke their rights.[3]

"Non-compliance with GDPR stipulations can result in substantial fines and therefore understanding and complying with the GDPR requirements can be a daunting task. This has resulted in a particularly challenging situation for small and medium-sized organizations and companies, but even larger bodies, such as the EMA, have to devote considerable resources to ensuring GDPR compliance and the development of an effective system for the anonymization of patient-level data.[4]"

[2] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application
[3] https://academic.oup.com/spp/article/47/5/616/5780440 (p.618)
[4] https://academic.oup.com/spp/article/47/5/616/5780440 (p.617)

Solutions

What these regulations mean for clinical trial stakeholders

Life sciences companies face significant daily pressure from regulatory requirements. They struggle to address the needs of regulators and remain compliant.

- Growth in decentralized clinical trials increases the need for oversight of new processes and workflows to ensure compliance.
- Regulatory agencies require that clinical trial results be strictly auditable and reproducible.
- Using unsecured transmission methods, like postal delivery or personal emails, for the collection and submission of critical documents from clinical research sites, can result in rejection.

Increased data security and a secure environment

Investigator sites must routinely deal with confidentiality, data privacy and integrity. They must ensure that any Personal Health Information (PHI) is anonymized before data is shared across a complex clinical trial ecosystem of stakeholders and decision makers. Data in clinical trials must be supported by a secure environment where the right stakeholders with the proper credentials can query and gain insight from the data to ensure faster, and better, decision making.

The good news is that Judi helps these dilemmas.

Through ongoing partnerships with clients and years of software development, AG Mednet built Judi with a keen eye for compliance, including:

- Providing secure collection, transfer and storage of core data in any format (SAS, xls, pdf, doc, ppt, or jpg), distribution of blinded and unblinded reports, and the ability to manage all real-time communications in an auditable, 21 CFR Part 11 compliant manner.
- Robust and compliant audit logging of all actions within Judi.
- De-identification - integrated tools enabling removal of protected health information (PHI) from document submissions.
- Provides the required workflows, security mechanisms, de-identification and HIPAA/GDPR storage requirements to meet the most stringent needs defined by international subject privacy standards.
- Control over who can see subject information and when this information must be removed from view. Access to data is strictly controlled, audit logged and reportable.

Judi is compliant and configurable.

Judi is designed to enable any complex clinical trial workflow, with compliance with global and industry standards built in. Our platform is fully compliant with:

21 CFR Part 11, HIPAA, & GDPR

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Client Centricity

We understand off the shelf solutions are not built to meet your specific needs, and developing bespoke solutions can be both costly and time consuming. For that reason, we offer a range of focused, innovative solutions designed to deliver your desired business outcomes, while adapting to your workflows.

Orchestrated Collaboration

We operate in a complex ecosystem, with data shared across multiple stakeholders at different points in time. We know integration is critical, so we seamlessly connect teams, sites and partners across the journey, enabling extensive collaboration.

Robust Simplicity

Clinical trial workflows can be complex and time consuming, especially if done manually. We recognize and reduce complexity to enable a more seamless, transparent and tailored experience.

Efficient & Secure Workflows

Manual processes can compromise clinical trial data security. We use purposeful automation with leading security to ensure optimized process management and deeper insights.

One collaboration platform

Cloud based

Built-in close collaborations with trial experts

Judi for Adjudication

Adjudication workflow solution for Clinical Endpoint/Event Adjudication.

Judi for Imaging

Medical Imaging workflow solution for Central Image Collection Storage and Review.

Judi for DSMB

DSMB workflow solution for Data Safety Monitoring Activities

Judi for Eligibility

Eligibility workflow solution for Central Screening Committees/ Eligibility Reviews

Judi for Monitoring

Monitoring workflow solution for Remote Source Data Review and Verification

Judi Flex

Workflow solutions for everything else. If you can map it, Judi can manage it.

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Contact us today to learn more about how Judi can automate, expedite, and improve your clinical trial.

Request a demo

www.judi.io

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