



Scalable eTMF Deployment Enables 21 CFR Part 11 Compliance for Multi-Sponsor Gene Therapy Studies

EXECUTIVE SUMMARY

Court Square Group delivered a fully validated, scalable Electronic Trial Master File (eTMF) system to support multi-sponsor gene therapy studies. The solution reduced manual effort and ensured 21 CFR Part 11 compliance, enabling seamless collaboration across NIH initiatives.

THE CLIENT

A global CRO supporting gene therapy studies under the NIH's Center for Gene Therapy (CGT) and the Bespoke Gene Therapy Consortium (BGTC).

THE CHALLENGE

The client needed a compliant, audit-ready platform that could manage documentation for gene therapy studies involving multiple sponsors and stakeholders.

THE SOLUTION

Court Square Group implemented RegDocs365™ using its CGT-in-a-Box model, which included standard operating procedures (SOPs), user training, and a scalable configuration framework.

THE RESULTS

A 21 CFR Part 11-compliant eTMF environment that reduced manual workload and created a scalable infrastructure for ongoing NIH collaborations. The CRO was able to work in a single environment while clients only had visibility into their own environment.

ABOUT COURT SQUARE GROUP

Court Square Group is a leading managed services technology company dedicated to empowering those who change lives. Our Audit Ready, Compliant Cloud™ (ARCC) infrastructure provides Life Science companies with the highest level of data integrity from pre-clinical to clinical and regulatory approval through manufacturing. We manage the 21CFR Part 11 validated infrastructure so you can focus on secure Clinical Collaboration & Content Management.

Our unique business-focused approach has supported many Life Science start-ups as well as some of the largest international Life Science companies. Our suite of solutions provides a secure, validated environment that creates, protects, and retains digital information, no matter the size of the need. Additionally, the expertise of our team can provide technical, compliance, and audit readiness support.

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