

CASE STUDY

From Manual Chaos to Automated Compliance: Streamlining Multi-Sponsor Clinical Operations



OVERVIEW

A global CRO supporting gene therapy studies under the NIH's Center for Gene Therapy (CGT) and the Bespoke Gene Therapy Consortium (BGTC) needed a compliant, scalable system to manage documentation across multiple sponsors and stakeholders.

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

OBJECTIVES

REGULATORY COMPLIANCE

- Ensure all clinical documentation meets 21 CFR Part 11 and audit requirements.

SCALABLE COLLABORATION

- Enable multiple sponsors to securely work within a single eTMF environment

OPERATIONAL EFFICIENCY

- Reduce manual document handling and administrative burden through automation.

BUSINESS CHALLENGES

- Multi-sponsor complexity
- Regulatory compliance risk
- Manual documentation workload
- Lack of scalable infrastructure

SOLUTIONS IMPLEMENTED

Court Square Group implemented the RegDocs365™ eTMF platform using its CGT-in-a-Box model. This included standardized SOPs, user training, and a validated, scalable configuration framework. The solution provided a fully compliant eTMF environment that allowed the CRO to operate in one centralized system, while ensuring each sponsor had visibility only into their own data.

CONCLUSION

By implementing a validated, scalable eTMF platform, the CRO achieved regulatory compliance while significantly reducing manual workload and enabling secure collaboration across multiple sponsors. The solution established a future-proof foundation for ongoing gene therapy studies, ensuring audit readiness, operational efficiency, and long-term scalability for NIH-led initiatives.



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