

BRIDGING THE STUDY CLOSURE GAP

CASE STUDY



GOAL

Implement a cost effective, dependable, and secure data archiving solution for a sponsor's study closure process.



SITUATION

As EDC continues to become the primary medium for clinical data collection, sponsors and contract research organizations continue to run into a myriad of hurdles while adjusting. This particular customer was facing difficulties with performing their site closure services. Being that it is not their primary business to figure out how to bridge the technical gap when dealing with EDC functions, they were struggling to efficiently and consistently get their subject data back to the study sites. In addition, their organization was in the process of doing a reallocation of resources and a headcount reduction in their department. They were faced with a corporate initiative to significantly improve their study closure timelines.



SOLUTION

As a long-time customer of Imperial Graphics, a meeting was requested to explore possible solutions. Fully equipped with the appropriate technology, as well as an auditable and proven process, it was clear to teams on both sides that Imperial Graphic's study closure services could provide the necessary deliverables. Working in collaboration, Imperial Graphics modified its process to mirror certain elements of the customer's current operational procedures, enabling a smoother and more efficient transition. Beta testing was conducted prior to full implementation, mitigating the risk of an unsuccessful launch. The end product incorporated the Imperial Marketplace®, an online inventory management and file collaboration tool, through which they were able to initiate study closure requests. Upon a closure request, Imperial Graphics managed the process with the individual sites through completion. As part of the solution, Imperial Graphic's systems were mapped and integrated into the customers systems, allowing for seamless data transfer and information validation by Imperial Graphics. Information was burned onto CD's, with site/subject specific information printed with a four color waterproof process onto the disc. The media and other related materials were then distributed to sites globally via Imperial Graphics trained logistics team. A training program revolving around the solution was put together by Imperial Graphics and presented to all relevant sponsor associates.



ACHIEVEMENTS

- > Removed on minimum 2 weeks out of study closure timeline
- > Successfully filled the void of an internal unit
- > Enabled client to better implement their larger organizational structure goals
- > Implemented a customizable solution in under 90 days

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SUMMARY

Technology continues to play an evolving role in the Life Sciences industry, and along with that comes constant change and adaptation for companies. In this case, the client was faced with bridging a technology gap, which they had neither the time nor expertise to fill. Unlike suppliers that provide a product or service where the customer must mold their processes around, as a support organization, Imperial Graphics puts focus on listening to customer problems, and building solutions that work for them.

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40+ years in life sciences.

4,000 active protocols under management.

50,000+ global shipments to sites annually with **98% on-time delivery**.

Imperial Graphics is a known and proven leader in the development, production and delivery of site materials and supporting solutions. Across the world clinical teams rely on the experience and quality our teams consistently provide, keeping studies on track and on time.

SERVICES INCLUDE

- › Trial Theme and Graphic Identity
- › Study Design from Protocol
- › Investigator Meeting and Materials Support
- › Web-Based Global Collaboration
- › Production, Printing and Distribution of Study Materials
- › Study Closure and Archiving
- › Real-Time Information Management
- › Design Services
- › Imperial Marketplace®
- › File Library/Document Management
- › Case Report Forms
- › CRF Builder
- › PRO Documents
- › EDC Launch Kits
- › Source Documents
- › Regulatory and Pharmacy Binders
- › Mini Protocols
- › Patient Education Materials

PART OF THE FAMILY

Imperial Graphics is proud to be a part of the Imperial Family of Companies—a clinical research support organization also comprising DAC Patient Recruitment Services and ClinicaLingua Translation Services. Together, these three vertically integrated brands focus on patient recruitment, translation services and site material production and fulfillment. Imperial Graphics is poised to provide efficiencies and savings not found with other production houses. Working in synergy with our sister companies, we offer start-to-finish clinical trial solutions with the power of three companies through the convenience of one contact and one contract.