

BUILT TO SUIT

CASE STUDY



GOAL

Develop a validated and GCP-compliant solution that enables customers to generate site archive requirements from multiple EDC platforms and redistribute as required.



SITUATION

- › As EDC becomes an increasingly predominant tool for data capture and collection in the clinical trial process, system users face the growing pains of adapting these systems to existing processes. The customer in this instance faced the following hurdles to combining EDC platforms and site closure requirements:
 - Facilitating and managing the distribution of site archive data back to the study sites
 - Visibility to confirmation of site receipt of the archive packet
 - Quality controls to ensure sites received the appropriate archived information
 - Reporting of metrics on Imperial Graphic's performance relative to the SLA



SOLUTION

- › The client's situation was a perfect fit for Imperial Graphic's Study Closure solution. To provide 24-hour, real-time global access, a web-based interface was developed and tied into Imperial Graphic's online order management platform, Imperial Marketplace®. Study Data Managers closing a study were able to login at any time and submit an electronic archival request. Imperial Graphics then managed the study data archive generation process from the EDC vendor and performed the following data quality verification checks:
 - Brought the archive files (PDFs) into Imperial Graphic's system and attached with a hash mark (algorithmic ID#), enabling versioning history if a file were to be changed while in Imperial Graphic's possession.
 - Validated that the number of expected site and subject archive files matched the number of archives received.
 - Performed ample data verification to confirm that archive data matched actual data in the EDC system.
 - Confirmed that PDFs were functional and not corrupt.
- › Files were burned onto media with study and site labeling. Included in each site archive packet were the archive media (DVD/CD), client-directed site documentation, and a hard copy site receipt acknowledgement form.
- › Strong global logistics competency, an Imperial Graphics skill set, was a required component for this solution to be effective. During the distribution life cycle the customer was able to log into Imperial Marketplace® to get real-time delivery information and confirmation. Imperial Graphics proactively monitored shipments and interacted on the client's behalf with shipping officials and delegates to ensure timely delivery.
- › The final component to the solution was a customer reporting tool that displayed Imperial Graphic's performance from request to completion on individual assignments.

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SUMMARY

What once was a significant resource drain and potential liability for the client now occurs securely with a couple of clicks on the computer. Imperial Graphic's Study Closure solution has enabled the customer to have confidence that the required site archives are safely and accurately being delivered to the necessary sites around the globe. It is a model that, with its proven success and ease of use, has been adopted for all similar EDC site closure activities within the client.

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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

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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.