

## Organized Chaos

### Goal

Develop a site kit that enabled the client to collect a variety of specimens at specific time points pre and post medication

### Situation

In the majority of cases, pharmaceutical companies utilize central laboratories to collect site specimens for analyses. These central laboratories facilitate the collection process from beginning to end, relieving responsibility from the sponsor to undertake any supporting activities. This particular client had a different process flow, where they gave individual sites the autonomy to select a local laboratory. In doing this however they were not able to capitalize on a number of supporting services often provided by a central lab. In this particular study the customer needed a kit that would allow them to collect site specimen samples both pre and post medication. The scope was across multiple studies and therefore multiple laboratories, making clear and effective tracking of the specimens critical – the client wasn't sure where to begin, and turned to Imperial

### Solution

Imperial assembled an internal team of experts from production, packaging, design, and logistics to meet with the client's Early Development Clinical Trial Team and tackle the issue at hand. With a large number of patients and multiple independent analysis laboratories, it was clear to the team that the solution required clear and auditable tracking for the sponsor to review. Once the needs for the customer were clearly defined, Imperial went to work and developed custom lab kit solution that comprised the following:

- Twenty eight different kits comprised of varying layouts and components specific to the days and cycles of the study
- Imperial handled all graphic design and theming – every kit was graphically differentiated by collection dates (color coded)
- Specialized bar coding system enabled tracking from the analysis, to the specimen, to the specific kit, all the way back to the original production run
- Custom specimen logistics program
  - The cryo specimens needed to be shipped from each site to the analysis lab. Imperial made modifications to standard cryo shipping containers to meet the client's specific needs
  - Imperial provided custom cryo shipping labels
- Imperial designed requisition forms from study protocol and developed a multi-part requisition forms binder
- Weekly phone conferences on trial progress giving Imperial visibility to trial enrollment and ability to do proactive inventory management
- Provided customer with ability to do on-demand drop shipments to site locations as needed
- Imperial project team managed over 15 suppliers, enabling the client to benefit from a substantial reduction in the number of vendors and open channels of communication required
- Kit components included:
  - Two collection kits identified by cycle and day of trial
  - Biohazard bags
  - Transfer Pipettes
  - Blood collection tubes
  - Spin Tubes
  - Cryovials
  - Cryotubes
  - Urine testing cryovials
  - Requisition form binders designed straight from protocol – themed to match





## Achievements

- Developed an all inclusive collection and distribution solution without requiring use of a central lab service
- Enabled client the flexibility to use analysis labs of their choice, including in-house labs
- Customer was easily able to meet all patient collection dates
- System developed and put into place that proactively manages the expiration timelines of collection equipment to ensure site always has usable and current kits
- Comprehensive self contained kits improved collection timelines and minimized site errors.

## Summary

Having a partner that understands the responsibilities and requirements that their customers face can be an invaluable asset. At Imperial we have made Life Sciences our focus, this is what enables us to speak our customer's language. When time isn't spent translating, the results are improved timelines, greater collaboration and increased productivity. In this instance the issue was clearly understood, relationship dynamics allowed for creativity and joint problem resolution, resulting in unique solution development that met the customer's needs.

## About Imperial

Imperial is a leading supplier of custom solutions for the clinical research market. Using an innovative and vertically-integrated approach to provide study support materials, Imperial improves study rollout and management for leading pharmaceutical, biotech, and medical device companies, as well as for contract research organizations (CROs).



## 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
- eClinical study closure and archiving
- Real time information management
- Late Phase Solutions
- Design Services
- Translation Management Services
- Patient Recruitment Retention
- Imperial Marketplace®
- File Library/Document Management
- Case Report Forms
- CRF Builder
- PRO Documents
- EDC Launch Kits
- Source Documents