

## CASE STUDY

# KEEPING IT UNDER CONTROL

## Meeting the Evolving Needs of Clinical Study Supply Procurement



### SITUATION

The head of strategic sourcing at a top-five CRO contacted Imperial about ancillary supplies needed for an ulcerative colitis clinical study. The study medication needed to be maintained at a specific temperature range at all times, which included periods when the medication would be in the possession of study participants away from the study site.

The plan called for each site to provide study medication to patients in a soft-sided cooler bag containing an ice pack and a data logger. The data logger would monitor the temperature and begin blinking if the temperature left the required range. If the data logger was blinking when the patient returned to the site, the remaining medication in the kit would be discarded.

The CRO had already acquired the coolers and the ice packs. Imperial was called on to identify, procure, and supply data loggers that would meet the requirements of the study.



### SOLUTION

Imperial's ancillary supplies team, under the direction of the Imperial project manager, began a comprehensive review of the project requirements, then set up kit testing with data loggers and coolers. The program developed by Imperial delivered positive results and was approved to move forward by the sponsor and CRO.

The sponsor's original plan had each site taking on the responsibility of programming the data loggers. Imperial recommended its study supply team program the data loggers prior to shipment to ensure the consistency and integrity of each data logger's programming and performance. The CRO and sponsor agreed.

Each data logger was given a unique name based on the site number so it could be identified at any point. Each was programmed to:

- › Constantly display the current temperature on its LCD
- › Sample the temperature every 30 minutes around the clock
- › Begin blinking if the temperature exceeded the preset threshold of +25.0 degrees or -5.0 degrees Celsius by blinking a red warning light continuously

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### SOLUTION CONT.

Imperial assessed the length of time the data logger would be used during multiple trips by patients, calculated the battery life, and supplied the required additional batteries.

Imperial also authored written instructions (in English and Japanese) for site personnel to download the information stored in the data logger and reset it for subsequent use by the patient.

As part of its thorough testing process, Imperial shipped a kit to its United Kingdom facilities to understand the performance of kit components while in flight transit. The experiment proved the components would function and meet the CRO and sponsor requirements.

Because of demonstrated project management and logistics expertise, Imperial was chosen to serve as the central point for the project. The CRO shipped the already obtained coolers and ice packs to Imperial, where the kits were assembled and shipped to the sites. Also included in the kits were sharps containers, cotton balls, and alcohol wipes procured by Imperial.



### SUMMARY

Within weeks, Imperial was able to give the CRO and sponsor a single contact to provide testing, procurement, assembly, and shipping of key study supplies. This centralized, timely, and cost-effective solution resulted in the successful, on-time delivery of kits to 325 sites worldwide.

### ABOUT IMPERIAL

Speed and flawless execution is what matters today. Our customers live in an environment with a thousand moving pieces and parts, each one with its own timeline, budget, and other associated challenges. Imperial is structured to plug in exactly where our hundreds of sponsor and CRO clients need us.

#### SERVICES INCLUDE

- › Project Management
- › Patient Recruitment and Engagement
- › Creative Services
- › Clinical Translation Services
- › Global Logistics
- › Ancillary Supplies
- › Study Startup
- › Study Closure Services