



## Leveraging a Dynamic Drug Allocation Plan to Reduce Study Costs

### **Situation: Balancing Study Costs and Patient Enrollment**

A leading biotechnology company was initiating a Phase II clinical trial for a new cardiovascular drug by testing two dosages against a placebo. The pressure to enroll patients rapidly forced the company to engage more investigational hospitals than originally planned. Unless drug production increased, fewer treatment kits would be available to each hospital. Because the drug was costly, the company faced a difficult choice: produce more kits and dramatically increase study costs, or stock fewer kits and risk missed enrollments.

### **Challenge: Minimizing Inventory Complications**

Drug production can be a very complex, expensive process. Often, contamination and replication errors cause entire batches of material to be wasted. Given these circumstances, companies typically manufacture a minimal amount of drug to conduct clinical trials. Small inventories can create serious complications, including increased costs from more frequent shipments and enrollment, and patient balance issues due to drug shortages.

### **Solution: Creating an Algorithm**

A unique algorithm was designed to draw from a limited number of kits available at each site while maintaining patient balance across treatment groups. The algorithm was based on dynamic randomization and prioritized the four treatment groups to maintain patient balance, then assigned each new patient to the top-ranked treatment group that had a kit in stock. This allowed the company to stock one kit for each treatment group at each site and re-supply after two kits were used instead of stocking four kits for each treatment group, as originally planned.

The new algorithm reduced the total amount of drug shipped by 40 percent and enabled the use of 66 additional sites to meet enrollment targets without jeopardizing patient balance. Teamwork between the IVRS provider, study designers, clinical operations team and the clinical supply managers provided a solution that resolved competing priorities. Identifying the inventory management issue early in the process allowed the statisticians to change the study design to dynamic randomization. This allowed more predictive inventory management, thereby eliminating unnecessary drug production and potential study delays.

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- 1,000 employees
- 30% of employees hold advanced science degrees
- 10% hold PhDs
- > 90% client retention rates
- < 10% employee turnover
- 2,000+ peer-reviewed publications
- 365,000 patients
- 82,000 study sites
- 3,000 clinical protocols
- 20,000 investigators trained in 60 countries

### Technologies

- Interactive voice response systems (IVRS)
- Interactive web response systems (IWRS)
- Dynamic randomization
- Electronic data capture (EDC)
- Electronic patient diaries
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- Client portals
- Web-based learning management system
- Searchable databases: MetaHub, RaterHub, Site Database

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