

How a Thorough Reimbursement Analysis Gave a Research Institution Leverage for Better Budgets

The Challenge

With recent turnover in internal staff, the office of clinical research at a major academic research site lacked internal expertise in clinical trial budget analysis and negotiation.

Solution

The client had originally turned to BRANY's experts to undertake Medicare Coverage Analysis to ensure billing compliance and appropriate reimbursement for clinical services delivered to study participants.

To help fill an internal gap in expertise, the BRANY team undertook a systematic review and analysis of study protocols. This included a detailed Medicare Coverage Analysis, as well as a review of other sources of reimbursement and administrative costs to manage the protocol. The team then leveraged the analysis results to negotiate budgets with study sponsors.

Some of the administrative issues that the BRANY team evaluated included staff time and resources for:

- › Protocol changes and amendments
- › Re-consenting study participants
- › FDA and other regulatory audits
- › Preparing for monitoring visits
- › Regulatory training for staff

The BRANY team went beyond evaluating the per-participant costs of managing the trial. Using their extensive industry knowledge, they were able to leverage the analysis results to justify budgets and provide detailed rationale for increased sponsor budgets.

Results

In the course of 10 studies, the BRANY team was able to negotiate an average of 33 percent increase over the initial sponsor-proposed budget. Additionally, in all the projects, the sponsors agreed to reimburse the institution for the cost of the payor analysis conducted by BRANY.

This increase allowed research office staff to leverage their resources to provide more thorough service to investigators and to more closely monitor compliance and regulatory issues.

BRANY

The Biomedical Research Alliance of New York (BRANY) provides support services to sponsors and investigators in a wide variety of therapeutic areas, medical devices, biologic and diagnostic trials. Staffed by multi-disciplinary experts, BRANY is an AAHRPP-accredited "end-to-end solution" for clinical trials.

BRANY is able to offer turnkey solutions for:

- › Site identification
- › Expedited study startup
- › Payor coverage analysis
- › Central IRB
- › Monitoring & auditing