



Sopherion Therapeutics, Inc.

From:	Senior Director, Clinical Operations
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We are a biotechnology company conducting a complicated first line HER2+ metastatic breast cancer study who ran into patient recruitment issues which were extending our project timelines beyond where we were financially comfortable. Our solution was to start enrollment in a twelfth country (the Ukraine), We hired GCT, due to a personal relationship as well as references, and Informed them of our aggressive timelines. GCT was able to identify 8 trial centers such that they targeted to recruit up to 30 patients in a 6-month period. The team performed pre-study visits, held the Investigators' Meeting, managed study drug supply (3 products through a central depot), helped with customs clearance, managed the site and study budgets, maintained listing asked questions, initiated and monitored sites. All processes involving regulatory approval were done by GCT personnel. We were always informed on approval status. Enrollment was started in the Ukraine in December 2008 and enrollment was stopped on March 4th, 2009. Forty screened for a final enrollment number of 18 patients. All patient's inclusion and exclusion criteria were reviewed by the medical monitor prior to enrollment. Enrollment was one of the best that any country did during a 4-month enrollment period.

Laboratory supplies for central FISH testing were managed by GCT. The study utilizes paper CRFS and a central imaging company. All data are sent to the USA. There have been no shipment issues.

The Management team and the CRAS are physicians, and the lead monitor for our breast cancer trial is an oncologist. The monitoring and the reporting of data are exceptional. The team is extremely responsive to the trial demands and always performs at an optimal level. This is a pleasant change from some of the other CROs we have worked with where the team is not quite as experienced.

My experience with GCT lends me the credibility to say that I would highly recommend them for your project. While all studies are different and enrollment rates vary due to protocol criteria, GCT has the knowledge and expertise required to conduct and manage a well-executed trial.

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