CASE STUDY

George Clinical
Science. Service. Solutions.

# George Clinical's Full-Service Offerings Aid Acute Myelogenous Leukemia Study in Elderly Patients

*George Clinical takes over study management at start of Phase II as a rescue study.*

## SITUATION

When George Clinical was called upon to enter this Acute Myelogenous Leukemia Study in Elderly Patients at the start of Phase II, the client was dealing with a non-cooperative CRO, delays in site activation and low subject recruitment and enrollment activity. The sponsor team was also experiencing high turnover. This was a small study but required George Clinical to employ a full-service approach to the problems in order to build trust, improve communications and support a smooth transition from Phase I to Phase II.

## CHALLENGES

Sponsor and George Clinical were not initially provided with documents/forms used in Phase I to support a smooth transition to Phase II. It was necessary to transition from a non-cooperative CRO who was providing no interaction with the client or with George Clinical. There were site activation delays, budget issues and insufficient subject recruitment and site engagement.

## SOLUTIONS

George Clinical immediately prepared a transition plan that was independent of former CRO support and also used our own templates as needed to build the project as new. Our Project Manager increased the frequency of communication with the sponsor lead and began increasing teamwork, building trust and establishing a routine of successful task delivery.

In order to mitigate the delays in site activation related to study treatment requirements and site budgets, George Clinical established weekly meetings with the sponsor to review study start-up activities and developed a tracker to communicate study start-up progress and roadblocks. Deadlines were clearly communicated to the sponsor in order to respond to Institutional Review Boards (IRBs) in a timely manner. Site budgets were reviewed on a streamlined basis.

In response to low recruitment and enrollment activity, George Clinical focused on site engagement, and the sponsor was invited to attend site initiation visits with clinical research associates. Weekly email blasts to sites gave updates, reminders of enrollment targets and recognition of accomplishments. Ad hoc training teams were created, and weekly principal investigator calls were instigated so that investigators could share experiences, express concerns and maintain good sponsor sharing during the study. Communication was further enhanced with a monthly newsletter that included all site metrics, highlighting of one site's principal investigator and study team and a review of shared recruitment strategies.

## RESULTS

George Clinical's comprehensive engagement in the project ensured a smooth transition between Phase I and Phase II, established trust and robust communications, streamlined budget reviews and put recruitment and enrollment back on track. With site engagement a priority, investigators were more clearly aligned with both the project objectives and with overall strategies and processes of all study sites. Order was restored to the study, timeline and budgets were organized and monitored, and morale was improved among those involved in the study.

*George Clinical brought a full-service approach to this small study with services including:*

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| Feasibility/ Site Identification | Critical Document Collection | Site Budget/ Contract Negotiations & Payment Management | Trial Master File | Project Management | Clinical Operations: Monitoring & Site Management |
| Data Management | Biostatistics | Safety/ Pharmacovigilance | Medical Monitoring | Medical Writing | Vendor Management (Safety) |

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