

CASE STUDY

Exceeding enrollment expectations in a rescue study: A phase III registrational trial in multiple myeloma

Situation

Precision for Medicine was selected by a sponsor to rescue global and US management of a phase III registrational trial in patients with relapsed, refractory multiple myeloma. This study targeted the enrollment of 780 patients at 155 sites in 20 countries. The sponsor's primary motivation for pursuing the shift to Precision from the other contract research organization was based on the sponsor's recognition that clinical research associates (CRAs) with little to no multiple myeloma experience and only minimal monitoring experience had been placed on their study. As a result of inefficiencies in operations, the study's start-up was delayed.

Focus was placed on activating study sites quickly and reengaging those sites already activated

Challenges

Precision was able to quickly transition onto this study and assess areas of risk, including

- Qualified and interested sites had delays in communication and start-up procedures, resulting in missed timelines for study activation and potential loss of interest with delayed sites
- Projected patient enrollment timelines were missed due to delays in study start-up

Solutions

- Seasoned CRAs with experience in multiple myeloma were placed on the study and were deployed to immediately interact with study sites
- Focus was placed on activating study sites quickly and reengaging those sites already activated
- Top-performing countries and sites received priority recognition and support for patient enrollment
- Detailed patient enrollment plans were implemented with sites, including
 - Personal site interactions and engagement visits to reinforce benefits of study participation, assess trial interest and motivation, and identify potential enrollment and/or study conduct issues
 - Enrollment news flashes to stimulate competition and to recognize high enrollers
 - Investigator-led caucuses for peer-to-peer dialogue and information exchanges
 - Authorship guidelines to stimulate competition and to recognize high enrollers
 - Patient advocacy initiatives

Results

As a result of Precision's experience and the clinical monitor's proactive approach to study start-up and patient enrollment activities, the enrollment goal was satisfied 1 month in advance of the originally projected completion.

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