PRECISION for medicine

CASE STUDY

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

Situation

Precision for Medicine was identified by a sponsor to rescue global and US management of a phase III registrational trial in relapsed, refractory multiple myeloma patients. 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 (CRO) was based on their 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.

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

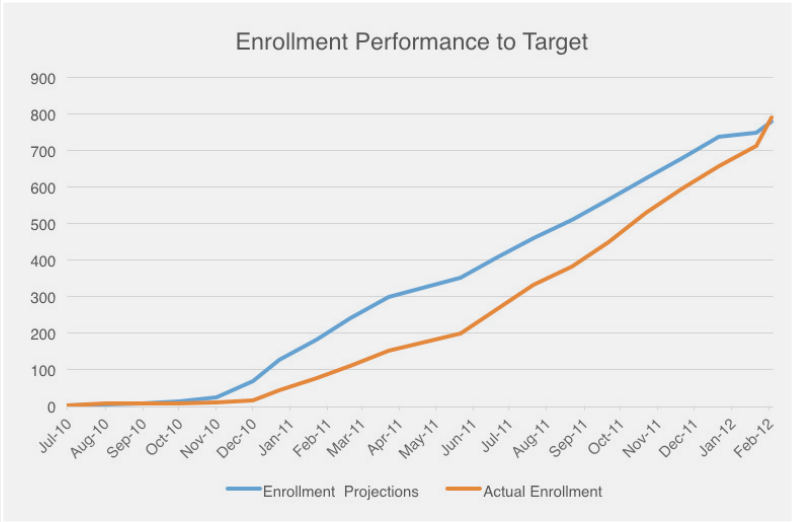
Challenges

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 missed patient enrollment timelines 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 re-engaging 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 one month in advance of the originally projected completion.

For more information about our clinical trial solutions, please contact us at info@precisionformedicine.com, or visit precisionformedicine.com.

PRECISION for medicine
shift the curve