

Innovative Approach Completed Enrollment 14 Months Ahead of Schedule on Adaptive Design Study



Challenges

The client wanted to expand enrollment and revise the study from a Phase II study with 180 patients in Protocol Amendment 2 to a Phase IIb registration study with 564 patients in Protocol Amendment 3. Due to the timing of Amendment 3 finalization just prior to planned enrollment close under Amendment 2 and the increasingly rapid enrollment, the Syneos Health™ team developed an action plan to ensure that enrollment was seamless between the two amendments.



Solution

The Syneos Health project team introduced innovative and proactive strategies to expedite approvals of Amendment 3 and keep sites engaged during the transition.

- Syneos Health collated information from all Competent Authorities (CA) and Ethics Committees (EC) to identify their interpretation of the word “approximately” in relation to the total number of enrolled subjects. The sponsor’s regulatory group concluded that 10% enrollment over the protocol designated amount would be allowed under this interpretation; therefore, a total of 198 subjects could be enrolled under Amendment 2.
- Syneos Health established a plan of action with the client ahead of the anticipated transition between the two amendments. The Syneos Health project team worked together to develop communications and trackers to obtain and provide the client with rules on the interpretation of subject enrollment numbers at a country and site level for each CA/EC. Submissions were prioritized for the countries, which would not allow recruitment to exceed 180 subjects, and then by the expected timeline to obtain approval of Amendment 3 with 564 subjects.

CASE STUDY

Area

- Hematology & Oncology

Clinical Phase

- Phase II-III

Highlights

With innovative and proactive strategies, Syneos Health ensured that enrollment was seamless during transition from a Phase II to Phase IIb study

- Syneos Health accelerated submissions to ensure that there were no delays in obtaining approval and feedback, and questions from CAs/ECs were escalated to the client immediately to provide a rapid review and response. The Syneos Health team encouraged the investigators and sites to assist on follow-up for submissions to gain a rapid approval.
- While protocol Amendment 3 was being reviewed by CAs/ECs, enrollment was closely monitored to ensure it did not exceed the current number of subjects allowed under Amendment 2. The team balanced competing priorities of keeping sites enrolling, ensuring the enrollment target was not exceeded, and maintaining study momentum and excitement.
- Potential subjects were tracked for screening and enrollment dates in order not to exceed 198 subjects. Syneos Health kept all sites aware of the subject enrollment and approval status, and followed up with sites that had received Amendment 3 approval to ensure that they enrolled their subjects under that amendment to allow for additional subjects to be enrolled under Amendment 2. Enrollment between the two amendments was seamless as well as in line with regulatory and ethical requirements, and sites kept their momentum and interest in the study.
- The first approvals of Amendment 3 were received prior to the 198th subject being enrolled, which allowed for those specific sites to enroll their subjects under Amendment 3 and thus allowed subjects at other sites to be enrolled under Amendment 2, keeping enrollment fluid.
- The final subject was enrolled under Amendment 2 in April 2014; at that time, 30 sites had approval for Amendment 3 and were continuing to enroll under that amendment.

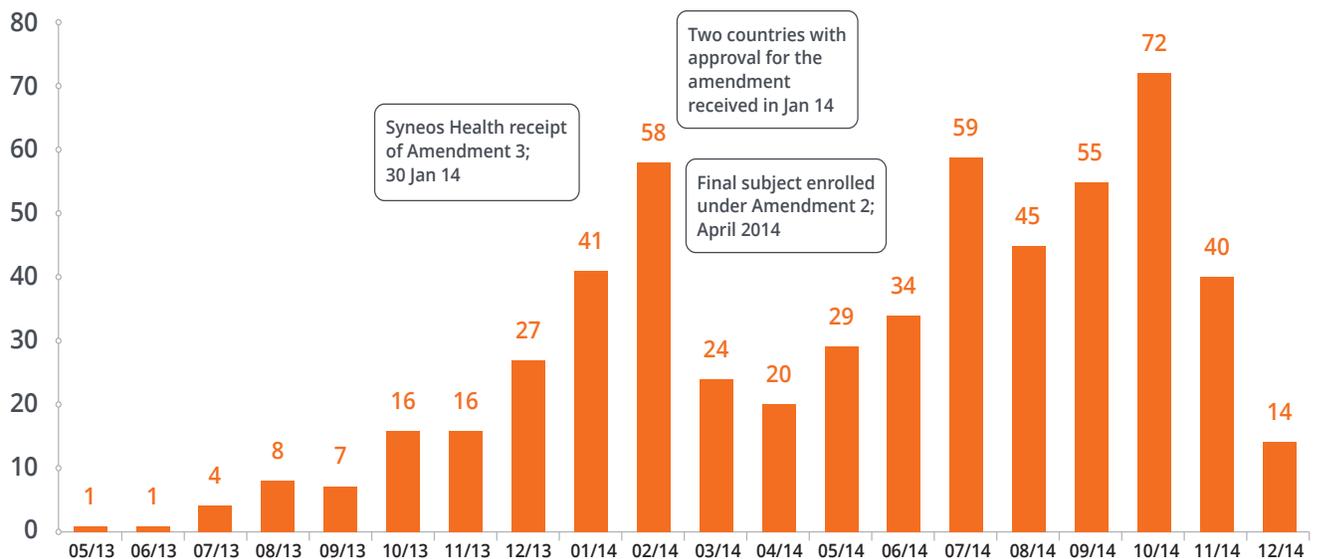
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IMPACT

- The close management of the transition resulted in rapid approvals of Amendment 3 with little to no slowdown of recruitment. Note there was a significant boost in enrollment during the months of January and February 2014 as sites learned recruitment was nearing completion for the Phase II portion of the study.
- Phase II recruitment was completed 6 months ahead of schedule and the overall study enrollment was completed 14 months ahead of schedule.

Subjects Dosed by Month



About Syneos Health

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