Phase 3 Radiopharmaceutical Study in Oncology

Achieving FDA approval in four years

Sponsor Challenges

The major challenges in global nuclear medicine trials include the complexity of regulatory requirements in each country and the necessity for experienced, highly trained sites either within close proximity to the material's manufacturing site or with the ability to provide at the site level. The investigational product in this study had a half-life of three days, necessitating diligent time management and site engagement to deliver the study on schedule.

At a glance

Radiopharmaceutical studies face a host of logistical challenges from startup through the clinical phase. A sponsor of a pivotal Phase 3 prostate cancer study investigating a radiopharm product approached PSI for support based on our experience and established network of over 400 global radiopharmaceutical sites. By working closely with our sites and vendors, PSI met or beat all critical milestones, helping our client secure FDA approval for their radiopharmaceutical product in under four years.

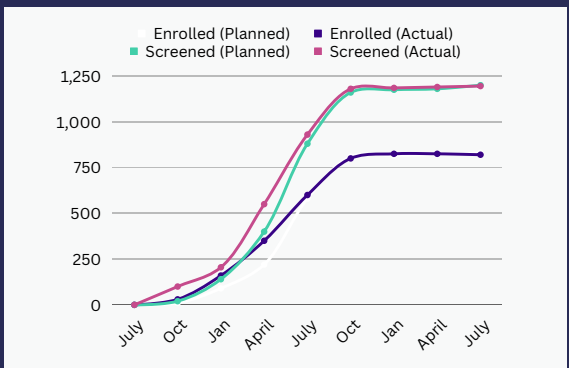
Key Metrics

1200
Screened Patients

860
Randomized Patients

10
Countries

90
Trial Sites



PSI Strategy

To make sure eligible patients didn't miss these three-day windows, PSI's CRAs encouraged sites to maintain frequently updated pre-screening logs and regularly discuss the pool of potential patients with the investigators. We also worked closely with sites and the manufacturing facilities to time the inclusion of each patient appropriately, especially around local bank holidays when a manufacturing facility would not be available.

Results

1. **Expedited Study Timelines**
   PSI met or beat all critical milestones during the study, including achieving FPI in the US in less than 3 months and completing NDA submission one month ahead of schedule.
2. **99% Enrolling Sites**
   Only one out of all initiated sites did not enroll a patient.
3. **Regulatory Approval**
   After passing three FDA inspections without major findings, PSI's regulatory experts helped our client secure FDA approval in under four years.

> "I would personally like to acknowledge and thank the entire PSI team and leadership for the dedication, perseverance and determined support that supported the early completion of the study. Your team have showcased all the capabilities and attributes of a best-in-class CRO for project delivery."

--Global Head, External Relationship Management

Contact us