propharma

CASE STUDY

Early Phase Oncology Program in Patients with Solid Tumors

Learn how our Clinical Research Solutions team is working in partnership with an emerging biotech company to successfully deliver multiple early phase global oncology programs that are meeting patient enrollment timelines.

An emerging Biotech Sponsor needed management and full-service delivery for multiple early phase oncology programs for patients with solid tumors.

ProPharma worked in partnership with the Sponsor to build a governance model, leading regular Strategic Leadership Meetings to identify and collaborate on program-level risks, financial status, important milestones, and upcoming work. To adapt to changing project priorities, we applied staffing scalability, flexing as needed within the program.

> By using a cooperative approach between ProPharma and the Sponsor, sites and Investigators have significant commitment in the study, resulting in the following:
>
> - Enrollment Rate = 0.97, above the Industry Benchmark for solid tumor trials (0.26)
> - Average time from Site Activation to First Patient Identified for 12 active sites = 13 days

Contact us to learn how our experienced team can help ensure successful outcomes throughout the product lifecycle.

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challenge

Multiple Parallel Cohort Modules:
Multiple modules enrolling simultaneously requires complex management of open cohort slots, communication regarding potential patients across sites, IP availability at sites, and accurate enrollment planning.

Managing Enrollment:
Rapid enrollment requires robust enrollment tracking and open communication with sites regarding open slots and potential patients and utilization of enrollment tracking tools, IVRS and EDC reporting.

Source Data Verification:
Rapid enrollment at a small number of sites causes a large amount of required source data verification. Our team worked with sites to allow extra monitoring allowance including co-monitoring.

Some sites requested data entry support due to staffing issues, which were obtained and provided via vendor staffing through a sister company.

solution

Team Program Allocation:
The ProPharma team, including Project Directors, Project Managers, Clinical Leads, SSU Leads and Clinical Trial associates, is fully allocated to this program and does not work on studies for other sponsors while assigned to this particular program.

This allows for knowledge accumulation and lessons learned sharing between project teams within the program without being overwhelmed by projects from multiple sponsors as is common at larger CROs.

Site Recruitment Plan:
Sites were utilized across multiple studies for familiarity. In order to not over-saturate sites with newer studies, a more geographic feasibility plan was implemented to reach out to newer sites.

Site feasibility to select sites with Solid Tumor experience, adequate staff and facilities, capacity with competing studies, appropriate testing capabilities.

Program Management:
Our team ensures consistency in study processes and plans across projects. We instituted key project indicators to track key metrics monthly.

A governance structure was established to strategically resolve issues and plan for future activities.

results

Q4 2019. Status – Enrolling
Study 1: Phase 1/2a Study of the Safety, Pharmacokinetics, Pharmacodynamics

As of the end of December 2021, 125 patients are enrolled, 10 sites are active across Canada, the Netherlands, USA, and UK.
By using a cooperative approach between ProPharma, the sponsor's Clinical Lead, and Medical Monitor to ensure site engagement, sites and Investigators have significant commitment in the study, resulting in the following:

- Enrollment Rate = 0.97, above the Industry Benchmark for solid tumor trials (0.26).
- Average time from Site Activation to First Patient Identified for 12 active sites = 13 days. The site with the longest duration was 38 days. This is extraordinary consistency and engagement across sites.

Q4 2019. Status – Enrolling
Study 2: Phase 1 Study of the Safety, Pharmacokinetics, Pharmacodynamics

- First site active and first patient enrolled in Q2 2021 as projected.
- As of the end of December 2021, 10 active patients and 8 sites are active.

Q2 2021. Status – Enrolling
Study 3: Phase 1 Study of Advanced Solid Tumors
First site active and first patient enrolled in Q3 2021 as projected.

Study 4: Phase 1 Study of Advanced Solid Tumors

- First site active and first patient screened in Q4 2021 as projected

improve the health and safety of patients.

From early concept development through each clinical phase, product launch, and commercialization, we partner with pharmaceutical, biotechnology, and medical device clients to tackle complex challenges. We help to ensure regulatory goals are met, business objectives are achieved, and patient health and safety is improved.

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