Driving Site Performance With Study Coordination Support Services

CHALLENGE

Myelofibrosis is a rare and highly complex indication, limiting the pool of eligible patients and making recruitment inherently challenging. Screening requires careful review of clinical history, lab results, and eligibility criteria, while study participation demands numerous procedures, visits, and assessments. These factors create a heavy operational and administrative burden, particularly for sites with limited resources.

At the start of the study, the site was conservatively expected to enroll only two patients, reflecting the challenges of recruitment, patient management, and maintaining compliance and safety throughout the trial.

THE RESULTS

With the support of Milestone One's Study Coordination services, **patient recruitment quadrupled**, increasing from 2 planned to 8 enrolled, with 12 expected.

Operational efficiency improved, as the site team spent less time on administrative tasks and focused more on patient care.

Data quality and timeliness increased through prompt EDC entry and rapid query resolution, supporting consistent protocol adherence.

Sponsor satisfaction was high, leading to requests to **extend support to additional sites**.

MILESTONE ONE

THE SOLUTION: MILESTONE ONE'S STUDY COORDINATION SUPPORT SERVICES

From the outset, Milestone One's team provided study coordination support services. The services were comprehensive to include:

- **Study Start-Up:** Led operational start-up at the site level, including scheduling and coordination of SIVs, oversight of protocol and study documentation roll-out, and verification that site personnel were familiar with study manuals and trial processes. Milestone One also supported the set-up of access rights to study systems, checked the availability of essential supplies, and coordinated study-specific trainings.
- **Patient Management:** Supported screening, scheduling, education, and adherence, providing hands-on assistance to patients and clinical staff during visits.
- **Operational Support:** Managed logistics, including study kits, sample collection, storage, and shipment, ensuring critical materials were handled correctly.
- **Data & Documentation:** Prioritized on-time EDC data entry and prompt query resolution, supporting high-quality, inspection-ready trial documentation, as well as managed the On-Site File, ensuring compliance of all study logs.
- **Team Enablement:** Reduced the investigator's administrative workload and coordinated communications with the CRO, allowing the site team to focus on patient care and core study activities.

This holistic support empowered the site team, streamlined workflows, and reduced stress, without the need for new tools or systems.