

CASE STUDY

Providing site support with Fortrea Mobile Clinical Services (MCS) to enhance enrollment



Many sponsors face challenges in patient recruitment, especially when multiple trials are competing for eligible patients in the same therapeutic area. This case study shares how the Mobile Clinical Services team at Fortrea helped enhance a sponsor's patient recruitment approach by providing site support services at key investigator sites.

Evaluating the sponsor's needs

A sponsor was conducting a global Phase III trial for an investigational treatment that targeted ulcerative colitis, Crohn's Disease and irritable bowel syndrome (IBS). Several of their key investigator sites were recruiting for similar studies, which threatened to impact the availability of eligible patients. The sponsor wanted to ensure that their trial was well supported at the site level to promote rapid patient recruitment and achieve on-time enrollment.

Reducing the recruitment burden for investigators

The sponsor partnered with Fortrea Mobile Clinical Services to provide site support staff at certain sites in the U.S., Bulgaria, Poland, Lithuania, Russia, Ukraine and South Korea. To ease the burden on investigators and site staff, they asked Fortrea to:

- **Support pre-screening** activities such as database review to identify potential patients or follow up with patients who had been identified in a public awareness campaign
- **Perform patient assessments** such as obtaining vital signs, performing ECGs and biologic sample collection

KEY TAKEAWAYS

How Fortrea supported patient recruitment at the site level:

- Performed routine tasks to support investigator staff across seven countries
- Reduced the sites' burden of patient enrollment
- Provided a competitive advantage for the sponsor's trial in a highly saturated therapeutic area
- Helped promote rapid patient recruitment to achieve on-time enrollment

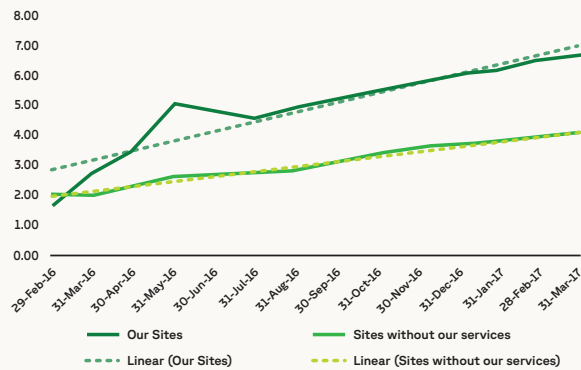
- **Coordinate shipments** by processing packaging and shipping to the central lab
- **Prepare and administer the investigational product** where the preparation was unblinded and administration was blinded
- **Provide documentation support** with data entry into EDC/eCRF and IWRS/IRT as well as query resolution

Fortrea Mobile Clinical Services then aligned their efforts across three regions (North America, Europe and Asia Pacific), providing more than 1100 instances of these on-site services over two years.

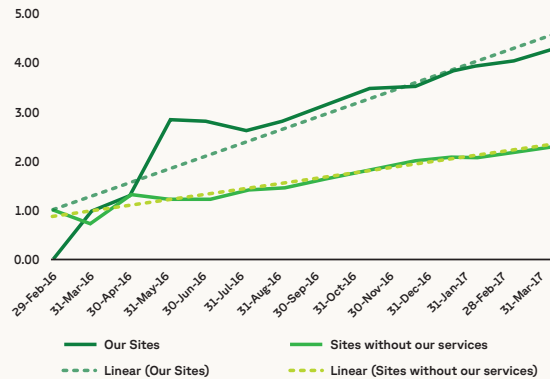
Evaluating the value of site support to promote enrollment

As the Fortrea site support staff took over a portion of sites' routine work, the sponsor found that sites preferentially enrolled patients for their study due to the availability of sponsor-paid support staff, which helped their patient recruitment efforts succeed in a competitive environment. A partnership with Fortrea Mobile Clinical Services also reduced the workload for the site, allowing site staff to increase their efficiencies as they worked with patients.

Screened



Randomized



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