

Site Management, Training and Monitoring

Services

At REGISTRAT-MAPI, we understand that Late Phase programs may require a different approach to site management and monitoring than traditional Phase II/III trials.

Our Clinical Services team is the primary interface with the site for the conduct of the study. We can employ a variety of site management and monitoring strategies depending on the design of the program and the individual requirements of the Sponsor.



Remote Site Management for Data Quality

As a cost-effective alternative to on-site monitoring, we can utilize remote site management calls to ensure quality data integrity. REGISTRAT-MAPI utilizes a unique blend of procedures and practices to perform comprehensive remote data review. Our site management personnel conduct remote visits via phone interviews with the site coordinator and address the same items as on-site monitoring, except for 100% source document verification. Similar to on-site monitoring, remote management calls may be conducted at study initiation, with interim contacts, at study close out, or for cause.

Site Management

The clinical team at REGISTRAT-MAPI is dedicated to providing the highest level of support to investigative sites. We provide a single point of contact for investigative sites to provide ongoing assistance, guidance, issue resolution, and training throughout all stages of the study. Site management personnel understand complex protocols and are experienced in site recruitment and selection, remote data quality review, essential document collection, and regulatory submissions.

Effective Site Training

Effective site training is central to the success of any program. REGISTRAT-MAPI knows and prepares for the reality that Late Phase research often requires developing relationships with research-naïve physicians. Many may require training particularly suited to their experience level. Our trainers bring years of experience catering to the unique needs of both research naïve sites as well as seasoned Investigators. To ensure the success of site training we create a comprehensive study-specific training plan that covers the protocol, and regulatory, clinical, and technological aspects of the study.

On-Site Monitoring

Our Clinical Services team can provide on-site clinical monitoring and management of investigative sites, the extent and nature of which is defined in a study-specific Monitoring Plan. On-site monitoring varies significantly, and may be performed at study initiation, at interim visits, at study close out, and for cause. Our CRAs are selected for on-site monitoring based on experience and geographic proximity to the site.

Training Methods

Our clinical team is highly skilled in training sites on study conduct using a variety of methods, including:

- Study Reference Manual and study materials
- Teleconferences
- Web casts
- One-on-one sessions
- Train-the-trainer sessions
- On-site initiation visits
- Online presentations
- Online tutorials for EDC
- Call Center support and follow-up

Clinical Monitoring Services

- Pre-study qualification visits
- Initiation, monitoring and close-out visits
- For cause, booster, and quality visits
- Site management
- Query resolution

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