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SMOs, India's Next Frontier in Clinical Research

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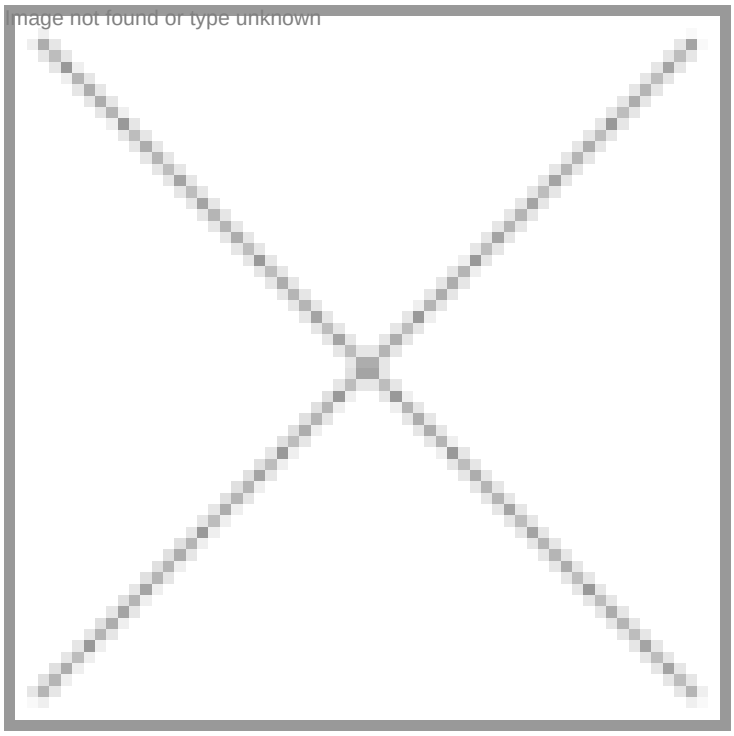

SMOs, India's Next Frontier in Clinical Research

Site Management Organizations are the new breed of service providers helping in principal investigator selection, patient recruitment and regulatory and contract management and research support for multiple sites.

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Quality assurance and timelines have always been a serious concern to the rapidly growing clinical research market in India. With India now being seen as a hub for clinical trials, the challenge is to gear up to accomplish these expected standards. The growing demand for new ICH-GCP compliant sites, qualified investigators, vast patient pool and experienced staff only adds commotion to the industry. It is under such circumstances that a new set of service providers has emerged in the clinical research market-Site Management Organizations (SMOs). These SMOs' role in meeting the sponsor's and the CRO's requirements is being greatly appreciated.

Multi-site SMOs

- SMOs play a major role in the trials offering
- Training and assisting the investigators throughout the study
- Ensuring faster recruitment of the subjects
- Assisting PI s in adhering to the protocol
- High-quality data entry
- Mounting the protocol-specific infrastructure in tim

The market share

CROs will continue to increase their share in the next five years, but the mix of non-CRO players is also a dynamic one. Though Non-CROs are many, the major chunk of the business is enjoyed by the Academic Medical Centers (AMCs). The SMOs are expanding their operations and striving to provide quality services to increase their share in the clinical research market pie.

Role of SMOs in clinical research

While CROs offer a variety of services to the sponsor such as monitoring, contract administration, study supplies shipping and receiving and data management, SMOs offer principal investigator selection, patient recruitment and regulatory and contract management and research support for multiple sites.

There are two operational models which SMOs follow--one which is confined to a single site or a therapeutic segment and the other which work on multiple sites and specialty segments.

SMOs have substantiated their contribution from training young, dynamic and inexperienced investigators with GCP guidelines and providing them an opportunity to conduct clinical trials. The investigators are relieved from time-consuming, non-clinical tasks like data entry and documentations, thus allowing them to concentrate more on the recruitment.

An advantage of working with the site and investigator in close proximity and an access to the local clinical and logistic requirements keeps them far ahead for planning and completion of an assignment. Unlike the sponsors or the CROs, they also have an access to the various hospital data at the site. This helps them in giving a proper feasibility report regarding the sites and also plan for a faster recruitment.

The SMOs keep their study staff in continuous monitoring of the study subjects to assess the SAEs and prevent a follow up loss. Often the coordinators are given patient assessment charts to monitor the symptoms by phone before the next visit is planned.

Retention of subjects, which is one of the major challenges in India, is overcome by continuous reminders and calls to the subject by the study coordinators.

Another major offering from the SMOs is providing the administrative support to the investigator. The study staff is trained with responsibilities of preparing and maintaining informed consent documents, subject case histories, assisting the investigator to conduct research in accordance with the protocol, data entry, maintaining study records, regulating disposition of the study drug/device13 and assisting in project close-out documentations thus reducing the work of a PI.

A central contract with its investigators and various sites enables the Multi site SMOs to play a vital role in bringing together the various potential sites and investigators all over the country, thus providing research support to tier-2 cities.

Multisite SMOs have the bandwidth for selecting the most appropriate investigators and sites on a study to study basis. Thus by interacting with several potential sites, they are free to select the sites according to the protocol requirements. An SMO with these attributes will be a sponsor's ideal partner to work with.

Challenges of CROs

It has not been a smooth ride for the sponsors to perform their trial related activities. While the dearth of skilled staff and trained investigators continues to be a hindrance, the ethics committee formalities remain a major challenge.

Experienced sites being limited to urban areas and with several projects already on hand, the investigators have always faced a problem with more incoming studies. It has been estimated that there are only about 1,000 experienced investigators available in the country, and there is a need for many more who understand the ICH-GCP, DCGI guidelines and the protocol specific requirements.

Some of the major issues during the study have been retention of subjects due to lack of regular follow-up, protocol adherence and the data quality. Delays in recruitment have always been a concern in meeting the stipulated timelines. Moreover the time spent on documentations and data quality by the investigators themselves with inexperienced site staff impaired and delayed several studies.

Giving the impetus

SMOs have made an enormous difference to overcome several hurdles throughout the study, reassuring the market escalation.

Both the pharma majors and CROs would greatly benefit working with SMOs for a more efficient research thus bringing an extensive cost advantage.

The much apprehensive data quality standards and time factors can be reassured further by working with these SMOs.

With over 16,000 hospitals, 500,000 doctors and 270 medical institutions, there is a major scope for these SMOs to expand their network throughout the country reaching out to the
tier-2 cities.

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