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Publication policy is a must

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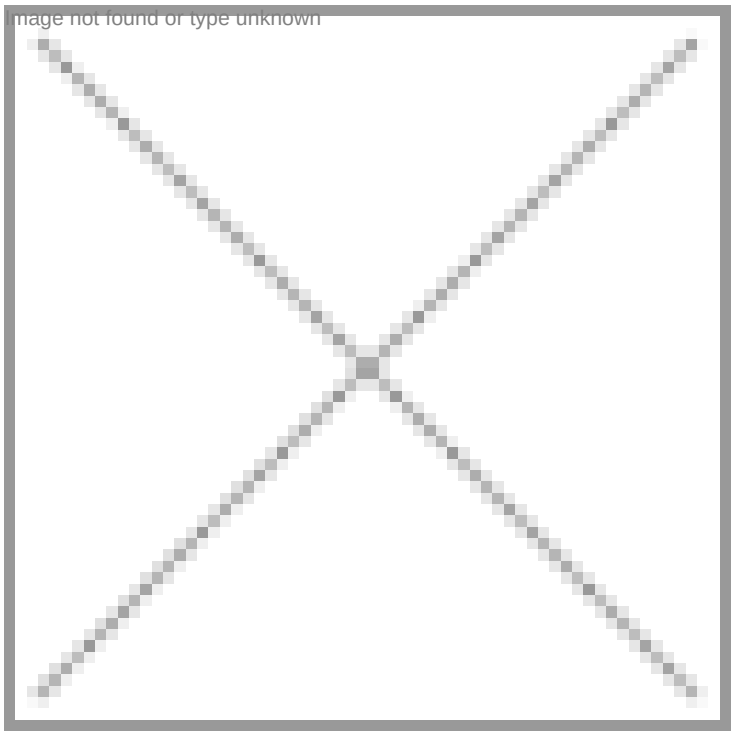

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Today, India is poised as a preferred location for conducting global clinical trials due to the inherent advantages of cost, speed and quality associated with the overall development of a drug.

India's success is evident by the sheer numbers of clinical trials happening in the country, which is projected to reach 15 percent of all global clinical trials over the next five years.

India's total clinical trials market is estimated to reac 9,347 crore ($2 billion) by 2012, and pharmaceutical companies are outsourcing much of this work to contract research organizations.

CROs are fast gaining importance because of their global presence, specialized local and therapeutic expertise, and competitive pricing strategies. A significant number of new CROs have established operations in India over the past few years, and many pharmaceutical and biotech companies are viewing CROs as strategic partners.

Though guidelines for conducting global clinical trials remains uniform (ICH-GCP guidelines), interpretation of these guidelines changes to comply with applicable regulatory requirements in a given country. These changes pose great challenges for CROs. Since a CRO customizes its operations based on a sponsor's

specific requirements, it must account for cultural and procedural differences.

There are many challenges for CROs in India:

1. Variable standard operating procedures

In the absence of uniform standard operating procedures (SOPs) across companies, various working procedures change from company to company. It becomes particularly difficult when there are different procedures required by different sponsors for CROs working with the same investigator on the same activity. For example, considering the procedure of Informed Consent Form (ICF) administration, some sponsors require only an impartial witness to sign the document, if a study subject is unable to sign by himself/herself, yet other sponsors may require a legally acceptable representative, to sign the ICF document on behalf of the study subject.

In addition, various documentation requirements for critical trial activities vary among sponsors. Requirement changes may create confusion for investigator site personnel, leading to more deviations. When questioned on variable SOPs by site personnel, CROs must base their response on the sponsor's requirements. Investigator sites often fail to understand why there is a non-uniform interpretation of so-called uniform guidelines.

2.Contractual obligations and answerability

The clinical trial agreement (CTA), which is executed between a trial sponsor and investigator site, is another element that creates difficulties for CROs. While in some cases a CRO is considered a party to the CTA, in a majority of the cases agreements are executed only between the sponsor and the site. Hence, most of the time, a CRO does not have control over contractual obligations set forth between the sponsor and trial site.

However, the CRO is held fully-accountable on contractual obligations by both sponsors and investigator sites. Whether it is schedule of payments or utilization of study/administrative grant, a CRO may be in a difficult position to maintain agreement between the sponsor and investigator site.

3. Publication policy

This area is the most common element of disagreement between investigator sites and CROs. There is no publication policy in a majority of trials. In the absence of a clearly defined policy, a CRO struggles to address this issue effectively with investigator sites. Though the authorship in a trial publication is directly linked to the contribution made by an investigator, there have been instances where Indian investigators have been excluded from providing authorship in spite of being among the highest recruiters for patients worldwide.

4. Inexperienced CROs

The growth in the clinical research industry has led to the operation of CROs that do not have a serious understanding of clinical research. Many of them are set-up for short-term gains rather than being a long-term partner in developing this sector in the country. Often these organizations do not have sufficient well-trained, qualified employees and lack the processes, systems and infrastructure to conduct quality global trials.

5. Development of new investigator sites

Sponsors often prefer to work with investigator sites that can devote time to its study and that are not already participating in too many clinical trials. With the sudden rise in the number of clinical trials being conducted in India, most trained investigator sites have been saturated with multiple studies, which are creating quality issues.

CROs, like sponsors, want to work with sites that have prior clinical trial experience. It is a challenge for CROs to identify trained sites that are not currently participating in many studies.

As an alternative, CROs need to identify new investigator sites and train staff on international guidelines and procedures to ensure quality in conducting clinical trials. Scaling of new investigator sites toward global clinical research, requires investment of additional time and efforts by the CROs. India continues to be a competitive place for conducting trials and to ensure that quality training takes place, CROs need to assume additional investments at their own cost.

6. Archival of study documents

After the completion of a clinical trial, there is a requirement for archiving study documents for a specified period of time. This time frame varies from 10 to 20 years across the industry.

Since CROs often approach investigator sites on behalf of multiple sponsors, they are under pressure to provide the archival facility/space. This issue may lead to delays in initiating new trials, therefore CROs must often work out alternate archival arrangements for the trial sites, at their own cost.

7. Attrition rate and trained staff

High turnover rates in the rapidly growing Indian clinical research industry are posing a challenge for CROs. To retain

employees, CROs must offer competitive compensation packages while ensuring projects are properly resourced. Currently, there is a shortage of approximately 50,000 trained personnel in India's clinical research industry.

A key success factor of any clinical trial depends on how well an investigator has assumed his/her role, therefore, it is important that other sponsors and CROs develop a consistent and collaborative working environment with investigators. Whether it requires bringing harmony in operating procedures, or a uniform interpretation of regulatory guidelines; initiatives taken by sponsors and CROs will go a long way to ensure the successful execution of global clinical trials in India.
Recent initiatives led by the Drug Information Association aim to bring uniformity in the taxonomy of trial files to the industry for uniform documentation practices.

Some of the sites have started electronic archival of study documents, but validation of the archival process as per CFR Part 11 is still a challenge. The Drug Controller General of India has taken some initiatives like CRO registration, that is still in draft stage. A similar initiative for bringing uniformity in working procedures seems warranted.

For India to remain a key to the global clinical trials market, pharmaceutical companies, CROs and investigator sites need to work together closely, to address these challenges, which will bring greater quality and efficiency to conducting global research in the country.