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Local CROs and their challenges

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Singapore: Monitoring a clinical study is an important challenge faced by local as well as global CRO where the sponsor company spends majority of their budget and energy. Global CROs develop and implement services such as data management, data analysis or central laboratory for their global projects in hundreds of sites all over the world. Though global CRO's have the budget to develop information technology solutions to overcome these challenges, local CROs are often short of resources to develop their own solution.

Besides monitoring, local CROs face host of challenges such as inexperienced senior Clinical Research Associates (CRAs), attrition of manpower, low service fees by sponsors, and continuous competition with global CROs.

A local CRO, with his intelligent and experience can sail successfully in resource restrained developing countries and add its experience as an advantage.

Firstly, to provide a full range of services, local CROs can outsource the services to develop protocol and through consultation build the clinical trial strategy, perform study start-up including Ethics Committee (EC) submission and Import/Export License application, provide clinical monitoring, closing the study sites, perform data management on paper or electronic Case Report Form (eCRF), statistical analysis, clinical study report writing as well as support the publication.

By providing full service, local CROs can attract more local projects or corporate with other local CROs in different countries in the same or different regions, to share the market for regional studies with other global or regional CROs. Also they can save cost significantly, especially for data management because software developed by local IT talents still can fulfill the technical and clinical requirements of ICH-GCP (International Conference on Harmonization of technical requirements for registration of pharmaceuticals for human use - Good Clinical Practice) with more reasonable fees. In certain situations, these software/programs can be built up on a more economic database than if they have to pay for global vendors in this field such as Oracle or IMPACT.

Secondly, with regards to the relatively low professional fee that local CROs can receive from their clients compared to regional or global CROs, the local CROs can win more relatively small or not so complex projects from some big pharmaceutical companies than other global or regional CROs.

One of the reasons is that the global/regional CROs may not alter or customize the structure because of a small project. However, with the number of these small projects increasing, local CROs can recruit more CRAs and later, with their more experienced CRAs, they can win bigger projects and/or outsourcing these experienced/senior CRAs. For a country like Vietnam, with large patient pool and potential to grow in clinical trial industry, requests from foreign countries to conduct the clinical trials in Vietnam in order to accelerate the recruitment as well as lower the hospital and patient fee. Especially India, where regulatory structure is not transparent and approval time could stretch upto 12 months.

Last but not least, the most challenging is the quality standard that local CROs have to achieve amid all the challenges as all CROs, global or local, have to achieve quality standards of ICH-GCP.