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Challenges of monitoring and quality managment of clinical trials in Asia

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Monitors often face site challenges with respect to performance issues, and other clinical study conduct issues. Additionally, monitors may routinely be seen as the police of the clinical trials process instead of a part of the trial team due to their necessary but often off-putting rigidity and curtness when presenting findings or recommendations. By doing this both monitors and sites lose multiple opportunities to implement quality managment (ICH-GCP R2), to identify root causes of errors, analysis and corrective action plans. As Regulatory agencies are advocating sponsors to take risk-based approaches in various clinical trial related activities especially in the area of monitoring. Now it is mandatory to build beneficial relationships that will help decrease errors, improve performance, and create a more proactive dynamic between site staff and monitors. Further sponsors are looking at and beginning to use "centralized monitoring" along with onsite monitoring to enhance data quality on clinical trials. Remote monitoring is no longer a futuristic idea, it is a current necessity. Most research studies use electronic data capture/remote data capture systems now instead of the paper case report forms. With many electronic medical record systems, sponsors now have the ability to monitor studies remotely. However this is still not the case for many Asian sites. The challanges will be discussed with presentation of case study.

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