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Effective monitoring plan in clinical trial process

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Clinical trial monitoring is defined by the International Conference on Harmonisation of Good Clinical Practice (ICH GCP) as 'the act of overseeing the progress of a clinical trial and of ensuring that it is conducted, recorded and reported in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP) and the applicable regulatory requirements. Main goal of clinical trial monitoring is to ensure 100% source data verification to avoid errors like protocol violation and safety. Outcome of clinical trial depend upon the gathered data from clinical trial sites and that too again reflect the quality documents retrieved. To minimize errors in clinical trial monitoring process various 'hybrid methods' have been developed and some of them endorsed by regulatory governing body. Some of advanced adopted methods include (1) Central Monitoring (2) On-site monitoring (3) Targeted SDV (4) Remote Monitoring (5) Risk base Monitoring or SDV. Central monitoring process is cost effective, convenient and reduces the need of site visit every time. Central monitoring approach allows monitoring of all clinical trial sites at a time on real time basis. Onsite monitoring (OSM) is conventional method for clinical trial monitoring process which allows trial monitor/representative/CRA to perform SDV on trial site. OSM approach is effective where all prospects including trial process documentation at site will be rectify; although OSM is time consuming process. Targeted SDV comprises of fixed field approach or random field approach; where SDV of high risk data will be done. This method will give complete SDV of high risk data. Remote monitoring includes remote access to patient electronic medical records (eMRs) for SDV which make limited resource allocation and cost effective. Risk-based monitoring approach focuses on the high risk data points i.e., data points which are prone to mistakes or difference in interpretation or transcription and which have a high impact on the quality of the data and the outcome of the study. In addition to the specific study details, several other factors are kept into account while formulating a risk-based monitoring plan including the data quality from similar studies, experience level of site in handling such studies. At consensus, by establishing quality management process in clinical trial monitoring, the possible errors in monitoring process should be rectified and 'error free' data generation will be possible. Various operational aspects such as process monitoring, task monitoring, resource monitoring and product monitoring will be helpful to minimise error and strengthen the vigilance over trial progress and outcome. By looking towards present scenario of monitoring methods adopted in the field of clinical trials; it is worth for industries to adopt "hybrid approach" of clinical trial monitoring (integrated by existing system) which is more convenient, reduce total cost and ensure 100% SDV along with data integrity.

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Cluster randomized trial of WHO option A vs. B in prevention of mother to child transmission of HIV

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Vertical transmission of HIV remains an important public health problem in Sub-Saharan Africa. The World Health Organization's Option A and Option B regimens for preventing vertical HIV transmission have been shown to be of similar efficacy. However, there is little evidence on their comparative cost, effectiveness, feasibility and acceptability when actually implemented in public sector programs in Sub-Saharan Africa. This study aimed to determine the effectiveness, cost-effectiveness, acceptability, and feasibility of the World Health Organization's Option A versus B, when implemented in the Tanzanian public healthcare system and was implemented between July 2012 and April 2014. This study was a cluster-randomized controlled trial design set in Dar es Salaam. In which sites within 60 wards were randomly allocated to receiving either Option A or B. Key outcome indicators include the proportion of infants born to HIV-infected mothers who have acquired HIV. A total of 3772 and 5214 women were enrolled in option B and Option A respectively. After the follow up period a total 1546 and 2626 HIV exposed Infants in Option A and B respectively, were eligible and had confirmatory HIV test done. There was no significant difference in the 18 months transmission rate, which was found to be 3.4 and 3.0 percent in option A and Option B arms respectively (P-Value 0.07). In conclusion, virtual elimination of Mother to Child Transmission of HIV is possible with Option A and Option B if well implemented.

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