



Pharmacovigilance for Decentralized Clinical Trials: Challenges and Way Forward

Dr. Parul Singla – Sr. Director, PV Operations



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Decentralised clinical trials make clinical trials easier for patients by reducing the need to travel to clinical sites. They are also known as “Direct-to-participant trials” or “virtual” studies.

DCTs are highly technology driven that often require the use of the following:



Telemedicine, wearable medical devices, Visits to patient’s homes



Virtual health care interfaces



Direct delivery of study drugs and materials to patient’s homes

Depending upon the clinical trial design and practicality, DCTs may be:



Fully centralized



Hybrid



Fully decentralized

Challenges posed by multiple data systems and processing teams

- ❁ Challenges in consolidation of data at the time of document preparation.
- ❁ Reconciliation of data can potentially take longer.
- ❁ Submission delays.
- ❁ Inspections & Audits become more complex.
- ❁ Vendor management is complex and more expensive.
- ❁ Partner Notifications/Exchange of Information, additional tracked activities.

Requirements of the Centralized Safety System

A Centralized Safety System requires the following key elements to cater to the challenging requirements of ensuring prompt monitoring of safety:

- ✿ Technical Agreement
- ✿ Safety Management Plans
- ✿ Central SOPs with Work Instructions
- ✿ Site Communication Protocol
- ✿ Safety Database + Processes
- ✿ Compliance and Governance
- ✿ Validated Safety Database System
- ✿ EDC <> Safety Data Exchange
- ✿ Secure Notifications to Sites
- ✿ Follow Ups and Site Queries Tracking Tools
- ✿ Literature Management Tools
- ✿ Signal and Trending Tools, Volume Dependent
- ✿ AI Based Tools to process large volumes of data
- ✿ Data Migration Tools to support product transfers, etc.

Author



Dr. Parul Singla – Sr. Director, PV Operations

Parul is an M.D. in Pharmacology with over 15 years of experience in pharmacovigilance and clinical research. He has managed the expectations of multiple clients on quality and compliance for complex analytical work in medical safety such as signal management, risk management, aggregate report preparation, and on the immediate impact case management functions. He has participated in over 10 regulatory inspections with successful outcomes. Parul has experience across pre and post-marketing pharmacovigilance including signal management, aggregate report, ICSR case processing, SAE/ SUSAR processing and reporting, analysis of similar events, safety management plans, SAE reconciliation plan, etc. In his previous role, he headed the pharmacovigilance department of a global pharmaceutical company where he successfully accomplished global harmonization of the pharmacovigilance function to create a Centre of Excellence.

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