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Pharmacovigilance for Decentralized Clinical Trials:
Challenges and Way Forward

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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

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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.

About Soterius

Soterius is a strong team of pharma professionals who design customized, innovative, and cost-efficient processes for clinical safety, pharmacovigilance, and medical affairs. Our deep industry knowledge and up to date insights let us combine agile, people powered intelligence in pioneering customer centric solutions. Our innovative technology solutions include engagement tools and communications platforms to create a unified and compliant medical access facility. With a strong global presence, we provide comprehensive clinical and post marketed safety services, that include aggregate report writing, signal detection and management, global literature surveillance, risk management, case processing and regulatory reporting. We use state-of-the-art technologies to solve complex safety operations problems, be it case processing, intake, site reporting for clinical trials, or literature search and management. We have one of the most accurate solutions for case intake and case processing using AI.

We support companies from the initial development stage of a drug/vaccine to the approval and ultimate marketing of the therapy, supporting ongoing operations and regulatory commitments globally.