Data & Digital

PPD Monitoring Application (MApp)

A flexible technical solution for subject data sampling activities

The clinical trial landscape is continuously evolving, presenting new opportunities to enhance monitoring methodologies. While there is no universal industry standard for subject data sampling methodologies or targets, this opens the door for innovative solutions that enable flexible approaches to support targeted risk-based strategies while improving efficiency.

Traditional SDV approaches have demonstrated limited impact on improving data quality, reinforcing the need for advanced solutions that adjust to risks and shift monitoring activities to the things that matter. As the industry shifts from pure transcription checking via SDV to a greater focus on source data review, technology enhancements – along with sampling and tracking of targeted monitoring activities – are needed to streamline processes and enhance oversight.

Our proprietary Monitoring Application (MApp) is designed to support clinical trial monitoring by offering a highly flexible, scalable and system-agnostic approach. MApp empowers sponsors and monitoring teams to efficiently manage SDV and SDR activities while ensuring data integrity and regulatory adherence.

Industry barriers leave clinical trial teams without a clear methodology

Limited impact of SDV

SDV alone has not demonstrated meaningful improvements in data quality as a monitoring measure.

Lack of industry standards

There is no consensus or standardization for SDV/SDR approaches within the industry.

Limited impact of SDV

Guidance from authorities such as the FDA remains vague, emphasizing targeted risk management but offering little direction on specific methods.

Limited impact of SDV

The manual effort required to track sampling activities, particularly for source data review, creates inefficiencies and compliance risks.

We have developed a streamlined and adaptable sampling solution to tackle these challenges effectively: a system-agnostic platform capable of seamlessly consuming both EDC and non-EDC data sources. This flexibility allows the solution to accommodate the varied needs of modern clinical trials, ensuring it remains versatile and untethered to specific systems or methodologies.

MApp offers support for multiple levels of sampling, including subjects, visits and forms (pages), enabling a tailored approach to meet trial-specific demands. Additionally, dynamic adjustments to target percentages are supported, allowing the sampling strategy to adapt as study requirements evolve.

Break through barriers with MApp

MApp is a cutting-edge tool that enables flexible approaches to SDV and SDR sampling while seamlessly consuming both EDC and non-EDC data sources.

Key Features

- **System-Agnostic Flexibility:**
  - Supports sampling at study, country and site levels.
  - Allows sampling for specific forms, visits or subjects.
- **SDR-Only Sampling:**
  - Offers the ability to sample for SDR independently of SDV.
- **Consumes EDC and non-EDC data sources:**
  - Compatible with multiple EDC systems (e.g., RAVE, Veeva) and non-EDC data sources (vendor data, labs, imaging, digital data).
- **Random Sampling Algorithm:**
  - Utilizes simple random sampling to assign monitoring requirements, ensuring systematic selection.
- **Dynamic Updates:**
  - Automatically updates database modifications, marking visits/pages as “No Longer Expected.”

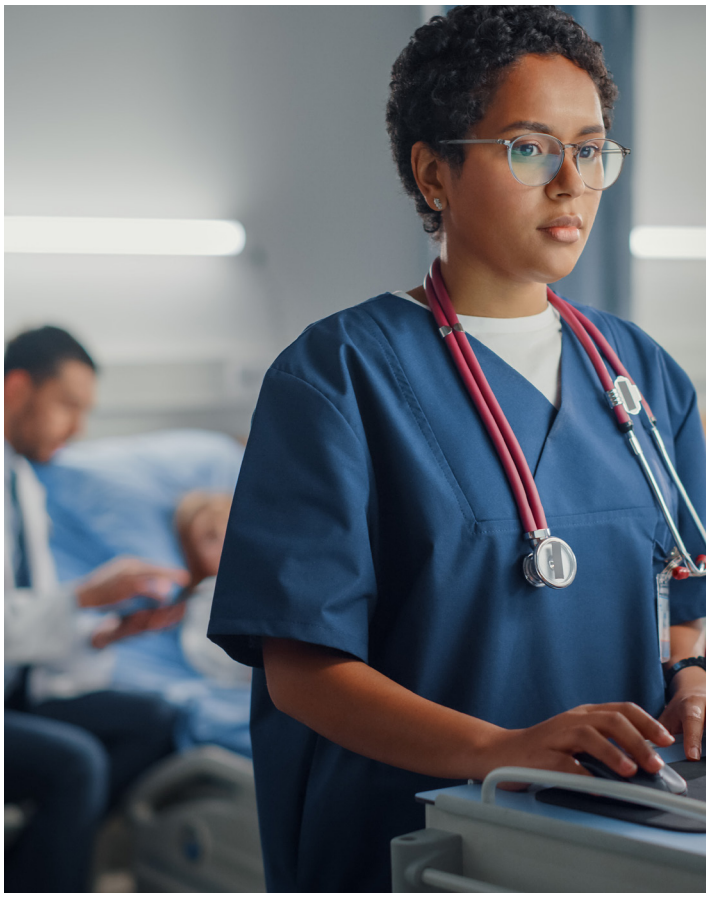
Operational Benefits

- **Enhanced Efficiency:**
  - Eliminates the need for manual trackers and logs for SDR activities.
  - Streamlines monitoring strategies through data-driven decision-making.
- **Improved Compliance:**
  - Enables clear documentation of SDR activities and monitoring plans.
  - Tracks re-monitoring activities when requested by sponsors.

Addressing the industry gap

In the absence of clear industry standards or regulatory directives, MApp provides a much-needed structured and flexible solution. Its ability to integrate with diverse data systems and adapt to evolving study needs positions it as a leader in advancing SDV and SDR methodologies. By enabling systematic sampling and reducing manual effort, MApp aligns with the growing industry demand for efficiency and scalability.

MApp redefines monitoring strategies by addressing the core challenges of SDV and SDR methodologies. Its innovative features empower clinical trial teams to implement flexible, efficient and compliant sampling approaches, ultimately driving better data quality and operational success.



Contact us to learn more about MApp, visit us at **ppd.com/digital**