medidata

12/2013 WHITE PAPER

Why Monitoring Is More Than Just SDV

The Proof Is in the Pudding

If...

1. The 2011 FDA draft guidance and the EMA reflection paper encourage a risk-based monitoring approach;
2. The Clinical Trials Transformation Initiative (CTTI) advocates that the clinical research industry build Quality by Design (QbD) into clinical trials, recommending a monitoring approach that rapidly detects and corrects issues while the study is ongoing with a goal of fit-for-purpose data, not error-free data;
3. Data analytics from the Medidata Clinical Cloud™—representing thousands of clinical trials across the globe over the past five years—show that less than three percent of all case report form (CRF) data is actually ever changed due to post-data capture monitoring and data cleaning; and
4. The recent TransCelerate BioPharma position paper on risk-based monitoring methodologies observes that the "rate of SDV-only discrepancies in Critical Data was 2.4%, suggesting that SDV has a negligible effect on data quality;"

Then...

Sending armies of site monitors out to conduct 100 percent source document verification (SDV) at every investigative site is not the answer for ensuring data quality, nor is it an efficient use of resources. Furthermore, clinical monitoring entails much more than just SDV. It comprises:

- Training, e.g. protocol, good clinical practice (GCP), electronic data capture (EDC) and electronic CRF (eCRF) completion guidelines
- Informed consent review
- Review for adherence to GCP
- Review for data consistency
- Site relationship building
- Drug accountability
- Investigator file review
- Review for fraud/misconduct

Sending armies of site monitors out to conduct 100 percent SDV at every investigative site is not the answer for ensuring data quality, nor is it an efficient use of resources.

Because many of these tasks occur during SDV, we tend to lump them with SDV; however, we don't have to perform 100 percent SDV to do them effectively. Thus, it's time to shift our focus. TransCelerate's recommendations follow the industry-pioneering thinking Medidata has seen in our most cutting-edge customers:

TransCelerate-Identified Issue	Solution
Building QbD into Trials	**Benchmarked Protocol Design** – Medidata Designer® has shown that more efficient and effective protocol design—built with guidance from industry benchmarks—can reduce trial costs by up to 25 percent, reduce risk by lowering protocol complexity and greatly enhance the experience of the subject who is exposed to a potentially reduced number of invasive procedures.
Early and Ongoing Risk Assessment	**Facilitated Review** – Medidata Designer supports facilitated protocol review by linking the schedule of assessments to benchmark data on frequency and cost for individual procedures. Other risk assessment and management tools, such as Medidata's leading business analytics solution Medidata Insights™, can be used to benchmark enrollment and data cleaning rates by therapeutic area and help to forecast resource allocation at the portfolio level.
Focus on Critical Processes and Critical Data	**Linking Protocol Endpoints to Critical Activities** – Medidata Designer provides "line of sight" by linking protocol endpoints to procedures and visits.
Use of Risk Indicators and Thresholds	**Key Performance Indicators** – Medidata's site quality management solution, Medidata SQM, allows for centralized, remote monitoring of site performance in real time. The solution is linked to EDC for all sites within a single study in a single dashboard and utilizes Medidata CTMS™, Medidata's clinical trial management system, for structured monitoring and site interaction reporting.
Adjustment of Monitoring Activities Based on the Issues and Risks Identified Throughout the Study	**Dynamic Monitoring** – Combining Medidata's targeted SDV solution (Medidata Rave® Targeted SDV) with SQM allows for adaptive, real-time modification of SDV plans right in the EDC system in response to study and site performance. **Workload Reduction** – Medidata CTMS pulls eCRF and other EDC data into structured visit reports, which reduces the clinical research associate (CRA) workload and improves the documentation quality. And with offline access to the monitoring tool, CRAs can still be productive during travel or at a site without access to the Internet.

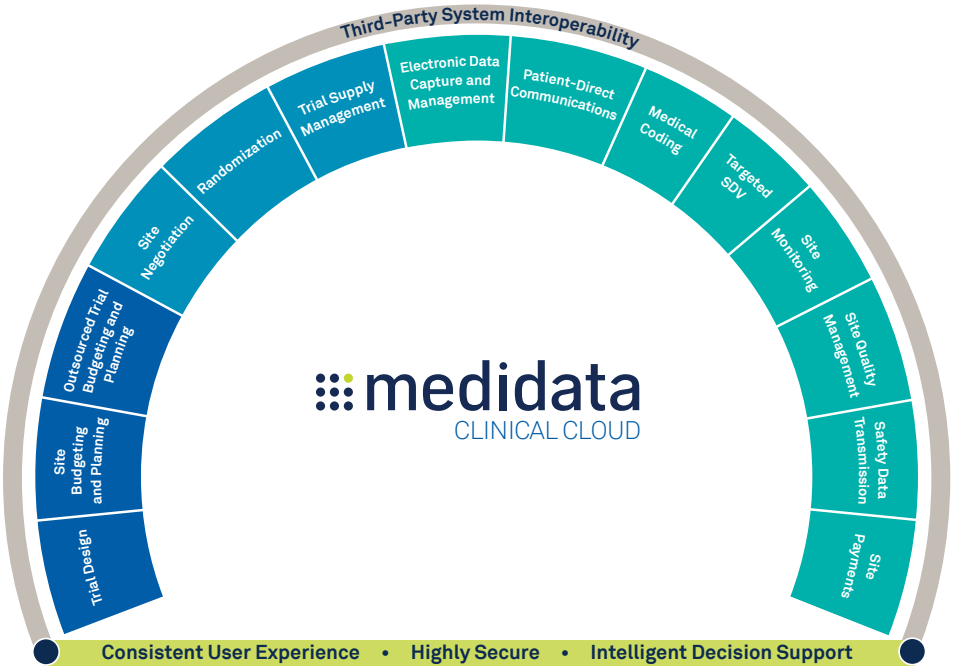
The Power of the Cloud—Leveraging the Medidata Clinical Cloud

In order to truly reap the benefits of TransCelerate's promise, whether across the entire enterprise or within a single study, clinical development organizations will need to put in place both the process change and technology enablers— not only to reduce SDV and implement centralized and off-site monitoring, but also to implement a holistic and unified solution. The right solution encompasses study design and protocol development through site engagement and study start-up to data collection, management and study closeout, supported by a single, transparent source of truth. It's this unified approach—enabled by cloud technology, where all data is available all the time to all the right people—that will ultimately lead to better therapeutics in the hands of patients faster and at a lower cost.

The Medidata Clinical Cloud is the industry-leading platform for planning, setting up and executing clinical trials in the cloud. It streamlines clinical research with a seamless platform of technologies, lowering costs, minimizing risk and shortening timelines with innovative capabilities to support key clinical research processes:

- Study design and protocol development
- Budgeting and planning
- Site negotiation
- Patient randomization
- Trial supply management
- Medical coding
- Data capture and management
- Patient reported outcomes
- Risk-based monitoring and site quality management
- Safety data capture
- Operational trial management
- Business analytics

From study design to study conclusion, the **Medidata Clinical Cloud is Driving the Future of Clinical Research** in order to fully realize TransCelerate's promise.



About Medidata

Medidata Solutions is the leading global provider of cloud-based solutions for clinical research in life sciences, transforming clinical development through its advanced applications and intelligent data analytics. The Medidata Clinical Cloud™ brings new levels of productivity and quality to the clinical testing of promising medical treatments, from study design and planning through execution, management and reporting. We are committed to advancing the competitive and scientific goals of global customers, which include over 90% of the top 25 global pharmaceutical companies; innovative biotech, diagnostic and device firms; leading academic medical centers; and contract research organizations.

info@mdsol.com | mdsol.com
+1 866 515 6044