

Analytical Risk-Based Monitoring (ARBM): From Targeted to Zero Source Data Verification (SDV) – are teams ready for the revolution?

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Evolution of SDV and SDR

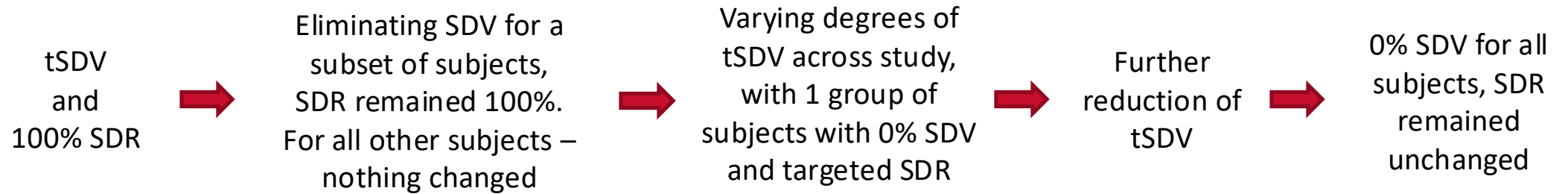


SDV and SDR processes in clinical trials



Case study

- SDR/SDV processes strategically adapted to align with changing study dynamics



Why consider SDV shut off

- Low risk to subject safety and data quality as substantial amount of data available.
- Learning curve of sites and study team awareness on risks lowers the risk of entering data wrong.
- Oversight tools in place supports data quality oversight.
- Shifting focus from SD Verification to SD Review: reduction in time spent on SDV to allow CRAs to focus on data quality and site processes over data transcription errors, allowing CRAs to focus on most critical tasks.

Data quality verification after tSDV shut off?

- CRA support: allows CRAs to be more flexible and focus on critical issues.
- Central team support: various systems and roles oversee critical data to assure data quality and subject safety.
- Enhanced data analytics provides insight and oversight of errors and systemic issues across the trial and support CRAs with remote activities/ MV preparations.
- Trainings for CRAs to ensure focus on continuous data review.



Lessons learned for teams monitoring “No SDV” trials

Teams should:

- conduct SDR during monitoring visits on critical data points and site processes where risk flags are identified, including opening EDC to make sure data is in the system.
- communicate with sites frequently in between monitoring visits to keep them up to date on study information and updates, and to provide EDC metrics reports.



Lessons learned for teams monitoring “No SDV” trials

Recommendations:



Train CRAs on changes to SDV/SDR approach, including after SDV switch off that EDC is still expected to be opened as part of SDR review requirements.



Include guidance in CRA on-site monitoring guidelines for CRAs on SDR activities, including details on forms expected to be SDRd.



Have a robust central monitoring process in place that includes a multi-pronged, cross-functional approach to holistic monitoring of all trial data.

Thank you

If you have more questions, please contact:
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