Innovative Clinical Development Solutions

SDV: What is it good for? Absolutely nothing?

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SDV vs SDR

- Source Document Verification
- Source Data Review

Source Document Verification (SDV)

- The process by which the information reported by an investigator is compared with the source records or original records to ensure that it is complete, accurate and valid.

Source Document Verification (SDV)

- Some suggest that SDV is intended to mean the simplest form of transcription checking.
- The goal is to simply ensure that what is in the eCRF matches what is in the patient source.

Source Data Review (SDR)

- A review of source documentation to check quality of source, review protocol compliance, ensure critical processes and source documentation are adequate.

Most Common Inspection Findings

Audit/Inspection: Systematic and independent examination and evaluation to determine whether processes, events, and results comply with planned actions and/or requirements and whether the actions have been implemented effectively and are suitable to achieve the protocol objectives.

- Non-adherence to protocol
- Incomplete Informed Consent
- Poor drug accountability
- IRB not informed of protocol changes
- Unapproved concomitant therapy
- Records not available
- Sub-investigators/personnel not listed
- Inappropriate follow up on AEs
- Submission of false information

SDR and SDV should not be thought of as completely exclusive of each other

- SDV should be thought of as more than simply a blind consistency check between source and eCRF
- It should also check that eCRF and source together meet various protocol and clinical expectations.

SDR and SDV should not be thought of as completely exclusive of each other

- The “consensus on the level of SDR and SDV” and “working smarter” should be based on a robust risk assessment:
  - Utilization of *Quality by Design* should reduce some risks up front (i.e. updating protocol prior to finalization).
  - Those risks that cannot be removed should form the basis of the monitoring strategy (i.e. the level of SDV/SDR on your critical data/processes).
  - Define other types of monitoring activities: centralized monitoring (which includes data cleaning), medical monitoring, and Key Risk Indicator (KRI) review

100% SDV

- There is no evidence that improves data quality.
- FDA & ICH regulations do not require monitors to check every source data point at each and every investigative site.
  - It is Costly and time-consuming and diverts attention and resources from more critical clinical trial activities.
  - Main driver in industry is now the ICH E6 (R2) addendum.
- ICH 5.18.3 allows for flexibility in monitoring approach...a combination of onsite, off site and centralized monitoring.
  - In fact, it allows in some circumstances the use of centralized monitoring alone

Enough with 100% SDV

- Focus is on quality
- Working “smarter” and defining “accurate enough” is the core of this.
  - Reduced SDV so that CRAs can focus upon site monitoring activities that cannot be checked remotely – such as review of training records, review of subject records, calibration of equipment, compliance with GCP, investigator oversight etc.
  - Anything that can be reviewed from the data should be done centrally and in near real-time.

Risk Assessment

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Risk Assessment Tool(s)

- @RACT tool is from Transcelerate but others are available, or can be modified.

  https://ract.rbm.cloud/dashboard

- For ICH E6 (R2) must demonstrate that you have
  - Identified critical data and processes and
  - Performed a risk assessment.

Risk Assessment Tool(s)

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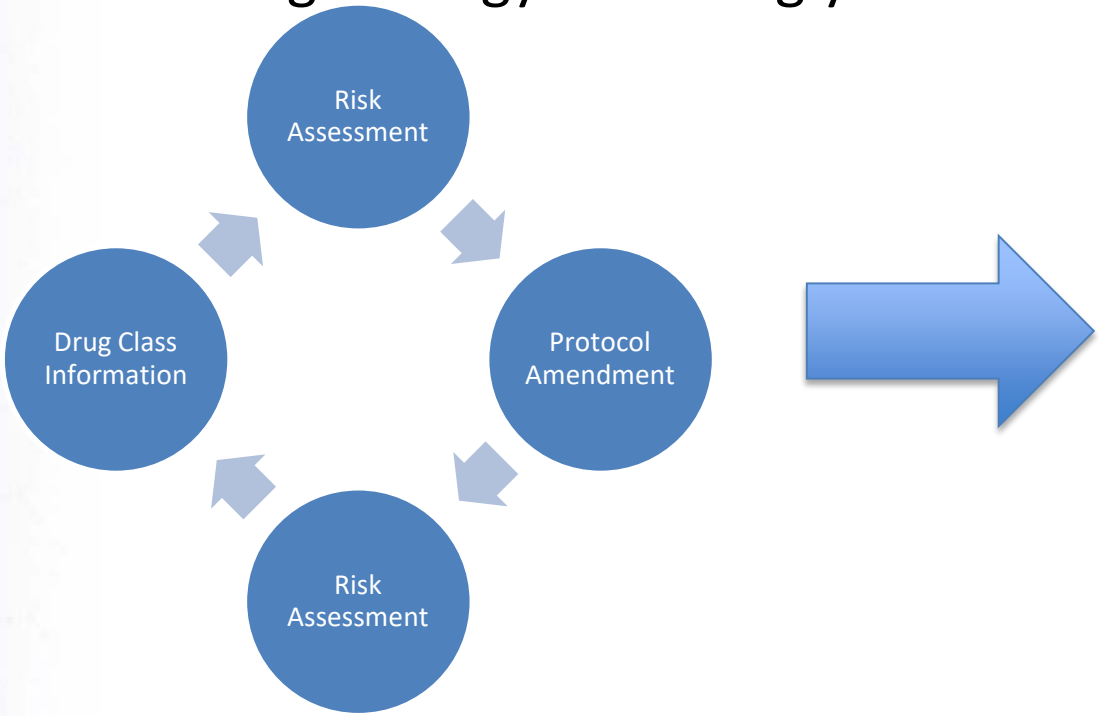
  ht[illegible]d/dashboard

- *"TransCelerate BioPharma Inc. is a non-profit organization with a mission to collaborate across the biopharmaceutical research and development community to identify, prioritize, design and facilitate the implementation of solutions to drive efficient, effective and high-quality delivery of new medicines, improving the health of people around the world."* - http://www.transceleratebiopharmainc.com/

Risk Management is Cyclical

Do as many risk assessments as necessary and adjust monitoring strategy accordingly



Over all monitoring strategy

Targeted SDV

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Targeted SDV Workflow

Targeted SDV Design	Assign Subjects	Perform and Track SDV	Review Site Quality	Adjust SDV Plan
• Configure block plan • Subject exclusion rule • Estimated SDV ratio • Plan activation	• Embedded statistical algorithm controls SDV coverage at desired levels, assigning patients as they are enrolled.	• Site visit planning • Data fields verification • Study and site SDV progress	• # and type of SDV issues • Remedy actions for 'identified' sites	• New plan creation • Additional SDV block • Subject SDV override

medidata
THE ARCHITECTURE OF HOPE™

Targeted SDV

- Need a way to easily assign and track monitoring assignments
- Should be able to increase and decrease these assignments based upon site risk
  - Identified at site qualifications/ initiations and ongoing through centralized monitoring and other observations
- Risk does not mean a site is performing poorly
  - Only an indication that something is more likely to happen
- SDR should be assigned and tracked in the same way as SDV

Questions?

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