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ASSOCIATION OF CLINICAL RESEARCH ORGANIZATIONS

GCP StEM

Source Data Review / Verification

Monday 15 March 2021

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ICH GCP and SDR/SDV

- ICH E6R2 refers to source data, source documents and availability for review; **not** to the differences between;
  - Source Data **Review**
  - Source Data **Verification**

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Remote Reduced SDR

- Reduced Source Data Review (SDR)
  - Source Data Review (SDR) (sometimes referred to as "Source Document Review") is review of source documentation to check quality of source, review protocol compliance, ensure the critical processes and source documentation are adequate (e.g. ALCOA-C: Accurate, Legible, Contemporaneous, Original, Attributable, and Complete), to ascertain Investigator involvement and appropriate delegation, and assess compliance to other areas (e.g. SOPs, ICH GCPs). SDR is not a comparison of source data against CRF data.

Notes:

"Reduced" refers to anything less than 100%

Unless otherwise specified these were originally adopted from the AVOCA Quality Consortium RBQM Terminology and Definitions document dated 24 Sept 2019.

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Remote Reduced SDV

- Reduced Source Data Verification (SDV)
  - Commonly known as 'transcription checking', the process by which data within the CRF or other data collection systems are compared to the original source of information (and vice versa) to confirm that the data were transcribed accurately (i.e. data from the source matches data in the CRF or other system and vice versa).

Notes:

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Post Remote Review On-Site Requirements

- EMA: Data subject to remote source data verification are likely to require re-monitoring, in particular if it was based on pseudonymised documents, which cannot be considered as source documents, and considering that remote monitoring is expected to only have focused on the most critical information
- US FDA: FAQ (Jan2021) discusses source document review but not pseudonymisation or on-site follow-up.
- MHRA/HRA: Trial participants will need to consent to any identifiers leaving the site and be assured that their confidentiality will be protected; no mention of on-site follow-up.

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Discussion points (last slide)

- MHRA draft definitions and requirements for clarity and consistency?
- Good examples of rSDR/SDV techniques implemented over the pandemic
- Examples of poor implementation over the pandemic

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