Data sharing, systematic reviews and meta-analyses

PO - (8495) - DATA SHARING IS PART OF DATA MANAGEMENT: THE NEED FOR A HOLISTIC AND COHERENT VIEW ON RESEARCH DATA MANAGEMENT.

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**Background:** Awareness on data management (DM) is often restricted to ‘the cost of computers’ or ‘the need for a database’. Recently, ‘data sharing’ can be added to this shortlist. Indeed, in recent years data sharing became often required or so promoted that one continued with overlooking the importance of all other aspects related to DM or data handling in clinical research. However, the development of data sharing guidelines and associated privacy regulations (e.g. General Data Protection Regulation) created a new momentum for highlighting the importance of qualitative data management.

**Methods:** An overview of the DM processes is given, within the framework and challenges of conducting non-commercial clinical trials in North-South partnerships.

**Results:** The DM workflow of a clinical trial is presented, highlighting essential DM tasks, deliverables and milestones. Pre-study tasks and deliverables are addressed: SOPs, a data management plan, the implementation of a GCP-compliant validated data management system and compliancy to data quality, privacy, security and standards (e.g. MedDRA, CDISC). Subsequent study specific processes including the collection, entry, querying and cleaning of the data are discussed. In addition, DM metrics important to guide quality, productivity and timelines are reviewed while considering their impact on post-study activities such as data sharing.

**Conclusion:** Data sharing is only one of many DM tasks, at the end of the DM workflow. Focusing too much on data sharing while neglecting other DM aspects might lead to underestimating the workload, resources, quality assurance and time needed for data management and by large for the trial itself. Integrating data sharing into a holistic vision on data management is paramount for clinical research.