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 of 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 strongly promoted that the importance of all other aspects related to DM or data handling in clinical tended still to be overlooked. However, the development of data sharing guidelines and associated privacy regulations (e.g. the EU General Data Protection Regulation) created a new momentum for highlighting the importance of data management.

Methods An overview of 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 compliance 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 and large for the trial itself. Integrating data sharing into a holistic vision on data management is paramount for clinical research.

DETERMINANTS AND PREVALENCE OF PARASITE RESISTANCE AMONG PREGNANT WOMEN RECEIVING IPTP WITH SULPHADOXINE-PYRIMETHAMINE IN NIGERIA

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Background Malaria in pregnancy carries a risk of significant adverse maternal and infant outcomes. Intermittent preventative treatment in pregnancy (IPTp) is advocated to reduce its occurrence, but resistance to sulphadoxine-pyrimethamine (SP) is being reported. This study aims to describe the burden of SP resistance and determinants of its occurrence among pregnant women receiving IPTp in Nigeria.

Methods A prospective observational study is to be conducted in Ogun State over 24 months. Pregnant women 16–28 weeks of gestation meeting the eligibility criteria are being enrolled; blood samples are taken for analysis pre- and post- IPTp administration at scheduled intervals. Microscopy-confirmed parasitaemic samples will be analysed using PCR to detect drug resistance markers (pfdhfr and pfdhps). Participants will be followed up until 28 days post-delivery and assessed for maternal and foetal outcomes (anaemia, low birth weight, pre-term delivery, placental parasitaemia, stillbirth, neonatal death). The primary endpoint is the prevalence of the SP resistance gene markers. Secondary endpoints include the prevalence of peripheral and placental parasitaemia at delivery; incidence of maternal and newborn morbidity; parasitaemia pre-IPTp and day 28 post-IPTp; risk factors for SP resistance and haemoglobin changes at delivery.

Results Following statistical analysis with STATA 14, results will be displayed in appropriate formats. Geometric mean parasite densities with 95% confidence intervals will be calculated, and proportions compared using the t-test, Chi-square