

What is Data Management?



Data management refers to the processes involved in planning, collecting, organising, processing, storing and maintaining data within research trials for the duration of the study.

Data management begins at study set-up where data management planning takes place, through the live study period involving the day-to-day management of data and its collection, to closure and beyond where data is analysed, preserved and shared for use and publication.

Why should I consider Data Management

Good data management practices and processes are essential when conducting research to ensure high quality research output and data integrity i.e. ensuring that data is accurate, consistent and complete.

A crucial element of managing research data is adhering to the relevant trial and data management regulations and ensuring that all data is being managed in line with these regulations.

If I fund a Data Manager how will they spend their day/time.

Set up phase



- ▶ Creating the Case Report forms so that all data points are collected to meet the trial objectives
- ▶ Creating a data matrix so all data points are reflected in the database
- ▶ Producing a database specification so that the requirements of the study database are clear
- ▶ Conducting rigorous User Acceptance Testing of the database following pre-approved testing scripts to ensure that the database meets all specifications and is fit for purpose.
- ▶ Producing a Data Management Plan so it is clear how all data will be managed throughout the study.

Recruitment/ Follow up phase



- ▶ Querying data to ensure that the dataset remains error free and with the maximum amount of data points collected.
- ▶ Producing reports so that items such as recruitment, follow up rates, number of withdrawals and data completeness can be monitored.
- ▶ Completing monitoring so trends can be established if there are certain centres where there are a higher number of data queries/low recruitment so that action can be taken as soon as possible.
- ▶ Processing withdrawals to ensure that participants rights are being respected in terms of what part of the study they wish to withdraw from
- ▶ Working to the pre specified Data Management Plan to ensure all data management processes are robust and regulatory compliant.

Study close down phase



- ▶ Finalising the datasets and ensuring the accuracy and completeness of all data
- ▶ Locking the database to ensure no unauthorised changes can be made to the data once it has been deemed complete.
- ▶ Returning the datasets to site to ensure that regulatory compliance is adhered to.

