

GD025

Data Sharing

Clinical trial data is an important part of all trials and how this data is shared must be managed. Data must be shared in compliance with Data Protection Act (2018) and General Data Protection Regulations (2018).

1. Why – Before data is shared, it must be clear why it is being shared. All data sharing must be explicitly permitted by the trial consent form or trial protocol. A data sharing agreement must be considered when the data is going outside of PTUC.
2. What – Before sharing data, to comply with the Data Protection Act, only the data that is required should be shared. The following should be considered:
 - a. Depending on who is receiving the data, sending a limited subset of the data, that will be sufficient for their needs.
 - b. Removing or reviewing free text fields for sensitive or superfluous data.
 - c. Supplying Data Dictionaries or copies of pCRFs alongside the data so the data can be clearly understood.
3. When – Usually data is only released at the end of the study but, if covered by the protocol, it can be shared earlier.
 - a. Interim Analysis/Lock - Sometimes in a trial it is agreed that there will be an early analysis for safety or other reasons. This is usually covered in the protocol or Statistical Analysis Plan (SAP), which should include what data is to be analysed and who will review it.
 - b. End of Study/Database Lock – This is the time that data is usually shared.
 - c. Other times
 - i. Often, before the above two time points, a draft dataset might be shared to either prepare the analysis or to look for data errors using statistical methods.
 - ii. Some studies may have other time points written into the protocol.
 - iii. Any time a Data and Safety Monitoring Board or a Data Monitoring and Ethics Committee meet, even at a timepoint not specified by the protocol. Such meetings might be due to an unexpected SAE etc.
 - iv. At publication - the data might be shared as part of the publication process.
 - v. During the study - data might be shared within the study team for reporting purposes.
4. Who – Data should be only shared with groups covered by the consent form and other data sharing agreements specific to the trial. If in doubt, before sharing, consult with the CPM of the trial to get confirmation.
 - a. Study team – Often, during a study, the study team get access to some of the data for various reporting needs. This can be monthly recruitment, SAE reports, etc., but

can also be reports to help on the data cleaning and general study management.

Care must be taken to make sure that the study team understand that no analysis of the study endpoints is permitted, as this could affect and bias the study.

- b. Statisticians – The needs of the statisticians are a high priority for data management, as their analysis is usually the outcome of the trial. They should be contacted early in the trial to discuss how and when they would like their data. They will often request draft or dummy data, and data dictionaries to prepare their analysis.
 - i. PTUC – No data sharing agreements are needed within PTUC.
 - ii. Non-PTUC – As external statistician might not be used to how our standard outputs are generated; discussions should start as early as possible.
 - c. Sponsor – Trial data should not get released to sponsor unless it was agreed in the trial contract and usually not until after database lock.
 - d. External – Occasionally, for a particular trial, the data might need to go somewhere else externally.
5. Where/how – Data can only be sent via secure methods, the following three are examples that are acceptable. Other methods must be approved by the Trust’s Information Governance Manager.
- a. NHS emails – Emails between nhs.net and nhs.net addresses. There are other addresses that meet the security standard (DCB1596) and details on this can be found here <https://digital.nhs.uk/services/nhsmail/guidance-for-sending-secure-email> and <https://digital.nhs.uk/services/nhsmail/the-secure-email-standard>.
 - b. Secure messaging – Using <https://sft.royalpapworth.nhs.uk/> messages and files can be transferred to and from Papworth.
 - c. Secure hard drives – If a hard drive is encrypted and password protected very large files, which are too big for the above options, can be used. This should not be used unless other options have been excluded.