Asthma UK Centre for Applied Research

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Introduction to sharing individual participant data

What is "sharing individual participant data"?

- This guide concerns **sharing** data for use beyond the original study analyses.
- **Individual participant data** is data that is associated with an individual participant.
- Identifiable participant data is study data that might be used, by itself or in conjunction with other available data, to identify individuals. Confidentiality must be preserved when sharing individual participant data, this can be done by anonymising data before it is shared. Anonymization is a spectrum, the more anonymization the less useful the data may become. A point needs to be reached that allows useful data to be shared with a low chance of identification.

Why share individual participant data?

- Sharing individual participant data allows maximum use of the data.
- Shared data can be used to validate published results and answer research questions beyond those in the original study (e.g. to investigate other outcomes, for meta-analyses, to create or validate prediction models, and in methodology research).

Who is involved in data sharing?

- There can be many data sharing stakeholders, e.g.:
    - **Participants** - Identifiable participant data is confidential. Consent forms and participant information sheets should explain how data may be shared after the study.
    - **Sponsor** An individual, company, institution or organisation which takes responsibility for the initiation, management and/or financing of a clinical trial
    - The **study funder** may have requirements for sharing data. Plans for data management and sharing can be required in funding applications.
    - **Chief Investigator**
    - If collaborating with a **clinical trials unit** or other research organisation, they may have a data sharing policy and procedures in place.
- Regulations to consider:
    - Legal requirements (e.g. Data Protection Act (1998))
    - Regulatory requirements (e.g. Information Governance)
- **Journals** may require data sharing (e.g. PLOS journals require authors to make data available)
- Data sharing processes and preparing data to be shared takes time and resources. It can involve work by the **chief investigator**, **study team**, **statisticians**, **data managers**, **data sharing committee**, **programming team**, and many others.

How can we share data?

- **Data sharing activities should be considered early in the study planning process.** It is easier if the detail of sharing is planned from the outset, rather than dealing with it at the end of the study. You should:
    - Include funding for data sharing in grant applications.
    - Outline plans for sharing data in the study protocol.
    - Identify roles and responsibilities.
    - Refer to relevant data sharing policy and procedures.
    - Add possibility of data sharing to patient information sheets
- There are two main **approaches to data sharing:**
    - Publish/Open access: Data is made available for everyone to access and use.
    - Controlled access: Researchers request data, which is then reviewed and approved. Sharing the data will require assurances about data transfer and storage, and a data sharing agreement. (This approach is recommended by MRC HTMR Guidance.)
- **Data sharing agreements** are legal agreements between the data owner, data custodian and the recipient organisation to set out responsibilities and restrictions on shared data.
- **Anonymisation** is a process of ensuring a dataset does not contain information that may identify an individual. Anonymisation often involves removing data fields of identifiable data, or applying pseudonymisation, when sensitive data fields are replaced with pseudonyms, such as replacing calendar dates with relative dates, grouping data fields into categories, and randomisation the order of the records in the database to minimise the risk of identification of individuals from the data.
- **Study data should always be transferred securely** to ensure integrity of the information and prevent unauthorised access. (Emails may not be secure. Seek advice from data management for secure methods.) The data transfer method should be documented in the data sharing agreement. Data may not need to be transferred but only accessed securely, allowing the data to remain behind the established firewall.
- Publish details of your available data set to the **AUKCAR data sharing directory**, so that other researchers are aware you have data to share.

Where can I turn for more advice?

- If you are collaborating with a clinical trials unit, seek their expertise and check their policies and procedures.
- The AUKCAR Methodology Platform can provide guidance on sharing data from AUKCAR projects feel free to contact Dr Chris Newby c.newby@qmul.ac.uk who can point you to resources or raise specific issues with the AUK CAR methodology platform.

Where can I read more?

Tudur Smith C, Hopkins C, Sydes M, Woolfall K, Clarke M, Murray G, Williamson P. (2015). Good Practice Principles for Sharing Individual Participant Data from Publicly Funded Clinical Trials.

Institute of Medicine. Sharing Clinical Trial Data: Maximizing Benefits, Minimizing Risk. Washington, DC: The National Academies Press, 2015. doi:10.17226/18998 (http://nap.edu/18998)

Varnai P, Rentel MC, Simmonds P, Sharp TA, Mostert B, de Jongh T. (2014). Assessing the research potential of access to clinical trial data. A report to the Wellcome Trust. Study led by Technopolis Group (UK). (http://www.wellcome.ac.uk/stellent/groups/corporatesite/%40msh_peda/documents/web_document/WTP058912.pdf)

Tudur Smith C, Hopkins C, Sydes MR, Woolfall K, Clarke M, Murray G, & Williamson P. (2015). How should individual participant data (IPD) from publicly funded clinical trials be shared? BMC Medicine, 13(1), 298. (http://doi.org/10.1186/s12916-015-0532-z)

Hrynaszkiewicz I, Norton ML, Vickers AJ, & Altman DG. (2010). Preparing raw clinical data for publication: guidance for journal editors, authors, and peer reviewers. BMJ (Clinical Research Ed.), 340(jan28_1), c181. (http://doi.org/10.1136/bmj.c181)

Sydes MR, Johnson AL., Meredith SK, Rauchenberger M, South A, & Parmar MKB. (2015). Sharing data from clinical trials: the rationale for a controlled access approach. Trials, 16(1), 104. (http://doi.org/10.1186/s13063-015-0604-6)

https://ico.org.uk/for-organisations/guide-to-data-protection/anonymisation/

https://ico.org.uk/media/1061/anonymisation-code.pdf

https://ico.org.uk/media/1554/determining-what-is-personal-data.pdf