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## Plan Overview

*A Data Management Plan created using DMPonline*

**Title:** Developing a Data Note reporting guideline for qualitative health and social care research datasets (the D'NOTE study)

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**Affiliation:** University of Manchester

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### Copyright information:

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# Developing a Data Note reporting guideline for qualitative health and social care research datasets (the D'NOTE study)

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## Manchester Data Management Outline

1. Will this project be reviewed by any of the following bodies (please select all that apply)?

- Ethics

2. Is The University of Manchester collaborating with other institutions on this project?

- Yes - Part of a collaboration and owning or handling data

3. What data will you use in this project (please select all that apply)?

- Acquire new data

4. Where will the data be stored and backed-up during the project lifetime?

- P Drive (postgraduate researchers and students only)
- University of Manchester Research Data Storage Service (Isilon)

5. If you will be using Research Data Storage, how much storage will you require?

- < 1 TB

6. Are you going to be receiving data from, or sharing data with an external third party?

- No

7. How long do you intend to keep your data for after the end of your project (in years)?

- 0-4 years

### *Guidance for questions 8 to 13*

Highly restricted information defined in the [Information security classification, ownership and secure information handling SOP](#) is information that requires enhanced security as unauthorised disclosure could cause significant harm to individuals or to the University and its ambitions in respect of its purpose, vision and values. This could be: information that is subject to export controls; valuable intellectual property; security sensitive material or research in key industrial fields at particular risk of being targeted by foreign states. See more [examples of highly restricted information](#).

If you are using 'Very Sensitive' information as defined by the [Information Security Classification, Ownerships and Secure Information Handling SOP](#), please consult the [Information Governance Office](#) for guidance.

Personal information, also known as personal data, relates to identifiable living individuals. Personal data is classed as special category personal data if it includes any of the following types of information about an identifiable living individual: racial or ethnic origin; political opinions; religious or similar philosophical beliefs; trade union membership; genetic data; biometric data; health data; sexual life; sexual orientation.

Please note that in line with [data protection law](#) (the UK General Data Protection Regulation and Data Protection Act 2018), personal information should only be stored in an identifiable form for as long as is necessary for the project; it should be pseudonymised (partially de-identified) and/or anonymised (completely de-identified) as soon as practically possible. You must obtain the appropriate [ethical approval](#) in order to use identifiable personal data.

8. What type of information will you be processing (please select all that apply)?

- Anonymised personal data
- Personal information, including signed consent forms

9. How do you plan to store, protect and ensure confidentiality of any highly restricted data or personal data (please select all that apply)?

Question not answered.

10. If you are storing personal information (including contact details) will you need to keep it beyond the end of the project?

Data will be collected and stored in accordance with the General Data Protection Regulation (GDPR), the Data Protection Act 2018, the University of Manchester's [Privacy Notice for Research Participants](#) and Research Data Management Policy. A Data Management Plan for the D'NOTE study will be registered with [DMPonline](#).

#### Personal information

Participants' names, place of work, and professional contact details are personal information that is already in the public domain. These details will be collected and stored in a file on the University of Manchester's secure P:Drive server.

During consent-taking, participants will be given the options of (a) being contacted with the study findings when the research is completed and (b) being contacted about future related research. Both are optional. Once the D'NOTE steering committee have published the research findings and disseminated these findings to any participants who requested a copy, participants' personal contact details will be destroyed, unless participants consented to be contacted about future related research (in which case, contact details will be securely stored for 5 years and then destroyed).

During consent-taking for the online questionnaire and online consensus workshop, participants will also be given the opportunity to be recognised as a co-author for their role as 'investigator' during data construction in the expert workshop. If participants consent to this role, this means that their name and place of work will be personal information that is subsequently reported in the study outputs (e.g., when named as a co-author of a peer reviewed journal article reporting the study and the DN reporting guideline). If participants do not consent to this role, their involvement will be kept anonymous and confidential. However, the identities of participants will necessarily be known to the other participants attending the workshop.

Electronic consent processes (in the online questionnaire and consent form emailed to participants prior to the consensus workshop) will record participants' names and personal contact details (e.g., email address) so that they can be contacted regarding research activities and study arrangements. The consent files will be stored in a password-protected, encrypted file on the University's secure P:Drive server for up to 5 years after the research findings have been published, at which point the files will be destroyed. The above is in line with the University's Research Data Management Policy and Record Retention Schedule.

Only members of the D'NOTE steering committee will have access to the above data. However, individuals from the University of Manchester or regularly authorities may need to look at the data to make sure that the research is being carried out appropriately.

#### Anonymised personal data

Participants' data generated during the research will be linked to and labelled with an identification (ID) number. Specifically, the ID numbers will be used to anonymise participants' online questionnaire responses, the online consensus workshop transcript(s), and other data collected during the workshop that can be exported directly (e.g., private voting of the proposed reporting guideline items; any messages sent by participants using the Microsoft Teams 'chat' function).

The online consensus workshop will be audio- and video-recorded using Microsoft Teams for later transcription through Microsoft Teams. The transcript will be checked for accuracy using the recordings. All identifying information (e.g., personal, place or organisation names) in the dataset will be replaced or deleted. Participants will therefore be anonymous. The consensus workshop will be recorded and transcribed so that the D'NOTE steering committee have a record of the key topics, ideas, and opinions shared during discussion. This will inform the writing group activities when drafting the DN guideline as well as subsequent study report writing. It is not expected that anonymised participant quotes will be used in study outputs. However, if quotes are used, we will minimise personal identifying information as much as possible to reduce the risk of identifying the participant in the quote. A file containing participants' names and ID numbers (the 'key') will be stored in a password-protected, encrypted file on the University's

secure P:Drive server, separately to all other data collected in the study, which will be stored in password-protected, encrypted files on the University's Research Data Storage Server.

Should participants wish to withdraw their data, it will be possible to identify their data using their ID number. However, once analysis of the online questionnaire data and, separately, consensus workshop data is completed the files linking participants' names to their ID number will be destroyed as this data will no longer be needed. Beyond this point, participants will no longer be able to withdraw their questionnaire exercise data or consensus workshop data from the study, as it will no longer be possible to re-identify their data once the file containing their names and linked ID numbers has been destroyed. However, upon request by participants, it may still be possible to redact specific data (e.g., a specific view or opinion shared) after this point, if it can be identified in the consensus workshops transcripts.

Researchers facilitating the discussions at the online consensus workshop will also take field notes. This is to capture the subtle aspects of the interactions but also means that the D'NOTE steering committee will have a back-up record of the key topics, ideas, and opinions shared during discussion, in case the audio- and video-recordings were to fail. These notes will not record any personal identifiable information. This will be checked and any identifiable information will be redacted. It will not be possible to identify and withdraw specific participants' data from field notes.

The research data will be password-protected, encrypted, and stored on the University's Research Data Storage Server for up to 5 years after the last research report has been published, at which point the data will be destroyed. Only members of the D'NOTE steering committee will have access to the above data. However, individuals from the University of Manchester or regularly authorities may need to look at the data to make sure that the research is being carried out appropriately.

**11. Will the participants' information (personal and/or sensitive) be shared with or accessed by anyone outside of the University of Manchester?**

- No

**12. If you will be sharing personal information outside of the University of Manchester will the individual or organisation you are sharing with be outside the EEA?**

- Not applicable

**13. Are you planning to use the personal information for future purposes such as research?**

- Yes

Participants will be given the option to have their data stored in a public repository for use in future research and/or teaching. This is explained in the study protocol, the participant information sheet, and an explicit item is included in the two consent forms.

It reads:

I agree to a **fully anonymised dataset** being deposited in an **open data repository** at the end of the project. This means that any anonymised data collected may be made available to other researchers.

**14. Will this project use innovative technologies to collect or process data?**

- No

**15. Who will act as the data custodian for this study, and so be responsible for the information involved?**

Dr Hannah Long

**16. Please provide the date on which this plan was last reviewed (dd/mm/yyyy).**

2024-10-18

## Project details

### What is the purpose of your research project?

The aim of the study is to produce a novel reporting guideline for Data Note articles describing qualitative health and social care research datasets. The specific objectives are to:

- Conduct a rapid scoping exercise to identify existing DN reporting guidelines, templates, and guides to authors in health, social care, and allied social science disciplines.
- Synthesise and categorise elements (items) of existing DN reporting guidelines to determine their relevance and suitability for reporting qualitative health and social care research datasets.
- Use group consensus methods with experts to review and consolidate the results of (b), to identify further items, and to agree the essential items for a DN reporting guideline for qualitative health and social care research datasets.
- Produce a draft DN reporting guideline and seek feedback from expert participants.
- Produce a finalised, exemplar reporting guideline for DNs describing qualitative health and social care research datasets, with endorsement from expert participants.

### What policies and guidelines on data management, data sharing, and data security are relevant to your research project?

Data will be collected and stored in accordance with the General Data Protection Regulation (GDPR), the Data Protection Act 2018, the University of Manchester's [Privacy Notice for Research Participants](#), Research Data Management Policy and Record Retention Schedule.

## Responsibilities and Resources

### Who will be responsible for data management?

Dr Hannah Long (Chief Investigator) will have overall responsibility for data management and she will ensure that data is stored in the correct manner.

### What resources will you require to deliver your plan?

Access to the University's Research Data Storage Server will be required to securely store the research data.

At the end of the project, the data will be archived in a data repository service such as ReShare (UK Data Service) or Figshare (University of Manchester).

## Data Collection

### What data will you collect or create?

The study will generate data via a rapid scoping exercise and collect data via an online questionnaire; an audio- and video-recording of an online workshop; private voting responses given during the workshop; a transcript of the conversation between participants at the workshop (including any comments in the 'chat' function; and written feedback on a Word document from participants to Hannah Long (the CI).

Also, personal data (e.g., names and contact details) already in the public domain will be collected.

### How will the data be collected or created?

The four stages of the study procedure to generate and collect data are described below.

#### **Rapid scoping exercise to identify existing relevant reporting guidelines**

To the best of our knowledge, there are no existing reporting guidelines (or other formal guidance or templates) for DN articles specific to qualitative health and social care research datasets. To investigate this further, we will begin with a rapid scoping exercise to identify relevant documents and publications on the reporting of DN articles. This is necessary to describe what guidance is currently in place, the extent to which this guidance is relevant and applicable to qualitative health and social care data and DNs and, where appropriate, to use this guidance to inform the next stages of the study.

The steps of the rapid scoping exercise will be fourfold. Firstly, Scopus will be searched to identify existing DN-specific reporting guidelines, guides to authors, article templates, or similar. The search strategy will include appropriate thesaurus terms, free text terms, and key words for DNs (e.g., “data note”, “data paper”, “data article” and “data descriptor”) and guides for authors (e.g., “guide”, “reporting criteria”, “template”, “guidance” and “guidelines”). The searches will be limited to documents published in English. There will be no restriction on publication type. Up to 1000 search results will be retrieved and screened. If the searches return many more results than 1000, other limits may be applied (e.g., a date/year restriction).

Secondly, the websites of relevant publishers and journals will be hand searched for suitable DN reporting guidelines and/or guidance to authors producing DNs. Target publishers and journals will include, but may not be limited to, the highest ranking (based on impact factor) health, social care, and social science journals and the top Open Access publishers in these fields. Further, the websites of leading relevant research funders, organisations, and bodies (e.g., NIHR Open Research, Open Research EU) will be hand searched to identify relevant guidance to authors reporting DN articles (including that which is published in webpage form only).

Thirdly, the EQUATOR Network database of journal article reporting guidelines will be searched to identify relevant reporting guidelines for qualitative primary research. Three relevant reporting guidelines are already known to the D’NOTE steering committee: (1) the American Psychological Association (APA) style Journal Article Reporting Standards (JARS) (18), (2) the CONSolidated criteria for REporting Qualitative research (COREQ) (19), and (3) the Reflexive Thematic Analysis Reporting Guidelines (RTARG) (20). It is possible that other relevant reporting guidelines exist. It is believed that these guidelines are likely to include existing items or criteria related to the reporting of data that are transferrable or extendable to a reporting guideline for DNs.

Finally, relevant experts known to the D’NOTE steering committee will be contacted to recommend existing DN article reporting guidelines and/or guidance documents to authors producing DNs for qualitative health and social care datasets. These experts may include, but not be limited to, individual academics known to be active publishing qualitative health and social care research and open research, as well as members of relevant special interest, committee, and society groups.

All identified documents will be imported into appropriate reference management software (e.g., EndNote and/or Rayyan). One member of the D’NOTE steering committee will screen all documents against prespecified eligibility criteria. In instances where document eligibility is unclear, the document will be discussed by two or more steering committee members until a decision is agreed. The eligibility criteria for the inclusion of documents are:

- Documents must explicitly present guidelines (including criteria, items, domains, flow diagrams, templates, or instructive statements) for the reporting of DN articles. The DN guidance in question must relate to data generated in human health, social care, and social sciences research, *or* be general and generic (i.e., subject- or discipline-free). Documents that do not explicitly address the *reporting of data* will be excluded (e.g., those providing general guidance on open data, data sharing, and data management policies).
- The guidelines can pertain to either quantitative or qualitative research data.
- Existing recognised reporting guidelines (i.e., those registered in the EQUATOR Network database) for primary qualitative research studies, covering all or part of the area in question, are eligible. This excludes reporting guidelines for systematic reviews of qualitative research (also known as qualitative evidence syntheses and qualitative meta syntheses), as well as other review types (e.g., rapid, scoping, and umbrella).
- The document must be written in English.
- A full text version or equivalent must be available.

All identified documents will be reviewed for relevant information and synthesised. A systematic content analysis of the identified documents will be performed to identify common domains, items, criteria, and guidance across the eligible documents that are relevant to the reporting of DNs for qualitative health and social care datasets. The key domains and items (etc.) from each document will be extracted and assessed in terms of whether they are relevant, partially relevant, or of no/unclear relevance (and thus not transferrable) to the reporting of qualitative health and social care data. It is anticipated that DN guidance pertaining to data *generated in human health, social care, and social sciences research* will be assessed first, as this will be most relevant and transferrable. A preliminary item list will be produced. This item list will then be compared and contrasted with *general* DN guidelines to identify any additional relevant items. The resulting item list (and any accompanying item statements) will form the basis for the next stages of the study

#### **Pre-consensus workshop: expert review of existing items and eliciting of new items**

Expert participants will be identified and purposively recruited to complete an online questionnaire. Use of an online questionnaire allows input from international experts without geographical constraints.

Participants will receive an email with a link to an online questionnaire (hosted on Qualtrics, Microsoft Forms, or similar) and other materials relevant to the study and research task. The questionnaire will be piloted with a small group of academics known to the D’NOTE steering committee and amended where necessary before being shared with the consensus workshop participants.

In the questionnaire, participants will be asked to indicate items needed for a DN reporting guideline for qualitative health and social care data. The list of reporting items generated from existing literature during the scoping exercise will be presented. Participants will be invited to rate the importance of items identified from the literature and, crucially, to propose new or missing items to the list. This will allow participants to propose and frame what they consider to be important to the development of the reporting guideline. Participants will be encouraged to include textual item statements that explain the item (e.g., a sentence or two to summarise the essential concept, feature, or indicator in the item). The items should be designed to inform, steer, and support individuals who are reporting a DN article. Views of participants may be further elicited using a small number of open and/or close-ended questions to gain insight into the sorts of issues relevant to the reporting guideline, which may need to be discussed at the online consensus workshop, as well as participants’ experiences of using reporting guidelines and producing DN articles in their research. Therefore, the questionnaire exercise will identify specific items and issues relevant to producing a reporting guideline for DNs of qualitative health and social care research.

The D'NOTE steering committee may merge similar items or remove items that were rated as less important to reach a more manageable number for discussion at the consensus workshop. A report of the questionnaire procedure and the list of proposed items will be shared with participants prior to the consensus workshop, alongside information on the format and logistics of the workshop.

#### **Online consensus workshop: consolidate and agree final items**

The same participants will be invited to take part in an online consensus workshop held on Microsoft Teams in early 2025. Inviting the same participants to both the questionnaire and the workshop ensures continuity and consistency in the exploration of ideas and fosters a greater sense of group ownership over the ideas. It allows participants to clarify and refine their initial responses during the workshop. The central objective of the consensus workshop will be to explore and as far as possible combine the views of experts to reach agreement on the precise items that the reporting guideline will cover (i.e., the scope of the items and their guiding statements). This will mainly involve reviewing, consolidating, and reducing the list of potential items identified via the online questionnaire, which will form the central part of the reporting guideline. The optimal format and phrasing of the reporting guideline will also be discussed. The online workshop format will consist of a combination of small group discussions and plenary sessions. The workshop will be transcribed using the inbuilt Microsoft Teams transcription function and be audio- and video-recorded in order to later check the transcription for accuracy.

At the start of the workshop, the D'NOTE steering committee will present the background information to the study, any relevant empirical evidence from the literature, the rationale for including items in a reporting guideline, and the results of the online questionnaire. Participants will have the opportunity to seek clarification on any unclear results.

Participants will then be invited to work together in small groups to discuss, review, and refine the items proposed in the online questionnaire. Depending on the results of the online questionnaire, it may be pragmatic to assign different clusters of related items to different groups of participants (with diverse expertise) to discuss. A key feature will be eliciting from participants what they consider to be the most important items and issues. These discussions will focus on the content of item information, rather than the precise wording of the items at this stage. It will be emphasised that the final items to be included should represent a minimum essential set of items to report, and therefore a discussion of participants' perspectives on this will be highly valuable.

A member of the D'NOTE steering committee will chair each group discussion. If necessary, prompt questions may include: What makes certain items more important than others? Which items do you consider essential? Are the proposed items sufficiently distinct? Are any items too similar? Is anything missing? The suggestions made by the small groups will then be presented back to the whole group and discussed in a plenary session. This will also allow for any within-group disagreements to be considered and resolved as a whole group.

The revised list of items will be presented back to the whole group. Participants will vote privately via an online form to determine which items to include in the final reporting guideline. In the case of mixed consensus, further discussion may be required, either as a whole group or in smaller groups, to reach verbal consensus, and/or further voting (either during the workshop or via a follow-up questionnaire sent after the workshop). If agreement is not reached, the process will nevertheless identify where consensus has not been possible.

#### **Finalising the Data Note reporting guideline**

Following the consensus workshop, the D'NOTE steering committee will serve as the 'writing group' responsible for drafting the proposed DN reporting guideline. Other individuals who can make a clear contribution to the writing of the reporting guideline may be included in the writing group. The process is likely to involve several iterations. The writing group will aim to translate the workshop discussions into clear, precise, and unambiguous reporting items, while also determining the most appropriate order for the items and structure of the guideline.

The draft DN reporting guideline will be circulated to the workshop participants ('the D'NOTE group') for a minimum of one round of feedback. Based on this input, the writing group will finalise the DN reporting guideline. All participants will be asked to formally approve the final version via email before it is submitted to a journal. Participants will be given two opportunities (email reminders) to do this; if no response is received, the final version will be submitted without participants' explicit endorsement.

## **Documentation and Metadata**

### **What documentation and metadata will accompany the data?**

The study team will create a record of the data produced over the course of the study, including its format and how it is being securely stored. This will include (but is not limited to) all study documents (e.g., study protocol, invitations, participant information sheets, consent forms, questionnaire format, workshop materials) and materials and all study data (e.g., consent forms, responses to the questionnaire, workshop transcript)

## **Ethics and Legal Compliance**

### **How will you manage any ethical issues?**

Ethical approval will be obtained from the University of Manchester Research Ethics committee.

Potential participants will receive an email with a study invitation, participant information sheet, and consent forms to participate in

the online questionnaire and online consensus workshop. The participant information sheet will describe the aims and procedure of the study, to give potential participants enough information to allow them to make an informed decision as to whether to take part. The initial email and study materials will include the contact details (i.e., email address) of the lead researcher (HAL) so that potential participants can contact her with any questions and/or to express an interest in taking part in the study.

Participants will be asked to provide their informed consent on two occasions: prior to the online questionnaire and prior to attending the online consensus workshop. Consent procedures will be built into the online questionnaire hosted on Qualtrics/Microsoft Forms, such that participants can only proceed to the questionnaire once their electronic consent has been provided. A consent form (Microsoft Word document) will be emailed to participants before the online consensus workshop, to be completed and returned by email prior to attending the workshop.

Participants will be explicitly informed in the participant information sheet about how their data will be used in the D'NOTE study. Participants will be offered the opportunity of group authorship of the study outputs. Participants who consent to group authorship will be named and listed as part of the D'NOTE group on all study outputs, which include a peer-reviewed journal article of the DN reporting guideline, archived study data, and any other study outputs (e.g., conference proceedings). Participants who do not consent to this role will remain anonymous and confidential in all study outputs. However, the identities of all participants will necessarily be known to the researchers and fellow participants. This offering is in line with the CRediT authorship taxonomy; participants who consent will be classified as an 'investigator' for their collective role in constructing the data through their participation (i.e., 'performing data collection') (22). This classification includes group authorship of the study outputs in acknowledgement of participants' contributions

It is important to note that the D'NOTE group is distinct from the writing group, which will be responsible for preparing the study outputs (for which participants have the option to claim group authorship). The opportunity for group authorship will be introduced in the study invitation and further explained in the participant information sheet. Participants will be explicitly informed in the participant information sheet of the conditions that must be met to qualify for group authorship, which include completing all research activities and providing feedback on the draft DN reporting guideline.

Overall, we do not anticipate there being any significant risks to participants or researchers during this study. It is unlikely that the discussions between participants at the online consensus workshop will involve sensitive topics, as the research tasks are entirely academic in nature. The only likely inconvenience to participants is the time taken to participate in the study. As such, we do not anticipate any undue discomfort or distress to participants during this study. However, should participants express any distress during the online consensus workshop, we will follow the University of Manchester's Managing Distress policy. This will involve offering the participant the chance to take a break and to leave the workshop without needing to give a reason, and we will emphasise that there are no consequences to withdrawing from the study if participants wish.

### **How will you manage copyright and Intellectual Property Rights (IPR) issues?**

The University of Manchester will own the copyright and IPR of any data generated in the study.

## **Storage and backup**

### **How will the data be stored and backed up?**

Participants' names, contact details, and ID numbers (the 'key') will be securely stored on the University of Manchester's secure server (P:Drive).

The consent files will be stored in a password-protected, encrypted file on the University's secure P:Drive server for up to 5 years after the research findings have been published, at which point the files will be destroyed.

All other data collected in the study, which will be stored in password-protected, encrypted files on the University's Research Data Storage Server (on Hannah Long's University account).

Both the University's P:Drive and Research Data Storage Server are backed up regularly and automatically.

### **How will you manage access and security?**

Data will be collected and stored in accordance with the General Data Protection Regulation (GDPR), the Data Protection Act 2018, the University of Manchester's [Privacy Notice for Research Participants](#), Research Data Management Policy and Record Retention Schedule.

Participants' names, contact details, and ID numbers (the 'key') will be securely stored on the University of Manchester's secure server (P:Drive).

The consent files will be stored in a password-protected, encrypted file on the University's secure P:Drive server for up to 5 years after the research findings have been published, at which point the files will be destroyed.

All other data collected in the study, which will be stored in password-protected, encrypted files on the University's Research Data Storage Server (on Hannah Long's University account). Hannah Long will have primary access, as data custodian. Internal study team members based at the University of Manchester can request shared access to the files hosted on the University's Research



Data Storage Server. External study team members (collaborators) will not have access to these data. No data will be stored on personal laptops or external storage devices.

## **Selection and Preservation**

### **Which data should be retained, shared, and/or preserved?**

The data will be stored in accordance with the University's Research Data Management policy and Records Retention Schedule. For auditing purposes, consent forms containing the participants' names will be retained and preserved for up to 5 years after the research findings have been published.

It is anticipated that the D'NOTE study data will be made publicly available where possible. Participants will be given the option (during consent taking) to have their anonymised data (i.e., online questionnaire responses, online consensus workshop voting responses, consensus workshop transcripts, and 'chat' transcript) securely archived in a data repository service such as ReShare (UK Data Service) or Figshare (University of Manchester) for use in future research, teaching, and learning. No personal information will be shared and participants will not be identifiable. This is optional and will only be done with participant's explicit consent to archive their data. The data of any participants who do not consent to their data being made public will be redacted from the dataset. This redaction will be done after data analysis and before anonymisation (i.e., before the files linking participants' names to their ID number are destroyed – see **Anonymised personal data** above).

### **What is the long-term preservation plan for the dataset?**

It is anticipated that the D'NOTE study data will be made publicly available in a data repository service (such as ReShare (UK Data Service) or Figshare (University of Manchester)) for use in future research, teaching, and learning.

For auditing purposes, consent forms containing the participants' names will be retained and preserved for up to 5 years after the research findings have been published. After this point, the consent forms will be destroyed.

## **Data Sharing**

### **How will you share the data?**

Following study completion, the results will be presented at academic conferences and published in a suitable Open Access peer-reviewed journal. This report will be disseminated widely through the academic and research community.

It is anticipated that the study data will be made publicly available in a data repository such as ReShare or Figshare.

Consent procedures for this study will involve statements on sharing data with individuals at the University of Manchester, from regulatory authorities, in study outputs e.g. published journal articles, and in the data archive. This is explicit in the participant information sheets.

### **Are any restrictions on data sharing required?**

Individuals who wish to access the archived data will need to be registered with ReShare (UK Data Service) or Figshare.