

The DASHED Study Data Sharing Plan



Study Title	The DASHED study
Chief Investigator	Dr Rachel McLatchie
Clinical Trials.gov	NCT05582967
Sponsor	University of Edinburgh & NHS Lothian
Version	1.0; 1 st May 2023

Table of Contents

1	Introduction	2
2	Data type	2
2.1	Type of scientific data expected to be generated in the trial.....	2
2.2	Dataset responsibility	2
2.3	Other associated documentation	2
2.3.1	Protocol	2
2.3.2	Publication material.....	2
3	Data preservation, access, and timelines	2
3.1	Where will scientific data be archived	2
3.2	Archiving timelines	2
3.3	When and how long will the scientific data be made available for	2
3.4	Data Access.....	2
3.4.1	Application Process	2
3.4.2	Application Review Process.....	3
4	Access, Distribution, or Reuse Considerations.....	3
4.1	Factors affecting subsequent access	3
4.2	What form will the sharable dataset take	3
4.3	Restrictions on data sharing	3
4.4	Protections for privacy, rights, and confidentiality of human research participants.....	3
5	Oversight of Data Management and Sharing	3
6	Acknowledgement in output.....	3

1 Introduction

This is the DASHED data sharing plan, written in line with the 2017 ICMJE requirements on data sharing statements for clinical trials [https://www.icmje.org/news-and-editorials/data_sharing_june_2017.pdf]. Study data is held within the Emergency Medicine Research Group Edinburgh (EMERGE).

2 Data type

2.1 Type of scientific data expected to be generated in the trial

The data to be shared includes both meta data including the study protocol, case report forms and data dictionaries, and research participant data.

2.2 Dataset responsibility

The study team are responsible for the sharing of datasets arising from the DASHED study. The Sponsor (University of Edinburgh and NHS Lothian) are joint data controllers for the study.

2.3 Other associated documentation

2.3.1 Protocol

The DASHED study was registered on the Clinical Trials.gov clinical trials registry; (NCT05582967; <https://clinicaltrials.gov/ct2/show/NCT05582967>) before participant recruitment commenced and the study protocol was published on the DASHED study website (<https://www.emergeresearch.org/trial/dashed/>) along with the DASHED Patient Information Sheet/Consent form.

2.3.2 Publication material

Aggregated data collected by the DASHED study will be made available through high impact peer-reviewed publication as soon as possible. We will also disseminate the study results through presentations at international conferences, local and national websites, and charity newsletters and websites. We will also share our results through specific interest groups such as The Aortic Dissection Charitable Trust (TADCT).

3 Data preservation, access, and timelines

3.1 Where will scientific data be archived

Once the study is closed and the statistical analysis has been completed, all study metadata will be transferred to EMERGE, NHS Lothian, and will be retained in a suitable secure space.

3.2 Archiving timelines

Anonymised study data and metadata will be preserved for future reuse for a minimum of 3 years from the protocol defined end of study point. When the minimum retention period has elapsed, study documentation will not be destroyed without permission from the sponsor.

3.3 When and how long will the scientific data be made available for

Study data and metadata will be available for as long as it has been retained.

3.4 Data Access

3.4.1 Application Process

In the first instance, email requests for study data should be made via email to: emergeresearchedinburgh@gmail.com.

Applications should include:

- Name of Study
- Chief Investigator Name
- Study stage (e.g. recruiting, in follow-up etc)
- Requester name and contact email
- Study summary
- Funding obtained / required
- Sponsor
- Opportunities for collaboration with DASHED team members
- Data required and proposed data use
- Ethics permissions in place for proposed data use
- Information Governance permissions in place for proposed data use
- Study timeline

3.4.2 Application Review Process

Once the completed application form has been received, EMERGE will review the application.

4 Access, Distribution, or Reuse Considerations

4.1 Factors affecting subsequent access

If the application is approved, EMERGE will also consider the method of access and whether any additional agreements will be required prior to the access being granted. It may be necessary to further consult with external colleagues (e.g. contracts) at this stage.

4.2 What form will the sharable dataset take

The sharable dataset will include the study analysis dataset including derived outcomes.

4.3 Restrictions on data sharing

If the study results have not yet been published, it may be appropriate to embargo any data access requests until post-publication to ensure the results are not undermined.

4.4 Protections for privacy, rights, and confidentiality of human research participants

All shared data will be de-identified prior to release and in accordance with permissions listed in the DASHED protocol, ethical approvals, and Patient Information Sheet Consent Form (PISCF)

5 Oversight of Data Management and Sharing

EMERGE will retain oversight of all data management and sharing processes.

6 Acknowledgement in output

Secondary users of data should credit the original Chief Investigator and DASHED trial team and acknowledge Royal College of Emergency Medicine for funding the original research.