Academic and Clinical Central Office for Research and Development

The ASPIRED Study Data Sharing Plan

Study Title	The ASPIRED study
Chief Investigator	Professor Matt Reed
ISRCTN Number	10278811
Sponsor	University of Edinburgh & NHS Lothian
Version	1.0; 9th January 2023

Table of Contents

1 Introduction

This is the ASPIRED data sharing plan, written in line with the 2017 ICMJE requirements on data sharing statements for clinical trials **[1]** and the British Heart Foundation clinical trial guidelines **[2].**

Study data is held within Edinburgh Clinical Trials Unit (ECTU) and the ASPIRED data sharing plan therefore aligns with the ECTU Central Office SOP ECTU_OP_15: Data Access Request and Application Management SOP (Version 2.0; 11 Oct 2021) **[3].**

This data sharing plan has been approved by the ASPIRED Project Management Group, the Sponsor (University of Edinburgh and NHS Lothian) and the ASPIRED trial statistician in Edinburgh Clinical Trials Unit (ECTU).

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 ASPIRED study including Electrocardiogram (ECG) monitoring reports. The Sponsor (University of Edinburgh and NHS Lothian) are joint data controllers for the study. ECG monitoring raw data is owned by Preventice Technologies, Inc.

2.3 Other associated documentation

2.3.1 Protocol

The ASPIRED trial was registered on the ISRCTN clinical trials registry (www.isrctn.com/ISRCTN10278811**)** before participant recruitment commenced and the study protocol was published on the ISRCTN registry and on the ASPIRED study website (https://www.ed.ac.uk/usher/edinburgh-clinical-trials/our-studies/all-current-studies/aspired-study) along with the ASPIRED Patient Information Sheet/Consent form. The protocol will also be published in an open access journal.

2.3.2 Statistical Analysis Plan / Health Economics Analysis Plan

The Statistical Analysis Plan (SAP) and Health Economics Analysis Plan (HEAP) will be published on the ASPIRED study website (https://www.ed.ac.uk/usher/edinburgh-clinical-trials/our-studies/all-current-studies/aspired-study).

2.3.3 Publication material

Aggregated data collected by the ASPIRED 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, charity newsletters and websites and media outlets such as television and radio. We will also share our results through specific interest groups such as Arrhythmia Alliance and disseminate findings amongst guideline development groups such as ESC, SIGN, NICE and American College of Cardiology (ACC).

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 Edinburgh University's Edinburgh Datashare (https://datashare.ed.ac.uk/). The data will be retained in a suitable secure space in Edinburgh University.

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.

We have sought participant consent to store patient identifiable data for up to 15 years at local sites in order that it may be used for future ethically approved studies (likely long term follow-up studies) which may involve re-contacting study participants, as well as accessing their routine hospital electronic healthcare records.

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 Type

There are two categories of data access request. A Data Access Request Application Type A is made when the study is currently recruiting participants, closed to recruitment with participants in follow-up or when the study is closed (all recruitment and follow-up completed) but the main statistical analysis is not yet complete. This should be made using form Data Access Application Form Type A (OP-F02).

A Data Access Request Application Type B is made when the study is closed, and the statistical analysis has been completed. This should be made using form Data Access Application Form Type B (OP-F03)

3.4.2 Application Process

In the first instance, Email requests for study data should be made via email to: ECTUdatashare@ed.ac.uk.

Further details about this process are available in ECTU Central Office SOP ECTU_OP_15 **[3].** There will also be a link in the Edinburgh University Datashare system that will communicate with ECTU.

3.4.3 Application Review Process

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

The review panel will consider the following:

- Permissions listed in ASPIRED Ethics/Patient Information Sheet Consent Form (PISCF)
- Risk of re-identification

- Risk of affecting ASPIRED study outcomes/data access embargo date
- Stage of study
- Requester evaluation (e.g. relationship to CI, ECTU etc)
- Scientific merit of proposed data use
- Overlap with other study projects
- Permissions (i.e. ethical, information governance) in place for proposed data use

4 Access, Distribution, or Reuse Considerations

4.1 Factors affecting subsequent access

If the application is approved, the review panel 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 and the health economic analysis dataset. Source dataset tables will not be shared.

4.3 Restrictions on data sharing

Electrocardiogram (ECG) monitoring raw data is owned by Preventice Technologies, Inc. Sharing of this data does not form part of this Data Sharing Plan. Any application for this data should be made directly to Preventice Technologies, Inc.

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 ASPIRED protocol, ethical approvals, and Patient Information Sheet Consent Form (PISCF)

4.5 Process of de-identification/anonymisation of the data

Data will be de-identified prior to release. The ASPIRED statistical team will strip out identifiers and the dataset will be shuffled to ensure anonymity whilst maintaining data integrity.

5 Oversight of Data Management and Sharing

ECTU 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 ASPIRED trial team and acknowledge British Heart Foundation for funding the original research.

7 References

1. https://www.icmje.org/news-and-editorials/data_sharing_june_2017.pdf (accessed 11th November 2022)

2. https://www.bhf.org.uk/for-professionals/information-for-researchers/managing-your-grant/guidelines-for-researchers-conducting-clinical-trials (accessed 11th November 2022)
3. ECTU Central Office SOP ECTU_OP_15: Data Access Request and Application Management SOP; Version 2.0; 11 Oct 2021; available at https://www.ed.ac.uk/sites/default/files/atoms/files/ectu_sop_op_15_data_access_request_and_application_management_v2.0.pdf (accessed 11th November 2022).