

SHORE-C Departmental Procedure

Data storage, transfer and archive

Introduction

SHORE-C investigator led research involves the collection and storage of patient reported outcome (PRO) and other data. In addition, SHORE-C undertakes collection of PRO data for other clinical research studies sponsored and managed by external academic or pharmaceutical organisations.

Ownership of data

SHORE-C owns all PRO data collected for SHORE-C led studies.

The ownership of data collected for externally sponsored and managed studies will be negotiated during study design and may form part of a sponsor and/or funder contract.

Data quality

SHORE-C undertakes quality checks at the point of data entry and also conducts data cleaning. Data cleaning may form the preparations for analysis for small data sets or those collected over a short period of time. Data sets collected over longer periods of time, e.g. for large clinical trials, may be subject to cleaning during the data collection period in addition to final cleaning before analysis.

Note: SHORE-C may receive and hold externally collected data during the course of a study. SHORE-C will not be responsible for the quality or integrity of this data.

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Data transfer for analysis

Data collected for SHORE-C led studies may be transferred to an external statistician for analysis. SHORE-C will provide data in the format required by the statistician and will work with the statistician to resolve data queries and undertake any further data cleaning required.

Data collected by SHORE-C for externally sponsored and managed studies will be transferred according to protocol and according to any other arrangements e.g for trials reports or as stated in a contract. SHORE-C will provide data in the format requested and will provide assistance to resolve data queries and undertake any further data cleaning required.

Requests for data sharing (not related to protocol analysis)

Any requests for data collected and held by SHORE-C must be made in writing. This includes requests from members of study oversight committees, including the chief investigator, where the proposed use of the data does not form part of the protocol analysis or study contract.

SHORE-C led research

The SHORE-C Director will authorise transfer of any data. A confidentiality or other agreement may be issued according to the nature, proposed use and storage of the transferred data.

Externally sponsored and managed research – SHORE-C owned data

The request for data sharing will be forwarded to the trial sponsor and any relevant trial oversight committees (Trial Management Group, Trial Steering Committee, Data Monitoring Committee). If no objections are raised, the SHORE-C Director will make the final decision regarding transfer of data.

Externally sponsored and managed research – externally owned data

The request for data sharing will be forwarded to the trial sponsor and any relevant trial oversight committees (Trial Management Group, Trial Steering Committee, Data Monitoring Committee). If no objections are raised, SHORE-C will transfer the data according to the instructions of the data owner/trial sponsor. Note: if the request for data transfer

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relates to externally collected data held at SHORE-C, SHORE-C will not be responsible for the quality or integrity of the data transferred.

Record keeping

The SHORE-C data manager will keep records of all datasets transferred from the department, including data transferred according to protocol or contract. This will include a copy of the dataset transferred, its name, version number and date and details of the recipient.

Data archiving

SHORE-C will archive SHORE-C owned data. Arrangements for archiving data collected for externally sponsored and managed studies will be determined during study design and may be written into a protocol or contract.