SDRN: Scottish Diabetes Research Network

Archiving of Linked Data

Epidemiology S.O.P. No.: 6

Version 1

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CHIEF SCIENTIST OFFICE

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Introduction

ICH GCP states that "systems with procedures that assure the quality of every aspect of the trial should be implemented". This SOP details the procedure.

Background

It is important for audit and other purposes that analyses can be re-examined or repeated at any time in the future. When the data on SCI-DC is linked and anonymised, it is a snapshot picture of the source datasets and should be recognised as such. Much of the data on SCI-DC is very fluid and can change quickly so archiving the data which was used for research purposes is important. The procedure for archiving the data should be clearly defined so that this data can be retrieved easily, if necessary.

Procedure

1. Each data source maintains an exact copy of any data sent to researchers for a given study. The independent institution also maintains a copy of the random identifiers it distributed.

2. The institution to which the researcher belongs, eg. The University of Edinburgh, holds the anonymised, linked data which was used for the study along with intermediate datasets, processing procedures and final outputs. This institution should archive the data and any derived material for an agreed period eg. 10 years in a secure store which is approved for the archiving of clinical trial records. This store should be run by another institution such as the national e-science Digital Curation Centre.

3. The location of all data and material is known and any study analysis can be replayed. This should not require the original investigators to be involved. By applying the procedures in the study archive with the exact copies of the data held by the data sources it must be possible to replicate the intermediate datasets and outputs held in the archive.

This procedure defines the archiving process to be followed and conforms to ICH GCP guidelines.