SDRN: Scottish Diabetes Research Network

Feedback of Clinical Data Anomalies

Epidemiology S.O.P. No.: 7

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 to be used.

Background

Within the context of SDRN, data sources are the origin of any data transferred to the SDRN. For example SCI-DC is considered a single data-source.

When a researcher is examining the linked dataset, he/she may find data which is inconsistent or in error. Researchers are asked to provide feedback to data sources to improve the quality of source data. It is the duty of the data source to respond to feedback when this is of high risk to the associated patient, e.g. possible drug interactions. Where the data source cannot reliably identity the patient and their current address and GP registration, the linker can co-operate with the National CHI to obtain the identity and contact details of the health care professional responsible for the patients' clinical care (e.g. GP).

Procedure

1. The researcher finds a significant anomaly within the dataset. He/She must use their judgment to decide if they wish to report this.

2. The researcher should report this anomaly to the data source for this item along with the random subject identifier. The source should confirm the data and then address the issue, which may involve contacting the patient if there are safety concerns.

3. Where the anomaly involves more than one data source, feedback is to all the relevant data sources.

4. Where the anomaly involves multiple data-sources and is potentially clinically significant, the GP will be notified after consultation with the SDRN clinical advisor. Under these circumstances, the patient is identified with help of the linker and the National CHI.

This process ensures that the data is quality assured and all processes conform to ICH GCP guidelines.