

Completing the SDRN Minimum Dataset Form

Clinical S.O.P. No.: 18

Version 2.1

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DOCUMENT HISTORY

Version number	Detail of purpose / change	Author / edited by	Date edited
1.0	New SOP	Shona Brearley	
2.0	SOP completely revised to correspond with the new SDRN Minimum Dataset Form	Louise Greig	June 2012
2.1	Fields removed to improve ease of completion	Louise Greig	November 2014

1 Introduction

The SDRN Portfolio holds information relating to individual studies taking place in Scotland and is used to give an overall picture of Diabetes Research in Scotland.

2 Objectives

The aim of this SOP is to provide assistance on how to complete the SDRN Minimum Dataset Form.

3 Responsibility

It is the responsibility of the nurses working in each region to obtain up-to-date information about studies taking part in their area. They should notify the SDRN Office on first hearing of a new study, and complete the Minimum Dataset Form as soon as possible.

4 Equipment

Staff should, wherever possible, complete the form electronically and then e-mail the form to the appropriate SDRN contact. The form can be downloaded from the SDRN website:

<http://www.sdrn.org.uk/clinicalsops>

If preferred the form can be completed by hand, in black ink, and posted to the SDRN office in Dundee.

5 General Points

The SDRN Minimum Dataset Portfolio form should be completed as fully as possible providing as much information as practical.

6 Fields to be completed on the Minimum Dataset Form

- **Site name** – Enter the name of the site where you are based e.g., Ninewells Hospital Dundee, Glasgow CRF etc.
- **NIHR\UKCRN ID** – This is the ID assigned to the study when it is put on the National Institute of Health Research UKCRN portfolio database. Website link to the Portfolio Database: <http://public.ukcrn.org.uk/search/>
- **Acronym / Short name** – Enter the appropriate acronym e.g. STEPPS or short name for the study. It is important this information is provided as it helps establish the uniqueness of a study.
- **Study title** – This should be the full scientific title of the study e.g., A 24 randomised double blind placebo controlled multi-centre study of safety and efficacy of PPM-204 in subjects with Type 2 Diabetes. It is important this information is provided as it helps establish the uniqueness of a study.

- **Active status** – Record the status of the study using one of the following descriptions.
 - In set up
 - Open i.e., actively recruiting patients to the study
 - Closed to recruitment but follow up is ongoing
 - Closed completely

- **R & D permission\FPFV** – Record the dates when the following occurred.
 - R & D permission was granted
 - SIV took place
 - Date of your FPFV (first patient first visit)

The FPFV should take place within 30 calendar days of R & D permission being granted, or the SIV (Site Initiation Visit) taking place, whichever is the latest.

- **Per patient fee** – The per patient fee can be found in the Clinical Trial Agreement in the section titled Financial Agreement. A copy of the CTA should be held in the study site file.

- **Sub-topics** – Record the diagnosis type of diabetes in this section.
 - Type 1
 - Type 2
 - Both
 - Other

- **Disease\Diagnosis** – From the list provided select the disease term that is applicable to your study.

- **Primary study design** – First establish whether your study is interventional or observational.
 - **If Interventional** - Use one of the following descriptions to specify the nature of the intervention.
 - Treatment
 - Screening
 - Diagnosis
 - Prevention
 - Process of care

 - **Interventional detail** – Use one of the following descriptions to specify the nature of the intervention.
 - Drug
 - Device
 - Gene therapy
 - Immunotherapy

- **If Observational** – Use one of the following descriptions to indicate the type of the observational study.
 - Care controlled
 - Cross sectional
 - Cohort
 - Genetic epidemiology
 - Qualitative
 - Clinical laboratory study
 - Validation study (outcome measure\investigation\therapeutic process)

- **Your local SITE recruitment target** – please record the number of patients that your site has agreed to recruit to the study. This information should be documented in the Clinical Trial Agreement.

- **Geographical scope** – From the list below please state the geographical scope of the study.
 - International multi-centre
 - UK multi-centre
 - Single centre

- **Phase** – From the following selection please indicate the category your study falls into.
 - Pilot\feasibility
 - I
 - II
 - III
 - IV
 - Device
 - Academic

- **Is this a randomised study?** – This section only requires a yes or no answer to this question.

- **Blind\Open label** - From the following selection please indicate the category your study falls into.
 - Blind
 - Open
 - Unknown

- **Placebo controlled** - From the following selection please indicate the category your study falls into.
 - Yes
 - No
 - Unknown

- **Eligibility** – Under the following headings please list the main inclusion/exclusion criteria for the study.
 - Main inclusion criteria
 - Main exclusion criteria
- **Has the study been fully funded?** – Straightforward Yes/No answer required.
- **Name of funder(s)** – Record the name of the funder(s). If more than one funder please list in order of the degree of financial involvement i.e., largest financial contribution first.
- **Name of sponsor** – Record the name of the sponsor in the free text section.
- **Detail of commercial participation (if industry supported)** – From the list below select the relevant classification.
 - None
 - Industry supported and industry sponsored
 - Industry supported but non-industry sponsored
 - Not specified
- **Recruitment** – provide information on the following recruitment criteria.
 - **Planned opening date** – This is the date when the study is due to open to recruitment.
 - **Actual opening date** – This is the date when the first patient was recruited in the UK.
 - **Planned end of recruitment** – This is the date when recruitment to the study will close.
 - **Actual end of recruitment (if closed and in follow up)** – This is the date when that the last patient was recruited to the study.
 - **Study settings** – Please record whether the study is being conducted in secondary care, primary care.
- **Management and contacts** – Please complete the contact details (name, telephone number, e-mail address) for all the staff detailed below.
 - Principal Investigator (local PI i.e., based at your site)
 - Study Coordinator