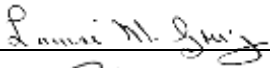
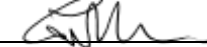


# Completing the SDRN Study Tracker

**Clinical S.O.P. No.: 30**  
Version 2..1

Compiled by:	
Approved by:	
Review date:	November 2016

# Completing the SDRN Study Tracker

**S.O.P. No. 30**  
Version 2.1

## DOCUMENT HISTORY

Version number	Detail of purpose / change	Author / edited by	Date edited
1.0	New SOP	Louise Greig	
2.0	Additional information added to the SOP	Louise Greig	June 2012
2.1	Additional information added to the SOP in relation to new data to be collected for the CSO annual report	Louise Greig	June 2013
2.2	Minor changes made to the additional information added to this SOP in June 2013.	Louise Greig	November 2014

## 1. Introduction

ICH GCP states that 'systems with procedures that assure the quality of every aspect of the trial should be implemented'.

## 2. Objective

The tracker should function as a point of reference for site staff to help them in the planning of their workload when determining what studies to undertake at any given time.

## 3. Background

The purpose of the study tracker is to support the SDRN management team report the level of research activity at Diabetes Research active sites across Scotland. The information collected is used to compose the annual report that is sent to the Chief Scientist Office at the end of each year. This SOP details the procedure to be used when completing the SDRN study tracker.

## 4. Responsibility

It is the responsibility of the research nurse/study co-ordinator based at the local site to update the tracker on a monthly basis and return the completed tracker to the SDRN Co-ordinating office in Dundee.

The tracker should be updated on the last day of each month.

## 5. Procedure

The columns in the spreadsheet should be completed as follows –

- **Column A - SDRN No:** The SDRN office assigns this number when a study is put on the SDRN Portfolio Database. The number will be entered on the study tracker by SDRN staff as soon as one is assigned to a specific study.
- **Column B - Study Name/No:** The study protocol number/acronym should be recorded here as this ensures that multi centre studies are entered onto the database under the correct name.
- **Column C - Sponsor:** Record the name of the organisation responsible for the initiation and management of the clinical trial in this column.
- **Column D - PI/Lead Nurse:** Record the name of the Principal Investigator and lead nurse/coordinator at your site for each study.
- **Column E - Proposed Start Date:** As soon as you are contacted regarding a potential trial enter the study onto the tracker and record the proposed start date when patient recruitment to the study will open.

- **Column F - Proposed End Date:** As soon as you are contacted regarding a potential trial enter the study onto the tracker and record the date that it is anticipated when patient recruitment to the study will close.
- **Column G - Date of R & D Permissions/SIV:** Record the date your R & D department approved the study (i.e., green light is given for study to go ahead) and the date the Site Initiation Visit is carried out.

Once studies have R & D approval or the Site Initiation Visit has been carried out then you should record the information in the section titled –

- Active commercial studies
- Active academic studies

(This information has been requested by the Chief Scientist Office Scotland in order to look at the time between R & D approval being granted or the SIV being carried out and the date of the First Patient First Visit - FPFV.)

- **Column H – Date of FPFV:** Record the date that you see your first patient for their first visit. This information should be recorded in the section titled –
  - Active commercial studies
  - Active academic stage
- **Column I - In Set-up, Recruiting, In Follow-up, Closed:** When you are contacted regarding a potential study you should enter the study details onto the tracker and record the stage that it is currently at i.e., enquiry, feasibility, in set-up, pending etc. The tracker is divided into sections to make this process clearer.

Information relating to studies in the recruiting, in follow-up and closed stage signifies the following –

- Recruiting is when you are actively recruiting new patients to a study.
- In follow-up is when the study has closed to new recruits, but patients are still being seen the research team.
- Closed is when patients are no longer being seen by the research team and the study has been closed.

Information relating to studies at the enquiry / feasibility / pending or set-up stage should be recorded in the section titled -

- Commercial studies at the feasibility / pending or set-up stage
- Academic studies at the feasibility / pending or set-up stage

- **Column J - Recruitment Target:** In this field you should record the number of participants that you agree as a site, with the sponsor, to recruit into the study. This information is available in the mCTA a copy of which should be retained in the study site file.
- **Column K – No. of new patients recruited this month:** In this column record the number of new patients recruited to a particular study in any given month.

- **Column L – Total number of patients screened:** In this column record the cumulative number of patients that have consented to take part in a study and completed visit 1. (NB not the number of notes screened.)
- **Column M – Total number of patients randomised:** In this column record the number of patients who are successfully randomised into a study.
- **Column N - Per Patient Fee/Grant:** For commercial studies please record the agreed per patient fee. This information should be stated in the mCTA for the study, a copy of which should be in the study site file. For academic studies record the value of the grant awarded for the study.
- **Column O - Minimum Dataset Form Completed:** All studies on the SDRN Portfolio Database require a Minimum Database Form to be completed. Please indicate that a SDRN Minimum Dataset Form has been completed by entering **Yes** in the relevant field.

If you enter **No** in this column then you need to complete a SDRN Minimum Dataset Form. The form can be downloaded from the SDRN website and then sent to the SDRN Office in Dundee.

- **Column P - Comments:** Please record all information you consider relevant or significant.

**Example of possible comments:**

- Feasibility questionnaire completed on 00/00/00 and sent to company.
- Site selection visit carried out on 00/00/00.
- Site selected on 00/00/00.
- Awaiting site initiation visit/ initiation visit due 00/00/00.
- Attended investigator meeting.
- Study coming to a close/data lock soon.
- Awaiting close out monitoring visit.
- Insulin initiation study.
- Insulin titration study.
- Insulin switch study.
- Insulin comparator study.
- Cardiovascular outcome study.
- Study terminated by the company.
- Long term endpoint study.
- FPFV (First patient First visit planned for 00/00/00)

# Completing the SDRN Study Tracker

(APPENDIX 1)

SITE NAME - Diabetes Research Unit Tracker															
SDRN No.	Study Name/No.	Sponsor	PI/Lead nurse	Proposed Start Date	Proposed End Date	Date of R&D Permissions / SV	Date of FFPV	In Set-up Recruiting In Follow-up Closed	Recruitment Target	No. of new patients recruited this month	Total number of patients screened	Total number of patients randomised	Per Patient Feedback Form Completed	Minimum Dataset Form Completed	Comments
<b>ACTIVE COMMERCIAL STUDIES</b>															
7															
8															
9															
10															
11															
12															
13															
14															
15															
16															
17															
18															
19															
20															
21															
<b>COMMERCIAL STUDIES: ENQUIRY STAGE - FEASIBILITY STAGE - SITE SELECTION VISIT STAGE - IN SET-UP</b>															
23															
24															
25															
26															
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31															
32															
33															
34															
35															
36															
<b>ACTIVE ACADEMIC STUDIES</b>															
38															
39															
40															