| SOP number | **50.025** | Version | **1.0** |
|---|---|---|---|
| Title | **Quality Check of Project Entries on SReDA** | | |

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| Prepared by<br>Signature | Radoslaw Penar<br>Date |
| Approved by<br>Signature | Melissa Robert<br>Date |
| Released by<br>Signature | Julie Brittenden<br>Date |

| SOP category | NHS GG&C General |
|---|---|
| Staff category | |

| Staff Category | R | A | C | I |
|---|---|---|---|---|
| Research Information Officer | | X | | |
| Research Co-ordinator | X | | | |
| Research Facilitator | X | | | |
| Senior Research Administrator | X | | | |
| Research Administrator | X | | | |

## 1. Scope

All research activity in NHS Research Scotland is recorded on the Scottish Research Database Application (SReDA) for project management and reporting purposes. This procedure covers the quality check (QC) of data held in SReDA. This SOP should be reviewed for updates every 3 years unless required.

## 2. Purpose

The purpose of this SOP is to define the single data entry method and validation of data within SREDA, and provide guidance to QC the required minimum dataset recorded.

**3. Procedures**

SReDA users enter the minimum dataset for each study following SOP 50.010. Data in SReDA must be updated when new information becomes available. Once the local review is complete and permission letter issued, the dataset is checked for quality. This includes both project and local level data. The dataset is again checked for quality when an amendment is approved by the R&I department.

The following table details the QC process for each study type and staff group completing QC and signing-off the report:

| **Study Type** | **Staff group** | **Frequency of QC** | |
|---|---|---|---|
| | | After Approval*, ** | After Amendment*** |
| Commercial | Research Co-ordinator/ Facilitator or deputised team member | All | 1 per month |
| Eligible | Research Administrator/ Senior Research Administrator | All | 1 per month |
| Adopted | Research Administrator/ Senior Research Administrator | All | 1 per month |
| CTIMP GG&C Sponsored | Research Co-ordinator/ Facilitator or deputised team member | All | 1 per month |
| CTIMP GG&C/GU Co-Sponsored | Research Co-ordinator/ Facilitator or deputised team member | All | 1 per month |
| NEF | Research Administrator/ Senior Research Administrator | 2 per month | 1 per month |
| Pilot | Senior Research Administrator/ Research Administrator | 2 per month | 1 per month |
| Research Database & Tissue Bank | Research Administrator/ Senior Research Administrator | 2 per month | 1 per month |

*Projects of respective category to have received approval within the month

**Each project is only QC'd once after Approval unless a relevant amendment is put in place

***Projects of respective category to have an amendment approved within the month that impacts areas highlighted in 3.4

**n.b. if fewer projects than number specified of relevant category are approved or receive an amendment within the month then only those possible will be carried out.**

Once permission has been issued and the study record on SReDA is set to 'Active' the Research Administrator/Senior Research Administrator is responsible for fully updating SReDA. This will include completing all fields following SOP 50.010, as well as checking if data already entered is correct. They will then create a QC report from SReDA. For Research Database and Tissue Bank studies go to section 3.2, for all other study types go to section 3.1.

QC check reports are to act as a guide for those completing/reviewing datasets. The information must be checked for quality by all staff groups.

### 3.1. Creating QC Report for all other study types - Research Administrator/Senior Research Administrator

a) In the individual project record on SReDA, click **Documents** tab then **Letters** and scroll down to generate letter section.
b) Select **QC Report** within letters table.
c) Select **Funder**, **Sponsor**, **Registered Events:Clock status**, **Check**, **Check Complete**, **Notes**.
d) Click **Generate Letter**. The QC report will open in a Word document.
e) 'NOT SET' should not be recorded in the QC report. If there are any fields blank or 'NOT SET' the data in these fields must be updated. Repeat section 3.1 until the QC report is correct.
f) Save into the project e-folder.
g) Select 'SReDA updated by Research Administrator' button on SReDA Pharmacy/custom tab.
h) If the QC report is being run created for an amendment then select 'QC sign-off AMD RC/CA.'

### 3.2. Creating QC Report for Research Database & Tissue Bank studies - Research Administrator/Senior Research Administrator

a) In the individual project record on SReDA, click click **Documents** tab and scroll down to generate letter section.
b) Select **QC Report – DB and TB** within letters table.
c) Select **Funder**, **Sponsor**
d) Click **Generate Letter**. The QC report will open in a Word document.
e) 'NOT SET' should not be recorded in the QC report. If there are any fields blank or 'NOT SET' the data in these fields must be updated. Repeat section 3.2 until the QC report is correct.
f) Save into the project e-folder.
g) Select ' SReDA updated by Research Administrator'' button on SReDA Pharmacy/Custom tab.
h) If the QC report is being run created for an amendment then select 'QC sign-off AMD RC/CA.'

### 3.3. Completing QC Checks - Research Co-ordinator/Research Facilitator/Senior Research Administrator/Research Administrator/Research Information Officer

a) QC reports are saved in the project e-folder.
b) Using source documentation check each field has the correct data entered.
c) If all fields are correct select appropriate QC sign-off button on SReDA Pharmacy/Custom tab.

### 3.4. Amendments

Study amendments may impact the data recorded. QC reports will be created and data checked for amendments which impact the following:

- Change to Sponsor.
- Change to funder (may also impact the project type).
- Study extension (may also impact target recruitment and proposed end date).
- Protocol version.

If amendment(s) change any of the above fields the Research Administrator/senior research administrator will re-run the QC report following sections 3.1-3.3 as necessary.

### 3.5. Research Information Officer Reports

The Research Information Officer will pull a monthly QC Report detailing all projects and amendments ready for QC and circulate to all Portfolio teams. The report will also indicate if any QC checks have been done by the Informatics Team, and if yes which fields need to be completed or corrected. The 'QC sign-off Informatics Team' checkbox will be ticked by the Informatics Team for any projects they have checked.

## 4. Referenced documents

- SOP 50.010 - Project Data Entry on SReDA

## 5. Related documents

- NRS-SOP-008 - Procedure for Use of SReDA within NHS Research Scotland Research and Development Offices

## 6. Document history

| Version | Date | Description |
|---|---|---|
| 1.0 | 03/05/2024 | Number changed from 52.011. Update to the QC process, Admin updates, R&D change to R&I. |