# STU-SOP-DMS-003 – Standard Operating Procedure on Qualitative Analysis Quality Assurance

## 1. Purpose

This Standard Operating Procedure (SOP) describes the procedure of undertaking qualitative data analysis to assure the quality of qualitative data collected within trials and studies. To provide an audit trail of the process of analysing qualitative data as well as the reporting of qualitative data.

## 2. Background

Quality assurance (QA) refers to planned and systematic production processes that provide confidence in a product's suitability for its intended purpose. QA is characterised by a commitment to ensuring processes are "fit for purpose". Qualitative data analysis by its very nature has no “right” answers but a transparent and approved process of checking the analysis must be followed in all cases.

## 3. Roles and Responsibilities

The **Sponsor** has overall responsibility for confirming that the process of quality assuring the analysis of qualitative data set out in this SOP has been followed. This role will usually be delegated to the Chief Investigator, with appropriate oversight by the relevant trial committees e.g. TSC.

The **Chief Investigator (CI)** usually has delegated responsibility for ensuring the process of quality assuring the analysis of qualitative data has been undertaken in accordance with this SOP.

A **Qualitative Researcher (QR)** should be designated, and will have appropriate qualifications and experience and assume responsibility for all qualitative aspects of the trial or study.

A **Second Qualitative Researcher (QR2)** who will verify that the QA process set out here has been undertaken should be identified before data analysis begins.

The **Trial Manager** (TM) should ensure the QA documents are filed in the TMF before commencing the qualitative analysis of trial or study data.

**External use of SOP**: this SOP and Associated Documents (AD) may be used for research projects not adopted by STU where Swansea University (SU) staff and associated NHS organisations require guidance. In such instances, oversight responsibility for any associated tasks will not be the responsibility of STU.

## 4. Procedure

The steps suggested for QA of qualitative analysis are listed below and should be documented in the relevant qualitative data analysis plan (Q-DAP). A process flow of the procedure can be found in Appendix 1. Qualitative analysis is iterative and therefore the order of presentation here is indicative only. (Step 5.1 will be undertaken first in all cases.)

### 4.1 Pre-analysis

The QR will develop the Q-DAP, which will detail the QA procedures to be followed in the study.

The QR must ensure that all documentation is filed and a copy of the QDAP is included in the Trial Master File (TMF).

Depending on the study design and methods used all data should be prepared for analysis according to the principle of best practice in relation to issues such as transcription and anonymisation.

### 4.2 Starting Analysis

The QR should create and document the coding framework (or equivalent) to be used in the analysis. This will be tailored to each study and will be revised throughout the analysis period.

The coding framework should clearly describe the approach to the data and should be discussed and agreed with other QRs. At least one other QR who will undertake the second coding of an agreed subsample of data should be identified at this stage.

### 4.3 During Analysis

The QR should keep the coding framework documents under review and it should be annotated such that researchers unfamiliar with the study would be able to replicate and understand the analysis.

The coding should be discussed by the QRs as per the Q-DAP until consensus is reached and the coding framework is finalised.

Updated versions of the coding framework document should be saved under a new version number and circulated to the team involved in the analysis.

Changes to the analysis as a result of these processes should be recorded in the Qualitative Analysis Log (QAL) (STU-AD-TMP-014).

### 4.4 Checking the Analysis

The analysis should be checked by QR2 under the terms set out in the Q-DAP.

Any discrepancies identified should be resolved and the process of resolution should be recorded in the accompanying QAL. This step must be undertaken at least once in all cases.

### 4.5 Post Analysis

The QR should ensure that decisions about the coding framework are recorded in the QAL.

The QR must ensure that the most up-to-date Q-DAP and the QAL is filed in the TMF.

A final and complete version of the coded data should be locked when analysis is completed and this file must be saved in an appropriate format for archiving.

## 5. References

- O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med 2014; https://www.ncbi.nlm.nih.gov/pubmed/24979285

- Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. Int J Qual Health Care 2007;19:349–57.
- Pope C, Ziebland S, Mays N. 2006 (3rd ed.). Analysing qualitative data. In Qualitative Research in Health Care. Pope C, Mays N. (Eds.) Blackwell Publishing: Massachusetts. 63-81.
- Ritchie, J and Lewis, J (eds.) 2003. Qualitative Research Practice: A Guide for Social Science Students and Researchers. UK, Sage


It is assumed that by referencing the principal regulations that all subsequent amendments are included in this citation.

## 6. Associated Documents

| Number | Title | Location |
|---|---|---|
| STU-AD-TMP-014 | QA of Qualitative Analysis Log | Q-Pulse |
| STU-AD-TMP-015 | Q-DAP Template | Q-Pulse |

## 7. Abbreviations

| List of Abbreviations | |
|---|---|
| **CI** | Chief Investigator |
| **GCP** | Good Clinical Practice |
| **Q-DAP** | Qualitative Data Analysis Plan |
| **QAL** | Qualitative Analysis Log |
| **QR** | Qualitative Researcher |
| **SOP** | Standard Operating Procedure |
| **STU** | Swansea Trials Unit |
| **TMF** | Trial Master File |

## 8. Appendices

**Appendix 1: Document History**

| **Version No:** | 3 | **Effective Date:** | 22-Apr-2024 |
|---|---|---|---|
| **Description of changes:** | Typographical corrections<br>Updated to SOP Template v5 | | |

## Appendix 2: Process Flowchart