STU-SOP-DMS-005 – Standard Operating Procedure on Creating a Qualitative Data Analysis Plan

1. Purpose and Definitions

To describe the procedure for preparing a qualitative data analysis plan (Q-DAP) for a trial or study using qualitative methods.

Definitions	
Qualitative Data Analysis Plan	A comprehensive description of the methods and presentation of data analysis, and expands the detail contained in the protocol.

2. Background

The Q-DAP is the guiding document for all qualitative analysis in the trial or study and should carefully align with the research objectives and hypotheses stated in the trial or study protocol to avoid post hoc decisions that may affect the interpretation of trial or study findings. In trials and studies that include qualitative methods there must be a pre-specified methodology.

3. Roles and Responsibilities

The **Sponsor** has overall responsibility for confirming that a Q-DAP has been finalised before commencing the qualitative analysis. 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 Q-DAP reflects the requirements of the approved protocol.

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. The QR is responsible for developing Q-DAP, which should be signed off.

The **Trial Manager** (TM) should provide appropriate support to the drafting of the Q-DAP and ensure the document is 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 Q-DAP must be based on the trial protocol qualitative methods section and should be version controlled, dated, written, finalised and signed off prior to data analysis. A flow chart of the development procedure is available as Appendix 1 to this SOP.

NOTE: Saved Copies of Standard Operating Procedures are UNCONTROLLED. Please ensure to use most recent versions contained within the QMS.

4.1 Developing draft

The Q-DAP is a detailed description of the planned analyses and the methodological considerations of the qualitative section of the trial or study protocol and should contain as a minimum the following items:

- Qualitative Researcher details
- Objectives of the study
- Method(s) of data collection
- Data produced
- Data management
- Stopping data collection
- Method of analysis
- QA of analysis
- QA of analysis process
- Combining qualitative analysis findings with other findings
- Handling missing data/withdrawals

The Q-DAP Template (STU-AD-TMP-015) should be used to draft the Q-DAP. Template sections can be amended as appropriate, depending on the trial or study requirements.

The initial Q-DAP and any updates shall be circulated for review and comment to the CI and TM, and where required for an external review e.g. DMC, TSC.

Any changes to the Q-DAP during the trial or study must be documented, the reasons for change noted and assessment made of the need for a protocol amendment.

4.2 Finalised version

The finalised Q-DAP should include sufficient details for any suitably qualified QR to replicate the analysis.

The finalised Q-DAP must be ratified by the relevant trial oversight group(s) e.g. TSC, DMC.

Subsequent secondary analyses of a more exploratory nature will not be bound by the Q-DAP, although they are expected to follow the broad principles laid down within it.

5. References

- Health Research Authority website (HRA) - http://www.hra.nhs.uk/
- Medicine and Healthcare products Regulatory Agency website (MHRA) - https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/services-information
- UK policy framework for health and social care research (2017) - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

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

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6. Associated Documents

Number	Title	Location
STU-AD-TMP-015	Q-DAP Template	Q-Pulse

7. Abbreviations

List of Abbreviations	
CI	Chief Investigator
CRF	Case Report Forms
CTIMP	Clinical Trial of an Investigational Medicinal Product
DMEC	Data Monitoring and Ethics Committee
GCP	Good Clinical Practice
MHRA	Medicines and Healthcare products Regulatory Agency
PI	Principal Investigator
QA	Quality Assurance
Q-DAP	Qualitative Data Analysis Plan
QR	Qualitative Researcher
SOP	Standard Operating Procedure
STU	Swansea Trials Unit
TM	Trial Manager
TMF	Trial Master File
TSC	Trial Steering Committee

8. Appendices

Appendix 1: Document History

Version No:	3	**Effective Date:**	22-Apr-2024
Description of changes:	Updated to template v5 Typographical corrections		

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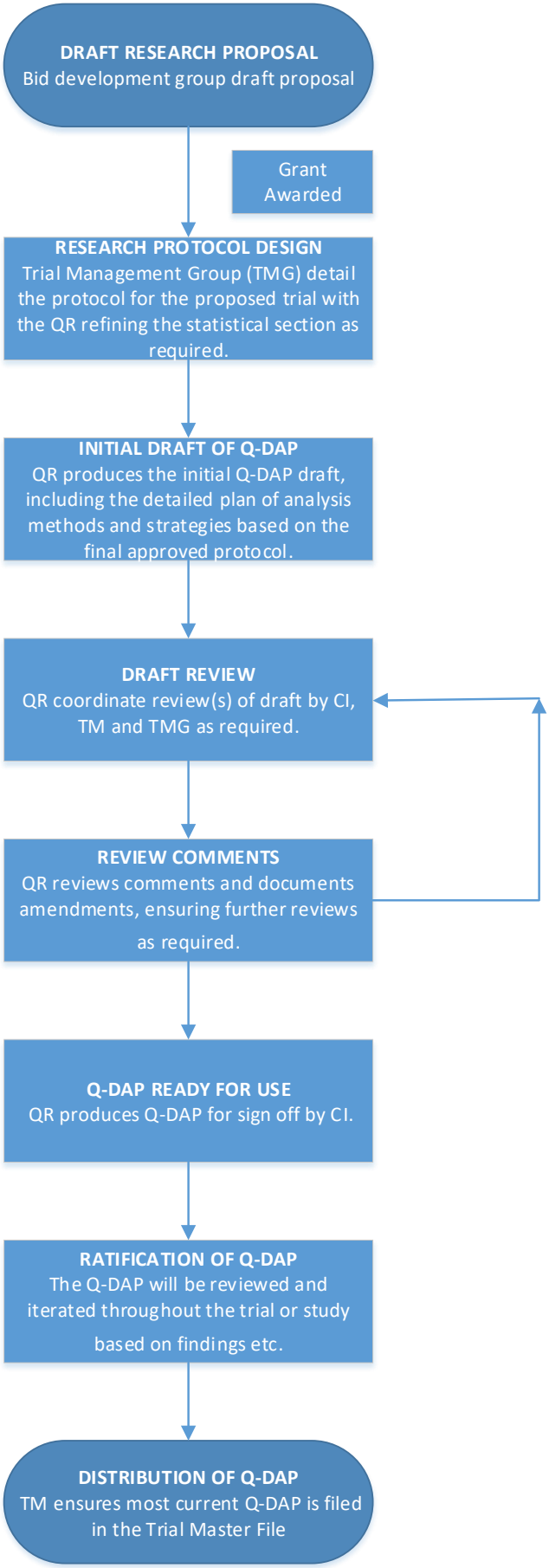
Appendix 2: QDAP Flowchart



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