

## SET-UP

Plan for closure included in grant application

CI . SPM

Set appropriate review date in Risk Assessment to ensure closure activities begin before end of follow-up

QA . SPM

Define end of trial in protocol

SOP 4 . T15 . T16

CI

Write dissemination & implementation plan

SOP 22

CI

Key:

Closure task

Responsibilities

## RECRUITMENT

Data collection and ongoing cleaning and validation

SOP 15(1) . T03 . C02 . G01

TM . DEC . Stats

Write close down plan\*

TM

Finalisation and sign off SAP and HEAP

SOP 21 . SOP 33 . G02

HE . Stats

Notify end of recruitment: Sites, R&D and other relevant parties

TM

IMP disposal, accountability

SOP 27 . T06

TM

Sample arrangements  
Collection, ongoing storage arrangements

TM

Study equipment reconciliation

TM

Financial reconciliation

SPM . TM

Anonymisation and preparation of final dataset for sharing

UKCRC Guidance on Anonymisation

Stats

Ensure review and compliance with all contracts throughout

SPM . TM . QA . HE . Stats

## FOLLOW-UP

## END OF TRIAL

End of Trial Notification (MHRA/REC)

SOP 5(3) . C10

TM

Notify other parties of notification CRN, Insurance, Registries, Website, Sponsor, QA, Trust R&D, Funder

TM

Completion of data entry

DEC . TM

SAE Reconciliation (Contact QA Team)

TM . QA Support

Cancel Royal Mail Licence fees (if applicable)

DEC . TM

## ANALYSIS

Data lock

SOP 15(4) . T46 . T47

TM . Stats . CI

Transfer of data to collaborators for analysis (if applicable)

SOP 15(3)

TM . Stats . CI

Unblinding (if applicable)

SOP 4 . T43 . T44

TM . Stats . CI

Final oversight meetings

TM . Stats . CI

Closure of sites (Inc. Copy of electronic data to sites)

SOP 20 . T32-T35

TM

Summary findings to REC and MHRA

SOP 5

TM

Upload findings to registries (required within 1 year of end of trial date submitted on the EOT notification)

SOP 28

TM . Stats

Ingestion into archive. Transfer to named archivist.

SOP 23

QA . CI

Archive Data Asset

SPM

## REPORTING

Prepare final report to funder and publish (should be within 1 year of end of trial date submitted on the EOT notification)

TM . CI . Stats

Prepare papers as per dissemination plan

SOP 22

Stats . CI . HE . TM

Inactivate trial documents on Q-Pulse

Communicate results to participants

TM . CI

## ARCHIVING

Prepare to archive all TMF repositories

SOP 23

TM

\*There is no template trial closure plan, it is suggested that the road map is used to pull out relevant tasks and assign responsible people and timelines which can be reviewed at relevant meetings that have oversight of study closure.