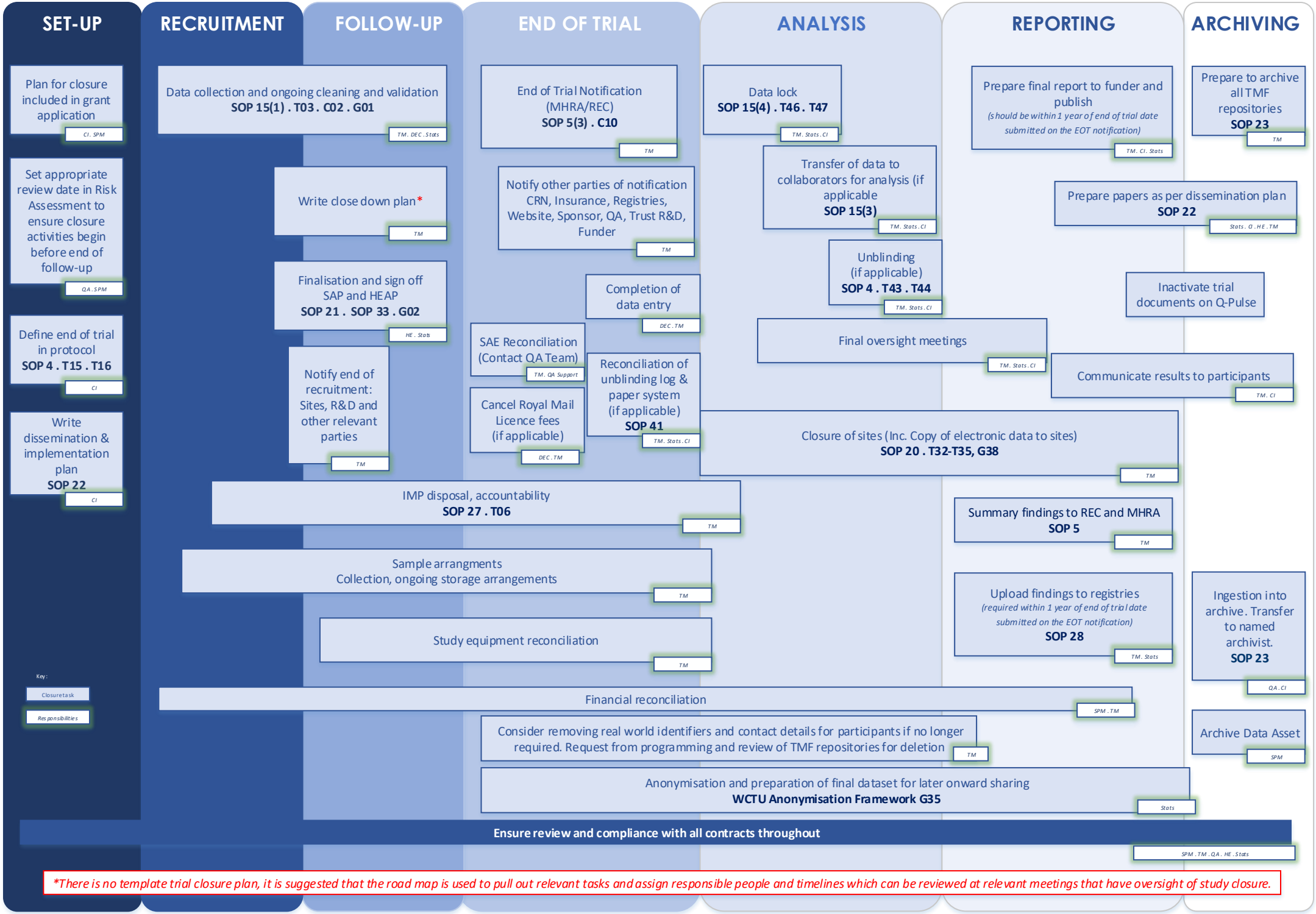
SET-UP
RECRUITMENT
FOLLOW-UP
END OF TRIAL
ANALYSIS
REPORTING
ARCHIVING
Plan for closure included in grant application
CI. SPM
Set appropriate review date in Risk Assessment to ensure closure activities begin before end of follow-up
QA. SPM
Define end of trial in protocol
SOP 4 . T15 . T16
CI
Write dissemination & implementation plan
SOP 22
CI
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 arrangments
Collection, ongoing storage arrangements
TM
Study equipment reconciliation
TM
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
Reconciliation of unblinding log & paper system (if applicable)
SOP 41
TM. Stats. CI
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, G38
TM
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
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
Prepare to archive all TMF repositories
SOP 23
TM
Ingestion into archive. Transfer to named archivist.
SOP 23
QA. CI
Archive Data Asset
SPM
Key:
Closure task
Responsibilities
Financial reconciliation
SPM . TM
Consider removing real world identifiers and contact details for participants if no longer required. Request from programming and review of TMF repositories for deletion
TM
Anonymisation and preparation of final dataset for later onward sharing
WCTU Anonymisation Framework G35
Stats
Ensure review and compliance with all contracts throughout
SPM . TM . QA . HE . Stats
*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.