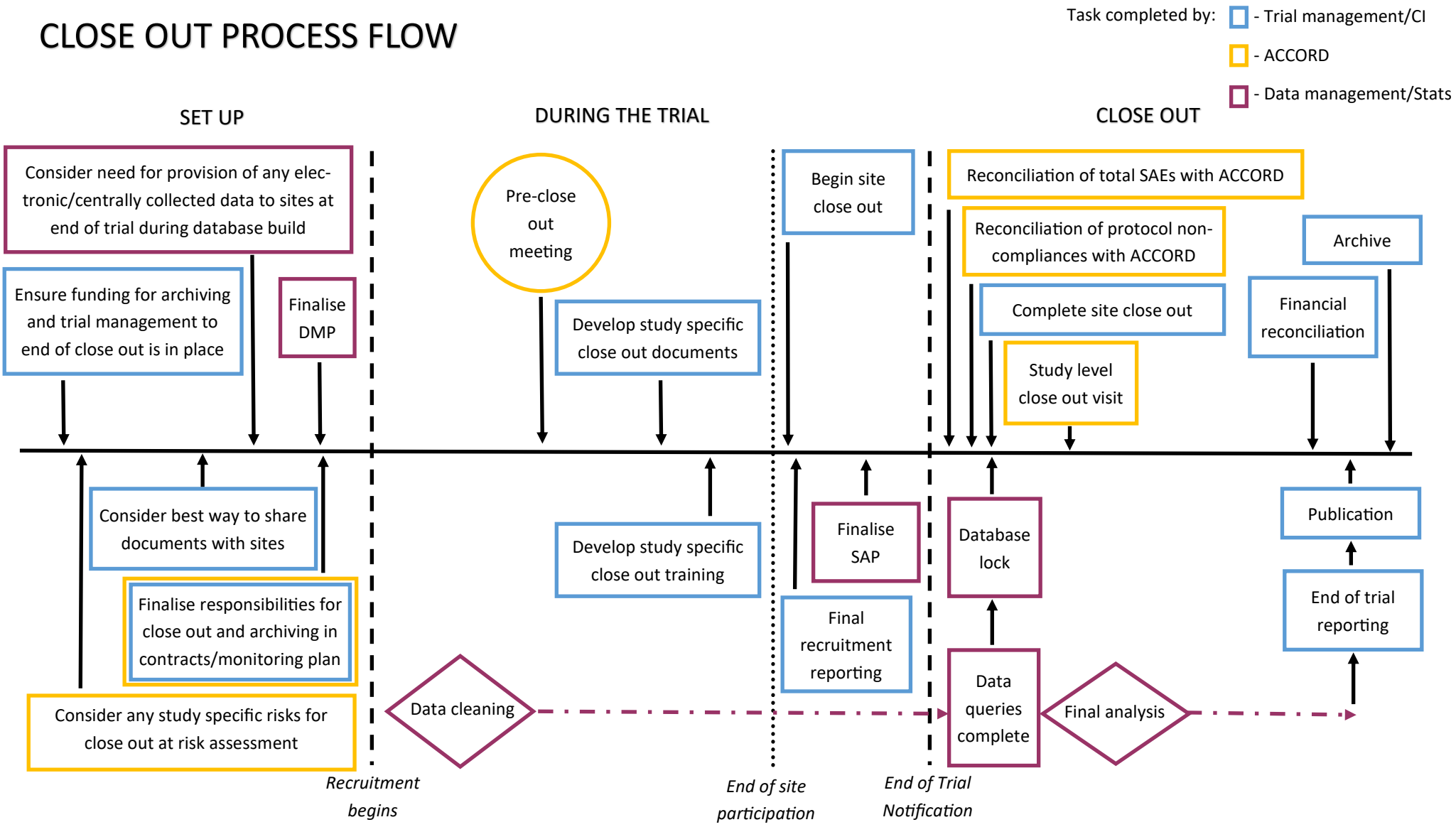
CLOSE OUT PROCESS FLOW



The tasks required during the close out process will depend on individual study design. Above is an example of the tasks required and the timings of these but these will change between studies, for example some studies may require active site participation right up until end of trial notification, some may involve processing of batched blood or urine samples after the end of trial which would require completion prior to database lock. For the most part the order of the tasks above should remain the same unless agreed with the lead ACCORD monitor e.g database lock should not take place prior to finalising the SAP or reconciliation of SAEs with ACCORD. Responsibility for task completion may also change dependent on study design. Data cleaning, including QC, should be an ongoing process throughout the trial and must be complete for all data prior to database lock, see SOP CR018 (Data Management) for further details.