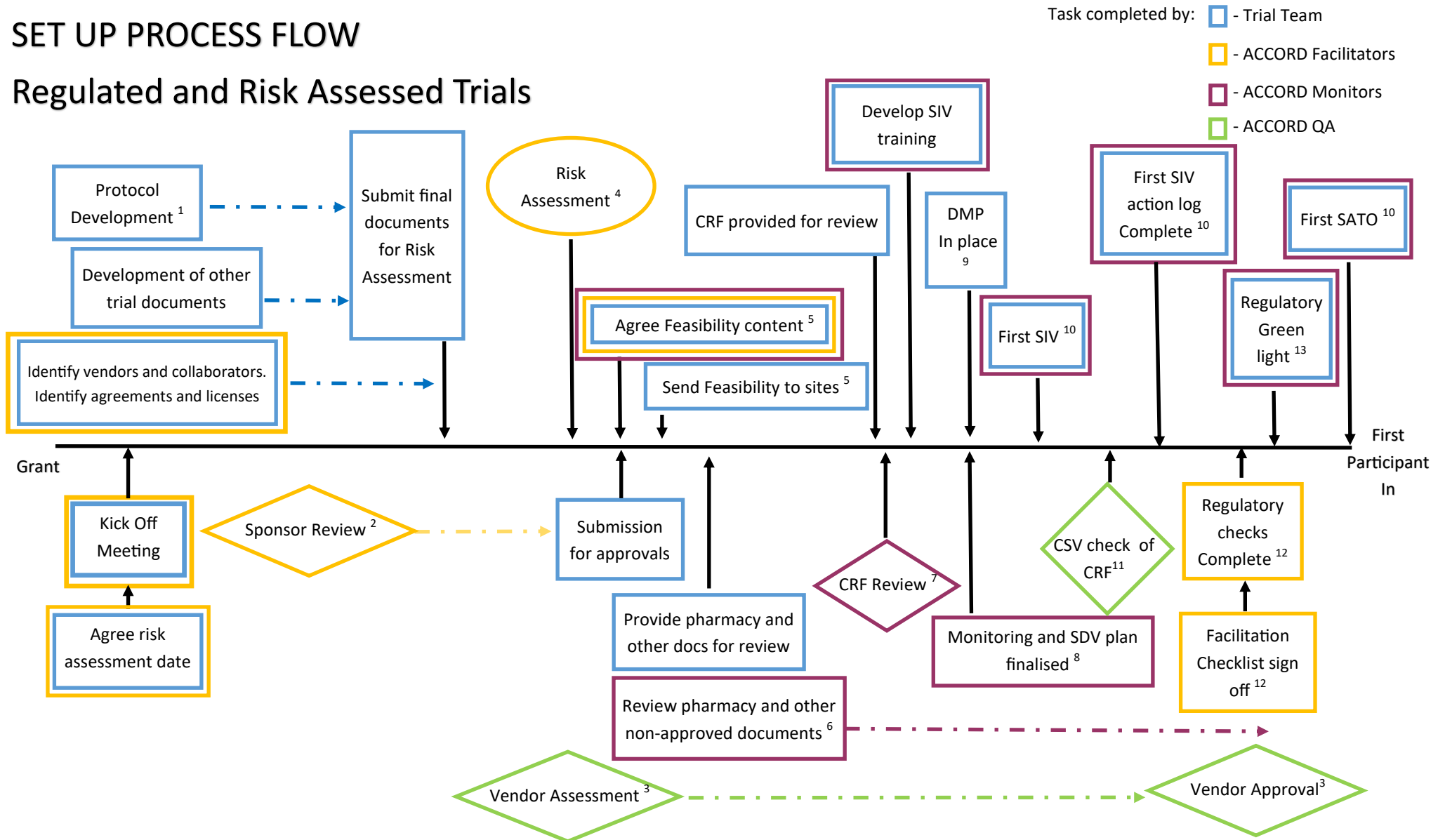


SET UP PROCESS FLOW

Regulated and Risk Assessed Trials



The tasks required during set up will depend on individual study design. Above is an example of the tasks required and the approximate timings of these but these will change between studies. The diagram does not represent length of time, just order of tasks. Some tasks must be performed in a particular order—for example the first SIV can not take place until the initial CRF review has taken place, the monitoring and SDV plan are signed, local submission to R&D has been made and the feasibility questionnaire is complete. All of the set up steps required for the study design must be complete prior to first SATO.

CRF = Case Report Form, CSV = computer system validation, DMP = Data Management Plan, SIV = Site Initiation Visit, SATO = Sponsor Authorisation to Open

See the following ACCORD SOPs for more information on processes referenced:

1: CR007 2: GS003, 3: QA009, 4: GS002, 5:GS013, 6: GS010, 7: CR013, 8: CM004, 9: POL012 10: CM001, 11: QA010, POL007, 12: FA001, 13: GS010, CM001