

						Time points	
Step	Name	STEP START	Actions	STEP ENDS	Recording	CRN	DH/NIHR (PII/PID)
1	IDENTIFY	First approach about study but no protocol	Early discussions between Sponsor, PI, team and R&D Review study synopsis/summary	Email from PI/R&D/team confirming interest	Nothing	N/A	N/A
2	ASSESS	Date Participating Organisation Invited Receipt by R&D of a protocol from Sponsor	Carry out quick check of study Have we got PI/team in place? Have we got required facilities/support depts? Have we got required patient/participant type?	Email response sent to Sponsor acknowledging receipt of protocol	Record "Participating Site Invited" date on EDGE Create EDGE record Use IRAS number as study identifier Include PI name, Sponsor, Funder etc	3 days <i>(expectation not a measured metric)</i>	N/A
3	ARRANGE	Date Participating Site Selected Receipt of 'Local Information Pack' from Sponsor Includes HRA Initial Assessment Letter Includes all associated documents Includes Statement of Activities (non-commercial) Includes Schedule of Events Includes costing template/mCTA etc	R&D staff carry out site checks for capacity and capability by email R&D review costings, contract, SoA etc. Negotiate terms of contract/SoA where required Send investigator agreement to PI and inform PI/team about EDGE reporting requirements <i>Note: investigator agreement is a local C&W document</i>	Record "Participating Site Selected" date on EDGE Save all study documents in study folder For each completed review save email chain/confirmation in study folder	Start of CRN 40-day "selected to site confirmation" metric HLO 4 40 days	Start of DH 70-day "selected to first patient" metric 70 days	
		Receipt of HRA approval letter from Sponsor		Record "Date of HRA approval letter" on EDGE			
		Date participating organisation confirmed by Sponsor	First party signs contract/mCTA or Sponsor emails final agreed SoA to site (R&D generic mailbox)	Date of the FIRST signature on the agreement/contract or date final SoA received by email from Sponsor	Record "Date participating organisation confirmed by Sponsor" date on EDGE		
4	CONFIRM	Date participating organisation confirmed Date Participating Organisation ready to start Non-confirmation	Fully executed study agreement/mCTA or emails confirming acceptance of SoA from both Sponsor and site R&D emails Sponsor using template email confirming capacity and capability (attaching fully executed agreement/mCTA or SoA) Date Sponsor confirms that recruitment can begin at site (by email) Sponsor declines site or site confirms no capacity and capability	Date of the LAST signature on the agreement/contract or date SoA accepted by both site and Sponsor (evidence by email) Site unable to take part in study	Record "Date participating organisation confirmed" on EDGE Ensure EDGE record is complete including status, start and end dates etc Record date in "Open to Recruitment" field on EDGE Record "Non-confirmation" on EDGE	Start of CRN 30 day confirmed by Sponsor to first patient metric HLO 5 30 days	
5	FIRST PATIENT RECRUITED	First patient is recruited at site	<i>Patients consented but failing screening do not count</i>	PI/team to record first patient recruited on EDGE	End of CRN 30 days to 1st patient metric	End of 70 day selected to 1st patient metric	
	DURING RECRUITMENT WINDOW	Patients recruited at site	R&D to review amendments R&D to check that recruitment is being uploaded by PI/team Where study payments are due, R&D to check that invoices are raised at agreed timepoints	PI/team to maintain recruitment record on EDGE			
6	LAST PATIENT RECRUITED	Last patient recruited at site	R&D to check that PI/team have fully recorded recruitment on EDGE	PI/team to record date of last patient recruited on EDGE			

