Appendix 3
Dates & Targets

Minimum data set for the Performance in Initiating and Delivering Clinical Research exercise

As of Quarter 1 2018-19, improvement in clinical trial performance and reducing site set up and participant recruitment time will no longer be assessed with a 70 day benchmark. A renewed focus will be placed on transparency, accuracy, and meeting sponsor expectations. The minimum data set has been updated to reflect this change.

#	Data Field Name	Definition	Context
1	Integrated Research Application System (IRAS) Identification Number	The identifier assigned to a study record in the Integrated Research Application System (IRAS).	Main study identifier
		Initiation/Start-up	
2	Date Site Invited	Date on the Sponsor email received by the site providing the protocol in the version to be submitted for regulatory review	A clear record from the sponsor's perspective of the date that engagement with a site started. This email must be sent to the generic R&D email address and Local CRN (for NIHR CRN Portfolio studies) as listed on the R&D forum website at a minimum and may take place before or after the site has been listed in Part C of the IRAS Form and e-submitted to the HRA. Start of assessing capacity and capability.
3	Date Site Selected	Date on the Sponsor email received by the site providing the minimum defined documents to enable site to commence arrangement and/or confirmation of local capacity and capability as applicable representing that the site has been selected to take part in the study. Where the Sponsor	The date of the email provides formal written communication at a discrete time point of the joint decision between the Sponsor and the site that the site will undertake assessment, arrangement and/or confirmation of its capability and capacity to deliver the Sponsor's study as applicable. Start of arranging capacity and capability. This email must be sent to the generic R&D email address and Local CRN (for NIHR CRN Portfolio studies) as listed on the R&D forum website at a minimum. This email can only be provided after the IRAS Form has been e-submitted to the HRA. The email can only be sent after

		is also the site, this is the date of the HRA initial assessment letter.	the 'Initial Assessment' letter has been released by the HRA to the Sponsor. The minimum local document set that the site would need to start this process is as described by the latest HRA guidance on the HRA website. Versions should be as submitted to HRA unless the activity is taking place after HRA Approval in which case the documents should be the versions as approved by HRA, and in this case the package should include the HRA Approval letter. Please refer to the following document for more information on the Date Site Selected for studies not receiving an HRA initial assessment letter or for sites added to HRA approvals studies via amendment: Clarification on Date Site Selected.
4	HRA Approval Date	Date of HRA Approval for study as per HRA Approval Letter	Site confirmation cannot take place prior to HRA Approval. Provision of this date enables robust data collection.
5	Date Site Confirmed By Sponsor	Date of the first contract signature of all the organisations involved (i.e. sponsor, site, 3rd party) or Date on the email received from Sponsor providing the final statement of activity ready for final agreement.	The date represents the date when the Sponsor regards that all arrangements and negotiations for the study with that site to be complete and that the site will take part in the study, and is documented by the Sponsor providing the complete agreement or Statement of Activity. End of arranging and start of confirming capacity and capability. This demonstrates (i) the Sponsor is satisfied all site capacity and capability has been agreed in principle and arrangements have been put in place (ii) study finances agreed (iii) site agreement fully drafted prior to execution or statement of activity fully drafted and costs agreed by the site prior to final agreement by all parties (iv) HRA approval has been given. Where an agreement is not required, the Statement of Activity must be sent to the generic R&D email address (as listed on the R&D Forum website) at a minimum.
6	Date Site Confirmed	Date of the last contract signature of all the organisations involved (i.e.	The recorded date is the date of fully executed site contract (as evidenced by the signature date box within the contract) or date statement of activity accepted by

		sponsor, site, 3rd party) or date of final written agreement of statement of activity (as applicable)	both the site and sponsor (evidenced by formal written communication of this agreement). This confirms all capacity and capability has been put in place in preparation to start and that all parties confirm their agreement with terms of these arrangements. If the site agreement is the only item required, then the last signature would be used as the date to confirm. All requirements from the site must be completed prior to exchange of contract eg staff in post, honorary research contracts issued.
7	Non-Confirmation Status	Record reason for non-confirmation of a site to start the study	Status selected as either a) Sponsor declined site confirmation b) Site confirmed no capacity and capability (declined to participate)
8	Date Site Ready To Start	Date that the site is ready to start (i.e. recruit study participants, provide data or tissue) defined by all other requirements to start, additional to contract signature and/or Statement of Activity agreement, are satisfied	Depending on the type and nature of study there could be one or several factors that inform this date. The date recorded is the date that the sponsor confirms that all activities required by the sponsor have been satisfied or a date by which these will be satisfied i.e. site initiation completed, site file in place, IMP shipped to site as applicable. All requirements from the site must be completed prior to exchange of contract e.g. staff in post, honorary research contracts issued.
9	First Participant Recruited Date	The date of consent to participate for an eligible participant	Where a participant consents to both screening and participation into a study and they then fail to pass screening, their consent date cannot be used. The next date of consent to participate of an eligible participant will be defined as the first participant. The confirmation of the first participant will be a retrospective verification as will require the outcome of screening to ensure the participant is eligible for the study before this data point can be captured.
10	Reason For Delay In Recruiting First Participant	Reason for delay of recruitment of first participant.	Both Reasons and Source are captured conditionally for Clinical Trials only as described in the latest version of the PID guidance document on the NIHR website.
11	Source Of Delay In Recruiting First	Requirement to report where responsibility for delay sits, when citing	Source of delay can be NHS (host site), Sponsor (including NHS Sponsor), Both NHS and Sponsor, Neither NHS (host site) nor Sponsor. For each trial

	Participant	possible reasons for delay for Performance in Initiating Clinical Research.	where delays occurred, Sites must select a source of delay in addition to at least one reason for delay.
12	Comment	Further information for the reason for delay in recruiting participants; please see the feedback document in the NIHR website for more details on how to complete this field.	An optional free text field to accommodate further explanation, typically of a delay at the given site, but may also be used to provide any additional information about the record. It is necessary to complete this item in some circumstances. Please see the feedback document on the NIHR website.
Recruitment to Time and Target (commercial contact studies)			
13	Recruitment Target	Number of unique participants planned to provide informed consent and be deemed eligible (i.e. excluding screen failures) at the site for the study as jointly agreed between the sponsor and the site.	The target number of participants to be recruited to participate in the study which is suitably documented (e.g. study milestone schedule for CRN portfolio studies or the study agreement). Any changes to recruitment targets are managed and formalised through site process. For CRN portfolio studies, the processes for target revision and study record management will apply. Where there is a range then the minimum and maximum range are entered as data points but the minimum range is deemed as the target. Where there is no range but just one target, this number is entered into both data the minimum and maximum data field.
14	Target Number Of Participants Available	Whether or not the target number of participants to be recruited to participate in the study has been specified in the relevant agreement between the commercial sponsor and the site conducting the study	Ensure data provision can be determined as either: a) Not available/not agreed b) Number agreed c) Range agreed
15	Minimum Number Of Participants Agreed	The minimum number of participants agreed to be recruited, if a range has been agreed. This will be	Reflects the recruitment target as jointly agreed between the Sponsor and site.

		the same as the maximum and recruitment target if a fixed number has been agreed. This will be the same as the recruitment target (item 13) where a range has been agreed.	
16	Maximum Number Of Participants Agreed	The maximum number of participants agreed to be recruited, if a range has been agreed. This will be the same as the minimum and recruitment target if a fixed number has been agreed.	Reflects the recruitment target as jointly agreed between the Sponsor and site.
17	Target Date To Recruit Participants Available	Whether or not there is a target date agreed by which the target number of participants must be recruited.	Ensure data provision can be determined as either: a) Not available/not agreed b) Date agreed
18	Date Agreed To Recruit Target Number Of Participants	The date by which the target number of participants must be recruited, if a date has been agreed / is available.	The target date for the last participant to be recruited specified in the study agreement between the commercial sponsor of the study and the site conducting the study.
19	Total Number Of participants Recruited At The Agreed Target Date	Total number of study participants recruited into the study at the site by the agreed target date.	Total number of eligible study participants who gave informed consent to take part in the study at the research site, aligning with the definition for setting the recruitment target, calculated on the date agreed as the site target date
20	Total Number Of Study Participants Recruited	Total number of study participants randomised / recruited into the study at that site.	Uploading of recruitment data should be done on an ongoing basis but as a minimum once a month.
21	Date The Study Closed To Recruitment	Date that the study stopped recruiting participants	This would need to be a joint discussion between the sponsor and site if there is ambiguous reason why a site is closed to recruitment. If it is clear why

			recruitment has been stopped then there is no need for a joint agreement on this i.e. nationally recruitment has been halted by the sponsor on grounds of good efficacy or poor safety or global recruitment target has been reached.
22	Closure Reason	The reason that the study closed to recruitment at the site	Provides information as to why the site closed early for sponsor reasons or host reasons or if they actually closed because the site finished recruitment. a) Recruitment finished b) Withdrawn by Sponsor c) Withdrawn by Host
23	Recruitment to Time and Target Comment	Further explanation of the Recruitment to Time and Target related circumstances of the study, as necessary.	An optional free text field to provide further explanation in relation to the recruitment to time and target for the study at the given site
Additional initiation/start-up data points for evaluating set-up timeline (NOT FOR CAPTURE OR REPORTING BY SITES)			
24	Date Study Initiated	Date of Sponsor submission for HRA Approval	A robust date of the start of formal study set-up