**PERFORMANCE IN INITIATING AND DELIVERING CLINICAL RESEARCH**

**INFORMATION SUBMISSION GUIDELINES**

<table>
<thead>
<tr>
<th>Version Control</th>
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<table>
<thead>
<tr>
<th>Items 26, 27</th>
<th>Update of Submission and Publication Timetable</th>
</tr>
</thead>
</table>
INTRODUCTION

1. The Government wishes to see a dramatic and sustained improvement in the performance of providers of NHS services in initiating and delivering clinical research. The aim is to increase the number of participants who have the opportunity to participate in research and to enhance the nation’s attractiveness as a host for research.

2. The Government’s Plan for Growth\(^1\), published in March 2011, announced the transformation of incentives at local level for efficiency in initiation and delivery of research.


4. NHS providers holding NIHR contracts issued after Autumn 2011 are required to provide, on a quarterly basis, information on recruitment to clinical trials, including commercial trials. This applies to all clinical trials hosted by the organisation, as specified in paragraphs 12 and 16. These data must be submitted to the NIHR Central Commissioning Facility (CCF) via the Clinical Trial Performance (CTP) Submission Platform in the format specified in this document.

5. The following organisations may be subject to a LCRN Partner contract, provide services and recruit clinical trial participants, but should not currently submit a return:

   - General Practices
   - Clinical Commissioning Groups

   If in doubt, please contact the NIHR-CCF Clinical Trials Performance team.

6. NHS providers are required to publish the information on recruitment to clinical trials and recruitment to time and target for commercial contract clinical trials in an accessible part of their website. The minimum dataset is listed in paragraphs 15 and 17. Individual NHS providers might wish to consider publishing additional information, especially where they have identified delays to recruitment. The link to the data will be published in the NIHR website. Please provide the URL where the information is published as soon as possible after your webpage goes live and no later than the publication and submission deadline.

7. The collection of NHS provider data on initiating and delivering clinical research, described here, is a separate exercise from the collection of performance data by the NIHR Clinical Research Network (CRN) against the CRN High Level Objectives. However both exercises have, as overall aims, increasing the number of participants able to participate in research, and enhancing the nation’s attractiveness as a host for research and they are based on a common minimum data set for HRA Approval trials.

8. From Quarter 4 2015-16, the submission platform changed to be able to collect information on clinical trials which go through the HRA approval process. The update to the CTP platform reflects the minimum data set developed by CCF, CRN and HRA to provide greater flexibility for understanding performance at all points across set-up the study life-cycle at both a site and study level and provides consistent definitions on which each organisation will base their respective metrics. Further details on how the new metrics will be analysed will be communicated to providers of NHS services in due course.

Further information can be found in supplementary documents (see paragraph 28) and here [http://www.nihr.ac.uk/research-and-impact/nhs-research-performance/hra-approvals-and-nihr-metrics.htm](http://www.nihr.ac.uk/research-and-impact/nhs-research-performance/hra-approvals-and-nihr-metrics.htm).

9. From Quarter 1 2017-18, the submission platform will only be accepting information on trials which have gone through the HRA Approval process; all data fields related to the collection of trials with NHS Permission will be removed.

**REQUIREMENTS**

10. NHS providers are required to submit information via the NIHR CTP submission platform in two areas:
- Initiating clinical research
- Delivering commercial contract clinical research to time and target.

**Initiating Clinical Research**

11. Providers of NHS services must submit to the CCF, within 30 days of the end of each quarter (see timetable in paragraph 26), the following information for every clinical trial (regardless of funder or inclusion in NIHR CRN Portfolio) where the Date Site Selected falls within the previous twelve months:

- The Research Ethics Committee (REC) reference number
- The Integrated Research Application System (IRAS) Number
- The name of the clinical trial
- The date the site was invited
- The date the site was selected
- The HRA Approval date

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• The date the site was confirmed by the sponsor
• The date the site was confirmed
• The non-confirmation status
• The date when the site is ready to start
• The date of the recruitment of the first participant to the clinical trial (if this has occurred)
• If no date of recruitment of the first participant is given, whether the first participant has not yet been recruited or the date of recruitment is not available.

The Department of Health and Social Care is committed to improving clinical trial performance and reducing site set up and participant recruitment time. As of Quarter 1 2018-19, this will no longer be assessed with a 70 day benchmark for the duration between Date Site Selected and date of First Participant Recruitment. A renewed focus will be placed on transparency, accuracy, and meeting sponsor expectations. Please continue to report any and all delays which have affected or may affect agreed study timelines in line with the minimum data set fields outlined above.

If there is a delay in recruiting the first participant into a trial:

• The reason for any delay in recruiting the first participant into a trial in relation to the site being selected.

Please do not submit information on studies for which the NHS provider is only a Patient Identification Centre (PIC).

Please do not include trials in your Performance in Initiating return where your site is being added to an existing study which was brought under HRA Approval after 31 March 2016. Please review the letter of HRA Approval for the trial to see if this applies. The letter will show ‘Pre-HRA’ or will make reference to the trial being ‘brought under HRA Approval’. If you are unsure if your trial falls in to this category, please contact the Clinical Trial Performance Team well in advance of the submission deadline for advice.

12. We recognise that there are a number of reasons why the recruitment of the first participant into clinical trials might be delayed. The main reasons are listed in Annex 2. One or more appropriate reasons should be selected on the template and any additional information provided in the comments field. Please note that the inclusion of a possible reason for non-compliance on this list does not necessarily mean that this reason will be deemed to be acceptable. Provision of full data and explanation will help us all identify and clarify recurring issues that partners in the health research system will need to address.

13. NHS Providers are required to report where responsibility for delays sits, when citing possible reasons for delay for Performance in Initiating Clinical Research. The four sources of delay correspond to:

• NHS (host site)
• Sponsor (including NHS sponsors)
• Both NHS and Sponsor
• Neither NHS (host site) nor Sponsor.

For example:
• Delayed HRA Approval would correspond to Neither NHS (host site) nor Sponsor.
• Delayed delivery of IMP would (normally) correspond to Sponsor delay.
• Costing and Contractual negotiation would (normally) correspond to either/or Both NHS and trial Sponsor.
• Staff absence or shortage resulting in delayed confirmation of capacity and capability would (normally) correspond to NHS (host site)
• Some delays, such as rare or very rare disease, correspond to Neither.

For additional information regarding sources of delay for trials, please refer to the feedback document available on the CCF website at: https://www.nihr.ac.uk/research-and-impact/documents/PID%20Documents/Guidance%20Documents/Clinical%20Trials%20Data%20Record%20Feedback%20Process%20-%20HRA%20approved%20trials%20Published.pdf.

14. For Performance in Initiating Clinical Research, NHS providers shall publish, in an accessible part of their website and within 30 days from the end of the quarter, the following information for every clinical trial where the Date Site Selected falls within the previous twelve months:

• The Research Ethics Committee (REC) reference number
• The Integrated Research Application System (IRAS) Number
• The name of the clinical trial
• The date the site was invited
• The date the site was selected
• The HRA Approval date
• The date the site was confirmed by the sponsor
• The date the site was confirmed
• The date when the site is ready to start
• The date of the recruitment of first participant, and
• The source of the delay in recruiting the first participant into a trial (NHS Provider/ Sponsor/ Both/ Neither).

Plus, in the event that a trial initiation did not proceed to confirmation:

• The non-confirmation status.

Delivering Clinical Research

15. NHS providers must submit to the CCF, within 30 calendar days of the end of each quarter (see timetable in paragraph 26), the following information for every
commercial contract clinical trial **hosted** by the NHS provider **closed to recruitment** in the previous twelve months.

Please do not submit information on studies for which the NHS provider is only a Patient Identification Centre (PIC).

From Quarter 4 2015-16, providers must submit the following information **only for trials closed to recruitment in the previous 12 months**:

- The Research Ethics Committee (REC) reference number
- The Integrated Research Application System (IRAS) Number
- The name of the clinical trial
- Whether or not a target number of participants was agreed
- The minimum number of participants agreed to be recruited (if a range has been agreed; this will be the same as the maximum if a fixed number has been agreed)
- The maximum number of participants agreed to be recruited (if a range has been agreed; this will be the same as the minimum if a fixed number has been agreed)
- Whether or not a target date to recruit participants was agreed
- The date agreed to recruit the target number of participants
- The total number of participants recruited at the agreed target date
- The total number of study participants recruited
- The date that the trial closed to recruitment
- The reason for the closure of the trial.

16. For Performance in Delivering Clinical Research the Contractor shall publish, in an accessible part of their website and within 30 days from the end of the quarter, the following information for every commercial contract clinical trial **hosted** by the NHS provider **closed to recruitment in the previous twelve months**:

- The Research Ethics Committee (REC) reference number
- The Integrated Research Application System (IRAS) Number
- The name of the clinical trial
- Whether or not a target number of participants was agreed
- The minimum number of participants agreed to be recruited (if a range has been agreed; this will be the same as the maximum if a fixed number has been agreed)
- The maximum number of participants agreed to be recruited (if a range has been agreed; this will be the same as the minimum if a fixed number has been agreed)
- Whether or not a target date to recruit participants was agreed
- The date agreed to recruit the target number of participants
- The total number of participants recruited at the agreed target date
- The total number of study participants recruited
- The date that the trial closed to recruitment
- The reason for the closure of the trial.
Publication Transparency

17. For the publication of data for initiation and delivery of clinical research, the clinical trial data and associated statistics and descriptive information provided to the public via web pages should reflect the data submitted in the quarterly submission to CCF.

18. Where NHS Providers are submitting and publishing data for fifty clinical trials or more and publications are in PDF or Word format, it is requested that these data records be sequentially numbered (i.e. 1-51) for the efficiency and accuracy of comparing submission data to those data published on Trust websites.

19. Where NHS Providers have submitted a nil return for Performance in Initiating or Performance in Delivering, or both, it is requested that this is clearly stated on the Trust website.

20. If the website address of the Trust has changed, the provider must inform the CTP team in advance of the publication deadline.

SUBMISSION OF INFORMATION

21. The NIHR CCF CTP Submission Platform (https://ccfctp.nihr.ac.uk) has been created for NHS providers to submit their information. The CCF will provide each NHS provider that is required to submit information with the necessary information to log in and upload data on initiating and delivering clinical research.

22. Platform Users should attempt to enter and validate some data in advance of the submission deadline so that any technical issues can be addressed without delaying returns. If the NHS Provider does not host any clinical trials, they are still required to “submit” an empty return.

23. CTP Submission Platform Instructions³ accompany these Performance in Initiating and Delivering Clinical Research Submission Guidelines.

24. NHS Providers are responsible for verifying that their data has been successfully submitted each quarter and that it is true and accurate to the best of their knowledge. If the NHS Providers experience issues with the platform, they must contact the CTP team well in advance of the deadline.

25. Any queries on the format of the data or the submission process should be directed to the CCF at CTP@nihr.ac.uk.

SUBMISSION AND PUBLICATION TIMETABLE

26. Information should be provided to the CCF and published in an accessible part of the NHS provider’s website within **30 calendar days of the end of each quarter**. For the data collection for Quarter 1, 2019-20, the relevant information should be provided for the period of 01 July 2018 to 30 June 2019. Please note that the data cut off is the last day of the quarter, not the submission deadline. Any changes occurring between the end of the quarter and the submission deadline should not be included on the return (for example recruitment dates after 30 June 2019). The submission opens on **Monday 01 July 2019**, and the deadline for **submission and publication** of this information is **5pm Tuesday 30 July 2019**.

27. For the following four quarters, the timetable is as follows:

<table>
<thead>
<tr>
<th>Quarter</th>
<th>Period Start Date</th>
<th>Period End Date</th>
<th>Submission &amp; Publication Deadline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q2 2019-20</td>
<td>01 October 2018</td>
<td>30 September 2019</td>
<td>Wednesday 30 October 2019 5pm</td>
</tr>
<tr>
<td>Q3 2019-20</td>
<td>01 January 2019</td>
<td>31 December 2019</td>
<td>Friday 31 January 2020 5pm</td>
</tr>
<tr>
<td>Q4 2019-20</td>
<td>01 April 2019</td>
<td>31 March 2020</td>
<td>Thursday 30 April 2020 5pm</td>
</tr>
<tr>
<td>Q1 2020-21</td>
<td>01 July 2020</td>
<td>30 June 2020</td>
<td>Thursday 30 July 2020 5pm</td>
</tr>
</tbody>
</table>
FURTHER INFORMATION

28. Definitions of the terms used in this document are provided in Annex 1.


FURTHER INFORMATION: ENQUIRIES

30. Enquiries should be sent to the NIHR Central Commissioning Facility at CTP@nihr.ac.uk.

Róisín Tooke-Mitchell, Senior Analyst – 020 8843 7102
Adam Judd, Data Analyst – 020 8843 8059
**DEFINITIONS**

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
<th>Format</th>
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</thead>
</table>
| **Clinical Trial**                        | A set of medical research procedures conducted on human participants to allow safety and adverse effects of interventions, their efficacy, or their effectiveness to be established often by comparison with alternative or placebo/sham interventions. Interventions may be drugs, diagnostics, prophylactics, surgery, devices, non-invasive therapies, screening or other healthcare procedures or technologies. This definition does not just refer to studies which fall within the remit of the MHRA; the relevant categories of study in the Integrated Research Application System (IRAS) Project Filter Question 2 (Type of Research) on the IRAS application form, are as follows:  
  • Clinical trial of an investigational medicinal product  
  • Clinical investigation or other study of a medical device  
  • Combined trial of an investigational medicinal product and an investigational medical device  
  • Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice |        |
<p>| <strong>Research Ethics Committee (REC) Reference Number</strong> | The reference number allocated to the trial by the National Research Ethics Service.                                                                                                                                                                                                                                                                                                                                                                                     | Free text |
| <strong>Integrated Research Application System (IRAS) Number</strong> | The identifier assigned to a study record in the Integrated Research Application System (IRAS). Studies without an IRAS ID (i.e., never used IRAS/CSP) should enter 0.                                                                                                                                                                                                                                                                                         | Free text |
| <strong>Name of the Clinical Trial</strong>            | The full title of the clinical trial, as stated on the Research Ethics Committee form.                                                                                                                                                                                                                                                                                                                                                                                   | Free text |
| <strong>Recruitment of First Participant</strong>      | The date the first eligible participant consented to the study. Further context can be found in the <a href="#">Minimum Data Set</a>.                                                                                                                                                                                                                                                                                                                                   | dd/mm/yy |
| <strong>Date Site Invited</strong>                     | The date on the sponsor email received by the site providing the protocol in the version to be submitted for regulatory review.                                                                                                                                                                                                                                                                                                                      | dd/mm/yy |</p>
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
<th>Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Site Selected</td>
<td>The 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.</td>
<td>dd/mm/yy</td>
</tr>
<tr>
<td>Clarification of 'Date Site Selected' for sites added to HRA approval studies via amendment:</td>
<td>The provision of the HRA amendment validation letter does not provide any additional information to enable local capacity and capability activities for a new site added via an amendment. Sites are expected to commence arranging local capacity and capability based on the local information pack from the sponsor which reflects the current document versions, including any submitted with the amendment to the HRA. This pack does not need to include the HRA amendment validation letter. The date of sending of the pack should be reflected in the 'Date Site Selected' data field. Local set-up is expected to commence prior to HRA Approval and therefore the same principle applies to amendments: the site should issue confirmation of capacity and capability (where required) once the HRA has approved the amendment. For the purpose of completing PID returns, if a delay in completing site set-up occurs as a result of HRA amendment processing, this can be captured by selecting 'A – Permissions Delayed/Denied' and including a brief explanation in the comments section.</td>
<td></td>
</tr>
<tr>
<td>HRA Approval Date</td>
<td>The date of HRA approval for the study, as per the HRA Approval Letter</td>
<td>dd/mm/yy</td>
</tr>
<tr>
<td>Date Site Confirmed by Sponsor</td>
<td>The date of the first contract signature of all the organisations involved (i.e., sponsor, site, third party) or date on the email received from the sponsor providing the final statement of activity ready for final agreement.</td>
<td>dd/mm/yy</td>
</tr>
<tr>
<td>Date Site Confirmed</td>
<td>The date of the last contract signature of all the organisations involved (i.e. sponsor, site, third party) or date of final written agreement of statement of activity, as applicable.</td>
<td>dd/mm/yy</td>
</tr>
<tr>
<td>Non-Confirmation Status</td>
<td>The reason why the site was not confirmed, where applicable. This is a drop-down field with the following options:</td>
<td>Drop-down</td>
</tr>
<tr>
<td></td>
<td>- Sponsor declined site confirmation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Site declined to participate</td>
<td></td>
</tr>
<tr>
<td>Term</td>
<td>Definition</td>
<td>Format</td>
</tr>
<tr>
<td>------</td>
<td>------------</td>
<td>--------</td>
</tr>
<tr>
<td>Date Site ready to start</td>
<td>The 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.</td>
<td>dd/mm/yy</td>
</tr>
</tbody>
</table>
| Commercial Contract Clinical Trial | A clinical trial that is solely funded and sponsored by industry in which:  
- The trial sponsor is the industrial company  
- The trial is carried out with the aim of generating data for purposes such as Marketing Authorisations, safety monitoring and supportive evidence for claims  
- The sponsor owns all the trial data and all Intellectual Property and Know How arising directly from the trial. | |
| Target number of participants available | Whether or not the target number of clinical trial subjects to be recruited to participate in the trial has been specified in the relevant Clinical Trials Agreement between the commercial sponsor of the trial and the NHS provider conducting the trial. This field is supplied as a drop-down, with the following options:  
- Not available/ not agreed  
- Number agreed  
- Range agreed | Drop-down |
| Minimum number of participants agreed | The minimum number of participants agreed to be recruited, if a range has been agreed. This will be the same as the maximum if a fixed number has been agreed. | Integer |
| 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 if a fixed number has been agreed. | Integer |
| Target Date To Recruit Participants Agreed? | Whether or not there is a target date agreed by which the target number of participants must be recruited. This is supplied as a drop-down field, with the following options:  
- Not available / not agreed  
- Date agreed | Drop-down |
<p>| 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. | dd/mm/yyyy |</p>
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
<th>Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Number Of Participants Recruited At The Agreed Target Date</td>
<td>The number of participants which were recruited by the target date, if a target date was agreed / is available.</td>
<td>Integer</td>
</tr>
<tr>
<td>Total number of study participants recruited</td>
<td>Total number of study participants randomised / recruited into the study at that site.</td>
<td>Integer</td>
</tr>
<tr>
<td>Date That The Trial Closed To Recruitment</td>
<td>The date that the trial stopped recruiting participants.</td>
<td>dd/mm/yyyy</td>
</tr>
<tr>
<td>Reason for Closure of Trial</td>
<td>The reason why the trial was closed. This is supplied as a drop-down field, with the following options:</td>
<td>Drop-down</td>
</tr>
<tr>
<td></td>
<td>• Recruitment finished</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Withdrawn by Sponsor</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Withdrawn by Host</td>
<td></td>
</tr>
</tbody>
</table>
POSSIBLE REASONS FOR DELAYS TO FIRST PARTICIPANT RECRUITMENT

In order to facilitate data collection and analysis, a number of possible reasons for delays to first participant recruitment have been provided on the template:

a) Relevant permissions delayed and not granted in time
   - HRA approval process not completed in time
   - Study-wide review not completed in time
   - Local review not completed in time
   - NHS Research Ethics Committee review not completed in time
   - Medicines and Healthcare products Regulatory Agency (MHRA) review not completed in time
   - CE mark process not completed in time
   - Other regulatory reviews not completed in time

b) Study suspended by sponsor
   - Study suspended at all sites
   - Study suspended at this site

c) Study closed by sponsor:
   - Safety reasons
   - Lack of clinical equipoise, as defined by the sponsor
   - Change in development pipeline within sponsor company
   - Strategic/financial reasons within sponsor company
   - Study-wide recruitment completed

d) Delays caused by sponsor:
   - Delay in provision of pharmacy manual
   - Protocol amendments
   - Delayed site initiation visit
   - Delayed confirmation from sponsor of study open to recruitment at site (i.e. delays in receiving “Green Light”)

e) Staff availability issues at site

f) No eligible participants seen during the reported period
   - Participants sought but no eligible participants identified
   - Strict participant eligibility criteria

NB: CCF requires a greater level of detail in the comments section for records where the reason for delay is ‘F-No Participants Seen’ and the source of delay is ‘Neither’ in order to ensure that the actual cause of why no participants were seen (i.e., participants were screened but none were eligible, a small participant population due to tight inclusion/exclusion criteria or rare diseases meant that few participants presented with the condition, etc.) is clear.

g) Eligible participants seen during the relevant period but did not consent to participate in the trial

h) Contracting delays
   - Within NHS provider
   - Within sponsor company
   - Other contracting delays
i) Rare or very rare diseases studies
j) Other (please describe)

In addition NHS providers are now required to identify the source that reasons for delay correspond to (please refer to paragraph 13 for further details).

**Please note:** Labels for these reasons within the CTP submission platform are abbreviated and vary slightly as stated, though the definitions and letter codes remain the same as described herein.

All relevant reasons for delay should be selected on the template; the reasons for delay can also be expanded upon in the comments section, if desired. Please note that the inclusion of a possible reason for delay on this list does **not** necessarily mean that this reason will be deemed to be acceptable.

Please find more detailed information regarding reasons for delay, and examples of delays here: https://www.nihr.ac.uk/research-and-impact/documents/PID%20Documents/Guidance%20Documents/Clinical%20Trials%20Data%20Record%20Feedback%20Process%20-%20HRA%20approved%20trials%20Published.pdf

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4 A rare disease in Europe is defined by EURORDIS as a disease affecting less than 1 in 2,000 citizens. The NIHR considers a very rare disease as one that affects less than 1 in 100,000 of the general population.