

Performance in Initiating and Delivering Clinical Research

Submitting to the NIHR Central Commissioning Facility
PID Submission

Prepared by Champions for Research Support

- Purpose of the slide set
- Background
- Data collection and submission
- Data analysis and Reports
- Improving performance
- Examples- test your knowledge
- Definitions
- Useful links

Purpose of the slide set

- NHS providers have been submitting PID data since 2012/13 and the number of submitting Trusts reached 60 for 2013-14 Quarter 4 (NHS providers with prior experience of PID submission can be found at: <http://www.nihr.ac.uk/systems/Pages/ClinicalTrialPerformance.aspx>)
- A large number of additional NHS Providers will need to start submitting PID data under the new LCRN step down contracts in July 2014
- The slide set is designed to share learning from NHS providers with experience of PID data collection and submission
- The slide set also details the NIHR analysis process to aid understanding of data requirements
- This slide set sits alongside NIHR guidance on PID <http://www.ccf.nihr.ac.uk/Pages/PID.aspx>
- Please note that NIHR guidance on PID maybe updated and the NIHR guidance should always be referred to for the most current information

Background



HM TREASURY

BIS

Department for Business
Innovation & Skills

The Plan for Growth

March 2011

- In the Budget 2011, the Chancellor launched the Government's '[Plan for Growth](#)', which sets out reforms in areas that act as barriers to enterprise.
- The Healthcare and Life Sciences section of the Plan for Growth highlights that health research has a key role in the national economy as well as in improving health and care

The aim of Performance in Initiating and Delivering Clinical research (PID)

- The Government wishes to see a dramatic and sustained improvement in the performance of providers of NHS services in initiating and delivering clinical research.
- Making the NHS more attractive for research for researchers and investors
- Focuses on reducing the time taken to recruit the first patient to trials and recruiting to time and target on commercial trials
- Builds on existing work to reduce the time taken to issue research permissions
- The overall aim is to increase the number of patients who have the opportunity to participate in research and to enhance the nation's attractiveness as a host for research.

Introduction of PID

- From July 2012, all NHS providers who hold new contracts with the NIHR (issued after Autumn 2011) are required to submit data on their performance in initiating clinical trials and delivering commercial contract clinical trials.
- The new LCRN host contracts and step down agreements mean that all category A partners* will now be subject to the contract condition and therefore required to submit data on PID
- Data are submitted on a quarterly basis through a central web based platform- NIHR Central Commissioning Facility (CCF) Clinical Trial Performance (CTP) Submission Platform
- NHS Providers are required to publish PID data of a specified data content on a quarterly basis. This must be in a publically accessible part of the NHS Provider's website. CCF also ask that trials are numbered where there are significant volumes of trials.

* **Category A partners:** Providers of NHS services with substantial levels of research activity, such that the organisation will receive a planned annual allocation of LCRN funding

- Category B** Partners will not have to submit data on PID in 2014/15
- Category B partners have an important part to play in increasing performance and NIHR Clinical Research Network Coordinating Centre (CRN CC) will investigate options and pilot data collection in 14/15

****Category B Partners:** Providers of NHS services with relatively low levels of research activity, typically ad-hoc or intermittent in nature, involving low numbers of patients and/or low numbers of research studies, such that the organisation will not require a planned annual allocation of LCRN funding and instead will be reimbursed as required for costs incurred; this category is likely to include most primary care service providers, and other non-NHS organisations providing NHS services

Consequences of not meeting PID expectations

- According to the contract, if NHS providers do not meet the NIHR expectation for trial initiation for two successive quarters, and DH considers explanations unsatisfactory, DH reserves the right to implement financial consequences
- DH will act in a reasonable and fair way taking into consideration factors outside of the provider's control
- DH intends to take forward financial consequences through Research Capability Funding (RCF) for the first year of consequences. Future approaches are yet to be determined, but DH is minded to use RCF
- Providers new to the requirements in April 2014 should expect the first consequences to be based on their performance reported to Q2 2015-16 (on trials given permission between Oct-14 and Sep-15)
- Repeated failure to meet the NIHR benchmark may have a negative effect on future NIHR funding applications

Data Collection and submission

Format of submissions

- PID data are submitted within 30 days of the end of each quarter
- Clinical Trial Performance (CTP) Submission Platform allowing data to be uploaded in 2 ways
 - Entered directly in to the table provided in the platform <https://ccfctp.nihr.ac.uk>
 - Entered in to a downloaded spreadsheet and uploaded to the platform via a button in the spreadsheet (you need to be able to “Enable Macros” in your Microsoft office system)
- Once entered in to the submission platform data can be edited online in the platform up to the point of submission
- Validation tool in both upload options to highlight missing/incorrect mandatory fields
- Prescribed format with some free text boxes and some drop down boxes.
 - Drop down boxes in Excel can be pasted in to but text will only be accepted if it is identical to that within the drop down options

Performance in Initiating Research

Benchmark of 70 days from receipt of a valid research application (VRA) to recruitment of the first participant in a trial

- NHS providers must submit data for all interventional trials that were issued with NHS permission within the last 12 months
- If permission was issued within the last 12 months but 70 days has not yet passed since receipt of VRA you must still include these trials in your submission
- Data must be submitted within 30 days of the end of each quarter

NHS providers submitting data for the first time under the step down LCRN contracts will submit data on trials issued NHS permission since 1st April 2014

- Q1 submit data for trials issued permission 1st April 2014 - 30th June 2014
- Q2 submit data for trials issued permission 1st April 2014 – 30th Sept 2014
- Q3 submit data for trials issued permission 1st April 2014 – 31st Dec 2014
- Q4 submit data for trials issued permission 1st April 2014 – 31st March 2015

From 1st April 2015 all NHS providers will submit data on trials where NHS permission was issued in the last 12 months

Data required for Performance in Initiating research

- Research Ethics Committee Ref N°
- Name of the Clinical Trial
- Date of receipt of a VRA
- Date of NHS Permission
- Date of recruitment of the first patient to the Clinical Trial (if this has occurred)

- The database calculates the duration in calendar days for:
 - VRA to NHS permission
 - NHS Permission to first patient recruited
 - VRA to first patient recruited

- If the 70 day benchmark has not been met the NHS organisation must provide:
 - the reason for this
 - the source of the delay (NHS, Sponsor, both or neither)
 - Supporting comments

VRA = A complete research application that has been received by the NHS provider following IRAS submission, that enables regulatory reviews to be conducted in parallel with work on NHS permission by the contractor. For CSP studies this is the valid application pack for local review and, for non-CSP studies, the pack for both local and study-wide review

Clinical trial = Projects selecting one of the first 4 options in Filter Question 2 (Type of Research) on the IRAS application form:

1. Clinical trial of an investigational medicinal product
2. Clinical investigation or other study of a medical device
3. Combined trial of an investigational medicinal product and an investigational medical device
4. Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

Trials can be NIHR portfolio, non-portfolio and commercial

Recruitment of first patient = Means the date the first eligible patient consented to the study

- The date the consent form is signed should be used
- If a consent form is signed but the patient then later fails screening (i.e. is not eligible) then that would NOT count as a recruited patient and that date should not be used

Format of the Submission (Initiating)



Upload Submission

Validate

Id	Research Ethics Committee Reference Number	Name of Trial	Date of Receipt of Valid Research Application	Date of NHS Permission	First Patient Recruited?
Auto fill	Free text	free text	free text	free text	Drop down Y/N

Date of First Patient Recruited	Duration between VRA and NHS Permission	Duration between NHS Permission and First Patient	Duration between VRA and First Patient	Benchmark Met	A - Permissions delayed/denied
free text	auto fill	auto fill	auto fill	Autofill - Y/N	Drop down - blank/Y

B - Suspended by sponsor	C - Closed by sponsor	D - Sponsor Delays	E - Staff availability issues	F - No patients seen	G - No patients consented	H - Contracting delays
Drop down - blank/Y	Drop down - blank/Y	Drop down - blank/Y	Drop down - blank/Y	Drop down - blank/Y	Drop down - blank/Y	Drop down - blank/Y

I - Rare diseases	J - Other	Comments	Reasons for delay correspond to:
Drop down - blank/Y	Drop down - blank/Y	Free text	Drop down - NHS/sponsor/both/neither

The Name of Trial field is restricted to 2000 characters

The Comments field is restricted to 500 characters

Completing the “reason for delay” section

- Performance in Initiating research submission

a) Relevant permissions delayed and not granted in time

- Study-wide review not completed in time
- Local review not completed in time
- NHS Research Ethics Committee review not completed in time
- 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

Select “Y” from the drop down in the submission template against all of the reasons that contributed to the delay

d) Delays caused by sponsor:

- Delay in provision of pharmacy manual
- Protocol amendments
- Delayed site initiation visit
- Delayed confirmation of “Green Light”

e) Staff availability issues at site

f) No eligible patients seen during the reported period

- Patients sought but no eligible patients identified
- Strict patient eligibility criteria

g) Eligible patients seen 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)

Completing the “source of delay” section

- Performance in Initiating research submission

- Explain the source of delay by selecting from the drop down menu
 - **NHS Provider** – should be selected where the delay was within the control of the NHS provider and relates to site responsibilities/tasks (including those delivered by R&D, the PI, support services and the research team)
 - **Sponsor** - should be selected where the delay was within the control of the Sponsor and relates to Sponsor responsibilities/tasks
 - **Both** - should be selected where the delay was within the control of both the Sponsor and NHS provider
 - **Neither** - should be selected where the delay was not within the control of either the Sponsor or NHS provider

- The source of delay needs to reflect
 - the primary reason(s) given for delay
 - the relevant time periods and how they relate to the 70 day period (VRA to NHS permission, NHS Permission to first patient recruited, VRA to first patient recruited)
- If the source of delay is the broader NHS but not directly within the control of the NHS provider submitting the data then NHS provider should not be selected
 - E.g. If the delay was due to the CCG delaying agreement of excess treatment costs
 - E.g. If the PI was involved in accident and the research was delayed
- If the NHS provider is also acting as the sponsor for the trial you will need to consider whether the reasons for delay correspond to your role as sponsor (under the accepted definitions of Sponsor responsibilities) or your role as the NHS provider (research site) delivering the research in order to select the correct source
 - Performance in initiating Research separates the roles of sponsor and NHS provider (research site) and the source should be selected according to the role that caused the delay

Explaining the delay – comments section

- Performance in Initiating research submission

- Include a narrative in the comments section for ALL trials where the benchmark is not met
 - This allows the reason and source codes to be validated
 - Explain what caused the delay
 - Remember the character limit of 500 - be concise
 - If multiple reasons for delay have been selected explain the priority of reasons to justify the source of delay that has been selected
 - Include dates to support your narrative for instance the date of the SIV if it contributed to missing the 70 day benchmark

NB: Trials where permission was issued within the last 12 months, but 70 days has not yet passed since receipt of VRA, must be included in your submission. You do not need to select a reason for delay or source of delay for these trials. You do not need to include comments

Performance in Delivering Research

Target of recruiting the target number of participants within the agreed time for all commercial trials

- NHS providers must submit data for all commercial research trials that have been open to recruitment at some point within the last 12 months
- Data must be submitted within 30 days of the end of each quarter

NHS providers submitting data for the first time under the step down LCRN contracts will submit data on trials hosted (in set up post-NHS permission, open to recruitment, closed – in follow-up or suspended) from 1st April 2014. Do not include trials that were “withdrawn” or “closed – follow-up complete” prior to 1st April. Meaning data will be submitted as follows:

- Q1 submit data for trials hosted between 1st April 2014 - 30th June 2014
- Q2 submit data for trials hosted between 1st April 2014 – 30th Sept 2014
- Q3 submit data for trials hosted between 1st April 2014 – 31st Dec 2014
- Q4 submit data for trials hosted between 1st April 2014 – 31st March 2015

From 1st April 2015 all NHS providers will be consistent in submitting data on trials hosted in the previous 12 months

Data required for Performance in delivering Research

- Research Ethics Committee Ref N°
- Name of the commercial research trial
- The target number of patients
- The date by which it has agreed to recruit the target
- The trial status: *e.g. in set-up, open, withdrawn closed in follow-up or closed follow-up complete*
- If trial recruitment has finished: whether the agreed Target Number of patients was recruited within the Agreed Time.
- There is a comments section for including supporting comments where the expected performance was not met

Commercial Contract Clinical Trial = a clinical trial that is solely funded and sponsored by industry

Target number of patients = the recruitment target listed in the Contract

The agreed time limit = the target date for the last Clinical Trial Subject to be recruited as specified in the contract

The Format of the Submission (Delivering)



Id	Research Ethics Committee Reference Number	Name of Trial	Target number of patients available	Target number of patients
Auto fill	Free text	free text	Drop down- Y/N	free text

Date Agreed to recruit target number of patients available	Date Agreed to recruit target number of patients	Trial Status	Target met within the agreed time	Comments
Drop down- Y/N	free text	Drop down- open/ closed in follow up/ closed follow up complete/ withdrawn	Drop down - Y/N	free text

The Name of Trial field is restricted to 2000 characters

The Comments field is restricted to 500 characters

- Where the target number of patients was not recruited within the agreed time an explanation should be provided in the comments section
- The comments section is limited to 500 characters so consider what information is needed
- The Name of Trial field is limited to 2000 characters

DH is currently working with stakeholders to identify ways to improve the data submitted and how to collect reasons when expectations of performance are not met

Tips for data collection

The aim of collecting PID data is to improve your understanding of your current performance and to help you improve your future performance

- Collect all the data required for the submission in a database and keep it up to date
 - governance database or bespoke databases can be used
- Use the labels in the PID submission platform for data in your database to avoid confusion
- Collect data that helps explain delays as they occur e.g. date of SIV, date of green light, delays during NHS permissions process, trial suspensions
- Set up automatic reports from the database so the data is easy to transfer in to the submission platform
- Set up a system to monitor 70 day deadlines as they progress (weekly/frequent report or real time system)

- Set up a system to monitor recruitment against time and target- if possible set it up so researchers can record this directly in the database
- Work with research teams to collect the dates the first patient is recruited- if possible set it up so researchers can record this directly in the database
- Work with research teams to facilitate recruitment- record difficulties in the database to provide narrative in the comments section
- Record delays in recruitment in the database using the reporting reason codes and source definitions to make data upload and analysis easy

Good data collection helps understand performance and where and why delays are occurring so that solutions can be identified

Data Analysis and reports

Reports received on data analysis

- You will receive a quarterly report approximately 2 months after data submission
- The report is also sent to your Chief Executive and Director of Finance
- The report allows comparison against other trusts
- The report identifies high performing trusts that you could contact to share good practise
- Currently the report is split in to 2 sections:
 - 1) Performance in initiating research
 - groups trusts in to 4 groups by the number of trials they submit
 - Ranks trusts against their performance both within your group and overall
 - Details stats and analysis on times from VRA to NHS permission, time from NHS permission to first patient and proportions of reason codes assigned.
 - 2) Performance in delivering research
 - Groups trusts in to 4 groups by number of commercial trials they submit
 - Ranks trusts against their performance both within your group and overall

Data analysis

- Performance in Initiating research submission

Data submissions are analysed to assess performance against the benchmark

Clinical trials data records automatically included in to PI Analyses

- Clinical trial records that are reported as having met the 70 day benchmark are automatically included to the adjusted PI analyses
- Clinical trial data records where 'NHS Provider' or 'Both' are cited as the source of delay (benchmark not met) are automatically included in the PI analysis

Clinical trials data records automatically excluded from PI analyses

- Those clinical trials that are reported as still eligible to meet the benchmark on the PI submission deadline ('Within 70 days') are automatically excluded from adjusted PI analyses.

Clinical trial data records where the source of delay is listed as ‘Sponsor’ or ‘Neither’ are not automatically included or excluded

These clinical trial records are assessed as to whether the provider reported benchmark durations, reasons for delay and supporting comments are consistent with the attributed source of delay. This results in the record being assigned a status by the assessor, as described in the following table:

Assessment of Attributes	Assigned Status
Attributes are consistent	“Match”
Attributes are not consistent	“Mismatch”
There is insufficient information to determine consistency	“Need more information”

Match

- Delays are adequately explained by reasons and/or commentary, and are consistent with the associated durations and cited source of delay
- These records are automatically excluded from the PI analysis
- These trials will not contribute to the percentage of trials not meeting the benchmark in your results/report

Mis-match

- The relationship between all reported data within the clinical trials record is unclear.
- The reasons and/or commentary are not consistent with the associated durations and/or the cited source of delay
- These records are automatically included in the PI analysis
- These trials will contribute to the percentage of trials not meeting the benchmark in your results/report

Need more information

- The relationship between all reported data within the clinical trial record is not sufficiently complete/coherent to enable a decision that it is either a match or a mismatch
- This status may also indicate that data was not supplied/correct e.g. REC number
- These records are automatically included in the PI analysis
- These trials will contribute to the percentage of trials not meeting the benchmark in your results/report

- Clinical trial records with the status “Mis-match” or “need more information” can be highlighted to you by request to NIHR CCF
 - There is no opportunity to provide corrected/more detailed information that quarter for any trial records that are highlighted
- If a trial is still eligible to be submitted in the following quarter then you should submit modified data - that addresses any inconsistencies or gaps in information - in the submission for the following quarter. Otherwise, the status will not be resolved.

Mismatch examples

Time between VRA and NHS permission is long/unacceptable, the reason code is listed as “F-patients not seen” and the source is listed as “Neither”.

Need to explain delay in issuing NHS permission as this will contribute to overall delay and may alter the source from “neither”

Time between VRA and first patient recruited is over 70 days, the reason code is listed as “D-sponsor delays”, the source is listed as “Sponsor” and no comments are provided.

Need to provide comments confirming what the sponsor delay was and how long a delay it caused. You need to provide enough information to make it clear that the source of the delay was not the NHS

If time between VRA and first patient recruited is over 70 days, the reason code is listed as “E-staff availability issues”, the source is listed as “Neither” and limited comments are provided.

Need to explain the delay and provide enough information to make it clear that the source of the delay was not the NHS e.g. if the project is run externally to the NHS Trust and a separate institute was responsible for providing staff

If time between VRA and first patient recruited is over 70 days, the reason code is listed as “J-other”, the source is listed as “Neither” and comments regarding the delay are provided but do not provide enough information to support the source of delay.

You need to provide enough information to make it clear that the source of the delay was not the NHS

Improving Performance

Monitoring your performance

The data you collect for your submission can be used to improve your understanding of your current performance and to help you improve your future performance

Top tips

- **Set up a system to monitor 70 day deadlines as they progress**
 - run a weekly/frequent report from your database
 - If possible allow researchers to record first patient recruited dates in real time in the database
 - Contact researchers on a frequently to monitor their progress. This will also allow you to help with any issues and identify key themes
 - Work with researchers to help them meet the targets, what can you do to help?
- **Set up a system to monitor recruitment to your commercial trials**
 - If possible allow researchers to record recruitment in real time in the database
 - Run a monthly report that allows you to “match percentage of recruitment achieved” against the “percentage of the time period that has passed” to manage recruitment to time and target in real time

- **Use the data you have collected to identify themes for delay**
 - What are your most common reasons for trials not meeting performance expectations?
 - What parts of your process contribute to your frequent delays?
 - Which trials (against the 4 IRAS classifications) are more likely to experience delays?
 - Which researchers/research areas are more likely to experience delays and why (difficulty due to patient pathways, patient tailored/very specific inclusion criteria, trial complexity etc.)?
- **Use the themes you collect to identify ways to improve your processes**
 - If contracting is your biggest reason for delays how can you improve this?
 - If cTIMPs are most likely to have delays why is this and what can you do to resolve it e.g. quicker pharmacy processes?
 - How can you support researchers in areas where recruitment is often difficult/delayed due to the patient pathway?
- **Use the data you collect on themes to monitor your performance over time**
 - Are you reducing delays due to the key themes?
 - Is your performance improving as you address key themes?
 - Are you identifying different key themes? What can you do about these?

Use the data you collect, it allows you to target specific areas for improvement and measure your progress

How to improve PID

Feasibility

- Encourage robust feasibility prior to VRA submission
- Where possible R&D staff are involved in feasibility meetings
- Discuss the 70 day benchmark with study teams and sponsors
- Identify and mitigate risks to increase the chances of the study recruiting within the 70 day benchmark

Submission

- On receipt of a VRA highlight the 70 day deadline to researchers
- The benchmark applies to all trials however it maybe useful to discuss with researchers any concerns for why they may not meet the benchmark e.g. in rare patient studies, trials with external influences such as seasonal influenza studies
- Hold further discussions around feasibility, targets and recruiting the first patient

Approval

- Outline 70 day timelines in approval email
- Make recruitment responsibilities clear to the PI
- Identify R&D staff who will liaise with the study team with regards to recruitment.

Post Submission

- R&D staff keep in close contact with study team
- R&D staff to identify ongoing delays and resolve/mitigate where possible
- Communicate with sponsor where delays are identified
- Consider staffing options to facilitate recruitment

Data

- Ensure your data collection is robust
- Collect data that will help monitor and identify problems early
- Analyse data collected and provided in reports to identify key/common delays in the process and address these

Communication

- Produce information sheets for researchers detailing the expectations and what they need to do to meet them
- Communicate with the NIHR CCF CTP team CTP (ctp@nihr-ccf.org.uk) to ensure good quality submissions
- Report on this KPI frequently at board level to ensure ongoing oversight
- Provide a narrative to accompany the report the Board receive from NIHR CCF CTP

Benchmark

- Communicate with local NHS providers experienced in submitting PID data – share processes and learning
- Benchmark against other NHS providers

Examples- test your knowledge

Examples to work through

Date of VRA	Date of local permission	Date first patient recruited	VRA to permission	permission to fpfv	VRA to fpfv	benchmark met?	Reason codes	Source of delay	Comments
31/10/2013	25/11/2013	03/02/2014	25	68	93	?	?	?	The sponsor did not issue the green light for recruitment until 45 days after the VRA and 20 days after local permission. The delay in green light then meant that recruitment started in the bank holiday period. Eligible patients seen did not consent due to not wanting to start a new treatment across the bank holiday period and the treatment needed to start immediately following consent.
02/10/2013	26/11/2013	not yet recruited but 186 days since VRA	54	N/A	N/A	?	E (Staff availability), D (sponsor SIV delay), G (patients didn't consent)	?	What do you need to cover?
16/01/2013	09/07/2013	10/08/2013	173	31	204	?	?	?	Concerns over funding for the trial, particularly around excess treatment costs, required lengthy negotiation with the local CCG. This delayed local approval until after 70 days had elapsed.
13/02/2014	28/03/2014	not yet recruited but 50 days since VRA	45	N/A	N/A	?	?	?	What do you need to cover?

Reason codes are on the next page for reference
Answers are on the page after that

“reason for delay” codes

- Initiating research report

a) Relevant permissions delayed and not granted in time

- Study-wide review not completed in time
- Local review not completed in time
- NHS Research Ethics Committee review not completed in time
- 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

Pick all of the reasons that apply

d) Delays caused by sponsor:

- Delay in provision of pharmacy manual
- Protocol amendments
- Delayed site initiation visit
- Delayed confirmation of “Green Light”

e) Staff availability issues at site

f) No eligible patients seen during the reported period

- Patients sought but no eligible patients identified
- Strict patient eligibility criteria

g) Eligible patients seen 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)

Answers to examples

Date of VRA	Date of local permission	Date first patient recruited	VRA to permission	permission to fpfv	VRA to fpfv	benchmark met?	Reason codes	Source of delay	Comments
31/10/2013	25/11/2013	03/02/2014	25	68	93	No	D (sponsor green light delay), G (patients didn't consent)	Sponsor	The sponsor did not issue the green light for recruitment until 45 days after the VRA and 20 days after local permission. The delay in green light then meant that recruitment started in the bank holiday period. Eligible patients seen did not consent due to not wanting to attend appointments across the bank holiday period.
02/10/2013	26/11/2013	not yet recruited but 186 days since VRA	54	N/A	N/A	No	E (Staff availability), D (sponsor SIV delay), G (patients didn't consent)	Both	1) Reason for delayed approval 2) How long the SIV was after VRA 3) How many patients have been approached
16/01/2013	09/07/2013	10/08/2013	173	31	204	No	A) Local permission delayed	Neither	Concerns over funding for the trial, particularly around ability of the department to meet the excess treatment costs, required lengthy negotiation with internal and external parties. This delayed local approval until after 70 days had elapsed.
13/02/2014	28/03/2014	not yet recruited but 50 days since VRA	45	N/A	N/A	N/A	none	none	No comments needed, within 70 days

NB: These are examples from a previous submission for one NHS provider and are provided for learning purposes only

Explanations for answers

Example 1

- The delayed green light caused the patients seen to refuse consent due to the timing.
- Patients reported they would have consented if they had been approached earlier. The main reason for delay was therefore the delayed green light so the source of delay = sponsor
- If it had taken a long time to recruit the first patient after the green light and patients were not consenting for a different reason then patients not consenting may be the main reason. The source code would then be Neither.

Example 2

- The delay in approval needs detailing, in this case it was staff availability
- Staff availability is normally an NHS provider delay (unless the trial is being run externally and this would need to be explained).
- The delayed SIV is a sponsor delay but this will depend on timings of the SIV. If the SIV was 10 days after local permission it would not be appropriate to state that the sponsor was the source of delay.
- In this instance the SIV was 95 days after VRA and therefore the NHS provider and Sponsor were both the source of delay

Example 3

- The reason for delay was delayed NHS permission and this will often mean the NHS provider was the source of delay.
- In examples where the NHS provider could not alter the delay e.g. REC approval was the reason NHS permission was not issued this will need detailing in the comments section
- Where there were delays due to negotiations with an external party (e.g. the CCG) and the NHS provider could not influence the delay this will need detailing in the comments section

Example 4

- 70 days had not yet passed since receipt of the VRA.
- The 70 day target can still be met and so the benchmark has not been missed
- Therefore no reasons for delay or source of delay are required

Definitions

VRA = A complete research application that has been received by the NHS provider following IRAS submission, that enables regulatory reviews to be conducted in parallel with work on NHS permission by the contractor. For CSP studies this is the valid application pack for local review and, for non-CSP studies, the pack for both local and study-wide review

Clinical trial = Projects selecting one of the first 4 options in Filter Question 2 (Type of Research) on the IRAS application form:

1. Clinical trial of an investigational medicinal product
 2. Clinical investigation or other study of a medical device
 3. Combined trial of an investigational medicinal product and an investigational medical device
 4. Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
- Trials can be NIHR portfolio, non-portfolio and commercial

Recruitment of first patient = Means the date the first eligible patient consented to the study

- The date the consent form is signed should be used
- If a consent form is signed but the patient then later fails screening (i.e. is not eligible) then that would NOT count as a recruited patient and that date should not be used

Commercial Contract Clinical Trial = a clinical trial that is solely funded and sponsored by industry

Target number of patients = the recruitment target listed in the Contract

The agreed date = the target date for the last Clinical Trial Subject to be recruited as specified in the contract

Links

- Performance in Initiating and Delivering Clinical Research Guidelines
 - Information on data submissions, including data requirements, timetable of submission and definitions
 - <http://www.ccf.nihr.ac.uk/Documents/Performance%20Guidelines%20Public.pdf>
- CTP submission platform instructions
 - Practical user guide for interacting with the submission platform and submitting data
 - <http://www.ccf.nihr.ac.uk/Documents/CTP%20Submission%20Platform%20Instructions.pdf>
- Frequently Asked Questions on Data Requirements
 - Further information on areas of common interest or enquiry
 - <http://www.ccf.nihr.ac.uk/Documents/Contract%20Performance%20FAQs.pdf>
- CTP platform – you will be provided with a log in
 - <https://ccfctp.nihr.ac.uk>
- NHS providers with prior experience of PID submission
 - <http://www.nihr.ac.uk/systems/Pages/ClinicalTrialPerformance.aspx>