Guideline number	**53.004A**	Version	**2.0**
Title	**Q-Pulse guidance for Monitoring visit**		

NHSGGC R&I step by step guide for the creation and completion of Monitoring visit reports using the Q-Pulse Audit module.

A. Creating a new Monitoring visit and report
B. Conducting a Monitoring visit
C. Creating a new non-compliance/action from a monitoring visit
D. Creating an Actions Resolution document
E. Resolution of a non-compliance from a monitoring visit
F. Completing a Monitoring visit and report
G. Uploading supporting visit documentation

A. Scheduling a new Monitoring visit
Open the Audit module from the Launchpad

- Select **File – New – From Wizard**
- In the first Wizard window click **Next**
- Select the type of visit from the **Type** dropdown list by clicking on the arrows through the selection
- Complete the **Title** in the format - *type in the trial name, type of visit and name of the site*
- click **Next**
- In the **Audit Schedule** window select **single audit**
- Complete the **Scheduled start** and **Scheduled end** dates
- click **Next**
- Click on the first icon at the top of the right hand side of the **Audit Scope** window to open the search wizard.
- Select **Trial** in the search dropdown list and select the trial title by clicking on the arrows through the type of trial selection, click on the trial name and click **Ok**
- Select **Supplier** in the search dropdown list, enter a keyword from the site name in the Keyword box and click search
- Click on the site name and click **Ok**
- click **Next**
- In the **Key Participants** window
- Click on the first icon on right hand side of the **Auditors** box to open the search wizard.
- Search by keyword, select the Monitor from the list and click **Ok**
- Click on the first icon on right hand side of the **Auditees** box to open the search wizard.
- Search by keyword, select the Investigator from the list and click **Ok**

- click **next**
- Click on the first icon at the top of the right hand side of the **Add Checklist Scope** window to open the search wizard.
- Select the checklist from the list and click **Ok**
- Click **Finish**

Notes
If the Trial, Site or Investigator name is not in the Q-Pulse system, the Administrator (QA Manager) should be notified. These sections can be left blank in the wizard and added to the audit record during completion.

The scheduled dates can be changed if required. Once the dates have been confirmed tick the "Schedule Confirmed" box. The dates cannot be changed once this box is ticked except by the administrator.

The main audit page can be updated to show newly added audits by clicking on search or reopening the main page

In the Audit list on the main page each audit can have one of the following statuses;

- ☐ - Audit has been scheduled but not confirmed
- ☒ - Audit has been scheduled and the schedule has been confirmed
- ☒ - Audit has been performed
- ☒ - Audit performed and audit report accepted
- ☒ - Audit performed, audit report accepted and any associated non-conformances (CA/PAs or Incidents) have been completed
- ☒ - Audit has been closed

B. Conducting a Monitoring visit

Open the Audit module from the Launchpad

- double click on the audit title to open the audit record
- In the top section of the audit record complete the **Actual Start** date
- In the top section of the audit record Lead Auditor add the name of the **Monitor**
- **Save** the record
- In the Audit record click on downwards arrows to right hand side of the **Checklists** tab to expand the tab.
- Select the checklist that corresponds to the type of visit.
- Click on the third icon on right hand side of the **Checklists** tab and click **Ok** to open the **Edit Checklist** wizard.
- Select **Complete Checklist** and click **Ok**
- Answer a specific question by double-clicking on it or answer the questions in order by clicking **Start**
- Type the response and any notes in the **response** box
    - NB – please ensure the response given provides sufficient detail in order to understand the visit in the years following the visit.
    - List the participant monitored/SDV'd during the visit
    - Expand on simple responses such as Yes/No
    - Ensure the response captures guidance provided to the site by the monitor, such as PID, consent issues etc.
    - Specific details e.g. specific missing documentation, IMP issues – was sponsor pharmacy consulted etc

Note - Leave the area of standard, score and guidance blank

- Click **Next** to progress through each question in the checklist. If you wish
- To save and finish or return to completing the checklist later click **Summary** and then **Finish**.
- Once all the questions have been answered, complete the **Completed on / Completed by** and then click **Finish**.
- If you have completed the checklist but need to make changes to any responses later, double-click the checklists within the **Checklists section** and select "**Review Checklist and related findings**", select the appropriate question, and change the text in the Response field.
- Once completed or to return to the audit record click **ok**
- Once the visit is finished, in the top section of the audit record, complete the **actual end date of visit**

- Once the monitoring report and ARD along with the associated documents are ready for review, **the monitor will email the Lead CTM** (RGM, appropriate Governance team member) to notify them the report is review for review. The monitor and Lead CTM should document these dates in the User/Note section.
- The email review exchange should also be saved.

To add a non-compliance using the Q-Pulse CAPA module refer to section D.

To add an observation which is not considered a non-compliance, in the Audit record click on the **Findings** tab to expand the tab.

- Click on the second icon on right hand side of the **Findings** tab

Type in the **observation details** and click **Ok.**

For example: an observation can be an issue that doesn't fit with a standard non-compliance, however is worth documenting in case it leads to further issues.

To add notes or supporting documents to the Audit record, click on downwards arrows to right hand side of the **Properties** tab to expand the tab.

- Click on the first icon on right hand side of the **Properties** tab to add a note to the audit record
- Type in the **note / comment** and click **ok**
- Click on the second icon on right hand side of the **Properties** tab to add supporting documents to the audit record
- Complete the **Attachment description** text
- Attach the documents using the add file box
- The following documents at a minimum should be uploaded – **Agenda, FU letter, ARD document** Monitoring notes can also be uploaded if appropriate.
- The fully signed off and completed ARD should be uploaded once report is **Closed.**

C. Creating a new non-compliance (Category 3 & 4) from a monitoring visit

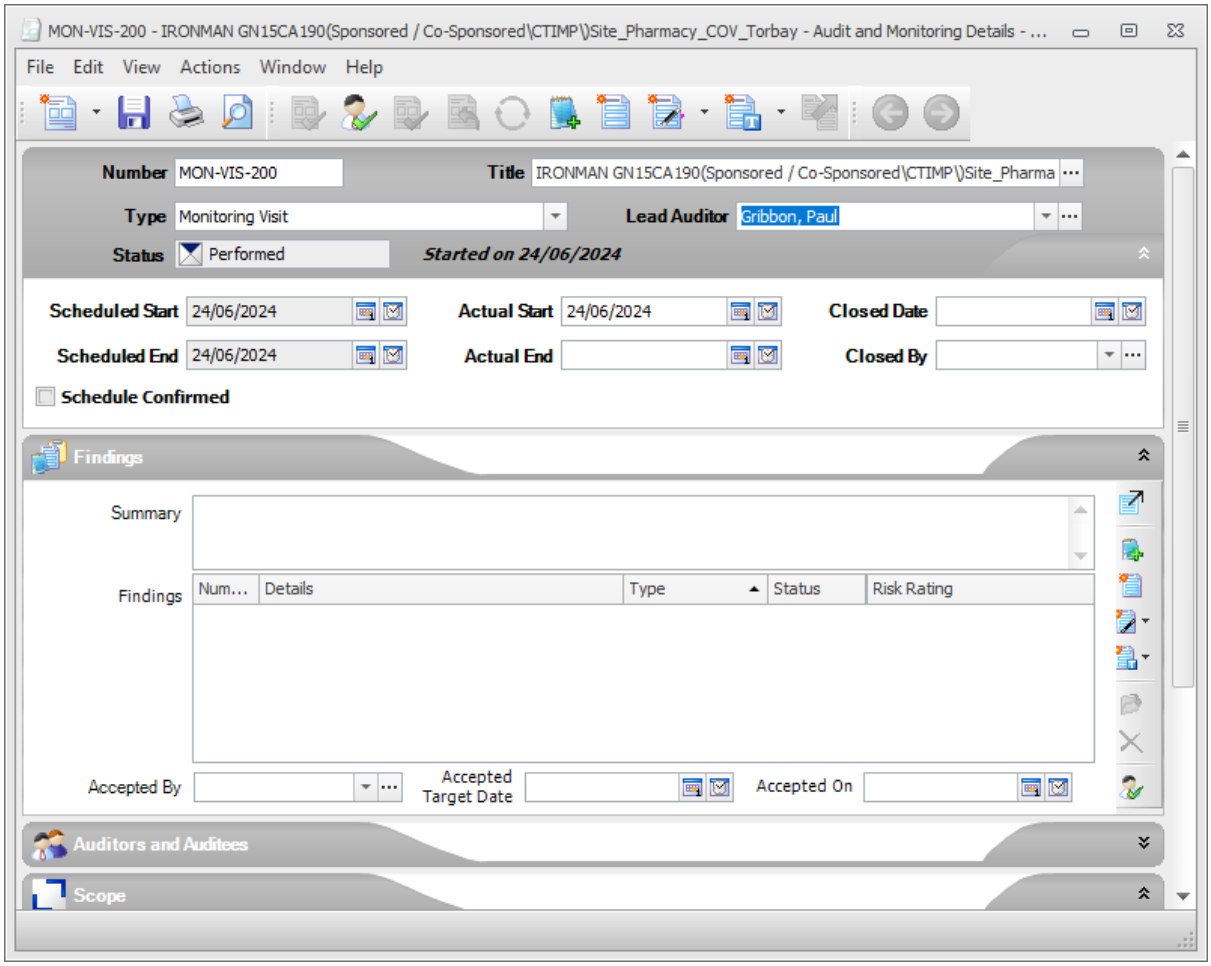
Notes

Identified Category 3&4 non compliances must be notified to the Research Governance Manager and/or Lead Pharmacist Clinical Trials (as per SOP 51.008, Category 3 & 4). The Monitors will not raise this in Q-Pulse.

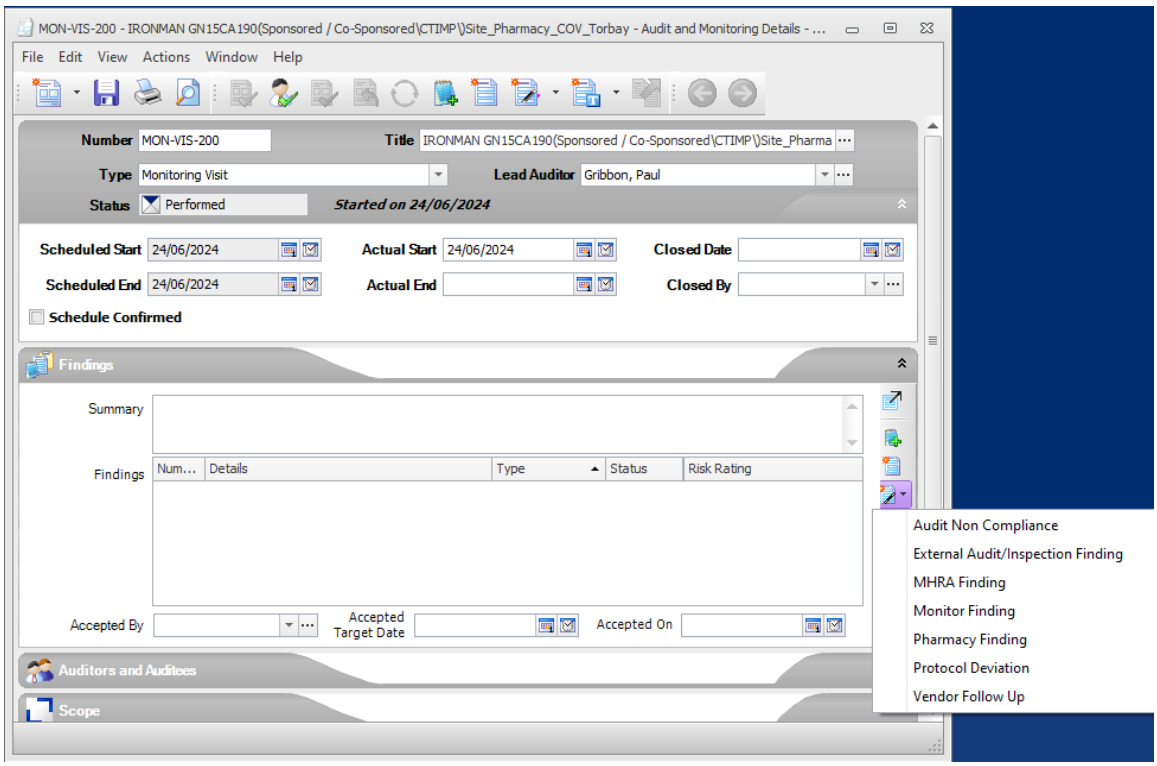
A protocol deviation, identified during a monitoring visit, should first be raised as a protocol deviation in the monitoring record. The resolution of this for category 3 & 4 non-compliance should require completion of a protocol deviation form, which will then be added as a separate protocol deviation record to the CAPA module. For category 1 & 2 non-compliance should be added to the PD log.

Raising A Protocol Deviation from a Monitoring Visit

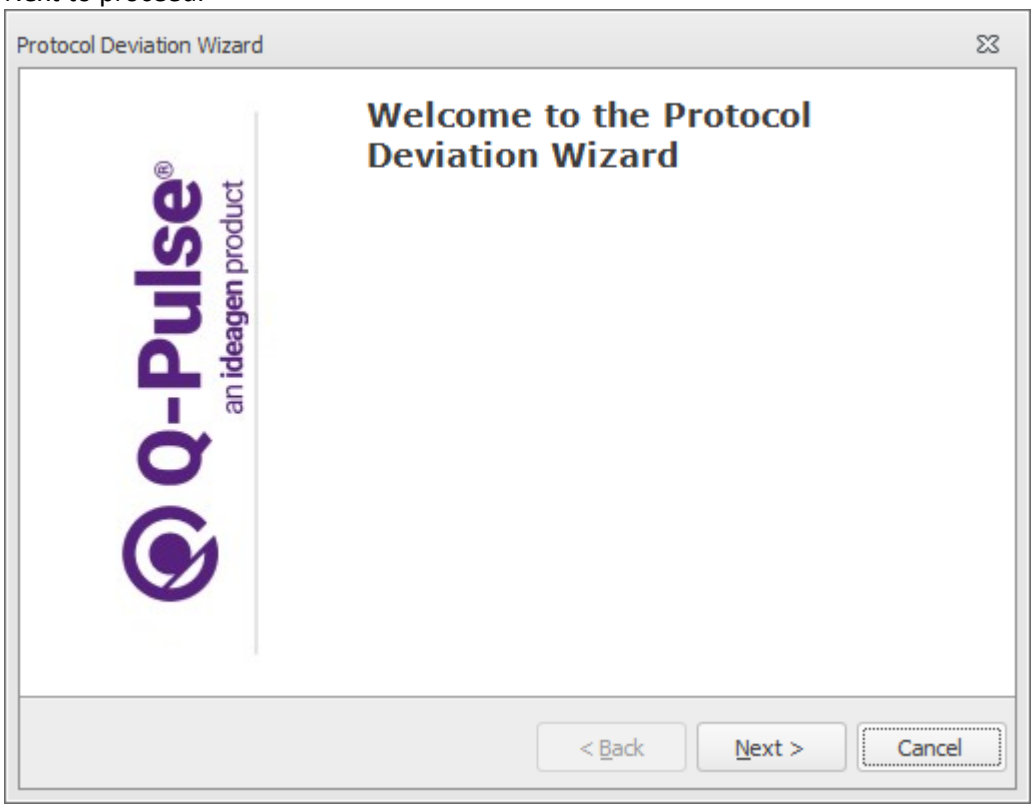
When carrying out a monitoring visit of any type, you can raise a Protocol Deviation from the visit record. To do this, you must have a date entered in the actual start date of the record window.



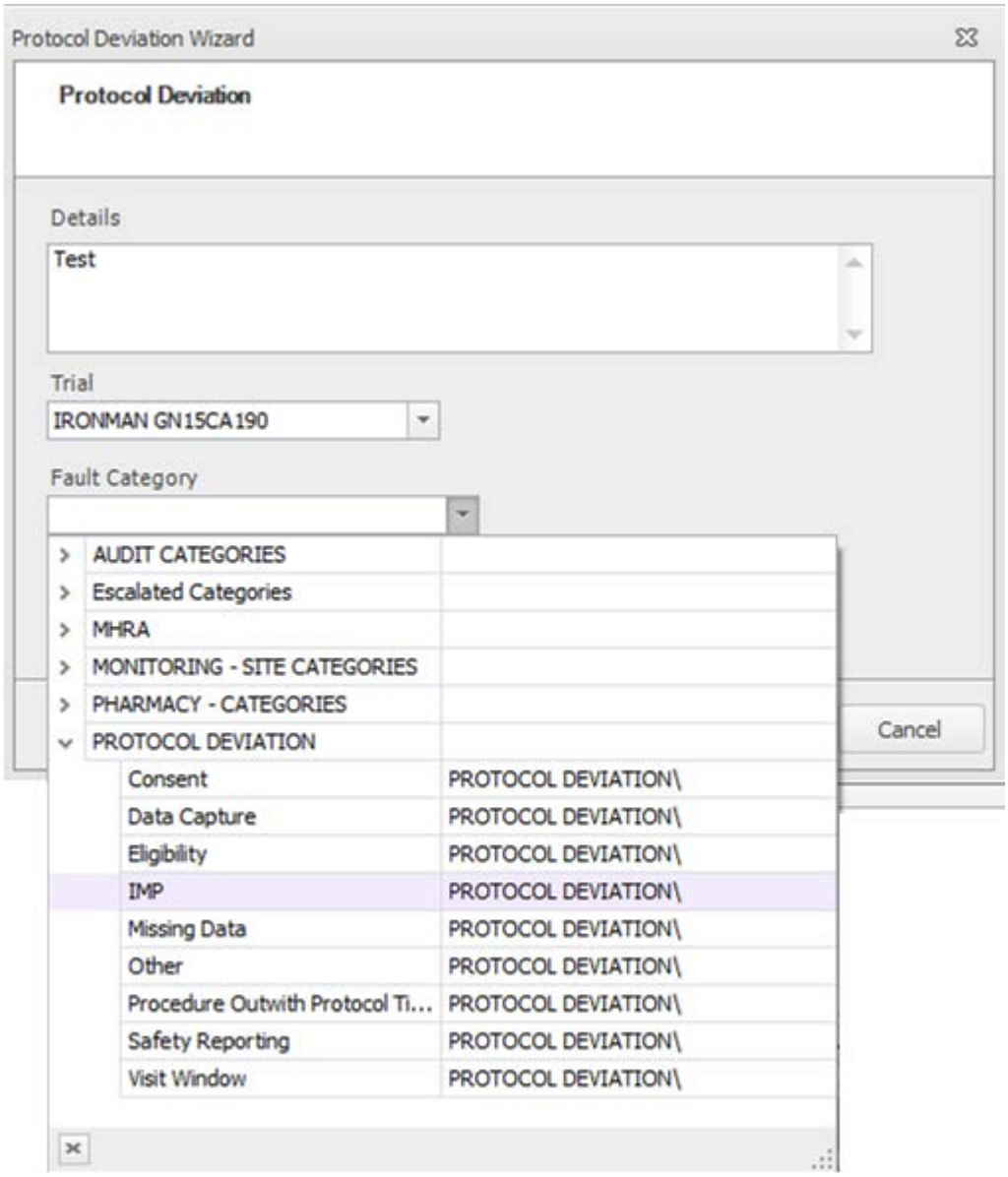
From here, you can then expand the “Findings” tab and select the “Raise Non-Conformance from Wizard” button. This will show the options of the different types of findings that can be raised, select “Protocol Deviation” from the list.



This will then open a new window with the wizard that will guide you through the process, select Next to proceed.

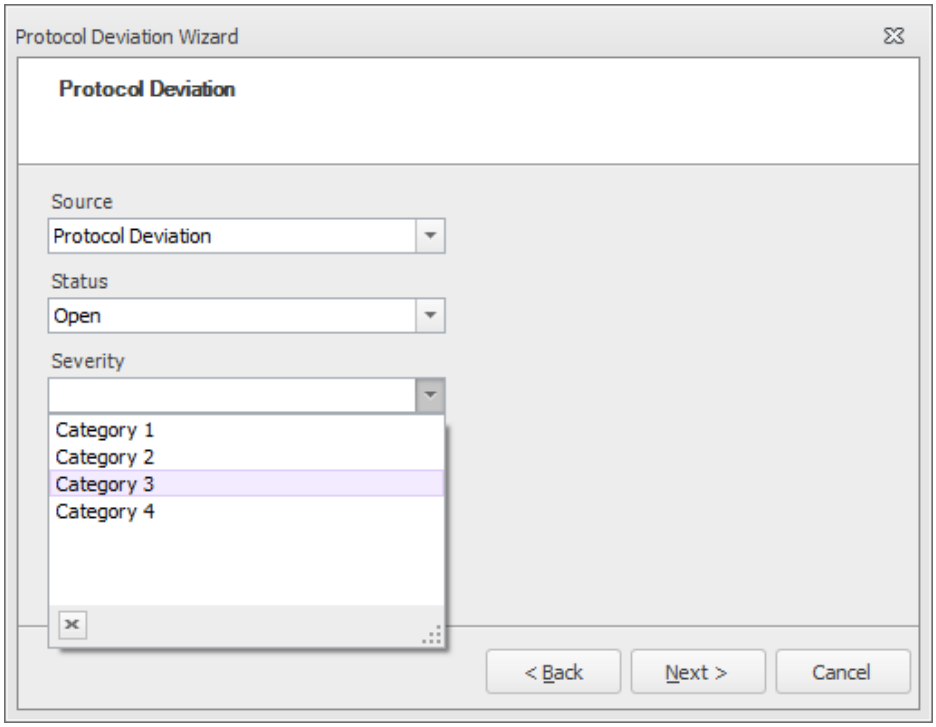


The first screen presented will have 3 fields to complete, the first will ask for details of the Protocol Deviation. Using free text provide information to explain the nature of the deviation and include the patient ID #'s of any impacted patients. The 2nd field will be prepopulated based on the visit record, if incorrect this can be updated. The final field will be to provide a fault category, from the drop down expand the Protocol Deviations options and select the most appropriate category.



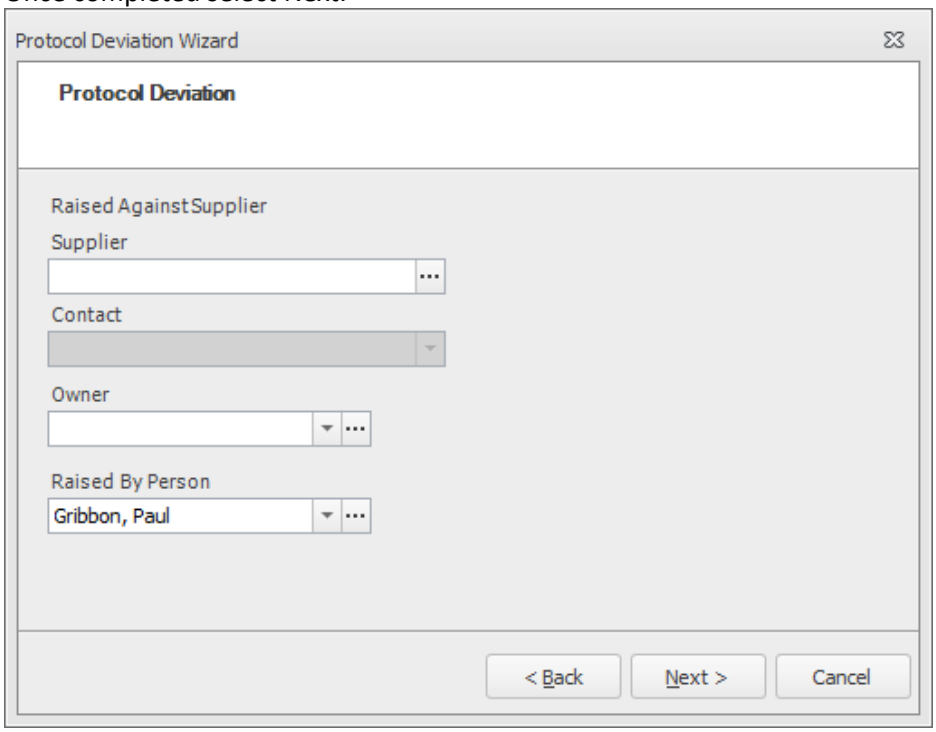
Once this has been completed, select Next to continue.

The next page will again have 3 fields, the first 2 will be pre populated. From the 3rd field select the appropriate category for the deviation based on what is outlined in SOP 51.008. If Category 3 or 4 is selected the Research Governance Manager or Lead Pharmacist Clinical Trials R&I should be notified via email immediately.

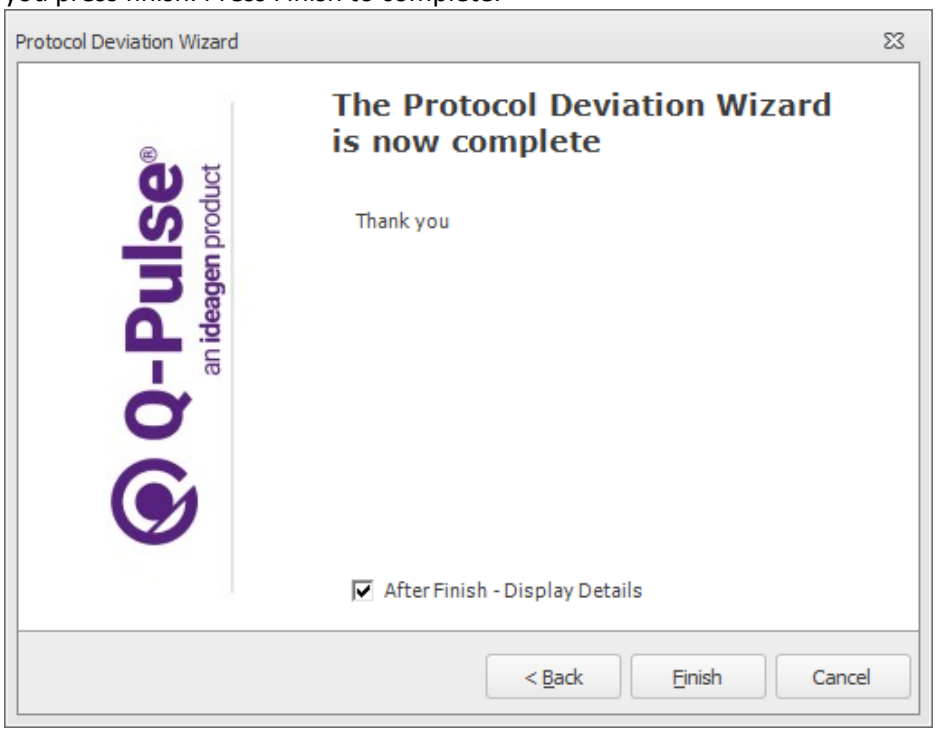


Once this is completed, select next for the final page.

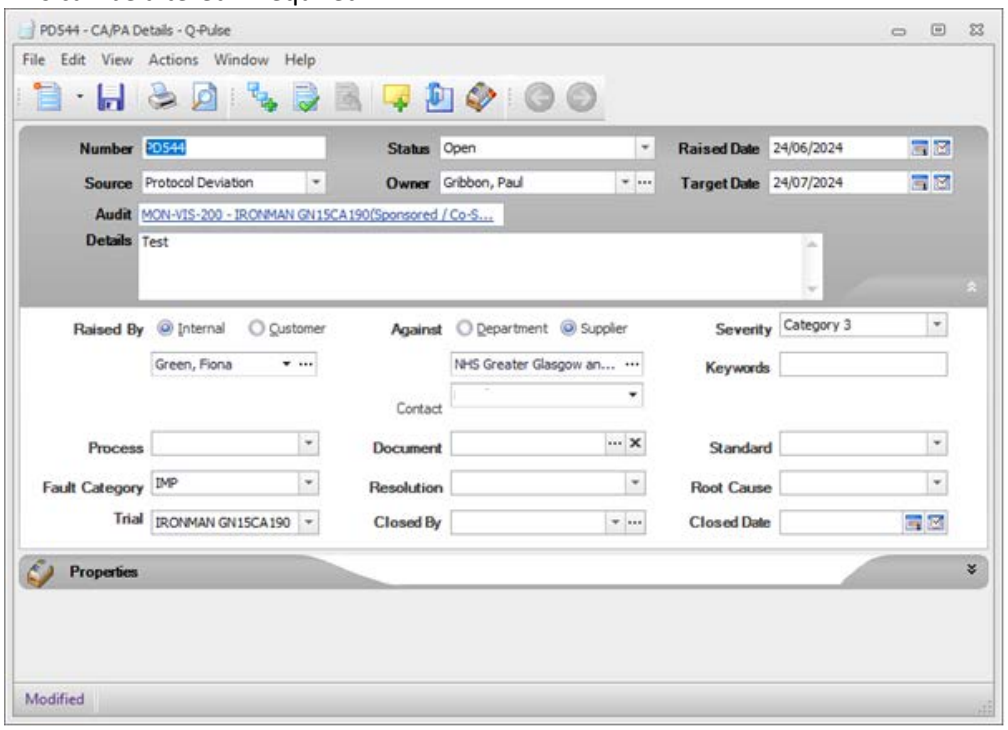
From here there will be 4 fields. The first requires you to select the site at which the deviation as been identified, press the button with the 3 dots to open the search window and find the appropriate site. Once the site has been selected you must then select the point of contact at this site, this may be the PI. The 3rd field will require an owner for the action, this will be the monitor for the trial so select your own name and the final field should also be pre populated with your name. Once completed select Next.



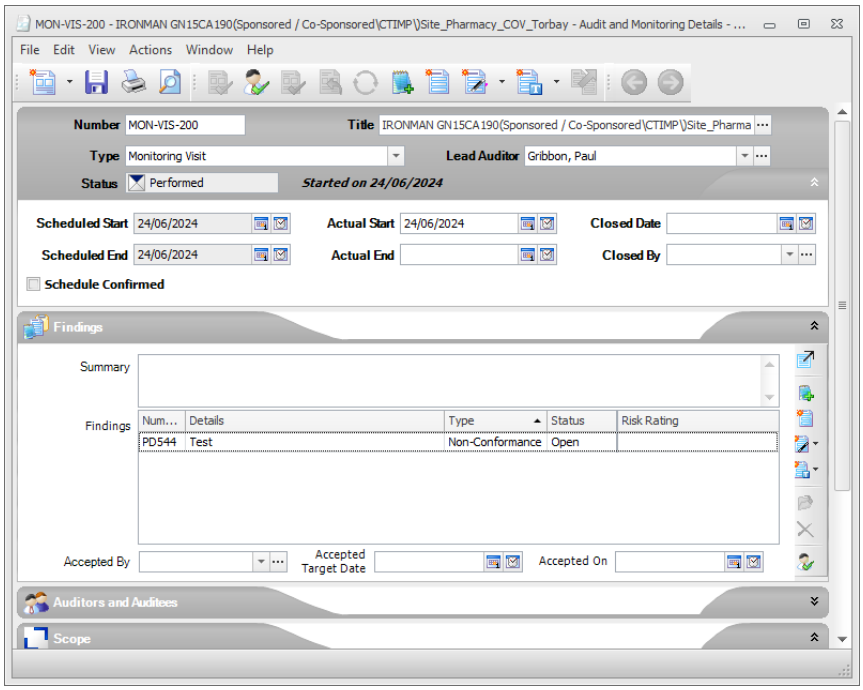
The final page will just be a confirmation that everything has been entered, the box asking if you want to display details will not be checked. Check this if you wish to open the created record when you press finish. Press Finish to complete.



Once finished, a record will be created that contains all of the information you entered in the wizard. This can be altered if required.



This will also now appear linked to the Monitoring Visit Record with a PD number as shown below. Once the ARD is returned confirming the actions can then be closed.



Note - for non-compliances identified as severity 3 or 4 the CTM escalates immediately via email to the Research Governance Manager or if IMP/Lab related to the Lead Sponsor Pharmacist Clinical Trials as per SOP 51.008. The Research Governance Facilitator should be included in the email and will provide a PD reference RAG number will be provided from the non-compliance log, this should be documented within the notes of the Q pulse and PD closed once all documentation has been provided from the site.

D. Creating an Actions Resolution document

To print a list of the non-compliances in the actions resolution document to send to site;

- In the audit main page
- Select **file – print preview**
- Select **site monitoring report** from the dropdown list and click **preview**

Note the report is already set up to print all the details required for the actions resolution document

- In the preview screen select **file – print**

E. Resolution of a non-compliance from a monitoring visit

On resolution of the non-compliance from the CA/PA Main page:

- **Status** should be changed to 'closed'
- **Closed by** and **closed by date** should be completed (this is the date the monitor signs off the actions document)

F. Completing a Monitoring visit and report

Once all the actions from the visit have been closed the audit report can be closed

- In the main audit record, complete the **closed date** and **closed by**
- **Save** the audit

Guideline signatories

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Document history

Version	Date	Description
1.0	08/01/2019	First release
2.0	29/10/2024	Updates including – • Added more guidance to the phrasing of responses in section B • Added guidance on the minimum documents to be uploaded to Q-pulse in section B • Added screen shots and instructions on creating a new non-compliance in section C • Added clearer direction for reporting a PD and closing it.