Quality Control Document:

Analytical Plan

# Purpose

Prior to sample analysis an Analytical Plan should be created detailing the procedures which will be used to perform the analysis. The Analytical Plan needs to contain enough detail to allow the analyst to perform their duties and allow for the assay to be reconstructed if necessary. The circumstances that allow repeat analysis must also be and clearly defined and transparent.

This document contains a template which can be used to create an Analytical Plan, a Repeat Analysis Record that can be used to document repeat analysis if it is required, and instructions on how to complete these documents.

This document is designed to be used for clinical trials of investigation medicinal products (CTIMPs), however it could also be utilised for non-CTIMP trials and studies using human tissue to support best practice. It is possible to set up a project specific Analytical Plan and Repeat Analysis Record, in which case it should contain the specifications outlined in Laboratory Analysis SOP (UoB-CRL-SOP-004).

# Instructions

1. Remove this first instruction page.
2. Update the header to include the trial/study ID.
3. Update the footer; include a version date and retain the document reference information relating to this quality control document (QCD).
4. Record the assay name.
5. Write a brief description of the assay. Consider the nature and purpose of the assay, who will perform the assay and where it will be performed.
6. Record the type of samples this assay will be used to analyse.
7. Record the number of anticipated that will be analysed in total using this assay.
8. List all the equipment and reagents required to perform the assay, including the names and suppliers.
9. List the quality controls and experimental controls required to carry out the assay.
10. Define the assay acceptance criteria.
11. Define the procedure to be followed if repeat analysis needs to be performed. Consider the circumstances that allow for repeat analysis, for example, what defines an ‘anomalous’ result, a consideration of sample availability and stability.
12. Document the analytical method that is to be followed to conduct the assay. Make clear which steps in the method are critical to the analyses.
13. Document where source data will be stored and what the back-up arrangements are for digital data.
14. Repeat the steps above as necessary for all the assays that will be performed as part of the trial.
15. Record the version number of the Analytical Plan.
16. Record the date on which the analytical plan was approved.
17. Ensure the name and signature of who approved the analytical plan is recorded.
18. Store the completed Analytical Plan safely and securely in the Laboratory Master File throughout the trial and archive with the other trial records upon closure. See Archiving SOP (UoB-CLN-ARC-SOP-001).

## **Set up the Repeat Analysis Record**

1. Set up a separate Repeat Analysis Record form each time repeat analysis is required.
2. Update the header to include the trial ID.
3. Record the assay name.
4. Record the date the analysis was originally performed.
5. Record the date that repeat analysis was performed.
6. Record the rationale for performing repeat analysis.
7. Record the identification of the samples that were reanalysed.
8. Record the justification for selection of reported data.
9. Record the name and signature of who performed the reanalysis.
10. Record the date on which the repeat analysis was performed.
11. Store the Repeat Analysis Record safely and securely in the Laboratory Master File throughout the trial and archived with the other trial documents when the trial closes. See Archiving SOP (UoB-CLN-ARC-SOP-001).
12. Related documents
* UoB-CLN-ARC-SOP-001 Archiving
* UoB-CRL-SOP-001 Laboratory Set Up and Management
* UoB-CRL-SOP-002 Laboratory Facilities
* UoB-CRL-SOP-003 Sample Management
* UoB-CRL-SOP-004 Laboratory Analysis
* UoB-CRL-SOP-005 Reportable Issues

UoB QMS documents can be found on the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT (mailto:crct@contacts.bham.ac.uk) and/or from the RGT (researchgovernance@contacts.bham.ac.uk).

|  |  |
| --- | --- |
| **Assay Name:** |  |
| **Description of Assay:** |  |
| **Type of samples to be analysed:** |  |
| **Number of samples to be analysed:** |  |
| **Equipment:****(name and supplier)** |  |
| **Reagents** **(name, batch number, supplier, storage requirements)** |  |
| **Quality controls:** |  |
| **Experimental controls:** |  |
| **Acceptance Criteria:** |  |
| **Repeat analysis procedure:** |  |
| **Analytical Method:** |  |
| **Source data storage location:** |  |
| **Back-up arrangements for source data:** |  |

**Repeat the above as necessary for all assays that will be performed as part of this trial**

|  |  |
| --- | --- |
| **Version Number:** |  |
| **Analytical plan approval date:** |  |
| **Analytical plan approved by:** | Name: | Signature: |

<Enter document code, name, date and version number here>

Page 3 of 4

|  |  |
| --- | --- |
| **Assay Name:** |  |
| **Date of original analysis:** |  | **Date of repeat analysis:** |  |
| **Rationale for performing repeat analysis:** |  |
| **ID of reanalysed samples:** |  |
| **Justification for selection of reported data:** |  |
| **Name of person performing repeat analysis:** |  |
| **Signature of person performing repeat analysis:** |  |