

Purpose

To achieve a consistent approach for maintaining a transparent, accurate and traceable history of study documents using required identifiers in the footer content and document file names. Bellberry understands that sites will have their own internal SOP for version control. However, below are some guidelines about how consistency can be maintained when updating documents to ensure regulatory compliance.

Guidance

The names of all document files must be labelled to clearly reflect the type of document and the study title, including version numbers and dates. There may be variations in the order of wording or required details, however the file name, document title and footer details must reconcile.

The footer in the first page of a document should include these required details and where possible, on every succeeding page.

The inclusion of the study protocol number or study title acronym as an identifier is an acceptable way to reference the study title.

Please ensure page numbering is included in all documents (preferably in the format page x of y or x/y).

When attaching documents for submission, please note that the eProtocol platform may not recognise file names with more than 100 characters. To avoid any automated errors when uploading documents, please consider making document file names succinct.

Where a document is being updated, please include in the document file name and footer if the version is 'Clean' or 'Tracked'. Abbreviations are acceptable for indicating this (e.g., CL, TK/TC).

All documents submitted to the HREC are to be titled in the document file name as they are required to appear on the HREC approval letter. Once approved, submitted documents are unable to be edited by Bellberry.

The document file name and title should remain the same throughout the study. The only changes to the document file name should be to the version number and date. However, if the title of an approved document requires significant change, the HREC must be notified via an amendment and the change clearly stated on the amendment form. Where a site needs to correct a minor administrative error in an approved document file name or footer, this is not required to be submitted to the HREC. In this instance, it is the responsibility of the site to create a 'Note to File' documenting this correction which should be saved locally and can be reviewed by the HREC if requested.

Previous versions of any updated documents must not be deleted from the application or a submission unless instructed by Bellberry. These versions must remain as a reference for document control and auditing purposes.

To maintain accurate document control, site-specific versions of documents should always be created from the approved Master document, and not copied from the last site-specific version to avoid missing any approved updates to the Master that have been made.

Please see the following examples of recommended file name and footer formats incorporating the required identifiers:

Protocol:

- Protocol number - (VRP1001)
- Version number - (V2.0)
- Version date - (17Jan2020)
- Bellberry preferred name:
 - VRP1001_Protocol_V2.0_17Jan2020

Investigator Brochure:

- Drug name - (AROU-486)
- Version or Edition number - (Ed1) or (V1)
- Version date - (05Dec2019)
- Bellberry preferred name:
 - AROU-486_IB Ed1_05Dec2019 or
 - AROU-486_IB V1_05Dec2019

Investigator Brochure Summary of Changes:

- Drug name - (ARO-486)
- Version or Edition number - (Ed2) or (V2)
- Version date - (05Jun2020)
- Bellberry preferred name:
 - AROU-486_IB Ed2_05Jun2020_Summary of Changes or
 - AROU-486_IB V2_05Jun2020_Summary of Changes

PICFs:

- Protocol number - (VRP1001)
- Type of PICF - (BB Master Main - BB Master Optional Future Research - BB Master Pregnancy Partner)
- Version number - (V1.0)
- Version Date - (30Mar2020)
- Bellberry preferred name:
 - Multi-Centre: VRP1001 BB Master Main PICF V1.0_30Mar2020
 - Single Centre: VRP1001_MyHospitalAcronym_Main PICF V1.0_30Mar2020
- Site specific clauses document (BA F1.1.12):
 - Protocol Number_MyHospitalAcronym_Site Specific Clauses_Version#_DD/MMM/YYYY

Participant Documents:

- Protocol number - (VRP1001)
- Type of participant document - (Master Participant ID Card)
- Version number - (V2.0)
- Version Date - (05Feb2020)
- Bellberry preferred name:
 - VRP1001_Master Participant ID Card V2_05Feb2020

Questionnaires:

- Protocol number - (VRP1001)
- Type of participant document - (Questionnaire)
- Version number - (V2.0)
- Version Date (if known) - (09Jul2024)
- Bellberry preferred name:

- *VRP1001_Questionnaire_EQ-5D-5L_AUS(en)_v2.0_09Jul2024*

All Updated Documents:

- Standard naming conventions with the addition of either 'Clean' or 'Tracked'. Abbreviations are acceptable (e.g., CL, TK/TC).
- Bellberry preferred name:
 - Multi-Centre: *VRP1001 BB Master Main PICF V1.0_30Mar2020_Clean*
 - Multi-Centre: *VRP1001 BB Master Main PICF V1.0_30Mar2020_Tracked*

References

BA F1.1.1 Submission Requirements Checklist

BA G5 Participant Information and Consent Form Development