

Purpose

The purpose of this document is to achieve a consistent approach for maintaining the history of trial documents using the footer content. 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.

Guidance

Before submission, please check the names of the files. They must be labelled to reflect the document and the study title (including version numbers and dates).

The document file name/title is to 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 is changed, an amendment must be submitted to notify the HREC.

Do not delete any previous versions of any updated documents. These must remain as a reference for document control and auditing purposes.

Site-specific versions of documents should always be created from the approved Master, and not copied from the last site-specific version to avoid missing major updates from the Master.

Please ensure all submitted documents include the following identifiers, as outlined below. There may be variations in the order of wording; however, the minimum requirements are a title, version and date. Examples include:

Protocol: a file name for a Protocol should include:

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

Investigator Brochure: a file name for an IB should include:

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

Investigator Brochure Summary of Changes: This document will be listed on the approval letter. A file name for Summary of Changes should include:

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

PICFs: File names for PICFs should include:

- 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 file 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: File names for Participant Documents should include:

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

References

BA G5 Sample Participant information sheet

BA F1.1.1 Submission requirements checklist