Australian Government
Department of Health
Therapeutic Goods Administration

eCTD baseline sequences

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TGA Health Safety Regulation

Contents

About this guidance

This guidance is for sponsors converting their dossier format from paper, Common Technical Document (CTD) or Non eCTD electronic Submission (NeeS) to electronic Common Technical Document (eCTD).

Baseline sequences

The resubmission of currently valid documents already provided to the TGA in another format such as paper, CTD or NeeS is known as **a baseline**.

This guidance provides information on how to compile and submit an eCTD baseline sequence.

Using a baseline

We strongly recommend that you use a baseline as the start of your eCTD dossier when changing from paper, CTD or NeeS.

A strong baseline creates a solid foundation to develop a new eCTD lifecycle. It also provides an opportunity to resolve any issues with structure or format issues associated with the NeeS format.

You should submit an eCTD baseline if you are making significant changes to your dossier structure including:

- combining two or more NeeS dossiers into one eCTD dossier
- splitting one NeeS dossier into multiple eCTD dossiers.

Baselines are **not assessed**; however, the content and layout can affect future applications.

When to submit a baseline

Submit your baseline when you have no applications related to the dossier under evaluation.

What to include in a baseline sequence

Document requirements

A baseline must only contain currently valid and approved documents that you have previously provided to us.

We prefer that you submit a complete baseline consisting of a full module 1, 2, 3, 4 and 5. However, we recognise that this is not always practical.

At a minimum, include the:

- cover letter
- tracking table (if transitioning from NeeS you can include your NeeS tracking table history)
- approved PI
- approved CMI

- approved labelling
- information relating to pharmacovigilance (such as RMP)
- Module 2, 3, 4 or 5 data that will be referenced in future applications.

The cover letter must**:**

- clearly identify the sequence as an eCTD baseline sequence
- list the products and ARTG numbers included in the baseline
- provide details on the format used for the previous dossier, for example 'transitioning from NeeS (n123456) to e123456'
- provide assurances that:
  - all information included is a resubmission of currently valid documents and no new or unapproved information is included in the sequence
  - formatting is the only change to the previous dossier and there are no amendments to the content
  - any omissions in the baseline do not cause the content to be misleading.

Format

When formatting your baseline:

- use high-quality electronic source documents (if not available, we will accept good quality scanned images with Optical Character Recognition (OCR))
- hyperlinks are not required.

Sequence requirements

When providing the sequence:

- include the Sequence Type: **Baseline {seq-type-46}**
- include the Sequence Description: **Reformat {seq-desc-25}**
- relate the baseline to itself
- use the therapeutic area prefix as the submission number (for example 'PM' for prescription medicines)
- do not provide any other applications within this sequence.

What not to include

Do not include the following in your baseline:

- Documents that have already been provided in the eCTD format.
- Any new information.

Submitting a baseline

Initial sequence baseline

We recommend you submit your baseline as your initial sequence in eCTD. This sets a solid foundation for your eCTD lifecycle.

Initial sequence baselines should be sequence number [0000]. **Do not use** the next available NeeS dossier sequence number.

Example: Baseline as an initial sequence

Sequence	Sequence Type	Sequence Description	Related Sequence
0000	Baseline	Reformat	0000
0001	C – Extension of Indication	Initial	0001
0002	Supplementary Information	Response to Request for Information	0001
0003	H – Minor variation, not resulting in a new register entry	Initial	0003
0004	F – Major variation – new Strength	Initial	0004

Mid-baseline sequence

If an initial sequence baseline is not possible, you can submit your baseline later in the eCTD lifecycle. This is known as **mid-baseline**.

Ensure that the eCTD lifecycle is not damaged when submitting a mid-baseline. Only provide baseline documents where no current content exists in the eCTD lifecycle. **Do not replace** current content with baseline content.

Example: Baseline later in the product lifecycle (mid-baseline)

Sequence	Sequence Type	Sequence Description	Related Sequence
0001	J – PI Change with Data	Initial	0001
0002	Supplementary Information	Response to Request for Information	0001
0003	Baseline	Reformat	0003

Sequence	Sequence Type	Sequence Description	Related Sequence
0004	C – Extension of Indication	Initial	0004
0005	Supplementary Information	Response to Request for Information	0004

Multiple baseline sequences

You should include all required content in one baseline sequence. **Avoid multiple partial baselines** as they create unnecessary complexity in the lifecycle.

Transitioning without a baseline

Although we recommend that you submit an eCTD baseline for all dossiers transitioning to eCTD, it is not a requirement.

When you transition to eCTD, you can choose to **not baseline** and submit a new application without resubmitting any previous documents.

If you choose not to baseline, adhere to the following guidelines in your initial eCTD sequence:

- submit your first sequence as [0001] – this demonstrates that a baseline has not been provided for this dossier
- within the cover letter provided in module 1.0.1:
  - state that no baseline has been submitted
  - provide details on the format used for the previous dossier (for example, 'transitioning from NeeS (n123456) to e123456')
- include the NeeS sequence history within the tracking table in module 1.0.2.

If you need to refer back to documents submitted in the previous format, you should provide a table indicating the location of the documents as an attachment to the cover letter.

Within the cross-reference table include the:

- submission number
- file name
- page number (if appropriate)
- sequence number (if appropriate).

Version history

Version	Description of change	Author	Effective date
V1.0	Original publication	BSRR / PMAB / MRD	30 November 2020

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