Australian Government
Department of Health
Therapeutic Goods Administration

# AU NeeS specification: Module 1 and regional information

Version 1.0, June 2015

TGA Health Safety Regulation

# Contents

# Introduction

This guidance:

- needs to be used in conjunction with the General dossier requirements
- provides general information on producing an electronic copy of a dossier in the NeeS format
- relates to preparing and structuring the data to be submitted in an electronic format to support applications to:
  - register a medicine under Section 23 of the *Therapeutic Goods Act 1989* (the Act)
  - vary the registration of a medicine Section 9D of the Act.

The NeeS specification is an interim arrangement as applicants plan the move to full eCTD.

# Difference between NeeS and eCTD

NeeS differs from the eCTD format in that NeeS does not have:

- the following two XML files that provide the backbone of Modules 1 to 5:
  - the index.xml
  - au-regional.xml
- the *util* folder.

The navigation through a NeeS format dossier is based on:

- electronic tables of contents
- bookmarks
- hypertext links.

# Organising NeeS submissions

All dossiers must be structured in accordance with the Common Technical Document (CTD) format, a format Australia initially adopted in 2004.

For electronic dossiers using the NeeS format:

- Use the CTD folder structure as detailed in the Annex to the ICH guideline Organisation of the Common Technical Document for the Registration of Pharmaceuticals for Human Use.
- Make sure the breakdown of the electronic submission conforms with the ICH Granularity Document (the Annex to the Organisation of the Common Technical Document for the Registration of Pharmaceuticals for Human Use).
- Follow the ICH and AU eCTD file naming conventions.

# Preparing for your NeeS transaction

Before you submit your regulatory activity in NeeS format, you will need to:

1. Obtain an esubmission identifier
2. Prepare your cover letter
3. Validate the NeeS submission
4. Structure the folder
5. Select the electronic media
6. Pack and send the dossier

## Obtain an eSubmission Identifier

You will need an eSubmission Identifier before you submit your regulatory activity[1] for an application in the NeeS format.

To obtain an eSubmission Identifier:

- send an email to esubmissions@tga.gov.au.
- include the following information in your email:
  - the applicant's name as listed in the eBS client database
  - name of medicine (the AAN[2] or proposed AANs) or subject of Master File
  - a description of the Application (application type, dosage form), if referring to a medicine
  - name and address of manufacturing site, if referring to a Master File.

The identifier is:

- made up of a letter and six digits. Example: n123456 ('n' indicates the identifier refers to a NeeS application)
- valid throughout the entire lifecycle of a product unless the product is split from a package as explained elsewhere.

### eSubmission Identifiers when transferring sponsorship

The eSubmission Identifier and the sequences[3] will transfer to the new sponsor when you transfer all the medicines included under an eSubmission Identifier.

We will assign new eSubmission Identifiers to the new sponsor/s if you are only transferring a portion of the medicines included under the same eSubmission Identifier.

[1] A subgroup of an Application which can be a group of related sequences for one approval or notification process. Usually defined for the lifecycle of the specific approval process
[2] Australian Approved Name
[3] A package of information bundled together in an electronic structure providing information to the agency

## Acquiring sponsor

Begin the first sequence of the new application with the next sequence number that would have been submitted under the old eSubmission Identifier (see Table 1 below). This will indicate to evaluators that the medicine was initially reviewed under a different identifier.

Make sure you include the eSubmission Identifier of the previous application in the cover letter of the new application.

## Relinquishing sponsor

The further sequences of the medicines that remain under the initial Identifier will continue as usual, however you should mention their removal in the cover letter of your next regulatory activity.

**Table 1 - eSubmission Identifiers and transfer of Sponsor activities/tasks**

| Sponsor FFF | Sponsor PPP | Sponsor YYY | Activity/Task |
|---|---|---|---|
| Product A<br>Product B<br>Product C<br>Product D<br>n000111Text | | | |
| 0001 | | | Application for Products A, B, C and D from Sponsor FFF |
| 0002 | | | A regulatory activity or notification |
| Product A<br>Product B<br>n000111 | Product C<br>Product D<br>n000222 | | PPP submits first sequence as 0003 referencing the transfer from n000111 and submitting a regulatory activity. |
| | 0003 | | |
| 0003 | 0004 | | Companies FFF and PPP undertake business as usual |
| Product A<br>Product B<br>n000111 | Product C<br>n000222 | Product D<br>n000333 | |
| | | 0005 | YYY submits first sequence as 0005 referencing n000222 |
| 0004 | 0005 | 0006 | Companies FFF, PPP and YYY undertake business as usual |

# Prepare your cover letter

Include the following information in the cover letter in addition to the CTD requirements for the Cover Letter:

- The eSubmission Identifier, the sequence and related sequence in the subject line.
- A description of the eSubmission:
  - type and number of electronic media
  - approximate submission size
  - any characteristics concerning the media that we might need to know.
- A description of the software used to check the files for viruses and a statement as to whether the submission is virus free.
- The regulatory and information technology points of contact for the submission.
- Information about the validation including:
  - the validation tool and version used
  - any findings e.g. errors, warnings or possible missing documents as designated by the eSubmission Document Matrix that would be expected for your specific sequence type.
- Include a paper copy of the Cover Letter with the physical media containing the NeeS sequence. This is only necessary until we develop an electronic portal.

# Validate the NeeS submission

There are two types of NeeS validation findings:

- Pass/Fail – Critical finding:
  - validation findings categorised as 'Pass/Fail' must be addressed
  - noncompliance will lead to rejection of the sequence.
- Best Practice – Best practice recommendations:
  - You should address validation findings categorised as 'Best practice'.
  - We recommend you eliminate best practice recommendations whenever possible.
  - We may request you to fix the sequence[4] and resubmit if there are repeated or excessive issues.

[4] A package of information bundled together in an electronic structure providing information to the agency

Please minimise sequences with best practice recommendations and address any findings in the Cover Letter.

We recommend you use one of the validation tools on our website to validate your applications prior to submitting to us.

### Sequences with errors or deficiencies

We will reject sequences with critical validation findings and you will need to re-submit unless you gain our agreement.

If your sequence has content deficiencies, you will need to submit changes in a follow-up sequence.

### Related information and guidance

Australian eCTD regional specification and validation criteria 3.0

## Structure the folder

Use an application folder named after the eSubmission Identifier and include in this application folder the sequence folder(s) as sub-folder(s) with their contents.

Example-D:\n123456\0001

## Select the electronic media

The size of an eSubmission is only limited by the size of your media format.

Refer to 'Electronic media delivery' in the general dossier requirements for guidance on the types of electronic media you can use for a NeeS sequence to submit as one unit.

## Pack and send your dossier

Refer to 'How and where to send your dossier' in the general dossier requirements for guidance on how to pack and send your dossier.

We will contact you if we have any issues during the validation and/or uploading a NeeS sequence.

# AU regional content

## Regional content

### Module 1 administrative and prescribing information

The ICH Common Technical Document (CTD) specifies that:

- Modules 1 should contain region-specific administrative and product information.
- Module 3.2.R should be used for any additional drug substance and/or drug product information specific to Australia.

Use the eCTD Sequence Matrix spreadsheet in the AU Regional Specification and Validation Criteria 3.0 Excel workbook Australian eCTD regional specification and validation criteria 3.0 to determine the content that is relevant to your specific regulatory activity.

### Related information and guidance

CTD Module 1 Administrative information and prescribing information for Australia is being updated for the new content and numbering of Modules 1 and 3.2R.

## Regional file formats

### Module 1

**Table 2 - File formats that can be included in Module 1**

| Section ID | Business Terminology | File Format |
|---|---|---|
| **1.0** | **Correspondence** | |
| 1.0.1 | Cover letter | PDF |
| 1.0.2 | Lifecycle management tracking table | PDF |
| **1.2** | **Administrative Information** | |
| 1.2.1 | Application forms | PDF |
| **Other** | | PDF |

Where possible, generate PDFs from an electronic source.

Signatures may be embedded as a graphic file in the PDF.

All PDF files, in any module, should be v1.4, v1.5, v1.6 or v1.7 except where there is a specific requirement for a later version is defined.

### Modules 2 to 5

In addition to the file formats defined for Modules 2 to 5 in the ICH eCTD Specification, we will allow comma separated value (CSV) and plain text (TXT) files in Modules 4 and 5 to allow for specialist analysis, e.g. population pharmacokinetics analysis.

## Electronic signatures

Whilst electronic signatures – for example, public key digital signatures – will be crucial, particularly for authentication of electronic submissions and documents, we are currently accepting:

- Digital signatures as an adjunct to written signatures.
- Scanned signatures where the documents make up part of the checksum of a NeeS submission.

## Empty or missing sections

In applications for medicines:

- Provide detailed statements justifying the absence of data or specific CTD sections in the relevant Quality Overall Summary and/or Nonclinical/Clinical Overviews e.g. Module 2.3, 2.4, or 2.5.
- Include a statement in the cover letter on the absence of expected Module 1 content (based on information in the Australian eCTD regional specification and validation criteria 3.0).

**Do Not:**

- û Use documents with no substantive content – for example, documents that contain words like “not applicable” - in the NeeS structure. This creates causes delays for evaluators who must open and assess documents with no substantive content.
- û Provide a justification for content that is typically absent for applications for generic medicines.

## Table of contents, bookmarks and hyperlinks

### Tables of contents

A NeeS format dossier must contain tables of contents (TOC) in PDF format.

### For small dossiers

You may have one TOC referring directly to all dossier documents especially when only one module beside Module 1 is included. Example: certain variations.

### For larger dossiers

The main TOC must be linked to module TOCs which are then further linked to the documents in each module.

- û Do not include hyperlinks in the module TOCs to the documents in other modules.

The file containing:

- the main, submission-level TOC must be named ctd-toc.pdf and be located in the four digit number named folder for the NeeS submission. This folder comes next to the root or top level folder (named using the eSubmission Identifier).
- the module tables of contents are named m1-toc.pdf, m2-toc.pdf, m3-toc.pdf, m4-toc.pdf and m5-toc.pdf and are located in the corresponding top level module folders.

TOCs included at the document level must be located within the same file as the rest of the document.

All documents lodged in a NeeS format dossier must be referenced from a hyperlinked table of contents. Hyperlinks for a document should always be provided to the first page of the appropriate file.

## Examples for tables of contents

The following examples of the Table of contents are for guidance and illustrative purposes only.

The bold text in column 3 indicates where hyperlinks to the individual documents should be added.

**Table 3 - Example: Main CTD table of contents**

| Module | Title | Hyperlink |
|---|---|---|
| Module 1 | Administrative and prescribing information for Australia | **Module 1** |
| Module 2 | Common technical document summaries | **Module 2** |
| Module 4 | Nonclinical study reports | **Module 4** |
| Module 5 | Clinical study reports | **Module 5** |

**Table 4 - Example: Module 1 Table of contents Module 1**

| Module 1 | Administrative and prescribing information for Australia | Reference |
|---|---|---|
| 1.0 | Correspondence | 1.0 |
| 1.0.1 | Cover letter | **1.0.1** |
| 1.0.2 | Lifecycle management tracking table | **1.0.2** |
| 1.0.3 | Response to request for information | 1.0.3 |
| 1.2 | Administrative information | 1.2 |
| 1.2.1 | Application forms | **1.2.1** |
| 1.2.2 | Pre-submission details | **1.2.2** |

| Module 1 | Administrative and prescribing information for Australia | Reference |
|---|---|---|
| 1.2.3 | Patent certification | 1.2.3 |
| 1.2.4 | Change in sponsor | 1.2.4 |
| 1.3 | Medicine information and labelling | 1.3 |
| 1.3.1 | Product information and package insert | 1.3.1 |
| 1.3.1.1 | Product information-clean | **1.3.1.1** |
| 1.3.1.2 | Product information-annotated | **1.3.1.2** |
| 1.3.1.3 | Package insert | 1.3.1.3 |
| 1.3.2 | Consumer medicines information | 1.3.2 |
| 1.3.2.1 | Consumer medicines information-clean | 1.3.2.1 |
| 1.3.2.2 | Consumer medicines information-annotated | 1.3.2.2 |
| 1.3.3 | Label mock-ups and specimens | 1.3.3 |
| 1.4 | Information about the experts | 1.4 |
| 1.4.1 | Quality | 1.4.1 |
| 1.4.2 | Nonclinical | **1.4.2** |
| 1.4.3 | Clinical | **1.4.3** |
| 1.5 | Specific requirements for different types of applications | 1.5 |
| 1.5.1 | Literature based submission documents | 1.5.1 |
| 1.5.2 | Orphan drug designation | 1.5.2 |
| 1.5.3 | Genetically modified organisms consents | 1.5.3 |
| 1.5.4 | Additional trade name declarations | 1.5.4 |
| 1.5.5 | Co-marketed medicine declarations | 1.5.5 |
| 1.5.6 | Combination medicine consent | 1.5.6 |
| 1.5.7 | OTC product assurances | 1.5.7 |

| Module 1 | Administrative and prescribing information for Australia | Reference |
|---|---|---|
| 1.5.8 | Umbrella brand assessment | 1.5.8 |
| 1.6 | Master files and Certificates of Suitability | 1.6 |
| 1.6.1 | Relevant external sources | 1.6.1 |
| 1.6.2 | Applicants declaration | 1.6.2 |
| 1.6.3 | Letters of access | 1.6.3 |
| 1.7 | Compliance with meetings and pre-submission processes | 1.7 |
| 1.7.1 | Details of compliance with pre-submission meeting outcomes | **1.7.1** |
| 1.7.2 | Details of any additional data to be submitted | 1.7.2 |
| 1.7.3 | Declaration of compliance with pre-submission planning form and planning letter | **1.7.3** |
| 1.8 | Information relating to pharmacovigilance | 1.8 |
| 1.8.1 | Pharmacovigilance systems | 1.8.1 |
| 1.8.2 | Risk management plan | 1.8.2 |
| 1.9 | Summary of biopharmaceutic studies | 1.9 |
| 1.9.1 | Summary of a bioavailability or bioequivalence study | **1.9.1** |
| 1.9.2 | Justification for not providing biopharmaceutic studies | 1.9.2 |
| 1.10 | Information relating to paediatrics | 1.10 |
| 1.11 | Foreign regulatory information | 1.11 |
| 1.11.1 | Foreign regulatory status | **1.11.1** |
| 1.11.2 | Foreign product information | **1.11.2** |
| 1.11.3 | Data similarities and differences | 1.11.3 |
| 1.11.4 | Foreign evaluation reports | 1.11.4 |
| 1.12 | Antibiotic resistance data | 1.12 |

**Table 5 - Example: Module 2 Table of contents**

| Module 2 | Common technical document summaries | Reference |
|---|---|---|
| 2.4 | Nonclinical overview | **2.4** |
| 2.5 | Clinical overview | **2.5** |
| 2.6 | Nonclinical written and tabulated summary | **2.6** |
| 2.7 | Clinical summary | **2.7** |

**Table 6 - Example: Module 4 Table of contents**

| Module 4 | Nonclinical study reports | Reference |
|---|---|---|
| 4.2 | Study reports | 4.2 |
| 4.2.1 | Pharmacology | 4.2.1 |
| 4.2.1.1 | Primary pharmacodynamics | 4.2.1.1 |
| | Study report 1 | **4.2.1.1** |
| | Study report 2 | **4.2.1.1** |
| | Study report 3 | **4.2.1.1** |
| 4.3 | Literature references | 4.3 |
| | Reference 1 | **4.3** |
| | Reference 2 | **4.3** |
| | Reference 3 | **4.3** |

**Table 7 - Example: Module 5 table of contents**

| Module 5 | Clinical study reports | References |
|---|---|---|
| 5.2 | Tabular listing of all clinical studies | **5.2** |
| 5.3 | Clinical study reports | 5.3 |
| 5.3.1 | Reports of biopharmaceutic studies | 5.3.1 |
| 5.3.1.1 | Bioavailability (BA) study reports | 5.3.1.1 |
| | Study report 1 | **5.3.1.1** |

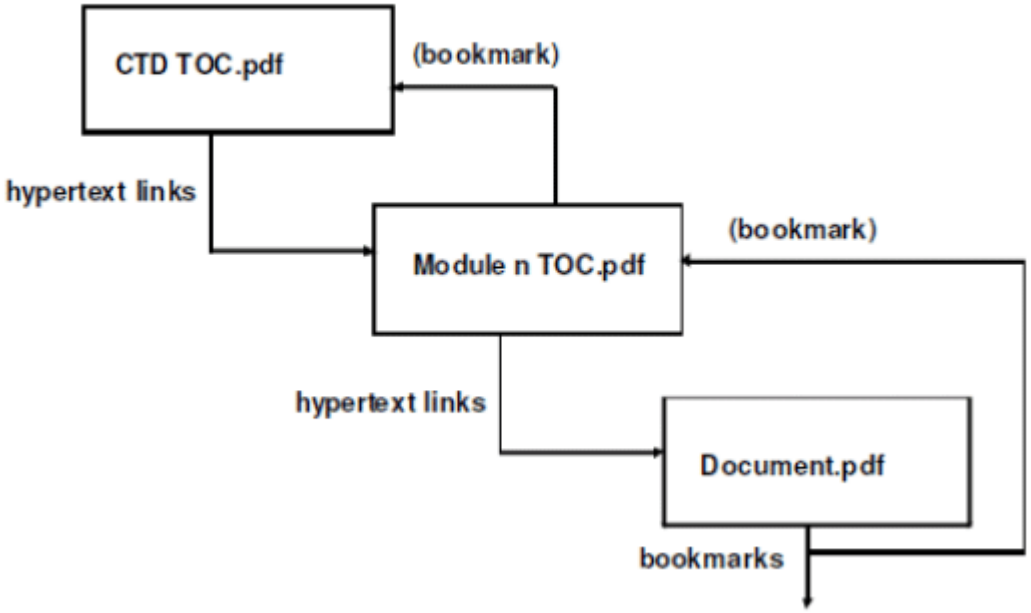
### Bookmarks and hyperlinks

We can increase the efficiency in evaluating your application if you prepare the documents so we can quickly locate content.

We recommend you:

- Use bookmarks and/or Tables of Content to assist us with navigating through PDF documents to quickly find information.
- Include Table of Contents, and/or if appropriate, a Table of Tables, Table of Figures, etc. on the first page for documents with more than five pages and with multiple sections.

The following image describes the hierarchy for tables of contents and bookmarks.




### Related information and guidance

ICH eCTD Specifications - Appendix 7

## Baseline submissions

A baseline submission is a resubmission of currently valid documents that you have already provided to us in a paper format.

## Cover letter for baseline submissions

When making a baseline submission, you need to include a statement about each of the following points in the covering letter:

- the format used for the previous dossier(s)
- when the previous dossier(s) was submitted
- verify that the formatting is the only change to the previous dossier(s) and there are no amendments to content
- all the information in the baseline submission was in the previous version(s) of the dossier
- any omissions in the baseline submission do not cause the content to be misleading

## Changing from paper to NeeS

When changing from paper to NeeS we recommend you:

- use a baseline sequence as a start of a NeeS application
- provide as much content as possible in the NeeS baseline sequence.

You can define the sections provided in a baseline sequence, but make sure that any omissions do not cause the content to be misleading.

We prefer the baseline submission to consist of high quality electronic source documents, but we will accept good quality scanned images with Optical Character Recognition (OCR) as this will help us search the text during the evaluation process.

We do not evaluate the baseline submissions and you do not need hyperlinks between documents.

## Baseline sequence

Use the sequence type `Baseline` and sequence description `Reformat` in the lifecycle management table.

## Initial baselines of paper submissions

The baseline should:

- normally be submitted as sequence 0000
- always be a separate sequence
- never include new regulatory activities.

The first new regulatory activity[5] – for example, the next variation, in NeeS format should then be submitted as sequence[6] 0001.

[5] A subgroup of an Application which can be a group of related sequences for one approval or notification process. Usually defined for the lifecycle of the specific approval process.
[6] A package of information bundled together in an electronic structure providing information to the agency

**Table 8 demonstrates the baseline as an initial NeeS sequence**

| Sequence | Sequence type | Sequence description | Related sequence |
|---|---|---|---|
| 0000 | Baseline | Reformat | 0000 |
| 0001 | C-Extension of Indication of COPD | Initial | 0001 |
| 0002 | Supplementary information | Response to Request for Information | 0001 |
| 0003 | H-Minor Variation | Initial | 0003 |
| 0004 | F-Major Variation—New Strength | Initial | 0004 |

# Structure and naming requirements

## Folder and file structure

The structure of a NeeS format dossier[7] must conform to both:

- the Annex to the ICH guideline Organisation of the Common Technical Document for the Registration of Pharmaceuticals for Human Use and
- the requirements set out in CTD Module 1 - Administrative information and prescribing information for Australia.

Name the root folder of the dossier with the eSubmission Identifier of the medicine followed by the subfolder name (sequence number) of four digits

The eSubmission Identifier for a NeeS dossier will be in the format “n” followed by 6 digits.

Example, n123456/0000/.

## Sequence number

Sequence numbers for eCTD submissions are not applicable for NeeS format dossiers; however, the use of a four digit number in the top level folder name should be followed.

The initial submission should normally have a sequence number of 0000.

As additional data is submitted in response to questions etc, the sequence number of the submission will advance, 0001, 0002, etc.

Only in the case of a technically invalid submission should a sequence be replaced with one using the same number, e.g. the initial sequence “0000” will be replaced by another “0000”.

[7] A collection of documents and each document is provided as a separate file

Any time an electronic submission in the NeeS format is submitted, an updated Lifecycle management tracking table named "tracking.pdf" should be placed in Module 1.0.2. This will support transparency and ease tracking of sequences regardless of the format.

**Table 9 - Lifecycle management tracking table**

| Sequence | Sequence type | Sequence description | Related sequence |
|---|---|---|---|
| 0000 | Baseline | Reformat | 0000 |
| 0001 | C-Extension of Indication of COPD | Initial | 0001 |
| 0002 | Supplementary information | Response to Request for Information | 0001 |
| 0003 | Supplementary information | Pre-Advisory Committee response | 0001 |
| 0004 | Supplementary information | Product Information | 0001 |
| 0005 | F-Major Variation—New Strength | Initial | 0005 |

# Folder and file naming conventions

The top level folder will be part of the submitted NeeS.

## For Module 1 dossiers

Follow our recommended folder names.

## For Modules 2-5, dossiers

Follow the ICH eCTD folder naming conventions as specified in Appendix 3 of the *ICH eCTD specification*.

## File naming

Follow the eCTD file naming conventions described in the *ICH eCTD Specification*.

If you are submitting multiple files in one section and there is only one recommended name, you can use a suffix to the filename: using the file name–var.pdf convention, where the – var component have no dashes or illegal characters (for example: *pharmaceutical–development–container.pdf*).

The number of characters in a folder/file path must not exceed 180 characters.

Counting starts from the first digit of the four digit folder name in which the ctd-toc.pdf is placed.

The maximum length of the name of a single folder or file is 64 characters including the extension.

## Legend for Table 10 - Recommended folder names for Module 1

**Bold text** - Fixed folder name

Normal text - Fixed file name component

*Italicised text* - Variable file name component

**Table 10 - Recommended folder names for Module 1**

| Content | Correlating AU Module 1 Section |
|---|---|
| **nXXXXXX (eSubmission identifer)** | |
| **0000** | |
| ctd-toc.pdf | |
| **m1** | |
| m1-toc.pdf | |
| **au** | |
| **100-correspondence** | 1.0 Correspondence |
| **1001-cover** | 1.0.1 Cover letter |
| cover-*var*.pdf | |
| **1002-tracking** | 1.0.2 Lifecycle management tracking table |
| tracking-*var*.pdf | |
| **1003-response** | 1.0.3 Response to request for information |
| response-*var*.pdf | |
| **102-admin-info** | 1.2 Administrative Information |
| **1021-app-form** | 1.2.1 Application forms |
| app-form-*var*.pdf | |
| **1022-pre-sub** | 1.2.2 Pre-submission details |
| pre-sub-*var*.pdf | |
| **1023-patent** | 1.2.3 Patent certification |
| pat-cert-*var*.pdf | |

| Content | Correlating AU Module 1 Section |
|---|---|
| **1024-sponsor** | 1.2.4 Change in sponsor |
| change-sponsor-*var*.pdf | |
| **103-med-info** | 1.3 Medicine information and labelling |
| **1031-pi** | 1.3.1 Product information and package insert |
| **10311-pi-clean** | 1.3.1.1 Product information - clean |
| pi-clean-*var*.pdf | |
| **10312-pi-annotated** | 1.3.1.2 Product information - annotated |
| pi-annotated-*var*.pdf | |
| **10313-pack-ins** | 1.3.1.3 Package insert |
| pack-ins-*var*.pdf | |
| **1032-cmi** | 1.3.2 Consumer medicines information |
| **10321-cmi-clean** | 1.3.2.1 Consumer medicines information - clean |
| cmi-clean-*var*.pdf | |
| **10322-cmi-annotated** | 1.3.2.2 Consumer medicines information - annotated |
| cmi-annotated-*var*.pdf | |
| **1033-mockup** | 1.3.3 Label mock-ups and specimens |
| mockup-*var*.pdf | |
| **104-expert** | 1.4 Information about the experts |
| **1041-quality** | 1.4.1 Quality |
| quality-*var*.pdf | |
| **1042-nonclinical** | 1.4.2 Nonclinical |
| nonclinical-*var*.pdf | |
| **1043-clinical** | 1.4.3 Clinical |
| clinical-*var*.pdf | |

| Content | Correlating AU Module 1 Section |
|---|---|
| **105-specific** | 1.5 Specific requirements for different types of applications |
| **1051-lit-based** | 1.5.1 Literature-based submission documents |
| lit-based-*var*.pdf | |
| **1052-orphan** | 1.5.2 Orphan drug designation |
| orphan-*var*.pdf | |
| **1053-gmo** | 1.5.3 Genetically modified organisms consents |
| gmo-consents-*var*.pdf | |
| **1054-add-tradename** | 1.5.4 Additional trade name declarations |
| add-tradename-*var*.pdf | |
| **1055-co-marketed** | 1.5.5 Co-marketed medicines declarations |
| co-marketed-*var*.pdf | |
| **1056-comb-med** | 1.5.6 Combination medicine consent |
| comb-med-cons-*var*.pdf | |
| **1057-otc-prod-assurance** | 1.5.7 OTC product assurances |
| otc-prod-assurance-*var*.pdf | |
| **1058-umbrella-brand-assess** | 1.5.8 Umbrella brand assessment |
| umbrella-brand-assess-*var*.pdf | |
| **106-master-files** | 1.6 Master files and certificates of suitability |
| **1061-external-sources** | 1.6.1 Relevant external sources |
| external-sources-*var*.pdf | |
| **1062-app-decl** | 1.6.2 Applicant's declaration |
| app-decl-*var*.pdf | |
| **1063-loa** | 1.6.3 Letters of access |
| loa-*var*.pdf | |

| Content | Correlating AU Module 1 Section |
|---|---|
| **107-compliance** | 1.7 Compliance with meetings and pre-submission processes |
| **1071-pre-sub-outcomes** | 1.7.1 Details of compliance with pre-submission meeting outcomes |
| pre-sub-outcomes-*var*.pdf | |
| **1072-additional-data** | 1.7.2 Details of any additional data to be submitted |
| additional-data-*var*.pdf | |
| **1073-pre-sub-planning** | 1.7.3 Declaration of compliance with pre-submission planning form and planning letter |
| pre-sub-planning-*var*.pdf | |
| **108-pharmacovigilance** | 1.8 Information relating to pharmacovigilance |
| **1081-phvig-system** | 1.8.1 Pharmacovigilance systems |
| phvigsystem-*var*.pdf | |
| **1082-riskmgt-system** | 1.8.2 Risk management plan |
| riskmgtsystem-*var*.pdf | |
| **109-sum-biopharm** | 1.9 Summary of biopharmaceutic studies |
| **1091-sum-ba-be** | 1.9.1 Summary of bioavailability or bioequivalence study |
| sum-ba-be-*var*.pdf | |
| **1092-justif-no-study** | 1.9.2 Justification for not providing biopharmaceutic studies |
| justif-no-study-*var*.pdf | |
| **110-paediatrics** | 1.10 Information relating to paediatrics |
| paediatrics-*var*.pdf | |
| **111-foreign** | 1.11 Foreign regulatory information |
| **1111-reg-status** | 1.11.1 Foreign regulatory status |

| Content | Correlating AU Module 1 Section |
|---|---|
| foreign-reg-status-*var*.pdf | |
| **1112-pi** | 1.11.2 Foreign product information |
| foreign-pi-*var*.pdf | |
| **1113-similarities** | 1.11.3 Data similarities and differences |
| similarities-*var*.pdf | |
| **1114-eval-reports** | 1.11.4 Foreign evaluation reports |
| eval-reports-*var*.pdf | |
| **112-antibiotic** | 1.12 Antibiotic resistance data |
| antibiotic-*var*.pdf | |

The naming of folders in Modules 2 to 5 must follow the format described in Appendix 3: General Considerations for the CTD Modules of the *ICH eCTD specification*.

### Placement of documents

Go to Australian eCTD regional specification and validation criteria 3.0 for guidance on the placement of documents within the CTD structure for particular submission types

Document Table of contents should be located within the document itself. Provide bookmarks for every entry in the document's Table of Contents to the appropriate location of each document.

If there is no Table of Contents, provide bookmarks to a sufficiently detailed level, typically to Level 3 or 4 headings.

## Correspondence

Similar to eCTD, NeeS will support users having a compiled view of the information submitted in the appropriate place in the dossier over time. Therefore, you should also submit formal responses to questions in NeeS format, as well as any correspondence that relates directly to the content of the dossier.

### Additional guidance

Module 1.0.3 Responses to requests for information of CTD – Module 1 for additional information.

### Moving from NeeS to eCTD format applications

You, as the applicant can switch from NeeS to eCTD at the start of any new regulatory activity.

- û Do not change from eCTD back to NeeS.

### Additional guidance

AU eCTD Specification section 3.8 - principles concerning change of format.

# Module specific information

## Module 1.0.3 Responses to requests for information

You must provide any additional information or data relating to the submitted dossier (for example, s. 31 responses, and new safety data), in the CTD format and meet the requirements specified in CTD Module 1.

Follow the NeeS folder and file structure and lodge as a new sequence.

### Further guidance

Module 1.0.3 Responses to requests for information in CTD Module 1.

If you submit responses to more than one question a single file, use bookmarks within the PDF file to clearly identify each response.

## Module 1.2.1: Application form

Always provide the application form as a PDF file within the NeeS format structure.

### Further guidance

Module 1.2.1 Application forms in CTD Module 1.

Contact streamlinedsubmission@tga.gov.au

# Version history

| Version | Description of change | Author | Effective date |
|---|---|---|---|
| V1.0 | Original publication | Medicines Authorisation Branch | July 2015 |

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