COLLABORATIVE WORKSPACES FOR THE CADTH COMMON DRUG REVIEW

Filing a CADTH Common Drug Review (CDR) Submission or Resubmission Using Collaborative Workspaces

The submission or resubmission requirements must adhere to the content, format, and organization in the current version of the *Submission Guidelines for the CADTH Common Drug Review* and applicable CDR Updates.

- Applicants must be registered with CADTH before filing a submission or resubmission. For detailed information on how to register please consult CADTH Collaborative Workspaces Registration.
    - Ensure both primary and secondary contacts and any submitting consultants working on a CDR application are registered with Collaborative Workspaces.

- Submissions and resubmissions must be filed using Collaborative Workspaces. To file a submission or resubmission, the manufacturers must upload one copy of all category 1 requirements to the corresponding CDR review using Collaborative Workspaces following the electronic file folder and file format specified below.

- Category 2 requirements may be filed at the same time as category 1 requirements, if available. When not provided at the same time as category 1 requirements, one copy of all category 2 requirements must be filed using Collaborative Workspaces at least 20 business days before the targeted Canadian Drug Expert Committee (CDEC) meeting at which the submission or resubmission will be considered.

- Submissions and resubmissions must be filed using Collaborative Workspaces during CADTH business hours of between 8:00 a.m. and 4:00 p.m. ET. If filed outside of CADTH business hours, the next business day will be considered the date of transmittal.

- Applicants who experience difficulties filing a submission or resubmission using Collaborative Workspaces should contact CADTH by email (requests@cadth.ca) for support or to arrange an alternate delivery method for the submission or resubmission requirements; e.g., by email or mailing a USB memory stick or CD.

CADTH CONTACT AND CDR APPLICATION FILING INFORMATION

How and Where to Direct CDR-Related Inquiries or CDR Applications	
Type of Inquiry or CDR Application	**How and Where to Direct**
• **General CDR inquiries** • **CDR process or procedure-related inquiries**	In writing to: **Email:** requests@cadth.ca **Fax:** 613 226 5392 **Mail**[1]**:** Central Intake CADTH 600-865 Carling Avenue Ottawa, ON K1S 5S8
Filing CDR applications for a submission or resubmission	By Collaborative Workspaces
Inquiries regarding an active CDR review	By email to: • the designated submission coordinator contact provided in the category 1 requirement acceptance letter
Inquiries regarding CDR application fees	In writing to: **Email:** accountsreceivable@cadth.ca

Delivery Times	
Means of Delivery	**When Information Is Considered to Have Been Delivered**
By courier, registered mail, regular mail, in person	• On the day of receipt by CADTH's reception desk.
Email or fax	• On the day of transmittal if sent during CADTH business hours of 8:00 a.m. to 4:00 p.m. ET. • On the next business day if sent outside of regular CADTH business hours. For the CADTH holiday schedule please check the CADTH website, www.cadth.ca, under "Contact Us."
Collaborative Workspaces	• On the day of transmittal if sent during CADTH business hours 8:00 a.m. to 4:00 p.m. ET. • On the next business day, if sent outside of regular CADTH business hours.

[1] If the party sending a CADTH CDR-related inquiry or other correspondence knows, or should reasonably know, of any disruption or difficulty with the postal system that might affect the delivery of mail, any such inquiry, correspondence, or CADTH Common Drug Review application should not be mailed, and should instead be delivered to CADTH by electronic means, by courier, or in-person delivery.

ELECTRONIC FILE STRUCTURE AND NAMING FORMAT

Instructions for Manufacturers

Please carefully review the following electronic file structure and naming convention before assembling CDR submission or resubmission requirements. If you have any questions regarding the CDR application process for a submission or resubmission, please email requests@cadth.ca with the complete details of your question(s).

Filing Category 1 and Category 2 Requirements:

- All materials must be submitted using the Collaborative Workspaces. To file a submission, manufacturers are to use the Submit and Contribute — Pharmaceutical Manufacturers function to upload the file and complete the online submission form.
    - Files should be submitted as zipped (.zip) files. The maximum file size is approximately 1GB. If there are several .zip files, the number of files should be noted in the additional comments box of the submission form (e.g., File 1 of 4). The root folder(s) should be clearly named with the brand or generic drug name and submission requirement (e.g., Brand Name — Category 1).
- An email notification will be sent to the submitter when the file is successfully submitted.
- File names cannot exceed 64 characters or contain special characters; therefore, manufacturers are asked to use abbreviations as necessary.
- Documents must be provided in PDF or Microsoft Word format, unless otherwise indicated in the requirement descriptions. These files must be unlocked, searchable, and printable. Document users must be able to extract information or combine documents.
- Documents must be organized and labelled according to the file structure and naming format provided in this appendix.
- If any extra supporting documents that do not have a designated folder are being submitted at the applicant's discretion (e.g., Clinical Study Reports), these should be appropriately named and filed in a logical location in the file structure.

Providing Additional Information During the Review:

- If CADTH requests additional information during the course of the review, manufacturers can provide the requested information to CADTH using Collaborative Workspaces.
- The documents must be provided in PDF or Microsoft Word format. These files must be unlocked, searchable, and printable. Document users must be able to extract information or combine documents.
- File names cannot exceed 64 characters or contain special characters; therefore, manufacturers are asked to use abbreviations as necessary.

A. Category 1 Requirements for a Standard CDR Review: New Drug, Drug with a New Indication, or New Combination Product Submission

The following folder and file structure reflects each of the CDR category 1 requirements for a new drug, drug with a new indication, or new combination product submission and the order in which they are to be provided as .zip files through the Collaborative Workspaces.

Represents one folder

Represents a PDF or Microsoft Word file (unlocked, searchable, and printable)

Brand Name – Category 1

- 1_Brand Name_General Information
  - 1 - Application Overview
  - 2 - Signed Cover Letter
  - 3 - Executive Summary
  - 4 - Product Monograph
- 2_Brand Name_Health Canada Documentation
  - 1 - Health Canada Notice of Compliance (NOC)
  - 2 - Letter of Undertaking *(Note: only if applicable; adjust following file numbers if necessary)*
  - 3 - Health Canada Reviewer Report(s)
  - 4 - Table of Clarifaxes
- 3_Brand Name_Clinical Information
  - 3.1_Common Technical Document
    - 1 - Section 2.5
    - 2 - Section 2.7.1
    - 3 - Section 2.7.3
    - 4 - Section 2.7.4
    - 5 - Section 5.2
  - 3.2_Clinical Studies and Errata
    - _List of Studies and Errata
    - _No Errata *(Note: placeholder document, only if applicable)*
    - 1 - Trial Name_Author_Year
    - 2 - Trial Name_Author_Year
    - 3 - Trial Name_Author_Year Erratum
  - 3.3_Table of Studies
    - Table of Studies
  - 3.4_Editorials
    - _List of Editorials
    - 1 - Author_Year

- 3.5_Search Strategies
  - Search Strategies
- 3.6_Disclosure of Studies
  - Signed Disclosure of Studies
- 3.7_CONSORT Diagrams
  - 1 - CONSORT (Study Name)
  - 2 - CONSORT (Study Name)
- 3.8_New Data
  - _List of New Data
  - 1 - Trial Name_Author_Year
- 3.9_Validity of Outcomes
  - _List of References
  - 1 – Author_Year
- 3.10_Indirect Comparison *(Note: not a requirement; may be provided at discretion of the applicant)*
  - Indirect Comparison

- 4_Brand Name_Economic and Epidemiologic
  - 4.1_Economic Information
    - Pharmacoeconomic evaluation
    - Economic model
    - Economic model supporting documentation
  - 4.2_Epidemiologic Information
    - Number of Patients Accessing New Drug (*Note: this requirement is only for a new drug submission or a new combination product submission if one of the components is a new drug*)
    - Disease Prevalence and Incidence
- 5_Brand Name_Pricing and Distribution
  - Pricing and Distribution
  - Commitment for Submitted Price
- 6_Brand Name_Sharing of Information
  - Information Sharing Letter

B. Category 1 Requirements for a Tailored CDR Review: New Combination Product (Funded Components or CADTH-Designated for Tailored CDR Review) Submission

The following folder and file structure reflects each of the category 1 requirements for a new combination product (funded components or CADTH-designated for tailored CDR review) and the order in which they are to be provided as .zip files through the Collaborative Workspaces.

Represents one folder

Represents a PDF or Microsoft Word file (unlocked, searchable, and printable)

Brand Name — Category 1

- 1_Brand Name_General Information
  - 1 - Application Overview
  - 2 - Signed Cover Letter
  - 3 - Executive Summary
  - 4 - New Combination Submission Template
  - 5 - Product Monograph
- 2_Brand Name_Health Canada Documentation
  - 1 - Health Canada NOC
  - 2 - Letter of Undertaking *(Note: only if applicable; adjust following file numbers if necessary)*
  - 3 - Health Canada Reviewer Report(s)
  - 4 - Table of Clarifaxes
- 3_Brand Name_Clinical Information
  - 3.1_Common Technical Document
    - 1 - Section 2.5
    - 2 - Section 2.7.1
    - 3 - Section 2.7.3
    - 4 - Section 2.7.4
    - 5 - Section 5.2
  - 3.2_Source Documentation
    - _List of Documentation
    - 1 - Name_Year
    - 2 - Name_Year
- 4_Brand Name_Epidemiologic Information
  - Disease Prevalence and Incidence
- 5_Brand Name_Pricing and Distribution
  - Pricing and Distribution
  - Commitment for Submitted Price
- 6_Brand Name_Sharing of Information
  - Information Sharing Letter

C. Category 1 Requirements for a Tailored CDR Review: Biosimilar Submission

The following folder and file structure reflects each of the category 1 requirements for a biosimilar submission and the order in which they are to be provided as .zip files through the Collaborative Workspaces.

Represents one folder

Represents a PDF or Microsoft Word file (unlocked, searchable, and printable)

Brand Name — Category 1

- 1_Brand Name_General Information
  - 1 - Application Overview
  - 2 - Signed Cover Letter
  - 3 - Executive Summary
  - 4 - Biosimilar Submission Template
  - 5 - Product Monograph
- 2_Brand Name_Health Canada Documentation
  - 1 - Health Canada NOC
  - 2 - Letter of Undertaking *(Note: only if applicable; adjust following file numbers if necessary)*
  - 3 - Health Canada Reviewer Report(s)
  - 4 - Table of Clarifaxes
- 3_Brand Name_Clinical Information
  - 3.1_Common Technical Document
    - 1 - Section 2.3
    - 2 - Section 2.5
    - 3 - Section 2.7.1
    - 4 - Section 2.7.2
    - 5 - Section 2.7.3
    - 6 - Section 2.7.4
    - 7 - Section 5.2
  - 3.2_Clinical Studies and Errata
    - _List of Articles and Errata
    - _No Errata *(Note: placeholder document, only if applicable)*
    - 1 - Trial Name_Author_Year
    - 2 - Trial Name_Author_Year
    - 3 - Trial Name_Author_Year Erratum
  - 3.3_Table of Studies
    - Table of Studies
  - 3.4_Editorials
    - _List of Editorials
    - 1 - Author_Year
  - 3.5_Search Strategies
    - Search Strategies
  - 3.6_Disclosure of Studies
    - Signed Disclosure of Studies

- 3.7_CONSORT Diagrams
  - 1 - CONSORT (Study Name)
  - 2 - CONSORT (Study Name)
- 3.8_New Data
  - _List of New Data
  - 1 - Trial Name_Author_Year
  - 2 - Trial Name_Author_Year
- 3.9_Validity of Outcomes
  - _List of References
  - 1 – Author_Year

4_Brand Name_Disease Prevalence and Incidence
- Disease Prevalence and Incidence

5_Brand Name_Pricing and Distribution
- Pricing and Distribution
- Commitment for Submitted Price

6_Brand Name_Sharing of Information
- Information Sharing Letter

D. Category 1 Requirements for All Resubmissions

The following folder and file structure reflects each of the category 1 requirements for all CDR resubmissions and the order in which they are to be provided as .zip files through the Collaborative Workspaces.

Represents one folder

Represents a PDF or Microsoft Word file (unlocked, searchable, and printable)

Brand Name — Category 1

- 1_Brand Name_General Information
  - 1 - Application Overview
  - 2 - Signed Cover Letter
  - 3 - Executive Summary
  - 4 - Product Monograph
- 2_Brand Name_New Clinical Information
  - 2.1_New Clinical Studies
    - _List of New Clinical Studies
    - 1 - Trial Name_Author_Year
    - 2 - Trial Name_Author_Year
  - 2.2_ New Editorials and Errata
    - _List of Editorials and Errata
    - _No Editorials or No Errata *(Note: placeholder document, only if applicable)*
    - 1 - Author_Year_Editorial
    - 2 - Trial Name_Author_Year_Erratum
  - 2.3_Other New Clinical Information *(Note: add files, as applicable, for any other new clinical information included in the resubmission)*
    - _List of Other New Information
    - _Name of New Information
  - 2.4_CONSORT Diagrams
    - 1 - CONSORT (Study Name)
    - 2 - CONSORT (Study Name)
  - 2.5_Updated Table of Studies
    - Table of Studies
  - 2.6_Updated Search Strategies
    - Search Strategies
  - 2.7_Disclosure of Studies
    - Signed Disclosure of Studies
- 3_Brand Name_Economic and Epidemiologic
  - 3.1_Economic Information
    - Pharmacoeconomic evaluation
    - Economic model
    - Economic model supporting documentation
  - 3.2_Epidemiologic Information

- Number of Patients Accessing New Drug *(Note: this requirement is only for a new drug submission or a new combination product submission if one of the components is a new drug)*
- Disease Prevalence and Incidence

4_Brand Name_Pricing and Distribution
- Pricing and Distribution
- Commitment for Submitted Price

5_Brand Name_Sharing of Information
- Information Sharing Letter

6_Brand Name_Drug Plan Decisions
- Drug Plan Decisions

E. Category 2 Requirements for all Submissions and Resubmissions

The following folder and file structure reflects each of the category 2 requirements for all CDR submission types and resubmissions, and the order in which they are to be provided as .zip files through the Collaborative Workspaces.

Represents one folder

Represents a PDF or Microsoft Word file (unlocked, searchable, and printable)

Brand Name — Category 2

1_Cover Letter *(Note: only include if category 2 requirements are not submitted at the same time as category 1 requirements)*

- Signed Cover Letter

2_Brand Name BIAs

- 2.1_BIAs
  - 1 - BIA Report BC
  - 2 - BIA Model BC
  - 3 - BIA Report AB
  - 4 - BIA Model AB
  - 5 - BIA Report SK
  - 6 - BIA Model SK
  - 7 - BIA Report MB
  - 8 - BIA Model MB
  - 9 - BIA Report ON
  - 10 - BIA Model ON
  - 11 - BIA Report NB
  - 12 - BIA Model NB
  - 13 - BIA Report NS
  - 14 - BIA Model NS
  - 15 - BIA Report PEI
  - 16 - BIA Model PEI
  - 17 - BIA Report NL
  - 18 - BIA Model NL
  - 19 - BIA Report NIHB
  - 20 - BIA Model NIHB
- 2.2_BIA Supporting Documentation
  - _List of References
  - 1 - Name of document

3_Brand Name CPID *(Note: The Certified Product Information Document (CPID) is required **only** for a **submission** and not for a resubmission)*

- CPID