**Table of Studies Template**

**Instructions for Sponsors**

The purpose of this table is to provide Canada’s Drug Agency (CDA-AMC) with an overview of all published and unpublished studies for the drug and indication under review. Please read the instructions below and consult the recommended documentation before completing the template. If you have any questions regarding the application process or requirements, please [contact us](https://www.cda-amc.ca/contact-us) with the complete details of your question(s).

Before Completing the Template:

Please review the following to ensure an understanding of the reimbursement review procedures:

* [Procedures for Reimbursement Reviews](https://cadth.ca/sites/default/files/Drug_Review_Process/Drug_Reimbursement_Review_Procedures.pdf)
* Pharmaceutical Review Updates for any applicable information.

Studies to include in each section of the table:

Contact CDA-AMC for guidance if the drug for the indication(s) to be reviewed, or a component active ingredient, has been available for more than 10 years in Canada or internationally.

Studies are to be listed in the table irrespective of their publication status (i.e., both published and unpublished studies must be listed).

The table of studies must be divided into the following four sections:

|  |
| --- |
| **List of all pivotal for the indication(s) to be reviewed by CDA-AMC** |
| * All pivotal studies for the indication(s) to be reviewed.
 |
| **List of additional completedRCTs for the indication(s) to be reviewed by CDA-AMC:** |
| * Any additional interventional phase 2, 3 or phase 4 studies.
* Any institution- or investigator-initiated randomized controlled trials (i.e., clinical trials not initiated by a commercial sponsor).
 |
| **List of completed non-randomized studies for the indication(s) to be reviewed CDA-AMC:** |
| * All non-randomized studies for the indication(s) to be reviewed.
* All extension phase studies for the indication(s) to be reviewed.
 |
| **List of all ongoing studies for the indication(s) to be reviewed by CDA-AMC:** |
| * All ongoing randomized controlled trials for the indication(s) to be reviewed.
* All ongoing non-randomized studies for the indication(s) to be reviewed.
* All ongoing extension phase studies for the indication(s) to be reviewed.
 |

Completing the table:

**Study ID(s)**

* Provide the combination of numbers and/or letters used to identify the study.
* If the study has multiple identifiers, please list the most commonly used one first.

**Sponsor**

* Please provide the complete name of the study sponsor.

**Description**

* Provide the title of the study.
* Using the sub-headings provided in the template, briefly describe the study design (e.g., duration, randomized, blinded, etc.), number of patients, intervention and comparators, key outcomes, and the patient population.

*Phase*

* Indicate if study is in phase 2, 3, or 4 (do not include phase 1 studies in the table unless they are considered pivotal).

*Analyses*

* In the ‘Provided to CDA-AMC’ column please indicate one of the following options:
	+ **Included**
	+ **Not included**
	+ **Forthcoming** (add date it will be provided to CDA-AMC)
* In the ‘Location in Application’ column please indicate the primary location within the application where the study is reported. This does not need to be comprehensive list of all locations, please refer to the primary documents only (e.g., Clinical Study Report, Clarifax, publication).

**Abstracts, Publications and Errata**

* Using the JAMA Oncology format, provide complete citations for all abstracts and publications for each listed study.

All abbreviations used in the table are to be listed in alphabetical order below the table.

When the template is complete, please delete the cover pages with the instructions (including the CDA-AMC document header). Please feel free to add company-specific elements such as a cover page, disclaimer, header, footer, etc. as required.

Filing the Completed Template:

Incorporate the completed template into the package of required documents. Please consult the relevant procedural documentation for details on how to file the application.

**Table of Studies for [insert Brand Name of drug]**

|  |  |  |  |
| --- | --- | --- | --- |
| **Study ID(s)** | **Sponsor** | **Description** | **Abstracts, Publications and Errata** |
| 1. **List of all pivotal for the indication(s) to be reviewed by CDA-AMC**
 |
|  |  | **Title:** **Phase:****Study Design:** *Brief description (e.g., double blind, placebo-controlled, multicentre RCT)* **Randomized N:** *Total sample size***Population:** *Brief description***Intervention(s):** *Drug under review, dosage, administration frequency***Comparator(s):** *Comparator(s) dosage, administration frequency***Outcomes:** *Primary and key secondary endpoints***Start:** *MM/YYYY***End:** *MM/YYYY***Analyses:** *List all applicable analyses.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Type** | **Date** | **Provided to CDA-AMC** | **Location in Application** |
| *Interim analysis* | *DD-MM-YYYY* | *Included* *Not included* *Forthcoming (add date it will be provided)* | *Please refer to the primary documents only (e.g., CSR, Clarifax).* |
| *Final analysis* | *DD-MM-YYYY* | *As above* | *As above* |
| *Add rows*  | *As above* | *As above* | *As above* |

 | 1. Citation #1 2. Citation #2 |
| 1. **List of all additional completed RCTs for the indication(s) to be reviewed by CDA-AMC**
 |
|  |  | **Title:** **Phase:****Study Design:** *Brief description (e.g., double blind, placebo-controlled, multicentre RCT)* **Randomized N:** *Total sample size***Population:** *Brief description***Intervention(s):** *Drug under review, dosage, administration frequency***Comparator(s):** *Comparator(s) dosage, administration frequency***Outcomes:** *Primary and key secondary endpoints***Start:** *MM/YYYY***End:** *MM/YYYY***Analyses:** *List all applicable analyses.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Type** | **Date** | **Provided to CDA-AMC** | **Location in Application** |
| *Interim analysis* | *DD-MM-YYYY* | *Included* *Not included* *Forthcoming (add date it will be provided)* | *Please refer to the primary documents only (e.g., CSR, Clarifax).* |
| *Final analysis* | *DD-MM-YYYY* | *As above* | *As above* |
| *Add rows* | *As above* | *As above* | *As above* |

 | 1. Citation #1 2. Citation #2 |
| 1. **List of completed non-randomized studies for the indication(s) to be reviewed by CDA-AMC**
 |
|  |  | **Title:** **Study Design:** *Brief description* **Randomized N:** *Total sample size***Population:** *Brief description***Intervention(s):** *Drug under review, dosage, administration frequency***Comparator(s):** *Comparator(s) dosage, administration frequency***Outcomes:** *Primary and key secondary endpoints* | 1. Citation #1 2. Citation #2 |
| 1. **List of all ongoing studies for the indication[s] to be reviewed by CDA-AMC**
 |
|  |  | Provide a brief description | 1. Citation #1 2. Citation #2 |

**Abbreviations:** (Add to the following alphabetical list of abbreviations used in the table, as appropriate)

**N** = total number of patients; **RCT** = randomized controlled trial.