**Presubmission and Pipeline Meeting Request Form**

**Instructions for Sponsors**

To request a presubmission or pipeline meeting, sponsors are required to complete this template and upload it to the Pharmaceutical Submissions SharePoint site’s “Presubmission Meeting” folder within the “Sponsor Submissions” subfolder.

Please read the instructions below and consult the recommended documentation before completing the template. If you have any questions regarding the submission filing process or requirements, please [contact us](https://www.cda-amc.ca/contact-us) with the complete details of your question(s). Meetings are scheduled on a first-come, first-served basis. Should you be targeting a specific time frame for the meeting, please indicate this on the form and Canada’s Drug Agency (CDA-AMC) will do its best to accommodate.

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.

Completing the Template:

Section 1 must be completed for all meeting requests. Section 2 or 3 must be completed for presubmission and pipeline meetings, respectively. Please delete the section that is not applicable for the sponsor’s request.

When the template is complete, delete this cover page with the instructions (including the CDA-AMC document header). Please feel free to add company-specific elements such as a disclaimer, header, footer, etc. as required. Save the completed template in Microsoft Word format.

Submitting the Template:

Sponsor’s must request access to the Pharmaceutical Submissions SharePoint site a minimum of 10 business days prior to the intended date of submitting the meeting request form, so that your account can be created. Please refer to the [Pharmaceutical Submissions SharePoint Site – Set-Up Guide](https://www.cadth.ca/sites/default/files/Drug_Review_Process/CADTH_SP_Application_Instructions.pdf) for full instructions on requesting access and uploading files. In the event the sponsor has not requested or received access prior to their target date for requesting the meeting, please contact CDA-AMC immediately (support@cda-amc.ca). CDA-AMC will work with the sponsor to ensure that the application is not delayed due to the timeframe for setting up the platform to securely receive the required documents.

Once sponsors have received access to the Pharmaceutical Submissions SharePoint site, the completed meeting request form should be uploaded to the “Presubmission Meeting” folder within the “Sponsor Submissions” subfolder for their assigned project. For pipeline meetings, once given access to the SharePoint site, the meeting request form must be uploaded directly into the assigned folder for the meeting.

**Presubmission Meeting Request Form**

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| **Confidentiality Guidelines** |
| By filing this document with Canada’s Drug Agency (CDA-AMC), the sponsor accepts and agrees to the terms of the *Procedures for Reimbursement Reviews* and its Confidentiality Guidelines and consents to comply with the requirements of the Confidentiality Guidelines, which form an agreement between CDA-AMC and the sponsor. For clarity, the sponsor acknowledges that CDA-AMC may share certain information, including presubmission materials with authorized recipients. |

**SECTION 1: MEETING AND CONTACT INFORMATION**

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| --- | --- |
| **Information Requested** | **Details** |
| **Type of Meeting** | [ ]  Presubmission meeting [ ]  Presubmission meeting (time-limited recommendation)[ ]  Pipeline meeting |
| **Sponsor** | Insert sponsor name |
| **Contact information** | **Primary contact** Name:Title:Email:Phone number: | **Secondary contact** Name:Title:Email:Phone number: |
| **Preferred meeting times**  | * Presubmission meetings are only offered in the timeslots noted in the  [schedule](https://www.cadth.ca/sites/default/files/Drug_Review_Process/CADTH_Drug_Meeting_Dates.pdf) (no exceptions will be made).
* State the preferred dates in the table below. Ensure that each date aligns with one of the available timeslots.
* If you are providing multiple options, please include a ranking for preference.

|  |  |
| --- | --- |
| **Date** | **Rank** |
| *Month-Day-Year* |  |
|  |  |
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**SECTION 2: PRESUBMISSION MEETINGS**

Table 1: Drug Information

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| **Information for a Presubmission Meeting** |
| **Drug name**  | Insert the brand name and the non-proprietary name |
| **Anticipated date of filing with CDA-AMC** | Provide the anticipated date of filing (if known).  |
| **Indication, as per NOC or anticipated NOC** | Provide the exact wording of the indication(s) approved by Health Canada or the anticipated indication(s) as filed with Health Canada, to be reviewed. |
| **Anticipated or actual date of NOC or NOC/c** | Provide the actual or anticipated date for issuance of the NOC or NOC/c.  |

Table 2: Screening Eligibility for Time-Limited Recommendations based on Regulatory Status, Conduct of a Phase III Trial, and Reassessment Commitment

|  |  |
| --- | --- |
| **Eligibility for time-limited recommendations** | **Response** |
| **Regulatory status** |
| The drug has been issued an NOC/c by Health Canada or is undergoing review through Health Canada’s advance consideration process under the NOC/c policy. | [ ]  | Yes |
| [ ]  | No |
| **Evidence generation**  |
| A phase III clinical trial is being planned and/or conducted at the time of the submission to CDA-AMC . | [ ]  | Yes |
| [ ]  | No |
| The phase III trial is being or will be conducted in a patient population that is reflective of the indication being reviewed by CDA-AMC.  | [ ]  | Yes |
| [ ]  | No |
| The phase III trial will be completed within a time frame that will not exceed 3 years from the target expert committee meeting date. | [ ]  | Yes |
| [ ]  | No |
| [ ]  | N/Aa |
| Target expert committee meeting dateb | Month day, year |
| **Commitment to file for reassessment (choose 1 of the following options)*****Note: only complete if answered ‘Yes’ to the regulatory status and evidence questions above*** |
| Sponsor is **willing to commit** to file a reassessment application with CDA-AMC in accordance with the time frames specified in the procedures for time-limited recommendations.  | [ ]  | Yes |
| Sponsor **will not commit** to filing a reassessment application with CDA-AMC in accordance with the time frames specified in the procedures for time-limited recommendations. The sponsor acknowledges that the CDA-AMC expert committee will be informed of the sponsor’s decision and that a time-limited recommendation will not be an option for the drug under review.  | [ ]  | Yes |

NA = not applicable; NOC/c = Notice of Compliance with Conditions

a Please check N/A if the sponsor does not have a relevant phase III trial planned or ongoing for the indication of interest to the CDA-AMC submission.

b Please refer to the [*Expert Committee Meeting Schedule*](https://www.cadth.ca/sites/default/files/Drug_Review_Process/CADTH_Drug_Expert_Committee_Schedule.pdf).

Table 3: Screening Eligibility for Time-Limited Recommendations Based on Details of the Evidence Generation Plans

*Note: only complete if answered ‘Yes’ to the regulatory status and evidence questions above*

|  |  |
| --- | --- |
| **Evidence Generation Plans** | **Response** |
| Summary of key evidentiary gap(s) and how it will be addressed through evidence generation  | Clearly identify the gaps and/or limitations with the preliminary evidence that will be submitted to CDA-AMC and briefly state how the forthcoming phase III trial will address the issues.  |
| **Confirmed or Anticipated Post-Market Study Requirements** |
| **Population** | Please state the patient populations where additional phase III evidence will be generated.  |
| **Intervention** | Please state the intervention(s) that will be studied in the phase 3 trial, including all relevant background therapies, dosage strength(s), frequency of administration.  |
| **Comparator(s)** | Please identify the comparator(s) that will be used in the phase 3 trial, including dosage strength and frequency of administration. |
| **Outcome(s)** | Please identify the outcomes that may be included to address the confirmed or anticipated regulatory conditions (e.g., as stated within the qualifying notice issued by Health Canada).Please include additional primary, secondary, or exploratory endpoints that are or will be investigated in the pending phase 3 trial.CDA-AMC acknowledges that sponsors may not have all this information at the time of completing this form, particularly for files that will be filed prior to regulatory approval by Health Canada. Please provide as much detail as possible to help inform initial discussions regarding eligibility for consideration to receive a time-limited recommendation.  |
| **Timing (required follow-up)** | Please state the required follow-up to address the conditional market authorization issued by Health Canada (please focus on the relevant phase III trial).  |
| **Study design** | Please briefly state the design of the phase III trial.  |
| **Study protocol**  | If available, please provide a link to the study protocol (or indicate that it is not currently published). If a protocol is currently unavailable, please note this within this section. |
| **Clinicaltrials.gov** | Please provide the clinicaltrials.gov identification number (or indicate that it is not currently available). |
| **Target dates for Phase III Study*****If dates are uncertain, please estimate to inform initial discussions regarding eligibility for consideration to receive a time-limited recommendation.***  |
| **Start a** | Month day, year |
| **Primary completion b** | Month day, year |
| **Study completion c** | Month day, year |
| **Clinical Study Report completion d** | Month day, year |
| **Filing SNDS-c with Health Canada (if known)** | Day, Month, Year (or state if unknown) |

SNDS-c: Supplement to a New Drug Submission - Confirmatory

a Estimated date on which the clinical trial will be open for patient recruitment or the actual date on which the first patient was enrolled.

b Date that the final study participant was examined or received an intervention for the purpose of the final collection of data for the primary outcome.

c Date that the final study participant was examined or received an intervention for the purpose of the final collection of data for the primary and secondary outcome measures and adverse events.

d Estimate of the time required to finalize the Clinical Study Report after the study has been completed (CDA-AMC appreciates this information may not be known. Please provide an estimate based on prior experience).

**SECTION 3: PIPELINE MEETINGS**

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| **Information for a Pipeline Meeting** |
| **Date of most recent CDA-AMC pipeline meeting** | Add date for the most recent pipeline discussion between CDA-AMC and the sponsor |
| **Approximate volume of submissions to be discussed** | Please state the estimated number of submissions that would be discussed at the pipeline meeting |
| **Therapeutic area(s)** | Please indicate if the pipeline meeting would focus on the complete pipeline or on a specific therapeutic area (e.g., cancer or non-cancer).  |