

# A Cross-sectional Assessment of the Relative Timing of CDA and INESSS Sponsor-submitted Reimbursement Reviews and pCPA Engagement

Sydney Whitney<sup>1</sup>; Nathashi Jayawardena<sup>1</sup>; Aidan Dineen<sup>1</sup> · <sup>1</sup>EVERSANA, Value & Evidence Services, Burlington, Ontario, Canada

## Background

- There is growing expectation from stakeholders that promising therapies will be promptly available to Canadians.
- There are two health technology assessment (HTA) bodies in Canada that provide recommendations as to whether new drugs should be funded throughout Canada: Canada's Drug Agency (CDA-AMC) and institut national d'excellence en santé et en services sociaux (INESSS).
- Manufacturers are encouraged to submit requests for evaluation to CDA-AMC and INESSS at the same time to reduce access delays, particularly for negotiations conducted jointly by the provinces, such as those conducted by the pan-Canadian Pharmaceutical Alliance (pCPA).
- However, it remains unclear how many requests for evaluation are promptly submitted to both CDA-AMC and INESSS, and how the relative timing of submission to each HTA body may affect subsequent pCPA engagement timing.

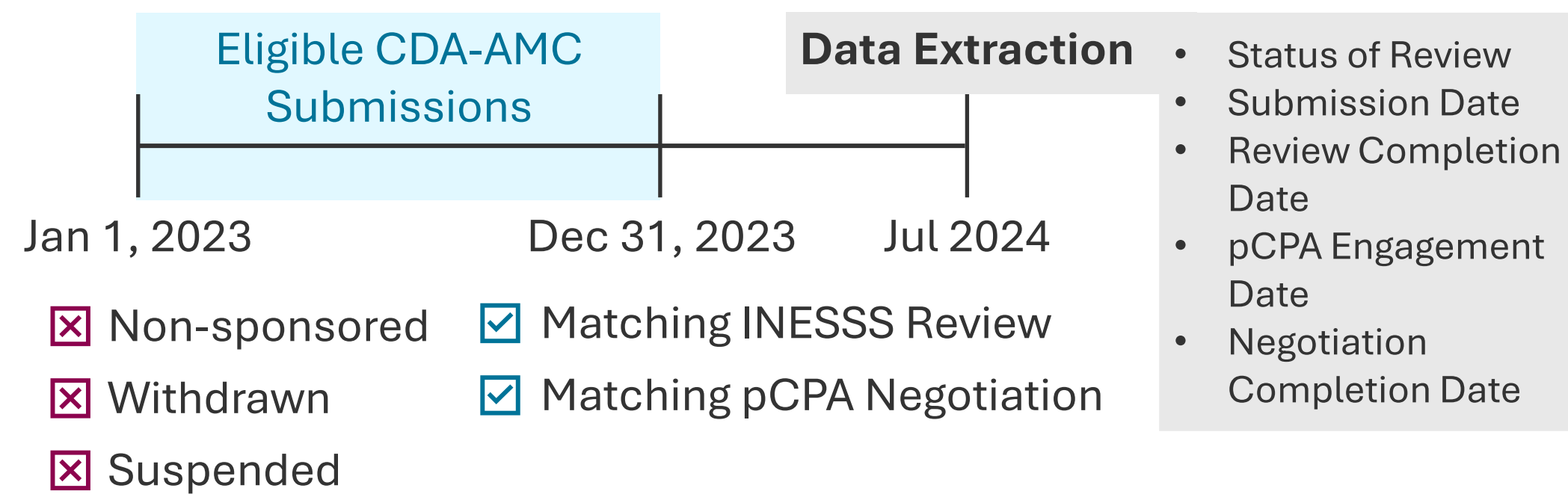
## Objective

- To understand the relative timing of sponsor-submitted reimbursement reviews by CDA-AMC and INESSS, and pCPA engagement timing.

## Methods

- A targeted search of the CDA-AMC website in July 2024 identified all 2023 reimbursement submissions. Matched INESSS and pCPA records were identified.

Figure 1: Overview of study design and methodology

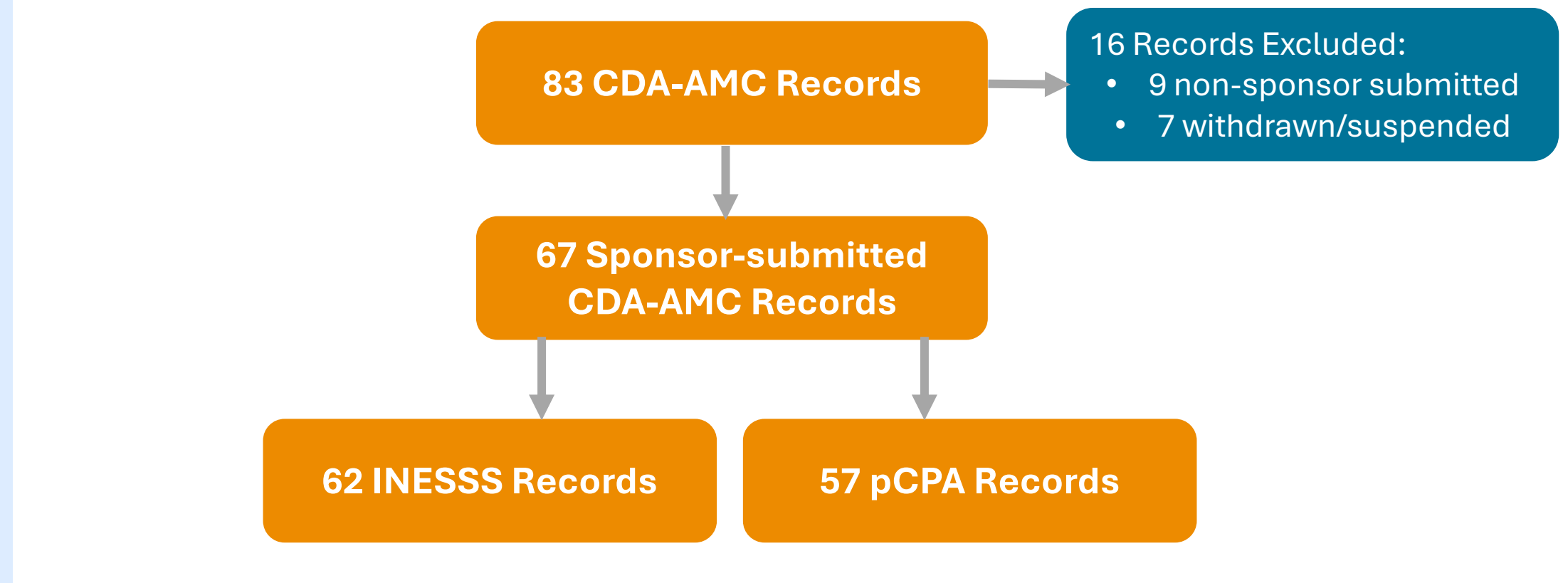


- The specific date of submission for INESSS reviews is not publicly available, and therefore could not be examined in this analysis.
- CDA-AMC and INESSS reviews were considered complete if a final recommendation was issued, with the completion date recorded as the final recommendation date.

## Results

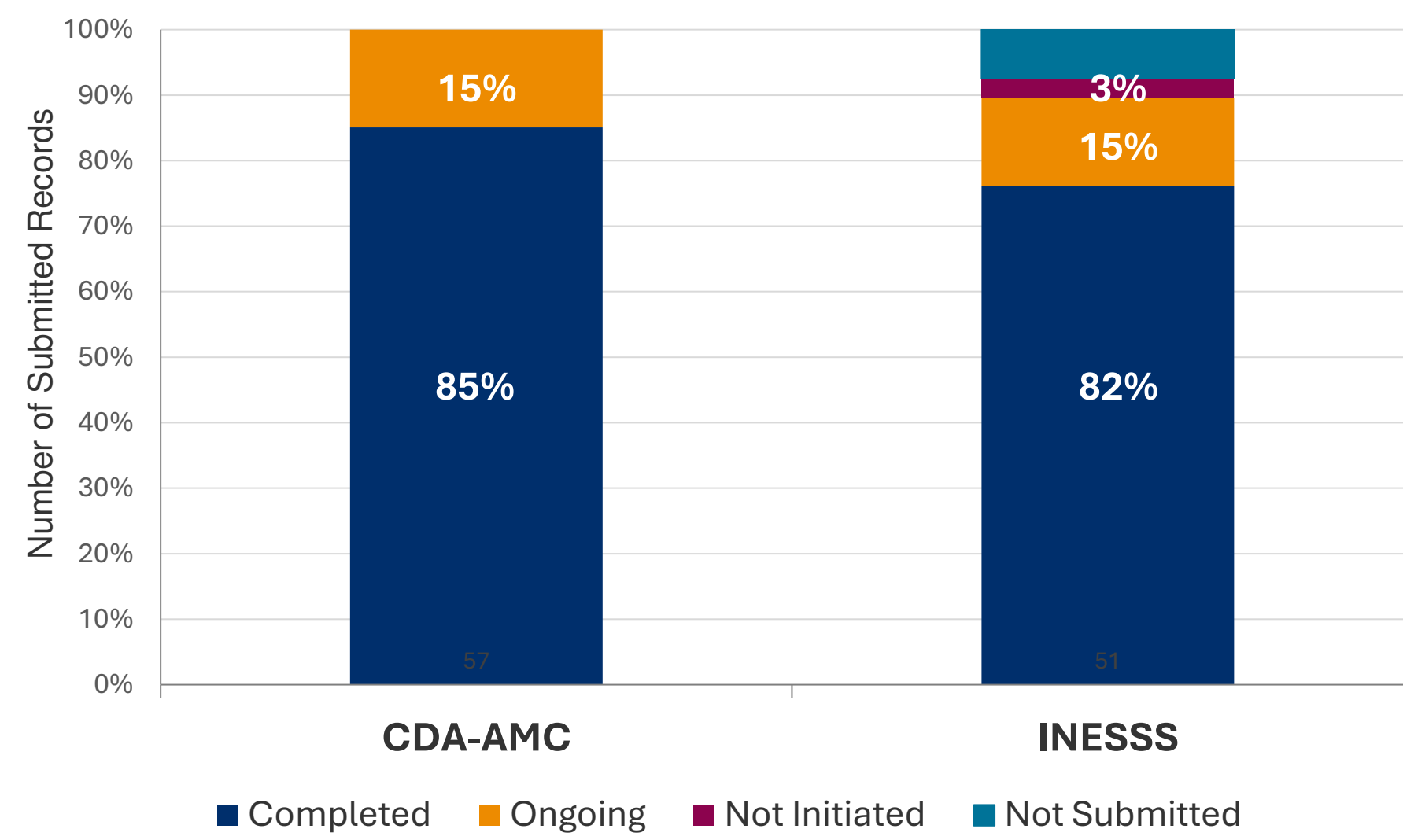
- 83 submissions to CDA-AMC were identified; 16 were excluded, resulting in 67 included CDA-AMC submissions.
- A total of 62 and 57 matching INESSS submissions and pCPA negotiations were identified, respectively (Figure 2).

Figure 2: Overview of CDA Submissions with Matching INESSS and pCPA Records



- Comparing CDA-AMC and INESSS, 67 (100%) vs. 60 (97%) reviews were initiated and 57 (85%) vs. 51 (82%) were completed as of July 5, 2024, respectively (Figure 3). Of the 67 total records submitted to CDA-AMC, 76% were completed by INESSS.
- Of the 42 reviews that were completed by both CDA-AMC and INESSS, 16 (38%) were completed by CDA-AMC first and 26 (62%) were completed by INESSS first.
- Two months or less separated the CDA-AMC and INESSS review completion timing for 34 (79%) of the 43 overlapping reviews.

Figure 3: CDA-AMC and INESSS Submitted Submissions Initiated vs. Completed



- Of the 57 matching pCPA records, 36 (63%) were under consideration for negotiation, 9 (16%) had signed letters of intent (LOIs), and 12 (21%) were in active negotiations (Figure 4).
- A range of 0 to about 6 months elapsed between CDA-AMC and INESSS review completion and a pCPA engagement letter.
- Of records with a signed LOI, pCPA engagement came, on average, 1.3 months before CDA-AMC review completion (Table 1).
  - The 16% of CDA-AMC submissions in 2023 that had a signed LOI by July 2024 represent outlier cases, of which several had pCPA engagement before HTA review completion.
  - Records still under consideration for negotiation had an average of three months without engagement after CDA-AMC review completion, as of July 2024.

Figure 4: Status of pCPA Records

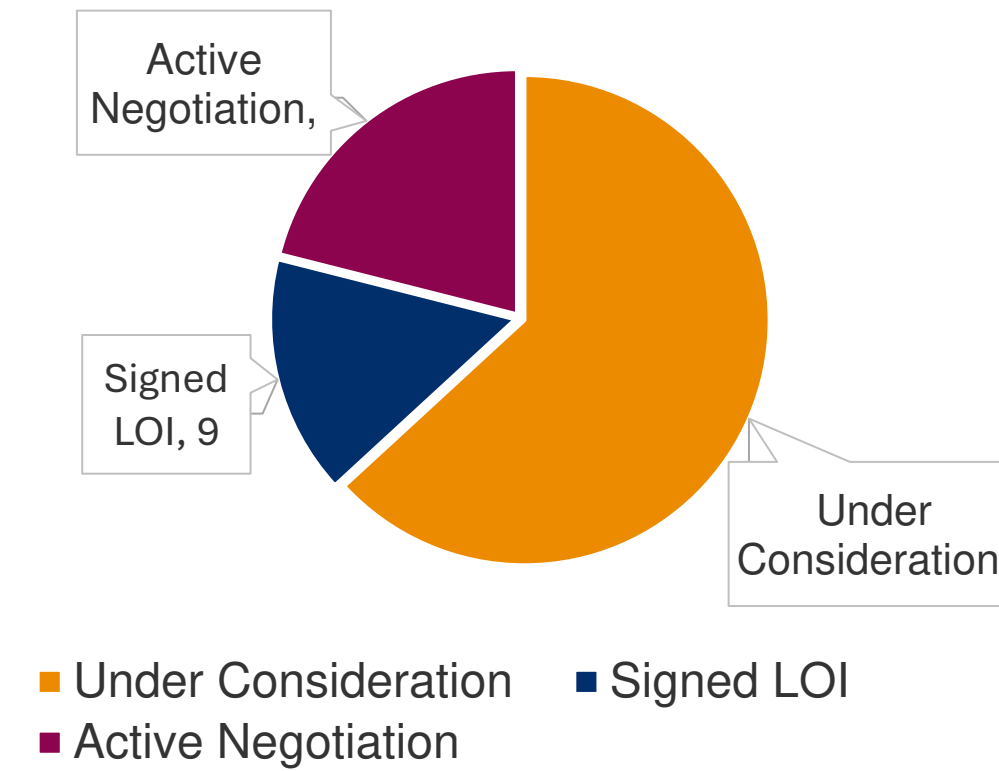


Table 1: Average timing of CDA-AMC Review vs. pCPA Negotiation

pCPA Record Status	Submission to Completion	Completion to pCPA Engagement	pCPA Engagement to LOI	Total
Signed LOI (n=9)	8.1 months	-1.3 months	2.8 months	9.6 months
Active Negotiation (n=12)	7.6 months	2.7 months	N/A	10+ months
Under Consideration (n=36)	8.0 months	3+ months	N/A	11+ months
Average	8.0 months	1.6 months	2.8 months	12+ months

## Conclusions

- These results demonstrate that five fewer sponsored submissions were made to INESSS than CDA in 2023. As INESSS submission dates are not publicly available, the specific relative timing of CDA-AMC and INESSS submissions is unclear.
  - Potential explanations for fewer reimbursement submissions to INESSS than CDA-AMC include: (1) no intention to submit to INESSS; (2) delayed submission to INESSS; or (3) CDA-AMC records reflect resubmissions that were previously given a positive recommendation by INESSS.
  - INESSS may initiate reviews later than CDA-AMC but completion timepoints were similar for reviews submitted in 2023.
- The time between HTA submission and a signed LOI is lengthy. Of the 57 HTA submissions in 2023 with matching pCPA records, 63% were still awaiting negotiation engagement, as of July 2024.

**Abbreviations** CDA-AMC = Canada's Drug Agency; HTA = health technology assessment; INESSS = institut national d'excellence en santé et en services sociaux; LOI = letter of intent; N/A = not applicable; pCPA = pan-Canadian Pharmaceutical Alliance.

**References** 1. Canada's Drug Agency. <https://www.cda-amc.ca> (Accessed July 2024). 2. Institut National d'Excellence en Santé et en Services Sociaux. <https://www.inesss.qc.ca> (Accessed July 2024). 3. pan-Canadian Pharmaceutical Alliance. <https://www.pcpacanada.ca> (Accessed July 2024).

**Contact Information**

**Aidan Dineen**  
E-mail: aidan.dineen@eversana.com

**Sydney Whitney**  
E-mail: sydney.whitney@eversana.com

3228 South Service Road, Suite 113, Burlington, Ontario, Canada L7N 3H8  
[www.eversana.com](http://www.eversana.com)

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