Canadian Network for Observational Drug Effect Studies (CNODES)
Publications Policy
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1. Preamble

Proper acknowledgment and attribution of authorship are important at all stages of preparing, presenting, and publishing the scientific output from CNODES. All CNODES products must include all individuals who contributed intellectually to the work. This document provides exact language for acknowledgement in CNODES products, including abstracts, slide presentations, working papers, technical reports, and scientific manuscripts.

There are various types of CNODES products. The most common types are: 1) those prepared by a CNODES Projects Team in response to a Drug Safety and Effectiveness Network (DSEN) query; and 2) publications on specific issues of more limited focus by a subgroup of authors (e.g., methods papers, secondary papers stemming from projects conducted in response to a DSEN query, literature reviews, commentaries, working papers, technical reports, etc.). In the following sections, we describe the authorship and acknowledgement policies as well as the processes for internal review for these two types of manuscripts separately. We also address procedures for abstracts, slide presentations, and poster presentations.

All documents produced within CNODES or acknowledging CNODES must be approved by the CNODES Publications Committee.

2. CNODES Products in Response to a DSEN Query

For each project (DSEN query), there is one nominated researcher from each of the participating sites called the Site Liaison, who oversees the contribution of its site and is the designated contact person for that site. Moreover, the Project Team includes one nominated methodologist from the CNODES Methods Team, called the Methods Lead, who provides methodological support on each project. As needed, a substantive area expert and/or a Steering Committee Liaison may be added to the Project Team. Finally, one analyst is nominated by the Project Lead to serve as the Lead Analyst for the project. Collectively, the Project Team works together under the direction of a Project Lead.

Note: If investigators at a CNODES site are already conducting a study on the same topic as the query, they are permitted to continue to pursue their site-specific study and are permitted to participate in the corresponding CNODES study.

2.1 Authorship Criteria

Authorship of the manuscript reporting the results of a project typically includes the Project Lead, who usually becomes the lead author, all liaisons (Methods, Site, Steering Committee), Content Area Expert, and the Lead Analyst. A liaison may suggest an
alternative author from their site with written agreement from the liaison and the site’s Principal Investigator.

The Project Lead suggests the order of authors when seeking approval from the Publications Committee. All authors must meet the following 3 requirements for authorship as made explicit by the International Committee of Medical Journal Editors (ICMJE):

1) Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data;
2) Drafting the manuscript or revising it critically for important intellectual content; and
3) Final approval of the version to be published.

Final approval of authorship is made by the CNODES Publications Committee.

2.2 Attribution and Acknowledgement Policies
The list of authors ends with “for the Canadian Network for Observational Drug Effect Studies (CNODES) Investigators*”.

The following statement appears immediately after the title page of all scientific manuscripts written in response to a DSEN Query: “*The Canadian Network for Observational Drug Effect Studies (CNODES) Investigators are: Samy Suissa (Principal Investigator); Colin R. Dormuth (British Columbia); Brenda R. Hemmelgarn (Alberta); Gary F. Teare (Saskatchewan); Patricia Caetano and Dan Chateau (Manitoba); David A. Henry and J. Michael Paterson (Ontario); Jacques LeLorier (Québec); Adrian R. Levy (Atlantic [Nova Scotia, Newfoundland and Labrador, New Brunswick, Prince Edward Island]); Pierre Ernst and Kristian B. Filion (UK Clinical Practice Research Datalink (CPRD); Robert W. Platt (Methods); and Ingrid S. Sketris (Knowledge Translation). CNODES, a collaborating centre of the Drug Safety and Effectiveness Network (DSEN), is funded by the Canadian Institutes of Health Research (Grant Number DSE-146021).”

The following statement appears in the acknowledgements section of all scientific manuscripts written in response to a DSEN Query (with the list of provinces modified depending on which data are presented in the manuscript): “This study was made possible through data sharing agreements between CNODES member research centres and the respective provincial governments of Alberta, British Columbia, Manitoba (HIPC # XXX), Nova Scotia, Ontario, Quebec, and Saskatchewan. The opinions, results, and conclusions reported in this paper are those of the authors. No endorsement by the provinces is intended or should be inferred.”

The acknowledgements section also includes the names of contributing analysts from all sites as well as the sentence “We would like to acknowledge the important
contributions of the CNODES collaborators and assistants at each site”. Others may be acknowledged at the discretion of the Project Lead.

2.2.1 Additional Site-Specific Requirements:
Studies using data from Manitoba must also include the study specific HIPC number.

Studies using CPRD data must include the ISAC approval number as well as the following sentence: “This study was approved by the Independent Scientific Advisory Committee (ISAC; protocol number XXX) of the CPRD; the approved protocol was made available to journal reviewers.” This should appear either in Methods or following the data sharing agreement statement (listed above).

Studies using British Columbia data must include the following statement: “The BC Ministry of Health and the BC Vital Statistics Agency approved access to and use of BC data facilitated by Population Data BC for this study.” In addition, the data sources must be cited in all publications (e.g., articles, journals, theses, and dissertations) as follows:


This should be listed following the data sharing agreement statement.

Studies using Ontario CIHI data (e.g., DAD, NACRS, etc.) must include the following statement “Parts of this material are based on data and information compiled and provided by the Canadian Institute for Health Information (CIHI). However, the analyses, conclusions, opinions, and statements expressed herein are those of the author, and not
necessarily those of CIHI.” This should be listed following the data sharing agreement statement.

**2.3 Processes for Internal Review**

I. A project manuscript is drafted by the Project Lead (or designate) with a Project Writing Team and reviewed by Project Liaisons. This iterative process is repeated as many times as needed until consensus is reached. Please refer to the Project Guide for a description of the roles and responsibilities of each.

II. The manuscript is submitted to the CNODES Coordinating Centre, where it undergoes an initial review to ensure adherence to the CNODES Publications policy.

III. The manuscript is then submitted to the Publications Committee via the CNODES Coordinating Centre for approval and returned to the Project Lead within 14 days.

IV. If approved by the Publications Committee with substantial revisions, the manuscript is recirculated to co-authors for yes/no approval. If changes are minor, the manuscript is submitted simultaneously to:
   a. Co-authors by the Project Lead;
   b. The Steering Committee by the Coordinating Centre. The Site Leads are then responsible to send the submitted manuscript to the provincial ministries and database guardians (as applicable), which require a review period of up to 45 days prior to submission to a journal or public release. Please refer to Appendix 1 for the approval requirements for each site.

Note: Prior to submission of the manuscript to a scientific journal, a final report must have been provided to the query submitter. Please refer to the CNODES Project Guide.

V. Once approval has been granted by provincial ministries whose approval is required prior to submission, the Project Lead then submits to a scientific journal for publication.

VI. After addressing journal editor and reviewers’ comments, a revised draft of the manuscript is sent to the listed authors for their review. No reply within 72 hours is considered approval. Any co-authors who do not approve the revision must immediately inform the lead author and Publications Committee as to the reason(s). The lead author, in consultation with the Publications Committee, decides if and how the publication will be revised. Any co-author may withdraw their name if they are unsatisfied with the final version.
VII. Following co-author review, the revised manuscript is sent to the Publications Committee for their review and approval. If the Publications Committee makes substantial changes to the manuscript at this stage, it is re-circulated to the co-authors for their yes/no approval. No reply within 72 hours is considered approval.

VIII. Once final approval is granted, the manuscript is resubmitted to the journal by the lead author. At this time, it is also circulated to co-authors and the Coordinating Centre for their records.

IX. Once final acceptance is provided by the journal, the manuscript is circulated simultaneously to:
   a. Co-authors and the Coordinating Centre by the lead author;
   b. The Steering Committee by the Coordinating Centre (it is the responsibility of the Site Leads to forward to data custodians as needed);
   c. DSEN by the Coordinating Centre.

X. Once published, the published version of the manuscript or hyperlink to an open source publication is circulated to DSEN by the Coordinating Centre (Appendix 2).

3. CNODES Products by a Subgroup of Authors

CNODES products that fall under this category include publications on specific issues of more limited focus, such as methods papers, secondary papers stemming from projects conducted in response to a DSEN query, literature reviews, commentaries, working papers, technical reports, etc. Student projects conducted using data obtained via CNODES as well as manuscripts acknowledging CNODES support (either for the project or individual authors) are also covered by this category.

3.1 Manuscript Proposal

Prior to beginning a CNODES project being conducted by a subgroup of authors (i.e., not the primary response to a DSEN query), a manuscript proposal is drafted by the lead of the subgroup. This proposal, for which a 2-page form is available on the CNODES website here, includes the following sections:

I. Proposed Lead Author
II. Proposed Co-Authors
III. Background
IV. Methods
V. Proposed Data Source
VI. Proposed Timeline
The manuscript proposal is submitted to the Publications Committee via the CNODES Coordinating Centre for approval and returned to the lead author within 14 days. All approved manuscript proposals are archived by the Coordinating Centre. At the time of manuscript proposal submission, all authors must also submit completed conflict of interest forms related to the proposed study. Please refer to the CNODES Conflict of Interest Policy for further detail.

Note: It is essential that all projects conducted by a subgroup of authors submit a manuscript proposal and obtain approval prior to the start of the project to ensure that it falls within CNODES’ mandate.

3.2 Authorship Criteria

The lead author of a CNODES product produced by a subgroup of authors suggests the order of authors when seeking approval from the Publications Committee. All authors must meet the requirements for authorship as made explicit by the ICMJE (stated in section 2.1). Please note that analysts who contribute substantially to such projects are eligible for authorship.

Final approval of authorship is made by the CNODES Publications Committee.

3.3 Attribution and Acknowledgement Policies

I. When acknowledging CNODES, the following text must appear on all scientific manuscripts by subgroups of authors: “The Canadian Network for Observational Drug Effect Studies (CNODES), a collaborating centre of the Drug Safety and Effectiveness Network (DSEN), is funded by the Canadian Institutes of Health Research (Grant Number DSE-146021).”

II. CNODES support for manuscripts by subgroups can take many forms; it is left to the authors’ discretion to describe the support as accurately as possible. Some suggested descriptions are provided below, which can be combined for the sake of brevity as needed.

a. This study was financially supported by ...
b. This study was financially supported in part by ...
c. This study used data from ...
d. This study was based on a protocol of ...
e. This study was made possible by ...
f. Resources and support were provided by ...
g. In cases where an individual also receives financial support from CNODES, add the following “Dr. (insert name) received financial support from ...”
III. If administrative data are presented in the paper, corresponding data sharing agreements must be acknowledged (with the list of provinces modified depending on which data are presented in the manuscript). The suggested acknowledgment is: “This study was made possible through data sharing agreements between CNODES and the respective provincial governments of Alberta, British Columbia, Manitoba (HIPC # XXX), Nova Scotia, Ontario, Quebec, and Saskatchewan. The opinions, results, and conclusions reported in this paper are those of the authors. No endorsement by the provinces is intended or should be inferred.”

IV. The acknowledgements also include the names of individuals who contribute to the project but do not meet the authorship criteria.

V. For papers that are secondary papers that result from answering a query, the following sentence also appears “We would like to also thank the CNODES investigators and collaborators for their contribution to developing the study protocol evaluated in this paper”.

VI. Please refer to section 2.2.1 for additional site-specific requirements.

3.4 Processes for Internal Review

I. A manuscript is drafted by the lead author with assistance from co-authors.

II. The manuscript is submitted to the CNODES Coordinating Centre, where it undergoes an initial review to ensure adherence to the CNODES Publications policy.

III. The manuscript is then submitted to the Publications Committee via the CNODES Coordinating Centre for approval and returned to the lead author within 14 days.

IV. If approved by the Publications Committee with substantial revisions, the manuscript is recirculated to co-authors for yes/no approval. If changes are minor, the final manuscript is submitted by the lead author simultaneously to:
   a. Co-authors;
   b. The Coordinating Centre;
   c. If the manuscript involves the use of original data, approval from data custodians must be obtained at each participating site. If the manuscript does not involve the use of original data (e.g., simulation study, editorial, etc.), the manuscript does not need approval from data custodians. However, it is still sent to the Site Leads for record keeping purposes. If approval is required, the Site Leads whose sites contributed original data are then responsible to send the submitted
manuscript to the provincial ministries and database guardians (as applicable), which require review 45 days prior to submission to a journal or public release.

V. Once approval has been granted by provincial ministries whose approval is required prior to submission, the lead author then submits to a scientific journal for publication.

Note: Please refer to Appendix 1 for the approval requirements for each site.

Note: If the secondary paper is related to a query response, and the primary paper has not yet been published, the lead author must discuss timelines for this paper’s submission with the Publications Committee. Depending on the status of the primary paper (e.g., submitted, resubmitted, in press) and the content of the secondary paper, the Publications Committee may require that submission be delayed until the primary paper is in press or published.

VI. After addressing journal editor and reviewers’ comments, a revised draft of the manuscript is sent by the lead author to the listed authors for review. Any co-authors who do not approve the revision must immediately inform the lead author and Publications Committee as to the reason(s). The lead author, in consultation with the Publications Committee, decides if and how the publication will be revised. Any co-author may withdraw their name if they are unsatisfied with the final version.

VII. Following co-author review, the revised manuscript is sent to the CNODES Coordinating Centre. If the Publications Committee makes substantial changes to the manuscript at this stage, it is re-circulated to the co-authors for their yes/no approval. No reply within 72 hours is considered approval.

VIII. Once final approval is granted, the manuscript is resubmitted to the journal by the lead author. At this time, it is also circulated to co-authors and Coordinating Centre for their records.

IX. Once final acceptance is provided by the journal, the manuscript is circulated simultaneously to co-authors and the Coordinating Centre by the lead author. It is the responsibility of the Site Leads to forward to data custodians as needed.

X. Once published, the manuscript is circulated to DSEN by the Coordinating Centre.
4. Abstracts

4.1 Authorship Criteria

The Lead of any CNODES project is typically the individual who submits abstracts related to the project. Other members of the project team may do so provided they have obtained the prior approval of the Project Lead. Given the various embargo rules of conferences and journals, the Project Lead decides the most appropriate course for abstract submission, including both the conference and presenter.

Note: If the majority of the abstract is the same abstract used in the publication, the order of authors must remain the same, regardless of who is the abstract submitter/presenter.

Abstracts typically fall into one of the following three categories:

1. Abstracts of CNODES projects responding to DSEN queries;
2. Abstracts of other CNODES projects by a subgroup of authors. CNODES products that fall under this category include publications on specific issues of more limited focus, such as methods papers, secondary papers stemming from projects conducted in response to a DSEN query, literature reviews, commentaries, working papers, technical reports, etc. Student projects conducted using data obtained via CNODES as well as manuscripts acknowledging CNODES support (either for the project or individual authors) are also covered by this category;
3. Abstracts of symposia, panel discussions, teaching workshops, knowledge translation, and educational activities.

For the first abstract category, the policies regarding named authors stated in section 2 apply. This list of authors includes the project lead and all liaisons and ends with “for the Canadian Network for Observational Drug Effect Studies (CNODES) Investigators”.

For the second abstract category, the named authors should include those in the subgroup and, if the project is a secondary analysis directly related to a project conducted in response to a DSEN query, the Project Lead.

For the third abstract category (i.e., abstracts of symposia, panel discussions, teaching workshops, and educational activities), the named authors should include all presenters. Where possible, Project Liaisons should also be included. However, given the nature of such sessions and the number of presentations included as part of a single abstract, this often is not possible.

4.2 Attribution and Acknowledgement Policies

For all abstracts, the funding source should include the “Canadian Network for Observational Drug Effect Studies, a collaborating centre of the Drug Safety and
Effectiveness Network, funded by the Canadian Institutes of Health Research”. If needed, appropriate acronyms may be used. Other relevant funding may also be listed.

4.3 Processes for Internal Review

The abstract is submitted to the CNODES Coordinating Centre, where it undergoes an initial review to ensure adherence to the CNODES Publications policy.

Note: When submitting to the Coordinating Centre, the lead author must describe the type(s) of CNODES support (either in the abstract or the accompanying email).

The manuscript is then submitted to the Publications Committee via the CNODES Coordinating Centre for approval a minimum of 15 days before the abstract deadline.

The abstract is submitted by the lead author to the Site Leads to obtain approval from data custodians (where necessary) a minimum of 12 days before the abstract deadline. A detailed description of the approval requirements at each site is found in Appendix 1.

A copy of the submitted abstract is provided to the CNODES Coordinating Centre by the lead author. In addition, it is circulated to all co-authors for their records.

It is the responsibility of the lead author to notify the CNODES Coordinating Centre and co-authors of the outcome of the abstract submission. If the abstract is published as part of conference proceedings, the published version is also circulated to the CNODES Coordinating Centre and all co-authors.

5. Slide Presentations

5.1 PowerPoint Template

CNODES has created a PowerPoint template for slide presentations. This template is used for all CNODES-related presentations and includes the following five mandatory slides:
a. Title Slide (must be 1st slide)

b. Project Team Acknowledgement Slide (must be 2nd slide)

Note: For non-DSEN query projects, this slide may be modified to acknowledge the contributions of the relevant subgroup of authors. If the presentation is for a workshop and does not involve the use of project-specific data, this slide may be omitted.
c. Steering Committee Acknowledgment Slide (must be 3rd slide)

**CNODES: FUNDING & INVESTIGATORS**

Canadian Network for Observational Drug Effect Studies (CNODES), a collaborating center of the Drug Safety and Effectiveness Network (DSN), funded by the Canadian Institutes of Health Research (CIHR, Grant #RSC-146021).

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<td>Atlantic (NB, NS, PEI):</td>
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<td>UK CPRD:</td>
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<td>Knowledge Translation:</td>
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<td>Methods:</td>
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Note: If a disclosure slide is required by conference organizers, it should appear after the Steering Committee Acknowledgement Slide. We understand that some organizations may request that the disclosure slide appear earlier. However, some members of the Project Team and/or Steering Committee may have relationships to disclose. Consequently, the members of these groups are introduced before the displaying of the disclosure slide.

d. General Acknowledgement Slide (2nd to last slide)

**ACKNOWLEDGEMENTS**

- This study was made possible through data sharing agreements between CNODES member research centres and the respective provincial governments of Alberta, British Columbia, Manitoba, Nova Scotia, Ontario, Québec and Saskatchewan.

- The opinions, results, and conclusions reported in this paper are those of the authors. No endorsement by the provincial governments is intended or should be inferred.

- Other Acknowledgements:
If desired, a picture slide can be inserted between the general acknowledgement slide and the final slide.

5.2 Processes for Internal Review

There is no internal review process for slide presentations. However, the CNODES Coordinating Centre must be advised ahead of time of all presentations of CNODES-related material.

Furthermore, for presentations involving the use of original data, some sites require approval from data custodians 10 days before presentation. Please refer to Appendix 1 for site-specific details. For these sites, slide decks should be circulated via the CNODES Coordinating Centre to the relevant Site Leads a minimum of 12 days before presentation. If the presentation includes data from British Columbia, a 45-day review period is required. The slide deck should therefore be submitted via the CNODES Coordinating Centre to the relevant Site Leads a minimum of 47 days before presentation.

In addition, final copies of slide presentations should be provided to the Coordinating Centre for record-keeping purposes.

6. Poster Presentations

The following text is to appear in the Acknowledgements section of the poster: “The Canadian Network for Observational Drug Effect Studies (CNODES) is a collaborating centre of the Drug Safety and Effectiveness Network, funded by the Canadian Institutes of Health Research”. In addition, the CNODES logo is to appear on the poster.
There is no internal review process for poster presentations. However, the CNODES Coordinating Centre must be advised ahead of time of all presentations of CNODES-related material.

Furthermore, for poster presentations involving the use of original data, some sites require approval from data custodians 10 days before presentation. Please refer to Appendix 1 for site-specific details. For these sites, posters should be circulated via the CNODES Coordinating Centre to the relevant Site Leads a minimum of 12 days before presentation. If the poster presentation includes data from British Columbia, a 45-day review period is required. The poster should therefore be submitted via the CNODES Coordinating Centre to the relevant Site Leads a minimum of 47 days before presentation.

In addition, electronic copies of final poster presentations should be provided to the Coordinating Centre for record-keeping purposes.
### Appendix 1. Provincial Approval Requirements for Manuscript Submission

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<th>Site</th>
<th>Prior to Submission</th>
<th>Prior to Publication</th>
<th>Other</th>
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| British Columbia| 45 days             | None                 | - Presentation of materials to colleagues: Results must be marked "DRAFT, not for public dissemination" and small cell sizes (<5) must be suppressed.  
- Research materials for public dissemination: Research materials must be vetted with data stewards (through PopData) 45 days in advance of use. This would include presentations (other than to just colleagues), articles, theses/dissertations, lectures, or media interviews. For this purpose, a form is available online: [https://www.popdata.bc.ca/forms/prepublication_review](https://www.popdata.bc.ca/forms/prepublication_review).  
- For manuscript resubmission: If changes are made following data steward vetting, then a revised version must be submitted for their information, but it will not need to go through the review process (i.e., 45 days) again. The exception to this is if new data and/or analysis have been used in the revised publication, in which case, it requires resubmission for pre-publication review.  
- Please note that if comments are not received within 45 days, it could be assumed that they have no comments. |
| Alberta         | 45 days             | None                 | Modifications made in response to reviewers comments do not require resubmission. |
| Saskatchewan    | 30 days             | None                 | For manuscripts, the 30 day requirement is a review period; no approval is required.  
- For every poster or oral presentation where such presentation material will by physically released or distributed, or posted on a website, 10 calendar days prior notice are required. |
| Manitoba        | None                | None                 | For every poster or oral presentation where such presentation material will by physically released or distributed, or posted on a website, 10 calendar days prior notice are required.  
- If there are any changes to the numbers or tables in the manuscript originally submitted to HIPC, it must be re-submitted to HIPC once edited; once the final paper has been published, it must be forwarded to HIPC.  
- Although 30 days are required prior to submission, the manuscript can be submitted to the data custodians at the same time as journal submission. |
| Ontario         | None                | 30 days              | The Ontario site must submit a copy of the accepted manuscript to their ministry. Although 30 days are required for approval, it can still be published a few days ahead of time. In special circumstances |
(e.g.: fast-tracked publication), the manuscript can be submitted to the ministry at the time of journal submission and resubmitted when accepted to expedite the approval process.

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<th>Site</th>
<th>Prior to Submission</th>
<th>Prior to Publication</th>
<th>Other</th>
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<td>CPRD</td>
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<td>• A copy of the published manuscript must be submitted to the CPRD.</td>
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<tr>
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Appendix 2. CNODES Open Access Policy

CNODES will meet (or exceed) CIHR requirements regarding open access publications, which require that the manuscript be freely available within 12 months of publication (http://www.cihr-irsc.gc.ca/e/32005.html).

For all CNODES publications written directly in response to a DSEN query and where immediate open access publication is possible, it is CNODES policy to cover the costs of open access publication.

For CNODES publications not written directly in response to a DSEN query (e.g., secondary papers, methods papers) and those published in journals that do not allow immediate open access publication, it is CNODES policy to deposit the manuscript in an open-access repository, such as PubMed Central Canada (http://pubmedcentralcanada.ca/pmcc/). It is the responsibility of the Lead Author (with assistance from the Research Coordinator) to deposit the manuscript such that CNODES fulfills the CIHR policy, while respecting the copyright agreement with the publishing journal. Authors should consult journal publishers’ policies regarding open access publication.