CaMos

Canadian Multicentre Osteoporosis Study
Étude Canadienne multicentrique sur l'ostéoporose

Analysis and Publications Policy

22th Edition, December 12, 2018

It is in the interest of all involved with the Canadian Multicentre Osteoporosis Study (CaMos) that data generated by the study be published in respected peer reviewed journals as expeditiously as possible. The following policy has been implemented to assist in this process.

Project identification

Any CaMos project, if approved, will involve only the release of data specific to the analysis proposed and the filing of the agreement concerning release of CaMos data.

Centre-specific analyses may be conducted as and when a Centre Director or Co-Director chooses, but notification to the Design, Analysis and Publications (DAP) Committee must precede starting the analysis.

Non-CaMos investigators and Industry Partners may be included in any analysis projects (CaMos-wide or Centre-specific) as long as a CaMos investigator is involved as a co-investigator on the analysis, and serves as a liaison to CaMos.

An analytic database will track all analyses conducted and planned using CaMos data, and will include information on investigators leading the analysis, time lines for completion, and dissemination of results.

Project review

1. The research proposal needs to be prepared according to a defined format and submitted electronically to Dr. Suzanne Morin (suzanne.morin@mcgill.ca) who will distribute it to the DAP Committee. The format is:

(1-2 pages)	title (clearly describing the project) key words (unique to the project objective) background and rationale objectives
	sample selection (inclusions/exclusions), sample size, and power
(1-3 pages)	list of variables requested description of analysis timeline to complete the project and targeted journal funding source(s)
(1-2 pages)	references

General guidelines for meeting the requirements of DAP's peer review system**:**

- Identify the CaMos responsible applicant first and describe the position, expertise and role in the DAP proposal of each outside investigator named on the project.

- Clearly state who will be performing the statistical analyses.

- Assess the number of individuals available for a particular question and specify that you have the power to do the particular analyses requested *before* submission. Include the specific subsample of participants that you wish to use (identify all variables needed in an Appendix)

- Identify a single principal outcome, variable**s** of interest and covariables/confounders in each proposal.

- Please comply with the required maximum of five pages.

2. All members of the DAP Committee, and other CaMos researchers will receive the proposal and review form. DAP members and other CaMos researchers will send written comments to the committee's secretary within 4 weeks. The committee will meet on a monthly basis or as needed to review the project proposal(s).

3. The DAP Committee will review the proposal for:

   scientific justification for the objectives
   methodological soundness
   impact on CaMos (including workload imposed on the Analysis Centre and overlap with CaMos' own analysis planning)
   dissemination plan (including conference and journal submissions)

4. The proposal may be approved, approved with requirement for revision, or not approved.

5. Following approval, the authors of the proposal will be notified of the release of data, and will sign an agreement, stating that they will only use the data for the purpose described, will follow the timeline specified for the analysis, and will destroy the data files by (date). No data will be released until a copy of the approval certificate, from the Research Ethics Board (REB) or Institutional Review Board (IRB), is submitted to the CaMos Coordinating Office.

6. If the analysis has not been completed one year after the date specified in the timeline, then the investigators will relinquish "rights" to that analysis and must destroy the data.

7. Once a proposed analysis is approved, the process for vetting abstracts and manuscripts will focus on information-sharing with the DAP and the Centre Directors, rather than a scientific review of the material.

8. Once the project manuscript is approved for publication, the lead investigator will record the study title and authors, objective(s), methodology, results, conclusions and manuscript citations on the CaMos slide templates and submit the project slides to the CaMos Coordinating office.

Publication

The following criteria of authorship have been developed by the International Committee of Medical Journal Editors and are to be applied to CaMos publications.

> "Each author should have participated sufficiently in the work to take public responsibility for the content. Authorship credit should be based only on substantial contributions to:
>
> a) conception and design, or analysis and interpretation of data;
> b) drafting the article or revising it critically for important intellectual content;
> c) final approval of the version to be published.
>
> Conditions a), b), and c) must all be met."

It is recommended that these guidelines be followed, but it is also recognized that any CaMos researcher may make a case for his /her inclusion on a given publication. The first/responsible author shall have the right and responsibility to determine the final author list and order of naming. CaMos investigators, if they err, may consider doing so on the side of inclusion rather than exclusion. In the case of a project designed for credit for an MSc degree or PhD degree only the student and immediate mentors need be included as authors, although other interested investigators may be included if they contribute to the papers arising from the student's research. In any case, all publications will name the "The CaMos Research Group" as last author.

Funding agency acknowledgement for CaMos manuscripts and presentations

The Canadian Multicentre Osteoporosis Study (CaMos) is currently funded by the Canadian Institutes of Health Research (CIHR) and Amgen Canada Inc; CaMos has received support from the Canadian Institutes of Health Research (CIHR); Amgen Canada Inc; Actavis Pharma Inc (previously Warner Chilcott Canada Co); Dairy Farmers of Canada; Eli Lilly Canada Inc: Eli Lilly and Company; GE Lunar; Hologic Inc; Merck Frosst Canada Ltd; Novartis Pharmaceuticals Canada Inc; P&G Pharmaceuticals Canada Inc; Pfizer Canada Inc; Roche (F. Hoffmann-La Roche Ltd); Sanofi-Aventis Canada Inc (previously Aventis Pharma Inc); Servier Canada Inc; and The Arthritis Society.

Agreement Concerning the Release of CaM*os* Data

Project title: _____

I, the undersigned, hereby acknowledge that I will be granted access to CaMos data under the following terms and conditions:

1. **I will not release the data to any other persons and will keep all information strictly confidential.**
2. **I will only use the data in connection with the objectives outlined in my approved research protocol.**
3. **I agree to report any suspected errors or inconsistencies in the data to the CaMos Data Analysis Centre.**
4. **I will pay the Data Access Fees charged by CaMos, no later than 30 days after I receive the data.**
5. **I will note the contribution of the CaMos Research Group and will include an acknowledgement in all reports or publications resulting from my use of the CaMos data, as follows:**

   "The authors wish to acknowledge the CaMos Research Group, for its role in implementing and overseeing the project."

   Funding Agency Acknowledgement For CaMos Manuscripts

   The Canadian Multicentre Osteoporosis Study (CaMos) is currently funded by the Canadian Institutes of Health Research (CIHR); Amgen Canada Inc and has received support from the Canadian Institutes of Health Research (CIHR); Amgen Canada Inc; Actavis Pharma Inc (previously Warner Chilcott Canada Co); Dairy Farmers of Canada; Eli Lilly Canada Inc: Eli Lilly and Company; GE Lunar; Hologic Inc; Merck Frosst Canada Ltd; Novartis Pharmaceuticals Canada Inc; P&G Pharmaceuticals Canada Inc; Pfizer Canada Inc; Roche (F. Hoffmann-La Roche Ltd); Sanofi-Aventis Canada Inc (previously Aventis Pharma Inc); Servier Canada Inc; and The Arthritis Society.
6. **I will submit the final manuscript or report, prior to submission for publication (or presentation in the case of an abstract for a meeting), for review to the CaMos DAP Committee, for their information.**
7. **I will be using the CaMos data at the following location:**

_____

_____ _____

Signature Date (yyyy-mm-dd)

_____ _____

Name (printed) Date by which data will be destroyed (yyyy-mm-dd)

Attach a copy of the REB or IRB approval certificate, for this project.

Appendix A

CaMos Research Group

David Goltzman (co-principal investigator, McGill University), Nancy Kreiger (co-principal investigator, University of Toronto), Alan Tenenhouse (principal investigator emeritus, Toronto).

McGill University, Montreal, Quebec: Elham Rahme (biostatistician), J. Brent Richards (investigator), Suzanne N. Morin (investigator); Data Analysis Centre: Claudie Berger (study statistician)

Memorial University, St. John's Newfoundland: Carol Joyce (director), Christopher S. Kovacs (co-director).

Dalhousie University, Halifax, Nova Scotia: Susan Kirkland, Stephanie M. Kaiser (co-directors).

Laval University, Quebec City, Quebec: Jacques P. Brown (director), Louis Bessette (co-director), *GRMO*.

Queen's University, Kingston, Ontario: Tassos P. Anastassiades (director), Tanveer Towheed (co-director), Wilma M. Hopman (investigator).

University of Toronto, Toronto, Ontario: Angela M. Cheung (director), Robert G. Josse (co-director), Andy Kin On Wong (co-director).

McMaster University, Hamilton, Ontario: Jonathan D. Adachi (director), Alexandra Papaioannou (co-director).

University of Saskatchewan, Saskatoon, Saskatchewan: Wojciech P. Olszynski (director), K. Shawn Davison (co-director).

University of Calgary, Calgary, Alberta: David A. Hanley (director), Steven K. Boyd (co-director).

University of British Columbia, Vancouver, British Columbia: Jerilynn C. Prior (director), Shirin Kalyan (co-director), Brian Lentle (investigator/radiologist), Millan S. Patel (investigator).

University of Alberta, Edmonton, Alberta: Stuart D. Jackson (medical physicist).

University of Manitoba, Winnipeg, Manitoba: William D. Leslie (investigator/nuclear medicine physician).

Funding Agencies

The Canadian Multicentre Osteoporosis Study (CaMos) is currently funded by the Canadian Institutes of Health Research (CIHR); Amgen Canada Inc and has received support from the Canadian Institutes of Health Research (CIHR); Amgen Canada Inc; Actavis Pharma Inc (previously Warner Chilcott Canada Co); Dairy Farmers of Canada; Eli Lilly Canada Inc: Eli Lilly and Company; GE Lunar; Hologic Inc; Merck Frosst Canada Ltd; Novartis Pharmaceuticals Canada Inc; P&G Pharmaceuticals Canada Inc; Pfizer Canada Inc; Roche (F. Hoffmann-La Roche Ltd); Sanofi-Aventis Canada Inc (previously Aventis Pharma Inc); Servier Canada Inc; and The Arthritis Society.