



## *Collaboration for Research Integrity and Transparency*

A PROGRAM OF YALE LAW SCHOOL, YALE SCHOOL OF MEDICINE AND THE YALE SCHOOL OF PUBLIC HEALTH

June 25, 2018

Office of Information Management  
Resource Management and Operations Directorate  
Health Products and Food Branch  
Health Canada  
Graham Spry Building  
250 Lanark Avenue  
Ottawa, Ontario  
K1A 0K9  
**via electronic mail**

**Re: Public Comment on the Health Canada Draft Guidance Document,  
Public Release of Clinical Information, made available on April 10,  
2018**

The Collaboration for Research Integrity and Transparency (CRIT) at Yale University supports and applauds the substantial changes in policy supporting transparency outlined in Health Canada's Draft Guidance Document on Public Release of Clinical Information. The proposed policy change will expand public access to clinical trial information, helping Canadians and their health care providers make more informed health decisions. The initiative will also facilitate independent research that will generate new knowledge regarding the safety and effectiveness of drugs, biologics, and medical devices. The new policies outlined, once implemented, will bring Health Canada's policy closer to the current proactive release policy of the European Medicines Agency (EMA), and in some cases, will result in more transparency than currently provided by the EMA.

In particular, we support Health Canada's mirroring of the modules in the ICH CTD/eCTD and the Clinical Study Report currently designated for proactive disclosure by the EMA. We also support Health Canada's proposed provision of an alternative method for manufacturer submission of documents for release, by permitting the manufacturer to submit "final redacted documents that were previously accepted by the EMA." This is a positive step forward because it will decrease the burdens associated with compliance, while accelerating the release of information.



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Nevertheless, we believe further steps can, and should, be taken to promote the sharing of clinical research data and to enhance open science initiatives. Specifically, we are concerned about the two exceptions contained in the Draft Guidance Document, which permit Health Canada to protect the following clinical information categories from public release based upon justification from the manufacturer:

Clinical information that was not used by the manufacturer in the submission, application or supplement to support the proposed conditions of use for the new drug or the purpose for which the new drug is recommended; or  
Clinical information that describes tests, methods or assays that are used exclusively by the manufacturer. (Draft Guidance, p. 15, l. 432-435)

In our public comment on the Regulations Amending the Food and Drug Regulations (Public Release of Clinical Information) and the Regulations Amending the Medical Devices Regulations (Public Release of Clinical Information), posted in the Canada Gazette on December 9, 2017, we urged Health Canada to substantially limit the exception to the disclosure policy for clinical information not used to “support the proposed conditions of use.” We remain concerned that use of the exception could result in some information related to patient safety being exempt from disclosure. The final Guidance and Regulations should require Health Canada to proactively release all clinical trial data submitted by a sponsor seeking market authorization that pertains to patient safety, not just the data reviewed by Health Canada to grant or deny approval.

In our prior public comment, we urged Health Canada to remove the exception for “tests, methods or assays used exclusively by the manufacturer.” This exemption would be detrimental to public health because it would effectively prohibit independent researchers from obtaining and re-analyzing data. The exemption is broad enough to cover everything from vaccine assays to modified questionnaires to laboratory tests. If submissions for regulatory approval rely on these methodological details, this information should not be kept confidential. For example, if a surrogate marker is used, any unusual modification to the collection or analysis of that surrogate marker should also be released.

We applaud Health Canada’s proposed procedure for publishing clinical information contained in pre-2019 submissions through the web portal after an individual request for the information is received. This new procedure promotes transparency because once a



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request is reviewed and processed and the records are identified, the requested information is published on the “clinical information portal,” enabling others to see it besides the individual requestor. This is a welcome change from the current Health Canada procedure for individual requests of information under Vanessa’s Law, where individuals who receive information pursuant to a request are prohibited from disclosing it to others. Notably, this proactive disclosure after request for pre-implementation submissions is more transparent than the EMA process for responding to requests for information pertaining to submissions prior to the effective date of Policy 0070.

We also applaud Health Canada’s extension of its proactive release policy to medical device submissions for higher-risk devices in Steps 3 and 4 of the implementation schedule. This will put Canada ahead of all other regulatory agencies in transparency of information regarding medical devices. We particularly appreciate that the commencement of proactive disclosure regarding device submissions is anticipated to correspond with Canada’s adoption of the International Medical Device Regulators Forum Table of Contents (IMDRr ToC) submission structure for medical device submissions. This will allow patients, medical providers and researchers worldwide, in addition to those in Canada, to make use of the disclosed information.

While the Draft Guidance Document indicates that Health Canada is considering mechanisms that would allow release of individual patient records on request, a procedure for release of de-identified individual patient records should be developed as soon as possible. EMA Policy 0070 includes a future Phase II which will involve the release of “individual patient data.”

We urge Health Canada to promptly begin a consultation on release of individual patient records contained in submissions and we suggest that the consultation be coordinated with the EMA so that policies and procedures can be similar across agencies.

Again, we applaud the proposed policies outlined in the Draft Guidance Document on Public Release of Clinical Information. However, we urge the agency to adopt the changes we outlined above, to increase the availability and use of clinical research data that has the potential to benefit science and public health.



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Sincerely,

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