



## *Collaboration for Research Integrity and Transparency*

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

May 25, 2017

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

Re: Public Comment on the Health Canada White Paper on the “Public Release of Clinical Information in Drug Submissions and Medical Device Applications”

The Collaboration for Research Integrity and Transparency (CRIT) at Yale University supports and applauds the proposed policies within the White Paper prepared by Health Canada entitled “Public release of clinical information in drug submissions and medical device applications.” 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. While this would be a major step toward greater transparency, we believe that further steps can, and should, be taken when drafting the forthcoming regulations to promote the sharing of clinical research data and to enhance open science initiatives.

1. The final regulation should require Health Canada to proactively release clinical trial information, rather than requiring explicit individual requests. There should be no limitation on who can receive clinical trial information, or how it will be used once it is released, other than to prohibit efforts to re-identify trial participants.
2. The final regulation should provide for the proactive release of redacted clinical information no later than 60 days after a final regulatory decision. This is consistent with the European Medicines Agency's timetable.
3. The regulation should provide a timetable for release of clinical information for medical products where a final regulatory decision predates the implementation date of the regulations.



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4. The final regulation should require Health Canada to release de-identified individual patient data (IPD), when available, as part of efforts to proactively release clinical trial information. The European Medicines Agency plans to release IPD in Phase 2 of implementation of Policy 0070. Explicitly including IPD as among the types of information that Health Canada will release will put Canada at the forefront of international efforts to improve clinical trial transparency and enhance open science.

5. The final regulation should define Case Report Forms in eCTD Module 5.3.7 as IPD. Therefore, rather than being excluded from clinical information for public release, these forms could be appropriately redacted according to commonly accepted de-identification procedures, and then released.

6. The final regulation should require Health Canada to proactively release **all** clinical trial data submitted by a sponsor seeking market authorization, not just the data reviewed by Health Canada to grant or deny approval. This includes, but is not limited to, summary results, safety analyses, and de-identified IPD from phase 1 and 2 clinical trials of drugs and biological products and small feasibility studies of medical devices.

7. The white paper includes several exemptions from release of information, which we address in turn, each of which should be removed or limited in their use.

### **a. Secondary or Exploratory End Points Which May Constitute a Component of an On-Going Development Programme**

If submissions for regulatory approval rely on secondary or exploratory end points, release of the data and results relating to these end points should also occur, regardless of whether they may constitute part of an ongoing development programme.

### **b. Interim Clinical Study Results**

Once a clinical trial for a drug or a clinical study for a device has been completed, the interim clinical study reports or results should not be excluded from the definition of completed clinical study or completed clinical trial. For those medical products granted Priority Review status, interim reports may have played a key role in regulatory decision-making.

### **c. Methodological Details (e.g. In-House Modifications or Procedures to Analytical, Immunogenicity, Bioassay, or Sample Size Calculations Methods not Commonly Used by the Industry)**

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.



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Again, we applaud the proposed policies proposed by Health Canada in this White Paper. However, we urge the agency to adopt the proposed policy change as modified with 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.

Sincerely,

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