Johnson & Johnson MEDICAL DEVICES COMPANIES

Public Release of Medical Device Clinical Information in Canada

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Medical Devices Companies
Johnson & Johnson

Health Canada Transparency Mandate

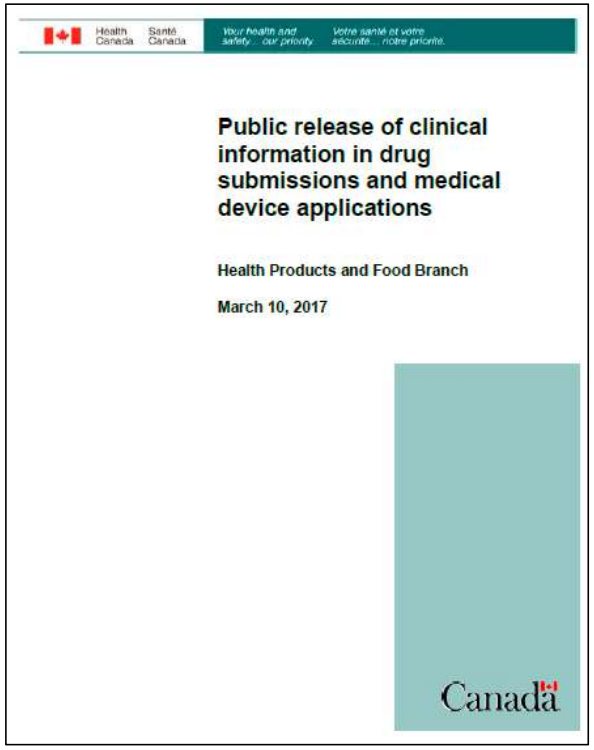
Transparency has been an increasing focus at Health Canada in recent years as part of the Government of Canada's 'Open Government' initiative.

In 2014 Health Canada was mandated by federal legislation to increase transparency initiatives, including to specify what information received from manufacturers would *no longer be considered Confidential Business Information* (CBI) and could therefore be publicly released

Public Release of Clinical Information (PRCI) – Health Canada's Intent

In Spring 2017 Health Canada released a White Paper for consultation outlining a process to publish submission clinical information in a public database

- Process intended to be similar to the current European Medicines Agency (EMA) *Policy 70* but will apply to drugs and devices
- Personal data would be required to be de-identified, and a narrow scope of confidential business information (CBI) will be redacted



Public Release of Clinical Information – Proposed Process

Public Release of Clinical Information – Proposed Timeline

2.5 Implementation schedule for the proactive disclosure of clinical information in drug submissions and medical device applications

Health Canada intends to proactively release clinical information in drug submissions and medical device applications according to the following implementation stages, following the circumstances outlined in paragraph C.08.009.2 of the FDR and Section 43.12 (1) of the MDR.

Table: Implementation steps of proactive public release of clinical information

Stage	Proposed Phase-in	Scope of application types
1	Year 1	NDS-NAS + SNDS-c + Rx-switch
2	Year 2	All NDS + SNDS-c + Rx-switch
3	Year 3	All NDS, all SNDS & Class IV devices
4	Year 4	All NDS, SNDS, ANDS, SANDS + Class III & IV devices

Novel Approach – Creation of Stakeholder Reference Group

Meeting	Purpose
1 **October 13, 2017** 12:00-14:00 EST	**Launch** This meeting will launch the stakeholder engagement process, introduce members, clarify the purpose and operation of the group, provide the feedback from last consultations and discuss the proposed agenda for future meetings.
2 **November 24 2017** 12:00-14:00 EST	**Overview of operations and key implementation issues** RMOD will present an overview of the proposed operation and seek member comments on key implementation issues including: • proposed approach to applying regulations to specify the information that ceases to be CBI and will be publicly released • phased implementation options; and • platform and format for public release of clinical information.
3 **January 11 2018** 12:00-14:00 EST	**Protection of personal information** RMOD will discuss the proposed approach to protecting personal information within clinical information, obligations under Canada's Privacy Act, and will seek member comments on related issues, including: • risks of re-identification using indirect identifiers; and • leading practices to minimize risk of re-identification while maintaining data utility.
4 **February 15 2018** 14:00-16:00 EST	**Process to specify clinical information, safeguards against commercial use** RMOD will introduce its proposed approach to applying regulations to specify the information that ceases to be CBI and can be publicly released, and will seek member views on issues including: • process and technical requirements for consulting sponsors, redaction, and anonymization of information; • user identification and sign-in; and • safeguards against commercial use of released data.
5 **March 29 2018** 14:00-16:00 EST	**Public release options and health system impacts** RMOD will present options under consideration for the public portal for release of clinical information, and for monitoring and evaluating impacts. Members will be invited to comment on related issues including: user needs and requirements; and indicators of health system impact of clinical data release.

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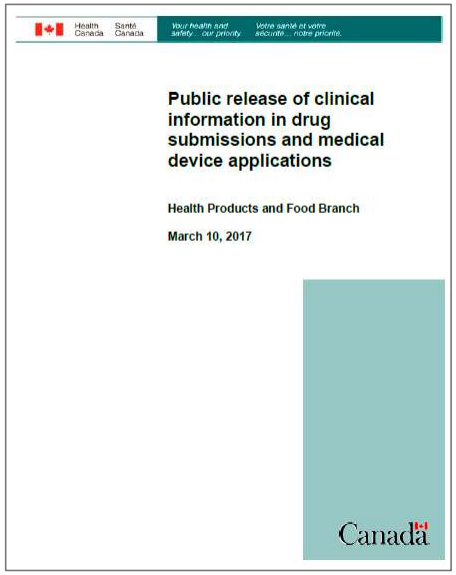
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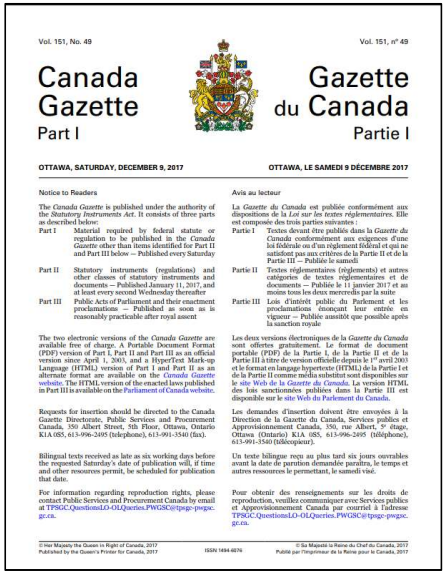
Public release of clinical information in drug submissions and medical device applications

Health Products and Food Branch

March 10, 2017

Canada

March 2017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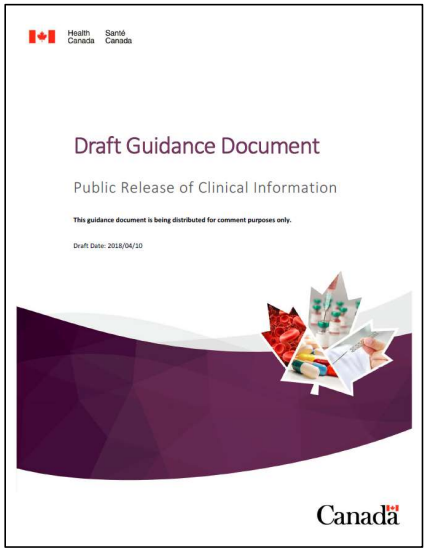
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Public Release of Clinical Information

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Draft Date: 2018/04/10

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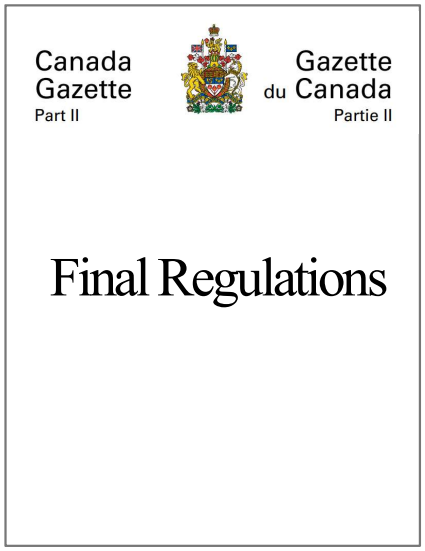
Canada Gazette Part II — Gazette du Canada Partie II

Final Regulations

TBD

Draft Device Regulations Canada Gazette Part I December 9th, 2017

Disclosure of Information in Respect of Clinical Studies or Investigational Testing

43.11 In sections 43.12 and 43.13, *information in respect of a clinical study or investigational testing* means information in respect of a clinical study, or investigational testing, involving human subjects that is contained in an application for a Class III or IV medical device licence made under section 32 or in an application to amend such a licence made under section 34.

43.12 (1) Information in respect of a clinical study or investigational testing that is confidential business information ceases to be confidential business information when one of the following circumstances occurs with respect to the application:

(a) the Minister issues a licence under paragraph 36(1)(a);

(b) the Minister amends a licence under paragraph 36(1)(b);

(c) the Minister refuses to issue a licence or amend a licence under section 38.

(2) Subsection (1) does not apply to information in respect of a clinical study or investigational testing that

(a) was not used by the manufacturer in the application to support the information referred to in paragraph 32(3)(b) or (4)(b); or

(b) describes tests, methods or assays that are used exclusively by the manufacturer.

43.13 The Minister may disclose, without notifying the person to whose business or affairs the information relates or obtaining their consent, any information in respect of a clinical study or investigational testing that has ceased to be confidential business information.

Transitional Provisions

2 (1) Despite section 43.11 of the *Medical Devices Regulations*, *information in respect of a clinical study or investigational testing*, as defined in section 43.11 of those Regulations, that is confidential business information and that is contained in an application with respect to which one of the following circumstances occurred before the day on which these Regulations come into force ceases to be confidential business information on the day on which these Regulations come into force:

(a) the Minister issued a licence under paragraph 36(1)(a) of the *Medical Devices Regulations*;

(b) the Minister amended a licence under paragraph 36(1)(b) of the *Medical Devices Regulations*;

(c) the Minister refused to issue or amend a licence under section 38 of the *Medical Devices Regulations*.

(2) Subsection (1) does not apply to information referred to in subsection 43.12(2) of the *Medical Devices Regulations*.

Coming into Force

3 These Regulations come into force on the day on which they are registered.

Draft Regulations – Key Points

- Scope of “Information in respect of a clinical study or investigational testing” is not defined in the regulations

- Only two exclusions where clinical information will still be considered CBI:
  1. Information that does not provide ‘a description of the features of the device that permit it to be used for the medical conditions, purposes and uses for which it is manufactured, sold or represented’
  2. Tests, methods or assays that are used exclusively by the manufacturer

- Regulations as drafted apply to all Class III & IV clinical data in Health Canada’s possession
  - Both Prospective and Retrospective application

- Coming into Force Provision:
  - Power to release information is granted when regulations are published
  - Health Canada has proposed to delay devices to Phase 3 implementation (~2021?)

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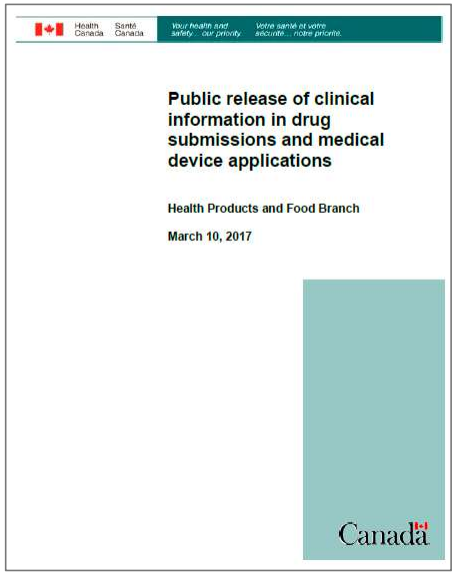
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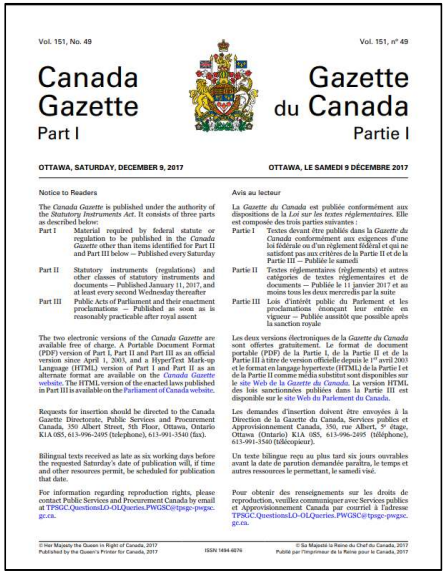
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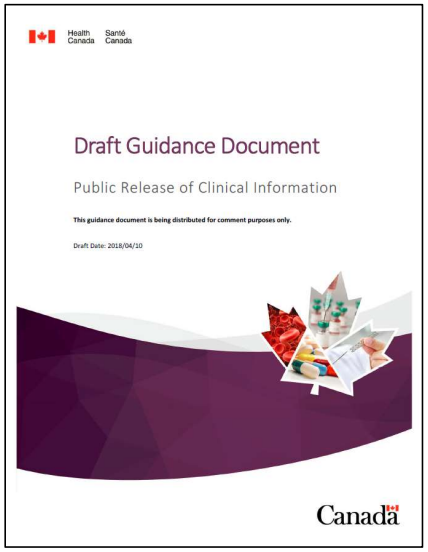
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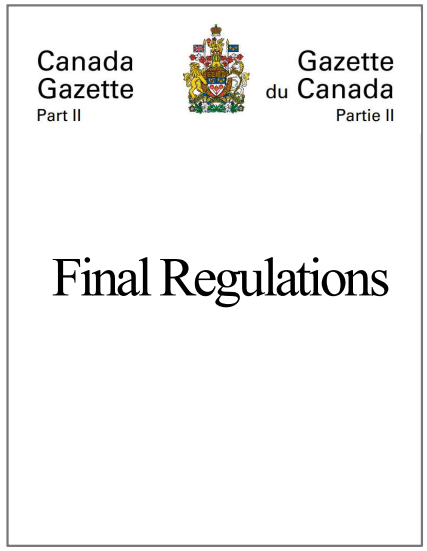
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Final Regulations

TBD

Draft Guidance – Public Release of Clinical Information

Section	Description	CBI	Public Proactive Release
4.1 - Chapter Table of Contents		Not CBI	No
4.2 - Overall Clinical Evidence Summary	A brief summary of the available clinical evidence being presented in support of the submission	Not CBI	Yes
4.2.1 Clinical Evaluation Report	An objective critical evaluation of all of the clinical data submitted in relation to the device.	Not CBI	Yes
4.2.2 Device Specific Clinical Trials			
4.2.2.1	Trial description, protocol number, date of initiation	Not CBI	Yes
4.2.2.1.1	Clinical Trial Synopsis	Not CBI	Yes
4.2.2.1.2	Clinical trial report	Not CBI	Yes
4.2.2.1.3	Clinical trial data	Not CBI	Yes
4.2.3	Clinical literature review and other reasonable known information	Not CBI	Yes
4.3 - IRB Approved Informed Consent Forms	US regional information not submitted to Health Canada	NA	NA
4.4 - Investigators Sites – IRB Contact Information	US regional information not submitted to Health Canada	NA	NA
4.5 - Other Clinical Evidence		Not CBI	Yes
4.5.1.1	Summaries of specific studies	Not CBI	Yes
4.5.1.2	Full test report for specific studies	Not CBI	Yes

Proposed Medical Device Submission Scope (Appendix C):

- **Based on IMDRF ToC Submission Format**
- **Includes most sub-folders in Section 4**

Draft Guidance – Public Release of Clinical Information

Draft Guidance – Public Release of Clinical Information

Appendix G: Anonymisation report template

*Note: two versions of the anonymization report will be generated. The first submitted version must include detailed information on the anonymization methodology. Each data transformation must be identified and a rationale provided. Upon acceptance of the anonymization approach, Health Canada will remove any information that presents a risk of disclosing personal information within the anonymization report.

Product name:

Active substance:

Submission control number:

Applicant/ Market Authorization Holder:

1. Anonymization methodology

- Describe the approach taken, the risk threshold used and the rationale for the chosen approach.

2. Identification of data variables (direct and indirect identifiers) and measurement of re-identification risk

- Classify the variables considered personal information into directly-identifying and indirectly-identifying categories.

- State and justify the reasons for describing information as personal information.

- State and justify the reference population used.

- Discuss the measured data risk associated with individual trial subjects found to be at risk of re-identification and how the data was transformed to reduce the risk.

- State the measured risk following the process of anonymization.

3. Data utility considerations

- State the efforts made to maximize the utility of the anonymized information.

Appendix F: Proposed redaction control sheet

Document Name	Page Number(s)	Text proposed for redaction	Qualifying exception for regulations	Not clinical information	Detailed justification of proposed redaction	Health Canada's response to proposed redaction	Health Canada's rationale
			E.g. exceptions: C.08.009.2 (2)(a) or C.08.009.2 (2)(b)	E.g. chemistry, manufacturing information		Rejected / Partially Accepted / Accepted	

Draft Guidance – Key Areas for Consideration

- **Scope of Confidential Business Information to be Protected**
  - Only two exclusions in the draft regulations where clinical information will still be considered CBI
  - Draft Guidance clarifies that 'other non-clinical information' contained within the clinical section will be excluded from the scope of PRCI as well
- **Scope of Clinical Information to be Released**
  - MEDEC & AdvaMed Recommendation: Implementation should focus on device submissions containing new clinical data vs. all Class III & IV submissions with clinical information
  - Focus on achieving the key objectives of disclosure while reducing the resource burden on industry & Health Canada
- **Requesting Clinical Information from Past Submissions**
  - Health Canada intends to publish clinical information from past submissions upon receipt of a request from the public
- **Draft Guidance is Focused on Drugs but Devices are also included**
  - MEDEC & AdvaMed Recommendation: Remove device details from this version of guidance, and update or create new guidance once device implementation is further developed

Transparency Comparison – Canada vs. the EU

Canada Draft Guidance Proposal

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4.5 - Other Clinical Evidence		Not CBI	Yes
4.5.1.1	Summaries of specific studies	Not CBI	Yes
4.5.1.2	Full test report for specific studies	Not CBI	Yes

EU MDR/IVDR Requirements

EU MDR:

- the clinical investigation report
- a summary of the clinical investigation report presented in terms that are easily understandable to the intended user

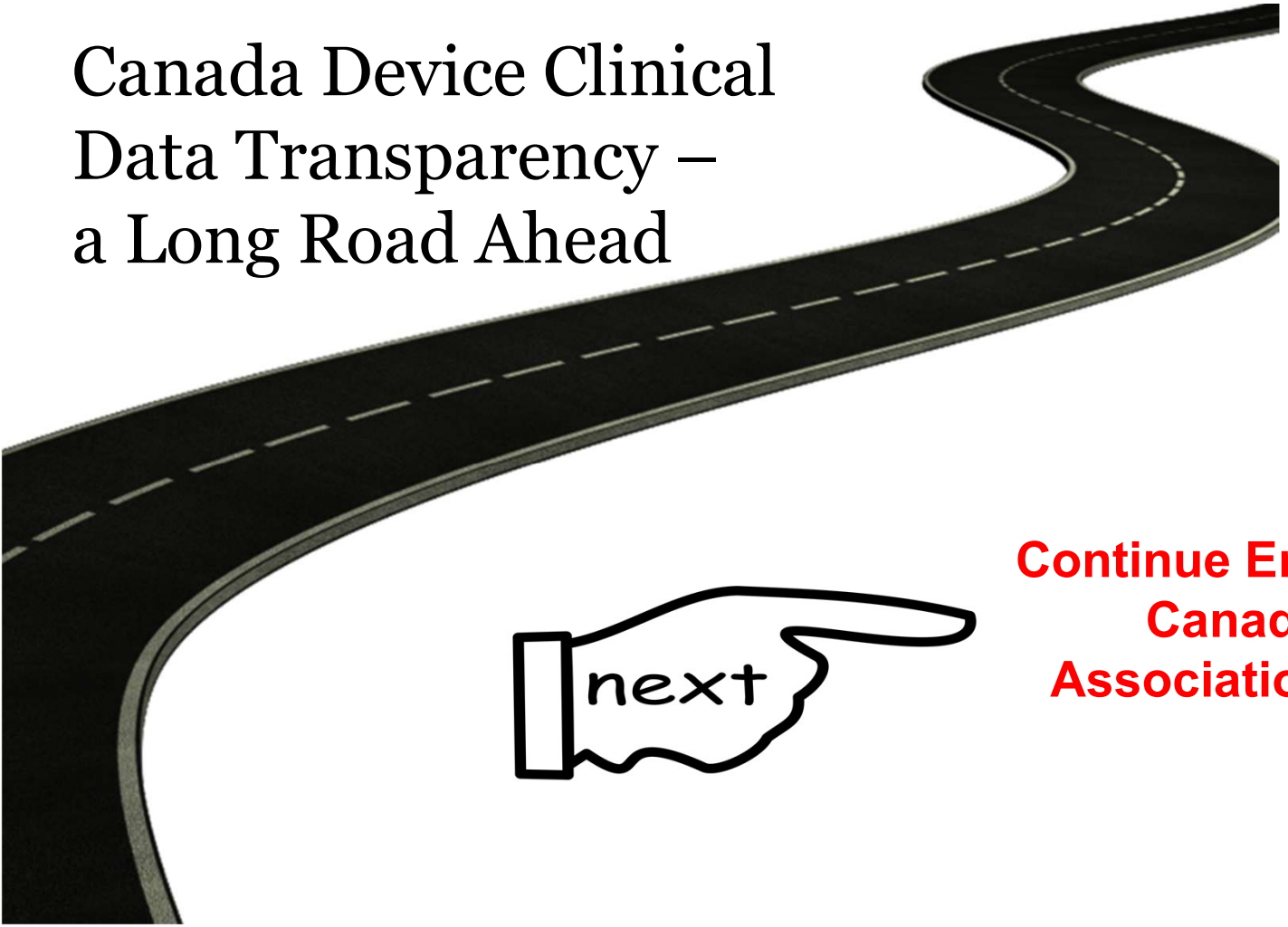
EU IVDR:

- the performance study report
- A summary of the performance study report presented in terms that are easily understandable to the intended user

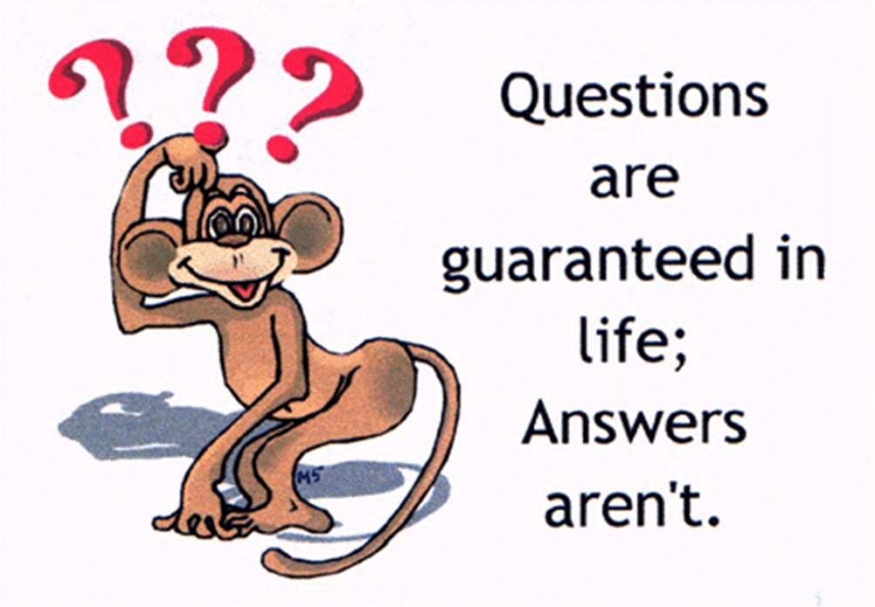
Balance Health Canada's Key Objectives of Disclosure with the Resource Burden on Industry & Health Canada

- **Focus on device submissions containing new clinical data**
- **Apply requirements prospectively**
- **Leverage EU MDR published Clinical Investigation Reports in some capacity to reduce Canada-specific requirements**

Canada Device Clinical Data Transparency – a Long Road Ahead



Continue Engagement with Health Canada & Global Trade Associations through 2018 and beyond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