Managing Clinical Research Involving Medical Devices

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What is a "Medical Device"

What is a “Medical Device”

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The ‘sale’ of medical devices in Canada is regulated by the Medical Devices Regulations

means an instrument, apparatus, contrivance or other similar article, or an in vitro reagent, including a component, part or accessory of any of them, **that is manufactured, sold or represented for use in**

(a) diagnosing, treating, mitigating or preventing a disease, disorder or abnormal physical state, or any of their symptoms, in human beings or animals,

(b) restoring, modifying or correcting the body structure of human beings or animals or the functioning of any part of the bodies of human beings or animals,

(c) diagnosing pregnancy in human beings or animals,

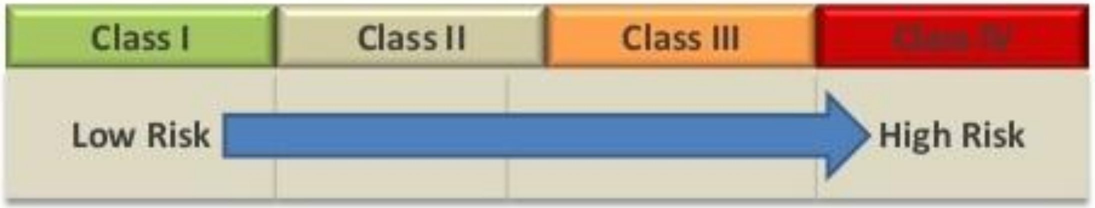
(d) caring for human beings or animals during pregnancy or at or after the birth of the offspring, including caring for the offspring, or

(e) preventing conception in human beings or animals;

NOT a medical device

- Effect primarily through pharmacological, immunological or metabolic means
- intended for use in relation to animals

Classifying Medical Devices



- Medical devices are categorized into **<u>4 classes</u>** based on “intended use”

- Degree of regulation imposed on any medical device is proportional to its potential risk:
  - degree of invasiveness
  - duration of contact
  - body system affected
  - local versus systemic effects

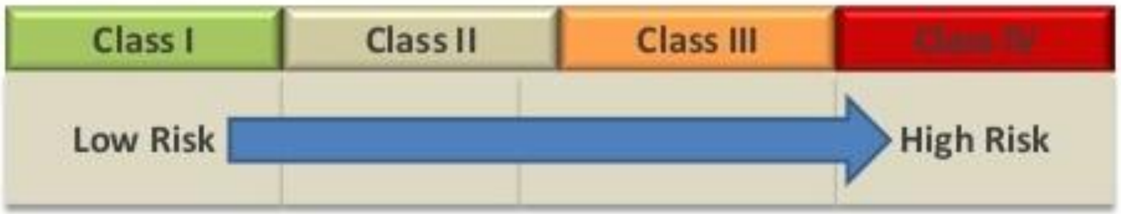
	Class I	Class II	Class III	Class IV
Non-Invasive	Bandages, gauze [Rule 4]	IV fluid bags [Rule 5]	Parallel flow dialyser [Rule 6]	Stem cell separator [Rule 6]
Invasive	Oropharyngeal airway (only as far as the pharynx) [Rule 2]	Daily wear, soft contact lenses [Rule 2]	Shoulder prosthesis [Rule 1]	Fetal blood sampling endoscope [Rule 1]
Active	All Other active medical devices [Rule 12]	Air pressure tourniquet [Rule 9]	Bone densitometer [Rule 8]	Implantable rate responsive pacemaker [Rule 9]

Software as a Medical Device (SaMD)

Software as a Medical Device (class I, II, or III):

- is intended or represented for use in the diagnosis or treatment
- only means to acquire data from a medical device for aiding directly in diagnosis/treatment; or
- replaces a diagnostic or treatment decision made by a physician

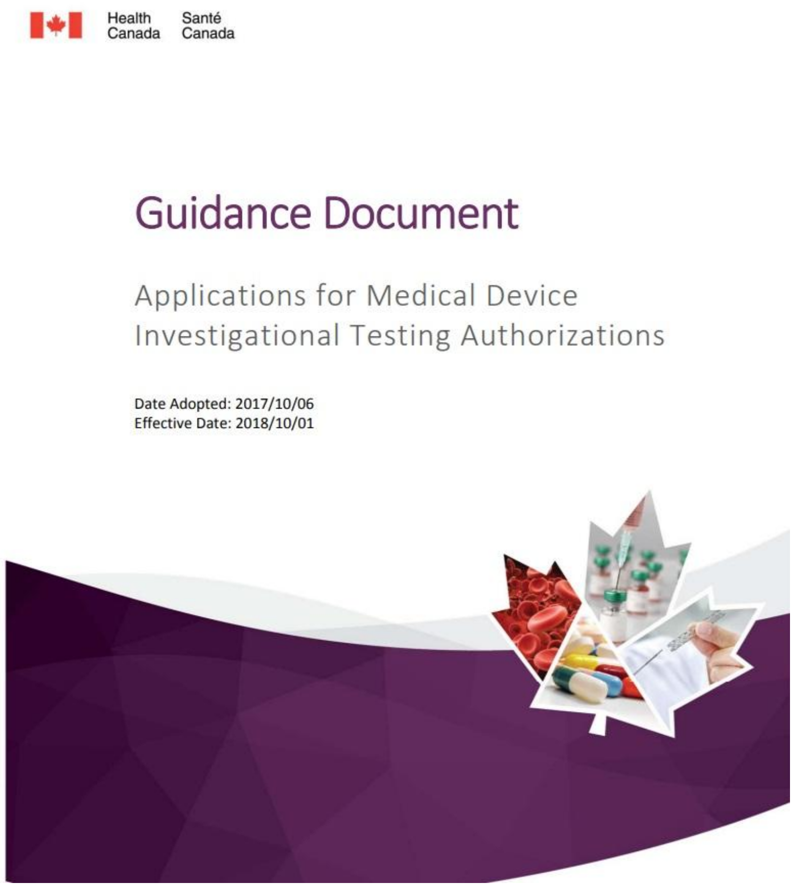
State of Healthcare situation or condition	Significance of information provided by SaMD to healthcare decision		
	Treat or diagnose	Drive clinical/patient management	Inform clinical/patient management
Critical	III	III	I or II
Serious	II or III	II or III	I or II
Non-serious	I or II	I or II	I or II



Comparing Drug and Device Research

Pharmaceutical trials	Medical device trials
Pharmacological efficacy	Device safely and performance
Phase 1-IV	Smaller pilot trials
Often large controlled studies	Pivotal trials, real-world
Blinding, placebos	Limited blinding, placebos
Over multiple years	More flexibility in design
Health Canada "No Objection Letter"	Health Canada "Investigational Testing Authorization"

Health Canada *Investigational Testing Authorization*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Guidance Document

Applications for Medical Device Investigational Testing Authorizations

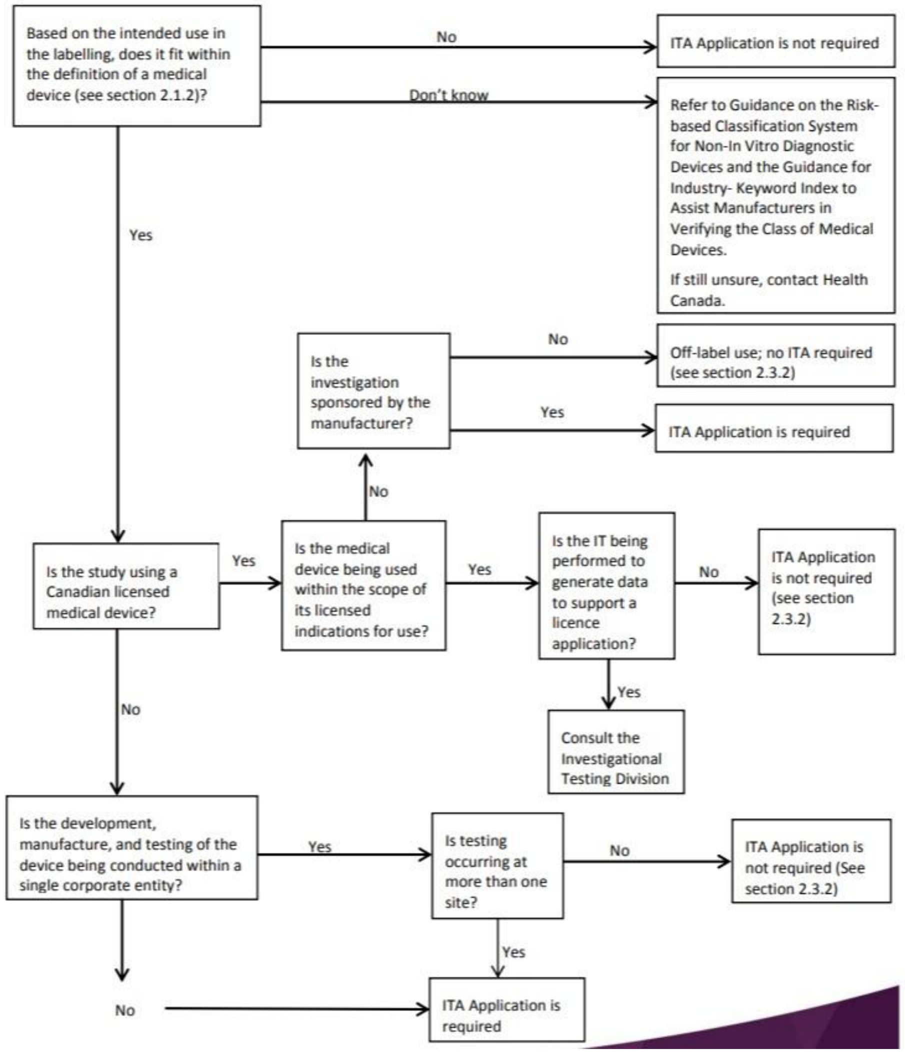
Date Adopted: 2017/10/06
Effective Date: 2018/10/01

Part 3 of the Medical Devices Regulations Investigational Testing

- Classifying medical devices
- What is Investigational Testing Authorization
- Manufacturer vs. Investigator
- Only manufacturers and importers can apply for an Investigational Testing Authorization (ITA)
- When an ITA is needed
- How to communicate with Health Canada (pre-ITA meetings)
- What's required in an ITA application
- Review Timelines

When is *Investigational Testing Authorization* needed?

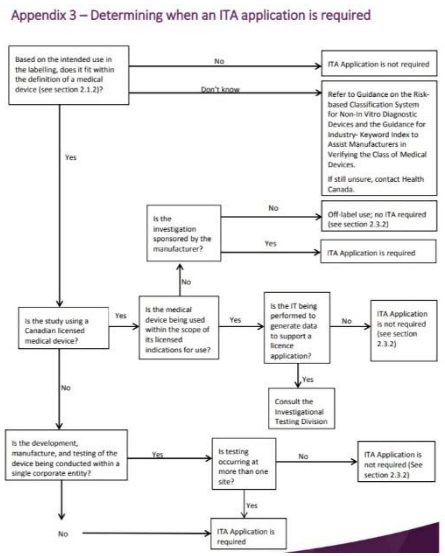
Appendix 3 – Determining when an ITA application is required



ITA is required when….

- It is a medical device (based on intended use)
- Not licensed for use in Canada
- Class II, III, IV
- Licensed, but used to research in new indication (Class II, III, IV)
- Changes in Investigational Plan required new ITA

When is *Investigational Testing Authorization* needed?



ITA is NOT required when….

- Not a 'medical device'
- Does not involve human participants
- Class 1 medical device (see Classification Criteria)
- Licensed medical device used according to label
- An investigator-sponsored study (no manufacturer involved) where device (Class II – IV) is used in a new indication
- No 'sale' is occurring – developed, manufactured, and tested within a single corporate entity

Different than the CTA (drug) process

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When is *Investigational Testing Authorization* needed?

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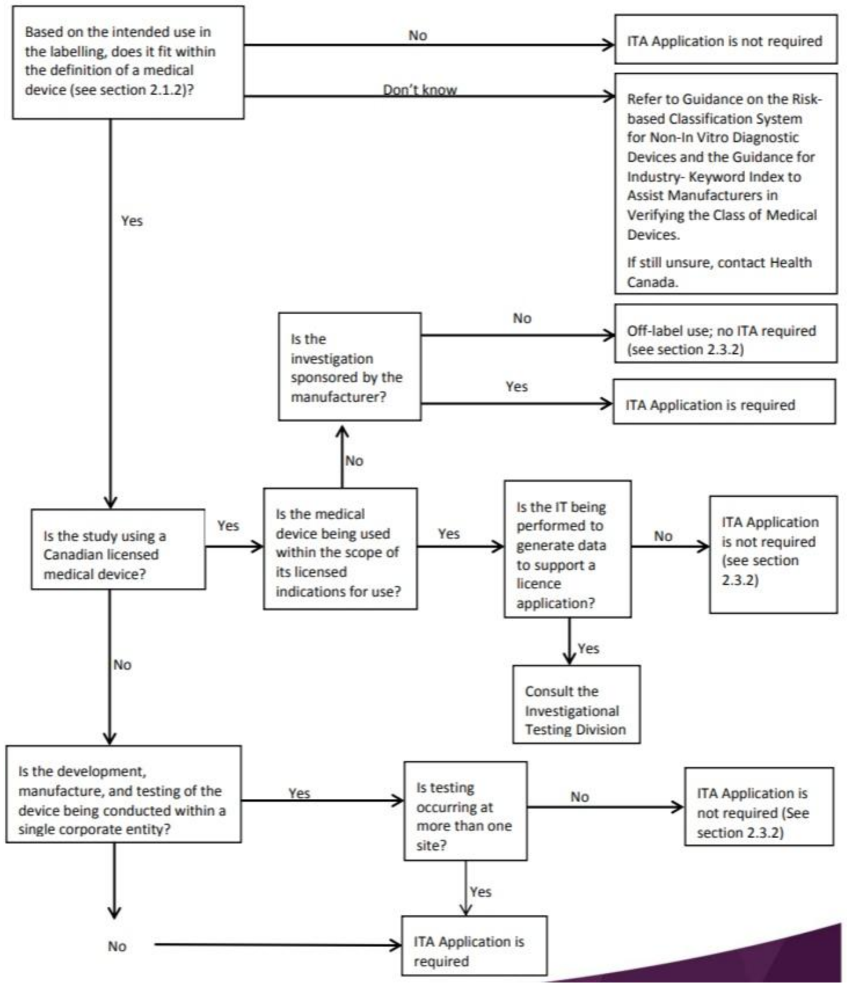

May require dialogue with Health Canada….

- Truly a 'Medical Device'?
- Basic exploratory studies? Studying physiological responses not treatment/ diagnosis?
- 'Research Only' Medical Device?

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Contact us

ITA email enquiries: hc.it-ee.sc@canada.ca

ITA Applications

Records Required (Section 81):

Manufacturer

- Device ID and Class
- Device description/ materials
- Design/ performance specs
- Marketing history
- Previous testing
- Risk Assessment

Investigator

- Device ID and Class
- Device description/ materials
- Study Protocol
- Institutions/PIs
- Device label
- REB approval

	Class I	Class II	Class III	Class IV
Risk	Low	Low	Moderate	High
Investigational Testing Authorization	*<u>Not</u>* Required But must keep records (section 81 of regulations)	Required ITA Application requires: • Manufacturer • Device ID • Risk Classification • Institutions/PIs • Study Protocol/ Consent form • Device label	Required ITA Application requires: • Manufacturer • Device ID • Risk Classification • **Device description/ Materials** • **Design/ Performance Specs** • **Marketing history** • **Risk Assessment (ISO 14971)** • **Previous studies** • **Alternate Treatments** • **Precautions** • **Investigator Agreement / CV** • **REB approval** • Institutions/PIs • Study Protocol/ Consent form • Device label	

Investigator Agreement

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INVESTIGATOR'S AGREEMENT IN ACCORDANCE WITH SUBSECTION 81(k) OF THE *MEDICAL DEVICES REGULATIONS*

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SUBSECTION 81(k) OF THE *MEDICAL DEVICES REGULATIONS*

Device Name:

Protocol Number:

I undertake, in accordance with Subsection 81(k) of the *Medical Devices Regulations*, as outlined below, to:

(i) conduct the investigational testing in accordance with the protocol:

(ii) inform a patient who is to be diagnosed or treated with the device of the risks and benefits associated with its use and obtain the written consent of the patient,

(iii) not use the device or permit it to be used for any purpose other than the investigational testing specified in the protocol,

(iv) not permit the device to be used by any person other than myself, except under my direction,

(v) in the event of an incident that is related to a failure of the device or a deterioration in its effectiveness, or any inadequacy in its labelling or in its directions for use and has led to the death or a serious deterioration in the state of health of a patient, user or other person, or could do so were it to recur, report the incident and the circumstances surrounding it to the Director and the manufacturer or importer of the device, within 72 hours after its discovery.

Good Clinical Practice – ICH vs. ISO 14155

More similarities than differences ICH or ISO 14155

- Investigators Qualifications & Agreements
- Study protocol, consent forms, data collection tools
- Site selection/ oversight
- Investigational device distribution records
- REB and regulatory approval
- Ongoing monitoring/ quality assurance
- Medical Care of Participants
- Compliance with study protocol
- Informed Consent of participants
- Safety reporting
- Final reports / Premature Termination or Suspension
- Record Retention

Good Clinical Practice – ICH vs. ISO 14155

Aspect	ICH GCP (ICH E6)	ISO 14155
Scope & Applicability	Primarily for drug and biologic clinical trials; mandatory in ICH regions (e.g. Canada, EU, Japan, USA)	Designed for medical device research (especially higher-risk devices); widely adopted though not legally required everywhere
Regulatory Status	Legally enforced in ICH member regions; essential for regulatory submissions	Recognized under EU MDR and FDA IDE process; also used by Health Canada
Risk Management Integration	Includes monitoring and safety reporting, but less prescriptive about device-specific risk plans.	Explicitly incorporates risk management and device performance evaluation throughout the investigation
Trial Design Nuances	Suited to large, multi-phase drug trials with randomized, blinded, controlled methodologies.	Device trials often have smaller samples, shorter timelines, and allow adaptive or unblinded designs due to practical constraints
Documentation Focus	Heavy emphasis on trial master file, investigator credentials, monitoring plans, and investigational product accountability	Adds device-specific documentation—risk management files, device labeling, handling, and performance assessments
Safety Reporting	AEs, SAEs • Serious, Unexpected, At least potential casualty • 7 days – death/life-threatening • 15 days – other SAEs	Medical device incident: • Related to a failure of the device; and led to the death or a serious deterioration in health • 72 hours from identifying the event

Summary

- Know when Investigational Testing Authorization is required
- Work with your manufacturer on the ITA
- Consult Health Canada’s Medical device regulations (Part 3)
- Ensure your protocol includes a risk assessment
- Create an SOP for mandatory safety reporting
- Create documentation for medical device traceability (use, distribution)
- Consider any internal safety, electrical, facilities requirements/ policies

Questions & Discussion