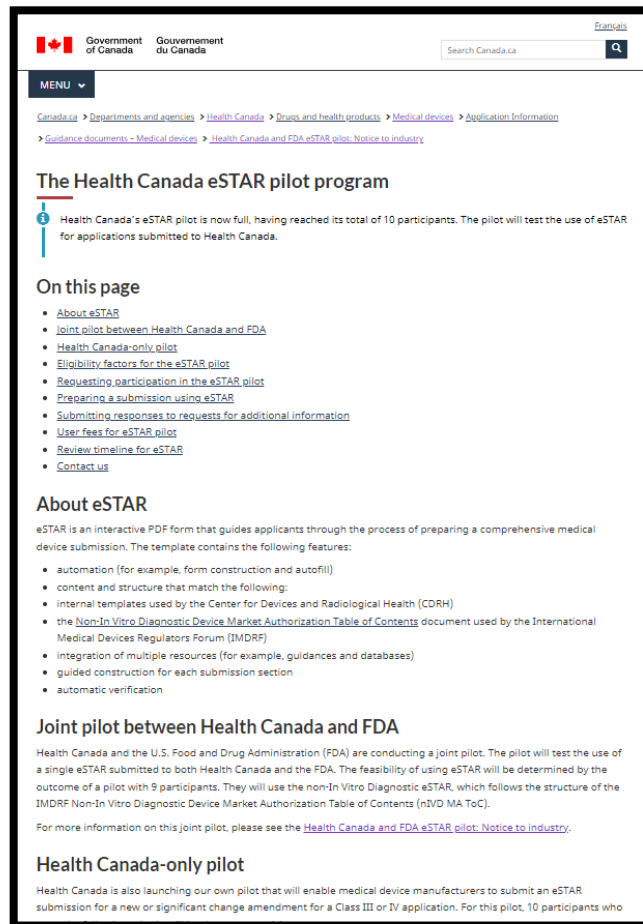

Health Canada's eSTAR pilots

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Advancing harmonization for premarket submissions – Health Canada eSTAR pilot program



- eSTAR is a dynamic pdf form that assists medical device manufacturers with building their submissions.
- In 2023 Health Canada (HC) and the FDA announced a joint pilot to test the use of eSTAR to submit a premarket application to both Health Canada and the FDA.
- HC also conducted an additional HC-only pilot for Class III and IV non-IVD submissions.

What is eSTAR? How does it work?

- Dynamic PDF – adds a user-friendly façade to ToC structure
- Integrates IMDRF Table of Contents and jurisdictional helper text

Application/Submission Type	
Application Jurisdiction	<input type="radio"/> US FDA <input checked="" type="radio"/> Health Canada ?
Application Purpose	<input type="radio"/> Class II <input checked="" type="radio"/> Class III ? <input type="radio"/> Class IV
Hide Application Introduction	
Please find related Health Canada IMDRF table of contents guidance for completing this form	
Draft Health Canada IMDRF table of contents for medical device applications guidance: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/international-medical-device-regulators-forum.html	
Medical Device Application Submission related resources:	
Guidance documents – Medical device https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents.html	
Medical device application forms: https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/forms.html	
Application Sub-Type (Modify the Original eSTAR when necessary. See Help Text)	

Performance Testing	
Was Bench Testing used in order to support this submission?	Yes
Was Animal Testing used in order to support this submission?	No
Was Clinical Testing used in order to support this submission?	No
Bench Testing ?	
Add Attachment	Please attach documentation that includes details of the bench testing performed with your device (test report, characterization, etc). A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions, and an explanation of how the data generated from the test support this submission. ?
Physical and Mechanical Characterization	
Open Attachment	Sentimag Bench Testing.pdf
Delete Attachment	

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Contains information about any tests/studies/evidences conducted to support the submission. This should include:

- A summary of the non-clinical evidence that falls within this category
- A discussion of the non-clinical testing considered for the device and support for their selection or omission from the verification and validation studies conducted in this category (i.e. what tests were considered and why they were or were not performed)
- Discussion to support why the evidence presented is sufficient

NOTE: The sponsor/applicant should explicitly address any existing regional regulatory guidance related to the non-clinical study results provided in this section regarding the subject device. In addition, the sponsor/applicant should consult any existing regional regulatory guidance related to where these attachments should be included.

Physical and Mechanical Characterization: Evidence that support the physical or mechanical properties of the subject device is to be included in this section. If applicable, this should include particulate testing from wear or device coatings.

Chemical/Material Characterization: Tests that describe the chemical or structural composition of the device and its components are to be included in this section.

Radiation Safety: Studies supporting radiation safety, where the device emits ionizing and/or non-ionizing radiation or where the device is exposed to radiation are to be included in this section. This includes bench tests ensuring safety and performance to support the MRI safety labelling of the device.

Non-Material-Mediated Pyrogenicity: Studies to support pyrogenicity evaluation of final release, such as endotoxin levels, are to be included in this section.

Safety of Materials of Biological Origin (human/animal): Evaluations performed to demonstrate the safety of materials of biological origin (e.g. animal sourced, human sourced material) are to be included in this section.

Usability/Human Factors: Studies specifically assessing the instructions and/or device design in terms of impact of human behaviour, abilities, limitations, and other characteristics on the ability of the device to perform as intended should be included here.

OK

Warning: JavaScript Window

Overview of the Health Canada eSTAR Pilots

- Joint pilot objective was to test the use of a single eSTAR (with regional specific content) submitted separately to both HC and the FDA.
- Types of eligible submissions:
 - HC: Class III or IV
 - FDA: 510(k), De Novo, PMA
 - Exclusions: combination products, IVDs, CBER-led or FDA dual 510(k)/CLIA waiver
- Stakeholders expressed strong interest in both pilots.
- Following the pilots HC gathered feedback from pilot participants, as well as HC reviewers and screeners.

What We Heard

- Users found the eSTAR template to be user friendly and intuitive.
 - Built-in guidance within the template was valuable in building the submission.
- Recognition that incorporating corresponding IMDRF/TOC section numbers into the template would be helpful and improve organization.
- Manufacturers expressed their eagerness to leverage the electronic gateway in Canada, citing limitations with email submissions.
- Stakeholders would like to see pilot expansion, including for the use of IVDDs and Additional Information requests.

Next Steps

- Pilots demonstrated the potential of the eSTAR template to streamline and harmonize medical device submissions across multiple jurisdictions.
- HC and US FDA are assessing the results of the pilot, with plans to conduct additional pilot(s).
- Next steps include:
 - integrating pilot feedback into eStar templates/processes
 - incorporate Table of Content (ToC) updates from recent [IMDRF N9 and N13 updates](#)
 - Evaluate areas for pilot expansion e.g. IVDD submissions, French language and additional information requests, additional jurisdictions



Questions?