Health Canada's eSTAR pilots

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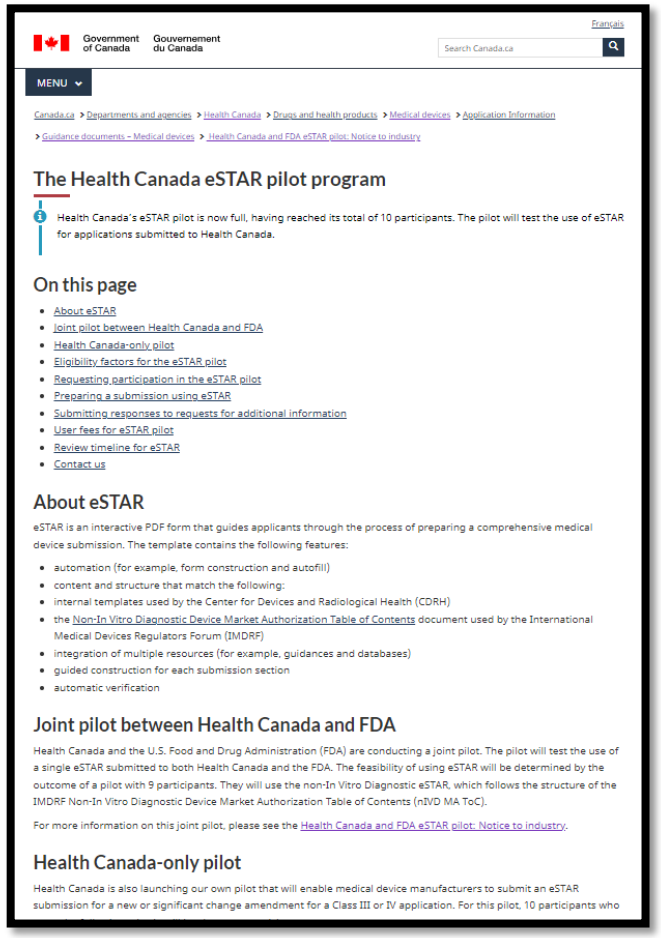
Advancing harmonization for premarket submissions – Health Canada eSTAR pilot program



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Canada.ca > Departments and agencies > Health Canada > Drugs and health products > Medical devices > Application Information > Guidance documents – Medical devices > Health Canada and FDA eSTAR pilot: Notice to industry

The Health Canada eSTAR pilot program

Health Canada's eSTAR pilot is now full, having reached its total of 10 participants. The pilot will test the use of eSTAR for applications submitted to Health Canada.

On this page

- About eSTAR
- Joint pilot between Health Canada and FDA
- Health Canada-only pilot
- Eligibility factors for the eSTAR pilot
- Requesting participation in the eSTAR pilot
- Preparing a submission using eSTAR
- Submitting responses to requests for additional information
- User fees for eSTAR pilot
- Review timeline for eSTAR
- Contact us

About eSTAR

eSTAR is an interactive PDF form that guides applicants through the process of preparing a comprehensive medical device submission. The template contains the following features:

- automation (for example, form construction and autofill)
- content and structure that match the following:
- internal templates used by the Center for Devices and Radiological Health (CDRH)
- the Non-In Vitro Diagnostic Device Market Authorization Table of Contents document used by the International Medical Devices Regulators Forum (IMDRF)
- integration of multiple resources (for example, guidances and databases)
- guided construction for each submission section
- automatic verification

Joint pilot between Health Canada and FDA

Health Canada and the U.S. Food and Drug Administration (FDA) are conducting a joint pilot. The pilot will test the use of a single eSTAR submitted to both Health Canada and the FDA. The feasibility of using eSTAR will be determined by the outcome of a pilot with 9 participants. They will use the non-In Vitro Diagnostic eSTAR, which follows the structure of the IMDRF Non-In Vitro Diagnostic Device Market Authorization Table of Contents (nIVD MA ToC).

For more information on this joint pilot, please see the Health Canada and FDA eSTAR pilot: Notice to industry.

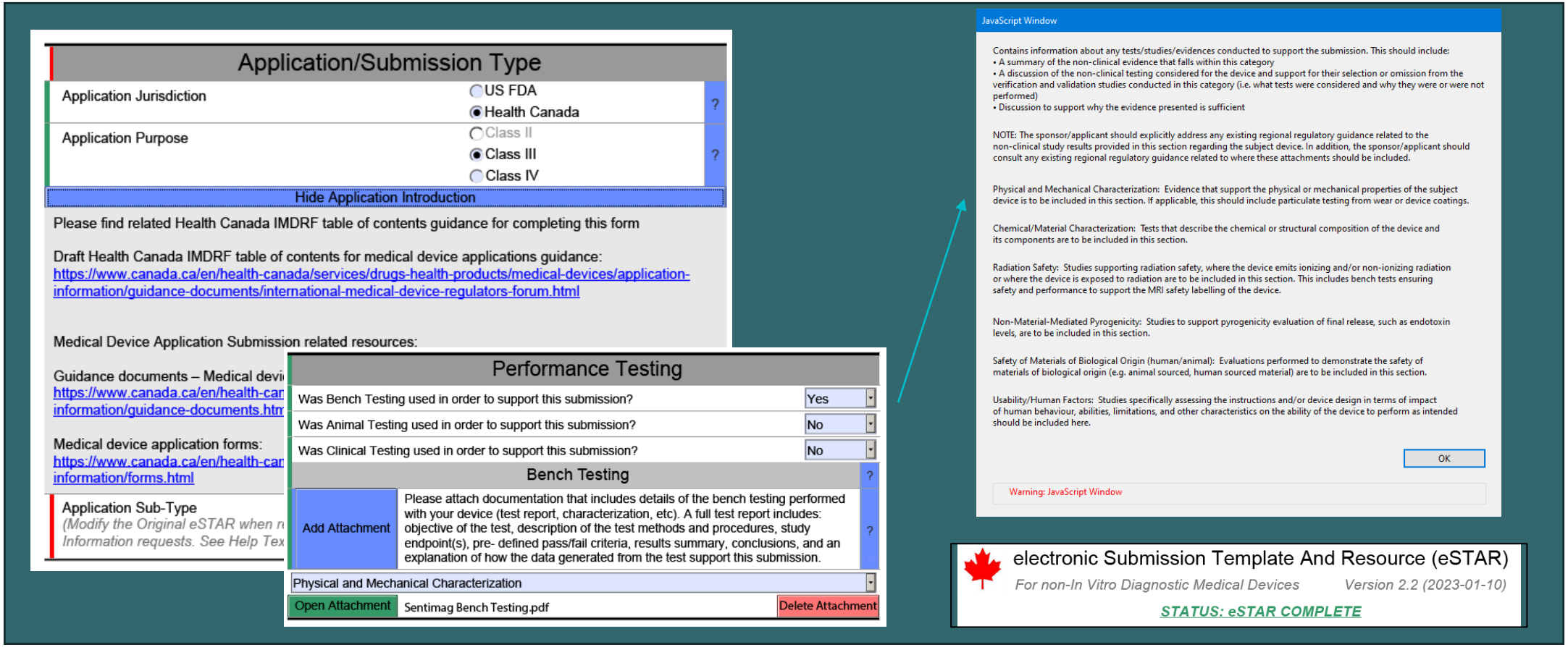
Health Canada-only pilot

Health Canada is also launching our own pilot that will enable medical device manufacturers to submit an eSTAR submission for a new or significant change amendment for a Class III or IV application. For this pilot, 10 participants who

- 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



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?