Health Canada's eSTAR pilots

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Advancing harmonization for premarket submissions – Health Canada eSTAR pilot program

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| The Health Canada eSTAR pilot program | |
| The fleath canada es fAit phot program | |
| Health Canada's eSTAR pilot is now full, having reached its total of 10 par | ticipants. The pilot will test the use of eSTAR |
| for applications submitted to Health Canada. | |
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| About eSTAR | |
| eSTAR is an interactive PDF form that guides applicants through the process o | 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 | n (CDRH) |
| the Non-In Vitro Diagnostic Device Market Authorization Table of Content | s 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 conducti | ng a joint pilot. The pilot will test the use of |
| a single eSTAR submitted to both Health Canada and the FDA. The feasibility o | of using eSTAR will be determined by the |
| outcome of a pilot with 9 participants. They will use the non-In Vitro Diagnosti | |
| IMDRF Non-In Vitro Diagnostic Device Market Authorization Table of Contents | (nIVD MA ToC). |
| For more information on this joint pilot, please see the <u>Health Canada and FD</u> | A 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 |

- 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

| Appli | ication/Sub | omission Type | | |
|---|--|---|--|--|
| Application Jurisdiction | | ⊂ US FDA | ? | |
| Application Purpose | | OClass II | 2 | |
| | | Class IV | | |
| | Hide Application | Introduction | | |
| information/guidance-documents/inter | nauonai-medical | -device-requiators-forum.html | | |
| Medical Device Application Submissio | on related resourd | | g | |
| Guidance documents – Medical devi https://www.canada.ca/en/health-car | | ces: | g | Yes |
| Suidance documents – Medical devi ttps://www.canada.ca/en/health-car | Was Bench Testir | Performance Testin | g | Yes |
| Guidance documents – Medical devi https://www.canada.ca/en/health-car nformation/guidance-documents.htm Medical device application forms: | Was Bench Testir Was Animal Testi | ces: Performance Testin ng used in order to support this submission? | g | |
| Guidance documents – Medical devi https://www.canada.ca/en/health-car nformation/guidance-documents.htm Medical device application forms: https://www.canada.ca/en/health-car | Was Bench Testir Was Animal Testi | res: Performance Testin ng used in order to support this submission? ng used in order to support this submission? | g | No |
| Guidance documents – Medical devi | Was Bench Testir Was Animal Testi | res: Performance Testin ng used in order to support this submission? ng used in order to support this submission? ing used in order to support this submission? | s of the ber :). A full tes ds and pro summary, | No No nch testing performed st report includes: ocedures, study conclusions, and an |
| Guidance documents – Medical devi https://www.canada.ca/en/health-car information/guidance-documents.htm Medical device application forms: https://www.canada.ca/en/health-car information/forms.html Application Sub-Type (Modify the Original eSTAR when n | Was Bench Testir Was Animal Testi Was Clinical Testi Add Attachment | res: Performance Testin Ing used in order to support this submission? Ing used in order to support this submission? Ing used in order to support this submission? Bench Testing Please attach documentation that includes details with your device (test report, characterization, etc objective of the test, description of the test method endpoint(s), pre- defined pass/fail criteria, results | s of the ber :). A full tes ds and pro summary, | No No nch testing performed st report includes: ocedures, study conclusions, and an |

JavaScript Window

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 electronic Submission Template And Resource (eSTAR) For non-In Vitro Diagnostic Medical Devices Version 2.2 (2023-01-10)

STATUS: eSTAR COMPLETE

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 <u>IMDRF N9 and N13 updates</u>
 - Evaluate areas for pilot expansion e.g. IVDD submissions, French language and additional information requests, additional jurisdictions

Questions?