electronic **S**ubmission **T**emplate **A**nd **R**esource

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Agenda

- eSTAR description and information regarding its use
- eSTAR tips based on questions received
- Timeline and plans
- Pilot with Health Canada and international harmonization

eSTAR Description and Use Information

eSTAR (electronic Submission Template And Resource): A dynamic PDF submission template used by medical device applicants to prepare a medical device submission. It contains automation, guides, integrated databases, and integrated policies and procedures in a single package to guide the applicant through the process of preparing a comprehensive medical device submission.

Questions and content mirror the complementary Smart Template used by reviewers, and includes content from multiple International Medical Device Regulators Forum (IMDRF) documents.

880 nIVD and IVD eSTARs received as of April 3, 2023

- 401 authorized for marketing
- 20 not authorized for marketing

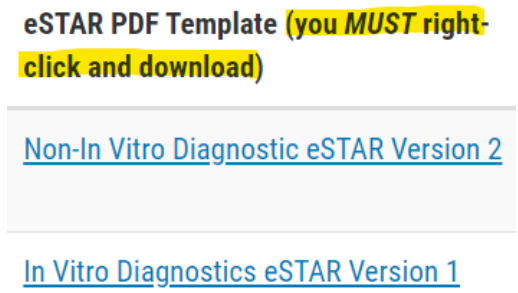
eSTAR Description and Use Information

Download eSTAR (it is the top hit when you Google “fda estar”):

- https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program/

Right-click and download the eSTAR PDF

- Web browsers can’t open dynamic PDFs like From 3514 the IFU form, and eSTAR

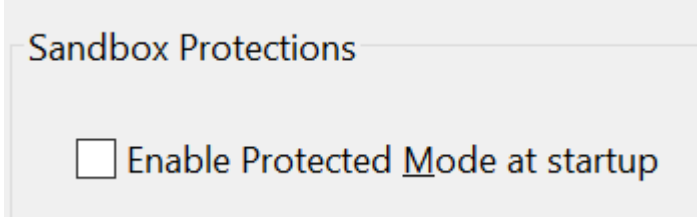


Refer to Lili Duan’s YouTube presentation regarding eSTAR use

- https://www.youtube.com/watch?v=9t74xtVNoDw&t=18140s
- Use the CDRH Portal instead: https://ccp-aws.fda.gov/

Windows Adobe Acrobat Pro slowness bug:

- Uncheck the checkbox under: Edit → Preferences → Security (Enhanced) → Enable Protected Mode at startup
- Contact DICE@fda.hhs.gov if you still encounter slowness



eSTAR Tips: FAQ and Versioning

FAQ

Q: Where can I send questions, feedback, and/or bug reports?
A: For technical issues or bug reports please email eSubPilot@fda.hhs.gov.
For regulatory process or content questions please email:
USFDA: DICE@fda.hhs.gov
Health Canada: meddevices-instrumentsmed@hc-sc.gc.ca

Q: When I click on a bookmark, the view jumps to the beginning of eSTAR. Why did this happen?
A: The bookmarked section is not applicable based on your submission choices and therefore should be ignored.

Q: Is there an attachment type or size restriction?
A: eSTAR will prevent unacceptable attachment types from being added. If your eSTAR is greater than 1GB, file

Version History

A major version update will consist of policy changes, regulatory changes, or major changes to the template and will be denoted by a major version number increment (e.g., 1.2 to 2.0). A minor version update will consist of other changes and will be denoted by a minor version number increment (e.g., 1.2 to 1.3). eSTARs updated with policy or regulatory changes will be made available before the implementation date of those changes, and the previous eSTAR will be removed on the implementation date. **Be sure you submit using the major version that is currently implemented, otherwise you may receive additional information requests related to the changes.**

Version History

2.2 (2023-01-10): FDA PMA and Health Canada content finalized, disabled for all but pilot participants.

eSTAR Tips: Additional Information

Help Text for Application Sub-Type Question:

"New Application/Submission" should be chosen if the application/submission is new.

When visible, the "Change to Application/Submission" option should be chosen if the submission is requesting a change to the content of an approved/authorized application, and the change requires a regulatory review according to the receiving jurisdiction.

"Additional Information" should be chosen when submitting additional information for an application/submission currently under review.

Once you receive an email that your eSTAR passed user fee validation, your original submission is grandfathered in to that eSTAR version. You should always use the eSTAR with your latest information when responding to an Additional Information request. For example, if you already modified your original eSTAR when responding to an Additional Information request and later you receive a second Additional Information request, you should modify the eSTAR you submitted in response to the first Additional Information request.

When you indicate “Additional Information”:

When submitting a response to an Additional Information request, you can either:

1) provide such responses in the section "Additional Information Response" near the end of eSTAR. This means you can update the original eSTAR sent to FDA without transferring content to a newer eSTAR, or

2) provide responses and attachments as an eCopy (i.e., an updated eSTAR would not be included in your response).

If the reviewer used interactive review via phone or email, please reply to the reviewer via email with the requested attachments and additional information.

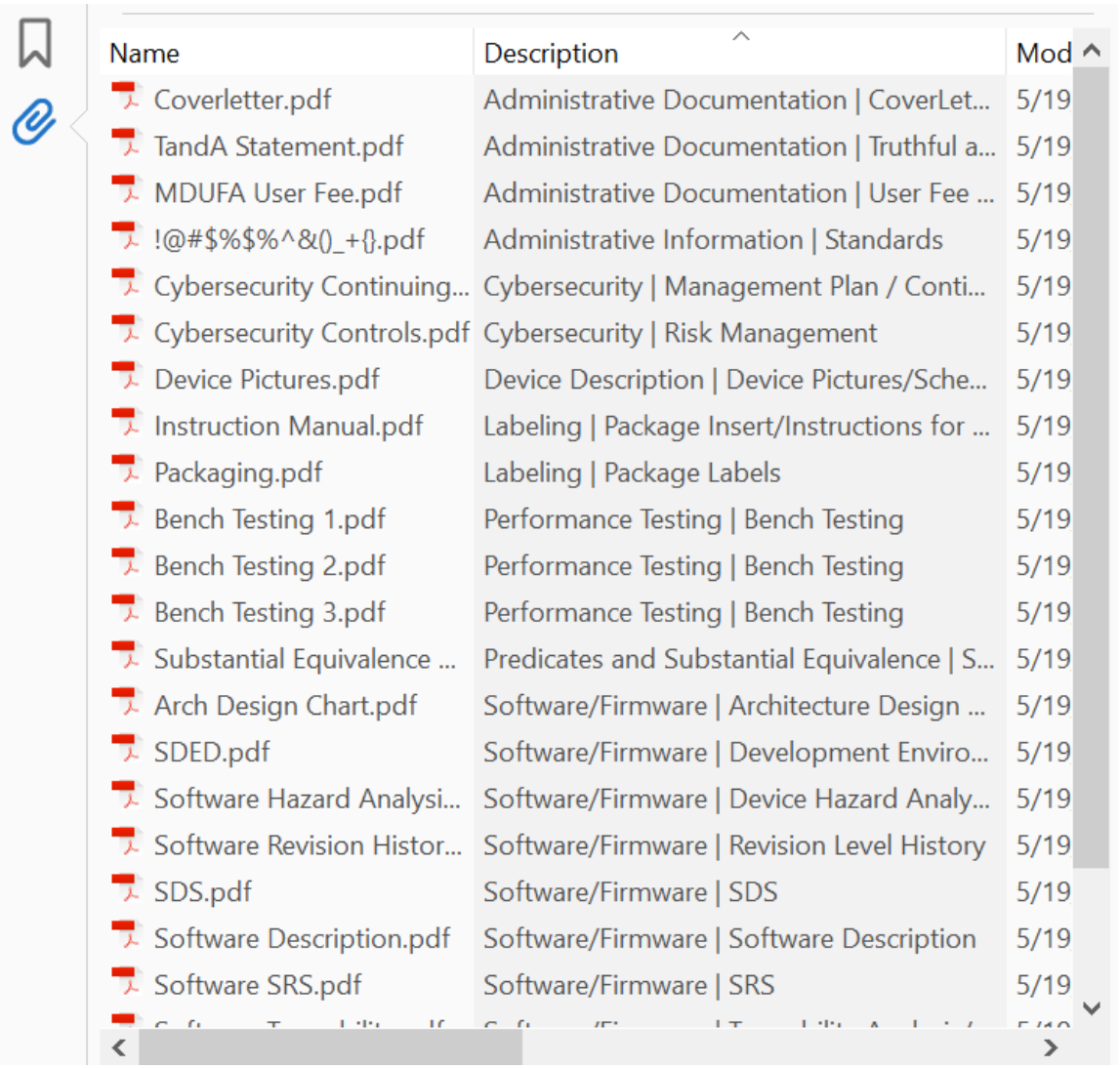
If you are providing additional information that is not in response to an Additional Information request, please indicate this in the Additional Information section near the end of eSTAR.

Text in “Additional Information” section:

Changes that are necessary to resolve deficiencies should be made in the respective section. If attachments need to be updated, remove the old attachments and replace them with the new attachments.

eSTAR Tips: Attachments

Attachment Pane in Adobe Acrobat Pro:



Name	Description	Mod
Coverletter.pdf	Administrative Documentation | CoverLet...	5/19
TandA Statement.pdf	Administrative Documentation | Truthful a...	5/19
MDUFA User Fee.pdf	Administrative Documentation | User Fee ...	5/19
!@#$%$%^&()_+{}.pdf	Administrative Information | Standards	5/19
Cybersecurity Continuing...	Cybersecurity | Management Plan / Conti...	5/19
Cybersecurity Controls.pdf	Cybersecurity | Risk Management	5/19
Device Pictures.pdf	Device Description | Device Pictures/Sche...	5/19
Instruction Manual.pdf	Labeling | Package Insert/Instructions for ...	5/19
Packaging.pdf	Labeling | Package Labels	5/19
Bench Testing 1.pdf	Performance Testing | Bench Testing	5/19
Bench Testing 2.pdf	Performance Testing | Bench Testing	5/19
Bench Testing 3.pdf	Performance Testing | Bench Testing	5/19
Substantial Equivalence ...	Predicates and Substantial Equivalence | S...	5/19
Arch Design Chart.pdf	Software/Firmware | Architecture Design ...	5/19
SDED.pdf	Software/Firmware | Development Enviro...	5/19
Software Hazard Analysi...	Software/Firmware | Device Hazard Analy...	5/19
Software Revision Histor...	Software/Firmware | Revision Level History	5/19
SDS.pdf	Software/Firmware | SDS	5/19
Software Description.pdf	Software/Firmware | Software Description	5/19
Software SRS.pdf	Software/Firmware | SRS	5/19

eSTAR accepts nearly every attachment type:

The attachment "Updates to SMART for Publication of EMC Guidance v2.zip" is not an acceptable attachment type.

Please do not attach the following file types in eSTAR, since these file types cannot be opened in or saved from a PDF form:
- compressed/archived file types (e.g., .zip)
- macro-enabled documents (e.g., .docm, .xlsm)
- binary files or executables (e.g., .exe)

Please combine similar documents where possible to reduce the number of attachments. Combining PDFs is possible with Adobe Acrobat Pro by choosing "Tools" then "Combine Files."

If you must submit any of these file types in an eSTAR, please email eSubPilot@fda.hhs.gov for help.

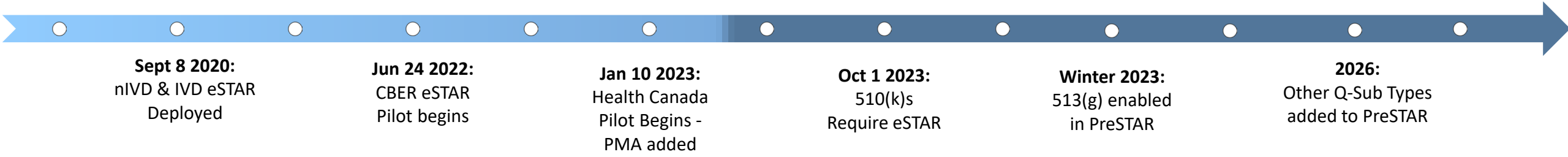
Don’t delete or add with the attachment pane:

The following attachments were added with the "Add Attachment" buttons but then manually deleted from the eSTAR Attachment Pane (i.e., the "Delete Attachment" buttons were not used).

Please click the "Delete Attachment" button next to each of these attachments (use Edit->Find to find each) and then, if you would like to re-add any, click the "Add Attachment" button to re-add each to this eSTAR. If the eSTAR was already signed, the original signee should right-click and clear all their signatures first (e.g., in the T&A Statement, and/or in the Declaration of Conformity) before you click "Delete Attachment" for each missing attachment.

Biocompatibility Test Reports.pdf

Timeline and Plans



PDF

nIVD eSTAR

510(k) [Trad, Abbrev, Spec]

De Novo

PMA [Orig, PTS, 180D, RT]*

HDE (future)

PDF

IVD eSTAR

510(k) [Trad, Abbrev, Spec]

De Novo

PMA [Orig, PTS, 180D, RT]*

HDE (future)

PDF

PreSTAR

513(g)

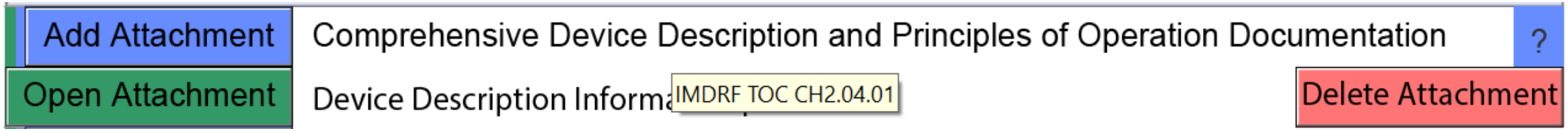
IDE*

Q-Sub

* May not include Reports, which may be more efficiently handled via webforms or standalone non-dynamic forms

International Pilot with Health Canada

- Testing HC Class III, IV, and FDA PMA submission types, as well as multi-region use
- IMDRF Table of Contents documents N9 and N13, as well as N19, built into eSTAR
  - Hover text indicates the subchapter to which each attachment question corresponds



  - Regional Content questions and help text change based on chosen region
  - Common Content (globally harmonized content) doesn't change between jurisdictions

https://www.imdrf.org/working-groups/regulated-product-submission

International Harmonization

IMDRF ToC documents N9 and N13 for nIVD and IVD updated

- Posted for public comment on 14 February 2023
- Increased international harmonization (e.g. Chapter 6)
- Harmonization helps define a proper balance in regulatory burden

Regional divergencies:

- Increase regional requirements and unnecessary work
- Create more complexity and adds costs to maintain
- Decrease the possibility of a harmonized template

Promote harmonization and discourage regional divergencies

- Increased adherence to international standards
- Increased adherence to IMDRF documents
- Ensuring the proper level of regulatory burden should be the goal of all regulators

https://www.imdrf.org/working-groups/regulated-product-submission

Questions/Feedback During MedCon: I'm available to talk, take feedback, and address questions in person anytime.

Questions/Feedback After MedCon: dice@fda.hhs.gov or eSubpilot@fda.hhs.gov

eSTAR Program information is located at (Google "fda estar"):
https://www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program