

eSTAR: CDRH's PDF Template for Premarket Submissions

FDA Small Business Regulatory Education for Industry (REdI)

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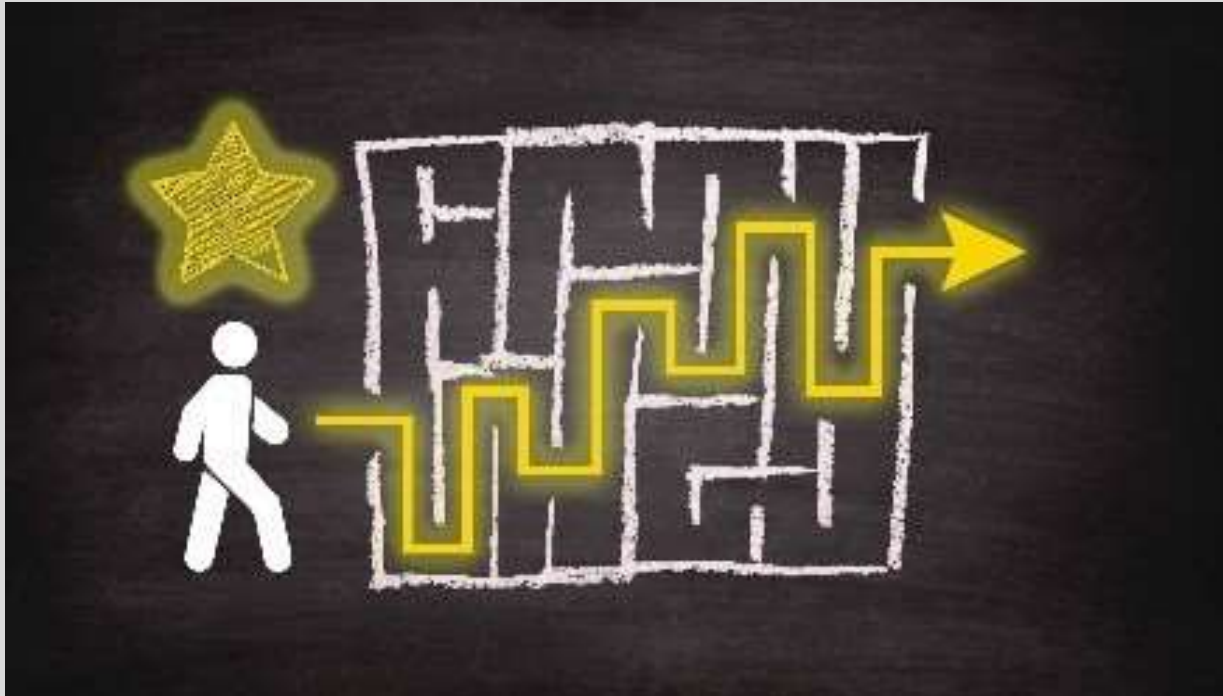
Office of Regulatory Programs (ORP)

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

U.S. Food and Drug Administration

electronic Submission Template And Resource (eSTAR)



Learning Objectives

- Explain what is eSTAR
- Show how to download eSTAR
- Describe how to enter data into eSTAR
- Show how to submit eSTAR to FDA
- Explain the eSTAR review timeline

What is eSTAR?

electronic Submission Template And Resource

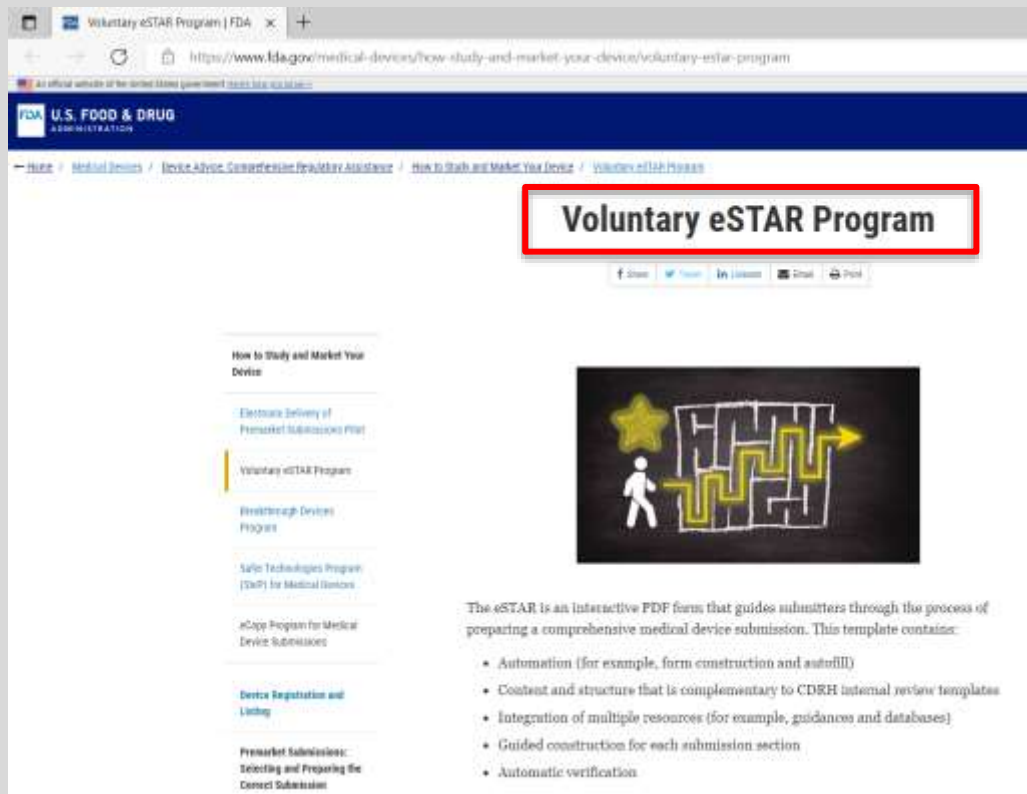
- Dynamic PDF submission template
- Contains resources for submission preparation

Why eSTAR?

- Enhances submission quality
- Improves CDRH's premarket review efficiency

How to Download eSTAR

Download eSTAR?



The screenshot shows the FDA's Voluntary eSTAR Program webpage. The title "Voluntary eSTAR Program" is highlighted with a red box. The page includes a sidebar with navigation links and a main content area with a graphic and descriptive text.

Voluntary eSTAR Program

How to Study and Market Your Device

- Electronic Delivery of Premarket Submissions Pilot
- Voluntary eSTAR Program**
- Breakthrough Devices Program
- Safe Technologies Program (STP) for Medical Devices
- eCopy Program for Medical Device Submitters

Device Registration and Listing

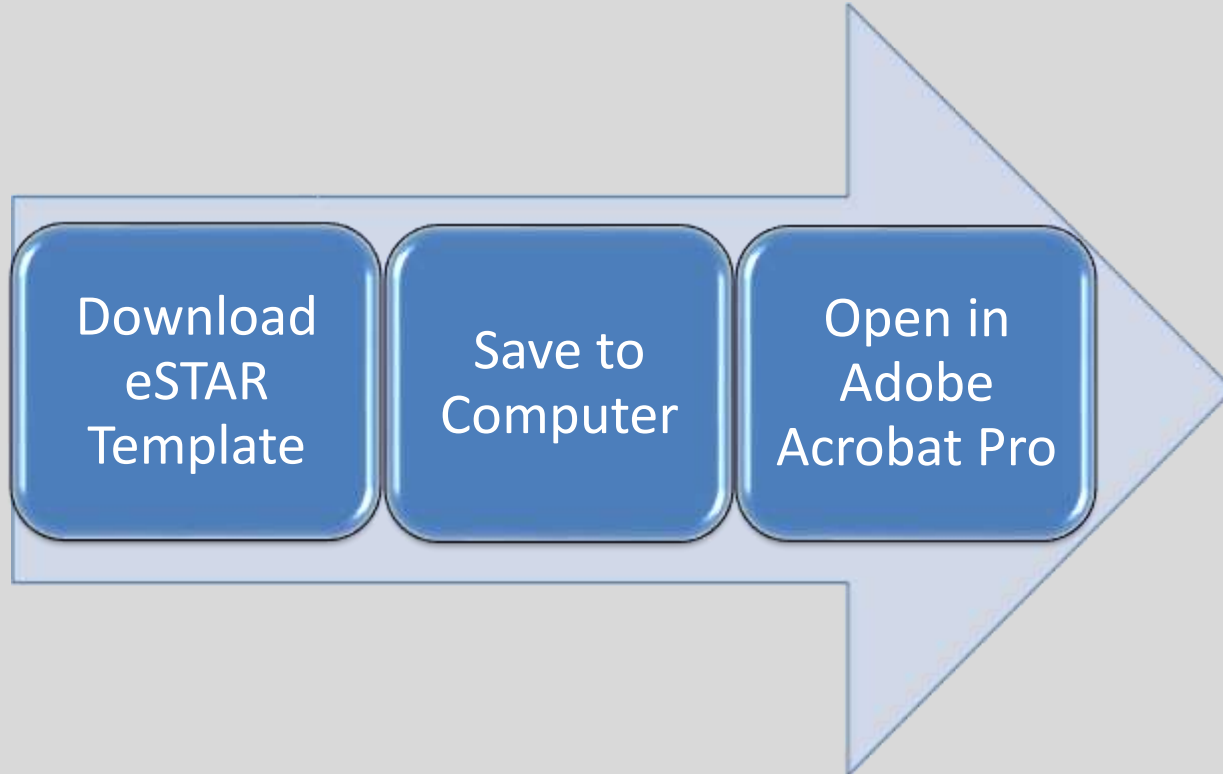
Premarket Submissions: Selecting and Preparing the Correct Submission

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

- Automation (for example, form construction and autofill)
- Content and structure that is complementary to CDRH internal review templates
- Integration of multiple resources (for example, guidances and databases)
- Guided construction for each submission section
- Automatic verification

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

Download eSTAR?



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

How to Enter Data into eSTAR

Tip #1 for eSTAR Data Entry

- **DO**
 - Use Adobe Acrobat Pro
- **DON'T**
 - Don't use web browsers
 - Don't use Adobe Reader

Tip #2 for eSTAR Data Entry

Read and follow instructions
on page 1 of eSTAR

STATUS: eSTAR INCOMPLETE

This eSTAR is incomplete, and will be treated as an improperly prepared eCopy and not reviewed. You will be notified by a standard eCopy Hold email.

Introduction

This template is intended for use in both constructing a non-*in vitro* diagnostic medical device premarket application/ submission, and in being a resource of non-*in vitro* medical device premarket regulations. It contains regulatory information pulled from both [International Medical Device Regulators Forum \(IMDRF\)](#) documents, as well as regulatory documents (e.g., guidance documents).

This template is only used for constructing, not submitting, your application or submission. Directions at the end of the template provide instructions on how to submit it.

Key

A **Red Bar** indicates the associated required question, or a required question in that section, wasn't answered.

A **Green Bar** indicates the associated required question, or all required questions in that section, was answered.

A **Grey Bar** indicates the associated question is optional. Green and Grey Bars act as left borders when present.

Blue Help Text Buttons when clicked display regulatory information pertaining to the question or section heading they immediately follow. Assistive Technology (AT) users including text to speech, will hear "Help Text Button." If activated, the help text windows will open, and can be closed by tabbing to the OK key and pressing return.

Hover Text Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an [IMDRF](#) harmonized section, the hover text will display the chapter number of the [IMDRF Table of Contents](#).

FAQ

Q: Where can I send questions, feedback, and/or bug reports?

A: Send questions and feedback to DICE@fda.hhs.gov and bug reports to eSubPilot@fda.hhs.gov.

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.

Understand eSTAR Before Data Entry

How to Enter Data into eSTAR



Application Purpose


-  ☒ Premarket Notification 510(k)
☐ De Novo
☐ Premarket Application PMA

?

Show Application Introduction

Application Type



(Choose Abbreviated if you are submitting a Safety & Performance based submission.)

-  ☒ Traditional
☐ Abbreviated
☐ Special

Show Application Type Introduction

Application Sub-Type

(Modify the Original eSTAR when responding to Additional Information requests. See Help Text)

-  ☒ New Application/Submission
 ☐ Additional Information

?

How to Enter Data into eSTAR

Cover Letter / Letters of Reference

Add Attachment

Attach your Cover Letter

Add attachment

?

Open Attachment

Cover Letter.docx

Delete Attachment

Add Attachment

Attach any Letters of Reference

?

Applicant Information

?

Contact

Title

Mr.

▼

Last Name

Smith

Enter Text

First Name

John

Email

John.Smith@ABC.com

Phone Number

(123) 456-7890

Occupation Title

Regulatory Affairs Specialist

How to Enter Data into eSTAR

Is the device life-supporting or life-sustaining?	No	?
Are there any direct or indirect tissue contacting components?	No	?
Does the device use software/firmware?	Yes	?
<ul style="list-style-type: none"> Is the device, or does it contain, digital health technology? 	Yes	?
<ul style="list-style-type: none"> Please check the attributes that are applicable to your device. 	<input type="checkbox"/> Cloud Communication <input checked="" type="checkbox"/> Network connection (active or not) <input checked="" type="checkbox"/> Wireless communication in any form <input type="checkbox"/> USB/serial ports/removable media <input checked="" type="checkbox"/> Software upgrades (this includes patches) <input type="checkbox"/> None of the above	?

Choose from
drop down lists

Click Checkbox

Tip #3 for eSTAR Data Entry

Fill in the template from beginning to end

Show Application Introduction

Application Type

(Choose Abbreviated if you are submitting a Safety & Performance based submission.)



☒ Traditional

☐ Abbreviated



☐ Special

How to Enter Data into eSTAR



General Device Characteristics		
Is the device life-supporting or life-sustaining?	No	?
Are there any direct or indirect tissue contacting components?	No	?
Does the device use software/firmware?	Yes	?
• Is the device, or does it contain, digital health technology?	Yes	?
• Please check the attributes that are applicable to your device.	<input type="checkbox"/> Cloud Communication <input checked="" type="checkbox"/> Network connection (active or not) <input checked="" type="checkbox"/> Wireless communication in any form <input type="checkbox"/> USB/serial ports/removable media <input checked="" type="checkbox"/> Software upgrades (this includes patches) <input type="checkbox"/> None of the above	?
Is the device or a component packaged as sterile?	No	?
The device/system uses or is... (choose all that apply)	<input checked="" type="checkbox"/> a single use device(s), non-sterile or packaged as sterile <input type="checkbox"/> a single use device(s), terminal/end user sterilized <input type="checkbox"/> a reusable single patient use device(s) <input type="checkbox"/> a reusable multi-patient use device(s)	?
Is the device electrical (battery or wall powered)?	Yes, it is mains powered only.	?
• Does the device/system include wireless technology?	Yes	?

- Biocompatibility
- Software/firmware
- Cybersecurity
- Sterility
- Reprocessing
- EMC
- Wireless

Tip #4 for eSTAR Data Entry

Be sure the eSTAR status changes to
“eSTAR COMPLETE” once you finish



electronic Submission Template And Resource (eSTAR)

For non-In Vitro Diagnostic Medical Devices

Version 1.2 (2022-03-11)

STATUS: eSTAR INCOMPLETE

This eSTAR is incomplete, and will be treated as an improperly prepared eCopy and not reviewed. You will be notified by a standard eCopy Hold email.



electronic Submission Template And Resource (eSTAR)

For non-In Vitro Diagnostic Medical Devices

Version 1.2 (2022-03-11)

STATUS: eSTAR COMPLETE

How to Enter Data into eSTAR

Verification

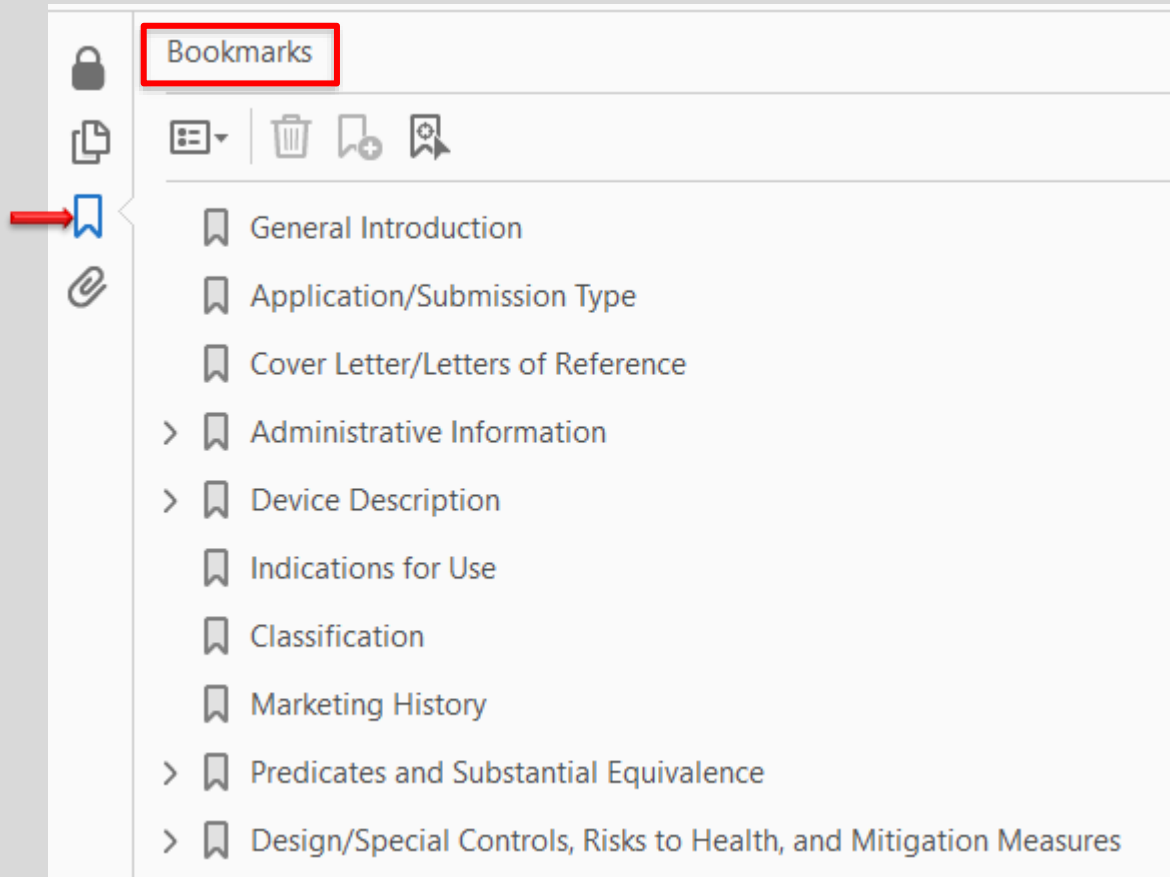
The following sections are complete:

Cover Letter / Letters of Reference
 Administrative Information
 Indications for Use
 Classification
 Predicates and Substantial Equivalence
 Biocompatibility
 Software/Firmware & Cybersecurity/Interoperability
 EMC, Wireless, Electrical, Mechanical, and Thermal Safety
 References
 Additional Information Response

The following sections are incomplete:

Application/Submission Type
 Device Description
 Labeling
 Reprocessing, Sterility, and Shelf-Life
 Performance Testing
 Administrative Documentation

Use Bookmarks as Table of Contents



How to Submit eSTAR to FDA

How to Submit eSTAR

Delivery Directions

You only need to [mail this eSTAR PDF](#) with embedded attachments on a CD, DVD, or USB Drive (SD cards are not accepted) with a printed cover letter to our Document Control Center. As an example, an acceptable submission package would consist of a printed cover letter accompanying a USB drive with only this eSTAR PDF on it. **The submission does not need to be eCopy compliant, nor does the eSTAR PDF need to be zipped and placed in a MISC FILES folder.**



How to Submit Responses to FDA's Additional Information Requests

- Either eCOPY or eSTAR is acceptable
- If using eSTAR:

Show Application Type Introduction	
<p>Application Sub-Type</p> <p><i>(Modify the Original eSTAR when responding to Additional Information requests. See Help Text)</i></p>	<p><input type="radio"/> New Application/Submission</p> <p><input checked="" type="radio"/> Additional Information</p>
<p>Please enter the parent application/submission number.</p>	<p>K220000</p>



Additional Information Response

Is this a response to an Additional Information request?

Yes

Additional Information

Changes that are necessary to resolve deficiencies should be made in the respective section. For example, if additional Sterilization information will be provided to resolve a deficiency, this documentation should be added to the Sterilization documentation that is already present. If attachments need to be updated, remove the old attachments and replace them with the new attachments (be sure to give new attachments a different name in comparison to the old attachments to ensure they are distinguished). Data that are typed in can also be modified. If you need to respond to subsequent Additional Information requests, you should replace the deficiencies below with those from the latest Additional Information request when responding. Although previously submitted data and attachments will remain in the FDA database, old data superseded by new data will not be considered the final data in our final review.

Please restate the deficiency to which you are responding. Begin the statement by the deficiency reference (e.g., 2(a)).



Provide your response to the deficiency. For multi-part deficiencies, respond separately to each (i.e., click the Add Response button for each part).



Add Response

Delete Response

How to submit Additional Information responses

eSTAR Review Timeline

eSTAR Review Timeline

- eSTAR review timeline same as eCOPY
- Within 15 days Technical Screening (TS) to verify:
 - responses are accurate and
 - at least one relevant attachment per attachment-type question

Knowledge Check

Which type(s) of premarket submission can be prepared using eSTAR now?

- ☐ 510(k)
- ☐ De Novo
- ☐ PMA

Knowledge Check

Which of the following types of attachments are NOT acceptable to eSTAR?

- ☐ compressed file (e.g., .zip)
- ☐ macro-enabled file (e.g., .docm)
- ☐ executable file (e.g., .exe)
- ☐ All of the above

Summary

- Dynamic PDF submission template for 510(k) and De Novo (*other submission types coming*)
- Mail the eSTAR PDF on a CD, DVD or USB Drive with printed cover letter to FDA
- Review timeline same as eCOPY

Questions

