eSTAR: CDRH's PDF Template for Premarket Submissions

October 19, 2023

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Learning Objectives

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

What is eSTAR?

electronic Submission Template And Resource

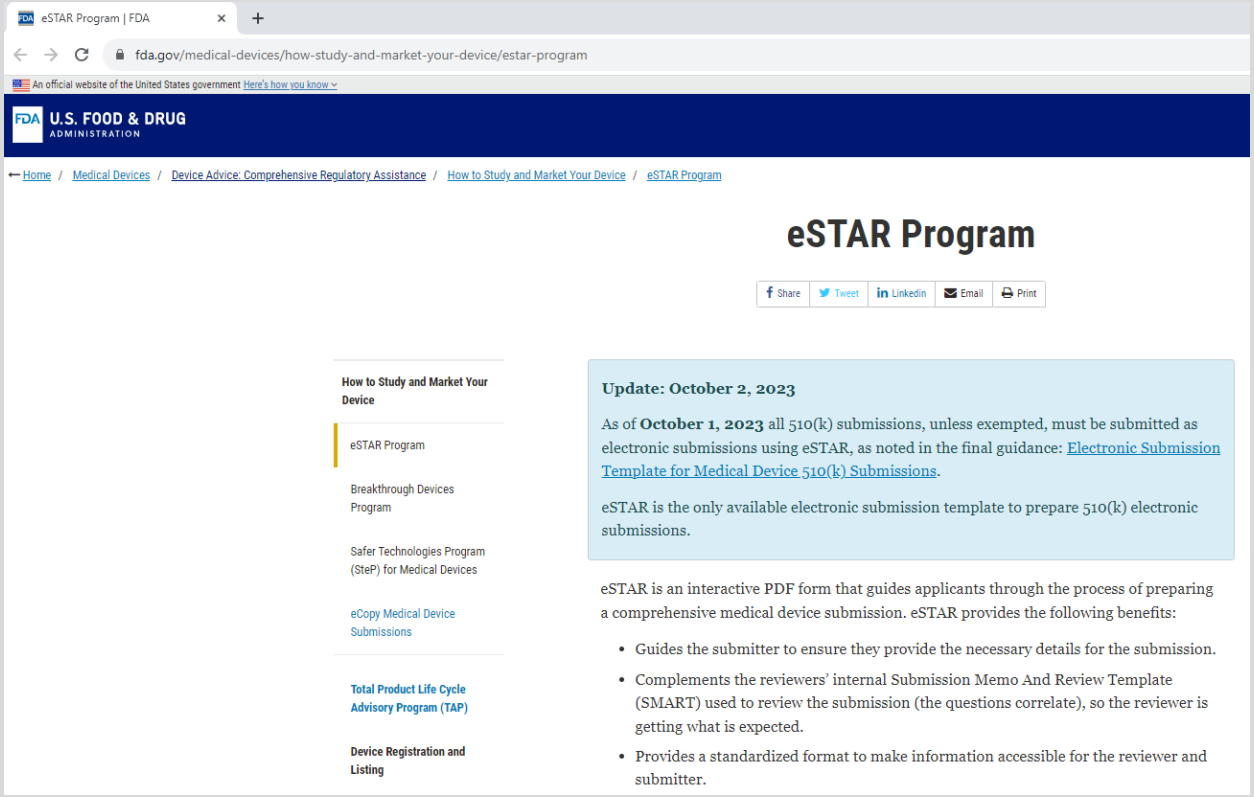
- Dynamic PDF submission template
- Contains resources for submission preparation

Why eSTAR?

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

How to Download eSTAR

Download eSTAR?



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

Download eSTAR?

Current eSTAR Versions[1]:

eSTAR PDF Template (you *MUST* right-click and download)	This eSTAR template may be used to submit to CDRH:	Content is approved for collection under OMB numbers[2]:
Non-In Vitro Diagnostic eSTAR Version 4	510(k) and De Novo medical device submissions for Non-In Vitro Diagnostic devices	0910-0120, 0910-0844
In Vitro Diagnostics eSTAR Version 4	510(k) and De Novo medical device submissions for In Vitro Diagnostic devices	0910-0120, 0910-0844
Early Submission Requests eSTAR (PreSTAR) Beta Version	Pre-Submissions (a type of Q-Submission) for Non-In Vitro and In Vitro Diagnostic devices.[3]	0910-0756

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

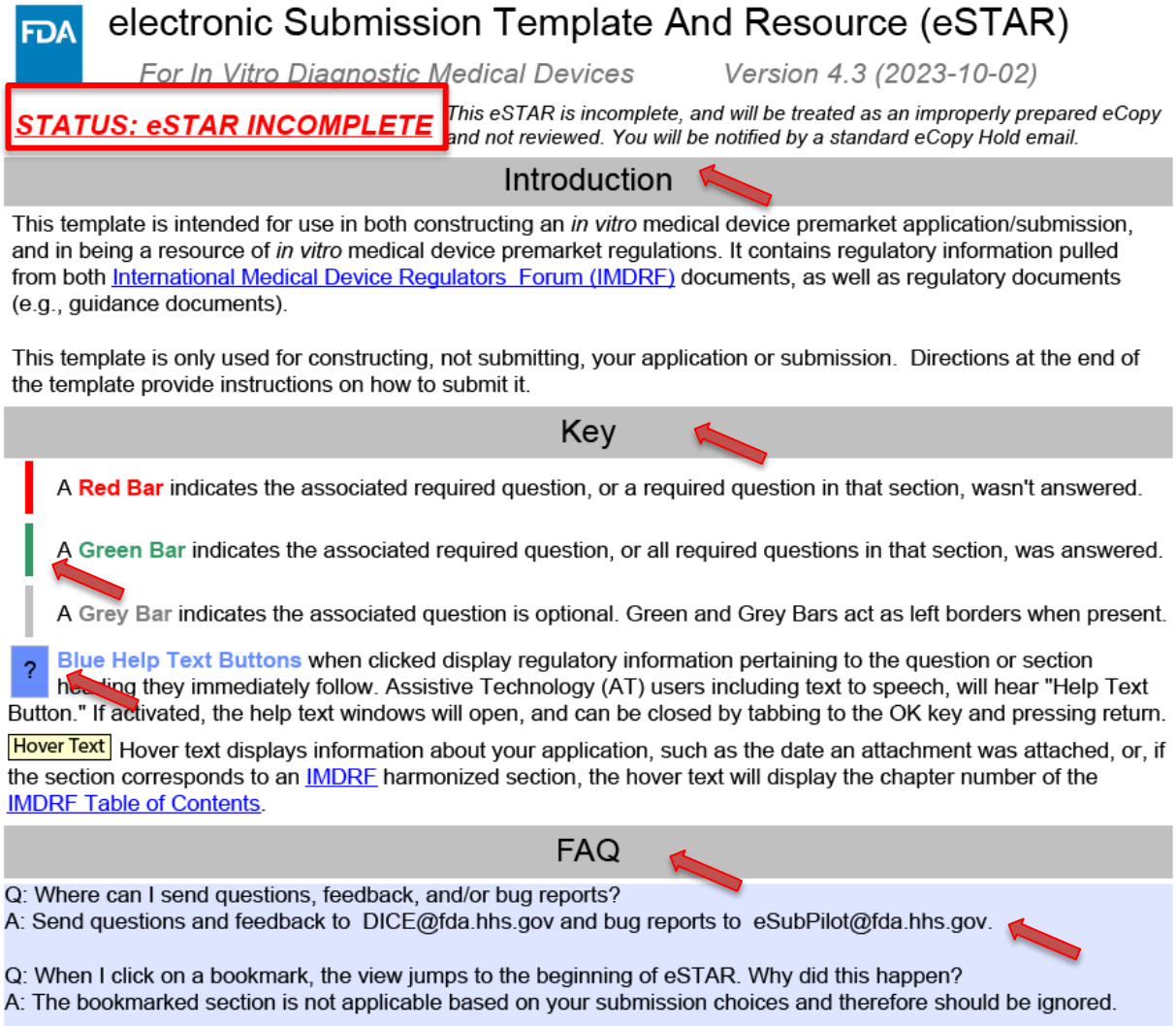
How to Enter Data into eSTAR

Tip #1 for eSTAR Data Entry

- DO
  - Use Adobe Acrobat Pro
  - May use FoxIt PDF Reader or PDF-XChange Editor
- DON’T
  - Don’t use web browsers
  - Don’t use Adobe Acrobat Reader

Tip #2 for eSTAR Data Entry

Read and follow instructions on page 1 of eSTAR



electronic Submission Template And Resource (eSTAR)

For In Vitro Diagnostic Medical Devices *Version 4.3 (2023-10-02)*

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 an *in vitro* medical device premarket application/submission, and in being a resource of *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.

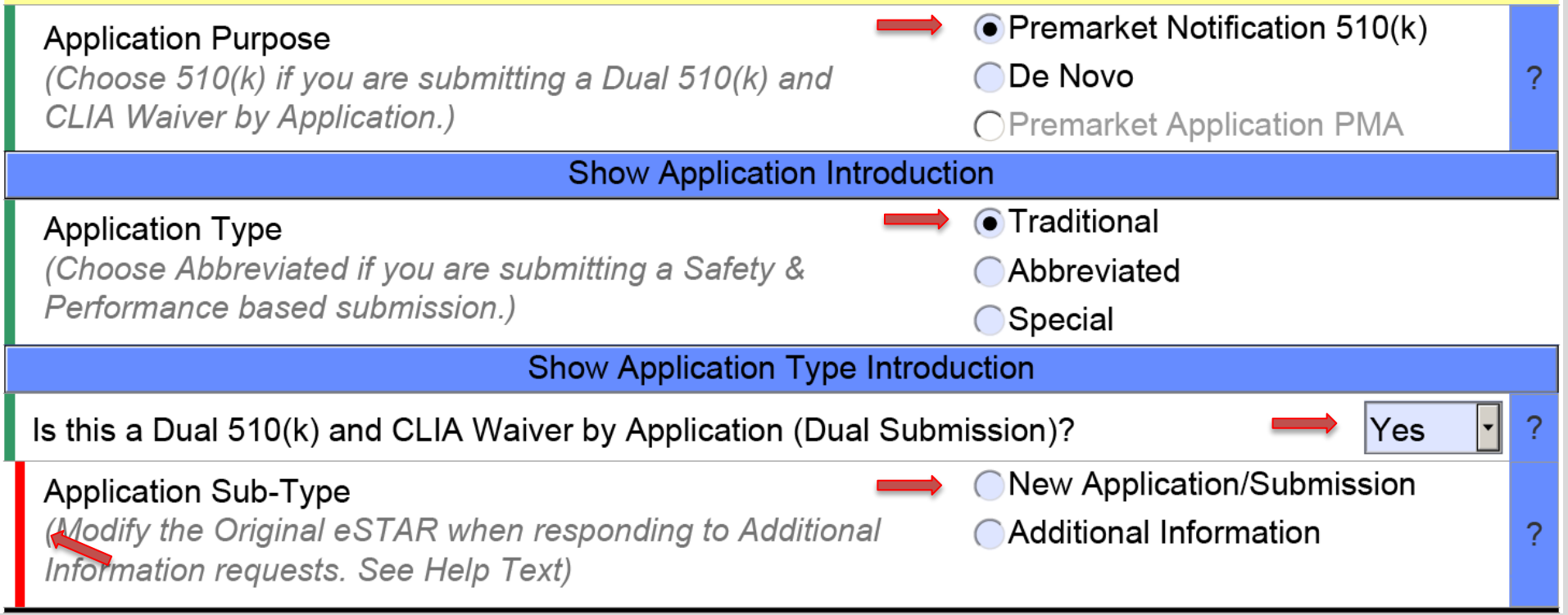
FAQ

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.

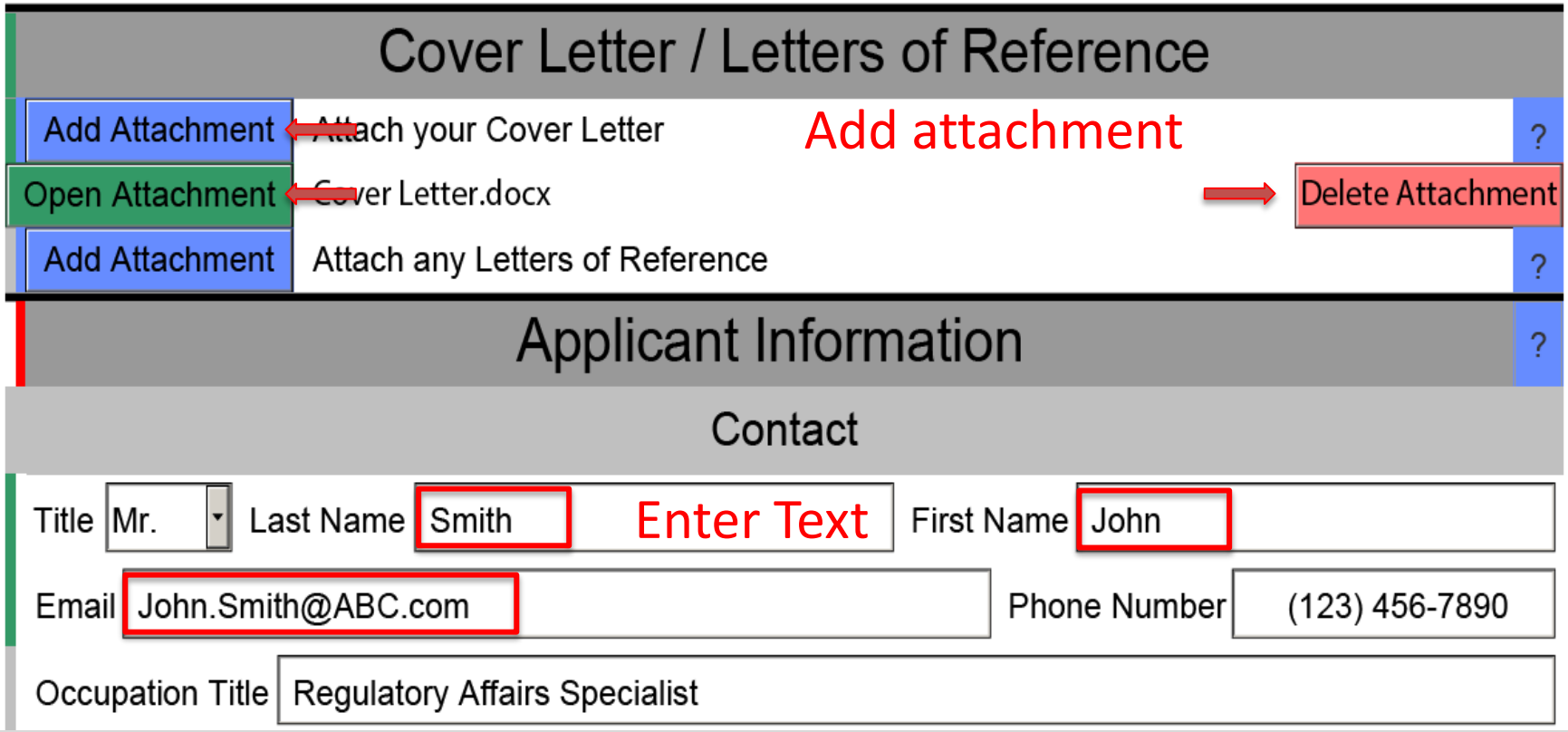
Q: When I click on a bookmark, the view jumps to the beginning of eSTAR. Why did this happen?
A: The bookmarked section is not applicable based on your submission choices and therefore should be ignored.

Understand eSTAR Before Data Entry

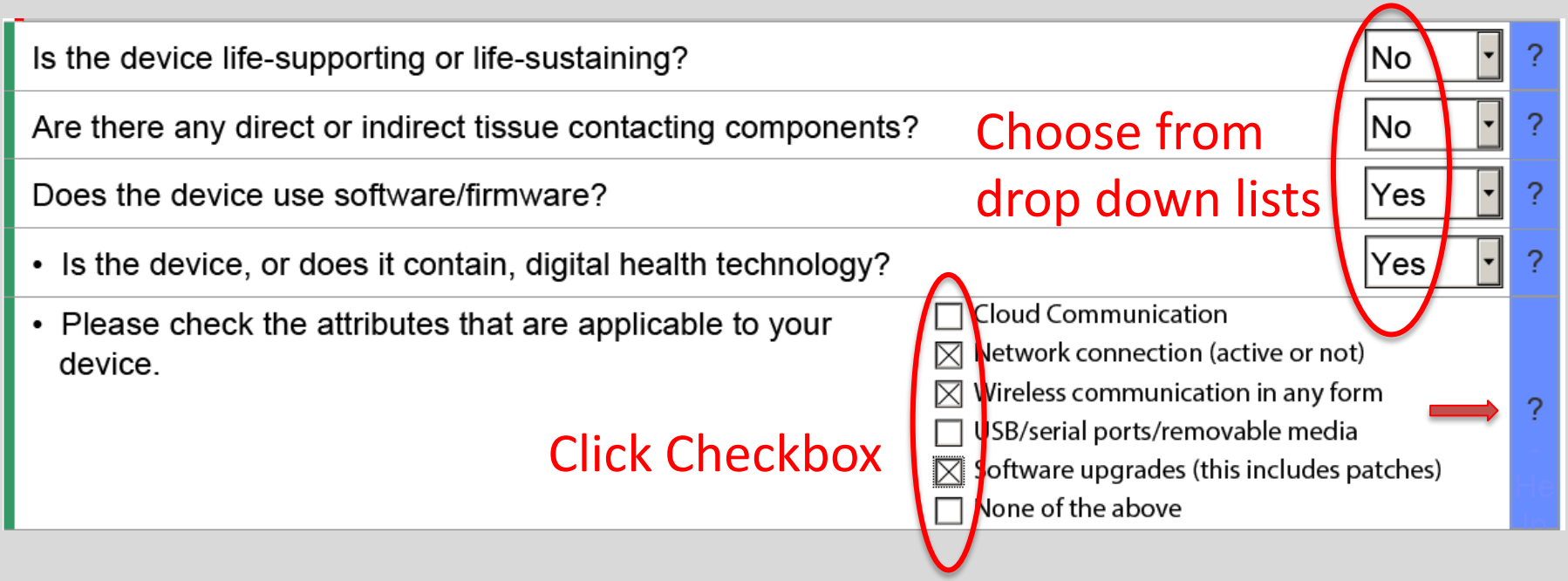
How to Enter Data into eSTAR



How to Enter Data into eSTAR

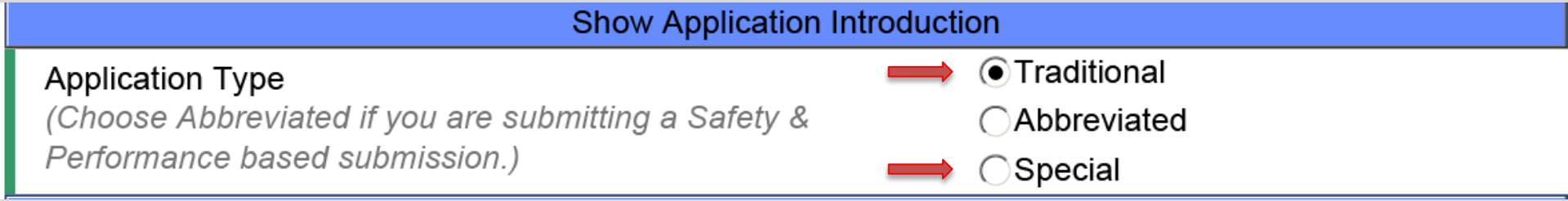


How to Enter Data into eSTAR

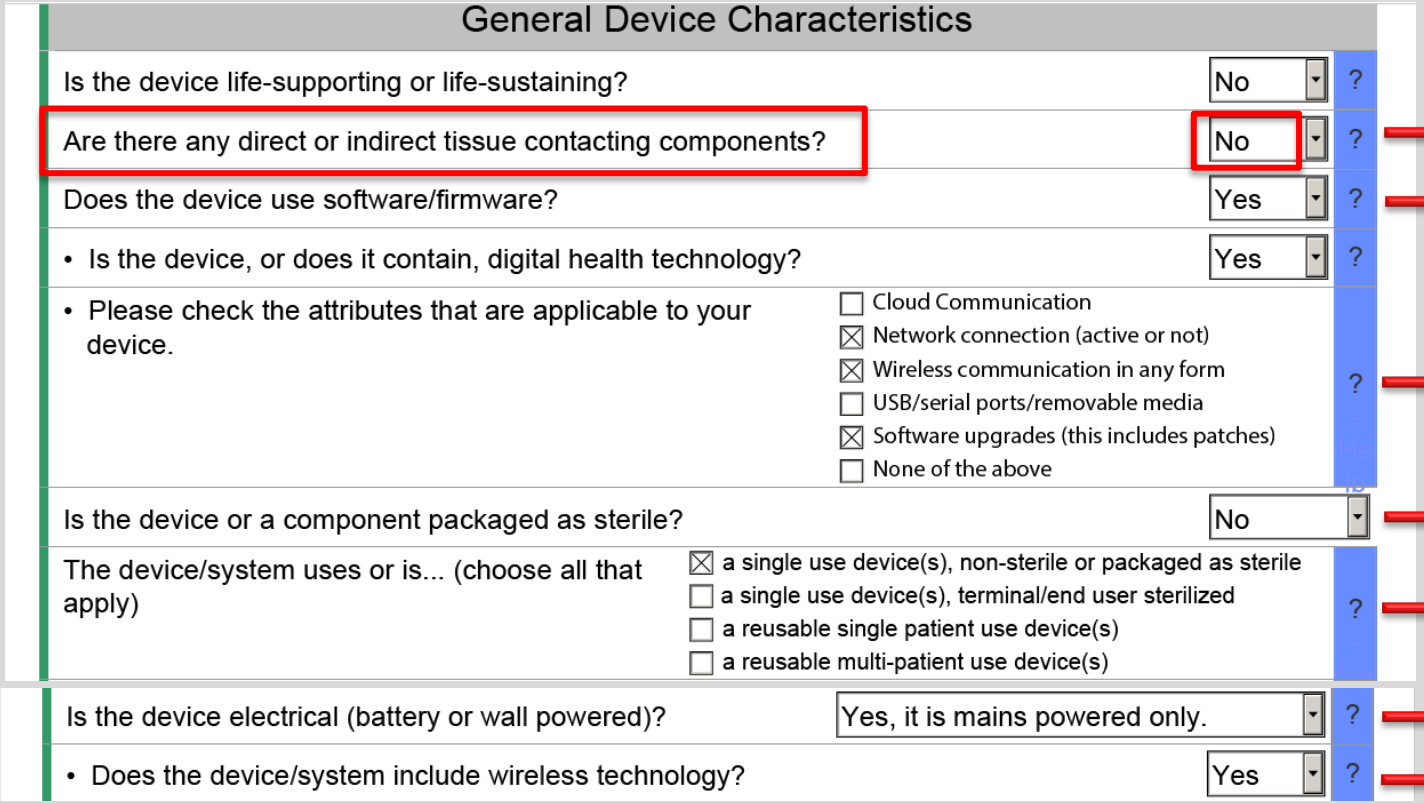


Tip #3 for eSTAR Data Entry

Fill in the template from beginning to end



How to Enter Data into eSTAR

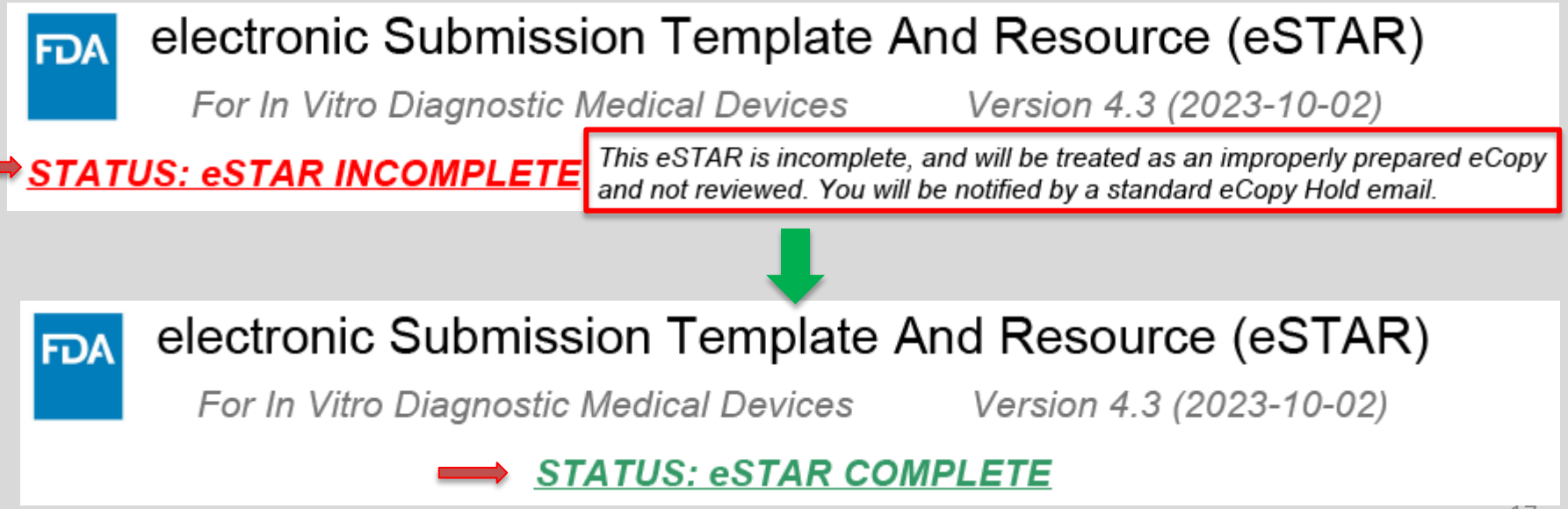


General Device Characteristics

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

Tip #4 for eSTAR Data Entry

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



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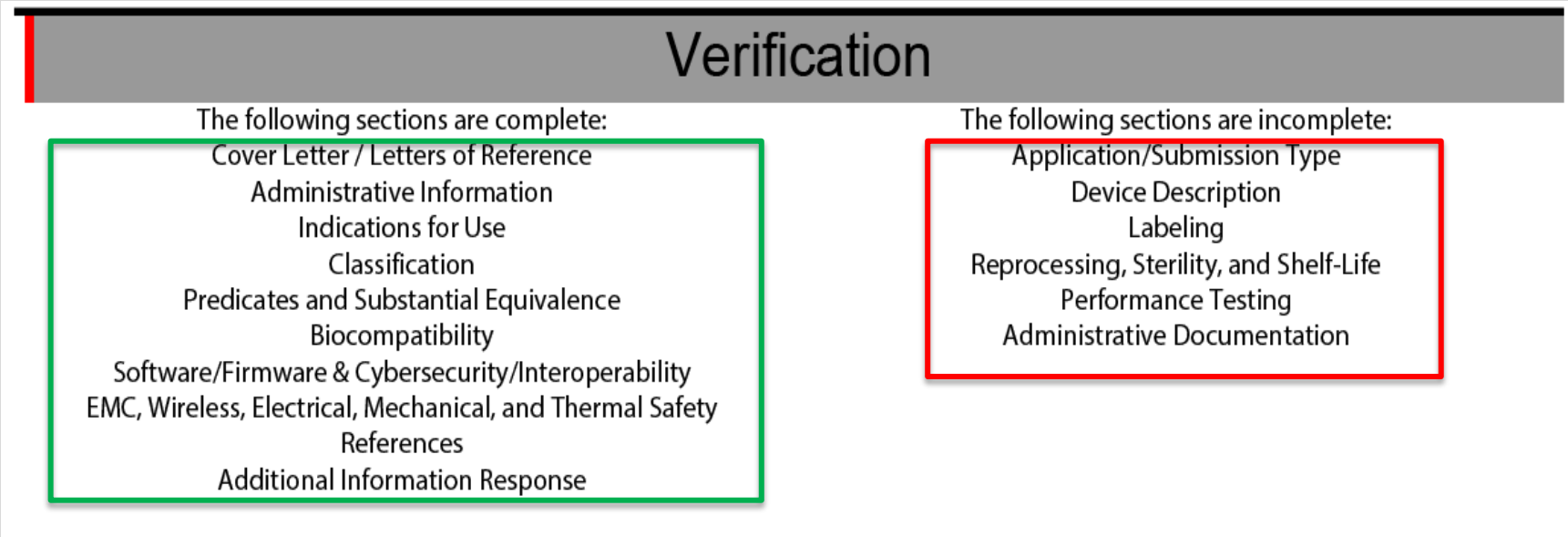
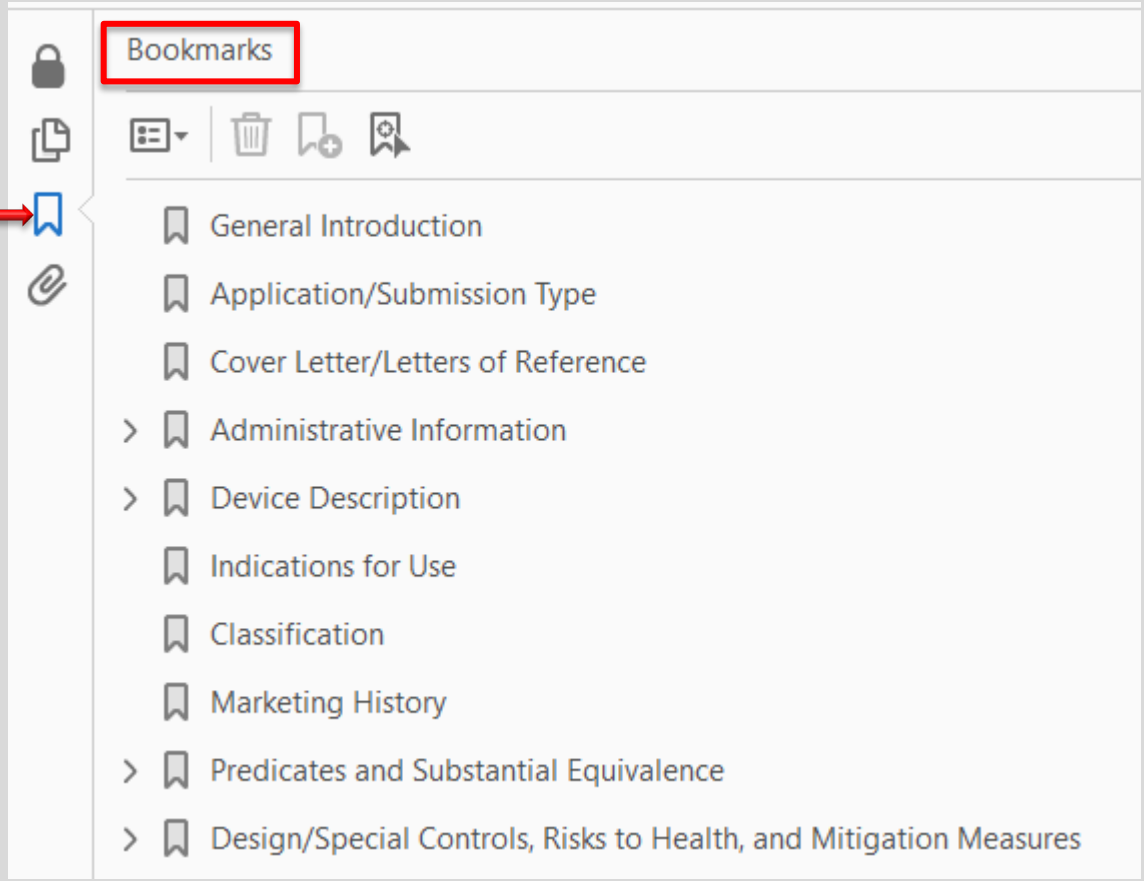


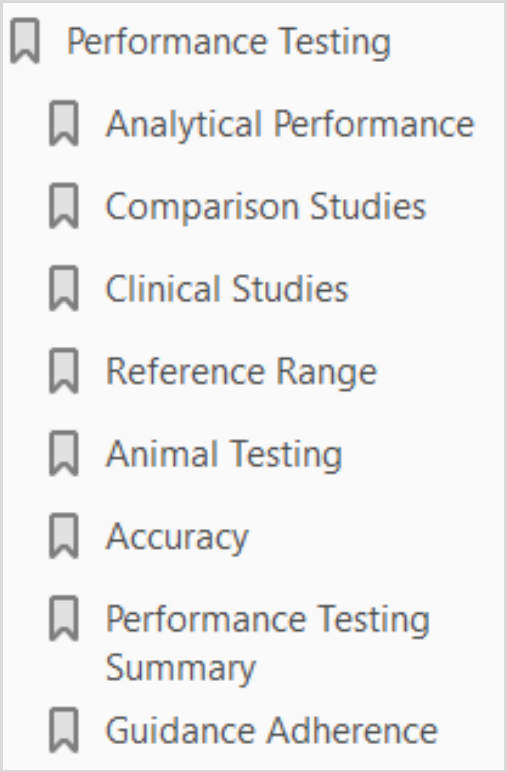
Use Bookmarks as Table of Contents



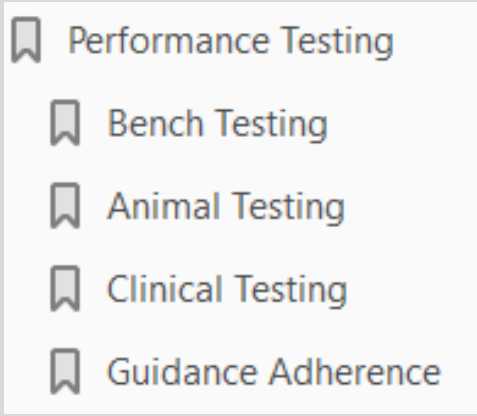
Unique Features in IVD eSTAR

- Dual 510(k)/CLIA Waiver Option
- Detailed Performance Testing List
- Labeling Requirements

Unique Features in IVD eSTAR



IVD
vs.
nIVD



How to Submit eSTAR to FDA

How to Submit eSTAR

Delivery Directions

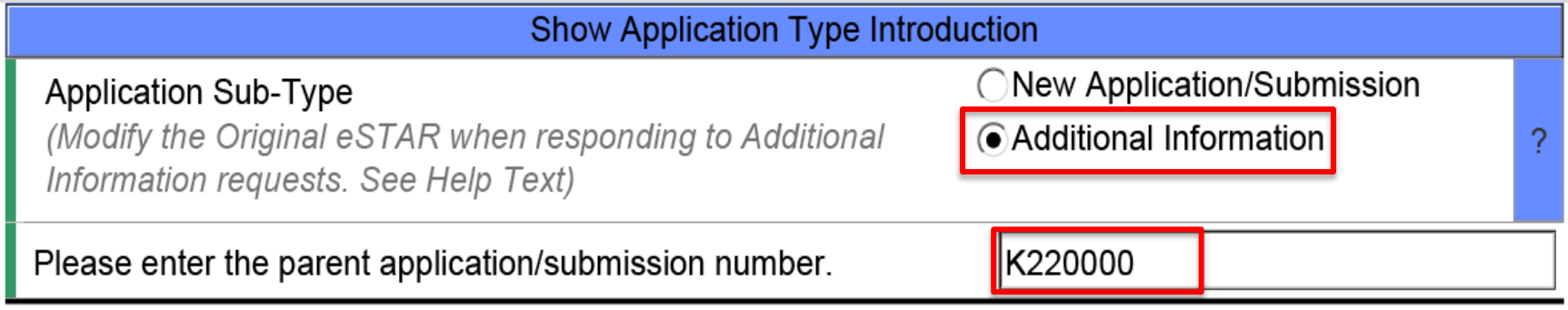
Please submit this eSTAR PDF for review using the CDRH Portal unless your medical device is regulated by the Center for Biologics Evaluation and Research (CBER) or is a combination product where CBER is the lead. You do not need to send any documentation in physical form using mail couriers.

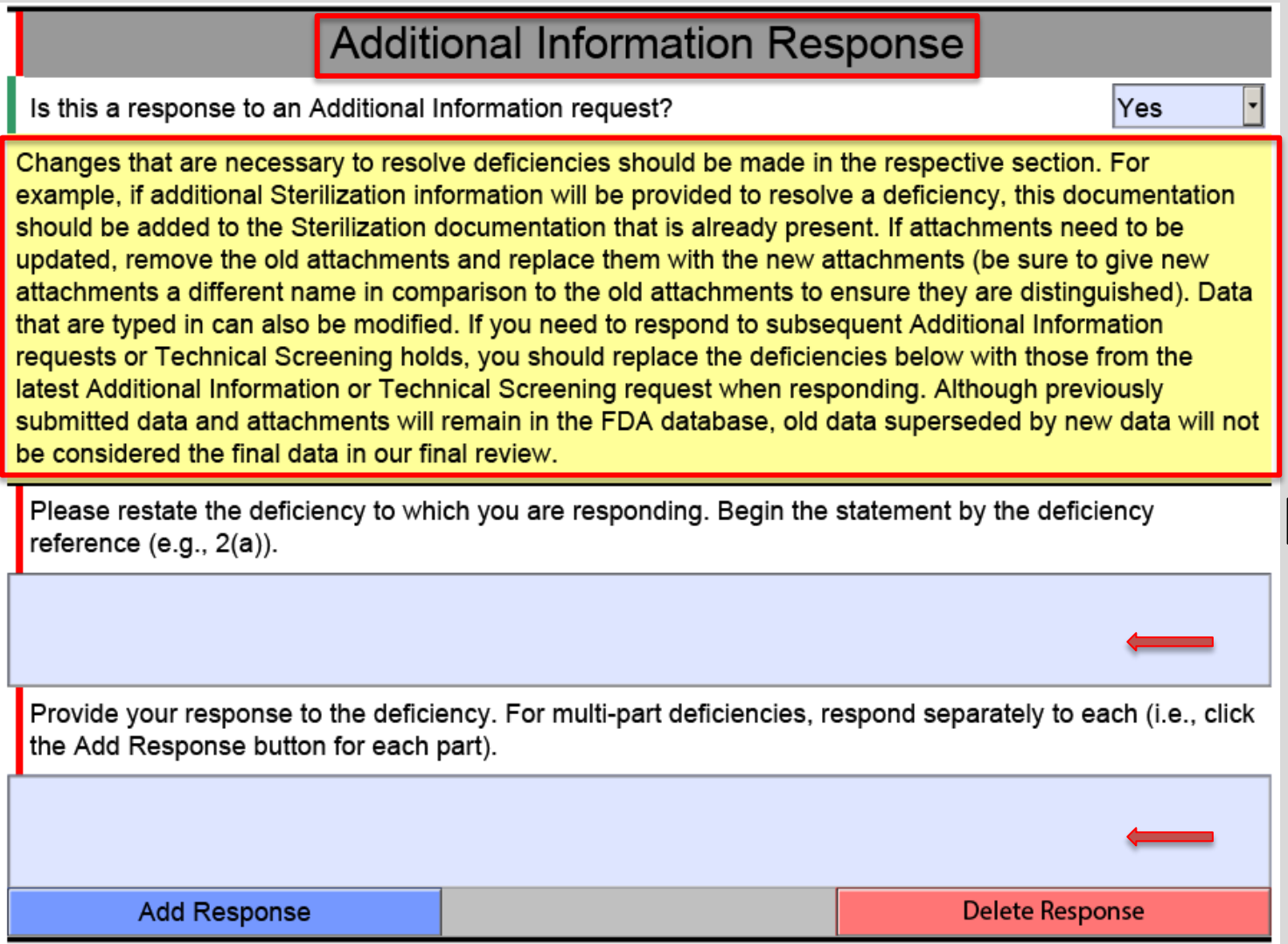
For CBER-regulated medical devices or for combination products where CBER is the lead, please refer to Regulatory Submissions in Electronic and Paper Format for CBER-Regulated Products for information on how to submit to CBER through the Electronic Submission Gateway.

https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal

How to Submit Responses to FDA's Additional Information Requests

- Either eCOPY (if original 510(k) was submitted before 10/1/2023) or eSTAR is acceptable
- If using eSTAR:





How to submit Additional Information (AI) 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
- ☑ Pre-submission

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
- Uploading directly to CDRH Portal
- Review timeline same as eCOPY

Questions