

# US FDA's Electronic Submission Template and Resource (eSTAR)

An evaluation of best practices and recommendations on utilizing eSTAR

The logo for Veeva MedTech, featuring a stylized white 'V' icon followed by the text 'veeva MedTech' in a white, sans-serif font.



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# Agenda

1 eSTAR Overview

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2 Evolution of eSTAR

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3 eSTAR Benefits

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4 Recommendations for using eSTAR

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5 The Future of eSTAR

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6 Q&A

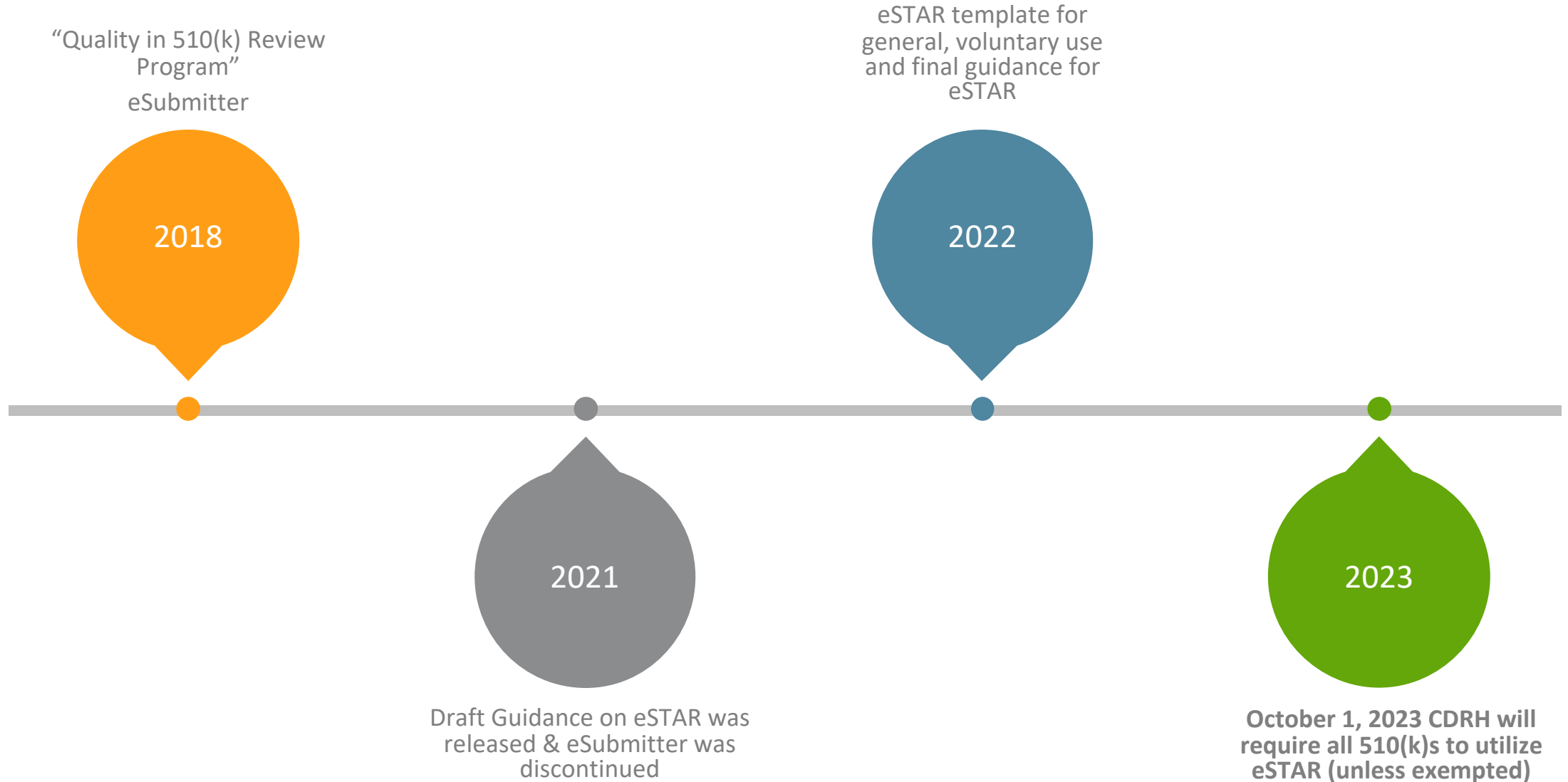


# eSTAR Overview

- “Electronic Submission Template and Resource” (eSTAR) is an interactive submission template created by FDA that will be the **ONLY** way to submit 510k(s) starting October 1, 2023 (unless exempt).
- eSTAR is free and available for use for 510k(s), De Novo requests and Pre-Submissions
- Currently the FDA has three versions of the template available –IVD, nIVD & PreSTAR

Cover Letter / Letters of Reference	
<a href="#">Add Attachment</a>	Attach your Cover Letter ?
<a href="#">Add Attachment</a>	Attach any Letters of Reference ?
Applicant Information ?	
Contact	
Title <input type="text"/>	Last Name <input type="text"/> First Name <input type="text"/>
Email <input type="text"/>	Phone Number <input type="text"/>
Occupation Title <input type="text"/>	
Company	
Company Name <input type="text"/>	
Address - Line 1 <input type="text"/>	
Address - Line 2 <input type="text"/>	
City <input type="text"/>	State <input type="text"/> Zip <input type="text"/> Country/Region <input type="text" value="United States"/>
<a href="#">Add Correspondent/Consultant</a>	
Pre-Submission Correspondence & Previous Regulator Interaction	
Are there prior related submissions or regulator interaction for the subject device(s)? <input type="text"/> ?	
Standards ?	
<a href="#">Add Standard</a>	Please list the standards used in your submission (if any). If only certain sections were used, or there were deviations, cite these in an attachment. A recognition number is only applicable to certain regulators, see help text. Instead of typing in information, some regulators request standards information be attached, see help text.

# Background



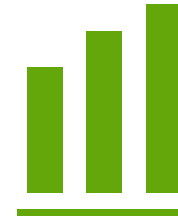
# Benefits of eSTAR



Follows the content of SMART templates utilized by reviewers



Intuitive, guided workflows, integrated databases



Automation-relevant fields are populated based on answers to initial questions



Eliminates the need for an eCopy validation & RTA assessment

# eSTAR Quick Tips



eSTAR is free, but ensure your organization has Adobe Pro, 2017, DC or Foxit



Study the eSTAR **template & website** in advance of your submission. Learn the format of the template, navigation, help features, and limitations



Validate responses to the “**Application/Submission Type**” & “**Device Description**”. eSTAR will populate the required sections based on responses to these questions



eSTAR is for submission compilation, the **Customer Collaboration Portal** is for submission....ensure you understand the portal and its limitations

# eSTAR Additional Recommendations



Establish a **single source of truth** for submission source files



Utilize the **export/import** xml data function for submission backup, saving and future submissions



Establish a process for **technical review** of submissions



Review **current processes** for submissions to ensure they account for eSTAR changes



Monitor the **eSTAR website** to check for tips, template updates & additional information



# eSTAR Future State

1



PMA is planned as the next submission type

2



FDA/Health Canada joint pilot & Health Canada only pilot underway

3



“Hypothesis” is that additional markets will conduct pilots

# Next Steps?

## Going to RAPS?

Visit Veeva MedTech at Booth #501

Or email us: [estar@veeva.com](mailto:estar@veeva.com) to see a demo of Vault RIM eSTAR capabilities!

For regulatory process or content questions please email:

USFDA: [DICE@fda.hhs.gov](mailto:DICE@fda.hhs.gov)

Health Canada: [meddevices-instrumentsmed@hc-sc.gc.ca](mailto:meddevices-instrumentsmed@hc-sc.gc.ca)





Questions