US FDA’s Electronic Submission Template and Resource (eSTAR)

An evaluation of best practices and recommendations on utilizing eSTAR

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Agenda

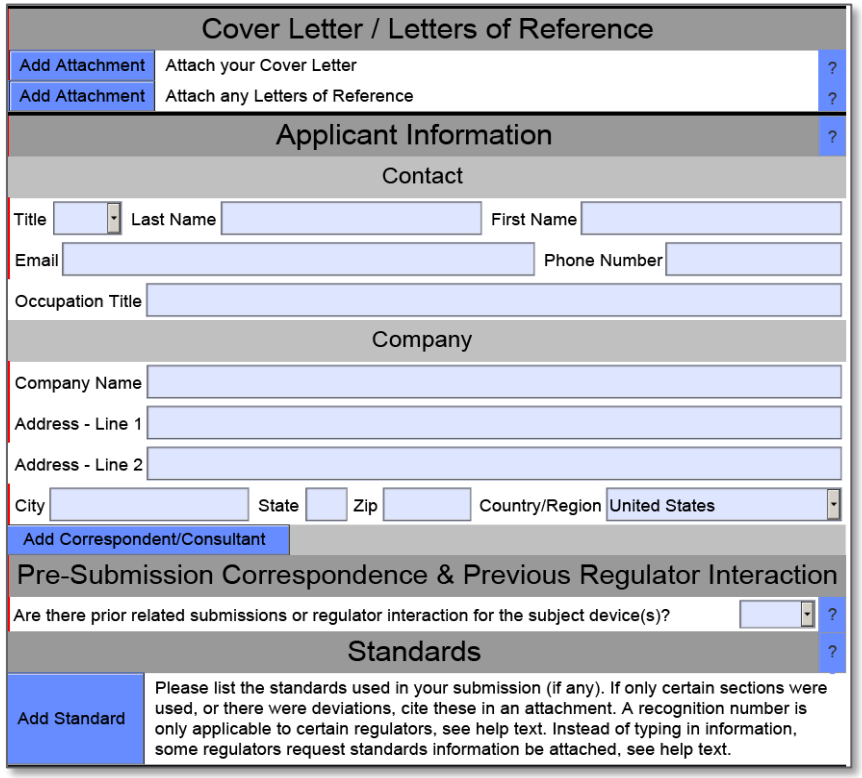
1. eSTAR Overview
2. Evolution of eSTAR
3. eSTAR Benefits
4. Recommendations for using eSTAR
5. The Future of eSTAR
6. Q&A

eSTAR Overview

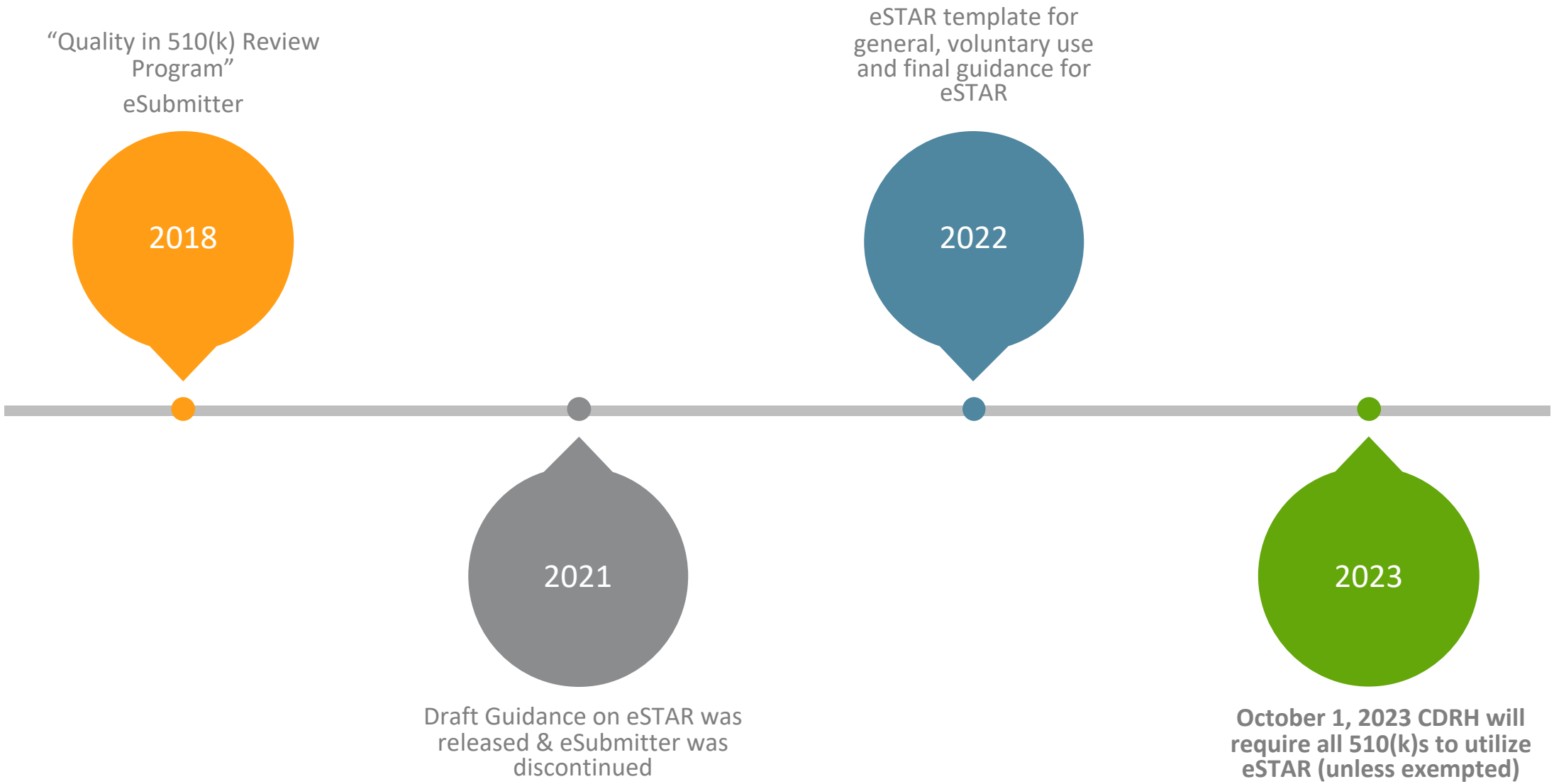
- "Electronic Submission Template and Resource" (eSTAR) is an interactive submission template created by FDA that will be the **ONLY** way to submit 510k(s) starting October 1, 2023 (unless exempt).

- 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



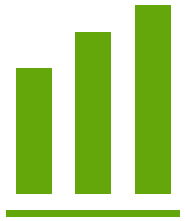
Background



Benefits of eSTAR

Follows the content of SMART templates utilized by reviewers

Intuitive, guided workflows, integrated databases



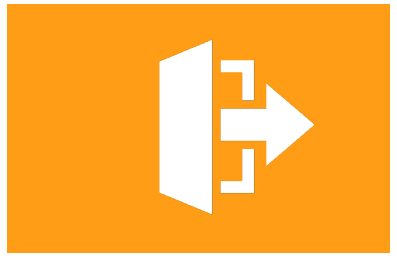
Automation-relevant fields are populated based on answers to initial questions

Eliminates the need for an eCopy validation & RTA assessment

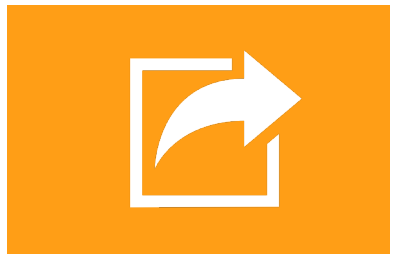
eSTAR Quick Tips

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

U.S. FOOD & DRUG ADMINISTRATION

PMA is planned as the next submission type

2

Health Canada

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

3

IMDRF International Medical Device Regulators Forum

“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 to see a demo of Vault RIM eSTAR capabilities!

For regulatory process or content questions please email:

USFDA: DICE@fda.hhs.gov

Health Canada: meddevices-instrumentsmed@hc-sc.gc.ca

Questions