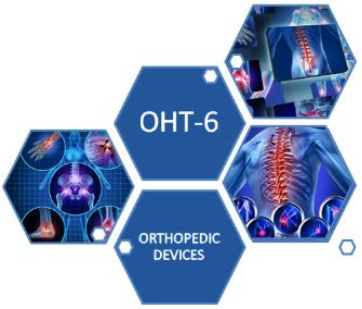

FDA U.S. FOOD & DRUG ADMINISTRATION

How To Avoid an eCopy Hold and The New electronic Submission Template and Resource (eSTAR)

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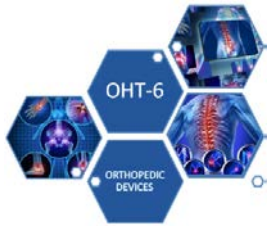
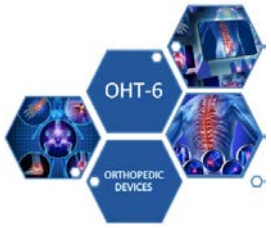


Outline

- What is an eCopy Hold
- eCopy Guidance
- Most Common Reasons for an eCopy Hold
- What is eSTAR
- Benefits
- Deployment Plans
- Recent Updates
- Future Plans

What is an eCopy Hold???

- Guidance Update Issued April 27, 2020
- https://www.fda.gov/media/83522/download
- An eCopy is an electronic version of your medical device submission created and submitted on a CD, DVD, or flash drive
- An eCopy is NOT an “eSubmission”, which is a submission package created by an electronic submission template
- The FDA will process your eCopy for intake into our internal databases, if your submission fails the technical requirements for intake and archival, your submission will be placed on eCopy Hold



Contains Nonbinding Recommendations

eCopy Program for Medical Device Submissions

Guidance for Industry and Food and Drug Administration Staff

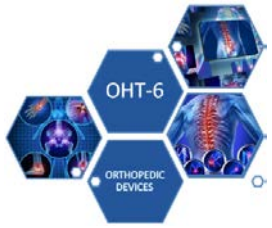
Document issued April 27, 2020.

This document supersedes the guidance of the same title dated December 16, 2019.

For questions regarding this document, contact CDRH’s eCopy Program Coordinators at 240-402-3717 or cdrh-eCopyinfo@fda.hhs.gov or CBER’s Office of Communication, Outreach and Development, at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

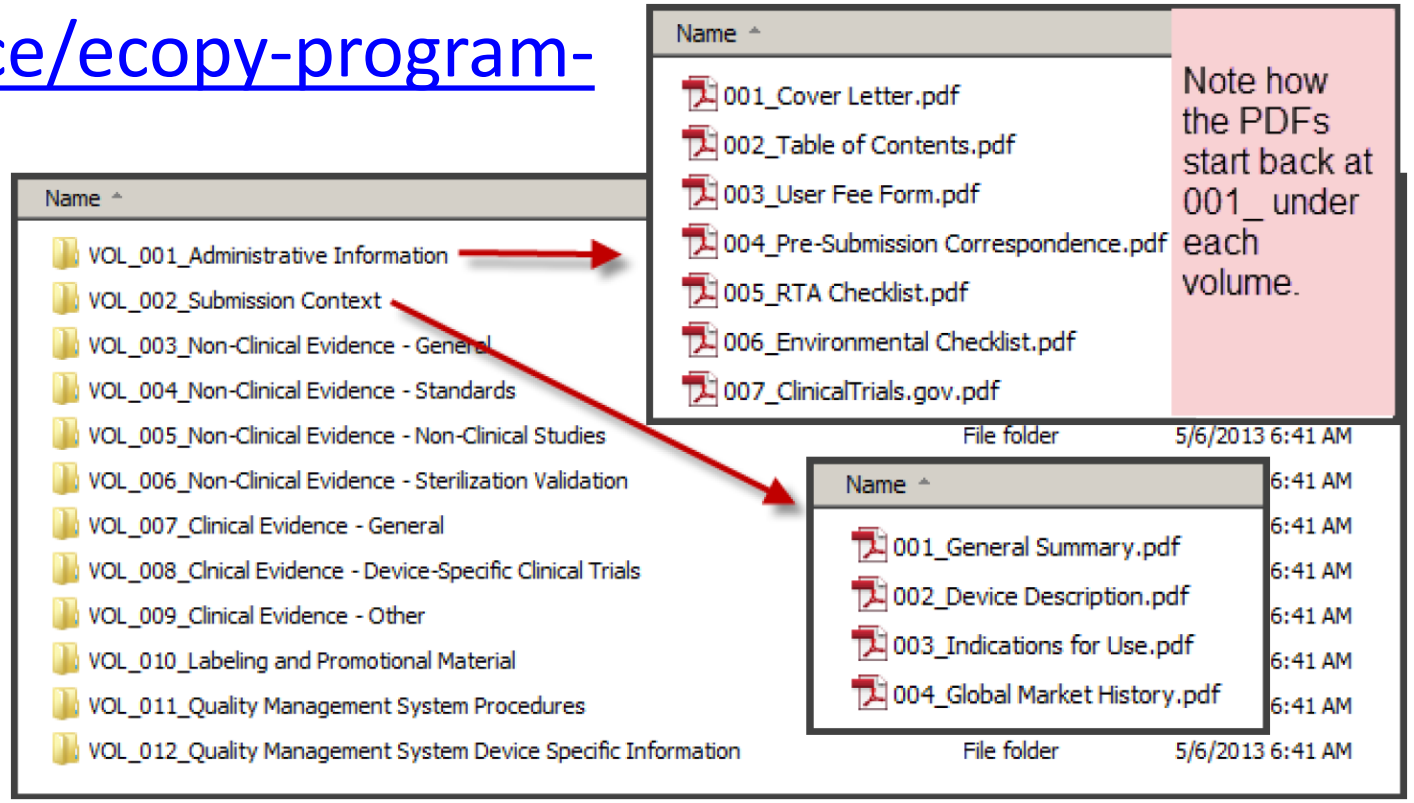


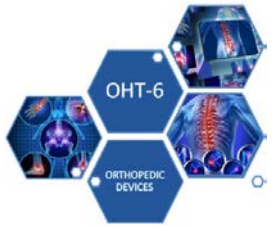
Technical Standards for eCopies

- No Security Settings
- Specific PDF File Naming Convention "[**XXX]_Descriptive Name" (e.g., 001_Cover Letter, 002_MDUFA Form, 003_Table of Contents)**
- PDF File Size Limited to 50 MB or Below
- Requirements for how to add non-PDF files to an eCopy
  - spell the folder name precisely (i.e., "STATISTICAL DATA", "MISC FILES"), although not case sensitive
  - put the folder at the root level of the eCopy
  - include all content in one or more zip file(s) under the folder
- *"STATISTICAL DATA"* folder (no size limit but total package size limit of 1GB)
  - Statistical information, such as metadata and data line listings
  - Metadata includes data dictionaries and terminologies, formats, annotated case report forms
  - Keep files in native format (e.g., SAS, XPORT, XML, ASCII, Excel)
- *"MISC FILES"* folder (no size limit but total package size limit of 1GB)
  - Videos, x-rays, source code
  - Keep files in native format (e.g., .gif, .tif, .jpg)
  - Word versions of some of the PDFs (e.g., labeling, predicate device comparison table for 510(k)s, 510(k) Summary, SSED)

eCopy Validation

- eCopy Validation Module on FDA Website
- https://www.fda.gov/medical-devices/how-study-and-market-your-device/ecopy-program-medical-device-submissions
- eSubmitter

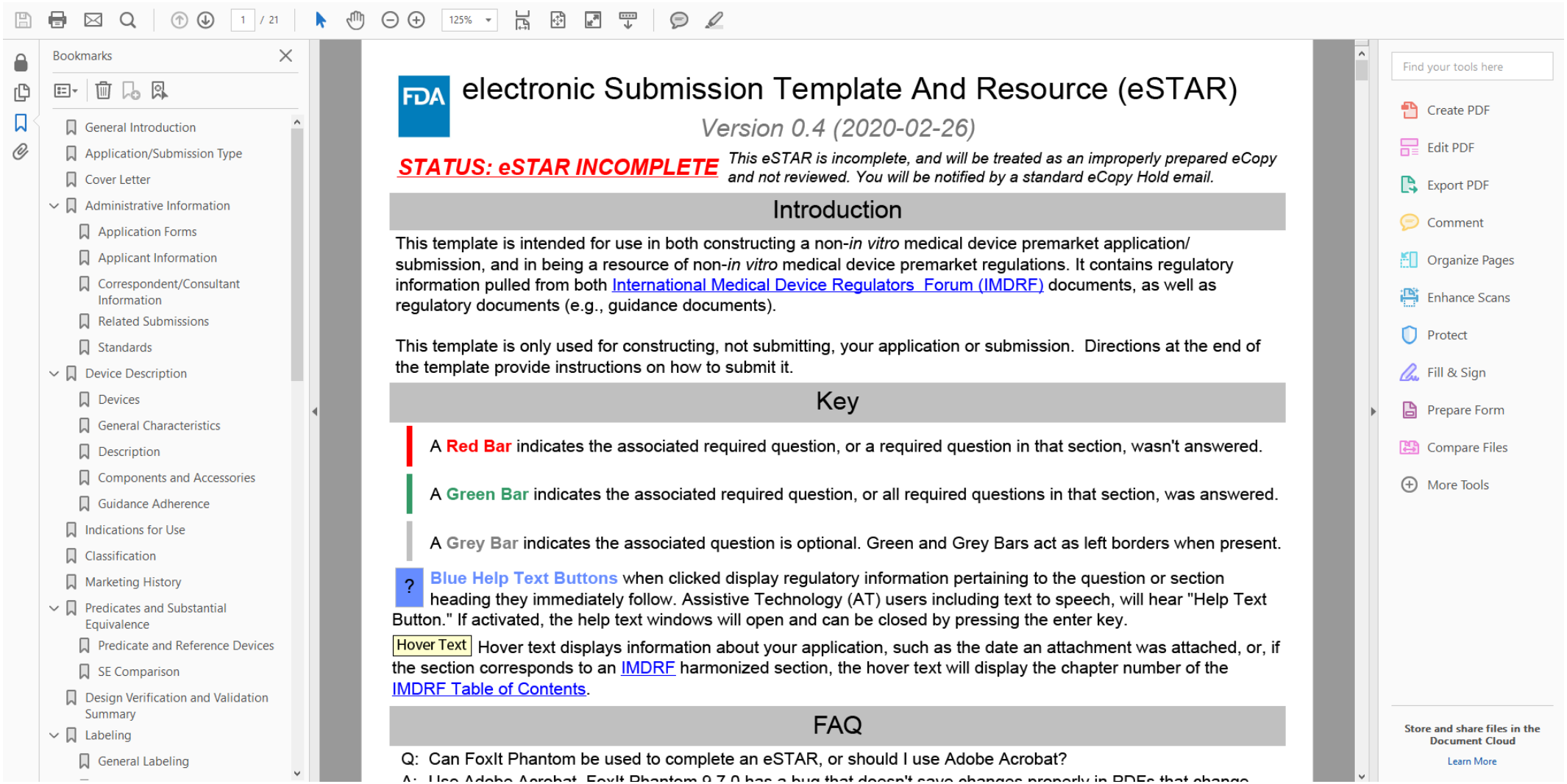


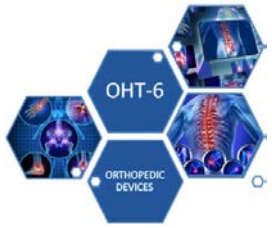


Top Reasons for eCopy Failure

- Approximately 7% of current premarket submissions are placed on a eCopy Hold
- 510(k)s (43%), Q-Subs (30%), IDEs (13%), and PMAs (6%)
- The PDF Files had an invalid naming convention. The PDF Files did not begin with the 3 digits followed by an underscore (25% of eCopy holds)
- The files contained file extensions that are not accepted by FDA (.in, .tmp., .db) OR has files/folders that are hidden. (23% of eCopy holds)
- The folder was placed at the root level of the eCopy. Only the *STATISTICAL DATA* folder or *MISC FILES* folder are allowed at the root level of the eCopy submission. (10% of eCopy holds)

Moving To A New Paradigm…

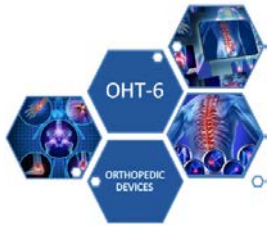




What is eSTAR?

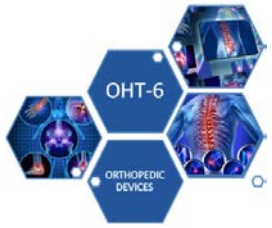
- **eSTAR (electronic Submission Template And Resource)**: A *dynamic* PDF submission template used by medical device applicants to prepare a medical device submission. It contains automation, guides, integrated databases, and integrated policies and procedures in a single package to guide the applicant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

- Questions and content mirror the complementary Smart Review Templates used by FDA reviewers to assess submissions.



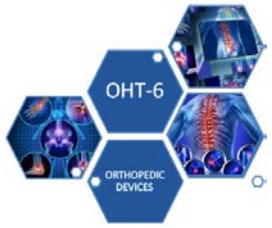
Benefits

- **Content mirrors the reviewer's Smart Template**
  - less Additional Information requests expected
- **Integration and elimination of guidances**
  - Contents of guidances are integrated in
  - Many other guidances not applicable (e.g., eCopy, RTA, Format)
- **Automation and Integrated Databases**
  - Form construction, field auto-population, displays only relevant questions, final verification
- **Guides**
  - Ensures all questions and content that are needed are provided
- **No special software install or training (only Adobe Acrobat)**
- **Works on mobile and Macs, and is free to use**
- **Users can and should download the template to work off their local drives**
- **100% built by ex-reviewers, not contractors**
  - Better designed by experts of the content
- **Future integration into submission portal**



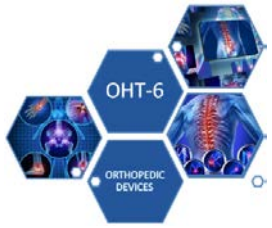
Deployment Plans

- **eSTAR pilot began on February 26, 2020**
  - Nine Participants (all filled)
  - Uses Non-In-Vitro Diagnostic (nIVD) 510(k) eSTAR
  - No RTA review
  - Normal MDUFA performance goals apply
  - Supplement and Amendments can be submitted the current way
  - Attachments can include videos, 1 GB total size was tested.
  - eSTAR is posted on FDA.gov for all to download and test
- **De Novo and IVD eSTAR Pilots**
  - De Novo content and IVD eSTAR pilots in Summer 2020
  - IVD and nIVD 510(k) content was approved on June 9, 2020 for use beyond nine (9) submissions.
- **Intending to replace eSubmitter template in Quality in 510(k) Pilot in the summer of 2020**



Latest Updates

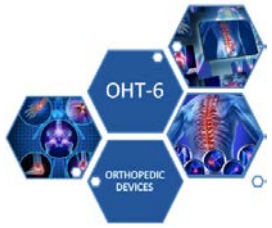
- **Fully complementary with De Novo & 510(k) FDA Smart Review Template**
- **508 Compliant**
  - Tested with NVDA (non-visual disability) Assistive Technology software
- **Ability to import and export data**
  - Does not include attachments
- **Device specific guidance links added, per product code**
  - Device specific guidance name and link will be displayed for associated product codes
- **Further harmonized with the International Medical Device Regulators Forum (IMDRF) Table of Contents document**
- **Many small refinements and bug fixes**
  - enlarged many textboxes, updated help text, visual refinements, bug preventing addition of multiple standards under certain circumstances is fixed



Future Plans

- **Add PMA Content to nIVD and IVD eSTAR**
  - Begin by adding Quality Management from the IMDRF TOC document (Chapter 6)

- **Develop a third and final eSTAR that contains IDE, Q-Sub, and 513(g) content**
  - Already under development
  - Separate into a third eSTAR since IMDRF does not cover these submission types
  - This third eSTAR is intended for use with IVDs and nIVDs, which complements our smart review templates used for both IVD and nIVD IDE, Q-Sub, and 513(g) reviews



Questions and Links

- **Questions/Feedback**:
  eSubpilot@fda.hhs.gov

- **eSTAR Pilot information is located at**:
  https://www.fda.gov/medical-devices/premarket-notification-510k/510k-program-pilots

- **eSTAR Link is located at:**
  https://www.fda.gov/media/135527/download

Thank You!

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