



# **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](mailto: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](mailto:ocod@fda.hhs.gov).



# 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

Note how the PDFs start back at 001\_ under each volume.

Name ^		
VOL_001_Administrative Information		
VOL_002_Submission Context		
VOL_003_Non-Clinical Evidence - General		
VOL_004_Non-Clinical Evidence - Standards		
VOL_005_Non-Clinical Evidence - Non-Clinical Studies		
VOL_006_Non-Clinical Evidence - Sterilization Validation		
VOL_007_Clinical Evidence - General		
VOL_008_Clinical Evidence - Device-Specific Clinical Trials		
VOL_009_Clinical Evidence - Other		
VOL_010_Labeling and Promotional Material		
VOL_011_Quality Management System Procedures		
VOL_012_Quality Management System Device Specific Information		

Name ^		
001_Cover Letter.pdf		
002_Table of Contents.pdf		
003_User Fee Form.pdf		
004_Pre-Submission Correspondence.pdf		
005_RTA Checklist.pdf		
006_Environmental Checklist.pdf		
007_ClinicalTrials.gov.pdf		

Name ^		
001_General Summary.pdf		6:41 AM
002_Device Description.pdf		6:41 AM
003_Indications for Use.pdf		6:41 AM
004_Global Market History.pdf		6:41 AM

File folder 5/6/2013 6:41 AM

File folder 5/6/2013 6:41 AM



# 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...

**FDA** electronic Submission Template And Resource (eSTAR)  
Version 0.4 (2020-02-26)

**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* 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 pressing the enter key.
- 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: Can FoxIt Phantom be used to complete an eSTAR, or should I use Adobe Acrobat?  
A: Use Adobe Acrobat. FoxIt Phantom 9.7.0 has a bug that doesn't save changes properly in PDFs that change



# 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](mailto: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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ADMINISTRATION

