

# eMDR System Overview and Submission Walkthrough

**FDA Small Business Regulatory Education for Industry (REdI)**

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U.S. Food and Drug Administration

# Introduction

- Question: What did CDRH receive over 2 million of last year?
- Answer: Medical Device Reports
- Is your medical device firm submitting MDRs today?
- If you became aware of an adverse event involving one of your devices today, what would you do?

# Learning Objectives

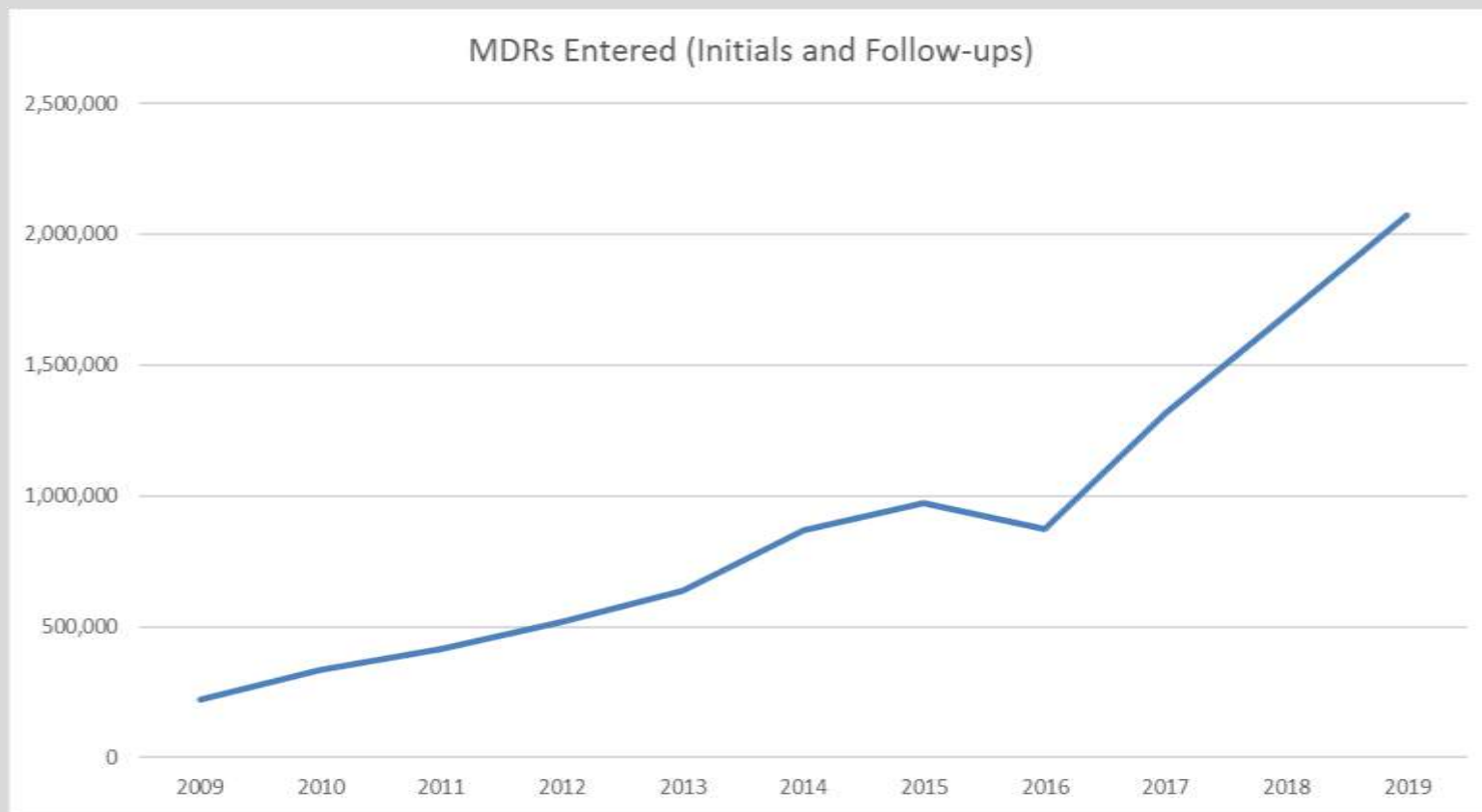
- Describe the purpose of the eMDR system and explain the MDR ingestion process
- Illustrate the relationships between the systems that store MDR data
- Review eMDR 2020 updates
- Demonstrate the process of submitting an electronic MDR to CDRH
- List the most common errors made when submitting an MDR

# Background

- MDR = Medical Device Report
- Requirements specified under 21 CFR Part 803
- Industry are required to submit electronically
- Today's focus: logistics of reporting

# MDR Attributes

- MedWatch form series (3500, 3500A, 3500B)
- Event type – Death, Serious Injury, Malfunction
- Reporter – Manufacturer, Importer, User Facility, Voluntary
- Device – Product Code, Brand Name, Model #
- Event – Patient, Problem, Investigation



# eMDR Goals

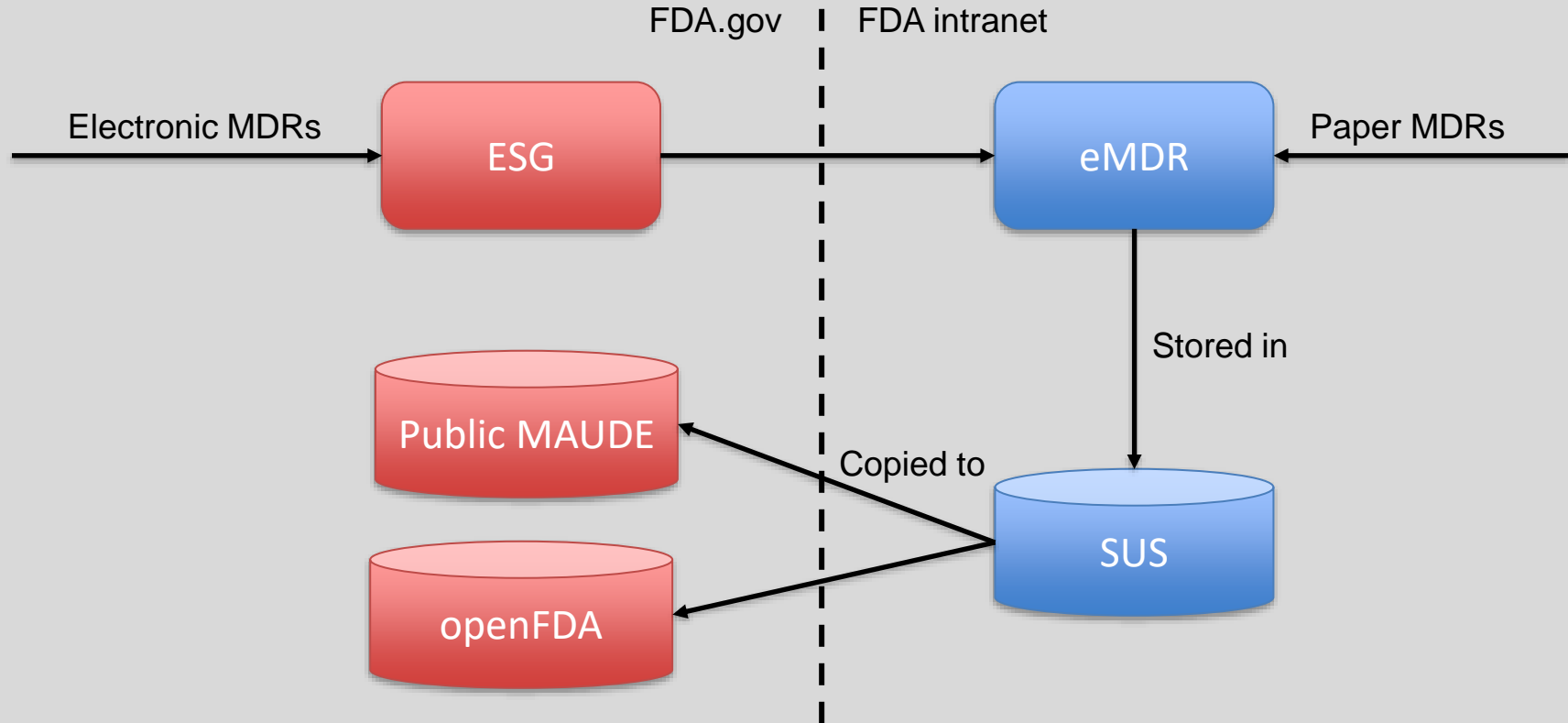
- eMDR = Electronic Medical Device Reporting
- Increase MDR quality
- Decrease MDR processing time
- Provide timely feedback to submitters

# System Overview

# IT Systems

- eMDR
- Electronic Submissions Gateway (ESG)
- System for Uniform Surveillance (SUS)
- Public MAUDE
- openFDA

# Architecture



# Submission Methods

- Low Volume (of Reports)
  - eSubmitter and WebTrader (provided by FDA)
- High Volume (of Reports)
  - HL7 ICSR XML and AS2 (customized system)
- Both methods are available to all submitters

# 2020 eMDR Update

- 3500A form updates
- Adverse event code harmonization with IMDRF
- New instructions for summary reporting

# Knowledge Check

**Which of the following MDR fields is visible to the public in MAUDE?**

- A. Patient age and gender
- B. Device model number
- C. Device serial number
- D. Report attachments

# Submission Walkthrough

# eMDR Setup Tasks

- Request ESG account
  - Obtain a digital certificate
  - Sign letter of non-repudiation
- Download and install eSubmitter
- Complete test submission

# Low Volume Method

1. Create MDR using eSubmitter
2. Send submission using WebTrader
3. View acknowledgments in WebTrader
4. For test submissions, send your Ack3 to eMDR Helpdesk with production account request

# eSubmitter Walkthrough



eSubmitter - TEST

File Edit View Table Output Tools Help

eSubmitter  
Electronic Submissions Software

Menu Options Messages

Welcome Alerts and News Helpful Tips Addresses and Contacts Links Frequently Asked Questions History

Create New Submission...  
Open Existing Submission...  
eSubmitter Quick Guide...  
Exit Application

## Welcome to eSubmitter! An FDA Electronic Submissions Software Initiative

**Overview:** This software application enables electronic submission of regulatory information to FDA in an effort to automate the submission process. It contains a number of data capturing tools and helpful dialog boxes to reduce redundant responses, and to allow FDA to capture data in a more useful, structured format. These benefits enable Centers within the FDA to improve our review process and reduce lengthy review times.

**Getting Started:** To familiarize yourself with the eSubmitter application, see the "Getting Started" section of the "eSubmitter Quick Guide", which provides layout information as well as tips for navigating the intro screen. In addition, the "eSubmitter Quick Guide" also provides information on creating a new submission through to the submission packaging process. The "eSubmitter Quick Guide" can be launched from the corresponding menu option on the left-hand side of this intro screen.

**Contact Us:** Please email any questions or comments concerning this software application to the eSubmitter team at: [esubmitter@fda.hhs.gov](mailto:esubmitter@fda.hhs.gov). Please be sure to include your name, company name and contact information in the email. Otherwise, for Regulatory questions, contact the appropriate office. See [Addresses](#) and [Contacts](#) for further details.

**Application Updates:** Updates to this software are automatic. These updates will occur, as available, if you are logged onto the internet at the time that the application is launched.

Thank you again for using our electronic submission software. We look forward to hearing from you soon.

Version: 3.31.00 Build 2  
Last Updated: 07/26/2025

FDA U.S. Food and Drug Administration  
Protecting and Promoting Your Health

U.S. Department of Health & Human Services

# eSubmitter Walkthrough



eSubmitter - TEST

File Edit View Table Output Tools Help

**eSubmitter**  
Electronic Submission Software

Menu Options

**Create New Submission...**

Open Existing Submission...

eSubmitter Quick Guide...

Exit Application

**New Submission Dialog**

Create New Submission

Step 1 Select Submission Type

List of Available Submission Types

Name	Version	Version Date
CDRH: Allegation Reporting (Medical Devices) (OMB No. 0910-NEW)	1.2	06/19/2014 10:14:11
CDRH: In Vitro Diagnostic Device - 5100k	1.3	01/01/2015 11:00:27
	1.2.1	05/01/2017 02:34:30
<b>CDRH: MedWatch Form 3500A (OMB No. 0910-0292)</b>	<b>2.3</b>	<b>08/03/2020 05:29:41</b>
	3.2	08/28/2018 06:31:24
CDRH: Non-In Vitro Diagnostic Device - De Novo		05/30/2018 09:28:31
CDRH: Radiation Emitting Product (OMB NO. 0910-9525)	2.6	12/03/2019 11:53:33

Description of Selected Submission Type

**MedWatch Form 3500A (OMB No. 0910-0291)**

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH) initiated the eMDR (electronic Medical Device Reporting) project to enable reporters to voluntarily submit medical device adverse event reports (MDRs) electronically.

The eSubmitter tool enables program participants to electronically complete and submit MDR.

Cancel Previous Next Create

Version: 3.31.00 Build 2  
Last Update: 07/08/2020

U.S. Food and Drug Administration  
Protecting and Promoting Your Health

U.S. Department of Health & Human Services

# eSubmitter Walkthrough



eSubmitter - TEST

File Edit View Tables Output Tools Help

Submission Name: demo  
Report Type: CDRL MedWatch Form 3500A (OMB No. 0910-0292)

Last Modified:  
Date Packaged:

Screen View Report: Introduction

## Medical Device Adverse Event Report

U.S. Department of Health and Human Services  
Public Health Service  
Food and Drug Administration

**For use by user-facilities, importers, and manufacturers for MANDATORY reporting**

Form FDA 3500A  
Form Approved: OMB No. 0910-0291, Expires 9/30/2018

OMB Statement:  
"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

If you need assistance with or have questions about the electronic 3500A submission process or messages, please contact the eMDR helpdesk at [eMDR@fda.hhs.gov](mailto:eMDR@fda.hhs.gov)

Submission of a report does not constitute an admission that medical personnel, user facility, importer, manufacturer or product caused or contributed to the event.

The public reporting burden for this collection of information has been estimated to average one hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services  
Food and Drug Administration  
MedWatch, HFD-410  
5600 Fishers Lane  
Rockville, MD 20857

Please DO NOT RETURN this form to this address.

Outline View

# eSubmitter Walkthrough



eSubmitter - TEST

File Edit View Table Output Tools Help

Submission Name: demo  
Report Type: CDRH MedWatch Form 3500A (OMB No. 0910-0292)

Last Modified:  
Date Packaged:

Outline View Report: Report Number

Report

- Introduction
- Report Number
- A. Patient Information
- B. Adverse Event or Product Problem (B1 - B4)
- B. Adverse Event or Product Problem (B5)
- B. Adverse Event or Product Problem (B6)
- B. Adverse Event or Product Problem (B7)
- C. Suspect Products
- C. Suspect Products Information (C1 - C9)
- D. Suspect Medical Device (D1 - D2)
- D. Suspect Medical Device (D3)
- D. Suspect Medical Device (D4 - D6)
- D. Suspect Medical Device (D7 - D9)
- D. Suspect Medical Device (D10)
- E. Initial Reporter (E1)
- E. Initial Reporter (E2 - E4)
- F. For Use by User Facility/Importer (F1 - F2)
- F. For Use by User Facility/Importer (F3 - F7)
- F. For Use by User Facility/Importer (F8 - F10)
- F. For Use by User Facility/Importer (F11 - F13)
- F. For Use by User Facility/Importer (F14)
- G. All Manufacturers (G1)
- G. All Manufacturers (G1) Continued
- G. All Manufacturers (G2 - G3)
- G. All Manufacturers (G4 - G5)
- G. All Manufacturers (G6 - G8)
- H. Device Manufacturers Only (H1 - H3)
- H. Device Manufacturers Only (H4 - H8)
- H. Device Manufacturers Only (H7 - H9)
- H. Device Manufacturers Only (H10/H11)
- File Attachments

Screen View Select

# eSubmitter Walkthrough

Screen View

Report: Report Number



 Manufacturer Report Numbers can be entered using either of the following two coding schemes:  
 - 7 digit CFN, followed by a 4 digit year, followed by a 5 digit sequence number, or  
 - 10 digit FEI, followed by a 4 digit year, followed by a 5 digit sequence number.

User Facility Report Numbers can be entered using the following coding scheme:  
 - 10 digit HCFA, followed by a 4 digit year, followed by a 4 digit sequence number.

Importer Report Numbers follow the same coding scheme as manufacturers.

All Report Numbers require entry in all three sections to qualify. The sequence number at the end will automatically pad with zeros if not completed fully.

Identify the Report Numbers to be included

- MFR Report Number

- User Facility Report Number

- Importer Report Number

MFR Report Number



☒ CFN-based ☐ FEI-based

1234567 - 2020 - 00001

☒ CFN-based ☐ FEI-based

# eSubmitter Walkthrough



Screen View	Report: B. Adverse Event or Product Problem (B5) 
B5	<div data-bbox="79 354 1906 398">Describe Event or Problem </div> <div data-bbox="79 398 1906 819">Event description here</div>


# eSubmitter Walkthrough



Screen View		Report: D. Suspect Medical Device (D1 - D2)			
<b>PART D</b> SUSPECT MEDICAL DEVICE					
<hr/>					
D1	Brand Name				
	<input type="text" value="My Brand"/>				
<hr/>					
D2	Type of Device				
	Common Device Name				
	<input type="text" value="Powered rotation bed"/>				
	Device Product Code				
	Product Code				
	<input type="text" value="IKZ"/>				
	Product Code Name				
	PATIENT ROTATION, POWERED				
	Device Class				
	CLASS II				
	Classification Panel				
	89-PHYSICAL MEDICINE				
	C.F.R. Section				
	890.5225 - POWERED PATIENT ROTATION BED.				

# eSubmitter Walkthrough



Screen View		Report: H. Device Manufacturers Only (H1 - H3)			
<div><div>PART H</div><div>DEVICE MANUFACTURERS ONLY</div></div>					
H1	Type of Reportable Event	<div><div><input type="radio"/> Death</div><div><input type="radio"/> Serious Injury</div><div><input checked="" type="radio"/> Malfunction</div></div>			
	Summary Report	<div><input checked="" type="checkbox"/></div>			
	No. of Events Summarized	<div><input type="text" value="100"/></div>			

# eSubmitter Walkthrough

Screen View

Report: G. All Manufacturers (G6 - G8)



For all reports, choose Initial or Follow-up and choose either 5-day or 30-day. The remaining numerical-day values may be selected for Combination Product reports.

G6 Type of Report (check all that apply)

- ☐ 5 - day
- ☐ 7 - day
- ☐ 15 - day
- ☐ 30 - day
- ☐ Periodic
- ☐ Initial
- ☒ Follow-up

• Follow-up Number

2

# eSubmitter Walkthrough



Screen View Report: H. Device Manufacturers Only (H4 - H6)

H6 Adverse Event Problem (Refer to coding manual)

Health Effect - Clinical Code

Code

Health Effect - Impact Code

Code

Medical Device Problem Code

Code

Component Code

Code

Type of Investigation

Code

Health Effect - Impact Codes Filter Dialog

Provide Impact Code filter criteria (keywords)

Impact Code Impact Code Name

Impact Codes matching the specified filter criteria (Note: (\*) denotes the sort order, double-click column header to change)

Code	Name*
4611	ABSENCE OF TREATMENT
4625	ADDITIONAL SURGERY
4642	ADDITIONAL DEVICE REQUIRED
4626	AMPUTATION
4650	APPROPRIATE HEALTH IMPACT TERM CODE NOT AVAILABLE
4637	BIOPSY
4643	BLOOD TRANSFUSION
4602	BRAIN DEATH
4601	CHANGE IN THERAPEUTIC RESPONSE

64 Impact Codes in the filtered list

Impact Codes currently selected

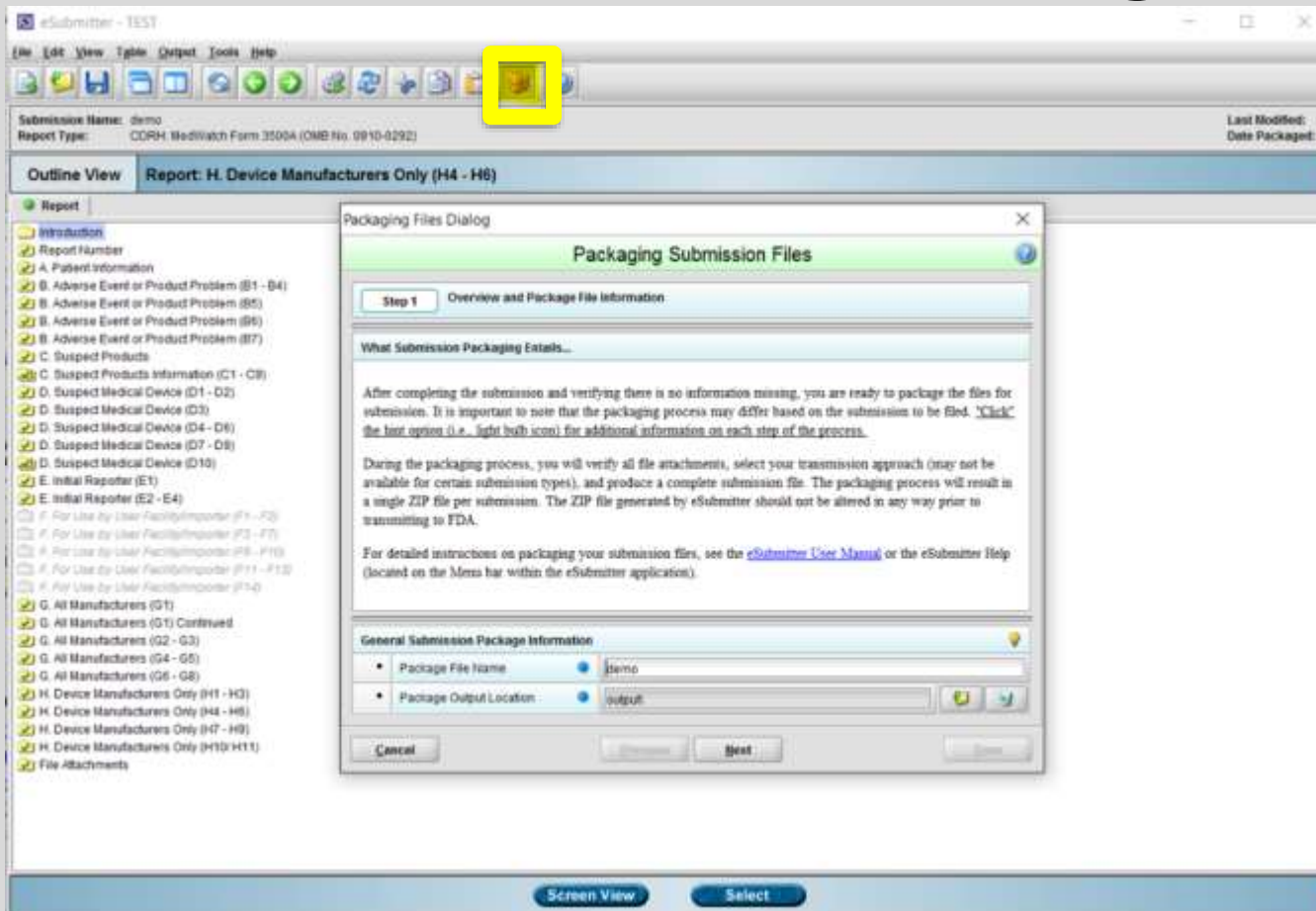
Code	Name
4625	ADDITIONAL SURGERY

1 Impact Code in the selected list

Clear Filter Select Delete OK Cancel

Outline View

# eSubmitter Walkthrough



# eSubmitter Walkthrough



eSubmitter - TEST

File Edit View Table Output Tools Help

Submission Name: demo  
Report Type: CDRH Medical Device Form 2500A (CME No. 0810-0292)

Last Modified: 08/05/2020 10:45:29 AM  
Date Packaged: 08/05/2020 10:45:29 AM

Outline View Report: H. Device Manufacturers Only (H4 - H6)

Report

- Introduction
- Report Number
- A. Patient Information
- B. Adverse Event or Product Problem (B1 - B4)
- B. Adverse Event or Product Problem (B5)
- B. Adverse Event or Product Problem (B6)
- B. Adverse Event or Product Problem (B7)
- C. Suspect Products
- C. Suspect Products Information (C1 - C9)
- D. Suspect Medical Device (D1 - D2)
- D. Suspect Medical Device (D3)
- D. Suspect Medical Device (D4 - D6)
- D. Suspect Medical Device (D7 - D9)
- D. Suspect Medical Device (D10)
- E. Initial Reporter (E1)
- E. Initial Reporter (E2 - E4)
- F. For Use by User Facility/Importer (F1 - F2)
- F. For Use by User Facility/Importer (F3 - F7)
- F. For Use by User Facility/Importer (F8 - F10)
- F. For Use by User Facility/Importer (F11 - F12)
- F. For Use by User Facility/Importer (F14)
- G. All Manufacturers (G1)
- G. All Manufacturers (G1) Continued
- G. All Manufacturers (G2 - G3)
- G. All Manufacturers (G4 - G5)
- G. All Manufacturers (G6 - G8)
- H. Device Manufacturers Only (H1 - H3)
- H. Device Manufacturers Only (H4 - H6)
- H. Device Manufacturers Only (H7 - H8)
- H. Device Manufacturers Only (H10/H11)
- File Attachments

Packaging Files Dialog

Packaging Submission Files

Step 3 Package Creation

Produce Submission Package

After completing all steps to this point, click the "Package Submission Files" button below to begin creating the

Package Submission Files Complete.

Cancel Previous Next Done

Screen View Select

# WebTrader Walkthrough

A screenshot of a web browser showing the login page for the FDA Electronic Submissions Gateway - Test System. The browser's address bar shows the URL "https://esgtest.fda.gov/login". The page has a dark blue header with the FDA logo and the text "U.S. FOOD & DRUG ADMINISTRATION". The main content area is light blue and contains a white login box. Inside the box, the text "FDA ELECTRONIC SUBMISSIONS GATEWAY - TEST SYSTEM" is displayed. Below this text are two input fields: a username field and a password field labeled "Password". Under the password field is a checkbox with the text "I agree to the terms set forth in the Rules of Behavior. View Rules of Behavior". At the bottom of the login box is a blue "Log in" button. The footer of the page is dark blue and contains links for "ESG Web Help", "FAQs", and "System Status".

# WebTrader Walkthrough



Send Document

Alerts 1

In Progress

Inbox 46

Sent Items

Send Document

Routing Information

Recipient: FDATST

\*Center:

CDRH

\*Submission Type:

Adverse Events

Document Selection

\*Documents:

1 file has been selected

C:\Users\Public\Sub\_Home\output\sample3500A.zip

+ Add documents Remove all documents

Document Signing

\*Signing Certificate:

C:\Users\FXM4\Desktop\ESG Password.p12 Select a different certificate

Certificate Password:

.....

Send

Reset

# WebTrader Walkthrough



WebTrader

Welcome  
FXM41

Send Document

Sent Items 18 results

1 of 2

<input type="checkbox"/>	Status	Document Name	Center	Type	File Size	Date
<input type="checkbox"/>	Delivered	sample3500A.zip	CDRH	Adverse_Events	14 KB	Jul 25th 2019, 11:10:30 am
<input type="checkbox"/>	Delivered	UAT5A.zip	CDRH	Adverse_Events	14 KB	Dec 12th 2018, 8:58:32 am
<input type="checkbox"/>	Delivered	UAT3E.zip	CDRH	Adverse_Events	14 KB	Dec 12th 2018, 8:57:54 am
<input type="checkbox"/>	Delivered	UAT3D.zip	CDRH	Adverse_Events	14 KB	Dec 12th 2018, 8:57:26 am
<input type="checkbox"/>	Delivered	UAT3C.zip	CDRH	Adverse_Events	14 KB	Dec 12th 2018, 8:56:52 am
<input type="checkbox"/>	Delivered	UAT3B.zip	CDRH	Adverse_Events	14 KB	Dec 12th 2018, 8:54:30 am
<input type="checkbox"/>	Delivered	test3.zip	CDRH	Adverse_Events	14 KB	Mar 16th 2018, 11:58:23 am
<input type="checkbox"/>	Delivered	test.zip	CDRH	Adverse_Events	15 KB	Feb 26th 2018, 1:25:26 pm

# WebTrader Walkthrough



**WebTrader**

Send Document

Alerts 1

In Progress

Inbox 98

Sent Items

**Sent Items** 18 results

Status	Document Name	File Size	Date
Delivered	sample3500A	14 KB	Jul 25th 2019, 11:10:30 am
Delivered	UAT5A.zip	14 KB	Dec 12th 2018, 8:58:32 am
Delivered	UAT3E.zip	14 KB	Dec 12th 2018, 8:57:54 am
Delivered	UAT3D.zip	14 KB	Dec 12th 2018, 8:57:28 am
Delivered	UAT3C.zip	14 KB	Dec 12th 2018, 8:56:52 am
Delivered	UAT3B.zip	14 KB	Dec 12th 2018, 8:54:30 am
Delivered	test3.zip	14 KB	Mar 16th 2018, 11:58:23 am
Delivered	test.zip	15 KB	Feb 28th 2018, 1:25:26 pm
Delivered	test.zip	15 KB	Feb 28th 2018, 1:13:36 pm
Delivered	test.zip	15 KB	Feb 28th 2018, 1:02:14 pm

**Document Details**

▼ Acknowledgement

File Name: ci1564067430812.47853@fidsuv05652\_te1.xml  
Status: Delivered  
Date: Jul 25th 2019, 11:14:41 am  
File Size: 872 bytes  
Submission Message Id: <30973739.4.1564067430099@DRL0195254.fda.gov>  
Sender: [FDA/ST](#)  
Recipient: [FDA/CDRH - FM](#)

File Name: ci1564067430812.47853@fidsuv05652\_te1.html  
Status: Delivered  
Date: Jul 25th 2019, 11:14:41 am  
File Size: 4 KB  
Submission Message Id: <30973739.4.1564067430099@DRL0195254.fda.gov>  
Sender: [FDA/ST](#)  
Recipient: [FDA/CDRH - FM](#)

Download

# MDR Acknowledgments

- Ack1 (receipt) sent by ESG
- Ack2 (txt) sent by CDRH
- Ack3 (**HTML**, XML) sent by eMDR
- Ack3 contains report number and success/fail
- Save Ack3 for your records!

Submission Summary	
Environment:	PRODUCTION This submission has been sent to the PRODUCTION system and has been processed by the FDA. Please refer to the Summary section below to determine if this submission has passed or failed.
Submission Type:	3500A - ICSR R2
Core ID:	ciTEST12345679255.12345678@abc123
Batch ID:	1
Date Entered:	Tue Aug 09 14:39:36 EDT 2016
Summary:	passed: 1, Failed: 0
Report List:	
Report Number:	12139515056812, passed.

# Helpdesks

- ESG Helpdesk - [ESGHelpDesk@fda.hhs.gov](mailto:ESGHelpDesk@fda.hhs.gov)
- CeSub Helpdesk - [CeSubHelpDesk@fda.hhs.gov](mailto:CeSubHelpDesk@fda.hhs.gov)
- eMDR Helpdesk - [eMDR@fda.hhs.gov](mailto:eMDR@fda.hhs.gov)
- Policy Response Line - [MDRPolicy@fda.hhs.gov](mailto:MDRPolicy@fda.hhs.gov)

# Knowledge Check

**You submit an initial MDR, but realize after receiving a success Ack3 that it contained an error. What do you do?**

- A. Send a corrected follow-up with the same number
- B. Send a corrected initial with the same number
- C. Send a corrected initial with a new number
- D. Do nothing; Ack3 success is the only requirement for eMDR submissions

# Common Mistakes

# Top 3 Submitter Mistakes

- Waiting to sign up
- Attempting to submit a PDF
- Not reading or saving Ack3

# Top 3 Content Mistakes

- Invalid CFN/FEI
- Blank or incorrect product code
- Missing critical review information

# Resources

Slide Number	Cited Resource	URL
9	Public MAUDE	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm">www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm</a>
9	openFDA	<a href="http://open.fda.gov">open.fda.gov</a>
12	eMDR site	<a href="http://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/emdr-electronic-medical-device-reporting">www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/emdr-electronic-medical-device-reporting</a>
15	ESG	<a href="http://www.fda.gov/industry/electronic-submissions-gateway">www.fda.gov/industry/electronic-submissions-gateway</a>
15	eSubmitter download	<a href="http://www.fda.gov/industry/fda-esubmitter/esubmitter-download-and-installation">www.fda.gov/industry/fda-esubmitter/esubmitter-download-and-installation</a>

# Summary

- eMDR = ingestion system for MDRs
- ESG controls access
- Submitted reports are visible in MAUDE
- Prepare early to submit MDRs
- Avoid common mistakes

# Questions



