eMDR System Overview and Submission Walkthrough

FDA Small Business Regulatory Education for Industry (REdI)

Silver Spring, MD

August 28, 2020

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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

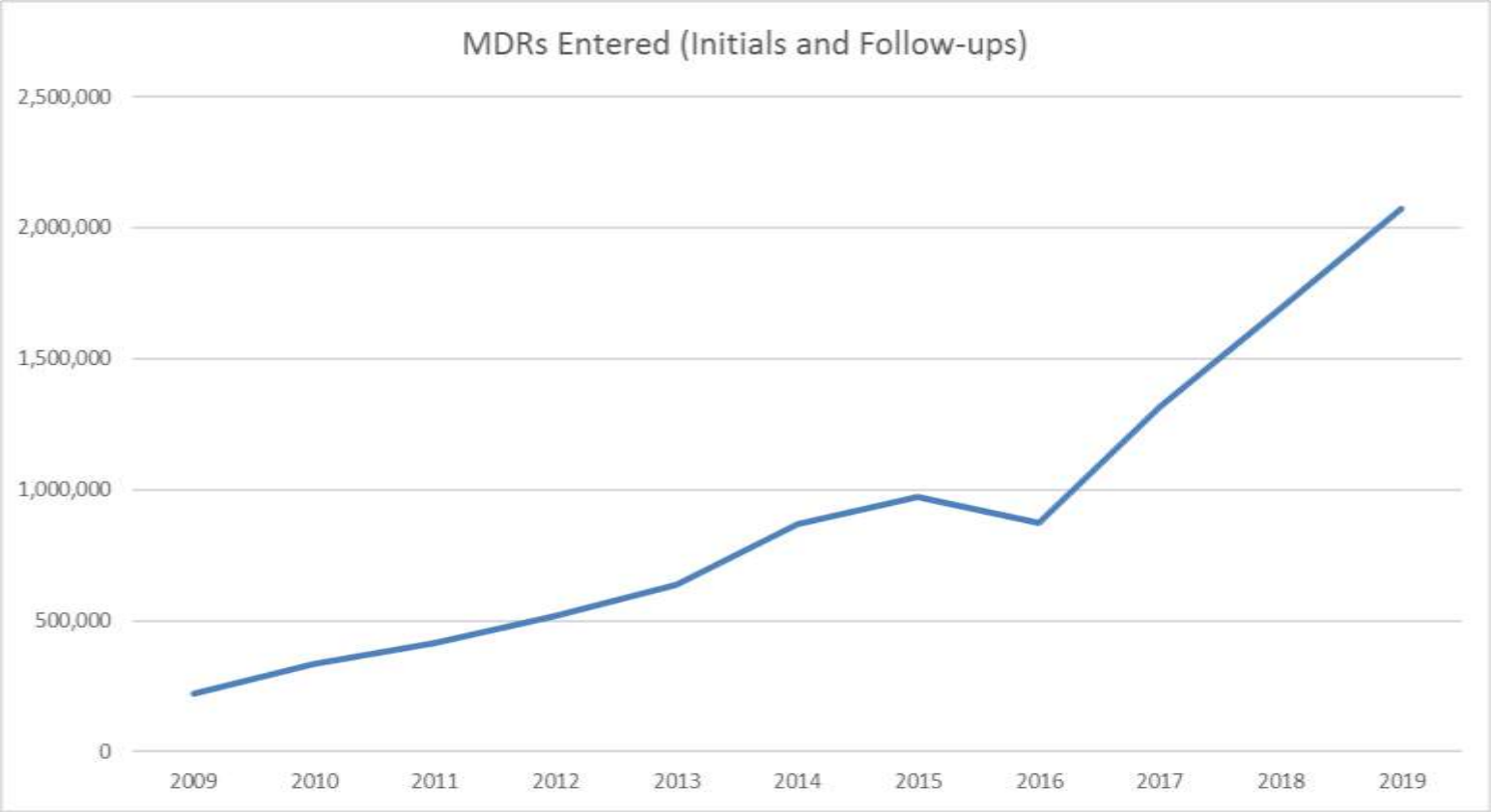
- Describe the purpose of the eMDR system and explain the MDR ingestion process
- Illustrate the relationships between the systems that store MDR data
- Review eMDR 2020 updates
- Demonstrate the process of submitting an electronic MDR to CDRH
- List the most common errors made when submitting an MDR

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


MDRs Entered (Initials and Follow-ups)
2,500,000
2,000,000
1,500,000
1,000,000
500,000
0
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018
2019

eMDR Goals

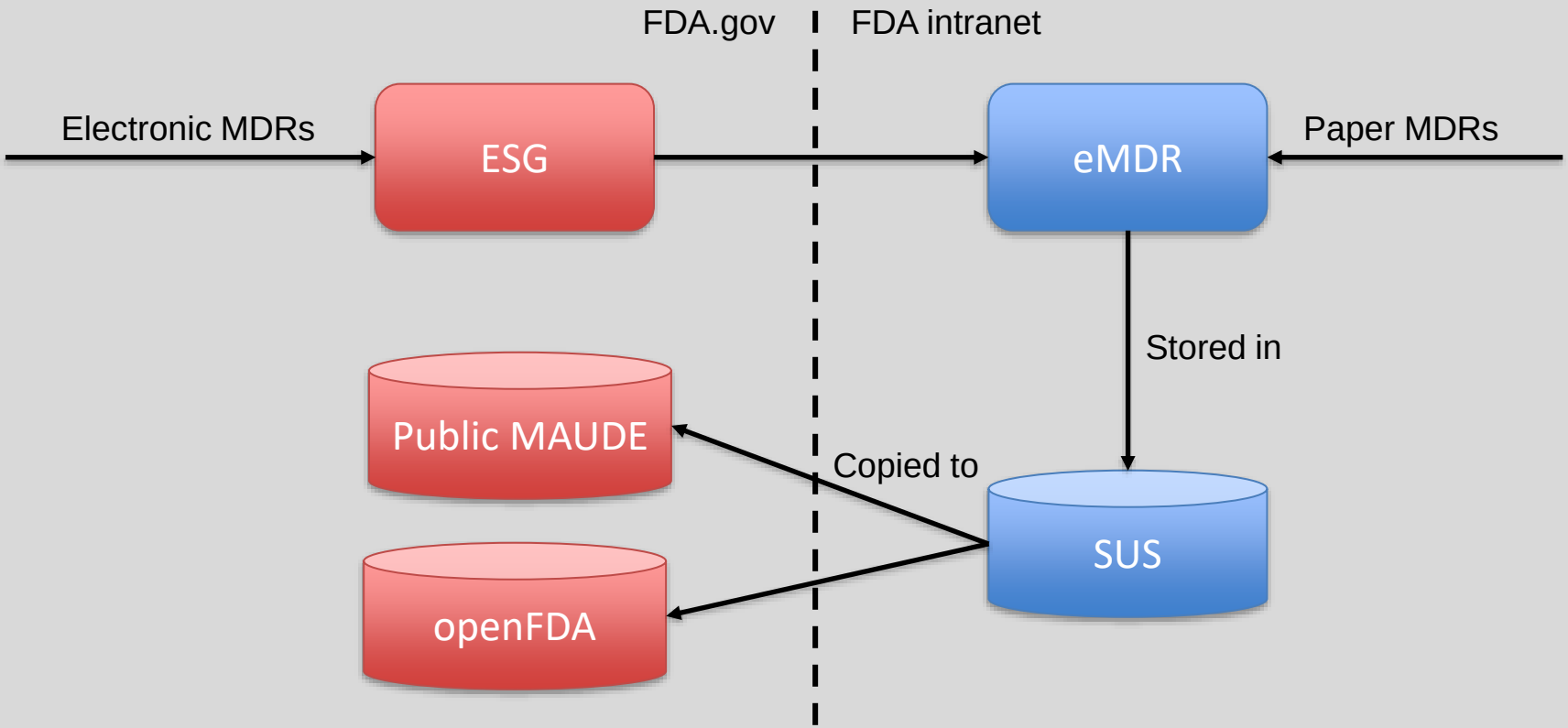
- eMDR = Electronic Medical Device Reporting
- Increase MDR quality
- Decrease MDR processing time
- Provide timely feedback to submitters

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

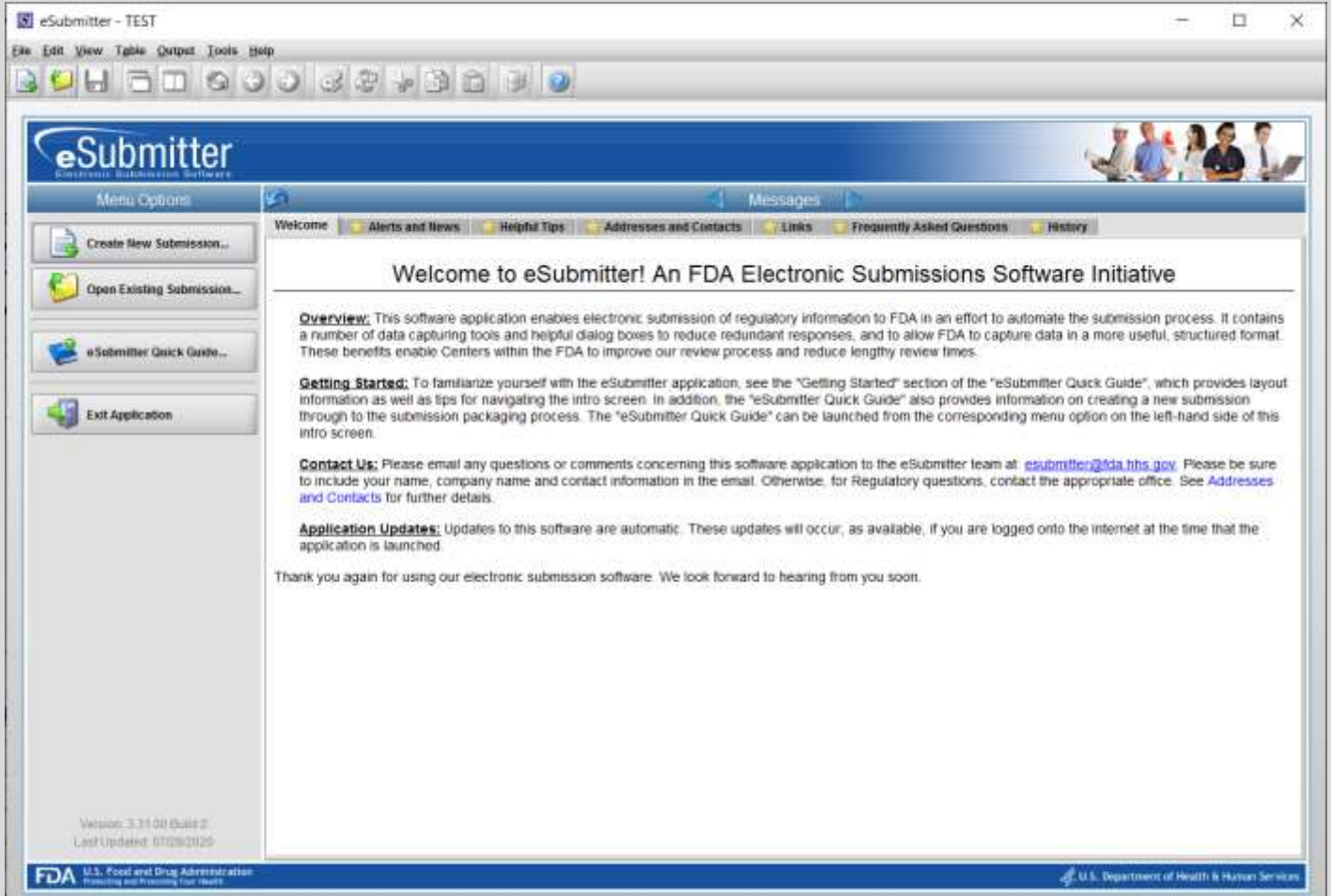
eMDR Setup Tasks

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

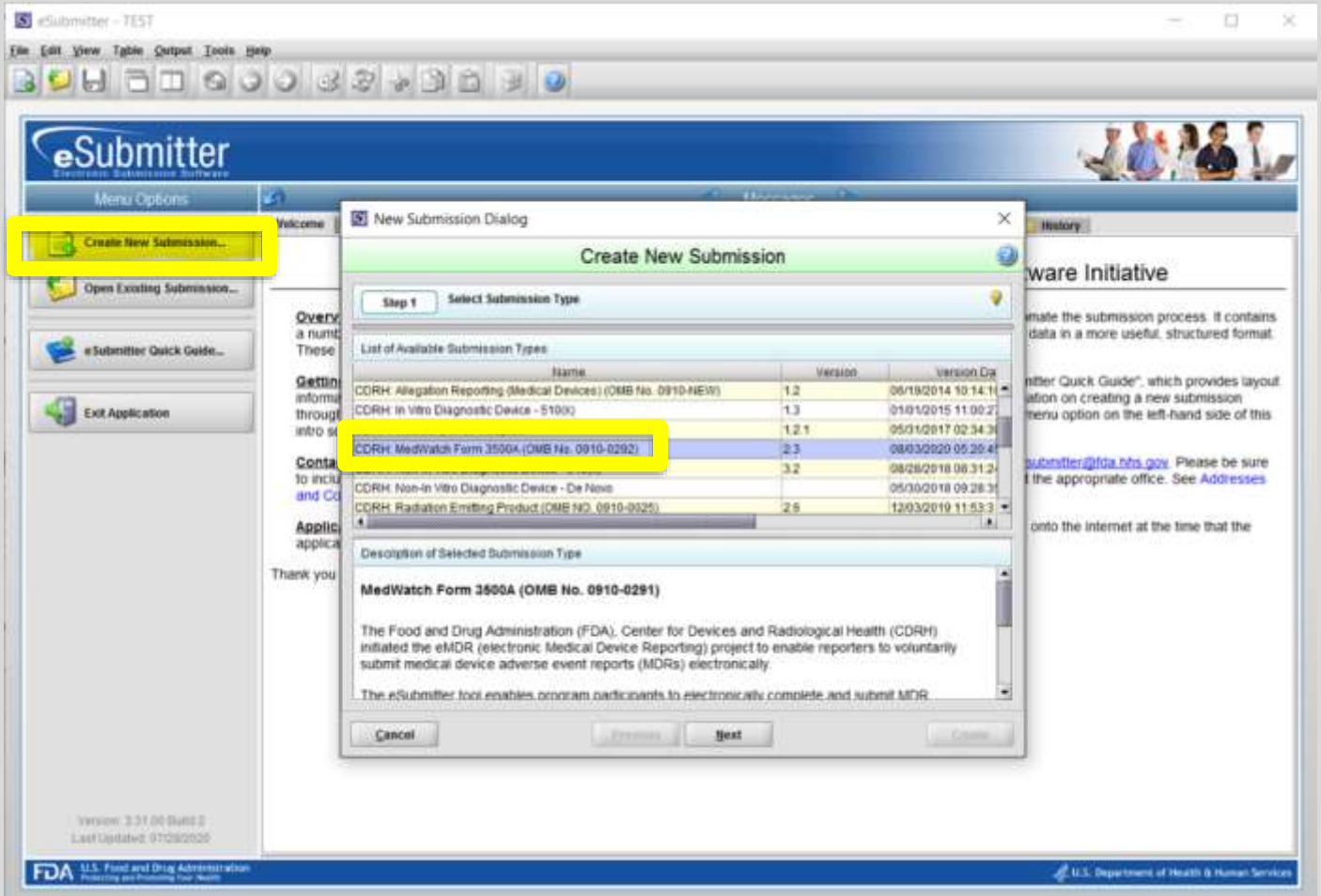
Low Volume Method

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 Walkthrough



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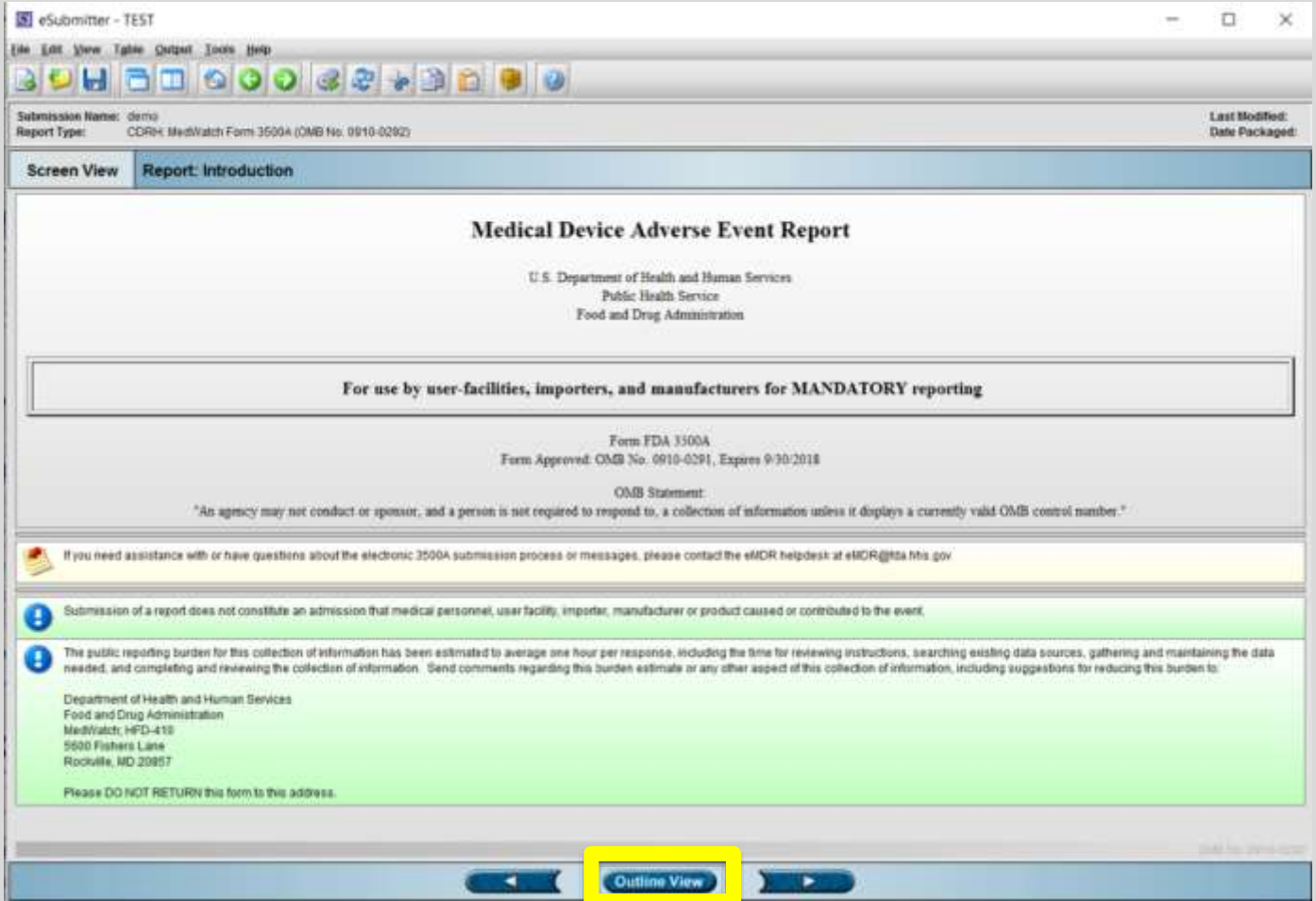

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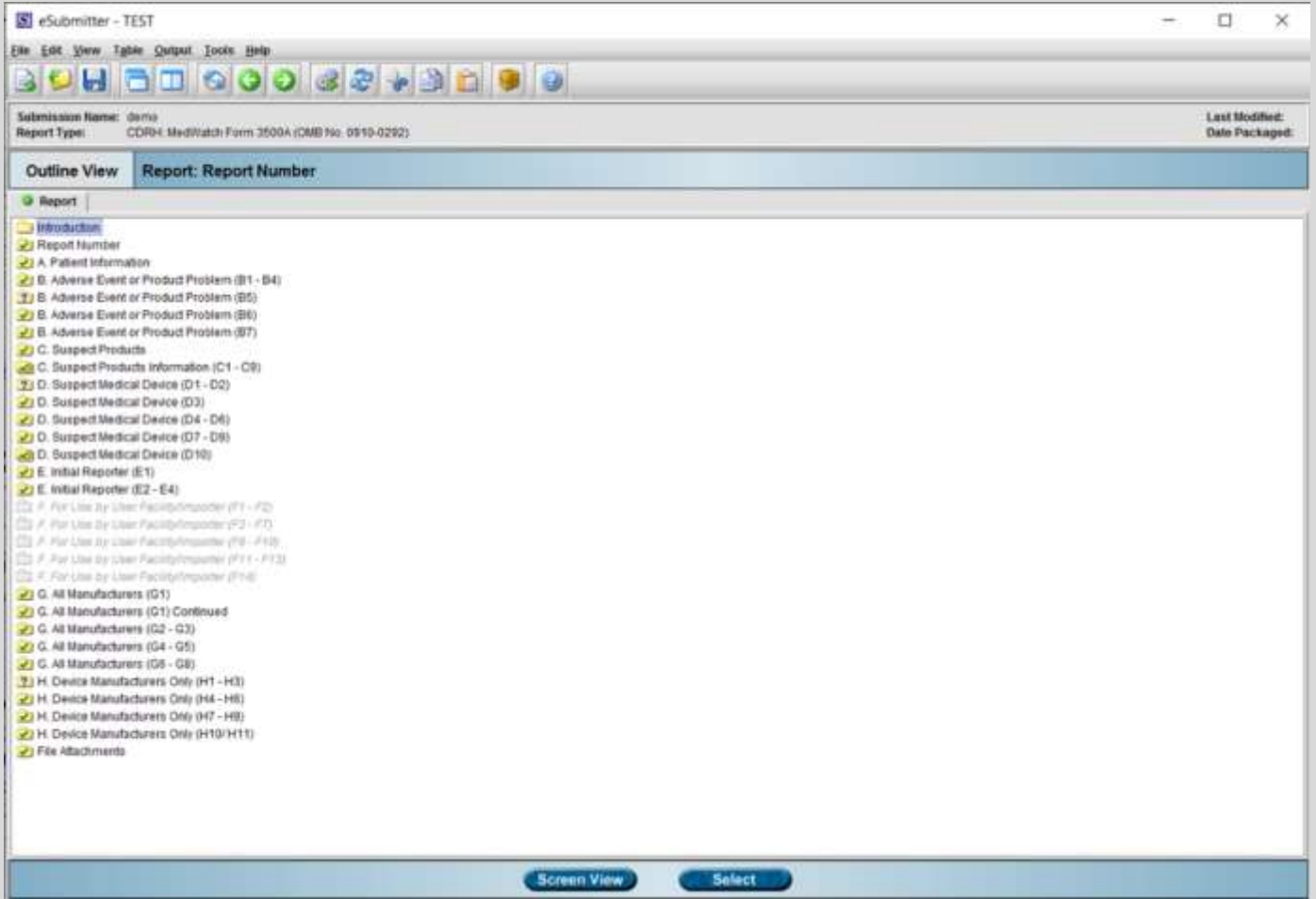

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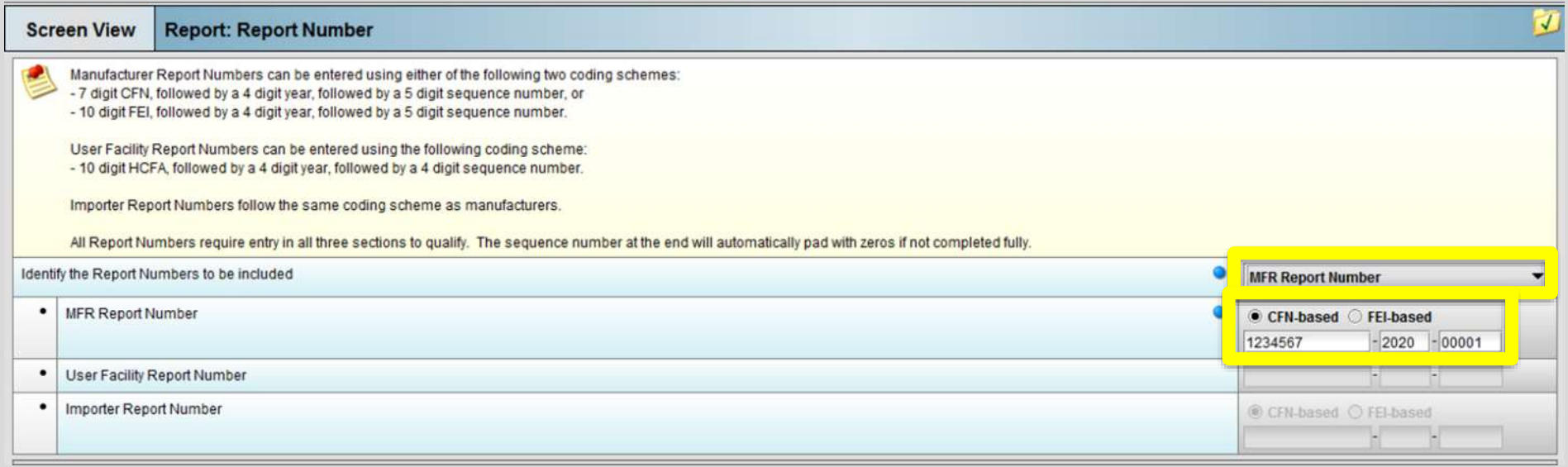

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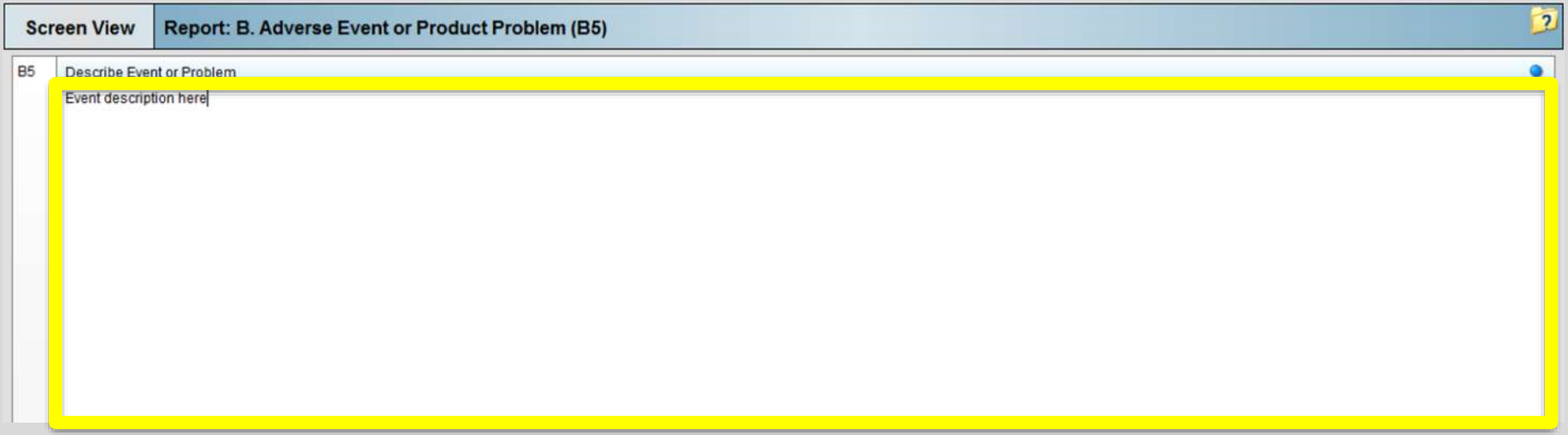

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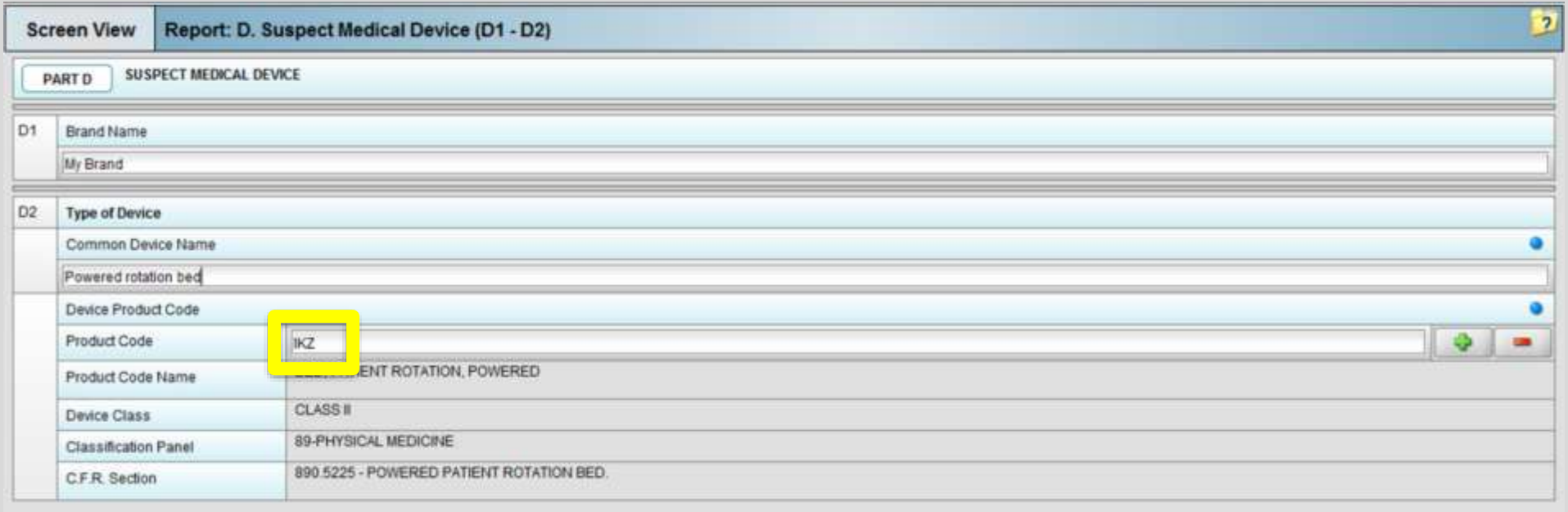

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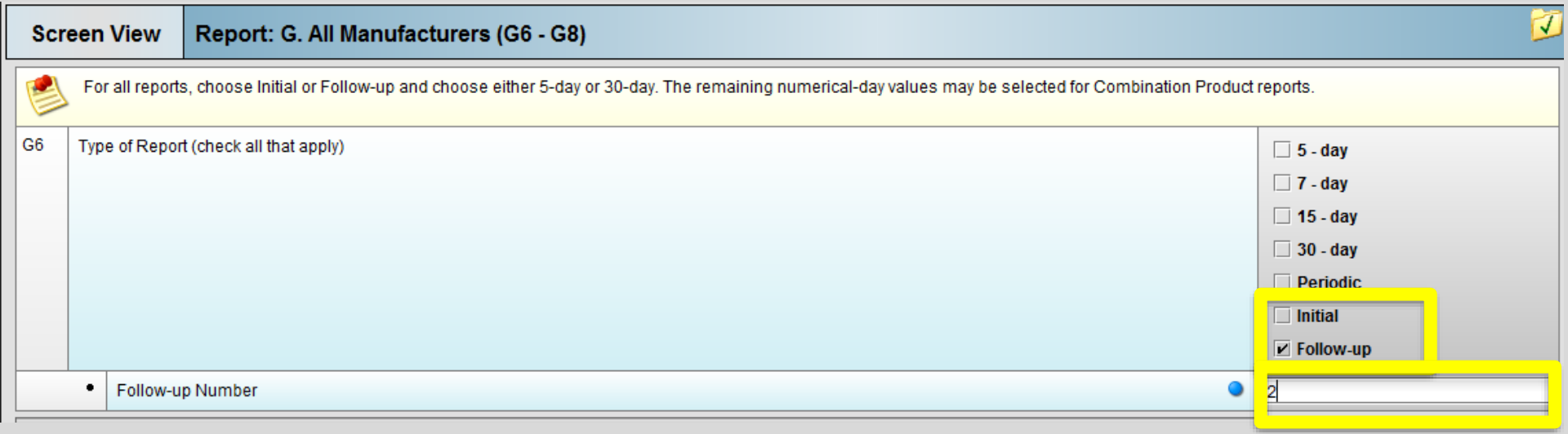

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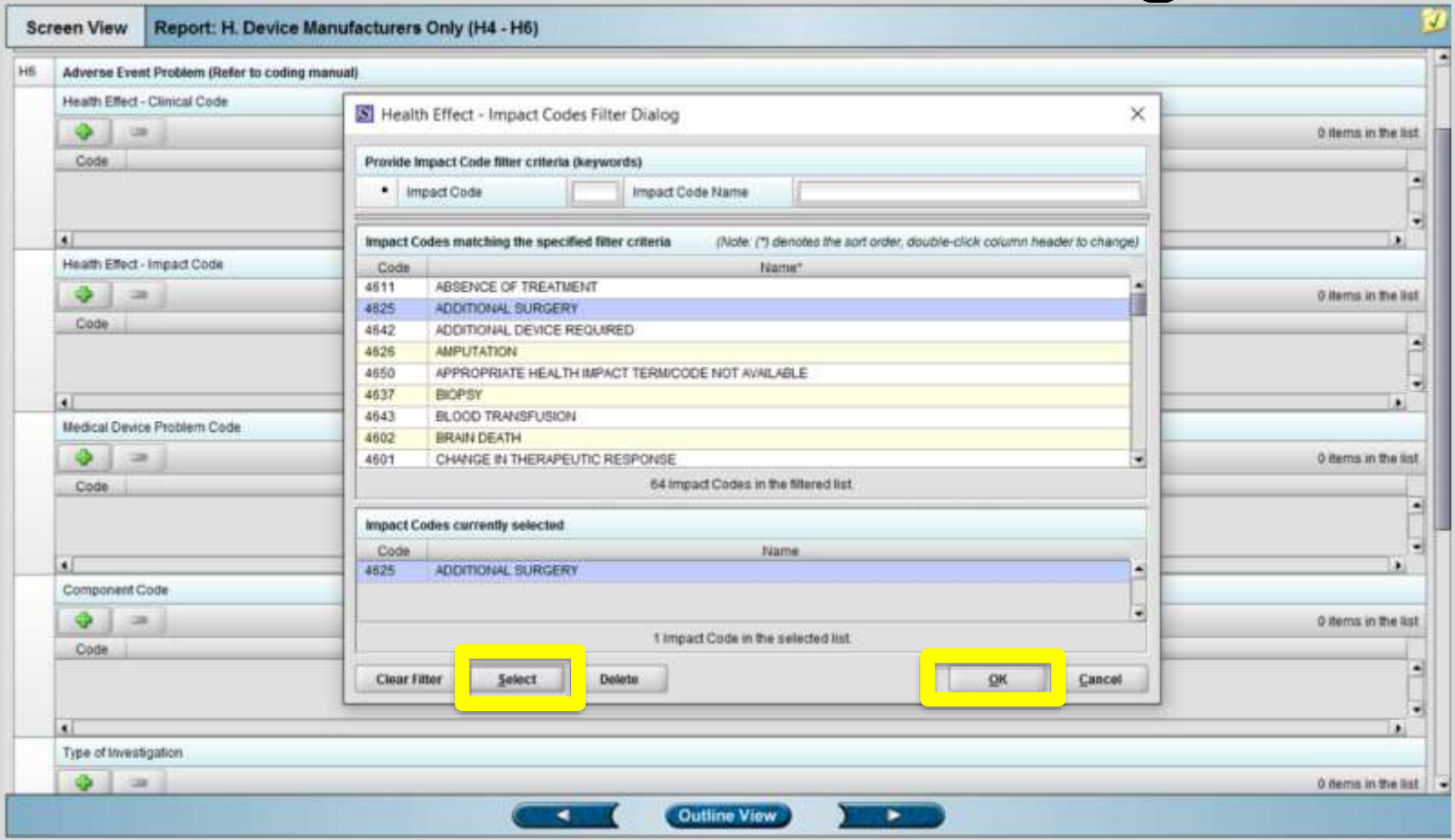

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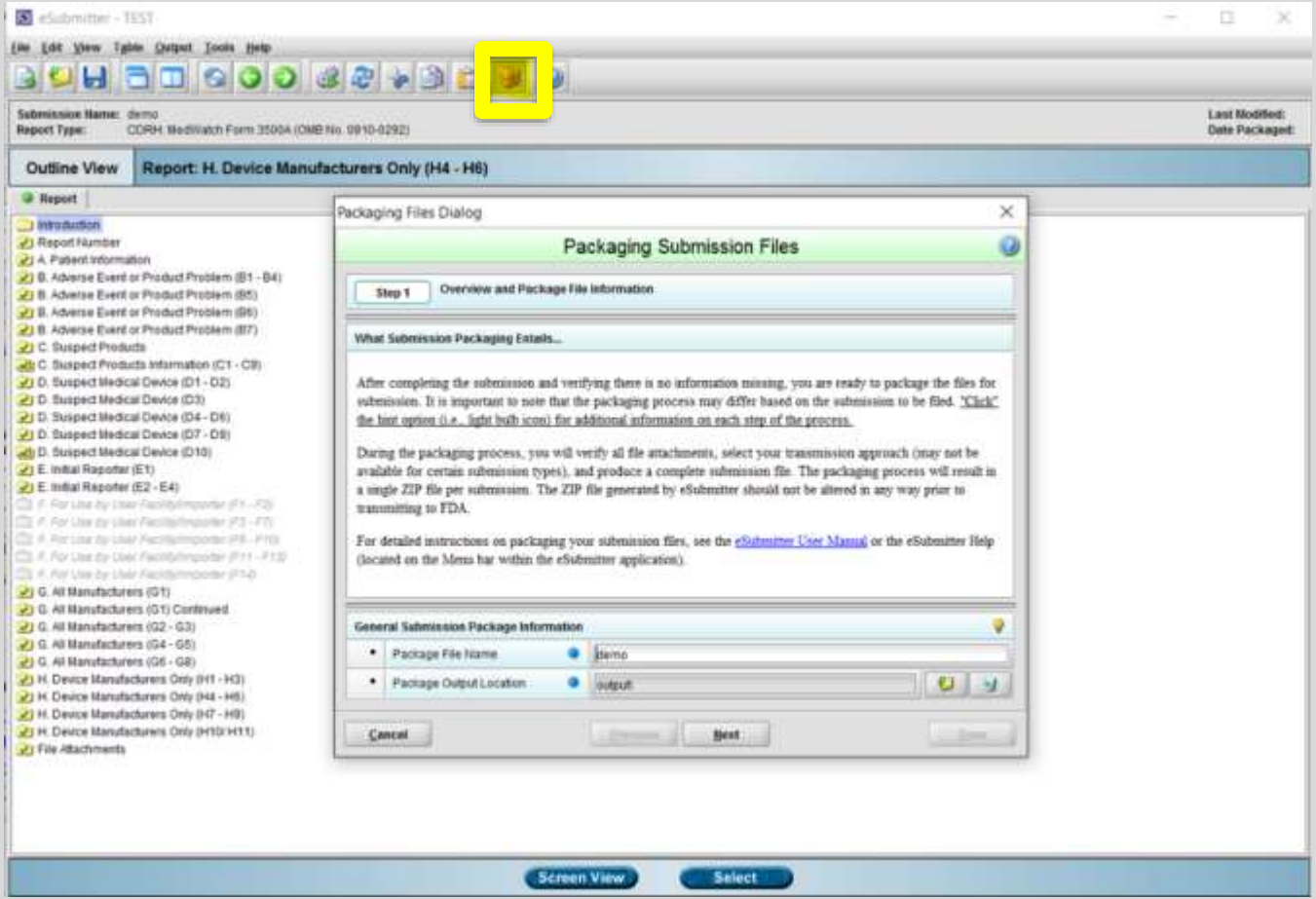

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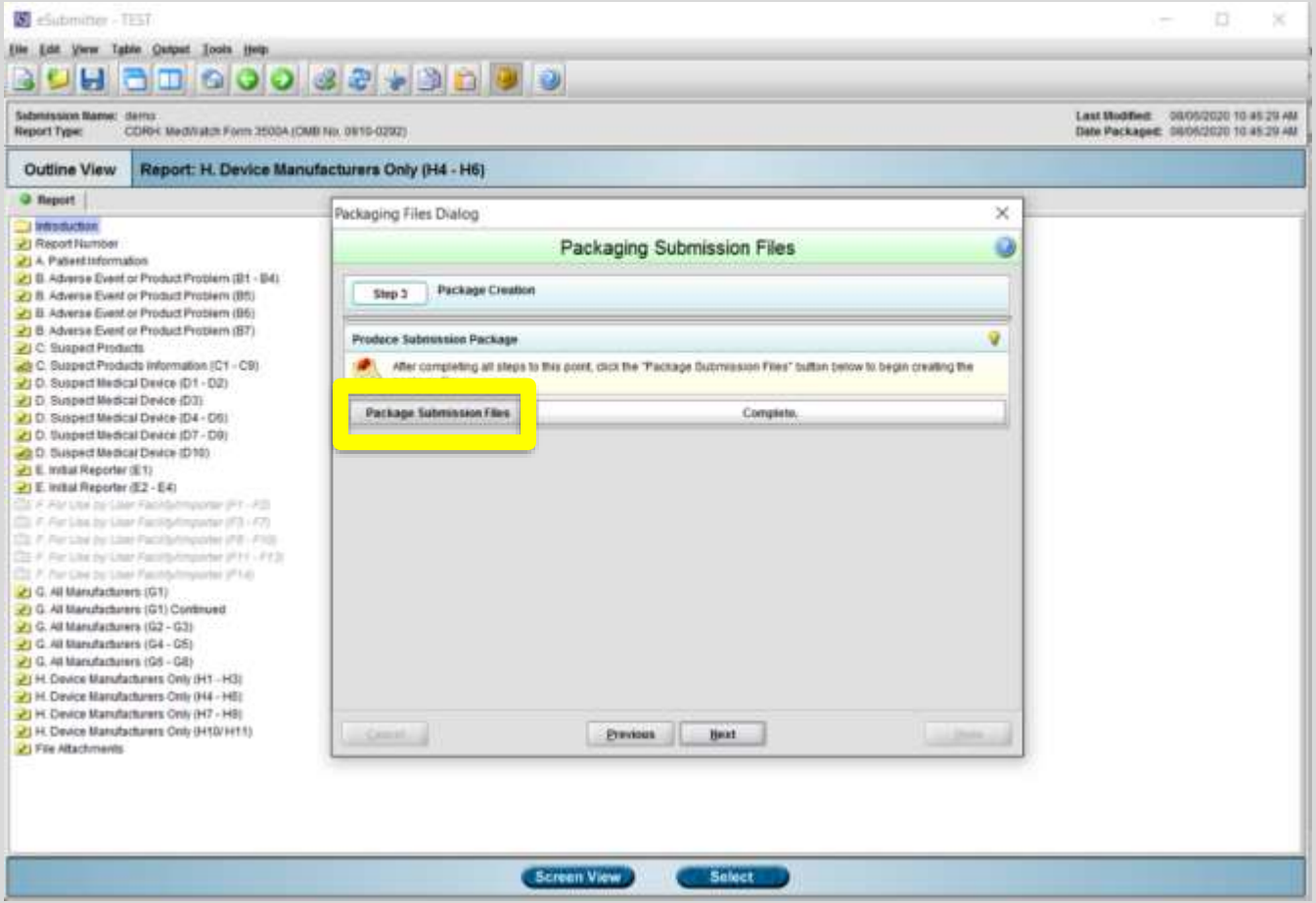
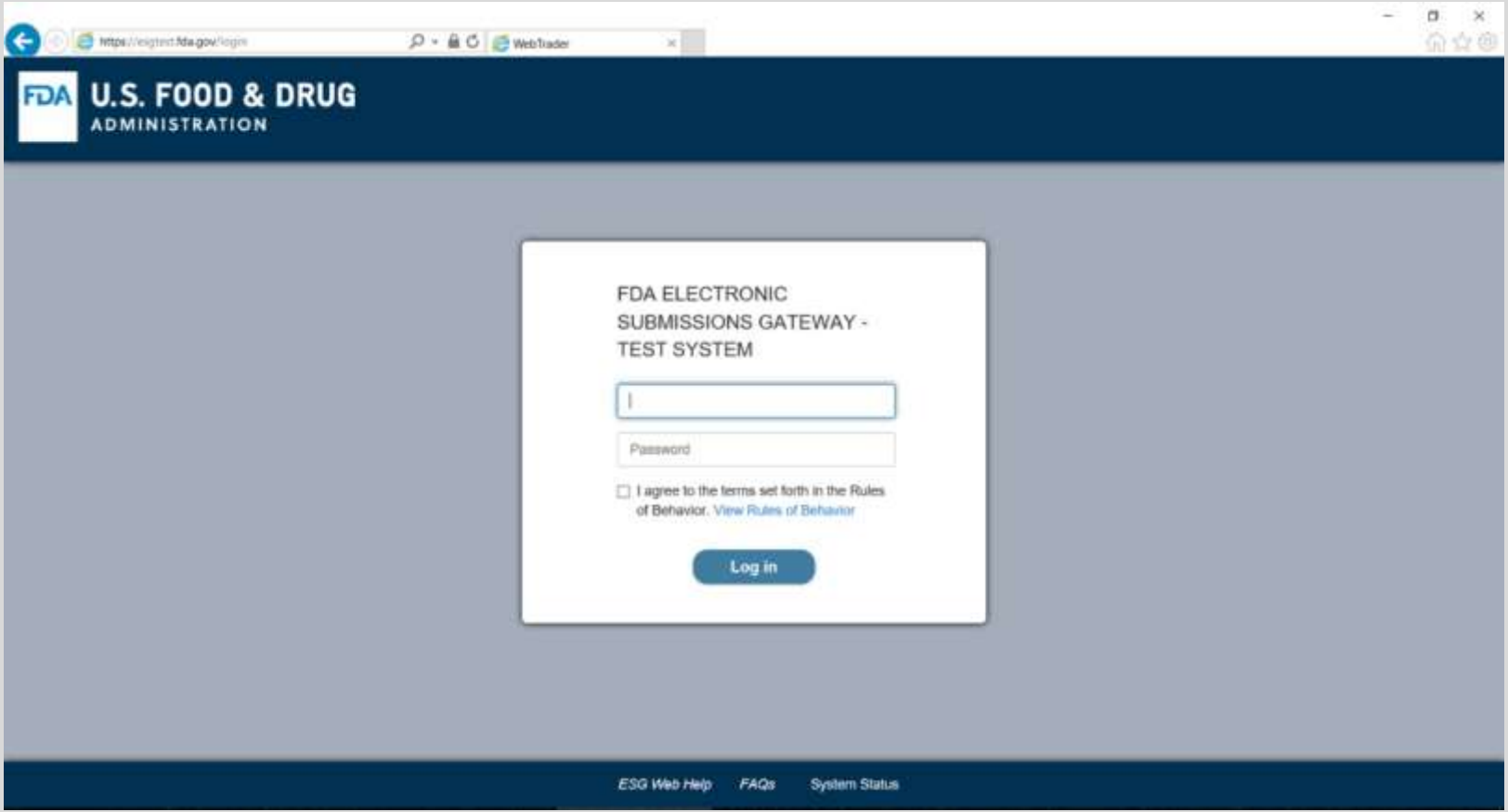
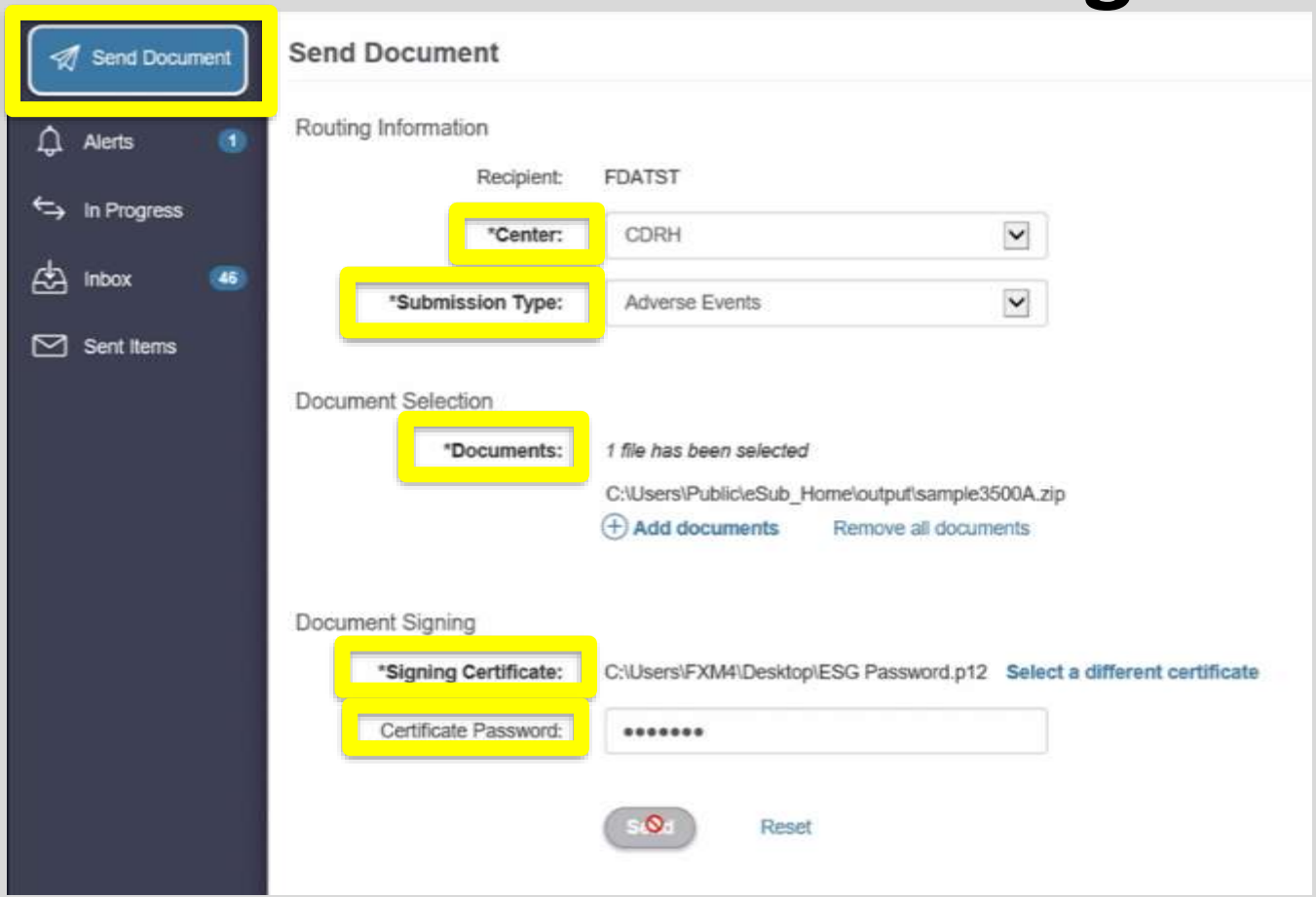


WebTrader Walkthrough



WebTrader Walkthrough



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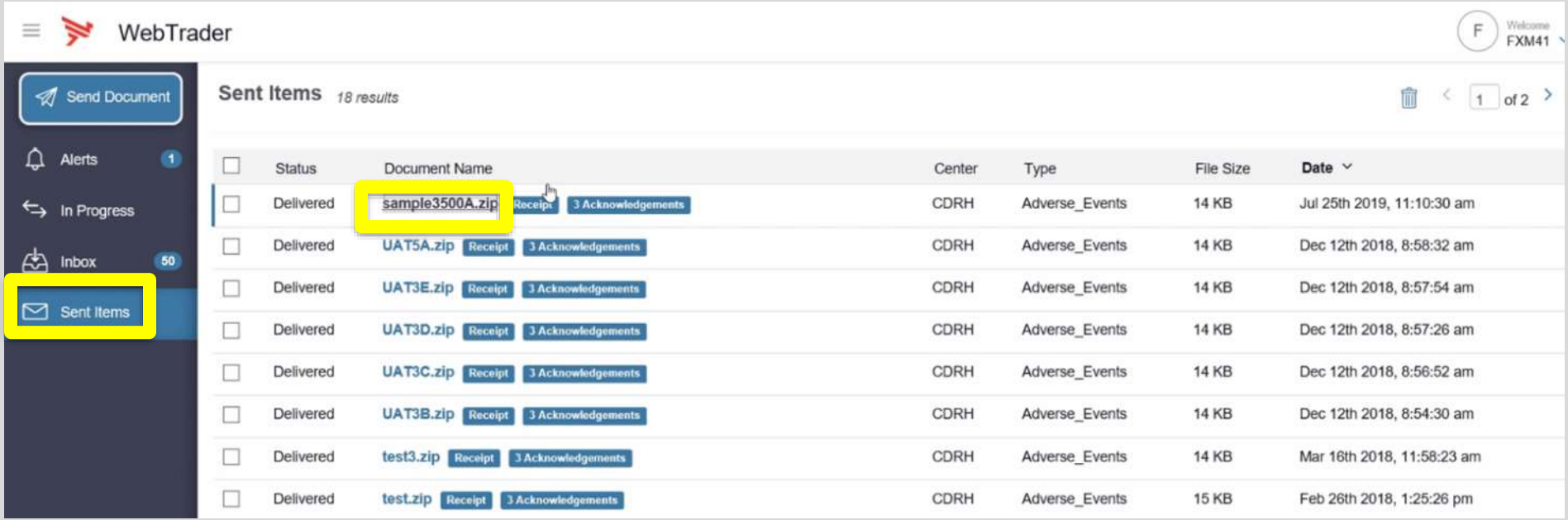

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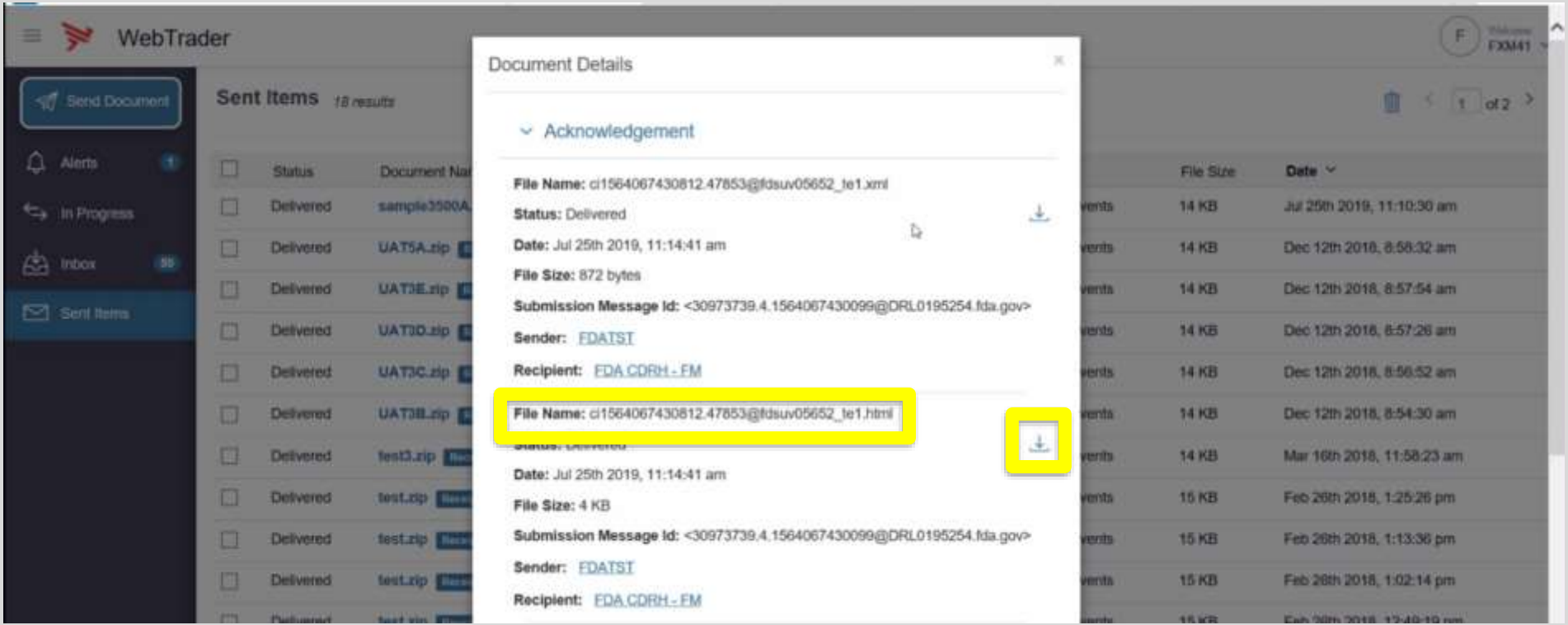

MDR Acknowledgments

- 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
- CeSub Helpdesk - CeSubHelpDesk@fda.hhs.gov
- eMDR Helpdesk - eMDR@fda.hhs.gov
- Policy Response Line - 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	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm
9	openFDA	open.fda.gov
12	eMDR site	www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/emdr-electronic-medical-device-reporting
15	ESG	www.fda.gov/industry/electronic-submissions-gateway
15	eSubmitter download	www.fda.gov/industry/fda-esubmitter/esubmitter-download-and-installation

Summary

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

Questions


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