



The eMDR Challenge

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Agenda – The eMDR Challenge

- Terminology
- High-Volume Basic Requirements
- Low –volume Requirements
- Decision tree – high volume vs. low volume
- Lessons Learned & Tips for Successful eMDR Implementation



Terminology

What is eMDR?

eMDR stands for electronic Medical Device Reporting. The eMDR process allows for electronic **receipt** and **processing** of medical device adverse event reports to CDRH, through the following steps:

1. **Build & Transform Data**: generate **MedWatch data file** (xml) using HL7, ICSR Release 1 message format that is mapped to the 3500A.
2. **Transmit the Information**: The file will be transmitted electronically to the FDA's Electronic Gateway (FDA ESG) where it will automatically "load" the MedWatch file into the FDA's databases.

FDA ESG

FDA ESG (FDA Electronic Submission Gateway)

- FDA Electronic Submissions Gateway is an FDA agency-wide entry point for all electronic submissions; it is an electronic portal that routes submissions to the appropriate FDA Center. This is the single point of entry for the receipt and processing of all electronic submissions in a highly secure environment that complies with secure messaging standards.

Letter of Non-Repudiation

- A letter of Non-Repudiation Agreement must be submitted to the FDA. The non-repudiation agreement allows the FDA to receive electronically signed submissions in compliance with 21 CFR Part 11.100
- Non-Repudiation letter is to affirm that your digital signature is equivalent to your hand-written signature
- Sample letters are on the FDA ESG website.
- <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm113964.htm>
- Recommendation: Use Letter #2 to reduce maintenance of submitting updates for any personnel changes

Letter of Authorization - US Agents / Consultants

- You will have to register for separate account(s) for each of your clients with the FDA ESG.
- Your client must submit an authorization to FDA. Please make sure the authorization lists your company name in the letter authorization.
- Your company must submit a Letter of Non-Repudiation to FDA.
- <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm334201.htm>

Digital Certificate

- This is a two-part electronic key, that when matched together defines who you are as the company or submitter. You have to have a digital certificate if you submit through Web Trader or through your EDI mechanism.
 - Must be X.509 compliant, see website
 - List of vendors at the FDA ESG website
 - Digital Certificates average cost \$20 - \$90 annually
 - One for each user submitting eMDR's

<http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm334781.htm>

eSubmitter

- Free downloadable software that the FDA has made available to help “**build & transform**” the electronic files to replace the manual 3500A “PDF” fillable reports.
- Generates the eMDR file, then need to “transmit” this file to the FDA ESG.
- This can reside on a PC or on a server in your company.
- <http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm>

Web Trader

- Free mechanism that the FDA has made available for “**transmitting**” the electronic eMDR file to the FDA ESG.
- Need Internet Browser and Digital Certificate.
- The FDA ESG Web Interface sends submissions via Hyper Text Transfer Protocol Secure (HTTPS) through a web browser according to Applicability Statement 2 (AS2) standards.
- <http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm114831.htm>

WebTrader

U.S. Food and Drug Administration

FDA Electronic Submissions Gateway

User ID:

Password:

I agree to the terms set forth in the System Notification below.

Remember my user ID

- Log into Web Trader
- Select the FDA center: CDRH
- Browse to select your eSub zipped file
- Select Adverse Events
- Browse to select your half of the digital Certificate, private key

[Login Help](#) [Web Trader Help](#)

WebTrader Help Logout

Send document

Select who will receive the document

Gateway: FDATST

Center:*

Select the contents of the submission

Enter a path to a file or a directory. If a directory is entered, then the entire contents of the directory will be included in the submission. All the paths stored in the submission will be relative from the provided directory path unless an alternate root directory is entered.

Path:*

Root directory:

Submission type:*

Select a signing certificate

Current file: C:\Documents and Settings\kacerad\Desktop\SS8_MR1_eMDR\FDA ESG Gateway\Digital Certificate\export_demo_key.pfx

New file:
MyCertificate.p12 or MyPrivateKey.pfx

FDA Web Trader Requirement

- **NOTE:** The FDA will only allow you to storing up to 10 submissions with their associated Acknowledgements. *They will be automatically deleted for all files over 10 by the FDA ESG. There will be no notification of this deletion.*
- You must remove all four of the Acknowledgements and store them in Complaint/Adverse Event system/file for possible review during FDA Audit/inspection.
- **RECOMMENDATION:** Create a SOP to pull all four acknowledgements from Web Trader once eMDR file is accepted and store in your Complaint/Adverse Event handling file.

FDA Web Trader Requirement's

- FDA ESG Web Interface users need the following:
- Web browser: Internet Explorer 6, 7, 8 or 9. (You may also use Internet Explorer 10 or 11 in IE 9 mode.)
- Software: Java Version 7; Java Runtime Environment (JRE) 1.7. [JRE 1.7 Installation Instructions](#).
- Hard disk: space of at least three times the size of the submission.
- A high-speed internet connection.
- **RECOMMENDATION:** Disable Java Updater on client that is submitting eMDR's or you will be frozen when you need to submit, if it updates to the latest version!

FDA Web Trader Hosted (WTHS)- 5/22/14

- WTHS is a web-based solution that will eliminate the need for installing JRE (Java Runtime Environment) on the user's machine or create a backup if the JRE computer is down. The benefits of WTHS are:
 - WTHS eliminates the need for JRE installation and maintenance for WebTrader users' computers
 - WebTrader users can make submissions from both Windows and Mac operating systems
 - Users may make submissions from almost any Web Browser
- Are there any requirements to utilize WTHS?
 - WTHS login session will have a limit of 60 minutes per login
 - WTHS option is recommended for submissions smaller than 250MB
 - Only one login session is allowed per user
 - Only one WTHS account is allowed per individual users. Users that have multiple WebTrader accounts will only be issued one WTHS account
- The [WTHS Tutorial](#) outlines how the WTHS and WebTrader account login and submission process works.

B2B Requirement's

- This is the communication method that a company can use as their B2B\B2B\EDI tool so that they can electronically send information from their company directly to the FDA ESG.
- Applicability Statement 2 (AS2) Gateway-to-Gateway
 - An electronic submission protocol that uses HTTP/HTTPS for communications.
- Header information will be used to route submission to the appropriate center. (Center and Report Type)
- **TAKE AWAY:** your EDI has to be AS2 compliant!!!
- Your EDI AS2 is compatible with IETF EDIINT RFC 4130 – SHA-2 version compatible as of June 28, 2014

Acknowledgements



Regulation requires you maintain the 3 Acks

Maintain all 4 Acks (including both xml/html Ack 3)

Acknowledgment 1

```
This MDN (Message Disposition Notification) was automatically built on Tue, 31 Jul 2007 22:15:56 GMT in response to a message with id <8180602.1185920139411.JavaMail.qdn@DR2MM5102150> received from ZZFDATST on Tue, 31 Jul 2007 22:15:51 GMT. Unless stated otherwise, the message to which this MDN applies was successfully processed.
```

Ack1: Regulatory Date Using Reporter Time Zone *IF* Ack3 Passes.

Acknowledgment 2

```
MessageId: <8180602.1185920139411.JavaMail.qdn@DR2MM5102150>  
CoreId: 1185920151277.11322@llntap02  
DateTime Receipt Generated: 07-31-2007, 18:17:27  
CDRH has received your submission
```

Acknowledgment 3

Submission Summary	
Core ID:	1185920151277.11322@llntap02
Batch ID:	2939301-20070731181208
Date Entered:	Tue Jul 31 18:18:17 EDT 2007
Summary:	passed: 1, Failed: 0

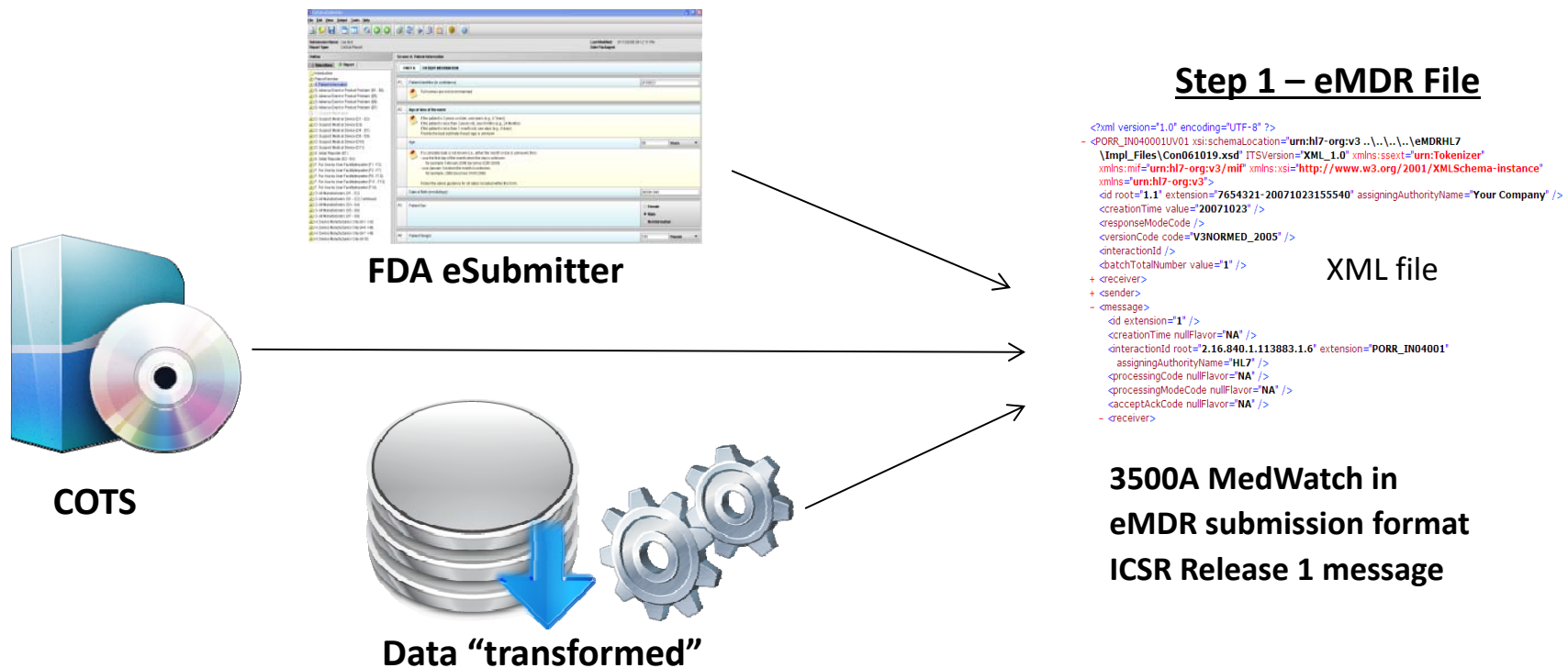
Report List:	
Report Number:	██████████-2007-06009, passed.



Low/High Volume Options for managing eMDR requirements

How to create your eMDR file

- Low Volume(manual): FDA eSubmitter – free downloadable software

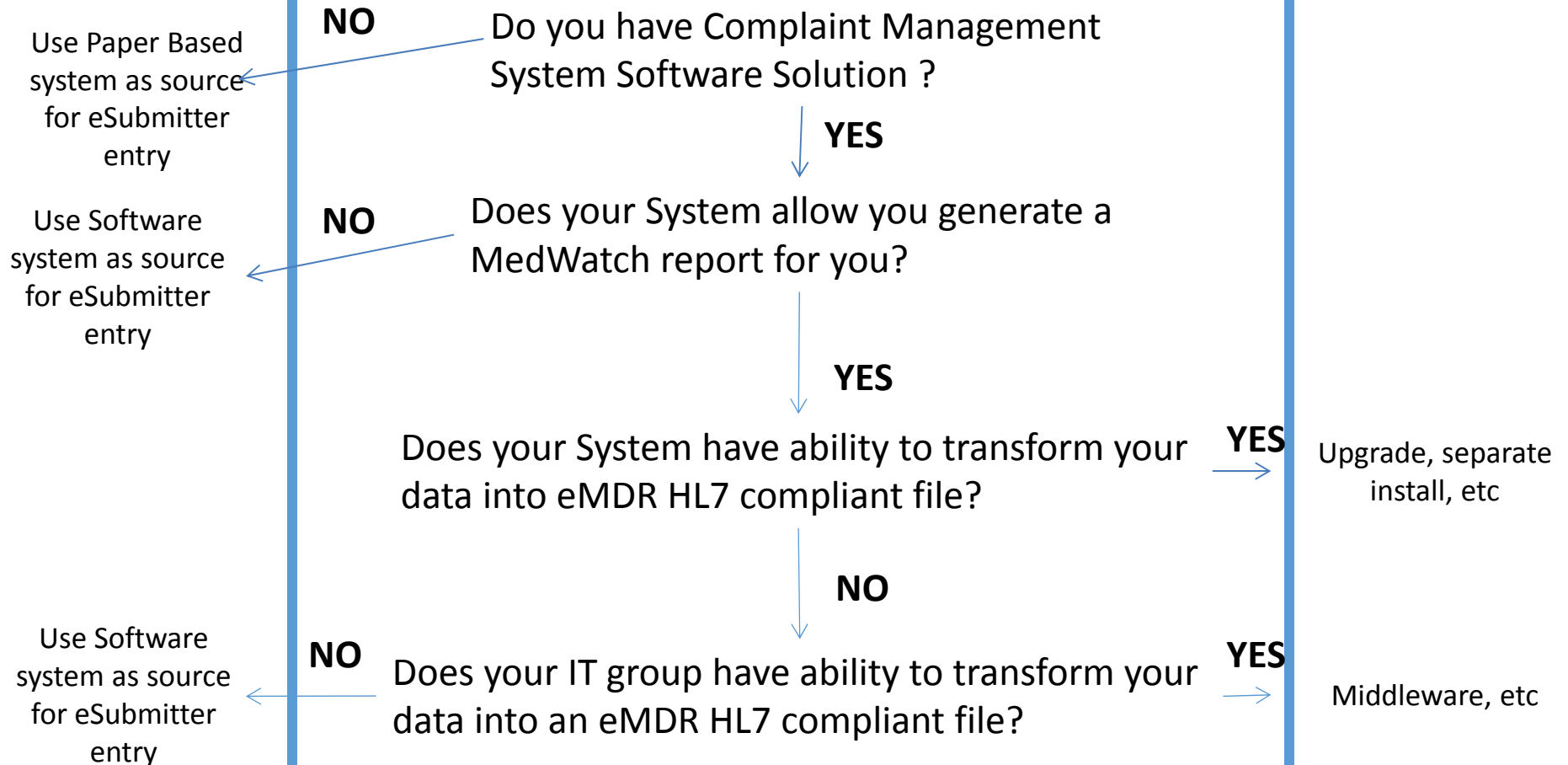


- High Volume(automated): a) Commercial Off the Shelf Software b) Internally built solutions c) middleware solutions that “Transform” data.

Step 1 Decision Chart



How will You create the eMDR File



Step 2 Decision Chart

WebTrader (AS2)
WebTrader Hosted



Utilize free FDA connector for one at a time submissions

NOTE: Only 10 Submissions can Be kept inside This portal at one time.

How will You send the eMDR File

Does your company have a B2B in place?

YES →

Leverage existing EDI

↓ **NO**

NO ←

Do you have a Pharma division that uses a EDI?
Currently submitting electronically to the FDA?
Do you have resources to maintain a EDI?
Do you have skill set to implement a EDI?
Can you justify with your submission volume
Purchasing an EDI solution?

YES →

Purchase or Leverage existing B2B and resources

EDI/B2B (AS2)





Lessons Learned

What can go Wrong?

- Capture the types of failures you find during testing and then capture these as metrics as you go live to Continuously Improve!
- The types of failures below are dependent on the system used to create the eMDR File and transmit it to CDRH. These are the “typical” failures that have been consistently seen during implementations.
- Phone Format
- No Initial
- Wrong Code Used
- State / Country Format
- Connectivity Issues
- Java Version

eMDR Transition – What to Do

- Cross-Functional Planning (IT/RA) to ensure you do not have any late MDR's
 - Perform a mock cut over
 - What are the issues your team uncovers
- Back-up plan for generating eMDR file and transmitting the file.
- Reduce your internal MDR due date for 30 day MDR's to 25 days
- Start NOW!

Lessons Learned

- When starting your program reduce your internal target to submit to FDA; for example, if you have 30 day MDR, set goal to submit by day 25
- If you need to do a follow-up report after you have gone live on a MDR reported manually, submit manually, as the initial MDR may not be in the system yet
- Start with the Web Trader for your initial rounds of testing and familiarity with the entire process (if using B2B, web trader should be your backup)
 - Web Trader requires a specific version of Java on the client (PC) to be compatible
 - Consider new Web Trader Hosted Solution with no Java requirements
- Use a Digital Certificate that has an expiration date (2 years)
- When using Web Trader, make sure your SOP clears out the acknowledgements returned before you have 10 stored.

Lessons Learned

- Some fields have field length restrictions due to the MAUDE database and may not be the same size as what you are used to using or your systems allow
- Date fields are required in full format now
- Phone number formats are strictly adhered to
- Make sure you test for all your registration numbers (manufacturer, importer, User Facility) in the FDA test environment – you might be surprised to see what happens, they are validating all the numbers.
- Ensure that your vocabulary for Patient/Device/Results, Occupation, etc. are current as they are validated prior to submission to MAUDE.

Lessons Learned

- Files other than PDF submitted with eMDR must be zipped
- Paradigm shift
 - Moving away from the physical form to “information”
 - Putting all information into the discrete data sections instead of H10/11
- Manufacturer’s IT and Functional groups have to work together to work through the testing and plans for moving to production
- Commonly used characters such as: <, >, “,/ , @, etc. cannot be used in the text as they are utilized as markers in the xml code
- Foreign adverse event reports can be a problem because FDA is currently using UTF-8 schema which does not permit foreign characters (e.g., ñ, ü, é, etc.)

eMDR Website

- Reporters should subscribe at eMDR Home Page for updates!
- <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/eMDR-ElectronicMedicalDeviceReporting/default.htm>

The screenshot shows the FDA website's navigation and content area. At the top, the FDA logo and name are displayed, along with the tagline "Protecting and Promoting Your Health". Navigation links include "Home", "Food", "Drugs", "Medical Devices", "Radiation-Emitting Products", "Vaccines, Blood & Biologics", "Animal & Veterinary", "Cosmetics", and "Tobacco Products". A search bar is located on the right side. Below the navigation, the "Medical Devices" section is highlighted, with a breadcrumb trail: "Home > Medical Devices > Device Advice: Comprehensive Regulatory Assistance > Postmarket Requirements (Medical Devices)". The main content area features a section for "eMDR – Electronic Medical Device Reporting" with a link to "CDRH Industry: Get e-mail updates" and a list of "eMDR News" items, including "Guidance for Industry, User Facilities and FDA Staff: eMDR - Electronic Medical Device Reporting" and "Final Rule on Electronic Medical Device Reporting (eMDR)". A sidebar on the left contains a "Device Advice: Comprehensive Regulatory Assistance" menu with options for "Postmarket Requirements (Medical Devices)", "Mandatory Reporting Requirements: Manufacturers, Importers and Device User Facilities", and "eMDR – Electronic Medical Device Reporting".

CDRH Contacts

- eMDR Questions
- Email Contact eMDR Project Team
 - eMDR@fda.hhs.gov
- CDRH Policy
- Email: MDRPolicy@fda.hhs.gov



Thank you...

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