Electronic Medical Device Reporting (eMDR)

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What will you learn?

• what is eMDR and why do we need it
• the eMDR system overview and process
• what options do I have
• steps for approval
• lessons learned
Medical Device Reporting (MDR)

MDR Regulation
21 CFR 803

MAUDE
Manufacturer and User Facility Device Experience

MDR MedWatch 3500A

ASR
Alternate Summary Reporting
MDR’s Reported

- Focus on Mandatory Reports
- Number of MDR’s are increasing
The way it is for Manufacturers

Mandatory MedWatch fillable PDF Form or solution generated

Manufacturer → Manufacturer’s mail, overnight, Burn CD’s and express MDR’s to the FDA.

Did the FDA get It in time?  Do they need something else?
The way it is for the FDA

Mandatory MedWatch

FDAs receives report and has contractors type Data into MAUDE database

Attachments

MAUDE

Summary Reports
Proposed Regulation

• § 803.12 How do I submit reports and supplements?
• (a) Manufacturers, user facilities, and importers must submit initial and supplemental reports to FDA in an electronic format that FDA can process, review, and archive. FDA will provide and update information on how to provide the electronic submission (e.g., preparation and organization of files, file formats, media and method of transmission).
FDA eMDR Goals

- Receive accurate and timely information
- Eliminate human error for data entry
- Reduce non-value added costs
- Analyze and Trend on elements in Adverse Event Reports
**What is eMDR?**

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

1. **Build & Transform Data**: generate *MedWatch data file* (xml) using HL7 v3, 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 called (FDA ESG) where it will automatically “load” the MedWatch file into the FDA’s databases.
eMDR Process – Step 1

• **Build & Transform the Data**: enter your MedWatch information into an application and generate *MedWatch data file*.
  - What the application has to use?
    - HL7 standard (ANSI accredited standards organization)
    - ICSR Release 1– Individual Case Safety Report messaging format, mapped to the 3500A
    - Utilizing codes defined by National Cancer Institute (NCI) and unique FDA codes

1) Enter (build) your MedWatch information

2) Transform data into an xml file

```
- <!-- Patient Identifier, BOX A1 -->
  <name>XYZ12345</name>
- <!-- Sex, BOX A3, Code is populated with Male -->
  <administrativeGenderCode code="C20197"
    codeSystem="2.16.840.1.113883.3.26.1.1"
    codeSystemName="Sex"/>
- <!-- Date of Birth, BOX A2 -->
  <birthTime value="20000101"/>
```
eMDR Process – Step 2

- **Transmit the Information**: The file will be transmitted electronically to the FDA’s Electronic Gateway called (FDA ESG) where it will automatically “load” the MedWatch file into the FDA’s database.
  - What you have to use?
    - Connector to FDA ESG Portal – Web Trader
    - AS2 protocol
    - NOT EMAIL
Acknowledgements

Reporters → FDA ESG → CDRH/eMDR → MAUDE

Ack1

Ack2

Ack3
Acknowledgements

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
CoreID: 1185920151277.11322@llntap02
BatchID: 2939301-20070731181820
Date Entered: Tue Jul 31 18:18:17 EDT 2007
Summary: passed: 1, Failed: 0

Report List:
- **Manual File Creation**: FDA eSubmitter – free downloadable software

- **Automated File Creation**: a) Commercial Off the Shelf Software, b) Internally built solutions, c) middleware solutions that “Transform” data.
How to transmit the eMDR file?

- **Manual Transmission**
  - Web Trader – free connector for electronic file submission to the FDA ESG

- **Automated Transmission**
  - Deploy an AS2 compatible transport mechanism that can connect to the FDA ESG (i.e., B2B)
  - XML file
  - 3500A MedWatch in eMDR submission format
Steps to FDA ESG Approval

- Go to the FDA ESG website
  - Follow the FDA ESG Implementation steps in the User guide
  - Initially
    - Determine how you are going to do your eMDR submissions
    - Submit a Letter of Non-repudiation (examples at website)
    - Obtain Digital certificate (see FDA ESG website)
- Register as a Trading Partner
  - Send an email and then register on-line
  - Signup for the test environment (web trader or AS2)
  - Initial testing through Web Trader or your AS2 connector
Steps to CDRH eMDR Approval

- Request your submission testing to the eMDR team
  eMDR@fda.hhs.gov
- Below are six types of reports that are requested for testing. If a particular report does not apply to your situation, please discuss with an eMDR team
  - Initial 3500A
  - Initial 3500A with an attachment
  - Initial 3500A followed by a supplemental 3500A (supplemental should be submitted after initial is loaded successfully)
  - Initial 3500A with section F filled out (section F is used to provide information from user facility or importer source report)
  - Initial 3500A and source report(s) as attachments
  - Batch submission that includes more than one 3500A
Submitting In General

• Once you begin electronic reporting, submit all documents electronically
  – Initial reports
  – Supplemental/follow-up reports
  – Attachments (must be either .pdf or .zip)
  – Responses to Additional Information letters
  – Source reports (e.g. user facility reports)
• What happens when a report is late because FDA was unable to process my submission?
  – Resubmit the (now late) report when FDA’s system is back online.
  – In H10 document your initial attempt with times, dates, message ids, and core ids.
Lessons Learned

• Manufacturer’s IT and Functional groups have to work together to work through the testing and plans for moving to production
• Start with the Web Trader for your initial rounds of testing and familiarity with the entire process
• If using AS2 still utilize Web Trader as a backup
• Special characters can cause problems with generation of an xml file and the validation as it goes to MAUDE
• Requires Java 1.5 w/ JCE (**OLD JAVA**) – Where to run WebTrader from?
Lessons Learned

- Attachments must be zipped and submitted within the xml file (except for PDF files)
- All testing has to be done with valid registration numbers for manufacturing numbering, Importer or User Facility numbering in Section F
- Paradigm shift
- Moving away from the physical form to “information”
- Putting all information into the discrete data sections instead of H10/11
- Some manufacturers were struggling with internal systems to get digital certificates for testing using the Web Trader
• **Which method?**
  – Cost/Benefit decision made by the reporter.

• **When to start?**
  – No time like the present!
  – Little to no changes to submission methods expected so no need to wait to start.

• **Who to engage?**
  – Regulatory/Complaint Coordinators
  – IT

• **Why start?**
  – Better/faster processing by FDA.
  – Receipt of submission.
  – And hopefully, a better system of reporting for submitters.
• Reporters should subscribe at eMDR Home Page for updates!
eMDR Information

• Manual File Creation - eSubmitter “download and installation”
  – http://www.fda.gov/ForIndustry/FDAeSubmitter/ucm108165.htm

• Automated File Creation – HL7 Requirements
  – http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm127951.htm

• Email Contact eMDR Project Team
  – eMDR@fda.hhs.gov

• FDA Electronic Submission Gateway (FDA ESG)
  – http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm
Thank You and Questions

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