Establishing Electronic Medical Device Report (eMDR) account for submission of reports to FDA

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Outline

1. Manufacturer's reporting requirements
2. Alternatives to individual reporting
3. Electronic Medical Device Reporting (eMDR): Methods, set up, test requirements, best practices & resources
4. Questions

Medical Device Reporting (MDR)

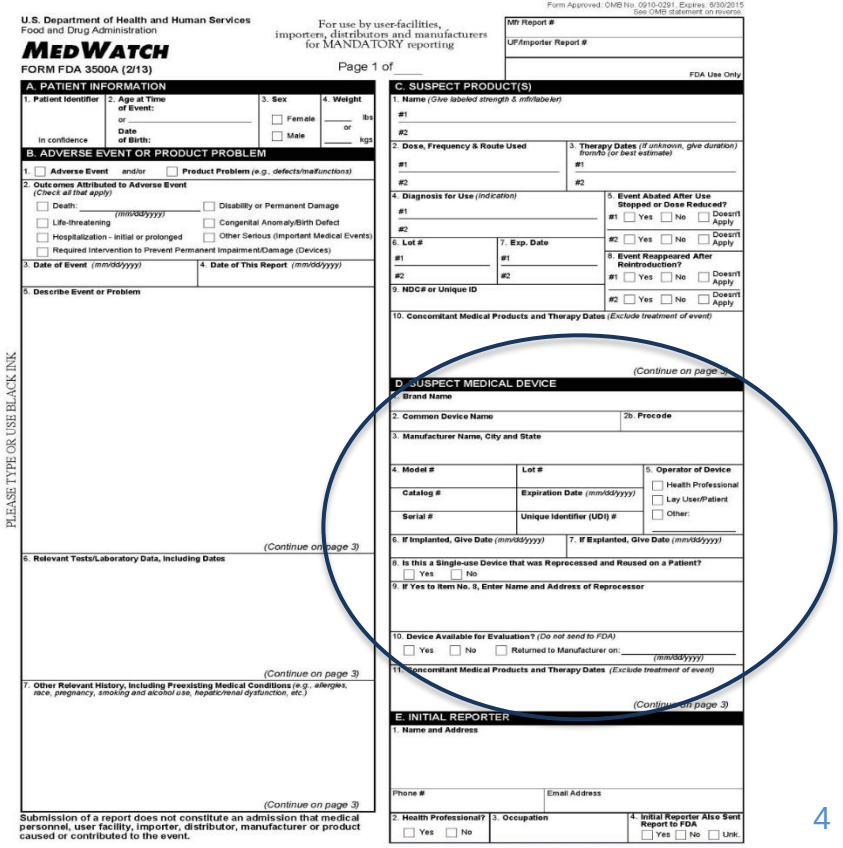
[Manufacturer's reporting requirements]

REPORTER	WHAT TO REPORT	WHERE	WHEN	Regulation#
Manufacturer (Mfr.) **21 CFR 803.50**	Deaths, Serious Injuries	FDA	Within 30 calendar days	21 CFR 803.50(a)(1)
	Malfunctions	FDA	Individual Reports: Within 30 calendar days; Summary Reports: Quarterly (VMSRP) if eligible and self-selected	Individual: 21 CFR 803.50(a)(2) Summary: 803.19(c)
	Events that require remedial action to prevent an unreasonable risk of substantial harm	FDA	Within 5 work days	21 CFR 803.53(a)
	Supplements (F/U Reports)	FDA	Within 30 calendar days	21 CFR 803.56

Mandatory reporting timeframe begin on the day after the reporting entity becomes aware of:
A reportable event; A request from FDA for 5-day report; Identification of a remedial action (5-day report only); or when a manufacturer acquires additional/corrected information (supplement)

MDR Reportable Event

- An event that manufacturers or importers become aware of that reasonably suggests that one of their marketed devices:
  - May have caused or contributed to a death or serious injury, or
  - Has malfunctioned and that device or similar device marketed by the manufacturer would be likely to cause or contribute to a death or serious injury, if it were to recur



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

MEDWATCH

FORM FDA 3500A (2/13)

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

Page 1 of ____

Form Approved: OMB No. 0910-0291, Expires: 6/30/2015
See OMB statement on reverse.

MW Report #

UF/Importer Report #

FDA Use Only

A. PATIENT INFORMATION

1. Patient Identifier — In confidence
2. Age at Time of Event: or Date of Birth:
3. Sex — Female / Male
4. Weight — lbs or kgs

B. ADVERSE EVENT OR PRODUCT PROBLEM

1. Adverse Event and/or Product Problem (e.g., defects/malfunctions)
2. Outcomes Attributed to Adverse Event (Check all that apply)
   - Death: (mm/dd/yyyy)
   - Life-threatening
   - Hospitalization - initial or prolonged
   - Required Intervention to Prevent Permanent Impairment/Damage (Devices)
   - Disability or Permanent Damage
   - Congenital Anomaly/Birth Defect
   - Other Serious (Important Medical Events)
3. Date of Event (mm/dd/yyyy)
4. Date of This Report (mm/dd/yyyy)
5. Describe Event or Problem

(Continue on page 3)

6. Relevant Tests/Laboratory Data, Including Dates

(Continue on page 3)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

(Continue on page 3)

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

C. SUSPECT PRODUCT(S)

1. Name (Give labeled strength & mfr/labeler) #1 #2
2. Dose, Frequency & Route Used #1 #2
3. Therapy Dates (If unknown, give duration) from/to (or best estimate) #1 #2
4. Diagnosis for Use (Indication) #1 #2
5. Event Abated After Use Stopped or Dose Reduced? #1 Yes No Doesn't Apply; #2 Yes No Doesn't Apply
6. Lot # #1 #2
7. Exp. Date #1 #2
8. Event Reappeared After Reintroduction? #1 Yes No Doesn't Apply; #2 Yes No Doesn't Apply
9. NDC# or Unique ID
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

D. SUSPECT MEDICAL DEVICE

1. Brand Name
2. Common Device Name — 2b. Procode
3. Manufacturer Name, City and State
4. Model # — Lot # — 5. Operator of Device: Health Professional, Lay User/Patient, Other:
   Catalog # — Expiration Date (mm/dd/yyyy)
   Serial # — Unique Identifier (UDI) #
6. If Implanted, Give Date (mm/dd/yyyy) — 7. If Explanted, Give Date (mm/dd/yyyy)
8. Is this a Single-use Device that was Reprocessed and Reused on a Patient? Yes No
9. If Yes to Item No. 8, Enter Name and Address of Reprocessor
10. Device Available for Evaluation? (Do not send to FDA) Yes No Returned to Manufacturer on: (mm/dd/yyyy)
11. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)

(Continue on page 3)

E. INITIAL REPORTER

1. Name and Address
   Phone # — Email Address
2. Health Professional? Yes No
3. Occupation
4. Initial Reporter Also Sent Report to FDA Yes No Unk.

PLEASE TYPE OR USE BLACK INK

Unique Device Identifier (UDI)

D. SUSPECT MEDICAL DEVICE	
1. **Brand Name**	
2a. **Common Device Name**	
3. **Manufacturer Name, City and State**	
4. **Model #**	**Lot #**
Catalog #	**Expiration Date** *(dd-mmm-yyyy)*
Serial #	**Unique Identifier** *(UDI) #*

Include the ***full UDI*** including all parentheses and symbols with your adverse event submissions

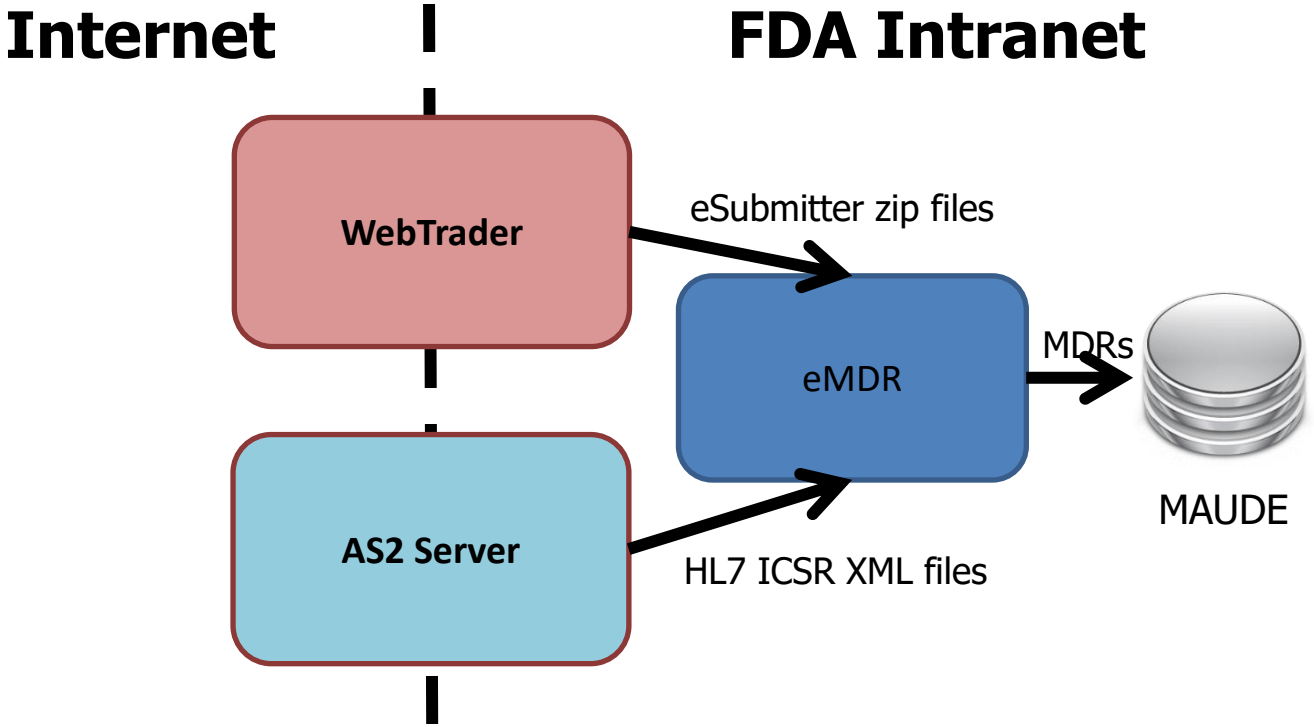
Exemptions, Variances, and Alternate Forms of Adverse Event Reporting

- Regulations in 803.19 permit FDA to grant exemptions, variances and alternatives under certain situations and with conditions
- Manufacturers who wish to request a new exemption, variance, or alternative—or to request a modification to an existing exemption—may contact CDRH at MDRPolicy@fda.hhs.gov.

Additional Requirements

21 CFR 803.17	21 CFR 803.18	21 CFR 803.12
• Develop, maintain and implement written MDR procedures • Have a system in place that ensures access to information that facilitates timely follow up/ inspection by FDA	• Establish and maintain MDR event files	• Submit initial and supplemental or follow-up reports to FDA in an electronic format that FDA can process, review, and archive • eMDR – Electronic Medical Device Reporting | FDA

eMDR Architecture



Electronic Submission Gateway (ESG)

eMDR Setup Tasks

Request ESG Account

- Send an email to ESGHelpDesk@fda.hhs.gov

Preparatory Activities

- Obtain a digital certificate
- Sign letter of non-repudiation

CompleteTest Submissions

- Connectivity Test for ESG
- eMDR Guidance-Complaint Test Submission(s) for eMDR

eMDR Submission Methods

Low Volume Reporting: (provided by FDA)	High Volume Reporting: (customized by reporter)
• eSubmitter: Free downloadable app • WebTrader: ESG Submission account • Less effort to set up • Each report has to be packaged individually	• HL7 ICSR and AS2 (customized system) • More effort to set up • When attached to its own complaint handling database it may create efficiencies for report submission

How to Enroll in eMDR Program | FDA

eMDR Guidance-Compliant Test Submissions

Required by CDRH

Should be complete MDRs

Report data should not be a real event

- Use a real CFN/FEI
- Do not use a previously-sent report number

Send it to Center: CDRH with Submission Type: Adverse_Events

Read Ack3 and verify that your report "passed"

eMDR Low Volume Method

For test submissions, send your Ack3 to eMDR Helpdesk with production account request

eMDR Low Volume Method

[eSubmitter Testing Scenario]

- Single required submission
- Create a complete 3500A in eSubmitter
- Submit and verify Ack3 in WebTrader
- Send Ack3 to eMDR@fda.hhs.gov and request final account approval

eSubmitter Best Practices

Only submit a zip file generated by FDA's eSubmitter application

Ensure that you send the zip file, and not a folder containing the zip file in WebTrader

Do not send a PDF file

eMDR is only reachable through WebTrader, you cannot mail a CD or submit through eSubmitter

eMDR High Volume Method

eMDR High Volume Method

[HL7 Testing Scenario]

Multiple required submissions

Required

- A complete initial MDR
- A supplemental MDR to submission #1

Optional

- An initial MDR with an attachment
- An initial MDR with section F filled out
- Batch submission (2 reports in 1 XML)

You may request exemption from tests that are not relevant to your firm

Email eMDR@fda.hhs.gov to schedule your firm's final tests for approval

- eMDR Helpdesk will request core IDs and human-readable copies for your final test reports

HL7 Best Practices

You may develop in-house or purchase COTS

Perform Internal Testing

- Validate XML produced by your system
- Use XML processing tools to verify schema compliance

Test eMDR system is available for testing at any time

- Verify that your XML passes using Ack3
- You may request a copy of the human-readable report PDF generated by eMDR, for Content Testing

MDR Acknowledgments

Ack1 (receipt)

Sent by ESG

Includes:

- timestamp,
- message ID

Ack2 (txt)

Sent by CDRH

Includes:

- message ID,
- core ID

Ack3 (HTML, XML)

Sent by eMDR

Includes

- Pass/fail message,
- core ID

Submission Summary	
Environment:	Ack3: This submission has been sent to the TEST 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:	Form 3500A - ICSR R2
Core ID:	ci1650401571231.99858@fdslv05766_te1
Batch ID:	1057985-20220419165242
Date Entered:	Tue Apr 19 16:55:42 EDT 2022
Summary:	passed: 1, Failed: 0

Report List:	
Report Number:	1057985-2021-05106, passed.

Contact eMDR Helpdesk for assistance with eMDR account creation: eMDR@fda.hhs.gov

eMDR Related Resources

eMDR Resources: eMDR Website

- How to Enroll in eMDR Program | FDA
- eMDR program news and information
- Email list signup
- eMDR Implementation Package
- Troubleshooting and FAQs
- Adverse event code resources
- Tutorial video
  - eMDR HelpDesk: eMDR@fda.hhs.gov

ESG Resources: ESG Website

- http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm
- Account sign-up checklist
- Letters of Non-repudiation Agreement
- WebTrader local configuration
- ESG User Guide
  - Digital certificate information
  - AS2 header information (routing IDs, etc.)
- ESG Helpdesk
  - ESGHelpDesk@fda.hhs.gov

eSubmitter Resources

- eSubmitter Website
  - http://www.fda.gov/ForIndustry/FDAeSubmitter/
  - Download link
  - Tutorials
- eSubmitter Helpdesk
  - eSubmitter@fda.hhs.gov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