

# Siemens Healthcare Diagnostics

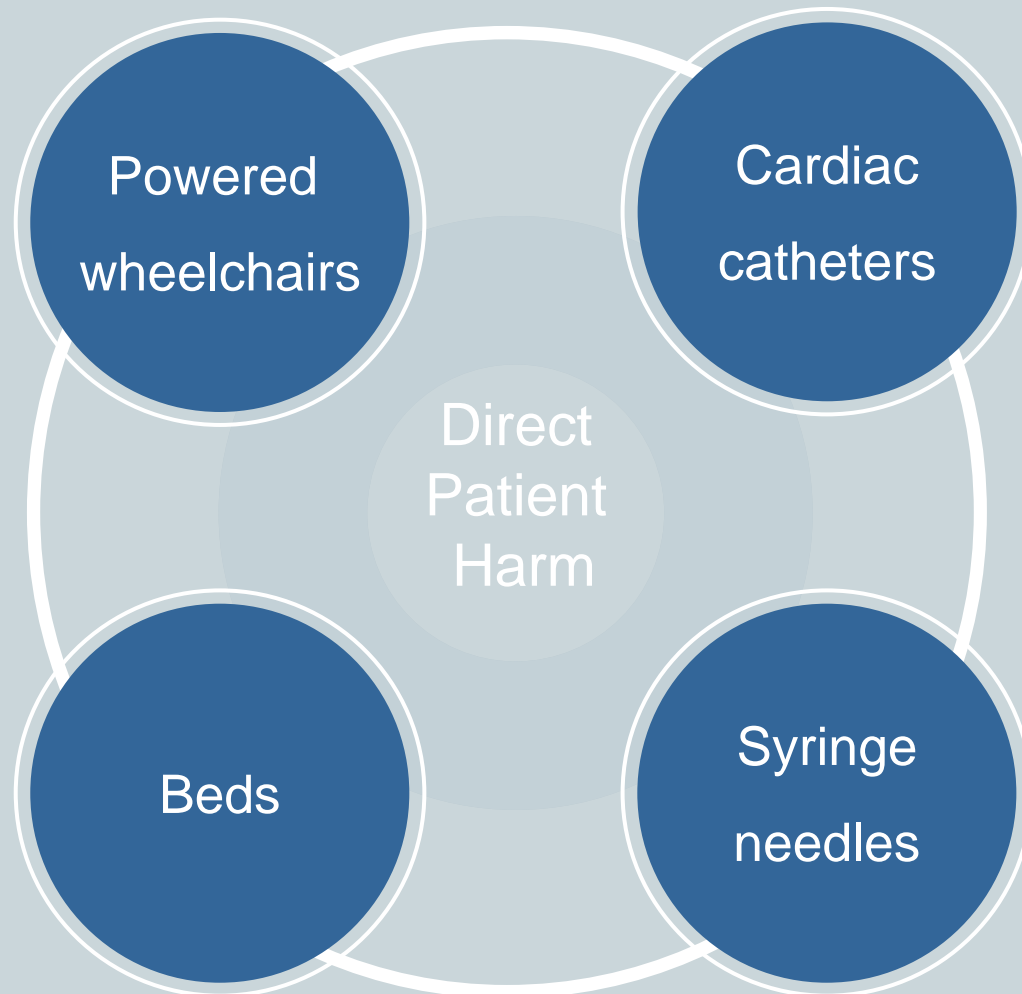
## MDR Reporting – Challenges for the IVD Industry

**Carolyn Chastain**

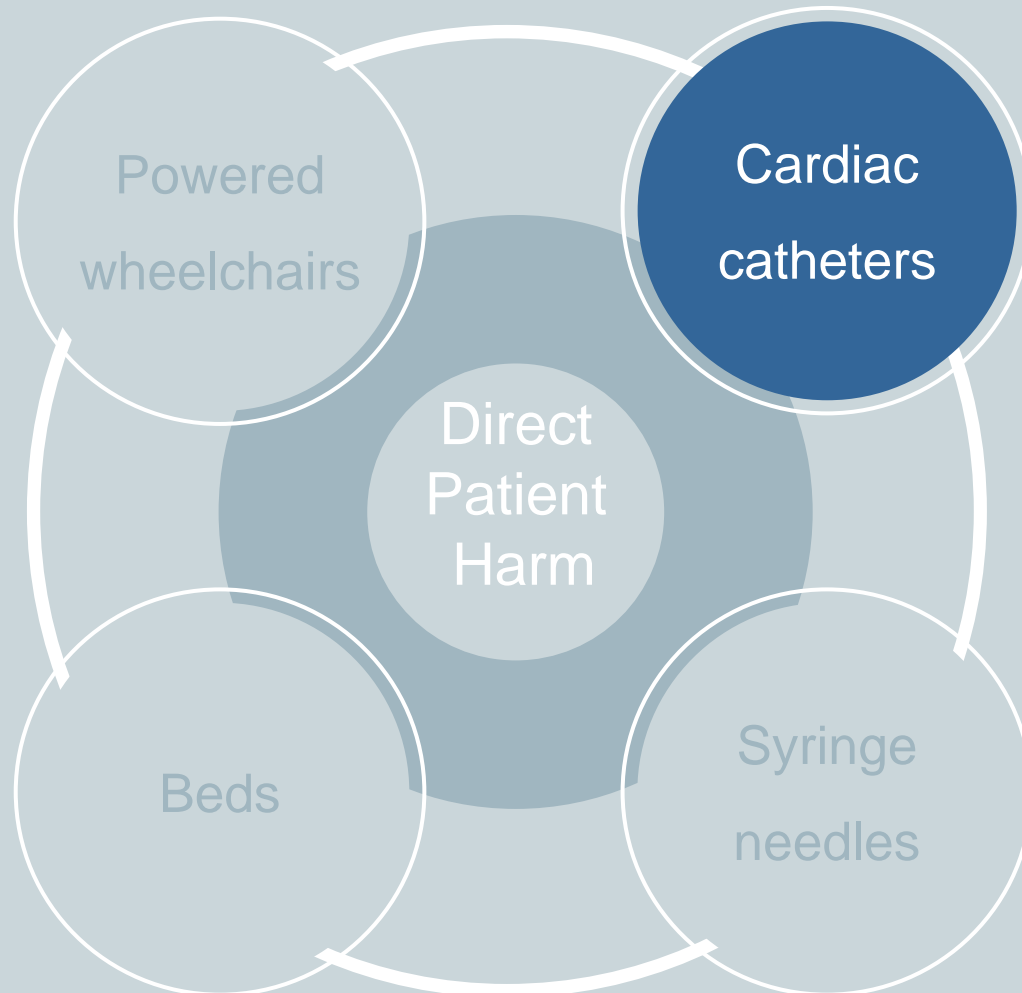
**Quality Engineer**



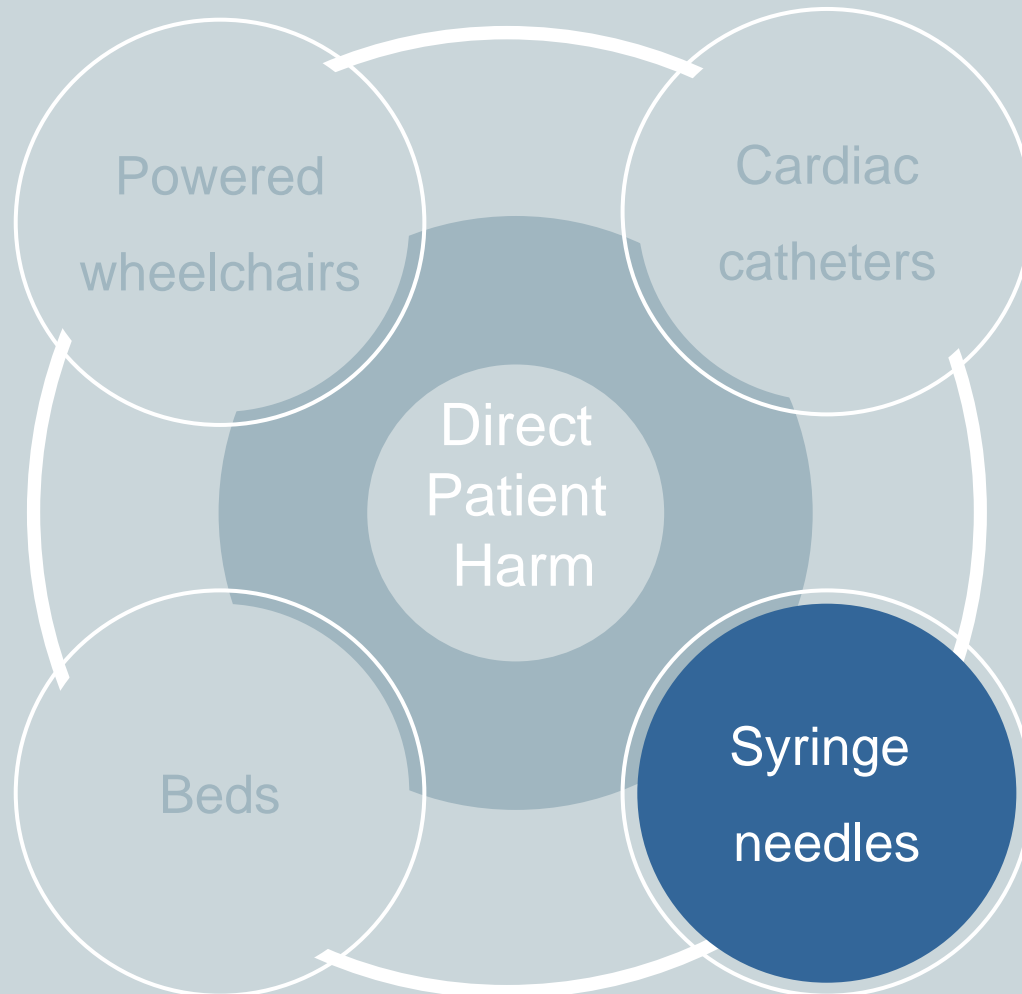
## Adverse events in Medical Devices



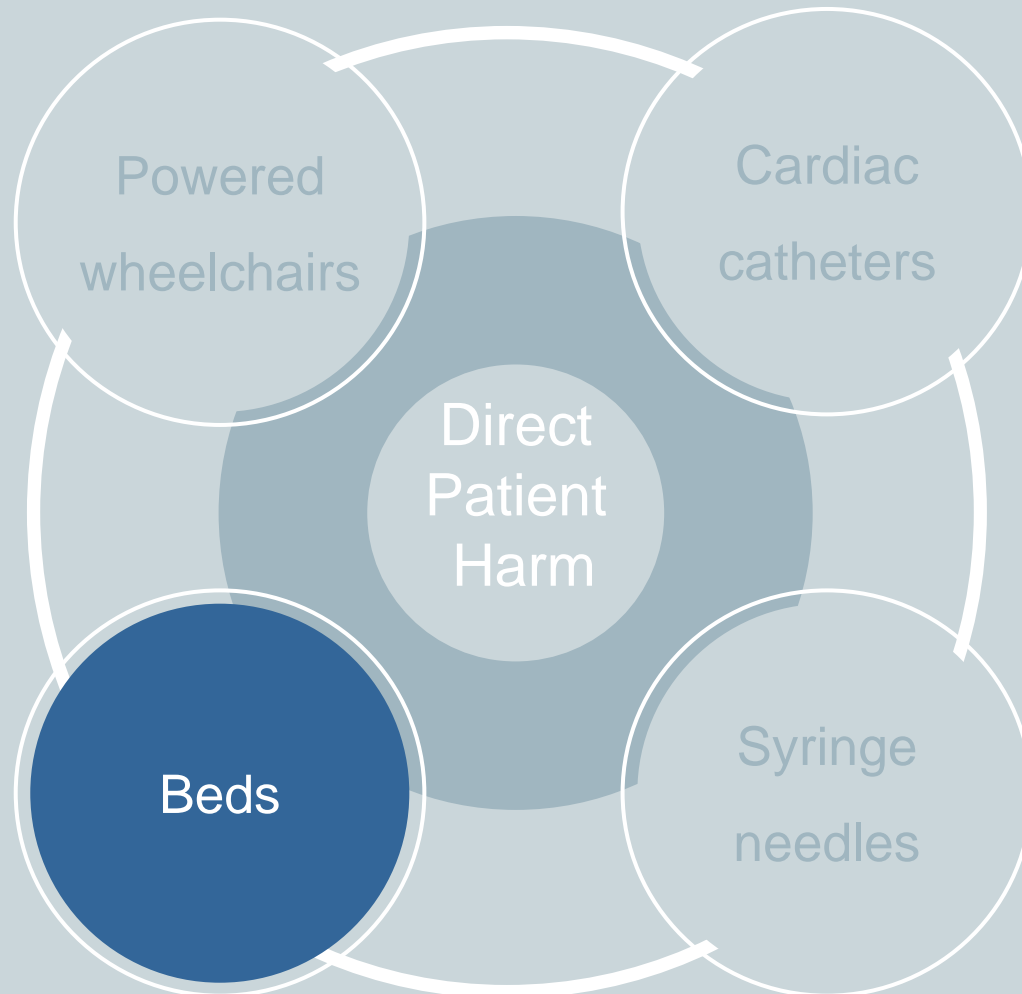
## Adverse events in Medical Devices



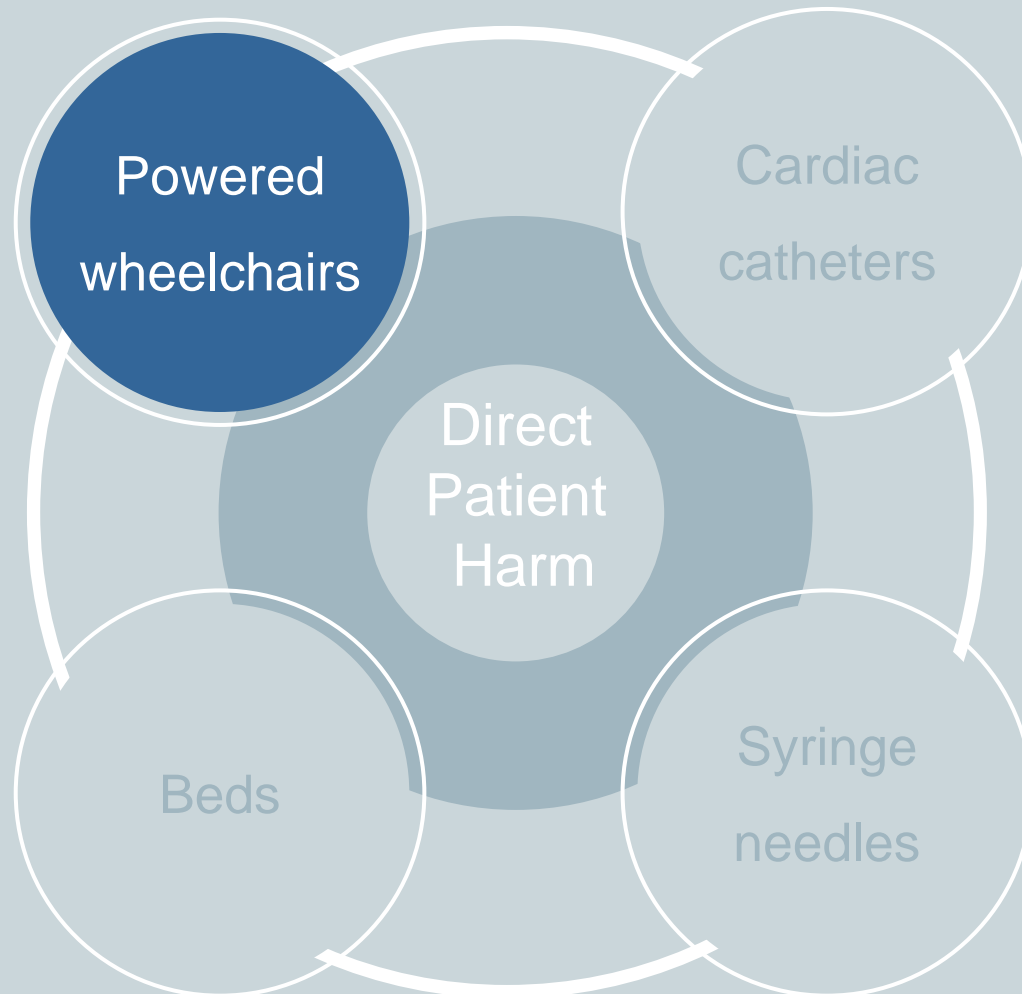
## Adverse events in Medical Devices



## Adverse events in Medical Devices



## Adverse events in Medical Devices



## Differences in the IVD Industry

Results of  
laboratory  
blood/other bodily  
fluid testing

The diagram features a large white circle on the left side of a dark blue background. Three horizontal light blue bars extend from the right side of the circle, each containing a different text label. The bars are stacked vertically, with the top bar labeled 'Erroneous but believable results', the middle bar labeled 'Lab results reported to the physician', and the bottom bar labeled 'Delayed results'.

Erroneous but believable results

Lab results reported to the physician

Delayed results

## Adverse events in the IVD Industry

### Adverse events

- Issues that **would be likely to cause or contribute** to a death or serious injury if the malfunction were to recur.
- Erroneous but believable results
- Change to treatment or medication
- Need for clinical significance of erroneous result



### Examples

- Low glucose – treatment not harmful – candy, OJ
- High glucose – insulin
- False positive HCG – mental anguish, delayed x-ray, delayed surgery or treatment
- False negative HCG – missed ectopic pregnancy
- Incorrect TDM results – changes in medication dosages



## Clinical Significances – Erroneous but believable results

<i>Assay/group</i>	<i>MDR</i>	<i>Potential Clinical Impact</i>	<i>No MDR</i>
<b>Bilirubin</b> Critical Value: Newborn Lower – N/A Upper - >15mg/dL Ref Value 0-3 months: >15mg/dL 4-6 months: >20 mg/dL	Falsely low, potential under treatment for infant	Missed diagnosis and treatment of neonate	Falsely high > 3mg/dL, greater likelihood for overtreatment in infants – low risk Falsely low or high for adults
<b>BUN</b>	Falsely low	Missed or underestimated kidney diseases, fail to identify ineffective dialysis	Falsely high – causes further investigation
<b>Ca</b>  (Use IFU range)	Falsely high or low  .....if difference between discrepant and true value is >2mg/dL or 0.5 mmol but <4mg/dL	Incorrect or missed diagnosis/intervention in response to electrolyte imbalance and/or hypo-hyper conditions	If it is Falsely high, greater likelihood to cause investigation

## Causes of erroneous but believable results



Sample  
integrity

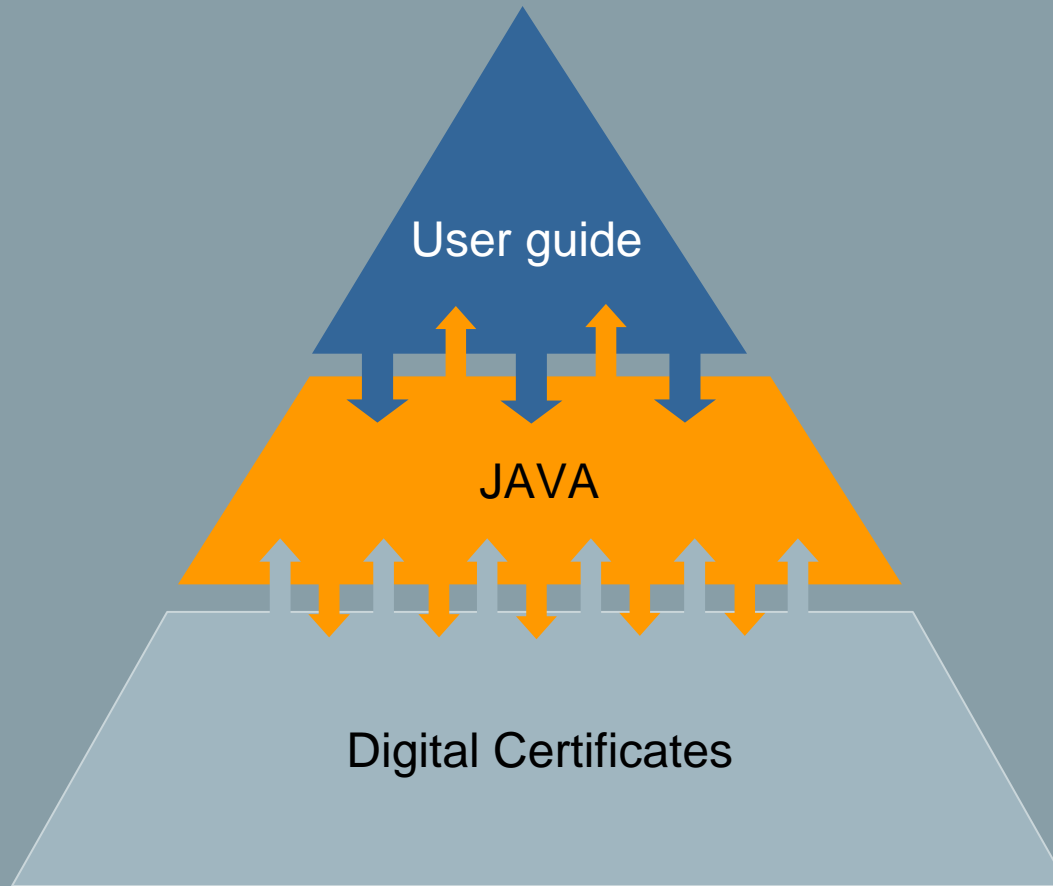
User error

Instrument  
malfunction

Contamination

Unknown

# Electronic MDR filing – Getting started



User guide – getting started

**Weblink:** <http://www.accessdata.fda.gov/esg/userguide/>

JAVA - Challenges

**Weblink:** <http://www.accessdata.fda.gov/esg/userguide/webhelp/default.htm>

Digital Certificates

**Weblink:** [http://www.accessdata.fda.gov/esg/userguide/webhelp/Digital\\_Certificates.htm](http://www.accessdata.fda.gov/esg/userguide/webhelp/Digital_Certificates.htm)

# Electronic MDR filing – Getting started

U.S. Department of Health & Human Services | www.hhs.gov

**FDA U.S. Food and Drug Administration**

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**For Industry**

Home > For Industry > FDA eSubmitter

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## Electronic Medical Device Reporting (eMDR)

Collection of adverse event information on medical devices is mandated by Medical Device Reporting (MDR) requirements of the Food Drug and Cosmetics Act (FD&C Act) (21 USC 360i), and comes primarily from manufacturers, user facilities, importers and voluntary reporters. Currently a majority of these reports are entered manually by data entry contractors.

The **electronic Medical Device Reporting (eMDR)** project provides the capability for electronic data entry and processing of medical device adverse event reports. The project utilizes Health Level Seven (HL7) Individual Case Safety Report (ICSR) standard to receive medical device adverse events (MDRs). The eMDR application accepts electronic medical device reports via two options, designed for low and high volume reporters. Both options are open to all reporters.

(1) FDA eSubmitter – a free **downloadable application** that will allow submission of MDR reports one at a time. This option is suitable for low volume reporters. The software contains data elements from the current MedWatch and generates an HL7 ICSR message for each MDR the user generates using the software. See [Technical Information on eMDR](#).

(2) Health Level 7 (HL7) Individual Case Safety Report (ICSR) – This option provides the capability to receive and process electronic MDR files either individually or as a batch and is particularly suitable for high volume reporters. Users of this option submit MDRs formatted as an HL7 ICSR message.

eMDR utilizes the FDA Gateway, an agency-wide entry point for all electronic submissions, to receive electronic MDRs. The Gateway authenticates and validates electronic submissions and routes it to CDRH. See the [Electronic Submissions Gateway site](#) to register as a trading partner. If you have any questions regarding the registration process or the Gateway in general, please contact the help desk as indicated on the website.

For further information, please write to [eMDR@fda.hhs.gov](mailto:eMDR@fda.hhs.gov).

### Additional Resources

- [Technical Information on eMDR](#)
- [Draft Guidance for Industry, User Facilities and FDA Staff: eMDR - Electronic Medical Device Reporting](#)
- [Federal Register - Medical Device Reporting: Electronic Submission Requirements](#)

## eSubmitter

- Select “download Application

**Weblink:** <http://www.fda.gov/ForIndustry/FDAesubmitter/ucm108165.htm>

# Electronic MDR filing – Getting started

The screenshot shows the FDA eSubmitter website. The header includes the U.S. Department of Health & Human Services logo and the FDA logo. The main navigation bar lists various product categories. The 'For Industry' section is active, and the 'FDA eSubmitter' link is highlighted in the left sidebar. The 'Download and Installation' section is highlighted with a red box, containing the following content:

## Download and Installation

### Download Software

To download the FDA eSubmitter software, click on the following link. Save the installation zip file to your computer and extract the jinstall.exe file. Double-click the jinstall.exe file to run the installation. Follow the instructions provided in the installation wizard.

- [Download eSubmitter Software](#)
- [Download User Manual \(Updated March 11, 2011\)](#)
- [Download Quick Guide \(Updated March 11, 2011\)](#)
- [Download eSubmitter FAQ \(Updated March 11, 2011\)](#)

Persons with disabilities having problems accessing the PDF files may call 1-877-CTP-1373 for assistance.

### System Requirements

- Windows Operating System
  - If installing on Vista, please see the additional [Instructions for Using eSubmitter on Microsoft Vista](#).
- Adobe Acrobat Reader v5.0 or greater (for attaching files)
- Software capable of viewing HTML, such as a Web browser, Microsoft Word or Adobe Acrobat (full install version, not the Reader)
- 30 MB of disk space

### Installation Instructions

**Before installation, uninstall any other versions of the eSubmitter software.** If you do not have a prior version of eSubmitter, proceed to installing the current version of FDA eSubmitter.

**To uninstall** the previous versions of eSubmitter, use Windows Explorer to navigate to the **eSub** folder of the installed drive (e.g., C:). Then, double-click on the **uninstall.exe** and follow the instructions provided. (If you do not see **uninstall.exe**, locate and double-click to open the JExpress file folder. Then, double-click on the **uninstall.bat** and follow the instructions provided.)

**To install** the latest version of the FDA eSubmitter software, navigate to the software's download directory and double-click on the **jinstall.exe**. Following the instructions of the installer, the FDA eSubmitter software will be installed locally.

**If you're using a proxy server** to connect to the Internet, then you will need to change the application's properties file (**eSubmission.properties**) to reference the server. See your System Administrator for help in changing the properties file. The properties file is located in the

## eSubmitter

- Select “Download eSubmitter Software”
- Request a test account
- Request a production account

Thank you!

