Med Watch Form	MedWatch Field/Section Name	HL7 mapping of FDA Medwatch 3500A (paper) - XML specification	HL7 ICSR Implementation pointers
		OMB Control No. 0910-0437 Expiration Date xx / xx /xxxx	
		The public reporting burden for this collection of information has been estimated to average 9 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Health and Human Services, Food and Drug Administration, MedWatch HFD-410, 5600 Fishers Lane, Rockville, MD 20857	
		Please DO NOT RETURN this form to this address	
		OMB Statement; An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number	
Med Watch Form	**MedWatch Field/Section Name**	**Medwatch 3500A (paper) Instructions (http://www.fda.gov/medwatch/report/instruc_10-25-05.htm#B2)**	**HL7 ICSR Implementation pointers**
NOTE: Please use the following three values for all instances of null - ASKU, NI, NA			
VALIDATION -- the following are validated on your submission: CFN/FEI/HCFA number, field lengths, required fields, FDA/NCI Codes and additional fields marked on this spread-sheet, F10 and H			
Initial reports -- we strongly encourage you to use null values defined above instead of blank fields			
Supplemental/Follow-up Reports - required fields are -- report number and G7 -- check follow-up and provide a follow-up number; leave fields blank unless information is 'new' or 'updated'; provide dis appropriate field vs. H10. Refer to ICSRImplementationGuide for more details			
A	***Patient Information***		
	Report Number		For Manufacturer report number, please use the following format -- 10 digitFEI-4 digit year-5 digit sequence number E.g. 1234567890-2006-00001; 7 digit CFN-4 digit year-5 digit sequence number E.g.- 5555555-2006-00001; for User Facility, same format but replace FEI/CFN with HCFA number and pad with enough zeros in the beginning to make the first part a 10 digit number; CFN, FEI and HCFA numbers are validated; **during testing, please use a leading 7 with sequence numbers -- example -- CFN-YEAR-70001 or FEI/HCFA-YEAR-70001; REQUIRED FIELD**
A1	Patient Identifier	Provide the patient's initials or some other type of identifier that will allow both the submitter and the initial reporter (if different) to locate the case if contacted for follow-up. Do not use the patient's name or social security number. The patient's identity is held in strict confidence by FDA and protected to the fullest extent of the law.	
A2	Date of birth	Provide the most precise information available. Enter the patient's birthdate, if known, or the patient's age at the time of event onset.	DOB is preferred. use YYYYMMDD format; use full date format; if month or day is unknown, then use 01 for either
A2	Age at time of event	If the patient is 3 years or older, use years (e.g., 4 YR) If the patient is less than 3 years old, use months (e.g., 24 MO) If the patient is less than 1 month old, use days (e.g., 5 DA) Provide the best estimate if exact age is unknown	See MedWatch instructions. Indicate time units used as DA - day; MO - month; YR - Year; HR - Hours. Stored unit of measure is Days.
A2	Age text		
A3	Sex	Enter the patient's gender. If the adverse event is a congenital anomaly, report the sex of the child	Please look at the vocabulary attachment. Use a code to indicate the appropriate gender
A4	Weight	Indicate whether the weight is in pounds (lbs.) or kilograms (kgs). Make a best estimate if exact weight is unknown.	Indicate weight units used as LBS - pounds; G - grams; KG - kilograms. Stored unit of measure is kilograms.
B	***Adverse Event or Product Problem***		

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B1	Report Type	Choose the appropriate box. Both boxes should be checked if a product problem may have caused or contributed to the adverse event. Adverse event: Any incident where the use of a medication (drug or biologic, including human cell, tissue, or cellular or tissue-based product (HCT/P), at any dose, or a medical device (including in vitro diagnostics) is suspected to have resulted in an adverse outcome in a patient. Product problem (e.g., defects/malfunctions): Any report regarding the quality, performance, or safety of any medical product. This category is selected when reporting device malfunctions that could lead to a death or serious injury if the malfunction were to recur.	Please look at the vocabulary attachment. Use a code to indicate adverse event or product problem
B2	Outcomes attributed to adverse event	Indicate ALL that apply to the reported event: Death: Check if death was an outcome of the adverse event, or if the cause of the death is unknown. Include the date of death, if known. DO NOT check if: The patient died while using a medical product, but there was no suspected association between the death and the use of the product A fetus is aborted because of a congenital anomaly, or is miscarried Life-threatening: Check if suspected that: The patient was at substantial risk of dying at the time of the adverse event, or Use or continued use of the device might have resulted in the death of the patient Hospitalization (initial or prolonged): Check if admission to the hospital or prolongation of hospitalization was a result of the adverse event. DO NOT check if: A patient in the hospital received a medical product and subsequently developed an otherwise nonserious adverse event, UNLESS the adverse event prolonged the hospital stay DO check if: A patient is admitted to the hospital for one or more days, even if released on the same day An emergency room visit results in admission to the hospital Note: Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage; other serious (medically important event) Disability or Permanent Damage: Check if the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions. Congenital Anomaly/Birth Defect: Check if suspected that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child. Required Intervention to Prevent Permanent Impairment/Damage (Devices): if either situation may be due to the use of a medical device and medical or surgical intervention was necessary to: Preclude permanent impairment of a body function, or Prevent permanent damage to a body structure. Other Serious (Important Medical Events): Check when, based on appropriate medical judgement, the event may jeopardize the patient and may require medical or surgical intervention to prevent one of the other outcomes. Examples include allergic bronchospasm	Please look at the vocabulary attachment. Use a code(s) to indicate an outcome(s).
B2	Date of death		Populate Date of Death in 'deceaseTime Value'; use YYYYMMDD format
B3	Date of Event	Provide the actual or best estimate of the date of first onset of the adverse event. If day is unknown, month and year are acceptable. If day and month are unknown, year is acceptable. When a newborn baby is found to have a congenital anomaly, the event onset date is the date of birth of the child When a fetus is aborted because of a congenital anomaly, or is miscarried, the event onset date is the date pregnancy is terminated. If information is available as to time during pregnancy when exposure occurred, indicate that information in narrative block B5.	Use YYYYMMDD format
B4	Date of this report	Drugs and Biologics, including Human Cells, Tissues, and Cellular and Tissue-Based Products: The date the report is filled out. Devices: The date the initial reporter provided the information about the event [i.e., the first person or entity who initially provided the information to the user facility, manufacturer, or distributor (importer)].	Populate with the 'Date report filled out' by manufacturer. CDRH will be changing medwatch instructions to coincide with Drugs and Biologics for electronic reporting; Use YYYYMMDD format

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B5	Describe event or problem	For an adverse event: Describe the event in detail using the reporter's own words, including a description of what happened and a summary of all relevant clinical information (medical status prior to the event; signs and/or symptoms; differential diagnosis for the event in question; clinical course; treatment; outcome, etc.). If available and if relevant, include synopses of any office visit notes or the hospital discharge summary. To save time and space (and if permitted by the institution), attach copies of these records with any confidential information deleted. DO NOT identify any patient, physician, or institution by name. The initial reporter's identity should be provided in full in section E. Information as to any environmental conditions that may have influenced the event should be included, particularly when (but not exclusive to) reporting about a device.	**REQUIRED FIELD**
B6	Relevant tests/laboratory data	Provide all appropriate information, including relevant negative test and laboratory findings, in order to most completely convey how the medical work-up/assessment led to strong consideration of medical-product-induced disease as etiology for clinical status, as other differential diagnostic considerations were being eliminated. Include: Any relevant baseline laboratory data prior to the administration or use of the medical product All laboratory data used in diagnosing the event; Any available laboratory data/engineering analyses (for devices) that provide further information on the course of the event If available, include: Any pre- and post-event medication levels and dates (if applicable) Synopses of any relevant autopsy, pathology, engineering, or lab reports If preferred, copies of any reports may be submitted as attachments, with all confidential information deleted. DO NOT identify any patient, physician or institution by name. The initial's reporter's identity should be provided in full in section E.	Please look at the vocabulary attachment. Use the 'text' area to describe relevant tests/laboratory data
B7	Other relevant history, including preexisting medical conditions	If available, provide information on: Other known conditions in the patient, e.g., Hypertension Diabetes mellitus Renal/hepatic dysfunction, etc. Significant history Race Allergies Pregnancy history Smoking and alcohol use Drug abuse, etc.	Please look at the vocabulary attachment. Use 'text' for narrative description
D	***Suspect medical device***		
D1	Brand Name	The trade or proprietary name of the suspect medical device as used in product labeling or in the catalog (e.g., Flo-Easy Catheter, Reliable Heart Pacemaker, etc.). This information may 1) be on a label attached to a durable device, 2) be on a package of a disposable device, or 3) appear in labeling materials of an implantable device. Single use reprocessed devices may bear the OEM's brand name. If the suspect device is a reprocessed single-use device, enter "NA".	
D2	Type of Device	Provide both Product Code and Common Device Name	
D2 - Part 1	Type of device - Product Code	Use the Product Code assigned to the device based upon the medical device product classification designated under 21 CFR Parts 862-892. Product codes may be found at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/PCDSimpleSearch.cfm	Provide Product Code which was assigned at the time the device was approved under a PMA or cleared under a 510(k). (it lies within the "code" element in the XML instance); Note that Concept Code is not used for product code in the xml file, populate actual product code in the 'code' element. Please refer to VOCAB sheet for FDA OID; **REQUIRED FIELD**
D2 - Part 2	Type of Device - Common Device Name	Use the generic or common name of the suspect medical device or a generally descriptive name (e.g., urological catheter, heart pacemaker, patient restraint, etc.). Do not use broad generic terms such as "catheter", "valve", "screw", etc.	Provide Common Device Name under 'text'; **REQUIRED FIELD**

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D3	Manufacturer name & address	If available, enter the full name and mailing address of the manufacturer of the suspect medical device. If Block D8 below is 'Yes", enter the name and address of the reprocessor.	For HL7 Name and Address, please provide the following, as applicable -- Manufacturer Name, Street Address Line 1, Street Address Line 2, City, State, Postal Code, Country;
	Manufacturer Name		
	Manufacturer Address Street Line 1		
	Manufacturer Address Street Line 2		
	Manufacturer City		Enter US City or Foreign (State/Territory/Province)
	Manufacturer State Code		Please refer to http://www.usps.com/ncsc/lookups/abbreviations.html#states for appropriate state codes for United States
	Manufacturer Zip Code		The Five digit zip code
	Manufacturer Zip Code Extension		The 4 digit zip code extension
	Manufacturer Country Code		Current CDRH Implementation will support both 2 character and 3 character country codes. Please refer to the countryCodeMapping sheet.
	Manufacturer Postal Code		Postal Code for international addresses - 10 digit string
	Manufacturer Email		
	Manufacturer Fax Number		provide a string with no formatting, can not be longer than 26 chars
D4	Model #, Lot #, Catalog #, Expiration Date, Serial #, Other #	Model #, Catalog #, Serial #, Lot #, Expiration date If available, provide any expiration date or any or all identification numbers associated with the suspect medical device exactly as they appear on the device or device labeling. This includes spaces, hyphens, etc. Model #: The exact model number found on the device label or accompanying packaging Catalog #: The exact number as it appears in the manufacturer's catalog, device labeling, or accompanying packaging Serial #: This number can be found on the device label or accompanying packaging; it is assigned by the manufacturer and should be specific to each device Lot #: This number can be found on the label or packaging material Expiration date: If available; this date can often be found on the device itself or printed on the accompanying packaging. Other #: Any other applicable identification number (e.g., component number, product number, part number, barcoded product ID, etc.)	
D4	Model Number		
D4	Lot Number		
D4	Catalog Number		
D4	Expiration Date		Use YYYYMMDD format
D4	Serial Number		
D4	Other Number		
D5	Operator of device - Code	Indicate the type (not the name) of person operating or using the suspect medical device on the patient at the time of the event as follows: Health professional = physician, nurse, respiratory therapist, etc. Lay user/patient = person being treated, parent/spouse/friend of the patient Other = nurses aide, orderly, etc.	Please look at the vocabulary attachment.
D5	Operator of Device - Other		Use the 'text' area to describe 'other'
D6	If Implanted give date	For medical devices that are implanted in the patient, provide the implant date or best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable.	Use YYYYMMDD format
D7	If explanted, give date	If an implanted device was removed from the patient, provide the explant date or best estimate. If day is unknown, month and year are acceptable. If month and day are unknown, year is acceptable.	Use YYYYMMDD format
D8	Is this a single-use device that was reprocessed and reused on a patient?	Indicate "Yes" or "No" If the original equipment manufacturer (OEM) is unable to determine if their single use device was reprocessed and reused on a patient, then the OEM should enter 'UNK' in Block D8 and in Block H10 (Additional Manufacturer Narrative) describe the efforts made to obtain the information and any responses.	Please look at the vocabulary attachment. Choose a code; populate TRUE if answer is YES; populate FALSE if answer is NO under 'value'; for unknown, use ASKU

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D9	If yes to item 8, enter name and address of reprocessor	Enter the name and address of the reprocessor of the single-use device. Any entity that reprocesses single-use devices for reuse in humans is the manufacturer of the reprocessed single-use device.	For Name and Address, please provide the following, as applicable -- Reprocessor Name, Street Address Line 1, Street Address Line 2, City, State, Postal Code, Country;
	Reprocessor Name		
	Reprocessor Address Street Line 1		
	Reprocessor Address Street Line 2		
	Reprocessor City		Enter US City or Foreign (State/Territory/Province)
	Reprocessor State Code		Please refer to http://www.usps.com/ncsc/lookups/abbreviations.html#states for appropriate state codes for United States
	Reprocessor Zip Code		The Five digit zip code
	Reprocessor Zip Code Extension		The four digit Zip code extension
	Reprocessor Country Code		Current CDRH Implementation will support both 2 character and 3 character country codes. Please refer to the countryCodeMapping sheet.
	Reprocessor Postal Code		Postal Code for international addresses - 10 digit string
	Reprocessor Email		
	Reprocessor Fax Number		provide a string with no formatting, can not be longer than 26 chars
D10	Device available for evaluation? Date returned to Manufacturer	Indicate whether the device is available for evaluation by the manufacturer. Indicate if the device was returned to the manufacturer and, if so, the date of the return. Do not send the device to FDA.	Please look the vocabulary attachment. Choose a code; populate TRUE if answer is YES; populate FALSE if answer is NO under 'value'
D10 Part 2	Date device returned to manufacturer	Indicate whether the device is available for evaluation by the manufacturer. Indicate if the device was returned to the manufacturer and, if so, the date of the return.	populate a date if answer is YES under 'effectiveTime value';Use YYYYMMDD format
D11	Concomitant medical products	List and provide product names and therapy dates for any other medical products (drugs, biologics, including human cells, tissues, and cellular and tissue-based products (HCT/Ps), or medical devices, etc.) that the patient was using at the time of the event. Do not include products used to treat the event.	Please look at the vocabulary attachment. ; Use 'text' for narrative; multiple products can be entered
D11 - Part 2	Concomitant medical products - therapy dates		Indicate Therapy date if available under 'effectiveTime value'; Use YYYYMMDD format; multiple dates can be entered
E	***Initial Reporter***		
E1	Initial Reporter Name	Please provide the name, mailing address, and phone number of the person who initially reported the adverse event to the user facility, manufacturer, or distributor (importer), and who can be contacted to provide information on the event if follow-up is necessary. If available, provide reporter's E-mail address and/or fax number. For medical device reporting by user facilities, this person may or may not be the designated medical device reporting (MDR) contact.	Name should be reported as -- First Name, Middle Name, Last Name;
	Initial Reporter First Name		
	Initial Reporter Middle Name		
	Initial Reporter Last Name		
	Initial Reporter Title		
E1	Address		Address as -- Street Address Line 1, Street Address Line 2, City, State, Postal Code, Country;
	Initial Reporter Facility Name		
	Initial Reporter Street Address Line 1		
	Initial Reporter Address Street Line 2		
	Initial Reporter City		Enter US City or Foreign (State/Territory/Province)
	Initial Reporter State Code		Please refer to http://www.usps.com/ncsc/lookups/abbreviations.html#states for appropriate state codes for United States
	Initial Reporter Zip Code		The Five digit zip code
	Initial Reporter Zip Code Extension		The four digit Zip code extension
	Initial Reporter Country Code		Current CDRH Implementation will support both 2 character and 3 character country codes. Please refer to the countryCodeMapping sheet.
	Initial Reporter Postal Code		Postal Code for international addresses - 10 digit string
	Initial Reporter Email		provide email address under 'telecom value' following prefix "mailto:"
	Initial Reporter Fax Number		provide a string with no formatting, can not be longer than 26 chars
E1	Phone #		Please provide phone number in the following format -- "+" country_code "(" area_code ")" 3-digit prefix "-" 4-digit number "x" up to 5-digit extension e.g. +1(240)276-0001 x12345; if extension is not applicable, leave it out; international numbers would follow the same format -- e.g. "+" phone_country "(" phone_city ")" phone_local -- 011(123)1234567890 or if there is no phone_city: 011()1234567890

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E2	Health Professional?	E2: Health Professional?: Indicate whether the initial reporter is a health professional (e.g., physician, pharmacist, nurse, etc.) or not. If not a health professional, complete block E3 by filling in NA.	For HL7, value of E2 will be inferred from E3
E3	Occupation	Indicate the initial reporter's occupation (particularly type of health professional), and include specialty if appropriate.	Please look at the vocabulary attachment. Choose an appropriate code
E3	Occupation - text		Provide explanation for Other here
E4	Initial reporter also sent report to FDA	Indicate whether the initial reporter also notified or submitted a copy of this report to FDA.	populate 'false' if answer is YES; populate 'true' if answer is NO; use nullflavor for UNK
F	***For Use by User Facility/Importer (Devices Only)***		
F1	Check one: user facility, importer	Indicate whether the report is from a user facility or importer.	Please look at the vocabulary attachment under Type_of_Reporter. Choose an appropriate code
F2	UF/Importer Report Number	Enter the complete number of the report exactly as entered in the upper right corner of the front page. For a follow-up report, the UF/Importer report number must be identical to the number assigned to the initial report.	
F3	User Facility or Importer Name/Address	Enter the full name and address of the user facility or importer reporting site.	For Name and Address, please provide the following, as applicable -- User Facilty Name, Street Address Line 1, Street Address Line 2, City, State, Postal Code, Country;
	User Facility Name		
	User Facility Address Street Line 1		
	User Facility Address Street Line 2		
	User Facility City		Enter US City or Foreign (State/Territory/Province)
	User Facility State Code		Please refer to http://www.usps.com/ncsc/lookups/abbreviations.html#states for appropriate state codes for United States
	User Facility Zip Code		The Five digit zip code
	User Facility Zip Code Extension		The four digit Zip code extension
	User Facility Country Code		Current CDRH Implementation will support both 2 character and 3 character country codes. Please refer to the countryCodeMapping sheet.
	User Facility Postal Code		Postal Code for international addresses - 10 digit string
F4	Contact person	Enter the full name of the medical device reporting (MDR) contact person. This is the person designated by the facility's most responsible person as the device user facility/importer contact for this requirement. FDA will conduct its MDR correspondence with this individual. The contact person may or may not be an employee of the facility. However, the facility and its responsible officials will remain the parties ultimately responsible for compliance with the MDR requirements.	Name should be reported as -- First Name, Middle Name, Last Name; provide title if applicable
	User Facility Contact Last Name		
	User Facility Contact First Name		
	User Facility Contact Middle Initial		
	User Facility Contact Title		
F5	Phone #	Enter the phone number of the MDR contact person.	Please provide phone number in the following format -- “+” country_code “(“ area_code “)” 3-digit prefix “-“ 4-digit number “x“ up to 5-digit extension e.g. +1(240)276-0001 x12345; if extension is not applicable, leave it out; International numbers would follow the same format -- e.g. “+” phone_country “(“ phone_city “)” phone_local -- 011(123)1234567890 or if there is no phone_city: 011()1234567890
	User Facility Contact email address		provide email address under 'telecom value' following prefix "mailto:"
F6	Date user facility or distributor became aware of event	Enter the date that the user facility's medical personnel or the importer became aware that the device has or may have caused or contributed to the reported event.	Use YYYYMMDD format

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F7	Type of report	Check the appropriate box to identify the type of report being filed, i.e., an initial report of an event or a follow-up to a previously submitted report. If a follow-up report, make sure that the UF/ Importer report number for the previously submitted initial report is recorded in block F2. In the blank provided in block F7, record the appropriate sequence of follow-up to that particular initial report (e.g., first follow-up report=follow-up #1, second follow-up report=follow-up #2, and so on). Follow-up reports should not repeat material that was submitted in the initial report, but should ONLY provide additional or corrected information on the previously reported event.	Please look at the vocabulary attachment. Choose an appropriate code;
	Type of Report\Follow-up Number		populate follow-up number under /pertinentInformation1/sequenceNumber value/
F8	Date of this report	Enter the date that the report was forwarded to the manufacturer and/or the FDA.	This will be pre-filled from date provided in either F11 or F13
F9	Approximate age of device	Enter the age of the device or a best estimate (include unit of time used: e.g., month, year).	Please look at the vocabulary attachment. Choose an appropriate code. Populate appropriate number or text; Indicate time units used as DA - day; MO - month; YR - Year; HR - Hours.
F9	Approximate age of device\Text		Please look at the vocabulary attachment. Choose an appropriate code. Device age text
F10	Event problem codes	Enter up to 3 "patient" and 3 "device" codes from the Codes Manual that most accurately describe the event. Patient codes describe what happened to the patient as a result of the event and device codes describe device failures or problems encountered during the event. If more than 3 "patient" codes or more than 3 "device" codes are needed, record them on a separate sheet, mark it "F10", and provide the report number and page number. If a user facility or an importer has reason to believe that a reused device has or may have caused or contributed to an adverse event, the device problem code 1537 ("Reuse") should be entered in F10 along with any other applicable device and/or patient-related codes.	Provide as many patient and device problem codes as appropriate; no limitation on number of values; Please look at the vocabulary attachment; Choose an appropriate concept code; these codes are validated; visit http://www.fda.gov/cdrh/mdr/appendixc.pdf or http://www.fda.gov/cdrh/mdr/373_appdxb.html for actual code values; NOTE -- Please use codes to indicate unknowns whenever possible instead of using null-flavor values in the xml document
F11	Report sent to FDA?	Check yes or no and indicate the date sent, if applicable.	Please look at the vocabulary attachment. Populate 'false' if answer is YES; populate 'true' if answer is NO
F11 Part 2	Date Report Sent	Check yes or no and indicate the date sent, if applicable.	If answer is YES, provide date report sent to FDA under 'time value'; Use YYYYMMDD format
F12	Location where event occurred	Check the location of the actual occurrence of the event. If none of the designated location options apply, check the other box and provide the location.	Please look at the vocabulary attachment. Choose an appropriate code.
	Location where event occurred\text to explain OTHER		Use 'text' to describe 'Other'
F13	Report sent to manufacturer?	Check yes or no and indicate the date sent, if applicable.	Please look at the vocabulary attachment. Populate 'false' if answer is YES; populate 'true' if answer is NO; Please look at the vocabulary attachment.
F13 Part 2	Date Sent to Manufacturer		If answer is YES, provide date report sent to FDA under 'low value' (Beginning of the time interval captures when the report was sent to manufacturer. 'high value' will be populated under G4 to indicate when the report was received by the manufacturer; Use YYYYMMDD format
F14	Manufacturer name/address	Enter full name and address of the device manufacturer, if available. This would normally be identical to the address in D3. However, if the device was reprocessed, then F14 is identical to D9, the name and address of the reporcessor.	For Name and Address, please provide the following, as applicable -- Manufacturer Name, Street Address Line 1, Street Address Line 2, City, State, Postal Code, Country;
	Manufacturer Name		
	Manufacturer Address Street Line 1		
	Manufacturer Address Street Line 2		
	Manufacturer City		Enter US City or Foreign (State/Territory/Province)
	Manufacturer State Code		Please refer to http://www.usps.com/ncsc/lookups/abbreviations.html#states for appropriate state codes for United States
	Manufacturer Zip Code		The Five digit zip code
	Manufacturer Zip Code Extension		The four digit Zip code extension

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	Manufacturer Country Code		Current CDRH Implementation will support both 2 character and 3 character country codes. Please refer to the countryCodeMapping sheet.
	Manufacturer Postal Code		Postal Code for international addresses - 10 digit string
	Manufacturer Email		
	Manufacturer Fax Number		provide a string with no formatting, can not be longer than 26 chars
G	***All manufacturers***		
G1	Manufacturer contact information	Enter the full name and address of the manufacturer reporting site [contact office], including contact name. If the manufacturing site of the device is not the same as the contact office, enter site and the name and address of the manufacturing site after the contact office name and address.	Please ALWAYS submit the MDR CONTACT information as the *first* address in the HL7 message. Repeat the <contactParty> block *second* time and provide MANUFACTURING SITE address. *Please note that the sequence of the address is extremely important and you MUST maintain the order of MDR Contact Info first and Manufacturing Site info second*. For Name and Address, please provide the following, as applicable -- Name -- Title or prefix, First Name, Middle Name, Last Name; Address -- Manufacturer Facility Name, Street Address Line 1, Street Address Line 2, City, State, Postal Code, Country;
	Manufacturer Contact Title		
	Manufacturer Contact First Name		
	Manufacturer Contact Middle Name		
	Manufacturer Contact Last Name		
	Manufacturer Contact Facility Name		
	Manufacturer Contact Address Street Line 1		
	Manufacturer Contact Address Street Line 2		
	Manufacturer Contact City		Enter US City or Foreign (State/Territory/Province)
	Manufacturer Contact State Code		Please refer to http://www.usps.com/ncsc/lookups/abbreviations.html#states for appropriate state codes for United States
	Manufacturer Contact Zip Code		The Five digit zip code
	Manufacturer Contact Zip Code Extension		The four digit Zip code extension
	Manufacturer Contact Country Code		Current CDRH Implementation will support both 2 character and 3 character country codes. Please refer to the countryCodeMapping sheet.
	Manufacturer Contact Postal Code		Postal Code for international addresses - 10 digit string
	Manufacturer Contact Email		provide email address under 'telecom value' following prefix "mailto:"
	Manufacturer Contact Fax Number		provide a string with no formatting, can not be longer than 26 chars
G2	Phone number	Enter the telephone number of the contact office (devices) or a representative knowledgeable about the report (drugs; biologics, including HCT/Ps) .	Please provide phone number in the following format -- "+" country_code "(" area_code ")" 3-digit prefix "-" 4-digit number "x" up to 5-digit extension e.g. +1(240)276-0001 x12345; if extension is not applicable, leave it out; International numbers would follow the same format -- e.g. "+" phone_country "(" phone_city ")" phone_local -- 011(123)1234567890 or if there is no phone_city: 011()1234567890
G3	Report source	Check the box(es) that most accurately describe(s) how the manufacturer [contact office] became aware of the reported adverse event or from where the information about the adverse event originated. Foreign: Foreign sources include foreign governments, foreign affiliates of the application/license holder, foreign licensors and licensees, foreign medical facilities, etc. The country of origin should be included. Study: Postmarketing, clinical trial, surveillance, or other study that involves a systematic collection of adverse events from a protocol designed specifically to investigate product safety. Literature: If the report source is the scientific literature or an unpublished manuscript, a copy of the article or manuscript must be attached. Foreign language articles should be translated into English. Record the date of the article as the date of the event (block B3), and provide a full literature citation in block H10. Drugs and Biologics, including HCT/Ps : A separate 3500A form must be completed for each identifiable patient described in the article or manuscript. Consumer (including attorneys): Additional information, whenever possible, should be sought from the treating healthcare provider. A determined effort should be made to obtain additional detailed information from health professionals for all serious reactions, adverse events & product problems initially reported by consumers. When this additional information is obtained, the follow-up report should check health professional rather than consumer in block G3. Health professional: Physician, pharmacist, nurse, etc. User facility: User facility should be checked if the manufacturer received the report from the MDR contact in a user facility as identified in section F. The health professional should be listed as the initial reporter on the front page of the form. Company representative: This check box would be selected if a company representative reported the event to the contact office based on information received from a health professional. The health professional should be listed as the initial reporter in Section E. Distributor: This check box would be selected for a report received from the distributor (importer) of the suspect product. The health professional or other reporter should be listed as the	Please look at the vocabulary attachment. Choose an appropriate code; use 'text' to explain 'OTHER'
G4	Date received by manufacturer	This means the date when the applicant, manufacturer, corporate affiliate, etc. receives information that an adverse event or medical device malfunction has occurred. This would apply to a report received anywhere in the world. (mm/dd/yyyy format) Follow-up reports: Use the date that the follow-up information was received.	Populate the date as 'high value' under /pertinentInformation1/secondaryCaseNotification/receiver negationInd/time/high value; Use YYYYMMDD format

Med Watch Form	MedWatch Field/Section Name	HL7 mapping of FDA Medwatch 3500A (paper) - XML specification	HL7 ICSR Implementation pointers
G5	Premarket Numbers	This block is for use by all manufacturers of drug, device, biological products [including cell, tissue, and cellular and tissue-based products (HCT/P)] and combination products.Provide whatever information is applicable to the suspect product identified in section C or suspect medical device identified in Section D. If the report lists two products by the same applicant as suspect, the report should be submitted to the application file of the product thought by the initial reporter to be the more likely cause of the adverse event. If they are equally suspect, the report should be submitted to the application file of the product that is first alphabetically. (A)NDA #: The abbreviated new drug application or the new drug application (NDA) number. The report should be filed to the first approved NDA if a product has several NDAs and the specific one cannot be determined. PMA/510(k) #: The pre-market application (PMA) or pre-market notification [510(k)] submission number for the approved / cleared medical device or combination product. If a product has several applicable PMA/510(k)'s and the specific one cannot be determined, then the first approved / cleared PMA or 510(k) number should be reported. Combination Product: Check the box if the suspect product is comprised of a drug-device, device-biological, drug-biological , or a drug-device-biological product, Pre-1938: Check the box if the suspect medication was marketed prior to 1938 and does	Only PMA and 510(k) used at present; please provide the appropriate number; do not add text such as 'PMA' or '510K' etc. in front of the number; just provide the number assigned by CDRH during premarket submission
G6	NOT USED FOR CDRH		
G7	Type of report	Select ALL the check boxes that apply to reported event. 5-day: As specified in the device regulations, for reports of adverse events that necessitate remedial action to prevent an unreasonable risk of substantial harm to the public health, or are required by FDA by written notice. **30-day:** This choice was added in the 2006 version of the 3500A. **DO NOT USE THIS OPTION for an initial report - preferred selection is *Initial.*** As specified in device regulations, for initial reports of a device that may have caused or contributed to a death or serious injury or for a device malfunction that would be likely to contribute to a death or serious injury if it were to recur. Periodic: As specified in the drug and biologic regulations, for reports of serious labeled and non-serious (labeled and unlabeled) adverse events. **Initial**: Check if the report is the first submission of a manufacturer report. For devices, this is the 30-day report. **USE INITIAL report, NOT 30-day report, to specify an initial report to the FDA CDRH.** Follow-up: Check if the report is a follow-up to a previously submitted report.Follow-up reports on devices should not repeat material that was submitted in the initial report, but should only provide additional or corrected information on the previously reported event. Follow-up reports on drugs and biologics, including HCT/Ps, should contain information that was submitted in the original report if the information is still correct. If a follow-up report, make sure that the manufacturer report number for the previously submitted initial report is recorded in block G9. In the blank provided in block G7 after follow-up, record the appropriate sequence of follow-up to that particular initial report (e.g., first follow-up report=follow-up #1, second follow-up report=follow-up #2,	Please look at the vocabulary attachment. Note: Use **'Initial report'** not '**30-day**' for an initial report to the FDA. Choose an appropriate code. Use 'text' to populate 'follow-up' number
	Type of Report\Follow-up Number	Preferred	
G8	NOT USED FOR CDRH		
G9	MFR Report #	For all manufacturers: Enter the Manufacturer report number exactly as it appears in the "Mfr Report #" field in the upper right corner of the first page. For a follow-up report, the Manufacturer report number must be identical to the number assigned to the initial report For drug and biologic manufacturers: The manufacturer report number is the number the manufacturer chooses to uniquely identify the report, and should conform to any applicable regulations or guidances. If submitting a follow-up to a report originally obtained from FDA through a MedWatch to Manufacturer program transmission of a serious direct report, check the other box in block G3 and enter the FDA-assigned report number there. For human cell, tissue, and cellular and tissue-based product (HCT/P) manufacturers: The report number should consist of three numbers separated by dashes. The first number will be the 10-digit FDA Establishment Identifier (FEI) number, which was assigned to you as part of the Human Cells and Tissue Establishment Registration (HCTERS). The second number should be the year that you are submitting the report. The last number should be a consecutive 5-digit number for each report filed during the year by the manufacturer. Example: 1234567890-2005-00005.	
H	***Device manufacturers only***		
H1	Type of reportable event	Check the appropriate box. These choices represent the categories of events that device manufacturers are required to report. Death: Check only if the death was an outcome of the adverse event. Serious injury: An adverse event that is life-threatening; results in permanent impairment of a body function or permanent damage to a body structure; or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure. Malfunction: See the guidelines. ("See the guidelines" refers to the applicable sections in 21 CFR Part 803 reporting guidelines associated with device malfunctions).	Please look at the vocabulary attachment.

Med Watch Form	MedWatch Field/Section Name	HL7 mapping of FDA Medwatch 3500A (paper) - XML specification	HL7 ICSR Implementation pointers
H2	If follow-up, what type?	Check the box(es) that most accurately describes the nature of the follow-up report. Correction: Changes to previously submitted information. Additional information: Information concerning the event that was not provided in the initial report because it was not known/available when the report was originally submitted. Response to FDA request: Additional information requested by FDA concerning the device/event. Device evaluation: Evaluation/analysis of device.	Please look at the vocabulary attachment. Choose an appropriate code. For all follow-up MDRs, please provide 'NEW' or 'Updated' information ONLY. Do not submit an MDR that includes old (prior submitted information) and new or updated information; if you want to send attachments, please submit them under /pertinentInformation3/document. Base64 is an encoding method that converts binary data (zeros and ones) into ASCII text and vice versa. It was originally devised to make it possible to reliably transmit data and is one of the methods used by MIME. Base64 divides each three bytes of the original data into four 6-bit units, which it represents as four 7-bit ASCII characters. It is typical to use MIME base64 encoding to encode email attachments as well as binary data in XML files. To embed a filetype within an XML document, you have to encode it in a fashion that is compatible with text. Base64 encoding is used to accomplish this. As an example, the process would roughly be the following to encode a PDF: 1. Run a program/method which would convert the PDF file to base-64: PDFInBase64 = convertToBase64("c:\myAttachment.pdf") 2. Insert it into a XML instance after converting to string. <document><text mediaType="text/plain">Base64 representation of PDF</text></document> There are several free, base64 encoding utilities and libraries available on the internet in a variety of languages and platforms.
H3 part 1	Device evaluated by mfr? YES/NO	Check the box marked not returned to mfr. if an evaluation could not be made because the device was not returned to, or made available to, the manufacturer. Check the box marked yes if an evaluation was made of the suspect or related medical device. If an evaluation was conducted, attach a summary of the evaluation and check the box marked evaluation summary attached. If an evaluation of a returned suspect or related medical device was not conducted, check the box marked no and attach a page to explain why not or provide the appropriate code from the codes manual in the space provided.	Please look at the vocabulary attachment. Populate 'true' for YES, Device Evaluated; 'false' for NO, Device not evaluated
H3 part 2	Device evaluated by mfr? Summary Attached YES/NO		Please look at the vocabulary attachment. Populate 'true' for YES, Evaluation Summary Attached; 'false' for NO, Evaluation Summary not attached;
H3 part 3	Device evaluated by mfr? Evaluation Summary or reason for not evaluating		Please look at the vocabulary attachment. Please use the appropriate concept code; use FDA codes to explain reason for non-evaluation as defined in http://www.fda.gov/cdrh/mdrcode.pdf, for section H3. For other, please provide explanation under the text field
H3 part 4	Device Returned to Manufacturer for Evaluation?		Please look at the vocabulary attachment.
H4	Device manufacture date	Enter the month and year of manufacture of the suspect medical device using a MM/YYYY date format.	Use YYYYMMDD format
H5	Labeled for single use?	Indicate whether the device was labeled for single use or not. If the question is not relevant to the device being reported (e.g., an X-ray machine), check no.	Please look at the attached vocabulary. Choose an appropriate code. Populate 'true' for YES; 'false' for NO;
H6	Evaluation Codes	Enter the applicable codes from the codes manual for one or more of the categories listed. Conclusion codes must be entered even if the device was not evaluated. If the reuse of a device may have caused or contributed to the adverse event, then the appropriate manufacturer Result codes are to be entered from the codes manual. Applicable reuse codes are 230-233 and may be used alone or with any other applicable results codes. (see H8).	
H6	Evaluation Codes\Method		Please look at the attached vocabulary. Choose an appropriate code. Multiple codes can be provided
H6	Evaluation Codes\Result		Please look at the attached vocabulary. Choose an appropriate code. Multiple codes can be provided
H6	Evaluation Codes\Conclusion		Please look at the attached vocabulary. Choose an appropriate code. Multiple codes can be provided
H7	If remedial action initiated, check type	Indicate the applicable action(s). If other, specify the type of action in the space provided. Most of these terms are defined or further explained in the Act or in the FDA regulations concerning remedial action (see 21 USC 360h and 21 CFR Parts 7, 803 and 806).	Please look at the attached vocabulary. Choose an appropriate code.
H7	If remedial action initiated, check type\Explanation for Other		Use 'originalText' to explain 'Other'

Med Watch Form	MedWatch Field/Section Name	HL7 mapping of FDA Medwatch 3500A (paper) - XML specification	HL7 ICSR Implementation pointers
H8	Usage of device	Indicate whether the use of the suspect medical device was the initial use, reuse, or unknown. If a manufacturer receives an adverse event report that indicates that the event was caused by or contributed to by reuse of a single use device they manufactured, this block is to be appropriately marked and the facts of the firm's investigation provided with an explanation of how the reuse of the product contributed to the outcome. The appropriate manufacturer Result codes for reuse are also to be entered into H6.	Please look at the attached vocabulary. Choose an appropriate code. Use nullFlavor attribute to indicate unknown.
H9	If action reported to FDA under 21 USC 360i(f), list correction/removal reporting number	Enter the number that FDA assigned to the corrective action. If a number has not yet been assigned by FDA, the number assigned by the firm for the action may be used.	Please look at the attached vocabulary. Choose an appropriate code. Populate removal reporting number under 'value'
H10/H11	Additional manufacturer narrative and corrected data checkbox	Enter any additional information, evaluation, or clarification of data presented in previous sections. Do not duplicate information that has already been provided elsewhere.	Additional information can be included under 'originalText' or as embedded files as described in section H2 above. If you have additional information that can be provided as a discrete data element on the 3500A form, please provide it with the appropriate tags. For example, if you would like to add/append/change device problem codes, please do not include it as part of 'originalText' under H10. Instead, include it in the document where you would normally provide device problem codes with right xml tags attached.

Field Lengths
Field Lengths
6 codes
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VARCHAR2(10)
DATE
NUMBER(5)
VARCHAR2(10)
NUMBER(3)

Field Lengths
DATE
DATE
DATE

Field Lengths
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LONG
LONG
VARCHAR2(80)
VARCHAR2(3)
VARCHAR2(80)

Field Lengths
VARCHAR2(50)
VARCHAR2(30)
VARCHAR2(30)
VARCHAR2(30)
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VARCHAR2(5)
VARCHAR2(4)
VARCHAR2(10)
VARCHAR2(50)
VARCHAR2(26)
VARCHAR2(80)
VARCHAR2(30)
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Field Lengths
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Field Lengths
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DATE

Field Lengths
NUMBER(3)
NUMBER(5)
VARCHAR2(10)
VARCHAR2(1)
DATE
VARCHAR2(40)
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Field Lengths
VARCHAR2(10)
VARCHAR2(50)
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VARCHAR2(4)
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VARCHAR2(10)
VARCHAR2(50)
VARCHAR2(26)
VARCHAR2
DATE

Field Lengths
VARCHAR2(12)
NUMBER(3)
VARCHAR2(21)

Field Lengths
DATE
VARCHAR2(40)

Field Lengths
VARCHAR2(24)
LONG