

## **Study Management SM 306.01**

### **STANDARD OPERATING PROCEDURE Adverse Event Reporting**

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**04 Feb 2021**

(Signature and Date)

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**04 Feb 2021**

(Signature and Date)

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#### **1. INTRODUCTION AND PURPOSE**

Subject safety is of scientific, clinical, and ethical significance for the clinical trial, study subjects, and Investigators conducting clinical trials. Investigators are required to report all adverse events occurring during the treatment and follow-up periods of a clinical trial to the Sponsor. If the event is serious and unexpected, prompt reporting to the manufacturer of the investigational product and to the IRB is mandatory.

The purpose of this SOP is to describe the responsibilities of Georgia CORE staff, consultants, Research Network site Investigators and staff in recognizing, managing, reporting, and documenting adverse events occurring during the course of a clinical trial.

## **2. SCOPE**

This SOP applies to all Georgia CORE staff and consultants involved monitoring, reporting, and documenting adverse events from the time Georgia CORE is notified that an adverse event is identified until all follow-up activities associated with it resolution have been completed.

This SOP also describes the mechanisms used to provide information necessary for Georgia CORE staff and consultants to prepare Investigational New Drug (IND) safety

reports. Finally, the procedures for Georgia CORE to process and transmit IND safety reported received from the manufacturer of the drug and the sponsor to the IRB are defined.

## **3. APPLICABLE REGULATIONS AND GUIDELINES**

The Code of Federal Regulations and the International Conference on Harmonization, Good Clinical Practice: Consolidated Guideline and selected program and guidance documents apply to this SOP (Appendix A).

## **4. REFERENCES TO OTHER APPLICABLE SOPS**

GA -102 Sponsor Responsibility and Delegation of Responsibility  
SM - 301 Communication  
SM - 302 Interactions with the IRB  
SM -304 Routine Monitoring Visits  
SM - 305 Closeout Visits  
DM - 401 Data Management

## **5. ATTACHMENTS**

A. Procedures for Managing Adverse Events  
B. FDA Form 3500  
C. FDA Form 3500 A  
D. Algorithm for Review and Distribution of IND Safety and MedWatch Reports

## **6. RESPONSIBILITY**

This SOP applies to those members of Georgia involved in ensuring appropriate management of adverse event reporting, including,

- President and CEO
- Chief Medical Officer
- Georgia CORE Research Network site Investigator, Subinvestigators, and staff
- Georgia CORE staff and consultants

## **7. DEFINITIONS**

The following definitions apply to this SOP (Appendix B):

Adverse event

Associated with the use of the drug

Disability

Life-threatening adverse drug experience  
Serious adverse drug experience (ADE) (also known as a serious adverse event (SAE))  
Sponsor  
Unexpected adverse drug experience

## 8. PROCESS OVERVIEW

- A. Managing adverse events
- B. Handling IND safety reports from the drug manufacturer or Sponsor
- C. Reporting to the IRB

## 9. PROCEDURES

### A. Managing Adverse Events

- |                                                               |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|---------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Georgia CORE staff<br>and consultants                         | <p>When a Research Network site reports an adverse change in a subject from baseline or pre-treatment condition, ensure that all appropriate resources have been directed toward subject safety and well-being and that the subject is followed until the event is resolved (Attachment A: Site Procedures for Managing Adverse Events).</p> <p>At the next site visit, ensure that details of the adverse event are recorded in the source documentation and the appropriate CRFs are completed.</p> <p>At the next site visit, ensure that originals or photocopies of all relevant documentation, including facsimile confirmations have been filed in the study binder and document findings in the monitoring report.</p>                                                                                                                 |
| PI for Study<br>Georgia CORE<br>CORE Chief Medical<br>Officer | <p>If necessary for the immediate medical care of the subject only, facilitate breaking the drug blind after consultation (if possible) with the Investigator who initiated the study or the Georgia CORE Chief Medical Officer.</p> <p>Determine if the adverse event is serious and/or unexpected with the assistance of the Investigator who initiated the study and/or Chief Medical Officer, if needed, and inform the drug manufacturer <del>pharma</del> as directed in the protocol.</p> <ul style="list-style-type: none"><li>- Provide as much information as is available from the site using the Med Watch Form FDA 3500 or 3500A (Attachment B and Attachment C) and/or the Serious Adverse Event Report Form in the protocol, if applicable.</li><li>- For NCI NCTN trials report online at CTEP-AERs within 24 hours.</li></ul> |

<https://ctepcore.nci.nih.gov/ctepaers/pages/task?rand=1490109392775>

## **B. Handling IND Safety Reports from Drug Manufacturer or Sponsor ~~Pharma~~**

Georgia CORE staff  
and consultants  
Research Network  
site Investigators  
and staff

Promptly review IND safety reports received from drug manufacturers or Sponsors and follow the algorithm for review and Distribution of IND Safety and MedWatch Reports (Attachment D).

File IND safety reports and MedWatch Reports and related communications in the Georgia CORE: IND Safety Report electronic folder for the appropriate clinical trial.

All serious or adverse events occurring at a Georgia CORE Research Network site, which is using the Central IRB, should be reported using the Central IRB guidance.

For NCTN trials approved by the local IRB or NCI CIRB, notify the local IRB of all serious or alarming events. If no local IRB of record, report SAEs and any updates to Georgia CORE by including them on the CTEP-AERS report.

Ensure that all IND safety reports received from the drug manufacturer or Sponsor are submitted to the Central IRB according to the Central IRB guidelines and the Algorithm for Review and Distribution of IND Safety and MedWatch Reports (Attachment D).

Ensure that all routine adverse events are reported to the Central IRB as part of the periodic or annual reporting requirements as outlined in the Central IRB guidelines.

Obtain documentation from Georgia CORE Research Network sites using local IRBs, showing that they have completed reports to the local IRB as noted in the above 3 action items.

File documentation in the Georgia CORE IND Safety Report electronic folder for the appropriate trial.

## **10. HISTORY**

Version Number	Section Number	Modification	Approval Date
306.00	All	Original Version	
306.00	All	No change necessary	09 March 2012
306.00	All	No change necessary	01 June 2014
306.00	3,7,9A, C	Additional guidelines added, clarification, NCTN and NCI CIRB report guidelines added	21 March 2017
306.01	All	Edits for clarification and consistency,	30 June 2020

**ATTACHMENT A:  
Procedures for Managing Adverse Events**

**1. Identification, assessment and management of an adverse event by the Georgia CORE Network Sites**

REGULATIONS	PROCEDURES
<p>Definition of an adverse event (AE):</p> <ul style="list-style-type: none"> <li>Any adverse change from baseline (pretreatment) intercurrent illness which occurs during the course of a clinical study after treatment has started, whether considered related to treatment or not</li> <li>Any effect that is unintended and unfavorable, such as a sign, a symptom, a laboratory abnormality or a disease or condition</li> </ul> <p>Serious adverse events (SAEs) include:</p> <ul style="list-style-type: none"> <li>Death</li> <li>Life-threatening experience</li> <li>Inpatient hospitalization or prolongation</li> <li>Persistent or significant disability/incapacity</li> <li>Congenital anomaly/birth defect</li> <li>Events that would require medical or</li> </ul>	<p>Ensure that the following are appropriately investigated:</p> <ul style="list-style-type: none"> <li>Spontaneous reports by subjects</li> <li>Observations by clinical research staff</li> <li>Reports to research staff by family or medical care providers</li> <li>Possible AEs documented in medical records, progress notes, etc.</li> <li>Reports of a subject death within four weeks after stopping treatment or during the protocol-defined follow-up period, whichever is longer, whether considered treatment-related or not.</li> </ul> <p>Manage the adverse event to ensure that all appropriate resources are directed toward subject safety and well-being. Institute therapeutic intervention/support measures. If applicable:</p> <ul style="list-style-type: none"> <li>Discontinue the investigational product, comparator, or placebo</li> <li>Reduce dosage (as per protocol)</li> </ul>

surgical intervention to prevent any of the above

- Interrupt drug (as per protocol)
- Challenge (as per protocol)

Follow the subject and assess the adverse event until stabilized/resolved

## 2. Georgia CORE Research Network Site SAE Reporting

- Report **serious and unexpected** adverse experiences, whether considered drug-related or not, to the Sponsor as directed in the protocol.
- Provide details to the Sponsor as they become available. If additional information cannot be obtained for whatever reason, document this.
- Inform the Sponsor when no other information is expected.

SPONSOR RESPONSIBILITIES	SITE RESPONSIBILITIES
<p>Sponsors are required to notify the FDA by IND safety reports of <b>any serious adverse experience associated with use of the drug</b> in the clinical studies conducted under an IND as soon as possible but no later than <b>10 calendar days</b> after initial receipt of the information.</p> <p>Georgia CORE is required to notify the drug manufacturer as specified in the protocol.</p> <p>If the event is <b>fatal or life-threatening and associated with use of the drug</b>, sponsors are required to notify the FDA by telephone or fax within <b>7 calendar days</b> of initial receipt of the information.</p>	<p>To meet expedited reporting requirements, inform the sponsor as soon as possible after the subject is stabilized.</p> <p>Provide as much of the following information as is available:</p> <ul style="list-style-type: none"> <li>• Protocol name and number</li> <li>• The possible test articles: investigational product, comparator, or placebo</li> <li>• Lot number and expiration date</li> <li>• Subject identifiers</li> <li>• Demographic data</li> <li>• The nature of the event</li> <li>• The severity of the event</li> <li>• The probable relationship of the AE to the investigational product</li> <li>• The date (and time) of AE onset</li> <li>• The date (and time) of AE resolution, if available</li> <li>• The dose, frequency, and route of administration</li> <li>• The start and stop dates of test article administration</li> <li>• Concomitant medications and therapies</li> <li>• Clinical assessment of the subject at this time</li> <li>• The results of any laboratory and/or diagnostic procedures, treatment, autopsy findings</li> </ul>

- The follow-up plan
- The outcome

### 3. Site Research documentation

SOURCE DOCUMENTATION	CASE REPORT FORM COMPLETION
<p>Record in the source documentation, noting</p> <ul style="list-style-type: none"> <li>• The nature of the event</li> <li>• The severity of the event</li> <li>• The probable relationship of the AE to the investigational product</li> <li>• The date (and time) of AE onset</li> <li>• The date (and time) of AE resolution, if available</li> <li>• The possible test articles: investigational product, comparator, or placebo, the dose, frequency, and route of administration</li> <li>• The start and stop dates of test article administration</li> <li>• Concomitant medications and therapies</li> <li>• Clinical assessment of the subject at this time</li> <li>• The results of any laboratory tests and/or diagnostic procedures</li> <li>• The follow-up plan</li> <li>• The outcome</li> </ul>	<p>Complete the appropriate case report form(s)</p> <ul style="list-style-type: none"> <li>• The site-prepared data collection form for SAEs or</li> <li>• The sponsor-generated CRF for routine AEs</li> </ul>

### 4. Pharma-generated IND safety reports

RESPONSIBILITIES TO IRB	RESPONSIBILITIES TO Pharma
<ul style="list-style-type: none"> <li>• Submit IND <b>safety reports</b> to the IRB if applicable, see Algorithm for Review and Distribution of IND Safety and MedWatch Reports (Attachment D) and retain a copy of the transmittal memo in the study regulatory binder.</li> </ul>	<ul style="list-style-type: none"> <li>• Acknowledge receipt of expedited safety report to Pharma with letter/facsimile.</li> <li>• Copy Pharma on the transmittal memo to the IRB, if required.</li> <li>• Inform Pharma of action required by the IRB, such as revisions to the informed consent form.</li> <li>• Follow up with the Pharma as required.</li> </ul>

**ATTACHMENT B:  
Form FDA 3500**

Reset Form

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

**MEDWATCH**

FORM FDA 3500 (2/19)  
The FDA Safety Information and  
Adverse Event Reporting Program

For VOLUNTARY reporting of  
adverse events, product problems  
and product use/medication errors

Form Approved: OMB No. 0910-0291, Expires: 11-30-2021  
See PRA statement on reverse.

Page 1 of 2

FDA USE ONLY	
Triage unit sequence #	
FDA Rec. Date	

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year; for example, 01-Jul-2018.

**A. PATIENT INFORMATION**

1. Patient Identifier: [ ] In Confidence

2. Age:  Year(s)  Month(s)  Week(s)  Day(s) or Date of Birth (e.g., 08 Feb 1925)

3. Gender (check one):  Female  Male  Intersex  Transgender  Prefer not to disclose

4. Weight:  lb  kg

5. Ethnicity (check one):  Hispanic/Latino  Not Hispanic/Latino

6. Race (check all that apply):  Asian  American Indian or Alaskan Native  Black or African American  White  Native Hawaiian or Other Pacific Islander

**B. ADVERSE EVENT, PRODUCT PROBLEM**

1. Type of Report (check all that apply):  Adverse Event  Product Problem (e.g., defects/malfunctions)  Product Use/ Medication Error  Problem with Different Manufacturer of Same Medicine

2. Outcome Attributed to Adverse Event (check all that apply):  Death Date of death (dd-mmm-yyyy):  Life-threatening  Hospitalization (initial or prolonged)  Other Serious or Important Medical Events  Disability or Permanent Damage  Congenital Anomaly/Birth Defects  Required Intervention to Prevent Permanent Impairment/Damage

3. Date of Event (dd-mmm-yyyy): [ ] 4. Date of this Report (dd-mmm-yyyy): [ ]

5. Describe Event, Problem or Product Use/Medication Error: [ ] (Continue on page 2)

6. Relevant Tests/Laboratory Data: [ ] Date (dd-mmm-yyyy): [ ] (Continue on page 2)

7. Other Relevant History, Including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.): [ ] (Continue on page 2)

**C. PRODUCT AVAILABILITY**

1. Product Available for Evaluation? (Do not send product to FDA)  Yes  No  Returned to Manufacturer on (dd-mmm-yyyy)

2. Do you have a picture of the product? (check yes if you are including a picture)  Yes

**D. SUSPECT PRODUCTS**

1. Name, Strength, Manufacturer/Compounder (from product label). Does this report involve cosmetic, dietary supplement or food/medical food? #1  Yes  No #2  Yes  No

#1 - Name and Strength	#1 - NDC # or Unique ID
#1 - Manufacturer/Compounder	#1 - Lot #
#2 - Name and Strength	#2 - NDC # or Unique ID
#2 - Manufacturer/Compounder	#2 - Lot #

2. Dose or Amount: #1 [ ] #2 [ ] Frequency: #1 [ ] #2 [ ] Route: #1 [ ] #2 [ ]

3. Treatment Dates/Therapy Dates (give best estimate of length of treatment (start/stop) or duration.) #1 Start [ ] #1 Stop [ ] Is therapy still on-going?  Yes  No #2 Start [ ] #2 Stop [ ] Is therapy still on-going?  Yes  No

4. Diagnosis for Use (Indication) #1 [ ] #2 [ ]

5. Product Type (check all that apply) #1  OTC  Compounded  Generic  Biosimilar #2  OTC  Compounded  Generic  Biosimilar

6. Expiration Date (dd-mmm-yyyy) #1 [ ] #2 [ ]

7. Event Abated After Use Stopped or Dose Reduced? #1  Yes  No  Doesn't apply #2  Yes  No  Doesn't apply

8. Event Reappeared After Reintroduction? #1  Yes  No  Doesn't apply #2  Yes  No  Doesn't apply

**E. SUSPECT MEDICAL DEVICE**

1. Brand Name: [ ]

2a. Common Device Name: [ ] 2b. Procode: [ ]

3. Manufacturer Name, City and State: [ ]

4. Model #: [ ] Lot #: [ ] Catalog #: [ ] Expiration Date (dd-mmm-yyyy): [ ] Serial #: [ ] Unique Identifier (UDI) #: [ ]

5. Operator of Device:  Health Professional  Patient/Consumer  Other

6a. If Implanted, Give Date (dd-mmm-yyyy): [ ] 6b. If Explanted, Give Date (dd-mmm-yyyy): [ ]

7a. Is this a single-use device that was reprocessed and reused on a patient?  Yes  No 7b. If Yes to Item 7a, Enter Name and Address of Reprocessor: [ ]

8. Was this device serviced by a third party servicer?  Yes  No  Unknown

**F. OTHER (CONCOMITANT) MEDICAL PRODUCTS**

1. Product names and therapy dates (Exclude treatment of event): [ ] (Continue on page 2)

**G. REPORTER (See confidentiality section on back)**

1. Name and Address: Last Name: [ ] First Name: [ ] Address: [ ] City: [ ] State/Province/Region: [ ] ZIP/Postal Code: [ ] Country: [ ] Phone #: [ ] Email: [ ]

2. Health Professional?  Yes  No 3. Occupation: [ ] 4. Also Reported to:  Manufacturer/Compounder  User Facility  Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, please mark this box:

FORM FDA 3500 (2/19)

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.  
\* Please see instructions

Source: <https://www.fda.gov/media/76299/download>

Reset Form

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

**MEDWATCH**

FORM FDA 3500 (2/19) (continued)  
The FDA Safety Information and  
Adverse Event Reporting Program

(CONTINUATION PAGE)  
For VOLUNTARY reporting of  
adverse events, product problems  
and product use/medication errors

Page 2 of 2

B.5. Describe Event or Problem (continued)

Back to Item B.5

B.6. Relevant Tests/Laboratory Data (continued)

Date (dd-mmm-yyyy)	Relevant Tests/Laboratory Data	Date (dd-mmm-yyyy)

Additional comments

Back to Item B.6

B.7. Other Relevant History (continued)

Back to Item B.7

F.1. Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (continued)

Back to Item F.1

Source: <https://www.fda.gov/media/76299/download>

**ATTACHMENT C:  
Form FDA 3500A**

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

**MEDWATCH**

FORM FDA 3500A (2/19)

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

Page 1 of 2

Form Approved: OMB No. 0910-0291, Expires: 11/30/2021  
See PRA statement on reverse.

Mfr Report #
UF/Importer Report #
FDA Use Only

Note: For date prompts of "dd-mmm-yyyy" please use 2-digit day, 3-letter month abbreviation, and 4-digit year, for example, 01-Jul-2018.

A. PATIENT INFORMATION			
1. Patient Identifier	2. Age <input type="checkbox"/> Year(s) <input type="checkbox"/> Month(s) <input type="checkbox"/> Week(s) <input type="checkbox"/> Day(s) or Date of Birth (e.g., 08 Feb 1925)	3. Gender (check one) <input type="checkbox"/> Female <input type="checkbox"/> Male <input type="checkbox"/> Intersex <input type="checkbox"/> Transgender <input type="checkbox"/> Prefer not to disclose	4. Weight <input type="checkbox"/> lb <input type="checkbox"/> kg
5. Ethnicity (check one) <input type="checkbox"/> Hispanic/Latino <input type="checkbox"/> Not Hispanic/Latino		6. Race (check all that apply) <input type="checkbox"/> Asian <input type="checkbox"/> American Indian or Alaskan Native <input type="checkbox"/> Black or African American <input type="checkbox"/> White <input type="checkbox"/> Native Hawaiian or Other Pacific Islander	
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. Type of Report (check all that apply) <input type="checkbox"/> Adverse Event <input type="checkbox"/> Product Problem (e.g., defects/ malfunctions)			
2. Outcome Attributed to Adverse Event (check all that apply) <input type="checkbox"/> Death Date of death (dd-mmm-yyyy): <input type="checkbox"/> Life-threatening <input type="checkbox"/> Disability or Permanent Damage <input type="checkbox"/> Hospitalization (initial or prolonged) <input type="checkbox"/> Congenital Anomaly/Birth Defects <input type="checkbox"/> Other Serious or Important Medical Events <input type="checkbox"/> Required Intervention to Prevent Permanent Impairment/Damage			
3. Date of Event (dd-mmm-yyyy)		4. Date of this Report (dd-mmm-yyyy)	
5. Describe Event or Problem  <p style="text-align: right;">(Continue on page 3)</p>			
6. Relevant Tests/Laboratory Data		Date (dd-mmm-yyyy)	
7. Other Relevant History, including Preexisting Medical Conditions (e.g., allergies, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)  <p style="text-align: right;">(Continue on page 3)</p>			
C. SUSPECT PRODUCTS			
1. Name, Strength, Manufacturer/Compounder			
#1 - Name and Strength	#1 - NDC # or Unique ID		
#1 - Manufacturer/Compounder	#1 - Lot #		
#2 - Name and Strength	#2 - NDC # or Unique ID		
#2 - Manufacturer/Compounder	#2 - Lot #		
2. List Medical Product and Treatment Given at the Same Time Of the Event and Date (Do not include treatment for initial event)  <p style="text-align: right;">(Continue on page 3)</p>			

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.

3. Dose		Frequency	Route Used
#1			
#2			
4. Treatment Dates/Therapy Dates (give length of treatment (start/stop) or your best estimate.)		5. Diagnosis for Use (indication)	
#1 Start		#1	
#1 Stop			
#2 Start		#2	
#2 Stop			
6. Product Type (Check all that apply)		7. Expiration Date (dd-mmm-yyyy)	
#1 <input type="checkbox"/> OTC	#2 <input type="checkbox"/> OTC	#1	
<input type="checkbox"/> Compounded	<input type="checkbox"/> Compounded	#2	
<input type="checkbox"/> Generic	<input type="checkbox"/> Generic		
<input type="checkbox"/> Biosimilar	<input type="checkbox"/> Biosimilar		
8. Event Abated After Use Stopped or Dose Reduced?		9. Event Reappeared After Reintroduction?	
#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply		
#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't apply		
D. SUSPECT MEDICAL DEVICE			
1. Brand Name			
2a. Common Device Name		2b. Procode	
3. Manufacturer Name, City and State			
4. Model #	Lot #	5. Operator of Device	
Catalog #	Expiration Date (dd-mmm-yyyy)	<input type="checkbox"/> Health Professional	
Serial #	Unique Identifier (UDI) #	<input type="checkbox"/> Patient/Consumer	
6a. If Implanted, Give Date (dd-mmm-yyyy)		<input type="checkbox"/> Other	
6b. If Expanted, Give Date (dd-mmm-yyyy)			
7a. Is this a single-use device that was reprocessed and reused on a patient?		7b. If yes, Enter Name and Address of Reprocessor	
<input type="checkbox"/> Yes <input type="checkbox"/> No			
8. Was this device serviced by a third party?			
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown			
9. Device Available for Evaluation? (Do not send to FDA) <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Returned to Manufacturer on:			
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)  <p style="text-align: right;">(Continue on page 3)</p>			
E. INITIAL REPORTER			
1. Name and Address			
Last Name:		First Name:	
Address:			
City:		State/Province/Region:	
ZIP/Postal Code:		Country:	
Phone #:		Email:	
2. Health Professional?	3. Occupation (Select from list)	4. Initial Reporter Also Sent Report to FDA	
<input type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unk	

Source: <https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>

Reset Form

**MEDWATCH**

FORM FDA 3500A (2/19) (continued)

For use by user-facilities, importers,  
distributors and manufacturers for  
MANDATORY reporting  
Page 2 of 2

FDA USE ONLY

**F. FOR USE BY USER FACILITY/IMPORTER (Devices Only)**

1. Check One  
 User Facility     Importer

2. User Facility/Importer Report Number

3. User Facility or Importer Name/Address

4. Contact Person

5. Phone Number

6. Date User Facility or Importer Became Aware of Event (dd-mmm-yyyy)

7. Type of Report  
 Initial  
 Follow-up # \_\_\_\_\_

8. Date of This Report (dd-mmm-yyyy)

9. Approximate Age of Device

10. Adverse Event Problem (Refer to coding manual)

Health Effect - Clinical Code	Health Effect - Impact Code
Medical Device Problem Code	Component Code

11. Report Sent to FDA? (If Yes, enter date (dd-mmm-yyyy))  
 Yes  
 No

12. Location Where Event Occurred  
 Ambulatory Surgical Facility     Nursing Home  
 Home     Outpatient Diagnostic Facility  
 Hospital     Outpatient Treatment Facility  
 Other: \_\_\_\_\_ (Specify)

13. Report Sent to Manufacturer? (If Yes, enter date (dd-mmm-yyyy))  
 Yes  
 No

14. Manufacturer Name/Address

**G. ALL MANUFACTURERS**

1. Contact Office (and Manufacturing Site for Devices) or Compounding Outsourcing Facility

Name

Email Address

Address

Phone Number

Compounding Outsourcing Facility 503B?  Check box if applicable

Outsourcing Facility

2. Report Source (check all that apply)

Foreign  
 Study  
 Literature  
 Consumer  
 Health Professional  
 User Facility  
 Company Representative  
 Distributor/Importer  
 Other (Please list): \_\_\_\_\_

3. Date Received by Manufacturer (dd-mmm-yyyy)

4. NDA # \_\_\_\_\_  
 ANDA # \_\_\_\_\_  
 IND # \_\_\_\_\_  
 BLA # \_\_\_\_\_  
 PMA/ 510(k) # \_\_\_\_\_

5. IF IND/PreANDA, Give Protocol # \_\_\_\_\_

6. Type of Report (check all that apply)

<input type="checkbox"/> 5-day	<input type="checkbox"/> Periodic
<input type="checkbox"/> 7-day	<input type="checkbox"/> Initial
<input type="checkbox"/> 15-day	<input type="checkbox"/> Follow-up # _____
<input type="checkbox"/> 30-day	

7. Adverse Event Term(s)

8. Manufacturer Report Number

Check all that apply:  
 Combination Product  
 PreANDA  
 Pre-1938  
 OTC  
 Compounded Product

**H. DEVICE MANUFACTURERS ONLY**

1. Type of Reportable Event (check all that apply.)

Death  
 Serious injury  
 Malfunction  
 Summary Report

No. of events summarized \_\_\_\_\_

2. If Follow-up, What Type?

Correction  
 Additional Information  
 Response to FDA Request  
 Device Evaluation

3. Device Evaluated by Manufacturer?  
 Yes     No  
 (Attach page to explain why not) or provide code: \_\_\_\_\_

4. Device Manufacture Date (dd-mmm-yyyy)

5. Labeled for Single Use?  
 Yes     No

6. Adverse Event Problem (Refer to coding manual)

Health Effect - Clinical Code	Health Effect - Impact Code
Medical Device Problem Code	Component Code
Type of Investigation	Investigation Findings
Investigation Conclusions	

7. If Remedial Action Initiated, Check Type

Recall     Notification  
 Repair     Inspection  
 Replace     Patient Monitoring  
 Relabeling     Modification/Adjustment  
 Other: \_\_\_\_\_

8. Usage of Device  
 Initial Use of Device  
 Reuse  
 Unknown

9. If action reported to FDA under 21 USC 360(f), list correction/removal reporting number: \_\_\_\_\_

10. Additional Manufacturer Narrative

11. Corrected Data

This section applies only to requirements of the Paperwork Reduction Act of 1995. This section applies only to requirements of the Paperwork Reduction Act of 1995. The public reporting burden for this collection of information has been estimated to average 73 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 this 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  
 Office of Chief Information Officer  
 Paperwork Reduction Act (PRA) Staff  
 PRAStaff@fda.hhs.gov  
 Please DO NOT RETURN this form to the above PRA Staff email 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."

Source: <https://www.fda.gov/safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>

**ATTACHMENT D:**  
**Algorithm for Review and Distribution of IND Safety and Med Watch Reports**

