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## Purpose of this Manual

The purpose of this manual is to provide guidance on how to use the system for entering adverse events. It includes instructions on how to navigate the system, steps for entering adverse events, and how to use various tools and features within the system.
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Chapter 1  Introduction

Welcome to IRMS

Now that you have implemented the Information Request Management System (IRMS) with Adverse Events from Online Business Applications, Inc. (OBA) for your medical communications solution, its time to get familiar with the features and functionality of the software. This guide describes the features and functionality for the Adverse Events processes.

Purpose of this Manual

The purpose of this guide is to explain the features and functionality of the Adverse Events system. This includes procedures to capture and report Adverse Events with IRMS.

This manual is intended for IRMS Adverse Event Reporters.

How to Use this Guide

What this guide includes

This guide includes the documentation needed to efficiently record and report adverse events received from consumer and health professionals. Other features include adverse event resolution tracking, periodic reports, and CIOMS reporting.

How this guide is setup

Each chapter in this guide provides information on a specific function related to setting up and processing Adverse Events.

Chapter 2 System Administration and Setup steps through the process of setting up IRMS to use the Adverse Event module. Topics include User Preferences, Division Parameters, Client Data Fields, Group Security, Reporting Agency, Product Manufacturing, Product, and Shift.

Chapter 3 Entering Adverse Events steps through the process of entering an adverse event into the IRMS system. Each tab is discussed in detail.

Chapter 4 – AE Reporting explains how to print the various reports in adverse events.

Chapter 5 – Regulatory Reporting explains how to generate the periodic reports for various regulatory agencies. Included is a detailed step by step example of how to create the report. The regulatory reports include the 3500A, CIOMS, MDR, PSUR, and Periodic Reporting.

Chapter 6 – E2B Interface Processing explains how to create an electronic file in an E2B format for transmitting adverse events to other reporting agencies.

Chapter 7 – Appendix provides a listing of the Reportable Field Names and Query Results List Field Names.

Chapter 8 – Index provides a listing of the topics discussed in the guide.

Key to the Guide:

- Explanation of data field
- Explanation of Checkbox
- Explanation of Radio Button
Explanation of Command Button

Recommendation from OBA

Important Information – Please Read

Make a Note
Additional information is explained here.
Communicating with Online Business Applications, Inc.

Via Phone

Account Management  (630) 243-9810 ext 215.
Sales  (630) 243-9810 ext 209.
Technical Support  (630) 243-9810 extension 250.
Training  (630) 243-9810 ext 218.

Support Team Hours – 8:00 AM to 6:00 PM US Central Standard Time.

Via Website

Our website is www.IRMSOnline.com. To contact us from our website, go to the Quick Links section on the Home page and click Email Support or Email Sales.

Visit our website for information on new releases, documentation, training, the IRMS User Group, and the latest information at Online Business Applications, Inc.

Via E-mail

E-mail us at Support@IRMSOnline.com.

Via Fax

Fax number is 630-243-9811.
Browsing our Website

Our website at [www.IRMSOnline.com](http://www.IRMSOnline.com) contains the latest information on OBA and IRMS.

Everything from information on our products, news articles on the latest workshops, current and previous newsletters, registration for training classes and workshops, to User Group information is available. This is the place with the latest updates on new IRMS releases, education, and documentation.

We are creating a new User Center with IRMS Knowledge Base Articles, Tips & Tricks, FAQ’s, Client Workshop Presentations, and Focus Group Results. It should be available soon on the website.

Information on the latest version of IRMS

The Support menu provides information about new features and functionality added to IRMS. Information for previous versions is also available here. From the Support menu, click Release Notes or Documentation. The following information is available.

**Release Notes**

View the latest release notes to find out what’s changed in IRMS.

Release Notes for previous versions are also found here.

**Release Documents**

View the latest documents for a release. The set of documents for a new version includes User Requirement Specifications, Functional Specifications, Upgrade Instructions, and Deployment Plans.

**Documentation Guides**

View the guides for current and previous releases of IRMS. In 2006 OBA began releasing documentation for each major release.

Information on IRMS Education

The Services menu provides information about training courses and training class availability. From the Service menu, click Education. The following information is available.

**Course Descriptions**

View the latest courses offered to efficiently operate IRMS.

**Training Classes**

Find out when and what training courses are offered at the IRMS Education Center in Lemont, Illinois.

**Training Packet**

Download a Training Packet containing all the information needed to select and schedule a training class at the OBA Education Center. You can also register for classes online.
IRMS Support

The Support Team answers questions and responds to problems encountered in IRMS. Important information about our Support Team is listed below.

Contacting the Support Team

Support Team Hours: Monday through Friday
8:00 AM to 6:00 PM US Central Standard Time

Phone: (630) 243-9810 extension 250
Email: support@IRMSOnline.com

How the Support Team Works

When a call is received by the Support Team it is logged into a Support Database. At this time a case number and priority is assigned. The case is assigned to a member of the Support Team.

The question or problem is investigated by the Support Team. During the investigation the Support Team may request additional information. This may include additional questions, screen prints, and reports. If a problem cannot be resolved quickly, sometimes a workaround is provided until the problem can be fixed.

If the problem is not resolved in a reasonable amount of time, the problem is escalated to the next level of support. The Support Team member assigned to the case will provide periodic updates on the status of the problem and call with a resolution or workaround.

Reporting a Problem to Online Business Applications

It is important to notify OBA of problems. Any information provided (screen name, action being taken, etc.) will help to eliminate these issues in future releases of IRMS. Serious problems affecting the operation of IRMS will be addressed as soon as possible.

The Best Way to Report a Problem

When problems are found in IRMS, they should be reported to the Support Team at OBA with as much detail as possible. Below is a list of information that may be requested to aid in resolving problems. Additional information may be requested after contacting our Support Team.

☐ Provide a screen printout (if needed)

A screen can be captured by executing the following steps:

1. Move the error message so any important information can be seen in the screen capture.

2. With the error displayed on the screen, press the Print Screen key located on the top row of the keyboard.

3. Activate Microsoft Word and start a new document.

4. Perform a Paste. (Point to Edit from the menu bar and click Paste from the options presented.)

5. Print the screen to fax to OBA. Provide details on the process being executed. For example, what was clicked and data that was entered.
6. If manually faxing a screen print, fax it to 630-243-9811. If electronically faxing or e-mailing, save the document to a file to be attached to the message or use File Send to support@IRMSOnline.com.

- **Provide a report sample (if needed)**

  If there is a problem with a report, a report sample will be requested by the Support Team. If providing a report in error, follow the steps below to send the report to OBA:
  1. Email the report as a PDF. Provide the Report Type and Criteria. Provide any other details about how the report was printed, what options were selected, and what parameters were entered. Email the report to support@IRMSOnline.com.
  2. If manually faxing a report, print the report and fax it to 630-243-9811. Include the company name, contact information, a brief description of the problem, the report type and criteria with any additional information.

- **Capture workstation settings (if needed)**

  Workstation settings can be emailed to OBA by executing the following steps:
  1. From the IRMS toolbar point to Help and click About IRMS. The About IRMS screen is displayed.
  2. An email screen is opened with the current IRMS values. Enter a brief description of the error in the subject line and enter your contact information in the body of the email. Click Send Email to Online.

- **Schedule a Webex session (if needed)**

  If a problem is persistent and cannot be resolved based on the requested information, the Support Team may request a Webex session to walk through the problem. If requested, the Support Team will provide the necessary information for the Webex session.
IRMS Education

Online Business Applications, Inc. offers a variety of education for all its products. Training is provided in Continuing Education Courses and Workshops.

- Continuing Education Classes offered at the IRMS Education Center in Lemont, Illinois.
- Continuing Education Courses offered at the Client’s location.
- Semi-Annual IRMS Workshops offered at the Drug Information Association show and various locations throughout the country.

How to Find Education Information

Available Courses:  www.IRMSOnline.com  Services / Education
Workshop Information:  www.IRMSOnline.com  Home Page
Class Location:  IRMS Education Center in Lemont, Illinois or Client’s Location

Contacting the Education Team

Phone:  (630) 243-9810 extension 218
Email:  training@IRMSOnline.com

Overview of Training

During the implementation of IRMS, Administration and Basic User courses are taught. At this time, the training courses are tailored to meet the client’s business requirements defined during the Business Development Meeting.

After IRMS has been used for a while, clients can receive additional training by attending workshops, attending continuing education courses at OBA, or scheduling training at the client’s location. Courses are tailored to meet the requirements of the individual and client.

Who Should Receive Training?

New Users - After the initial training of IRMS personnel during implementation, new employees may move into the Medical Information Department to work with IRMS. New Users should receive Basic User Training. If the employee will have Administration responsibilities, they should receive Administration Training.

Users Needing In Depth Knowledge – After using IRMS for a while, some clients request additional training for specific functions in IRMS. Continuing Education Courses meet this request.

Continuing Education Courses

For more information on our courses, visit our website at www.IRMSOnline.com.

Basic User Training  Advanced User Training  Reporting & Query
Documents in Depth  System Administration  System IT Training
Adverse Events  Product Complaints
Effective Tables Admin for Effective Entry and Reporting
IRMS Documentation

There are several documentation guides available which describe how to efficiently operate IRMS. Each guide focuses on a specific function of IRMS. The documentation guides are updated to match new releases of IRMS. The guides are available on the website.

How to find Documentation Guides

Website: www.IRMSOnline.com Support / Documentation
New Installation: Documentation Folder installed during installation

Contacting the Documentation Team

Phone: (630) 243-9810 extension 203
Email: documentation@IRMSOnline.com

Current Documentation Guide

IRMS Adverse Events Guide

A detailed guide explaining how to use the Adverse Events module of IRMS. (Module purchased separately.)

Additional Guides Available from Online Business Applications, Inc.

IRMS Administration Guide
A detailed guide explaining how to setup IRMS, define system security, add users, define parameters, and setup initial table values.

IRMS Content Management Guide
A detailed guide explaining how to use the Content Management module for creating and updating documents in a web environment.

IRMS Document Management Guide
A detailed guide explaining how to add and maintain documents, set up letter formats, and use letter templates in IRMS.

IRMS Fields Codes Guide
A guide containing a complete listing of merge and replacement fields in IRMS.

IRMS Maintenance Guide
A detailed guide explaining how to maintain the IRMS environment for efficient operations, IRMS maintenance that may be performed, and an overview of the IRMS upgrade process.

IRMS Product Complaints Guide
A detailed guide explaining how to use the Product Complaints module of IRMS. (Module purchased separately.)

IRMS Quality Assurance Guide
A detailed guide explaining how to use the Quality Assurance module in IRMS. (Module purchased separately.)

IRMS Query and Reporting Guide
A detailed guide explaining how to process queries in IRMS. Also included is an explanation of the reports available in IRMS and how to setup ad hoc reports using the IRMS Report Wizard.

IRMS Users Guide
A more advanced, detailed guide explaining how to launch IRMS, enter cases, create letters, process letters, find information, and more.
The IRMS User Group was established in 2006. The purpose of the IRMS User Group is to provide effective two-way communications between Online Business Applications (OBA) and its customers. The goal of the user group is to provide:

- A means by which customers can influence the direction, development and support of the IRMS software product
- An efficient mechanism for OBA to share information about IRMS
- A forum for the exchange of practical IRMS implementation and user experiences

Contacting the User Group Liaison at OBA

Phone: US Code (630) 243-9810 extension 215
Email: David.Hayward@IRMSOnline.com

How to Join the IRMS User Group

The IRMS User Group is a fully independent organization. The User Group Chairperson is elected from participating clients. Focus Groups are offered that meet regularly to discuss issues that directly affect the enhancement process of our software. In addition, issues of a general nature affecting the gathering of medical information and industry issues are discussed.

Any client with IRMS installed is welcome to join the user group. Conference calls are held frequently to discuss User Group business. Participation from our clients is encouraged. The meetings are organized and chaired by one of the User Group Members (client).

User Group meetings are held at our semi-annual workshops.

For more information on the User Group, visit our website. To join the IRMS User Group register at www.IRMSOnline.com Support / User Group.
Chapter 2  System Administration and Setup

Overview

System Administration for Adverse Events customizes the module to meet the clients’ requirements. This includes defining user preferences and parameters. This chapter includes the following topics:

- Setting up User Preferences.
- Defining Division Parameters
- Setting up Client Defined Fields
- Setting up Group Security
- Setting up PDF Security
- Setting up Product Maintenance
- Setting up Shift Maintenance
- Setting up Reporting Agencies
- Setting up Product Manufacturers
- Setting up Term Maintenance
- Setting up Drug Dictionary
- Setting up FDA Device Report Codes

Reasons to Access the System Administration features

- Change User Preferences
- Define or change Division Parameters
- Grant and remove rights to Adverse Events
- Define Client Defined fields for Adverse Events
- Update tables related to Adverse Events

Cautions Prior and Prerequisites Prior to using System Administration Features

- The person executing this feature must have access to the Division Parameters and Group Security.
- The person accessing the tables must have access to the specific tables.
- Changing the parameters defined in the Division Parameters may affect how the Adverse Events module operates.
Division Parameters

General Tab

If AE Reporting is used, then the *Keep a Record of All Changes* checkbox must be selected from the General tab.  

1. To access the Division Parameters, select **Division Parameters** from the **System** menu.

![Division Parameters - General Tab](image)

The **General** tab is displayed. Review the **Change Control / Logging Rules** section for checkboxes related to adverse events.

**Review the Adverse Event Parameters**

2. Review the following Adverse Event parameters in the **Change Control / Logging Section**.

- **Keep a Record of All Changes (Required for AE Reporting)**.
  This checkbox must be selected if using the Adverse Event module.

- **Require a Reason for Any Change to an Adverse Event Record**.
  Select this checkbox to require the user to enter a reason for changing the data when exiting the adverse event.

---

**Keep a Record of All Changes**

**Important** - This parameter must be selected to successfully process AE Reporting and Periodic Reports.

**Require a Reason for Any Change to an Adverse Event Record**.
Select this checkbox to require the user to enter a reason for changing the data when exiting the adverse event.
“Require a Password to Close a Case with an Adverse Event”
Select this checkbox to require the user to enter a password to close an adverse event. The Service Rep’s Login screen is displayed. Once the password is entered, the adverse event is closed.
Case Entry/Response Letter Tab

There are a couple of parameters that should be reviewed for the Adverse Events module. ..Error! Bookmark not defined.

1. Click the Case Entry/Resp Letters tab.

The Case Entry/Resp Letters tab is displayed. Review the following parameters on this tab.

Customizable Actions Section

2. Review the following checkboxes in the Customizable Actions Section.

   - **Suppress AE (Capture Only)**
     Select this checkbox to indicate that Adverse Events (Capture Only) is not available for this Division.

   - **Suppress AE (Full Reporting)**
     Select this checkbox to indicate that Adverse Events (Full Reporting) is not available for this Division.

Numbering Options Section

3. Review the Numbering Mask and Lock checkbox for Adverse Events.

   - **AE # Mask**
     To customize the AE Report Number, select an AE # mask from the pick list. The AE Report Number can be customized using one of the following masks.

     "Automatic" – Assigns an AE Report number using year, country, and product.
“Case Number” – Assigns an AE Report number using the Medical Information Case Number already assigned.

“None” – Allows the user to assign the AE Report number.

“Sequence” – Assigns the next sequential number to the AE Report.

“US<<YY>> ######” – Assigns the AE Report number using country, year and the next sequential number.

Using Product Code
To assign the Report Number to a specific Product, use <<MFGCODE>> as part of the mask. The Manufacturing Code is defined for the manufacturer in the Product Manufacturer table. The Product Manufacturer is assigned to the drug in the Company field in the Product Master. For example, if the AE# Mask is setup as <<MFGCODE>>-<<YY>>-####, the Report Number will look like: NAB-10-0001 where NAB is the Manufacturing Code.

✅ Lock
Select this checkbox to prevent users from changing the AE Report Number for this Division.
Required Fields Tabs for Adverse Events

A required field means that IRMS will not allow the user to exit the Adverse Event module until this field has been populated. IRMS provides a warning message to notify the user that the required field(s) have not been populated.

**Note:** The system checks the required field based on how the “RequiredFieldBehavior” is set in the Other tab in the Division Parameters.

1. Click the Required Fields tab.
2. Select the AE, AE (Meds), or the AE Events - Hosp subtab.
3. Select the checkbox for any field that should be a required field. Deselect the checkbox to change the required field.
4. Any fields that are selected as required are preceded with an * before the field name on the tab. The example below shows the Report Type as a required field. If this field is not populated and the user tries to exit the Adverse Event windows, a warning message is displayed as shown below.

![Example of required field warning message](image-url)

Please correct the following before exiting this Adverse Event:

- The following required fields are missing:
  - Report Type
Below are screenshots of the Required Field tabs for Adverse Events.

**Required Fields – Adverse Events Tab**

<table>
<thead>
<tr>
<th>Required Fields – Adverse Events Tab</th>
</tr>
</thead>
<tbody>
<tr>
<td>General...</td>
</tr>
<tr>
<td>Case Entry...</td>
</tr>
<tr>
<td>Case Entry</td>
</tr>
</tbody>
</table>

**Division Parameters - Required Fields for Adverse Events**

**Required Fields – Adverse Events Medications Tab**

<table>
<thead>
<tr>
<th>Required Fields – Adverse Events Medications Tab</th>
</tr>
</thead>
<tbody>
<tr>
<td>General...</td>
</tr>
<tr>
<td>Case Entry...</td>
</tr>
<tr>
<td>Case Entry</td>
</tr>
</tbody>
</table>

**Division Parameters - Required Fields for Suspect and Concomitant Medications**

**Version 5.8.4.2**
**Required Fields – Adverse Events Events and Hospital Data Tab**

<table>
<thead>
<tr>
<th>Required Fields...</th>
<th>AE Events - Hosp</th>
<th>Other...</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case Entry</td>
<td><a href="http://www.olv.com">www.olv.com</a></td>
<td></td>
</tr>
<tr>
<td>Case Entry/Resp</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Letters...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adverse Event...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product Complaint</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PC</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PC Activity</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PC Invst/Corr</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Document</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FAQ</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Product</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Events
- Term Verbatim
- MedDRA Preferred Term
- Event Severity
- Event Serious
- Event Start Date
- Event Stop Date
- Event Duration
- Outcome
- Event Serious Details
- Event Product Code
- Event Action Taken
- Result
- Event ReChallenge
- Latency (First Dose)
- Latency (Last Dose)

### History
- Priority
- Event Date
- Start Date
- Stop Date
- History

### Hospital
- Hospital
- Admission Date
- Discharge Date
- Emergency Room
- Length of Stay in ER

### Comments
- Comments Date
- Comments Type
- Comments

### Regulatory
- Due Dates Report Type
- Agency
- PSUR Comments

---

Division Parameters - Required Fields for AE Events and Hospital Data

Version 5.8.4.2
Adverse Events Tab

The Adverse Event tab defines the default 3500A Contact Information and Adverse Events Client Data Fields.

1. Click the Adverse Event tab.

The contact information for 3500A reporting and the AE Client Field Names are displayed.

3500A Information Section

2. Enter the contact information for the 3500A reports. This information is printed in Section G on the 3500A Reports when a Product Manufacturer has not been defined in the Product Table.

AE Client Data Field Names Section

Enter any client data fields for adverse events. Each field can be setup as a text, numeric, date or a yes/no format. A maximum of ten client data fields can be setup.

3. In the Custom Field Names section, enter a title for Field 1 (For example, “NumberofMeds”).

4. Select “Text”, “Numeric”, “Date”, or “Yes/No” from the pick list next to the field name.

5. The name of the fields assigned to the Client Data fields are displayed on the Hospital/Client Data tab in Adverse Events. In addition, the format of the field is enabled in the corresponding field for data entry.
## Other Parameters for Adverse Events

### Overview

The Other Parameters are used to customize some of the functionality in IRMS. The parameters should be reviewed to see if the settings should be changed. All the parameters in this section apply specifically to Adverse Events. Tab

### Other tab screen shot

![Other tab screen shot](image)

### Other tab field definitions

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Parameter</strong></td>
<td>A brief description of how the parameter can be customized. Select the pick list to view the parameters with a brief description of how the parameter is used</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>The value to assign to this parameter.</td>
</tr>
</tbody>
</table>

### Adverse Event Parameters

- **AE_CheckNarrative**  
  (Yes/No) If the value is “Yes”, the narrative is checked for changes if the Priority on the Suspect Meds tab is changed. For example, the second suspected medication is changed to “1”, and the first suspected medication is changed to “2”, the user is prompted to check the Narrative for References to the Suspected Medications.

- **AE_ContactTypeToOccupation**  
  (Yes, No, Prompt) This parameter indicates if the occupation assigned to the Initial Reporter is determined by the Contact Type assigned to the contact in Case Entry.

  “Yes” – the Initial Reporter’s Contact Type is automatically copied to **Occupation**. If the occupation is “Health Professional”, then the **Health Professional?** checkbox is automatically selected.

  “Prompt” – the user is asked if the Initial Reporter’s Contact Type should be copied to **Occupation**. The user then clicks “Yes” or “No” to the message in Adverse Events and the occupation field is updated appropriately. If the occupation is “Health Professional”, then the **Health Professional?** checkbox is automatically selected.

  “No” – the Initial Reporter’s Contact Type is not copied to **Occupation**. The user must manually select the **Occupation** and **Health Professional?** checkbox for the Initial Reporter.

- **AE_EmailDays**  
  Defines the number of days (prior to today) to check what AE Reports are due. The system will automatically send an e-mail for reports that are due in the specified time frame. The users to receive the e-mails are defined in the “Notify” Shift using the “AE - Reports Due” Event. The default is 1 day. For example, if the value is “1”, an email notification is sent to the shift regarding any regulatory reports that are due tomorrow.
AE_Export_folder
Defines the location of the default folder for E2B Individual Case Safety Reports created for transmission. The default can be overridden when the ICSR is created.

AE_PRODUCT
This parameter determines what Product Code is displayed on the Suspected Medications tab for Priority “1”. The values are:
- Product Code – This value displayed on the Suspected Medications tab, but can be changed by selecting a product form the pick list.
- “*DEFAULT*” – The Product from the Question section is displayed on the Suspected Medication tab, but can be changed by selecting a product from the pick list.
- “*FORCE*” – The Product from the Question section is displayed on the Suspected Medications tab, but cannot be changed.

AE_Terms  (MedDRA, COSTART) Identifies the medical dictionary used in Adverse Events. The current values are “MedDRA” or “COSTART”.

AESusMedPriorityCopy
This parameter specifies how the Priority on the Suspected Medications tab should be handled when a case is copied. The values are:
- “Keep” – the Priority numbers assigned on the Suspected Medications tab will be retained when the case is copied. This is the default value.
- “Clear” – the Priority numbers assigned in the Suspected Medication tab will be cleared and the user must enter the Priority when the case is copied.

E2B Parameters

E2B_ForceDestination
The full filename and path of the E2B file to export with replacement fields for the filename. The Replacement fields are: <<AE No>>, <<YYYYMMDD>>, <<YYMMDD>>, <<HHNNSS>>, and <<HHNN>>

E2B_IncludeCompanyNumb
Values are “Yes” or “No”. Determines if the company number should come from the Adverse Event record. Select “Yes” to set the Company Number to AEID. Any other value (or blank) will send an empty tag.

E2B_IncludeTransmissionDate
Values are “Yes” or “No”. Determines if the transmission date should be sent. Select “Yes” to send the Transmission Date. Any other value (or blank) will send an empty tag.

E2B_MessageReceiverIdentifier
Identifies what system will be receiving the ICSR file if other than the IRMS system. The maximum number of characters is 60. The default message is “ae software”.

E2B_ReceiverDepartment
Indicates the department that will receive the transmission. The maximum number of characters is 60. The default message is “adverse events”.

**E2B_ReceiverOrganization**
Indicates the organization that will receive the transmission. The maximum number of characters is 60. The default message is “internal”.

**E2B_SenderDepartment**
Indicates the department that will send the transmission. The maximum number of characters is 60. The default message is “medical information”.

**E2B_SenderOrganization**
Indicates the organization that will send the transmission. The maximum number of characters is 60. The default message is “internal”.

**ForceE2BRules**
Values are “Yes” or “No”. Indicates that E2B rules should be enforced for date and duration. This parameter is used when exporting ICSR cases.

**Other Parameters Associated with Adverse Events**

**RequiredFieldBehavior**
Indicates when required fields will be checked in Case Entry, Adverse Events, or Product Complaints. The values are “Entry” or “Completed”.

“Entry” – The required fields are checked before the user exits the tab or window. This is the default if no parameter is specified.

“Completed” – The required fields are checked when the user completes or closes the case.

**Note:** This parameter applies to Medical Information, Adverse Event, and Product Complaint cases.

**Note:** If a user is printing a letter and IRMS is automatically set to close the case once the letter is printed, the case will not be closed if a required field is not populated.

To exit the **Division Parameters**, click the **Close** toolbar button.
Group Security

Case Options Tab

Group Security for the Adverse Event Screens

Group Security determines who has access to adverse event information. There is a set of check boxes in Group Security for the Adverse Events module that grant and restrict access to information. The security options described below apply specifically to the Adverse Events module. For additional information, refer to the Group Security section in the System Administration chapter in the IRMS Administration Guide.

1. To access Group Security, from the System menu, point to Security, and then click Group Security. The Security window displays the current Security Group for the administrator. Use the arrows on the Navigation Bar to display the Security Group to be changed.

The System Options tab is displayed. Click the Case Options tab as shown.

Select the checkbox(es) to grant authority to the options. Clear the checkbox(es) to restrict authority to the options. The Adverse Event options are explained below.

- **Enter AE Screen**
  Allows this group to add and maintain cases in Adverse Events. If this box is not checked, the AE button in Case Entry is dimmed. If this checkbox is selected, additional rights are granted by using the check boxes below.

- **Modify Other Users AE’s**
  Allows this group to maintain another representative’s Adverse Event data.

- **Re-open Latest AE Version**
  Allows this group to re-open the latest version of an Adverse Event. This checkbox grants access to the Open Latest Version button on the Adverse Events tabs.

- **Export E2B**
  Allows this group to execute the E2B Export feature.
Table Options Tab

2. Click the **Table Options** tab as shown.

Select the checkbox(es) to grant authority to the options. Clear the checkbox(es) to restrict authority to the options. The tables used in Adverse Event are explained below.

- **Product Maintenance**
  Allows this group to update the product information with the Product Manufacturer and Approval Dates.

- **Shift Maintenance**
  Allows this group to update the “Notify” Shift information for regulatory reporting.

- **Reporting Agency Maintenance**
  Allows this group to define the regulatory agencies who will receive the regulatory reports.

- **Product Manufacturer**
  Allows this group to define the manufacturers who produce the product. The Product Manufacturer is assigned in the Product Table.

- **Terms Maintenance**
  Allows this group access and populate the MedDRA® Terms Maintenance.

- **Drug Dictionary**
  Allows this group access and populate the Drug Dictionary. The Drug Dictionary is used on the Concomitant Medications tab in Adverse Events.

- **FDA Device Report Codes**
  Allows this group access and update the Event Problem Codes and The Manufacturer Evaluation Codes used on the Manufacturers tab in Adverse Events.
PDF Security

Overview

PDF Security can be setup to create secured PDFs for CIOMS Reports. For additional information on the other types of reports, refer to the PDF Security section in the System Administration chapter in the IRMS Administration Guide.

1. To access PDF Security, from the System menu, point to Setup, and then click PDF Security. The PDF Security window is displayed.

Acrobat Distiller field definitions

Secured PDFs can be created for specific reports in IRMS. Enter the following information to create secured pdfs within IRMS. Create a new record for each Output Type that is applicable. Use caution when working in this field.

Top Section:

- **Division**: Shows the active Division for the current user. This field cannot be changed.
- **Output Type**: Select Output Type from the pick list. Verify the correct record by using the record navigation buttons at the bottom of the window. The values for Output Type are explained below.

  “CIOMS” – creates secured pdfs when CIOMS Reports are submitted.

Passwords Section:

- **Open Document**: Designate a password that will be required to open the PDF. Leave it blank if there is no password required to open the PDF.

- **Change Security**: Designate a password that will be required to change the security settings of the PDF. Leave it blank if there is no password required to change the security settings.
Do Not Allow Section:

☐  Printing  Select this checkbox to prevent the reader from printing the PDF.
☐  Changing the Document  Select this checkbox to prevent the reader from changing the PDF.
☐  Selecting Text and Graphics  Select this checkbox to prevent the reader from selecting (Edit-Copy) portions of the PDF.
☐  Adding or Changing Notes or Form Fields  Select this checkbox to prevent the reader from adding annotations or form fields to the PDF.
General Table Maintenance

General Table Maintenance is used to define the values for some of the fields used throughout the IRMS application. This section specifically reviews the tables used in Adverse Events. For additional information on the other tables, refer to the General Table Maintenance section in the Tables Administration chapter in the IRMS Administration Guide.

1. To access General Table Maintenance, select General from the Tables menu. The Table Maintenance window is displayed.

2. Select the Table Name from the pick list. This bottom half of the window displays the values defined for the table. If the table is defined as a Divisional table, the table for the user’s current Division is displayed.

Table Names and Explanations

- **Adverse Event Activity Type**
  The Adverse Event Activity Type table defines the various activity steps a case goes through to completely process and report on the adverse event. This pick list is displayed on the Comments tab in Adverse Events.

- **Adverse Event Age Category**
  The Adverse Event Age Category table defines different categories for the age of a patient. This pick is displayed on the Demographics tab in Adverse Events.

Note: If ForceE2BRules in Division Parameters is set to “Yes”, the restricted values are enforced. See Appendix – Restricted Field Values for E2B on page 185 for the specific values for this table.
Adverse Event Causality (See OBA)
The Adverse Event Causality table defines the relatedness of the drug to the adverse event. This field is currently not used in the Adverse Event module.

Adverse Event Causality Method
The Adverse Event Causality Method table defines the methods used to determine the relatedness of the drug to the event. This pick list is displayed in the Causality section on the Events tab in Adverse Events.

Adverse Event Causality Result
The Adverse Event Causality Result table defines the relatedness of the suspected drug to the event. This pick list is displayed in the Causality section on the Events tab in Adverse Events.

Adverse Event Causality Source
The Adverse Event Causality Source table defines the source used to assess the relatedness of the drug to the adverse event. This pick list is displayed in the Causality section on the Events tab in Adverse Events.

Adverse Event DeChallenge
The Adverse Event DeChallenge table defines the effect on the adverse event when a drug or device is withdrawn. This pick list is displayed on the Suspect Meds and Con Meds tab in Adverse Events.

Note: If ForceE2BRules in Division Parameters is set to “Yes”, the restricted values are enforced. See Appendix – Restricted Field Values for E2B on page 185 for the specific values for this table.
Adverse Event Filed with FDA
The Adverse Event Filed with FDA table defines the values for determining if the appropriate Reporting Agency has been notified. The label used in Adverse Events is **Filed with Agency**. This pick list is displayed on the Demographic tab in Adverse Events.

![Filed with Agency](image)

Adverse Event Frequency
The Adverse Event Frequency table defines how often a medication is administered. This pick list is displayed on the Suspect Meds and Con Meds tab in Adverse Events.

![Frequency](image)

Adverse Event Gender
The Adverse Event Gender table defines the gender of the patient. This pick list is displayed on the Demographic tab in Adverse Events.

![Gender](image)

**Note:** If *ForceE2BRules* in Division Parameters is set to “Yes”, the restricted values are enforced. See Appendix – [Restricted Field Values for E2B](#) on page 185 for the specific values for this table.

Adverse Event Outcome
The Adverse Event Outcome table defines various end results of an adverse event. This pick list is displayed on the Events tab in Adverse Events.

![Outcome](image)

**Note:** If *ForceE2BRules* in Division Parameters is set to “Yes”, the restricted values are enforced. See Appendix – [Restricted Field Values for E2B](#) on page 185 for the specific values for this table.

Adverse Event Race
The Adverse Event Race table defines the nationality of the patient. This pick list is displayed on the Demographic tab in Adverse Events.
- **Adverse Event ReChallenge**
  The Adverse Event ReChallenge table defines the effect on the adverse event when a drug or device is re-introduced. This pick list is displayed on the Suspect Meds, Con Meds, and Events tab in Adverse Events.

  ![ReChallenge pick list]

  **Note:** If *ForceE2BRules* in Division Parameters is set to “Yes”, the restricted values are enforced. See Appendix – Restricted Field Values for E2B on page 185 for the specific values for this table.

- **Adverse Event Report Type**
  The Adverse Event Report Type table describes the type of report indicated in the complaint. This pick list is displayed on the Demographic tab in Adverse Events.

  ![Report Type pick list]

- **Adverse Event Reporter Occupation**
  The Adverse Event Reporter Occupation table defines the occupations of the Initial Reporter and Patient. This pick list is displayed in the Initial Reporter and Patient sections on the Demographic tab in Adverse Events.

  ![Occupation pick list]

  **Note:** If *ForceE2BRules* in Division Parameters is set to “Yes”, the restricted values are enforced. See Appendix – Restricted Field Values for E2B on page 185 for the specific values for this table.

- **Adverse Event Route**
  The Adverse Event Route table defines the method of administration used with the medication. This pick list is displayed on the Suspect Meds and Con Meds tab in Adverse Events.

  ![Route pick list]

  **Note:** If *ForceE2BRules* in Division Parameters is set to “Yes”, the restricted values are enforced. See Appendix – Restricted Field Values for E2B on page 185 for the specific values for this table.
- **Adverse Event Seriousness**
  The Adverse Event Seriousness table defines the seriousness for the overall adverse event as well as each event. Enter the Code, AE Description, and Serious Indicator (1,2). Enter a Serious Indicator of “1” (Non Serious) to calculate a due date for the PSUR and Periodic Reports. Enter a “2” (Serious) to calculate the due date for 3500A, CIOMS, or MDR Reports. This pick list is displayed in the header section on each tab and on the **Events** tab in **Adverse Events**.

  ![Record Selection Parameters](image)

  **Note**: If **ForceE2BRules** in **Division Parameters** is set to “Yes”, the restricted values are enforced. See Appendix – **Restricted Field Values for E2B** on page 185 for the specific values for this table.

- **Adverse Event Severity**
  The Adverse Event Severity table defines a level of severity for a specific event. This pick list is displayed on the **Event** tab in **Adverse Events**.

  ![Severity](image)

- **Adverse Event Terms (MedDRA)**
  This table has been replaced by **Terms Maintenance**.

- **Adverse Event Test Type**
  The Adverse Event Test Type table defines the types of tests a patient has undergone as a result of the adverse event. This pick list is displayed on the **Labs & Hist** tab in **Adverse Events**.

  ![Type](image)

- **Adverse Event Treatment Status (See OBA)**
  The Adverse Event Treatment Status table defines the current status of the adverse event. This table is currently only used by specific clients.
Dose Form
The Dose Form table defines the pharmaceutical form of the drug or medication. This pick list is displayed in Product Maintenance, and on the Suspect Meds and Con Meds tabs in Adverse Events.

Dose Unit
The Dose Unit table defines the size of a single dose. This pick list is displayed in Product Maintenance, and on the Suspect Meds and Con Meds tabs in Adverse Events.

Note: If ForceE2BRules in Division Parameters is set to “Yes”, the restricted values are enforced. See Appendix – Restricted Field Values for E2B on page 185 for the specific values for this table.

Global Product
The Global Product table assigns a universal name to medications that may be marketed and sold under different names in multiple countries. The Global Product is selected in Periodic Reports for Periodic and PSUR Reporting. This pick list is displayed in Periodic Reports.
Product Maintenance

There are a few fields that are used specifically with Adverse Events. The fields are outlined below in red. The Global Product, Company, and Approval Dates section should be reviewed prior to creating regulatory reports. For additional information about the other fields, refer to the **Product Maintenance** section in the **Table Administration** chapter in the *IRMS Administration Guide*.

1. To access Product Maintenance, select **Product** from the **Tables** menu. The Product Maintenance window is displayed.

![Product Maintenance Window]

**Product Information**

- **Global Product**
  Verify that a Global Product is assigned for this product. The Periodic Reports cannot be selected for this product if a Global Product is not defined. The **Global Product** is defined in the **General** option from the **Tables** menu in the “Global Product” table.

- **Company**
  Verify that a Company is assigned for this product. The Company is defined in **Product Manufacturer** on the **Tables** menu. The information for the manufacturer is printed in the 3500A, CIOMS, and MDR reports.

**Approval Date(s) Section**

Verify that the **Approval Date(s)** section is populated with the appropriate information. This section determines what Reporting Agencies will receive Regulatory Reports and when the reports will be submitted for this product.

- **Drug Authorization Number**
  Enter the Drug Authorization Number (DAN) assigned by the Reporting Agency.
Reporting Agency
Select a Reporting Agency from the pick list. The Reporting Agency is defined in Reporting Agency on the Tables menu.

Approval Date
Enter the date the drug was approved or click the Calendar Control button to select a date.

Serious
Click the Serious button. The Serious Reportability window is displayed.

This table defines the number of days needed to prepare regulatory reports before the reports are due.

◊ Seriousness
Define if the event is serious for regulatory reporting. Select the Seriousness from the pick list. The Seriousness is defined in the General option from the Tables menu in the “Adverse Event Seriousness” table.

◊ Reporting Days
Enter the number of days the company has to submit the Regulatory Report (3500A, CIOMS, and MDR) to the Reporting Agency.

◊ Business Days
Select this checkbox to indicate the Reporting Days includes only business days. Of this checkbox is selected, weekends are not counted when calculating the due date for the report.

Click X to close the Serious Reportability window and return to the Product Maintenance window.

Non-Serious
Select a non-serious time frame from the pick list or enter the number of days a non-serious report (Periodic and PSUR Reports) is due.

2. Click the Close toolbar button to exit Product Maintenance.
Shift Maintenance

Overview

The Shift Maintenance table defines a “Notify” Shift for Adverse Events. This table lists the resources that are notified when a regulatory report is due. Different “Notify” shifts can be defined for the various Regulatory Agencies.

The explanation below applies specifically to adverse events. For additional information of the other Shift Types and Notification Types, refer to the Shift Maintenance Table in the Table Administration chapter in the IRMS Administration Guide.

Setting Up a Notify Shift

The purpose of the Notify shift is to send an email notification for a pre-defined set of events that occurs. In Adverse Events, a notification can be sent for the following events:

♦ AE Periodic Reports are created
♦ AE Regulatory Reports are due

Specific individuals or groups are notified by email.

1. To access Shift Maintenance, click Shift from the Tables menu. The Shift Maintenance window is displayed.

2. In the Select Shifts to Work With section, select “Notify” from the pick list. The “Notify” Shift Type is displayed.

3. Once the “Notify” shift has been selected, enter the following information.

   ♦ **Division and Shift**
   Populates from the previous window. These fields are grayed out and cannot be changed.

   ♦ **Shift Name**
   Enter a Shift Name that uniquely identifies the shift. This name is displayed in pick lists throughout the IRMS software.
**Bottom section**

**Description**
Enter a brief description of the Shift.

**Event**
Select an Event from the pick list. An email notification can be sent in Adverse Events for the following events.

"AE – Periodic Rpts Created" – Notifies the group when the Periodic or PSUR Reports have been created.

"AE Reports Due" – Notifies the group that AE Reports are due. The timing of the email is determined by the number of days defined in the Serious field in the Product Master.

**Subject Text**
Enter a brief description that will appear on the Subject Line of the email. The text can include replacement fields.

**Message Text**
Enter a brief description that will appear in the body of the email. The text can include replacement fields.

**Note:** The following Replacement Fields can be used in the Subject Text and Message Text for “AE – Periodic Rpts Created”.

```
<<Tab>>  <<Today>>  <<UserName>>
<<SignName>>  <<SignInit>>  <<SignTitle>>
<<SignPhone>>  <<SignPhoneExt>>  <<SignEmail>>
<<SignPhoneEmail>>  <<RefInit2>>  ((SignDept>>
<<SignInit>>
```

**Note:** The following Replacement Fields can be used in the Subject Text and Message Text for “AE – Reports Due”.

All Replacement fields used with the Basic Case section in Case Entry can be used with this “Notify” type.

The following AE fields can also be used: <<AENumber>>.

**Last Run**
This field is automatically populated when an email is sent for the following events: “AE – Periodic Rpts Created” and “AE – Reports Due”.
Adding or Changing Resources for a Notify Shift

1. Click the (Maintain Resource) button to maintain resources.

2. The “Resources Datasheet” view in the On-Call Staff Calendar window is displayed. Resources are maintained by adding or deleting the Resource from this window. The email address is defined in the Contact Address field. Any notifications are emailed to all the resources with a the Contact Address.

3. To return to Shift Maintenance, click Close.

4. To exit Shift Maintenance, click Close.
Reporting Agency Maintenance

Overview

The Reporting Agency table is used with the Adverse Events module. It defines the various reporting agencies who receive regulatory reports when an adverse event occurs. An adverse event can be reported to multiple agencies.

1. To access Reporting Agency Maintenance, select Reporting Agency from the Tables menu. The Reporting Agency Maintenance window is displayed.

Reporting Agency Maintenance Window

![Reporting Agency Maintenance Window](image)

Reporting Agency Maintenance Field Definitions

- **Code**
  Enter an abbreviation for the Reporting Agency. This code is displayed in pick lists throughout IRMS.

- **Agency**
  Enter the name of the reporting agency who will receive the report. The Agency Name is displayed in pick lists throughout IRMS.

- **Attention**
  Enter the Department or name of the person who should receive the report.

- **Address**
  Enter the Address of the agency.

- **Country**
  Select the Country of the agency from the pick list.

- **Postal**
  Enter the Postal or Zip Code of the agency.

- **City**
  Enter the City of the agency.
Region
Select the Region or State of the agency from the pick list.

Phone
Enter the Phone number of the agency.

Fax
Enter the Fax number of the agency

EMail
Enter an Email address for the agency.

Serious Report Type
Select the type of report for a serious adverse event. The choices are:
"3500A" – Prints a 3500A report for serious events for this reporting agency.
"CIOMS/MDR" – Prints a CIOMS report for drug events or an MDR report for device events that are serious for this reporting agency.
"None" – A report is not printed for a serious event for this agency.

Non-serious Report Type
Select the type of report for a non-serious adverse event. The choices are:
"Periodic" – All non-serious events are printed on the Periodic Report for this reporting agency.
"PSUR" – All non-serious events are printed on the PSUR Report for this reporting agency.
"None" – A report is not printed for non-serious events for this agency.

Shift
Select a Notification shift from the pick list. A shift must be defined to submit Periodic and PSUR reports. Shifts are explained in Shift Maintenance on page 35.

Grace Period
The grace period defines the number of days before which the user should be notified of cases that are due for reporting. If no manual regulatory report has been created for the period, the listing and tabulation reports are sent to the user(s) prior to the due date of the reports when a grace period is entered.
Product Manufacturer Maintenance

Overview

The Product Manufacturer table is used with the Adverse Events module. It defines the manufacturer that produced the drug or device. The Product Manufacturer is assigned in Product Maintenance.

1. To access Product Manufacturer Maintenance, select Product Manufacturer from the Tables menu. The Product Manufacturer Maintenance window is displayed.

Product Manufacturer Maintenance Window

Product Manufacturer Maintenance Field Definitions

- **Code**
  Enter a unique code for the manufacturer.

- **Company Name**
  Enter the name of the Company that produced the product.

- **Address**
  Enter the Address of the company.

- **City**
  Enter the City of the company.

- **Country**
  Select the Country of the company from the pick list.

- **Region**
  Enter the Region or State from the pick list.

- **Phone**
  Enter the Phone number of the company.

- **Fax**
  Enter the Fax number of the company.
**EMail**
Enter an Email address for the company.

**Contact**
Enter the Contact of the company.
Terms Maintenance

Overview

The Terms Maintenance defines the MedDRA® Terms used for the suspected medication in the Adverse Events module.

This table can be set to Divisional in the Table Names Definition window on the System menu. For more information, refer to the Table Names Definition section in the IRMS Administration Guide.

The MedDRA® terms can be imported using the Import Wizard. For additional information, refer to the Import Wizard section in the Tables Maintenance chapter in the IRMS Administration Guide.

1. To access Terms Maintenance, select Terms Maintenance from the Tables menu. The Terms Maintenance window is displayed.

Terms Maintenance Field Definitions

- **Verbatim**
  The term used by the patient describing the reaction or event.

- **Lowest Level Term**
  The most general term describing the reaction or event.

- **Preferred Term**
  A middle level term describing the reaction or event.

- **High Level Term**
  The most specific term describing the reaction or event.

- **System Organ Class**
  A classification system for the reaction or event.

- **Status**
  Indicates if the term is current. If a term is current, the status is “Y”.
System Administration and Setup

Drug Dictionary

Overview

The Drug Dictionary defines other drugs that may be taken concurrently with the suspected medication.

The Drug Dictionary data can be imported from an external file using the Import Wizard. To import the drugs using the Import Wizard, refer to the Import Wizard section in the Tables Maintenance chapter in the IRMS Administration Guide.

The drugs defined are used on the Con Meds tab in Adverse Events.

1. To access the Drug Dictionary, select Drug Dictionary from the Tables menu. The Drug Dictionary window is displayed.

Drug Dictionary Field Definitions

- **DrugName**
  Enter the drug name. The drugs defined on this table do not need to be defined in the Product Master. The drugs entered are concomitant medications taken with the suspected medication for an adverse event.

- **DoseForm**
  Enter the dose form of the drug.

- **DoseUnit**
  Enter the dose unit of the drug.

- **Route**
  Enter the route of administration for the drug.

- **NDC Number**
  Enter the NDC Number for the drug.
FDA Device Report Codes Maintenance

Overview

The FDA Device Report Codes are used on the Manufacturers tabs in the Adverse Events module. It defines the codes used to identify Event Problems the Manufacturers Evaluation Codes that are reported to the FDA.

The FDA Device Report Codes can be imported from an external file using the Import Wizard. To import the drugs using the Import Wizard, refer to the Import Wizard section in the Tables Maintenance chapter in the IRMS Administration Guide.

1. To access the FDA Device Report Codes, select FDA Device Report Codes from the Tables menu. The FDA Codes window is displayed.

FDA Codes Field Definitions

- **Type**
  Select the type of code from the pick list. Valid types include “Method”, “Result”, “Conclusions”, “Device”, and “Patient”. This is a fixed pick list.

- **Code**
  Enter an FDA device code.

- **Description**
  Enter a description for the device code.
User Preferences

User Preferences for the Adverse Events module

User Preferences are setup by each individual user to automatically populate certain information that is usually the same for each adverse event.

For additional information on the other User Preferences tabs, refer to the User Preferences section in the Launching IRMS chapter in the User Guide.

Adverse Event Tab

1. To access the User Preferences, select User Preferences from the Tools menu. The User Preferences Window is displayed.
2. Click the AE… tab. The AE tab is displayed.

Field Defaults Section

3. Select any information that should automatically populate in the Adverse Events tabs when a new adverse event is started.

- **Report Type**
  Select a Report Type from the pick list. The Report Type is displayed in the General Information section on the Demographic tab. Report Type is defined in the General option from the Tables menu in the “Adverse Event Report Type” table.

- **Age Category**
  Select an Age Category from the pick list. The Age Category is displayed in the Patient Information section of the Demographic tab. Age Category is defined in the General option from the Tables menu in the “Adverse Event Age Category” table.

- **Height/Weight**
  Indicates which system if measurement is used. The values are “English” or “Metric”. These checkboxes are displayed in the Patient Information section on the Demographic tab.

Action Defaults Section

- Display “No Information” on the 3500A when no data provided checkbox
  Indicates that “No Information” should print on the 3500A when no data is provided.
Other Tab of User Preferences

The Other tab defines the parameters in IRMS that apply specifically to the user. The parameters specifically related to Adverse Events are explained below.

1. Click the Others tab. The Others window is displayed.

![Image of Others window]

2. Other Parameters
   Select the Parameter pick list to display the list of parameters. The Description contains a brief explanation and the values for that parameter. The parameters below apply specifically to Adverse Events.

   **AEINBOXDAYS**
   Indicates the number of days before today to notify the user that AE Reports are due. In a separate step, an e-mail notification is sent and the AE cases are placed in the AE folder in My Inbox. For example, if the value is “1”, then the system will check for AE Reports that are due tomorrow. The cases that are due tomorrow are displayed in My Inbox today. Enter the number of days prior to the due date of the AE Reports that the user would like to review the reports.

3. Click the Close toolbar button to exit User Preferences.

4. Reset security to ensure that the changes are implemented. (To reset security, select Reset Security from the Tools menu.)
Chapter 3 Entering Adverse Events

Overview

The Adverse Events module provides the ability to enter, track, follow-up and report an adverse event. The module is accessed from the Case Entry window. Case Query provides easy access to adverse event information.

In addition, IRMS can produce a Case Snapshot and other miscellaneous reports. Regulatory reports can be submitted to multiple reporting agencies. Regulatory Reports include 3500A, CIOMS, MDR, Periodic and PSUR Reporting.

Data can also be created in an E2B format for electronic transfer to another system.

Adverse Events includes the following functionality:

- Record patient information
- Provide a narrative of the adverse event
- Enter suspected and concomitant medications
- Enter device information including manufacturer data
- Enter specific event information for reactions and events
- Enter information about the relatedness of the reaction to the suspected medication
- Enter laboratory tests and patient history data
- Enter related hospital and specific client data
- Enter and submit 3500A, CIOMS, and MDR regulatory reports
- Enter comments and track remarks from multiple users
- Submit Periodic and PSUR Reports
- Create an E2B interface file for transfer to another software

Reasons to Use Adverse Events

- Capture Adverse Event information
- Report Adverse Event information to the appropriate governmental agencies

Prerequisites (Cautions) Prior to using Adverse Events

- The person running Adverse Events must be granted access to the Adverse Event module.
- The User Preferences should be reviewed. The Adverse Event tab and Other tab in User Preferences should be reviewed.
- Prior to entering adverse event cases, the parameters and tables in the System Administration and Setup chapter on page 11 should be reviewed.
Creating a Case for Initial Reporting

This section explains the overall steps that should be followed when creating a case to submit to a reporting agency. These steps apply to the case after the initial case information has been entered.

1. Enter all the available information in the various tabs following the Processing Steps for Entering an Adverse Event. Do not select Reportability in the header information.

2. When the information is entered and a report should be generated, change Reportability to “Initial Report”. The records for all regulatory reports (3500A, CIOMS, MDA (Device), PSUR, and Periodic Report) defined in Product Maintenance are created. A version number of “01” is assigned to the reports. The events entered in the Events tab are assigned Version Number “01” and are included in the regulatory reports.

3. If the event is serious as defined in the Seriousness field, submit the appropriate reports (3500A, CIOMS, MDR) from the Regulatory tab. When a report is submitted, a Report Date and File Location is populated for the report. Once all the reports are submitted, the Reportability is automatically changed to “Submitted”.

4. If the adverse event is non-serious, then a record for the appropriate Periodic and/or PSUR report is created. The adverse event case is selected when the Periodic or PSUR report is run at a later date.

5. When the reporting period is complete and the reports are due, run the Periodic Reports from the Reports menu. Process the Periodic Reports by following the steps in the Periodic and PSUR Report section on page 134.
Entering Adverse Events

Updating a Case for a Follow-up Report

After the Initial Report is submitted, and a Follow-up Report is required, the information should be entered using the following steps prior to creating the Follow-up Report.

1. Navigate to the Adverse Event case. Go to the Regulatory tab. Change Reportability to “Follow-up Response”. The user is asked if the version number should be incremented. The user should select “Yes” if a new set of regulatory reports should be created. A new set of reports are created and the version number for the regulatory reports are incremented by 1.

2. Navigate to the various tabs and enter any additional information.

3. Navigate to the Events window and enter a new event. When a new event is added, the version number is automatically populated and should match the version number of the new reports on the Regulatory tab. If version number does not match the version number on the Regulatory tab, this event will not be included in the report.

4. Enter the agency and labeling information in the Labeling section. If this information is not entered, the event will not show up on the Regulatory Report Listings and Tabulation reports.

5. Once the information has been entered or updated on all the tabs, return to the Regulatory tab. If the event is serious, submit the appropriate regulatory reports (3500A, CIOMS, MDA (Device)) defined for the version. When a report is submitted, the Report Date and File Location is populated for the report.

6. If the event is non-serious, it will be included when the Periodic or PSUR Reports are run. If a case has multiple events, each event is displayed in the Periodic and PSUR listing and tabulation reports.

7. When the reporting period as complete and the reports are due, run the Periodic or PSUR Report from the Reports menu. Process the Periodic or PSUR Reports by following the steps in the Periodic and PSUR Report section.
Adverse Event Toolbar

The Adverse Event toolbar below is displayed in most of the AE tabs. Below is the Adverse Event toolbar with an explanation of each button. This toolbar is available for the following tabs: Demographic, Narrative, Suspect Meds, Con Meds, Device, Manufacturers, Events, Labs & Hist, Comments, and Hospital/Client Data tabs. There is a different toolbar for the Regulatory tab that is defined in Step 11 – Regulatory Tab on page 86.

<table>
<thead>
<tr>
<th>Button</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>📝 3500A</td>
<td>Previews the 3500A Report. This option is only active from the Regulatory tab.</td>
</tr>
<tr>
<td>📝 CIOMS</td>
<td>Previews the CIOMS Report. This option is only active from the Regulatory tab.</td>
</tr>
<tr>
<td>📝 Devices</td>
<td>Previews the Medical Device Problem Report. This option is only active from the Regulatory tab.</td>
</tr>
<tr>
<td>📝 Export (E2B)</td>
<td>Starts the process for creating an E2B file.</td>
</tr>
<tr>
<td>📝</td>
<td>Opens the Case Correspondence Management screen.</td>
</tr>
<tr>
<td>📝</td>
<td>Prints a Case Snapshot for the current case.</td>
</tr>
<tr>
<td>📝</td>
<td>Previews a Case Snapshot for the current case.</td>
</tr>
<tr>
<td>📝</td>
<td>Saves the current adverse event information.</td>
</tr>
<tr>
<td>📝</td>
<td>Deletes the current highlighted record. IRMS will provide a warning message to verify that the current record should be deleted.</td>
</tr>
<tr>
<td>📝</td>
<td>Exits the Adverse Events module.</td>
</tr>
</tbody>
</table>
Processing Steps for Entering an Adverse Event

Step 1 – Starting a New Adverse Event Case

1. To enter a new adverse event, start by entering a new case. To access the Case Entry screen, click Case Entry from the Main Menu. The Case Entry window is displayed.

Capture any contact information regarding the Adverse Event. Contact information should be entered for the Initial Reporter. Additional contact information may needed for the Suspected Medication Prescriber, Facility/Importer Name, Reprocessor (Devices) Reporter to the Manufacturer, and Hospital.

2. To enter information regarding the adverse event, click the AE toolbar button, or click the AE button in Case Entry (circled above). When an Adverse Event is added to a case, the Adverse Event number is added to the Case Entry title bar and the font on the AE button changes to the color red (AE).

The Adverse Event window is displayed.
Adverse Event Window for a New Case

The background on the AE window is displayed in the same color as the Inactive Title Bar defined for Windows. Once information is entered, the background changes to the Active Title Bar color defined for windows.

In addition, a Report Number is assigned and Version ‘1’ is assigned to Versions of this AE.

Some of the fields in the Header section are automatically populated.

Information Common to all Adverse Events Tabs

When a new adverse event case is created, some of the fields in the Header section are automatically populated. These fields are displayed on every Adverse Events tab. As a result, the Initial Receipt Date, Last Receipt Date, Event Start Date, Report Number, Case Number, End Date, Seriousness, and Reportability are available on each tab as shown.

- Initial Receipt Date
  The Initial Receipt Date is automatically populated from the Case Entry window. It is the same as the Received Date in Case Entry.
The **Initial Receipt Date** can only be changed from the **Demographic** tab. The field is displayed with a yellow background on the other windows indicating that the field cannot be changed. This date is used to calculate the Due Date for the “Initial Report” for Regulatory Reporting.

The **Initial Receipt Date** will be validated as follows:
- The **Initial Receipt Date** cannot exceed the **Last Receipt Date**.
- The **Initial Receipt Date** cannot precede the **Event Start Date**.
- The **Initial Receipt Date** cannot precede the earliest **Start Date** on the **Events** tab.
- The **Initial Receipt Date** cannot precede any **Start Date** on the **Suspect Meds** tab.

**Last Receipt Date**
The **Last Receipt Date** is automatically populated from the current date. This date is used to calculate the Due Date for the “Follow-up Report” for Regulatory Reporting.

**Event Start Date**
The **Event Start Date** is automatically populated from the current date. To change the date, either enter a different date or click **Calendar Control** and select a date.

The **Event Start Date** will be validated as follows:
- The **Event Start Date** cannot precede the **Suspected Medication Start Date**.

**Report Number**
The **Report Number** is assigned based on the numbering rules set in the **Tailoring Options** section of the **Case Entry/Response Letters** tab of **Division Parameters**. It is a unique identifier for the Adverse Event case.

**Case Number**
The **Case Number** is automatically populated from the **Case Entry** window. It is the Case Number assigned to the Medical Information case.

**End Date**
The **End Date** is automatically populated with the current date. To change the date, either enter a different date or click **Calendar Control** and select a date.

**Seriousness**
The **Seriousness** is not automatically populated. The **Seriousness** is used to calculate the due dates for the appropriate regulatory reports. The Seriousness can be assigned when the seriousness of the reaction or event has been established. Select the Seriousness from the pick list. The Seriousness is defined in the **General** option from the **Tables** menu in the “Adverse Event Seriousness” table.

If one symptom is “Serious”, then the overall adverse event is serious. If a Serious symptom is entered, and “Not Serious” has been selected, a warning message is displayed to verify that the adverse event should be changed to “Serious”.

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Reportability
The Reportability is not automatically populated. The Reportability defines the regulatory reporting status for this adverse event. The user can select Reportability from a pre-defined set of values in the pick list on any tab. For an explanation of the Reportability values, see How Reportability Works with Regulatory Reports on page 88.

Note: The Reportability should not be selected until the user is ready to create the Regulatory Reports for the event.
**Required Field Processing**

The client can define fields that require data to be entered prior to leaving the adverse event tab or completing an adverse event. The required fields are identified with an asterisk at the beginning of the field name. All required fields must be populated.

There are two steps to defining a required field.

- Select the required fields from the Required Fields Adverse Event subtab in Division Parameters.
- Review the “**RequiredFieldBehavior**” parameter on the Other tab in **Division Parameters**. This determines when the required fields are checked. The fields can be checked when information is entered or when the case is completed.

For additional information about required fields, refer to the **Division Parameters** section on page 12.

If a required field has not been populated, a warning message is displayed. The user cannot leave the tab or close the case as determined by the “**RequiredFieldBehavior**” parameter as shown below.

![Warning Message](image)

**Unknown Information**

If specific information is not known at the time an Adverse Event is entered, the information can be captured at a later date unless the field is a required field.

**Navigating Between Cases with the AE Window Open**

If the Adverse Event screen is open and the user navigates to a different case without an Adverse Event, the background on the AE window is displayed in the same color as the Inactive Title Bar defined for Windows. In the example, the Inactive Title Bar is displayed in green, therefore the AE background is displayed in green as shown.

![Navigating Between Cases](image)
Multiple Versions of an Adverse Event

Overview:

The Adverse Events module allows multiple versions of the same Adverse Event. Each version provides a snapshot of the available information at a specific point in time. That version of the event can be sent to another department for further investigation. As additional information is received, it can be captured in a new version and forwarded to the appropriate departments. This functionality allows the client to know exactly what information was sent at different points in time.

Processing Multiple Versions:

The Version of this AE window is displayed on each tab of Adverse Events. The window displays the current and previous versions of the Adverse Event case.

Version Number 1.0 is assigned to the initial case. When the information is completed for this version, the version can be closed and a new version created. When a version is closed, it is closed and locked from further updates. Any version can be viewed, but only the latest version can be modified.

Each version can be viewed on any tab of the Adverse Event window. The current version can be closed and a new version created from any tab.

Any version can be viewed from any tab by clicking the version on the Version of This AE window. Click any tab to see the information for that tab. Any report selected from the Adverse Event window displays the version that is highlighted.

The user controls when a version is closed and a new version is created.

Adverse Events Entry window

The panel on the left side of the Adverse Events window displays the Versions for this AE. The latest version is displayed first in the list.

Close Latest Version

The Close Latest Version button closes the current version of the adverse event. A new version is not created. Once the version is closed, the background is changed to yellow and the data can be viewed but not changed. The closed version appears in the Versions of This AE list with the Version Number, Date the version was closed, and the Regulatory Report Version.

Click Close Latest Version to close the version.
If there are any data validation errors, the version cannot be closed. Correct any errors and then close the current version.

If a reason is required for a change to an Adverse Event case, an **AE Update** message window is displayed.

Enter a reason in the text box and click **Yes** to close the latest AE version. To cancel the process, click **No**.

**Open Latest Version**

The **Open Latest Version** button re-opens the latest Adverse Event version if it is closed. This button is only available if the latest AE version is closed. Otherwise, the button is dimmed. Previous versions of an Adverse Event cannot be re-opened. When the latest version is re-opened, the background is changed from yellow to gray and data can be updated.

Specific rights to open the latest version of an AE are granted in **Group Security**. For additional information, refer to the **Group Security** section on page 23.

Click **Open Latest Version** to re-open the latest version.

If a reason is required for a change to an Adverse Event case, an **AE Update** message window is displayed.

Enter a reason in the text box and click **Yes** to open the latest AE version. To cancel the process, click **No**.
Create a New Version

The **Create a New Version** button closes the latest version if it is not already closed and creates a new version. The **Versions of This AE** window displays the version that was just closed and the new version that was created.

Click **Create a New Version** to create a new version.

If a reason is required for a change to an Adverse Event record, an **AE Update** message window is displayed.

![AE Update Message Window]

Enter a reason in the text box and click **Yes** to create a new version. To cancel the process, click **No**.

Crosslink

The **Crosslink** button opens the **AE Crosslink** window. This window links this case with one or more other cases within IRMS. For more information, refer to the **Crosslink** section 96.
Step 2 – Demographic Tab

The Demographic tab is the first tab displayed after opening the Adverse Events module. General information about the adverse event, the patient, the reporter, and the report source is captured on this tab.

1. If not already active, click the Demographic tab.

Entering Information into the Demographic Tab

- When a new Adverse Event is started, the Demographic tab is displayed. Header information is automatically populated if it is known. This includes the Initial Receipt Date, Last Receipt Date, Event Start Date, Report Number, Case Number, End Date, Seriosness, and Reportability. As additional information becomes available, the fields are populated.

- Some of the information in the header section is automatically populated from Case Entry. Refer to the previous section for information about these fields. Tab to the Initial Reporter section. Enter the information for the Initial Reporter, Report Source, General Information and Patient Information sections.

- Field definitions are found at the end of this guide in the Adverse Event Field Definitions section on page 172. The definitions are in alphabetical order. The merge and replacement field names are located in the Field Codes Guide for MI, AE, and PC.

- All Required fields are preceded with an asterisk (*) on the label name.

- Other fields may be automatically-populated based on how User Preferences are set up. These fields include Report Type, Age Category, and Height/Weight system of measurement. For additional information, refer to the User Preferences section on page 45.
**Initial Reporter section**

This section gathers information about the person reporting the Adverse Event. Enter information about the Initial Reporter.

- **Initial Reporter**
  The person who reported the Adverse Event. This person is one of the contacts for the case. Select the Initial Reporter from the pick list or start to enter a name. If the name is not a case contact, the user is asked if a new contact should be setup. If the user clicks “Yes”, the Case Entry window becomes active and the user can enter a new contact.

- **Occupation**
  Either enter an occupation or select the occupation from the pick list. The Occupation is defined in the General option on the Tables menu in the “AE Reporter Occupation” table.

  **Note:** If the Division Parameter named AE_ReportType is set to “Yes” or “Prompt”, the Occupation is populated from the Contact Type entered for the Initial Report in the Contact section.

- **Health Professional?**
  Identifies the reporter as a health professional. Select this checkbox if the reporter is a health professional.

  **Note:** If the Occupation is “Health Professional”, this checkbox is automatically selected. If the occupation is “Patient” or “Consumer”, this checkbox is cleared.

**Report Source section**

- **Report Source**
  Indicates the source of any reporting information. Select all the checkbox(es) that apply to the Report Source.

  If no checkboxes apply, select the “Other” checkbox and enter a description in the text box to the right.

  If “Consumer” or “Health Professional” is selected, the user is asked if “Spontaneous” should be checked. The user can select “Yes” or “No” for the appropriate action.

**General Information section**

This section gathers general information about the adverse event.

- **Report Type**
  Defines the type of report to generate for this adverse event. Either enter a Report Type or select the Report Type from the pick list. The Report Type is defined in the General option from the Tables menu in the “AE Report Type”. Example of the Report Type includes “Initial Report”, “Product Problem”, and “Literature”.

- **Medically Confirmed**
  Identifies that this adverse event has been confirmed by a hospital or doctor. Select the checkbox to identify this case has been medically confirmed.
Country of Occurrence
Identifies the country where the adverse event occurred. Select the Country from the pick list. The Country is defined in the General option from the Tables menu in the “Country” table.

Filed with Agency
Indicates this adverse event was already filed with a reporting agency. If this adverse event has been reported, select “Yes” from the pick list. The default is “No”. If a report was filed, enter the date or select the date from Calendar Control in the field to the right. The Filed with Agency is defined in the General option from the Tables menu in the “Adverse Event Filed with FDA” table.

Filed with Manufacturer
Indicates this adverse event was already filed with the manufacturer. If this Adverse Event has been reported, select “Yes” from the pick list. The default is “No”. If a report was filed, enter the date or select the date from Calendar Control in the field to the right.

Mfr Report #
If a report was filed with the manufacturer, enter the report number assigned by the manufacturer.

IND #
Enter the Investigational New Drug number.

Protocol #
Enter the Protocol #. This number is used when the IND # is entered.

STN #
Enter the Submission Tracking Number for the device.

PMA #
Enter the Pre-Marketing Application or Pre Market Notification (510k) number. This is used with device and drug combination products.

Combo
Indicates that the product is combination of both a drug and a device. This checkbox should be selected if the product is classified as a Drug-Device, Drug-Biological, Device-Biological, or Drug-Device-Biological.

Pre-1938
Select this check box if the product was available prior to 1938.

OTC Product
Select this check box if the product is available over the counter.

Patient Information section
This section gathers information about the patient involved in the adverse event.

Identifier/ RMP
Enter an identifier for the patient who experienced the adverse event, otherwise enter the RMP number. This can be either a numeric or alphabetic identifier. Normally, the patient’s initials are used.
RMP Check box
Select this check box if this adverse event is already part of a Risk Management Program, then select the RMP fields.

Gender
From the Gender pick list, select the Gender. If the gender is unknown, click unknown. The Gender is defined in the General option from the Tables menu in the “Adverse Event Gender” table.

Weight
Enter the weight of the patient. Select the appropriate check box for pounds or kilograms. The check boxes may be pre-populated from User Preferences.

Height
Enter the height of the patient. Select the appropriate check box for inches or centimeters. The checkboxes may be pre-populated from User Preferences.

Occupation
From the Occupation pick list, select the occupation of the patient. If the occupation is unknown, select unknown. The Occupation is defined in the General option on the Tables menu in the “AE Reporter Occupation” table.

Date of Birth
Enter the date of birth of the patient.

Age at Time of Event
The Age at Time of Event is automatically calculated using the Date of Birth and Start of Event fields. The age can also be entered manually. The age is calculated based on the following birth date.
- If the patient is 3 years or older, use years (for example, 4 years)
- If the patient is less than 3 years old, use months (for example, 24 months)
- If the patient is less than 1 month old, use days (for example, 5 days)

Age Category
From the Age Category pick list, select the patient’s age category. The Age Category is defined in the General option from the Tables menu in the “Adverse Event Age Category” table.

Pregnancy/Due Date
If the patient is pregnant, select the Pregnancy checkbox and enter the patient’s Due Date in the text box to the right. The Pregnancy check box cannot be selected if the patient is male.

Race
Either enter the Race or select Race from the pick list. The Race is defined in the General option from the Tables menu in the “Adverse Event Race” table.

Date of Death
If the adverse event resulted in death, enter the date of the death or select a date from the Calendar Control button.

Cause of Death
Enter the cause of death.
Autopsy Performed?
From the Autopsy Performed? pick list, select “Yes”, “No”, or “NR’ for Not Required. This is a fixed pick list.

Autopsy Date
If an autopsy was performed, enter the date of the autopsy or select a date from the Calendar Control button.
Step 3 – Narrative Tab

The Narrative tab captures detailed information about the adverse event. The text box allows for a detailed description of what happened during the event and any other pertinent information. There is also a text box to describe the treatment necessary to alleviate the adverse event that occurred.

1. To access the Narrative information, click the Narrative tab.

Entering Information into the Narrative Tab

- The header information includes the Initial Receipt Date, Last Receipt Date, Event Start Date, Report Number, Case Number, End Date, Seriousness, and Reportability.

Describe Event or Problem Section

Template

- The Template allows the user to select an Email template defined in Document Maintenance. The E-mail Template can be used to prompt or populate information from the Medical Information case or other Adverse Event tabs. To use a Template, select a Template from the pick list.

- The template information is appended to the end of the existing text in the Describe Event or Problem field. Multiple templates can be selected.

- For additional information on E-mail templates, refer to Creating Email Templates in the Building a Document Repository chapter in the Document Management Guide.

- There is a complete list of replacement fields in the Field Codes for MI AE and PC Guide.
Re-Merge
The template may contain replacement fields that are populated when the template is selected. Any replacement field values that are blank are displayed with double arrows (<<>>). For example, if Hospital is one of the replacement fields and the hospital information is blank, the field is displayed as <<Hospital>>. After missing replacement information is entered, click the Re-Merge button to update the replacement fields. Any merge fields already containing data will not be changed.

Multiple templates can be selected. Additional templates are appended to the end of the existing narrative text.

There is a complete list of replacement fields in the Field Codes for MI AE and PC Guide.

- **Describe Event or Problem**
  Enter a detail description of the adverse event that the patient experienced as provided by the reporter. The narrative can be entered before or after any template information that is already in the field.

- **Treatment**
  Enter a detailed description of the treatment for the reaction or event provided by the Initial Reporter.
Step 4 – Suspect Medications Tab

The Suspect Medications tab captures information about the medication(s) that is allegedly causing the reaction or adverse event.

1. To access the Suspected Medications information, click the Suspect Meds tab.

Entering Information into the Medications Tab

- The header information includes the Initial Receipt Date, Last Receipt Date, Event Start Date, Report Number, Case Number, End Date, Seriousness, and Reportability.

Suspect Medication(s) section

The suspected medication is the drug(s) used to treat a condition at the time the adverse event occurred. The first suspected medication should be the drug owned or distributed by the company. An unlimited number of medications can be captured in this section. The record navigation bar at the bottom of the Tab indicates the number of suspect medications that have been entered.

- **Priority**
  - If there are multiple drugs suspected, enter the most highly suspected drug first. If only one drug is entered, the Priority is “1”.
  - If the Division Parameter “AE_PRODUCT” is set to “*DEFAULT*” , “*FORCE*”, or Product Code, enter a “1” to automatically populate Name with the suspected medication.

- **Name**
  - If the name is not populated, select the Name from the pick list.
Note: The Division Parameter “AE_PRODUCT” determines if the Product Code defaults from the Question section or a specific Product Code defaults from the Division Parameter. If this parameter is not set, the Name is initially blank and the user can select a suspected medication from the Name pick list.

- **DAN**
  From the Drug Authorization Number pick list, select the DAN #.

- **Lot #**
  Enter the Lot Number of the suspected medication.

- **Indication**
  Either enter an Indication or select an Indication from the pick list. The Indication is defined in Product Maintenance.

- **Prescriber**
  From the Prescriber pick list, select the doctor who prescribed the product. The Prescriber should be set up as one of the contacts in Case Entry.

- **OK to Contact**
  Select this check box if the Prescriber can be contacted.

- **NDC / DIN #**
  From the NDC / DIN pick list, select the National Drug Code Number or DIN number.

- **Dose Form**
  From the Dose Form pick list, select the Dose Unit. The dose form is determined by the NDC # entered in Product Maintenance.

- **Dose Unit**
  From the Dose Unit pick list; select the Dose Unit. The dose unit is determined by the NDC # entered in Product Maintenance.

- **Route**
  Either enter the Route or select the Route from the pick list. The route of administration is defined in the General option on the Tables menu in the “Adverse Event Route” table.

- **Frequency**
  Either enter the Frequency or selected the Frequency from the pick list. The Frequency is defined in the General option on the Tables menu in the “Adverse Event Frequency” table.

- **DeChallenge**
  From the DeChallenge pick list, select either “Yes”, “No”, or “Does Not Apply”. The DeChallenge is defined in the General option on the Tables menu in the “Adverse Event DeChallenge” table.

- **ReChallenge**
  From the ReChallenge pick list, select either “Yes”, “No”, or “Does Not Apply”. The ReChallenge is defined in the General option on the Tables menu in the “Adverse Event ReChallenge” table.

- **Start Date**
  Enter the date the patient started taking the suspected medication or click the Calendar Control button to select a date.

Note: The Suspected Medication Start Date must precede the Event Start Date.
Stop Date
Enter the date the patient stopped taking the suspected medication or click the Calendar Control button to select a date.

Duration
If the Duration is blank, it is automatically calculated from the Start and Stop dates for the suspected medication. Otherwise, enter the number of days the medication was taken.

Exp. Date
Enter the date the suspected medication expired or click the Calendar Control button to select a date.

Entering Additional Suspected Medications

2. To enter additional suspected medications, tab to the next Priority field and start entering information, or click New on the Navigation Bar.
Step 5 – Con Meds Tab

The Concomitant Medications tab captures information about any medications including other prescriptions or over the counter medications taken at the same time as the suspected drug when the adverse event occurred.

1. To access the Concomitant Medication information, click the **Con Meds** tab.

**Entering Information into the Concomitant Medications Tab**

- The header information includes the Initial Receipt Date, Last Receipt Date, Event Start Date, Report Number, Case Number, End Date, Seriousness, and Reportability.

**Concomitant Medication(s) section**

A Concomitant Medication is any drug that is prescribed or taken over the counter for a different diagnosis other than the suspected drug(s) taken for the diagnosis that caused the adverse event. An unlimited number of medications can be captured in this section. The record navigation bar at the bottom of the screen indicates the number of concomitant medications that have been listed.

- **Priority**
  - If there are multiple concomitant drugs for the Adverse Event, enter the most highly suspected drug first. If only one drug is entered, the Priority will be “1”.

---
Name
Either enter the drug name or select the drug name from the pick list. If a drug is selected from the pick list, the following fields are automatically populated from the table: NDC / DIN, Dose Form, Dose Unit, and Route.

The concomitant medications are defined in the Drug Dictionary on the Tables menu.

Lot #
Enter the Lot Number for the concomitant medication.

Indication
Enter the Indication for the concomitant medication.

NDC #
If not already populated, enter the NDC # for the concomitant medication.

Dose Form
If not already populated, either enter the Dose Form or select the Dose Form from the pick list. The Dose Form is defined in the General option from the Tables menu in the “Dose Form” table.

Dose Unit
Enter the Dose Unit for the concomitant medication.

Daily Dose
Enter the Daily Dose for the concomitant medication.

Route
If not already populated, either enter the Route or select the Route from the pick list. The Route is defined in the General option from the Tables menu in the “Adverse Event Route” table.

Frequency
Either enter the Frequency or selected the Frequency from the pick lists. The Frequency is defined in the General option from the Tables menu in the “Adverse Event Frequency” table.

DeChallenge
From the DeChallenge pick list, select either “Yes”, “No”, or “Does Not Apply”. The DeChallenge is defined in the General option from the Tables menu in the “Adverse Event DeChallenge” table.

ReChallenge
From the ReChallenge pick list, select either “Yes”, “No”, or “Does Not Apply”. The ReChallenge is defined in the General option from the Tables menu in the “Adverse Event ReChallenge” table.

Start Date
Enter the date the patient started taking the concomitant medication or click the Calendar Control button to select a date.

Stop Date
Enter the date the patient stopped taking the concomitant medication or click the Calendar Control button to select a date.
Entering Adverse Events

- **Duration**
  If the Duration is blank, it is automatically calculated from the Start and Stop dates for the concomitant medication. Otherwise, enter the number of days the medication was taken.

- **Exp. Date**
  Enter the date concomitant medication expired or click the Calendar Control button to select a date.

**Entering Additional Concomitant Medications**

2. To enter additional concomitant medications, tab to the next Priority field and start entering information, or click New on the Navigation Bar.
Step 6 – Device Tab

The **Device** tab captures device and facility information about any medical device suspected in this adverse event.

1. To access the device information, click the **Device** tab.

**Entering Information into the Device Tab**

- The header information includes the Initial Receipt Date, Last Receipt Date, Event Start Date, Report Number, Case Number, End Date, Seriousness, and Reportability.

**Suspect Medical Device section**

A suspected device is any device implanted internally or used externally that is suspected in the adverse event.

- **Brand Name**
  The brand name of the suspected device as defined in Product Maintenance. Select the Brand Name from the pick list.

- **Operator**
  The type of person who is using the suspected device. Either enter the operator or select the operator from the pick list. Currently, the values are “**Health Professional**” and “**Lay User/Patient**”. Select one of the values from the pick list.
Reprocessed Checkbox
Indicates if this is a single use device that was reprocessed and reused on a patient. Select the checkbox to indicate that the device was reprocessed.

Reprocessor
If this device is reprocessed and the Reprocessed checkbox is selected, select the name of the Reprocessor from the pick list. The Reprocessor is defined in Case Entry as an additional Contact.

Available for Evaluation checkbox
Indicates if the suspected device is available for evaluation. Select the checkbox to indicate that the device is available for evaluation.

Available Date
If this device is available and the Available for Evaluation checkbox is selected, enter the date the device is expected to be returned.

Labeled Sterile
Indicates is this device was labeled as sterile. Select the checkbox if the device is labeled as sterile.

Device Age
Enter the age of the device in months or years including the time the device was used.

Event Location
Select the name of the location from the pick list where the device was used when the adverse event occurred.

MFR/Importer Aware Date
Enter the date that the manufacturer or importer’s medical personnel became aware that the device may have caused the adverse event.

Manufacturer Est License #
Enter the manufacturer’s establishment license number for the device that may have caused the adverse event.

Model #
Enter the exact Model Number found on the device label or accompanying packaging.

Catalog #
Enter the exact Catalog Number as it appears in the manufacturer’s catalog, device label, or packaging.

Serial #
Enter the Serial Number as it appears on the device label or packaging. The number is assigned by the manufacturer and should be unique for this device.

Lot #
Enter the Lot Number as it appears on the label or packaging material.

License #
Enter the License Number as it appears on the label or packaging material.
Control #
Enter the Control Number as it appears on the label or packaging material.

Identifier #
Enter the Identifier Number as it appears on the label or packaging material.

Other #
Enter any additional identification number that applies to the suspected device.

Software Version
If software is used with the device, enter the software version.

Expiration Date
Enter the date the suspected device can no longer be used or implanted into a patient.

Implant Date
Enter the date the suspected device was implanted into a patient.

Explant Date
Enter the date the suspected device was removed from the patient.

Purchased From
Enter the name of the vendor that the device was purchased from.

Address
Enter the address of the vendor that the device was purchased from.

Facility/Importer section
This section defines what type of facility used the device.

User Facility or Importer
Indicates whether a device was used in a facility or by an importer (distributor). Select either “User Facility” or “Importer” from the pick list.

Facility/Importer Name
The name of the facility or importer (distributor) using the device. Select the name from the pick list. The facility or importer is defined in Case Entry as an additional Contact.

UF/IMP #
Enter the user facility or importer (distributor) number that implanted or used the suspected device.

Importer Est License #
Enter the importer’s establishment license number for the device that may have caused the adverse event.

Event Reported To section
This section indicates who this adverse event was reported to and who reported the event.
Vendor
Select the appropriate checkbox for the type of vendor this event was reported to. The values are “Manufacturer”, “Distributor”, and “Importer”.

Report
Select the Reporter from the pick list. The Reporter must be set up in Case Entry as an additional Contact in Case Entry.

Note: If the Reporter is a Contact Type of “Consumer” or “Patient”, then “WITHHELD” is printed in the Name and Address box on the MDR Report. If the Reporter is a Health Professional, then the Name and Address is printed on the MDR Report.

Comments and Proposed Action

Manufacturer Preliminary Comments
Enter the preliminary comments from the manufacturer.

Course of Action Proposed
Enter the course of action suggested by the manufacturer.
Step 7 – Manufacturers Tab

The Manufacturers tab captures manufacturing information about the suspected device in this adverse event.

1. To access the manufacturers information, click the Manufacturers tab.

Entering Information into the Manufacturers Tab

- The header information includes the Initial Receipt Date, Last Receipt Date, Event Start Date, Report Number, Case Number, End Date, Seriousness, and Reportability.

Manufacturer Information Section

This section contains the manufacturing information for the suspected device in the adverse event.

- Event Type
  The type of reportable event that occurred as a result of the suspected device. Select a value from the pick list arrow. The fixed values are “Death”, “Malfunction”, or “Serious Injury”.

- Usage
  The way the suspected device was used. Select a value from the pick list. The fixed values are “Initial Use of Device”, “Reuse”, or “Unknown”.

- Evaluated by Manufacturer
  Indicates the suspected device was evaluated by the manufacturer. Either enter the evaluation or select an evaluation from the pick list. The fixed values are “Evaluation Summary Attached”, “Not Returned to Manufacturer”, or “Yes”.
Entering Adverse Events

- **Correction/Removal #**
  If the suspected device was corrected or removed, enter the number.

- **Manufacturer Date**
  Enter the date the suspected device was manufactured.

- **Labeled for Single Use**
  Indicates the suspected device was labeled for single use. Select the checkbox if the device was labeled for single use.

**Event Problem Codes Section**

- **Event Problem Codes Matrix**
  Enter the applicable problem codes. The codes are defined in the FDA Device Report Codes option on the Tables menu.
  
  - **Patient** – Either enter the applicable event code or select a code from the pick list.
  
  - **Device** – Either enter the applicable event code or select a code from the pick list.

**Manufacturer Evaluation Codes Section**

- **Manufacturer Evaluation Codes Matrix**
  Enter the applicable evaluation codes. The device codes are defined in the FDA Device Report Codes option on the Tables menu.
  
  - **Method** – Either enter the applicable evaluation code or select a code from the pick list.
  
  - **Results** – Either enter the applicable evaluation code or select a code from the pick list.
  
  - **Conclusions** – Either enter the applicable evaluation code or select a code from the pick list.

**Remedial Action Initiated section**

Select the checkboxes to indicate the remedial action taken. If none of the selections apply, select the **Other** checkbox and enter the action taken in the text box.

- **Recall** – the device is recalled
- **Repair** – the device is repaired
- **Replace** – the device is replaced
- **Relabeling** – the information for the device is changed
- **Notification** – the customer is notified
- **Inspection** – the device is inspected
- **Patient Monitoring** – the patient will continue to be monitored
- **Modification/Adjustment** – the device is adjusted
- **Other** – enter additional remedial action taken

**Follow-up Type section**
Select the checkboxes to indicate the follow-up type needed.

- **Response to FDA Request**
  The report generated was in response to a request from the FDA

- **Device Evaluation** – follow-up is needed for evaluating the device

- **Additional Information** – follow-up is needed for the information provided

- **Correction** – follow-up is needed for correcting the problem

**Manufacturer Narrative section**

This section contains the manufacturer’s narrative

- **Additional Narrative**
  Indicates that the information data in the text box is an additional narrative

- **Corrected Narrative**
  Indicates that the data entered in the text box is a correction to the previous narrative

- **Narrative Text Box**
  A text box containing narrative information from the manufacturer. The information can be additional or corrected information
Step 8 – Events Tab

The Events tab captures data regarding the reaction or events of the adverse event. Each reaction or event is captured separately.

1. To access the events information, click the **Events** tab.

### Entering Information into the Events Tab

- The header information includes the Initial Receipt Date, Last Receipt Date, Event Start Date, Report Number, Case Number, End Date, Seriousness, and Reportability.

### Events Reaction section

Enter information about the reaction or event. One reaction should be listed for per event. Multiple events can be entered.

- **Verbatim**
  Enter the term exactly how it is stated by the reporter for the adverse event.

- **MedDRA®**
  Start entering the MedDRA® term, then click the pick list to select the remaining information. If the **Status** field is a “Y”, then the term is current.

**Note**: If MedDRA® codes are not used, any code can be entered in this field.
 Preferred and System
If MedDRA® codes are used, the Preferred and System fields are automatically populated from the MedDRA® Term selected. If this field is blank, enter the Preferred and System codes.

 Primary?
Indicates this is the primary reaction of the adverse event. Values are “Yes” or “No”. This value determines how the event is printed on the Periodic and PSUR Listing Report. Only one primary event can be defined for a case.

“Yes” – If the event is primary, it is listed under the System on the Periodic and PSUR Listing Report with non-primary events following it. Each event is printed separately on the Periodic and PSUR Tabulation Report.

“No” – If the event is not primary, it is listed below the System’s primary event on the Periodic and PSUR Listing Report. Each event is printed separately on the Periodic and PSUR Tabulation Report.

 Severity
Indicates the level of severity of the event. Either enter the Severity or select the Severity from the pick list. The Severity is defined in the General option on the Tables menu in the “Adverse Event Severity” table.

 Serious
From the Serious pick list, select Serious. The Serious field is defined in the General option on the Tables menu in the “Adverse Event Seriousness” table.

 Start Date and Stop Date
Enter the date the reaction or event started and ended. The following checks are performed for the Event Start and Stop Dates.

◊ The Event Start Date cannot precede the Start Date on the Suspected Medications tab.
◊ The Event Stop Date cannot precede the Event Start Date.

 Duration
If a Start and Stop Date is entered, the Duration is automatically calculated. To enter the Duration manually, enter the length of time of the reaction or event.

 Outcome
From the Outcome pick list, select an outcome. The Outcome field is defined in the General option from the Tables menu in the “Adverse Event Outcome” table.

 Version Number
The Version Number is pre-populated. This number indicates the version of the Regulatory Report this reaction or event applies to. If additional information or events are added after the Initial Report is submitted, the number is automatically be incremented when the Follow-up Reports are created.

 Serious Criteria Section
Select the checkboxes to indicate the outcome attributed to the adverse event. Select all that apply. If no checkboxes apply, select the Other checkbox and enter criteria in the text box.
Entering Adverse Events

- **Death** – the patient died as a result of the event
- **Hospitalization** – the patient required hospitalization as a result of the event
- **Disability** – the patient was disabled as a result of the event
- **Required Intervention** – the patient required medical intervention to prevent permanent damage or impairment as a result of the event
- **Life Threatening** – the event was life threatening
- **Hospitalization Prolonged** – hospitalization was prolonged because of the event
- **Congenital Anomaly** – a congenital anomaly made the event worse
- **Other** – select the checkbox and enter additional criteria in the text box

**Labeling Section**

The Labeling section allows the user to enter the reporting agency for the adverse event and how the drug was labeled for use based on the information on the drug label.

**Note:** This section must be populated for each reaction or event entered.

- **Agency**
  Either enter an Agency or select an Agency from the pick list. The pick list contains the Reporting Agencies defined in Product Maintenance for the suspected drug.

- **Labeled**
  Either select or deselect the Labeled checkbox. If the checkbox is selected (checked), the term appeared as part of the drug label information. If the label is deselected (unchecked), the term did not appear as part of the drug label information.

  **Note:** This checkbox must be specifically selected or deselected, otherwise, the event will not be included on the Periodic or PSUR Tabulation reports using labeled and unlabeled data.

2. To enter an additional reactions or events, click the **New** button on the Navigation Bar on the left panel.

**Product Assessed Section**

The Products Assessed section allows the user to apply an assessment for each suspected product. Multiple products can be assessed for the event.

- **Product Code**
  From the Product Code pick list, select the suspected product. The Product Code is defined on the Suspected Medications tab.

- **Action Taken**
  From the pick list, select the action taken to eliminate or reduce the adverse event. The values for Action Taken are pre-defined in the system. The values are: "Drug Reduced", "Dose Reduced", "Dose Increase", "Dose Not Changed", "Unknown", and "Not Applicable".

- **Action Result**
  This field is automatically populated from the **Dechallenge** field on the **Suspect Meds** tab. To change the Action Result, either enter a different Action Result or select an Action Result
from the pick list. This field was formerly called “Dechallenge”. The Action Result field is defined in the General option from the Tables menu in the “Adverse Event DeChallenge” table.

**Rechallenge**
This field is automatically populated from the Rechallenge field on the Suspect Meds tab. To change the Rechallenge, either enter a different Rechallenge or select a value from the pick list. The ReChallenge field is defined in the General option from the Tables menu in the “Adverse Event ReChallenge” table.

**Latency (First Dose)**
This is the time duration from the start of the drug to the start of the reaction. The duration is automatically calculated from the Start and Stop dates entered for the event. (Event Start Date – Suspected Med Start Date) To change the Latency, enter the time from the first dose to the start of the reaction. For example, the first dose is taken on day 1 and the symptom starts on day 2, then the latency is calculated as 2 days.

**Latency (Last Dose)**
This is the time duration from the end of the drug to the start of the reaction. The duration is automatically calculated from the Start and Stop Dates entered for the event. (Event Start Date – Suspected Med Stop Date) To change the Latency, enter the time from the last dose to the start of the reaction. If the symptom appears while the drug is taken, the latency for the last dose will be blank. For example, if the last dose was taken on day 3 and the symptom appears on day 4, the latency is calculated as 1 day.

**Causality**
The Causality section allows the user to enter the degree to which the suspected drugs are related to the reaction or event. The Causality is determined by using the Source, Method, and Result of the assessment.

**Source**
Either enter the Source or select the Source from the pick list. The Action Result field is defined in the General option from the Tables menu in the “Adverse Event Causality Source” table.

**Method**
Either enter the Method or select the Method from the pick list. The Action Result field is defined in the General option from the Tables menu in the “Adverse Event Causality Method” table.

**Result**
Either enter the Result or select the Result from the pick list. The Action Result field is defined in the General option from the Tables menu in the “Adverse Event Causality Result” table.

3. To enter a new product assessment, click the New button on the Navigation Bar on the right panel.
Step 9 – Labs & History Tab

The Labs & History tab captures data about laboratory and diagnostic tests run as result of the adverse event. In addition, any medical history, including pre-existing conditions and allergies are captured.

1. To access the laboratory and history information, click the Labs & Hist tab.

![Image of Labs & History Tab]

**Entering Information into the Labs & History Tab**

- The header information includes the Initial Receipt Date, Last Receipt Date, Event Start Date, Report Number, Case Number, End Date, Seriousness, and Reportability.

**Relevant Test & Laboratory Data section**

This section captures any relevant tests and test results that are used in the medical work-up and assessment of the Adverse Event.

- **Priority**
  Enter the Priority starting with “1” that applies to this section. The most important test information should be entered first.

- **Type**
  Either enter the Type of test or select the Type of test from the pick list. The type of test is defined in the General option on the Tables menu in the “Adverse Event Test Type” table.

- **Test**
  Enter the name of the test that was performed.
Date
Enter the date the test was performed or click Calendar Control and select a test date.

Result
Enter the results of the test in the text box.

Normal Range
If the test Type is “Lab”, and the Normal Range field is enabled, enter the Normal Range for the test.

To capture additional tests and laboratory data, click the New button on the Navigation Bar or tab to the next Priority field and start entering information.

Other Relevant History Including Pre-existing Medical Conditions section
This section captures medical history that is relative to the adverse event, pre-existing conditions, and allergy information.

To enter History information, click the arrow in the Other Relevant History Including Pre-existing Medical Conditions section and start entering data.

Priority
Enter the Priority starting with “1” that applies to this section. The most important historical information should be entered first.

Onset Date and Stop Date
Enter the dates the historical or pre-existing condition started and ended or click Calendar Control to select an Onset and Stop Date. If the condition is ongoing, leave the stop date blank.

History
Enter detailed information about the history or pre-existing condition of the patient.

To capture additional history or pre-existing conditions, click the New button on the Navigation Bar or tab to the next Priority field and start entering information.
Step 10 – Comments Tab

The Comments tab allows the user to enter additional information when evaluating the adverse event. The Activity Type can be used to keep track of the status of the review process for the adverse event.

1. To access the comments information, click the Comments tab.

Entering Information into the Comments Tab

- The header information includes the Initial Receipt Date, Last Receipt Date, Event Start Date, Report Number, Case Number, End Date, Seriousness, and Reportability.

Causality & Case Review Comments section

- **Date**
  The date is automatically populated with the current date. To change the date, enter a date or click Calendar Control and select a date.

- **Activity Type**
  The Activity Type appears below the date. Either enter the Activity Type for the comment or select the Activity Type from the pick list. The activity type is defined in the General option from the Tables menu in the “Adverse Event Activity Type” table.

- **Comment**
  Enter a comment in the text field next to the Date and Activity Type.

2. To capture additional comments, click the New button on the Navigation Bar or tab to the next date field and start entering information.
Step 11 – Regulatory Tab

Overview

The Regulatory tab records and maintains the information for the regulatory reports required for the case. The following features are available in this window.

☐ The user can preview the 3500A, CIOMS, or Device report for Serious events.
☐ The 3500A, CIOMS, and Devices report can be submitted for Serious events.
☐ Follow-up reports can be created and submitted for drugs and devices.
☐ The records for Periodic and PSUR Reports can be created.
☐ Non-Reportable events can be tracked.
☐ Events can be recorded for record only.
☐ Manual Reports can be created.
☐ Create multiple Regulatory Reports

Prerequisites and Setup for Regulatory Reports

The following tables should be setup and/or reviewed prior to creating Regulatory Reports.

☐ The Reporting Agency should be created in the Reporting Agency table. This includes the FDA and Health Canada.
☐ Product Maintenance should be reviewed. The Global Product, Company, and Approval Dates section are used in Regulatory Reporting.
Regulatory Reporting Toolbar

Below is the toolbar for the Regulatory Report tab. The toolbar buttons are explained below.

<table>
<thead>
<tr>
<th>Button</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>📄 3500A</td>
<td>Previews the 3500A Report.</td>
</tr>
<tr>
<td>📄 CIOMS</td>
<td>Previews the CIOMS Report.</td>
</tr>
<tr>
<td>📄 Devices</td>
<td>Previews the Medical Devices Problem Report.</td>
</tr>
<tr>
<td>📘 Export (E2B)</td>
<td>Starts the process for creating and exporting an E2B file.</td>
</tr>
<tr>
<td>📞</td>
<td>Opens the Case Correspondence Management screen.</td>
</tr>
<tr>
<td>🔴 Submit 3500A</td>
<td>Submits the 3500A Report.</td>
</tr>
<tr>
<td>🔴 Submit CIOMS</td>
<td>Submits the CIOMS Report.</td>
</tr>
<tr>
<td>🔴 Submit Devices</td>
<td>Submits the Medical Devices Problem Report.</td>
</tr>
<tr>
<td>🌡️ Preview</td>
<td>Previews the selected Regulatory Report that has been submitted. If it is a secured pdf, the user is prompted for the password</td>
</tr>
<tr>
<td>📕</td>
<td>Prints the Case Snapshot for the current case.</td>
</tr>
<tr>
<td>📕</td>
<td>Displays the Case Snapshot for the current case.</td>
</tr>
<tr>
<td>📖</td>
<td>Saves the current Adverse Event record.</td>
</tr>
<tr>
<td>🗑️</td>
<td>Deletes the current highlighted record. IRMS provides a warning message to verify that the current record should be deleted.</td>
</tr>
<tr>
<td>🗒️</td>
<td>Exits the Adverse Events module.</td>
</tr>
</tbody>
</table>
Regulatory Report Processing

Once the Reporting Agency is defined and the Reporting Agencies assigned to specific products, the appropriate regulatory reports can be generated.

The Appendix contains the steps to Error! Reference source not found. and Error! Reference source not found.

How Reportability Works with Regulatory Reports

Creating regulatory reports is driven by Reportability in the Header section. When selecting an option from the Reportability pick list, the records for the regulatory reports are created and assigned a version number.

The Reportability values that create entries for the 3500A, CIOMS, and Devices (MDR) are: “Initial Report”, “Follow-up Response”, and “Follow-up Unsolicited”.

The Reportability values that create additional reports for devices (MDR) are: “Submitted by Manufacturer”, “Voluntary Report”, “Update to Mandatory Report”, and “Final Mandatory Report”.

♦ Reportability

The Reportability defines the regulatory reporting status for this adverse event. The user can select Reportability from a pre-defined set of values in the pick list. Initially this value is blank. The values are:

“Initial Report” – This value indicates a regulatory report is due, but the records for the report have not been created. For serious events, records are created for the A3500A, CIOMS, and MDR Report. For non-serious events, records are created for the Periodic and PSUR reports. A Version Number of “1” is assigned to the reports. The Report Due Date is calculated from the Initial Receipt Date. The adverse event is printed on the Line Listing and Tabulation Reports for Periodic and PSUR Reports.

“Follow-up Response” – This value indicates an Initial Report has been submitted, and a Follow-up Report is required. For serious events, records are created for the A3500A, CIOMS, and MDR Report. For non-serious events, records are created for the Periodic and PSUR reports. The user is prompted to update the Version Number for this set of regulatory reports. The Report Due Date is automatically calculated from the Last Received Date. The adverse event is printed in the appropriate sections on the Line Listing and Tabulation Reports for Periodic and PSUR Reports.

“Follow-up Unsolicited” – This value indicates an Initial Report has been submitted, and a Follow-up Report is required. For serious events, records are created for the A3500A, CIOMS, and MDR Report. For non-serious events, records are created for the Periodic and PSUR reports. The user is prompted to update the Version Number for this set of regulatory reports. The Report Due Date is automatically calculated from the Last Received Date. The adverse event is printed in the appropriate sections on the Line Listing and Tabulation Reports for Periodic and PSUR Reports.

“Addendum Report” – This value is currently not used.

“Submitted” – This value indicates that the Serious regulatory reports (3500S, CIOMS, and MDR) have been submitted and no other regulatory reports are due at this time. The Reportability is automatically changed to “Submitted” when all the reports for the adverse event
have been submitted. The Reportability remains in this state until the user selects a different value.

“Not Reportable” – This value indicates that this event is not reportable. Any existing reports are deleted and any additional reports cannot be initiated.

“Submitted by Manufacturer” – This value indicates that the manufacturer has already submitted the appropriate regulatory report for a suspected medication or device and the company is capturing the information for the manufacturer. This value functions the same way as “For Record Only”.

“Voluntary Report” – This value is used with the MDR and indicates that a consumer has reported a non-serious event that does not require a mandatory report, but a report was submitted to the appropriate regulatory agency.

“Update to Mandatory Report” – This value is used with the MDR and is selected if a follow-up report is required for a serious device event. Prior to selecting this value, an Initial Report must already be submitted for an MDR. This function works the same as the Follow-up Report.

“Final Mandatory Report” – This value is used with the MDR and is selected when a Final Mandatory report is due for a serious device event. Prior to selecting this value, an Initial Report must already be submitted for an MDR. This function works the same as the Follow-up Report.

“For Record Only” – This value indicates that this event should be recorded. Any existing reports are saved, but no additional reports can be initiated.
Regulatory Report Processing

Once the Reporting Agencies are defined, assigned to specific products, and a Reportability value selected, the appropriate regulatory reports can be created.

1. To access the Regulatory Report information, click the Regulatory tab.

Entering Information into the Regulatory Tab

- The header information includes the Initial Receipt Date, Last Receipt Date, Event Start Date, Report Number, Case Number, End Date, Seriousness, and Reportability.

Regulatory Section

If Reportability has been selected and is one of the values that creates regulatory records, the records are already created. If the case is “Serious”, the user must submit the appropriate report (3500A, CIOMS, and MDA) to the Reporting Agency. If the case is non-serous, records are created for the Periodic and PSUR report. The Serious and Non-serious cases are displayed on these reports.

When the Regulatory Report records are created, the fields for the reports are automatically populated. The fields are populated from the information in the Reporting Agency and Product table. If the case is “Serious”, then the 3500A, CIOMS, and/or Devices Report(s) must be submitted.

Records and information for other reports must be entered manually.
Entering Adverse Events

Field Definitions

When Reportability is changed to a value that creates records, the following fields are automatically populated: Agency, Report, Days, Version, and Due Date. The Report Date and File Location are populated when a “Serious” report is submitted and a PDF is created.

Additional reports must be entered manually. To enter a manual report, enter the following information.

- **Agency**
  Either enter the Agency or select the agency from the pick list. The Agency must be defined in the Approval Dates section in Product Maintenance.

- **Report**
  Either enter the Report or select the Report from the pick list. The reports available are based on Seriousness and the regulatory reports defined for the primary suspected medication or device.

- **Days**
  Select the Days the report is due from the pick list. The pick list is based on the reporting days defined in the Approval Dates section in the Product table for the report selected.

- **Version**
  The Version is automatically populated from the type of report.

- **Due Date**
  Enter the due date of the report. If the even is “Non-serious”, the case will be included in the Periodic or PSUR Report when it is generated.

- **Report Date**
  Once the report is submitted, the Report Date is automatically populated with the date the report was submitted.

- **File Location**
  Once the report has been submitted, the File Location of the report is automatically populated.
Generating a 3500A, CIOMS or MDR (Device) Report

Once the records for the reports are created, the reports must be submitted to create the PDFs to submit to the reporting agencies. The reports can be previewed prior to submitting them. Below are the steps for generating the reports.

1. Check the Reportability field in the Header section. If Reportability is blank, select “Initial Report” from the pick list. The records for the appropriate Regulatory Reports are created. For additional information about the Reportability field, refer to the How Reportability Works with Regulatory Reports section on page 88.

2. Select the Report record (3500A, CIOMS, or MDR) to submit from the list of report(s).

3. To view the report prior to submitting the report, click the 3500A, CIOMS, or Devices toolbar button. The selected report is displayed. An example of each report is included in the Regulatory Reports chapter. There is also a table in the Appendix that shows where the fields from IRMS are printed on the different regulatory reports.

4. To submit the reports, click Submit 3500A, Submit CIOMS, or Submit Devices. A PDF is created and the Report Date and File Location are populated.

   If all the regulatory reports are complete for the version, the following message is displayed when the last report is completed.

   Click OK to continue. The Reportability is changed to “Submitted” and the Regulatory tab becomes active.

   Caution When Changing Reportability

   Do not change the Reportability from “Submitted” to “Follow-up Response” or “Follow-up Unsolicited” unless Follow-up reports are required for this event. Once the Reportability value is changed to “Follow-up …”, the records for the regulatory reports are created and the case will print in the Follow-up sections on the Periodic and PSUR reports.

5. Repeat this process for each report to be submitted.

6. To preview a submitted report, select the 3500A, CIOMS, or MDA (Device) Report record from the list of report(s) and then click the Preview toolbar button. If the PDF is secured, the user is required to enter a password. Enter the password and click OK. The report is displayed.

   To see an example of the 3500A, CIOMS, and Device Reports, refer to Processing 3500As, CIOMS, and MDR Reports on page 112.
Step 12 – Hospital/Client Data Tab

The Hospital/Client Data tab captures information about any hospital visit that resulted from the adverse event. Any additional client specific information is also captured. The Client Data fields are defined in the Division Parameters on the Adverse Events tab. For additional information, refer to the Adverse Events Tab section in the Division Parameters on page 19.

1. To access the hospital and client data information, click the Hospital/Client Data tab.

Entering Information into the Hospital/Client Data Tab

- The header information includes the Initial Receipt Date, Last Receipt Date, Event Start Date, Report Number, Case Number, End Date, Seriousness, and Reportability.

Hospital: section

- Hospital
  Select the Hospital from the pick list. The Hospital must be set up in Case Entry as an additional Contact for the case.

If the hospital is not found in the pick list, type the name of the Hospital and tab to the next field. A message window is displayed asking if the hospital should be entered.
Click “Yes” to display the Contact section in Case Entry. Enter the contact information and then click the Adverse Event button to return to the case and then click the Hospital/Client Data tab.

Click “No” to return to the Hospital/Client Data tab and select the hospital from the pick list.

- **Admission Date**
Enter the date the patient was admitted.

- **Discharge Date**
Enter the date the patient was discharged from the hospital.

- **Emergency Room**
Indicates the patient was taken to the emergency room. Select this checkbox if the patient arrived in the Emergency Room.

- **Length of Stay**
Enter how long the patient was in the emergency room.

**Client Data: section**

Capture any client specific information in the Client Data fields. The Client Data fields are displayed if the fields are defined in the Division Parameters. Otherwise, this section is blank.

- **Client Data Information**
The field name is defined on the left side of the tab. Data can be entered in a text, numeric, date, or Y/N format. The format defined for the field is available for entry. All other fields are dimmed. Enter the client data as needed.
Step 13 – Exiting the Adverse Event Module

The user can access the adverse event case as many times as necessary and add additional information and print reports before completing the case. When a user exits an adverse event case, several processes occur.

To exit the Adverse Event case, click the Close toolbar button or click X in the upper right hand corner.

♦ The required fields are checked for data. If a required field has not been entered and the Required Field Behavior is defined as “Entry”, a message window is displayed telling the user what fields need data. Click OK to return to the tab and enter the required information. For additional information, refer to Required Field Processing on page 55.

♦ If the Reportability value is “Submitted”, and additional information has been added to the adverse event case, the user is asked if Follow-Up Reports should be created prior to exiting the adverse event case.

Click Yes if the reports are complete. The Adverse Event window is closed and the user is returned to Case Entry.

Click No to return to the Adverse Event window.

♦ If the adverse event case is still open, the user is asked if the case should be held open after all the response letters have been sent. The following window is displayed:

Click Yes to keep the case open and not automatically close the case for any reason.

Click No to complete when the Response Letters are sent. If the case is already completed, the warning message is not displayed.

Once these processes are complete, the user is returned to Case Entry.
Crosslink

The Crosslink button on the Case Entry window allows this case to be linked to other Medical Information, Adverse Entry, and Product Complaint cases. This feature is used to link shared or common problems, reactions, events, quality, labeling, distribution or other common issues. This Crosslink button is also available from the Adverse Events and Product Complaints windows.

Reasons to Use the Crosslink

- Link a Medical Information cases to other medical information cases with similar issues or problems.
- Link a Medical Information case with Adverse Event or Product Complaint case(s).

Cautions Prior and Prerequisites Prior to using Case Query features

- The person using this feature must have access to the Medical Information module.
Entering Information into the Crosslink Window

1. To open the Crosslink window, click the Crosslink button on the bottom right of the Case Entry window.

![Crosslink Window](image)

The Crosslink window is displayed.

![Crosslink Window](image)

Any cases that are currently cross-linked with this case are displayed.
2. To associate a case with this medical information case, click Search. The Crosslink Search window is displayed.

The Case Query Search window is displayed.

3. Enter the search criteria and click **Find to Results List**. The records meeting the criteria are displayed. To select one case, click **Select One Case**. The case is displayed in the Crosslink window. To select multiple cases, click **All Cases**. All selected cases are displayed in the Crosslink window.

For more information about the Search window, see the **Basic Search** chapter in the *Query and Reporting Guide*.

4. To view a crosslinked case, click the **Goto Case** button. The case is displayed in the Case Entry window.

5. To close the **Crosslink** window, click the **Close** toolbar button or click **X** on the window.

6. When a case is crosslinked with another case, the following process occurs:

   - The **Crosslink** button on the Adverse Event window changes to red to indicate that this case has been linked to other case(s). The Crosslink button on the other case(s) also turns red.
Crosslink Toolbar

The following are explanations of the toolbar buttons available on the AE Crosslink window.

<table>
<thead>
<tr>
<th>Button</th>
<th>Explanation and Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="formview.png" alt="Form view" /></td>
<td>Form view</td>
</tr>
<tr>
<td><img src="datasheetview.png" alt="Datasheet view" /></td>
<td>Datasheet view</td>
</tr>
<tr>
<td><img src="print.png" alt="Print" /></td>
<td>Print</td>
</tr>
<tr>
<td><img src="printpreview.png" alt="Print preview" /></td>
<td>Print preview</td>
</tr>
<tr>
<td><img src="newrecord.png" alt="Starts a new record" /></td>
<td>Starts a new record</td>
</tr>
<tr>
<td><img src="cut.png" alt="Cut" /></td>
<td>Cut</td>
</tr>
<tr>
<td><img src="copy.png" alt="Copy" /></td>
<td>Copy</td>
</tr>
<tr>
<td><img src="paste.png" alt="Paste" /></td>
<td>Paste</td>
</tr>
<tr>
<td><img src="find.png" alt="Find" /></td>
<td>Find</td>
</tr>
<tr>
<td><img src="filterbyselection.png" alt="Filter by selection" /></td>
<td>Filter by selection</td>
</tr>
<tr>
<td><img src="applyfilter.png" alt="Apply filter" /></td>
<td>Apply filter</td>
</tr>
<tr>
<td><img src="sortascending.png" alt="Sort Ascending" /></td>
<td>Sort Ascending</td>
</tr>
<tr>
<td><img src="sortdescending.png" alt="Sort Descending" /></td>
<td>Sort Descending</td>
</tr>
<tr>
<td><img src="cannotundo.png" alt="Can’t undo" /></td>
<td>Can’t undo</td>
</tr>
<tr>
<td><img src="undo.png" alt="Undo" /></td>
<td>Undo</td>
</tr>
<tr>
<td><img src="deleterecord.png" alt="Delete record" /></td>
<td>Delete record</td>
</tr>
<tr>
<td><img src="exit.png" alt="Exit" /></td>
<td>Exit</td>
</tr>
</tbody>
</table>
Chapter 4  AE Reporting

Case Snapshot

Overview

The Case Snapshot previews or prints all the data entered for the adverse event in an organized format. All the data entered for the case, including the adverse event is displayed.

Previewing and Printing the Case Snapshot

The Case Snapshot can be previewed and/or printed from the Adverse Event module. For additional information about the Case Snapshot, see the Case Snapshot section in the IRMS User Guide.

♦ To Preview the Case Snapshot, click the View toolbar button. The Case Snapshot is displayed. From this window the Case Snapshot can be emailed or saved in a variety of formats. Click the Close toolbar button to exit and return to Adverse Events.

♦ To Print the Case Snapshot, click the Print toolbar button. The Case Snapshot is printed to the user’s default printer. The user is returned to the Adverse Event window.

Case Snapshot Adverse Event Sections

The Case Snapshot is divided into several sections. The Medical Information is displayed first with the Adverse Event information following. Each section in the Case Snapshot is associated with a specific tab in Adverse Events. Below is an example of each Adverse Event tab as it is printed in the Case Snapshot.

Header Section

Left Side

♦ Company Name - (the example above is “Online Business Applications, Inc.”) is captured in System Parameters on the General tab in the Licensee Name field.

♦ AE # is the Adverse Event Report Number found in the Header section on the Adverse Event tabs in the Report Number field.

♦ Version: - the version of the Adverse Event case printed on the report. This number appears in the Version of This AE window on the left panel of the Adverse Event window. If a version is not selected, the latest version is printed.
Page Number, and Date: - the page with number of pages in the snapshot and the date the Case Snapshot was printed.

Right Side

- **Case** is the number assigned to the Medical Information Case assigned in the Basic Case section when the case is created. The field is called **Case Number** field.

- **Run by:** - the **User Id** of the person running the report.

Contact Section

The Contact information is entered in the Medical Information case. A contact should be setup for the consumer (patient), doctor, pharmacy and any other contacts associated with the adverse event. Below is an example of the contacts for an adverse event.

<table>
<thead>
<tr>
<th>Name &amp; Address</th>
<th>Gender &amp; Phone</th>
<th>Specialty &amp; Account</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hannah Heather</td>
<td>(111) 222-3333</td>
<td>Consumer</td>
</tr>
<tr>
<td>1011 State St.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lomart, IL 60439</td>
<td></td>
<td></td>
</tr>
<tr>
<td>United States</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>James Davidson</td>
<td>(630) 243-9810</td>
<td>HithProf</td>
</tr>
<tr>
<td>New Hospital Pharmacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1011 State St.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lomart, IL 60439</td>
<td></td>
<td></td>
</tr>
<tr>
<td>United States</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emil Sunshine</td>
<td>(555) 444-8888</td>
<td>HithProf</td>
</tr>
<tr>
<td>Medical Doctor</td>
<td>(555) 999-3333</td>
<td></td>
</tr>
<tr>
<td>1012 State St.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lomart, IL 60439</td>
<td></td>
<td></td>
</tr>
<tr>
<td>United States</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Demographic Section

The Adverse Event Data including Initial Reporter, Report Source, General Information, and Patient Information is entered in the Demographic tab. Below is the information as it is presented in the Case Snapshot.

```
<table>
<thead>
<tr>
<th>Adverse Event Data</th>
<th>Version: 2.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial Rec Date</td>
<td>2/6/2000</td>
</tr>
<tr>
<td>Last Rec Date</td>
<td>1/1/2011</td>
</tr>
<tr>
<td>Report Number</td>
<td>0001-000002</td>
</tr>
<tr>
<td>Event Start Date</td>
<td>2/6/2000</td>
</tr>
<tr>
<td>Event End Date</td>
<td>2/6/2000</td>
</tr>
<tr>
<td>Seriousness</td>
<td>Serious</td>
</tr>
<tr>
<td>Responsibility</td>
<td>Follow-up Response</td>
</tr>
</tbody>
</table>

| Initial Reporter                  | Sunshine, Erin |
| Report Source                      | Health Professional |
| Foreign                           | Yes          |
| Study                             | Yes          |
| Manufacturer Information          | Other        |
| General Information               |              |
| Report Type                       | Product Problem |
| Med Confirmed                     | No           |
| Country of Occ                    | United States |
| Filled w/Agency                   | No           |
| Date of Birth                     | 4/5/1970     |
| Place of Death                    | Cancer       |
| Gender                            | Female       |
| Age Category                      | Adult        |
| Weight                            | 185 Lbs      |
| Pregnancy                         | Yes          |
| Height                            | 65 In        |
| Race                              | Caucasian    |
| Date of Death                     | 4/5/1970     |
| Cause of Death                    | Cancer       |
| Autopsy Date                      | Yes          |
| Suspected Medication Information  |              |
| Name                              | James        |
| Dose                              | 500 mg       |
| Route                             | Intravenous  |
| Contact                           | Yes          |
| Prescriber                        | James        |
| Indication                        | Lack of energy |
| Dose Form                         | Capsules     |
| Frequency                         | 4x/8        |
| Start Date                        | 4/5/1970     |
| Side Effect                       | 2 days       |

```

Narrative Section

The Narrative and Treatment information is entered in the Narrative tab. Below is the information as it is presented in the Case Snapshot.

```
<table>
<thead>
<tr>
<th>Narrative</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient took 3 doses for Cerazat was feeling dizzy and passed out.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Dear Dr. Sunshine,</td>
<td></td>
</tr>
<tr>
<td>On (02/02/2000), the Drug Information Unit received an information that we determined to be an Adverse Event. We need additional information regarding the event. Please provide us with the following additional information below:</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Was there an ER visit? Yes</td>
<td></td>
</tr>
<tr>
<td>What was the length of stay? 5 hours</td>
<td></td>
</tr>
<tr>
<td>Where hospital? Duke Hospital</td>
<td></td>
</tr>
<tr>
<td>What was the suspected medication? Suggester, indomethacin</td>
<td></td>
</tr>
<tr>
<td>Are the any pre-existing conditions? Congential profile</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Thank You.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Treatment</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>The patient stopped taking the medication immediately.</td>
<td></td>
</tr>
</tbody>
</table>

```

Suspected Medication Section

The Suspected Medication information is entered in the Suspect Meds tab. If multiple suspected medications are entered, each one is printed in this section. Below is the information as it is presented in the Case Snapshot.

```
<table>
<thead>
<tr>
<th>Suspect Medication</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Name</td>
<td>James</td>
</tr>
<tr>
<td>Dose</td>
<td>500 mg</td>
</tr>
<tr>
<td>Route</td>
<td>Intravenous</td>
</tr>
<tr>
<td>Contact</td>
<td>Yes</td>
</tr>
<tr>
<td>Prescriber</td>
<td>James</td>
</tr>
<tr>
<td>Indication</td>
<td>Lack of energy</td>
</tr>
<tr>
<td>Dose Form</td>
<td>Capsules</td>
</tr>
<tr>
<td>Frequency</td>
<td>4x/8</td>
</tr>
<tr>
<td>Start Date</td>
<td>4/5/1970</td>
</tr>
<tr>
<td>Side Effect</td>
<td>2 days</td>
</tr>
<tr>
<td>Daily Dose</td>
<td>100 mg</td>
</tr>
<tr>
<td>Repeat Challenge</td>
<td>Yes</td>
</tr>
<tr>
<td>Exp. Date</td>
<td>4/4/1970</td>
</tr>
</tbody>
</table>
```
**Concomitant Medication Section**

The Concomitant Medication information is entered in the Con Meds tab. If multiple concomitant medications are entered, each one is printed in this section. Below is the information as it is presented in the Case Snapshot.

<table>
<thead>
<tr>
<th>Concomitant Medication</th>
<th>Name</th>
<th>Route</th>
<th>Frequency</th>
<th>Start Date</th>
<th>Exp Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Indication</td>
<td></td>
<td></td>
<td>Lot #12345</td>
<td>1/2/2023</td>
</tr>
<tr>
<td></td>
<td>NDC: 1234</td>
<td>POD</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dose Form</td>
<td>Table</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dose Unit</td>
<td>10 mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Daily Dose</td>
<td>10 mg</td>
<td></td>
<td></td>
<td>12/31/2023</td>
</tr>
</tbody>
</table>

**Suspected Medical Device Section**

The Suspected Medical Device information is entered in the Device tab. Below is the information as it is presented in the Case Snapshot.

**Manufacturers Section**

The Manufacturers information is entered in the Manufacturers tab. Below is the information as it is presented in the Case Snapshot.
**Event Section**

The Event information is entered in the Events tab. If multiple events are entered, each event is printed. Below is the information as it is presented in the Case Snapshot.

<table>
<thead>
<tr>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Event</strong></td>
</tr>
<tr>
<td><strong>Preferred</strong></td>
</tr>
<tr>
<td><strong>Severity</strong></td>
</tr>
<tr>
<td><strong>Start Date</strong></td>
</tr>
<tr>
<td><strong>Duration</strong></td>
</tr>
<tr>
<td><strong>Version</strong></td>
</tr>
</tbody>
</table>

**Laboratory and Medical History Section**

The Relevant Tests & Lab Data and Relevant History information is entered in the Lab & Hist tab. Below is the information as it is presented in the Case Snapshot.

<table>
<thead>
<tr>
<th>Relevant Tests &amp; Lab Data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Type</strong></td>
</tr>
<tr>
<td>Lab</td>
</tr>
<tr>
<td>Urinalysis</td>
</tr>
<tr>
<td><strong>Relevant History</strong></td>
</tr>
<tr>
<td>Priority</td>
</tr>
<tr>
<td>1</td>
</tr>
</tbody>
</table>

**Comments Section**

The Causality and Case Review information is entered in the Comments tab. Below is the information as it is presented in the Case Snapshot.

<table>
<thead>
<tr>
<th>Causality &amp; Case Review</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Date</strong></td>
</tr>
<tr>
<td>12-Mar-09</td>
</tr>
</tbody>
</table>
**Regulatory Section**

The Report Due Dates and PSUR information is entered in the Regulatory tab. Below is the information as it is presented in the Case Snapshot.

<table>
<thead>
<tr>
<th>Agency</th>
<th>Report</th>
<th>Days</th>
<th>Version</th>
<th>Due Date</th>
<th>Report Date</th>
<th>File Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA</td>
<td>350DA</td>
<td>10</td>
<td>3</td>
<td>1/1/2010</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FDASafe</td>
<td>350DA</td>
<td>15</td>
<td>3</td>
<td>1/1/2009</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Hospital and Client Data Section**

The Hospital Info and AE Client Data information is entered in the Hosp/Client Data tab. Below is the information as it is presented in the Case Snapshot.

**Hospital info**
- Contact: Sunshine, Erin
- Admission Date: 1/1/2010
- Emergency Room: Yes
- Length of Stay in ER: 5 hours
  - Discharge Date: 1/1/2010

**AE Client Data**

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Text Information</th>
<th>Numeric</th>
<th>Date</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Meds</td>
<td>2</td>
<td>0</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Vitamin Taken</td>
<td>No</td>
<td>0</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Allergy/Food</td>
<td>0</td>
<td>0</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Allergy/med</td>
<td>0</td>
<td>0</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Last Visit</td>
<td>0</td>
<td>0</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Siblings</td>
<td>2</td>
<td>22/2/2010</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Children</td>
<td>1</td>
<td>22/2/2010</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Parental Age</td>
<td>2</td>
<td>22/2/2010</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Last Energy Drink</td>
<td>0</td>
<td>22/2/2010</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Last Physical</td>
<td>0</td>
<td>3/1/1998</td>
<td>No</td>
<td></td>
</tr>
</tbody>
</table>
View a Version of an Adverse Event

To view a previous version of an Adverse Event, use the following steps.

1. Navigate to the Medical Information case and click the AE button.
2. Click the version to view in the Versions of This AE window.
3. Click the appropriate tab to view the data. If the version is closed, the tab is displayed with a yellow background and the data cannot be changed.
4. To view a different version, click a different version in the Versions of This AE Window.

Audit Trail and Case Log

To view the Case Audit Trail or Case Log, use the following steps.

1. Exit the Adverse Event case.
2. Click Case Audit Train or Case Log from the Shortcuts menu.

The Audit Trail and Case Log displays the AE Version that is highlighted in the Versions of this AE panel. The AE Version Number is shown below.

Case Snapshot

To view or print the Case Snapshot for the selected version of AE, use the following steps.

Click the View or Print toolbar button.

The Case Snapshot displays the AE Version Number as shown. The Version Number is also shown in the Adverse Event section.
Table Listings

The Table Listings option on the Reports menu lists the pre-defined reports that can be run in IRMS. The Table Listings below are specifically for Adverse Events. For additional information on Table Listings, refer to the Table Listings chapter in the IRMS Query and Reporting Guide.

Select a Table Listing

1. To access the Table Listings, select Table Listings from the Reports menu. The Table Listings window is displayed. The listings specific to Adverse Events are included in the red box.

2. Select the appropriate Department and Division from the pick lists.

3. Select the dates by manually entering a date in the From and To fields or click the Calendar Control buttons.

4. Select the checkbox for the report from the Choice List. To deselect a report, re-click the checkbox. To deselect all the reports, click the Clear All button.

5. To select all the reports in the Choice List, click the Select All button.

6. To preview the report, click the Preview button.

7. To send the report directly to the default printer, click the Print button.

8. The toolbar buttons provide the ability to print to HTML, RTF, and SNP by selecting the appropriate toolbar button.
Adverse Event Table Listings

The following is a list of reports that are specific to Adverse Events. Some of the reports require additional information. In those cases, a pop up window is displayed prompting the user for the appropriate information.

- **AE Number Reconciliation Report**

  This report prints all the Adverse Event case numbers and their status for the specified criteria in **AE Entered Date** order.

  **Note:** Authorization to access and run this report is granted in “ReconciliationReportUsers” parameter on the Other tab in System Parameters.

  ![AE Number Reconciliation Report](image)

- **Adverse Event Terms – By Body System and Dose Report**

  This report prints a tabulation of the body systems by dose for a selected product. After selecting the report, the user is prompted to enter an Additional Report Filter.

  ![Adverse Event Terms – By Body System and Dose Report](image)

  Select a product from the pick list and then click **OK**. The report is displayed.

  ![Tabulation By Body System of All Events Reported by Dose](image)
Adverse Event Terms – By Body System and Dose Report

This report prints a tabulation of the body systems by dose for a selected product. After selecting the report, the user is prompted to enter an Additional Report Filter.

Select a product from the pick list and then click OK. The report is displayed.
Chapter 5  Regulatory Reports

Overview
The IRMS Adverse Event module can process and submit various regulatory reports. IRMS supports the following regulatory reports: 3500A, CIOMS, Device (MDR), Periodic Reports, and PSUR Reports. The reports can be used with both the AE Capture and AE Reporting modules. The regulatory reports can also be used with the E2B Interface.

Multiple reporting agencies can be defined for a product and a specific event.
Multiple regulatory reports can be submitted for an adverse event.

Reasons to Use Regulatory Reporting

➢ Preview and print reports for case review.
➢ Print and submit 3500A reports for serious events to the FDA.
➢ Print and submit CIOMS and MDA reports for serious events to other regulatory agencies.
➢ Create records for E2B reporting.
➢ Print and submit Periodic Reports and PSUR reports for non-serious events.
➢ Print and submit Follow-up Regulatory Reports.
➢ Preview and print reports for entry into another AE reporting application.

Cautions Prior and Prerequisites Prior to using Case Query features

➢ The person using this feature must have access to the Adverse Events module in Case Entry to run the 3500A, CIOMS, and MDA reports.
➢ The person using this feature must have access to the Periodic Reports on the Reports menu.
➢ The Regulatory Agencies must be setup in the Reporting Agencies table.
➢ The Reporting Agencies must be defined in the Approval Dates section in Product Maintenance on the Tables menu.
PROCESSING 3500As, CIOMS, AND MDR REPORTS

Overview

The 3500As, CIOMS, and MDR Reports are submitted when an adverse event involves a drug, device or both and the event is serious. The system populates the data from the Adverse Events tabs and provides the ability to submit the form to the appropriate Regulatory Agencies.

The following information must be setup prior to printing and submitting the reports.

◊ Prior to processing the report, the Regulatory Agency must be setup in Reporting Agency Maintenance. A “Notify” Shift must be assigned for the agency. For additional information, go to the System Administration and Setup chapter in this guide.

◊ Verify in Shift Maintenance that a “Notify” Shift has been setup for creating regulatory reports.

◊ In Product Maintenance, the Reporting Agency must be setup as a reporting agency in the Approval Dates section in the Product Maintenance table. The required number of days for reporting serious and no-serious events are defined in this section.

For step-by-step instructions about how to submit the 3500A, CIOMS, and Device Report, refer to Generating a 3500A. CIOMS or MDR (Device) Report on page 92.

The appendix contains a Data Map for the 3500A, CIOMS, and Device Reports.

Below are examples of the 3500A, CIOMS, and Device Reports.
**Toolbar for the 3500A Reports, CIOMS Reports, and Periodic Report**

The following is an explanation of the toolbar available when previewing the 3500A, CIOMS, and Device (MDR) Reports.

<table>
<thead>
<tr>
<th>Button</th>
<th>Explanation and Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>![Print]</td>
<td>Prints the report</td>
</tr>
<tr>
<td>![Zoom]</td>
<td>View the report one page at a time.</td>
</tr>
<tr>
<td>![Zoom]</td>
<td>View the report multiple pages at a time.</td>
</tr>
<tr>
<td>![Zoom]</td>
<td>Zoom into different sections of the report</td>
</tr>
<tr>
<td>![Fit]</td>
<td>Adjust the size of the report</td>
</tr>
<tr>
<td>![Email As...]</td>
<td>E-mail the report in a PDF, Rich Text, or Snapshot format.</td>
</tr>
<tr>
<td>![Save As...]</td>
<td>Save the report in an Excel, PDF, Rich Text Format, Snapshot, or Text format.</td>
</tr>
<tr>
<td>![Close]</td>
<td>Closes the report window.</td>
</tr>
</tbody>
</table>
3500A Form

The 3500A is submitted in the United States for any adverse events involving drugs, devices, or both.

Below is an explanation of the 3500A Report. To explain the 3500A form and show where the data was extracted from in IRMS, each section of the 3500A form is separated and a screen print is displayed showing that section. This is followed by an explanation of where the data came from in IRMS with a screen shot of where the data is located.

The Appendix contains a map of the fields in IRMS with the corresponding fields on the 3500A Report.

If the event is non-serious, the adverse event is submitted either quarterly or annually as part of the Periodic Reports.

Section A. Patient Information

<table>
<thead>
<tr>
<th>Patient Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Patient identifier</td>
</tr>
<tr>
<td>2. Age at time of event</td>
</tr>
<tr>
<td>3. Sex</td>
</tr>
<tr>
<td>4. Weight</td>
</tr>
</tbody>
</table>

- **Patient Identifier** – captured in the Identifier field of the Demographic tab.
- **Age at time of event and/or Date of birth** – captured in the Age at Time of Event field and Date of Birth field in the Demographic tab.
- **Sex** – captured in the Gender field of the Demographic tab.
- **Weight** – captured in the Weight field and Lb or Kg fields of the Demographic tab.

All of the fields in this section are found in the Demographic tab in the Patient Information section.
Section B. Adverse Event or Product Problem

- Adverse Event or Product Problem – since this data is captured in the Adverse Events module, the Adverse Event box is always checked.

- Outcomes attributed to Adverse Event – captured in the **Outcome** field of the **Adverse Events** tab.

- Date of Event – captured in the **Start of Event** field of the **Demographic** tab.

- Date of this Report – captured in the **Report Date** field of the **Demographic** tab.
- Describe event or problem – captured in the **Describe Event or Problem** field of the **Narrative** tab.

```
<table>
<thead>
<tr>
<th>Describe Event or Problem:</th>
</tr>
</thead>
<tbody>
<tr>
<td>This is the area in which you should describe the adverse event</td>
</tr>
</tbody>
</table>
```

- Relevant tests/lab data – including dates – captured in the **Relevant Test & Laboratory Data** section of the Labs & History tab.

```
<table>
<thead>
<tr>
<th>Priority</th>
<th>Type</th>
<th>Test</th>
<th>Date</th>
<th>Result</th>
<th>Normal Range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Lab</td>
<td>Blood</td>
<td>2/7/2005</td>
<td>Low iron</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>20-50</td>
</tr>
</tbody>
</table>
```

- Other relevant history, including preexisting medical conditions – captured in the **Other Relevant History including Pre-Existing Medical Conditions** section of the Labs & History tab.

```
<table>
<thead>
<tr>
<th>Priority</th>
<th>Date</th>
<th>History</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1/1/2003</td>
<td>High cholesterol</td>
</tr>
</tbody>
</table>
```
Section C. Suspect Medication(s)

- Name – captured in the **Name** fields of the Medications tab.
- Dose, frequency, and route used – captured in the **Dose Unit**, **Frequency**, and **Route** fields of the Medications tab.
- Therapy dates – captured in the **Start Date** and **Stop Date** fields of the Medications tab.
- Diagnosis for use – captured in the **Indication** field of the Medications tab.
- Event abated after use stopped or dose reduced – captured in the **DeChallenge** field of the Medications tab.
- Lot # – including dates – captured in the **Lot #** field of the Medications tab.
- Exp. Date – captured in the **Exp. Date** field of the Medications tab.
- Event reappeared after re-introduction – captured in the **ReChallenge** field of the Medications tab.
- NDC# - captured in the **NDC #** field of the Medications tab.

- Concomitant medical products and therapy dates – captured in the **Name** field and **Route** field in the Concomitant Medication(s) section of the Medications tab.
Section G. All Manufacturers

- **Contact Office** - captured in the Product Manufacturer table. The Product Manufacturer is defined in the Product table. If a Product Manufacturer is not defined in the Product table, the 3500A information entered in the **Adverse Events** tab in **Division Parameters** is used.

- **Phone Number** - captured in the Product Manufacturer table. The Product Manufacturer is defined in the Product table. If a Product Manufacturer is not defined in the Product table, the 3500A information entered in the **Adverse Events** tab in **Division Parameters** is used.
Periodic Reports

- Report Source – captured in the **Report Source** section of the **Demographic** tab.

  ![Report Source](image)

- Date received by manufacturer – captured in the **Receipt Date** field of the **Demographic** tab.

  ![Receipt Date](image)

- IND#, PLA#, pre 1938, OTC Product – captured in the **Demographic** tab.

  ![Demographic](image)

- Protocol # – captured in the **Demographic** tab.

  ![IND #](image)

- Type of report – captured in the **Reportability** field of the **Demographic** tab and the **Activity Type** field of the **Causality & Case Review Comments** section of the **Comments** tab. (The default for the 3500A is set to “Initial Report” as of IRMS Version 5.5.7.)

  ![Reportability](image)

- Adverse Event term(s) – captured in the **Preferred Term** column of the **MedDRA** field on the **Adverse Events** tab.

  ![Adverse Events](image)

- Mfr. Report number – captured at the top of all of the tabs in the **Report Number** field.

  ![Report Number](image)
Section E. Initial Reporter

- Name & address and phone # – captured in the Initial Reporter field in the Demographic tab. The address and phone number are captured in the Case Entry Contact section of IRMS.


- Occupation – captured in the Occupation field of the Demographic tab.

- Initial reporter also sent report to FDA – captured in the Filed with FDA field of the Demographic tab.
### Sample of the 3500A Form

**Periodic Reports**

#### United States

For use by user facilities, distributors, and manufacturers for MANDATORY reporting Part I of 2

**FDA Passignii Approval 12-As**

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. Initial Information</td>
<td></td>
</tr>
<tr>
<td>1. Patient identifier (e.g., name, age, gender, date of birth)</td>
<td></td>
</tr>
<tr>
<td>2. Date of event</td>
<td></td>
</tr>
<tr>
<td>3. Date of first report</td>
<td></td>
</tr>
<tr>
<td>B. Adverse event or reportable problem</td>
<td></td>
</tr>
<tr>
<td>1. Name (give related strength &amp; route of admin., if known)</td>
<td>Omnipur Cures everything.</td>
</tr>
<tr>
<td>2. Dose, frequency &amp; route used</td>
<td></td>
</tr>
<tr>
<td>3. Any problem will be cured.</td>
<td></td>
</tr>
<tr>
<td>4. Lot/Serial No. (if known)</td>
<td></td>
</tr>
<tr>
<td>5. Exp. date (if known)</td>
<td></td>
</tr>
<tr>
<td>6. Event reported after use stopped or dose reduced</td>
<td></td>
</tr>
<tr>
<td>7. Event reported after reintroduction</td>
<td></td>
</tr>
<tr>
<td>8. NDC (for product only if known)</td>
<td></td>
</tr>
<tr>
<td>C. Suspect medication(s)</td>
<td></td>
</tr>
<tr>
<td>1. Name (give related strength &amp; route of admin., if known)</td>
<td>Omnipur Cures everything.</td>
</tr>
<tr>
<td>2. Dose, frequency &amp; route used</td>
<td></td>
</tr>
<tr>
<td>3. Any problem will be cured.</td>
<td></td>
</tr>
<tr>
<td>4. Lot/Serial No. (if known)</td>
<td></td>
</tr>
<tr>
<td>5. Exp. date (if known)</td>
<td></td>
</tr>
<tr>
<td>6. Event reported after use stopped or dose reduced</td>
<td></td>
</tr>
<tr>
<td>7. Event reported after reintroduction</td>
<td></td>
</tr>
<tr>
<td>8. NDC (for product only if known)</td>
<td></td>
</tr>
<tr>
<td>D. All manufacturers</td>
<td></td>
</tr>
<tr>
<td>1. Contact office - name/address &amp; missing item for decision</td>
<td></td>
</tr>
<tr>
<td>2. Test Company Address</td>
<td></td>
</tr>
<tr>
<td>3. United States</td>
<td></td>
</tr>
<tr>
<td>E. Initial report</td>
<td></td>
</tr>
<tr>
<td>1. Name &amp; address</td>
<td></td>
</tr>
<tr>
<td>2. Phone number</td>
<td></td>
</tr>
<tr>
<td>3. Initial reporter also used report to FDA</td>
<td></td>
</tr>
</tbody>
</table>

#### Details of the Event

- **Blood Test - Low Iron - Date 2/2005**
- **1/1/2003 - High cholesterol**

#### Other Relevant History

- Including medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, immunosuppression, etc.)

---

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

Overview

The CIOMS is submitted in countries outside the United States for an adverse events involving suspected drugs. The system populates the CIOMS Report with data from the Adverse Events tabs and provides the ability to submit the form to the proper reporting agency.

Below is an explanation of the CIOMS Report. To explain the CIOMS Report, each section of the form is separated followed by an explanation of where the data is located in the Adverse Events module.

The Appendix contains a map of the fields in IRMS with the corresponding fields on the CIOMS Report.

If an adverse event is non-serious, the case is printed as part of the PSUR report that is submitted either quarterly or annually.

Header Section

♦ Report Number – captured in the Header information on the Demographic tab. The information is displayed on every tab.
Section I. Reaction Information

- (1) Patient Initials – captured in the Demographic tab.
- (1a) Country – captured in the Country of Occurrence on the Demographic tab.
- (2) Date of Birth – captured in Date of Birth on the Demographic tab.
- (2a) Age – captured in Age at Time of Event on the Demographic tab.
- (3) Sex – captured in Gender on the Demographic tab.
- (3a) Weight – Captured on the Demographic tab.
- (4 – 6) Reaction Onset – captured in Start Date on the Events tab.
- (8 – 12) Check all appropriate to Adverse Reaction – captured in Serious Criter section on the Events tab.
- (7 – 13) Describe Reaction(s) – captured Describe Event or Problem on the Narrative tab.
Section II. Suspect Drug(s) Information

- (14) Suspect Drug(s) – captured in Name on the Suspect Meds tab.
- (15) Daily Dose(s) – captured in Daily Dose on the Suspect Meds tab.
- (16) Route(s) of Administration – captured in Route on the Suspect Meds tab.
- (17) Indication(s) for use – captured in Indication on the Suspect Meds tab.
- (18) Therapy Dates – captured in the Start and Stop Dates on the Suspect Meds tab.
- (19) Therapy Duration – captured in Duration on the Suspect Meds tab.
- (20) Did Reaction Abate After Stopping Drug – captured in DeChallenge on the Suspect Meds tab.
- (21) Did Reaction Reappear After Reintroduction – captured in ReChallenge on the Suspect Meds tab.

Section III. Concomitant Drug(s) and History

- (22) Concomitant Drugs & Date of Administration – captured in Start and Stop Dates on the Con Meds tab.
- (23) Other Relevant History – captured in the Other Relevant History Including Pre-existing Medical Conditions section on the Labs & Hist tab.
Section IV. Manufacturer Information

- (24) Name and Address of Manufacturer – captured in the Company field in Product Maintenance. If no company is selected, the company defined in the Adverse Events tab in Division Parameters is printed.

- (24b) Mfr Control No. – captured in the Report No in the Header section on each tab.

- (24c) Date Received by MFG – captured in Initial Receipt Date in the Header section on each tab.


- (25a) Report Type – captured in Report Type on the Demographic tab.

- (25b) Name and Address of Reporter – captured in the Contact section on the Case Entry window and selected in the Name field in the Initial Reporter section on the Demographic tab. The Occupation is captured in Occupation in the Initial Report section on the Demographic tab.

  **Note:** If the Occupation is “Patient” or “Consumer” and the PI Security is set to “Visible”, then “NAME AND ADDRESS WITHHELD” is printed in this box. If the Occupation is “Patient” or “Consumer” and the PI Security is set to “Hidden”, then “PERSONALLY IDENTIFIABLE INO WITHHELD” is printed in this box.

- Date of this report – captured in Last Receipt Date on the Demographic tab.

- (26) Remarks – captured in the third Client Data field on the Hospital/Client Data tab.
Section VI – Event Information

**Event Information**

- Event – captured in the Preferred Terms on the Events tab.
- SOC – captured in System on the Events tab.
- Outcome – captured in Outcome on the Events tab.
- Severity – captured in Severity on the Events tab.
- Seriousness – captured in Serious on the Events tab. Serious applies specifically to this event.
- Onset Date – captured in Start Date on the Events tab.
- Resolved Date – captured in Stop Date on the Events tab.
- Duration – captured in Duration on the Events tab.

**Relation To Information**

- Action Taken: - captured in Action Taken in the Product Assessed section on the Events tab.
- AE reappeared: - captured in ReChallenge in the Product Assessed section on the Events tab.
- Causality Per Reporter: - captured in Result in the Causality section on the Events tab.
- Latency (First Dose): - captured in Latency (First Dose) on the Events tab.
- Latency (Last Dose): - captured in Latency (Last Dose) on the Events tab.
### Sample of the CIOMS Form

**CIOMS FORM**

**US10-000003**

#### I. REACTION INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient Initials</td>
<td>(First, last)</td>
</tr>
<tr>
<td>Ex. Country</td>
<td>CA</td>
</tr>
<tr>
<td>Date of Birth</td>
<td>Day 15, Month Jun, Year 1984</td>
</tr>
<tr>
<td>Age</td>
<td>25 Female</td>
</tr>
<tr>
<td>Reaction Onset</td>
<td>Day 20, Month Aug, Year 2009</td>
</tr>
</tbody>
</table>

7-13. Describe Reaction(s) (including relevant tests/lab data): Sinus [Abdominal pain upper]

#### II. SUSPECT DRUG(S) INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Suspect Drugs</td>
<td>Chenzac (Chenzac Happy Formula)</td>
</tr>
<tr>
<td>Daily Dose</td>
<td>1000 mg</td>
</tr>
<tr>
<td>Route(s) of Administration</td>
<td>PO, OD</td>
</tr>
</tbody>
</table>

#### III. CONCOMITANT DRUG(S) AND HISTORY

22. Concomitant Drug(s) and Dates of Administration (exclude those used to treat reaction): No information

#### IV. MANUFACTURER INFORMATION

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name and Address of Manufacturer</td>
<td>Joan Scott, 1011 State Street, Lemont, Illinois, 60439, US</td>
</tr>
<tr>
<td>MFR Control No.</td>
<td>US10-000003</td>
</tr>
<tr>
<td>Date Received by Manufacturer</td>
<td>21/5/2010</td>
</tr>
<tr>
<td>Date of this Report</td>
<td>15-Feb-10</td>
</tr>
</tbody>
</table>

#### Report Source

- [ ] Study
- [x] Literature
- [ ] Health Professional
- [ ] Other

Report Type:
- [x] Initial
- [ ] Follow up

Date of this Report: 15-Feb-10

**CIOMS Example Report**

Version 5.8.4.2
MDR Form

Overview

The MDR Report is submitted in countries outside the United States for adverse events involving suspected devices. The system populates the MDR form with data from the Adverse Events tabs and provides the ability to submit the form to the reporting agency.

Below is an explanation of the MDR Report. To explain the MDR Report, each section of the form is separated followed by an explanation of where the data is located in the Adverse Events module.

The Appendix contains a map of the fields in IRMS with the corresponding fields on the MDR Report.

If an adverse event is non-serious, the report is submitted either quarterly or annually as part of the PSUR Reports.

Header Information

- Report Number – captured in the Header information on the Demographic tab. The information is displayed on every tab.
General Information

1. Preliminary Mandatory Report 10-Day _____ 30-Day _____
   Update to Mandatory Report _____
   Final Mandatory Report _____
   Voluntary Report _____
2. Name of Reporter: {last name} {first name} _____
3. Manufacturer _____ Importer _____ Distributor _____ User _____
4. Institution/Company: {organization name} _____
5. Address: {street address} _____
6. Postal Code/Zip Code: {zip code} _____
7. Telephone: {phone number} _____
8. Fax: {fax number} _____
9. Contact Person (if Different from reporter): _____
10. Problem Reported to: Manufacturer _____ Importer _____ Distributor _____
11. Where was the device purchased?: _____
12. Address: _____
13. Is the Device available for evaluation?  Yes [X] No _____
14. Date of Problem Occurrence (Y/M/D): 2009/02/01
15. Manufacturer/Importer Awareness Date(Y/M/D): 2009/03/15

- (2.) Name of Reporter – captured in the Contact section on the Case Entry window and selected in the Name field in the Initial Reporter section on the Demographic tab.
- (3.) Manufacturer, Reporter, Distributor or User – captured in the Report Source section on the Demographic tab.
- (4.) Institution/Company – captured in the Contact section in Case Entry and selected in Company Name in the Initial Reporter section on the Demographic tab.
- (5.) Address – captured in the Contact section in Case Entry and the selected in Company Name in the Initial Reporter section on the Demographic tab.
- (6.) Postal Code/Zip Code – captured in the Contact section in Case Entry and selected in the Name field in the Initial Reporter section on the Demographic tab.
- (7.) Telephone: – captured in the Contact section in Case Entry and selected in the Name field in the Initial Reporter section on the Demographic tab.
- (8.) Fax: – captured in the Contact section in Case Entry and selected in the Name field in the Initial Reporter section on the Demographic tab.
- (9.) Contact Person (if Different from reporter): – captured in Attention in the Contact section in Case Entry and selected in the Name field in the Initial Reporter section on the Demographic tab.
- (10.) Problem Reported to: Manufacturer, Importer, or Distributor – captured in the Event Reported To section on the Device tab.
- (11.) Where was the device purchased?: - captured in Purchased From on the Device tab.
- (12.) Address: - captured in Address (below Purchased From) on the Device tab.

(14.) Date of Problem Occurrence (Y/M/D): - captured in Event Start Date in the Header section on the Demographic tab.

(15.) Manufacturer/Importer Awareness Date (Y/M/D): - captured in MFR/Importer Aware Date on the Device tab.

**Medical Device Information**

<table>
<thead>
<tr>
<th>Medical Device Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>16. Trade Name: <strong>Knee Stainless Steel Small™</strong></td>
</tr>
<tr>
<td>17. Manufacturer Medical Device Identifier (catalogue/model #)</td>
</tr>
<tr>
<td>18. Control/Lot/Serial#: / 1005 / 10251</td>
</tr>
<tr>
<td>19. Device License Number:</td>
</tr>
<tr>
<td>20. Age of Device:</td>
</tr>
<tr>
<td>21. Software Version:</td>
</tr>
<tr>
<td>22. Was the device labeled as sterile? Yes ___ No ____</td>
</tr>
</tbody>
</table>

(16.) Trade Name – captured in Brand Name on the Device tab.

(17.) Manufacturer Medical Device Identifier (catalogue/model #) – captured in Identifier # on the Device tab.

(18.) Control/Lot/Serial#: – captured in the Control #, Lot #, and Serial # on the Device tab.

(19.) Device License Number: – captured in License # on the Device tab.

(20.) Age of Device: – captured in Device Age on the Device tab.


(22.) Was the device labeled as sterile? – captured in the Labeled Sterile checkbox on the Device tab.

**Manufacturer Information**

If this is a mandatory report from the Importer, fields 23 through 28 will be printed. If this is a mandatory report from the Manufacturer, only field 28 will be printed because the information for fields 23 through 27 is printed in fields 4 through 8.

<table>
<thead>
<tr>
<th>23. Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>24. Address:</td>
</tr>
<tr>
<td>25. Postal Code/Zip Code:</td>
</tr>
<tr>
<td>26. Telephone:</td>
</tr>
<tr>
<td>27. Fax:</td>
</tr>
<tr>
<td>28. Establishment License Number (if applicable): MFG12385513</td>
</tr>
</tbody>
</table>

If the Facility/Importer (Company Name) name is blank, and a Product Manufacturer is selected in the Product Master, then the name and address information in the Product Manufacturer is printed. If a manufacturer is selected from one of the Contacts entered in the Contact section in Case Entry, then the contact information is printed.

(23.) Manufacturer – captured in the First and Last Name fields in the Contact section in Case Entry and selected in the Reprocessor field on the Device tab or Company Name in the Product Manufacturer Master.
(24.) Address – captured in the Address field in the Contact section in Case Entry or Address in the Product Manufacturer Master.

(25.) Postal Code/Zip Code – captured in the Zip/Postal field in the Contact section in Case Entry or Postal in the Product Manufacturer Master.

(26.) Telephone – captured in the Phone field in the Contact section in Case Entry or Phone in the Product Manufacturer Master.

(27.) Fax – captured in the Fax field in the Contact section in Case Entry or Fax in the Product Manufacturer Master.

(28.) Establishment License Number (if applicable): – captured in Manufacturer Est License # on the Device tab.

**Importer Information**

If this is a mandatory report from the Manufacturer, fields 29 through 34 will be printed. If this is a mandatory report from the Importer, only field 34 will be printed because the information for fields 29 through 33 is printed in fields 4 through 8.

<table>
<thead>
<tr>
<th>Field</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>29. Importer</td>
<td>OBA Surgical Hospital</td>
</tr>
<tr>
<td>30. Address</td>
<td>9018 Heritage Parkway Woodridge IL</td>
</tr>
<tr>
<td>31. Postal Code/Zip Code</td>
<td>60517</td>
</tr>
<tr>
<td>32. Telephone</td>
<td>(444) 555-6666</td>
</tr>
<tr>
<td>33. Fax</td>
<td>(777) 888-9991</td>
</tr>
<tr>
<td>34. Establishment License Number (if applicable)</td>
<td>IMP31231</td>
</tr>
</tbody>
</table>

If the Facility/Importer Name is blank, then no information is printed. If the Facility/Importer Name is selected from one of the Contacts entered in the Contact section in Case Entry, then the contact information is printed.

(29.) Importer – captured in the First and Last Name fields in the Contact section in Case Entry and selected in the Facility/Importer Name on the Device tab.

(30.) Address – captured in the Address field in the Contact section in Case Entry.

(31.) Postal Code/Zip Code – captured in the Zip/Postal field in the Contact section in Case Entry.

(32.) Telephone – captured in the Phone field in the Contact section in Case Entry.

(33.) Fax – captured in the Fax field in the Contact section in Case Entry.

(34.) Establishment License Number (if applicable): – captured in Importer Est License # on the Device tab.
Name of Report to Manufacturer/Importer Information

- (35.) Reporter to Manufacturer: – captured in the First and Last Name fields in the Contact section in Case Entry and selected in the Event Report To section on the Device tab.
- (36.) Address – captured in the Address field in the Contact section in Case Entry.
- (37.) Postal Code/Zip Code – captured in the Zip/Postal field in the Contact section in Case Entry.
- (38.) Telephone – captured in the Phone field in the Contact section in Case Entry.
- (39.) Fax – captured in the Fax field in the Contact section in Case Entry.
- (40.) Signature and Date is handwritten by the user submitting the report.

Product Description Information

- (41.) Details of incident including consequences to patient, user or other person, and description of other devices or accessories involved in the incident: – captured in Describe Event or Problem on the Narrative tab.
- (42.) Manufacturer’s preliminary comments: – captured in the Manufacturer Preliminary field on the Device tab.
- (43.) Course of action proposed – captured in Course of Action Proposed on the Device tab.
Sample of the MDR Form

Health Products and Food Branch Inspectorate
Medical Devices Problem Report Form

Reported File Number: US09-000003
This area for HPFB office use only - Incident ID:

General Information
1. Preliminary Mandatory Report 10-Day _____ 30-Day _____
   Update to Mandatory Report _____
   Final Mandatory Report _____
   Voluntary Report
2. Name of Reporter: Harriah Herne
3. Manufacturer: Distributor: User:
4. Institution/Company: OBA Medical Specialties
5. Address: 9018 Heritage Way
   Suite 600 Room 1435
   Woodbridge, ON
7. Telephone: (111) 222-3333
8. Fax: (777) 888-9999
9. Contact Person (if different from reporter):
10. Problem Reported to: Manufacturer: Importer: Distributor:
11. Where was the device purchased?
12. Address:
13. Is the Device available for evaluation? Yes X No
14. Date of Problem Occurrence (Y/M/D): 2009/02/01
15. Manufacturer/Importer Awareness Date (Y/M/D): 2009/03/15

Medical Device Information
16. Trade Name: Knee Stainless Steel Small
17. Manufacturer/Device Identifier (catalogue/model #)
18. Control/Lot/Serial #: 1005 / 10251
19. Device License Number:
20. Age of Device:
21. Software Version:
22. Was the device labeled as sterile? Yes ___ No ___

23. Manufacturer
24. Address:
25. Postal Code/Zip Code:
26. Telephone:
27. Fax:
28. Establishment License Number (if applicable): MFG12385513

29. Importer: OBA Surgical Hospital
30. Address: 9018 Heritage Parkway
   Woodbridge, ON
31. Postal Code/Zip Code: 60517
32. Telephone: (444) 555-5666
33. Fax: (777) 888-9991
34. Establishment License Number (if applicable): MFG123131

25. Name of Reporter to Manufacturer/Importer:
26. Address:
27. Postal Code:
28. Telephone:
29. Fax:
30. Signature:

40. This problem report has been submitted by: Date (Y/M/D):

Problem Description:
41. Details of incident including consequences to patient, user or other person, and description of other devices or accessories involved in the incident.
   The caller states that the knee is stiff after the knee replacement. The patient does not have the range of motion expected.
42. Manufacturer's preliminary comments:
   The knee joint seems stiff because the tendons have not had a chance to fully work with the knee. The knee joint works as expected.
43. Course of action proposed including timetable for investigation and submission of final report:
   Additional Physical Therapy is recommended for the patient.
PERIODIC AND PSUR REPORTING

Overview

The Periodic Report is submitted in the United States for all adverse events involving drugs and devices. The Periodic Report allows the user to select the Reporting Agency, Reporting Period and Global Product. The report includes serious and non-serious adverse events.

If the adverse event is serious, and the 3500A reports have been submitted, the counts are included in the listing and tabulation reports.

If an adverse event is non-serious, the counts are included when the Periodic Reports are created.

Preparing for Periodic and PSUR Reporting

The following options should be reviewed prior to processing the first Periodic Reports. An explanation of these options is included in the System Administration and Setup chapter in this guide. The parameters and fields are listed below.

- **Division Parameters**
  “Keep a Record of all Changes (Required for AE Reporting)” checkbox in the Change Control/Logging Rules on the General tab of Division Parameters. Verify that this checkbox is selected. For additional information, go to the General Tab section.

- **Product Maintenance**
  Verify that a Global Product is assigned to the product.
  Verify that a manufacturer is entered in the Company field.
  Check the Approval Date(s) section in Product Maintenance. Verify that the Reporting Agency, Drug Authorization Number, and Seriousness is defined for the drug being selected. Select the Seriousness button to define the Days to Report for Seriousness.
  For additional information, go to the Product Maintenance section on page 33.

- **Shift Maintenance**
  Verify that a Notify shift has been setup for “AE – Periodic Rpts Created” and “AE – Reports Due”.
  For additional information, go to the Shift Maintenance section on page 35.

- **Reporting Agency**
  Define the Reporting Agency that will receive the report. For example, the Food and Drug Administration. Verify that the appropriate reports are selected for the agency. Verify that a Grace Period is selected if necessary and a Notification Shift is assigned.
  For additional information, go to the Reporting Agency Maintenance section on page 38.
Automatically Submitted Periodic and PSUR Reports

The Periodic and PSUR Reports can be created automatically or manually. The process described above creates the Regulatory Reports manually with the user initiating the report. Reports that are automatically generated use the Task Scheduler to initially create the report. Below are step-by-step instructions on how to setup a Regulatory Report to process automatically.

Preliminary Setup

The preliminary setup includes the steps outlined in Preparing for Periodic and PSUR Reporting on page 134.

In addition, a batch job must be setup in the Task Scheduler using the following command:

“C:\PROGRAM FILES\MICROSOFT ACCESS\RUNTIME\OFFICE10\MSACCESS.EXE”

“C:\IRMS5NET_58\IrmsProg/mde”/cmd”BuildPeriodic” (Client File Path)

Automated Periodic and PSUR Report Process

1. Setup a batch job in the Task Scheduler to execute the Periodic Reports.
2. When the batch job automatically executes, the following processes occur.
   ◊ The Listing and Tabulation Reports for the product(s) within the due date period are emailed to the users defined in the “Notify” Shift for “AE – Periodic Rpts Created”. If a Grace Period is defined for the Reporting Agency, the Listing and Tabulation reports are sent that number of days prior to the report’s due date.
   ◊ The Status of the Periodic or PSUR Report is set to “Pending”
3. The user navigates to the appropriate Periodic or PSUR Report window and completes the Cover Page, Cover Letter, Table of Contents, and Narratives for the report.
4. After the report tabs are completed, the user changes the Status to “Approved”.
5. When the report has been approved, the user submits the Periodic or PSUR Report from the Periodic Reports window. The Submitted Date and Location of the report are populated on the Periodic Report window.

Issues Affecting Automatic Report Creation

♦ If a Periodic Report has been created manually and the Status is “Open”, the Listing and Tabulation reports are sent to the users defined in the Notification List when the due date has occurred. If a Grace Period is defined, the reports are sent the number ahead.

♦ If a Periodic Report has been created manually and the Status is “Pending”, no email is automatically sent to the user(s) in the Notification List. The user needs to complete the additions and changes to the report. Any 3500As that have not been submitted, should be processed from the Periodic Reports menu. When the report is ready, the user should change the Status to “Approved” prior to submitting the report.

♦ If a Periodic Report has been created manually and the Status is “Approved”, the complete Periodic or PSUR Report is sent to the user(s) defined in the Notification List. The Listing and Tabulation reports are included. When the report is complete, the user needs to submit the report.
PERIODIC REPORT

Step 1 – Initiate a Periodic Report

The same window is used to generate the Periodic and the PSUR Report. Below is an explanation of how to generate a Periodic Report.

1. To access the Periodic Reports, click **Periodic Reports** from the **Reports** menu. The **Product** tab on the Periodic Reports window is displayed.

   ![Periodic Report window](image)

   The Agency, Global Product, and Previous fields must be selected to find the data and proceed with the report.

Selecting Information on the Left Panel

- **Agency**
Select a Reporting Agency from the pick list. The Reporting Agency is defined in the Reporting Agency Table and in the Approval Dates section in the Product table.

- **Global Product**
Select the Global Product from the pick list. Once the Global Product is selected, the existing reports are displayed in the **Previous** section. The Global Product is defined in the **General** option on the **Tables** menu in the “Global Product” table and in the **Product** table.

- **Previous**
Double-click one of the report dates from the Previous list. Once a date is selected, the bottom half of the left panel is automatically populated with the existing information and becomes active.

Once the above information is populated, the **Cover Page**, **Cover Letter**, **Table of Contents**, and **Narrative(s)** tabs are activated. These tabs are explained in the steps below. The **Find/List** toolbar button is also displayed. Review the additional fields below prior to continuing.
Entering Selection Criteria on the Left Panel

- **Date From**
The Date From is automatically populated from the selections above. All adverse event cases starting with date are selected. If necessary, change the from date or click the Calendar Control button to select a different date.

- **Date To**
The Date To is automatically populated from the selection above. All adverse event cases prior to and including this date are selected. If necessary, change the to date or click the Calendar Control button to select a different date.

- **Calculate Page Numbers**
This checkbox is used when 3500As are printed and included in the Periodic Report. Select the checkbox to automatically calculate the page number for each 3500A Report. For example, if there are six reports and the total number of pages is 15, the 3500A Reports will print 1 of 15 through 15 of 15 on the final page. If this box is not selected, then the Restart Page Numbers checkbox should be selected.

- **Restart Page Numbers**
This checkbox is used when 3500As are printed and included in the Periodic Report. Select the checkbox to restart the page numbering for each 3500A Report. For example, if there are six reports and the total number of pages is 15, then each 3500A Report will print the total number of pages for that report. The next report will start over at page 1 and print the total number of pages for that report. If this box is not selected, then the Calculate Page Numbers checkbox should be selected.

- **List Foreign Non-Expedited Reports**
Indicates the adverse event cases from foreign countries for the product selected should be included in the report.

- **List Follow-up? And List Non-Medically Confirmed? Cases**
These options are used with the PSUR Report and are not used in the Periodic Report.

- **Status**
This is the overall status of a Periodic Report. When a Periodic report is created, the Status defaults to “Open”. From “Open”, the report is changed to “Pending”, “Approved” and “Completed”. Below is an explanation of the values for Status.

  - **Open** – Indicates that the Periodic Report for the period has been created. Once the report is created, change the status to “Pending” for additional review by the appropriate users.

  - **Pending** – Indicates that the Periodic Report is currently being reviewed and updated by the appropriate users. Each tab should be reviewed and populated with the appropriate information. Once the information is correct, change the status to “Approved”.

  - **Approved** – Indicates that the Periodic Report has been approved and is ready to be submitted. Once the information is correct, submit the report and change the status to “Completed”.

  - **Completed** – Indicates that the Periodic Report has been submitted and the report is completed. Once the report is submitted, the Submitted fields area updated with the date the report was submitted and location of the Periodic Report.
Step 2 – Create Cover Page

The Cover Page tab defines the information that is printed on the first page of the Periodic Report.

1. Click the **Cover Page** tab. The Cover Page window is displayed.

![Cover Page Window](image)

Some of the information is automatically populated from a previous report that was created. The information in each of the fields may need to be updated. The information entered in this window is printed on the Cover Page of the Periodic Report.

**Entering or Changing Information on the Cover Page Tab**

Enter or change the information for the Cover Page.

- **Product**
  If the product is blank, enter the product of the adverse event cases included in the report.

- **Include with Report?**
  Select this checkbox to print this page in the Periodic Report. Deselect the checkbox to exclude this page from the Periodic Report.

- **Title**
  Enter or change the Title of the report.

- **Date From**
  Enter or change the From Date for the adverse event cases included in the report.

- **Date To**
  Enter or change the To Date for the adverse event cases included in the report.

- **DAN**
  Enter or change the Drug Authorization Number for the product in the report.
**Author**
Select the author of the report from the pick list.

**Type**
Enter or change the Type of report (Report value should be “Quarterly” or “Annual”).

**Status**
Enter or change the product status of the drug. The Product Status is defined in the Product Master.

**Release Date**
Enter or change the date this report will be released.

**Disclosure**
Enter or change the disclosure statement for this report.
Step 3 – Create Cover Letter

The Cover Letter tab defines the information that is incorporated into the Cover Letter of the Periodic Report.

1. Click the Cover Letter tab. The Cover Letter window is displayed.

Entering Information on the Cover Letter Tab

- **Report Date**
  Enter the date to print on the Periodic Report.

- **Include with Report?**
  Select this checkbox to print this page in the Periodic Report. Deselect the checkbox to exclude this page from the Periodic Report.

- **Mailing Address**
  Enter the mailing address of the organization receiving the report.

- **Body**
  Enter the text to be included in the body of the letter.

- **Signature**
  Select the signature from the pick list of the person signing the report. This signature will be incorporated in the cover letter.
## Step 4 – Create Table of Contents

The Table of Contents tab defines the information that is incorporated into the Cover Letter of the Periodic Report.

1. Click the **Table of Contents** tab. The Table of Contents window is displayed.

![Periodic Reports - Table of Contents](image)

**Entering Information on the Table of Contents Tab**

- **Number of Pages in Pre-Printed Package Insert**
  If a pre-printed insert is included with the report, enter the number of pages of the insert. The paging will automatically be adjusted for the insert.

- **Include with Report?**
  Select this checkbox to print this page in the Periodic Report. Deselect the checkbox to exclude this page from the Periodic Report.

**Table of Contents Entries**

This section defines the entries for the Table of Contents. Multiple entries can be created. The number of entries is displayed at the bottom of the window on the navigation bar. The entries will be incorporated into the Table of Contents page.

- **Section**
  Enter the section number for this entry.

- **Description**
  Enter a description or title for this section.

- **Page**
  Enter the number of pages for this section.
Step 5 – Create Narratives

1. Click the **Narrative(s)** tab. The Narratives window is displayed.

![Periodic Reports - Narrative(s) Information](image)

**Entering Information on the Narratives Tab**

- **Section**
  Select the section number to be updated. The narrative is automatically populated with a default value that can be modified.

- **Force New Page?**
  Select this checkbox to force a new page when printing the section. Deselect the checkbox to continue printing where the previous section ended.

**Section Entries**

This section defines the information for the sections. After selecting a Section, additional information can be entered.

- **Caption**
  The Caption is automatically populated based on the section selected. Enter or change the caption as needed.

- **Narrative**
  The Narrative is automatically populated based on the section selected. Enter or change the Narrative as needed.

2. Repeat entering the **Caption** and **Narrative** information for each section.
Step 6 – Preview the Periodic Reports

Once the information is selected and the remaining tabs are populated, the report is ready for processing. This section explains how to view the different reports that comprise the Periodic Report.

1. To select the cases for the report, click the **Find/List** toolbar button. The Adverse Event cases that meet the criteria are displayed in the window.

   ![Periodic Report Window with Selected Cases for the Periodic Report](image)

   The remaining toolbar buttons are now active. The Listing, Tabulation, and Periodic Report can be previewed.

   If no reports are due within the Agency, Product and Date criteria selected, the following message is displayed.

   ![Find/List has completed, but no reports are due within the Agency/Product/Date criteria.](image)

   Click **OK** to return to the Periodic Reports window. The **Preview Periodic**, **Submit Periodic**, and **View Periodic** toolbar buttons are active. The Listing and Tabulation Reports are not available.

   **Preview Periodic Report Listing**

   Select the Listing toolbar button to preview the Listing report.

   2. To preview the Listing, click the **Listing** toolbar button. The **Index of Domestic Non-Expedited Reports** and **Index of Domestic Non-Expedited Reports** is displayed. Minimize the first report to view the second report.
3. The reports can be printed, saved, or emailed by using the toolbar buttons. Below is a brief explanation of the \textbf{Print}, \textbf{Save} and \textbf{Email} toolbar buttons.

- To print the report, select the \textbf{Print} toolbar button.
- To email the report, click \textbf{Email As} and then select either \textit{PDF}, \textit{Rich Text (RTF)}, or \textit{Snapshot (SNP)}.
- To save the report, click \textbf{Save As} and then select either Excel, \textit{PDF}, \textit{Rich Text (RTF)}, or \textit{Snapshot (SNP)}, or \textit{Text (TXT)}.

4. Click the \textbf{Close} toolbar button to exit the report window. The \textbf{Periodic Report} window is displayed.

\textbf{Periodic Report Listing Example:}

\begin{center}
\includegraphics[width=\textwidth]{Periodic_Report_Example.png}
\end{center}

\textit{Preview Periodic Report Tabulation}

Select the Tabulation toolbar button to preview the Tabulation report.

1. To preview the Tabulation Report, click the \textbf{Tabulation} toolbar button. The \textbf{Tabulation by Body System of All Events Reported} is displayed.

2. The report can be printed, saved, or emailed by using the toolbar buttons. Below is a brief explanation of the \textbf{Print}, \textbf{Save} and \textbf{Email} toolbar buttons.

- To print the report, select the \textbf{Print} toolbar button.
- To email the report, click \textbf{Email As} and then select either \textit{PDF}, \textit{Rich Text (RTF)}, or \textit{Snapshot (SNP)}.
- To save the report, click \textbf{Save As} and then select either Excel, \textit{PDF}, \textit{Rich Text (RTF)}, or \textit{Snapshot (SNP)}, or \textit{Text (TXT)}. 

3. Click the Close toolbar button to exit the report window. The Periodic Report window is displayed.

Periodic Report Tabulation Example.

<table>
<thead>
<tr>
<th>Body System of All Events Reported</th>
<th>Severe</th>
<th>Serious</th>
<th>Non-Serious</th>
<th>Total Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Source: Internal Medicine</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

Abdominal pain upper

1 0 0 1

Periodic Report Tabulation Example Version 5.8.4.2
**Preview Periodic Report**

Prior to submitting the Periodic Report, the report can be viewed or printed for final review.

1. To preview the Periodic Report, click the **Preview Periodic** toolbar button. The **Periodic Report** is displayed. Included in the report are the Cover Page, Cover Letter, Table of Contents, Narratives, Listing, and Tabulation Reports. The Cover Page, Cover Letter, Table of Contents, and Narratives are defined on the tabs on the Periodic Reports window.

2. The report can be printed, saved, or emailed by using the toolbar buttons. Below is a brief explanation of the **Print**, **Save** and **Email** toolbar buttons.
   - To print the report, select the **Print** toolbar button.
   - To email the report, click **Email As** and then select either **PDF**, **Rich Text (RTF)**, or **Snapshot (SNP)**.
   - To save the report, click **Save As** and then select either Excel, **PDF**, **Rich Text (RTF)**, or **Snapshot (SNP)**, or **Text (TXT)**.

3. Click the **Close** toolbar button to exit the report window. The **Periodic Report** window is displayed.

**Print 3500A's**

Select the Print 3500s toolbar button to print the 3500As that are included in this Periodic Report. Once the 3500As are printed, the reports can be reviewed prior to printing and submitting the Periodic Report.

1. To print the 3500As, click the **Print 3500As** toolbar button. The 3500As are printed to the user's default printer.
Step 7 – Submit the Periodic Report

The last step in processing the Periodic Report is submitting the report. The steps below explain how to submit the Periodic Report.

Prior to submitting the Periodic Report, a Notification Shift must be setup with Resources assigned. The Notify Shift must also be defined in the Reporting Agency Table.

1. Navigate to the Periodic Reports. Populate the Product tab as specified in Periodic Report
2. **Step 1 – Initiate a** Periodic Report on page 136.
3. Click the **Find/List** toolbar button to select the Adverse Event cases that meet the criteria. The product window is displayed with the adverse event cases.

<table>
<thead>
<tr>
<th>Report Number</th>
<th>Ver</th>
<th>Date</th>
<th>Case Number</th>
<th>Initial Reporter</th>
</tr>
</thead>
<tbody>
<tr>
<td>US10-000001</td>
<td>1</td>
<td>13-Mar-09</td>
<td>US09-000003</td>
<td>Tammy Sammy</td>
</tr>
<tr>
<td>US10-000003</td>
<td>1</td>
<td>20-Aug-09</td>
<td>US09-000009</td>
<td>Stella Della</td>
</tr>
</tbody>
</table>

**Periodic Report Selected Sample Cases** Version 5.8.4.2

4. Click the **Submit Periodic** toolbar button. The Periodic Report is submitted for processing and a PDF is created. When the report is complete, a completed message window is displayed.

Click **OK**. The message window is closed and the **Periodic Report** window is displayed.

Once the report is submitted, the **Status** is changed to “Completed” and the **Submitted** fields are updated with the Date and Location of the Periodic Report.

5. Click the **Close** toolbar button to exit the Periodic Reports and return to the IRMS Main Menu.
Viewing Submitted Periodic Reports

1. Click Periodic Reports from the Reports menu. Populate the Product tab as specified in Periodic Report.

2. **Step 1 – Initiate a** Periodic Report on page 136. If a report has been submitted, the Status is “Completed” and the Submitted fields are populated with the Submitted Date and Submitted File Location.

<table>
<thead>
<tr>
<th>Status</th>
<th>Submitted</th>
<th>Submitted Date</th>
<th>Submitted File Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Completed</td>
<td>2/5/2010</td>
<td>20090101-20100131-Periodic.pdf</td>
<td></td>
</tr>
</tbody>
</table>

3. To display the report, click the View Periodic toolbar button. The Periodic Report is displayed in a PDF format.

4. To exit from the Report, click X.

5. To exit from the Periodic Reports, click Close.
## Toolbar for Processing Periodic Reports

The following is an explanation of the toolbar buttons for processing the Periodic Reports.

<table>
<thead>
<tr>
<th>Button</th>
<th>Explanation and Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Find/List</td>
<td>Searches and lists the Adverse Event cases meeting the criteria for the Periodic Report.</td>
</tr>
<tr>
<td>Listing</td>
<td>Previews a Periodic Listing that can be printed or saved as a file.</td>
</tr>
<tr>
<td>Tabulation</td>
<td>Previews a Periodic Tabulation report that can be printed or saved as a file.</td>
</tr>
<tr>
<td>Preview Periodic</td>
<td>Previews the Periodic Report.</td>
</tr>
<tr>
<td>Print 3500A's</td>
<td>Prints the 3500As that meet the criteria for the Periodic Report.</td>
</tr>
<tr>
<td>Submit Periodic</td>
<td>Submits the Periodic Report using the criteria selected.</td>
</tr>
<tr>
<td>View Periodic</td>
<td>Previews the previously submitted Periodic Report.</td>
</tr>
<tr>
<td>Close</td>
<td>Closes the Periodic Reports window.</td>
</tr>
</tbody>
</table>
PSUR REPORT

Overview

The PSUR Report is submitted in Canada and Europe to the appropriate regulatory agency for all adverse events involving drugs. The Periodic Report window allows the user to populate the information for the PSUR Report. The serious and non-serious adverse events are included where appropriate.

If the adverse event is serious, and the CIOMS reports have been submitted, the counts are included in the listing and tabulation reports.

If an adverse event is non-serious, the counts are included in the listing and tabulation reports when the PSUR Report is created.

Preparing for PSUR Reporting

The following options should be reviewed prior to processing the first PSUR Reports. An explanation of these options is included in the System Administration and Setup chapter in this guide. The parameters and fields are listed below.

- **Division Parameters**
  “Keep a Record of all Changes (Required for AE Reporting)” checkbox in the Change Control/Logging Rules on the General tab of Division Parameters. Verify that this checkbox is selected. For additional information, go to the General Tab section.

- **Product Maintenance**
  Verify that a Global Product is assigned to the product.
  Verify that a Manufacturer is entered in the Company field.
  Check the Approval Date(s) section in Product Maintenance. Verify that the Reporting Agency, Drug Authorization Number, and Seriousness is defined for the drug being selected. Select the Seriousness button to define the Days to Report for Seriousness.
  For additional information, go to the Product Maintenance section on page 33.

- **Shift Maintenance**
  Verify that a Notify shift has been setup for “AE – Periodic Rpts Created” and “AE – Reports Due”.
  For additional information, go to the Shift Maintenance section on page 35.

- **Reporting Agency**
  Define the Reporting Agency that will receive the report. For example, Health Canada.
  Verify that the appropriate reports are selected for the agency. Verify that a Grace Period is selected if necessary and a Notification Shift is assigned.
  For additional information, go to the Reporting Agency Maintenance section on page 38.
Overview Steps for Processing PSUR Reports

The PSUR Reports can be created automatically or manually. Below is an overview of what happens if a report is manually or automatically created.

**Note:** Any CIOMS reports that are due, but have not been submitted are not included in the PSUR Report.

### No Manual Report Created

- If a manual report has not been created, the listing and tabulation report for all the cases for the product due in that period is sent to the users defined in the “AE Report Due” Notification list defined in Shift Maintenance. If a Grace Period is defined for the Reporting Agency, the listing and tabulation reports are sent that number of days prior to the report’s due date.

### Manual Report Created

- If a PSUR Report has been created manually and the Status is “Open”, the listing and tabulation report are sent to the users defined in the Notification List when the due date has occurred. If a Grace Period is defined, the reports are sent the number ahead.

- If a PSUR Report has been created manually and the Status is “Pending”, no e-mail is automatically sent to the user(s) in the Notification List. The user needs to complete the additional changes to the report. When the report is ready, the user should change the Status to “Approved” prior to submitting the report.

- If a PSUR Report has been created manually and the Status is “Approved”, the complete PSUR Report is sent to the user(s) defined in the Notification List. The listing and tabulation reports are included. When the report is complete, the user needs to submit the report.
PSUR Report Processing

Step 1 – Initiate a PSUR Report:

1. To access the Periodic Reports, Periodic Reports from the Reports menu. The Product tab is displayed. The tabs used to create a PSUR Report at the same as those for creating a Periodic Report. Please refer to the appropriate section for information on how to populate the following tabs. The Product window has a couple of additional parameters not used in the Periodic Report. Those parameters are explained below.

Entering the Information for the Product Tab

Below is an explanation for the fields specific to the PSUR report. For additional information about the other fields, refer to Periodic Report

Step 1 – Initiate a Periodic Report on page 136 in this guide.

Calculate Page Number, Restart Page Number, and List Foreign Non-Expeditied
These checkboxes are not available for the PSUR report. The fields are dimmed and cannot be selected.

List Follow-ups?
This checkbox indicates that Follow-up reports will be included in the report. Select this checkbox to include the Follow-up Reports in the PSUR.

List Non-medically Confirmed?
This checkbox indicates that adverse event cases that are not medically confirmed will be included in the PSUR Report. A case is medically confirmed if the Medically Confirmed? checkbox is selected on the Demographic tab in Adverse Events. Select this checkbox to include the non-medically confirmed cases.
Step 2 – Create a PSUR Cover Page

The Cover Page tab defines the information that is printed on the first page of the PSUR Report.

1. Click the Cover Page tab. The Cover Page window is displayed.

Enter the information for the cover page. The information entered in this window is printed on the Cover Page of the PSUR Report. For additional information about the cover page fields, refer to Step 2 – Create Cover Page on page 138 in this guide.
Step 3 – Create the PSUR Cover Letter

The Cover Letter tab defines the information that is incorporated into the Cover Letter of the PSUR Report.

1. Click the Cover Letter tab. The Cover Letter window is displayed.

Enter the information for the cover letter. The information entered in this window is printed on the Cover Letter of the PSUR Report. For additional information about the cover page fields, refer to Step 3 – Create Cover Letter on page 140 in this guide.
Step 4 – Create PSUR Table of Contents

The Table of Contents tab defines the information that is incorporated into the Cover Letter of the Periodic Report.

1. Click the **Table of Contents** tab. The Table of Contents window is displayed.

Enter the information for the table of contents. The information entered in this window is printed on the Cover Letter of the PSUR Report. For additional information about the cover page fields, refer to **Step 4 – Create Table of Contents** Step 3 – Create Cover Letter on page 141 in this guide.
Step 5 – Create PSUR Narratives

1. Click the **Narrative(s)** tab. The Narratives window is displayed.

Enter the information for the table of contents. The information entered in this window is printed on the Cover Letter of the PSUR Report. For additional information about the cover page fields, refer to **Step 5 – Create Narratives** Step 3 – Create Cover Letter on page 142 in this guide.
Step 6 – Preview the PSUR Reports

Once the information is selected and the remaining tabs are populated, the report is ready for processing. This section explains how to view the different reports that comprise the PSUR Report.

1. To select the cases for the report, click the Find/List toolbar button. The Adverse Event cases meeting the criteria are displayed in the window.

The remaining toolbar buttons are now active. The Listing, Tabulation, and PSUR Report can be previewed.

If no reports are due within the Agency, Product and Date criteria selected, the following message is displayed.

Click OK to return to the Periodic Reports window. The Preview PSUR, Submit PSUR, and View PSUR toolbar buttons are active. The Listing and Tabulation Reports are not available.

**Preview Listing Report**

Select the Listing toolbar button to preview the Listing report.

2. To preview the Listing, click the Listing toolbar button. The Listing previews Medically Confirmed and Non-Medically Confirmed cases for the following Report Types: Spontaneous, Regulatory, Study, Literature, and Other.

3. The reports can be printed, saved, or emailed by using the toolbar buttons. Below is a brief explanation of the Print, Save and Email toolbar buttons.
To print the report, select the **Print** toolbar button.

To email the report, click **Email As** and then select either **PDF**, **Rich Text (RTF)**, or **Snapshot (SNP)**.

To save the report, click **Save As** and then select either **Excel**, **PDF**, **Rich Text (RTF)**, or **Snapshot (SNP)**, or **Text (TXT)**.

4. Click the **Close** toolbar button to exit the report window. The **Periodic Report** window is displayed.
PSUR Report Listing Example.

Preview Tabulation Report

Select the Tabulation toolbar button to preview the Tabulation report.

1. To preview the Tabulation Report, click the Tabulation toolbar button. The Tabulation by Body System of All Events Reported is displayed.

2. The report can be printed, saved, or emailed by using the toolbar buttons. Below is a brief explanation of the Print, Save and Email toolbar buttons.
   - To print the report, select the Print toolbar button.
   - To email the report, click Email As and then select either PDF, Rich Text (RTF), or Snapshot (SNP).
   - To save the report, click Save As and then select either Excel, PDF, Rich Text (RTF), or Snapshot (SNP), or Text (TXT).

3. Click the Close toolbar button to exit the report window. The Periodic Report window is displayed.

PSUR Tabulation Example.
Preview PSUR Report

Prior to submitting the PSUR Report, the report can be viewed or printed for final review.

1. To preview the PSUR Report, click the Preview PSUR toolbar button. The PSUR Report is displayed. Included in the report are the Cover Page, Cover Letter, Table of Contents, Narratives, Listing, and Tabulation Reports. The Cover Page, Cover Letter, Table of Contents, and Narratives are defined on the tabs on the Periodic Reports window.

2. The report can be printed, saved, or emailed by using the toolbar buttons. Below is a brief explanation of the Print, Save and Email toolbar buttons.
   - To print the report, select the Print toolbar button.
   - To email the report, click Email As and then select either PDF, Rich Text (RTF), or Snapshot (SNP).
   - To save the report, click Save As and then select either Excel, PDF, Rich Text (RTF), or Snapshot (SNP), or Text (TXT).

3. Click the Close toolbar button to exit the report window. The Periodic Report window is displayed.
Step 7 – Submit the PSUR Report

The last step in processing the PSUR Report is submitting the report. The steps below explain how to submit the PSUR Report.

Prior to submitting the PSUR Report, a Notification Shift must be setup with Resources assigned. The Notify Shift must also be defined in the Reporting Agency Table.

1. Navigate to the Periodic Reports. Populate the Product tab as specified in Periodic Report.
3. Click the Find/List toolbar button to select the Adverse Event cases that meet the criteria. The product window is displayed with the adverse event cases.

<table>
<thead>
<tr>
<th>Report Number</th>
<th>Ver</th>
<th>Date</th>
<th>Case Number</th>
<th>Initial Reporter</th>
</tr>
</thead>
<tbody>
<tr>
<td>US10-000001</td>
<td>1</td>
<td>13-Mar-09</td>
<td>US09-000003</td>
<td>Tammy Sammy</td>
</tr>
<tr>
<td>US10-000003</td>
<td>1</td>
<td>20-Aug-09</td>
<td>US09-000009</td>
<td>Stella Della</td>
</tr>
</tbody>
</table>

Periodic Report Selected Sample Cases

4. Click the Submit PSUR toolbar button. The PSUR Report is submitted for processing and a pdf is created. When the report is complete, a completed message window is displayed.

Click OK. The message window is closed and the PSUR Report window is displayed.

Once the report is submitted, the Status is changed to “Completed” and the Submitted fields are updated with the Date and Location of the PSUR Report.

5. Click the Close toolbar button to exit the Periodic Reports and return to the IRMS Main Menu.
Viewing Submitted PSUR Reports

1. Click Periodic Reports from the Reports menu. Populate the Product tab as specified in Step 1 – Initiate a Periodic Report on page 136. If a report has been submitted, the Status is “Completed” and the Submitted fields are populated with the Submitted Date and Submitted File Location as shown below.

   ![Image of status and submitted fields]

2. To display the report, click the View PSUR toolbar button. The PSUR Report is displayed in a pdf format.

3. To exit from the PSUR Reports, click X to exit from the pdf.

4. To exit from the Periodic Reports, click Close.
**Toolbar for Processing PSUR Reports**

The following is an explanation of the toolbar buttons for processing the PSUR Reports:

<table>
<thead>
<tr>
<th>Button</th>
<th>Explanation and Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Find/List</strong></td>
<td>Searches and lists the Adverse Event cases meeting the criteria for the Periodic Report</td>
</tr>
<tr>
<td><strong>Listing</strong></td>
<td>Previews a PSUR Listing report that can be printed or saved as a file.</td>
</tr>
<tr>
<td><strong>Tabulation</strong></td>
<td>Previews a PSUR Tabulation report that can be printed or saved as a file.</td>
</tr>
<tr>
<td><strong>Preview PSUR</strong></td>
<td>Displays a preview of the PSUR Report including the Cover Page, Cover Letter, Table of Contents, Narratives, Listing, and Tabulation reports.</td>
</tr>
<tr>
<td><strong>Submit PSUR</strong></td>
<td>Submits the PSUR Report</td>
</tr>
<tr>
<td><strong>View PSUR</strong></td>
<td>Previews a copy of a PSUR Report that was previously submitted.</td>
</tr>
<tr>
<td><strong>Close</strong></td>
<td>Closes the PSUR Reports window.</td>
</tr>
</tbody>
</table>
Chapter 6  IRMS E2B Interface

Overview

The Adverse Events module provides the ability to create an E2B file that can be transmitted to a different Safety Reporting system.

An international standard is used in creating the Individual Case Safety Report (ICSR) that is platform, application, and vendor independent. The file is created using the guidelines published in “Data Elements for Transmission of Individual Case Safety Reports” by the ICH E2B Expert Working Group. This guideline standardizes the data elements for the transmission of ICSRs by identifying and defining the data elements for the transmission of all types of ICSRs, regardless of source and destination. This includes case safety reports for both pre- and post-approval periods and covers both adverse drug reaction and adverse event (AE) reports.

The E2B features include the following functionality:

- Create an E2B file for an Individual Case Safety Report
- Create a transaction record in the Case Log when an E2B file is created

Reasons to Use the E2B functionality

- Create Individual Case Safety Reports for transmission to a different Case Safety Reporting System

Prerequisites (Cautions) Prior to using the E2B Functionality

- The person creating E2B files must be granted access to the Adverse Event module and rights to generate E2B files.
- The following Division Parameters should be reviewed prior to exporting E2B files for the first time. The parameters are defined in the Other tab in Division Parameters.
  - E2B_ForceDestination
  - E2B.IncludeCompanyNumb
  - E2B.IncludeTransmissionDate
  - E2B.MessageReceiverIdentifier
  - E2B.ReceiverDepartment
  - E2B.ReceiverOrganization
  - E2B.SenderDepartment
  - E2B.SenderOrganization
Create an E2B Transmission File

To create an E2B Transmission file, a case with an adverse event must first be entered.

There is specific information that is required before a file can be created. The minimum information required is explained below.

Some of the data that can be entered into IRMS will be truncated to meet the E2B requirements for the field. Those fields are also identified.

There is also a list containing the values that will be submitted for specific fields.

Below is the list of validation that will be performed when exporting the E2B file.

♦ User is warned when non-essential fields contain invalid data. (For example, Gender is not “Male” or “Female”.)
♦ If Patient Height and Weight are not populated, the user is warned and the fields are not exported.
♦ The user is warned if the Suspected Medication Drug Authorization Number is truncated.
♦ The user is warned of unacceptable Outcome values.
♦ The User is warned if Patient Birth Date and Death Date contain invalid data.

Below are the steps to create the file.

Enter a Case in Case Entry

1. To access the Case Entry screen, click Case Entry from the Main Menu. Capture any Contact information regarding the reporter of the Adverse Event. (Additional contact information may also be required for the doctor, hospital, and device manufacturer.) For additional information about entering a case, refer to “Creating a Case” section in the IRMS User Guide.

2. Enter Question and Response information.

3. Enter any other basic case information.

Enter an Adverse Event

1. To access Adverse Events, click the toolbar button or click the button in Case Entry. The Adverse Event window is displayed with the Demographic tab.

2. Click in each tab and enter any available information. Enter drug information in the Suspect Meds and Con Meds window. Enter device information in the Device and Manufacturers window. For additional information on entering adverse events, refer to Processing Steps for Entering an Adverse Event section in the Entering Adverse Events chapter.

Create an E2B File

1. To create an E2B file for an ICSR, click the Export (E2BM) button. The following processes are run to verify that the minimum information is available and the data meets the criteria for an E2B file.

Verify that the minimum required information is available
Minimum Case Information Required:

♦ One identifiable patient
♦ One identifiable reporter (Patient and Reporter can be the same person)
♦ One reaction or event
♦ One Suspected drug

Minimum Administration Information Required

♦ Sender’s unique case safety report number (AE Report Number)
♦ Receipt Date of the most recent information (AE Receipt Date)
♦ Unique worldwide case identification number (AE Report Number)
♦ Sender’s identifier number

If the minimum information required to create an E2B is not available, the following warning is displayed.

2. If this window is displayed, click “Yes” to continue and create a case safety report without the information. Click “No” to return to Adverse Events.

Verify that IRMS fields will not be truncated.

The length of some IRMS fields is more than allowed in the E2B format. If an IRMS field is longer than is allowed, a warning message is displayed.

The following field values may be truncated when generating the E2B file.

<table>
<thead>
<tr>
<th>IRMS Field Names</th>
<th>IRMS Field Length</th>
<th>E2B Data Length</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identifier</td>
<td>20</td>
<td>10</td>
</tr>
<tr>
<td>Contact Title</td>
<td>100</td>
<td>50</td>
</tr>
<tr>
<td>Contact Company</td>
<td>100</td>
<td>60</td>
</tr>
<tr>
<td>Contact Dept</td>
<td>128</td>
<td>60</td>
</tr>
<tr>
<td>Contact Address</td>
<td>255</td>
<td>100</td>
</tr>
<tr>
<td>Contact City</td>
<td>50</td>
<td>35</td>
</tr>
<tr>
<td>Describe Event or Problem</td>
<td>Long</td>
<td>2000</td>
</tr>
<tr>
<td>Product</td>
<td>100</td>
<td>70</td>
</tr>
<tr>
<td>Lot#</td>
<td>50</td>
<td>35</td>
</tr>
</tbody>
</table>
If the IRMS Field is too long for the E2B file, the following warning is displayed.

![E2B Warning Message for Truncated Fields](image)

3. If this window is displayed, click “Yes” to continue and truncate the data. Click “No” to return to Adverse Events.

**Restricted Values for Some Fields in the E2B File**

The values of certain IRMS fields with pick lists are limited to a defined set of values to facilitate the data transfer in the E2B format. The table in Appendix D – Restricted Field Values summarizes the field names and the allowed values.

**System Verification complete**

After the system has completed the verification process, the user is prompted to enter an Export File Name as shown.

![E2B Export File Name Window](image)

4. Enter a File name for the exported file in the **File name** field and click **Select**. An XML file is created and the window is closed.

   To change the location of the exported file, browse to locate the appropriate folder.

The E2B file has been created and the process is completed.
### Verify Message Header Information

The message header information will be populated with the following information: A couple of the values are defined in the Division Parameters as indicated.

<table>
<thead>
<tr>
<th>E2B Field Name</th>
<th>E2B Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>messagetype</td>
<td>“ichicsr”</td>
</tr>
<tr>
<td>messageformatversion</td>
<td>“2.1”</td>
</tr>
<tr>
<td>messageformatrelease</td>
<td>“2.0”</td>
</tr>
<tr>
<td>messagenumb</td>
<td>The message number is a unique tracking number assigned via a new E2BM-Sequence sequence record in Sequence Table Maintenance.</td>
</tr>
<tr>
<td>messagesenderidentifier</td>
<td>“IRMS”</td>
</tr>
<tr>
<td>messagereceiveridentifier</td>
<td>Defined in E2B_MessageRecieverIdentifier in Division Parameters. Default is “AE Software”</td>
</tr>
<tr>
<td>messagedate</td>
<td>The E2B file created date.</td>
</tr>
<tr>
<td>safetyreportid</td>
<td>AE Report Number</td>
</tr>
<tr>
<td>receiptdate</td>
<td>AE Receipt Date</td>
</tr>
<tr>
<td>senderorganization</td>
<td>Defined in E2B_SenderOrganization in Division Parameters. Default is “Internal”</td>
</tr>
</tbody>
</table>
Chapter 7   Appendixes

A  Adverse Event Field Definitions
B  Periodic Report Flowchart
C  Restricted Field Values for E2B
D  E2B Process Flowchart
E  3500A Report – Data Map of IRMS Fields
F  CIOMS Report – Data Map of IRMS Fields
G  Medical Device Report – Data Map of IRMS Fields
## Appendix A

### Adverse Event Field Definitions

Below are definitions for the Adverse Event fields.

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Definition</th>
<th>Screen Name</th>
<th>Table Maintenance</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Action Result</strong></td>
<td>Indicates if the reaction or event was reduced or eliminated when the drug was stopped. (Dechallenge)</td>
<td>Events tab</td>
<td>Tables Menu – General – Adverse Event DeChallenge</td>
</tr>
<tr>
<td><strong>Action Taken</strong></td>
<td>The action taken to reduce or eliminate the reaction or adverse event.</td>
<td>Events tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Admission Date</strong></td>
<td>The date the patient was admitted to the hospital for the adverse event.</td>
<td>Hospital/ Client Data tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Age at Time of Event</strong></td>
<td>The patient’s age at the time of the adverse event calculated from the Birth Date to the Start Date.</td>
<td>Demographic tab</td>
<td>n/a</td>
</tr>
<tr>
<td><strong>Age Category</strong></td>
<td>The group the patient belongs to if the specific age is not known.</td>
<td>Demographic tab</td>
<td>Tables Menu – General – Adverse Event Age Category</td>
</tr>
<tr>
<td><strong>Agency</strong></td>
<td>The Reporting Agency for the regulatory report defined in Product Maintenance.</td>
<td>Regulatory tab</td>
<td>Fixed Pick List</td>
</tr>
<tr>
<td><strong>Autopsy Date</strong></td>
<td>Indicates the date the autopsy was performed.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Autopsy Performed?</strong></td>
<td>Indicates an autopsy was performed. (Yes/No/NR)</td>
<td>Demographic tab</td>
<td>Fixed Pick List</td>
</tr>
<tr>
<td><strong>Available for Evaluation</strong></td>
<td>Indicates the device is available for evaluation.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Available for Evaluation Date</strong></td>
<td>The date the device was returned to the manufacturer for evaluation.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Brand Name</strong></td>
<td>The trade or proprietary name of the suspected medical device as used in labeling.</td>
<td>Device tab</td>
<td>Tables Menu – Product – Product Maintenance</td>
</tr>
<tr>
<td><strong>Case No. (Header)</strong></td>
<td>The number assigned to the Medical Information case created in Case Entry.</td>
<td>Header Information All Tabs</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Catalog #</strong></td>
<td>The exact Catalog Number as it appears in the manufacturer’s catalog, device label, or packaging.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Causality – Method</strong></td>
<td>The type of causality assessment used to determine relatedness to the drug to the adverse event.</td>
<td>Events tab</td>
<td>Tables Menu – General – Adverse Event Causality Method</td>
</tr>
<tr>
<td><strong>Causality – Result</strong></td>
<td>The conclusion of the relatedness of the drug to the adverse event.</td>
<td>Events tab</td>
<td>Tables Menu – General – Adverse Event Causality Result</td>
</tr>
<tr>
<td><strong>Causality – Source</strong></td>
<td>The type of reporter assessing the relatedness of the drug to the adverse event.</td>
<td>Events tab</td>
<td>Tables Menu – General – Adverse Event Causality Source</td>
</tr>
<tr>
<td><strong>Cause of Death</strong></td>
<td>The reason the patient died as a result of the adverse event.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Field Name</td>
<td>Definition</td>
<td>Screen Name</td>
<td>Table Maintenance</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>----------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td><strong>Client Data – Date Information</strong></td>
<td>The field for date information as assigned in the Client Data fields.</td>
<td>Hospital/Client Data</td>
<td></td>
</tr>
<tr>
<td><strong>Client Data - Numeric Data</strong></td>
<td>The field for numeric information as assigned in the Client Data fields.</td>
<td>Hospital/Client Data</td>
<td></td>
</tr>
<tr>
<td><strong>Client Data – Text Information</strong></td>
<td>The field for text information as assigned in the Client Data fields.</td>
<td>Hospital/Client Data</td>
<td></td>
</tr>
<tr>
<td><strong>Client Data – Y/N Indicator</strong></td>
<td>The field to indicate a Yes/No response as assigned in the Client Data fields.</td>
<td>Hospital/Client Data</td>
<td></td>
</tr>
<tr>
<td><strong>Client Data Field Name</strong></td>
<td>The name of field assigned by the customer used to capture additional adverse event information. Only displayed is Client Data fields are created.</td>
<td>Hospital/Client Data</td>
<td>System Menu – Division Parameters – Adverse Event Tab</td>
</tr>
<tr>
<td><strong>Combo</strong></td>
<td>Indicates the product is a combination of both a drug and device. Used for products classified as a Drug-Device, Drug-Biological, Device-Biological, or Drug-Device-Biological.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Comments</strong></td>
<td>Description of the activity to be performed to review the case.</td>
<td>Comments tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Control #</strong></td>
<td>The Control Number as it appears on the device label or packaging material.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Correction/Removal #</strong></td>
<td>The number assigned if the suspected device was corrected or removed.</td>
<td>Manufacturers tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Country of Occurrence</strong></td>
<td>Identifies the country where the adverse event occurred.</td>
<td>Demographic tab</td>
<td>Tables Menu – General – States and Provinces</td>
</tr>
<tr>
<td><strong>Daily Dose</strong></td>
<td>The total amount of concomitant medication taken in a 24 hour period.</td>
<td>Con Meds tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Daily Dose</strong></td>
<td>The total amount of suspected medication taken in a 24 hour period.</td>
<td>Suspect Meds tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>DAN</strong></td>
<td>The Drug Authorization Number assigned by the Regulatory Agency.</td>
<td>Suspect Meds tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Date</strong></td>
<td>Date the comment was entered for this adverse event case.</td>
<td>Comments tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Date</strong></td>
<td>The date the test or lab work given to the patient.</td>
<td>Labs &amp; Hist tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Date of Birth</strong></td>
<td>The patient’s date of birth.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Date of Death</strong></td>
<td>The date the patient died as a result of the adverse event.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Days</strong></td>
<td>The number of days before the report is due. Defined by the Report.</td>
<td>Regulatory tab</td>
<td>Fixed Pick List</td>
</tr>
<tr>
<td><strong>DeChallenge</strong></td>
<td>Indicates if the reaction or event was reduced or eliminated when the concomitant drug was stopped.</td>
<td>Con Meds tab</td>
<td>Tables Menu – General – Adverse Event DeChallenge</td>
</tr>
<tr>
<td><strong>DeChallenge</strong></td>
<td>Indicates if the reaction or event was reduced or eliminated when the suspected medication was stopped.</td>
<td>Suspect Meds tab</td>
<td>Tables Menu – General – Adverse Event DeChallenge</td>
</tr>
<tr>
<td>Field Name</td>
<td>Definition</td>
<td>Screen Name</td>
<td>Table Maintenance</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>-------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Describe Event or Problem</td>
<td>A detailed event using the reporter’s own words, including a description of what happened and a summary of the relevant clinical information. If available and relevant, include a synopsis of any office visit notes or the hospital discharge summary.</td>
<td>Narrative tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Device Age</td>
<td>The age of the device in months or years including the time the device was used.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Discharge Date</td>
<td>The date that the patient was discharged from the hospital for the adverse event,</td>
<td>Hospital/Client Data tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Dose Form</td>
<td>The form of the concomitant medication (tablet, capsule, syrup, patch, etc).</td>
<td>Con Meds tab</td>
<td>Tables Menu – General – Dose Form</td>
</tr>
<tr>
<td>Dose Form</td>
<td>The form of the suspected medication (tablet, capsule, syrup, patch, etc).</td>
<td>Suspect Meds tab</td>
<td>Tables Menu – General – Dose Form</td>
</tr>
<tr>
<td>Dose Unit</td>
<td>The individual dosing unit of the concomitant medication (250 mg, 50 cc, etc).</td>
<td>Con Meds tab</td>
<td>Tables Menu – General – Dose Unit</td>
</tr>
<tr>
<td>Dose Unit</td>
<td>The individual dosing unit of the suspected medication (250 mg, 50 cc, etc).</td>
<td>Suspect Medications tab</td>
<td>Tables Menu – General – Dose Unit</td>
</tr>
<tr>
<td>Due Date</td>
<td>The date the regulatory is due.</td>
<td>Regulatory tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Duration</td>
<td>The time interval from the Start Date through the Stop Date the concomitant medication was administered.</td>
<td>Con Meds tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Duration</td>
<td>The time interval of the reaction or event from the Start Date through the Stop Date for the event.</td>
<td>Events tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Duration</td>
<td>The time interval from the Start Date through the Stop Date the suspected medication was administered.</td>
<td>Suspect Meds tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Emergency Room?</td>
<td>Indicates the Adverse Event resulted in a visit to the Emergency Room.</td>
<td>Hospital/Client Data</td>
<td>N/A</td>
</tr>
<tr>
<td>End Date (Header)</td>
<td>The actual or best estimate of the date the adverse event subsided.</td>
<td>Header Information All Tabs</td>
<td>N/A</td>
</tr>
<tr>
<td>Evaluated by Manufacturer</td>
<td>Indicates if the suspected device was evaluated by the manufacturer. (Evaluation Summary Attached, Not Returned to Manufacturer, or Yes)</td>
<td>Manufacturers tab</td>
<td>Fixed Pick List</td>
</tr>
<tr>
<td>Event Location</td>
<td>The name of the location where the device was used. (Ambulatory Surgical Facility, Home, Hospital, Nursing Home, Outpatient Diagnostic Facility, or Outpatient Treatment Facility)</td>
<td>Device tab</td>
<td>Fixed Pick List</td>
</tr>
<tr>
<td>Event Problem Codes – Device*</td>
<td>The event code for the device.</td>
<td>Manufacturers tab</td>
<td>Tables Menu – FDA Device Report Codes – Device Type</td>
</tr>
<tr>
<td>Event Problem Codes – Patient</td>
<td>The event code for the patient.</td>
<td>Manufacturers tab</td>
<td>Tables Menu – FDA Device Report Codes – Patient Type</td>
</tr>
<tr>
<td>Field Name</td>
<td>Definition</td>
<td>Screen Name</td>
<td>Table Maintenance</td>
</tr>
<tr>
<td>----------------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>----------------------</td>
<td>----------------------------</td>
</tr>
<tr>
<td>Event Reported To</td>
<td>Indicates who the adverse event was reported to.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>◦ Manufacturer</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Importer</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Distributor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Event Start Date (Header)</td>
<td>The actual or best estimate of the date of the first onset of the adverse event.</td>
<td>Header Information</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>All Tabs</td>
<td></td>
</tr>
<tr>
<td>Event Type</td>
<td>The type of event that occurred as a result of using the suspected device.</td>
<td>Manufacturers tab</td>
<td>Fixed Pick List</td>
</tr>
<tr>
<td></td>
<td>(Death, Malfunction, or Serious Injury)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Exp. Date</td>
<td>The expiration date on the label for the concomitant medication.</td>
<td>Con Meds tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Exp. Date (Suspect Medication)</td>
<td>The expiration date on the label for the suspected medication.</td>
<td>Suspect Medications tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Expiration Date#</td>
<td>The date the suspected device can no longer be used or implanted into a patient.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Expplant Date#</td>
<td>The date the suspected device was removed into the patient.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Facility/Importer Name</td>
<td>The name of the user facility or importer (distributor) using the suspected device. Entered in the Contact Section in Case Entry.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td>File Location</td>
<td>The location of the PDF file after the regulatory report is submitted.</td>
<td>Regulatory tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Filed with Agency</td>
<td>Indicates this adverse event was already filed with a Reporting Agency. (Yes/No)</td>
<td>Demographic tab</td>
<td>n/a</td>
</tr>
<tr>
<td>Filed with Agency Date</td>
<td>If a report was filed, identifies when the report was filed with the Reporting Agency.</td>
<td>Demographic tab</td>
<td>n/a</td>
</tr>
<tr>
<td>Filed with Manufacturer</td>
<td>Indicates this adverse event was already filed with the manufacturer. (Yes/No)</td>
<td>Demographic tab</td>
<td>n/a</td>
</tr>
<tr>
<td>Filed with Manufacturer Date</td>
<td>If a report was filed, identifies when the report was filed with the manufacturer.</td>
<td>Demographic tab</td>
<td>n/a</td>
</tr>
<tr>
<td>Follow-Up Type</td>
<td>Indicates the type of follow-up needed to prevent a recurrence of the event. The values are:</td>
<td>Manufacturers tab</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>◦ Response to FDA Request</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Device Evaluation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Additional Information</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Correction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency</td>
<td>The number of times the concomitant medication was administered within a specific period of time. (once a day, once a week)</td>
<td>Con Meds tab</td>
<td>Tables Menu – General – Adverse Event Frequency</td>
</tr>
<tr>
<td>Field Name</td>
<td>Definition</td>
<td>Screen Name</td>
<td>Table Maintenance</td>
</tr>
<tr>
<td>----------------------------</td>
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<td>---------------------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Frequency</td>
<td>The number of times the suspected medication was administered within a specific period of time. (once a day, once a week)</td>
<td>Suspect Meds tab</td>
<td>Tables Menu – General – Adverse Event Frequency</td>
</tr>
<tr>
<td>Gender</td>
<td>Identifies the gender of the patient.</td>
<td>Demographic tab</td>
<td>Tables Menu – General – Adverse Event Gender</td>
</tr>
<tr>
<td>Health Professional?</td>
<td>Identifies the Initial Reporter as a health professional.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Height</td>
<td>The height of the patient in inches or centimeters.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Height - Cm</td>
<td>Indicates the height is in centimeters.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Height - In</td>
<td>Indicates the height is in inches.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td>History</td>
<td>The disease, surgical procedure, allergy, or any other relevant historical information about the patient.</td>
<td>Labs &amp; Hist tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Hospital</td>
<td>The name of the hospital the patient received care from. Entered in the Contact Section in Case Entry</td>
<td>Hospital/ Client Data tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Identifier</td>
<td>A unique number or text used to identify the patient other than the patient’s name or social security number. (patients initials)</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Identifier #</td>
<td>The Identifier Number as it appears on the device label or packaging material.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Implant Date</td>
<td>The date the suspected device was implanted into the patient.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Importer Est License #</td>
<td>The importer’s establishment license number for the suspected device.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td>IND #</td>
<td>The Investigational New Drug application number.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Indication</td>
<td>The symptom the concomitant medication was used for.</td>
<td>Con Meds tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Indication</td>
<td>The symptom the suspected medication was used for.</td>
<td>Suspect Meds tab</td>
<td>Tables Menu – Product – Product Maintenance</td>
</tr>
<tr>
<td>Initial Receipt Date (Header)</td>
<td>The date the Adverse Event Report was received.</td>
<td>Header Information All Tabs</td>
<td>N/A</td>
</tr>
<tr>
<td>Labeled for Single Use</td>
<td>Indicates the device was labeled for a single use.</td>
<td>Manufacturers tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Labeled Sterile</td>
<td>Indicates the device was labeled as sterile.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Labeling: Agency</td>
<td>The Reporting Agency such as the FDA or Health Canada who will receive the regulatory report. Reporting Agency is assigned in Product Maintenance.</td>
<td>Events tab</td>
<td>Tables Menu – Reporting Agency</td>
</tr>
<tr>
<td>Labeling: Labeled</td>
<td>Indicates the term was included in the drug label information as a potential side effect.</td>
<td>Events tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Field Name</td>
<td>Definition</td>
<td>Screen Name</td>
<td>Table Maintenance</td>
</tr>
<tr>
<td>------------</td>
<td>------------</td>
<td>------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td><strong>Last Receipt Date (Header)</strong></td>
<td>The date the Adverse Event Report was last updated.</td>
<td>Header Information All Tabs</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Latency (First Dose)</strong></td>
<td>The time duration from the start of the drug to the start of the reaction. (Event Start Date – Suspected Med Start Date)</td>
<td>Events tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Latency (Last Dose)</strong></td>
<td>The time duration from the end of the drug to the start of the reaction. (Event Start Date – Suspected Med Stop Date)</td>
<td>Events tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Length of Stay in ER</strong></td>
<td>The length of time the patient was in the Emergency Room</td>
<td>Hospital/Client Data</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>License #</strong></td>
<td>The License Number as it appears on the label or packaging material.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Lot #</strong></td>
<td>The Lot or Batch number from the concomitant medication container.</td>
<td>Con Meds tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Lot #</strong></td>
<td>The Lot Number as it appears on the label or packaging material.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Lot #</strong></td>
<td>The Lot or Batch number from the suspected medication container.</td>
<td>Suspect Meds tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Manufacturer Date</strong></td>
<td>The date the suspected device was manufactured.</td>
<td>Manufacturers tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Manufacturer Est License #</strong></td>
<td>The manufacturer’s establishment license number for the device.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Manufacturer Narrative</strong></td>
<td>Indicates the type of narrative being sent. The values are: ◦ Additional Narrative ◦ Corrected Narrative</td>
<td>Manufacturers tab</td>
<td>Tables Menu– FDA Device Report Codes – Method Type</td>
</tr>
<tr>
<td><strong>Manufacturer Narrative Text</strong></td>
<td>The narrative from the manufacturer.</td>
<td>Manufacturers tab</td>
<td>Tables Menu– FDA Device Report Codes – Evaluation Type</td>
</tr>
<tr>
<td><strong>Manufacturer Preliminary Comments</strong></td>
<td>The preliminary comments from the manufacturer regarding the device.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Manufacturer Preliminary Comments</strong></td>
<td>The course of action suggested by the manufacturer.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Manufacturers Evaluation Codes - Conclusion</strong></td>
<td>The conclusion drawn from the evaluation of the device.</td>
<td>Manufacturers tab</td>
<td>Tables Menu– FDA Device Report Codes – Conclusions Type</td>
</tr>
<tr>
<td><strong>Manufacturers Evaluation Codes - Method</strong></td>
<td>The method used to evaluate the device</td>
<td>Manufacturers tab</td>
<td>Tables Menu– FDA Device Report Codes – Method Type</td>
</tr>
<tr>
<td><strong>Manufacturers Evaluation Codes - Results</strong></td>
<td>The results from the evaluation of the device.</td>
<td>Manufacturers tab</td>
<td>Tables Menu– FDA Device Report Codes – Evaluation Type</td>
</tr>
<tr>
<td><strong>MedDRA®</strong></td>
<td>The Lowest Level Term from the MedDRA® drug dictionary for this event.</td>
<td>Events tab</td>
<td>Tables Menu – Terms Maintenance</td>
</tr>
<tr>
<td>Field Name</td>
<td>Definition</td>
<td>Screen Name</td>
<td>Table Maintenance</td>
</tr>
<tr>
<td>----------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>----------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td>Medically Confirmed?</td>
<td>Identifies that this adverse event has been confirmed by a hospital or doctor. Used on the Listing and Tabulation Reports for PSUR.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Mfr Report #</td>
<td>The report number assigned by the manufacturer if a report was filed with the manufacturer,</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td>MFR/Importer Aware Date</td>
<td>The date the manufacturer or importer’s medical personnel became aware that the device may have caused the adverse event.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Model #</td>
<td>The exact model # found on the device label or accompanying packaging.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Name</td>
<td>Trade name of suspected medication as it is marketed. If unknown or the medication has no trade name, the generic name may be used (with the manufacturer or labeler’s name – if known).</td>
<td>Con Meds tab</td>
<td>Tables Menu – Drug Dictionary</td>
</tr>
<tr>
<td>NDC #</td>
<td>The National Drug Code number exactly as shown on the concomitant medication label.</td>
<td>Con Meds tab</td>
<td>N/A</td>
</tr>
<tr>
<td>NDC / DIN</td>
<td>The National Drug Code or Drug Information Number exactly as shown on the suspected medication label.</td>
<td>Suspect Meds tab</td>
<td>Tables Menu – Product</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>– Product Maintenance</td>
</tr>
<tr>
<td>Normal Range</td>
<td>The upper and lower acceptable values for results of tests and lab work performed.</td>
<td>Labs &amp; Hist tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Occupation (Initial Reporter)</td>
<td>The occupation of the initial reporter.</td>
<td>Demographic tab</td>
<td>Tables Menu – General</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>– Adverse Event Reporter Occupation</td>
</tr>
<tr>
<td>Occupation (Patient)</td>
<td>The occupation of the patient.</td>
<td>Demographic tab</td>
<td>Tables Menu – General</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>– Adverse Event Reporter Occupation</td>
</tr>
<tr>
<td>OK to Contact</td>
<td>Indicates the doctor who prescribed the suspected medication can be contacted?</td>
<td>Suspect Meds tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Onset Date</td>
<td>The date the historical medical condition or allergy started, not including the reaction or event.</td>
<td>Labs &amp; Hist tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Operator</td>
<td>Indicates the type of person operating or using the suspected medical device. (Health Professional or Lay User/Patient)</td>
<td>Device tab</td>
<td>Fixed Pick List</td>
</tr>
<tr>
<td>Field Name</td>
<td>Definition</td>
<td>Screen Name</td>
<td>Table Maintenance</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>------------------------------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td>OTC Product</td>
<td>Indicates the suspect medication can be purchased without a prescription.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Other #</td>
<td>Any additional number that applies to the suspected device.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Outcome</td>
<td>The end result of this reaction or event.</td>
<td>Events tab</td>
<td>Tables Menu – General – Adverse Event Outcome</td>
</tr>
<tr>
<td>PMA #</td>
<td>The Pre-Marketing Application or Pre Market Notification (510k) number used with device and drug combination products.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Pre-1938</td>
<td>Indicates the suspected medication was marketed prior to 1938 and therefore has no NDA#.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Preferred</td>
<td>The Preferred Term from the MedDRA® drug dictionary for this event.</td>
<td>Events tab</td>
<td>Tables Menu – Terms Maintenance</td>
</tr>
<tr>
<td>Pregnancy/Due Date</td>
<td>Indicates the patient is pregnant and the date the patient is due.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber</td>
<td>The name of the doctor who prescribed the suspected medication.</td>
<td>Suspect Meds tab</td>
<td>Contacts from Case Entry</td>
</tr>
<tr>
<td>Primary?</td>
<td>Indicates that this event is the main reaction or event.</td>
<td>Events tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Priority</td>
<td>For multiple concomitant medications, this number determines the most suspect medication.</td>
<td>Con Meds tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Priority</td>
<td>For multiple suspected medications, this number determines the most suspected medication.</td>
<td>Suspect Meds tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Priority (Other Relevant History section)</td>
<td>Indicates the most relevant history including pre-existing conditions and allergies that may be relevant to the adverse event.</td>
<td>Labs &amp; Hist tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Priority (Relevant Test section)</td>
<td>Indicates the most relevant test or lab data that applies to the adverse event.</td>
<td>Labs &amp; Hist tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Product Code</td>
<td>The suspected product causing the reaction or event. Selected from the Suspected Medications.</td>
<td>Events tab</td>
<td>Tables Menu – Product – Product Maintenance</td>
</tr>
<tr>
<td>Protocol #</td>
<td>The Protocol for the IND# (only entered if the IND# is provided).</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Purchased From</td>
<td>The name of the vendor the suspected device was purchase from.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Purchased From Address</td>
<td>The address of the vendor the suspected device was purchased from.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Field Name</td>
<td>Definition</td>
<td>Screen Name</td>
<td>Table Maintenance</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>----------------------</td>
<td>--------------------------------</td>
</tr>
<tr>
<td>Race</td>
<td>The race of the patient.</td>
<td>Demographic tab</td>
<td>Tables Menu – General</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>– Adverse Event Race</td>
</tr>
<tr>
<td>Receipt Date</td>
<td>The date the Adverse Event was entered into IRMS. It is consistent with</td>
<td>On all of the Adverse</td>
<td>n/a</td>
</tr>
<tr>
<td></td>
<td>the Entered Date from Case Entry.</td>
<td>Event tabs</td>
<td></td>
</tr>
<tr>
<td>ReChallenge</td>
<td>Indicates that the reaction or event re-occurred when the concomitant</td>
<td>Con Meds tab</td>
<td>Tables – General –</td>
</tr>
<tr>
<td></td>
<td>drug was re-introduced.</td>
<td></td>
<td>Adverse Event ReChallenge</td>
</tr>
<tr>
<td>ReChallenge</td>
<td>Indicates that the reaction or event re-occurred when the drug was</td>
<td>Events tab</td>
<td>Tables Menu – General –</td>
</tr>
<tr>
<td></td>
<td>re-introduced.</td>
<td></td>
<td>Adverse Event ReChallenge</td>
</tr>
<tr>
<td>ReChallenge</td>
<td>Indicates that the reaction or event re-occurred when the suspected</td>
<td>Suspect Meds tab</td>
<td>Tables Menu – General –</td>
</tr>
<tr>
<td></td>
<td>medication was re-introduced.</td>
<td></td>
<td>Adverse Event ReChallenge</td>
</tr>
<tr>
<td>Remedial Action</td>
<td>Indicates the action(s) taken to resolve the event. The values are:</td>
<td>Manufacturers tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Initiated</td>
<td>◦ Recall</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Repair</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Replace</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Relabeling</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Other: __________</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Notification</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Inspection</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Patient Monitoring</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Modification/Adjustment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report</td>
<td>Identifies the type of regulatory report for the adverse event. Defined</td>
<td>Regulatory tab</td>
<td>Fixed Pick List</td>
</tr>
<tr>
<td></td>
<td>by the Reporting Agency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Report Date</td>
<td>The date the regulatory report was submitted.</td>
<td>Regulatory tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Report No (Header)</td>
<td>The number assigned to the Adverse Event case.</td>
<td>Header Information</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>All Tabs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Field Name</td>
<td>Definition</td>
<td>Screen Name</td>
<td>Table Maintenance</td>
</tr>
<tr>
<td>--------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>-------------------</td>
<td>-----------------------------------</td>
</tr>
<tr>
<td><strong>Report Source</strong></td>
<td>Indicates the source of any reporting information. Select all that apply.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Foreign</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Study</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Manufacturer</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Literature</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Consumer</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ User Facility</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Importer</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Other: __________</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Health Professional</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Company Representative</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Distributer</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Spontaneous</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ Regulatory</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>◦ User</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Report Type</strong></td>
<td>Defines the type of report to generate for the adverse event. (Initial Report, Product Problem, and Literature)</td>
<td>Demographic tab</td>
<td>Tables Menu – General – Adverse Event Report Type</td>
</tr>
<tr>
<td><strong>Reportability</strong></td>
<td>Defines the regulatory reporting status for the adverse event.</td>
<td>Header Information All Tabs</td>
<td>Fixed pick list</td>
</tr>
<tr>
<td>(Header)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Reporter</strong></td>
<td>The name of the person who reported the adverse event to the user facility or importer.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Reprocessed</strong></td>
<td>Indicates the device was reprocessed.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Reprocessor</strong></td>
<td>The name of the Reprocessor of the device. Entered in the Contact Section of Case Entry.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Result</strong></td>
<td>The results as written by the health professional of the test or lab work given to the patient.</td>
<td>Labs &amp; Hist tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>RMP</strong></td>
<td>Indicates the adverse event is already part of a Risk Management Program.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td><strong>Route</strong></td>
<td>The method by which the concomitant drug was administered (Oral, Intravenous, Topical, etc).</td>
<td>Con Meds tab</td>
<td>Tables Menu – General – Adverse Event Route</td>
</tr>
<tr>
<td><strong>Route</strong></td>
<td>The method by which the suspected medication was administered. (Oral, Intravenous, Topical, etc).</td>
<td>Suspect Meds tab</td>
<td>Tables Menu – General – Adverse Event Route</td>
</tr>
<tr>
<td><strong>Serial #</strong></td>
<td>The Serial Number as it appears on the device label or packaging.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Field Name</td>
<td>Definition</td>
<td>Screen Name</td>
<td>Table Maintenance</td>
</tr>
<tr>
<td>---------------</td>
<td>---------------------------------------------------------------------------</td>
<td>----------------------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td>Serious</td>
<td>A value assigned to determine the seriousness of this reaction or event. If one event is serious, then the entire case is serious.</td>
<td>Events tab</td>
<td>Tables Menu – General – Adverse Event Seriousness</td>
</tr>
<tr>
<td>Serious Criteria</td>
<td>A set of checkboxes that indicates the different criteria that makes the reaction or event serious. The values are: ◊ Death ◊ Hospitalization Required ◊ Disability ◊ Required Intervention ◊ Other: ____________ ◊ Life Threatening ◊ Hospitalization Prolonged ◊ Congenital Anomaly</td>
<td>Events tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Seriousness (Header)</td>
<td>A value assigned to determine the seriousness of the overall adverse event case.</td>
<td>Header Information All Tabs</td>
<td>Tables Menu – General – Adverse Event Seriousness</td>
</tr>
<tr>
<td>Severity</td>
<td>Indicates the level of severity of this reaction or event.</td>
<td>Events tab</td>
<td>Tables Menu – General – Adverse Event Severity</td>
</tr>
<tr>
<td>Software Version</td>
<td>The version of the software used with the suspected device.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Start Date</td>
<td>The date of first administration of the concomitant drug.</td>
<td>Con Meds tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Start Date</td>
<td>The date the reaction or event started.</td>
<td>Events tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Start Date</td>
<td>The date of first administration of the suspected medication.</td>
<td>Suspect Meds tab</td>
<td>N/A</td>
</tr>
<tr>
<td>STN #</td>
<td>The Submission Tracking Number for a device.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Stop Date</td>
<td>The date of the last administration of the concomitant drug.</td>
<td>Con Meds tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Stop Date</td>
<td>The date the reaction or event stopped</td>
<td>Events tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Stop Date</td>
<td>The date the historical medical condition or allergy ended, not including the reaction or event.</td>
<td>Labs &amp;Hist tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Stop Date</td>
<td>The date of the last administration of the suspected medication.</td>
<td>Suspect Meds tab</td>
<td>N/A</td>
</tr>
<tr>
<td>System</td>
<td>The system, order, or class designation from the MedDRA® drug dictionary. Automatically populated from MedDRA®.</td>
<td>Events tab</td>
<td>Tables Menu – Terms Maintenance</td>
</tr>
<tr>
<td>Test</td>
<td>The name of the actual test given to the patient.</td>
<td>Labs &amp; Hist tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Field Name</td>
<td>Definition</td>
<td>Screen Name</td>
<td>Table Maintenance</td>
</tr>
<tr>
<td>-------------------------</td>
<td>---------------------------------------------------------------------------</td>
<td>-------------------</td>
<td>--------------------------------------------------------</td>
</tr>
<tr>
<td>Treatment</td>
<td>A detailed explanation of the treatment used to reduce or eliminate the adverse event in the reporter’s own words.</td>
<td>Narrative tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Type</td>
<td>The type of activity to be performed to review the case.</td>
<td>Comments tab</td>
<td>Tables Menu – General – Adverse Event Activity Type</td>
</tr>
<tr>
<td>Type</td>
<td>The type of test or lab work completed related to the adverse event.</td>
<td>Labs &amp; Hist tab</td>
<td>Tables Menu – General – Adverse Event Test Type</td>
</tr>
<tr>
<td>UF/Imp. #</td>
<td>The number of the User Facility or Importer (distributor) that implanted the suspected device.</td>
<td>Device tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Usage</td>
<td>The way the suspected device was used. (Initial Use of Device, Reuse, or Unknown)</td>
<td>Manufacturers tab</td>
<td>Fixed Pick List</td>
</tr>
<tr>
<td>User Facility or Importer</td>
<td>Indicates the location the suspected device was used is a User Facility or Importer. (User Facility or Importer)</td>
<td>Device tab</td>
<td>Fixed Pick List</td>
</tr>
<tr>
<td>Verbatim</td>
<td>The specific term used by the reporter to describe the adverse event.</td>
<td>Events tab</td>
<td>Tables Menu – Terms Maintenance</td>
</tr>
<tr>
<td>Version</td>
<td>The version number assigned to the report. The initial report is version 1. Follow-up reports are assigned the next sequential number.</td>
<td>Regulatory tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Version Number</td>
<td>The version of the 3500A, CIOMS, or MDR report this event is associated with.</td>
<td>Events tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Weight</td>
<td>The weight of the patient in pounds or kilograms.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Weight – Kg</td>
<td>Indicates the weight is in kilograms.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
<tr>
<td>Weight – Lb</td>
<td>Indicates the weight is in pounds.</td>
<td>Demographic tab</td>
<td>N/A</td>
</tr>
</tbody>
</table>
Appendix B

Periodic Report Flowchart

Below is a flowchart for the Periodic Reports.
## Appendix C

### Restricted Field Values for E2B

Below is a table containing the fields with the allowed values.

<table>
<thead>
<tr>
<th>IRMS Field Name</th>
<th>Table Names</th>
<th>List Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td>Adverse Event Gender</td>
<td>• Male&lt;br&gt;• Female</td>
</tr>
<tr>
<td>Age Category</td>
<td>Adverse Event Age Category</td>
<td>• 1 = Neonate&lt;br&gt;• 2 = Infant&lt;br&gt;• 3 = Child&lt;br&gt;• 4 = Adolescent&lt;br&gt;• 5 = Adult&lt;br&gt;• 6 = Elderly</td>
</tr>
<tr>
<td>Occupation</td>
<td>Adverse Event Reporter Occupation</td>
<td>• 1 = Physician&lt;br&gt;• 2 = Pharmacist&lt;br&gt;• 3 = Other Health Professional&lt;br&gt;• 4 = Lawyer&lt;br&gt;• 5 = Consumer or other non health professional</td>
</tr>
<tr>
<td>Age at Time of Event</td>
<td>N/A – Text box</td>
<td>• 801=Year&lt;br&gt;• 802=Month&lt;br&gt;• 803=Week&lt;br&gt;• 804=Day&lt;br&gt;• 805=Hour&lt;br&gt;• 806=Minute&lt;br&gt;• 807=Second</td>
</tr>
<tr>
<td>Report Type</td>
<td>Adverse Event Report Type</td>
<td>• 1 = Spontaneous&lt;br&gt;• 2 = Report from Study&lt;br&gt;• 3 = Other&lt;br&gt;• 4 = Unknown</td>
</tr>
<tr>
<td>IRMS Field Name</td>
<td>Table Names</td>
<td>List Values</td>
</tr>
<tr>
<td>-----------------</td>
<td>-------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Route</td>
<td>Adverse Event Route</td>
<td>• 001=Auricular (otic)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 002=Buccal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 003=Cutaneous</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 004=Dental</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 005=Endocervical</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 006=Endosinusial</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 007=Endotracheal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 008=Epidural</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 009=Extra-amniotic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 010=Hemodialysis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 011=Intra corpus cavernosum</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 012=Intra-amniotic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 013=Intra-arterial</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 014=Intra-articular</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 015=Intra-uterine</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 016=Intracardiac</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 017=Intracavernous</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 018=Intracerebral</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 019=Intracervical</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 020=Intracisternal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 021=Intracorneal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 022=Intracoronary</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 023=Intradermal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 024=Intradiscal (intraspinal)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 025=Intrahepatic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 026=Intralesional</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 027=Intralymphatic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 028=Intramedullar (bone marrow)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 029=Intrameningreal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 030=Intramuscular</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 031=Intraocular</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 032=Intrapericardial</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 033=Intraperitoneal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 034=Intrapleural</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 035=Intrasynovial</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 036=Intratumor</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 037=Intrathecal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 038=Intrathoracic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 039=Intratracheal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 040=Intravenous bolus</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 041=Intravenous drip</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 042=Intravenous (not otherwise specified)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 043=Intravesical</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 044=Iontophoresis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 045=Nasal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 046=Occlusive dressing technique</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 047=Ophthalmic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 048=Oral</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 049=Oropharyngeal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 050=Other</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 051=Parenteral</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 052=Periarticular</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 053=Perineural</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 054=Rectal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 055=Respiratory (inhalation)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 056=Retrobulbar</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 057=Sunconjunctival</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 058=Subcutaneous</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 059=Surgical</td>
</tr>
</tbody>
</table>

**Note:** This table provides a list of possible routes for adverse events, which can be used in clinical settings to indicate the method of administration or route of entry for a medication or treatment.
<table>
<thead>
<tr>
<th>IRMS Field Name</th>
<th>Table Names</th>
<th>List Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose Unit</td>
<td></td>
<td>• 001=kg kilogram(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 002=G gram(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 003=Mg milligram(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 004=µg microgram(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 005=ng nanogram(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 006=pg picogram(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 007=mg/kg milligram(s)/kilogram</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 008=µg/kg microgram(s)/kilogram</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 009=mg/m² milligram(s)/sq. meter</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 010=µg/m² microgram(s)/sq. meter</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 011=1 litre(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 012=ml millilitre(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 013=µl microlitre(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 014=Bq becquerel(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 015=GBq gigabeccquerel(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 016=MBq megabeccquerel(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 017=K bq kilobecquerel(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 018=Ci curie(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 019=MCi millicurie(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 020=µCi microcurie(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 021=NCi nanocurie(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 022=Mol mole(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 023=Mmol millimole(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 024=µmol micromole(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 025=Iu international unit(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 026=Kiu iu(1000s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 027=Miu iu(1,000,000s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 028=iu/kg iu/kilogram</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 029=Meq milliequivalent(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 030=% percent</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 031=Gtt drop(s)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 032=DF dosage form</td>
</tr>
</tbody>
</table>

| Duration in Medications tab | N/A – Text box | 801=Year  |
|                            |                | 802=Month |
|                            |                | 803=Week  |
|                            |                | 804=Day   |
|                            |                | 805=Hour  |
|                            |                | 806=Minute|

| DeChallenge | Adverse Event DeChallenge | 1 = Drug withdrawn |
|            |                            | 2 = Dose reduced   |
|            |                            | 3 = Dose increased |
|            |                            | 4 = Dose not changed|
|            |                            | 5 = Unknown        |
|            |                            | 6 = Not Applicable  |

<p>| ReChallenge | Adverse Event ReChallenge | 1 = Yes |
|            |                            | 2 = No   |
|            |                            | 3 = Unknown|</p>
<table>
<thead>
<tr>
<th>IRMS Field Name</th>
<th>Table Names</th>
<th>List Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious</td>
<td>Adverse Event Serious</td>
<td>• 1 = Yes, highlighted by the reporter, NOT serious&lt;br&gt;• 2 = No, not highlighted by the reporter, NOT serious&lt;br&gt;• 3 = Yes, highlighted by the reporter, Serious&lt;br&gt;• 4 = No, not highlighted by the reporter, Serious</td>
</tr>
<tr>
<td>Resolution</td>
<td>Adverse Event Outcome</td>
<td>• 1 = recovered/resolved&lt;br&gt;• 2 = recovering/resolving&lt;br&gt;• 3 = not recovered/not resolved&lt;br&gt;• 4 = recovered/resolved with sequelae&lt;br&gt;• 5 = fatal&lt;br&gt;• 6 = unknown</td>
</tr>
<tr>
<td>Duration in AE tab</td>
<td>N/A – Text box</td>
<td>• 801=Year&lt;br&gt;• 802=Month&lt;br&gt;• 803=Week&lt;br&gt;• 804=Day&lt;br&gt;• 805=Hour&lt;br&gt;• 806=Minute&lt;br&gt;• 807 = Second</td>
</tr>
</tbody>
</table>
Appendix D

E2B Process Flowchart

Below is a flowchart on how to create an E2B file (ICSR)
Appendix E

3500A Report – Data Map of IRMS Fields

Below is a table mapping the fields in IRMS to the appropriate sections in the 3500A Report. The tab that the IRMS field is located is listed first in the IRMS Field Name.

<table>
<thead>
<tr>
<th>IRMS Field Name</th>
<th>3500 A section</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic → Identifier</td>
<td>A1: Patient Identifier</td>
</tr>
<tr>
<td>Demographic → Age at Time of Event</td>
<td>A2: Age at Time of Event or Date of Birth</td>
</tr>
<tr>
<td>Demographic → Date of Birth</td>
<td>A2: Age at Time of Event or Date of Birth</td>
</tr>
<tr>
<td>Demographic → Gender</td>
<td>A3: Sex</td>
</tr>
<tr>
<td>Demographic → Weight</td>
<td>A4: Weight</td>
</tr>
<tr>
<td>Demographic → Product Problem</td>
<td>B1: Adverse Event and/or Product Problem</td>
</tr>
<tr>
<td>By Default, the Adverse Event will be checked.</td>
<td></td>
</tr>
<tr>
<td>Adverse Event → Serious Criteria</td>
<td>B2: Outcomes Attributed to Adverse Event</td>
</tr>
<tr>
<td>Event Start Date</td>
<td>B3: Date of Event</td>
</tr>
<tr>
<td>Demographic → Report Date</td>
<td>B4: Date of this Report</td>
</tr>
<tr>
<td>Narrative → Describe Event or Problem</td>
<td>B5: Describe Event or Problem</td>
</tr>
<tr>
<td>Labs &amp; History → Relevant Test and Laboratory Data</td>
<td>B6: Relevant Tests/Laboratory Data, Including Dates</td>
</tr>
<tr>
<td>Labs &amp; History → Other Relevant History Including Preexisting Medical Conditions</td>
<td>B7: Other Relevant History, Including Preexisting Medical Conditions</td>
</tr>
<tr>
<td>Suspect Meds → Name</td>
<td>C1: Name</td>
</tr>
<tr>
<td>Suspect Meds → Dose Unit, Suspect Meds → Frequency, Suspect Meds → Route</td>
<td>C2: Dose, Frequency &amp; Route Used</td>
</tr>
<tr>
<td>Suspect Meds → Start Date and Stop Date</td>
<td>C3: Therapy Dates</td>
</tr>
<tr>
<td>Suspect Meds → Duration</td>
<td>C3: Therapy Dates</td>
</tr>
<tr>
<td>Suspect Meds → Indication</td>
<td>C4: Diagnosis for Use</td>
</tr>
<tr>
<td>Suspect Meds → DeChallenge</td>
<td>C5: Event Abated After Use Stopped or Dose Reduced</td>
</tr>
<tr>
<td>Suspect Meds → Lot#</td>
<td>C6: Lot #</td>
</tr>
<tr>
<td>Suspect Meds → Exp Date</td>
<td>C7: Expiration Date</td>
</tr>
<tr>
<td>Suspect Meds → ReChallenge</td>
<td>C8: Event Reappeared After Reintroduction</td>
</tr>
<tr>
<td>Suspect Meds → NDC/DIN</td>
<td>C9: NDC # or Unique ID</td>
</tr>
<tr>
<td>Con Meds → Name</td>
<td>C10: Concomitant Medical Products and Therapy Dates</td>
</tr>
<tr>
<td>Start and End Date</td>
<td></td>
</tr>
<tr>
<td>Device → Brand Name</td>
<td>D1: Brand Name</td>
</tr>
<tr>
<td>Product Maintenance → GenericDesc</td>
<td>D2: Common Device Name</td>
</tr>
<tr>
<td>IRMS Field Name</td>
<td>3500 A section</td>
</tr>
<tr>
<td>------------------------------------------------------</td>
<td>-----------------------------------------------------</td>
</tr>
<tr>
<td>Division Parameters ➔ Adverse Event</td>
<td>D3: Manufacturer Name, City and State</td>
</tr>
<tr>
<td>Device ➔ Model #</td>
<td>D4: Model #, Catalog #, Serial #, Lot #, Expiration date</td>
</tr>
<tr>
<td>Device ➔ Catalog #</td>
<td></td>
</tr>
<tr>
<td>Device ➔ Serial #</td>
<td></td>
</tr>
<tr>
<td>Device ➔ Lot #</td>
<td></td>
</tr>
<tr>
<td>Device ➔ Expiration date</td>
<td></td>
</tr>
<tr>
<td>Device ➔ Other#</td>
<td></td>
</tr>
<tr>
<td>Device ➔ Operator</td>
<td>D5: Operator of Device</td>
</tr>
<tr>
<td>Device ➔ Implant Date</td>
<td>D6: If Implanted, Give Date</td>
</tr>
<tr>
<td>Device ➔ Explant Date</td>
<td>D7: If Explanted, Give Date</td>
</tr>
<tr>
<td>Device ➔ Reprocessed/Reprocessor (checkbox)</td>
<td>D8: Reprocessed and Reused on a Patient?</td>
</tr>
<tr>
<td>Device ➔ Reprocessed/Reprocessor</td>
<td>D9: Name and Address of Reprocessor</td>
</tr>
<tr>
<td>Device ➔ Available for Evaluation Date (Checkbox and date)</td>
<td>D10: Device Available for Evaluation?</td>
</tr>
<tr>
<td>Con Meds ➔ Concomitant section</td>
<td>D11: Concomitant Medical Products and Therapy Dates</td>
</tr>
<tr>
<td>Demographic ➔ Initial Reporter</td>
<td>E1 Name, Address &amp; Phone #</td>
</tr>
<tr>
<td>Demographic ➔ Health Professional</td>
<td>E2 Health Professional?</td>
</tr>
<tr>
<td>Demographic ➔ Occupation</td>
<td>E3 Occupation</td>
</tr>
<tr>
<td>Demographic ➔ Filed with FDA</td>
<td>E4 Initial Reporter Also Sent Report to FDA?</td>
</tr>
<tr>
<td>Device ➔ Facility/Importer</td>
<td>F1: Check One</td>
</tr>
<tr>
<td>Device ➔ UF/Imp#</td>
<td>F2: UF/Importer Report Number</td>
</tr>
<tr>
<td>Device ➔ Facility/Importer Name</td>
<td>F3: User Facility or Importer Name/Address</td>
</tr>
<tr>
<td>Contact Name associated with Facility/Importer Name</td>
<td>F4: Contact Person</td>
</tr>
<tr>
<td>Contact Phone associated with Facility/Importer Name</td>
<td>F5: Phone Number</td>
</tr>
<tr>
<td>Device ➔ Aware Date</td>
<td>F6: Date User Facility or Importer Became Aware of Event</td>
</tr>
<tr>
<td>Demographic ➔ Reportability</td>
<td>F7: Type of Report</td>
</tr>
<tr>
<td>Demographic ➔ Report Date</td>
<td>F8: Date of this Report</td>
</tr>
<tr>
<td>Device ➔ Device Age</td>
<td>F9: Approximate Age of Device</td>
</tr>
<tr>
<td>Device ➔ Patient and Device codes</td>
<td>F10: Event Problem Codes</td>
</tr>
<tr>
<td>Demographic ➔ Filed with FDA</td>
<td>F11: Report Sent to FDA?</td>
</tr>
<tr>
<td>Device ➔ Event Location</td>
<td>F12: Location Where Event Occurred</td>
</tr>
<tr>
<td>Demographic ➔ Filed with Mfg.</td>
<td>F13: Report Sent to Manufacturer?</td>
</tr>
<tr>
<td>Device ➔ Mfr. Date</td>
<td></td>
</tr>
<tr>
<td>Division Parameters ➔ Adverse Event</td>
<td>F14: Manufacturer Name/Address</td>
</tr>
<tr>
<td>IRMS Field Name</td>
<td>3500 A section</td>
</tr>
<tr>
<td>-----------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Division Parameters→Adverse Event</td>
<td><strong>G1:</strong> Contact office - Name/Address</td>
</tr>
<tr>
<td>Division Parameters→Adverse Event</td>
<td><strong>G2:</strong> Phone Number</td>
</tr>
<tr>
<td>Demographic→Report Type</td>
<td><strong>G3:</strong> Report Source</td>
</tr>
<tr>
<td>Demographic→Receipt Date</td>
<td><strong>G4:</strong> Date Received by Manufacturer</td>
</tr>
<tr>
<td>Demographic→NDA/MAA#</td>
<td><strong>G5:</strong> For use by manufacturers of drug, biologic, including human cell, tissue, and cellular and tissue-based product (HCT/P), device, and combination products</td>
</tr>
<tr>
<td>Demographic→IND #</td>
<td></td>
</tr>
<tr>
<td>Demographic→STN #</td>
<td></td>
</tr>
<tr>
<td>Demographic→PMA #</td>
<td></td>
</tr>
<tr>
<td>Demographic→Combo</td>
<td></td>
</tr>
<tr>
<td>Demographic→Pre-1938</td>
<td></td>
</tr>
<tr>
<td>Demographic→OTC Product</td>
<td></td>
</tr>
<tr>
<td>Demographic→Protocol</td>
<td><strong>G6:</strong> If IND, Give Protocol #</td>
</tr>
<tr>
<td>Demographic→Report Type Due Dates→Type</td>
<td><strong>G7:</strong> Type of Report</td>
</tr>
<tr>
<td>Adverse Event→Preferred (PT)</td>
<td><strong>G8:</strong> Adverse Event Term(s)</td>
</tr>
<tr>
<td>Demographic→Report Number</td>
<td><strong>G9:</strong> Manufacturer Report Number</td>
</tr>
<tr>
<td>Manufacturers→Event Type</td>
<td><strong>H1:</strong> Type of Reportable Event</td>
</tr>
<tr>
<td>Manufacturers→Correction</td>
<td></td>
</tr>
<tr>
<td>Manufacturers→Additional Information</td>
<td></td>
</tr>
<tr>
<td>Manufacturers→Response to FDA Request</td>
<td></td>
</tr>
<tr>
<td>Manufacturers→Device Evaluation</td>
<td></td>
</tr>
<tr>
<td>Manufacturers→Evaluated by Manufacturer</td>
<td><strong>H3:</strong> Device Evaluated by Manufacturer?</td>
</tr>
<tr>
<td>Manufacturers→Manufacturer Date</td>
<td><strong>H4:</strong> Device Manufacture Date</td>
</tr>
<tr>
<td>Manufacturers→Labeled for Single Use</td>
<td><strong>H5:</strong> Labeled for Single Use?</td>
</tr>
<tr>
<td>Manufacturers→Method</td>
<td></td>
</tr>
<tr>
<td>Manufacturers→Results</td>
<td><strong>H6:</strong> Evaluation Codes</td>
</tr>
<tr>
<td>Manufacturers→Conclusions</td>
<td></td>
</tr>
<tr>
<td>Manufacturers→Recall</td>
<td><strong>H7:</strong> If Remedial Action Initiated, Check Type</td>
</tr>
<tr>
<td>Manufacturers→Repair</td>
<td></td>
</tr>
<tr>
<td>Manufacturers→Replace</td>
<td></td>
</tr>
<tr>
<td>Manufacturers→Relabeling</td>
<td></td>
</tr>
<tr>
<td>Manufacturers→Notification</td>
<td></td>
</tr>
<tr>
<td>Manufacturers→Inspection</td>
<td></td>
</tr>
<tr>
<td>Manufacturers→Patient Monitoring</td>
<td></td>
</tr>
<tr>
<td>Manufacturers→Modification/Adjustment</td>
<td></td>
</tr>
<tr>
<td>Manufacturers→Other</td>
<td></td>
</tr>
<tr>
<td>Manufacturers→Usage</td>
<td><strong>H8:</strong> Usage of Device</td>
</tr>
<tr>
<td>IRMS Field Name</td>
<td>3500 A section</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>-----------------------------------------------------</td>
</tr>
<tr>
<td>Manufacturers ➔ Correction/Removal #</td>
<td>H9: Action reported to FDA under 21 USC 360i(f)</td>
</tr>
<tr>
<td>Manufacturers ➔ Additional Narrative</td>
<td>H10: Additional Manufacturer Narrative</td>
</tr>
<tr>
<td>Manufacturers ➔ Corrected Narrative</td>
<td>H11: Corrected Data</td>
</tr>
</tbody>
</table>
**Appendix F**

**CIOMS Report – Data Map of IRMS Fields**

Below is a table mapping the fields in IRMS to the appropriate sections in the CIOMS Report. The tab that the IRMS field is located is listed first in the IRMS Field Name. The section the data is printed in is in the right column.

<table>
<thead>
<tr>
<th>IRMS Field Name</th>
<th>CIOMS section</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographic → Identifier</td>
<td>1: PATIENT INITIALS</td>
</tr>
<tr>
<td>Demographic → Country of occurrence</td>
<td>1. a: COUNTRY</td>
</tr>
<tr>
<td>Demographic → Age at Time of Event</td>
<td>2. DATE OF BIRTH</td>
</tr>
<tr>
<td>Demographic → Date of Birth</td>
<td>2a. AGE</td>
</tr>
<tr>
<td>Demographic → Gender</td>
<td>3. SEX</td>
</tr>
<tr>
<td>Start of Event</td>
<td>4-6 REACTION ONSET</td>
</tr>
<tr>
<td>Events → Serious Criteria</td>
<td>8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION</td>
</tr>
<tr>
<td></td>
<td>7+ 13 DESCRIBE REACTION(S)</td>
</tr>
<tr>
<td>The following information will be included in this section</td>
<td></td>
</tr>
<tr>
<td>• Lists all the Events in the format Events → Verbatim (Preferred Term)</td>
<td></td>
</tr>
<tr>
<td>• <strong>Case Description/Narrative</strong>: Narrative → Describe Event or Problem</td>
<td></td>
</tr>
<tr>
<td>• <strong>Comments</strong>: Comments → Causality and Case Review Comments</td>
<td></td>
</tr>
<tr>
<td>• <strong>RELEVANT TEST (S)/LAB DATA</strong>: Labs &amp; History → Relevant Test and Laboratory Data</td>
<td></td>
</tr>
<tr>
<td>Suspect Meds → Name</td>
<td>14. SUSPECT DRUG(S)</td>
</tr>
<tr>
<td>Trade Name and Generic Description will be included</td>
<td></td>
</tr>
<tr>
<td>Suspect Meds → Dose Unit, Suspect Meds → Frequency, Suspect Meds → Route</td>
<td>15. DAILY DOSE(S) 16. ROUTE(S) OF ADMINISTRATION</td>
</tr>
<tr>
<td>Suspect Meds → Start Date and Stop Date</td>
<td>18. THERAPY DATES(from/to)</td>
</tr>
<tr>
<td>Suspect Meds → Duration</td>
<td>19. THERAPY DURATION</td>
</tr>
<tr>
<td>If start and Stop dates are unknown, the duration will be included</td>
<td></td>
</tr>
<tr>
<td>Suspect Meds → Indication</td>
<td>17 INDICATION(S) FOR USE</td>
</tr>
<tr>
<td>IRMS Field Name</td>
<td>CIOMS section</td>
</tr>
<tr>
<td>----------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Suspect Meds → DeChallenge Only the first suspected drug dechallenge information will be displayed.</td>
<td><strong>20</strong> DID REACTION ABATE AFTER STOPPING DRUG</td>
</tr>
<tr>
<td>Suspect Meds → ReChallenge Only the first suspected drug Rechallenge information will be displayed.</td>
<td><strong>21</strong> DID REACTION REAPPEAR AFTER REINTRODUCTION</td>
</tr>
<tr>
<td>Con Meds → Name Start and End Date</td>
<td><strong>22</strong> CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION</td>
</tr>
<tr>
<td>Labs &amp; History → Other Relevant History Including Preexisting Medical Conditions Labs &amp; History → Relevant Test and Laboratory Data The System will include diagnostics information.</td>
<td><strong>23</strong> OTHER RELEVANT HISTORY</td>
</tr>
<tr>
<td>Tables → Product Manufacturers Maintenance Based on the company associated with the suspect medication</td>
<td><strong>24a</strong> NAME AND ADDRESS OF MANUFACTURER</td>
</tr>
<tr>
<td>Report Number or Demographic → MFR Report# if there is value in this field.</td>
<td><strong>24b</strong> MFR CONTROL NO</td>
</tr>
<tr>
<td>• Initial Receipt Date for Initial report • Last Receipt Date for follow-up report</td>
<td><strong>24c</strong> DATE RECEIVED BY MANUFACTURER</td>
</tr>
<tr>
<td>Demographic → Report Source</td>
<td><strong>24d</strong> REPORT SOURCE</td>
</tr>
<tr>
<td>Regulatory → Report Date</td>
<td>DATE OF THIS REPORT</td>
</tr>
<tr>
<td>Reportability</td>
<td><strong>25a</strong> REPORT TYPE</td>
</tr>
<tr>
<td>Demographic → Initial Reporter If the Initial Reporter is &quot;Consumer&quot; or &quot;Patient&quot; the system will not display the information. It will display the text &quot;NAME AND ADDRESS WITHHELD&quot;</td>
<td><strong>25b</strong> NAME AND ADDRESS OF REPORTER</td>
</tr>
<tr>
<td>Hospital/Client Data → Client Data field 3</td>
<td><strong>26</strong> REMARKS</td>
</tr>
<tr>
<td>Drug Event Information section will be printed on the continuation page.</td>
<td>Continuation Sheet</td>
</tr>
</tbody>
</table>
Appendix G

Medical Device Report – Data Map of IRMS Fields

Below is a table mapping the fields in IRMS to the appropriate sections in the CIOMS Report. The tab that the IRMS field is located is listed first in the IRMS Field Name. The section the data is printed in is in the right column.

<table>
<thead>
<tr>
<th>IRMS Field Name</th>
<th>MDR section</th>
</tr>
</thead>
<tbody>
<tr>
<td>AE Report Number</td>
<td>Reporter File Number</td>
</tr>
<tr>
<td>Reportability Regulator Days</td>
<td>Box 1</td>
</tr>
<tr>
<td>Demographic Initial Reporter</td>
<td>Field 2</td>
</tr>
<tr>
<td>Demographic Report Source</td>
<td>Field 3</td>
</tr>
<tr>
<td>Demographic Initial Reporter Company Name (Case Entry Company Name)</td>
<td>Field 4</td>
</tr>
<tr>
<td>Demographic Initial Reporter Address (Case Entry Address, postal code, telephone, and fax numbers)</td>
<td>Field 5 to 8</td>
</tr>
<tr>
<td>Case Entry Attention based on the Initial Reporter</td>
<td>Field 9</td>
</tr>
<tr>
<td>Device Event Reported To</td>
<td>Field 10</td>
</tr>
<tr>
<td><strong>Applies to Voluntary report</strong></td>
<td></td>
</tr>
<tr>
<td>Device Purchased From and Address</td>
<td>Field 11 and 12</td>
</tr>
<tr>
<td>Device Available for Evaluation</td>
<td>Field 13</td>
</tr>
<tr>
<td>Event Start Date</td>
<td>Field 14</td>
</tr>
<tr>
<td><strong>Applies to Mandatory report</strong></td>
<td></td>
</tr>
<tr>
<td>Device MFR/Importer Aware Date</td>
<td>Field 15</td>
</tr>
<tr>
<td>Device Brand Name</td>
<td>Field 16</td>
</tr>
<tr>
<td>Device Identifier #</td>
<td>Field 17</td>
</tr>
<tr>
<td>Device Control# and/or Lot# and/or Serial#</td>
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## REVISION HISTORY

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| 1.0 | 5.9.1.1 | 12/01/2010 | Cheryl Nabors   | **Chapter 3 – Entering an Adverse Event**  
Step 2 – Demographic Tab section  
Add explanation for calculation for Age at Time of Event field. |
| 1.0 | 5.9.1.0 | 11/01/2010 | Cheryl Nabors   | No Changes for this version.                                             |
| 1.0 | 5.8.5.0 | 12/31/2009 | Cheryl Nabors   | **Chapter 2 – System Administration and Setup**  
Division Parameters - Other Tab section  
Remove “AE_3500A_Date”, “AE_Address”, “AE_City”, “AE_Contact”, “AE_Country”, “AE_Fax”, “AE_Phone”, “AE_Postal”, “AE_Region”.  
**Chapter 2 – System Administration and Setup**  
General Tables section  
Indicate what tables are affected when “ForceE2BRules” is set to “Yes”.  
**Chapter 3 – Entering an Adverse Event**  
Step 1 section  
Add note for validating Event Start Date.  
**Chapter 3 – Entering an Adverse Event**  
Step 4 – Suspected Meds Tab section  
Add note for validating Suspected Med Start Date.  
**Chapter 6 – E2B Processing**  
Add Message Header Information table. Add Validation Rules when E2B rules are enforced.. |
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| **Chapter 2 – System Administration and Setup**  
**Division Parameters - Case Entry/Resp Letters Tab** section  
Add explanation for **Suppress AE** checkboxes and **Lock** checkbox in Number Mask. |
| **Chapter 2 – System Administration and Setup**  
**Division Parameters - Other Tab** section  
Add “**AE_EmailDays**”, “**AE_CheckNarrative**”, “**AE_ContactTypeToOccupation**”. |
| **Chapter 2 – System Administration and Setup**  
**Product Maintenance section**  
Add new section for **PDF Security**. |
| **Chapter 2 – System Administration and Setup**  
**Product Maintenance section**  
Add new section for **Product** table. |
| **Chapter 2 – System Administration and Setup**  
**Shift Maintenance section**  
Add new section for **Shift** table. |
| **Chapter 2 – System Administration and Setup**  
**Reporting Agency Maintenance section**  
Add new section for **Reporting Agency** table. |
| **Chapter 2 – System Administration and Setup**  
**Product Manufacturer Maintenance section**  
Add new section for **Product Manufacturer** table. |
| **Chapter 2 – System Administration and Setup**  
**Terms Maintenance section**  
Add new section for **Terms** table. |
| **Chapter 2 – System Administration and Setup**  
**Drug Dictionary section**  
Add new section for **Drug Dictionary** table. |
| **Chapter 2 – System Administration and Setup**  
**FDA Device Report Codes Maintenance section**  
Add new section for **FDA Device Report Codes** table. |
| **Chapter 2 – System Administration and Setup**  
**User Preferences section**  
Add **AE_InboxDays** explanation to **Other Parameters** tab. |
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<td>Update AE Screens throughout Chapter</td>
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<td>Ch 4 – System Administration</td>
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<td>Add Group Security section to chapter</td>
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<td>Ch 5 – AE Worksheet …</td>
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<td>Update AE Worksheet information</td>
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<td>Ch 8 – Field Definitions</td>
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<td>Add new replacement fields</td>
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| 1.0     | 5.6.0  | Cheryl Nabors| Ch 2 – Entering an Adverse Events into IRMS  
Update Case Entry and Adverse Events screen shots.  
Ch 2 – Step 1-Starting a New Adverse Event Case  
Update Case Entry screen shot  
Ch 2 – Step 5 – Adverse Events tab  
Add update label information checkboxes to section.  
Ch 2 – Step 9 – Hospital/Client Data tab  
Add Emergency Room fields to section, update screen shot.  
Ch 4 – User Preferences and Required Fields  
Update User Preferences AE tab screen shot.  
Update Division Parameters – AE Required Fields tabs screen shots.  
Ch 7 – Merge Fields for Adverse Events  
Add Emergency Room fields to Merge Fields  
Ch 8 – Field Definitions  
Add Emergency Room fields Field definitions. |
| 1.0     | Initial Issue | Susie Pierce  | Major Revisions – Initial Issue |