

Oracle Life Sciences Argus

EC Manufacturer Incident Report (MIR) 7.3.1 Best Practices



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The Oracle logo, consisting of a solid red square with the word "ORACLE" in white, uppercase, sans-serif font centered within it.

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Preface

This preface contains the following sections:

- [About this content](#)
- [Related resources](#)
- [Revision history](#)

About this content

Except where noted, information in this guide applies to both Oracle Argus Safety and Oracle Safety One Argus environments.

Related resources

For information about Oracle Argus patches, see [My Oracle Support](#).

All documentation and other supporting materials are available on the [Oracle Help Center](#).

Revision history

Argus version	Description
8.2.2	First release
8.2.3	Updated for the release.
8.4	Republished
8.4.1	Updated for the release.
8.4.2	Republished
8.4.3	Updated the following sections: <ul style="list-style-type: none"> • Reporting Destination • Update Manufacturer Code List • Common Considerations for Coding Information • Medical Device Problem Coding • Health Impact Information and Clinical Signs and Symptoms Coding • Evaluation/Investigation Code Information Coding
8.4.4.3	Document is revised to upgrade to MIR 7.3.1 profile.
2026.1.01	Updated for the release.
2026.1.01	Revised the Similar Incidents Dialog section.

1

Introduction

This document provides best practices and recommendations to configure Device products and generate MIR reports using MIR 7.3.1 profile.

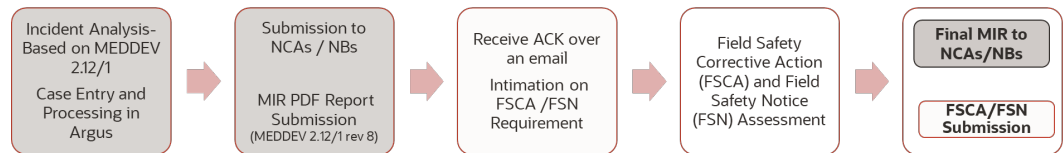
Oracle Argus Safety provides a solution for Reporting Manufacturer Incident Report (MIR) for a device product that has received marketing authorization in the European Region.

Manufacturer Incident Report (MIR) comprises of both PDF and XML report. The European Commission is planning to implement a new EUDAMED System, which will accept MIR XMLs sent by manufacturers and subsequently send out an acknowledgement which will be accepted/imported by the manufacturer's Oracle Argus Safety system.

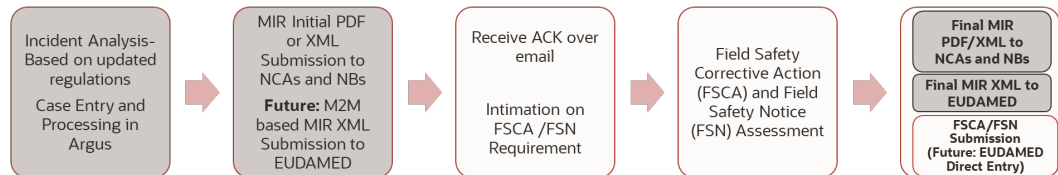
National Competent Authorities (NCA) will accept new MIR PDF or XML report, and manufacturers will continue to follow the existing MIR processing workflow. Also, in some cases, MIR XML is required to be submitted to Notified Bodies (NB), by the manufacturers.

Manufacturer Incident Reporting Process Overview

Current Process



To Be Process



Done in ARGUS

2

Minimum Requirement for MIR Report Generation

- General Tab
 - One identifiable reporter – A reporter can be a Patient, Lay User or HCP. It is recommended that at minimum the Role of the Reporter and the Country of the reporter are updated.
- Event Tab
 - One adverse event/reaction (or outcome) which has causality marked as related.
- Product Tab
 - One Suspect Device Product (License Information is updated: Risk Class, Notified Body Details).
 - One Health Impact Information is updated.
 - One Medical Device Problem Information is updated.
 - At least one Evaluation/Investigation code information and Device Component information for Combined Initial & Final and Final Report types.
 - Preliminary Comments are updated for Device Product.
 - EU CA Dialog information is updated (Manufacturer Awareness Date of Reportability, Location of Device, MIR Report Type, Root Cause Information, Investigation Result, Corrective Action, and Projected Timing Information and Comments).
 - Similar Incidents Tab is updated for Final Reports.

Note

For more information on validation rules, refer to the Conformance tab of *MIR Export Mappings* document.

3

Configurations to enable MIR Reporting

Use the following configurations to enable MIR reporting:

- [Reporting Destination](#)
- [Update Manufacturer Code List](#)
- [Update Existing Licenses](#)
- [Reporting Rules for MIR](#)

Reporting Destination

We recommend that you configure a Reporting Destination with the following settings to enable MIR reports to be sent in either PDF or XML format:

- [Agency Information Tab](#)
- [EDI Tab](#)
- [SMTP Tab](#)
- [Report Tab](#)

Agency Information Tab

Configuration of Contact Type in Reporting Destination

Contact Type: It is important that the accurate configuration of Contact Type at the Reporting Destination level is required. Considering the various reporting obligations by the manufacturers, Contact Type of the Reporting destination plays a critical role in categorizing the submission, as either **Manufacturer** or **Authorized Representative**, or **Other**.

It is recommended that only one Contact Type is selected, even though system allows multiple contact types selection. If none of the contact types is selected, system defaults the value to **Manufacturer**.

The screenshot shows the 'Add New Reporting Destination' form with the 'Agency Information' tab selected. The form includes fields for Agency Name, Agency Type, Department, Email Address, Preferred Method, Registration #, FAX, FAX Cover, and Contact Type. The Contact Type section has radio buttons for Manufacturer (checked), Importer, Distributor, Authorized Representative, and Offline Recipient. Below the main form is a 'Contact Information' section with fields for Title, First Name, Middle, and Last.

Email Attachments: When the MIR Profile is selected, the Attachments parameter under Report Transmissions Options in the Agency information tab is defaulted to **Single** and disabled. This ensures that the system will generate individual PDF or XML reports, and attach them to an email.

Example: If the **Report Transmissions Options - Report per email** is set to 10, **Attachments** is set to **Single** and when the user performs bulk transmit of 10 MIR cases, then single email will be sent with 10 individual PDF reports along with a summary report.

EDI Tab

Message Profile: Message profile to be selected as **EC-MIR V7.3.1 MESSAGE TEMPLATE** (standard profile for MIR).

When the MIR profile is selected:

- The acknowledgment profile field is set to blank and disabled.
- The encoding format is defaulted to UTF-8, and the field is disabled.
- The Preferred Method parameter in the Agency Information tab is defaulted to email and disabled. This ensures that the MIR reports (both XML and PDF) are sent over an email only.
- System will display a warning message `Email is the preferred method for MIR Profile` if value in the Agency Information/Preferred method is **Fax** and EDI/Message profile is MIR Profile (OOTB or Custom MIR); also if you override the message and update the Preferred method to **Fax**, system will show up the same warning message and update the Preferred method to **Email**.
- Based on the preferred method, the **Email ID** field of the Reporting destination must be updated.

The screenshot shows the 'Add New Reporting Destination' dialog box with the 'EDI' tab selected. The 'XML' radio button is selected under the format options. The 'Agency Identifier' field is highlighted. Other fields include 'Secondary Agency/ Department Identifier', 'Identification Code', 'Code Qualifier', 'Message Profile', 'ACK Profile', 'Method', 'EDI Gateway', and 'Webservice Name'. There are also checkboxes for 'Suppress Auto-scheduling' and 'Skip MDN polling', and text boxes for 'Incoming Folder', 'Outgoing Folder', and 'ICSR Attachment Outgoing Folder'.

SMTP Tab

The MIR report is transmitted via email only. It is recommended to configure the from **Email ID** within the SMTP configuration.

Report Tab

In the Report tab, select **MIR Report Format** as either PDF or XML format.

Add New Reporting Destination

Print Evaluation in light of similar events in the past in the "7 +13 DESCRIBE REACTION(S)" section

MIR Report Format

PDF
XML

Transmit Non-Company product causality for study cases

Transmit Non-Company product causality for non-study cases

Apply EMA Special Rules

Transmit WHO Medicinal Product ID

Update Manufacturer Code List

For Device Products with European licenses, Configuration of Manufacturers and Authorized representative is recommended. This ensures population of Submitter information Sec 1.3 of MIR report.

Manufacturer code list is used to support configuration of both Manufacturer and Authorized representatives.

For the Manufacturer or Authorized representative configured for a Device product, it is required to configure the **Single Registration Number** in the **SRN** attribute of the Manufacturer code list in **Code list > Flexible Data Re-categorization screen**.

It is recommended that the following fields of Manufacturer code list are updated to support the mandatory fields of the MIR report.

1. Name
2. Contact
3. City
4. Address
5. State/Province
6. Postal Code
7. Phone
8. Country
9. Email Address

Note

The **Contact** field in the Manufacturer Code list is used to derive Manufacturer/ Authorized Representative Contact's First Name and Contact's Last Name data. It is recommended that first name and last name are configured in a single field with the space (' ') delimiter.

Example: John Rich

- **Configure Authorized Representative** field and **Manufacturer** field available in the Product window.

- It is recommended that Device Products have **Manufacturer** and **Authorized Representative** fields configured. It is important that if the device product that is manufactured outside Europe, it has a mandatory authorized representative to support **Authorized Representative** data population.
- The European Commission (EC) recommends that the **Authorized Representative** must belong to EEA (European Economic Area) Country or Turkey.

Country Code	Country Name
AT	Austria
BE	Belgium
BG	Bulgaria
CZ	Czech Republic
CY	Cyprus
DE	Germany
DK	Denmark
EE	Estonia
ES	Spain
FI	Finland
FR	France
GR	Greece
HR	Croatia
HU	Hungary
IE	Ireland
IS	Iceland
IT	Italy
LI	Liechtenstein
LT	Lithuania
LU	Luxemburg
LV	Latvia
MT	Malta

Country Code	Country Name
NL	Netherlands
NO	Norway
PL	Poland
PT	Portugal
RO	Romania
SE	Sweden
SI	Slovenia
SK	Slovakia
TR	Turkey
XI	Northern Ireland

Update Existing Licenses

It is recommended that the Device Licenses for European Region are updated with device information; Following are the important considerations during License configuration. Note that only specific fields that require configuration considerations are mentioned below:

Field Label	Configuration Consideration
Medical Device Terminology	This field was earlier configured as part of the common profile switches which were common to all device products. For new MIR, it is required to configure Medical device terminology for each device license. This provides flexibility to configure different medical device terminologies of different device licenses.
Medical Device Information	This field is an existing field, and updated with new code list values, it covers important values to populate the product's risk class. It is recommended that this field is configured for device products marketed in Europe for which the MIR reports would be submitted.
Agency Delivering Scientific Opinion	It is recommended to configure these fields when Medical Device Information is selected with MDR class or IVDR class (class C or class D) and corresponding Risk Class Type is selected as Companion diagnostic .
Name(s) of the Medicinal Product associated with the device	It is recommended to configure these fields when Medical Device Information is selected with MDR class or IVDR class (class C or class D) and corresponding Risk Class Type is selected as Companion diagnostic .
Basic UDI-DI	EC recommends that for products which are classified with Risk Class of the device as IVDR and MDR, Basic UDI-DI field is mandatory. It is recommended that Manufacturer updates the Basic UDI-DI in the console for the device product license with Medical device information configured with IVDR and MDR values.

Field Label	Configuration Consideration
Issuing Entity Basic UDI-DI	Select from drop down the applicable designated entity (Example: GSI, HIBCC) that is used to assign Basic UDI-DI required for device registration in EUDAMED. Basic UDI-DI and Issuing Entity Basic UDI-DI fields are mandatory for Combined Initial and Final/ Final MIR report types.
Risk Class Type	Risk class type configuration is applicable if MDR, IVDR, MDD/AIMDD or IVDD values are configured in Medical device information. It is recommended that this field is mandatory and configured for Device products marketed in Europe for which the MIR reports would be submitted. This field is mandatory for Combined Initial and Final / Final MIR report types.
Nomenclature text and Nomenclature code	It is recommended to configure these fields when Medical device terminology is configured for the device license. This field is mandatory for Follow up, Combined Initial and Final, and Final MIR report types.
Device Description	It is recommended to configure this field when Medical device terminology is configured for the device license. This field is mandatory for Follow up, Combined Initial and Final and Final MIR report types.
Notified Body ID number (1) and (2)	This field is a numeric field and is recommended to be updated for all device products marketed in Europe for which the MIR reports would be submitted. This field is mandatory for Combined Initial and Final/Final MIR report types.
Certificate Number of the Notified Body (1) and (2)	There can be multiple Certificate numbers for each Notified Body, Multiple numbers is recommended to be configured by adding a placeholder ';' between multiple Certificate numbers. For example: Cert001; Cert002; Cert003
Conformity/Market Availability and Date of Conformity/Market Availability	Conformity Details and Conformity Date are recommended to be updated for all device products marketed in Europe for which the MIR reports would be submitted.

Note

For MIR Section 2.3p, refer to MIR regulations to determine the specific **Medical Device Information** and **Risk Class Type** field values for which the following fields must be configured as mandatory:

- Notified Body ID Number (1) and (2)
- Certificate Number of the Notified Body (1) and (2)

Reporting Rules for MIR

MIR Report is submitted in PDF or XML format to Notified Bodies, National Competent Authorities and European Commission. MIR Reporting Rules are configured based on the reporting obligations in the European region for the manufacturer.

It is recommended that Marketed Device Licenses and European Countries are considered for Reporting rule configurations.

Below is the summary of Reporting Rule configurations samples for MIR. If the manufacturer has additional obligations, additional configurations need to be considered.

License Type	Report Form	Rule Name	Time Frame	Advanced Condition (AC)
Mkt Device	MIR (PDF)	Related Serious Incident 15 Day MIR Report	15	Health Impact not equal to F20, F21, F02
Mkt Device	MIR (PDF)	Serious Public Health Threat 2 Day MIR Report	2	Health Impact = Serious Public Health Threat (F20)
Mkt Device	MIR (PDF)	Death 10 Day MIR Report	10	Health Impact = Death(F02) or Unanticipated serious deterioration (F21)
Mkt Device	MIR (XML)	Related Serious Incident 15 Day MIR Report	15	Health Impact not equal to F20, F21, F02
Mkt Device	MIR (XML)	Serious Public Health Threat 2 Day MIR Report	2	Health Impact = Serious Public Health Threat(F20)
Mkt Device	MIR (XML)	Death 10 Day MIR Report	10	Health Impact = Death (F02) or Unanticipated serious deterioration (F21)

Note

Refer to Section 5: [FAQs](#) on how MIR Reporting is handled for Non-Serious Reportable Incidents and how MIR XML and MIR PDF is transmitted together to the same destination.

4

Case Processing and Reporting

In this chapter:

- [MIR Report Type](#)
- [Data Entry to Support MIR Report](#)
- [Update EU CA Device Dialog](#)
- [Similar Incidents Dialog](#)
- [Schedule and Transmit MIR Report](#)
- [View MIR PDF and XML](#)

MIR Report Type

Report Type of the MIR Report is populated based on the previous report submitted to the same Reporting Destination and MIR Report Type field in the EU CA Device dialog.

Appropriate data entry in MIR Report type field is required, considering the MIR Report Cycle.

Note

Existing check boxes **Update to Initial Report (Follow-up Report)** and **Final Report** are specific to Canadian Device Report and will not be used for MIR Report.

Previous Report to the same destination	Value selected in MIR Report Type Field in EU CA Device Dialog	MIR Report Type	Comments
No	None	Initial	N/A
No	Final Reportable	Combined initial and final	N/A
No	Final Non-reportable	Initial	This is an Invalid data entry practice. However the Initial would be marked/populated in Report Type.
Yes	Follow up	Follow up	N/A
No	Follow up	Initial	N/A
Yes	Final Reportable	Final (Reportable Incident)	N/A
Yes	Final Non-reportable	Final (Non-reportable Incident)	N/A
Yes	None	Follow up	N/A

Data Entry to Support MIR Report

Case form Data Entry is a critical aspect to ensure accuracy of Data and generation of MIR Report, it is required to consider the below recommendations during data entry to ensure accuracy of MIR Report.

It is recommended that only one device product is configured in the case to facilitate MIR report generation for that particular product. Multiple device products for the same case that requires MIR Report generation for each of the device product are not recommended.

For more information, see:

- [Update Device Tab within the Product Tab](#)

Update Device Tab within the Product Tab

Important Data Entry considerations for various fields in the Product Tab are listed below.

Note

Fields that have direct mapping and do not have validation implications are not treated here.

Field Label	Date Entry Consideration
UDI-DI	EC recommends that for Products which are classified with Risk Class of the device as IVDR and MDR, the UDI-DI field is mandatory. It is recommended that Manufacturer updates the UDI-DI in the case form with products with Medical Device Information configured with IVDR and MDR values.
Issuing Entity UDI-DI	Select from dropdown the applicable designated entity (Example: GSI, HIBCC) that is used to assign UDI-DI required for device registration in EUDAMED. UDI-DI and Issuing Entity UDI-DI fields are mandatory for Combined Initial and Final/Final MIR report types.
UDI-PI	EC recommends that for Products which are classified with Risk Class of the device as IVDR and MDR, the UDI-PI field is mandatory. It is recommended that Manufacturer updates the UDI-PI in the case form with products with Medical Device Information configured with IVDR and MDR values.
Preliminary Comments	This field captures the Preliminary results and conclusions of manufacturer's investigation. This field is mandatory for Initial and Follow up MIR Reports. It is recommended to include this as part of the data entry guideline, so that, the required data is populated in the MIR Initial and Follow-up Reports.

Field Label	Date Entry Consideration
QC Result	This field captures the Manufacturer's evaluation of the Incident. This field is mandatory for Final and Combined Initial & Final MIR Reports. It is recommended to include this part of the data entry guideline, so that, the required data is populated in the MIR Final and Combined Initial & Final Reports.
Implant Duration	<p>If Implant and Explant dates are not known, it is important for the Manufacturer to provide information on approximate implant duration of the Device; It is recommended to enter data in the below format:</p> <ul style="list-style-type: none"> • If year is known, for example: 12 Years. Number of years: 12 • If Month is known, for example: 8 Months. Number of months: 8 • If Day is known, for example: 3 Days. Number of days: 3

For more information, see:

- [Common Considerations for Coding Information](#)
- [Medical Device Problem Coding](#)
- [Health Impact Information and Clinical Signs and Symptoms Coding](#)
- [Evaluation/Investigation Code Information Coding](#)
- [Device Component Coding](#)

Common Considerations for Coding Information

Consider the following points to add or update the coding information for Medical Device Problem, Health Impact, Clinical Signs, and Evaluation/Investigation:

- Medical Device, Patient Problem codes and Evaluation codes were part of the **Product > Device > MW Info** tab, are moved to **Product > Device > Patient Problem and Device Problem Information** starting Oracle Argus Safety 8.2.2 release. The Patient Problem codes are retained in the **Product > Device** tab to view any legacy data if present, but data entry is longer allowed.

- Device Coding is done only by invoking the look-up that displays both the FDA and IMDRF codes for Medical Device Problem Coding and Evaluation/Investigation Coding. Only the IMDRF codes are displayed in Health Impact Coding, Clinical Sign Coding, and Device Component Coding.
- The decode values are not displayed for obsolete codes. Coding User/Data Entry User is expected to recode such data against the latest IMDRF repository.
- If an appropriate or feasible code is not found to describe any of the Annex A–G, then it is recommended to explain the reason why the current terms or codes are not appropriate by using the free text field provided on the relevant Coding window. Select the check box labelled **If you think the incident is unique and a suitable IMDRF term is missing, briefly explain** and provide a clear explanation.

Following are the default Annex codes provided by the European commission in their regulations.

Annexures	Default IMDRF code
Annex- A	A27
Annex -E	E2402
Annex-F	F28
Annex-D	D17
Annex-G	G07002

Medical Device Problem Coding

Medical Device Problem coding is an integral part of the Device Reporting, All MIR Report Types require at least one Medical Device Problem to be entered.

Important Considerations during Medical Device Problem Coding are:

- Medical Device Problem Coding is based on Harmonized codes where an FDA Code has a corresponding IMDRF Code. Therefore Medical Device Problem Coding is required to be handled considering both US and Europe regions.
- For a MIR report to be generated there needs to be at least Medical Device problem available; It is recommended that the data entry guidelines are updated to ensure that for a Case which requires MIR Report to be Scheduled, Medical Device Problem Coding is Mandatory. This is applicable for all Report Types.

Health Impact Information and Clinical Signs and Symptoms Coding

Clinical Signs and Symptoms can be coded in the Events tab by clicking the **Select** button associated with Clinical Signs IMDRF Code.

Clinical Signs and Symptoms IMDRF are populated in the Section 3.3a: IMDRF 'Health Effect' terms and codes (Annex E, F) of the MIR report.

Health Impact Information coding determines the **Classification of Incident** and this information is crucial for all report types.

It is recommended that the data entry guidelines is updated to ensure at least one Health Impact Information is available for a case which requires MIR Report to be scheduled.

If the Health Impact is coded with the following terms, then respective fields in PDF and XML are affected as indicated in the below table.

All the valid IMDRF codes selected in the **Device > Health Impact Information** section, are populated in 3.3a section of MIR PDF with the corresponding element in MIR XML.

Health Impact Code available in Health Impact Information Section	Health Impact in Health Impact Information Section in PDF	Value transmitted in MIR XML	Comments
F20	Serious Public Health Threat	Serious Public Health Threat	Second Preference is given to Serious Public Health Threat. If any of the Health Impact information has Serious Public Health Threat and Death not present, Serious Public Health Threat is selected in the Report.
F02	Death	Death	First Preference is given to Death. If any of the Health Impact information has death, regardless of other values Death is selected in the Report.
F21	Unexpected Deterioration	Unanticipated Serious Deterioration in State of Health	Third Preference is given to Unexpected Deterioration, if Death and Serious Public Health Threat is not present in any of the Health Impact information, Unanticipated Serious Deterioration in State of Health is selected in the Report.
Any other Codes	Any other Health Impact Term Coded	All other reportable incidents	Any other health Impact information available, All other reportable incidents is selected in the Report.

Evaluation/Investigation Code Information Coding

Important considerations during Evaluation/Investigation Code Information Coding are:

- Evaluation/Investigation Coding is based on Harmonized codes where an FDA Code has a corresponding IMDRF Code. Therefore Evaluation/Investigation coding is required to be handled considering both US and Europe regions.
- For a Final MIR report and Combined Initial & Final MIR Report to be generated, there needs to be at least one Method/Type, Result/Findings and Conclusion available. It is recommended that the data entry guidelines are updated to ensure that for a Case which requires MIR Report to be Scheduled, Evaluation/Investigation Codes is Mandatory for Final and Combined Initial & Final MIR Reports.

Device Component Coding

We recommend that the Device Component Information in the **Product > Device Tab** is coded by using terms which has corresponding IMDRF Terms. The IMDRF Device Component Terms are populated in Section 4.2 f: IMDRF Component codes of the MIR Report.

Update EU CA Device Dialog

Field Label	Data Entry Consideration
Incident Classification Information	For Legacy cases, which has Incident classification information in the EU/CA Device Information header, we recommend that you update the Health Impact Codes based on the Information available in EU/CA Device Information header. Incident classification for the New MIR Report is based on Health Impact Information.
Identification of Notified Bodies Involved in Conformity Assessment	New MIR Report logic populates the field Notified body (NB) ID number(s) from the new field available at the Product > License level. We recommend that you verify the data available in the Identification of Notified Bodies Involved in Conformity Assessment field in Legacy cases with data in the Notified Body ID Number field available at the license level.
Associated Accessories	The earlier label of this field was Accessories/ Associated Devices . Existing data within this field has both Associated Devices and Accessories . It is recommended that the existing data is reviewed and data related to Accessories is retained and data related to Devices is updated in the new Associated Devices field.
NCA Reference Number	This field is updated based on the acknowledgment received by the NCA for Initial Report. For follow-up MIR reports the NCA number is populated and the same number is retained for Final Reports also.
Identification of Notified Involved in Conformity Assessment	This field is a legacy field and is not used in the New MIR Report. However if there is legacy data present in this field, we recommend that you verify the same with the Notified body (NB) ID number field in the License configuration of the Product for which the MIR Report is scheduled. Verification can also be done by generating a draft MIR Report.
MIR Report Type	This is a new field introduced specific to MIR Report. It is recommended that you enter the MIR Report type before scheduling of an MIR Report. Update to Initial Report and Final Report legacy fields are not applicable for MIR Report.
Expected Date of Next Report	For MIR Initial and follow-up Reports this field is mandatory. It is recommended to enter the field for Initial reports and update it based for follow-up report.

Field Label	Data Entry Consideration
Manufacturer Awareness Date of Reportability	When you set the Does the incident qualify to be reported? field to Yes , then the system date is auto-populated in this field. It is recommended to ensure the data is available in this field before scheduling an MIR report.

Similar Incidents Dialog

The identification and computation of count of similar incidents is done outside the Oracle Argus Safety system and fields to capture the results are provided in Oracle Argus Safety.

Device Similar Incidents -- Webpage Dialog

Similar Incidents

Similar Incident Device Category: Details of the Device Category:

Criteria for Number of Devices on the Market: Other:

Similar Incident Analysis Based on: Rationale:

Inhouse Medical Device Problem Code: Term: Inhouse Evaluation Result/Findings Code: Term:

Year	Start Date	End Date	Incident Country	Number of Similar Incidents			Incident Country	Number of Devices		
				EEA+CH+TR	EEA+TR+XI	World		EEA+CH+TR	EEA+TR+XI	World
N	00-MMM-0000	00-MMM-0000								
N-1	00-MMM-0000	00-MMM-0000								
N-2	00-MMM-0000	00-MMM-0000								
N-3	00-MMM-0000	00-MMM-0000								

Comments:

OK Cancel

Similar Incident Information is mandatory for MIR Combined Initial & Final and Final Reportable Incidents.

Schedule and Transmit MIR Report

Based on the Reporting rules, configured MIR Report Scheduled can be automated or manually scheduled based on the case data and determination by the Report Distribution group of the company.

MIR Report generated can be viewed via MIR Viewer as MIR PDF or MIR XML.

If Data present in the case does not meet the validation rules, the system will generate a MIR Validation report in a separate window as a PDF, which lists all the failing validation, upon satisfying the validation criteria on regeneration, the system will generate the MIR Report.

MIR Report is transmitted to recipient over an email and transmission can be tracked via Bulk Transmit screen.

View MIR PDF and XML

MIR PDF:

MIR PDF generated from Oracle Argus Safety would be read-only, and the action buttons at the end of the report after the coded summary of the report is read-only and no actions can be performed such as **Check the form, Save as XML, Save as PDF, Send XML to submit, Submit XML by Email, Save PDF to submit, and Submit PDF by Email.**

For fields which are identified as grow fields and multiline text fields, additional data can be viewed by invoking the scroll bar by selecting the select tool. Additionally, complete data for all the Grow fields is printed at the end of the report as additional pages.

Electronic Signatures for MIR PDF reports have to be done outside the system. As per MIR help text document published by EC, Electronic Signature is optional.

MIR XML:

MIR XML generated from Oracle Argus Safety is viewed in MIR Viewer, XML View is generated by default.

5

Frequently Asked Questions

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- [How are MIR XML and MIR PDF transmitted together to the same destination?](#)
- [Does Oracle Argus Safety generate electronically signed non-editable MIR PDF?](#)
- [Is Similar Incident Data automatically populated by the system?](#)
- [How to overcome population of non-existing countries such as "World" in the Other Countries field of Section 2.5 Market distribution of device in a MIR Report?](#)
- [Are IMDRF Codes auto populated for legacy cases after upgrade to Oracle Argus Safety 8.2.2 or 8.2.3?](#)
- [If obsolete FDA Codes are used in the legacy cases, how is the recoding of such cases handled?](#)
- [Are IMDRF codes automatically derived from MedDRA PT for Clinical Signs \(Annex E\)?](#)
- [If earlier version of MIR – EU Device Vigilance report in Oracle Argus Safety was used to send out the Initial Report, can the follow-up or Final Report be sent on the New MIR Report format?](#)
- [How is Incident Classification handled in the new MIR Report?](#)
- [Are FDA Coding and IMDRF done separately for Device Problem and Evaluation/ Investigation Code Information?](#)
- [How does the system determine the MIR Report type?](#)
- [When I generate an MIR Report generated by Oracle Argus Safety, would it be acceptable by NCAs or NBS?](#)
- [If multiple events in a case form are coded with IMDRF Clinical Sign Codes, which events are considered for clinical sign population in Section 3.3, Patient information, IMDRF Clinical signs, symptoms, and conditions codes \(Annex E\)?](#)
- [Can MIR XML be transmitted over email?](#)
- [If the MIR Report submitter is a Local Company Representative, what would be the required configuration?](#)
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- [Does the MIR 7.3.1 report populate the data entered in the Inhouse Medical Device Problem and Inhouse Evaluation Result/Findings fields under Device Similar Incidents?](#)
- [Does the MIR 7.3.1 report populate the data entered in the EEA+CH+TR field under Device Similar Incidents?](#)
- [Can the Manufacturer awareness date of reportability field be edited by the user after it has been auto-populated?](#)

How is MIR reporting handled for Non-serious Reportable Incidents?

The out-of-the-box MIR Profile requires at least one **Serious** or **Non-Serious** related event to populate the Incident Start and End Dates. A related event is considered Non-Serious if the Product to which the report is scheduled has Malfunction **Yes** and Malfunction Type **CIRM**.

How are MIR XML and MIR PDF transmitted together to the same destination?

There can be only one MIR report format per transmission and is based on the configuration of the MIR Report Type in the Reporting Destination (RD). It is recommended to configure Two Reporting Destination with one of the RD having the MIR Report Type as PDF and other having XML. Corresponding Reporting Rules should be updated for each Reporting Destination. This will ensure that there can be two MIR Transmission emails reaching the same configured Reporting destination configured.

Does Oracle Argus Safety generate electronically signed non-editable MIR PDF?

MIR PDF generated by Oracle Argus Safety is a non-editable PDF report and Electronic Signatures for MIR PDF reports have to be done outside the system. As per MIR help text document published by EC, Electronic Signature is optional.

Is Similar Incident Data automatically populated by the system?

Oracle Argus Safety does not support calculation of similar incidents as there is no common calculation logic followed by the manufacturers. Currently, each manufacturer follows different logic. EC had not provided any guidance on Similar Incident Analysis.

How to overcome population of non-existing countries such as "World" in the Other Countries field of Section 2.5 Market distribution of device in a MIR Report?

It is recommended to customize **EC-MIR V7.3.1 MESSAGE TEMPLATE** message profile by updating the SQL for device_info block to populate the tag **otherCountries** with name of the countries with a valid ISO Country code.

Are IMDRF Codes auto populated for legacy cases after upgrade to Oracle Argus Safety 8.2.2 or 8.2.3?

For Legacy cases, the system is not expected to populate IMDRF codes based on FDA codes. However you are expected to recode the Medical Device Information and Evaluation/ Investigation Information.

If obsolete FDA Codes are used in the legacy cases, how is the recoding of such cases handled?

If an obsolete FDA code is used in the case, the decode values are not displayed, and you are expected to recode data using the latest repository.

Are IMDRF codes automatically derived from MedDRA PT for Clinical Signs (Annex E)?

After Event encoding, you are expected to manually code the Clinical Signs by using the Look up provided. The system auto-populates the MedDRA LLT Term of the Event in the Term Text Box of the lookup and you will have to select the desired Row, containing IMDRF Code, MedDRA LLT Code, MedDRA LLT Term, Clinical Sign and Definition. Upon value selection, the system will populate the record in the **Event Tab > Clinical Signs IMDRF Code**.

If earlier version of MIR – EU Device Vigilance report in Oracle Argus Safety was used to send out the Initial Report, can the follow-up or Final Report be sent on the New MIR Report format?

It is expected that the MIR report cycle of the earlier version of MIR – EU Device Vigilance report is completed. The new MIR report type logic does not consider reports sent out using old MIR form and System will send out the Initial MIR using the new MIR form, even if there was a previously submitted MIR in the old format.

How is Incident Classification handled in the new MIR Report?

Classification of Incidents is based on Health Impact Coding in **Case Form > Product > Device > Health Impact Information**.

Are FDA Coding and IMDRF done separately for Device Problem and Evaluation/Investigation Code Information?

New CFG_FDA_IMDRF_CODES repository supports harmonized IMDRF and FDA Codes for Medical Device Problem (Annex A) and Evaluation/Investigation Codes (Annex B, C, D). When you use the lookup and select a record, the system stores FDA Code and corresponding IMDRF code, ensuring Common Coding for the IMDRF and FDA Codes.

How does the system determine the MIR Report type?

MIR Report is determined based on the field **MIR Report Type** in the **Case Form > EU CA Device** dialog.

When I generate an MIR Report generated by Oracle Argus Safety, would it be acceptable by NCAs or NBs?

The MIR Report generated by Oracle Argus Safety is validated against the XSDs provided by ECs.

The system performs validation checks based on conformance rules of the EC and shall list all the failing validations in the MIR Validation Report. Upon updating the case data to satisfy the validation rule, the system will then generate the MIR Report.

If multiple events in a case form are coded with IMDRF Clinical Sign Codes, which events are considered for clinical sign population in Section 3.3, Patient information, IMDRF Clinical signs, symptoms, and conditions codes (Annex E)?

The system picks the first six events in the case form that has the IMDRF Code coded for Clinical Signs based on the following priority:

- Priority 1 - Serious Related Events
- Priority 2 - Non Serious Related Events
- Priority 3 - Other Events with Clinical Sign IMDRF Code

Note

Relatedness is based on product for which the report is scheduled.

Can MIR XML be transmitted over email?

Yes, MIR XML can be transmitted over email. The report type considered for transmission is configured in **Reporting Destination** > **EDI Tab** > **MIR Report Format**. If you configure the XML option, the system will send out an email to the recipient with the MIR XML as attachment.

If the MIR Report submitter is a Local Company Representative, what would be the required configuration?

The submitter of the MIR Report is based on the Contact Type configured in the Reporting Destination. In order to ensure that the Submitter of the Report is **Local Company Representative**, please follow these steps:

1. Select both **Importer**, and **Distributor** in the **Contact Type** of the **Reporting Destination**.
2. Customize the **EC-MIR V7.3.1 MESSAGE TEMPLATE** message profile by updating the SQL for `admin_info` block to populate the `statusReporter` tag with **Others** and the `reporterOtherText` tag with **Local Company Representative**, if Contact Type is configured with both **Importer** and **Distributor**.

How are partial dates handled in MIR?

Based on the Q&A document released and further communication received from EC, Member State Authorities are to a large extent not in favor of the use of partial dates, therefore it is recommended to use full dates in all the date fields of the MIR Report. However, in Oracle Argus Safety OOTB EC MIR Message profile, partial dates are supported with the following logic:

If Date format:-Feb-2020: Date to be Transmitted: 2020-02-01 - Transmit the First Day of the Month if the Partial Date has Month/Year

If Date format:-???-2020: Date to be Transmitted: 2020-01-01 - Transmit the First Day of the Year if the Partial Date has Year.

Does the MIR 7.3.1 report populate the data entered in the Inhouse Medical Device Problem and Inhouse Evaluation Result/Findings fields under Device Similar Incidents?

According to the European Commission regulations, the use of Inhouse terms and codes for identifying similar serious incidents is permitted only until June 2025. Therefore, in the MIR 7.3.1 report, data entered in the Inhouse Medical Device Problem and Inhouse Evaluation Result/Findings under Device Similar Incidents will no longer be included in the generated MIR report from Oracle Argus Safety.

Does the MIR 7.3.1 report populate the data entered in the EEA+CH+TR field under Device Similar Incidents?

As per the MIR 7.3.1 PDF/XML template released by the European Commission, the **EEA+CH+TR** field has been replaced with **EEA+XI+TR**. As a result, the data entered in the **EEA+CH+TR** field is not used in MIR 7.3.1 report. To ensure compliance with the updated reporting requirements, please enter the necessary information in the new **EEA+XI+TR** field on the Device Similar Incidents window.

Can the Manufacturer awareness date of reportability field be edited by the user after it has been auto-populated?

Yes, the Manufacturer awareness date of reportability field can be edited by the user after it has been auto-populated.