

# Oracle Argus Safety

## EC Manufacturer Incident Report (MIR) Best Practices



Release 8.4  
F51734-01  
September 2022

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

ORACLE®

F51734-01

Copyright © 2020, 2022, Oracle and/or its affiliates.

This software and related documentation are provided under a license agreement containing restrictions on use and disclosure and are protected by intellectual property laws. Except as expressly permitted in your license agreement or allowed by law, you may not use, copy, reproduce, translate, broadcast, modify, license, transmit, distribute, exhibit, perform, publish, or display any part, in any form, or by any means. Reverse engineering, disassembly, or decompilation of this software, unless required by law for interoperability, is prohibited.

The information contained herein is subject to change without notice and is not warranted to be error-free. If you find any errors, please report them to us in writing.

If this is software, software documentation, data (as defined in the Federal Acquisition Regulation), or related documentation that is delivered to the U.S. Government or anyone licensing it on behalf of the U.S. Government, then the following notice is applicable:

U.S. GOVERNMENT END USERS: Oracle programs (including any operating system, integrated software, any programs embedded, installed, or activated on delivered hardware, and modifications of such programs) and Oracle computer documentation or other Oracle data delivered to or accessed by U.S. Government end users are "commercial computer software," "commercial computer software documentation," or "limited rights data" pursuant to the applicable Federal Acquisition Regulation and agency-specific supplemental regulations. As such, the use, reproduction, duplication, release, display, disclosure, modification, preparation of derivative works, and/or adaptation of i) Oracle programs (including any operating system, integrated software, any programs embedded, installed, or activated on delivered hardware, and modifications of such programs), ii) Oracle computer documentation and/or iii) other Oracle data, is subject to the rights and limitations specified in the license contained in the applicable contract. The terms governing the U.S. Government's use of Oracle cloud services are defined by the applicable contract for such services. No other rights are granted to the U.S. Government.

This software or hardware is developed for general use in a variety of information management applications. It is not developed or intended for use in any inherently dangerous applications, including applications that may create a risk of personal injury. If you use this software or hardware in dangerous applications, then you shall be responsible to take all appropriate fail-safe, backup, redundancy, and other measures to ensure its safe use. Oracle Corporation and its affiliates disclaim any liability for any damages caused by use of this software or hardware in dangerous applications.

Oracle®, Java, and MySQL are registered trademarks of Oracle and/or its affiliates. Other names may be trademarks of their respective owners.

Intel and Intel Inside are trademarks or registered trademarks of Intel Corporation. All SPARC trademarks are used under license and are trademarks or registered trademarks of SPARC International, Inc. AMD, Epyc, and the AMD logo are trademarks or registered trademarks of Advanced Micro Devices. UNIX is a registered trademark of The Open Group.

This software or hardware and documentation may provide access to or information about content, products, and services from third parties. Oracle Corporation and its affiliates are not responsible for and expressly disclaim all warranties of any kind with respect to third-party content, products, and services unless otherwise set forth in an applicable agreement between you and Oracle. Oracle Corporation and its affiliates will not be responsible for any loss, costs, or damages incurred due to your access to or use of third-party content, products, or services, except as set forth in an applicable agreement between you and Oracle.

# Contents

## Preface

---

Documentation accessibility	v
Diversity and Inclusion	v
Related resources	v
Access to Oracle Support	v

## 1 Introduction

---

## 2 Minimum Requirement for MIR Report Generation

---

## 3 Configurations to enable MIR Reporting

---

Reporting Destination	3-1
Agency Information Tab	3-1
EDI Tab	3-2
SMTP Tab	3-2
Update Manufacturer Code List	3-2
Update Existing Licenses	3-4
Reporting Rules for MIR	3-6

## 4 Case Processing and Reporting

---

MIR Report Type	4-1
Data Entry to Support MIR Report	4-2
Update Device Tab within the Product Tab	4-2
Common Considerations for Coding Information	4-3
Medical Device Problem Coding	4-4
Health Impact Information Coding	4-5
Evaluation/Investigation Code Information Coding	4-6
Device Component Coding	4-6
Update EU CA Device Dialog	4-6

Similar Incidents Dialog	4-7
Schedule and Transmit MIR Report	4-8
View MIR PDF and XML	4-8

## 5 Frequently Asked Questions

---

How is MIR reporting handled for Non-serious Reportable Incidents?	5-1
How are MIR XML and MIR PDF transmitted together to the same destination?	5-2
Does Oracle Argus Safety generate electronically signed non-editable MIR PDF?	5-2
Is Similar Incident Data automatically populated by the system?	5-2
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?	5-2
Are IMDRF Codes auto populated for legacy cases after upgrade to Oracle Argus Safety 8.2.2 or 8.2.3?	5-2
If obsolete FDA Codes are used in the legacy cases, how is the recoding of such cases handled?	5-3
Are IMDRF codes automatically derived from MedDRA PT for Clinical Signs (Annex E)?	5-3
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?	5-3
How is Incident Classification handled in the new MIR Report?	5-3
Are FDA Coding and IMDRF done separately for Device Problem and Evaluation/ Investigation Code Information?	5-3
How does the system determine the MIR Report type?	5-4
When I generate an MIR Report generated by Oracle Argus Safety, would it be acceptable by NCAs or NBs?	5-4
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)?	5-4
Can MIR XML be transmitted over email?	5-4
If the MIR Report submitter is a Local Company Representative, what would be the required configuration?	5-5
How are partial dates handled in MIR?	5-5

# Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Diversity and Inclusion](#)
- [Related resources](#)
- [Access to Oracle Support](#)

## Documentation accessibility

For information about Oracle's commitment to accessibility, visit the Oracle Accessibility Program website at <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=docacc>.

## Diversity and Inclusion

Oracle is fully committed to diversity and inclusion. Oracle respects and values having a diverse workforce that increases thought leadership and innovation. As part of our initiative to build a more inclusive culture that positively impacts our employees, customers, and partners, we are working to remove insensitive terms from our products and documentation. We are also mindful of the necessity to maintain compatibility with our customers' existing technologies and the need to ensure continuity of service as Oracle's offerings and industry standards evolve. Because of these technical constraints, our effort to remove insensitive terms is ongoing and will take time and external cooperation.

## 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](#).

## Access to Oracle Support

To receive support assistance, determine whether your organization is a cloud or on-premises customer. If you're not sure, use Support Cloud.

### **Cloud customers receive support assistance through Support Cloud**

Oracle customers that have purchased support have access to electronic support through Support Cloud.

Contact our Oracle Customer Support Services team by logging requests in one of the following locations:

- English interface of Oracle Health Sciences Customer Support Portal (<https://hsgbu.custhelp.com/>)
- Japanese interface of Oracle Health Sciences Customer Support Portal (<https://hsgbu-jp.custhelp.com/>)

You can also call our 24x7 help desk. For information, visit <http://www.oracle.com/us/support/contact/health-sciences-cloud-support/index.html> or visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

**On-premises customers receive support assistance through My Oracle Support**

Oracle customers that have purchased support have access to electronic support through My Oracle Support. For information, visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=info> or visit <http://www.oracle.com/pls/topic/lookup?ctx=acc&id=trs> if you are hearing impaired.

# 1

## Introduction

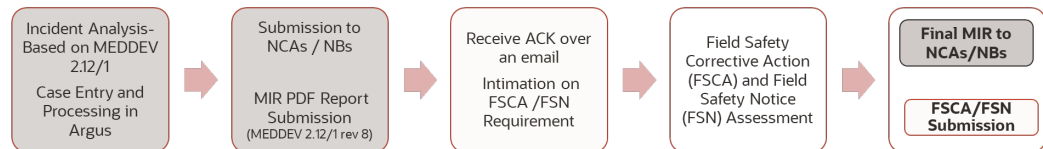
Oracle Argus Safety provides a solution for Reporting Manufacturer Incident Report (MIR) for a device product that has received marketing authorization in the European Region.

The European Commission has released a new version of the Manufacturer Incident Report (MIR), version 7.2.1, which 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. EUDAMED Implementation is expected by 2022.

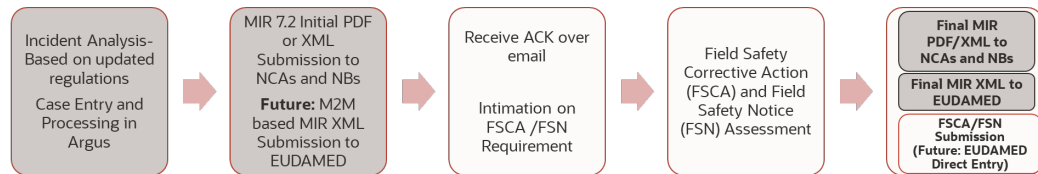
National Competent Authorities (NCA) will accept new MIR 7.2.1 PDF or XML report, and manufacturers will continue to follow the existing MIR processing workflow. Also, in some cases, MIR XML is required to be submitted to Notified Bodies (NB), by the Manufacturers.

## Manufacturer Incident Reporting Process Overview

### Current Process



### To Be Process



Done in ARGUS

# 2

## Minimum Requirement for MIR Report Generation

- General Tab Updates
  - 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 Updates
  - One adverse event/reaction (or outcome) which has causality marked as related.
- Product Tab Updates
  - 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
  - Preliminary Comments are updated for Device Product
  - EU CA Dialog information is updated (Location of Device, MIR Report Type, Root Cause Information, 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.xlsx`.



# 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](#)

### 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 'Modify Reporting Destination' form with the 'Agency Information' tab selected. The form contains several fields: Agency Name (IHA SPAIN DEVICE), Agency Type, Regulatory Authority, Department (Department of Device Safety and Surveillance), Email Address (saitya.sinha@oracle.com), Preferred Method (Email), Registration #, FAX, FAX Cover, and Contact Type. The Contact Type dropdown is open, showing 'Manufacturer' selected, with other options being 'Importer', 'Distributor', and 'Authorized Representative'. There are also checkboxes for 'Offline Recipient' and 'Authorized Representative'.

**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 Per email is set to 10, and Report per attachment is set to **Single**, 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 MESSAGE TEMPLATE (standard profile for MIR)

- Based on the Message Profile Selected EC-MIR MESSAGE TEMPLATE, the acknowledgment profile field is set to blank and disabled.
- When MIR Profile is selected, the encoding format is defaulted to UTF -8, and the field is disabled.
- When MIR profile is selected, 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.

## SMTP Tab

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

## 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.

It is recommended that the following fields of Manufacturer codelist 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 Codelist 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 ';' delimiter.

**Example:** John Rich; Configuration of Manufacturers and Authorized Representatives for Existing Products.

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

- 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. Therefore it is recommended that Authorized Representative's Country is one of the EEA Countries below.

 **Note:**

It is recommended that the EEA Attribute in Countries Flexible Codelist for CH - Switzerland is removed.

Country Code	Country Name
AT	Austria
BE	Belgium
BG	Bulgaria
CZ	Czech Republic

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

**Note:**

Harmonized Codes with IMDRF and FDA Codes for Annexures A to F are preloaded in the repository (CFG\_FDA\_IMDRF\_CODES). Annexure G is preloaded into DEVICE\_SUBCOMPONENT flexible code list.

## 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	<p>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.</p> <p>This provides flexibility to configure different medical device terminologies of different device licenses.</p>
Medical Device Information	<p>This field is an existing field, and updated with new code list values, it covers important values to populate the product's risk class.</p> <p>It is recommended that this field is configured for device products marketed in Europe for which the MIR Reports would be submitted.</p>
Risk Class Type	<p>Risk class type configuration is applicable if MDR and IVDR values are configured in Medical Device Information. Risk Class Type field will appear as blank and disabled, if the value selected in Medical Device Information field has as device category MDD/AIMDD, IVDD or if Medical Device Information is blank.</p> <p>It is recommended that this field is mandatory and configured for Device products marketed in Europe for which the MIR Reports would be submitted.</p> <p>This field is Mandatory for Combined Initial and Final / Final MIR Report Types.</p>
Nomenclature text	<p>Device description is required to be configured for device products marketed in Europe for which the MIR Reports would be submitted.</p> <p>This field is mandatory for Combined Initial and Final/Final MIR Report Types.</p>
Notified Body ID number (1)	<p>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.</p> <p>This field is Mandatory for Combined Initial and Final/Final MIR Report Types.</p>
Notified Body ID number	<p>This field is recommended to be updated for all device products marketed in Europe for which the MIR Reports would be submitted.</p>

Field Label	Configuration Consideration
Certificate Number of the Notified Body (1) and (2)	<p>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 Based on the above example nbCertNum: Cert001; Cert002; Cert003(Upto 50 AN) nbCertNumLI: Cert001((Upto 50 AN before the delimiter ‘;’) nbCertNumLI: Cert002((Upto 50 AN before the delimiter ‘;’) nbCertNumLI: Cert003((Upto 50 AN before the delimiter ‘;’)</p>
Conformity/Market Availability and Date of Conformity/Market Availability	<p>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.</p>

## 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

License Type	Report Form	Rule Name	Time Frame	Advanced Condition (AC)
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 <b>UDI-DI</b> 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.
UDI-PI	EC recommends that for Products which are classified with Risk Class of the device as IVDR and MDR, the <b>UDI-PI</b> 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 Page 13 of 22 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"> <li>• If year is known, for example : 12 Years Number of years: 12</li> <li>• If Month is known, for example: 8 Months Number of months: 8</li> <li>• If Day is known, for example: 3 Days Number of days: 3</li> </ul>

For more information, see:

- [Common Considerations for Coding Information](#)
- [Medical Device Problem Coding](#)
- [Health Impact Information 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:

- Entry of Coding Information is done only by invoking the look-up, **New Look Up** will have both FDA and IMDRF codes for Medical Device Problem Coding, Evaluation/ Investigation Coding, Health Impact Coding, Clinical Sign Coding and Device Component Coding.
- For a case which already has Medical Device Problem and Evaluation Codes and if an obsolete FDA code is used in the case, the decode values should not be displayed in

**Device Problem** and **Evaluation/Investigation Result, Method** and **Conclusion**. Coding User/Data Entry User is expected to recode such data against the new repository.

- For Legacy cases, you are expected to recode the **Medical Device Information** and **Evaluation/Investigation Information** to populate IMDRF Codes based on FDA codes.

The screenshot displays four main sections of the Oracle Argus Safety interface:

- Malfunction Information (8):** A table with columns: Reported Malfunction, Determined Malfunction, Likelihood, and Responsible.
- Health Impact Information (9):** A table with columns: IMDRF Code and Health Impact.
- Patient Problem and Device Problem Information (7):** A table with columns: #, FDA Code, Patient Problem, FDA Code, IMDRF Code, and Device Problem. It shows two rows of data.
- Evaluation / Investigation Code Information (1):** A table with columns: #, FDA Code, IMDRF Code, Method/Type, Subject, FDA Code, IMDRF Code, Result/Findings, Subject, FDA Code, IMDRF Code, and Conclusion. It shows one row of data.
- Event Coding:** A search window with a list of terms and their corresponding IMDRF codes:
  - System Organ Class (SOC) (Code): Product issues (10077536)
  - High Level Group Term (Code): Device issues (10069782)
  - High Level Term (Code): Device malfunction events NEC (10069795)
  - Preferred Term (Code): Device malfunction (10063829)
  - Lower Level Term (Code): Device malfunction (10063829)
  - Synonym (Code):
 Below the list is a field for "Clinical Signs IMDRF Code" with "Clear" and "Select" buttons.

- The **Clinical Signs IMDRF Code** field is added in the **Event** tab, System supports a look up to select the IMDRF Code for the Coded Event, system populates the English MedDRA LLT Term of the Event in the Term text box of the Search window to support Clinical Sign Coding, After the selecting the Clinical Sign Term, system displays the Clinical Sign Term and IMDRF Code in the IMDRF Code field  
**Example:** Balance Problems (E0101).

## 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.

Previously Medical Device Problems were part of the **MW Info** tab, and in the Oracle Argus Safety 8.2.2 Release Medical Device Problem Information is moved from **MW Info** to **Product > Device Tab > Patient Problem and Device Problem Information**.

MIR Report requires Patient Problem codes to be captured in the form of Clinical Sign and Health Impact, However FDA currently has only one type of patient problem codes which is currently available in **MW Info** dialog of the **Device Tab**.

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 is 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 Coding

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.

For more information, see:

- [MIR PDF Section Number: 1.2.f](#)

### MIR PDF Section Number: 1.2.f

#### MIR Element Name: eventClassification

Health Impact Code available in Health Impact Information Section	Health Impact in Health Impact Information Section	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, <b>Serious Public Health Threat</b> 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 <b>Death</b> 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, <b>Unanticipated Serious Deterioration in State of Health</b> is selected in the Report.
Any other Codes	Any other Health Impact Term Coded	All other reportable incidents	Any other health Impact information available, <b>All other reportable incidents</b> is selected in the Report.

## Evaluation/Investigation Code Information Coding

Previously Evaluation/Investigation Code Information were part of the **MW Info** tab, and in the Oracle Argus Safety 8.2.2 Release Evaluation/Investigation Code Information is moved from **MW Info** to **Product > Device Tab > Evaluation/Investigation Code Information**.

- 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. For MIR Report, 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 <b>Notified body (NB) ID number(s)</b> from the new field available at the <b>Product &gt; License</b> level. We recommend that you verify the data available in the <b>Identification of Notified Bodies Involved in Conformity Assessment</b> field in Legacy cases with data in the <b>Notified Body ID Number</b> field available at the license level.
Associated Accessories	The earlier label of this field was <b>Accessories/Associated Devices</b> . Existing data within this field has both <b>Associated Devices</b> and <b>Accessories</b> . 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 <b>Associated Devices</b> field.

Field Label	Data Entry Consideration
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 <b>Notified body (NB) ID number</b> 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. <b>Update to Initial Report and Final Report</b> 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.

## Similar Incidents Dialog

Similar Incidents occurring with the same device type/variant of a manufacturer with same investigation finding (IMDRF investigation finding; Annex C) and the same medical device problem (IMDRF medical device problem).

Annex A) have to be reported to European Commission (EC). EC also allows usage of the in-house codes for Identification of similar incidents.

Oracle Argus Safety supports capture of the in-house codes for Medical Device Problem and Evaluation Result/Findings that may be used for computation of similar incidents, in addition to the IMDRF Codes.

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.

Similar Incidents																																																																	
Similar Incident Device Category			Details of the Device Category																																																														
Criteria for No. of Devices on the Market			Other																																																														
Similar Incident Analysis based on			Rationale																																																														
Inhouse Medical Device Problem			Inhouse Evaluation Result/Findings																																																														
Code		Term	Code		Term																																																												
<table border="1"> <thead> <tr> <th rowspan="2">Year</th> <th rowspan="2">Start Date</th> <th rowspan="2">End Date</th> <th colspan="3">Number of Similar Incidents</th> <th colspan="4">Number of Devices</th> </tr> <tr> <th>Incident Country</th> <th>EEA + CH + TR</th> <th>World</th> <th>Incident Country</th> <th>EEA + CH + TR</th> <th>World</th> </tr> </thead> <tbody> <tr> <td>N</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>N-1</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>N-2</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>N-3</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>										Year	Start Date	End Date	Number of Similar Incidents			Number of Devices				Incident Country	EEA + CH + TR	World	Incident Country	EEA + CH + TR	World	N										N-1										N-2										N-3									
Year	Start Date	End Date	Number of Similar Incidents			Number of Devices																																																											
			Incident Country	EEA + CH + TR	World	Incident Country	EEA + CH + TR	World																																																									
N																																																																	
N-1																																																																	
N-2																																																																	
N-3																																																																	
Comments																																																																	
<input type="text"/>																																																																	
<input type="button" value="OK"/> <input type="button" value="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 PDF**, **Send XML by Email** and **Send PDF by Email**.

While viewing the MIR PDF Report, you are required to right click on the PDF to invoke the select tool and view additional data in the each field. Additional data can be viewed by horizontally scrolling. 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 is 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, however EC recommends that Manufacturers do not require electronically signed MIR Reports Submission.

**MIR XML:**

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



# 5

## Frequently Asked Questions

- How is MIR reporting handled for Non-serious Reportable Incidents?
- 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?
- How are partial dates handled in MIR?

### 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 Page 19 of 22 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 EC had confirmed that NCAs do not require the electronic signatures updated from device manufacturers.

## Is Similar Incident Data automatically populated by the system?

Initial version of the MIR support in Oracle Argus Safety does not support autocalculations 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 the Message Profile-EC MIR Message Template, by updating the SQL for device\_info block to populate 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 will not be displayed for patient problem, device problem and Evaluation code information, and you are expected to recode such data against the new repository upon upgrade to Oracle Argus Safety 8.2.3.

## 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 autopopulates 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 Page 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 Message Profile-EC MIR Message Template, 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.