

Oracle Argus

Release Notes—What's New



Release 8.2.3

F37327-03

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The Oracle logo, consisting of the word "ORACLE" in white, uppercase letters, centered within a solid red square.

ORACLE®

Oracle Argus Release Notes—What's New, Release 8.2.3

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Preface

This preface contains the following sections:

- [Documentation accessibility](#)
- [Related resources](#)
- [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.

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>.

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

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What's New

In this guide:

- [Technology Stack](#)
- [Oracle Argus Compatibility Matrix](#)
- [Enhancements to Oracle Argus Safety](#)
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- [Upgrade Oracle Argus Database](#)

Technology Stack

The following components have been added to the Oracle Argus 8.2.3 technology stack:

- Google Chrome version 84.0.4147.135 (Official Build) (64-bit)
- Microsoft Edge (Chromium based) version 84.0.522.52 (Official build) (64-bit)
- Oracle Database 19csupport on cloud (19.3)
- Oracle Database Client (64 Bit) 19c support on cloud (19.3)
- Axway B2Bi 2.6 SP2
- [Dictionary support](#)

Dictionary support

The following table lists the supported dictionary versions for this release:

| Dictionary | Supported versions |
|--|--|
| MedDRA Dictionary | 23.0 (April 2020), 23.1 (Sep 2020) 22.0 (Mar 2019), 22.1 (Sep 2019) 21.0 (Mar 2018), 21.1 (Sep 2018) |
| WHO Drug Dictionary (Format: B3 and C3) | Mar 2020 , Sep 2020 Mar 2019, Sep 2019 Mar 2018, Sep 2018 |
| J Drug Dictionary | Apr 2020 Apr 2019, Oct 2019 Apr 2018, Oct 2018 Apr 2017 |

Oracle Argus Compatibility Matrix

| Application | Compatible Version with this Argus Safety Release |
|--|---|
| Oracle Argus Insight | 8.2.3 |
| Oracle Argus Mart | 8.2.3 |
| Oracle Argus Analytics | 8.2.1 |
| Oracle Health Sciences Empirica Signal and Oracle Health Sciences Empirica Topics | 9.1.0.2 |

Enhancements to Oracle Argus Safety

The following are the enhancements to Oracle Argus Safety:

- [Alternate browser compatibility \(Enhancement 28581643\)](#)
- [CDRH eMDR updates \(Enhancement 31836633\)](#)
- [CBER eVAERS changes \(Enhancement 31557002\)](#)
- [South Korea MFDS updates](#)
- [EC Manufacturer Incident Report \(MIR\) updates](#)
- [Brexit-related changes \(Enhancement 32359983\)](#)
- [Sending reporter-related elements and Protect confidentiality check box is marked \(Enhancement 29745574\)](#)
- [Common profile switches updates \(Enhancement 32349328\)](#)
- [Reporter information display in codelist with large number of institutions associated \(Enhancement 19362177\)](#)
- [Argus Console enforces field configuration for E2B destinations \(Enhancement 32176831\)](#)
- [Chart option in CDA report configuration](#)
- [Updates to EMA E2B\(R2\) submissions when patient related fields are marked for Protect Confidentiality](#)

Alternate browser compatibility (Enhancement 28581643)

Oracle Argus Safety has been enhanced to support the following alternate modern browsers instead of Microsoft Internet Explorer IE 11:

- Google Chrome version 84.0.4147.135 (Official Build) (64-bit)
- Microsoft Edge (Chromium based) version 84.0.522.52 (Official build) (64-bit)

Functional updates

The following are the functional updates to support cross-browser compatibility:

- **Spell check:** With alternate browser support, we are now able to leverage enhanced build-in capabilities for spell checks. Argus web application now

supports the spell check feature as supported by the browsers rather than limiting to few screens. The spell check feature is available in all multi-line text fields provided by built-in capability of the browser. Hence, the spell check buttons are removed from the Oracle Argus case processing screens.

- **Button to minimize/maximize/close:** In modern browsers, the minimize, maximize, or cross buttons are not available in the pop-up screens. To enable user to close the pop-up screens in Oracle Argus, the **Close** button is added wherever it was not available. Now, you can close the window using the **Close** button instead of the cross button (X). Alternatively, you can use the **Esc** button to close the window. Examples of the pop-up screens with the Close button: ICSR Pending > Selective Acceptance screen, ICSR Pending > Duplicate Search screen.
- **IME (Input Method Editor) mode:** In modern browsers, the setting of IME mode has been deprecated. Due to this, the common profile switch in Console > Common profile switch > Argus J > Enable half-width Alphanumeric characters forced input for Alphanumeric only fields is removed.

UI updates

- **Drop-down fields:** In the modern browsers, the drop-down list of values appear with padding between values to enable easy use of the touch screen.
- **Text boxes:** Textbox does not have cross in text box to clear the data. This is a feature change in the modern browsers.
- **ICSR Viewer (Formatting):** In the modern browsers, XML and HL7 views display as plain text without coloring and formatting. There is no option to expand or collapse the structure.
- **Auto resizing of windows:** In the modern browsers, the size of the parent window or window with tabs is fixed. Due to this, the attachment is open in new tab/new window.
Example:
 - * Case Form > Analysis > Attachment > Open, the attachment is opened as a new tab in modern browsers
 - Worklist > Case Intake > Create New Case, the PDF file is opened as a new window in modern browsers
You can use window key + left arrow/right arrow to resize the parent window.
- **Emojis:** Using Emojis is not supported in Oracle Argus data entry. If used, it would lead to corruption of data entered.
- **Autofill password:** If the password save option is enabled in modern browsers, Oracle Argus Safety allows to select a saved password during the login. When you type the username, the Password field displays the hidden password for the selection and you can log in without actually typing the password.
- **File path display:** Due to security reasons in the modern browsers, file upload does not allow to fetch complete file path from the client machine, and only file name appears in the selected textbox. Whereas in IE, the complete file path from the client machine appeared.
- **Display of visited link:** In IE, when you click a hyperlink (for example, Draft or Final in the Case Form > Regulatory reports tab), the link would change to the visited link color. The modern browsers do not support this feature, the visited link does not change color for the security reasons.

- **Resize title field in Literary Citation:** The Title field in Console > Codelist > Literary Citation is changed from multi-line text field to a single line text field in both English and Japanese UI.
- **Refresh application window:** The modern browsers do not allow any customization for default behavior to refresh the window due to security reasons. It is recommended to use the **Logout** button for proper closure of the application. If the application is refreshed or closed abruptly, then it is recommended to save the data, and close all the Oracle Argus windows.
- **Oracle Argus Japan split screen:** It is recommended to use wider screens when you use vertical split screen for Japanese or English view.

CDRH eMDR updates (Enhancement 31836633)

CDRH has published revised guidelines for eMDR report submission in May 2020, and subsequently in September 2020. To be complaint with the latest regulation updates, Oracle Argus Safety underwent the following changes:

Console changes

- New countries have been added in the Country standard code list as per the GENC Standard.
- The GENC3 code attribute is provided in the COUNTRY flexible code list and the GENC3 data has been updated for all existing countries, as well as for new countries.
- The **Authorization Type** field length in Console > Business Configuration > Products and Licences > License Configuration was changed to ten characters.
- The list of countries field in the product license screen used to display the ISO A3 codes assigned to each country. Since the new countries do not have ISO A3 codes, this field now displays the country names with the semicolon as delimiter.
- The Country name and its corresponding Japanese text have been changed.
 - TAIWAN, PROVINCE OF CHINA is changed to TAIWAN
 - PALESTINIAN TERRITORY, OCCUPIED to PALESTINE, STATE OF
- The Gender codelist now includes new values as required by the CDRH regulations. The corresponding NCI_CODE data is provided for the new records in the Gender Flexible codelist.
- Factory data update for Occupation codelist to include **Third Party Servicer** and and NCI_CODE data is updated for REPORTER_OCCUPATION flexible codelist.
- The **Biosimilar** and **Pre-1938** check boxes have been provided under the Console > Business Configurations > Products and Licenses > Product License tab.
For more information, refer to the *ArgusInterchange823_E2B (R3) Export Mappings.xlsx*.

Case form changes

The need to perform dual coding of medical device codes based on Manufacturer or User facility report has been removed in the release. IMDRF coding for Device Problem, Health Impact, Device components, Evaluation codes can be coded from Device tab. Term coding from the **Analysis** tab is no longer required and the Add/

Delete buttons in Analysis > MedWatch Info section > 10. FDA Codes > Device Problem codes are now disabled.

Coding of Patient Problem codes from the following sections is no longer required:

- The **Add** button is disabled in Analysis > MedWatch Info section > 10. FDA Codes > Device Problem codes
- The **Select** button is removed in Device > Patient Problem and Device Problem Information
- The **Authorization Type** field length in Case form > Product > Drug or Device > Product Information was changed to ten characters.
- The **IMDRF Code** field length in Case form > Product > Device > Device Component Information was changed to ten characters.

For existing cases having data in Patient Problem codes, we recommend that you perform IMDRF coding for Clinical Signs and Health Impact code by referring to existing data that is present in the Patient Problem codes.

The **Biosimilar** and **Pre-1938** check boxes are provided under the Product Information sub-tab, Common to Device, Drug and Vaccine tabs.

- For company products, these check boxes are marked based on the data available in the License configuration and are ready-only.
- For non-company products, you can mark these check boxes as applicable.
- For the study products, these new fields are populated based on the primary license number selected in Console > Studies Configuration.
- When unblinded at case level, these new fields are enabled irrespective of the product selected in the Study Drug drop down.

 **Note:**

The **Pre-1938** field available under Case Form > Analysis > MedWatch tab will not be used in eMDR.

A new data entry field to capture **Serviced by Third Party** has been provided under the Device Information section to capture device serviced by third party with values **Yes**, **No**, and **Unknown**.

A new field **Exemption number** is added in the eMDR report, which is an alphanumeric value provided by FDA to track approved exemptions or variances of adverse event reporting. The typical format is E1234567.

 **Note:**

You must enter Exemption Number as a 7-digit number (without the leading letter E).

For more information, refer to the [Argus_Safety_8.2.3_CaseForm_Console_Updates_Summary.xlsx](#).

Interchange mapping changes

The mapping logic for the following elements has been revised to populate the GENC3 codes instead of the current 3-character ISO codes:

- MFRCOUNTRY (D3)
- REPORTERCOUNTRYR3 (E1)
- UFCOUNTRY (F3)
- FMFCOUNTRY (F14)
- MFRCONTACTCOUNTRYCODE (G1)

Changed country names for TAIWAN and PALESTINE, STATE OF have been updated in the allowed value repository of eMDR, eVAERS, all E2B(R2), and E2B(R3) profiles, to display the revised country names in the Decoded view of ICSR viewer.

Updates for IMDRF codes

According to the latest CDRH guidelines, IMDRF codes can be sent for the Medical Device codes.

The following new elements are provided in the eMDR profile to send IMDRF codes:

- FDACOMPONENTCODES [F10 Part 3]
- FDAHEALTHIMPACTCODE [F10 Part 4]
- MFRCOMPONENTCODE [H6]
- MFRHEALTHIMPACTCODE [H6]

The mapping logic for the following elements has been revised to populate GENC3 codes instead of the current 3 char ISO codes:

- FDAPATIENTCODES [F10 Part 1]
- FDADEVICECODES [F10 Part 2]
- MFRPATIENTCODE [H6]
- MFRDEVICECODE [H6]
- EVALCODEMETHOD [H6]
- EVALCODERESULT [H6]
- EVALCODECONCLUSION [H6]

The data length of the Device/Patient/Evaluation Codes elements has been changed from 4 to 7.

The data length of the Device, Patient, and Evaluation Codes elements have been changed from 4 to 7 to send IDMRF codes instead of FDA codes.

Field type of the Device, Patient, and Evaluation Codes elements has been changed from code list field to text code. This avoids allowed values check for the device codes at the time of the eMDR report generation.

Other updates to the eMDR Profile

The following new elements are provided in the eMDR profile:

- EXEMPTIONNO
- GENERIC [C6]

- BIOSIMILAR [C6]
- PREANDA [C6]
- PRE1938 [C6]
- THIRDPARTYSERVICED [D8]
- COMBINATIONPRODUCT (G4)

The mapping logic for the following elements has been revised:

- SUSPECTPRODUCTS [C]
- PREMARKETNUMBER [G4]

The Descriptive name of several elements has been updated according to the latest CDRH regulations. The element number for the following elements in the eMDR Profile and Comments provided in the XSL files has been updated:

- Device, Patient, or Evaluation Codes elements in F10 to include part numbers.
- Elements in C, D, and G blocks, as per the latest CDRH regulations.

For more information, refer to the *ArgusInterchange823_eMDR (R2) Export Mappings.xlsx > eMDR Mapping sheet*.

CBER eVAERS changes (Enhancement 31557002)

CBER published revised guidelines for eVAERS report submission in June 2020.

To be compliant with the latest regulation updates, Oracle Argus Safety underwent several changes.

Interchange mapping changes

As per the CBER guidelines, if a reportable malfunction occurred while using the device constituent parts of combination products marketed outside the United States, then the Combination Product applicant is required to submit Malfunction reports to FDA if the following conditions are met:

- there is a similar device that is part of Combination Product constituent in a US-marketed combination product
- the malfunction is likely to occur in the US-marketed combination product.

A new element, OTHERDRUGCHARACTERIZATION [G.k.1.a], is provided to identify the similar devices within the eVAERS report.

The following are the new elements in the updated eVAERS profile with the element number, name, mappings, allowed null flavors, and validations:

- MANUFACTURERADDRESS [FDA.G.k.12.r.7.1b]
- DEVICEUSAGE [FDA.G.k.12.r.8]
- DEVICELOTNUMBER [FDA.G.k.12.r.9]
- OPERATOROFDEVICE [FDA.G.k.12.r.10a]

In prior releases, the elements within the Primary source(s) of information [C.2.r] block ignored the protect confidentiality flag for all reporters if the primary reporter's country was United States and the protect confidentiality flag was considered for all reporters if the primary reporter's country was not United States.

In prior releases, most of the elements within Patient (D) block were populated with "None" for Malfunction reports.

The mappings for these elements within Patient (D) block has been revised to send the text "None" only when the product for which report was scheduled was not administered on the patient. To populate the Drug block with additional criteria for similar devices, the DRUG [G.k] element was revised.

For Vaccine Facility/Patient/Reporter Country as US, if the value entered in the State field is a two character text, compare the value with the **State_Code** attribute of the **US_States** code list. For valid values, the code is populated for the following elements:

- VACCFACILITYSTATE [FDA.G.k.4.r.14.3]
- PATIENTSTATE [FDA.D.1h]
- REPORTERSTATE [C.2.r.2.5]

If its a single entity combination , Trade name is picked up from the console and not at the case form level.

For single entity combination products, trade name is fetched from Console, the BRANDNAME [FDA.G.k.12.r.4] element is affected.

If the message type is expedited, and the timeframe between 15 to 30 days, the value of the FULFILLEXPEDITECRITERIAR3 [C.1.7] element is sent as **false** in additional condition:

The validations or conformance rules for the VACCFACILITYCOUNTRY [FDA.G.k.4.r.14.4] element have been removed from the eVAERS profile.

The validations or conformance rules for the following elements have been added or revised:

- PATIENTGIVENAME [FDA.D.1b]
- PATIENTFAMILYNAME [FDA.D.1d]
- PATIENTSTREETADDRESS [FDA.D.1e]
- PATIENTCITY [FDA.D.1g]
- PATIENTSTATE [FDA.D.1h]
- PATIENTCOUNTY [FDA.D.1i]
- PATIENTPOSTCODE [FDA.D.1k]
- PATIENTCOUNTRYCODE [FDA.D.1j]
- PATIENTTEL [FDA.D.1l]
- PATIENTEMAILADDRESS [FDA.D.1m]
- DRUGCHARACTERIZATION [G.k.1]
- VACCFACILITYSTATE [FDA.G.k.4.r.14.3]
- MALFUNCTION [FDA.G.k.12.r.1]

The Xpath of the following elements has been updated:

- PATPASTDRUGMPIDVERSION [D.8.r.2a]
- PATPASTDRUGMEDICINALPRODID [D.8.r.2b]

- PARPASTDRUGMPIDVERSION [D.10.8.r.2a]
- PARPASTDRUGMEDICINALPRODID [D.10.8.r.2b]
- DRUGMPIDVERSION [G.k.2.1.1a]
- DRUGMEDICINALPRODID [G.k.2.1.1b]
- VACCMPIDVERSION [FDA.G2.k.2a]
- VACCMPID [FDA.G2.k.2b]

The Xpath for Null flavors for the following elements has been updated:

- STUDYREGCOUNTRY [C.5.1.r.2]

Device code mapping updates (Enhancement 31199458)

Based on the data available for the device code under the `Product > License`, mapping for the `PRODUCTCODE` [FDA.G.k.12.r.6] element is provided.

For more information, refer to the *ArgusInterchange823_E2B (R3) Export Mappings.xlsx*.

South Korea MFDS updates

The MFDS E2B(R3) profile has been updated to incorporate the following:

- Updated business rules as of 14-May-2020 and 11-Jun-2020.
- Updated XML file reference as of 7-May-2020 and 20-Jul-2020.

Mappings of the following elements have been updated:

- DRUGADMINISTRATIONROUTETEXT [G.k.4.r.10.1] and DRUGPARADMINISTRATIONTEXT [G.k.4.r.11.1]
- DRUGROUTEOFADMINTERMIDVER and DRUGROUTEOFADMINTERMID [G.k.4.r.10.2a/ G.k.4.r.10.2b]
- DRUGPARROUTEOFADMINTERMIDVER and DRUGPARROUTEOFADMINTERMID [G.k.4.r.11.2a/ G.k.4.r.11.2b]
- Format change of output in PATIENTMEDICALPRODUCTVERSION [D.8.r.1.KR.1a], PARENTMEDICALPRODUCTVERSION [D.10.8.r.1.KR.1a], DRUGMEDICALPRODUCTVERSION [G.k.2.1.KR.1a], SUBSTANCEVERSION [G.k.2.3.r.1.KR.1a]
- PATIENTBIRTHDATER3 [D.2.1]
- PATIENTONSETAGE [D.2.2a] and PATIENTONSETAGEUNITR3 [D.2.2b]
- GESTATIONPERIOD [D.2.2.1a] and GESTATIONPERIODUNITR3 [D.2.2.1b]
- PATIENTAGEGROUP [D.2.3]
- REACTIONOCCURCOUNTRY [E.i.9]
- STUDYNAME [C.5.2]
- STUDYREGNUMB [C.5.1.r.1]

Validations of the following element has been updated:

- OTHERSTUDIESTYPE [C.5.4.KR.1]
- DRUGMEDICALPRODUCTID [G.k.2.1.KR.1b]

- REACTIONOCCURCOUNTRY [E.i.9]
- PATIENTINVESTIGATIONNUMB [D.1.1.4]
- PATIENTSEXR3 [D.5]

The XML reference file provided by the South Korea MFDS for Individual Case Safety Reports (ICSRs) has been incorporated.

Console changes

To transmit the STUDYNAME [C.5.2] element in the Korean language for E2B(R3) submissions to MFDS, `Console > Study Configuration > Study Description` has been enhanced to support multi-language data entry. The list of languages is the same as the standard set of languages supported in the case form fields, like Narratives. Data configured in French, German, Italian, or Spanish has been retained as-is in the multi-language data entry window.

For more information, refer to the *ArgusInterchange823_E2B (R3) Export Mappings.xlsx*.

EC Manufacturer Incident Report (MIR) updates

The European Commission has released updated version of Manufacturer Incident Report (MIR) 7.2.1 that allows data to be transmitted in PDF format and XML format to National Competent Authorities and Notified Bodies.

The following are the updates to support the new MIR 7.2.1:

- Mapping updates to the existing tags.
- Support for new XSD MIR 7.2.1 provided by the European Commission.
- New MIR 7.2.1 PDF report.

Regulation updates

Based on the new IMDRF Annexures released in August 2020 by IMDRF/FDA, the CFG_FDA_IMDRF repository has been updated to support storage of the new annexures for Device Problem, Evaluation Codes, Clinical Signs, and Health Impact.

Based on the updates to CFG_FDA_IMDRF_CODES, the allowed values for the following profiles has been updated with the new values:

| Profile Impacted | Element Name [Number] |
|--------------------------------------|--------------------------------------|
| ICH-ICSR V2.2 MESSAGE TEMPLATE - FDA | EVALUATIONVALUE [B.4.k.20.FDA.19.1b] |
| CBER EVAERS V1.0 MESSAGE TEMPLATE | DEVICEPROBLEMCODE [FDA.G.k.12.r.3.r] |

Case form changes

The Incident information and Manufacturer Final Investigation results sections in the `Product > Device` tab have been deprecated.

- Device Evaluation Type Level
- Device Event Type Level

Interchange mapping utility changes

The mapping logic of the following elements have been revised for the existing MIR Message Template EC-MIR MESSAGE TEMPLATE:

- imdrfClinicalCodeChoice1 to 6
- adverseEventDateFrom
- deviceClass
- otherCountries
- otherCountriesLi
- distribution_all

Validation check

Based on the MIR 7.2.1 XSDs released by the EC, XSD Version 7.2.1 of 05.2020 has been adapted as part of this release to support validation of the MIR Reports.

For more information, refer to the *ArgusInterchange823_MIR Export Mappings.xlsx*.

Brexit-related changes (Enhancement 32359983)

ICSR Reporting to MHRA -Post Brexit

Regulation updates published by EMA and MHRA effective from January 2021 for the implementation of the Protocol on Ireland/Northern Ireland have the following information regarding the ICSR submission:

1. Serious and Non-serious adverse reactions occurring in Great Britain, and Serious adverse reactions occurring from other countries must be submitted to MHRA.
2. For UK ICSRs that have not been previously submitted directly to the MHRA, the system schedules a downgrade or nullification report to the MHRA, and also to Eudra Vigilance.
3. Serious and Non-serious ICSRs for Northern Ireland must continue to be submitted to EudraVigilance and MHRA. A new ISO Country code is introduced specifically for Northern Ireland.
4. Non-serious adverse reactions occurring in the Great Britain [GB (England, Scotland and Wales)] are no longer submitted to EudraVigilance after the withdrawal date.
5. Follow-up reports (including nullifications) received for GB non-serious ADRs received prior to the withdrawal date, should continue to be submitted to EudraVigilance using country code GB.

Code List Updates

A new country, NORTHERN IRELAND, is included in the country code list and EEA flexible code list attribute is updated to include NORTHERN IRELAND as part of EEA.

EEA flexible code list attribute is updated to remove "United Kingdom" from the EEA Countries.

Interchange Updates

1. Import and Export Mapping Logic are updated for EMA R2 and R3 Profile for country code "XI".

| Profile | Elements for Export | Elements for Import |
|-------------------------------------|--|---|
| ICH-ICSR V2.1 MESSAGE TEMPLATE –EMA | REPORTERCOUNTRY [A.2.1.3] PRIMARYSOURCECOUNTRY [A.1.1] OCCURCOUNTRY [A.1.2] SENDERCOUNTRYCODE [A.3.1.4e] RECEIVERCOUNTRYCODE [A.3.2.3e] OBTAINDRUGCOUNTRY [B.4.k.2.3] DRUGAUTHORIZATIONCOUNTRY [B.4.k.4.2] | REPORTERCOUNTRY [A.2.1.3] OCCURCOUNTRY [A.1.2] OBTAINDRUGCOUNTRY [B.4.k.2.3] DRUGAUTHORIZATIONCOUNTRY [B.4.k.4.2] |
| ICH-ICSR V3.0 MESSAGE TEMPLATE –EMA | REPORTERCOUNTRYR3 [C.2.r.3] DRUGAUTHORIZATIONCOUNTRY [G.k.3.2] OBTAINDRUGCOUNTRY [G.k.2.4] REACTIONOCCURCOUNTRY [E.i.9] | REPORTERCOUNTRYR3 [C.2.r.3] SENDERCOUNTRYCODE [C.3.4.5] STUDYREGCOUNTRY [C.5.1.r.2] REACTIONOCCURCOUNTRY [E.i.9] OBTAINDRUGCOUNTRY [G.k.2.4] DRUGAUTHORIZATIONCOUNTRY [G.k.3.2] |

2. Allowed value are updated for EMA R2 and R3 Profile with new country code "X1" for the following elements:

| Profile | Elements |
|--------------------------------------|--|
| ICH-ICSR V2.1 MESSAGE TEMPLATE - EMA | DRUGAUTHORIZATIONCOUNTRY [B.4.k.4.2] OBTAINDRUGCOUNTRY [B.4.k.2.3] OCCURCOUNTRY [A.1.2] PRIMARYSOURCECOUNTRY [A.1.1] RECEIVERCOUNTRYCODE [A.3.2.3e] REPORTERCOUNTRY [A.2.1.3] SENDERCOUNTRYCODE [A.3.1.4e] |
| ICH-ICSR V3.0 MESSAGE TEMPLATE - EMA | DRUGAUTHORIZATIONCOUNTRY [G.k.3.2] OBTAINDRUGCOUNTRY [G.k.2.4] REACTIONOCCURCOUNTRY [E.i.9] REPORTERCOUNTRYR3 [C.2.r.3] SENDERCOUNTRYCODE [C.3.4.5] STUDYREGCOUNTRY [C.5.1.r.2] |

For more information on mappings refer to the following mapping documents:

| E2B R2 | E2B R3 |
|---|---|
| Import : ArgusInterchange823_E2B (R2) Import Mappings.xlsx | Import: ArgusInterchange823_E2B (R3) Import Mappings.xlsx |
| Export: ArgusInterchange823_E2B (R2) 2.1 Export Mappings.xlsx | Export: ArgusInterchange823_E2B (R3) Export Mappings.xlsx |

Sending reporter-related elements and Protect confidentiality check box is marked (Enhancement 29745574)

When you submit an ICSR to EMA with multiple reporters data and if data is missing for all of the elements REPORTERFAMILYNAME, REPORTERORGANIZATION, REPORTERPOSTCODE, and REPORTERCOUNTRY elements for a non-primary reporter, you get a Negative Acknowledgment: "At least one of these elements must contain a value: REPORTERFAMILYNAME, REPORTERORGANIZATION, REPORTERPOSTCODE, REPORTERCOUNTRY."

Mapping rules are now enhanced, such that REPORTERCOUNTRYR3 [C.2.r.3] is populated, even when the Protect confidentiality check box is marked. Additionally, new validation is provided to check if at least any one of the elements is present with a valid value in all the reporters included in ICSR REPORTERFAMILYNAME [C.2.r.1.4], REPORTERORGANIZATION [C.2.r.2.1], REPORTERPOSTCODE [C.2.r.2.6], and REPORTERCOUNTRY [C.2.r.3].

For more information, refer to the *ArgusInterchange823_E2B (R3) Export Mappings.xlsx*.

Common profile switches updates (Enhancement 32349328)

The DLP_EXPEDITED_E2B_REPORTS internal Common profile switch is now displayed in the UI in `Common Profile Switch > Case Form Configuration > Modify Case Form Configuration > Modify Data Lock Point > Run Expedited and E2B Reports on DLP`.

The Run Expedited and E2B Reports on DLP check box is enabled only when the Enable Data Lock Point option is checked.

If the Run Expedited and E2B Reports on DLP option is checked, then the Expedited and E2B reports are executed on the DLP database.

If the Run Expedited and E2B Reports on DLP option is unchecked, then the Expedited and E2B reports are executed on the Argus database directly.

Reporter information display in codelist with large number of institutions associated (Enhancement 19362177)

In Japan, pharma companies use the Ultmarc dictionary for Reporter and Institution data. This dictionary contains a large number of Reporter and Institution information. Oracle Argus Safety is enhanced such that `Codelist > Reporter Information` can display a large number of records, with optimal processing performance.

There are improvements made in the Oracle Argus Safety application to handle large number of records, listed below:

1. In the top section of the Reporter Information page, only one Institution name is displayed.
2. If the reporter is associated with multiple institutions, a (+) symbol is displayed next to the Institution name to depict that there are multiple institutions associated.

3. Searching based on Institution value using Filter continues to work as before, all reporters associated with that institution are retrieved even though only the first institution name is displayed for the reporter in the top section.
4. In the bottom section of the Reporter Information page, all the institutions associated with the selected reporter are displayed sorted in alphabetical order in the text box (instead of drop down). The same updates are applicable for the Reporter Information > J data entry screen also when logged in as Argus J user.
5. To add a new institution, click on the **Add** button to open a window with a search box to search based on Institution name.
6. Click the **Delete** button to delete the selected institution.
7. The **Print** button shows 2 options: **Current Selection**, and **Print All**.
 - a. The **Current Selection** option prints only the selected reporter record.
 - b. The **Print All** option prints all the reporter records displayed based on the filter criteria.
 - c. It is recommended to use the **Print all** option along with the filter. If there are a lot of reporter records, then **Print all** could take many hours to process, depending on the data.



Note:

The application works as expected on navigating to Argus Console > Code Lists > Reporter Information, even when there are large number of active reporters, as well as institutions.

Argus Console enforces field configuration for E2B destinations (Enhancement 32176831)

In the Reporting Destination configuration, under the EDI tab, if you select **Message Profile** and click on the **Save** button, the application validates the mandatory fields and does not allow you to save the information.

1. When the Incoming Folder or the Outgoing Folder path is not populated, the application displays the following error message: "Incoming Folder and Outgoing Folder paths cannot be blank if Message profile is selected."
2. When the file name is not populated, the application displays the following error message: "File Name cannot be blank if Message profile is selected."
3. If the EDI Header is checked when the XML option is selected, the application displays the following error message: "EDI Header should not be checked when XML option is selected."
4. If the selected message profile is R2, Argus Console additionally enforces the following validations:
 - a. If the Encoding value is not selected, the application will display the following error message: "Encoding cannot be blank if the Message profile selected is E2B(R2)."

- b. If the Transmit ICSR Attachments option is checked and the ICSR Attachment Outgoing folder is not populated, the application displays the following error message: "ICSR Attachment Outgoing folder cannot be blank if Transmit ICSR Attachments check box is checked and the Message profile selected is E2B(R2)."
 - c. When the XML radio option is selected in the EDI tab, the application will display the following error message: "URL for Message Schema cannot be blank if Message profile selected is of type E2B(R2)."
 - d. If the XML version is missing, the application will display the following error message: "Please enter a numeric value greater than zero for XML Version."
 - e. When the XML radio option and Ack profile are selected but the option URL for Ack Schema is not selected, the application will display the following error message: "URL for Ack Schema cannot be blank if the Ack profile is selected and the Message profile selected is E2B(R2)."
 - f. When the SGML radio option is selected, but the SGML Declaration File is not selected, the application will display the following error message: "SGML Declaration File cannot be blank if SGML option is selected."
5. If the EDI Header is checked when the XML option is selected, the application will display the following error message: "EDI Header should not be checked when XML option is selected."

Chart option in CDA report configuration

The chart option in the CDA report configuration screen has been deprecated. The **Report Display Type** drop down and the **Chart Options** box are removed from the CDA configuration screen.

If there are existing reports configured with the **Chart** option, then they are updated as **Data** in the back-end. When you open the existing report from `Reports > Aggregate Reports > System Reports Library`, then the **Report Display Type** drop-down and **Chart Options** does not appear.

Updates to EMA E2B(R2) submissions when patient related fields are marked for Protect Confidentiality

EMA GVP Module VI revision 2 recommends that data elements such as patient's age, age group and gender are submitted in non-redacted form. In order to handle this, the export mapping logic for the below elements of the ICH-ICSR V2.1 MESSAGE TEMPLATE – EMA profile is updated to send the available data even if Protect Confidentiality is checked in the `Case form > Patient Information` section:

1. PATIENTONSETAGE [B.1.2.2a]
2. PATIENTONSETAGEUNIT [B.1.2.2b]
3. PATIENTAGEGROUP [B.1.2.3]
4. PATIENTSEX [B.1.5]

For more information on mappings, refer to the *ArgusInterchange823_E2B(R2) 2.1 Export Mappings.xlsx* mapping document.

Enhancements to Oracle Argus Insight

The following are the enhancement to Oracle Argus Insight:

- [Removal of common profile switches related to BO/Cognos](#)

Removal of common profile switches related to BO/Cognos

- The following references and common profile switches have been removed in this release, along with any references made by the application:
 - FAILED RECIPIENTS STATUS EMAIL ADDRESS
 - BO WEB URL
 - COGNOS AUTHENTICATION ENTERPRISE
 - COGNOS SINGLE SIGN ON ENABLED
 - COGNOS WEB URL
- The Oracle Argus Insight menu to invoke BO and Cognos has been removed.

Merged Patches

The bug fixes from the following patches are merged with Oracle Argus 8.2.3:

- 8.2.1.4
- 8.1.2.504
- 8.1.3.2
- 8.2.2.1
- 8.2.1.6
- 8.2.1.7
- 8.2.0.8
- 8.2.1.501
- 8.2.1.8

Download Oracle Argus 8.2.3

Execute the following steps to download the patch from My Oracle Support (MOS):

1. Open an MOS (<https://support.oracle.com>) session in a browser.
2. Click the **Patches & Updates** tab.
3. In the **Patch Name** or **Number** field, enter the patch ID.
 - Argus Safety/Insight—**31973802**
 - Argus Mart—**31973812**
4. Click **Search**.

5. Click **Download** and save the compressed file to a temporary location on your local system.
6. Locate the downloaded file and extract it to a temporary directory. The file contains the Oracle Argus 8.2.3 Installer.

Install Oracle Argus 8.2.3

To install Oracle Argus Safety and Oracle Argus Insight, see the *Oracle Argus Safety and Oracle Argus Insight 8.2.3 Installation Guide*.

Note:

Oracle Argus Insight installation process has been moved from Schema Creation Tool to Liquibase for silent installation. The Schema Creation Tool (short cut from the Start Menu under Oracle Installation) has also been removed. You must use Liquibase for fresh schema creation or upgrade.

To install Oracle Argus Mart, see the *Oracle Argus Mart 8.2.3 Installation Guide*.

Upgrade Oracle Argus Database

See the respective Oracle Argus product installation guides for this release.

To upgrade Oracle Argus Safety, see:

- [Database upgrade version](#)
- [Upgrade Oracle Argus Safety from 8.1.x to 8.2.3](#)
- [Upgrade Oracle Argus Safety from 7.x to 8.0 and 8.0.0.x to 8.1](#)

Database upgrade version

You can upgrade database from either of the following versions:

- Oracle Argus Safety
 - 8.1
 - 8.1.1
 - 8.1.2
 - 8.1.2.1 to 8.1.2.6
 - 8.1.3
 - 8.1.3.1
 - 8.1.3.2
 - 8.2
 - 8.2.0.6 to 8.2.0.8
 - 8.2.1
 - 8.2.1.5 to 8.2.1.7

- 8.2.2
- 8.2.2.1
- Oracle Argus Insight
 - 8.1 to 8.2.1.4 including merged patches

Upgrade Oracle Argus Safety from 8.1.x to 8.2.3

See the *Oracle Argus Safety and Oracle Argus Insight 8.2.3 Installation Guide*.

Upgrade Oracle Argus Safety from 7.x to 8.0 and 8.0.0.x to 8.1

1. From Oracle Argus 8.0 Schema Creation Tool, validate the Oracle Argus Safety and DLP Schema (if DLP is currently installed), using the file `VLDN_80.CTL` located at `.\Oracle\Argus\DBInstaller\SchemaValidation`.
2. Verify the validation log file and make sure that there are no errors, missing and invalid objects.
3. Install the recommended Java version on the server from where the following steps will be executed.

Refer to the *Oracle Argus Safety and Oracle Argus Insight 8.2.3 Installation Guide, Section Oracle Components*.

4. From Oracle Argus Safety 8.9.9.003 patch (patch ID: 30398730), use one of the following upgrade folders and paste it on the server where Oracle Client is installed.
 - To upgrade from 7.x to 8.0, use `.\Argus_Database_Upgrade\1-Upgrade_from_7x_to_80`.
 - To upgrade to 8.0.0.x to 8.1, use `.\Argus_Database_Upgrade\2-Upgrade_from_800x_to_81`.

When copied, update the `dbinstaller.properties` file as mentioned below:

- **ArgusSecurekey** location
- **TDE** attribute (if required) with the required connection details.
- All the user details present in the properties file.
- Parameters as specified for the Oracle Argus Safety Database setup. For more details, refer to the *Oracle Argus Safety and Oracle Argus Insight 8.2.3 Installation Guide, Section Oracle Argus Safety Database Upgrade*.

Alternatively, to upgrade Oracle Argus Safety from the user interface, go to the `2-Upgrade_from_800x_to_81\dbinstaller` folder, open the command prompt, and run the `dbinstallerUI.bat` file as an administrator.

For more details to upgrade from the user interface and for silent upgrade (using the `dbinstaller.bat` file), refer to the *Oracle Argus Safety and Oracle Argus Insight 8.2.3 Installation Guide, Section Oracle Argus Safety Database Upgrade*.

5. Upgrade Oracle Argus Safety from 8.1.x to 8.2.3

6. Validate the Oracle Argus Safety and DLP Schema, refer to the *Oracle Argus Safety and Oracle Argus Insight 8.2.3 Installation Guide, Section Validate Oracle Argus Safety Database*.
7. Verify the validation log file and make sure that there are no errors, missing and invalid objects. Ignore any extra objects in validation due to `dlp_case_rev_master_bkp` and `tmp_dcrm_upd_data`, these objects are related to `dlp_case_rev_master` correction script.