Oracle Argus

Release Notes—What's New

Release 8.4.2
F89046-01
January 2024

Oracle Argus Release Notes—What's New, Release 8.4.2

F89046-01

Contents

Preface

This preface contains the following sections:

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 Life Sciences Support Cloud (https://hsgbu.custhelp.com/)
- Japanese interface of Oracle Life Sciences Support Cloud へようこそ (https://hsgbu-jp.custhelp.com/)

You can also call our 24x7 help desk. For information, visit Life Sciences Support | Oracle or visit Oracle Accessibility Learning and Support 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.

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What's New

Technology Stack

The following component has been updated to the Oracle Argus 8.4.2 technology stack:

- Axway 2.6 UP2023-10

See:

- Dictionary support

Dictionary support

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

Dictionary	Supported versions
MedDRA Dictionary	26.0 (March 2023), 26.1 (September 2023) 25.0 (March 2022), 25.1 (September 2022) 24.0 (April 2021), 24.1 (September 2021)
WHO Drug Dictionary (Format: B3 and C3, both English and Chinese)	March 2023, September 2023 March 2022, September 2022 March 2021, September 2021
J Drug Dictionary	April 2023, October 2023 April 2022, October 2022 April 2021, October 2021
JFMDA Dictionary	5.0 4.0

Oracle Argus Compatibility Matrix

Application	Compatible Version with this Argus Safety Release
Oracle Argus Analytics	8.4.1
Oracle Argus Insight	8.4.2
Oracle Argus Mart	8.4.2
Oracle Safety One Intake	23.4
Oracle Life Sciences Empirica Signal and Oracle Life Sciences Empirica Topics	9.2.2.1

Enhancements to Oracle Argus Safety

The following are the enhancements to Oracle Argus Safety:

MedWatch 2022 updates

Summary

FDA MedWatch 3500A form version 11/22 updates (Enhancement 34764890)

Description

Food and Drug Authority (FDA) has released new MedWatch form in November 2022 for Manufacturers, User Facilities, and Importers to submit adverse events reported for Drugs or Devices to FDA.

Oracle Argus Safety is enhanced to support 2022 template released by FDA for the MedWatch Drug report using a new Interchange profile.

The following sections lists the changes made in the application to support the new MedWatch Drug report.

Case Form changes

- New field named **Current Gender** is added in `Case Form > Patient`.

- In the Patient tab, the existing Gender field is renamed as **Gender at Birth**.
- The values that are populated in the Current Gender and Gender at Birth fields are controlled through MEDWATCH attribute in the GENDER flexible code list.

Console changes

- CBER-IND is added to the Clinical Reference Type code list as factory data and IND reference type is renamed for CDER-IND. These values are used for the IND number population logic in box G4.
- New values are added to the Gender code list along with new attribute MEDWATCH to control the values to be displayed in the Current Gender and Gender at Birth fields.
- The length of the Gender code list is increased from 15 to 25.
- The following changes are made to the Reporting Destination code list:
  - When the agency configured with MedWatch profile has Email address as blank, after selecting the Preferred Method as Email, a warning message appears asking you to fill in the email address.
  - The Attachments field in the `Agency Information > Report Transmissions` options are set to the default value of Single. This setting ensures that the system generates individual PDF reports and attach them to emails.
  - In the Reporting Destination EDI tab, transmission related fields are disabled when the MedWatch profile is selected in `EDI > Message profile` for both standard and custom MedWatch.
- New MedWatch attribute is introduced in DOSE_FREQUENCY.

> **Note:**
>
> - The MedWatch Device report is not upgraded to 2022 format as it is not used for regulatory reporting purpose.
> - Transmission of the MedWatch drug report using fax route is de-supported.
> - The common profile switches present in the following location are not used for the MedWatch Drug report, but are used in the MedWatch Device report as per the existing functionality:
>   - `Reporting > Expedited > MedWatch`
>   - `Reporting > Expedited > MedWatch > MedWatch Configuration`

For more information, refer to the *Argus_Safety_8.4.2_CaseForm_Console_Updates_Summary.xlsx.*

Interchange mapping updates

The **FDA MedWatch 3500A Drug Template** for MedWatch is now supported through the Interchange Mapping Utility framework with default profile and out of the box mappings. The system supports copy of the profile and allows editing of the copied profile.
For more information on the mappings, refer to the *ArgusSafety8.4.2_MWPaperReportMappings.xlsx.*

Generation, transmission, tracking of reports

- The MedWatch Drug report is scheduled through manual scheduling and auto scheduling, can be generated from the following locations:
  - Regulatory reports tab
  - Batch reports using Case actions > Open
  - Draft tool bar
  - ICH PSUR, CTPR, and NDA periodic reports
- The MedWatch Drug report is generated in PDF format and can be transmitted in the Email route.
- You can send and track MedWatch drug reports from `Worklist > Bulk Transmit`.
- The MedWatch Drug report form is used to invoke the MedWatch 2022 format and it can be invoked from the following locations as per the existing functionality:
  - Case Form > Regulatory Reports tab
  - Case Form > Draft tool bar
  - Case Form > Medical Review dialog
  - Worklist > Bulk transmits
  - Worklist > Reports
  - Reports > Compliance > Expedited
  - Reports > Compliance > Submitted
  - Reports > Bulk Reporting
  - Business Configuration > Expedited Reporting Rules > Report Form
  - Case Action > Open > Batch
  - LAM > Local Affiliate > Report Distribution
  - LAM > Local Affiliate > Report Submission (Submitted Reports/Non-Submit reports)
  - LAM > Local Affiliate > Bulk Reporting

Validation and attachments

The MedWatch Drug report is generated without any minimum data requirements. However, an error message is displayed when you try to generate the MedWatch report for a reporting destination that is not configured with the MedWatch profile (standard or custom).

The PDF attachments included in the `Case Form > Additional Information > Notes and Attachments` section are attached to the MedWatch report, if the **Incl. Reg. Sub** field is marked as per the existing functionality. The Appendix page prints details of the PDF attachments.

When MedWatch is selected in the Periodic Report selection criteria for PSUR, CTPR, and NDA, then the Reporting Destination drop-down displays only those agencies that has MedWatch profile (standard or custom) configured in the following sections.

- `Reports > Periodic Reports > ICH PSUR or CTPR > Summary Tabulations > Additional Expedited Report Forms (CIOMS/MedWatch/VAERS)> Print MedWatch > Forms of Agency`.
- `Reports > Periodic Reports > NDA > Line Listing > Print MedWatch > Forms of Agency`.

> **Note:**
>
> The existing Reporting Destination that are used for sending the MedWatch report must be updated by setting the Message profile to MedWatch drug report (standard or custom). If there are any Periodic reports that are configured to generate the MedWatch report, then make sure that the Reporting Destination is configured with MedWatch drug report profile (standard or custom).

New FDA E2B (R3) FAERS profile

Summary

New FAERS E2B(R3) profile for reporting to FDA (Enhancement 31990841)

Description

FDA E2B (R3) standards refer to a set of guidelines and regulations established by the U.S. Food and Drug Administration (FDA) for electronic submission of the adverse event reports in the pharmaceutical and healthcare industries to the FDA-FAERS system. FDA data elements conforms with ICH ICSR Implementation Guide and includes 28 regional elements.

The Argus application is enhanced with the capability to schedule, generate, transmit, track, and submit the E2B (R3) reports in accordance with the FAERS E2B(R3) Implementation Guide and Business Rules published by FDA. The new profile provided in this release enables E2B(R3) submission for both pre-market and post-market Safety report to FAERS. For more information, refer to the *Oracle Argus Safety E2B(R3) Best Practices*.

The following sections lists the changes made in the application to support FAERS E2B(R3).

Case Form changes

- A new field **FDA Additional Information on Drug** is added in the `Case Form > Product` tab.
- You can provide the cross-reported IND in the `Additional Information tab > Reference` section.

Console changes

- The following new fields are added in the Argus Console:
  - To capture the NDC codes, the **Product Identifier Type** and **Product Identifier** are added in the `Business Configurations > Products > Licenses` screen. Values configured in the License screen are copied to the respective fields in Case Form for company products.

- To configure separate submission paths within FDA divisions such as CDER, CBER-IND, and CDER-IND CDER_IND_EXEMPT_BA_BE, the **Secondary Agency/ Department Identifier** field is added in the `Code List > Reporting Destination > EDI > Agency Information` section.
- The standard code list and its respective flexible code lists are updated with additional factory data:
  - Clinical Reference Type
  - Reference Type
  - Formulation
  - Routes of Administration
- New criteria **Study Reference type** is added in the reporting rules to filter reporting rules based on the clinical reference associated with the study.
- Study configuration now allows you to capture the Cross Reference IND under the Clinical Reference section as free text. The CBER-IND, CDER-IND, and Pre-ANDA options allow you to select the investigation drug or vaccine license using the drop-down.

For more information, refer to the *ArgusSafety842_CaseFormConsoleUpdatesSummary.xlsx*.

Interchange mapping updates
A new message profile template (ICH-ICSR V3.0 MESSAGE TEMPLATE – FAERS) is provided to submit the report to FDA in the E2B(R3) format.

- Default mappings for export and conformance rules are provided in accordance with the FDA guidelines.
- This new profile is used to generate of the following type of reports:
  - Post-Marketed (Combination Product and Non combination product) reports
  - Pre-Market (IND and IND-exempt BA/BE) reports

> **Note:**
>
> Import of the E2B(R3) files from FDA is not supported by the ICH-ICSR V3.0 MESSAGE TEMPLATE – FAERS profile.

A new acknowledgment profile template (ICH-ICSR V3.0 ACKNOWLEDGMENT TEMPLATE - FAERS) is provided to receive acknowledgment from FDA in the E2B(R3) format.
For more information on the mappings, refer to the *ArgusInterchange842_E2B (R3) ExportMappings.xlsx*.

Generation, transmission, and tracking of reports
The FAERS E2B(R3) report is generated in the HL7 format, with appropriate comments and display names embedded in the XML, for easy identification of data elements. The ICSR Viewer for the report supports three views:

- XML view
- HL7 view

- Decoded view

You can send and track reports from `Worklist > Bulk ICSR Transmit` and `Utilities > ICSR > ICSR Transmit Status`.

Validation and attachments
The FAERS E2B(R3) profile is provided with validation rules as a part of factory data, based on the conformance rules in accordance with the FDA guidelines.
During E2B(R3) report generation, case data is validated against the conformance rules based on the IND, Pre-ANDA, and Post-Marketed report types. The ICSR validation report is displayed with the list of conformance rule failures as well as validation errors due to attachment file size and the overall report size exceeding the configured values in Reporting Destination.
If there are no failing conformance rules, then the E2B(R3) report is generated.
Attachments configured for the Reporting Destination are embedded by encoding them in the B64 format. Attachment types supported for FAERS E2B(R3) is provided as a part of factory data in `Console > Flexible Code Lists > Media Types`.
Attachments that does not comply with the Mediatype code list configuration for the FDA profile are not included in the E2B(R3) report.

Enhanced grid for duplicate search results

Summary

Duplicate search results grid update (Enhancement 35378754)

Description

The grid that displays the duplicate search results in the manual Book-in and ICSR Pending screens is enhanced to include the following additional fields:

- Reporter Occupation
- Reporter Institution
- Patient Gender
- Patient Age

The Pat Initials field is renamed as Patient Initials in the manual and E2B Book-in duplicate search results grid.

The pre-existing fields are moved to different positions to accommodate the new fields or columns, and maintain grouping per subject.

Multiple attachments in a single e-mail

Summary

Multiple attachments in a single e-mail from Oracle Argus Safety (Enhancement 35522259)

Description

The General Email AG Service is enhanced to enable multiple attachments being sent in a single e-mail when multiple records in the RPT_TRANSMIT_EMAIL_ATTACH table are mapped to a single record in the RPT_TRANSMIT_EMAIL table.

This is a middle layer functionality with no changes to the Oracle Argus Safety user interface.

Ability to view reports in read-only mode

Summary

View final generated reports when case is opened in read-only mode (Enhancement 35060186)

Description

When a case is opened in read-only mode, the application enables you to view the final reports whether generated, approved, or submitted based on the following scenarios:

- Case is opened by another user
- Workflow restriction
- Case Actions > Case Open > Open Read Only
- Worklist > New > Open Read Only
- Worklist > Open > Open Read Only
- Dashboards > Case Workload > Worklist Specific > Open Read Only
- Dashboards > Workflow Status > Worklist Specific > Open Read Only

You can view the final reports, when the case is opened in read-only mode due to security restrictions imposed via the following options:

- Argus Console > Argus > Groups > Case Form > View
- Argus Console > Argus > Users > Enable Site Security > View
- Argus Console > System Configuration > Workflow > Privileges to others > Read-Only

Added new languages

Summary

New languages added in the LANGUAGES flexible code list (Enhancement 35899977)

Description

The application is enhanced to include the following list of languages in the LANGUAGES flexible code list:

English	Japanese	ISO639-2
Albanian	アルバニア語	sqi
Arabic	アラビア語	ara
Georgian	グルジア語	kat
Hebrew	ヘブライ語	heb
Indonesian	インドネシア語	ind
Serbian	セルビア語	srp
Tagalog	タガログ語	tgl
Thai	タイ語	tha

English	Japanese	ISO639-2
Turkish	トルコ語	tur
Ukrainian	ウクライナ語	ukr
Vietnamese	ベトナム語	vie

These languages are loaded as factory data during the Oracle Argus Safety fresh install or upgrade process. For details on the new and updated values, refer to the *ArgusSafety842_CaseFormConsoleUpdatesSummary.xls*.

The list of languages is displayed in the Multi-Language Translations pop-up invoked from Case Form and Argus Console.

The list of languages is included as allowed values in the ICH-ICSR V3.0 MESSAGE TEMPLATE and ICH-ICSR V3.0 MESSAGE TEMPLATE - FAERS profiles for the CASESUMMARYLANG[H.5.r.1b] and PRIMARYSRCREACTREPORTEDLANG[E.i.1.1b] elements. No other profiles (such as NMPA, MFDS, or PMDA) are impacted.

> **Note:**
>
> These additional languages are not part of the Auto-narrative Configuration screen.

IMDRF 2023 updates

Summary

IMDRF 2023 Updates (Enhancement 36057359)

Description

IMDRF released AER Terminology codes annexures (A-G annexures) in March 2023, followed by FDA releasing Annexures by for the updated FDA codes in August 2023.

IMDRF Repository updates for Annex A-F
The CFG_FDA_IMDRF_CODES repository has been enhanced as specified below:

- Annex A
  - Added terms: A2501, A0514, A050408, and A0723
  - Modified terms: A050405, A07, A14, and A1412
  - Retired term: A071205
- Annex B
  - Added term: B25
  - Modified terms: B15, B16, and B24
- Annex C
  - Added terms: C0109, C0210, C0708, C2301, C2302, and C24

  - Modified terms: C1302 and C160504
- Annex D
  - Added terms: D20 and D21
- Annex E
  - Added terms: E0209, E0520, E0624, E0625, E0626, E0627, E0854, E0855, E0856, E0857, E1212, E1312, E1313, E1314, E1419, E1420, E1727, E2124, and E2343
  - Modified terms: E040202, E0607, E0824, E0827, E0845, E120501, E1308, E2012, E2302, E2322, and E2401
- Annex F
  - Added term: F2307
  - Modified terms: F11, F19, F1907, F2202, and F24

Device Component Repository updates for Annex G
The DEVICE_SUBCOMPONENTS flexible code list has been enhanced as specified below:

- Annex G
  - Added terms: G0200804, G03014, G03015, and G03016
  - Modified terms: G0200401 and G04097

CFG_M2 Repository updates
The Allowed Value repository (CFG_M2 table) for eVAERS and FDA 2.2 DTD profile has been updated.

For details on the new and updated values, refer to the *OracleArgusSafety842_CaseForm_Console_Updates_Summary.xls*

Added new Emperor in Argus Japan

Summary

Reiwa added in the Emperor code list due to change in emperor (Enhancement 35186626)

Description

The application is enhanced to include Reiwa in Console > Code Lists > Argus J > Emperor with the following details:

Field	Value
Emperor Name (J)	令和
Emperor Name	Reiwa
Date In Office	01-May-2019
Date Entry Abbreviation	R
Display	Yes

Added Select All check box in Worklists

Summary

Added Select All check box in the Worklist > New and Worklist > Open screens (Enhancement 35149842)

Description

The Worklist > New and Worklist > Open screens are enhanced to include a **Select All** check box to select all the cases displayed on that page.

Merged Patches

The following patch has been merged with Oracle Argus 8.4.2:

- 8.4.0.2
- 8.4.0.3

Download Oracle Argus 8.4.2

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.
   a. Argus Safety/Insight—**35805986**
   b. Argus Mart—**35806008**
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 8.4.2 Installer.

Install Oracle Argus 8.4.2

To install Oracle Argus Safety and Oracle Argus Insight, see the *Oracle Argus Safety and Oracle Argus Insight 8.4.1 Installation Guide*.

To install Oracle Argus Mart, see the *Oracle Argus Mart 8.4.1 Installation Guide*.

To install Oracle Argus Analytics, see the *Oracle Argus Analytics 8.4.1 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

You can upgrade the 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 to 8.1.3.2
  - 8.2
  - 8.2.0.1 to 8.2.0.8
  - 8.2.1 to 8.2.1.11
  - 8.2.2 to 8.2.2.2
  - 8.2.3
  - 8.2.3.001
  - 8.2.3.1 to 8.2.3.4
  - 8.4
  - 8.4.0.1 to 8.4.0.3
  - 8.4.1
- Oracle Argus Insight
  - 8.1 to 8.4.2 including merged patches
- Oracle Argus Mart
  - 8.1 to 8.4.2 including merged patches
- Oracle Argus Analytics
  - 8.1 to 8.4.1 including merged patches

Upgrade Oracle Argus Safety from 8.1.x to 8.4.2

See the *Oracle Argus Safety and Oracle Argus Insight 8.4.1 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 8.4.1 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 8.4.1 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 8.4.1 Installation Guide, Section Oracle Argus Safety Database Upgrade*.

5. Upgrade Oracle Argus Safety from 8.1.x to 8.4.2.
6. Validate the Oracle Argus Safety and DLP Schema, refer to the *Oracle Argus Safety and Oracle Argus Insight 8.4.1 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.