

Oracle Argus

Release Notes—What's New



Release 8.2.1

F28452-04

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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 8.2.1

F28452-04

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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>.

Related resources

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.

Revision History

Date, Version	Description
November 2019, Version 3	Updated Oracle Argus Compatibility Matrix .
September 2019, Version 2	Added Dictionary support .
August 2019, Version 1	Original version of the release notes.

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What's New

In this guide:

Technology Stack

The following components have been added to the Oracle Argus 8.2.1 technology stack:

- .NET Framework 4.7.2
- Oracle Database 18c
- Oracle Client 18c
- Oracle RAC 18c

Also, see:

Dictionary support

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

Dictionary	Supported versions
MedDRA Dictionary (English and Japanese)	22.0 (Mar 2019) 21.1 (Sep 2018), 21.0 (Mar 2018) 20.1 (Sep 2017), 20.0 (Mar 2017)
WHO Drug Dictionary (Format: B2, B3, C, and C3)	Mar 2019 Sep 2018 and Mar 2018 Dec 2017, Sep 2017, Jun 2017, and Mar 2017
J Drug Dictionary	Oct 2018 and Apr 2018 Apr 2017 and Sep 2016 Oct 2015, Aug 2015, and Apr 2015

Oracle Argus Compatibility Matrix

Application	Compatible Version with this Argus Safety Release
Argus Safety	8.9.9.89
Argus Insight	8.2.1
Argus Mart	8.2.1
Argus Analytics	8.2.1
Empirica Suite	9.0

Enhancements to Oracle Argus Safety

The following are the enhancements to Oracle Argus Safety:

Support for ReAuthentication with SSO system

Oracle Argus 8.2.1 introduces support for re-authentication with customer's corporate SSO system.

User Re-authentication

The following is the process overview that occurs when you attempt to re-authenticate from Oracle Argus Safety while performing privilege activity within the Case or Report workflow like **Case Lock** or **Unlock**, etc. Initial login does not utilize the re-authentication URI.

- Assumptions
 - Service Provider IDM (like OAM) supports Re-authenticate URI and sets the last re-authentication header every time a user is re-authenticated.
 - Re-authentication headers and URI are configured in **Argus Console > System Management > Single Sign-On**.
- Logical flow
 1. When you try to re-authenticate, say in case lock, a case locking authentication pop-up appears, where you re-authenticate yourself.
 2. When re-authentication is enabled, an **Authorize** link is provided instead of the **Password** field.
 3. On click of the **Authorize** link, you are redirected the IdP Login page, where the you enter your login credentials.
 4. IdP authenticates your credentials and responds to the Service Provider through the SAML assertions.
 5. Service Provider sets the Re-authentication HTTP Header value and redirects the request to Oracle Argus Safety post authentication process page.
 6. In the Case Locking screen, the signature icon changes to green and you can continue with the case lock operation.

Configure Re-authentication

In order to utilize the re-authentication feature, the following changes are done to the application:

- New profile switches are introduced under **Console > System Management > Single Sign-On**.

Profile switch	Type	Max length	Behavior	Default value
Enable Re-Authentication	Check box	—	Check this check box to enable the re-authentication fields.	Unchecked

Profile switch	Type	Max length	Behavior	Default value
Re-Authentication URL (For example, <protocol>://<host>:<port> / oamreauthenticate? redirect_url=)	Free text	2048	Re-authentication URL of the corporate LDAP system.	Empty
Re-Authentication HTTP Header	Free text	100	Header attribute	OAM_LAST_RE-AUTHENTICATION_TIME
Re-Authentication HTTP Header Date Time Format	Free text	100	Date format	Dy Mon dd hh24:mi:ss TZD yyyy

- In addition, the following logic is updated for the LDAP settings at a user configuration level: **Console > User Configuration Management Changes**:
 - **LDAP** check box is enabled if either **LDAP** or **Enable Re-Authentication** is enabled at the system level.
If neither is enabled, the check box is disabled.
 - **LDAP Server ID** drop-down is disabled and made blank when the **Enable Re-Authentication** check box is checked.
 - When both **Enable Re-Authentication** and **LDAP** details are configured simultaneously, then priority will be given to Re-Authentication feature.
You may skip providing LDAP details when Re-Authentication URL is configured.

Drop-downs converted to typeahead

For large codelist values, drop-down performance was slow.

To improve user experience and user response time, drop-down fields in the application are converted to typeahead where large codelist values are selected.

Drop-downs in Advanced Condition dialog box, **Local Affiliate** and **EOSU** have been updated to typeahead.

Merged installer for Oracle Argus Safety and Oracle Argus Insight

Oracle Argus Safety and Oracle Argus Insight maintain separate installers. As both the products are installed on the same web server, they have the same installation prerequisites. Having multiple installers require the product to maintain two separate code bases.

Oracle Argus Safety and Oracle Argus Insight are now merged into a common source repository and are built as a single unit and package.

This change impact both Oracle Argus Safety and Oracle Argus Insight installations but have no application functional change.

As a part of the merged installer, Oracle Argus Insight is available as an additional option in the Oracle Argus Safety Module Installer section. You may select or deselect it from installation on the server.

Both the products will be release through the common media.

Improved MedDRA Recode performance

The MedDRA Recode tool took days to execute a recode for the users with large volume of data. This led to delay in completing the activity within the required cut-over time. The application compared every case data row that had encoding against the new dictionary to validate if the term encoding required a re-encode. As encoding is stored in multiple tables for a single case, it would do multiple lookups to check for an update. This led to millions of checks for a large number of cases.

The application has been enhanced to lookup for an update through MedDRA Dictionary terms, and search the cases that may contain these terms and validate if updates are required. This enhancement reduces the overall number of checks and hence the time to re-encode.



Note:

Performance may not be as significant if the user selects the option to update the dictionary version for all the cases.

Enhanced MedDRA Recode to handle non-current LLT (Enhancement 28219520)

If LLT(E) is changed to a non-current LLT(E) in the target MedDRA dictionary, and recoding was done with the MedDRA J dictionary, then the Recode Tool replaces LLT(E) and LLT(J) with PT code and recodes if you have selected the **Process Non-Current Terms** option in the MedDRA recode configuration.

If LLT(J) is non-current but LLT(E) is current in the target MedDRA dictionary, then the application retains LLT(J) code as a non-current LLT(J) code is acceptable by PMDA.

A new column, **Messages**, is added to the following log files:

Log filename	Scenario	Message
<ul style="list-style-type: none"> (Case Form) - MedDRA_Recode_Success_NonCurrentJ_YYYY_MM_DD_HH_MIN (LM Data) - MedDRA_Recode_Success_LM_NonCurrentJ_YYYY_MM_DD_HH_MIN 	When LLT(E) and LLT(J) are replaced with PT code.	LLT(E) is non-current in target MedDRA dictionary: LLT(E) and LLT(J) replaced with PT.
<ul style="list-style-type: none"> (Case Form) - MedDRA_Recode_Success_YYYY_MM_DD_HH_MIN (LM Data) - MedDRA_Recode_Success_LM_YYYY_MM_DD_HH_MIN 	When LLT(J) is replaced with LLT(E).	LLT(E) and LLT(J) not under same hierarchy in target MedDRA dictionary: LLT(J) replaced with LLT(E).

Days Remaining calculated incorrectly based on most recent Aware Date for unsubmitted reports (Enhancement 29603540)

The **Worklist > Open** or **New** screen, displays the **Days Remaining** field is computed based on the **Due Soon – Current date**.

When managing unsubmitted reports for a case, Oracle Argus Safety calculated the value for **Days Remaining** based on the earliest known value for **Due Date**, instead of on the most recent **Aware Date** entered for the case.

A new common profile switch, **Days Remaining Calculation in Worklist**, is added in the **Workflow** node with the following options:

- Use earliest due date of reports pending submissions (default)

When...	...populate Due Soon date based on:
Auto-scheduling is done for the reports and the case contains scheduled reports.	Earliest due date of the report.
Auto-scheduling is done for the reports but the case does not contains any scheduled reports.	Latest aware date and duration as specified in the Due Soon Duration (in Days) for Worklist Calculation common profile switch.
Neither auto-scheduling is done for the reports nor likely to schedule a report.	Latest aware date and duration as specified in the Due Soon Duration (in Days) for Worklist Calculation common profile switch.
Auto-scheduling is not done for the reports but the reports are likely to be scheduled.	Earliest due date of the possible reports.

- Use latest aware date

When...	...populate Due Soon date based on:
Auto-scheduling is done for the reports, and may or may not contain any scheduled reports.	Latest aware date and duration as specified in the Due Soon Duration (in Days) for Worklist Calculation common profile switch.
Neither auto-scheduling is done for the reports nor likely to schedule a report.	Latest aware date and duration as specified in the Due Soon Duration (in Days) for Worklist Calculation common profile switch.
Auto-scheduling is not done for the reports but the reports are likely to be scheduled.	Earliest due date of the possible reports.

What's New in Oracle Argus 8.2.1 video available on Oracle Argus OHC page

A *What's New* video is now available on the Oracle Help Center (OHC) page for an overview of the enhancements in the latest release of Oracle Argus. Click [English](#) or [Japanese](#) to access the video.

DOCX format for Native Periodic Reports output

When printing Native Periodic Reports (PSUR, CTPR), the available output formats were PDF, RTF and CSV.

Now, the RTF format is no longer supported, instead the DOCX format is provided for report outputs.

Enhancements to Oracle Argus Safety Japan

The following are the enhancements to Oracle Argus Safety Japan:

Enhanced PSR and ReSD reports

As per the latest MHLW (parent agency of PMDA) guidance, MAH can submit the PSR and ReSD reports to PMDA as per the updated format. The following has been enhanced:

- Renamed ReSD Form 4 to Form 10 (Table).
- Renamed ReSD Form 5 to Form 11 (Listing).
- Added new ReSD Form 9 (Unlisted Events Table), ReSD Form 13 (Status of Overseas Measures Report), and ReSD Form 14 (Status of Study Report).
- Deprecated existing ReSD Form 7, Form 8, and Form 9.
 - If any of these reports are in the Submitted state, the user can open it without any errors.
 - If any of these reports are in any other state than Submitted, the application validates if the reports are generated successfully after the upgrade. As these reports are marked as deprecated, in the report output, the application fetches the existing data only.
- Impacted PSR Form 3 (Tables) and PSR Form 4 (Listing) due to changes in the ReSD Forms:

For more information, see:

Generic updates

- All the existing reports that are generated before the upgrade are retained as it is in the old format.
- All the reports that are generated or re-generated after the upgrade are generated in the updated format or layout as mentioned for individual forms.
- The existing profile switch **Event counting logic for P.S.R Form 3, 4 and ReSD Form 4, 5** is renamed as **Event counting logic for P.S.R Form 3, 4 and ReSD Form 10, 11**.
- The configuration parameters for PSR Form 3, PSR Form 4, ReSD Form 10, and ReSD Form 11 are editable even for the second time frame or above, similar to a fresh report (initial time frame).

A new option under the profile switch Event Counting Logic for PSR Form 3, PSR Form 4, ReSD Form 10, and ReSD Form 11 is added to allow the users to

configure the count each event field from a case with the timeframe where the case was **last** reported along with the count each event field from a case with the timeframe where the case was **first** reported.

- Common profile switch **Listedness Assessment Source for PSR and ReSD** is deprecated.

A new report-level configuration is added as **Listedness Assessed on** to configure the assessment parameter for the reaction: Case Assessment and Datasheet. PSR and ReSD reports based on the common profile switch considers the new report-level configuration for the new created reports. For the existing reports prior to upgrade, the option for **Listedness Assessed on** is set based on the value set in the common profile switch **Listedness Assessment Source for PSR and ReSD** during upgrade. This report-level parameter is considered for PSR Form 3, PSR Form 4, ReSD Form 10 (for Case listing only), ReSD Form 9, and ReSD tabulation (Listed and Unlisted tabulations).

- A new radio button is added in the **Report Configurations > Scheduling** tab to configure the **Inclusion Date** of the data:
 - For a new report it is set to the **Aware Date**.
 - For the existing reports prior to upgrade or copied reports is set to the **Date Submitted**.

This option cannot be edited for the second time frame report.

- To include the reaction reported to MHLW directly (cases sent from PMDA or MHLW to MAH):
 - In the Configuration screen, a new option is added to configure **Case Classification** using the **Classification for cases sent by PMDA** list box.
 - Filter the cases based on the case classification such that cases are fetched based on the configured classification from the Case Data tables.
 - Eliminate the cases already submitted to PMDA in the ESM.
 - Consider the cases based on Japan information receipt date.
 - Consider the PMDA Reporting criteria applicable for filter logic (Suspected, Serious, excluding un-reportable event)

ReSD Form 10 (old Form 4—Table)

- The report inclusion logic is enhanced such that the data inclusion logic validates if the **Aware Date** or **Date Submitted** of the report fall within the reporting time frame based on the report configuration.
- In addition to the existing configurations, it has been enhanced as listed below:
 - A new option under the profile switch **Event Counting Logic for PSR Form 3, PSR Form 4, ReSD Form 10, and ReSD Form 11** is added to allow the users to configure the count each event field from a case with the time frame where the case was last reported.
 - Case classification is configured in the **Classification for cases sent by PMDA** list box.
 - Data inclusion parameter is set to **Aware Date** or **Date Submitted**.
 - A report-level configurable option is added to print case count or event count for the PT/LLTs based on the report configuration.

- If **Case level count** is selected, and if same PT/LLT code appears in the case or E2B more than once, then the application counts the code only once.
- In addition to the existing data inclusion logic, it has been enhanced as below:
 - If the profile switch **Event counting logic for P.S.R Form 3, 4 and ReSD Form 10, 11** is set to **Count each event from a case with the timeframe where the case was reported last**, then the application prints the events from the latest submitted E2B report for the latest time frame where it was reported across all the time frames for which report is executed.
 - The Event Count logic is updated for case count or event count. The same is applicable for infection count.
 - Listed and Unlisted events are not segregated and printed separately.
 - Separate tables for case listing are added for **Listed** and **Unlisted ADR and Infections**.
 - Cases received by MAH from PMDA or MHLW and entered into the system, are included based on the inclusion criteria and configured case classifications.

ReSD Form 11 (old Form 5—Listing)

- There is no change to the counting logic.
- To include the reaction reported to MHLW directly (cases sent from PMDA or MHLW to MAH), same logic as ReSD Form 10 is applied.

ReSD Form 9 (Unlisted Events Table)

- The data is fetched directly from the case data.
- Data inclusion logic is same as that of the existing PSR NUPR Form 7.
- Includes Japan cases only.
- The data is fetched from the start of first time frame to the end of last time frame.
- Includes both **ADR** and **Infections**.
- Populates both **Serious** and **Non-Serious** Reactions which are segregated in the table layout in the form.
- Contains **Related** and **Unlisted Events** only (Listedness is determined based on both Case Assessment and Datasheet).
- Report output includes separate columns for **Case Count** and **Event Count**.
- Categorizes or groups preferred terms under SOC's.
- Generates the Case Listing report with an indication for events assessed as **Unknown** or blank.
- The report output supports advanced conditions and generation on DLP.

ReSD Form 13 (Status of Overseas Measures Report)

- The data inclusion logic is similar to that of the existing ReSD Form 7.
- Provides a report-level configurable option to include data based on the Aware Date of the submitted E2B or Paper report.

- Includes submitted E2B within the start of first time frame to the end of last-time frame.
- Cases are filtered based the **Reporting Category G(AG)**.
- The report output supports advanced conditions and generation on DLP.

ReSD Form 14 (Status of Study Report)

- The data inclusion logic is same as that of the existing ReSD Form 7.
- Provides a report-level configurable option to include data based on the **Aware Date** of the submitted E2B or Paper report.
- Includes submitted E2B within the start of first time frame to the end of last-time frame.
- Cases are filtered based on Category E(AE) and F(AF).
- The report output supports advanced conditions and generation on DLP.

PSR Form 3 (Tables)

- In addition to the existing configurations, it has been enhanced as listed below:
 - A new option under the profile switch **Event Counting Logic for PSR Form 3, PSR Form 4, ReSD Form 10, and ReSDForm 11** is added to allow the users to configure the count each event field from a case with the time frame where the case was last reported.
 - Case classification is configured in the **Classification for cases sent by PMDA** list box.
 - Data inclusion parameter is set to **Aware Date** or **Date Submitted**.
 - A report-level configurable option is added to print case count or event count for the PT/LLTs based on the report configuration.
 - If **Case level count** is selected, and if same PT/LLT code appears in the case or E2B more than once, then the application counts the code only once.
 - When the application is configured for the Case Counts of PT/LLT, then an option is provided to count **Count Listed & Unlisted as two separate events**.
- In addition to the existing data inclusion logic, it has been enhanced as below:
 - If the profile switch **Event counting logic for P.S.R Form 3, 4 and ReSD Form 10, 11** is set to **Count each event from a case with the timeframe where the case was reported last**, then the application prints the events from the latest submitted E2B report for the latest time frame where it was reported across all the time frames for which report is executed.
 - If **Count Listed** and **Unlisted** are checked as two separate events, and later the same reaction is marked as **Listed** for one entry in the case and **Unlisted** for the other entry, then the event is counted as two separate events.
 - If **Count Listed** and **Unlisted** are unchecked, and later the same reaction is marked as **Listed** for one entry in the case and **Unlisted** for the other entry, then the event is counted as **Unlisted** event.
 - The Event Count logic is updated for case count or event count. The same is applicable for infection count.

- Cases received by MAH from PMDA or MHLW and entered into the system, are included based on the inclusion criteria and configured case classifications.

PSR Form 4 (Listing)

- There is no changes to the counting logic.
- To include the reaction reported to MHLW directly (cases sent from PMDA or MHLW to MAH), same logic as PSR Form 3 is applied.

Updated new Japanese Era name in the PMDA Device Form 8 and 10 (Bug 29619644)

In Japan, the current era is Reiwa, which began on 1 May 2019, following the 31st (and final) year of the Heisei era.

The PMDA Device form 8 and 10 template published by PMDA contains Report Date in the format Emperor Name[Year of current in Emperor YY format]MMDD. The logic to print the Emperor Name is updated such that the latest Emperor Name is fetched from Codelist > Argus(J) > Emperor Name where Date In Office is less than the current date at the time of generation of the PMDA Device 8 and 10 report. If the Emperor Name is configured as (New Japanese Era) for the qualifying record in the codelist where Date In Office is less than the current date at the time of generation of the PMDA Device 8 and 10 report, then it is printed as Reiwa in the report output.

Enhancements to Oracle Argus Insight

The following are the enhancement to Oracle Argus Insight:

Merged installer for Oracle Argus Insight and Oracle Argus Safety

For details on the merged installer, see [Enhancements to Oracle Argus Safety > Merged installer for Oracle Argus Safety and Oracle Argus Insight](#)

Oracle Argus Insight now uses InstallShield for upgrades similar to Oracle Argus Safety. The external utility used by Oracle Argus Insight for upgrades is deprecated from this release.

Merged Patches

The bug fixes from the following patches are merged with Oracle Argus 8.2.1:

- 8.1.2.002
- 8.1.2.3
- 8.1.2.4
- 8.1.2.5
- 8.1.3
- 8.2.0.1
- 8.2.0.2

- 8.2.0.3
- 8.2.0.4
- 8.9.9.88

Download Oracle Argus 8.2.1

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—**29527006**
 - Argus Insight—**29527006**
 - Argus Mart—**30236757**
 - Argus Analytics—**30236782**
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 8.2.1 Installer.

Install Oracle Argus 8.2.1

The application does not support an in-place upgrade from any previous versions. Only a fresh application is supported.

For detailed instructions on how to install the various Oracle Argus products, see their respective installation guides.

Upgrade Oracle Argus Database

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

To upgrade Oracle Argus Safety, see:

Oracle Argus Safety upgrade version

You can upgrade the Oracle Argus Safety database from either of the following versions:

- 8.1
- 8.1.1
- 8.1.2
- 8.1.2.1 to 8.1.2.5
- 8.1.3
- 8.2

- 8.2.0.1 to 8.2.0.4

Upgrade Oracle Argus Safety from 8.1.x to 8.2.1

See the *Oracle Argus Safety 8.2.1 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 8.2.1 Installation Guide, Section 1.2.2 Oracle Components*.

4. From Oracle Argus Safety 8.9.9.002 patch, 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 8.2.1 Installation Guide, Section 11.2 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 8.2.1 Installation Guide, Section 11.2 Oracle Argus Safety Database Upgrade*.

5. [Upgrade Oracle Argus Safety from 8.1.x to 8.2.1](#).
6. Validate the Oracle Argus Safety and DLP Schema, refer to the *Oracle Argus Safety 8.2.1 Installation Guide, Section 10.4 Validate Oracle Argus SafetyDatabase*.
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.