Oracle Argus Safety
Argus Safety E2B(R3) Best Practices

Release 8.4.1

ORACLE®

Oracle Argus Safety Argus Safety E2B(R3) Best Practices, Release 8.4.1

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Preface

This preface contains the following sections:

- Documentation accessibility
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- 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 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.

1
Revision history

Argus version	Description
8.4	First release
8.4.1	Updated the Customize E2B(R3) profiles section.

2
Introduction

This document describes best practices and recommendations for configuring EMA and PMDA Agencies and Common profile switches for E2B(R3) reports.

3

Set up reporting destinations

You need to set up reporting destinations when sending E2B(R3) reports. Provide the following information in the **Agency Information** tab and **Local Company Contact** tab:

Agency Information tab

Enter Name and email address information of the Agency as applicable.

Local Company Contact tab

Enter Name and address information of the Local Company Contact that is responsible for ICSR submission. The following data can be updated for ICSR subset up reporting mission other than mandatory fields shown in UI:

- Sender Type
- Department
- Contact Name information
    - Title
    - First Name
    - Last Name
    - Address
    - City
    - State
    - Postal Code
    - Country
    - Phone
    - Fax
    - Email Address

For more information, see:

- Configure EDI

Configure EDI

The following table lists and describes the fields on the EDI tab:

Agency Identifier	EVCTM or EVPM	PMDA
File type	XML	XML
Company identifier	As applicable	As applicable
Message Profile	ICH-ICSR V3.0 MESSAGE TEMPLATE - EMA	ICH-ICSR V3.0 MESSAGE TEMPLATE - PMDA

Agency Identifier	EVCTM or EVPM	PMDA
ACK Profile	ICH-ICSR V3.0 ACKNOWLEDGMENT TEMPLATE - EMA	ICH-ICSR V3.0 ACKNOWLEDGMENT TEMPLATE - PMDA
Suppress ACK transmission	Marked	Unchecked (Default)
Transmit ICSR Attachments	Marked	Marked
Attachment Classification	As applicable	As applicable
Allowed attachment file size (in MB)	15 MB	15 MB
Allowed report size (in MB)	100 MB	AS1: 10 MB AS2: 50 MB
Incoming folder	Refer to the note below	Refer to the note below
Outgoing folder	Refer to the note below	Refer to the note below
ICSR Attachment Outgoing Folder	Not required	Not required
File Name	As required. For example: EVPM_########.xml	As required, for example: PMDA_########.xml
Method	E2B EDI gateway	E2B EDI gateway

> **Note:**
>
> If the Common profile Switch **Base directory path for gateway folders** is specified, then the Base directory path can be `\\10.100.80.100\Gatewaysharedfolder\`. The `In/Out` folders then need to be specified with sub folder path such as `EVPM\IN, EVPM\OUT`. Interchange services creates folders in the format `<Base folder path>\<Abbreviated Enterprise name >\<Sub folder path>`. If the folder name created by the Interchange services is not required when inserting the Abbreviated name of the Enterprise between the base directory path and the sub folder path, then the **Interchange service to exclude Enterprise abbreviated name for folder creation** parameter in the EDI tab of Reporting Destination codelist needs to be marked.

> **Note:**
>
> If the Common profile Switch **Base directory path for gateway folders** is not specified, then `In/Out` folders need to be specified with an absolute path such as `\\10.100.80.100\Gatewaysharedfolder\ EVPM\IN`. Interchange services creates folders using the folder structure provided in the Sub folder path.

4
Configure parameters for E2B(R3) reports

The following switches need to be reviewed and adjusted according to your requirements:

Number	Common profile switch	Description
1.	Default viewing format of the E2B R3 report	Allows you to configure the default view of displaying E2B(R3) in the ICSR viewer. The default value is Decoded view. The available options are XML View or HL7 View.
2.	Default viewing format of the PMDA E2B R3 report (used with Interchange-J)	Allows you to configure the default view of displaying PMDA E2B(R3) in the ICSR viewer. The default value is Decoded view. The options available are: • XML View • HL7 View • Paper View

5

Customize E2B(R3) profiles

Adherence to conformance rules and validation can be achieved during data entry by creating field validations in Argus Console.

For example, the below general date validations can be configured on the corresponding fields to warn user during data entry to take corrective action.

- Death Date must be greater than equal to Patient Date of Birth
- Parent date of birth must be earlier than date of birth for patient
- Date value in Date of Start of Reaction/Event must be lesser or equal to the Date of Death

For more details on how to configure field validations, refer to the Oracle Argus Safety Administration Guide > System Configuration > Configuring Field Validations.

For details on how to customize E2B(R3) profiles, refer to the *Oracle Argus Interchange ICSR Extensibility Guide*.