Oracle Argus Safety

Argus Safety E2B(R3) Best Practices

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Oracle Argus Safety Argus Safety E2B(R3) Best Practices, Release 8.4.4

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Contents

Preface

This preface contains the following sections:

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Revision history

Argus version	Description
8.4	First release
8.4.1	Updated the Customize Mappings and Validations section.
8.4.2	Updated the Set up reporting destinations to send E2B(R3) report and Introduction sections with FDA-specific recommendations.
8.4.3	Updated the Set up reporting destinations to send E2B(R3) report section to include the Apply EMA Special Rules parameter and added the Configure Folders section.
8.4.4	Updated the following sections: • Configure Attachments • Configure Folders • Configure Studies for FDA IND or Pre-ANDA reporting • Configure expedited rules • Configure parameters for E2B(R3) Reports and Acknowledgment

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Introduction

This document describes best practices and recommendations to configure the EMA, FDA, and PMDA agencies and common profile switches for the E2B(R3) reports.

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Set up reporting destinations to send E2B(R3) report

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 submission other than the 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 the EDI and Report tabs for EMA and PMDA
- Configure the EDI and Report tab for FDA
- Configure Attachments
- Configure Folders
- Configure Studies for FDA IND or Pre-ANDA reporting
- Configure expedited rules

Configure the EDI and Report tabs for EMA and PMDA

The following table lists and describes the fields on the EDI and Report tabs to be set up for the EMA and PMDA profiles:

Agency Identifier	EVCTM or EVPM	PMDA
Secondary Agency/Department Identifier	Not applicable	Not applicable
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
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 Configure Folders chapter	Refer to the Configure Folders chapter
Outgoing folder	Refer to the Configure Folders chapter	Refer to the Configure Folders chapter
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

Configure the EDI and Report tab for FDA

The following table lists and describes the fields on the EDI and Report tabs to be set up for the FDA profile:

Field	IND report	Pre-ANDA report	Post Marketed report
Agency Identifier	ZZFDA_PREMKT	ZZFDA_PREMKT	ZZFDA
Secondary Agency/ Department Identifier	CDER_IND or CBER_IND	CDER_IND_EXEMPT_BA_BE	CDER
File type	XML	XML	XML
Company identifier	As applicable	As applicable	As applicable
Message Profile	ICH-ICSR V3.0 MESSAGE TEMPLATE – FAERS	ICH-ICSR V3.0 MESSAGE TEMPLATE – FAERS	ICH-ICSR V3.0 MESSAGE TEMPLATE – FAERS

Field	IND report	Pre-ANDA report	Post Marketed report
ACK Profile	ICH-ICSR V3.0 ACKNOWLEDGMENT TEMPLATE – FAERS	ICH-ICSR V3.0 ACKNOWLEDGMENT TEMPLATE – FAERS	ICH-ICSR V3.0 ACKNOWLEDGMENT TEMPLATE – FAERS
Suppress ACK transmission	Unchecked (Default)	Unchecked (Default)	Unchecked (Default)
Transmit ICSR Attachments	Marked	Marked	Marked
Attachment Classification	As applicable	As applicable	As applicable
Allowed attachment file size (in MB)	15 MB	15 MB	15 MB
Allowed report size (in MB)	100 MB	AS1: 10 MB AS2: 50 MB	100 MB
Incoming folder	Refer to the Configure Folders chapter	Refer to the Configure Folders chapter	Refer to the Configure Folders chapter
Outgoing folder	Refer to the Configure Folders chapter	Refer to the Configure Folders chapter	Refer to the Configure Folders chapter
ICSR Attachment Outgoing Folder	Not required	Not required	Not required
File Name	As required, for example: `IND_########.xml`	As required, for example: `PREANDA_########.xml`	As required, for example: `NDA_########.xml`
Method	E2B EDI gateway	E2B EDI gateway	E2B EDI gateway
Apply EMA Special Rules	Marked	Marked	Marked

> **Note**
>
> You can check the **Apply EMA Special Rules** checkbox to apply EMA special instruction rules for cases that have at least one Reporter's Country that belongs to the European Union.

Configure Attachments

The file attachment types allowed for ICH, EMA, MFDA and NMPA E2B(R3) profiles are configured in **System Configuration > Common Profile Switch > Reporting > E2B**.

The file attachment types allowed for eVAERS and FDA E2B(R3) are configured in **Flexible Re-Categorization Code Lists > codelist name MEDIATYPE** with attributes FDA and FAERS respectively.

Configure Folders

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`.

The 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 code list needs to be marked.

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.

Configure Studies for FDA IND or Pre-ANDA reporting

IND Studies

Make sure to enter the clinical reference for IND studies, including the primary IND number associated with the study. Optionally, you can also add the cross-reported IND number, if applicable.

Reference Type	Country	Reference Number
CDER-IND or CBER-IND	United States	Select the Primary IND number.
Cross reported IND	United States	Enter the cross reported IND.

Pre-ANDA Studies

Make sure to enter the clinical reference for Pre-ANDA studies and include the primary IND number associated with the study.

Reference Type	Country	Reference Number
Pre-ANDA	United States	Enter the Pre-ANDA number.

> **Note**
>
> Cross-reported IND numbers [FDA C.5.6.r] for IND reports are auto-populated by Interchange based on the product's license configuration. Refer to the FAERS mappings in the E2B R3 mapping document for additional details. Additionally, manually configured INDs in the study will also be transmitted.

Configure expedited rules

Make sure to enter the following information in the reporting rules created for IND, Pre-ANDA and Spontaneous IND Study cases in addition to other reporting criteria that are configured in the expedited rules.

The following rules are based on the ICHICSR/E2B message type and report format. Except for the CDER-30 Day WORLD rule, all rules apply exclusively to the United States.

Rule	Reporting Destination	License Type	Time Frame	Condition
CDER-15 Day	ZZFDA/CDER	Marketed Drug	15	Serious (Event) = Yes

Rule	Reporting Destination	License Type	Time Frame	Condition
CDER-60 Day	ZZFDA/CDER	Marketed Drug	60	Case Serious = No; Any other condition as per your company's business process
CDER-5 Day	ZZFDA/CDER	Marketed Drug (for Combination Products)	5	Criteria using Advance conditions • Remedial Action exists • Case Classification = Combination Product any other condition as per your company's business process
CDER-30 Day	ZZFDA/CDER	Marketed Drug (for Combination Products)	30	Case Serious = No Criteria using Advance conditions • Malfunction = Yes • Case Classification = Combination Product Any other condition as per your company's business process
CDER-30 Day WORLD	ZZFDA/CDER	Marketed Drug (for Combination Products)	30	Case Serious = No Criteria using Advance conditions: • Case Classification = Combination Product • Malfunction = Yes • Product type = Treatment/ Other • Drug not administered = Yes • Similar Device = Yes
IND - CDER-15 Day IND-CBER-15 Day	ZZFDA_PREMKT/CDER_IND ZZFDA_PREMKT/CBER_IND	Investigational drug	15	Event Serious =Yes and Listedness (Event) = No Study Reference Type=CDER-IND/ CBER-IND Any other condition as per your company's business process
IND - CDER-7 Day IND - CBER-7 Day	ZZFDA_PREMKT/CDER_IND ZZFDA_PREMKT/CBER_IND	Investigational drug	7	Event Serious =Yes and Listedness (Event) = No S/UL/Fatal/LT = Yes Study Reference Type=CDER-IND/ CBER-IND Any other condition as per your company's business process
Pre-ANDA	ZZFDA_PREMKT/ CDER_IND_EXEMPT_BA_BE	Investigational drug	15	Event Serious =Yes and Listedness (Event) = No Study Reference Type=Pre-ANDA Any other condition as per your company's business process
IND for Post Marketed Cases	ZZFDA_PREMKT/CDER_IND or CBER_IND	Investigational drug	15 or 7	Event Serious =Yes and Listedness (Event) = No Study Reference Type=Ignore Any other condition as per your company's business process

If you are transitioning from MedWatch format to E2B(R3) for IND reporting to FDA, then it is recommended the existing rules used for reporting to FDA by updating the report form to E2B, and configure additional information required as specified above.

Note

If you are not transitioning from the MedWatch format to E2B(R3) for reporting to the FDA, we recommend modifying the `Reporting Destination > Message Profile` used for MedWatch reporting to FDA MEDWATCH 3500A DRUG TEMPLATE.

If the profile in the agency settings is changed to the FDA MEDWATCH 3500A DRUG TEMPLATE or the E2B R3 profile ICH-ICSR V3.0 MESSAGE TEMPLATE - FAERS, it is not recommended to switch back to the MedWatch paper reporting format.

If you decide to create a new agency, any case updates will be transmitted as an initial report to the new agency.

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Configure parameters for E2B(R3) Reports and Acknowledgment

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

Common profile switch	Description
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.
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

Configure parameters for E2B(R3) acknowledgment

The following parameters, located in `Console > Code Lists > Argus > Reporting Destination > EDI`, affect acknowledgment (ACK) and need to be reviewed and adjusted according to your requirements:

Parameter	Description
Local time zone to process Date/Timestamp values of Ack	Allows you to configure the offset to be applied to the following elements in the acknowledgment file if the offset is missing: E2B R3 ACK file - ACK.M.4 messagedater3 PMDA Device ACK file - ACK.6 ACKCREATEDATE

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Customize Mappings and Validations

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

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*.