

Oracle Argus Safety

China NMPA E2B(R3) Best Practices



Release 8.2.3.1

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Preface

This preface contains the following sections:

- [Documentation accessibility](#)
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Revision history

Argus version	Description
8.2.3.1	First release

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Introduction

This document lists best practices and recommendations for generating NMPA E2B(R3) report from Argus.

The National Medical Products Administration (NMPA), formerly known as the China Food and Drug Administration or CFDA, published the Regional Implementation Guide for the Electronic Transmission of Individual Case Safety Reports E2B(R3) Data Elements and Message Specification on November 22, 2019.

The guidelines include the following:

- The post-marketing ICSRs need to be submitted to NMPA in the E2B(R3) format along with the regional elements to comply with the final Implementation Guide. This is optional from July 01, 2019 and mandatory from July 1, 2022.
- The SUSAR (Suspected Unexpected Serious Adverse Reactions) ICSRs from clinical trials approved on or after May 1, 2018 must be transmitted in E2B(R3) format based on the ICH guidelines in Chinese for Narratives and Reaction reported by source (without regional elements). This is optional from May 01, 2018 and mandatory from May 01, 2019.

 **Note:**

NMPA has not published yet the effective date for submitting the SUSAR ICSRs in E2B(R3) format along with the regional elements (as of November 2021). For more information about the steps to create the E2B(R3) reports for clinical trial cases, refer to the article 2393471.1 on [My Oracle Support](#).

It is recommended to switch to the NMPA E2B(R3) out-of-the-box profile for clinical trial cases only after NMPA publishes the effective date.

Argus supports out-of-the-box E2B(R3) profile to submit PMSR and CT cases to the China Health Authority NMPA.

The implementation guide defines 19 China specific E2B(R3) regional data elements and business rules regarding the submissions of E2B(R3) to the Center for Drug Re-evaluation, NMPA, and to the Center for Drug Evaluation, NMPA.

Element ID	Element description (English)	Element description (Chinese)
C.1.CN.1	Source of Report	报告来源
C.1.CN.2	Report Categories	报告分类
C.1.CN.3	Holder Identification	持有人标识
C.2.r.CN.1	Reporter's Email	电子邮箱
D.CN.1	Minority	民族

Element ID	Element description (English)	Element description (Chinese)
D.CN.2	Race	种族
D.CN.3	Medical Institution Name	医疗机构名称
D.CN.4	Nationality	国籍
D.CN.5	Patient Telephone	患者电话
D.CN.6	Pregnancy Description	妊娠相关描述
G.k.CN.1	Generic Name of Drug	通用名
G.k.CN.2	Related Device	相关器械
G.k.CN.3	Is the product owned by the holder?	是否为本持有人产品 (必要时重复)
G.k.CN.4	Approval/Acceptance Number	批准文号/受理号
G.k.4.r.CN.1	Expiration Date/ Date of Expiry	失效日期/有效期至
G.k.9.i.CN.1	Is Reaction unexpected?	是否非预期
G.k.9.i.CN.2	Did the reaction disappear or was the reaction relieved after the drug was withdrawn or the dose was reduced?	停药或减量后, 反应是否消失或减轻?
G.k.9.i.2.r.CN.1	Original Reporter/ Source of Assessment	初始报告人/上市许可持有人评估来源
G.k.9.i.2.r.CN.2	Result of Assessment	评估结果

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Reporting destinations setup

The Center for Drug Evaluation (CDE) and the Center for Drug Reevaluation (CDR) are two NMPA agencies.

CDE is responsible with submitting clinical trial reports and CDR is responsible with submitting post-marketed reports.

To achieve this, set up two different reporting destinations with agency identifiers in Argus.

Agency Name ▲	Agency Type	Department	Registration #	Contact Type
CDE	Regulatory Authority	Drug Reporting Division		
CDR	Regulatory Authority	Drug Reporting Division		

[Add New](#)

Modify Reporting Destination

Agency Information | Local Company Contact | **EDI** | SMTP

SGML XML Suppress Auto-scheduling

Agency Information

▼ Agency Identifier: CDR Identification Code: Code Qualifier:

Message Profile

ICH-ICSR V3.0 MESSAGE TEMPLATE - NMPA Mark as Auto Submit

ACK Profile

ICH-ICSR V3.0 ACKNOWLEDGMENT TEMPLATE - ICH Submission date for ICSR's

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Reporting rules setup

Each report to NMPA has to be routed to the CDE/CDR Receiver Identifier depending on the case data, such as: Report Type, Primary Reporter Country and Observe Study Type.



Note:

Reporting rules should be set up in Argus with advanced conditions.

The below table displays some sample reporting rules.

Country	License type	Agency	Rule name	Timeframe calendar days	Advanced condition
China	Marketed Drug	CDR	Death/LT ADR Domestic	7	Primary Reporter Country = China Report Type = Spontaneous
China	Marketed Drug	CDR	Serious ADR Domestic	15	Primary Reporter Country = China Report Type = Sponsored Trial Observe Study Type = Individual Patient Use or Other Studies
United States	Marketed Drug	CDR	Death/LT Foreign	7	Primary Reporter Country <> China Report Type = Spontaneous
United States	Marketed Drug	CDR	Serious ADR Foreign	15	Primary Reporter Country <> China Report Type = Sponsored Trial Observe Study Type = Individual Patient Use or Other Studies

Country	License type	Agency	Rule name	Timeframe calendar days	Advanced condition
China	Investigational Drug	CDE	SUSAR CT Domestic	30	Primary Reporter Country = China Report Type = Sponsored Trial Observe Study Type = Clinical Trial
United States	Investigational Drug	CDE	SUSAR CT Foreign	30	Primary Reporter Country <> China Report Type = Sponsored Trial Observe Study Type = Clinical Trial

The following table describes the set of criteria for the Report Category (C.1.CN.2). All mappings, validations and conformance are formed based on this criteria.

C.1.CN.2 Reporting Category	Criteria
Domestic Study Case (NMPA code = 11)	<ul style="list-style-type: none"> Cases that have REPORTTYPE [C.1.3] = 2, OBSERVESTUDYTYPE [C.5.4] = 1 and REPORTERCOUNTRYR3 [C.2.r.3] for Primary Reporter = CN
Domestic Post-Market Case (NMPA code = 12)	<ul style="list-style-type: none"> Cases that have REPORTTYPE [C.1.3] = 2, OBSERVESTUDYTYPE [C.5.4] = 2 or 3 and REPORTERCOUNTRYR3 [C.2.r.3] for Primary Reporter = CN Cases that have REPORTTYPE [C.1.3] <> 2 and REPORTERCOUNTRYR3 [C.2.r.3] for Primary Reporter = CN
Foreign Study Case (NMPA code = 21)	<ul style="list-style-type: none"> Cases that have REPORTTYPE [C.1.3] = 2, OBSERVESTUDYTYPE [C.5.4] = 1 and REPORTERCOUNTRYR3 [C.2.r.3] for Primary Reporter <> CN
Foreign Post-Market Case (NMPA code = 22)	<ul style="list-style-type: none"> Cases that have REPORTTYPE [C.1.3] = 2, OBSERVESTUDYTYPE [C.5.4] = 2 or 3 AND REPORTERCOUNTRYR3 [C.2.r.3] for Primary Reporter <> CN Cases that have REPORTTYPE [C.1.3] <> 2 and REPORTERCOUNTRYR3 [C.2.r.3] for Primary Reporter <> CN

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Set up an E2B(R3) profile for ICSR and ACK

To generate NMPA E2B(R3), set the **Message Profile** to **ICH- ICSR V3.0 MESSAGE TEMPLATE – NMPA** in the Reporting Destination section.

To import NMPA ACK, set the **Acknowledgment Profile** to **ICH-ICSR V3.0 ACKNOWLEDGEMENT TEMPLATE – ICH** in the Reporting Destination section.

Agency Information	Local Company Contact	EDI	SMTP
<input type="radio"/> SGML <input checked="" type="radio"/> XML <input type="checkbox"/> Suppress Auto-scheduling			
Agency Information			
Agency Identifier	Identification Code	Code Qualifier	
CDR			
Message Profile			
ICH-ICSR V3.0 MESSAGE TEMPLATE - NMPA			<input type="checkbox"/> Mark as Auto Submit
ACK Profile			
ICH-ICSR V3.0 ACKNOWLEDGEMENT TEMPLATE - ICH			Submission date for ICSR's



Note:

The ACK ICH-ICSR V3.0 ACKNOWLEDGEMENT TEMPLATE – ICH profile is created using the new R3 framework and is designed to be used with the ICSR R3 profiles like NMPA.

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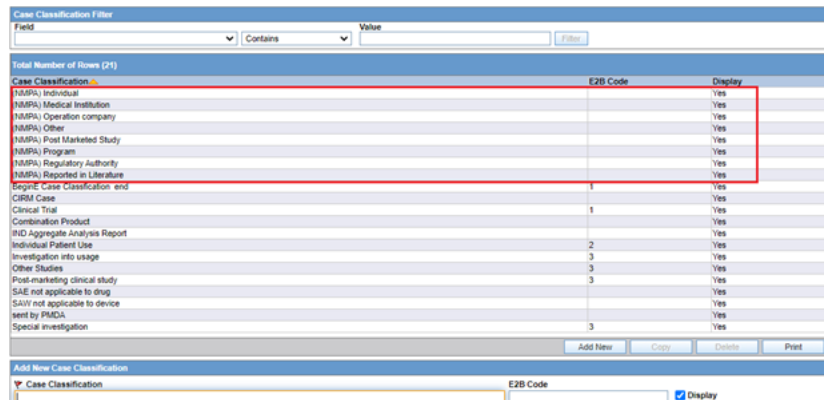
Source of Reports (C.1.CN.1)

REPORTSOURCE [C.1.CN.1] is used to identify from where the sender obtained the adverse reaction.

In Argus Console > Code Lists > Argus > Case Classification folder, the Case Classification standard code list includes the values required for REPORTSOURCE [C.1.CN.1].

 **Note:**

Review and update should be done based on your company requirement. You can update the description or choose to set Display = No.



Case Classification	E2B Code	Display
NMPA Individual		Yes
NMPA Medical Institution		Yes
NMPA Operation company		Yes
NMPA Other		Yes
NMPA Post Marketed Study		Yes
NMPA Program		Yes
NMPA Regulatory Authority		Yes
NMPA Reported in Literature		Yes
Original Case Classification - end	1	Yes
CIRM Case		Yes
Clinical Trial	1	Yes
Combination Product		Yes
IND Aggregate Analysis Report		Yes
Individual Patient Use	2	Yes
Investigation into usage	3	Yes
Other Studies	3	Yes
Post-marketing clinical study	3	Yes
SAE not applicable to drug		Yes
SAE not applicable to device sent by PMDA		Yes
Special investigation	3	Yes

In Argus Console > Code Lists > Flexible Data Re-Categorization > Flexible Re-Categorization folder > **CASE_CLASSIFICATION** Code List Name, the CASE_CLASSIFICATION flexible code list includes the NMPA attribute with the set of values allowed by NMPA.

 **Note:**

The NMPA attribute values should not be altered.

Flexible Re-Categorization Code Lists

Code List Name
CASE_CLASSIFICATION

Case Classification - CASE_CLASSIFICATION

is (21)

Display	CODE	en	E2B	ja	MFDS	NMPA
<input checked="" type="checkbox"/>	1	Clinical Trial	1	臨床試験		
<input checked="" type="checkbox"/>	10	Special investigation	3	特別調査	3	
<input checked="" type="checkbox"/>	100000	Begin Case Classification end	1	Begin Case Classification end		
<input checked="" type="checkbox"/>	100001	sent by PMDA		PMDAから送られた		
<input checked="" type="checkbox"/>	11	IND Aggregate Analysis Report		IND Aggregate Analysis Report		
<input checked="" type="checkbox"/>	12	(NMPA) Regulatory Authority		(NMPA)規制当局		1
<input checked="" type="checkbox"/>	13	(NMPA) Individual		(NMPA)個人		2
<input checked="" type="checkbox"/>	14	(NMPA) Medical Institution		(NMPA)医療機関		3
<input checked="" type="checkbox"/>	15	(NMPA) Operation company		(NMPA)運営会社		4
<input checked="" type="checkbox"/>	16	(NMPA) Reported in Literature		(NMPA)文献での報告		5
<input checked="" type="checkbox"/>	17	(NMPA) Post Marketed Study		(NMPA)上市販売後試験		6
<input checked="" type="checkbox"/>	18	(NMPA) Program		(NMPA)プログラム		7
<input checked="" type="checkbox"/>	19	(NMPA) Other		(NMPA)その他		8
<input checked="" type="checkbox"/>	2	Individual Patient Use	2	患者個人使用		
<input checked="" type="checkbox"/>	3	Other Studies	3	その他の試験	4	

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Minority (D.CN.1)

In Argus Console > Code Lists > Flexible Data Re-Categorization > Flexible Re-Categorization folder > **ETHNIC_GROUP** Code List Name, the ETHNIC_GROUP flexible code list includes the China ethnic groups along with the NMPA attributes: 01 to 56, according to the values allowed by NMPA.

These 56 ethnic groups are displayed in the Case Form window, on the Patient tab, in the Patient Information section, in the Ethnic Group field.



Note:

The NMPA attribute values should not be altered.

Flexible Re-Categorization Code Lists							
Code List Name							
ETHNIC_GROUP							
Ethnic Group - ETHNIC_GROUP							
Add Attribute							
Total Number of Rows (60)							
Displaying Rows 1-50							
Page Size 50							
Edit	Delete	Display	CODE	en	ja	NCL_CODE	NMPA
		<input checked="" type="checkbox"/>	1	Hispanic or Latino	ヒスパニックまたはラテン系	C17459	
		<input checked="" type="checkbox"/>	2	Not Hispanic or Latino	非ヒスパニックまたは非ラテン系	C41222	
		<input checked="" type="checkbox"/>	3	Unknown	不明	UNK	
		<input checked="" type="checkbox"/>	4	No Information	情報なし	NI	
		<input checked="" type="checkbox"/>	5	(China) HanZu	(中国) 汉族		01
		<input checked="" type="checkbox"/>	6	(China) MengGuZu	(中国) 蒙古族		02
		<input checked="" type="checkbox"/>	7	(China) HuiZu	(中国) 回族		03
		<input checked="" type="checkbox"/>	8	(China) ZangZu	(中国) 藏族		04
		<input checked="" type="checkbox"/>	9	(China) VietHuErZu	(中国) 维吾尔族		05
		<input checked="" type="checkbox"/>	10	(China) MaoZu	(中国) 苗族		06
		<input checked="" type="checkbox"/>	11	(China) LiZu	(中国) 彝族		07
		<input checked="" type="checkbox"/>	12	(China) ZhuangZu	(中国) 壮族		08
		<input checked="" type="checkbox"/>	13	(China) BuYiZu	(中国) 布依族		09
		<input checked="" type="checkbox"/>	14	(China) ChaoXianZu	(中国) 朝鲜族		10
		<input checked="" type="checkbox"/>	15	(China) ManZu	(中国) 满族		11
		<input checked="" type="checkbox"/>	16	(China) DongZu	(中国) 侗族		12
		<input checked="" type="checkbox"/>	17	(China) YaoZu	(中国) 瑶族		13

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Race (D.CN.2)

In Argus Console > Code Lists > Argus > Ethnicity folder, the Ethnicity standard code list includes the Australian value required for PATIENTRACE [D.CN.2]. The other required NMPA values are already available in the Argus Ethnicity code list.

In Argus Console > Code Lists > Flexible Data Re-Categorization > Flexible Re-Categorization folder > **ETHNICITY** Code List Name, the ETHNICITY flexible code list includes the NMPA attribute with the set of values allowed by NMPA.

Note:

Review and update should be done according to your company requirement. You may update the description or add the NMPA attribute for other Ethnicity options.



Flexible Re-Categorization Code Lists							
Code List Name							
ETHNICITY							
Ethnicity - ETHNICITY							
Total Number of Rows (9)							
Edit	Delete	Display	CODE	en	ja	NCL_CODE	NMPA
		<input checked="" type="checkbox"/>	4	Other	その他		
		<input checked="" type="checkbox"/>	5	African American	アフリカ系アメリカ人	C16352	
		<input checked="" type="checkbox"/>	6	American Indian or Alaska Native	アメリカ・インディアンまたはアラスカ先住民	C41259	
		<input checked="" type="checkbox"/>	7	Native Hawaiian or Other Pacific Islander	ハワイ先住民またはその他の太平洋諸島の原住	C41219	
		<input checked="" type="checkbox"/>	3	Asian	アジア人	C41260	1
		<input checked="" type="checkbox"/>	1	Caucasian	白人		2
		<input checked="" type="checkbox"/>	8	White	白人	C41261	2
		<input checked="" type="checkbox"/>	2	Black	黒人		3
		<input checked="" type="checkbox"/>	9	Australian	澳洲人		4

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Approval/Acceptance Number (G.k.CN.4)

For post-marketed cases, G.k.CN.4 is transmitted with the license number configured in the Product and Licenses window based on the product and the license for which the report is generated.

The License number should be configured as required by NMPA in the Console, in the Product and License window, License# field.

For clinical trial cases, G.k.CN.4 is transmitted with the application number configured on the Studies Configuration window in the Clinical References section based on the below logic. The Clinical References section should be configured so that G.k.CN.4 is transmitted as required by NMPA:

- Use Reference Type = CT Approval Number and Country = China
- Configure Reference Number in the format <License number>_<Application number>

For more details, refer to the business rule defined for G.k.CN.4 in the E2B(R3) export mapping document.

The screenshot displays the configuration interface for 'NMPA Study1'. The 'Clinical References (1)' section is highlighted with a red border and contains the following data:

Reference Type	Country	Reference Number
CT Approval Number	CHINA	L1_StudyNMPA001

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Result of Assessment (G.k.9.i.2.r.CN.2)

In Argus Console > Code Lists > Flexible Data Re-Categorization > Flexible Re-Categorization folder > **CAUSALITY_CATEGORY** Code List Name, Argus Flexible code list includes new NMPA attribute and values.

When a Medical Reviewer assesses the Causality as Reported Result and Causality as Determined Result column, in the Case Form window, on the Event tab, on the Event Assessment tab, the NMPA specific codes are populated by the out-of-the-box mapping logic in the CNRESULTASSESS [G.k.9.i.2.r.CN.2].

What this means to business users: No additional data entry required (and derived from existing Causality Result).



The screenshot shows the 'Flexible Re-Categorization Code Lists' interface. The 'Code List Name' is set to 'CAUSALITY_CATEGORY'. Below the header, there is a table with columns: en, REPORTABILITY, ja, EU_CODE, MFDS, and NMPA. The NMPA column is highlighted with a red border. The table contains the following data:

en	REPORTABILITY	ja	EU_CODE	MFDS	NMPA
Almost Certain	1	ほぼ確実に関連あり	1	1	1
Definitely related	1		1		
100% Certain	1				
Probable	1	おそらく関連あり	1	2	2
Possible	1	関連があるかもしれない	1	3	3
Unlikely	0	関連はありそうはない	2	4	4
Not Related	0	関連なし	2	4	4
Unknown	1	不明	1	5	5
Not Reported	1	未報告	1	6	6
None	0	なし	2	6	6

E2B(R3) elements with data in Chinese

NMPA mandates to transmit data for certain elements in Chinese. Argus supports multi-language data entry as required by NMPA.

The following fields are enhanced in Argus 8.2.3.1 to support multi-language data entries:

- Case Form > General tab > Reporter Information section > Institution
- Case Form > Patient or Parent tab > Pregnancy Information section > Delivery Notes
- Case Form > Products tab > Product Information section > Product Name
- Case Form > Product > Product Information > Generic Name

The below code list is enhanced to add the Chinese name for the manufacturer list. The Chinese name should be configured because it is required to transmit the DRUGAUTHORIZATIONHOLDER [G.k.3.3]:

- Argus Console > Code Lists > Flexible Data Re-Categorization > Flexible Re-Categorization folder > **MANUFACTURER** Code List Name



Note:

For all other elements that need Chinese data, Argus already supports multi-language data entry. The NMPA E2B(R3) mappings are updated to use Chinese data to transmit the elements. For more details, refer to the E2B(R3) mapping document.

The following table describes the list of elements with mandatory Chinese data:

#	Element description	Element conformance	Type of case
1	Name of Medical Institution/ Distributor (D.CN.3)	Optional	All cases
2	Pregnancy Description (D.CN.6)	Optional	All cases
3	Autopsy-determined Cause(s) of Death (free text) (D.9.4.r.2)	Conditional Mandatory	Domestic cases (Post marketed and Clinical trial)
4	Generic name of the drug (G.k.CN.1)	Conditional Mandatory	Domestic cases (Post marketed and Clinical trial) Foreign cases (Clinical trial)
5	Related device (G.k.CN.2)	Optional	All cases
6	Medicinal Product Name (G.k.2.2)	Mandatory	Domestic cases (Post marketed) Foreign cases (Post marketed)

#	Element description	Element conformance	Type of case
7	Name of holder/applicant (G.k.3.3)	Optional	All cases (The name of the company registered with NMPA. It may be all English characters if registered likewise)
8	Pharmaceutical form (G.k.4.r.9.1)	Optional	All cases
9	Route of Administration (G.k.4.r.10.1)	Optional	All cases
10	Parent Route of Administration (G.k.4.r.11.1)	Optional	All cases
11	Case Narrative (H.1)	Mandatory	Domestic cases (Post marketed and Clinical trial)
12	Reporter Comments (H.2)	Optional	Domestic cases (Post marketed and Clinical trial)
13	Sender Comments (H.4)	Optional	Domestic cases (Post marketed and Clinical trial)

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Observations during NMPA testing

Oracle tested the post-marketed ICSRs generated using the NMPA out-of-the-box profile in Argus 8.2.3.1.

This testing was performed by submitting the XMLs to the NMPA test gateway and by receiving ACKs from NMPA.

 **Note:**

NMPA does not allow software vendors to create test accounts, so Oracle was helped by Argus customers to perform it.

The below observations were made during the NMPA testing:

1. NMPA has a hard validation to check if RECEIVEDATER3 [C.1.4] and RECEIPTDATER3 [C.1.5] are transmitted with the same value for the initial reporting. If the values are different for the initial reporting, then a negative ACK is received. It may be a valid scenario to have these dates different when the initial information is received and it is not reportable, and then when the follow-up information is received at a different date and it becomes reportable.

Argus customers discussed with NMPA to clarify if they remove this validation, but at this moment, NMPA does not plan to remove it.

 **Note:**

RECEIVEDATER3 [C.1.4] and RECEIPTDATER3 [C.1.5] should be transmitted with the same value for the initial reporting.

2. NMPA has a hard validation to check if REACTIONSTARTDATER3 [E.i.4] is later than RECEIVEDATER3 [C.1.4]. ICSR is rejected when E.i.4 has date/time components and the date is the same in both elements. ICSR is accepted when E.i.4 has only a date component and the date is the same in both elements.

 **Note:**


RECEIVEDATER3 [C.1.4] and RECEIPTDATER3 [C.1.5] should be transmitted with the same value for the initial reporting.

3. The NMPA Implementation Guide states that DRUGAUTHORIZATIONHOLDER [G.k.3.3] should be provided in Chinese. During testing, it was observed that DRUGAUTHORIZATIONHOLDER [G.k.3.3] should be the name of the company registered with NMPA. It could have English, Chinese or mixed characters. NMPA accepts as a log the registered company name as it is.

 **Note:**

The company name should be carefully registered with NMPA in the Console > Code Lists drop-down menu > Flexible Data Re-categorization option > Flexible Re-Categorization folder > **MANUFACTURER** Code List Name > cn attribute.

4. NMPA has a hard validation to check if COMPANYNUMB [C.1.8.1] is the same as any previously submitted XML, but with different SAFETYREPORTID [C.1.1]. In this scenario, ICSR is rejected. The same case can be submitted from multiple companies with the same C.1.8.1 and with different C.1.1. However, within a company, C.1.1 should be the same.

 **Note:**

Ensure that the E2B company number is deleted from the Case references section while copying a case in Argus that has submitted the E2B report. Thus, you avoid sending the same COMPANYNUMB [C.1.8.1] as any previously submitted XML, but with different SAFETYREPORTID [C.1.1].

13

Frequently asked questions

This chapter contains the most frequently asked questions about NMPA.

- [Can the OOTB Argus E2B\(R3\) NMPA profile be used to submit post-marketed and clinical trial ICSRs to NMPA?](#)
- [What should you consider when sending the EDQM terms in Route of Administration and Dosage Formulation elements?](#)

Can the OOTB Argus E2B(R3) NMPA profile be used to submit post-marketed and clinical trial ICSRs to NMPA?

No, the OOTB Argus E2B(R3) NMPA profile is developed based on the Implementation Guide published by NMPA, which includes 19 regional elements in the E2B(R3) report. Although the Implementation Guide is applicable for both post-marketed and clinical trial ICSRs, the NMPA has not published the mandatory date for submitting the SUSAR ICSRs in E2B(R3) format along with the regional elements (as of November 2021). For post-marketed ICSRs, use the OOTB Argus E2B(R3) NMPA profile.

For clinical trial ICSRs, use the ICH R3 profile configured to transmit narratives and reported terms in Chinese language. For more information about the steps, refer to the article 2393471.1 on [My Oracle Support](#). Once NMPA announces the effective date for submitting the clinical trial ICSRs, including the 19 regional elements, then the OOTB Argus E2B(R3) NMPA profile is used.

What should you consider when sending the EDQM terms in Route of Administration and Dosage Formulation elements?

Refer to the Best Practices Document Usage of EDQM Routes of Administration (RoA) and Dose Forms (DF) published as part of Argus 8.2.3.1 release.