

Food and Drug Administration



**US Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine**

**Electronic Submission of Animal Adverse Events
HL7 Individual Case Safety Report (ICSR)**

**Electronic Transmission Implementation Specifications
[Validation Procedures]**

Version: 3.0.0

May 21, 2010

The document release supports the RQR1 release of the MedWatch^{PLUS}. The contents within this document are based on the September, 2009 release of the HL7 ICSR draft schema.

Document Control Number:

Revision History

Subject:		Validation Procedures for Veterinary Medicinal Products (VMP) Individual Case Safety Reports (ICSR)	
Author:		Charles Brown (SRA) Heather Goodman (BAH) – Howard Conrad (BAH)	
Distribution List:			
Initial Release Date:		March 31, 2009	
History of Changes			
Version #	Date of Change #	Description of Change	Change Made by Person (Organization)
1.0	3/30/09	Initial Submission	Charles Brown (SRA)
2.0.3	5/29/2009	Business Rules have been re-written for clarification. References to applicable sections in the Step-by-Step Guide have been added.	Heather Goodman (BAH)
2.0.6	7/24/2009	Business Rules updated per client review sessions	Heather Goodman (BAH)
2.0.7	8/3/2009	Business Rules updated per client review sessions. Additional updates per peer review	Heather Goodman (BAH)
2.0.8 – 2.0.9	9/4/2009	Business Rules updated per client review and internal team review	Heather Goodman (BAH)
2.0.10	10/5/2009	Business Rules updated per new requirements and internal review	Heather Goodman (BAH)
2.0.11	12/28/2009	Harmonization with Step-By-Step XXX – Guidance for Industry	Howard Conrad (BAH)
2.0.11.6	1/29/2010	<ul style="list-style-type: none"> - Update handling of Null Flavor options - Fixed incorrect OIDS - Fixed numerous reported errors and incorrect language 	Howard Conrad (BAH)
2.0.12	2/3/2010	1 st non-draft release	Howard Conrad (BAH)
2.0.13	3/5/2010	<ul style="list-style-type: none"> - Update Telecom null value ability - Change Dosage to 4 decimal places - Updated Vocabulary Names - Clarified numeric vs integer - Updated Supplemental Documents to latest standard 	
2.0.14	4/30/2010	-RQR1 Release	Howard Conrad (BAH)
2.0.15	5/3/2010	<ul style="list-style-type: none"> - Update to Female Physiological Status to include NI if Gender = Male – business rule 109.3 - Update to Species - Species is no longer a required element for a PP. Updates to section 1.9 and business rule 104 - Updates to section A.4.4.1 Type of Submission – updates to valid values based on 	Heather Goodman (BAH)

		<p>vocabularies</p> <ul style="list-style-type: none">- Updates to A.3 – Primary and Other Reporter information based on last name = withheld or NI and updates for telecom- Update to B.2.3.1 Expiration Date in order to accept cases where only year information is known for the expiration date	
3.0.0	5/21/2010	<ul style="list-style-type: none">- Release Version	Heather Goodman (BAH)

Approvals

I have read the attached plan and will abide by its terms and conditions and pledge my full commitment and support for the project.

[Approver's Name (Title)] _____ **Date:** _____

[Approver's Name (Title)] _____ **Date:** _____

[Approver's Name (Title)] _____ **Date:** _____

[Approver's Name (Title)] _____ **Date:** _____

Table of Contents

1. INTRODUCTION	1-1
1.1 PURPOSE AND SCOPE	1-1
1.2 BACKGROUND	1-1
1.3 ICSR DOCUMENTS	1-1
1.4 DOCUMENT ORGANIZATION	1-2
1.5 GL-42 DATA ELEMENTS	1-2
1.6 ERRORS	1-2
1.7 STEP-BY-STEP GUIDE	1-2
1.8 FIELD DESCRIPTION	1-3
1.9 REPORT TYPE	1-3
1.10 OBJECT IDENTIFIER (OID)	1-6
1.11 CARDINALITY	1-6
1.12 SPECIAL HANDLING OF ELEMENT FIELDS (NULL FLAVORS)	1-7
1.13 REFERENCED LIST OF VALUES	1-8
1.14 SCHEMA VALIDATION	1-9
1.15 DISCLAIMER	1-9
2. DATA ELEMENTS AND VALIDATION RULES	2-1
2.1 GL-42 SECTION A - ADMINISTRATIVE AND IDENTIFICATION INFORMATION	2-1
GL-42 SECTION A.1 REGULATORY AUTHORITY (RA)	2-1
GL-42 Section A.1 Regulatory Authority Name - (RA Name)	2-1
GL-42 Section A.1 Regulatory Authority Street Address (RA) -- Address	2-3
GL-42 Section A.1 Regulatory Authority City (RA) -- City	2-4
GL-42 Section A.1 Regulatory Authority State/County (RA) -- State	2-5
GL-42 Section A.1 Regulatory Authority (RA) -- Mail/Zip Code	2-6
GL-42 Section A.1 Regulatory Authority Country (RA) -- Country	2-7
GL-42 SECTION A.2 MARKETING AUTHORIZATION HOLDER (MAH)	2-8
GL-42 Section A.2.1 Marketing Authorization Holder (MAH) -- Business Name	2-8
GL-42 Section A.2.1 Marketing Authorization Holder (MAH) -- Street Address	2-9
GL-42 Section A.2.1 Marketing Authorization Holder (MAH) -- City	2-10
GL-42 Section A.2.1 Marketing Authorization Holder (MAH) -- State/County	2-11
GL-42 Section A.2.1 Marketing Authorization Holder (MAH) -- Mail/Zip Code	2-12
GL-42 Section A.2.1 Marketing Authorization Holder (MAH) -- Country	2-13
GL-42 Section A.2.2 Person Acting on Behalf of MAH -- (Contact Title)	2-14
GL-42 Section A.2.2 Person Acting on Behalf of MAH -- (First Name)	2-15
GL-42 Section A.2.2 Person Acting on Behalf of MAH -- (Last Name)	2-16
GL-42 Section A.2.2 Person Acting on Behalf of MAH -- (Telephone)	2-17
GL-42 Section A.2.2 Person Acting on Behalf of MAH -- (Fax)	2-19
GL-42 Section A.2.2 Person Acting on Behalf of MAH -- (Email)	2-21

GL-42 Section A.2.2 Person Acting on Behalf of MAH – (Sender Category)	2-22
GL-42 SECTION A.3 REPORTERS	2-23
GL-42 Section A.3.1 Primary Reporter – (Last Name)	2-23
GL-42 Section A.3.1 Primary Reporter – (First Name)	2-24
GL-42 Section A.3.1 Primary Reporter – (Telephone)	2-25
GL-42 Section A.3.1 Primary Reporter – (Fax)	2-27
GL-42 Section A.3.1 Primary Reporter – (Email)	2-29
GL-42 Section A.3.1 Primary Reporter – (Category)	2-30
GL-42 Section A.3.1 Primary Reporter – (Business Name)	2-32
GL-42 Section A.3.1 Primary Reporter – (Street Address)	2-33
GL-42 Section A.3.1 Primary Reporter – (City)	2-34
GL-42 Section A.3.1 Primary Reporter – (State/County)	2-35
GL-42 Section A.3.1 Primary Reporter – (Mail/Zip Code)	2-36
GL-42 Section A.3.1 Primary Reporter – (Country)	2-37
GL-42 Section A.3.2 Other Reporter – (Last Name)	2-38
GL-42 Section A.3.2 Other Reporter – (First Name)	2-39
GL-42 Section A.3.2 Other Reporter – (Telephone)	2-40
GL-42 Section A.3.2 Other Reporter – (Fax)	2-42
GL-42 Section A.3.2 Other Reporter – (Email)	2-44
GL-42 Section A.3.2 Other Reporter—(Business Name)	2-45
GL-42 Section A.3.2 Other Reporter – (Street Address)	2-46
GL-42 Section A.3.2 Other Reporter – (City)	2-47
GL-42 Section A.3.2 Other Reporter – (State/County)	2-48
GL-42 Section A.3.2 Other Reporter – (Mail/Zip Code)	2-49
GL-42 Section A.3.2 Other Reporter – (Country)	2-50
GL-42 Section A.3.2.1 Other Reporter – (Category)	2-51
GL-42 SECTION A.4 AER INFORMATION	2-53
GL-42 Section A.4.1 Unique Adverse Event Report Identification Number	2-53
GL-42 Section A.4.2 Date AER Received by MAH (Original Receive Date)	2-55
GL-42 Section A.4.3 Date of Current Submission	2-57
GL-42 SECTION A.4.4 TYPE OF REPORT	2-59
GL-42 Section A.4.4.1 Type of Submission	2-59
GL-42 Section A.4.4.2 Reason for Nullification Report	2-63
GL-42 Section A.4.4.3 Type of Information in Report	2-65
2.2 GL-42 SECTION B – ANIMAL DATA INFORMATION	2-67
GL-42 SECTION B.1 ANIMAL DATA	2-67
GL-42 Section B.1.1 Number of Animals Treated	2-67
GL-42 Section B.1.2 Number of Animals Affected	2-68
GL-42 Section B.1.2.1 Attending Veterinarian’s Assessment of the Health Status Prior to VMP Use	2-70
GL-42 Section B.1.3 Species (Type of Species)	2-72

GL-42 Section B.1.4 Breed (Breed Group)	2-73
GL-42 Section B.1.5 Gender	2-76
GL-42 Section B.1.6 Reproductive Status	2-77
GL-42 Section B.1.7 Female Physiological Status	2-79
GL-42 SECTION B.1.8 ANIMAL WEIGHT	2-81
GL-42 Section B.1.8.1 Measured, Estimated, Unknown Weights	2-81
GL-42 Section B.1.8.2 Minimum Weight	2-83
GL-42 Section B.1.8.3 Maximum Weight	2-85
GL-42 SECTION 1.9 ANIMAL AGE	2-87
GL-42 Section B.1.9.1 Measured, Estimated, Unknown Age	2-87
GL-42 Section B.1.9.2 Minimum Age	2-89
GL-42 Section B.1.9.2.1 Minimum Age Units	2-91
GL-42 Section B.1.9.3 Maximum Age	2-93
GL-42 Section B.1.9.3.1 Maximum Age Units	2-94
GL-42 SECTION B.2 VMP DATA AND USAGE	2-96
GL-42 Section B.2.1 Registered or Brand Name	2-96
GL-42 Section B.2.1.1 Product Code	2-97
GL-42 Section B.2.1.2 Registration Identifier	2-98
GL-42 Section B.2.1.3 Anatomical Therapeutic Chemical Vet (ATCvet) Code	2-100
GL-42 Section B.2.1.4 Company or MAH	2-101
GL-42 Section B.2.1.5 MAH Assessment	2-102
GL-42 Section B.2.1.6 Regulatory Authority Assessment	2-103
GL-42 Section B.2.1.7 Route of Exposure	2-103
GL-42 Section B.2.1.7.1.1 Product Dose or Amount Used (Numeric Value for Dose)	2-105
GL-42 Section B.2.1.7.1.3 Numeric Value for Interval of Administration	2-108
GL-42 Section B.2.1.7.1.4 Units of Value for the Interval of Administration	2-109
GL-42 Section B.2.1.7.1.2.2 Date of First Exposure	2-111
GL-42 Section B.2.1.7.1.2.3 Date of Last Exposure	2-112
GL-42 SECTION B.2.2 ACTIVE INGREDIENT	2-113
GL-42 Section B.2.2.1 Active Ingredient(s)	2-113
GL-42 Section B.2.2.1 Active Ingredient(s) Code	2-114
GL-42 Section B.2.2.1.1 Strength (Numerator)	2-115
GL-42 Section B.2.2.1.1.1 Strength Units (Numerator)	2-116
GL-42 Section B.2.2.1.1 Strength (Denominator)	2-118
GL-42 Section B.2.2.1.1.1 Strength Units (Denominator)	2-119
GL-42 Section B.2.2.2 Dosage Form	2-121
GL-42 Section B.2.3 Lot Number	2-123
GL-42 Section B.2.3.1 Expiration Date	2-124
GL-42 Section B.2.6.1 Manufacturer's Site Identifier (FDA Establishment Identifier #)	2-125
GL-42 Section B.2.6.2 Manufacturing Date	2-126

GL-42 Section B.2.6.3 Number of Defective Units _____	2-127
GL-42 Section B.2.6.4 Number of Returned Units _____	2-129
GL-42 Section B.2.4 Who Administered the VMP _____	2-131
GL-42 Section B.2.5 Use According to Label _____	2-133
GL-42 Section B.2.5.1 Explanation for Off-Label Use _____	2-134
GL-42 Section B.2.6.5 Office of Regulatory Affairs (ORA) District Field Office Reported _____	2-136
GL-42 SECTION B.3 ADVERSE EVENT DATA _____	2-138
GL-42 Section B.3.1 Narrative of AE/PP _____	2-138
GL-42 Section B.3.2 Adverse Clinical Manifestations (Adverse Event Reaction Term Name and Code) _____	2-139
GL-42 Section B.3.3 Date of Onset of AE _____	2-142
GL-42 Section B.3.4 Length of Time Between Exposure to VMP and Onset of AE _____	2-143
GL-42 Section B.3.5.1 AE Duration _____	2-145
GL-42 Section B.3.5.1.1 AE Duration Time Units _____	2-146
GL-42 Section B.3.6 Serious AE _____	2-147
GL-42 Section B.3.7 Treatment of AE _____	2-148
GL-42 SECTION B.3.8 OUTCOMES TO DATE _____	2-149
GL-42 Section B.3.8.1 Ongoing _____	2-149
GL-42 Section B.3.8.2 Recovered/Normal _____	2-150
GL-42 Section B.3.8.3 Recovered with Sequela _____	2-151
GL-42 Section B.3.8.4 Died _____	2-152
GL-42 Section B.3.8.5 Euthanized _____	2-153
GL-42 Section B.3.8.6 Outcome Unknown _____	2-154
GL-42 Section B.3.9 Previous Exposure to the VMP _____	2-155
GL-42 Section B.3.10 Previous AE to the VMP _____	2-156
GL-42 SECTION B.4 DECHALLENGE – RECHALLENGE INFORMATION _____	2-157
GL-42 Section B.4.1 Did AE Abate After Stopping the VMP _____	2-157
GL-42 Section B.4.2 Did AE Reappear after Re-introduction of the VMP _____	2-158
GL-42 SECTION B.5 ASSESSMENT OF AE _____	2-159
GL-42 Section B.5.1 Attending Veterinarian’s Assessment _____	2-159
GL-42 SECTION B.6 SUPPLEMENTAL DOCUMENTS _____	2-161
GL-42 Section B.6.1 Supplemental Document Filename _____	2-161
GL-42 Section B.6.2 Supplemental Document Description _____	2-162
GL-42 Section B.6.3 Supplemental Document Type _____	2-163
GL-42 Section B.6.4 Supplemental Document Data _____	2-165
B.7 US SPECIFIC ONLY SECTION _____	2-166
Section B.7.1 Report Identifier _____	2-166
Section B.7.2 Domestic Vs Foreign Report Category _____	2-167
Section B.7.3 US Pharmacovigilance Contact Person for the MAH _____	2-168
2.3 DATA ELEMENTS NOT CONTAINED WITHIN GL-42 SPECIFICATION _____	2-170
Individual Case Safety Report Number _____	2-170

Message Sender Identifier _____	2-171
Profile Identifier Code _____	2-173
Batch Identifier _____	2-174
Message Date _____	2-175
Message Version Number and Release Number _____	2-176

List of Tables

Table 1-1--HL7 ICSR Document Listing _____	1-1
Table 1-2--Data Element Information _____	1-2
Table 1-3--Submitted Elements versus Report Type _____	1-4
Table 1-4 Null Flavor Element Data Rules _____	1-7
Table 1-5--ICSR Vocabulary Listing _____	1-8
Table 2-1--Regulatory Authority Information _____	2-1

1. INTRODUCTION

1.1 Purpose and Scope

The purpose of this document is to provide validation procedures for Pharmacovigilance of Veterinary Medicinal Products (VMP) Individual Case Safety Reports (ICSR) submissions. These procedures will allow developers and designers to correctly build and validate their submissions. This document provides validation procedures for HL7 ICSR messages that are consistent with the [International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products \(VICH\) GL-42](#) guidelines. The GL-42 specification, which defines the data elements for the adverse event reports, covers data elements used in ICSRs containing adverse events, product problems and adverse events combined with product problems.

1.2 Background

This document should be used in conjunction with the [FDA/CVM GL-42 Guidance Document](#) and the [FDA/CVM Electronic Transmission Implementation Specification \(Step-by-Step Guide\)](#). The [FDA/CVM GL-42 Guidance for Industry #188](#) will provide an overview of this new reporting method. The Step-by-Step Guide will detail how to set up and organize the HL7 ICSR XML message. It is recommended that reporters familiarize themselves first with CVM's GL-42 Guidance for Industry #188, and then CVM's Step-by-Step Guide, as these documents will provide important details on the creation of the ICSRs.

1.3 ICSR Documents

The FDA has generated a number of documents to assist stakeholders in preparing, formatting and transmitting electronic submissions of HL7 ICSRs. The following table lists the documents.

Table 1-1--HL7 ICSR Document Listing

Title	Description	Organization Owner
#188 - Guidance for Industry - Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine	Guidance document on providing information (Data Elements) to the FDA CVM via Form 1932 - Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report	FDA CVM
Appendix 1 - Instructions for the Marketing Authorization Holder on Filling out Form FDA 1932 Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report	Appendix to Guidance for Industry - Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine	FDA CVM
HL7 Individual Case Safety Report (ICSR) Release 2 Normative: Implementation Guide for FDA Adverse Event and Product Problem Reporting	Technical conformance criteria for HL7 ICSR submissions to FDA.	FDA Data Council
Electronic Transmission Implementation Specifications [Step By Step]	Technical instructions for building compliant HL7 animal ICSRs	FDA CVM
Electronic Transmission Implementation Specifications [Validation Procedures]	Validation procedures for compliant HL7 animal ICSRs	FDA CVM
Generalized Data Models of GL-42, MedWatch+ ICSR	Pictorial views of the compliant GL-42 FDA CVM ICSR data models	FDA CVM
Instructions for Submitting Mandatory Electronic Adverse Event Reports to FDA CVM	High level instructions to assist in transmitting and submitting HL7 FDA CVM complaint ICSRs	FDA CVM
HL7 ICSR Vocabularies	MS Excel spreadsheet listing the vocabularies of compliant GL-42 ICSR data element selections	FDA CVM

1.4 Document Organization

The document is organized in accordance with the order in which individual data elements appear in sections of the GL-42 guidelines.

The following table describes the information provided for each data element:

Table 1-2--Data Element Information

Information	Description
Data Element	Data Element contained in ICSR
Requirement ID	Requirement ID from the FAERS/MedWatch+ Consolidated Spread Sheet (CSS)
Definition	Provides a description of the GL-42 data element
Business Rules	Describes business rules for the specified data element that will be used to validate the ICSR
Error	Describes the error type (Reject)
Comment	Further describes the associated business rule
Step-by-Step Guide Section	References the appropriate section of the Step-by-Step Guide where more information on the specified data element may be found
Field Description	Describes the field length and data type for the specified data element
Report Type	Describes the reporting type: adverse event (AE Only), product problem (PP Only) or adverse event with product problem (AE + PP) for which the data element is valid
OID	Object Identifiers
Cardinality	Describes required elements and relationships to other data elements

1.5 GL-42 Data Elements

The GL-42 data elements are defined within their organizational sections. Each data element has the Requirement ID from the CSS and the definition along with any applicable business rules. Other data element descriptions will be discussed below.

1.6 Errors

For the purposes of accepting and processing FDA/CVM HL7 ICSRs, the following error level will be used when validating FDA/CVM HL7 ICSRs:

Reject – the system will reject the ICSR and will not process the batch transmission of ICSRs. Therefore, if more than one ICSR is included in the transmission and a ‘reject’ error occurs, then all ICSRs in the transmission will be rejected. The system will continue to validate the ICSR containing the error (as well as all ICSRs included in the transmission) after a ‘reject’ error has occurred and will attempt to identify all other errors. Error notices will be returned back to the sender detailing the type of error (rejection) and the problem encountered.

1.7 Step-By-Step Guide

As mentioned above, readers should familiarize themselves with the [FDA/CVM Electronic Transmission Implementation Specification \[Step-By-Step\]](#) document referred to hereafter as the Step-by-Step Guide (SBS) before proceeding with this document. This document will expand on the information presented in the Step-by-Step Guide, providing readers with a full set of requirements for each specified data element. References to the related Step-by-Step Guide section will be included for each data element.

1.8 Field Description

The Field Description will display the maximum field length allowed for the specified data element as well as the data type. Common data types include open ended text (string), coded items (single choice code list), etc.

The system will validate maximum field length and reject ICSRs with data elements containing values above the maximum field length.

The system will also validate the data type (i.e. open ended text/string, coded items, numeric, etc) and reject ICSRs with data elements violating the specified data type.

1.9 Report Type

This piece of data element information describes the FDA/CVM specific reporting type for which the data element is valid. Reporting Types can include the following: Adverse Events (AE only), Product Problems (PP only) or Adverse Events with Product Problems (AE+PP). For example, a data element may be valid for only those reports containing adverse event information; therefore, the data element would only be valid for reporting types AE and AE+PP.

Only fields designated for the specified report type should be included in the ICSR for that report type (i.e. if the report type equals AE only, then PP data should not be included in the AE only ICSR). The only exception to this rule is if the element is not valid for the specified report type, but is required by the FDA HL7 ICSR schema. In this case, if the element is not valid for the specified report type and required by the FDA HL7 ICSR schema, then the element must be present in the ICSR, but contain a null flavor. The table below details the ICSR data sections, whether the specified information is required, optional, or should not be reporter per the FDA HL7 ICSR schema.

Table 1-3--Submitted Elements versus Report Type

GL 42 Section Title	GL-42 Section Number	Required Elements per ICSR Report		
		Adverse Event (AE) Only	Product Problem (PP) Only	AE + PP
Administrative and Identification Information – Section A				
Regulatory Authority (RA)	A.1	X	X	X
Marketing Authorization Holder (MAH) (Sender) -- Section A.2				
MAH Information	A.2.1	X	X	X
Person Acting on Behalf of MAH	A.2.2	*	*	*
Person(s) Involved in AER (Reporter) – Section A.3				
Primary Reporter Information	A.3.1	X	X	X
Other Reporter Information	A.3.2	*	*	*
AER Information (Sender Investigation/Report Information) – Section A.4				
Unique Adverse Event Identification Number	A.4.1	X	X	X
Original Receive Date	A.4.2	X	X	X
Date of Current Submission	A.4.3	X	X	X
Type of Report – Section A.4.4				
Type of Submission & Code	A.4.4.1	X	X	X
Reason for Nullification Report	A.4.4.2	*	*	*
Type of Information in Report & Code	A.4.4.3	*	*	*
Description of Animal Data Information – Section B				
Animal Data – Section B.1				
Number of Animals Treated	B.1.1	*	#	*
Number of Animals Affected	B.1.2	X	#	X
Attending Veterinarian's Assessment of Health Status Prior to VMP & Code	B.1.2.1	*	#	*
Species (Type of Species) & Code	B.1.3	X	*	X
Breed (Breed Group)	B.1.4	*	#	*
Gender & Code	B.1.5	*	#	*
Reproductive Status & Code	B.1.6	*	#	*
Female Physiological Status & Code	B.1.7	*	#	*
Animal Weight – Section B.1.8				
Weight Measured, Estimated or Unknown & Code	B.1.8.1	X	#	X
Minimum Weight	B.1.8.2	X	#	X
Maximum Weight	B.1.8.3	X	#	X
Animal Age – Section B.1.9				
Age Measured, Estimated or Unknown & Code	B.1.9.1	X	#	X
Minimum Age	B.1.9.2	X	#	X
Minimum Age Units	B.1.9.2.1	X	#	X
Maximum Age	B.1.9.3	X	#	X
Maximum Age Units	B.1.9.3.1	X	#	X
VMP Data and Usage – Section B.2				
Registered Name or Brand Name	B.2.1	X	X	X
Product Code (Product NDC Number or Unique ID)	B.2.1.1	*	*	*
Registration Identifier	B.2.1.2	X	X	X
Anatomical Therapeutic Chemical Vet (ATCvet) Code	B.2.1.3	X	X	X

GL 42 Section Title	GL-42 Section Number	Required Elements per ICSR Report		
		Adverse Event (AE) Only	Product Problem (PP) Only	AE + PP
Company or MAH	B.2.1.4	*	*	*
MAH Assessment	B.2.1.5	*	#	*
Route of Exposure & Dosage Information – Section B.2.1.7 & Section B.2.2				
Route of Exposure (Route of Administration)	B.2.1.7	*	#	*
Dose Per Administration	B.2.1.7.1	*	#	*
Interval of Administration	B.2.1.7.1.2	*	#	*
Date of First Exposure	B.2.1.7.1.2.2	*	#	*
Date of Last Exposure	B.2.1.7.1.2.3	*	#	*
Active Ingredient(s) & Code(s)	B.2.2.1	X	X	X
Dosage Form & Code	B.2.2.2	*	*	*
Manufacturing/Product Defect Information – Section B.2.3 & B.2.3.6				
Lot Number(s)	B.2.3	*	*	*
Expiration Date	B.2.3.1	*	*	*
Manufacturer's Site Id Number	B.2.6.1	#	*	*
Manufacturer's Identifier Type	B.2.6.1.1	#	*	*
Manufacturing Date	B.2.6.2	#	*	*
Number of Defective Units	B.2.6.3	#	*	*
Number of Units Returned	B.2.6.4	#	*	*
ORA District Field Office Where Product Quality Report was Filed and Code	B.2.6.5	#	X	X
Administration – Section B.2.4				
Who Administered the VMP & Code	B.2.4	*	#	*
Label Usage – Section B.2.5				
Use According to Label	B.2.5	*	#	*
Explanation for Off-Label Use & Code	B.2.5.1	*	#	*
Adverse Event Data – Section B.3				
Narrative of AE	B.3.1	X	X	X
Adverse Clinical Manifestations (AER Term Name(s) & Code(s))	B.3.2	X	X	X
Date of Onset of AE (AE Start Date)	B.3.3	X	#	X
Length of Time between Exposure to VMP & Onset of AE	B.3.4	*	#	*
AE Duration Time	B.3.5.1	*	#	*
AE Duration Time Units	B.3.5.1.1	*	#	*
Serious AER Reported	B.3.6	X	#	X
Treatment of AE	B.3.7	*	#	*
Outcome to Date	B.3.8	*	#	*
Previous Exposure to the VMP	B.3.9	*	#	*
Previous AE to VMP	B.3.10	*	#	*
Dechallenge - Rechallenge Information – Section B.4				
Did AE Abate After Stopping the VMP?	B.4.1	*	#	*
Did AE Reappear After Re-introduction of the VMP?	B.4.2	*	#	*
Veterinary Assessment of AE – Section B.5				
Attending Veterinarian's Assessment of AE	B.5.1	*	#	*
Supplemental Documents -- Section B.6				

GL 42 Section Title	GL-42 Section Number	Required Elements per ICSR Report		
		Adverse Event (AE) Only	Product Problem (PP) Only	AE + PP
Supplemental Document Filename	B.6.1	*	*	*
Supplemental Document Description	B.6.2	*	*	*
Supplemental Document Type	B.6.3	*	*	*
U.S. Specific Only – Section B.7				
Report Identifier	B.7.1	X	X	X
Domestic vs. Foreign Report Category	B.7.2	X	X	X
US Pharmacovigilance Contact Person for MAH	B.7.3	X	X	X
Key to Table: X = Required Element – Must Be Present – Null Flavor Required If Data Is Not Known * = Optional Element – If Reported the Element Data Must Follow the Established Validation Rules # = Element MUST Not Be Reported - = FDA Usage Only				

If fields are included that are not valid for the specified report type (and not required by the FDA HL7 ICSR schema) the ICSR will be rejected. For example, if any of the fields under the Animal Data Section (B.1) are included for the Product Problem Only (PP Only) Report Type, then the ICSR will be rejected.

1.10 Object Identifier (OID)

The Object Identifier (OID) will be supplied for the specified data element when applicable. This information can be obtained in the Step-by-Step Guide Appendix. The system will validate that the correct OID is used for coded items (when applicable). If a specified field is using an incorrect OID, the system will reject the ICSR.

[APPENDIX A.0 – SYSTEM OIDS](#) can also be found in CVM’s vocabulary listing.

1.11 Cardinality

Cardinality is used here to describe the relationships between data elements as well as the data element’s mandatory versus optional status as it relates to the specified CVM GL-42 report types (note that this may be different than the required versus optional status as it relates to the ICSR schema). The following example describes how cardinality will be used in this document. Whether a data element is optional or mandatory will also be noted.

Example:

[A.1 Regulatory Authority] 1..1 [A.1 Regulatory Authority Name]

This example states that there is only (1) Regulatory Authority Name allowed for (1) Regulatory Authority. Because this is a 1..1 relationship, the data element Regulatory Authority Name is mandatory.

Note: Even if an element field is optional, leaving the field blank (no response) is not allowed. Reporters must enter the appropriate null flavor (to indicate no response) in all optional fields.

The system will validate for required fields as well as cardinality (for example, if relationship states 1..1, then the specified relationship cannot have repeating elements). If the ICSR is missing required fields or violates the specified cardinality, the ICSR will be rejected.

1.12 Special Handling of Element Fields (Null Flavors)

This Implementation Guide applies to all three types of ICSR reports: Adverse Event Only Report (AE only), Product Problem Only Report (PP only), and Adverse Event plus Product Problem report (AE/PP report). Reporters should map every data element that is applicable to the specific type of report into the ICSR message, whether or not it is a required data element or an optional data element. However, reporters are advised that for any data element that is not applicable to a specific type of report, mapping such a data element into the ICSR message will result in a rejection of the message. For example, reporters should not send data about animal administration information in a Product Problem Only report.

All mandatory and optional elements of the ICSR message must be coded with an actual value or a null flavor selection specific to the associated data element. See [Section 7—List of Element Fields](#) of the *Electronic Transmission Implementation Specifications [Step By Step]* manual for a complete list of elements and the application of null flavors.

The process of selecting and employing a null flavor is controlled by two rules that have precedence. Rule one; is outlined in the table below and is the default set of rules for applying the null flavor to ICSR elements. Rule two; is contained in the individual validation business rules within this manual for the all elements. Rule two has precedence over Rule one. If the Validation Guide for the individual element does not definitively specify an element null flavor treatment then Rule one applies appropriately.

The following table documents the null flavor handling for each element type. It also indicates how CVM's ICSR processing systems will validate and process elements that are mandatory and/or optional and when a null value can be properly used as element data response.

Table 1-4 Null Flavor Element Data Rules

Element Type	Null Flavor Rule
Mandatory Coded Element	Submitters must use a valid value from the vocabulary list. Must use the best selection possible. 'Unknown' may be included in vocabulary lists.
Optional Coded Element	Must use the null flavor specified for the element when a valid value is not known. 'Unknown' may be included in vocabulary lists. Blank or empty fields are NOT permitted unless used in conjunction with a null flavor attribute.
Mandatory Text Field Element	Submitters must use a valid value. Use of a null flavor is NOT permitted. Blank/empty fields (for this element type) are NOT permitted.
Optional Text Field Element	Must use null flavors when a valid value is not known. 'NI – No Information' is the default null flavor for this data type. Blank or empty fields are NOT permitted unless used in conjunction with a null flavor attribute.
Mandatory Numeric Field Element	Must contain a valid value. Null flavor use is NOT permitted. Zero may be a valid value (unless otherwise specified by specific business rules).
Optional Numeric Field Element	Must use a null flavor when a valid value is not known. 'NI – No Information' is the default null flavor for this data type. Blank or empty fields are NOT permitted unless used in conjunction with a null flavor attribute.
Mandatory Date Field Element	Must contain a valid date. Null flavor use is NOT permitted. Blank or empty fields are NOT permitted.
Optional Date Field Element	Must use a null flavor when a valid date is not known. 'NI – No Information' is the default null flavor for this data type. Blank or empty fields are NOT permitted unless used in conjunction with a null flavor attribute.
Mandatory Text Element Related to Mandatory Coded Element	Reporters must use a valid value from the list. 'Unknown' may be a value included in vocabulary lists.
Optional Text Element Related to Coded Element	Must use a null flavor when a valid value is not known. 'NI – No Information' is the default null flavor for this element type. Blank or empty

Element Type	Null Flavor Rule
	fields are NOT permitted unless used in conjunction with a null flavor attribute.
Boolean Field Elements – Mandatory or Optional	Boolean elements have a number of null flavor terms and conditions and when a null flavor can be used. Appendix A.31 Boolean Information Table documents the allowable null flavors (“NA”, “NF”, and “UNK”) and the cases when the null flavor must/may be employed.

1.13 Referenced List of Values

For each coded data element a referenced list of values (vocabulary) is provided.

The system will validate that the data element uses the correct referenced list of values (vocabulary) and that the value of the data element is included in the referenced list of values (vocabulary). If either of these restrictions is violated, then the system will reject the ICSR. The following table lists the vocabularies defined for ICSR coding.

Table 1-5-ICSR Vocabulary Listing

ICSR Vocabulary
A.1-Sender Category Vocabulary
A.2-List of Reporter Categories
A.3-List of Type of Submission
A.4-List of Type of Information in Report
A.5-List of Domestic and Foreign Report Categories
A.6-List of Attending Veterinarian’s Assessment of Health Status Prior to VMP Use
A.7-List of Species
A.8-List of Breeds
A.9-List of Gender Categories
A.10-List of Reproductive Status Categories
A.11-List of Female Physiological Status Categories
A.12-List of Precision Categories for Weight and Age Data
A.13-List of Time Units
A.14-List of Assessment Categories
A.15-List of Routes of Exposure
A.16-Interval of Administration Vocabulary {To Be Deleted – Use A.13 List of Time Units}
A.17-Duration Vocabulary {To Be Deleted – Use A.13 List of Time Units}
A.18-List of Manufacturer Site Identifiers
A.19-List of Administrators of VMP(s)
A.20-ATCvet Code -- Information Only
A.21-VeDDRA Vocabulary
A.22-List of Length of Time Between Exposure and Onset of AE
A.23-ICSR Observation Locator Codes (Not a vocabulary)
A.24-List of Units of Measurement
A.25-List of Units of Presentation
A.26-Profile Identifier Code Vocabulary
A.27-List of Attending Veterinarian’s Causality Assessment
A.28-List of ORA District Field Offices
A.29-List of Package Types
A.30-List of Explanation for Off-Label Use – Coding System
A.31-Boolean -- Information Only
A.32-List of Attached Document Types
A.33-List of Dosage Forms
A.34-{Deleted}
A.35-List of US States & Territory Codes

ICSR Vocabulary
A.36-List of ISO 3-Digit Country Codes
A.37-{Deleted}
A.38-Substance Registration System Active Ingredient Codes

1.14 Schema Validation

The ICSR message will be validated against the FDA HL7 ICSR XML schema. Note that some elements may not be valid for specified report types, but are required by the FDA HL7 ICSR schema. In this case, the element must be present in the ICSR (but contain the appropriate null flavor) in order for the ICSR to pass schema validation.

1.15 Disclaimer

For any HL7 ICSR version 3 messages that are submitted to FDA/CVM, please note that CVM ICSR applications and systems will only capture and process the data elements that are described in this document. Any other data and/or information that is included with the messages but are not explicitly described here will be ignored and not processed.

2. DATA ELEMENTS AND VALIDATION RULES

2.1 GL-42 Section A - Administrative and Identification Information

Section A is the Administrative and Identification Information Section of the GL-42 Adverse Event and Product Problem Report.

GL-42 SECTION A.1 REGULATORY AUTHORITY (RA)

The “Regulatory Authority” section identifies the regulatory authority to which the Adverse Event Report (AER) is to be initially submitted based on which RA has the authority to regulate the product. See the table below for correct FDA CVM addresses information.

Table 2-1--Regulatory Authority Information

Regulatory Authority (RA) Identifier	RA Name	RA Street Address	RA City	RA State	RA Zip Code	RA Country
USFDACVM	Food and Drug Administration, Center for Veterinary Medicine	7500 Standish Place (HFV-199), Room 403	Rockville	Maryland (MD)	20855	USA

GL-42 Section A.1 Regulatory Authority Name - (RA Name)

Requirement ID: 4017.1

Definition:

The data element “Regulatory Authority Name” is a text field that contains the name of the regulatory authority (RA) to which this AER is to be initially submitted based on which RA has the authority to regulate the product.

Business Rule:

CVM_GL-42_059

If value of the “Regulatory Authority Name” field is blank or contains a null flavor, then reject the ICSR.

Error: Reject ICSR.

Comment: The ICSR must contain a “Regulatory Authority Name”; otherwise the ICSR will be rejected.

Step-by-Step Guide Section: 2.1

Field Description:

Max length is 60 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

OID:

Code system OID = National Cancer Institute Thesaurus

Code value = T95009

Cardinality:

[A.1 Regulatory Authority] 1..1 [A.1 Regulatory Authority Name]

Data element is mandatory – Use of Null value not allowed

GL-42 Section A.1 Regulatory Authority Street Address (RA) -- Address

Requirement ID: 4017.2

Definition:

The data element, “Regulatory Authority Street Address”, is a text field that contains the street address of the RA.

Business Rule:

CVM_GL-42_060

If the value of the “Regulatory Authority Street Address” is blank or contains a null flavor, then reject the ICSR.

Error: Reject ICSR.

Comment: The ICSR must contain a “Regulatory Authority Street Address”; otherwise, the ICSR will be rejected.

Step-by-Step Guide Section: 2.1

Field Description:

Max length is 100 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.1 Regulatory Authority] 1..1 [A.1 Regulatory Authority Street Address]

Data element is mandatory – Use of Null value not allowed

GL-42 Section A.1 Regulatory Authority City (RA) -- City

Requirement ID: 4017.3

Definition:

The data element, “Regulatory Authority City”, is a text field that contains the city of the RA.

Business Rule:

CVM_GL-42_061

If the value of the “Regulatory Authority City” is blank or contains a null flavor, then reject the ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a “Regulatory Authority City”; otherwise, the ICSR will be rejected.

Step-by-Step Guide Section: 2.1

Field Description:

Max length is 35 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.1 Regulatory Authority] 1..1 [A.1 Regulatory Authority City]

Data element is mandatory – Use of Null value not allowed

GL-42 Section A.1 Regulatory Authority State/County (RA) -- State

Requirement ID: 4017.4

Definition:

The data element, “Regulatory Authority State/County”, is a coded field (if the country equals ‘USA’) or an open text field (if the country is not ‘USA’) that contains the state or county of the RA.

Business Rule(s):

CVM_GL-42_062

If the value of the data element “RA State” and/or equivalent jurisdictional unit (such as County or Province) is blank or contains a null flavor, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a “Regulatory Authority State;” otherwise, the ICSR will be rejected.

CVM_GL-42_062.1

If the “RA Country” equals ‘USA’, and the “Regulatory Authority State;” field value is not found in the referenced list of values (See [APPENDIX A.35–LIST OF US STATES & TERRITORY CODES](#)), then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value “Regulatory Authority State;” (if “RA Country” = ‘USA’); otherwise, the ICSR will be rejected.

Step-by-Step Guide Section: 2.1

Field Description:

Max length (where “RA Country” = ‘USA’) is 15 characters for the code single choice code list

Max length (where “RA Country” does not equal ‘USA’) is 80 characters; open ended text

Report Type: AE Only, PP Only, AE + PP

OID:

No OID needed. For the ‘USA RA’ the system will validate for the correct 2 letter state abbreviations.

Cardinality:

[A.1 Regulatory Authority] 1..1 [A.1 Regulatory Authority State/County]

Data element is mandatory – Use of Null value not allowed

GL-42 Section A.1 Regulatory Authority (RA) -- Mail/Zip Code

Requirement ID: 4017.5

Definition:

The data element, “Regulatory Authority Mail/ZIP Code”, is a field that contains the Postal Code of the RA.

Business Rule:

CVM_GL-42_063

If the value of the data element “Regulatory Authority Mail/ZIP Code” is blank or contains a null flavor, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a “Regulatory Authority Mail/ZIP Code”; otherwise, the ICSR will be rejected.

Step-by-Step Guide Section: 2.1

Field Description:

Max length is 15 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.1 Regulatory Authority] 1..1 [A.1 Regulatory Authority Mail/ZIP code]

Data element is mandatory – Use of Null value not allowed

GL-42 Section A.1 Regulatory Authority Country (RA) -- Country

Requirement ID: 4017.6

Definition:

The data element, “RA Country”, is a three character country code that is taken from APPENDIX A.36-LIST OF ISO 3-DIGIT COUNTRY CODES values.

Business Rule(s):

CVM_GL-42_064

If the data element “RA Country” is blank or contains a null flavor, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a “Regulatory Authority Country” Code; otherwise, the ICSR will be rejected.

CVM_GL-42_065

If the value of the “RA Country” field is not found in the referenced lists of values (APPENDIX A.36-LIST OF ISO 3-DIGIT COUNTRY CODES list) then reject the ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for the “Regulatory Authority Country” Code; otherwise, the ICSR will be rejected.

Step-by-Step Guide Section: 2.1

Field Description:

Max field length is 15 characters for the code; single choice code list

Report Type: AE Only, PP Only, AE + PP

OID:

OID not required. For Country Code the system will use the APPENDIX A.36-LIST OF ISO 3-DIGIT COUNTRY CODES.

Cardinality:

[A.1 Regulatory Authority] 1..1 [A.1 Regulatory Authority Country]

Data element is mandatory – Use of Null value not allowed

GL-42 SECTION A.2 MARKETING AUTHORIZATION HOLDER (MAH)

GL-42 Section A.2.1 Marketing Authorization Holder (MAH) -- Business Name

Requirement ID: 48

Definition:

The “Marketing Authorization Holder (MAH)” is the applicant (or in some cases the non-applicant) responsible for reporting information to the RA responsible for regulating the VMP.

Business Rule:

CVM_GL-42_066

If the value of the “MAH Business Name” is blank or contains a null flavor, then reject the ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a “MAH Business Name (Sender Organization)”; otherwise, the ICSR will be rejected.

Step-by-Step Guide Section: 2.2

Field Description:

Max length is 60 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.2 Marketing Authorization Holder (MAH) Information] 1..1 [A.2 Marketing Authorization Holder (MAH) Business Name]

Data element is mandatory – Use of Null value not allowed

GL-42 Section A.2.1 Marketing Authorization Holder (MAH) -- Street Address

Requirement ID: 40

Definition:

The data element “MAH Street Address” is a field that contains the street address of the MAH.

Business Rule:

CVM_GL-42_067

If the value of the “MAH Street Address” is blank or contains a null flavor, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a “MAH Street Address” (Sender Street Address); otherwise, the ICSR will be rejected.

Step-by-Step Guide Section: 2.2

Field Description:

Max length is 100 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.2 Marketing Authorization Holder (MAH) Information] 1..1 [A.2 Marketing Authorization Holder (MAH) Street address]

Data element is mandatory – Use of Null value not allowed

GL-42 Section A.2.1 Marketing Authorization Holder (MAH) -- City

Requirement ID: 41

Definition:

The data element “MAH City” is a field that contains the City of the MAH.

Business Rule:

CVM_GL-42_068

If the value of the “MAH City” is blank or contains a null flavor, then reject the ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a Sender City; otherwise, the ICSR will be rejected.

Step-by-Step Guide Section: 2.2

Field Description:

Max length is 35 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.2 Marketing Authorization Holder (MAH) Information] 1..1 [A.2 Marketing Authorization Holder (MAH) City]

Data element is mandatory – Use of Null value not allowed

GL-42 Section A.2.1 Marketing Authorization Holder (MAH) -- State/County

Requirement ID: 42

Definition:

The data element “MAH State/County” is a field that contains the State/County of the MAH. This data element can also accept Province information for the MAH, if such information exists.

Business Rule:

CVM_GL-42_069

If the value of the data element “MAH State/County” and/or equivalent jurisdictional unit (such as County or Province) is null, then reject the ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a Sender State; otherwise, the ICSR will be rejected

CVM_GL-42_069.1

If the “MAH Country” equals ‘USA’, and the “MAH State/County” field value is not found in the referenced list of values ([APPENDIX A.35–LIST OF US STATES & TERRITORY CODES](#)), then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid “MAH State/County”; otherwise, the ICSR will be rejected.

Step-by-Step Guide Section: 2.2

Field Description:

Max length is 15 characters for the code (if the “MAH Country” = ‘USA’); single choice code list

Max length is 80 characters (if the “MAH Country” does not equal ‘USA’); text

Report Type: AE Only, PP Only, AE + PP

OID:

No OID needed. For ‘USA’ MAH the system will use [APPENDIX A.35–LIST OF US STATES & TERRITORY CODES](#).

Cardinality:

[A.2 Marketing Authorization Holder (MAH) Information] 1..1 [A.2 Marketing Authorization Holder (MAH) State/county]

Data element is mandatory – Use of Null value not allowed

GL-42 Section A.2.1 Marketing Authorization Holder (MAH) -- Mail/Zip Code

Requirement ID: 43

Definition:

The data element “MAH Mail/ZIP Code” is a field that contains the Postal Code information for the address of the MAH.

Business Rule:

CVM_GL-42_070

If the value of the “MAH Mail/ZIP Code” is blank or contains a null flavor, then reject the ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a “MAH Mail/ZIP Code”; otherwise, the ICSR will be rejected.

Step-by-Step Guide Section: 2.2

Field Description:

Max length is 15 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.2 Marketing Authorization Holder (MAH) Information] 1..1 [A.2 Marketing Authorization Holder (MAH) Mail/zip]

Data element is mandatory – Use of Null value not allowed

GL-42 Section A.2.1 Marketing Authorization Holder (MAH) -- Country

Requirement ID: 45

Definition:

The data element, "MAH Country" is a field that contains the code of the MAH country.

Business Rule:

CVM_GL-42_071

If the value of the "MAH Country" is blank or contains a null flavor, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid "MAH Country".

CVM_GL-42_072

If the value of the "MAH Country" field is not found in the referenced list of values ([APPENDIX A.36-LIST OF ISO 3-DIGIT COUNTRY CODES](#)), then the ICSR is rejected.

Error: Reject ICSR

Comment: The MAH (Sender) Country Code will be validated against [APPENDIX A.36-LIST OF ISO 3-DIGIT COUNTRY CODES](#).

Step-by-Step Guide Section: 2.2

Field Description:

Max length is 15 characters for the code; single choice code list

Report Type: AE Only, PP Only, AE + PP

OID:

OID not required. For "MAH Country" Code the system will use the [APPENDIX A.36-LIST OF ISO 3-DIGIT COUNTRY CODES](#).

Cardinality:

[A.2 Marketing Authorization Holder (MAH) Information] 1..1 [A.2 Marketing Authorization Holder (MAH) Country]

Data element is mandatory – Use of Null value not allowed

GL-42 Section A.2.2 Person Acting on Behalf of MAH -- (Contact Title)

Requirement ID: 4003.1

Definition:

The data element "Person Acting on Behalf of the MAH Contact Title" is a field that contains the title of the contact party for the MAH.

Business Rule:

CVM_GL-42_XXX

If the value of the MAH Contact Title is blank, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either a valid "MAH Contact Title" or a valid null flavor; otherwise the ICSR will be rejected.

Step-by-Step Guide Section: 2.2

Field Description:

Max length is 50 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.2 .2 Person Acting on Behalf of MAH] 0..1 [A.2.2 Person Acting on Behalf of MAH Contact Title]

Data element is optional; must enter "NI" to represent null/no response

GL-42 Section A.2.2 Person Acting on Behalf of MAH – (First Name)

Requirement ID: 38.2

Definition:

The data element “Person Acting on Behalf of the MAH First Name” is a field that contains the first name of the MAH contact party.

Business Rule:

CVM_GL-42_XXX

If the value of the ‘MAH First Name’ is blank, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either a valid “MAH First Name” or a valid null flavor; otherwise the ICSR will be rejected.

Step-by-Step Guide Section: 2.2

Field Description:

Max length is 35 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.2.2 Person Acting on Behalf of MAH] 0..1 [A.2.2 Person Acting on Behalf of MAH First Name]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.2.2 Person Acting on Behalf of MAH—(Last Name)

Requirement ID: 38.4

Definition:

The data element “Person Acting on Behalf of the MAH Last Name” is a field that contains the last name of the MAH contact party.

Business Rule:

CVM_GL-42_XXX

If the value of the “MAH Last Name” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either a valid “MAH Last Name” or a valid null flavor; otherwise the ICSR will be rejected.

Step-by-Step Guide Section: 2.2

Field Description:

Max length is 50 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.2.2 Person Acting on Behalf of MAH] 0..1 [A.2.2 Person Acting on Behalf of MAH Last Name]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.2.2 Person Acting on Behalf of MAH–(Telephone)

Requirement ID: 46

Definition:

The data element “Person Acting on Behalf of the MAH Telephone” is a field that contains the telephone number of the MAH contact party.

Business Rule:

CVM_GL-42_XXX

If the value of the “MAH Telephone” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either a valid “MAH Telephone” or a valid null flavor; otherwise the ICSR will be rejected.

CVM_GL-42_XXX

If the “MAH Country” equals ‘USA’ and the “MAH Telephone” number is not formatted numeric (with the exception of an ‘x’ for extensions), then reject ICSR.

Error: Reject ICSR

Comment: The “MAH Telephone” number must be formatted numeric if the “MAH Country” equals ‘USA’.

CVM_GL-42_XXX

If the “MAH Country” does not equal ‘USA’ and the telephone number is formatted numeric, then reject ICSR.

Error: Reject ICSR

Comment: The “MAH Telephone” number must be open ended text if the “MAH Country” does not equal ‘USA’.

CVM_GL-42_XXX

If the value of the “MAH Telephone” contains spaces, brackets or hyphens then reject ICSR.

Error: Reject ICSR

Comment: The “MAH Telephone” number must not contain spaces, brackets or hyphens otherwise reject ICSR.

CVM_GL-42_XXX

If the “MAH Telephone” number contains more than 5 digits prefixed by an ‘x’ (for extensions) then reject ICSR.

Error: Reject ICSR

Comment: The “MAH Telephone” number must not contain more than 5 digits prefixed by an ‘x’, otherwise reject ICSR.

Step-by-Step Guide Section: 2.2

Field Description:

Max length is 18 characters; formatted numeric when “MAH Country” equals ‘USA’; open ended text when “MAH Country” does not equal ‘USA’.

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.2.2 Person Acting on Behalf of MAH] 0..1 [A.2.2 Person Acting on Behalf of MAH Telephone]

Data element is optional; must enter "NI" to represent null/no response

GL-42 Section A.2.2 Person Acting on Behalf of MAH – (Fax)

Requirement ID: 4003.5

Definition:

The data element “Person Acting on Behalf of the MAH - Fax” is a field that contains the facsimile number of the MAH contact party.

Business Rule:

CVM_GL-42_XXX

If the value of the “MAH Fax” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either a valid “MAH Fax” or a valid null flavor; otherwise the ICSR will be rejected.

CVM_GL-42_XXX

If the “MAH Country” equals ‘USA’ and the “MAH Fax” number is not formatted numeric (with the exception of an ‘x’ for extensions), then reject ICSR.

Error: Reject ICSR

Comment: The “MAH Fax” number must be formatted numeric if the “MAH Country” equals ‘USA’.

CVM_GL-42_XXX

If the “MAH Country” does not equal ‘USA’ and the fax number is formatted numeric, then reject ICSR.

Error: Reject ICSR

Comment: The “MAH Fax” number must be open ended text if the “MAH Country” does not equal ‘USA’.

CVM_GL-42_XXX

If the value of the “MAH Fax” contains spaces, brackets or hyphens then reject ICSR.

Error: Reject ICSR

Comment: The “MAH Fax” number must not contain spaces, brackets or hyphens otherwise reject ICSR.

CVM_GL-42_XXX

If the “MAH Telephone” Fax contains more than 5 digits prefixed by an ‘x’ (for extensions) then reject ICSR.

Error: Reject ICSR

Comment: The “MAH Fax” number must not contain more than 5 digits prefixed by an ‘x’, otherwise reject ICSR.

Step-by-Step Guide Section: 2.2

Field Description:

Max length is 18 characters; formatted numeric when “MAH Country” equals ‘USA’; open ended text when “MAH Country” does not equal ‘USA’.

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.2.2 Person Acting on Behalf of MAH] 0..1 [A.2.2 Person Acting on Behalf of MAH Fax]

Data element is optional; must enter "NI" to represent null/no response

GL-42 Section A.2.2 Person Acting on Behalf of MAH – (Email)**Requirement ID:** 51**Definition:**

The data element “Person Acting on Behalf of the MAH - Email” is a field that contains the electronic mail address of the MAH contact party.

Business Rule:

CVM_GL-42_XXX

If the value of the “MAH Email” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either a valid “MAH Email” or a valid null flavor; otherwise the ICSR will be rejected.

CVM_GL-42_XXX

If the value of the “MAH Email” does not contain an ‘@’ symbol, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain an ‘@’ symbol in the email address; otherwise the ICSR will be rejected.

CVM_GL-42_XXX

If the value of the “MAH Email” does not contain one of the following domain extensions: .com, .net, .org, .biz, .info, .mobi, .name, .pro, .tel, .ar.com, .br.com, .bz, .ca, .gd, .gs, .ms, .com.mx, .qc.com, .tc, .us, .us.com, .uy.com, .vg, .edu, .gov, .am, .at, .be, .de, .de.com, .es, .com.es, .nom.es, .org.es, .eu, .eu.com, .gb.com, .gb.net, .hu.com, .im, .me, .no.com, .se.com, .se.net, .co.uk, .uk.com, .uk.net, .me.uk, .org.uk, .sa.com, .za.com, .cn, .cn.com, .com.cn, .org.cn, .in, .co.in, .firm.in, .gen.in, .ind.in, .net.in, .org.in, .jpn.com, .kr.com, .la, .ru.com, .tw, .com.tw, .org.tw, .cc, .cx, .fm, .co.nz, .net.nz, .org.nz, .tv, .ws, then reject the ICSR.

Comment [HC1]: Should this be a vocabulary?

Error: Reject ICSR

Comment: The ICSR must contain one of the listed domain extensions; otherwise the ICSR will be rejected.

Step-by-Step Guide Section: 2.2**Field Description:**

Max length is 100 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.2.2 Person Acting on Behalf of MAH] 0..1 [A.2.2 Person Acting on Behalf of MAH Email]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.2.2 Person Acting on Behalf of MAH – (Sender Category)

Requirement ID: 49.1

Definition:

The data element “Person Acting on Behalf of the MAH - Sender Category” is a field that contains the category of the MAH contact party.

Business Rule:

N/A

Step-by-Step Guide Section: 2.2

Field Description:

Max length is 15 characters for the code and 80 characters for the code description; single choice code list from [Appendix A –Sender Category](#).

Report Type: AE Only, PP Only, AE + PP

OID:

National Cancer Institute Thesaurus

Cardinality:

[A.2.2 Person Acting on Behalf of MAH] 0..1 [A.2.2 Person Acting on Behalf of MAH Category]

Data element is optional; select the best value from the vocabulary; enter “NI” to represent null/no response

GL-42 SECTION A.3 REPORTERS

GL-42 Section A.3.1 Primary Reporter – (Last Name)

Requirement ID: 400

Definition:

The data element “Primary Reporter - Last Name” is a field that contains the last name of the primary reporter of the AER.

Business Rule:

CVM_GL-42_073

If the value of the “Primary Reporter - Last Name” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a “Primary Reporter - Last Name”; otherwise, the ICSR will be rejected.

NOTE: Reporters can enter “WITHHELD” or “NI” as a valid “Primary Reporter - Last Name”.

CVM_GL-42_158

If the value of the “Primary Reporter - Last Name” equals “WITHHELD” or “NI”, then the value for the following data elements may use the null flavor (‘NI’): “Primary Reporter - First Name”, “Primary Reporter - Telecom – (Telephone, Fax and Email)”,.

Comment: If the “Primary Reporter - Last Name” is equal to “WITHHELD” or “NI” then the following data elements may be null: “Primary Reporter - First Name”, “Primary Reporter - Telecom (Telephone, Fax and Email)”.

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 50 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.3 Primary Reporter] 1..1 [A.3.1 Primary Reporter Last name]

Data element is mandatory – Use of Null value not allowed

GL-42 Section A.3.1 Primary Reporter – (First Name)

Requirement ID: 401

Definition:

The data element “Primary Reporter - First Name” is a field that contains the first name of the primary reporter of the AER.

Business Rule:

CVM_GL-42_XXX

If the value of the “Primary Reporter - First Name” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid “Primary Reporter - First Name” or a null value; otherwise, the ICSR will be rejected.

CVM_GL-42_158

If the value of the “Primary Reporter - Last Name” equals “WITHHELD” or “NI”, then the value for the following data elements may use the null flavor (‘NI’): “Primary Reporter - First Name”, “Primary Reporter - Telecom – (Telephone, Fax and Email)”,.

Comment: If the “Primary Reporter - Last Name” is equal to “WITHHELD” or “NI” then the following data elements may be null: “Primary Reporter - First Name”, “Primary Reporter - Telecom (Telephone, Fax and Email)”.

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 35 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.3.1 Primary Reporter] 0..1 [A.3.1 Primary Reporter First name]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.3.1 Primary Reporter – (Telephone)

Requirement ID: 404

Definition:

The data element “Primary Reporter - Telephone” is a field that contains the telephone number of the primary reporter of the AER.

Business Rule:

CVM_GL-42_XXX

If the value of the “Primary Reporter – Telephone” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid “Primary Reporter – Telephone” or a null value; otherwise, the ICSR will be rejected.

CVM_GL-42_XXX

If the “Primary Reporter - Country” equals ‘USA’ and the “Primary Reporter - Telephone” number is not formatted numeric (with the exception of an ‘x’ for extensions), then reject ICSR.

Error: Reject ICSR

Comment: The “Primary Reporter - Telephone” number must be formatted numeric if the “Primary Reporter - Country” equals ‘USA’.

CVM_GL-42_XXX

If the “Primary Reporter - Country” does not equal ‘USA’ and the telephone number is formatted numeric, then reject ICSR.

Error: Reject ICSR

Comment: The “Primary Reporter - Telephone” number must be open ended text if the “Primary Reporter - Country” does not equal ‘USA’.

CVM_GL-42_XXX

If the value of the “Primary Reporter - Telephone” contains spaces, brackets or hyphens then reject ICSR.

Error: Reject ICSR

Comment: The “Primary Reporter - Telephone” number must not contain spaces, brackets or hyphens otherwise reject ICSR.

CVM_GL-42_XXX

If the “Primary Reporter - Telephone” contains more than 5 digits prefixed by an ‘x’ (for extensions) then reject ICSR.

Error: Reject ICSR

Comment: The “Primary Reporter - Telephone” number must not contain more than 5 digits prefixed by an ‘x’, otherwise reject ICSR.

CVM_GL-42_XXX

If more than 1 Primary Reporter Telephone number is included, then reject ICSR

Error: Reject ICSR

Comment: The ICSR can only contain 3 Primary Reporter Telecom values; one Primary Reporter Telephone, one Primary Reporter Fax and one Primary Reporter Email, otherwise reject ICSR

CVM_GL-42_XXX

If all Primary Reporter Telecom values (Primary Reporter Phone, Fax and Email) are NOT present, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain at least one Primary Reporter Telecom instance (Primary Reporter Telephone, Fax or Email), otherwise reject ICSR. The included telecom instance may contain a valid null flavor.

CVM_GL-42_158

If the value of the “Primary Reporter - Last Name” equals “WITHHELD” or “NI”, then the value for the following data elements may use the null flavor (‘NI’): “Primary Reporter - First Name”, “Primary Reporter - Telecom – (Telephone, Fax and Email)”,.

Comment: If the “Primary Reporter - Last Name” is equal to “WITHHELD” or “NI” then the following data elements may be null: “Primary Reporter - First Name”, “Primary Reporter - Tele-com (Telephone, Fax and Email)”.

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 18 characters; formatted numeric when “Primary Reporter - Country” equals ‘USA’; open ended text when “Primary Reporter - Country” does not equal ‘USA’.

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.3.1 Primary Reporter] 0..1 [A.3.1 Primary Reporter Telephone]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.3.1 Primary Reporter – (Fax)

Requirement ID: 417

Definition:

The data element “Primary Reporter - Fax” is a field that contains the facsimile number of the primary reporter of the AER.

Business Rule:

CVM_GL-42_XXX

If the value of the “Primary Reporter - Fax” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid “Primary Reporter - Fax” or a null value; otherwise, the ICSR will be rejected.

CVM_GL-42_XXX

If the “Primary Reporter - Country” equals ‘USA’ and the “Primary Reporter - Fax” number is not formatted numeric (with the exception of an ‘x’ for extensions), then reject ICSR.

Error: Reject ICSR

Comment: The “Primary Reporter - Fax” number must be formatted numeric if the “Primary Reporter - Country” equals ‘USA’.

CVM_GL-42_XXX

If the “Primary Reporter - Country” does not equal ‘USA’ and the fax number is formatted numeric, then reject ICSR.

Error: Reject ICSR

Comment: The “Primary Reporter - Fax” number must be open ended text if the “Primary Reporter - Country” does not equal ‘USA’.

CVM_GL-42_XXX

If the value of the “Primary Reporter - Fax” contains spaces, brackets or hyphens then reject ICSR.

Error: Reject ICSR

Comment: The “Primary Reporter - Fax” number must not contain spaces, brackets or hyphens, otherwise reject ICSR.

CVM_GL-42_XXX

If the “Primary Reporter - Fax” contains more than 5 digits prefixed by an ‘x’ (for extensions) then reject ICSR.

Error: Reject ICSR

Comment: The “Primary Reporter - Fax” number must not contain more than 5 digits prefixed by an ‘x’, otherwise reject ICSR.

CVM_GL-42_XXX

If more than 1 Primary Reporter Fax number is included, then reject ICSR

Error: Reject ICSR

Comment: The ICSR can only contain 3 Primary Reporter Telecom values; one Primary Reporter Telephone, one Primary Reporter Fax and one Primary Reporter Email, otherwise reject ICSR

CVM_GL-42_XXX

If all Primary Reporter Telecom values (Primary Reporter Phone, Fax and Email) are NOT present, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain at least one Primary Reporter Telecom instance (Primary Reporter Telephone, Fax or Email), otherwise reject ICSR. The included telecom instance may contain a valid null flavor.

CVM_GL-42_158

If the value of the “Primary Reporter - Last Name” equals “WITHHELD” or “NI”, then the value for the following data elements may use the null flavor (‘NI’): “Primary Reporter - First Name”, “Primary Reporter - Telecom – (Telephone, Fax and Email)”,.

Comment: If the “Primary Reporter - Last Name” is equal to “WITHHELD” or “NI” then the following data elements may be null: “Primary Reporter - First Name”, “Primary Reporter - Tele-com (Telephone, Fax and Email)”.

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 18 characters; formatted numeric when “Primary Reporter - Country” equals ‘USA’; open ended text when “Primary Reporter - Country” does not equal ‘USA’

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.3.1 Primary Reporter] 0..1 [A.3.1 Primary Reporter - Fax]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.3.1 Primary Reporter – (Email)**Requirement ID:** 406**Definition:**

The data element “Primary Reporter - Email” is a field that contains the electronic mail address of the primary reporter of the AER.

Business Rule:

CVM_GL-42_XXX

If more than 1 Primary Reporter Email is included, then reject ICSR

Error: Reject ICSR

Comment: The ICSR can only contain 3 Primary Reporter Telecom values; one Primary Reporter Telephone, one Primary Reporter Fax and one Primary Reporter Email, otherwise reject ICSR

CVM_GL-42_158

If the value of the “Primary Reporter - Last Name” equals “WITHHELD” or “NI”, then the value for the following data elements may use the null flavor (‘NI’): “Primary Reporter - First Name”, “Primary Reporter - Telecom – (Telephone, Fax and Email)”.

Comment: If the “Primary Reporter - Last Name” is equal to “WITHHELD” or “NI” then the following data elements may be null: “Primary Reporter - First Name”, “Primary Reporter - Telecom (Telephone, Fax and Email)”.

CVM_GL-42_XXX

If all Primary Reporter Telecom values (Primary Reporter Phone, Fax and Email) are NOT present, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain at least one Primary Reporter Telecom instance (Primary Reporter Telephone, Fax or Email), otherwise reject ICSR. The included telecom instance may contain a valid null flavor.

CVM_GL-42_XXX

If the value of the “Primary Reporter - Email” does not contain a ‘@’ symbol, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain an ‘@’ symbol in the “Primary Reporter - Email” address; otherwise the ICSR will be rejected.

CVM_GL-42_XXX

If the value of the “Primary Reporter - Email” does not contain one of the following domain extensions: .com, .net, .org, .biz, .info, .mobi, .name, .pro, .tel, .ar.com, .br.com, .bz, .ca, .gd, .gs, .ms, .com.mx, .qc.com, .tc, .us, .us.com, .uy.com, .vg, .edu, .gov, .am, .at, .be, .de, .de.com, .es, .com.es, .nom.es, .org.es, .eu, .eu.com, .gb.com, .gb.net, .hu.com, .im, .me, .no.com, .se.com, .se.net, .co.uk, .uk.com, .uk.net, .me.uk, .org.uk, .sa.com, .za.com, .cn, .cn.com, .com.cn, .org.cn, .in, .co.in, .firm.in, .gen.in, .ind.in, .net.in, .org.in, .jpn.com, .kr.com, .la, .ru.com, .tw, .com.tw, .org.tw, .cc, .cx, .fm, .co.nz, .net.nz, .org.nz, .tv, .ws, then reject the ICSR.

Error: Reject ICSR

Comment: “Primary Reporter - Email” fields must contain one of the listed domain extensions; otherwise the ICSR will be rejected.

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 100 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.3.1 Primary Reporter] 0..1 [A.3.1 "Primary Reporter - Email"]

Data element is optional; must enter "NI" to represent null/no response

GL-42 Section A.3.1 Primary Reporter – (Category)

Requirement ID: 49

Definition:

The data element “Primary Reporter - Category” is a field that contains the category of the primary reporter of the AER.

Business Rule:

CVM_GL-42_074

If the value of the “Primary Reporter - Category” is null or blank, then reject the ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a “Primary Reporter - Category”; otherwise the ICSR will be rejected.

CVM_GL-42_075

If the data element “Primary Reporter - Category” does not reference the correct list of values (National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must use the correct vocabulary for the “Primary Reporter - Category”; otherwise the ICSR will be rejected.

CVM_GL-42_075.1

If the value of the “Primary Reporter - Category” is not found in the referenced list of values ([APPENDIX A.2-LIST OF REPORTER CATEGORIES](#)), then the ICSR is rejected.

Error: Reject ICSR

Comment: The ICSR must use a valid value from the correct vocabulary for the “Primary Reporter - Category”; otherwise the ICSR will be rejected.

CVM_GL-42_075.2

If the “Primary Reporter - Category” field displayName does not match the code value for the “Primary Reporter - Category” Code, then reject ICSR.

Error: Reject ICSR

Comment: The value for the “Primary Reporter - Category” displayName must match the appropriate value for “Primary Reporter - Category” code; otherwise the ICSR will be rejected.

CVM_GL-42_075.3

If the code system for the observation describing “Primary Reporter - Category” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Primary Reporter - Category” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR.

CVM_GL-42_075.4

If the code and displayName for the observation describing “Primary Reporter - Category” does not equal (code = "T95002" / displayName = “SourceReport”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Primary Reporter - Category” must equal (code = "T95002" / displayName = “SourceReport”); otherwise reject ICSR.

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 15 characters for the code and 80 characters for the code description; single choice code list

Report Type: AE Only, PP Only, AE + PP

OID:

codeSystem = National Cancer Institute Thesaurus

code = value from list – **APPENDIX A.2-LIST OF REPORTER CATEGORIES**

Cardinality:

[A.3.1 Primary Reporter] 1..1 [A.3.1 Primary Reporter Category]

Data element is mandatory – Reporters must select the best value from the vocabulary; Use of Null value is not allowed

GL-42 Section A.3.1 Primary Reporter – (Business Name)

Requirement ID: 403

Definition:

The data element “Primary Reporter - Business Name” is a field that contains the Business Name of the primary reporter of the AER.

Business Rule:

CVM_GL-42_XXX

If the value of the “Primary Reporter - Last Name” equals “WITHHELD”, the value for “Primary Reporter - Business Name” may contain a null value.

Comment: If the “Primary Reporter - Last Name” = “WITHHELD” then Primary Business Name may be null.

CVM_GL-42_XXX

If the value of the “Primary Reporter - Business Name” is blank, then reject ICSR

Error: Reject ICSR

Comment: The “Primary Reporter - Business Name” field must contain either a valid value or a null flavor (i.e. must not be blank); otherwise reject ICSR

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 60 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.3.1Primary Reporter] 0..1 [A.3.1 Primary Reporter Business name]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.3.1 Primary Reporter – (Street Address)

Requirement ID: 407

Definition:

The data element “Primary Reporter - Street Address” is a field that contains the Street Address of the primary reporter of the AER.

Business Rule:

CVM_GL-42_XXX

If the value of the “Primary Reporter - Street Address” is blank, then reject ICSR

Error: Reject ICSR

Comment: The “Primary Reporter - Street Address” field must contain either a valid value or a null flavor (i.e. must not be blank); otherwise reject ICSR

CVM_GL-42_XXX

If the value of the “Primary Reporter - Last Name” equals “WITHHELD”, the value for “Primary Reporter Street Address” may contain the “NI” null flavor value.

Comment: If the “Primary Reporter - Last Name” = “WITHHELD” then “Primary Reporter Street Address” may be null.

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 100 characters; open ended text

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.3.1 Primary Reporter] 0..1 [A.3.1 Primary Reporter Street Address]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.3.1 Primary Reporter – (City)

Requirement ID: 409

Definition:

The data element “Primary Reporter - City” is a field that contains the city of the primary reporter of the AER.

Business Rule:

CVM_GL-42_XXX

If the value of the “Primary Reporter - City” is blank, then reject ICSR

Error: Reject ICSR

Comment: The “Primary Reporter - City” field must contain either a valid value or a null flavor (i.e. must not be blank); otherwise reject ICSR

CVM_GL-42_XXX

If the value of the “Primary Reporter - Last Name” equals “WITHHELD”, the value for “Primary Reporter - City” may contain a null value.

Comment: If the “Primary Reporter - Last Name” = “WITHHELD” then “Primary Reporter - City” may be null.

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 35 characters; open ended text

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.3.1 Primary Reporter] 0..1 [A.3.1 Primary Reporter City]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.3.1 Primary Reporter – (State/County)**Requirement ID:** 410**Definition:**

The data element, “Primary Reporter - State/County”, is a coded field (if the country equals ‘USA’) or an open text field (if the country is not ‘USA’) that contains the state or county of the primary reporter of the AER. This data element can also accept Province information for the Primary Reporter, if such information exists.

Business Rule:

CVM_GL-42_XXX

If the value of the “Primary Reporter - State/County” is blank, then reject ICSR

Error: Reject ICSR

Comment: The “Primary Reporter - State/County” field must contain either a valid value or a null flavor (i.e. must not be blank); otherwise reject ICSR

CVM_GL-42_XXX

If the “Primary Reporter - Country” equals ‘USA’, and the “Primary Reporter - State/County” does not reference the correct list of values (APPENDIX A.35–LIST OF US STATES & TERRITORY CODES) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must reference the correct vocabulary for the “Primary Reporter - State/County”; otherwise reject the ICSR.

CVM_GL-42_XXX

If the “Primary Reporter - Country” equals ‘USA’, and the “Primary Reporter - State/County” field value is not found in the referenced list of values (APPENDIX A.35–LIST OF US STATES & TERRITORY CODES), then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid “Primary Reporter - State/County”; otherwise, the ICSR will be rejected.

Step-by-Step Guide Section: 2.3**Field Description:**

Max length is 15 characters for the code; single choice code list when Country = ‘USA’

Max length is 80 characters when Country does not equal ‘USA’; open end text

Report Type: AE Only, PP Only, AE + PP**OID:**

No OID needed. For ‘USA’ “Primary Reporter - State/County” the system will use APPENDIX A.35–LIST OF US STATES & TERRITORY CODES for validation.

Cardinality:

[A.3.1 Primary Reporter] 0..1 [A.3.1 Primary Reporter State/County]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.3.1 Primary Reporter – (Mail/Zip Code)

Requirement ID: 413

Definition:

The data element “Primary Reporter - Mail/ZIP Code” is a field that contains the postal code of the primary reporter of the AER.

Business Rule:

CVM_GL-42_XXX

If the value of the “Primary Reporter - Mail/ZIP Code” is blank, then reject ICSR

Error: Reject ICSR

Comment: The “Primary Reporter - Mail/ZIP Code” field must contain either a valid value or a null flavor (i.e. must not be blank); otherwise reject ICSR

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 15 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.3.1 Primary Reporter] 0..1 [A.3.1 Primary Reporter Mail/ZIP code]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.3.1 Primary Reporter – (Country)

Requirement ID: 412

Definition:

The data element “Primary Reporter - Country” is a field that contains the country of the primary reporter of the AER.

Business Rule(s):

CVM_GL-42_076

If the value of the “Primary Reporter - Country” is null or blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a “Primary Reporter - Country” code, otherwise the ICSR will be rejected.

CVM_GL-42_077

If the data element “Primary Reporter - Country” does not reference the correct list of values ([APPENDIX A.36-LIST OF ISO 3-DIGIT COUNTRY CODES](#)) then reject the ICSR

Error: Reject ICSR.

Comment: The ICSR must reference the correct vocabulary for the “Primary Reporter - Country”; otherwise the ICSR will be rejected

CVM_GL-42_077.1

If the value of the “Primary Reporter - Country” is not found in the referenced list of values ([APPENDIX A.36-LIST OF ISO 3-DIGIT COUNTRY CODES](#)), then reject ICSR

Error: Reject ICSR.

Comment: The ICSR must contain a valid value for the “Primary Reporter - Country”; otherwise the ICSR will be rejected.

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 15 characters for the code; single choice code list

Report Type: AE Only, PP Only, AE + PP

OID:

OID not required. For “Primary Reporter - Country” the system will use the [APPENDIX A.36-LIST OF ISO 3-DIGIT COUNTRY CODES](#).

Cardinality:

[A.3.1 Primary Reporter] 1..1 [A.3.1 “Primary Reporter - Country”]

Data element is mandatory – Reporters must select the best value from the vocabulary; Use of Null value is not allowed

GL-42 Section A.3.2 Other Reporter – (Last Name)

Requirement ID: 400

Definition:

The data element “Other Reporter - Last Name” is a field that contains the last name of another AER reporter.

Business Rule:

CVM_GL-42_XXX

If the value of the “Other Reporter - Last Name” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a Reporter Last Name; otherwise, the ICSR will be rejected.

NOTE: Reporters can enter “WITHHELD” or “NI” as a valid Reporter Last Name.

CVM_GL-42_XXX

CVM_GL-42_XXX

If the value of the “Other Reporter - Last Name” equals “WITHHELD” or “NI”, then the value for the following data elements may use the null flavor (‘NI’): “Other Reporter - First Name”, “Other Reporter - Telecom – (Telephone, Fax and Email)”.

Comment: If the “Other Reporter - Last Name” is equal to “WITHHELD” or “NI” then the following data elements may be null: “Other Reporter - First Name”, “Other Reporter - Telecom (Telephone, Fax and Email)”.

CVM_GL-42_XXX

If the value of “Other Reporter - Last Name” is not null, and the value of “Other Reporter - Country” and “Other Reporter - Category” is null or blank, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain an “Other Reporter - Country” and “Other Reporter - Category” if “Other Reporter - Last Name” is not null.

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 50 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.3.2 Other Reporter] 0..1 [A.3.2 Other Reporter Last name]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.3.2 Other Reporter – (First Name)

Requirement ID: 401

Definition:

The data element “Other Reporter - First Name” is a field that contains the first name of another AER reporter.

Business Rule:

CVM_GL-42_XXX

If the value of the “Other Reporter - First Name” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid Reporter First Name or a null value; otherwise, the ICSR will be rejected.

CVM_GL-42_XXX

If the value of the “Other Reporter - Last Name” equals “WITHHELD” or “NI”, then the value for the following data elements may use the null flavor (‘NI’): “Other Reporter - First Name”, “Other Reporter - Telecom – (Telephone, Fax and Email)”.

Comment: If the “Other Reporter - Last Name” is equal to “WITHHELD” or “NI” then the following data elements may be null: “Other Reporter - First Name”, “Other Reporter - Telecom (Telephone, Fax and Email)”.

Step-by-Step Guide Section: 2.3

Field Description:

Max length 35; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.3.2 Other Reporter] 0..1 [A.3.2 “Other Reporter - First Name”]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.3.2 Other Reporter – (Telephone)

Requirement ID: 404

Definition:

The data element “Other Reporter - Telephone” is a field that contains the telephone number of another AER reporter.

Business Rule:

CVM_GL-42_XXX

If the value of the “Other Reporter - Telephone” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid “Other Reporter - Telephone” or a null value; otherwise, the ICSR will be rejected.

CVM_GL-42_XXX

If the “Other Reporter - Country” equals ‘USA’ and the “Other Reporter - Telephone” number is not formatted numeric (with the exception of an ‘x’ for extensions), then reject ICSR.

Error: Reject ICSR

Comment: The “Other Reporter - Telephone” number must be formatted numeric if the “Other Reporter - Country” equals ‘USA’.

CVM_GL-42_XXX

If the “Other Reporter - Country” does not equal ‘USA’ and the telephone number is formatted numeric, then reject ICSR.

Error: Reject ICSR

Comment: The “Other Reporter - Telephone” number must be open ended text if the “Other Reporter - Country” does not equal ‘USA’.

CVM_GL-42_XXX

If the value of the “Other Reporter - Telephone” contains spaces, brackets or hyphens then reject ICSR.

Error: Reject ICSR

Comment: The “Other Reporter - Telephone” number must not contain spaces, brackets or hyphens, otherwise reject ICSR.

CVM_GL-42_XXX

If the “Other Reporter - Telephone” contains more than 5 digits prefixed by an ‘x’ (for extensions) then reject ICSR.

Error: Reject ICSR

Comment: The “Other Reporter - Telephone” number must not contain more than 5 digits prefixed by an ‘x’, otherwise reject ICSR.

CVM_GL-42_XXX

If more than 1 Other Reporter Telephone number is included, then reject ICSR

Error: Reject ICSR

Comment: The ICSR can only contain 3 Other Reporter Telecom values; one Other Reporter Telephone, one Other Reporter Fax and one Other Reporter Email, otherwise reject ICSR

CVM_GL-42_XXX

If all Other Reporter Telecom values (Other Reporter Phone, Fax and Email) are NOT present, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain at least one Other Reporter Telecom instance (Other Reporter Telephone, Fax or Email), otherwise reject ICSR. The included telecom instance may contain a valid null flavor.

CVM_GL-42_XXX

If the value of the “Other Reporter - Last Name” equals “WITHHELD” or “NI”, then the value for the following data elements may use the null flavor (‘NI’): “Other Reporter - First Name”, “Other Reporter - Telecom – (Telephone, Fax and Email)”.

Comment: If the “Other Reporter - Last Name” is equal to “WITHHELD” or “NI” then the following data elements may be null: “Other Reporter - First Name”, “Other Reporter - Telecom (Telephone, Fax and Email)”.

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 18 characters; formatted numeric when “Other Reporter - Country” equals ‘USA’; open ended text when “Other Reporter - Country” does not equal ‘USA’.

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.3.2 Other Reporter] 0..1 [A.3.2 “Other Reporter - Telephone”]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.3.2 Other Reporter – (Fax)

Requirement ID: 405

Definition:

The data element “Other Reporter - Fax” is a field that contains the facsimile number of another AER reporter.

Business Rule:

CVM_GL-42_XXX

If the value of the “Other Reporter - Fax” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid “Other Reporter - Fax” or a null value; otherwise, the ICSR will be rejected.

CVM_GL-42_XXX

If the “Other Reporter - Country” equals ‘USA’ and the “Other Reporter - Fax” number is not formatted numeric (with the exception of an ‘x’ for extensions), then reject ICSR.

Error: Reject ICSR

Comment: The “Other Reporter - Fax” number must be formatted numeric if the “Other Reporter - Country” equals ‘USA’.

CVM_GL-42_XXX

If the “Other Reporter - Country” does not equal ‘USA’ and the fax number is formatted numeric, then reject ICSR.

Error: Reject ICSR

Comment: The “Other Reporter - Fax” number must be open ended text if the “Other Reporter - Country” does not equal ‘USA’.

CVM_GL-42_XXX

If the value of the “Other Reporter - Fax” contains spaces, brackets or hyphens then reject ICSR.

Error: Reject ICSR

Comment: The “Other Reporter - Fax” number must not contain spaces, brackets or hyphens; otherwise reject ICSR.

CVM_GL-42_XXX

If the “Other Reporter - Fax” contains more than 5 digits prefixed by an ‘x’ (for extensions) then reject ICSR.

Error: Reject ICSR

Comment: The “Other Reporter - Fax” number must not contain more than 5 digits prefixed by an ‘x’, otherwise reject ICSR.

CVM_GL-42_XXX

If more than 1 Other Reporter Fax number is included, then reject ICSR

Error: Reject ICSR

Comment: The ICSR can only contain 3 Other Reporter Telecom values; one Other Reporter Telephone, one Other Reporter Fax and one Other Reporter Email, otherwise reject ICSR

CVM_GL-42_XXX

If all Other Reporter Telecom values (Other Reporter Phone, Fax and Email) are NOT present, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain at least one Other Reporter Telecom instance (Other Reporter Telephone, Fax or Email), otherwise reject ICSR. The included telecom instance may contain a valid null flavor.

CVM_GL-42_XXX

If the value of the “Other Reporter - Last Name” equals “WITHHELD” or “NI”, then the value for the following data elements may use the null flavor (‘NI’): “Other Reporter - First Name”, “Other Reporter - Telecom – (Telephone, Fax and Email)”.

Comment: If the “Other Reporter - Last Name” is equal to “WITHHELD” or “NI” then the following data elements may be null: “Other Reporter - First Name”, “Other Reporter - Telecom (Telephone, Fax and Email)”.

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 18 characters; formatted numeric when “Other Reporter - Country” equals ‘USA’; open ended text when “Other Reporter - Country” does not equal ‘USA’.

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.3.2 Other Reporter] 0..1 [A.3.2 Other Reporter Fax]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.3.2 Other Reporter – (Email)**Requirement ID:** 406**Definition:**

The data element “Other Reporter - Email” is a field that contains the electronic mail address of another AER reporter.

Business Rule:

CVM_GL-42_XXX

If more than 1 Other Reporter Email is included, then reject ICSR

Error: Reject ICSR*Comment:* The ICSR can only contain 3 Other Reporter Telecom values; one Other Reporter Telephone, one Other Reporter Fax and one Other Reporter Email, otherwise reject ICSR

CVM_GL-42_XXX

If all Other Reporter Telecom values (Other Reporter Phone, Fax and Email) are NOT present, then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain at least one Other Reporter Telecom instance (Other Reporter Telephone, Fax or Email), otherwise reject ICSR. The included telecom instance may contain a valid null flavor.

CVM_GL-42_XXX

If the value of the “Other Reporter - Last Name” equals “WITHHELD” or “NI”, then the value for the following data elements may use the null flavor (‘NI’): “Other Reporter - First Name”, “Other Reporter - Telecom – (Telephone, Fax and Email)”.

Comment: If the “Other Reporter - Last Name” is equal to “WITHHELD” or “NI” then the following data elements may be null: “Other Reporter - First Name”, “Other Reporter - Telecom (Telephone, Fax and Email)”.

CVM_GL-42_XXX

If the value of the “Other Reporter - Email” does not contain a “@” symbol, then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain an “@” symbol in the email address; otherwise the ICSR will be rejected.

CVM_GL-42_XXX

If the value of the “Other Reporter - Email” does not contain one of the following domain extensions: .com, .net, .org, .biz, .info, .mobi, .name, .pro, .tel, .ar.com, .br.com, .bz, .ca, .gd, .gs, .ms, .com.mx, .qc.com, .tc, .us, .us.com, .uy.com, .vg, .edu, .gov, .am, .at, .be, .de, .de.com, .es, .com.es, .nom.es, .org.es, .eu, .eu.com, .gb.com, .gb.net, .hu.com, .im, .me, .no.com, .se.com, .se.net, .co.uk, .uk.com, .uk.net, .me.uk, .org.uk, .sa.com, .za.com, .cn, .cn.com, .com.cn, .org.cn, .in, .co.in, .firm.in, .gen.in, .ind.in, .net.in, .org.in, .jpn.com, .kr.com, .la, .ru.com, .tw, .com.tw, .org.tw, .cc, .cx, .fm, .co.nz, .net.nz, .org.nz, .tv, .ws, then reject the ICSR.

Error: Reject ICSR*Comment:* “Other Reporter - Email” fields must contain one of the listed domain extensions; otherwise the ICSR will be rejected.**Step-by-Step Guide Section:** 2.3

Field Description:

Max length is 100 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.3.2 Other Reporter] 0..1 [A.3.2 Other Reporter Email]

Data element is optional; must enter "NI" to represent null/no response

GL-42 Section A.3.2 Other Reporter—(Business Name)

Requirement ID: 403

Definition:

The data element “Other Reporter - Business Name” is a field that contains the business name of another AER reporter.

Business Rule:

CVM_GL-42_XXX

If the value of the “Other Reporter - Last Name” equals “WITHHELD”, and the value for “Other Reporter - Business Name” is not null (NI) then reject ICSR.

Error: Reject ICSR

Comment: If the “Other Reporter - Last Name” = “WITHHELD” then “Other Reporter - Business Name” must be null; otherwise reject ICSR.

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 60 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.3.2 Other Reporter] 0..1 [A.3.2 “Other Reporter - Business Name”]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.3.2 Other Reporter – (Street Address)

Requirement ID: 407

Definition:

The data element “Other Reporter - Street Address” is a field that contains the street address of another AER reporter.

Business Rule:

CVM_GL-42_XXX

If the value of the “Other Reporter - Street Address” is blank, then reject ICSR

Error: Reject ICSR

Comment: The “Other Reporter - Street Address” field must contain either a valid value or a null flavor (i.e. must not be blank); otherwise reject ICSR

CVM_GL-42_XXX

If the value of the “Other Reporter - Last Name” equals “WITHHELD”, the value for “Other Reporter - Street Address” may contain a null value.

Comment: If the “Other Reporter - Last Name” = “WITHHELD” then “Other Reporter -Street Address” may be null.

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 100 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.3.2 Other Reporter] 0..1 [A.3.2” Other Reporter - Street Address”]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.3.2 Other Reporter – (City)

Requirement ID: 409

Definition:

The data element “Other Reporter - City” is a field that contains the city of another AER reporter.

Business Rule:

CVM_GL-42_XXX

If the value of the “Other Reporter - City” is blank, then reject ICSR

Error: Reject ICSR

Comment: The “Other Reporter - City” field must contain either a valid value or a null flavor (i.e. must not be blank); otherwise reject ICSR

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 35 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.3.2 Other Reporter] 0..1 [A.3.2” Other Reporter - City”]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.3.2 Other Reporter – (State/County)

Requirement ID:

410

Definition:

The data element, “Other Reporter – State/County”, is a coded field (if the country equals ‘USA’) or an open text field (if the country is not equal to ‘USA’) that contains the state or county of another AER reporter. This data element can also accept Province information for the Other Reporter State, if such information exists.

Business Rule:

CVM_GL-42_XXX

If the value of the “Other Reporter – State/County” is blank, then reject ICSR

Error: Reject ICSR

Comment: The “Other Reporter – State/County” field must contain either a valid value or a null flavor (i.e. must not be blank); otherwise reject ICSR

CVM_GL-42_XXX

If the “Other Reporter -- Country” equals ‘USA’, and the “Other Reporter – State” does not reference the correct list of values (APPENDIX A.35–US STATES CODES) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must reference the correct vocabulary for the “Other Reporter – State”; otherwise reject the ICSR.

CVM_GL-42_XXX

If the “Other Reporter – Country” equals ‘USA’, and the “Other Reporter – State” field value is not found in the referenced list of values (APPENDIX A.35–US STATES CODES), then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid “Other Reporter - State”; otherwise, the ICSR will be rejected.

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 15 characters for the code; single choice code list when Country = ‘USA’

Max length is 80 characters when Country does not equal ‘USA’; open end text

Report Type: AE Only, PP Only, AE + PP

OID:

No OID needed. For ‘USA’ “Other Reporter State” use APPENDIX A.35–US STATES CODES.

Cardinality:

[A.3.2 Other Reporter] 0..1 [A.3.2 Other Reporter - State/County]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.3.2 Other Reporter – (Mail/Zip Code)

Requirement ID: 413

Definition:

The data element “Other Reporter - Mail/ZIP Code” is a field that contains the postal code of another AER reporter.

Business Rule:

CVM_GL-42_XXX

If the value of the “Other Reporter - Mail/ZIP Code” is blank, then reject ICSR

Error: Reject ICSR

Comment: The “Other Reporter - Mail/ZIP Code” field must contain either a valid value or a null flavor (i.e. must not be blank); otherwise reject ICSR

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 15 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.3.2 Other Reporter] 0..1 [A.3.2 Other Reporter - Mail/zip code]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.3.2 Other Reporter – (Country)**Requirement ID:** 412**Definition:**

The A.3.2 “Other Reporter - Country” is the Country code of the Other Reporter.

Business Rule:

CVM_GL-42_XXX

If the value of the “Other Reporter - Country” is blank then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain an “Other Reporter - Country”, otherwise the ICSR will be rejected.

CVM_GL-42_080

If the data element “Other Reporter - Country” does not reference the correct list of values ([APPENDIX A.36-LIST OF ISO 3-DIGIT COUNTRY CODES](#)) then reject the ICSR

Error: Reject ICSR.*Comment:* The ICSR must reference the correct vocabulary for the “Other Reporter - Country”; otherwise the ICSR will be rejected

CVM_GL-42_080.1

If the value of the “Other Reporter – Country” is not found in the referenced list of values [APPENDIX A.36-LIST OF ISO 3-DIGIT COUNTRY CODES](#), then reject ICSR

Error: Reject ICSR.*Comment:* The ICSR must contain a valid value for the “Other Reporter - Country” (if provided); otherwise the ICSR will be rejected.

CVM_GL-42_XXX

If the value of “Other Reporter - Last Name” is not null, and the value of “Other Reporter - Country” and “Other Reporter – Category” is null or blank, then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain an “Other Reporter – Country” and “Other Reporter – Category” if “Other Reporter - Last Name” is not null.**Step-by-Step Guide Section:** 2.3**Field Description:**

Max length is 15 characters for the code; single choice code list

Report Type: AE Only, PP Only, AE + PP**OID:**

OID not required. For Country Code the system will use [APPENDIX A.36-LIST OF ISO 3-DIGIT COUNTRY CODES](#).

Cardinality:

[A.3.2 Other Reporter] 0..1 [A.3.2 “Other Reporter - Country”]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section A.3.2.1 Other Reporter – (Category)

Requirement ID: 49

Definition:

The A.3.2.1 “Other Reporter - Category” is the category to which the Other Reporter belongs.

Business Rule:

CVM_GL-42_XXX

If the value of the “Other Reporter - Category” is blank, then reject the ICSR.

Error: Reject ICSR

Comment: The ICSR must contain an “Other Reporter - Category”; otherwise the ICSR will be rejected.

CVM_GL-42_079

If the data element “Other Reporter - Category” is not null and the “Other Reporter - Category” does not reference the correct list of values (**APPENDIX A.2-LIST OF REPORTER CATEGORIES**), then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must use the correct vocabulary for the “Other Reporter - Category”; otherwise the ICSR will be rejected.

CVM_GL-42_079.1

If the data element “Other Reporter - Category” is not null and value of the “Other Reporter - Category” is not found in the referenced list of values (Participants), then the ICSR is rejected.

Error: Reject ICSR

Comment: The ICSR must use a valid value from the correct vocabulary for the “Other Reporter - Category”;

CVM_GL-42_079.2

If the data element “Other Reporter - Category” is not null and the “Other Reporter - Category” field displayName does not match the code value for the “Other Reporter - Category” Code, then reject ICSR.

Error: Reject ICSR

Comment: The value for the “Other Reporter - Category” displayName must match the appropriate value for “Other Reporter - Category” code; otherwise the ICSR will be rejected.

CVM_GL-42_079.3

If the code system for the observation describing “Other Reporter - Category” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Other Reporter - Category” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR.

CVM_GL-42_079.4

If the code and displayName for the observation describing “Other Reporter - Category” does not equal (code = "T95002" / displayName = “SourceReport”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Other Reporter - Category” must equal (code = "T95002" / displayName = “SourceReport”); otherwise reject ICSR.

CVM_GL-42_078:

If any of the following fields are provided: “Other Reporter - Last Name”, “Other Reporter - First Name”, “Other Reporter - Telephone”, “Other Reporter - Fax”, “Other Reporter - Email”, “Other Reporter - Business Name”, “Other Reporter - Street Address”, “Other Reporter - City”, “Other Reporter State/County”, “Other Reporter Mail/Zip Code”, and if either “Other Reporter - Country” Code or “Other Reporter - Category” is null then reject ICSR

Error: Reject ICSR

Comment: If any of the data elements under Other Reporter are provided (Last Name, First Name, Telephone, Fax, Email, Business Name, Street Address, City, State/County, Mail/Zip Code or Country Code), then the “Other Reporter - Country” Code and “Other Reporter - Category” must be provided, otherwise, reject ICSR.

Step-by-Step Guide Section: 2.3

Field Description:

Max length is 15 characters for the code and 80 characters for the code description; single choice code list

Report Type: AE Only, PP Only, AE + PP

OID:

codeSystem = National Cancer Institute Thesaurus

code = value from list – Primary Reporter & “Other Reporter - Category” – [APPENDIX A.2-LIST OF REPORTER CATEGORIES](#)

Cardinality:

[A.3.2 Other Reporter] 1..1 [A.3.2.1 “Other Reporter - Category”] if any information under Section A.3.2 Other Reporter is provided

Data element is mandatory

[A.3.2 Other Reporter] 0..0 [A.3.2.1 “Other Reporter - Category”] if reporter requests not to be identified (enter “WITHHELD” in “Last Name” field)

Data element is optional; select the best value from the vocabulary; enter “NI” to represent null/no response

GL-42 SECTION A.4 AER INFORMATION

GL-42 Section A.4.1 Unique Adverse Event Report Identification Number

Requirement ID: 600.6

Definition:

The data element “Unique Adverse Event Report Identification Number” is a field containing a unique identification number given to the AER by the MAH or RA.

Business Rule:

CVM_GL-42_081

If the value of the “Unique Adverse Event Report Identification Number” field is null or blank, then reject the ICSR.

Error: Reject ICSR

Comment: The “Unique Adverse Event Report Identification Number” must contain a valid value – it may not contain a null value or be blank; otherwise reject ICSR.

CVM_GL-42_082

If the value of the first 3 characters in the “Unique Adverse Event Report Identification Number” does not reference the correct list of values ([APPENDIX A.36-LIST OF ISO 3-DIGIT COUNTRY CODES](#)), then reject the ICSR.

Error: Reject ICSR

Comment: The “Unique Adverse Event Report Identification Number” must reference the correct vocabulary; otherwise reject ICSR.

CVM_GL-42_082.1

If the value of the first 3 characters in the “Unique Adverse Event Report Identification Number” is not found in the referenced list of values ([APPENDIX A.36-LIST OF ISO 3-DIGIT COUNTRY CODES](#)), then reject the ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for the “Unique Adverse Event Report Identification Number”; otherwise reject ICSR.

CVM_GL-42_XXX

If the value of the 4th character in the “Unique Adverse Event Report Identification Number” is not a dash (-), then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for the “Unique Adverse Event Report Identification Number”; otherwise reject ICSR.

CVM_GL-42_XXX

If the value of the 5th through 12th characters in the “Unique Adverse Event Report Identification Number” are not alpha numeric characters (representing the MAH code) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for the “Unique Adverse Event Report Identification Number”; otherwise reject ICSR.

~~CVM_GL-42_XXX~~

If the value of the 13th character in the “Unique Adverse Event Report Identification Number” is not a dash (-), then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for the “Unique Adverse Event Report Identification Number”; otherwise reject ICSR.

~~CVM_GL-42_XXX~~

~~If the value of the 14th through 60th characters in the “Unique Adverse Event Report Identification Number” is not numeric, then reject ICSR.~~

~~*Error:* Reject ICSR~~

~~*Comment:* The ICSR must contain a valid value for the “Unique Adverse Event Report Identification Number”; otherwise reject ICSR.~~

Step-by-Step Guide Section: 2.4.1

Field Description:

Max length is 60 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

OID:

codeSystem =

code = value from list [APPENDIX A.36-LIST OF ISO 3-DIGIT COUNTRY CODES](#)

Cardinality:

[A.4 AER Information] 1..1 [A.4.1 Unique Adverse Event Report Identification Number]

Data element is mandatory – Use of Null value not allowed

GL-42 Section A.4.2 Date AER Received by MAH (Original Receive Date)

Requirement ID: 88.1

Definition:

The data element “Date AER Received by MAH (Original Receive Date)” is a field that contains the date the AER was received by the MAH.

Business Rule:

CVM_GL-42_084

If the value of the “Date AER Received by MAH (Original Receive Date)” is null or blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a “Date AER Received by MAH (Original Receive Date)”; otherwise reject ICSR.

CVM_GL-42_085

If the date format for the “Date AER Received by MAH (Original Receive Date)” is not a complete valid date (in the format of YYYYMMDD HHMMSS.UUUU, where HHMMSS.UUUU are optional), then reject ICSR.

Error: Reject ICSR

Comment: The “Date AER Received by MAH (Original Receive Date)” must be a valid date; otherwise reject ICSR. ****NOTE: HHMMSS.UUUU represents hours, minutes, seconds and fraction of seconds****

CVM_GL-42_085.1

If the value of the “Date AER Received by MAH (Original Receive Date)” is not less than or equal to the FDA CVM processing system date then reject ICSR.

Error: Reject ICSR

Comment: The “Date AER Received by MAH (Original Receive Date)” must be less than or equal to the FDA CVM processing system date; otherwise reject ICSR.

CVM_GL-42_085.2

If the value of the month for “Date AER Received by MAH (Original Receive Date)” is not a valid calendar year month (01-12), then reject ICSR.

Error: Reject ICSR

Comment: The “Date AER Received by MAH (Original Receive Date)” must be a valid date; otherwise reject ICSR.

CVM_GL-42_085.3

If the value of the day for “Date AER Received by MAH (Original Receive Date)” is not a valid day for the specified month, then reject ICSR.

Error: Reject ICSR

Comment: The “Date AER Received by MAH (Original Receive Date)” must be a valid date; otherwise reject ICSR.

CVM_GL-42_085.4

If the code system for the observation describing “Date AER Received by MAH (Original Receive Date)” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Date AER Received by MAH (Original Receive Date)” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR.

CVM_GL-42_085.5

If the code and displayName for the observation describing “Date AER Received by MAH (Original Receive Date)” does not equal (code = "T95002" / displayName = “SourceReport”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Date AER Received by MAH (Original Receive Date)” must equal (code = "T95002" / displayName = “SourceReport”); otherwise reject ICSR.

Step-by-Step Guide Section: 2.4.2

Field Description:

Max length is 19 characters; Date

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.4.1 Unique AER Identification Number] 1..1[A.4.2 Date AER Received by MAH (Original Receive Date)]

Data element is mandatory – Use of Null value not allowed

GL-42 Section A.4.3 Date of Current Submission

Requirement ID: 13

Definition:

The data element “Date of Current Submission” is a field that contains the date that the current submission was sent to the Regulatory Authority

Business Rules:

CVM_GL-42_086

If the value of the “Date of Current Submission” is blank or contains a null value then reject ICSR

Error: Reject ICSR

Comment: The “Date of Current Submission” must contain a valid date - it can not be blank or contain a null value; otherwise reject the ICSR.

CVM_GL-42_087

If the date format for the “Date of Current Submission” is not a complete valid date (in the format of YYYYMMDD HHMMSS.UUUU, where HHMMSS.UUUU are optional), then reject ICSR.

Error: Reject ICSR

Comment: The “Date of Current Submission” must be a valid date; otherwise reject ICSR.

****NOTE:** HHMMSS.UUUU represents hours, minutes, seconds and fraction of seconds**

CVM_GL-42_087.1

If the value of the “Date of Current Submission” is not less than the FDA/CVM System Date then reject ICSR.

Error: Reject ICSR

Comment: The “Date of Current Submission” must be less than the FDA/CVM System Date; otherwise reject ICSR.

CVM_GL-42_087.2

If the value of the month for “Date of Current Submission” is not a valid calendar year month (01-12), then reject ICSR.

Error: Reject ICSR

Comment: The “Date of Current Submission” must be a valid date; otherwise reject ICSR.

CVM_GL-42_087.3

If the value of the day for “Date of Current Submission” is not a valid day for the specified month, then reject ICSR.

Error: Reject ICSR

Comment: The “Date of Current Submission” must be a valid date; otherwise reject ICSR.

CVM_GL-42_087.4

If the “Date of Current Submission” is not greater than or equal to the “Date AER Received by MAH (Original Receive Date)”, then reject ICSR.

Error: Reject ICSR

Comment: The “Date of Current Submission” must be greater than or equal to the “Date AER Received by MAH (Original Receive Date)”; otherwise reject the ICSR.

Step-by-Step Guide Section: 2.4.3

Field Description:

Max length is 19 characters; Date

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.4.1 Unique AER Identification Number] 1..1 [A.4.3 Date of Current Submission]

Data element is mandatory – Use of Null value not allowed

GL-42 SECTION A.4.4 TYPE OF REPORT

GL-42 Section A.4.4.1 Type of Submission

Requirement ID: N79

Definition:

The data element “Type of Submission” is a field that contains the type of adverse event report submitted.

Business Rule:

CVM_GL-42_034

If the value of “Type of Submission” equals “NULLIFICATION” and the “Reason for Nullification Report” is blank or contains a null value, then reject ICSR.

Error: Reject ICSR

Comment: If “Type of Submission” equals “NULLIFICATION”, then “Reason for Nullification” must not be blank or contain a null value; otherwise reject ICSR.

CVM_GL-42_35

If the value of “Type of Submission” does not equal “NULLIFICATION” and the “Reason for Nullification Report” is not null (“NI”), then reject ICSR.

Error: Reject ICSR

Comment: If “Type of Submission” does not equal “NULLIFICATION”, then “Reason for Nullification Report” should be null (“NI”); otherwise reject ICSR.

CVM_GL-42_083

If the value of “Type of Submission” equals “FOLLOW-UP” and the value for “Unique Adverse Event Report Identification Number” does not equal a value for a case for that application number in FDA CVM’s database, then reject the ICSR.

Error: Reject ICSR

Comment: If “Type of Submission” equals “FOLLOW-UP”, then the “Unique Adverse Event Report Identification Number” found in the report should match a “Unique Adverse Event Report Identification Number” in FDA/CVM’s database for the specified application number provided in the HL7 wrapper; otherwise reject ICSR.

CVM_GL-42_088

If the value of “Type of Submission” does not equal “FOLLOW-UP” and the value for “Original Received Date” is not less than or equal to the “Date of Current Submission”, then reject ICSR.

Error: Reject ICSR

Comment: If the “Type of Submission” does not equal “FOLLOW-UP”, then the “Original Received Date” must be less than or equal to “Date of Current Submission”; otherwise reject ICSR.

CVM_GL-42_089

If the value of “Type of Submission” equals “FOLLOW-UP” and the value of the “Original Received Date” is not less than the “Date of Current Submission” then reject ICSR.

Error: Reject ICSR

Comment: If the “Type of Submission” equals “FOLLOW-UP”, then the “Original Receive Date” must be less than the “Date of Current Submission”; otherwise reject ICSR.

CVM_GL-42_090

If the value of the data element “Type of Submission” is blank or contains a null value, then reject ICSR.

Error: Reject ICSR

Comment: The “Type of Submission” must not be blank or contain a null value; otherwise reject ICSR.

CVM_GL-42_091

If the data element “Type of Submission” does not reference the correct list of values (OID = National Cancer Institute Thesaurus) (APPENDIX A.3 – LIST OF TYPE OF SUBMISSION) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must use the correct vocabulary for the “Type of Submission”; otherwise reject the ICSR.

CVM_GL-42_091.1

If the value of the “Type of Submission” field is not found in the referenced list of values (APPENDIX A.3 – LIST OF TYPE OF SUBMISSION) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must use the correct values for the “Type of Submission”; otherwise reject the ICSR.

CVM_GL-42_091.2

If the “Type of Submission” field displayName does not match the code value for the “Type of Submission” code, then reject ICSR.

Error: Reject ICSR

Comment: The value for the “Type of Submission” displayName must match the appropriate value for “Type of Submission” code; otherwise the ICSR will be rejected.

CVM_GL-42_091.3

If the code system for the observation describing “Type of Submission” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Type of Submission” must equal (OID = National Cancer Institute Thesaurus); otherwise reject ICSR.

CVM_GL-42_091.4

If the code and displayName for the observation describing “Type of Submission” do not equal (code = “T95003” / displayName = “Type of Submission”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Type of Submission” must equal (code = “T95003” / displayName = “Type of Submission”); otherwise reject ICSR.

CVM_GL-42_092

For the “Report Identifier” in the Transmission Wrapper, if the value of “Type of Submission” does not equal “FOLLOW-UP” and the value for “Unique Adverse Event Report Identification Number” equals a “Unique Adverse Event Report Identification Number” for an AER application number in the database, then reject the ICSR.

Error: Reject ICSR

Comment: If the “Type of Submission” does not equal “FOLLOW-UP”, then the “Unique Adverse Event Report Identification Number” must not equal an existing “Unique Adverse Event Report Identification Number” for the specified AER application number; otherwise reject ICSR.

CVM_GL-42_093

If a match is found for a “FOLLOW-UP” (a “Unique Adverse Event Report Identification Number” and application number in a new ICSR match a “Unique Adverse Event Report Identification Number” and application number in the database) and the value for the “Original Receive Date” for the “FOLLOW-UP” report does not equal the “Original Received Date” of the original/initial AER then reject ICSR.

Error: Reject ICSR

Comment: If a match is found for the “FOLLOW-UP” report, then validate that the “Original Receive Date” for the “FOLLOW-UP” report equals the original review date of the original ICSR; otherwise reject the ICSR.

CVM_GL-42_094

If the value of “Type of Submission” equals “EXPEDITED” and value of “Type of Information in Report” (if provided) does not equal either “SAFETY ISSUE (CLINICAL STUDIES)”, “LACK OF EXPECTED EFFECTIVENESS (CLINICAL STUDIES)”, “BOTH SAFETY AND LOEE (CLINICAL STUDIES)”, “LACK OF EXPECTED EFFECTIVENESS (CLINICAL STUDIES)”, “BOTH SAFETY AND LACK OF EXPECTED EFFECTIVENESS” “SAFETY ISSUE” or “OTHER”, then reject ICSR.

Error: Reject ICSR

Comment: If the “Type of Submission” is “EXPEDITED”, then if valued “Type of Information in Report” should be either “SAFETY ISSUE (CLINICAL STUDIES)”, “LACK OF EXPECTED EFFECTIVENESS (CLINICAL STUDIES)”, “BOTH SAFETY AND LOEE (CLINICAL STUDIES)”, “LACK OF EXPECTED EFFECTIVENESS (CLINICAL STUDIES)”, “BOTH SAFETY AND LACK OF EXPECTED EFFECTIVENESS” “SAFETY ISSUE” or “OTHER”.

CVM_GL-42_095

If the value of “Type of Submission” equals “PERIODIC” and the value of “Type of Information in Report” (if provided) does not equal either “SAFETY ISSUE (CLINICAL STUDIES)”, “LACK OF EXPECTED EFFECTIVENESS (CLINICAL STUDIES)”, “BOTH SAFETY AND LACK OF EXPECTED EFFECTIVENESS”, “SAFETY ISSUE”, “LACK OF EXPECTED EFFECTIVENESS”, “BOTH SAFETY AND LOEE (CLINICAL STUDIES)”, “MANUFACTURING/PRODUCT DEFECT MANUFACTURING DEFECT WITH NO ADVERSE EVENTS”, “MANUFACTURING/PRODUCT DEFECT MANUFACTURING DEFECT (SAFETY)”, “MANUFACTURING/PRODUCT DEFECT MANUFACTURING DEFECT (LOEE)”, “MANUFACTURING/PRODUCT DEFECT MANUFACTURING DEFECT (BOTH SAFETY AND LOEE)”, or “OTHER” then reject ICSR.

Error: Reject ICSR

Comment: If “Type of Submission” is “PERIODIC”, then if valued “Type of Information in Report” must equal one of the above mentioned types; otherwise reject ICSR.

CVM_GL-42_096

If the value of “Type of Submission” equals “NULLIFICATION” and the value of “Type of Information in Report” (if provided) does not equal either “SAFETY ISSUE (CLINICAL STUDIES)”, “LACK OF EXPECTED EFFECTIVENESS (CLINICAL STUDIES)”, “BOTH SAFETY AND LACK OF EXPECTED EFFECTIVENESS”, “SAFETY ISSUE”, “LACK OF EXPECTED EFFECTIVENESS”, “BOTH SAFETY AND LOEE (CLINICAL STUDIES)”, “MANUFACTURING/PRODUCT DEFECT MANUFACTURING DEFECT WITH NO ADVERSE EVENTS”, “MANUFACTURING/PRODUCT DEFECT MANUFACTURING DEFECT (SAFETY)”, “MANUFACTURING/PRODUCT DEFECT MANUFACTURING DEFECT (LOEE)”, “MANUFACTURING/PRODUCT DEFECT MANUFACTURING DEFECT (BOTH SAFETY AND LOEE)”, or “OTHER”, then reject ICSR.

Error: Reject ICSR

Comment: If “Type of Submission” equals "NULLIFICATION", then if valued “Type of Information in Report” must equal one of the above mentioned types; otherwise reject ICSR.

CVM_GL-42_097

If the value of “Type of Submission” equals "3-DAY FIELD ALERT" and the value of “Type of Information in Report” (if provided) does not equal either “MANUFACTURING/PRODUCT DEFECT MANUFACTURING DEFECT WITH NO ADVERSE EVENTS”, "MANUFACTURING/PRODUCT DEFECT MANUFACTURING DEFECT (SAFETY)", “MANUFACTURING/PRODUCT DEFECT MANUFACTURING DEFECT (LOEE)” or “MANUFACTURING/PRODUCT DEFECT MANUFACTURING DEFECT (BOTH SAFETY AND LOEE)”, then reject ICSR.

Error: Reject ICSR

Comment: If “Type of Submission” equals 3-Day Field Alert, then if valued “Type of Information in Report” must equal one of the above mentioned types; otherwise reject ICSR.

CVM_GL-42_098

If the value of “Type of Submission” equals "OTHER" and the value of “Type of Information in Report”(if provided) does not equal either "SAFETY ISSUE (CLINICAL STUDIES)", "LACK OF EXPECTED EFFECTIVENESS (CLINICAL STUDIES)", "BOTH SAFETY AND LACK OF EXPECTED EFFECTIVENESS", “SAFETY ISSUE”, “LACK OF EXPECTED EFFECTIVENESS”, “BOTH SAFETY AND LOEE (CLINICAL STUDIES)”. “MANUFACTURING/PRODUCT DEFECT MANUFACTURING DEFECT WITH NO ADVERSE EVENTS”, "MANUFACTURING/PRODUCT DEFECT MANUFACTURING DEFECT (SAFETY)", “MANUFACTURING/PRODUCT DEFECT MANUFACTURING DEFECT (LOEE)”, “MANUFACTURING/PRODUCT DEFECT MANUFACTURING DEFECT (BOTH SAFETY AND LOEE)”, or “OTHER”, then the ICSR will be rejected.

Error: Reject ICSR

Comment: If the “Type of Submission” equals “OTHER”, then if valued “Type of Information in Report” must equal one of the above mentioned types; otherwise reject ICSR.

Step-by-Step Guide Section: 2.4.4

Field Description:

Max length is 15 characters for the code and 80 characters for the code description; single choice code list

Report Type: AE Only, PP Only, AE + PP

OID:

codeSystem = National Cancer Institute Thesaurus

code = single value from code list. [APPENDIX A.3 – LIST OF TYPE OF SUBMISSION](#)

Cardinality:

[A.4.1 Unique AER Identification Number] 1..1 [A.4.4.1 Type of Submission]

Data element is mandatory – Reporters must select the best value from the vocabulary; Use of Null value is not allowed

GL-42 Section A.4.4.2 Reason for Nullification Report**Requirement ID:** 9.3**Definition:**

The data element “Reason for Nullification” report is a field that contains the reason given for nullifying an ICSR.

Business Rule:**CVM_GL-42_XXX**

If Type of Submission equals “NULLIFICATION”, and “Reason for Nullification” is blank or contain a null value, then reject ICSR.

Error: Reject ICSR

Comment: If Type of Submission equals “NULLIFICATION” then “Reason for Nullification” must contain a valid value; otherwise reject ICSR.

CVM_GL-42_XXX

If “Type of Submission” does not equal “NULLIFICATION” and the “Reason for Nullification” is not null, then reject ICSR.

Error: Reject ICSR

Comment: If “Type of Submission” does not equal “NULLIFICATION” then “Reason for Nullification” should contain a valid null value; otherwise reject ICSR.

CVM_GL-42_XXX

If the code system for the observation describing the “Reason for Nullification” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Reason for Nullification” must equal (OID = National Cancer Institute Thesaurus); otherwise reject ICSR.

CVM_GL-42_XXX

If the code and displayName for the observation describing “Reason for Nullification” do not equal (code = “T95003” / displayName = “Type of Submission”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Reason for Nullification” must equal (code = “T95003” / displayName = “Type of Submission”); otherwise reject ICSR.

Step-by-Step Guide Section: 2.4.4**Field Description:**

Max length 200, open ended text

Report Type: AE Only, PP Only, AE + PP**Cardinality:**

[A.4.4.1 Type of Submission] 0..0 [A 4.4.2 Reason for Nullification Report]

Data element is optional; must enter “NI” to represent null/no response

If “NULLIFICATION” is selected for “Type of Submission” then:

[A.4.4.1 Type of Submission] 1..1 [A 4.4.2 Reason for Nullification Report]

Data element is mandatory – Use of Null value not allowed

GL-42 Section A.4.4.3 Type of Information in Report**Requirement ID:** 9.4**Definition:**

The data element “Type of Information in Report” is a field that contains the type of information that is contained in the ICSR. “Type of Information in Report” shall be set using a NCI code system with system OID set to “National Cancer Institute Thesaurus”, and code value set to one of the codes listed in [APPENDIX A.4 – LIST OF TYPE OF INFORMATION IN REPORT](#).

Business Rules:

CVM_GL-42_099

If the data element “Type of Information in Report” does not reference the correct list of values ([APPENDIX A.4 – LIST OF TYPE OF INFORMATION IN REPORT](#)), (OID = National Cancer Institute Thesaurus) then reject ICSR.

Error: Reject ICSR

Comment: The “Type of Information in Report” must reference the correct vocabulary ([APPENDIX A.4 – LIST OF TYPE OF INFORMATION IN REPORT](#)); otherwise reject ICSR.

CVM_GL-42_099.1

If the value of the data element “Type of Information in Report” is not found in the referenced list of values ([APPENDIX A.4 – LIST OF TYPE OF INFORMATION IN REPORT](#)), then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Type of Information in Report”; otherwise reject ICSR.

CVM_GL-42_099.2

If the “Type of Information in Report” field displayName does not match the code value for the “Type of Information in Report” Code, then reject ICSR.

Error: Reject ICSR

Comment: The value for the “Type of Information in Report” displayName must match the appropriate value for “Type of Information in Report” code; otherwise the ICSR will be rejected.

CVM_GL-42_099.3

If the “Type of Information in Report” field is blank, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value or acceptable null flavor for the data element Type of Information, otherwise reject ICSR.

CVM_GL-42_099.4

If the code system for the observation describing “Type of Information in Report” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Type of Information in Report” must equal (OID = National Cancer Institute Thesaurus); otherwise reject ICSR.

CVM_GL-42_099.5

If the code and displayName for the observation describing “Type of Information in Report” do not equal (code = **T95004** / displayName = “Type of Information in Report”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Type of Information in Report” must equal (code = T95004 / displayName = “Type of Information in Report”); otherwise reject ICSR.

Step-by-Step Guide Section: 2.4.4

Field Description:

Max length is 15 characters for the code and 80 characters for the code description; single choice code list

Report Type: AE Only, PP Only, AE + PP

OID:

codeSystem = National Cancer Institute Thesaurus

code = single value from code list. Refer to [APPENDIX A.4 – LIST OF TYPE OF INFORMATION IN REPORT](#)

Cardinality:

[A.4.4.1 Type of Submission] 0..1 [A 4.4.3 Type of Information in Report]

Data element is optional; select the best value from the vocabulary; enter “NI” to represent null/no response

2.2 GL-42 Section B – Animal Data Information

GL-42 SECTION B.1 ANIMAL DATA

GL-42 Section B.1.1 Number of Animals Treated

Requirement ID: 2024

Definition:

The data element “Number of Animals Treated” is a field that contains the number of animals treated with the VMP.

Business Rules:

CVM_GL-42_100

If the value of “Number of Animals Treated” is not null and the value of number of animals is not a positive integer number greater than zero, then reject ICSR.

Error: Reject ICSR

Comment: The value for “Number of Animals Treated” must be a positive integer greater than 0; otherwise reject ICSR.

CVM_GL-42_100.1

If the value of the “Number of Animals Treated” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The value for “Number of Animals Treated” must be a valid value or an acceptable null flavor otherwise reject ICSR.

Step-by-Step Guide Section: 3.1.1

Field Description:

Max length is 12 characters; integer

Report Type: AE Only, AE + PP

Cardinality:

[B.1 Animal Data] 0..1 [B.1.1 Number of Animals Treated]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.1.2 Number of Animals Affected**Requirement ID:** 2025**Definition:**

The data element “Number of Animals Affected” is a field that contains the number of animals affected by the VMP.

Business Rule:

CVM_GL-42_101

If the value of the data element “Number of Animals Affected” is null or blank, then reject ICSR.

Error: Reject ICSR*Comment:* “Number of Animals Affected” must contain a valid value (null flavors not accepted); otherwise reject ICSR.

CVM_GL-42_102

If the value of “Number of Animals Affected” is not a positive integer number then reject ICSR.

Error: Reject ICSR*Comment:* The “Number of Animals Affected” must be a positive integer (greater than 0); otherwise reject ICSR.

CVM_GL-42_143

If the sum of the values for the following data elements “Ongoing”, “Recovered/Normal”, “Recovered with Sequela”, “Died”, “Euthanized”, and “Unknown” do not equal the number entered in “Number of Animals Affected” then reject ICSR.

Error: Reject ICSR*Comment:* The value entered in “Number of Animals Affected” should equal the sum of the following fields B.3.8.1 “Ongoing”, B.3.8.2 “Recovered/Normal”, B.3.8.3 “Recovered with Sequela”, B.3.8.4 “Died”, B.3.8.5 “Euthanized”, B.3.8.6 “Unknown”; otherwise reject ICSR.

CVM_GL-42_XXX

If the code system for the observation describing “Number of Animals Affected” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR*Comment:* The code system for the observation describing “Number of Animals Affected” must equal (OID = National Cancer Institute Thesaurus); otherwise reject ICSR.

CVM_GL-42_XXX

If the code and displayName for the observation describing “Number of Animals Affected” do not equal (code = T95005 / displayName = “Number of Animals Affected”), then reject ICSR.

Error: Reject ICSR*Comment:* The code and displayName for the observation describing “Number of Animals Affected” must equal (code = T95005 / displayName = “Number of Animals Affected”); otherwise reject ICSR.**Step-by-Step Guide Section:** 3.1.2**Field Description:**

Max length is 12 characters; integer

Report Type: AE Only, AE + PP

Cardinality:

[B.1 Animal Data] 1..1 [B.1.2 Number of Animals Affected]

Data element is mandatory – Use of Null value not allowed

GL-42 Section B.1.2.1 Attending Veterinarian's Assessment of the Health Status Prior to VMP Use**Requirement ID:** 2009**Definition:**

The data element "Attending Veterinarian's Assessment of the Health Status Prior to VMP Use" is a field that contains the attending veterinarian's assessment of the health status of the animal(s) involved in the AE prior to their exposure to the VMP. The MAH should choose from the [Appendix A.6-List of Attending Veterinarian's Assessment of Health Status Prior to VMP Use](#). The definitions of these values will be left to the veterinarian's medical opinion. The MAH should select the value of "UNK - Unknown" if the attending veterinarian does not provide this information.

Business Rule:

CVM_GL-42_103

If the data element "Attending Veterinarian's Assessment of the Health Status Prior to VMP Use" does not reference the correct list of values (OID = 2.16.840.1.113883.3.26.1) then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must use the correct vocabulary ([Appendix A.6-List of Attending Veterinarian's Assessment of Health Status Prior to VMP Use](#)) for the "Attending Veterinarian's Assessment of the Health Status Prior to VMP Use"; otherwise reject ICSR.

CVM_GL-42_103.1

If the value of the field "Attending Veterinarian's Assessment of the Health Status Prior to VMP Use" is not found in the referenced list of values ([Appendix A.6-List of Attending Veterinarian's Assessment of Health Status Prior to VMP Use](#)) then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain a valid value for the "Attending Veterinarian's Assessment of the Health Status Prior to VMP Use"; otherwise reject ICSR.

CVM_GL-42_103.2

If the "Attending Veterinarian's Assessment of the Health Status Prior to VMP Use" field displayName does not match the code value from [Appendix A.6-List of Attending Veterinarian's Assessment of Health Status Prior to VMP Use](#) then reject ICSR.

Error: Reject ICSR*Comment:* The value for the "Attending Veterinarian's Assessment of the Health Status Prior to VMP Use" displayName must match the appropriate value from [Appendix A.6-List of Attending Veterinarian's Assessment of Health Status Prior to VMP Use](#); otherwise the ICSR will be rejected.

CVM_GL-42_103.3

If the value of the data element "Attending Veterinarian's Assessment of the Health Status Prior to VMP Use" is blank, then reject ICSR.

Error: Reject ICSR*Comment:* The data element "Attending Veterinarian's Assessment of the Health Status Prior to VMP Use" must contain a valid value or acceptable null flavor; otherwise reject ICSR.

CVM_GL-42_103.4

If the code system for the observation describing "Attending Veterinarian's Assessment of the Health Status Prior to VMP Use" does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing "Attending Veterinarian's Assessment of the Health Status Prior to VMP Use" must equal (OID = National Cancer Institute Thesaurus); otherwise reject ICSR.

CVM_GL-42_103.5

If the code and displayName for the observation describing "Attending Veterinarian's Assessment of Health Status Prior to VMP Use" do not equal (code = T95006 / displayName = "Assessment of Health Status Prior to the Exposure to Product"), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing "Attending Veterinarian's Assessment of the Health Status Prior to VMP Use" must equal (code = T95006 / displayName = "Assessment of Health Status Prior to the Exposure to Product"); otherwise reject ICSR.

CVM_GL-42_147.3

If the code and displayName for the assignedEntity describing "Attending Veterinarian's Assessment" do not equal (code = "C82470" / displayName = "Veterinarian"), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the assignedEntity describing the "Attending Veterinarian's Assessment" must equal (code = "C82470" / displayName = "Veterinarian"); otherwise reject ICSR

Step-by-Step Guide Section: 3.1.2.1

Field Description:

Max length is 15 characters for the code description and 80 characters for the code description; single choice code list

Report Type: AE Only, AE + PP

OID:

codeSystem = 2.16.840.1.113883.3.26.1

code = single value in code list. Refer to [Appendix A.6-List of Attending Veterinarian's Assessment of Health Status Prior to VMP Use](#)

Cardinality:

[B.1 Animal Data] 0..1 [B.1.2.1 Attending Veterinarian's Assessment of the Health Status Prior to VMP Use]

Data element is optional; select the best value from the vocabulary; enter "NI" to represent null/no response

GL-42 Section B.1.3 Species (Type of Species)**Requirement ID:** 2010**Definition:**

The data element “Species” is a coded field that contains the species of the animal(s) involved in the AER.

Business Rule:

CVM_GL-42_104

If the data element “Species” is blank then reject ICSR.

Error: Reject ICSR*Comment:* The data element “Species” must contain a valid value or an acceptable null flavor; otherwise reject ICSR.

CVM_GL-42_105

If the data element “Species” does not reference the correct list of values (OID = VICH – Species OID 2.16.840.1.113883.4.341) then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must use the correct vocabulary for “Species” ([Appendix A.7–List of Species](#)); otherwise reject ICSR.

CVM_GL-42_105.1

If the value of the “Species” field is not found in the referenced list of values ([Appendix A.7–List of Species](#)) then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain a valid value for “Species”; otherwise reject ICSR.

CVM_GL-42_105.2

If the “Species” field displayName does not match the code value for the “Species” code, then reject ICSR.

Error: Reject ICSR*Comment:* The value for the “Species” displayName must match the appropriate value for Species code; otherwise the ICSR will be rejected.**Step-by-Step Guide Section:** 3.1.3**Field Description:**

Max length is 15 characters for the code description and 80 characters for the code description; single choice code list

Report Type: AE Only, AE + PP**OID:**

codeSystem = VICH – Species OID 2.16.840.1.113883.4.341

code = single value in code list. Refer to [Appendix A.7–List of Species](#)**Cardinality:**

[B.1 Animal Data] 1..1 [B.1.3 Species]

Data element is optional; select the best value from the vocabulary; enter “NI” to represent null/no response

GL-42 Section B.1.4 Breed (Breed Group)**Requirement ID:** N32**Definition:**

The data elements within “Breed Group” are associated with the species chosen in element B.1.3. “Breed Group” elements consist of a number of data fields from two to one hundred entries. Data element one (“Are Animals Crossbred”) is a Boolean value and is always present. See *Vocabulary A.31 – Boolean Information* for allowed values.) Data element two (“Breed Components”) is always present and it indicates the animal breed taken from *Appendix A.8–List of Breeds*. Data element three to one hundred (“Breed Components”) should only be present when more than one animal is being reported on. This data element captures multiple animals for a single observation. It also satisfies the VICH requirements that all the breed components from animals existing in the herd should be listed in same observation.

Business Rule:

CVM_GL-42_XXX

If the value of the data element “Are Animals Crossbred” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The data element “Are Animals Crossbred” must contain a valid Boolean; otherwise reject ICSR.

CVM_GL-42_XXX

If the value for the data element “Are Animals Crossbred” is not null, and the value of element two “Breed Components” data element is null or blank, then reject ICSR

Error: Reject ICSR

Comment: If the ICSR contains a valid value for “Are Animals Crossbred”, then a valid value for “Breed Component” must be supplied; otherwise reject ICSR.

~~CVM_GL-42_XXX~~~~If the value for “Are Animals Crossbred” equals ‘false’ and more than one type of “Breed Component” is supplied, then reject ICSR.~~~~*Error:* Reject ICSR~~~~*Comment:* If the “Are Animals Crossbred” indicator equals ‘true’, and there are less than ninety nine types of “Breed Components” are allowed; otherwise reject ICSR.~~

CVM_GL-42_XXX

If the code system for the observation describing “Are Animals Crossbred” Indicator does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Are Animals Crossbred” Indicator must equal (OID = National Cancer Institute Thesaurus); otherwise reject ICSR.

CVM_GL-42_XXX

If the code and displayName for the observation describing the “Are Animals Crossbred” Indicator does not equal (code = “T95007” / displayName = “Are Animals Crossbred”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing the “Are Animals Crossbred” Indicator must equal (code = “T95007” / displayName = “Are Animals Crossbred”); otherwise reject ICSR.

CVM_GL-42_XXX

If the value of the data element “Breed Components” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The data element “Breed Component” must contain a valid value or an acceptable null flavor; otherwise reject ICSR.

CVM_GL-42_106

If the data element “Breed Components” does not reference the correct list of values ([Appendix A.8–List of Breeds](#) – OID = 2.16.840.1.113883.4.342) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must reference the vocabulary for “Breed Components”; otherwise reject ICSR.

CVM_GL-42_106.1

If the value of the “Breed Components” field is not found in the referenced list of values ([Appendix A.8–List of Breeds](#)) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Breed Components”; otherwise reject ICSR.

CVM_GL-42_106.2

If the “Breed Components” field displayName does not match the value of “Breed Components”, then reject ICSR.

Error: Reject ICSR

Comment: The value for the “Breed Components” displayName must match the appropriate value for Breed code; otherwise the ICSR will be rejected.

CVM_GL-42_XXX

If the code system for the observation describing “Breed Components” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Breed Components” must equal (OID = National Cancer Institute Thesaurus); otherwise reject ICSR.

CVM_GL-42_XXX

If the code for the observation describing “Breed Components” does not equal (code = “T95008”), then reject ICSR.

Error: Reject ICSR

Comment: The code for the observation describing “Breed Components” must equal (code = “T95008”); otherwise reject ICSR.

Step-by-Step Guide Section: 3.1.4

Field Description: “Are Animals Crossbred”

Max length 5; Boolean (true/false) value

Type of Report:

AE Only, AE + PP

Cardinality:

[B.1. Animal Data] 0..1 [B.1.4 Are Animals Crossbred]

Boolean Data Element is mandatory; Use of null value is governed by the Boolean Information Table for this specific element

Field Description: “Breed Components”

Max length is 15 characters for the code and 80 characters for the code description; multiple choice code list depending on (“Are Animals Crossbred”) Boolean value.

Type of Report:

AE Only, AE + PP

OID:

codeSystem = 2.16.840.1.113883.4.342

code = single code value from list. Refer to [Appendix A.8–List of Breeds](#)

Cardinality:

[B.1.4 Breed Components] 0..1 [B.1.4 “Are Animals Crossbred” Indicator is ‘false’ (Purebred)]

Data element is mandatory – Reporters must select the best value from the vocabulary; Use of Null value is not allowed

[B.1.4 Breed Components] 0..99 [B.1.4 Breed are “Are Animals Crossbred” Indicator is true (Crossbred)]

Data element is optional; select the best value from the vocabulary; ~~or enter “NI” to represent null/no response~~

GL-42 Section B.1.5 Gender**Requirement ID:** 4.1**Definition:**

The data element “Gender” is a coded field that contains the gender of the animal(s) involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of the data element “Gender” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The data element “Gender” must contain a valid value or an acceptable null flavor; otherwise reject ICSR.

CVM_GL-42_107

If the data element “Gender” does not reference the correct list of values (Gender Status – OID = National Cancer Institute Thesaurus) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must reference the correct vocabulary for “Gender” ([Appendix A.9–List of Gender Categories](#)); otherwise reject ICSR.

CVM_GL-42_107.1

If the value of the “Gender” field is not found in the referenced lists of values ([Appendix A.9–List of Gender Categories](#)) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Gender”; otherwise reject ICSR.

CVM_GL-42_107.2

If the “Gender” field displayName does not match the code value for the Gender Code, then reject ICSR.

Error: Reject ICSR

Comment: The value for the “Gender” displayName must match the appropriate value for Gender code; otherwise the ICSR will be rejected.

Step-by-Step Guide Section: 3.1.5**Field Description:**

Max length is 15 characters for the code description and 80 characters for the code description; single choice code list

Report Type: AE Only, AE + PP

OID:

codeSystem = National Cancer Institute Thesaurus

code = single code value from list. Refer to [Appendix A.9–List of Gender Categories](#)

Cardinality:

[B.1Animal Data] 0.1 [B.1.5 Gender]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.1.6 Reproductive Status

Requirement ID: 2012

Definition:

The data element “Reproductive Status” is a coded field that contains information on the reproductive status of the animal(s) involved in the AER.

Business Rule

CVM_GL-42_XXX

If the value of the data element “Reproductive Status” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The data element “Reproductive Status” must contain a valid value or an acceptable null flavor; otherwise reject ICSR.

CVM_GL-42_108

If the data element “Reproductive Status” does not reference the correct list of values (Reproductive Status – OID = National Cancer Institute Thesaurus) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must reference the correct vocabulary for “Reproductive Status”; otherwise reject ICSR.

CVM_GL-42_108.1

If the value of the “Reproductive Status” field is not found in the referenced list of values ([Appendix A.10–List of Reproductive Status Categories](#)) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Reproductive Status”; otherwise reject ICSR

CVM_GL-42_108.2

If the “Reproductive Status” field displayName does not match the code value for the Reproductive Code, then reject ICSR.

Error: Reject ICSR

Comment: The value for the “Reproductive Status” displayName must match the appropriate value for Reproductive Status code; otherwise the ICSR will be rejected.

CVM_GL-42_108.3

If the “Number of Animals Affected” equals 1, and the value of “Reproductive Status” equals ‘Mixed’, then reject ICSR.

Error: Reject ICSR

Comment: If the “Number of Animals Affected” equals 1, then the value of “Reproductive Status” can not equal ‘Mixed’; otherwise reject ICSR.

Step-by-Step Guide Section: 3.1.5

Field Description:

Max length is 15 characters for the code description and 80 characters for the code description; single choice code list

Report Type: AE Only, AE + PP

OID:

codeSystem = National Cancer Institute Thesaurus

code = single code value from list. Refer to [Appendix A.10–List of Reproductive Status Categories](#)

Cardinality:

[B.1Animal Data] 0.1 [B.1.6 Reproductive Status]

Data element is optional; select the best value from the vocabulary; enter “NI” to represent null/no response

GL-42 Section B.1.7 Female Physiological Status

Requirement ID: 2013

Definition:

The data element “Female Physiological Status” is a coded field that contains the female physiological status of the animal(s) involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of the data element “Female Physiological Status” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The data element “Female Physiological Status” must contain a valid value or an acceptable null flavor; otherwise reject ICSR.

CVM_GL-42_109

If the data element “Female Physiological Status” does not reference the correct list of values ([Appendix A.11 –List of Female Physiological Status Categories](#) – OID = 2.16.840.1.113883.13.49) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must reference the correct vocabulary for “Female Physiological Status”; otherwise reject ICSR.

CVM_GL-42_109.1

If the value of “Female Physiological Status” is not found in the referenced list of values ([Appendix A.11 –List of Female Physiological Status Categories](#)) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Female Physiological Status”; otherwise reject ICSR.

CVM_GL-42_109.2

If the “Female Physiological Status” field displayName does not match the code value for the “Female Physiological Status” Code, then reject ICSR.

Error: Reject ICSR

Comment: The value for the “Female Physiological Status” displayName must match the appropriate value for “Female Physiological Status” code; otherwise the ICSR will be rejected.

CVM_GL-42_109.3

If the value of “Gender” equals “Male” then the value for “Female Physiological Status” must equal either ‘NI’ or ‘NA’.

Error: Reject ICSR

Comment: If the value of “Female Physiological Status” is not null, then ‘Gender’ cannot equal ‘Female’ or ‘Mixed’; otherwise reject ICSR.

CVM_GL-42_109.4

If the “Number of Animals Affected” equals ‘1’, and “Female Physiological Status” equals ‘Mixed’, then reject ICSR.

Error: Reject ICSR

Comment: If the “Number of Animals Affected” equals ‘1’, then the “Female Physiological Status” cannot equal ‘Mixed’; otherwise reject ICSR.

CVM_GL-42_109.5

If the Gender equals ‘Male’, and the value of “Female Physiological Status” does not equal the null flavor for ‘Not Applicable’ or ‘No Information (NI)’, then reject ICSR.

Error: Reject ICSR

Comment: If the Gender equals ‘Male’, the value of “Female Physiological Status” must equal the null flavor for “Not Applicable” or “No Information”; otherwise reject ICSR.

CVM_GL-42_109.6

If the code system for the observation describing “Female Physiological Status” does not equal (OID = 2.16.840.1.113883.13.49), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Female Physiological Status” must equal (OID = 2.16.840.1.113883.13.49); otherwise reject ICSR.

CVM_GL-42_109.7

If the code and displayName for the observation describing “Female Physiological Status” do not equal (code = **T95010**/ displayName = “Female Physiological Status”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Female Physiological Status” must equal (code = **T95010**/ displayName = “Female Physiological Status”); otherwise reject ICSR.

Step-by-Step Guide Section: 3.1.5

Field Description:

Max length is 15 characters for the code description and 80 characters for the code description; single choice code list

Report Type: AE Only, AE + PP

OID:

codeSystem = 2.16.840.1.113883.13.49

code = single code value from list. Refer to [Appendix A.11 –List of Female Physiological Status Categories](#)

Cardinality:

[B.1Animal Data] 0.1 [B.1.7 Female Physiological Status]

Data element is optional; select the best value from the vocabulary; enter “NI” to represent null/no response

GL-42 SECTION B.1.8 ANIMAL WEIGHT

GL-42 Section B.1.8.1 Measured, Estimated, Unknown Weights

Requirement ID: 5.2

Definition:

The data element “Measured, Estimated, Unknown Weight” is a coded field ([A.12-List of Precision Categories for Weight and Age Data](#)) that identifies if the weight of the animal(s) involved in the AER is measured, estimated or unknown.

Business Rule:

CVM_GL-42_028

If the value of the field “Measured, Estimated, Unknown Weight” is blank, then reject ICSR.

Error: Reject ICSR

Comment: “Measured, Estimated, Unknown Weight” must contain a valid value or acceptable null flavor; otherwise reject ICSR.

CVM_GL-42_029

If the data element “Measured, Estimated, Unknown Weight” does not reference the correct list of values ([A.12-List of Precision Categories for Weight and Age Data](#)) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must reference the correct vocabulary for “Measured, Estimated, Unknown Weight”; otherwise reject ICSR.

CVM_GL-42_029.1

If the value of “Measured, Estimated, Unknown Weight” is not found in the referenced list of values ([A.12-List of Precision Categories for Weight and Age Data](#)) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Measured, Estimated, Unknown Weight”; otherwise reject ICSR.

CVM_GL-42_029.2

If the “Measured, Estimated, Unknown Weight” field displayName does not match the code value for the “Measured, Estimated, Unknown Weight” Code then reject ICSR.

Error: Reject ICSR

Comment: The value for the “Measured, Estimated, Unknown Weight” displayName must match the appropriate value for “Measured, Estimated, Unknown Weight” code; otherwise the ICSR will be rejected.

CVM_GL-42_030

If the value of “Measured, Estimated, Unknown Weight” equals unknown (‘UNK’) and the data elements “Minimum Weight” and “Maximum Weight” are valued then reject ICSR.

Error: Reject ICSR

Comment: If the value of “Measured, Estimated, Unknown Weight” equals unknown (‘UNK’), then “Minimum Weight” and “Maximum Weight” should be null; otherwise reject ICSR.

CVM_GL-42_031

If the value of “Measured, Estimated, Unknown Weight” equals ‘Measured’ or ‘Estimated’ and the value of “Number of Affected Animals” equals ‘1’ then “Minimum Weight” should not be null or blank and “Maximum Weight” should equal a null value; otherwise reject ICSR.

Error: Reject ICSR

Comment: If “Measured, Estimated, Unknown Weight” equal ‘Measured’ or ‘Estimated’ and “Number of Animals Affected” equals 1, then “Minimum Weight” should be valued and “Maximum Weight” should not be valued; otherwise reject ICSR.

CVM_GL-42_XXX

If the code and displayName for the observation describing “Measured, Estimated, Unknown Weight” does not equal (code = T95011/ displayName = “Weight”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Measured, Estimated, Unknown Weight” must equal (code = T95011/ displayName = “Weight”); otherwise reject ICSR.

Step-by-Step Guide Section: 3.1.6

Field Description:

Max length is 15 characters for the code and 80 characters for the code description; single choice code list

Report Type: AE Only, AE + PP

OID:

codeSystem = National Cancer Institute Thesaurus

code = single code value from list. Refer to [A.12-List of Precision Categories for Weight and Age Data](#)

Cardinality:

[B.1 Animal Data] 0..1 [B.1.8.1 “Measured, Estimated, Unknown Weight’s]

Data element is optional; select the best value from the vocabulary; enter “NI” to represent null/no response

GL-42 Section B.1.8.2 Minimum Weight

Requirement ID: 5.2.1

Definition:

The data element “Minimum Weight” is a field that contains the minimum weight for the animal(s) involved in the AER.

Business Rule:

CVM_GL-42_032

If the value of the “Minimum Weight” field is not a numeric value and greater than zero then reject ICSR.

Error: Reject ICSR

Comments: If “Minimum Weight” is valued, it must be a numeric value and greater than zero; otherwise reject ICSR.

CVM_GL-42_XXX

If the value associated with units for “Minimum Weight” does not equal ‘kg’, then reject ICSR.

Error: Reject ICSR

Comment: The value associated with units for “Minimum Weight” must equal ‘kg’; otherwise reject ICSR.

CVM_GL-42_XXX

If the “Minimum Weight” field is blank, then reject ICSR.

Error: Reject ICSR

Comment: The “Minimum Weight” field must contain a valid value or an acceptable null flavor; otherwise reject ICSR.

CVM_GL-42_XXX

If the value for the data element “Measured, Estimated, Unknown Weight” equals “Estimated” or “Measured” and the value of “Minimum Weight” is null, then reject ICSR.

Error: Reject ICSR

Comment: When the data element “Measured, Estimated, Unknown Weight” equals “Estimated” or “Measured”, then “Minimum Weight” must equal a valid value (must not contain a null flavor); otherwise reject ICSR.

CVM_GL-42_030

If the value of “Measured, Estimated, Unknown Weight” equals “Unknown” and the data elements “Minimum Weight” and “Maximum Weight” are valued then reject ICSR.

Error: Reject ICSR

Comment: If the value of “Measured, Estimated, Unknown Weight” equals “Unknown”, then “Minimum Weight” and “Maximum Weight” should use a null flavor; otherwise reject ICSR.

Step-by-Step Guide Section: 3.1.6

Field Description:

Max length shall be restricted to 12 total characters. Numeric value. Representation nnnnnnnn.nn

Report Type: AE Only, AE + PP

Cardinality:

If “Measured, Estimated, Unknown Weight” equals “Unknown”:

[B.1.8.1 Measured, Estimated, Unknown Weight] 0..0 [B.1.8.2 Minimum Weight]

Data element is optional; must enter “NI” to represent null/no response

If “Measured, Estimated, Unknown Weight” equals “Measured” or “Estimated”:

[B.1.8.1 Measured, Estimated, Unknown Weight] 1..1 [B.1.8.2 Minimum Weight]

Data element is mandatory

GL-42 Section B.1.8.3 Maximum Weight**Requirement ID:** 5.2.2**Definition:**

The data element “Maximum Weight” is a field that contains the maximum weight for the animal(s) involved in the AER.

Business Rule:

CVM_GL-42_033

If the value of the “Maximum Weight” field is not a numeric value then reject ICSR.

Error: Reject ICSR

Comments: If “Maximum Weight” is valued, it must be a numeric value and greater than zero; otherwise reject ICSR.

CVM_GL-42_XXX

If the “Maximum Weight” field is blank, then reject ICSR.

Error: Reject ICSR

Comment: The “Maximum Weight” field must contain a valid value or an acceptable null flavor; otherwise reject ICSR.

CVM_GL-42_XXX

If the value for the data element “Measured, Estimated, Unknown Weight” equals “Estimated” or “Measured” and the “Number of Affected Animals” is greater than 1, and the value of “Maximum Weight” is null, then reject ICSR.

Error: Reject ICSR

Comment: When the data element “Measured, Estimated, Unknown Weight” equals “Estimated” or “Measured” and the “Number of Affected Animals” is greater than ‘1’, then “Maximum Weight” must equal a valid value (must not contain a null flavor); otherwise reject ICSR.

CVM_GL-42_030

If the value of “Measured, Estimated, Unknown Weight” equals “Unknown” and the data elements “Minimum Weight” and “Maximum Weight” are valued then reject ICSR.

Error: Reject ICSR

Comment: If the value of “Measured, Estimated, Unknown Weight” equals “Unknown”, then “Minimum Weight” and “Maximum Weight” should be null; otherwise reject ICSR.

CVM_GL-42_031

If the value of “Measured, Estimated, Unknown Weight” equals “Measured” or “Estimated” and the value of “Number of Affected Animals” equals ‘1’ then “Minimum Weight” should not be null or blank and “Maximum Weight” should equal a null value; otherwise reject ICSR.

Error: Reject ICSR

Comment: If “Measured, Estimated, Unknown Weight” equal “Measured” or “Estimated” and the “Number of Animals Affected” equals ‘1’, then “Minimum Weight” should be valued and “Maximum Weight” should not be valued; otherwise reject ICSR.

Step-by-Step Guide Section: 3.1.6

Field Description:

Max length shall be restricted to 12 total characters. Numeric value. Representation nnnnnnnn.nn

Report Type: AE Only, AE + PP

Cardinality:

If “Measured, Estimated, Unknown Weight” equals “Unknown” or

If “Measured, Estimated, Unknown Weight” equals “Measured” or “Estimated” and “Number of Affected Animals” equals 1:

[B.1.8.1 Measured, Estimated, Unknown Weight] 0..0 [B.1.8.3 “Maximum Weight”]

Data element is optional; must enter “NI” to represent null/no response

If “Measured, Estimated, Unknown Weight” equals “Measured” or “Estimated” and the “Number of Affected Animals” is greater than 1:

[B.1.8.1 Measured, Estimated, Unknown Weights] 1..1 [B.1.8.3 Maximum Weight]

Data element is mandatory – Use of Null value not allowed

GL-42 SECTION 1.9 ANIMAL AGE

GL-42 Section B.1.9.1 Measured, Estimated, Unknown Age

Requirement ID: 2.2

Definition:

The data element “Measured, Estimated, Unknown Age” is a coded field that identifies if the age of the animal(s) involved in the AER is measured, estimated or unknown.

Business Rule:

CVM_GL-42_016

If the value of the field “Measured, Estimated, Unknown Age” is null or blank, then reject ICSR.

Error: Reject ICSR

Comments: “Measured, Estimated, Unknown Age” must contain a valid value (null flavor not allowed); otherwise reject ICSR.

CVM_GL-42_017

If the data element “Measured, Estimated, Unknown Age” does not reference the correct list of values ([A.12-List of Precision Categories for Weight and Age Data](#)) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must reference the correct vocabulary for “Measured, Estimated, Unknown Age”; otherwise reject ICSR.

CVM_GL-42_017.1

If the value of the data element “Measured, Estimated, Unknown Age” is not found in the referenced list of values ([A.12-List of Precision Categories for Weight and Age Data](#)) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Measured, Estimated, Unknown Age”; otherwise reject ICSR.

CVM_GL-42_017.2

If the “Measured, Estimated, Unknown Age” field displayName does not match the code value for the “Measured, Estimated, Unknown Age” Code then reject ICSR.

Error: Reject ICSR

Comment: The value for the “Measured, Estimated, Unknown Age” displayName must match the appropriate code value for “Measured, Estimated, Unknown Age” code; otherwise the ICSR will be rejected.

CVM_GL-42_018

If the value of “Measured, Estimated, Unknown Age” equals “Unknown” and the data elements “Minimum Age” and “Maximum Age” are valued then reject ICSR.

Error: Reject ICSR

Comment: If the value of “Measured, Estimated, Unknown Age” equals “Unknown”, then “Minimum Age” and “Maximum Age” should be null; otherwise reject ICSR.

CVM_GL-42_020

If the value of “Measured, Estimated, Unknown Age” equals Measured or Estimated and the value of “Number of Affected Animals” equals ‘1’ then “Minimum Age” (and “Minimum Age Units”) should not be null and “Maximum Age” (and “Maximum Age Units”) should equal a null value; otherwise reject ICSR.

Error: Reject ICSR

Comment: If “Measured, Estimated, Unknown Age” equal Measured or Estimated and “Number of Animals Affected” equals 1, then “Minimum Age” should be valued and “Maximum Age” should not be valued; otherwise reject ICSR.

CVM_GL-42_XXX

If the code and displayName for the observation describing “Measured, Estimated, Unknown Age” does not equal (code = T95012/ displayName = “Age”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Measured, Estimated, Unknown Age” must equal (code = T95012/ displayName = “Age”); otherwise reject ICSR.

Step-by-Step Guide Section: 3.1.6

Field Description:

Max length is 15 characters for the code and 80 characters for the code description; single choice code list

Report Type: AE Only, AE + PP

OID:

codeSystem = None

code = single code value from list. Refer to [A.12-List of Precision Categories for Weight and Age Data](#)

Cardinality:

[B.1.9 Age] 1..1 [B.1.9.1 Measured, Estimated, Unknown Age]

Data element is mandatory – Reporters must select the best value from the vocabulary; Use of Null value is not allowed

GL-42 Section B.1.9.2 Minimum Age

Requirement ID: 2.3

Definition:

The data element “Minimum Age” is a field that contains the minimum age for the animal(s) involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of the field “Minimum Age” is blank, then reject ICSR.

Error: Reject ICSR

Comments: “Minimum Age” must contain either valid value or an acceptable null flavor; otherwise reject ICSR.

CVM_GL-42_021

If the value of the “Minimum Age” field is not a numeric value then reject ICSR.

Error: Reject ICSR

Comments: If “Minimum Age” is valued, the value must be numeric only; and greater than zero otherwise reject ICSR.

CVM_GL-42_022

If the value for “Minimum Age” is not null and the value for “Minimum Age Units” is null then reject ICSR.

Error: Reject ICSR

Comments: If “Minimum Age” is valued, then “Minimum Age Units” must be valued; otherwise reject ICSR.

CVM_GL-42_018

If the value of “Measured, Estimated, Unknown Age” equals “Unknown” and the data elements “Minimum Age” and “Maximum Age” are valued then reject ICSR.

Error: Reject ICSR

Comment: If the value of “Measured, Estimated, Unknown Age” equals “Unknown”, then “Minimum Age” and “Maximum Age” should be null; otherwise reject ICSR.

CVM_GL-42_020

If the value of “Measured, Estimated, Unknown Age” equals ‘Measured or ‘Estimated and the value of “Number of Affected Animals” equals ‘1’ then “Minimum Age” (and “Minimum Age Units”) should not be null and “Maximum Age” (and “Maximum Age Units”) should equal a null value; otherwise reject ICSR.

Error: Reject ICSR

Comment: If “Measured, Estimated, Unknown Age” equal Measured or Estimated and “Number of Animals Affected” equals 1, then “Minimum Age” should be valued and “Maximum Age” should not be valued; otherwise reject ICSR.

Step-by-Step Guide Section: 3.1.6

Length:

Max length shall be restricted to 12 total characters. Numeric value. Representation nnnnnnnn.nn

Report Type: AE Only, AE + PP

Cardinality:

If B.1.9.1 “Measured, Estimated, Unknown Age” equals “Measured” or “Estimated”:

[B.1.9.1 Measured, Estimated, Unknown Age] 1..1 [B.1.9.2 Minimum Age]

Data element is mandatory – Use of Null value not allowed

If B.1.9.1 “Measured, Estimated, Unknown Age” equals “Unknown”:

[B.1.9.1 Measured, Estimated, Unknown Age] 0..0 [B.1.9.2 Minimum Age]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.1.9.2.1 Minimum Age Units

Requirement ID: 2.3.1

Definition:

The data element “Minimum Age Units” is a coded field that contains the minimum age units from [Appendix A13 – Age Vocabulary](#) for the animal(s) involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of the field “Minimum Age Units” is blank, then reject ICSR.

Error: Reject ICSR

Comments: “Minimum Age Units” must contain either valid value or an acceptable null flavor; otherwise reject ICSR.

CVM_GL-42_023

If the value of “Minimum Age” is not null and “Minimum Age Units” is null then reject ICSR.

Error: Reject ICSR

Comment: If “Minimum Age” is valued, then “Minimum Age Units” must be valued; otherwise reject ICSR.

CVM_GL-42_019.1

If the value of “Minimum Age Units” is not found in the referenced list of values ([Appendix A13 – Age Vocabulary](#) – OID = National Cancer Institute Thesaurus) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must reference the correct vocabulary for “Minimum Age Units”; otherwise reject ICSR.

CVM_GL-42_XXX

If the value of “Minimum Age Units” does not equal a valid Age/Time Unit found in the ([Appendix A13 – Age Vocabulary](#)), then reject ICSR.

Error: Reject ICSR

Comment: The value of “Minimum Age Units” must equal a valid Age/Time Unit; otherwise reject ICSR.

Step-by-Step Guide Section: 3.1.6

Field Description:

Max length is 15 characters for the code; single choice code list

Report Type: AE Only, AE + PP

OID:

codeSystem = No OID required. Use code value directly from vocabulary.

code = single code value from list. Refer to [Appendix A.13–List of Time Units](#)

Cardinality:

If B.1.9.2 “Minimum Age” is specified

[B.1.9.2 Minimum Age] 1..1 [B.1.9.2 Minimum Age Units]

Data element is mandatory – Use of Null value not allowed

Otherwise;
[B.1.9.2 Minimum Age] 0..0 [B.1.9.2 Minimum Age Units]

Data element is optional; must enter "NI" to represent null/no response

GL-42 Section B.1.9.3 Maximum Age

Requirement ID: 2.4

Definition:

The data element “Maximum Age” is a field that contains the maximum age for the animal(s) involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of the field “Maximum Age” is blank, then reject ICSR.

Error: Reject ICSR

Comments: “Maximum Age” must contain either valid value or an acceptable null flavor; otherwise reject ICSR.

CVM_GL-42_024

If the value of the “Maximum Age” field is not a numeric value then reject ICSR.

Error: Reject ICSR

Comments: If “Maximum Age” is valued, the value must be numeric only and greater than zero; otherwise reject ICSR.

CVM_GL-42_025

If the value for “Maximum Age” is not null and the value for “Maximum Age Units” is null then reject ICSR.

Error: Reject ICSR

Comments: If “Maximum Age” is valued, then “Maximum Age Units” must be valued; otherwise reject ICSR.

Step-by-Step Guide Section: 3.1.6

Field Description:

Max length shall be restricted to 12 total characters. Numeric value. Representation nnnnnnnnnn.nn

Report Type: AE Only, AE + PP

Cardinality:

If B.1.9.1 “Measured, Estimated, Unknown Age” equals “Measured” or “Estimated”:

[B.1.9.1 Measured, Estimated, Unknown Age] 1..1 [B.1.9.3 Maximum Age]

Data element is mandatory – Use of Null value not allowed

If B.1.9.1 “Measured, Estimated, Unknown Age” equals “Unknown”:

[B.1.9.1 Measured, Estimated, Unknown Age] 0..0 [B.1.9.3 Maximum Age]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.1.9.3.1 Maximum Age Units

Requirement ID: 2.4.1

Definition:

The B.1.9.3.1 “Maximum Age Units” is the units in which the animals’ maximum age is measured.

Business Rule:

CVM_GL-42_XXX

If the value of the field “Maximum Age Units” is blank, then reject ICSR.

Error: Reject ICSR

Comments: “Maximum Age Units” must contain either valid value or an acceptable null flavor; otherwise reject ICSR.

CVM_GL-42_025

If the value for Maximum Age is not null and the value for “Maximum Age Units” is null then reject ICSR.

Error: Reject ICSR

Comments: If Maximum Age is valued, then “Maximum Age Units” must be valued; otherwise reject ICSR.

CVM_GL-42_026

If the value of Maximum Age is not null and “Maximum Age Units” is null then reject the ICSR.

Error: Reject ICSR

Comment: If “Maximum Age Units” is valued, then Maximum Age must be valued; otherwise reject ICSR.

CVM_GL-42_027

If the value of “Maximum Age Units” is not found in the referenced list of values ([Appendix A.13–List of Time Units](#)) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must reference the correct vocabulary for “Maximum Age Units”; otherwise reject ICSR.

CVM_GL-42_XXX

If the value of “Maximum Age Units” does not equal a valid Age/Time Unit found in the ([Appendix A.13–List of Time Units](#)), then reject ICSR.

Error: Reject ICSR

Comment: The value of “Maximum Age Units” must equal a valid Age/Time Unit; otherwise reject ICSR.

Step-by-Step Guide Section: 3.1.6

Field Description:

Max length is 15 characters for the code; single choice code list

Report Type: AE Only, AE + PP

OID:

codeSystem = No OID required. Use code value directly from vocabulary.

code = single code value from list. Refer to [Appendix A.13–List of Time Units](#)

Cardinality:

If B.1.9.3 Maximum Age is specified

[B.1.9.3 Maximum Age] 1..1 [B.1.9.3 Maximum Age Units]

Data element is mandatory – Reporters must select the best value from the vocabulary; Use of Null value is not allowed

Otherwise;

[B.1.9.3 Maximum Age] 0..0 [B.1.9.3 Maximum Age Units]

Data element is optional; must enter “NI” to represent null/no response

GL-42 SECTION B.2 VMP DATA AND USAGE

GL-42 Section B.2.1 Registered or Brand Name

Requirement ID: 2028

Definition:

The data element “Registered or Brand Name” is the registered / brand name of the VMP involved in the AER.

Business Rule:

CVM_GL-42_041

If the value of all instances of “Registered or Brand Name” is/are null or blank then reject ICSR.

Error: Reject ICSR

Comments: “Registered or Brand Name” must contain a valid value for at least one product described in the ICSR; otherwise reject ICSR.

CVM_GL-42_42

For at least one product, if the values of “Registered or Brand Name”, “Active Ingredients”, Strength (Numerator and Denominator), Strength Units (Numerator and Denominator), ATC Vet Code, Active Ingredient Code or Registration ID are null then reject ICSR.

Error: Reject ICSR

Comments: For each ICSR the following information must be valued for at least one product: Registration ID, “Registered or Brand Name”, Active Ingredient, Active Ingredient Code, ATC Vet Code, Strength, and Strength Units; otherwise reject ICSR.

CVM_GL-42_43

If neither data element “Registered or Brand Name” nor Active Ingredient is valued for each product then reject ICSR.

Error: Reject ICSR

Comments: For each ICSR the following information must be valued for all products: the “Registered or Brand Name” or the Active Ingredient; otherwise reject ICSR.

Step-by-Step Guide Section: 3.2.1

Field Description:

Max length is 200 characters; open ended text (string)

Report Type: AE Only, AE + PP, PP Only

Cardinality:

For at least one product:

[B.2 VMP Data and Usage] 1..1 [B.2.1 Registered or Brand Name]

Data element is mandatory – Use of Null value not allowed

For other products:

[B.2 VMP Data and Usage] 0..1 [B.2.1 Registered or Brand Name]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.2.1.1 Product Code

Requirement ID: 26

Definition:

The data element “Product Code” (NDC number) is a field that contains the product code for the specified VMP involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of “Product Code” is blank, then reject ICSR.

Error: Reject ICSR

Comments: “Product Code” must contain either valid value or an acceptable null flavor; otherwise reject ICSR.

CVM_GL-42_044

If the value of “Product Code” contained in the ICSR is not a valid NDC number in the CVM CDP DPL database when “Registration Identifier” does not equal ‘Cannot Be Determined’ and the ‘3 character country code’ equals ‘USA’ and the “RA Identifier Code” equals ‘USFDACVM’ and the Registration Number is valid, then reject ICSR

Error: Reject ICSR

Comment: If the product is a US product and the registration number is valid and the “Product Code” is valued, then the “Product Code” will be validated against the NDC number in CVM’s database (CDP DPL).

CVM_GL-42_XXX

If the code system for the “Product Code” does not equal (OID = “2.16.840.1.113883.3.155”, “FDA Product Code OID”), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the “Product Code” must equal (OID = “2.16.840.1.113883.3.155”, “FDA Product Code OID”); otherwise reject ICSR.

Step-by-Step Guide Section: 3.2.1.1

Field Description:

Max length is 20 characters; open ended text (string)

Report Type: AE Only, AE + PP, PP Only

Cardinality:

[B.2.1 Registered or Brand Name] 0..1[B.2.1.1 Product Code]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.2.1.2 Registration Identifier**Requirement ID:** 2030**Definition:**

The data element "Registration Identifier" is a field that contains the product registration identifier for the specified product involved in the AER.

Business Rule:

CVM_GL-42_036

If the value of "Registration Identifier" is blank, then reject ICSR.

Error: Reject ICSR

Comments: The "Registration Identifier" must contain either valid values or an acceptable null flavor; otherwise reject ICSR.

CVM_GL-42_037

If the value of "Registration Identifier" does not equal 'CANNOT BE DETERMINED' and the '3 Character Country Code' portion of the "Registration Identifier" is not a valid value contained in the ([APPENDIX A.36-LIST OF ISO 3-DIGIT COUNTRY CODES](#)) referenced list of values, then reject ICSR.

Error: Reject ICSR

Comments: If the "Registration Identifier" does not equal 'CANNOT BE DETERMINED' then the 3 character country code portion of the "Registration Identifier" must use the correct vocabulary; otherwise reject ICSR.

CVM_GL_42_038

If the value of the "Registration Identifier" does not equal 'CANNOT BE DETERMINED' and the "RA Identifier Code" portion of the "Registration Identifier" does not equal "USFDACVM" then reject the ICSR.

Error: Reject ICSR

Comments: If the "Registration Identifier" does not equal 'CANNOT BE DETERMINED' then the "RA Identifier Code" must use the correct value; otherwise reject ICSR.

CVM_GL-42_039

If the ICSR "Domestic vs. Foreign Report Category" element equals "C62264 - DOMESTIC" and if the "3 character country code" = 'USA' and "RA Identifier Code" = 'USFDACVM' (portion of the "Registration Identifier") and if the "Registration Number" (portion of the "Registration Identifier") is listed in the CVM CDP database then the value of the "Registration Number" (portion of the "Registration Identifier") must be found in the CVM CDP database; otherwise reject ICSR.

Comment [HC2]: Domestic report

Error: Reject ICSR

Comment: The purpose of this rule is to determine if there is at least one US product being reported. Reject ICSR if there is not a valid "Registration Number" listed in CVM CDP database.

Step-by-Step Guide Section: 3.2.1.2**Field Description:** Max length is 35 characters; open ended text (string)**Report Type:** AE Only, PP Only, AE + PP**Cardinality:**

For at least one product:

[B.2.1 Registered or Brand Name] 1..1 [B.2.1.2 Registration Identifier]

Data element is mandatory

For other products:

[B.2.1 Registered or Brand] 0..1 [B.2.1.2 Registration Identifier]

Data element is optional; must enter "NI" to represent null/no response

GL-42 Section B.2.1.3 Anatomical Therapeutic Chemical Vet (ATCvet) Code

Requirement ID: 2031

Definition:

The data element “Anatomical Therapeutic Chemical Vet Code” (ATCvet Code) is a field that contains the ATCvet Code of the VMP involved in the AER.

Business Rule:

CVM_GL-42_054

If the values of all instances of the ATCvet Code are null or blank, then reject ICSR.

Error: Reject ICSR

Comment: The ATCvet Code must be valued for at least one product; otherwise reject ICSR.

CVM_GL-42_XXX

If the code and displayName for the observation describing Anatomical Therapeutic Chemical Vet Code do not equal (code = "T95013"/ displayName = “ATCvet Code”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing Anatomical Therapeutic Chemical Vet Code must equal (code = "T95013"/ displayName = “ATCvet Code”); otherwise reject ICSR.

Step-by-Step Guide Section: 3.2.1.3

Field Description: Max length is 10 characters; open ended text

Report Type: AE Only, PP Only, AE + PP

Cardinality:

For at least one product:

[B.2.1 Registered or Brand Name] 1..1 [B.2.1.3 Anatomical Therapeutic Chemical Vet (ATCvet) Code]

Data element is mandatory – Reporters must select the best value from the vocabulary; Use of Null value is not allowed

For other products:

[B.2.1 Registered or Brand Name] 0..1 [B.2.1.3 Anatomical Therapeutic Chemical Vet (ATCvet) Code]

Data element is optional; select the best value from the vocabulary; enter “NI” to represent null/no response

GL-42 Section B.2.1.4 Company or MAH

Requirement ID: 84

Definition:

The data element “Company or MAH” is a field that contains the company or the Marketing Authorization Holder responsible for the VMP involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of “Company or MAH” is blank, then reject ICSR.

Error: Reject ICSR

Comments: The “Company or MAH” data element must contain either a valid value or an acceptable null flavor; otherwise reject ICSR

Step-by-Step Guide Section: 3.2.1.4

Field Description:

Max length is 60 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[B.2.1 Registered or Brand] 0..1 [B.2.1.4 Company or MAH]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.2.1.5 MAH Assessment**Requirement ID:** 4000**Definition:**

The data element “MAH Assessment” is a field that contains the marketing authorization holder’s assessment of the AER.

Business Rule:

CVM_GL-42_XXX

If the code system for the observation describing “MAH Assessment” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR*Comment:* The code system for the observation describing “MAH Assessment” must equal (OID = National Cancer Institute Thesaurus); otherwise reject ICSR.

CVM_GL-42_XXX

If the observation code and displayName for the “MAH Assessment” do not equal (code = "T95001"/ displayName = “MAH”), then reject ICSR.

Error: Reject ICSR*Comment:* The observation code and displayName for the “MAH Assessment” must equal (code = "T95001"/ displayName = “MAH”), otherwise reject ICSR.

CVM_GL-42_XXX

If the code and displayName for the value describing “MAH Assessment” do not equal a code and displayName from [A.14- List of Assessment Categories](#), then reject ICSR.

Error: Reject ICSR*Comment:* The code and displayName for the observation describing “MAH Assessment” must equal a code and displayName from [A.14- List of Assessment Categories](#).**Step-by-Step Guide Section:** 3.2.1.5**Field Description:**

Max length is 250 characters; open ended text (string)

Report Type: AE Only, AE + PP**OID:**

codeSystem = National Cancer Institute Thesaurus

code = single code value from list.

Refer to [A.14- List of Assessment Categories](#)

Cardinality:

[B.2.1.4 Company or MAH] 0..1 [B.2.1.5 MAH Assessment]

Data element is optional; select the best value from the vocabulary; enter “NI” to represent null/no response

GL-42 Section B.2.1.6 Regulatory Authority Assessment

{This Section has been deleted}

GL-42 Section B.2.1.7 Route of Exposure

Requirement ID: 19.3

Definition:

The element “Route of Exposure” is a set of element fields that contains the route of exposure of the VMP involved in the AER. Two sets of “Route of Exposure” codes and terms are to be collected. Set number one is required and is the “FDA defined routes of exposure” and they are derived from Appendix A.15–List of Route of Exposure-GL-42 - columns three and four. Set number two are optional and are the “VICH Defined Routes of Exposure”. They are derived from Appendix A.15–List of Route of Exposure-GL-42 - columns one and two.

Business Rule:

CVM_GL-42_XXX

If the value of “Route of Exposure” is blank, then reject ICSR.

Error: Reject ICSR

Comments: The “Route of Exposure” data element must contain either a valid code value and term or an acceptable null flavor; otherwise reject ICSR

CVM_GL-42_110

If the data element “Route of Exposure” does not reference the correct list of values (Appendix A.15–List of Route of Exposure -GL-42 - columns three and four – OID = National Cancer Institute Thesaurus) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must reference the correct vocabulary for “Route of Exposure” Appendix A.15–List of Route of Exposure -GL-42 - columns three and four; otherwise reject ICSR.

CVM_GL-42_110.1

If the value of the “Route of Exposure” field is not found in the referenced list of values (Appendix A.15–List of Route of Exposure -GL-42 - columns three and four) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Route of Exposure”; otherwise reject ICSR.

CVM_GL-42_110.2

Unless the “Route of Exposure” code value equals the ‘OTH Other’, if the “Route of Exposure” field displayName does not match the code value for the Route of Exposure Code then reject ICSR.

Error: Reject ICSR

Comment: The value for the “Route of Exposure” displayName must match the appropriate value for “Route of Exposure” code, unless the “Route of Exposure” code value equals the code for (“OTH” other) (reporters may use the code for ‘Other’ and enter a VICH displayName); otherwise the ICSR will be rejected.

Step-by-Step Guide Section: 3.2.1.7

Field Description:

Max length is 15 characters for the code and 80 characters for the code description; single choice code list

Report Type: AE Only, AE + PP

OID:

codeSystem = National Cancer Institute Thesaurus

code = single code value from list. Refer to [Appendix A.15–List of Route of Exposure-GL-42-Columns three and four](#)

Since a translation is being used, a second OID is needed:

codeSystem: 2.16.840.1.113883.4.341

code: single code value from [Appendix A.15–List of Route of Exposure-GL-42-Columns one and two](#)

Cardinality:

[B.2.1 Registered or Brand Name] 0..999 [B.2.1.7 Route of Exposure]

Data element is Mandatory; Null flavor is not defined for this element. Reporter must select a value from the code list (“Unknown” or “Other”) if the value is not known or it is not defined in the vocabulary list.

GL-42 Section B.2.1.7.1.1 Product Dose or Amount Used (Numeric Value for Dose)

Requirement ID: 19.1

Definition:

The data element “Product Dose or Amount Used” is a field that contains the dose or amount used of the VMP involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of “Product Dose or Amount Used” is blank, then reject ICSR.

Error: Reject ICSR

Comments: The “Product Dose or Amount Used” data element must contain either a valid value or an acceptable null flavor; otherwise reject ICSR

Step-by-Step Guide Section: 3.2.1.7.1

Field Description:

Max length shall be restricted to 12 total characters. Numeric value. Representation nnnnnn.nnnn

Report Type: AE Only, AE + PP

Cardinality:

[B.2.1.7.1 Dose per Administration] 0..1 [B.2.1.7.1.1 Product Dose or Amount Used]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.2.1.7.1.1.2 Units of Value for Dose (Each Dosage or Serving UOM)**Requirement ID:** 621.7**Definition:**

The data element “Units of Value for Dose” is a coded field that contains the units used to express the dose of the VMP involved in the AER.

Business Rule:

CVM_GL-42_113

If the value of the data element “Units of Value for Dose” is not null and the value of the data element “Numeric Value for Dose” is null then reject ICSR.

Error: Reject ICSR*Comment:* If “Units of Value for Dose” is valued, then “Numeric Value for Dose” is required; otherwise reject ICSR.

CVM_GL-42_114

If the data element “Units of Value for Dose” does not reference the correct list of values ([Appendix A.24-List of Units of Measurement](#)–OID = [2.16.840.1.113883.3.151](#) or [Appendix A.25-List of Units of Presentation](#)–OID = National Cancer Institute Thesaurus) then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must reference the correct vocabulary for “Units of Value for Dose”; otherwise reject ICSR.

CVM_GL-42_114.1

If the value of the “Units of Value for Dose” field is not found in the referenced list of values ([Appendix A.24-List of Units of Measurement](#) or [Appendix A.25-List of Units of Presentation](#)) then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain a valid value for “Units of Value for Dose”; otherwise reject ICSR.

CVM_GL-42_114.2

If the “Units of Value for Dose” field displayName does not match the code value for the “Units of Value for Dose” code then reject ICSR.

Error: Reject ICSR*Comment:* The value for the “Units of Value for Dose” displayName must match the appropriate value for “Units of Value for Dose” code; otherwise the ICSR will be rejected.**Step-by-Step Guide Section:** 3.2.1.7.1**Field Description:**

Max length is 15 characters for the code and 80 characters for the description; single choice code list

Report Type: AE Only, AE + PP**OID:**

codeSystem = [2.16.840.1.113883.3.151](#) or National Cancer Institute Thesaurus

code = single code value from list. Refer to [Appendix A.24-List of Units of Measurement](#) and [Appendix A.25-List of Units of Presentation](#)

Cardinality:

If “Numeric of Value for Dose” is not null:

[B.2.1.7.1.1 Numeric Value for Dose] 1..1 [B.2.1.7.1.1.1 Units of Value for Dose]

Data element is mandatory – Reporters must select the best value from the vocabulary; Use of Null value is not allowed

Otherwise:

[B.2.1.7.1.1 Numeric Value for Dose] 0..0 [B.2.1.7.1.1.1 Units of Value for Dose]

Data element is optional; either select the best value from the vocabulary; or enter “NI” to represent null/no response

GL-42 Section B.2.1.7.1.3 Numeric Value for Interval of Administration

Requirement ID: 20.2

Definition:

The data element “Numeric Value for Interval of Administration” is a field that contains the numeric value of interval of administration of the VMP involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of “Numeric Value for Interval of Administration” is blank or not null, then reject ICSR.

Error: Reject ICSR

Comments: The “Numeric Value for Interval of Administration” data element must contain either a valid value or an acceptable null flavor; otherwise reject ICSR

CVM_GL-42_115

If the value of the data element “Numeric Value for Interval of Administration” is not null and the value for “Numeric Value for Interval of Administration” is not an integer then reject ICSR.

Error: Reject ICSR

Comment: The value for “Numeric Value for Interval of Administration” must be an integer only; otherwise reject ICSR.

CVM_GL-42_116

If the value for data element “Numeric Value for Interval of Administration” is not null and the value for the data element “Units of Value for Interval of Administration” is null then reject ICSR.

Error: Reject ICSR

Comment: If “Numeric Value for Interval of Administration” is valued, then “Units of Value for Interval of Administration” must be valued; otherwise reject ICSR.

Step-by-Step Guide Section: 3.2.1.7.2

Field Description:

Max length is 12 characters; Integer

Report Type: AE Only, AE + PP

Cardinality:

[B.2.1.7 Route of Exposure] 0..1[B.2.1.7.1.2.1 Numeric Value for Interval of Administration]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.2.1.7.1.4 Units of Value for the Interval of Administration

Requirement ID: 20.3

Definition:

The data element “Units of Value for the Interval of Administration” is a coded field that contains the units of value for the interval of administration of the VMP involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of “Units of Value for the Interval of Administration” is blank, then reject ICSR.

Error: Reject ICSR

Comments: The “Units of Value for the Interval of Administration” data element must contain either a valid value or an acceptable null flavor; otherwise reject ICSR

CVM_GL-42_117

If the value of the data element “Units of Value for the Interval of Administration” is not found in the referenced list of values ([Appendix A.13–List of Time Units](#)), then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Units of Value for the Interval of Administration”; otherwise reject ICSR.

CVM_GL-42_117.2

If “Numeric Value for Interval of Administration” is not null and Units of Value for the Interval of Administration is null, then reject ICSR.

Error: Reject ICSR

Comment: If “Numeric Value for Interval of Administration” is not null, then “Units of Value for the Interval of Administration” must contain a valid value (must not be null).

Step-by-Step Guide Section: 3.2.1.7.2

Field Description:

Max length is 15 characters for the code and 80 characters for the code description; single choice code list

Report Type: AE Only, AE + PP

OID:

code = None - UCOM

single code value from list. Refer to [Appendix A.13–List of Time Units](#)

Cardinality:

If “Numeric Value for Interval of Administration” is not null:

[B.2.1.7.1.2.1 Numeric Value for Interval of Administration] 1..1 [B.2.1.7.1.2.1.1 Units of Value for the Interval of Administration]

Data element is mandatory – Reporters must select the best value from the vocabulary; Use of Null value is not allowed

If “Numeric Value for Interval of Administration” is null:

[B.2.1.7.1.2.1 Numeric Value for Interval of Administration] 0..0 [B.2.1.7.1.2.1.1 Units of Value for the Interval of Administration]

Data element is optional; select the best value from the vocabulary; enter "NI" to represent null/no response

GL-42 Section B.2.1.7.1.2.2 Date of First Exposure**Requirement ID:** 5001**Definition:**

The data element "Date of First Exposure" is a field that contains the date the animal(s) was first exposed to the VMP involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of the "Date of First Exposure" is blank then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain an acceptable null flavor or a valid date for "Date of First Exposure"; otherwise reject ICSR.

CVM_GL-42_119

If the date format for the "Date of First Exposure" is not a complete valid date (in the format of YYYYMMDD HHMMSS.UUUU, where HHMMSS.UUUU are optional), then reject ICSR.

Error: Reject ICSR*Comment:* The "Date of First Exposure" must be a valid date; otherwise reject ICSR.****NOTE: HHMMSS.UUUU REPRESENTS HOURS, MINUTES, SECONDS AND FRACTION OF SECONDS****

CVM_GL-42_119.1

If the value for the data element "Date of First Exposure" is not null and the value of "Date of First Exposure" is greater than the transmission date then reject ICSR.

Error: Reject ICSR*Comment:* The value for "Date of First Exposure" must not be greater than the transmission date; otherwise reject ICSR.

CVM_GL-42_119.2

If the value of the month for "Date of First Exposure" is not a valid calendar year month (01-12), then reject ICSR.

Error: Reject ICSR*Comment:* The "Date of First Exposure" must be a valid date; otherwise reject ICSR.

CVM_GL-42_119.3

If the value of the day for "Date of First Exposure" is not a valid day for the specified month, then reject ICSR.

Error: Reject ICSR*Comment:* The "Date of First Exposure" must be a valid date; otherwise reject ICSR.**Step-by-Step Guide Section:** 3.2.1.7.2**Field Description:** Max length is 19 characters; Date**Report Type:** AE Only, AE + PP**Cardinality:** [B.2.1.7 Route of Exposure] 0..1[B.2.1.7.1.2.2 Date of First Exposure]*Data element is optional; must enter "NI" to represent null/no response*

GL-42 Section B.2.1.7.1.2.3 Date of Last Exposure**Requirement ID:** 5002**Definition:**

The data element "Date of Last Exposure" is a field that contains the date the animal(s) was last exposed to the VMP involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of the "Date of Last Exposure" is blank then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain an acceptable null flavor or a valid date for "Date of Last Exposure"; otherwise reject ICSR.

CVM_GL-42_120

If the date format for the "Date of Last Exposure" is not a complete valid date (in the format of YYYYMMDD HHMMSS.UUUU, where HHMMSS.UUUU are optional), then reject ICSR.

Error: Reject ICSR*Comment:* The "Date of Last Exposure" must be a valid date; otherwise reject ICSR. ****NOTE:** HHMMSS.UUUU represents hours, minutes, seconds and fraction of seconds**

CVM_GL-42_120.1

If the value for the data element "Date of Last Exposure" is not null and the value of "Date of Last Exposure" is not equal to or greater than the "Date of First Exposure", then reject ICSR.

Error: Reject ICSR*Comment:* The value for "Date of Last Exposure" must not be less than the "Date of First Exposure"; otherwise reject ICSR.

CVM_GL-42_120.2

If the value of the month for "Date of Last Exposure" is not a valid calendar year month (01-12), then reject ICSR.

Error: Reject ICSR*Comment:* The "Date of Last Exposure" must be a valid date; otherwise reject ICSR.

CVM_GL-42_120.3

If the value of the day for "Date of Last Exposure" is not a valid day for the specified month, then reject ICSR.

Error: Reject ICSR*Comment:* The "Date of Last Exposure" must be a valid date; otherwise reject ICSR.**Step-by-Step Guide Section:** 3.2.1.7.2**Field Description:** Max length is 19 characters; Date**Report Type:** AE Only, AE + PP**Cardinality:** [B.2.1.7 Route of Exposure] 0..1 [B.2.1.7.1.2.3 Date of Last Exposure]*Data element is optional; must enter "NI" to represent null/no response*

GL-42 SECTION B.2.2 ACTIVE INGREDIENT

GL-42 Section B.2.2.1 Active Ingredient(s)

Requirement ID: 2035

Definition:

The data element “Active Ingredient(s)” is a field that contains the active ingredients of the VMP involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of all instances of the “Active Ingredient(s)” is null then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain at least one product with a valid value for “Active Ingredient(s)”; otherwise reject ICSR.

Step-by-Step Guide Section: 3.2.2.1

Field Description:

Max length is 200 characters; open ended text

Report Type: AE Only, PP Only, AE + PP

Cardinality:

For at least one product:

[B.2.1 Registered or Brand Name] 1..999 [B.2.2.1 Active Ingredient(s)]

Data element is mandatory – Use of Null value not allowed

For other products:

[B.2.1 Registered or Brand Name] 0..999 [B.2.2.1 Active Ingredient(s)]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.2.2.1 Active Ingredient(s) Code

Requirement ID: 2035

Definition:

The data element “Active Ingredients Code” is a field that contains the active ingredients code of the VMP involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of all instances of the “Active Ingredients Code” is null then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain at least one product with a valid value for “Active Ingredients Code”; otherwise reject ICSR.

CVM_GL-42_XXX

If the specified portion of the “Registration Identifier” equals ‘USA’ and if the data element “Active Ingredients Code” is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must reference the correct vocabulary for “Active Ingredients Code”; otherwise reject ICSR.

Step-by-Step Guide Section: 3.2.2.1

Field Description:

Max length is 15 characters for the code; single choice code list

Report Type: AE Only, PP Only, AE + PP

OID:

codeSystem = "2.16.840.1.113883.4.9"

code = single code value from list. Refer to [Appendix A.38–Substance Registration System Active Ingredient Codes](#)

Cardinality:

For at least one product:

[B.2.1 Registered or Brand Name] 1..999 [B.2.2.1 Active Ingredient(s) Code]

Data element is mandatory – Use of Null value not allowed

For other products:

[B.2.1 Registered or Brand Name] 0..999 [B.2.2.1 Active Ingredient(s) Code]

Data element is optional; must use null flavor from vocabulary

GL-42 Section B.2.2.1.1 Strength (Numerator)

Requirement ID: 2033

Definition:

The data element “Strength (Numerator)” is a field that contains the strength numerator of the product involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of all instances of “Strength (Numerator)” is null then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain at least one product with a valid value for “Strength (Numerator)”; otherwise reject ICSR.

CVM_GL-42_046

If the value of the data element “Strength (Numerator)” is not numeric, then reject the ICSR.

Error: Reject ICSR

Comment: The value for “Strength (Numerator)” must be numeric only; otherwise reject ICSR.

CVM_GL-42_047

If the value of the data element “Strength (Numerator)” is not null and “Strength Units (Numerator)” is null then reject ICSR.

Error: Reject ICSR

Comment: If the “Strength (Numerator)” is valued, the “Strength Units (Numerator)” is required; otherwise reject ICSR.

Step-by-Step Guide Section: 3.2.2.1

Field Description:

Max length shall be restricted to 12 total characters. Numeric value. Representation nnnnnnn.nnnn

Report Type: AE Only, PP Only, AE + PP

Cardinality:

For at least one product:

[B.2.2.1 Active Ingredient(s)] 1..1 [B.2.2.1.1 Strength (Numerator)]

Data element is mandatory – Use of Null value not allowed

For other products:

[B.2.2.1 Active Ingredient(s)] 0..1 [B.2.2.1.1 Strength (Numerator)]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.2.2.1.1.1 Strength Units (Numerator)

Requirement ID: 2034

Definition:

The data element “Strength Units (Numerator)” is a field that contains the strength units (numerator) of the product involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of “Strength Units (Numerator)” is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either an acceptable null flavor or valid value for “Strength Units (Numerator)”; otherwise reject ICSR.

CVM_GL-42_XXX

If the value of “Strength (Numerator)” is not null and the value of “Strength Units (Numerator)” is null, then reject ICSR.

Error: Reject ICSR

Comment: If the “Strength (Numerator)” contains a valid value (not null), then “Strength Units (Numerator)” must contain a valid value (not be null); otherwise reject ICSR.

CVM_GL-42_048

If the value of the Strength Unit (Numerator) is not null and “Strength (Numerator)” is null then reject ICSR.

Error: Reject ICSR

Comment: If Strength Units (Numerator) is valued, then “Strength (Numerator)” is required; otherwise reject ICSR.

CVM_GL-42_050

If the data element “Strength Units (Numerator)” does not reference the correct list of values ([Appendix A.24-List of Units of Measurement](#)) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must reference the correct vocabulary for “Strength Units (Numerator)”; otherwise reject ICSR.

CVM_GL-42_050.1

If the value data element “Strength Units (Numerator)” is not found in the referenced list of values ([Appendix A.24-List of Units of Measurement](#)), then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Strength Units (Numerator)”, otherwise reject ICSR.

CVM_GL-42_050.2

If the “Strength Units (Numerator)” field displayName does not match the code value for “Strength Units (Numerator)” code then reject ICSR.

Error: Reject ICSR

Comment: The value for the “Strength Units (Numerator)” displayName must match the appropriate value for “Strength Units (Numerator)” code; otherwise the ICSR will be rejected.

Step-by-Step Guide Section: 3.2.2.1

Field Description:

Max length is 15 characters for the code and 80 characters for the code description; single choice code list

Report Type: AE Only, PP Only, AE + PP

OID:

codeSystem = "2.16.840.1.113883.3.151"

code = single code value from list. Refer to [Appendix A.24-List of Units of Measurement](#)

Cardinality:

If Strength (Numerator) is not null:

[B.2.2.1.1 Strength (Numerator)]1..1 [B.2.2.1.1 Strength Units (Numerator)]

Data element is mandatory – Reporters must select the best value from the vocabulary; Use of Null value is not allowed

If Strength (Numerator) is null:

[B.2.2.1.1 Strength (Numerator)]0..0 [B.2.2.1.1 Strength Units (Numerator)]

Data element is optional; must use null flavor included in vocabulary list

GL-42 Section B.2.2.1.1 Strength (Denominator)

Requirement ID: 2033.1

Definition:

The data element “Strength (Denominator)” is a field that contains the strength denominator of the product involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of all instances of “Strength (Denominator)” is null then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain at least one product with a valid value for “Strength (Denominator)”; otherwise reject ICSR.

CVM_GL-42_049

If the value of the data element “Strength (Denominator)” is not numeric, then reject the ICSR.

Error: Reject ICSR

Comment: The value for “Strength (Denominator)” must be numeric only; otherwise reject ICSR.

CVM_GL-42_051

If the value of the data element “Strength (Denominator)” is not null and “Strength Units (Denominator)” is null then reject ICSR.

Error: Reject ICSR

Comment: If the “Strength (Denominator)” is valued, the “Strength Units (Denominator)” is required; otherwise reject ICSR.

CVM_GL-42_XXX

If “Strength (Denominator)” is not null, and Strength (Numerator) is null, then reject ICSR.

Error: Reject ICSR

Comment: If the “Strength (Denominator)” is not null, then “Strength (Numerator)” must contain a valid value (must not be null); otherwise reject ICSR.

Step-by-Step Guide Section: 3.2.2.1

Field Description:

Max length shall be restricted to 12 total characters. Numeric value. Representation nnnnnn.nnnn

Report Type: AE Only, PP Only, AE + PP

Cardinality:

For at least one product:

[B.2.2.1 Active Ingredient(s)] 1..1 [B.2.2.1.1 Strength (Denominator)]

Data element is mandatory – Use of Null value not allowed

For other products:

[B.2.2.1 Active Ingredient(s)] 0..1 [B.2.2.1.1 Strength (Denominator)]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.2.2.1.1.1 Strength Units (Denominator)**Requirement ID:** 2034.1**Definition:**

The data element “Strength Units (Denominator)” is a field that contains the strength unit’s denominator of the product involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of “Strength Units (Denominator)” is blank then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain either an acceptable null flavor or valid value for “Strength Units (Denominator)”; otherwise reject ICSR.

CVM_GL-42_052

If the value of the “Strength Units (Denominator)” is not null and “Strength (Denominator)” is null then reject ICSR.

Error: Reject ICSR*Comment:* If “Strength Units (Denominator)” is valued, then “Strength (Denominator)” is required; otherwise reject ICSR.

CVM_GL-42_053

If the data element “Strength Units (Denominator)” does not reference the correct list of values (Appendix – A24 – Units of Measurements) then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must reference the correct vocabulary for “Strength Units (Denominator)”; otherwise reject ICSR.

CVM_GL-42_053.1

If the value data element “Strength Units (Denominator)” is not found in the referenced lists of values (Appendix A.24-List of Units of Measurement) then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain a valid value for “Strength Units (Denominator)”; otherwise reject ICSR.

CVM_GL-42_053.2

If the “Strength Units (Denominator)” field displayName does not match the code value for “Strength Units (Denominator)” code then reject ICSR.

Error: Reject ICSR*Comment:* The value for the “Strength Units (Denominator)” displayName must match the appropriate value for “Strength Units (Denominator)” code; otherwise the ICSR will be rejected.**Step-by-Step Guide Section:** 3.2.2.1**Field Description:**

Max length is 15 characters for the code and 80 characters for the code description; single choice code list

Report Type: AE Only, PP Only, AE + PP

OID:

codeSystem = "2.16.840.1.113883.3.151"

code = single code value from list. Refer to [Appendix A.24-List of Units of Measurement](#)

Cardinality:

If “Strength (Denominator)” is not null:

[B.2.2.1.1 Strength (Denominator)] 1..1 [B.2.2.1.1 Strength Units (Denominator)]

Data element is mandatory – Use of Null value not allowed

If “Strength (Denominator)” is null:

[B.2.2.1.1 Strength (Denominator)] 0..0 [B.2.2.1.1 Strength Units (Denominator)]

Data element is optional; must use null flavor included in vocabulary list

GL-42 Section B.2.2.2 Dosage Form**Requirement ID:** 2036**Definition:**

The data element “Dosage Form” is a field that contains the dosage form for the VMP involved in the AER. Two sets of “Dosage Form” codes and terms are to be collected. Set number one is required and is the FDA defined dosage form and they are derived from Appendix A.33–List of Dosage Forms-GL-42 - columns three and four. Set number two are optional and are the VICH defined dosage forms. They are derived from Appendix A.33–List of Dosage Forms-GL-42 - columns one and two.

Business Rule:

CVM_GL-42_XXX

If the value of “Dosage Form” is blank then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain either an acceptable null flavor or valid value for “Dosage Form”; otherwise reject ICSR.

CVM_GL-42_121

If the data element “Dosage Form” is not null and the data element “Dosage Form” does not reference the correct list of values (Appendix A.33–List of Dosage Forms-GL-42-Columns three and four – OID = National Cancer Institute Thesaurus) then reject ICSR.

Error: Reject ICSR*Comment:* If “Dosage Form” is not null, then the ICSR must reference the correct vocabulary for “Dosage Form”; otherwise reject ICSR.

CVM_GL-42_121.1

If the data element “Dosage Form” is not null and the value of the data element “Dosage Form” is not found in the referenced list of values (Appendix A.33–List of Dosage Forms-GL-42-Columns three and four) then reject ICSR.

Error: Reject ICSR*Comment:* If “Dosage Form” is not null then the ICSR must contain a valid value for “Dosage Form”; otherwise reject ICSR.

CVM_GL-42_121.2

If the “Dosage Form” field displayName does not match the code value for the “Dosage Form” code then reject ICSR.

Error: Reject ICSR*Comment:* The value for the “Dosage Form” displayName must match the appropriate value for the “Dosage Form” code; otherwise the ICSR will be rejected.**Step-by-Step Guide Section:** 3.2.2.2**Field Description:**

Max length is 15 characters for the code and 80 characters for the code description; single choice code list

Report Type: AE Only, PP Only, AE + PP**OID:**

codeSystem = National Cancer Institute Thesaurus

code = single code value from list. Refer to [Appendix A.33–List of Dosage Forms-GL-42-Columns three and four](#)

Since a translation is being used, a second OID is needed:

codeSystem: **2.16.840.1.113883.4.345**

code = single code value from [Appendix A.33–List of Dosage Forms-GL-42-Columns one and two](#)

Cardinality:

[B.2.1 Registered or Brand Name] 0..1 [B.2.2.2 Dosage Form]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.2.3 Lot Number

Requirement ID: 2037

Definition:

The data element “Lot Number” is a field that contains the lot number of the VMP involved in the AER

Business Rule:

CVM_GL-42_XXX

If the value of “Lot Number” is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either an acceptable null flavor or valid value for “Lot Number”; otherwise reject ICSR.

Step-by-Step Guide Section: 3.2.3

Field Description:

Max length is 35 characters; open ended text

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[B.2.1 Registered or Brand Name] 0..999 [B.2.3 Lot Number]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.2.3.1 Expiration Date

Requirement ID: 2038

Definition:

The data element “Expiration Date” is a field that contains the expiration date of the VMP involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of “Expiration Date” is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either an acceptable null flavor or valid value for “Expiration Date”; otherwise reject ICSR.

CVM_GL-42_123

If the date format for the “Expiration Date” is not a valid date (in the format of YYYYMMDD HHMMSS.UUUU, where MMDD and HHMMSS.UUUU are optional), then reject ICSR.

Error: Reject ICSR

Comment: The “Expiration Date” must be in a valid date format (YYYYMMDD HHMMSS.UUUU) and include at least the expiration year; otherwise reject ICSR.

*NOTE: HHMMSS.UUUU REPRESENTS HOURS, MINUTES, SECONDS AND FRACTION OF SECONDS**

CVM_GL-42_123.1

If the value of the month for “Expiration Date” is not a valid calendar year month (01-12), then reject ICSR.

Error: Reject ICSR

Comment: The “Expiration Date” must be a valid date; otherwise reject ICSR.

CVM_GL-42_123.2

If the value of the day for “Expiration Date” is not a valid day for the specified month, then reject ICSR.

Error: Reject ICSR

Comment: The “Expiration Date” must be a valid date; otherwise reject ICSR.

Step-by-Step Guide Section: 3.2.3

Field Description:

Max length is 19 characters; Date

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[B.2.3 Lot Number] 0..1 [B.2.3.1 Expiration Date]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.2.6.1 Manufacturer's Site Identifier (FDA Establishment Identifier #)

Requirement ID: 1700

Definition:

The data element "Manufacturer's Site Identifier" is a field that contains the manufacturing site identification information for the VMP involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of "Manufacturer's Site Identifier" is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either an acceptable null flavor or valid value for "Manufacturer's Site Identifier"; otherwise reject ICSR.

CVM_GL-42_XXX

If the data element "Manufacturer's Site Identifier" does not reference the correct list of values (Manufacturer's Identifier Type – FDA FEI OID = 2.16.840.1.113883.4.82 or DUNS OID = 1.3.6.1.4.1.519.1) and Appendix A.18–List of Manufacturer Site Identifiers then reject the ICSR.

Error: Reject ICSR

Comment: The ICSR must use the correct vocabulary for "Manufacturer's Site Identifier"; otherwise reject ICSR.

Step-by-Step Guide Section: 3.2.6.1

Field Description:

Max length is 50 characters; open ended text

Report Type: PP Only, AE + PP

OID:

codeSystem = (2.16.840.1.113883.4.82 - FDA FEI OID) OR (DUNS OID = 1.3.6.1.4.1.519.1)

code = single code value from list. Refer to Appendix A.18–List of Manufacturer Site Identifiers

Cardinality:

[B.2.3 Lot Number] 0..1 [B.2.6.1 Manufacturer's Site Identifier]

Data element is optional; select the best value from the vocabulary; enter "NI" to represent null/no response

GL-42 Section B.2.6.2 Manufacturing Date

Requirement ID: 1701

Definition:

The data element “Manufacturing Date” is a field that contains the manufacturing date of the VMP involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of “Manufacturing Date” is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either an acceptable null flavor or valid value for “Manufacturing Date”; otherwise reject ICSR.

CVM_GL-42_XXX

If the date format for the “Manufacturing Date” is not a complete valid date (in the format of YYYYMMDD HHMMSS.UUUU, where HHMMSS.UUUU are optional), then reject ICSR.

Error: Reject ICSR

Comment: The “Manufacturing Date” must be a valid date; otherwise reject ICSR.

****NOTE:** HHMMSS.UUUU REPRESENTS HOURS, MINUTES, SECONDS AND FRACTION OF SECONDS**

CVM_GL-42_XXX

If the value of the month for “Manufacturing Date” is not a valid calendar year month (01-12), then reject ICSR.

Error: Reject ICSR

Comment: The “Manufacturing Date” must be a valid date; otherwise reject ICSR.

CVM_GL-42_XXX

If the value of the day for “Manufacturing Date” is not a valid day for the specified month, then reject ICSR.

Error: Reject ICSR

Comment: The “Manufacturing Date” must be a valid date; otherwise reject ICSR.

Step-by-Step Guide Section: 3.2.6.2

Field Description:

Max length is 19 characters; date

Report Type: PP Only, AE + PP

Cardinality:

[B.2.3 Lot Number] 0..1 [B.2.6.2 Manufacturing Date]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.2.6.3 Number of Defective Units**Requirement ID:** 1702**Definition:**

The data element “Number of Defective Units” is a field that contains the number of defective units found for the VMP. It also contains a translational field that describes the type of packaging of the defective units.

Business Rule:

CVM_GL-42_XXX

If the value of “Number of Defective Units” is blank then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain either an acceptable null flavor or valid value for “Number of Defective Units”; otherwise reject ICSR.

CVM_GL-42_149

If the value of the data element “Number of Defective Units” is not numeric then reject ICSR.

Error: Reject ICSR*Comment:* The value for “Number of Defective Units” must be numeric; otherwise reject ICSR.

CVM_GL-42_149.1

If the code system for the observation describing “Number of Defective Units” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR*Comment:* The code system for the observation describing “Number of Defective Units” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR.

CVM_GL-42_149.2

If the code and displayName for the observation describing “Number of Defective Units” does not equal (code = “T95017” / displayName = “Number of Defective Units”), then reject ICSR.

Error: Reject ICSR*Comment:* The code and displayName for the observation describing “Number of Defective Units” must equal (code = “T95017” / displayName = “Number of Defective Units”); otherwise reject ICSR.

CVM_GL-42_XXX

If the translation data element is not null and the translation codeSystem does not reference the correct OID = National Cancer Institute Thesaurus) then reject ICSR.

Error: Reject ICSR*Comment:* If “translation element for “Package Type” does not reference the correct OID then reject ICSR.

CVM_GL-42_XXX

If the translational data element is not null and the value is not found in the referenced list of values ([Appendix A.29–List of Package Types](#)) then reject ICSR.

Error: Reject ICSR*Comment:* If translational data element is not null then the ICSR must contain a valid value for “Package Type”; otherwise reject ICSR.

CVM_GL-42_XXX

If the translational data element field displayName does not match the code value for the “Package Type” code then reject ICSR.

Error: Reject ICSR

Comment: The value for the “Package Type” displayName must match the appropriate code value; otherwise the ICSR will be rejected.

Step-by-Step Guide Section: 2.6.6.3

Field Description:

Max length shall be restricted to 12 total characters. Numeric value. Representation nnnnnnn.nnnn

Report Type: PP Only, AE + PP

OID:

codeSystem = National Cancer Institute Thesaurus

code = single code value from list. Refer to [Appendix A.29–List of Package Types](#)

Cardinality:

[B.2.3 Lot Number] 0..1 [B.2.6.3 Number of Defective Units]

Data element is optional; select the best value from the vocabulary; enter “NI” to represent null/no response

GL-42 Section B.2.6.4 Number of Returned Units**Requirement ID:** 1703**Definition:**

The data element “Number of Returned Units” is a field that contains the number of returned units of the VMP. It also contains a translational field that describes the type of packaging of the returned units.

Business Rule:

CVM_GL-42_XXX

If the value of “Number of Returned Units” is blank then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain either an acceptable null flavor or valid value for “Number of Returned Units”; otherwise reject ICSR.

CVM_GL-42_150

If the value of the data element Number of Units Returned is not numeric then reject ICSR.

Error: Reject ICSR*Comment:* The value for Number of Units Returned must be a numeric value; otherwise reject ICSR.

CVM_GL-42_150.1

If the code system for the observation describing “Number of Returned Units” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR*Comment:* The code system for the observation describing “Number of Returned Units” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR.

CVM_GL-42_150.2

If the code and displayName for the observation describing “Number of Returned Units” does not equal (code = “T95018” / displayName = “Number of Units Returned”), then reject ICSR.

Error: Reject ICSR*Comment:* The code and displayName for the observation describing “Number of Defective Units” must equal (code = “T95018” / displayName = “Number of Units Returned”); otherwise reject ICSR.

CVM_GL-42_XXX

If the translation data element is not null and the translation codeSystem does not reference the correct OID = National Cancer Institute Thesaurus) then reject ICSR.

Error: Reject ICSR*Comment:* If “translation element for “Package Type” does not reference the correct OID then reject ICSR.

CVM_GL-42_XXX

If the translational data element is not null and the value is not found in the referenced list of values ([Appendix A.29–List of Package Types](#)) then reject ICSR.

Error: Reject ICSR*Comment:* If translational data element is not null then the ICSR must contain a valid value for “Package Type”; otherwise reject ICSR.

CVM_GL-42_XXX

If the translational data element field displayName does not match the code value for the “Package Type” code then reject ICSR.

Error: Reject ICSR

Comment: The value for the “Package Type” displayName must match the appropriate code value; otherwise the ICSR will be rejected.

Step-by-Step Guide Section: 2.2.6.4

Field Description:

Max length shall be restricted to 12 total characters. Numeric value. Representation nnnnnnn.nnnn

Report Type: PP Only, AE + PP

OID:

codeSystem = National Cancer Institute Thesaurus

code = single code value from list. Refer to [Appendix A.29–List of Package Types](#)

Cardinality:

[B.2.3 Lot Number] 0..1 [B.2.6.4 Number of Returned Units]

Data element is optional; select the best value from the vocabulary; enter “NI” to represent null/no response

GL-42 Section B.2.4 Who Administered the VMP

Requirement ID: 2020

Definition:

The data element “Who Administered the VMP” is a field that contains the person who administered the VMP involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of “Who Administered the VMP” is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either an acceptable null flavor or valid value for “Who Administered the VMP”; otherwise reject ICSR.

CVM_GL-42_124

If the data element “Who Administered the VMP” does not reference the correct list of values ([Appendix A.19-List of Administrators of VMP\(s\)](#) – OID = National Cancer Institute Thesaurus) then reject the ICSR.

Error: Reject ICSR

Comment: The ICSR must use the correct vocabulary for “Who Administered the VMP”; otherwise reject ICSR.

CVM_GL-42_124.1

If the value of the data element “Who Administered the VMP” is not found in the referenced list of values ([Appendix A.19-List of Administrators of VMP\(s\)](#)) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Who Administered the VMP”; otherwise reject ICSR.

CVM_GL-42_124.2

If the data element “Who Administered the VMP” field displayName does not match the code value for “Who Administered the VMP” code then reject the ICSR.

Error: Reject ICSR

Comment: The value for “Who Administered the VMP” code displayName must match the appropriate code value for “Who Administered the VMP”; otherwise the ICSR will be rejected.

Step-by-Step Guide Section: 3.2.4

Field Description:

Max length is 15 characters for the code and 80 characters for the code description; single choice code list

Report Type: AE Only, AE + PP

OID:

codeSystem = National Cancer Institute Thesaurus

code = single code value from list. Refer to [Appendix A.19-List of Administrators of VMP\(s\)](#)

Cardinality:

[B.2.1 Registered or Brand Name] 0..1 [B.2.4 Who Administered the VMP]

Data element is optional; either select the best value from the vocabulary; or enter "NI" to represent null/no response

GL-42 Section B.2.5 Use According to Label**Requirement ID:** 2022**Definition:**

The data element “Use According to Label” is a Boolean field that indicates the use according to label of the VMP involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of “Use According to Label” is blank then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain either an acceptable null flavor or valid Boolean value for “Use According to Label”; otherwise reject ICSR.

CVM_GL-42_125

If the code system for the observation describing “Use According to Label” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR*Comment:* The code system for the observation describing “Use According to Label” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR.

CVM_GL-42_125.1

If the code and displayName for the observation describing “Use According to Label” does not equal (code = "T95015" / displayName = “Use According to Label”), then reject ICSR.

Error: Reject ICSR*Comment:* The code and displayName for the observation describing “Use According to Label” must equal (code = "T95015" / displayName = “Use According to Label”); otherwise reject ICSR.

CVM_GL-42_126

If the value of “Use According to Label” equals ‘False’ and the value of “Explanation for Off-Label Use” is null then reject ICSR.

Error: Reject ICSR*Comment:* If “Use According to Label” equals ‘False’, then “Explanation for Off-Label Use” is required; otherwise reject ICSR.**Step-by-Step Guide Section:** 3.2.5**Field Description:**

Max length is 5 characters; Boolean

Report Type: AE Only, AE + PP**Cardinality:**

[B.2.1 Registered or Brand Name] 0.. 1 [B.2.5 Use According to Label]

Data element is optional; Reference Appendix A.31—Boolean Information Table to select the proper null flavor response

GL-42 Section B.2.5.1 Explanation for Off-Label Use**Requirement ID: 2023****Definition:**

The data element “Explanation for Off-Label Use” is a field that contains the explanation for off-label use of the VMP involved in the AER.

Business Rule:

CVM_GL-42_XXX

If the value of “Explanation for Off-Label Use” is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either an acceptable null flavor or valid value for “Explanation for Off-Label Use”; otherwise reject ICSR.

CVM_GL-42_127

If the data element “Explanation for Off-Label Use” is not null and value of the data element “Use According to Label” is not ‘False’ then reject ICSR.

Error: Reject ICSR

Comment: If “Explanation for Off-Label Use” is valued, then “Use According to Label” must be equal to ‘false’; otherwise reject ICSR.

CVM_GL-42_128

If the data element “Explanation for Off-Label Use” does not reference the correct list of values (VICH Label Use – OID = 2.16.840.1.113883.13.51) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must reference the correct values for “Explanation for Off-Label Use” ([Appendix A.30-List of Explanation for Off-Label Use – Coding System](#)); otherwise reject ICSR.

CVM_GL-42_128.1

If the value of data element “Explanation for Off-Label Use” (Values ranges from 0 to 128) is not found in the referenced list of values ([Appendix A.30-List of Explanation for Off-Label Use – Coding System](#)) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for Explanation of Off-Label Use; otherwise reject ICSR.

CVM_GL-42_128.2

If the code system for the observation describing “Explanation for Off-Label Use” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Explanation for Off-Label Use” must equal (OID = 2.16.840.1.113883.13.51), otherwise reject ICSR.

CVM_GL-42_128.3

If the code and displayName for the observation describing “Explanation for Off-Label Use” does not equal (code = “T95016”/ displayName = “VICH Label Use”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Explanation for Off-Label Use” must equal (code = “T95016” / displayName = “VICH Label Use”); otherwise reject ICSR.

Step-by-Step Guide Section: 3.2.5

Field Description: Max length is 12 characters; integer

Report Type: AE Only, AE + PP

OID:

codeSystem = 2.16.840.1.113883.13.51

code = single integer code value from list. Refer to [Appendix A.30-List of Explanation for Off-Label Use – Coding System](#)

Cardinality:

If “Use According to Label” equals ‘False’ then:

[B.2.5 Use According to Label] 0..1 [B.2.5.1 Explanation for Off-Label Use]

Data element is optional; must enter ‘NI’ to represent null/no response

If Use According to Label equals ‘True’ then:

[B.2.5 Use According to Label] 0..0 [B.2.5.1 Explanation for Off-Label Use]

Data element is optional; must enter null flavor “NI” to represent null/no response

GL-42 Section B.2.6.5 Office of Regulatory Affairs (ORA) District Field Office Reported**Requirement ID:** N37**Definition:**

The data element “ORA District Field Office Reported” is a field that contains the FDA ORA District Field office in the region where the Product Problem AER was reported to.

Business Rule:

CVM_GL-42_XXX

If the value of “ORA District Field Office Reported” is blank then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain either an acceptable null flavor or valid value for “ORA District Field Office Reported”; otherwise reject ICSR.

CVM_GL-42_152

If the value of the data element “Type of Submission” equals ‘3 Day Field Alert’ and the value of “ORA District Field Office Reported” is null then reject ICSR.

Error: Reject ICSR*Comment:* When “Type of Submission” equals ‘3 Day Field Alert’, “ORA District Field Office Reported” data element is required; otherwise reject ICSR.

CVM_GL-42_153.3

If the code system for the observation describing “ORA District Field Office Reported” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR*Comment:* The code system for the observation describing “ORA District Field Office Reported” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR.

CVM_GL-42_153.4

If the code and displayName for the observation describing “ORA District Field Office Reported” does not equal (code = “T95019”/ displayName = ‘ORA District Field Office Reported’), then reject ICSR.

Error: Reject ICSR*Comment:* The code and displayName for the observation describing “ORA District Field Office Reported” must equal (code = “T95019”/ displayName = ‘ORA District Field Office Reported’); otherwise reject ICSR.

CVM_GL-42_153

If the data element “ORA District Field Office Reported” does not reference the correct list of values ([Appendix A.28–List of ORA District Field Offices](#) – OID = “2.16.840.1.113883.3.153”) then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must reference the correct vocabulary ([Appendix A.28–List of ORA District Field Offices](#)) for “ORA District Field Office Reported”; otherwise reject ICSR.

CVM_GL-42_153.1

If the value of the data element “ORA District Field Office Reported” is not found in the referenced list of values [Appendix A.28–List of ORA District Field Offices](#)) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “ORA District Field Office Reported”; otherwise reject ICSR

CVM_GL-42_153.2

If the value for the “ORA District Field Office Reported” displayName does not match the code value for “ORA District Field Office Reported” then reject ICSR.

Error: Reject ICSR

Comment: The value for the “ORA District Field Office Reported” displayName must match the appropriate code value for “ORA District Field Office Reported”; otherwise reject ICSR.

Step-by-Step Guide Section: 3.2.6.5

Field Description:

Max length is 15 characters for the code and 80 characters for the code descriptions; single choice code list

Report Type: PP Only, AE + PP

OID:

codeSystem = National Cancer Institute Thesaurus

code = single code value from list. Refer to [Appendix A.28–List of ORA District Field Offices](#)

Cardinality:

When “Type of Submission” = ‘3 Day Field Alert’:

[B.2.1 Registered or Brand Name] 1..1 [B.2.6.5 ORA District Field Office]

Data element is mandatory

When “Type of Submission” does not equal ‘3 Day Field Alert’:

[B.2.1 Registered or Brand Name] 0..1 [B.2.6.5 ORA District Field Office]

Data element is optional; must enter “NI” to represent null/no response

GL-42 SECTION B.3 ADVERSE EVENT DATA

GL-42 Section B.3.1 Narrative of AE/PP

Requirement ID: 14

Definition:

The data element “Narrative of AE/PP” is a field that contains textual description of various parts of the AER. The primary purpose of this field is to capture narrative sequences of adverse and/or product problems. It is also used to capture descriptive information related to “Supplemental Documents” embedded within the ICSR.

Business Rule:

CVM_GL-42_129

If the “Narrative of AE/PP” is blank or null then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Narrative of the AE/PP”; otherwise reject ICSR.

Step-by-Step Guide Section: 3.3.1

Field Description:

Max length is 20,000 characters; open ended text

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[B.3 Adverse Event Data] 1..1 [B.3.1 Narrative of AE/PP]

Data element is mandatory – Use of Null value not allowed

GL-42 Section B.3.2 Adverse Clinical Manifestations (Adverse Event Reaction Term Name and Code)

Requirement ID: 92, 92.1

Definition:

The data element “Adverse Clinical Manifestations” is a field that contains the adverse clinical manifestations for the AER.

Business Rule:

CVM_GL-42_130

If the value of all instances of “Adverse Clinical Manifestations” is null or blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for at least one “Adverse Clinical Manifestations”; otherwise reject ICSR.

CVM_GL-42_131.3

If the code system for the observation describing “Adverse Clinical Manifestations” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Adverse Clinical Manifestations” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR.

CVM_GL-42_131.4

If the code and displayName for the observation describing “Adverse Clinical Manifestations” does not equal (code = "T95020"/ displayName = “Reaction”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Adverse Clinical Manifestations” must equal (code = "T95020"/ displayName = “Reaction”); otherwise reject ICSR.

CVM_GL-42_131

If the data element “Adverse Clinical Manifestations” does not reference the correct list of values (OID = 2.16.840.1.113883.13.40) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must reference the correct vocabulary ([Appendix A.21–VEDDRA Vocabulary](#)) for “Adverse Clinical Manifestations”; otherwise reject ICSR.

CVM_GL-42_131.1

If the value of the data element “Adverse Clinical Manifestations” is not found in the referenced list of values ([Appendix A.21–VEDDRA Vocabulary](#)) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Adverse Clinical Manifestations”; otherwise reject ICSR.

CVM_GL-42_131.2

If the value for the “Adverse Clinical Manifestations” displayName does not match the code value for the “Adverse Clinical Manifestations” then reject ICSR.

Error: Reject ICSR

Comment: The value for the “Adverse Clinical Manifestations” displayName must match the appropriate code value for “Adverse Clinical Manifestations”; otherwise the ICSR will be rejected.

Step-by-Step Guide Section: 3.3.2

Field Description:

Max length is 15 characters for the code and 250 characters for the description (displayName); multiple choice code list

Report Type: AE Only, AE + PP

OID:

codeSystem = 2.16.840.1.113883.13.40

code = single code value from list.

Refer to the EMEA website: <http://www.emea.europa.eu/home.htm>; Guidance Notes on the Use of VeDDRA Terminology for Reporting Adverse Events in Animals

Cardinality:

[B.3 Adverse Event Data] 1..* [B.3.2 Adverse Clinical Manifestations]

Data element is mandatory – Null value is NOT allowed except in the case of a “Product Problem Report Only” being submitted.

GL-42 Section B.3.2.1 Number of Animals Associated With Each Clinical Manifestation

Requirement ID: NEW

Definition:

The data element “Number of Animals Associated with Each Clinical Manifestation” is a field that contains the number of animals associated with each clinical manifestation.

Business Rule:

CVM_GL-42_XXX

If the value for the data element “Number of Animals Associated with Each Clinical Manifestation” is blank, then reject ICSR.

Error: Reject ICSR

Comment: The “Number of Animals Associated with Each Clinical Manifestation” must contain a valid value; otherwise reject ICSR.

CVM_GL-42_XXX

If the value for the data element “Number of Animals Associated with Each Clinical Manifestation” is zero, then reject ICSR.

Error: Reject ICSR

Comment: The “Number of Animals Associated with Each Clinical Manifestation” must contain a valid (non-zero) value; otherwise reject ICSR.

CVM_GL-42_XXX

If the value for the data element “Number of Animals Associated with Each Clinical Manifestation” is greater than the “Number of Animals Affected”, then reject ICSR.

Error: Reject ICSR

Comment: The “Number of Animals Associated with Each Clinical Manifestation” must contain a valid (non-zero) value that is not greater than the total “Number of Animals Affected”; otherwise reject ICSR.

CVM_GL-42_XXX (internal use only)

If the value for the data element “Number of Animals Associated with Each Clinical Manifestation” is null, then CVM shall populate each instance of the “Number of Animals Associated with Each Clinical Manifestation” with the “Number of Animals Affected”.

Comment: N/A

Step-by-Step Guide Section: 2.7.2

Field Description:

Report Type: AE Only, AE + PP

Cardinality:

[B.3.2 Adverse Clinical Manifestations] 0..1 [B.3.2.1 Number of Animals Associated with Each Clinical Manifestation]

Data element is optional; Use of null flavor is not allowed; Insert zero into data element

GL-42 Section B.3.3 Date of Onset of AE

Requirement ID: 960

Definition:

The data element “Date of Onset of AE” is a field that contains the date of the onset of the adverse event.

Business Rule:

CVM_GL-42_132

If the value for the data element “Date of Onset of AE” is null or blank then reject the ICSR.

Error: Reject ICSR

Comment: The “Date of Onset of AE” must contain a valid value; otherwise reject ICSR.

CVM_GL-42_122

If the date format for the “Date of Onset of AE” is not a complete valid date (in the format of YYYYMMDD HHMMSS.UUUU, where HHMMSS.UUUU are optional), then reject ICSR.

Error: Reject ICSR

Comment: The “Date of Onset of AE” must be a valid date; otherwise reject ICSR. ****NOTE:** HHMMSS.UUUU represents hours, minutes, seconds and fraction of seconds**

CVM_GL-42_122.1

If the value of the “Date of Onset of AE” is not less than or equal to the transmission date then reject ICSR.

Error: Reject ICSR

Comment: The “Date of Onset of AE” must be less than or equal to the transmission date; otherwise reject ICSR.

CVM_GL-42_122.2

If the value of the month for “Date of Onset of AE” is not a valid calendar year month (01-12), then reject ICSR.

Error: Reject ICSR

Comment: The “Date of Onset of AE” must be a valid date; otherwise reject ICSR.

CVM_GL-42_122.3

If the value of the day for “Date of Onset of AE” is not a valid day for the specified month, then reject ICSR.

Error: Reject ICSR

Comment: The “Date of Onset of AE” must be a valid date; otherwise reject ICSR.

Step-by-Step Guide Section: 3.3.3

Field Description:

Max length 19 characters; date

Report Type: AE Only, AE + PP

Cardinality:

[B.3 Adverse Event Data] 1..1 [B.3.3 Date of Onset of AE]

Data element is mandatory – Use of Null value not allowed

GL-42 Section B.3.4 Length of Time Between Exposure to VMP and Onset of AE**Requirement ID:** 119**Definition:**

The data element “Length of Time Between Exposure to VMP and Onset of AE” is a field that contains the time interval between exposure to the VMP and the onset of the AE.

Business Rule:

CVM_GL-42_134

If the data element “Length of Time Between Exposure to VMP and Onset of AE” does not reference the correct list of values ([APPENDIX A.2 – List of Length of Time Between Exposure and Onset of AE](#)– OID = National Cancer Institute Thesaurus) then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must reference the correct vocabulary for “Length of Time Between Exposure to VMP and Onset of AE”; otherwise reject ICSR.

CVM_GL-42_134.1

If the value of the data element “Length of Time Between Exposure to VMP and Onset of AE” is not found in the referenced list of values ([APPENDIX A.2 – List of Length of Time Between Exposure and Onset of AE](#)) then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain a valid value for “Length of Time Between Exposure to VMP and Onset of AE”; otherwise reject ICSR.

CVM_GL-42_134.2

If the “Length of Time Between Exposure to VMP and Onset of AE” field displayName does not match the code value for “Length of Time Between Exposure to VMP and Onset of AE” then reject ICSR.

Error: Reject ICSR*Comment:* The value for the “Length of Time Between Exposure to VMP and Onset of AE” displayName must match the appropriate code value for “Length of Time Between Exposure to VMP and Onset of AE”; otherwise reject ICSR.

CVM_GL-42_134.3

If the code system for the observation describing “Length of Time Between Exposure to VMP and Onset of AE” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR*Comment:* The code system for the observation describing “Length of Time Between Exposure to VMP and Onset of AE” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR.

CVM_GL-42_134.4

If the code and displayName for the observation describing “Length of Time Between Exposure to VMP and Onset of AE” does not equal (code = “T95021” / displayName = “Length of Time Between Exposure to VMP on Onset of AE”), then reject ICSR.

Error: Reject ICSR*Comment:* The code and displayName for the observation describing “Length of Time Between Exposure to VMP and Onset of AE” must equal (code = “T95021” / displayName = “Length of Time Between Exposure to VMP and Onset of AE”); otherwise reject ICSR.

Step-by-Step Guide Section: 3.3.4

Field Description:

Max length is 15 characters for the code and 80 characters for the description; single choice code list

Report Type: AE Only, AE + PP

OID:

codeSystem = National Cancer Institute Thesaurus

code = single code value from list. Refer to [APPENDIX A.2 –List of Length of Time Between Exposure and Onset of AE](#)

Cardinality:

[B.3 Adverse Event Data] 0..1 [B.3.4 Length of Time Between Exposure to VMP and Onset of AE]

Data element is optional; must enter the “NI” null flavor

GL-42 Section B.3.5.1 AE Duration

Requirement ID: 118

Definition:

The data element “AE Duration” is a field that contains a numeric value representing the duration of the AE.

Business Rule:

CVM_GL-42_XXX

If the value for the data element “AE Duration” is blank then reject the ICSR.

Error: Reject ICSR

Comment: The “AE Duration” must contain a valid value or an acceptable null flavor; otherwise reject ICSR.

CVM_GL-42_055

If the value of the data element “AE Duration” is not a numeric value then reject ICSR.

Error: Reject ICSR

Comment: The value for “AE Duration” must be numeric only; otherwise reject ICSR.

CVM_GL-42_056

If the value of the data element “AE Duration” is not null and the value of the data element “AE Duration Time Units” is null then reject ICSR.

Error: Reject ICSR

Comment: If “AE Duration” is valued, then “AE Duration Time Units” is required; otherwise reject ICSR.

Step-by-Step Guide Section: 3.3.5

Field Description:

Max length shall be restricted to 12 total characters. Numeric value. Representation nnnnnnn.nnnn

Report Type: AE Only, AE + PP

Cardinality:

[B.3 Adverse Event Data] 0..1 [B.3.5.1 Duration]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.3.5.1.1 AE Duration Time Units**Requirement ID:** 118.1**Definition:**

The data element “AE Duration Time Units” is a field that contains the time unit associated with the duration of the AE.

Business Rule:

CVM_GL-42_057

If the value for “AE Duration Time Units” is not null and the value of the data element “AE Duration” is null then reject ICSR.

Error: Reject ICSR*Comment:* If “AE Duration Time Units” is valued, then “AE Duration” is required; otherwise reject ICSR.

CVM_GL-42_058

If the data element “AE Duration Time Units” does not reference the correct list of values ([Appendix A.13–List of Time Units](#)) then reject the ICSR.

Error: Reject ICSR*Comment:* The ICSR must reference the correct vocabulary for “AE Duration Time Units”; otherwise reject ICSR.

CVM_GL-42_058.1

If the value of the data element “AE Duration Time Units” is not found in the referenced list of values ([Appendix A.13–List of Time Units](#)) then reject the ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain a valid value for “AE Duration Time Units”; otherwise reject ICSR.**Step-by-Step Guide Section:** 3.3.5**Field Description:**

Max length is 15 characters for the code and 80 characters for the code description; single choice code list

Report Type: AE Only, AE + PP**OID:** None, Refer to [Appendix A.13–List of Time Units](#)**Cardinality:**

If “AE Duration” is null:

[B.3.5.1 AE Duration] 0..0 [B.3.5.1.1 Duration Time Unit]

Data element is optional; must enter “NI” to represent null/no response if valid value for “AE Duration” is not provided

If AE Duration is not null:

[B.3.5.1 AE Duration] 1..1 [B.3.5.1.1 Duration Time Unit]

Data element is mandatory – Use of Null value not allowed

GL-42 Section B.3.6 Serious AE

Requirement ID: 12.2

Definition:

The data element “Serious AE” is a field that identifies a serious AE.

Business Rule:

CVM_GL-42_135

If the value of the data element “Serious AE” is null or blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Serious AE” (must not be null or blank); otherwise reject ICSR.

CVM_GL-42_136

If the code system for the observation describing “Serious AE” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Serious AE” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR

CVM_GL-42_136.1

If the code and displayName for the observation describing “Serious AE” does not equal (code = T95022/ displayName = “Serious AE”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Serious AE” must equal (code = T95022/ displayName = “Serious AE”); otherwise reject ICSR.

Step-by-Step Guide Section: 3.3.6

Field Description:

Max length is 5 characters; Boolean

Report Type: AE Only, AE + PP

Cardinality:

[B.3 Adverse Event Data] 1..1[B.3.6 Serious AE]

Data element is mandatory – Null value is NOT allowed.

GL-42 Section B.3.7 Treatment of AE**Requirement ID:** 14.2**Definition:**

The data element “Treatment of AE” is a field that contains a coded value and description for information pertaining to the treatment of the AE.

Business Rule:

CVM_GL-42_XXX

If the value of the data element “Treatment of AE” is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either an acceptable null flavor (‘NI’) or valid value (True / False) for “Treatment of AE”; otherwise reject ICSR.

CVM_GL-42_XXX

If the code system for the observation describing “Treatment of AE” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Treatment of AE” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR

CVM_GL-42_XXX

If the code and displayName for the observation describing “Treatment of AE” does not equal (code = T95023/ displayName = “Treatment of AE”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Treatment of AE” must equal (code = T95023/ displayName = “Treatment of AE”); otherwise reject ICSR.

Step-by-Step Guide Section: 3.3.7**Field Description:**

Max length is 5 characters; Boolean

Report Type: AE Only, AE + PP

Cardinality:

[B.3 Adverse Event Data] 0..1 [B.3.7 Treatment of AE]

Data element is optional; Reference Appendix A.31—Boolean Information Table to select the proper null flavor response

GL-42 SECTION B.3.8 OUTCOMES TO DATE**GL-42 Section B.3.8.1 Ongoing****Requirement ID:** 1704**Definition:**

The data element “Ongoing” is a field that indicates the number of animals with an outcome that the AE is still ongoing.

Business Rule:

CVM_GL-42_XXX

If the value of the data element “Ongoing” is blank then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain either an acceptable null flavor or valid value for “Ongoing”; otherwise reject ICSR.

CVM_GL-42_137

If the value of the data element “Ongoing” is not an integer then reject ICSR.

Error: Reject ICSR*Comment:* The value for “Ongoing” must be an integer only; otherwise reject ICSR.

CVM_GL-42_XXX

If the code system for the observation describing “Ongoing” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR*Comment:* The code system for the observation describing “Ongoing” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR

CVM_GL-42_XXX

If the code and displayName for the observation describing “Ongoing” does not equal (code = “C53279” / displayName = “Ongoing”), then reject ICSR.

Error: Reject ICSR*Comment:* The code and displayName for the observation describing “Ongoing” must equal (code = “C53279” / displayName = “Ongoing”); otherwise reject ICSR.**Step-by-Step Guide Section:** 3.3.8**Field Description:**

Max length is 12 characters; integer

Report Type: AE Only, AE + PP**Cardinality:**

[B.3.8 Outcome to Date] 0..1 [B.3.8.1 Ongoing]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.3.8.2 Recovered/Normal

Requirement ID: 1705

Definition:

The data element "Recovered/Normal" is a field that indicates the number of animals with an outcome of that the animal(s) have recovered and are normal.

Business Rule:

CVM_GL-42_XXX

If the value of the data element "Recovered/Normal" is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either an acceptable null flavor or valid value for "Recovered/Normal"; otherwise reject ICSR.

CVM_GL-42_138

If the value of the data element "Recovered/Normal" is not an integer then reject ICSR.

Error: Reject ICSR

Comment: The value for "Recovered/Normal" must be an integer only; otherwise reject ICSR.

CVM_GL-42_XXX

If the code system for the observation describing "Recovered/Normal" does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing "Recovered/Normal" must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR

CVM_GL-42_XXX

If the code and displayName for the observation describing "Recovered/Normal" does not equal (code = "C82467" / displayName = "Recovered/Normal"), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing "Recovered/Normal" must equal (code = "C82467" / displayName = "Recovered/Normal"); otherwise reject ICSR.

Step-by-Step Guide Section: 3.3.8

Field Description:

Max length is 12 characters; integer

Report Type: AE Only, AE + PP

Cardinality:

[B.3.8 Outcome to Date] 0..1 [B.3.8.2 Recovered/Normal]

Data element is optional; must enter "NI" to represent null/no response

GL-42 Section B.3.8.3 Recovered with Sequela

Requirement ID: 1706

Definition:

The data element “Recovered with Sequela” is a field that indicates the number of animals with an outcome of that the animal(s) have recovered with Sequela.

Business Rule:

CVM_GL-42_XXX

If the value of the data element “Recovered with Sequela” is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either an acceptable null flavor or valid value for “Recovered with Sequela”; otherwise reject ICSR.

CVM_GL-42_139

If the value of the data element “Recovered with Sequela” is not an integer then reject ICSR.

Error: Reject ICSR

Comment: The value for “Recovered with Sequela” must be an integer only; otherwise reject ICSR.

CVM_GL-42_XXX

If the code system for the observation describing “Recovered with Sequela” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Recovered with Sequela” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR

CVM_GL-42_XXX

If the code and displayName for the observation describing “Recovered with Sequela” does not equal (code = C49495" / displayName = “Recovered with Sequela”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Recovered with Sequela” must equal (code = C49495" / displayName = “Recovered with Sequela”); otherwise reject ICSR.

Step-by-Step Guide Section: 3.3.8

Field Description:

Max length is 12 characters; integer

Report Type: AE Only, AE + PP

Cardinality:

[B.3.8 Outcome to Date] 0..1 [B.3.8.3 Recovered with Sequela]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.3.8.4 Died

Requirement ID: 1707

Definition:

The data element “Died” is a field that indicates the number of animals with an outcome of which is that the animal(s) has died.

Business Rule:

CVM_GL-42_XXX

If the value of the data element “Died” is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either an acceptable null flavor or valid value for “Died”; otherwise reject ICSR.

CVM_GL-42_140

If the value of the data element “Died” is not an integer then reject ICSR.

Error: Reject ICSR

Comment: The value for “Died” must be an integer only; otherwise reject ICSR.

CVM_GL-42_XXX

If the code system for the observation describing “Died” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Died” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR

CVM_GL-42_XXX

If the code and displayName for the observation describing “Died” does not equal (code = "C28554"/ displayName = “Died”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Died” must equal (code = "C28554"/ displayName = “Died”); otherwise reject ICSR.

Step-by-Step Guide Section: 3.3.8

Field Description:

Max length is 12 characters; integer

Report Type: AE Only, AE + PP

Cardinality:

[B.3.8 Outcome to Date] 0..1 [B.3.8.4 Died]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.3.8.5 Euthanized

Requirement ID: 1708

Definition:

The data element “Euthanized” is a field that indicates the number of animals with an outcome which is that the animal(s) was euthanized.

Business Rule:

CVM_GL-42_XXX

If the value of the data element “Euthanized” is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either an acceptable null flavor or valid value for “Euthanized”; otherwise reject ICSR.

CVM_G42_141

If the value of the data element “Euthanized” is not an integer then reject ICSR.

Error: Reject ICSR

Comment: The value for “Euthanized” must be an integer only; otherwise reject ICSR.

CVM_GL-42_XXX

If the code system for the observation describing “Euthanized” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Euthanized” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR

CVM_GL-42_XXX

If the code and displayName for the observation describing “Euthanized” does not equal (code = "C21115" / displayName = “Euthanized”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing Euthanized must equal (code = "C21115" / displayName = “Euthanized”); otherwise reject ICSR.

Step-by-Step Guide Section: 3.3.8

Field Description:

Max length is 12 characters; integer

Report Type: AE Only, AE + PP

Cardinality:

[B.3.8 Outcome to Date] 0..1 [B.3.8.5 Euthanized]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.3.8.6 Outcome Unknown

Requirement ID: 1709

Definition:

The data element “Outcome Unknown” is a field that indicates the number of animals with an outcome of which is that the AE is unknown.

Business Rule:

CVM_GL-42_XXX

If the value of the data element “Outcome Unknown” is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either an acceptable null flavor or valid value for “Outcome Unknown”; otherwise reject ICSR.

CVM_GL-42_142

If the value of the data element “Outcome Unknown” is not an integer then reject ICSR.

Error: Reject ICSR

Comment: The value for “Outcome Unknown” must be an integer only; otherwise reject ICSR.

CVM_GL-42_XXX

If the code system for the observation describing “Outcome Unknown” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Outcome Unknown” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR

CVM_GL-42_XXX

If the code and displayName for the observation describing “Outcome Unknown” does not equal (code = “C17998” / displayName = “Outcome Unknown”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Outcome Unknown” must equal (code = “C17998” / displayName = “Outcome Unknown”); otherwise reject ICSR.

Step-by-Step Guide Section: 3.3.8

Field Description:

Max length is 12 characters; integer

Report Type: AE Only, AE + PP

Cardinality:

[B.3.8 Outcome to Date] 0..1 [B.3.8.6 Outcome Unknown]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.3.9 Previous Exposure to the VMP

Requirement ID: 2024.1

Definition:

The data element “Previous Exposure to the VMP” is a field that contains information on a previous exposure to the VMP.

Business Rule:

CVM_GL-42_XXX

If the value of the data element “Previous Exposure to the VMP” is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either an acceptable null flavor or a valid value (True / False) for “Previous Exposure to the VMP”; otherwise reject ICSR.

CVM_GL-42_144

If the code system for the observation describing “Previous Exposure to the VMP” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Previous Exposure to the VMP” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR

CVM_GL-42_144.1

If the code and displayName for the observation describing “Previous Exposure to the VMP” does not equal (code = "T95024" / displayName = “Previous Exposure to the VMP”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Previous Exposure to the VMP” must equal (code = "T95024" / displayName = “Previous Exposure to the VMP”); otherwise reject ICSR.

Step-by-Step Guide Section: 3.3.9

Field Description:

Max length is 5 characters; Boolean

Report Type: AE Only, AE + PP

Cardinality:

[B.3 Adverse Event Data] 0..1 [B.3.9 Previous Exposure to the VMP]

Boolean Data Element is optional; Use of null value is governed by the Boolean Information Table for this specific element

GL-42 Section B.3.10 Previous AE to the VMP

Requirement ID: 2025.1

Definition:

The data element “Previous AE to the VMP” is a field that contains information relating to a previous adverse event related to the VMP

Business Rule:

CVM_GL-42_XXX

If the value of the data element “Previous AE to the VMP” is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either an acceptable null flavor (‘NI’) or valid value (True / False) for “Previous AE to the VMP”; otherwise reject ICSR.

CVM_GL-42_145

If the code system for the observation describing “Previous AE to the VMP” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Previous AE to the VMP” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR

CVM_GL-42_145.1

If the code and displayName for the observation describing “Previous AE to the VMP” does not equal (code = "T95025" / displayName = “Previous AE to the VMP”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Previous AE to the VMP” must equal (code = "T95025" / displayName = “Previous AE to the VMP”); otherwise reject ICSR.

Step-by-Step Guide Section: 3.3.10

Field Description:

Max length is 5 characters; Boolean

Report Type: AE Only, AE + PP

Cardinality:

[B.3 Adverse Event Data] 0..1 [B.3.10 Previous AE to the VMP]

Data element is optional; refer to Appendix A.31 – Boolean Information Table to select the appropriate null/no response value

GL-42 SECTION B.4 DECHALLENGE – RECHALLENGE INFORMATION**GL-42 Section B.4.1 Did AE Abate After Stopping the VMP****Requirement ID:** 2026**Definition:**

The data element “Did AE Abate After Stopping the VMP” is a field that contains information relating to whether the AE abated after stopping the VMP.

Business Rule:

CVM_GL-42_XXX

If the value of the data element “Did AE Abate After Stopping the VMP” is blank then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain either an acceptable null flavor (‘NI’) or valid value (True / False) for “Did AE Abate After Stopping the VMP”; otherwise reject ICSR.

CVM_GL-42_146

If the code system for the observation describing “Did AE Abate After Stopping the VMP” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR*Comment:* The code system for the observation describing “Did AE Abate After Stopping the VMP” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR

CVM_GL-42_146.1

If the code and displayName for the observation describing “Did AE Abate After Stopping the VMP” does not equal (code = "T95026" / displayName = “Did AE Abate After Stopping the VMP”), then reject ICSR.

Error: Reject ICSR*Comment:* The code and displayName for the observation describing “Did AE Abate After Stopping the VMP” must equal (code = "T95026" / displayName = “Did AE Abate After Stopping the VMP”); otherwise reject ICSR.**Step-by-Step Guide Section:** 3.4.1**Field Description:**

Max length is 5 characters; Boolean

Report Type: AE Only, AE + PP**Cardinality:**

[B.4 Dechallenge-Rechallenge Information] 0..1[B.4.1 Did AE Abate After Stopping the VMP]

Data element is optional; refer to Appendix A.31 – Boolean Information Table to select the appropriate null/no response value

GL-42 Section B.4.2 Did AE Reappear after Re-introduction of the VMP

Requirement ID: 2027

Definition:

The data element “Did AE Reappear After Re-introduction of the VMP” is a field that contains information relating to whether the AE reappear after restarting the VMP.

Business Rule:

CVM_GL-42_XXX

If the value of the data element “Did AE Reappear After Re-introduction of the VMP” is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either an acceptable null flavor or a valid value (True / False) for “Did AE Reappear After Re-introduction of the VMP”; otherwise reject ICSR.

CVM_GL-42_147

If the code system for the observation describing “Did AE Reappear After Re-introduction of the VMP” does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR

Comment: The code system for the observation describing “Did AE Reappear After Re-introduction of the VMP” must equal (OID = National Cancer Institute Thesaurus), otherwise reject ICSR

CVM_GL-42_147.1

If the code and displayName for the observation describing “Did AE Reappear After Re-introduction of the VMP” does not equal (code = “T95027” / displayName = “Did AE Reappear After Re-introduction of the VMP”), then reject ICSR.

Error: Reject ICSR

Comment: The code and displayName for the observation describing “Did AE Reappear After Re-introduction of the VMP” must equal (code = “T95027” / displayName = “Did AE Reappear After Re-introduction of the VMP”); otherwise reject ICSR.

Step-by-Step Guide Section: 3.4.2

Field Description:

Max length is 5 characters; Boolean

Report Type: AE Only, AE + PP

Cardinality:

[B.4 Dechallenge-Rechallenge Information] 0..1 [B.4.2 Did AE Reappear After Re-introduction of the VMP]

Boolean Data Element is optional; Use of null value is governed by the Boolean Information Table for this specific element

GL-42 SECTION B.5 ASSESSMENT OF AE**GL-42 Section B.5.1 Attending Veterinarian's Assessment****Requirement ID:** 2019**Definition:**

The data element "Attending Veterinarian's Assessment" is a field that contains the attending veterinarian's assessment of the AE.

Business Rule:

CVM_GL-42_147

If the code system for the observation describing "Attending Veterinarian's Assessment" does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR*Comment:* The code system for the observation describing "Attending Veterinarian's Assessment" must equal (OID = National Cancer Institute Thesaurus); otherwise reject ICSR.

CVM_GL-42_147.2

If the code system for the assignedEntity describing "Attending Veterinarian's Assessment" does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR*Comment:* The code system for the assignedEntity describing "Attending Veterinarian's Assessment" must equal (OID = National Cancer Institute Thesaurus); otherwise reject ICSR.

CVM_GL-42_147.3

If the code and displayName for the assignedEntity describing "Attending Veterinarian's Assessment" do not equal (code = "C82490" / displayName = "Veterinarian"), then reject ICSR.

Error: Reject ICSR*Comment:* The code and displayName for the assignedEntity describing the "Attending Veterinarian's Assessment" must equal (code = "C82490" / displayName = "Veterinarian"); otherwise reject ICSR.

CVM_GL-42_147.4

If the code system for the value describing "Attending Veterinarian's Assessment" does not equal (OID = National Cancer Institute Thesaurus), then reject ICSR.

Error: Reject ICSR*Comment:* The code system for the value describing "Attending Veterinarian's Assessment" must equal (OID = National Cancer Institute Thesaurus); otherwise reject ICSR.

CVM_GL-42_147.5

If the code and displayName for the value describing "Attending Veterinarian's Assessment" is not found in ([Appendix A.27-List of Attending Veterinarian's Causality Assessment](#)), then reject ICSR.

Error: Reject ICSR*Comment:* The code and displayName for the observation describing "Attending Veterinarian's Assessment" is not found in the referenced list of values ([Appendix A.27-List of Attending Veterinarian's Causality Assessment](#)); otherwise reject ICSR.**Step-by-Step Guide Section:** 3.5

Field Description:

Max length is 15 characters for the code and 80 characters for the code description; single choice code list

Report Type: AE Only, AE + PP

OID:

codeSystem = National Cancer Institute Thesaurus

code = single code value from list. Refer to [Appendix A.27–List of Attending Veterinarian’s Causality Assessment](#)

Cardinality:

[B.5 Assessment of AE] 0..1 [B.5.1 Attending Veterinarian’s Assessment]

Data element is optional; either select the best value from the vocabulary; or enter “NI” to represent null/no response

GL-42 SECTION B.6 SUPPLEMENTAL DOCUMENTS

GL-42 Section B.6.1 Supplemental Document Filename

Requirement ID: N51

Definition:

The data element “Supplemental Document Filename” is a field that contains the filename of the supplemental document.

Business Rule:

CVM_GL-42_XXX

If the value of the data element “Supplemental Document Filename” is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either an acceptable null flavor or value for “Supplemental Document Filename”; otherwise reject ICSR.

CVM_GL-42_XXX

If the data element “Supplemental Document Data” is not null and “Supplemental Document Filename” is null then reject ICSR.

Error: Reject ICSR

Comment: If a “Supplemental Document” is provided, then the user must provide a valid “Supplemental Document Filename”; otherwise reject ICSR.

CVM_GL-42_XXX

The “Supplemental Document Filename” element must be a properly defined filename. The filename must follow the standard filename conventions of a file title followed by a period followed by a valid file extension. Valid file extensions are defined in the *Electronic Transmission Implementation Specifications [Step By Step]* document “Supplemental Documents” Section 2.10 in *Table 2-2 Accepted Supplemental Document Kinds*.

Error: Reject ICSR

Comment: If a “Supplemental Document Data” element is provided, then the user must provide a valid “Supplemental Document Filename”; otherwise reject ICSR.

Step-by-Step Guide Section: 3.6.1

Length:

Max length is 256; open ended text

Report Type: AE Only, PP Only, AE + PP

Cardinality:

When “Supplemental Document Data” is present:

[B.6 Supplemental Documents] 1..1 [B.6.1 Supplemental Document Filename]

Data element is Mandatory-Use of null value not allowed

When “Supplemental Document Data” is not present:

[B.6 Supplemental Documents] 0..1 [B.6.1 Supplemental Document Filename]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.6.2 Supplemental Document Description

Requirement ID: N52

Definition:

The data element relating information to “Supplemental Document Description” is contained in the “Narrative” element field (See Section B.3.1 for description of text field.).

There are no cardinality or null flavor rules for this element.

GL-42 Section B.6.3 Supplemental Document Type

Requirement ID: N53

Definition:

The data element “Supplemental Document Type” is a field that contains the type of the supplemental document provided.

Business Rule:

CVM_GL-42_XXX

If the value of the data element “Supplemental Document Type” is blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain either an acceptable null flavor or valid value for “Supplemental Document Type”; otherwise reject ICSR.

CVM_GL-42_XXX

If the data element “Supplemental Document” is not null and “Supplemental Document Type” is null then reject ICSR.

Error: Reject ICSR

Comment: If a “Supplemental Document” is provided, then the user must provide a valid “Supplemental Document Type”; otherwise reject ICSR.

CVM_GL-42_XXX

If the data element “Supplemental Document Type” does not reference the correct list of values ([Appendix A.32–List of Attached Document Type](#)) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must use the correct vocabulary for “Supplemental Document Type”; otherwise reject ICSR.

CVM_GL-42_XXX

If the value of the data element “Supplemental Document Type” is not found in the referenced list of values ([Appendix A.32–List of Attached Document Type](#)) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Supplemental Document Type”; otherwise reject ICSR.

CVM_GL-42_XXX

If the “Supplemental Document Type” field displayName does not match the displayName for the “Supplemental Document Type” the reject ICSR.

Error: Reject ICSR

Comment: The value for “Supplemental Document Type” displayName must match the appropriate displayName for “Supplemental Document Type”; otherwise reject ICSR.

Step-by-Step Guide Section: 3.6.3

Length:

Max length is 15 characters for the code and 80 characters for the code description; single choice code list

Report Type: AE Only, PP Only, AE + PP

OID:

codeSystem = National Cancer Institute Thesaurus

code = single code value from list. Refer to [Appendix A.32–List of Attached Document Type](#)

Cardinality:

When “Supplemental Document Data” is present:

[B.6 Supplemental Documents] 1..1 [B.6.3 Supplemental Document Type]

Data element is Mandatory-Use of null value not allowed

When “Supplemental Document Data” is not present:

[B.6 Supplemental Documents] 0..1 [B.6.3 Supplemental Document Type]

Data element is optional; must enter “NI” to represent null/no response

GL-42 Section B.6.4 Supplemental Document Data

Requirement ID: ???

Definition:

The data element “Supplemental Document Data” is a field that contains the provided supplemental document.

Business Rule:

CVM_GL-42_XXX

If the value of the data element “Supplemental Document Type” is not blank and the “Supplemental Document Data” is blank or null then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Supplemental Document Data”; otherwise reject ICSR.

Step-by-Step Guide Section: 3.6.4

Length:

Max length is 10,000,000 Bytes

Report Type: AE Only, PP Only, AE + PP

OID:

[B.6 Supplemental Documents] 0..1 [B.6.1 Supplemental Document Data]

B.7 US SPECIFIC ONLY SECTION

Section B.7.1 Report Identifier

Requirement ID: ????

Definition:

The data element “Report Identifier” indicates the application / file number for the specified ICSR. This information is located in the Transmission Wrapper.

Business Rule:

CVM_GL-42_XXX

If the value of the data element “Report Identifier” is null or blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Report Identifier”; otherwise reject ICSR.

CVM_GL-42_XXX

If the first character in the “Report Identifier” (in transmission wrapper) is not one of the following letters (A, I, J, N or D), then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Report Identifier”; otherwise reject ICSR.

CVM_GL-42_XXX

If the last 6 characters in the “Report Identifier” (in transmission wrapper) are not numeric, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Report Identifier”; otherwise reject ICSR.

Step-by-Step Guide Section: 3.7.1

Length:

Max length is 7 characters; alpha-numeric

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[B.7 US Specific Only] 1..1 [B.7.1 Report Identifier]

Data element is mandatory – Use of Null value not allowed

Section B.7.2 Domestic Vs Foreign Report Category**Requirement ID:** N76**Definition:**

The “Domestic vs. Foreign Report Category” indicates if the specified ICSR is a domestic or foreign report. This information is located in the Transmission Wrapper.

Business Rule:

CVM_GL-42_XXX

If the value of the data element “Domestic vs. Foreign Report Category” is null or blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Domestic vs. Foreign Report Category”; otherwise reject ICSR.

CVM_GL-42_XXX

If the data element “Domestic vs. Foreign Report Category” does not reference the correct list of values ([Appendix A.5-List of Domestic and Foreign Report Categories](#)) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must use the correct vocabulary for “Domestic vs. Foreign Report Category”; otherwise reject ICSR.

CVM_GL-42_XXX

If the value of the data element “Domestic vs. Foreign Report Category” is not found in the referenced list of values ([Appendix A.5-List of Domestic and Foreign Report Categories](#)) then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Domestic vs. Foreign Report Category”; otherwise reject ICSR.

CVM_GL-42_XXX

If the “Domestic vs. Foreign Report Category” field displayName does not match the code value for the “Domestic vs. Foreign Report Category” then reject ICSR.

Error: Reject ICSR

Comment: The value for “Domestic vs. Foreign Report Category” displayName must match the appropriate code value for “Domestic vs. Foreign Report Category”; otherwise reject ICSR.

Step-by-Step Guide Section: 3.7.2**Length:**

Max length is 15 characters for the code and 80 characters for the code description; single choice code list

Report Type: AE Only, PP Only, AE + PP

OID:

codeSystem = National Cancer Institute Thesaurus

code = single code value from list. Refer to [Appendix A.5-List of Domestic and Foreign Report Categories](#)

Cardinality:[B.7 US Specific Only] 1..1 [B.7.2 Domestic vs. Foreign Report Category]

Data element is mandatory – Reporters must select the best value from the vocabulary; Use of Null value is not allowed

Section B.7.3 US Pharmacovigilance Contact Person for the MAH**Requirement ID: ????****Definition:**

The “US Pharmacovigilance Contact Person for the MAH” consists of the following information and represents the person within the US MAH that acts on behalf of and is responsible for the AE / PP / AE+PP report: Contact Person (first, last name), ~~Street Address, City, State, Postal Code, Country~~, Telephone, ~~Fax~~ and Email. This information is located in the Transmission Wrapper.

Business Rule:~~CVM_GL-42_XXX~~

If the value of any of the “US Pharmacovigilance Contact Person for the MAH” information (Contact Person, ~~Street Address, City, State, Postal Code, Country~~, Telephone, ~~Fax~~ and Email) is null or blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain valid values for “US Pharmacovigilance Contact Person for the MAH” information; otherwise reject ICSR.

~~CVM_GL_42_XXX~~

If the “US Pharmacovigilance Contact Person for the MAH” Country equals ‘USA’ and the US Pharmacovigilance Contact Person for the “MAH Telephone” number or Fax number is not formatted numeric (with the exception of an ‘x’ for extensions), then reject ICSR.

Error: Reject ICSR

Comment: The “US Pharmacovigilance Contact Person for the MAH” Telephone number and Fax number must be formatted numeric if the US Pharmacovigilance Contact Person for the “MAH Country” equals ‘USA’.

~~CVM_GL_42_XXX~~

If the “US Pharmacovigilance Contact Person for the MAH” Country does not equal ‘USA’ and the telephone number or fax number is formatted numeric, then reject ICSR.

Error: Reject ICSR

Comment: The “US Pharmacovigilance Contact Person for the MAH” Telephone number and Fax number must be open ended text if the US Pharmacovigilance Contact Person for the “MAH Country” does not equal ‘USA’.

~~CVM_GL_42_XXX~~

If the value of the “US Pharmacovigilance Contact Person for the MAH” Telephone number or Fax number contains spaces, brackets or hyphens then reject ICSR.

Error: Reject ICSR

Comment: The “US Pharmacovigilance Contact Person for the MAH” Telephone number or Fax number must not contain spaces, brackets or hyphens, otherwise reject ICSR.

~~CVM_GL_42_XXX~~

If the “US Pharmacovigilance Contact Person for the MAH” Telephone number or Fax number contains more than 5 digits prefixed by an ‘x’ (for extensions) then reject ICSR.

Error: Reject ICSR

Comment: The “US Pharmacovigilance Contact Person for the MAH” Telephone number or Fax number must not contain more than 5 digits prefixed by an ‘x’, otherwise reject ICSR.

CVM_GL_42_XXX

If the “US Pharmacovigilance Contact Person for the MAH” Country equals ‘USA’, and the “US Pharmacovigilance Contact Person for the MAH” State field value is not found in the referenced list of values ([Appendix A.35–List of US States & Territory Codes](#)), then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value “US Pharmacovigilance Contact Person for the MAH” State (if US Pharmacovigilance Contact Person for the “MAH Country” = ‘USA’); otherwise, the ICSR will be rejected.

CVM_GL_42_070

If the value of the “US Pharmacovigilance Contact Person” for the MAH Mail/ZIP Code” is blank or contains a null flavor, then reject the ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a “US Pharmacovigilance Contact Person for the MAH Mail/ZIP Code”; otherwise, the ICSR will be rejected.

CVM_GL_42_XXX

If the value of the “US Pharmacovigilance Contact Person for the MAH” Country is not found in the referenced list of values (ISO 3166 3 Character Country Code), then the ICSR is rejected.

Error: Reject ICSR

Comment: The “US Pharmacovigilance Contact Person for the MAH” Country Code will be validated against the ISO 3166 three character country code.

Step-by-Step Guide Section: 3.7.3**Length:**

Max length for US Pharmacovigilance Contact Person for the MAH First Name = 35 characters

Max length for US Pharmacovigilance Contact Person for the MAH Last Name = 50 characters

Max length for US Pharmacovigilance Contact Person for the MAH Street Address = 100 characters

Max length for US Pharmacovigilance Contact Person for the MAH City = 35 characters

Max length for US Pharmacovigilance Contact Person for the MAH State = 2 characters for the code

Max length for US Pharmacovigilance Contact Person for the MAH Mail / Zip Code = 15 characters

Max length for US Pharmacovigilance Contact Person for the MAH Country = 3 characters for the code

Max length for US Pharmacovigilance Contact Person for the MAH Telephone = 18 characters

Max length for US Pharmacovigilance Contact Person for the MAH Fax = 18 characters

Max length for US Pharmacovigilance Contact Person for the MAH Email = 100 characters

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[B.7 US Specific Only] 1..1 [US Pharmacovigilance Contact Person for the MAH]

Data element(s) are mandatory—Use of null value not allowed

2.3 Data Elements Not Contained Within GL-42 Specification

The following data elements are not within the VICH GL-42 data standard. These are FDA CVM's extensions to the GL-42 standard.

Individual Case Safety Report Number

Requirement ID: N54

Definition:

The data element "Individual Case Safety Report Number" is a field that contains the uniquely assigned ICSR identifier for the specified report. This number is assigned by the MAH or another RA.

Business Rule:

The form and format of this element is up to the creator of the ICSR. The ICSR creator must ensure that this identifier is unique and will not be re-used on another unique ICSR.

CVM_GL-42_XXX

If the value of "Individual Case Safety Report Number" is null or blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for "Individual Case Safety Report Number"; otherwise reject ICSR.

Step-by-Step Guide Section: 4.1

Field Description:

Max length is 60 characters; open ended text (string)

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[A.4.4.1 Type of Submission] 1..1 [A 4.4.3 Individual Case Safety Report Number]

Data element is mandatory – Use of Null value not allowed

Message Sender Identifier

Requirement ID: 38.2, 38.4, 46, 48, 51, 69

Definition:

The “Message Sender Identifier” consists of the following information and represents the sender who is responsible for any corresponding communications regarding the transmission batch: Contact Person (first, last name), Street Address, City, State, Postal Code, Country, Telephone, Fax and Email. This information is located in the Transmission Wrapper.

Business Rule:

~~CVM_GL-42_XXX~~

If the value of any of the “Message Sender Identifier” information (Contact Person, Street Address, City, State, Postal Code, Country, Telephone, Fax or Email) is null or blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain valid values for “Message Sender Identifier” information; otherwise reject ICSR.

~~CVM_GL_42_XXX~~

If the “Message Sender Identifier” Country equals ‘USA’ and the “Message Sender Identifier” Telephone number or Fax number is not formatted numeric (with the exception of an ‘x’ for extensions), then reject ICSR.

Error: Reject ICSR

Comment: The “Message Sender Identifier” Telephone number and Fax number must be formatted numeric if the “Message Sender Identifier” Country equals ‘USA’.

~~CVM_GL_42_XXX~~

If the “Message Sender Identifier” Country does not equal ‘USA’ and the telephone number or fax number is formatted numeric, then reject ICSR.

Error: Reject ICSR

Comment: The “Message Sender Identifier” Telephone number and Fax number must be open ended text if the “Message Sender Identifier” Country does not equal ‘USA’.

~~CVM_GL_42_XXX~~

If the value of the “Message Sender Identifier” Telephone number or Fax number contains spaces, brackets or hyphens then reject ICSR.

Error: Reject ICSR

Comment: The “Message Sender Identifier” Telephone number or Fax number must not contain spaces, brackets or hyphens otherwise reject ICSR.

~~CVM_GL_42_XXX~~

If the “Message Sender Identifier” Telephone number or Fax number contains more than 5 digits prefixed by an ‘x’ (for extensions) then reject ICSR.

Error: Reject ICSR

Comment: The “Message Sender Identifier” Telephone number or Fax number must not contain more than 5 digits prefixed by an ‘x’, otherwise reject ICSR.

~~CVM_GL_42_XXX~~

If the “Message Sender Identifier” Country equals ‘USA’, and the “Message Sender Identifier” State field value is not found in the referenced list of values (~~[Appendix A.35- List of US States & Territory Codes](#)~~), then reject ICSR.

~~Error: Reject ICSR~~

~~Comment: The ICSR must contain a valid value “Message Sender Identifier” State (if “Message Sender Identifier” Country = ‘USA’); otherwise, the ICSR will be rejected.~~

~~CVM_GL_42_XXX~~

If the value of the “Message Sender Identifier” Country is not found in the referenced list of values (~~[APPENDIX A.36-LIST OF ISO 3-DIGIT COUNTRY CODES](#)~~), then the ICSR is rejected.

~~Error: Reject ICSR~~

~~Comment: The “Message Sender Identifier” Country Code will be validated against the [APPENDIX A.36 LIST OF ISO 3-DIGIT COUNTRY CODES](#).~~

Step-by-Step Guide Section: 3.7.3

Length:

Max length for Message Sender Identifier First Name = 35 characters

Max length for Message Sender Identifier Last Name = 50 characters

Max length for Message Sender Identifier Street Address = 100 characters

Max length for Message Sender Identifier City = 35 characters

Max length for Message Sender Identifier State = 2 characters for the code

Max length for Message Sender Identifier Mail/ Zip Code = 15 characters

Max length for Message Sender Identifier Country = 3 characters for the code

Max length for Message Sender Identifier Telephone = 18 characters

Max length for Message Sender Identifier Fax = 18 characters

Max length for Message Sender Identifier Email = 100 characters

Report Type: AE Only, PP Only, AE + PP

OID:

eodeSystem = none

eode = single code value from list. Refer to ~~[Appendix A.35- List of US States & Territory Codes](#)~~

eodeSystem = none

eode = single code value from list. Refer to ~~[APPENDIX A.36 LIST OF ISO 3-DIGIT COUNTRY CODES](#)~~

Cardinality:

[B.7 US Specific Only] 1..1 [Message Sender Identifier]

Data elements are mandatory – Use of Null value not allowed

Profile Identifier Code**Requirement ID:** ???**Definition:**

The “Profile Identifier Code” indicates the type of report contained in the message. This information is located in the Transmission Wrapper.

Business Rule:

CVM_GL-42_XXX

If the value of "Profile Identifier Code" is null or blank then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain a valid value for "Profile Identifier Code"; otherwise reject ICSR.

CVM_GL-42_XXX

If the "Profile Identifier Code" does not reference the correct list of values ([Appendix A.26--Profile Identifier Vocabulary](#) – OID = [2.16.840.1.113883.3.156](#)) then reject ICSR.

Error: Reject ICSR*Comment:* The ICSR must use the correct vocabulary for “Profile Identifier Code”; otherwise reject ICSR.

CVM_GL-42_XXX

If the value of “Profile Identifier Code” is not found in the referenced list of values ([Appendix A.26--Profile Identifier Vocabulary](#)) then reject the ICSR.

Error: Reject ICSR*Comment:* The ICSR must contain a valid value for “Profile Identifier Code” otherwise reject ICSR.**Step-by-Step Guide Section:** 4.2**Length:** Max length is 60 characters**Report Type:** AE Only, PP Only, AE + PP**OID:**codeSystem = [2.16.840.1.113883.3.156](#)code = single code value from list. Refer to [Appendix A.26 -- Profile Identifier Vocabulary](#)**Cardinality:**

[ICSR Wrapper Information] 1..1 [Profile Identifier Code]

Data element is mandatory – Use of Null value not allowed

Batch Identifier

Requirement ID: ????

Definition:

The “Batch Identifier” identifies the reports in the batch as a whole message. This information is located in the Transmission Wrapper. The form and format of the “Batch Identifier” is up to the creator of the Batch. The “Batch Identifier” should be unique from one transmission to another.

Business Rule:

CVM_GL-42_XXX

If the value of “Batch Identifier” is null or blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Batch Identifier”; otherwise reject ICSR.

CVM_GL-42_XXX

If the “Batch Identifier” does not reference the correct “Submitting Organization OID”, then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must use a valid “Submitting Organization OID”; otherwise reject ICSR.

Step-by-Step Guide Section: 4.2

Length:

Max length is 60 characters; alpha-numeric

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[ICSR Wrapper Information] 1..1 [Batch Identifier]

Data element is mandatory – Use of Null value not allowed

Message Date

Requirement ID: ????

Definition:

The “Message Date” indicates the date the batch report is created. This information is located in the Transmission Wrapper.

Business Rule:

CVM_GL-42_XXX

If the value of “Message Date” is null or blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Message Date”; otherwise reject ICSR.

CVM_GL-42_XXX

If the date format for the “Message Date” is not a complete valid date (in the format of YYYYMMDD HHMMSS.UUUU, where HHMMSS.UUUU are optional), then reject ICSR.

Error: Reject ICSR

Comment: The “Message Date” must be a valid date; otherwise reject ICSR. ****NOTE: HHMMSS.UUUU represents hours, minutes, seconds and fraction of seconds****

CVM_GL-42_XXX

If the value of the “Message Date” is not less than the system date then reject ICSR.

Error: Reject ICSR

Comment: The “Message Date” must be less than the system date; otherwise reject ICSR.

CVM_GL-42_XXX

If the value of the month for “Message Date” is not a valid calendar year month (01-12), then reject ICSR.

Error: Reject ICSR

Comment: The “Message Date” must be a valid date; otherwise reject ICSR.

CVM_GL-42_XXX

If the value of the day for “Message Date” is not a valid day for the specified month, then reject ICSR.

Error: Reject ICSR

Comment: The “Message Date” must be a valid date; otherwise reject ICSR.

Step-by-Step Guide Section: 4.4

Length:

Max length is 19 characters; date

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[ICSR Wrapper Information] 1..1 [Message Date]

Data element is mandatory – Use of Null value not allowed

Message Version Number and Release Number

Requirement ID: ????

Definition:

The “Message Version Number and Release Date” indicates the HL7 Message Version and Release Number on which this batch report is based. This information is located in the Transmission Wrapper.

Business Rule:

CVM_GL-42_XXX

If the value of “Message Version Number and Release Date” is null or blank then reject ICSR.

Error: Reject ICSR

Comment: The ICSR must contain a valid value for “Message Version Number and Release Date”; otherwise reject ICSR.

CVM_GL-42_XXX

If the “Message Version Number and Release Date” is less than ‘V3200909’, then reject ICSR.

Error: Reject ICSR

Comment: The “Message Version Number and Release Date” must be greater than ‘V3200909’; otherwise reject ICSR.

Step-by-Step Guide Section: 4.5

Length:

Max length is 15 characters; alpha-numeric

Report Type: AE Only, PP Only, AE + PP

Cardinality:

[ICSR Wrapper Information] 1..1 [Message Version Number and Release Date]

Data element is mandatory – Use of Null value not allowed