Annex-1 Field Level Specification

Version Control

This document is DRAFT version 2.7, dated 19-Aug-2021. Revisions to data fields will be identified in the 'Version' column of the main tables.

Date	Version	Significant Changes
22-Feb-2021	2.0	First release, outstanding items include: VICH clarification, Acknowledgement message – see * for items that remain pending clarification
26-Apr-2021	2.1	B.2.1.2 Guidance Note corrected: YYYYYYYY is 8 character RA code. Added Acknowledgement message details
18-May-2021	2.2	Clarification of VICH items. Inconsistencies between GL35 and GL42 are being addressed and, generally, GL42 will be updated to align to GL35. Simply, when GL42 datatype differs from GL35, this document is correct, 'Version Published' is noted as V 2.0 and "GL42 expected to be updated" may be inferred.
19-May-2021	2.3	A.1 and A.2 VICH Clarification, either A.1 or A.2 and not both. Also, typos in Xpaths that mistakenly contained "\"s have been corrected.
20-May-2021	2.4	Clarified use of CR and CA in ACK message
1-Jun-2021	2.5	Confirmed use of CR and CA in ACK message and included list of sample files that accompany this annex
10-Aug-2021	2.6	Corrected decimal number format to state 'characters' and not digits e.g. Numeric, max 12 digits, max 3 d.p. becomes Numeric, max 12 characters including a decimal point , max 3 d.p.
20-Aug-2021	2.7	Corrected B.1.4.1.1 and B.1.4.2.1 - OID for Breeds is 2.16.840.1.113883.4.342, also provided Example 5 for multiple breeds. Corrected B.2.1.2. Registration Identifier i.e. use 'ZZZ' for Centrally Authorised Products
20-Oct-2021	3.0	Second release

Purpose of this Annex

This annex consolidates 'the documents', i.e. GL35, GL42 and Step by Step Guide, and identifies the essential data fields that are part of the domain model, together with datatypes and, to help ensure properly supplied data, a summary of the main business rules. Please refer to the detailed Business Rules for up to date definition of all business rules.

.xml snippets have been provided for clarity. Various tools have been used, resulting in differences in the order of XML attributes within an element. As with all XML, the order of attributes is not significant, the two examples, below, are equivalent:

```
<code code="T95003" codeSystem="2.16.840.1.113883.13.206" displayName="Type of Submission"/>
<code codeSystem="2.16.840.1.113883.13.206" code="T95003" displayName="Type of Submission"/>
```

Validation of AER data

Validation includes technical validation, pre-validation and business rule validation.

Technical and pre-validation processing ensures that the VICH batch message complies with the VICH schema prior to conversion into the domain model. Technical and pre-validation errors may prevent the data being stored, for example:

- Syntax checking, such as verification of pairs of "" and <>
- Removal of leading and trailing whitespaces
- Presence of essential, non-VICH elements such as <responseModeCode />, <interactionId />, <processingCode />,
- Elements in the correct order, for example A.1 is in a <SubjectOf> node at the end of the message, and not first as may be suggested by GL35 and GL42
- All mandatory elements, including XML locator Codes, must be present – missing mandatory elements may generate an ERROR
- Cardinality is correct and repeating values are as expected
- Size and structure of all datatypes is verified to be as specified in the table below. Dates, numbers and text must be valid and supplied in the correct format, correct length etc
- All numbers are expected to be positive values
- Telecom element values are prefixed with 'TEL:', 'FAX:' and or 'MAILTO:'

Business Rules validation determines if an AER is valid or invalid and helps to ensure that the data content describes an AER as accurately and unambiguously as possible. Please refer to the Business Rules document for all rules, some rules are repeated in the main body of this document, for example:

- All 'Country' elements must be valid ISO Country codes
- Coded elements must have values that exist in the GL30 controlled term lists
- Consistency of 'pairs' of fields for example, 'Nullification reason' is only expected when the report is if type 'Nullification', if gender of the animal is 'Male' then the Female Physiological status must be Not Applicable or No Information (a Male animal should not be reported as Pregnant Lactating)

Validation has the following outcomes:

BATCH ERROR = Batch Error, the whole Batch is rejected, for example, if Date of Batch Creation or Date of Message Creation is an invalid date or a future date
VALID MESSAGE = the message is valid, AER is stored and there is confirmation in the ACK .xml
ERROR = AER Error, the message is not valid, however, the AER is stored with errors and there is an ERROR message in the ACK.xml
WARNING = AER Warning, the message is valid, the AER is stored and there is a WARNING message in the ACK.xml

EMA processing will generate an ACK message for each VICH batch message received. Please refer to the Acknowledgements section at the end of this document.

Repeating Groups

Some of the data elements may be repeated, for example, multiple VMPs per report, multiple Lot Numbers per VMP, as illustrated below:

Batch	AER	Section	Repeating Groups within a section	
Batch Wrapper – one per Batch	AE Data– many per Batch	Transmission Wrapper – one per AER		
		Admin and Summary Data – one per AER		
		Animal Data – one per AER	Breed	
		Product Data – many per AER	VMP – many VMP per AER	**Repeating Groups within a VMP**
				RA Assessment – many per VMP
				Route of Exposure – many per VMP
				Active Ingredient – many per VMP
				Lot Number and Expiry Date – many per VMP
		AE Data– one per AER	Reaction – many Adverse Clinical Manifestations per AER	
			Linked Reports – many per AER	
			Supplemental Documents – many per AER	

Identifiers

Some data fields have a similar data format and are easily confused, they are listed below to explain the meaning of these critical data fields.

GL35 Ref	GL35 Name	EMA Name (may differ from GL42 name)	Example	Mandatory /Optional /Conditional	Additional Comments
A.4.1	Unique Adverse Event Report Identification Number	AER Identifier	NLD-ACMEGACO-7819	**Mandatory**	Text up to 60 characters uniquely identifies each adverse event. This means that, for example, initial and follow-up reports will have the same value for the AER Identifier. The first 3 letters are used to populate the internal data field 'country of occurrence'. A 2 letter country code is accepted for Follow-up AERs when the AER identifier uses the pre-VICH, DEG format
B.2.1.2	Registration Identifier	Registration Identifier (Product Registration Number)	USA-USXXYYAB-N98761	Conditional Guidance Note: Mandatory IF MAH's own VMP - if MAH does not know Identifier use "Cannot be determined" If the VMP is another MAH's product and no data use nullFlavor="NI"	Text up to 50 characters Centrally Authorised Products will use the letters 'ZZZ' for Country Code This statement differs from GL42
B.8.2.5	Report Identifier	Report Identifier	N141320	Optional, if no data use nullFlavor="NI"	Text up to 7 characters. Used by the Sender to identify and process information in their own IT systems
B.8.2.1.2	Message Number - Extension	Message Identifier	ACMEGACO-173771397952-NL2020_004773	**Mandatory**	Text up to 100 characters uniquely identifies each time a report is sent. This means that, for example, initial and follow-up reports will have different Message Identifiers (for the same AER Identifier).

Explaining Mandatory/Optional/Conditional

Not all data elements are required or applicable to every report. Data elements are described as Mandatory, Optional or Conditional as shown in the table below:

	Explanation	Example
Mandatory	This data field is required, a value is expected and nullFlavor="NI" is **not** a valid value	A.4.1 An AER must have an AER ID
Optional	This data field is not required and there is no obligation to supply a value. However, Optional data fields must still be present in the message and nullFlavor="NI" is used when there is no information or no wish to supply the information nullFlavor="NI" is always a valid value	A.4.4 Type of Information in Report Code may or may not be provided

Conditional	Some information is supplied as more than one data field. The presence of a value in one field may influence which related fields must or must not be populated.
	
	The related field is 'Conditional' and may be described as 'Mandatory IF' or 'Optional IF'.
	
	For 'Mandatory IF' data fields, sometimes nullFlavor="NI" is a valid value and sometimes it is not. Despite being described as Mandatory in the GL35 and GL42, these data fields are 'technically optional' because they will not always have a value.
	
	For 'Optional IF', there is no obligation to supply a value. However, the data fields must still be present in the message and nullFlavor="NI" is used when there is no information or no wish to supply the information. nullFlavor="NI" is always a valid value
	
	Guidance Note:
	Generally, the business rules that are applied to Conditional fields are for guidance and not always enforced.
		Example 1 – Mandatory IF
		A.4.4.1 Type of Submission (Mandatory) and related field A.4.4.2 Reason for Nullification Report (Conditional)
		IF A.4.4.1 Type of Submission = "Nullification" THEN
		    A.4.4.2 Reason for Nullification Report is **Mandatory** and there must be a value
		ELSE
		    A.4.4.2 Reason for Nullification Report is nullFlavor="NI" because there must not be a value
		B.1.9.1 Age precision code (Mandatory) and B.1.9.3 Maximum Age (Optional IF)
		Example 2 – Optional IF
		B.1.9.1 Age precision code (Mandatory) and related field B.1.9.3 Maximum Age (Conditional)
		IF B.1.9.1 Age precision code = 'Measured' or 'Estimated' THEN
		    B.1.9.3 Maximum Age is **Optional** and there may be a data value
		ELSE IF B.1.9.1 Age precision code = 'Unknown' THEN
		    B.1.9.3 Maximum Age is nullFlavor="NI" because there must not be a value

Explaining 'Unknown', 'Not Applicable' and 'No information'

All elements are expected to be provided, even when there is no information.

Specifying 'No Information' available

nullFlavor="NI" is not always a valid value, for example:

Data field is Mandatory and datatype is 'Code List'	A value is required and must be chosen from Controlled List
Data field is Mandatory open ended text	A value is required, free text value may be 'No information''
Data field is Mandatory numeric, date, boolean etc	A value is required

Specifying 'Unknown'

'Unknown' does not have the same meaning as 'No Information'. Unknown, NA, Other etc. are only valid values when they exist as a term in a Code List in GL30 or are specified as valid in GL42.

It is important to refer to the code lists and GL42 to understand the valid values, for example:

Female Physiological Status (OID 2.16.840.1.113883.13.49) has 'MIX' for Mixed, **C17998**' for Unknown and 'NA' for Not Applicable

Reproductive Status (OID 2.16.840.1.113883.13.199) has 'C25259' for Mixed and **C17998**' for Unknown but it does not allow Not Applicable

Gender (OID 2.16.840.1.113883.13.198) has 'C25259' for Mixed but it may only be used when the number of animals is more than 1

Route of Exposure (OID 2.16.840.1.113883.13.202) uses 'C38311' for Unknown even though most lists use '**C17998**' for Unknown

Units of Measurement (OID 2.16.840.1.113883.6.8) has both 'Unknown' and '**C17998**' as valid terms meaning Unknown

Some lists offer 'C17649' as a valid term for Other

	Datatype	Code List has term 'Unknown'	GL42 allows 'UNK'	How to specify 'Unknown'
Data field is Mandatory	Code List	Yes	No	Term 'Unknown'
Data field is Mandatory	Code List	No	Yes	nullFlavor="UNK"
Data field is Mandatory	Code List	No	No	A value is required and must be chosen from Controlled List
Data field is Optional	Code List	Yes	No	Term 'Unknown'
Data field is Optional	Code List	No	Yes	nullFlavor="UNK"
Data field is Optional	Code List	No	No	'Unknown' is not permitted and it is suggested to use nullFlavor="NI"
Data field is Mandatory	Open Ended Text	-	No	A value is required, free text value 'Unknown' is valid
Data field is Mandatory	Numeric, Integer, Date, Boolean	-	No	A value is required
Data field is Optional	Open Ended Text	-	No	Free text value 'Unknown' is valid
Data field is Optional	Numeric, Integer, Date, Boolean	-	No	nullFlavor="UNK" is not valid and it is suggested to use nullFlavor="NI"

Explaining Booleans

A data field that is described as a Boolean, i.e. has a value of true or false, may also be permitted to have other nullFlavor values, for example, B.3.9 Previous Exposure to VMP is True, False or Unknown.

If a data fields is permitted to have Boolean nullFlavor values, the values are listed alongside each data field in the main body of this document. When using a Boolean nullFlavor value, the Boolean data field value is null, as shown below:

	Boolean data field value	Boolean nullFlavor value
Boolean value 'Yes'	True	-
Boolean value 'No'	False	-
Boolean data field used for Not Applicable (refer to detailed Business Rules to see permitted values)	-	NA
Boolean data field allows Unknown (refer to detailed Business Rules to see permitted values)	-	UNK
For optional data fields, when there is no information, use 'NI'.	-	NI

Note: This guide does not prescribe the technical design or solution required for 'Booleans that have more values than true or false'.

Table of Contents

Data element description of VICH batch message

HL7 Batch wrapper and Transmission wrapper–B.8

B.8.1 elements occur once at the start of the batch.

B.8.2 elements may be repeated many times in a batch that has many reports. B.8.2 elements occur once at the start of each report. Each batch must contain at least one report else BATCH ERROR.

B.8.1 Batch wrapper

	Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
	143	B.8.1.1.1	Batch Number/Identifier - Identifier	ACMEGACO	**Mandatory**	Text up to 60 characters	**Pre-validation** 1) If mandatory elements are missing then **BATCH ERROR** 2) Text beyond the expected length will cause a **BATCH ERROR** **Business rules** Root and extension uniquely identify the batch.	Example <id root="ACMEGACO" extension="VICH_EU_Sample_AER"/>	/MCCI_IN200100UV01/id/@root	One per Batch	V 2.0
	144	B.8.1.1.2	Batch Number/Identifier - Name	VICH_EU_Sample_AER	**Mandatory**	Text up to 100 characters			/MCCI_IN200100UV01/id/@extension		

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published

145	B.8.1.2.1	Batch Sender - Organisation Identifier	ACMEGACO	Mandatory	Text up to 60 characters	**Pre-validation** 1) If mandatory elements are missing then **BATCH ERROR**	Example 1
							`<sender>`
							    `<device classCode="DEV" determinerCode="INSTANCE">`
							        `<id/>`
							        `<asAgent classCode="AGNT">`
							            `<representedOrganization classCode="ORG" determinerCode="INSTANCE">`
							                `<id root="ACMEGACO" extension="ACME Euro Chem B.V."/>`
							                `<notificationParty classCode="CON">`
							                    `<id/>`
							                    `<telecom value="TEL:+31205405800"/>`
							                    `<telecom value="FAX:+31205505800"/>`
							                    `<telecom value="MAILTO:info@acme.chem.bv"/>`
							                    `<contactPerson>`
							                        `<id/>`
							                        `<name>`
							                            `<prefix>Dr</prefix>`
							                            `<given>Jane</given>`
							                            `<family>Dorf</family>`
							                        `</name>`
							                    `</contactPerson>`
							                `</notificationParty>`
							            `</representedOrganization>`
							        `</asAgent>`
							    `</device>`
							`</sender>`
							
							Example 2 –only mandatory Batch Sender data, no Batch Sender – Name/Extension
							`<sender>`
							    `<device classCode="DEV" determinerCode="INSTANCE">`
							        `<id/>`
							        `<asAgent classCode="AGNT">`
							            `<representedOrganization classCode="ORG" determinerCode="INSTANCE">`
							                `<id root="ACMEGACO"/>`
							                `<notificationParty classCode="CON">`
							                    `<id/>`
							                    `<telecom nullFlavor="NI"/>`
							                    `<contactPerson>`
							                        `<id/>`
							                        `<name>`
							                            `<prefix nullFlavor="NI" />`
							                            `<given nullFlavor="NI"/>`
							                            `<family nullFlavor="NI"/>`
							                        `</name>`
							                    `</contactPerson>`
							                `</notificationParty>`
							            `</representedOrganization>`
							        `</asAgent>`
							    `</device>`
							`</sender>`
								/MCCI_IN200100UV01/sender/device/asAgent/representedOrganization/id/@root
								
								and for the other optional data elements
								
								/MCCI_IN200100UV01/sender/device/asAgent/representedOrganization/notificationParty
									One per Batch	V 2.0
										
										In GL35, B.8.1.2.1 Batch Sender - Organisation Identifier is referred to as Batch Sender - Root. Likewise, B.8.1.2.2. Batch Sender - Organisation Name Identifier is referred to as Batch Sender - Extension

146	B.8.1.2.2	Batch Sender - Organisation Name	ACME Euro Chem B.V.	Optional	Text up to 100 characters	2) Text beyond the expected length will cause a **BATCH ERROR**				
147	B.8.1.2.3	Batch Sender - Title	Dr	Optional, if no data use nullFlavor="NI"	Text up to 50 characters	3) Telecom elements have prefix TEL:, FAX: or MAILTO:, and if no prefix then **BATCH ERROR**				
148	B.8.1.2.4	Batch Sender - Last name	Dorf	Optional, if no data use nullFlavor="NI"	Text up to 50 characters	**Business rules** Batch Sender – Organisation Identifier/ Root and Batch Sender – Organisation Name/Extension uniquely identifies the sender as a registered Web Trader.				
149	B.8.1.2.5	Batch Sender - First name	Jane	Optional, if no data use nullFlavor="NI"	Text up to 50 characters					
150	B.8.1.2.6	Batch Sender - Telephone	+31205405800	Optional, if no data use nullFlavor="NI"	Text up to 20 characters **including prefix 'TEL:'**	<u>Note:</u> if contact information is not mandatory and no contact information provided, a single nullFlavor="NI" may be used instead of repeating the telecom element 3 times				
151	B.8.1.2.7	Batch Sender - Fax	+31205505800	Optional, if no data use nullFlavor="NI"	Text up to 20 characters **including prefix 'FAX:'**					
152	B.8.1.2.8	Batch Sender - e-mail	info@acme.chem.bv	Optional, if no data use nullFlavor="NI"	Text up to 100 characters **including prefix 'MAILTO:'**	<u>Note:</u> VICH format: • Batch sender- contact details outside `<contactPerson>` node • Message Sender - contact details within `<contactPerson>` node				

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published

153	B.8.1.3.1	Batch Receiver - Identifier	EVVETPROD	Mandatory	Text up to 60 characters	**Pre-validation** 1) If mandatory elements are missing then **BATCH ERROR** 2) Text beyond the expected length will cause a **BATCH ERROR** **Business rules** Identifier/root uniquely identifies the intended receiver	Example
							<receiver typeCode="RCV">
							    <device determinerCode="INSTANCE" classCode="DEV">
							        <id />
							        <asAgent classCode="AGNT">
							            <representedOrganization
							                determinerCode="INSTANCE" classCode="ORG">
							                <id root="EVVETPROD" extension="European Medicines" />
							            </representedOrganization>
							        </asAgent>
							    </device>
							</receiver>
							
							Example – No Batch Receiver –Name/Extension
							As above except for
							    <id root="EVVETPROD"/>
								/MCCI_IN200100UV01/receiver/device/asAgent/representedOrganization/id/@root	One per Batch	V 2.0

154	B.8.1.3.2	Batch Receiver - Name	European Medicines	Optional	Text up to 100 characters					
155	B.8.1.4	Date of Batch Creation	27-Jan 2020 at 6:44am	Mandatory	Date (YYYYMMDDHHMMSS+/-ZZZZ)	**Pre-validation** If missing or invalid date then **BATCH ERROR** <u>Note:</u> Refer to detailed business rules, for example, date must not be a future date	Example - batch created 27-Jan-2020 at 6:44 am UTC -5 (11:44 am UTC) <creationTime value="20200127064439-0500" />	/MCCI_IN200100UV01/creationTime/@value		V 2.0
156	B.8.1.5	VICH AER Version	VICHAER1.0.0	Mandatory	Text up to 15 characters	**Pre-validation** 1) If mandatory elements are missing then **BATCH ERROR** 2) Text beyond the expected length will cause an **ERROR** <u>Note:</u> EMA processing assumes that the value for this data field is 'VICHAER1.0.0'	Example <versionCode code="VICHAER1.0.0" />	/MCCI_IN200100UV01/versionCode/@code		V 2.2

B.8.2 Transmission wrapper for each AER

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
157	B.8.2.1.1	Message Sender - Identifier	ACMEGACO	Mandatory	Text up to 60 characters	**Pre-validation** 1) If mandatory elements are missing then **ERROR** 2) Text beyond the expected length will cause an **ERROR** **Business rules** 1) There must be at least one AER in a Batch else **ERROR** 2) Name/root and identifier/extension uniquely identifies the AER	Example `<id root="ACMEGACO" extension="ACMEGACO-173771397952-NL2020_004773" />`	/MCCI_IN200100UV01/PORR_IN049006UV/id/@root	Many AERs per Batch When there are multiple AERs in a batch, each AER is identified by its name/extension Each AER has a Message Identifier and a Message Sender together with a Message Receiver and Date of Message Creation	V 2.0
158	B.8.2.1.2	Message Identifier	ACMEGACO-173771397952-NL2020_004773	Mandatory	Text up to 100 characters		Example – Transmission Wrapper Message Number when there are two messages in a Batch `<id root="ACMEGACO" extension="ACMEGACO-173771397952-NL2020_004773" />` `<id root="ACMEGACO" extension="ACMEGACO-173771397952-NL2020_004774" />`			In GL35, B.8.2.1.1 Message Sender - Identifier is referred to as Message Number – Root. Likewise, B.8.2.1.2 Message Identifier is referred to as Message Number – Extension
159	B.8.2.2.1	Message Sender - Organisation Identifier	ACMEGACO	Optional, if no data use nullFlavor="NI"	Text up to 60 characters	**Pre-validation** 1) Text beyond the expected length will cause an **ERROR** 2) Telecom elements have prefix TEL:, FAX: or MAILTO:, if no prefix then **ERROR** Note: if no contact information provided, a single nullFlavor="NI" may be used instead of repeating the telecom element 3 times Note: VICH format: • Batch sender- contact details outside `<contactPerson>` node • Message Sender - contact details within `<contactPerson>` node	Example `<sender typeCode="SND">` `    <device classCode="DEV" determinerCode="INSTANCE">` `        <id/>` `        <asAgent classCode="AGNT">` `            <representedOrganization classCode="ORG" determinerCode="INSTANCE">` `                <id root="ACMEGACO" extension="ACME Euro Chem B.V." />` `                <notificationParty classCode="CON">` `                    <id/>` `                    <contactPerson>` `                        <id/>` `                        <name>` `                            <prefix>Dr</prefix>` `                            <given>Jane</given>` `                            <family>Dorf</family>` `                        </name>` `                        <telecom value="TEL:+31205405800"/>` `                        <telecom value="FAX:+31205505800"/>` `                        <telecom value="MAILTO:info@acme.chem.bv"/>` `                    </contactPerson>` `                </notificationParty>` `            </representedOrganization>` `        </asAgent>` `    </device>` `</sender>` Example –no Message Sender – Extension As above except for `    <id root="ACMEGACO"/>`	/MCCI_IN200100UV01/PORR_IN049006UV/sender/device/asAgent/representedOrganization/id/@root and for the other optional data elements /MCCI_IN200100UV01/PORR_IN049006UV/sender/device/asAgent/representedOrganization/notificationParty	Other elements, e.g. B.8.2.5 Report Identifier, are determined by the RA	V 2.0
160	B.8.2.2.2	Message Sender - Organisation Name	ACME Euro Chem B.V	Optional, and may not exist in the message	Text up to 100 characters					
161	B.8.2.2.3	Message Sender - Title	Dr	Optional, if no data use nullFlavor="NI"	Text up to 50 characters					
162	B.8.2.2.4	Message Sender - Last name	Jane	Optional, if no data use nullFlavor="NI"	Text up to 50 characters					
163	B.8.2.2.5	Message Sender - First name	Dorf	Optional, if no data use nullFlavor="NI"	Text up to 50 characters					
164	B.8.2.2.6	Message Sender - Telephone	+31205405800	Optional, if no data use nullFlavor="NI"	Text up to 20 characters **including prefix 'TEL:'**					
165	B.8.2.2.7	Message Sender - Fax	+31205505800	Optional, if no data use nullFlavor="NI"	Text up to 20 characters including **prefix 'FAX:'**					
166	B.8.2.2.8	Message Sender - e-mail	info@acme.chem.bv	Optional, if no data use nullFlavor="NI"	Text up to 100 characters **including prefix 'MAILTO:'**					
167	B.8.2.3.1	Message Receiver – Identifier	EVVETPROD	Mandatory	Text up to 60 characters	**Pre-validation** 1) If mandatory elements are missing then **ERROR** 2) Text beyond the expected length will cause an **ERROR**	Example `<receiver typeCode="RCV">` `    <device classCode="DEV" determinerCode="INSTANCE">` `        <id />` `        <asAgent classCode="AGNT">` `            <representedOrganization classCode="ORG" determinerCode="INSTANCE">` `                <id root="EVVETPROD" extension="European Medicines" />` `            </representedOrganization>` `        </asAgent>` `    </device>` `</receiver>`	/MCCI_IN200100UV01/PORR_IN049006UV/receiver/device/asAgent/representedOrganization/id/@root		V 2.0
168	B.8.2.4	Date of Message Creation	27-Jan 2020 at 6:44am	Mandatory	Date (YYYYMMDDHHMMSS+/-ZZZZ)	**Pre-validation** If missing or invalid date then **ERROR** Note: Refer to detailed business rules for example, date must not be a future date	Example - - message created 27-Jan-2020 at 6:44 am UTC -5 (11:44 am UTC) `<creationTime value="20200228064439-0500" />`	/MCCI_IN200100UV01/PORR_IN049006UV/creationTime/@value	One per AER	V 2.0

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
169	B.8.2.5	Report Identifier	N141320	Optional, if no data use nullFlavor="NI"	Text up to 7 characters	**Pre-validation** Text beyond the expected length will cause an **ERROR**	Example `<attentionLine>` `<keyWordText>Report Identifier</keyWordText>` `<value xsi:type="ST">N141320</value>` `</attentionLine>` Example – no report identifier `<attentionLine>` `<keyWordText>Report Identifier</keyWordText>` `<value xsi:type="ST" nullFlavor="NI" />` `</attentionLine>`	There are many attentionLine nodes, this element needs 'keyWordText' to be specified as 'Report Identifier' /MCCI_IN200100UV01/PORR_IN049006UV/attentionLine[keyWordText = 'Report Identifier']/value	One per AER	V 2.0
170	B.8.2.6	Domestic vs Foreign Report category	C62264	Optional, not expected for EEA report, for EEA reports use nullFlavor="NI"	Code List	**Business rules** Value expected is nullFlavor="NI". If there is a Domestic v Foreign value then the code must exist as a code as in 2.16.840.1.113883.13.212	Example 1 - EEA Reports – no report category `<attentionLine>` `<keyWordText>Domestic vs Foreign Report Category</keyWordText>` `<value xsi:type="SC" nullFlavor="NI" />` `</attentionLine>` Example 2 – an FDA Report `<attentionLine>` `<keyWordText>Domestic vs Foreign Report Category</keyWordText>` `<value xsi:type="SC" codeSystem="2.16.840.1.113883.13.212"` `displayName="Domestic" code="C62264" />` `</attentionLine>`	There are many attentionLine nodes, this element needs 'keyWordText' to be specified as 'Report Identifier' /MCCI_IN200100UV01/PORR_IN049006UV/attentionLine[keyWordText="Domestic vs Foreign Report Category"]/value/@code	One per AER	V 2.0
171	B.8.2.7	Profile Identifier		Optional, not required for EEA report, for EEA reports use nullFlavor="NI"	Text up to 60 characters	**Pre-validation** Text beyond the expected length will cause an **ERROR** Note: Any values supplied for this element are ignored	Example – no profile identifier `<profileId nullFlavor="NI"/>`	/MCCI_IN200100UV01/PORR_IN049006UV/profileId	One per AER	V 2.0

Admin and Summary data - A.1 to A.4

Each AER has Admin and Summary data

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1	A.1.1	RA Name	European Medicines Agency	Conditional
				
				Mandatory IF sender is RA
					Text up to 100 characters	**Pre-validation**
						1) XML Locator Code **T95009** is required. If no XML locator code then **ERROR**
						2) If mandatory elements are missing then **ERROR**
						3) Text beyond the expected length will cause an **ERROR**
						
						Business rules
						Country code must be a valid ISO country code else **ERROR**
						
						Note: GL35 implies that A.1 is mandatory. Please refer to Business Rules to see that A.1 is not mandatory when MAH is sending the report. However, follow up reports will have both A.1 and A.2.
						
						Note: USA and Canadian addresses are expected to use 2 character state code as in GL30. All other addresses require state/county/province name
						
						Note: The address shown is as provided in GL30 for illustration purposes only
							Example – RA is the Sender
							`<author typeCode="AUT">`
							`    <assignedEntity classCode="ASSIGNED">`
							`        <code code="T95009" codeSystem="2.16.840.1.113883.13.206" displayName="RA"/>`
							`        <addr use="WP">`
							`            <streetAddressLine>Domenico Scarlattilaan 6 </streetAddressLine>`
							`            <city>Amsterdam</city>`
							`            <state nullFlavor="NI"/>`
							`            <postalCode> Amsterdam </postalCode>`
							`            <country>NLD</country>`
							`        </addr>`
							`        <representedOrganization classCode="ORG" determinerCode="INSTANCE">`
							`            <name>European Medicines Agency</name>`
							`            <contactParty classCode="CON">`
							`                <telecom nullFlavor="NI"/>`
							`                <contactPerson classCode="PSN" determinerCode="INSTANCE">`
							`                    <name>`
							`                        <prefix nullFlavor="NI"/>`
							`                        <given nullFlavor="NI"/>`
							`                        <family nullFlavor="NI"/>`
							`                    </name>`
							`                </contactPerson>`
							`            </contactParty>`
							`        </representedOrganization>`
							`    </assignedEntity>`
							`</author>`
							
							Example –RA is not the Sender
							When the sender is not the RA, the sender is the MAH, please refer to GL35 Ref A.2.1 below
								RA and MAH details are in `<author>` node.
								
								Note the use of XML Locator Code 'T95009' to identify name and address of RA and 'T95001' to identify name and address of MAH.
								
								MCCI_IN200100UV01/PORR_IN049006UV /controlActProcess/subject/investigationE vent/subjectOf1/controlActEvent/author/ assignedEntity[code/@code="T95009"]/a ddr
								and
								MCCI_IN200100UV01/PORR_IN049006UV /controlActProcess/subject/investigationE vent/subjectOf1/controlActEvent/author/ assignedEntity[code/@code="T95009"]/r epresentedOrganization/name
									One per AER	V 2.3
										
										GL35 implies that a both RA and MAH are mandatory. An AER does not have both.

2	A.1.2	RA Street address	Domenico Scarlattilaan 6	Conditional Mandatory IF sender is RA	Text up to 100 characters					
3	A.1.3	RA City	Amsterdam	Conditional Mandatory IF sender is RA	Text up to 50 characters					
4	A.1.4	RA State/county		Optional, if no data use nullFlavor="NI"	Text up to 80 characters					
5	A.1.5	RA Postal/zip code	Amsterdam	Conditional Mandatory IF sender is RA	Text up to 35 characters					
6	A.1.6	RA Country code	NLD	Conditional Mandatory IF sender is RA	Code List					

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7	A.2.1.1	MAH Business Name	ACME Euro Chem B.V.	Conditional Mandatory IF sender is MAH	Text up to 100 characters	**Pre-validation** 1) XML Locator Code **T95001** is required. If no XML locator code then **ERROR** 2) If mandatory elements are missing then **ERROR** 3) Text beyond the expected length will cause an **ERROR** 4) Telecom elements have prefix TEL:, FAX: or MAILTO:, if no prefix then **ERROR** **Business rules** 1) Optional IF data is optional even when this is an MAH report. If there is no data then values must be nullFlavor="NI" else **ERROR** 2) Country code must be a valid ISO country code else **ERROR** Note: USA and Canadian addresses are expected to use 2 character state code as in GL30. Other addresses will supply the state/county/province name. Note: details of the person acting on behalf of the MAH are not required and if no contact information provided, a single nullFlavor="NI" may be used instead of repeating the telecom element 3 times	Example – AER is sent by MAH <author typeCode="AUT"> <assignedEntity classCode="ASSIGNED"> <code code="**T95001**" codeSystem="2.16.840.1.113883.13.206" displayName="MAH"/> <addr use="WP"> <streetAddressLine>Teleportboulevard 14000-1</streetAddressLine> <city>Amsterdam</city> <state>North Holland</state> <postalCode>2133 RA</postalCode> <country>NLD</country> </addr> <representedOrganization classCode="ORG" determinerCode="INSTANCE"> <name>ACME Euro Chem B.V.</name> <contactParty classCode="CON"> <telecom value="TEL:+31-6-1234-5678"/> <telecom value="FAX:+31-6-1234-8765"/> <telecom value="MAILTO:info@acmehealth.com"/> <contactPerson classCode="PSN" determinerCode="INSTANCE"> <name> <prefix>Dr</prefix> <given>Jane</given> <family>Dorf</family> </name> </contactPerson> </contactParty> </representedOrganization> </assignedEntity> </author> Example –MAH is not the Sender When the sender is not the MAH, the sender is the RA, please refer to GL35 Ref A.1.1 above	RA and MAH details are in <author> node. Note the use of XML Locator Code 'T95009' to identify name and address of RA and 'T95001' to identify name and address of MAH. MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf1/controlActEvent/author/assignedEntity[code/@code="T95001"]/addr and MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf1/controlActEvent/author/assignedEntity[code/@code="T95001"]/representedOrganization/name	One per AER	V 2.3 GL35 implies that a both RA and MAH are mandatory. An AER does not have both.
8	A.2.1.2	MAH Street address	Teleportboulevard 14000-1	Conditional Mandatory IF sender is MAH	Text up to 100 characters					
9	A.2.1.3	MAH City	Amsterdam	Conditional Mandatory IF sender is MAH	Text up to 50 characters					
10	A.2.1.4	MAH State/county	North Holland	Optional, if no data use nullFlavor="NI"	Text up to 80 characters					
11	A.2.1.5	MAH Postal/zip code	2133 RA	Conditional Mandatory IF sender is MAH	Text up to 35 characters					
12	A.2.1.6	MAH Country code	NLD	Conditional Mandatory IF sender is MAH	Code List					
13	A.2.2.1	MAH Title	Dr	Optional IF sender is MAH, else use nullFlavor="NI"	Text up to 50 characters					
14	A.2.2.2	Person Acting for MAH First name	Jane	Optional IF sender is MAH, else use nullFlavor="NI"	Text up to 50 characters					
15	A.2.2.3	Person Acting for MAH Last name	Dorf	Optional IF sender is MAH, else use nullFlavor="NI"	Text up to 50 characters					
16	A.2.2.4	Person Acting for MAH Telephone	+44-20-1234-5678	Optional IF sender is MAH, else use nullFlavor="NI"	Text up to 20 characters **including prefix 'TEL:'**					
17	A.2.2.5	Person Acting for MAH Fax	+44-20-1234-876	Optional IF sender is MAH, else use nullFlavor="NI"	Text up to 20 including **prefix 'FAX:'**					
18	A.2.2.6	Person Acting for MAH e-mail	john.doe@companypethealth.com	Optional IF sender is MAH, else use nullFlavor="NI"	Text up to 100 characters **including prefix 'MAILTO:'**					

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19	A.3.1.1	Primary Reporter Category code	C82470	**Mandatory**	Code List	**Pre-validation** 1)XML Locator Code **T95002** is required and Primary Reporter is `<priorityNumber value="1"/>` else **ERROR** 2) If mandatory elements are missing then **ERROR** 3) Text beyond the expected length will cause an **ERROR** 4) Telecom elements have prefix TEL:, FAX: or MAILTO:, if no prefix then **ERROR** **Business rule**s 1)Primary Reporter Category code must exist as a code as in GL30 2.16.840.1.113883.13.194 else **ERROR** 2) If Country code is not a valid ISO country code then **ERROR** Note: USA and Canadian addresses are expected to use 2 character state code as in GL30. Other addresses will supply the state/county/province name Note: Contact details of the primary reporter are optional and if no contact information is known a single nullFlavor="NI" may be used instead of repeating the telecom element 3 times	Example 1 – full details for a Primary Reporter `</outboundRelationship>` `<outboundRelationshiptypeCode="SPRT">` `<priorityNumber value="1"/>` `<relatedInvestigation classCode="INVSTG" moodCode="EVN">` `<code code="T95002" codeSystem="2.16.840.1.113883.13.206" displayName="Sourcereport"/>` `..` `..` `<participation typeCode="AUT">` `<assignedEntity classCode="ASSIGNED">` `<code code="C82470" codeSystem="2.16.840.1.113883.13.194" displayName="Veterinarian"/>` `<addr use="WP">` `<streetAddressLine>Meander</streetAddressLine>` `<city>Amsterdam</city>` `<state>North Holland</state>` `<postalCode>1185 WN</postalCode>` `<country>NLD</country>` `</addr>` `<telecom value="TEL:+31654363619"/>` `<telecom value="FAX:+31658363619"/>` `<telecom value="MAILTO:vet1@example.com"/>` `<assignedPerson classCode="PSN" determinerCode="INSTANCE">` `<name>` `<family>Peterson</family>` `<given>Glenn</given>` `</name>` `<asIdentifiedEntity classCode="IDENT">` `<assigningOrganization classCode="ORG" determinerCode="INSTANCE">` `<name>Prehistoric Pets Clinic</name>` `</assigningOrganization>` `</asIdentifiedEntity>` `</assignedPerson>` `</assignedEntity>` `</participation>` `</relatedInvestigation>` `</outboundRelationship>`	Primary reporter details are in `<addr>`, `<telecom>` and `<name>` nodes of assignedEntity. Note the use of XML Locator Code and priorityNumber value = "1" to differentiate between Primary and Other reporter. /MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/outboundRelationship[code/@value=1]/relatedInvestigation[code/@code="T95002"]/participation/assignedEntity	One per AER	V 2.0
20	A.3.1.2	Primary Reporter Last name	Peterson	**Mandatory, use WITHHELD to indicate that the reporter does not wish to be identified by name**	Text up to 50 characters					
21	A.3.1.3	Primary Reporter First name	Glenn	Optional, if no data use nullFlavor="NI"	Text up to 50 characters					
22	A.3.1.4	Primary Reporter Telephone	+31654363619	Optional, if no data use nullFlavor="NI"	Text up to 20 characters **including prefix 'TEL:'**					
23	A.3.1.5	Primary Reporter Fax	+31658363619	Optional, if no data use nullFlavor="NI"	Text up to 20 characters **including prefix 'FAX:'**					
24	A.3.1.6	Primary Reporter e-mail	vet1@example.com	Optional, if no data use nullFlavor="NI"	Text up to 100 characters **including prefix 'MAILTO:'**					
25	A.3.1.7	Primary Reporter Business Name	Prehistoric Pets Clinic	Optional, if no data use nullFlavor="NI"	Text up to 100 characters					
26	A.3.1.8	Primary Reporter Street address	Meander	Optional, if no data use nullFlavor="NI"	Text up to 100 characters					
27	A.3.1.9	Primary Reporter City	Amsterdam	Optional, if no data use nullFlavor="NI"	Text up to 50 characters					
28	A.3.1.10	Primary Reporter State/county code	North Holland	Optional, if no data use nullFlavor="NI"	Text up to 80 characters					
29	A.3.1.11	Primary Reporter Postal/zip code	1185 WN	Optional, if no data use nullFlavor="NI"	Text up to 35 characters					
30	A.3.1.12	Country code	NLD	**Mandatory**	Code List		Example 2 – partial snippet showing mandatory data only (note the single telecom nullFlavor value) `<assignedEntity classCode="ASSIGNED">` `<code code="C82470" codeSystem="2.16.840.1.113883.13.194" displayName="Veterinarian"/>` `<addr use="WP">` `<streetAddressLine nullFlavor="NI" />` `<city nullFlavor="NI" />` `<state nullFlavor="NI" />` `<postalCode nullFlavor="NI" />` `<country>NLD</country>` `</addr>` `<telecom nullFlavor="NI" />` `<assignedPerson determinerCode="INSTANCE" classCode="PSN">` `<name>` `<family>WITHHELD</family>` `<given nullFlavor="NI" />` `</name>` `<asIdentifiedEntity classCode="IDENT">` `<assigningOrganization determinerCode="INSTANCE" classCode="ORG">` `<name nullFlavor="NI" />` `</assigningOrganization>` `</asIdentifiedEntity>` `</assignedPerson>` `</assignedEntity>`			

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31	A.3.2.1	Other Reporter Category code	C53289	Conditional
				
				Mandatory IF any Other Reporter data is supplied
					Code List	**Pre-validation**
						1) XML Locator Code **T95002** is required and Other Reporter is `<priorityNumber value="2"/>` else **ERROR**
						2) Text beyond the expected length will cause an **ERROR**
						3) Telecom elements have prefix TEL:, FAX: or MAILTO:, if no prefix then **ERROR**
						
						Business rules
						1) All data for Other Reporter is optional. If there is any data in A.3.2.2 – A.3.3.12 then Other Reporter Category must exist as a code as in GL30 2.16.840.1.113883.13.194 else **ERROR**
						2) If Country code has a value then it must be a valid ISO country code then **ERROR**
						
						Note: USA and Canadian addresses are expected to use 2 character state code as in GL30. Other addresses will supply the state/county/province name
						
						Note: contact details of the other reporter are optional and if no contact information is known a single nullFlavor="NI" may be used instead of repeating the telecom element 3 times
						
						Note: Use WITHHELD for Other Reporter Last name if reporter prefers not send personal contact details
							Example1 –Other Reporter details supplied
							`<outboundRelationship typeCode="SPRT">`
							`<priorityNumber value="2"/>`
							`<relatedInvestigation classCode="INVSTG" moodCode="EVN">`
							`    <code code="T95002" codeSystem="2.16.840.1.113883.13.206" displayName="Sourcereport"/>`
							`        <participation typeCode="AUT">`
							`            <assignedEntity classCode="ASSIGNED">`
							`                <code code="C53289" codeSystem="2.16.840.1.113883.13.194" displayName="Other Health Care Professional"/>`
							`                <addr use="WP">`
							`                    <streetAddressLine>De Clercqstraat 64</streetAddressLine>`
							`                    <city>Amsterdam</city>`
							`                    <state>North Holland</state>`
							`                    <postalCode>1052 NJ</postalCode>`
							`                    <country>NLD</country>`
							`                </addr>`
							`                <telecom value="TEL:+31206558050"/>`
							`                <telecom value="FAX:+31206678050"/>`
							`                <telecom value="MAILTO:prinshendric@mac.com"/>`
							`                <assignedPerson classCode="PSN" determinerCode="INSTANCE">`
							`                    <name>`
							`                        <family>Gernard</family>`
							`                        <given>Tabeling</given>`
							`                    </name>`
							`                    <asIdentifiedEntity classCode="IDENT">`
							`                        <assigningOrganization classCode="ORG" determinerCode="INSTANCE">`
							`                            <name>PrinsHendric Clinic</name>`
							`                        </assigningOrganization>`
							`                    </asIdentifiedEntity>`
							`                </assignedPerson>`
							`            </assignedEntity>`
							`        </participation>`
							`</relatedInvestigation>`
							`</outboundRelationship>`
							
							Example 2 – Other Reporter not supplied is similar to the example above except for…
							`    outboundRelationship` node where `priorityNumber value="2"` is not needed
							
							Example 3–No information for Other Reporter
							`<outboundRelationship typeCode="SPRT">`
							`<priorityNumber value="2" />`
							`<relatedInvestigation classCode="INVSTG" moodCode="EVN">`
							`    <code codeSystem="2.16.840.1.113883.13.206" code="T95002" displayName="Sourcereport" />`
							`        <participation typeCode="AUT">`
							`            <assignedEntity classCode="ASSIGNED">`
							`                <code nullFlavor="NI" />`
							`                <addr use="WP">`
							`                    <streetAddressLine nullFlavor="NI" />`
							`                    <city nullFlavor="NI" />`
							`                    <state nullFlavor="NI" />`
							`                    <postalCode nullFlavor="NI" />`
							`                    <country nullFlavor="NI"/>`
							`                </addr>`
							`                <telecom nullFlavor="NI" />`
							`                <assignedPerson determinerCode="INSTANCE" classCode="PSN">`
							`                    <name>`
							`                        <family nullFlavor="NI"/>`
							`                        <given nullFlavor="NI" />`
							`                    </name>`
							`                    <asIdentifiedEntity classCode="IDENT">`
							`                        <assigningOrganization determinerCode="INSTANCE" classCode="ORG">`
							`                            <name nullFlavor="NI"  />`
							`                        </assigningOrganization>`
							`                    </asIdentifiedEntity>`
							`                </assignedPerson>`
							`            </assignedEntity>`
							`        </participation>`
							`</relatedInvestigation>`
							`</outboundRelationship>`
								Other reporter details are in <addr>, <telecom> and <name> nodes of assignedEntity.
								Note the use of XML Locator Code and priorityNumber value = "2" to differentiate between Primary and Other reporter.
								
								/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/outboundRelationship[priorityNumber/@value=2]/relatedInvestigation[code/@code="T95002"]/participation/assignedEntity/assignedPerson/name/given
									One per AER	V 2.0

32	A.3.2.2	Other Reporter Last name	Gernard	Optional**,** use WITHHELD when there is no data or to indicate that the reporter does not wish to be identified by name, if no data use nullFlavor="NI	Text up to 50 characters					
33	A.3.2.3	Other Reporter First name	Tabeling	Optional, if no data use nullFlavor="NI"	Text up to 50 characters					
34	A.3.2.4	Other Reporter Telephone	+31206558050	Optional, if no data use nullFlavor="NI"	Text up to 20 characters **including prefix 'TEL:'**					
35	A.3.2.5	Other Reporter Fax	+31206678050	Optional, if no data use nullFlavor="NI"	Text up to 20 including **prefix 'FAX:'**					
36	A.3.2.6	Other Reporter e-mail	prinshendric@mac.com	Optional, if no data use nullFlavor="NI"	Text up to 100 characters **including prefix 'MAILTO:'**					
37	A.3.2.7	Other Reporter Business Name	PrinsHendric Clinic	Optional, if no data use nullFlavor="NI"	Text up to 100 characters					
38	A.3.2.8	Other Reporter Street address	De Clercqstraat 64	Optional, if no data use nullFlavor="NI"	Text up to 100 characters					
39	A.3.2.9	Other Reporter City	Amsterdam	Optional, if no data use nullFlavor="NI"	Text up to 50 characters					
40	A.3.2.10	Other Reporter State/county	North Holland	Optional, if no data use nullFlavor="NI"	Text up to 80 characters					
41	A.3.2.11	Other Reporter Postal/zip code	1052 NJ	Optional, if no data use nullFlavor="NI"	Text up to 35 characters					
42	A.3.2.12	Other Reporter Country code	NLD	Optional, if no data use nullFlavor="NI"	Code List					

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43	A.4.1	AER Identifier	NLD-ACMEGACO-7819	Mandatory	Text up to 60 characters	**Pre-validation** 1) If mandatory elements are missing then **ERROR** 2) Text beyond the expected length will cause an **ERROR** **Business rules** Refer to detailed business rules to explain validation that is applied to AER ID, for example, first 3 characters are the ISO country code for where the Adverse Event occurred.	Example `<id root="1.2.3.4" extension="NLD-ACMEGACO-7819" />`	/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/id/@extension Note that id root is a static value that must be present, but it is neither validated or stored.	One per AER	V 2.2
44	A.4.2	Original Receive Date	20200123	Mandatory	Date (YYYYMMDD)	**Pre-validation** 1) If mandatory elements are missing then **ERROR** 2) if not a valid YYYYMMDD dates then,	Example `<effectiveTime value="20200218"/>`	/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/outboundRelationship[priorityNumber/@value=1]/relatedInvestigation[code/@code="**T95 002"**]/effectiveTime	One per AER	V 2.2
45	A.4.3	Current Submission Date	20200131	Mandatory	Date (YYYYMMDD)	**ERROR** **Business rules** 1) Original Receive Date must be on or before Current Submission Date 2) Date must not be in the future 3) Refer to detailed business rules to explain validation that is applied to Original Receive Date and Current Submission Date. For example, Original Receive date must be on or after B.3.3 Date of Onset	Example `<availabilityTime value="20200228"/>`	/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/availabilityTime	One per AER	V 2.2

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
46	A.4.4.1	Type of Submission code	C53578	Mandatory	Code List	**Pre-validation** 1) XML Locator Code **T95003** is required else **ERROR** 2) If mandatory elements are missing then **ERROR** 3) Text beyond the expected length will cause an **ERROR** **Business rules** 1) Value must exist as a code as in GL30 2.16.840.1.113883.13.195else **ERROR** 2) If Type of Submission is any other value than 'Nullification', then Reason for Nullification should be nullFlavor="NI"else **ERROR** 3) If Type of Submission is Nullification then Reason for Nullification must have a value else **ERROR**	Example 1 - A Periodic report (must not have a Reason for Nullification) `<subjectOf2 typeCode="SUBJ">` `<investigationCharacteristic classCode="CASE" moodCode="EVN">` `<code code="`**T95003**`" codeSystem="2.16.840.1.113883.13.206" displayName="Type of Submission"/>` `<value code="C53578" codeSystem="2.16.840.1.113883.13.195" displayName="Periodic" xsi:type="CE">` `<originalText nullFlavor="NI"/>` `</value>` `</investigationCharacteristic>` `</subjectOf2>` Example 2 - A Nullification report with a reason for nullification `<subjectOf2 typeCode="SUBJ">` `<investigationCharacteristic classCode="CASE" moodCode="EVN">` `<code codeSystem="2.16.840.1.113883.13.206" code="`**T95003**`" displayName="Type of Submission"/>` `<value xsi:type="CE" codeSystem="2.16.840.1.113883.13.195" code="C68625" displayName="Nullifcation">` `<originalText="Duplicate report "/>` `</value>` `</investigationCharacteristic>` `</subjectOf2>`	Type of Submission is /MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf2/investigationCharacteristic[code/@code="**T95003**"]/value/@code and, for the Reason for Nullification /MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf2/investigationCharacteristic[code/@code="**T95003**"]/value/originalText	One per AER	V 2.0
47	A.4.4.2	Reason for Nullification Report		Conditional Mandatory IF, if no data use nullFlavor="NI"	Text up to 200 characters					V 2.0
48	A.4.4.3	Type of Information in Report code	C82456	Optional, if no data use nullFlavor="NI"	Code List	**Pre-validation Rule** XML Locator Code **T95004** is required else **ERROR** **Business Rule** Value must exist as a code as in GL30 2.16.840.1.113883.13.196 or be nullFlavor="NI" else **ERROR**	Example 1 – Type of Information is LACK OF EXPECTED EFFECTIVENESS `<subjectOf2 typeCode="SUBJ">` `<investigationCharacteristic classCode="CASE" moodCode="EVN">` `<code code="`**T95004**`" codeSystem="2.16.840.1.113883.13.206" displayName="Type of Information in Report"/>` `<value code="C82456" codeSystem="2.16.840.1.113883.13.196" displayName="LACK OF EXPECTED EFFECTIVENESS" xsi:type="CE"/>` `</investigationCharacteristic>` `</subjectOf2>` Example 2 – No type of Information `<subjectOf2 typeCode="SUBJ">` `<investigationCharacteristic classCode="CASE" moodCode="EVN">` `<code code="`**T95004**`" codeSystem="2.16.840.1.113883.13.206" displayName="Type of Information in Report"/>` `<value xsi:type="CE" nullFlavor="NI" />` `</investigationCharacteristic>` `</subjectOf2>`	/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf2/investigationCharacteristic[code/@code="**T95004**"]/value	One per AER	V 2.0

Animal data - B.1

Each AER has Animal data, within Animal data, 'Breed' data may be repeated.

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
50	B.1.1	Number of Animals Treated	10	Optional, if no data use nullFlavor="NI"	Integer, max length 12	**Pre-validation** Number is a valid positive Integer that does not exceed 12 digits else **ERROR**	Example 1 `<quantity value="10"/>` Example 2 – no value `<quantity nullFlavor="NI"/>`	/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/player2/quantity/@value	One per AER	V 2.0
51	B.1.2	Number of Animals Affected	1	**Mandatory**	Integer, max length 12	**Pre-validation** 1) XML Locator Code **T95005** is required else **ERROR** 2) Number is a valid positive Integer that does not exceed 12 digits else **ERROR** 3) If mandatory elements are missing then **ERROR** **Business rules** Refer to detailed business rules to explain validation that is applied to number of animals affected. For example, B.3.2.1.1 number of animals with a specific reaction must not be greater than the number of animals affected	Example `<subjectOf2 typeCode="SBJ">` `<observation classCode="OBS" moodCode="EVN">` `<code code="T95005" codeSystem="2.16.840.1.113883.13.206" displayName="Number of Animals Affected"/>` `<value value="1" xsi:type="INT"/>` `</observation>` `</subjectOf2>`	There are many `<subjectOf2>`nodes, and the data supplied is identified by the XML Locator code /MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/observation[code/@code="T95005"]/value/@value	One per AER	V 2.0

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published

52	B.1.2.1	Attending Veterinarian's Assessment of Health Status Prior to VMP Code	C82488	Optional, if no data, use **C17998** for 'Unknown' or nullFlavor="NI"	Code List	**Pre-validation** XML Locator Code **T95006** is required else **ERROR**
						
						Business rules 1) Value must exist as a code as in GL30 2.16.840.1.113883.13.197 else **ERROR** 2) To avoid rejecting otherwise compliant reports, <author> is accepted, but not validated or stored. If B.1.2.1 has a value then value of author is assumed to be C82470/Veterinarian
							Example 1 – Animal in 'Excellent' condition prior to treatment
							`<subjectOf2 typeCode="SBJ">`
							`    <observation classCode="OBS" moodCode="EVN">`
							`        <code code="`**T95006**`" codeSystem="2.16.840.1.113883.13.206" displayName="Assessment of Health Status Prior to the Exposure to Product"/>`
							`        <value code="C82488" codeSystem="2.16.840.1.113883.13.197" displayName="EXCELLENT" xsi:type="CE"/>`
							`        <author typeCode="AUT">`
							`            <assignedEntity classCode="ASSIGNED">`
							`                <code code="C82470" codeSystem="2.16.840.1.113883.13.194" displayName="Veterinarian"/>`
							`            </assignedEntity>`
							`        </author>`
							`    </observation>`
							`</subjectOf2>`
							
							Example 2 – Animal condition prior to treatment is Unknown
							`<subjectOf2 typeCode="SBJ">`
							`    <observation classCode="OBS" moodCode="EVN">`
							`        <code code="`**T95006**`" codeSystem="2.16.840.1.113883.13.206" displayName="Assessment of Health Status Prior to the Exposure to Product"/>`
							`        <value code="`**C17998**`" codeSystem="2.16.840.1.113883.13.197" displayName="UNKNOWN" xsi:type="CE"/>`
							`        <author typeCode="AUT">`
							`            <assignedEntity classCode="ASSIGNED">`
							`                <code code=" C82470" codeSystem="2.16.840.1.113883.13.194" displayName="Veterinarian"/>`
							`            </assignedEntity>`
							`        </author>`
							`    </observation>`
							`</subjectOf2>`
							
							Example 3 – No information for animal condition prior to treatment
							`<subjectOf2 typeCode="SBJ">`
							`    <observation moodCode="EVN " classCode="OBS">`
							`        <code codeSystem="2.16.840.1.113883.13.206" code="`**T95006**`" displayName="Assessment of Health Status Prior to the Exposure to Product" />`
							`        <value xsi:type="CE" nullFlavor="NI" />`
							`        <author typeCode="AUT">`
							`            <assignedEntity classCode="ASSIGNED">`
							`                <code nullFlavor="NI" />`
							`            </assignedEntity>`
							`        </author>`
							`    </observation>`
							`</subjectOf2>`
								There are many `<subjectOf2>`nodes, and the data supplied is identified by the XML Locator code
								
								/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/observation[code/@code="**T95006**"]/value/@value
										V2.0

		Author for Attending Veterinarian's Assessment of Health Status Prior to VMP Code	C82470	If value provided for B.1.2.1 then 'C82470' else nullFlavor="NI" Not in GL35 or GL42 but used with B.1.2.1, as in Step by Step Guide						

53	B.1.3	Species code	CTT	**Mandatory**	Code List	**Pre-validation** If mandatory elements are missing then **ERROR**
						
						Business rules 1) Value must exist as a code as in GL30 2.16.840.1.113883.4.341 else **ERROR** 2) If the AER is for a person then Species is 'Human'
						
						Note: If the species is not known then use value C17649 for 'Other'
							Example - Cattle
							`<code code="CTT" codeSystem="2.16.840.1.113883.4.341" displayName="Cattle"/>`
							
							Example - Human
							`<code code="HUM" codeSystem="2.16.840.1.113883.4.341" displayName="Human"/>`
								/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/player2/code/@code		V 2.0

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
54	B.1.4.1.1	Purebred - Breed codes		Optional, if no data use nullFlavor="NI" Note: T95007 Value **False** or nullFlavor="NI" = Pure Breed	Code List	**Pre-validation** 1) There will always be TWO and only two **T95007** nodes. Each T9007 will have at least one **T95008** XML Locator Code else **ERROR** 2) One value for Are Animals Crossbred is False or NI and another value is True	*(see snippet column content below)*	There are two <subjectOf2>nodes for breed data, as identified by the XML Locator code**T95007** /MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/observation[code/@code="**T95007**" and value/@value=false()]/inboundRelationship /observation/value/@code	There are two <subjectOf2>nodes. One for Pure and one for Cross Breeds. Breed data is given as a list of nested <observation>nodes.	V 2.7

55	B.1.4.2.1	Crossbred- Breed codes		Optional, if no data use nullFlavor="NI"
				
				Note: T95007 Value **True** = Cross Breed
					Code List	*(see EMA Comment content below)*		Note that the AER Breed Data for the following scenario has two **T95007** nodes, despite there being 4 animals and 6 breeds.
								    Animal 1 = Pure Breed 1
								    Animal 2 = Pure Breed 2
								    Animal 3 = Cross Breed - Breed 3 known
								    Animal 4 = Cross of Breeds 4, 5 and 6
									Each of the Pure/Cross Breed <observation> nodes may have multiple <inboundRelationship> nodes.
									The Breed Code is an <observation> within the <inboundRelationship>
									
									There is no limit to the total number of Pure or Cross Breeds specified. However, for a single, cross bred animal, there is a maximum of 3 Breeds.	

EMA Comment (row 55, continued):

Business rules
1) Breed data is associated with the Species chosen in B.1.3. If the breed is not a valid breed for the Species then **ERROR**
2) Breed data refers to the affected animals and is optional. If breed data is not supplied then the Breed Indicator(s) and all Breed codes are nullFlavor="NI"
3) If Breed data is specified, breed values must exist as a code as in GL30 2.16.840.1.113883.4.342 else **ERROR**.

Note: GL30 has terms for Mixed, Other and Crossbred. nullFlavor="NI" is valid breed.

Note: Refer to detailed business to rules to explain validation that is applied to Breed with respect to the number of animals and Human reports etc

Guidance Note: GL35 allows up to 'n' breeds to be specified. GL42 limits the number of breeds that may be specified for a single animal to 3. In the case of a crossbred animal where only one breed is known, just list the one breed.

Refer to GL42 and the Step by Step Guide for more examples.

.xml snippet (row 54/55):

Example 1 – animals include Pure and Cross Breeds

	T95007 value – Breed Indicator	T95008 value(s) – Breed data
B.1.4.1.1	**False** or **NI**	Pure Breed 1
B.1.4.2.1	**True**	Cross Breed 1, Cross Breed

For snippet, please refer to the Step by Step Guide

Example 2 – reporter knows that the animal is CrossBred but is unable to supply the Breed

	T95007 value – Breed Indicator	T95008 value(s) – Breed data
B.1.4.1.1	**False** or **NI**	**NI**
B.1.4.2.1	**True**	e.g. BOV333 Cattle (unknown)

For snippet, please refer to the Step by Step Guide, see that Breed is OID

Example 3 – reporter does not provide any breed information

	T95007 value – Breed Indicator	T95008 value(s) – Breed data
B.1.4.1.1	**False** or **NI**	**NI**
B.1.4.2.1	**True**	**NI**

Snippet same as Example 4 below

Example 4 – Adverse Event applies to a Human, both T95007 nodes show Breed is 'NI'

	T95007 value – Breed Indicator	T95008 value(s) – Breed data
B.1.4.1.1	**False** or **NI**	**NI**
B.1.4.2.1	**True**	**NI**

```
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <code code="T95007" codeSystem="2.16.840.1.113883.13.206" displayName="Are Animals Crossbred"/>
    <value xsi:type="CE" nullFlavor="NI"/>
    <inboundRelationship typeCode="COMP">
      <observation classCode="OBS" moodCode="EVN">
        <code code="T95008" codeSystem="2.16.840.1.113883.13.206" displayName="Breed Components"/>
        <value xsi:type="CE" nullFlavor="NI"/>
      </observation>
    </inboundRelationship>
  </observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <code code="T95007" codeSystem="2.16.840.1.113883.13.206" displayName="Are Animals Crossbred"/>
    <value xsi:type="BL" value="true"/>
    <inboundRelationship typeCode="COMP">
      <observation classCode="OBS" moodCode="EVN">
        <code code="T95008" codeSystem="2.16.840.1.113883.13.206" displayName="Breed Components"/>
        <value xsi:type="CE" nullFlavor="NI"/>
      </observation>
    </inboundRelationship>
  </observation>
</subjectOf2>
```

Example 5 – within each of T95007 nodes, multiple inboundRelationships are used to specify as many Breeds as are needed, for example, two breeds of pig are shown as:

```
<inboundRelationship typeCode="COMP">
  <observation classCode="OBS" moodCode="EVN">
    <code codeSystem="2.16.840.1.113883.13.206" code="T95008" displayName="Breed Components"/>
    <value xsi:type="CE" codeSystem="2.16.840.1.113883.4.342" code="Pig33" displayName="Duroc"/>
  </observation>
</inboundRelationship>
<inboundRelationship typeCode="COMP">
  <observation classCode="OBS" moodCode="EVN">
    <code codeSystem="2.16.840.1.113883.13.206" code="T95008" displayName="Breed Components"/>
    <value xsi:type="CE" codeSystem="2.16.840.1.113883.4.342" code="Pig115" displayName="Yorkshire"/>
  </observation>
</inboundRelationship>
```

See Step by Step Guide for full snippet and note that there will always be pure breed and crossbred Breed Components even if one or other is NI, as Example 4.

xPath / Explanation (row 55, continued):

T95007 is the Breed Indicator:
− Pure Breeds (**T95007**=False)
− CrossBredBreeds (**T95007** <> False)

T95008 is used for the actual Breeds.

T95007 = False	**T95008** Breed 1
	T95008 Breed 2
T95007 = True	**T95008** Breed 3
	T95008 Breed 4
	T95008 Breed 5
	T95008 Breed 6

And not

T95007 = False	T95008 Breed 1
T95007 = False	T95008 Breed 2
T95007 = True	T95008 Breed 3
T95007 = True	T95008 Breed 4
T95007 = True	T95008 Breed 5
T95007 = True	T95008 Breed 6

Or

T95007 = False	T95008 Breed 1
T95007 = False	T95008 Breed 2
T95007 = True	T95008 Breed 3
	T95008 Breed 4
T95007 = True	T95008 Breed 5
	T95008 Breed 6

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
56	B.1.5	Gender code	C16576	Optional, if no data, select **C17998** for 'Unknown' or nullFlavor="NI" as appropriate	Code List	**Business rules** Value must exist as a code as in GL30 2.16.840.1.113883.13.198 else **ERROR** Refer to detailed business rules. For example, if number of animals affected is 1 and gender is 'MIXED' then WARNING	Example 1 – Male animal `<administrativeGenderCode code="C20197" codeSystem="2.16.840.1.113883.13.198" displayName="MALE"/>` Example 2 – A group of animals of Mixed gender `<administrativeGenderCode code="C25259" codeSystem="2.16.840.1.113883.13.198" displayName="MIXED"/>` Example 3 –gender unknown `<administrativeGenderCode code="C17998" codeSystem="2.16.840.1.113883.13.198" displayName="UNKNOWN"/>` Example 4 – no gender information `<administrativeGenderCode nullFlavor="NI" />`	/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/player2/administrativeGenderCode/@code	One per AER	V 2.0
57	B.1.6	Reproductive Status code	C54011	Optional, if no data, select **C17998** for 'Unknown' or nullFlavor="NI" as appropriate	Code List	**Business rules** Value must exist as a code as in GL30 2.16.840.1.113883.13.199 else **ERROR** Refer to detailed business rules. For example, if number of animals affected is 1 and reproductive status is 'MIXED' then WARNING	Example 1 `<genderStatusCode codeSystem="2.16.840.1.113883.13.199" code="C54011" displayName="Neutered"/>` Example 2 – reproductive status is unknown `<genderStatusCode codeSystem ="2.16.840.1.113883.13.199" code="C17998" displayName="Unknown"/>` Example 3 – no reproductive status information `<genderStatusCode nullFlavor="NI" />`	/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/player2/genderStatusCode/@code	One per AER	V 2.0
58	B.1.7	Female Physiological Status code	NA	Optional, if no data, select **C17998** for 'Unknown' or nullFlavor="NI" as appropriate	Code List	**Pre-validation** XML Locator Code **T95010** is required else **ERROR** **Business rules** Value code must exist as a code as in GL30 2.16.840.1.113883.13.49 else **ERROR** Refer to detailed business rules. For example, if number of animals affected is 1 and female physiological status is 'MIXED' then WARNING. If Gender code is Males then use NA or nullFlavor="NI" for female physiological status	Example 1 – Male animal and so Female Physiological Status is not applicable `<subjectOf2 typeCode="SBJ">` `<observation classCode="OBS" moodCode="EVN">` `<code code="T95010" codeSystem="2.16.840.1.113883.13.206" displayName="Female Physiological Status"/>` `<value code="NA" codeSystem="2.16.840.1.113883.13.49" displayName="NOT APPLICABLE" xsi:type="CE"/>` `</observation>` `</subjectOf2>` Example 2 – Female animal is not pregnant and lactating `<subjectOf2 typeCode="SBJ">` `<observation classCode="OBS" moodCode="EVN">` `<code codeSystem="2.16.840.1.113883.13.206" code="T95010" displayName="Female Physiological Status"/>` `<value xsi:type="CE" codeSystem=" 2.16.840.1.113883.13.49 " code="NPL" displayName="NONPREGNANT LACTATING"/>` `</observation>` `</subjectOf2>` Example 3 – no information for Female Physiological Status `<subjectOf2 typeCode="SBJ">` `<observation classCode="OBS" moodCode="EVN">` `<code code="T95010" codeSystem="2.16.840.1.113883.13.206" displayName="Female Physiological Status"/>` `<value xsi:type="CE" nullFlavor="NI"/>` `</observation>` `</subjectOf2>`	There are many `<subjectOf2>`nodes, and the data supplied is identified by the XML Locator code /MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/observation[code/@code="T95010"]/value/@code	One per AER	V 2.0

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published

59	B.1.8.1	Weight Precision code	C44473	Optional
				
				If no data use 'Unknown' or nullFlavor="NI"
					Code List	**Pre-validation**
						1) XML Locator Code **T95011** is required else **ERROR**
						2) Digits beyond the expected length or precision will cause an **ERROR**
						3) If mandatory elements are missing then **ERROR**
						4) If precision code is 'Measured' or 'Estimated' then specify unit="kg" because weight is always measured in kg, attempts to specify other units of measure or other defaults are ignored
						
						Business rules
						1) Precision code, e.g. 'Measured' or 'Estimated', must exist as a code as in GL30 2.16.840.1.113883.13.200 else **ERROR**
						2) If precision code is 'Measured' or 'Estimated' then there must be a value specified for minimum weight, else **ERROR**
						3) If precision code is not 'Measured' or 'Estimated' then minimum and/or maximum weights are expected to be nullFlavor="NI", else WARNING
						
						Refer to detailed business rules to explain validation that is applied to weight. For example, if the report is for more than 1 animal affected then there must be a maximum weight specified.
						
						Note:
						all weights are 'kg'.
							Example 1 – measured weight is 125 kg - 225 kg
							`<subjectOf2 typeCode="SBJ">`
							`    <observation classCode="OBS" moodCode="EVN">`
							`        <code code="T95011" codeSystem="2.16.840.1.113883.13.206" displayName="Weight"/>`
							`            <value xsi:type="IVL_PQ">`
							`                <low unit="kg" value="125"/>`
							`                <high unit="kg" value="225"/>`
							`            </value>`
							`        <methodCode code="C44473" codeSystem="2.16.840.1.113883.13.200" displayName="MEASURED"/>`
							`    </observation>`
							`</subjectOf2>`
							
							Example 2 – weight 13.125 kg
							`<subjectOf2 typeCode="SBJ">`
							`    <observation classCode="OBS" moodCode="EVN">`
							`        <code code="T95011" codeSystem="2.16.840.1.113883.13.206" displayName="Weight"/>`
							`            <value xsi:type="IVL_PQ">`
							`                <low unit="kg" value="13.125"/>`
							`                <high nullFlavor="NI" />`
							`            </value>`
							`        <methodCode code="C44473" codeSystem="2.16.840.1.113883.13.200" displayName="MEASURED"/>`
							`    </observation>`
							`</subjectOf2>`
							
							Example 3 – weight Unknown and so no Minimum and Maximum weight
							`<subjectOf2 typeCode="SBJ">`
							`    <observation moodCode="EVN" classCode="OBS">`
							`        <code codeSystem="2.16.840.1.113883.13.206" code="T95011" displayName="Weight"/>`
							`            <value xsi:type="IVL_PQ">`
							`                <low nullFlavor="NI" />`
							`                <high nullFlavor="NI" />`
							`            </value>`
							`        <methodCode code="C44473" codeSystem="2.16.840.1.113883.13.200" displayName="UNKNOWN"/>`
							`    </observation>`
							`</subjectOf2>`
								There are many `<subjectOf2>`nodes, and the data supplied is identified by the XML Locator code
								
								/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/observation[code/@code="T95011"]/methodCode/@code
									One per AER	V 2.6

60	B.1.8.2	Minimum Weight	125	Conditional Mandatory IF B.1.8.1 is 'Measured' or 'Estimated'. If B.1.8.1 is 'Unknown', use nullFlavor="NI"	Numeric, max 12 characters including a decimal point , max 3 d.p.					
61	B.1.8.3	Maximum Weight	225	Conditional Optional IF B.1.8.1 is 'Measured' or 'Estimated'. If B.1.8.1 is 'Unknown' or there is no data use nullFlavor="NI"	Numeric, max 12 characters including a decimal point , max 3 d.p.					

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published

62	B.1.9.1	Age Precision code	C25498	Optional
				
				If no data use 'Unknown' or nullFlavor="NI"
					Code List	**Pre-validation**
						1) XML Locator Code **T95012** is required else **ERROR**
						2) Digits beyond the expected length or precision will cause an **ERROR**
						3) If mandatory elements are missing then **ERROR**
						
						Business rules
						1) Precision code, e.g. 'Measured', 'Estimated', 'Unknown' must exist as a code as in GL30 2.16.840.1.113883.13.200 else **ERROR**
						2) If precision code is 'Measured' or 'Estimated' then there must be a value specified for minimum age, else WARNING
						3) If precision code is not 'Measured' or 'Estimated' i.e. it is 'Unknown' then minimum and maximum ages are expected to be nullFlavor="NI" and there should be no unit of measure codes, else **ERROR**
						4) If Minimum Age is specified then Minimum Age Units code must exist as a code with Category 'Time Unit' in GL30 list 2.16.840.1.113883.6.8 e.g. s, min, h, d, wk, mo or a else **ERROR**
						5) If Maximum Age is specified then Maximum Age Units code must exist as a code with Category 'Time Unit' in GL30 list 2.16.840.1.113883.6.8 e.g. s, min, h, d, wk, mo or a else **ERROR**
						
						Refer to detailed business rules to explain validation that is applied to age. For example, if the report is for more than 1 animal affected then there must be a maximum age specified.
							Example 1 – age is estimated as between 7 months and 3 years
							`<subjectOf2 typeCode="SBJ">`
							`<observation classCode="OBS" moodCode="EVN">`
							`<code code="`**T95012**`" codeSystem="2.16.840.1.113883.13.206" displayName="Age"/>`
							`<value xsi:type="IVL_PQ">`
							`<low unit="a" value="7"/>`
							`<high unit="a" value="3"/>`
							`</value>`
							`<methodCode code="C25498" codeSystem="2.16.840.1.113883.13.200" displayName="ESTIMATED"/>`
							`</observation>`
							`</subjectOf2>`
							
							Example 2 – age is measured as 1.25 years (equivalent to 15 months!)
							`<subjectOf2 typeCode="SBJ">`
							`<observation classCode="OBS" moodCode="EVN">`
							`<code code="`**T95012**`" codeSystem="2.16.840.1.113883.13.206" displayName="Age"/>`
							`<value xsi:type="IVL_PQ">`
							`<low unit="a" value="1.25"/>`
							`<high nullFlavor="NI" />`
							`</value>`
							`<methodCode code="C25498" codeSystem="2.16.840.1.113883.13.200" displayName="ESTIMATED"/>`
							`</observation>`
							`</subjectOf2>`
							
							Example 3 – no age data available
							`<subjectOf2 typeCode="SBJ">`
							`<observation moodCode="EVN " classCode="OBS">`
							`<code codeSystem="2.16.840.1.113883.13.206" code="`**T95012**`" displayName="Age" />`
							`<value xsi:type="IVL_PQ">`
							`<low nullFlavor="NI" />`
							`<high nullFlavor="NI" />`
							`</value>`
							`<methodCode codeSystem="2.16.840.1.113883.13.200" code="`**C17998**`" displayName="UNKNOWN"/>`
							`</observation>`
							`</subjectOf2>`
								There are many `<subjectOf2>`nodes, and the data supplied is identified by the XML Locator code/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/observation[code/@code=**T95012**"]/methodCode/@code	One Per AER	V 2.6

63	B.1.9.2	Minimum Age	7	Conditional Mandatory IF B.1.9.1 is 'Measured' or 'Estimated' If B.1.9.1 is 'Unknown', use nullFlavor="NI"	Numeric, max 12 characters including a decimal point , max 2 d.p.					
64	B.1.9.2.1	Minimum Age Units code	mo	Conditional Mandatory IF B.1.9.2 is specified	Code List					
65	B.1.9.3	Maximum Age	3	Conditional Optional IF B.1.9.1 is 'Measured' or 'Estimated' If B.1.9.1 is 'Unknown' or there is no data use nullFlavor="NI"	Numeric, max 12 characters including a decimal point , max 2 d.p.					
66	B.1.9.3.1	Maximum Age Units code	a	Conditional Mandatory IF B.1.9.3 is specified	Code List					

Product data- B.2 plus B.3.9, B.3.10 and B.4

There will be at least one VMP in the AER. There may be multiple VMP or Active Substances per report and each has a <substanceAdministration> block.

Within the <substanceAdministration> block:

- each VMP in needs either a B.2.1 Registered or Brand Name or B.2.2.1 Active Ingredient Name
- most data is 'One per VMP'
- however, there are repetitions of RA Assessment, Route of Exposure, Active Ingredient and Lot Number

The first VMP has a unique id e.g. <id extension="1">, the next may be <id extension="2"> etc, as shown in B.3.2

/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/substanceAdministration/id/@extension

	Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
	67	B.2.1	Registered Name or Brand Name	Very good drug 1620 mg fast acting	Conditional Mandatory IF no B.2.2 i.e. Active Ingredient(s), optional if B.2.2 is specified Guidance Note: Mandatory for MAH's own VMP, use nullFlavor="NI" for no data	Text up to 200 characters	**Pre-validation** Text beyond the expected length will cause an ERROR **Business rules** 1) There must be at least one VMP 2) At least one of the fields 'Registered Name or Brand Name - B.2.1' OR Active Ingredient(s)- B.2.2.1 must be provided Guidance Note: MAH must specify the Registered or Brand name of their VMPs If the VMP is another MAH's product then Registered Name or Brand Name may be nullFlavor="NI" and in that case the Active Ingredient must be specified, if not then **ERROR**	The Registered Brand name is found within the <kindOfProduct> node Example 1 <name xsi:type="TN">Very good drug 1620 mg fast acting</name> Example 2 – No Registered Name or Brand Name <name xsi:type="TN" nullFlavor="NI"/>	/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind/kindOfProduct/name	One per VMP	V 2.0
	68	B.2.1.1	Product Code	600000005744	Optional, if no data use nullFlavor="NI"	Text up to 50 characters	**Pre-validation** Text beyond the expected length will cause an ERROR **Business rules** Product code should exist in Code list 2.16.840.1.113883.3.6905.3.1 which is currently under development	Example 1 <kindOfProduct classCode="MMAT" determinerCode="KIND"> <code codeSystem="2.16.840.1.113883.3.6905.3.1" code="600000005744"/> Example 2 – No Product Code <code nullFlavor="NI"/>	/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind/kindOfProduct/code	One per VMP	V 2.2

	Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published

	69	B.2.1.2	Registration Identifier (Product Registration Number)	USA-USXXYYAB-N98761	Conditional
					
					Guidance Note:
					Mandatory IF MAH's own VMP - if MAH does not know Identifier use "Cannot be determined"
					
					If the VMP is another MAH's product and no data use nullFlavor="NI"
						Text up to 50 characters	**Pre-validation**
							Text beyond the expected length will cause an **ERROR**
							
							Guidance Notes:
							Format expected is XXX-YYYYYYYY-123456 where XXX is 3 character ISO country code where the product is approved, YYYYYYYY is 8 character code of the authorising RA and 123456 is a unique reference
							
							Centrally Authorised Products will use the letters 'ZZZ' for Country Code
								Example 1 – Registration Identifier is known
								\<asManufacturedProduct classCode="MANU">
								   \<manufacturerOrganization determinerCode="INSTANCE" classCode="ORG">
								      \<name>ACME Euro Chem B.V.\</name>
								   \</manufacturerOrganization>
								   \<subjectOf typeCode="SBJ">
								      \<approval moodCode="EVN" classCode="CNTRCT">
								         \<id extension="NLD-INDGAPSY-NL7819"/>
								      \</approval>
								   \</subjectOf>
								\</asManufacturedProduct>
								
								Example 2 – MAH does not know the Registration Identifier for their product
								\<asManufacturedProduct classCode="MANU">
								   \<manufacturerOrganization determinerCode="INSTANCE" classCode="ORG">
								      \<name>ACME Euro Chem B.V.\</name>
								   \</manufacturerOrganization>
								   \<subjectOf typeCode="SBJ">
								      \<approval moodCode="EVN" classCode="CNTRCT">
								         \<id extension="Cannot be determined"/>
								      \</approval>
								   \</subjectOf>
								\</asManufacturedProduct>
								
								Example 3 – No information
								\<asManufacturedProduct classCode="MANU">
								   \<manufacturerOrganization determinerCode="INSTANCE" classCode="ORG">
								      \<name nullFlavor="NI"/>
								   \</manufacturerOrganization>
								   \<subjectOf typeCode="SBJ">
								      \<approval classCode="CNTRCT" moodCode="EVN">
								         \<id nullFlavor="NI"/>
								      \</approval>
								   \</subjectOf>
								\</asManufacturedProduct>
									/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind/kindOfProduct/asManufacturedProduct/subjectOf/approval/id	One per VMP	V 2.7

	70	B.2.1.4	Company or MAH	ACME Euro Chem B.V.	Optional, if no data use nullFlavor="NI"	Text up to 100 characters			/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind/kindOfProduct/asManufacturedProduct/manufacturerOrganization/name	One per VMP	

	71	B.2.1.3	Anatomical Therapeutic Chemical Vet (ATCvet) code	QP54AB51	Conditional
					
					Guidance Note:
					Mandatory for MAH's own VMPs, a value is required and must be chosen from Controlled List
					
					If the VMP is another MAH's product and no data then use nullFlavor="NI"
						Text up to 10 characters	**Pre-validation**
							1) XML Locator Code **T95013** is required else **ERROR**
							2) Text beyond the expected length will cause an **ERROR**
							
							Business rules
							Value is expected to be a valid ATC vet code, else **ERROR**
								Example
								\<asSpecializedKind classCode="GEN ">
								   \<generalizedMaterialKind classCode="MAT" determinerCode="KIND">
								      \<code codeSystem="2.16.840.1.113883.13.206" code="T95013" displayName="ATCvet Code"/>
								      \<name xsi:type="TN">QP54AB51\</name>
								   \</generalizedMaterialKind>
								\</asSpecializedKind>
								
								Example 2 – no information for ATCvet Code
								\<asSpecializedKind classCode="GEN ">
								   \<generalizedMaterialKind classCode="MAT" determinerCode="KIND">
								      \<code codeSystem="2.16.840.1.113883.13.206" code="T95013" displayName="ATCvet Code"/>
								      \<name xsi:type="TN" nullFlavor="NI"/>
								   \</generalizedMaterialKind>
								\</asSpecializedKind>
									/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind/kindOfProduct/asSpecializedKind/generalizedMaterialKind[code/@code="T95013"]/name	One per VMP	V 2.2

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published

72	B.2.1.5	MAH Assessment	A product association cannot be discounted but other factors prevent a conclusion being drawn - seizures 2 days post administration would not be expected, especially when the dog has received the medication without incident monthly for almost 1 year.	Optional, if no data use nullFlavor="NI"	Text up to 4000 characters	**Pre-validation** Text beyond the expected length will cause an **ERROR** **Business rules** Assessment text <originalText> is matched with a VMP using <productUseReference>. If <id extension> not valid then **ERROR**	The MAH Assessment is part of the MAH data, as indicated by XML Locator Code ="**T95001**" and it is linked to the VMP using <productUseReference> node
							
							Example 1
							<causalityAssessment classCode="INVSTG" moodCode="EVN">
							    <value xsi:type="CE">
							        <originalText>
							        A product association cannot be discounted but other factors prevent a conclusion
							        being drawn - seizures 2 days post administration would not be expected, especially
							        when the dog has received the medication without incident monthly for almost 1
							        year.
							        </originalText>
							    </value>
							    <author typeCode="AUT">
							        <assignedEntity classCode="ASSIGNED">
							            <code codeSystem="2.16.840.1.113883.13.206" code="**T95001**" displayName="MAH"/>
							        </assignedEntity>
							    </author>
							    <subject2 typeCode="SUBJ">
							        <productUseReference classCode="INFO" moodCode="EVN">
							            <id extension="1"/>
							        </productUseReference>
							    </subject2>
							</causalityAssessment>
							
							Example 2 – no MAH Assessment information
							<causalityAssessment classCode="INVSTG" moodCode="EVN">
							    <value xsi:type="CE">
							        <originalText nullFlavor="NI"/>
							    </value>
							    <author typeCode="AUT">
							        <assignedEntity classCode="ASSIGNED">
							            <code codeSystem="2.16.840.1.113883.13.206" code="T95001" displayName="MAH"/>
							        </assignedEntity>
							    </author>
							    <subject2 typeCode="SUBJ">
							        <productUseReference classCode="INFO" moodCode="EVN">
							            <id extension="1"/>
							        </productUseReference>
							    </subject2>
							</causalityAssessment>
								/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/component/causalityAssessment[author/assignedEntity/code/@code="**T95001**"]/value/originalText	One per VMP VMP identified by id extension	V 2.2

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
73	B.2.1.6.1	RA Assessment Term code	C54154	Optional, if no data use nullFlavor="NI"	Code List	**1) Pre-validation** XML Locator Code **T95009** is required else	Note: the RA Assessment is part of the RA data, as indicated by XML Locator Code ="**T95009** " and it is linked to the VMP using <productUseReference> node	/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigation Event/component/adverseEventAssessment/component/causalityAssessment[author/assignedEntity/code/@code="**T95009** "]/value	Repeat for each RA Assessment	V 2.3
74	B.2.1.6.1.1	Explanation Relating to Assessment	The reason for RA's causality assessment can put here.	Optional, if no data use nullFlavor="NI"	Text up to 4000 characters	**ERROR** 2) Text beyond the expected length will cause an **ERROR** **Business rules** 1) Assessment text <originalText> is matched with a VMP using <productUseReference>. If <id extension>not valid then **ERROR** 2) RA Assessment Term must exist as a code as in GL30 2.16.840.1.113883.13.201 else **ERROR** Guidance Note: There may be multiple assessments per VMP. The RA who made the assessment is not identified explicitly.	Example 1 – Assessment for a single VMP <component typeCode="COMP"> <causalityAssessment classCode="INVSTG" moodCode="EVN"> <text>The reason for RA's causality assessment can put here. </text> <value code="C54154" codeSystem="2.16.840.1.113883.13.201" displayName="Probable" xsi:type="CE"/> <author typeCode="AUT"> <assignedEntity classCode="ASSIGNED"> <code code="**T95009** " codeSystem="2.16.840.1.113883.13.206" displayName="RA"/> </assignedEntity> </author> <subject2 typeCode="SUBJ"> <productUseReference classCode="INFO" moodCode="EVN"> <id extension="1"/> </productUseReference> </subject2> </causalityAssessment> </component> Example 2 – no RA Assessment information <component typeCode="COMP"> <causalityAssessment classCode="INVSTG" moodCode="EVN"> <text nullFlavor="NI"/> <value xsi:type="CE" nullFlavor="NI"/> <author typeCode="AUT"> <assignedEntity classCode="ASSIGNED"> <code codeSystem="2.16.840.1.113883.13.206" code="**T95009** " displayName="RA"/> </assignedEntity> </author> <subject2 typeCode="SUBJ"> <productUseReference classCode="INFO" moodCode="EVN"> <id extension="1"/> </productUseReference> </subject2> </causalityAssessment> </component> Example 3 – RA Assessment when multiple VMP Repeat <component> block, please refer to sample file		Multiple per VMP VMP identified by id extension	

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
75	B.2.1.7	Route of Exposure (Route of Administration) code	C38288	Optional, if no data use nullFlavor="NI"	Code List	**Pre-validation** Digits beyond the expected length or precision will cause an **ERROR** **Business rules** 1) Route of Exposure must exist as a code as in GL30 2.16.840.1.113883.13.202 else **ERROR** 2) If there is a numerator value for dose then numerator units of value must exist in one of two GL30 lists: 2.16.840.1.113883.13.203 or 2.16.840.1.113883.6.8 (excluding the Category 'Time Unit') else **ERROR** 3) If there is no value for the numerator then units of value should be nullFlavor="NI" else **ERROR** 4) If there is a denominator value for dose then units of value must exist in in one of three GL30 lists: 2.16.840.1.113883.13.203 or 2.16.840.1.113883.6.8 (excluding the Category 'Time Unit') or 2.16.840.1.113883.13.204 5) If there is no denominator value for dose then units of value should be nullFlavor="NI" else **ERROR** 6) If there is a denominator value then there must be a numerator value	Many Route of Exposures and their dose values may be provided. The first route of exposure is given in the \<routeCode>nodes within the \<substanceAdministration> node, repeated routes of exposure are given in the \<outboundRelationship2> using extension to link to the VMP Example 1 – dose is 1 tablet (no numerator) \<routeCode codeSystem="2.16.840.1.113883.13.202" code="C38288" displayName="Oral"/> \<doseCheckQuantity> \<numerator xsi:type="PQ" value="1"> \<translation codeSystem="2.16.840.1.113883.13.203" code="C48542" displayName="tablet"/> \</numerator> \<denominator xsi:type="PQ" value="1"> \<translation codeSystem="2.16.840.1.113883.13.203" code="C17998" displayName="Unknown"/> \</denominator> \</doseCheckQuantity> Example 2 – no dose information \<routeCode codeSystem="2.16.840.1.113883.13.202" code="C38288" displayName="Oral"/> \<doseCheckQuantity> \<numerator xsi:type="PQ" nullFlavor="NI"> \<translation nullFlavor="NI"/> \</numerator> \<denominator xsi:type="PQ" nullFlavor="NI"> \<translation nullFlavor="NI"/> \</denominator> \</doseCheckQuantity> Example 3 – a second Route of Exposure, 30mL per Animal for VMP 1, including Interval of Administration, Date of First and Last Exposure. \<outboundRelationship2 typeCode="SEQL" contextConductionInd="true"> \<substanceAdministration classCode="SBADM" moodCode="EVN"> \<id root="1.2.3.4" extension="1" /> \<effectiveTime xsi:type="SXPR_TS"> \<comp xsi:type="IVL_TS"> \<low value="20060602" /> \<high value="20060602" /> \</comp> \<comp xsi:type="PIVL_TS"> \<period value="1" unit="d" /> \</comp> \</effectiveTime> \<routeCode codeSystem="2.16.840.1.113883.13.202" code="C38288" displayName="Oral"> \</routeCode> \<doseCheckQuantity> \<numerator xsi:type="PQ" value="30"> \<translation codeSystem="2.16.840.1.113883.6.8" code="mL" displayName="mL" /> \</numerator> \<denominator xsi:type="PQ" value="1"> \<translation codeSystem="2.16.840.1.113883.13.204" code="C14182" displayName="Animal" /> \</denominator> \</doseCheckQuantity> \</substanceAdministration> \</outboundRelationship2> Example 4 – no Route of Exposure information Same as example 3 except \<routeCode nullFlavor="NI"/>	The first route of exposure is specified in \<routeCode> and further routes of exposure will be in \<outboundRelationship2> /MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/routeCode xPath for further routes of exposure is /MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/outboundRelationship2/substanceAdministration/routeCode	Repeat for each Route of Exposure Multiple per VMP The VMP for the Dose is identified by the extension	V 2.6
76	B.2.1.7.1.1	Numeric Value for Dose (Numerator)	1	Optional, if no data use nullFlavor="NI"	Numeric, max 12 characters including a decimal point , max 4 d.p.					
77 and 78	B.2.1.7.1.1.1	Units of Value for Dose (Numerator) code	C4854	Conditional Mandatory IF B.1.7.1.1 is specified, if no data, select **C17998** for 'Unknown' or nullFlavor="NI"	Code List					
79	B.2.1.7.1.2	Numeric Value for Dose (Denominator)	1	Optional, if no data use nullFlavor="NI"	Numeric, max 12 characters including a decimal point , max 4 d.p.					
80 and 81	B.2.1.7.1.2.1	Units of Value for Dose (Denominator) code	C17998	Conditional Mandatory IF B.1.7.1.2 is specified, if no data, select **C17998** for 'Unknown' or nullFlavor="NI"	Code List					

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82	B.2.1.7.1.3.1	Numeric Value for Interval Of Administration	1	Optional, if no data use nullFlavor="NI"	Integer	**Pre-validation** 1) Digits beyond the expected length or precision will cause an **ERROR** 2) if date specified and date is not a valid date then **ERROR** **Business rules** 1) If there is a value for Interval of Administration then units of value code must exist as a code with Category 'Time Unit' in GL30 list 2.16.840.1.113883.6.8 e.g. s, min, h, d, wk, mo or a else **ERROR** 2) If there is no value for Interval of Administration then units of value should be nullFlavor="NI" else **ERROR** Refer to detailed business rules to explain validation that is applied to Interval of Administration. For example, Date of First Exposure <= Date of Last Exposure.	Interval of Administration and Dates of Exposure values are found within the <substanceAdministration> node for the VMP. Please refer to the example above for the extended snippet. Example 1 – Dose once a month for a year <effectiveTime xsi:type="SXPR_TS"> <comp xsi:type="IVL_TS"> <low value="20170701"/> <high value="20180701"/> </comp> <comp xsi:type="PIVL_TS"> <period value="1" unit="mo"/> </comp> </effectiveTime> Example 2 – 1 Dose on a single day, date format YYYYMM <effectiveTime xsi:type="SXPR_TS"> <comp xsi:type="IVL_TS"> <low value="201911"/> <high value="201911"/> </comp> <comp xsi:type="PIVL_TS"> <period nullFlavor="NI"/> </comp> </effectiveTime> Example 3 – no Interval of Administration and no Dates of Exposure available <effectiveTime xsi:type="SXPR_TS"> <comp xsi:type="IVL_TS"> <low nullFlavor="NI" /> <high nullFlavor="NI" /> </comp> <comp xsi:type="PIVL_TS"> <period nullFlavor="NI" /> </comp> </effectiveTime>	Use one <substanceAdministration> block for: - Interval of Administration (B.2.1.7.1.3.1 and B.2.1.7.1.3.1.1) - Date of First Exposure (B.2.1.7.1.3.2) - Date of Last Exposure (B.2.1.7.1.3.3) /MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/effectiveTime	One per Route of Exposure The VMP that the Dose applied to is indicated by the extension in the section where the effectiveTime is present, for example: <id root="1.2.3.4" extension="1"/> id/@extension is used to link this Interval of Administration and First and Last Dates of Exposure to the **First Dose of the VMP**. Subsequent Doses have Interval of Administration and First and Last Dates of Exposure contained in the outboundRelationship 2. Refer to .xml snippet for B.2.1.7, Example 3 above. See that extension is used to link to the appropriate VMP.	V 2.2
83	B.2.1.7.1.3.1.1	Units of Value for Interval of Administration code	mo	Conditional Mandatory IF B.1.7.1.3.1 is specified, then use time units only If B.1.7.1.3.1 is not specified, then use nullFlavor="NI"	Code List					
84 and 85	B.2.1.7.1.3.2	Date of First Exposure	20170701	Optional, if no data use nullFlavor="NI"	Date (YYYY, YYYYMM or YYYYMMDD)					
86 and 87	B.2.1.7.1.3.3	Date of Last Exposure	20180701	Optional, if no data use nullFlavor="NI"	Date (YYYY, YYYYMM or YYYYMMDD)					

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88	B.2.2.1	Active Ingredient Name	BETAMETHASONE	Conditional
				
				Mandatory IF B.2.1 Registered or Brand Name for Product not specified then Active Ingredient(s) must be specified
				
				Guidance Note: Mandatory for MAH's own VMP, use nullFlavor="NI" for no data
					Text up to 200 characters	**Pre-validation**
						1) Text beyond the expected length will cause an **ERROR**
						2) Digits beyond the expected length or precision will cause an **ERROR**
						
						Business rules
						1) If there is a numerator value for strength then units of value for the numerator must exist in the GL30 list 2.16.840.1.113883.6.8 (excluding the Category 'Time Unit') else **ERROR**
						2) If there is no numerator value for strength then units of value should be nullFlavor="NI" else **ERROR**
						3) If there is a denominator value for strength then units of value for the denominator must exist in 2.16.840.1.113883.13.203 or 2.16.840.1.113883.6.8 (excluding the Category 'Time Unit') else **ERROR**
						4) If there is no denominator value for strength then units of value for the denominator should be nullFlavor="NI" else **ERROR**
						5) Active Ingredient code should exist in Code list 2.16.840.1.113883.3.6905.2.1 which is currently under development
						6) If there is a denominator value then there must be a numerator value
							Example 1 – 6mg / dose of BETAMETHASONE i.e. strength and active ingredient
							\<ingredient classCode="INGR"\>
							    \<quantity\>
							        \<numerator value="6" xsi:type="PQ"\>
							            \<translation code="mg" codeSystem="2.16.840.1.113883.6.8" displayName="mg" /\>
							        \</numerator\>
							        \<denominator value="1" xsi:type="PQ"\>
							            \<translation code="C25488" codeSystem="2.16.840.1.113883.13.203" displayName="dose" /\>
							        \</denominator\>
							    \</quantity\>
							    \<ingredientSubstance classCode="MMAT" determinerCode="KIND"\>
							        \<code code="100000146980" codeSystem="2.16.840.1.113883.3.6905.2.1" /\>
							        \<name xsi:type="TN"\>BETAMETHASONE\</name\>
							    \</ingredientSubstance\>
							\</ingredient\>
								Use one \<ingredient\> block for:
								- Active Ingredient (B.2.2.1 and B.2.2.1.3)
								- Numerator (B.2.2.1.1 an B.2.2.1.1.1)
								- Denominator (B.2.2.1.2 an B.2.2.1.2.1)
								
								/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind/kindOfProduct/ingredient
									Repeat for each Active Ingredient
									
									A VMP may have many Active Ingredients.
									
									Active Ingredients data fields may be repeated many times per VMP.
										V 2.6

89	B.2.2.1.1	Numeric Value for Strength (Numerator)	6	Conditional
				
				Guidance Note: Mandatory for MAH's own VMP, use nullFlavor="NI" for no data
					Numeric, max 12 characters including a decimal point , max 4 d.p.		Example 2 – Multiple Ingredients
							Refer to sample .xml i.e. MultipleVMPsAndRoutes.xml
							
							Example 3 – No Active Ingredient information
							\<ingredientSubstance determinerCode="KIND" classCode="MMAT"\>
							    \<code nullFlavor="NI" /\>
							    \<name xsi:type="TN"\>noinformationsupplied\</name\>
							\</ingredientSubstance\>			

90	B.2.2.1.1.1	Units for Numeric Value for Strength (Numerator) code	mg	Conditional
				
				Mandatory IF B.2.2.1.1 is specified (use **C17998** for no data) else use nullFlavor="NI" for no data
					Code List		Example 4 – Active Ingredient without any strength information
							\<ingredient classCode="INGR"\>
							    \<quantity\>
							        \<numerator xsi:type="PQ" nullFlavor="NI"/\>
							        \<denominator xsi:type="PQ" nullFlavor="NI"/\>
							    \</quantity\>
							    \<ingredientSubstance classCode="MMAT" determinerCode="KIND"\>
							        \<code code="100000146980" codeSystem="2.16.840.1.113883.3.6905.2.1" /\>
							        \<name xsi:type="TN"\>BETAMETHASONE\</name\>
							    \</ingredientSubstance\>
							\</ingredient\>			

91	B.2.2.1.2	Numeric Value for Strength (Denominator)	1	Conditional Guidance Note: Mandatory for MAH's own VMP, use nullFlavor="NI" for no data	Numeric, max 12 characters including a decimal point , max 4 d.p.					
92 and 93	B.2.2.1.2.1	Units for Numeric Value for Strength (Denominator) code	C25488	Conditional Mandatory IF B.2.2.1.1 is specified (use **C17998** for no data) else use nullFlavor="NI" for no data	Code List					
94	B.2.2.1.3	Active Ingredient code	100000146980	Optional, if no data use nullFlavor="NI"	Code List					

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
95	B.2.2.2	Dosage Form code	C42994	Optional, if no data use nullFlavor="NI"	Code List	**Business rules** If there is a value then the code must exist in GL30 2.16.840.1.113883.13.205else **ERROR**	`<formCode code="C42994" codeSystem="2.16.840.1.113883.13.205" displayName="SUSPENSION" />`		One per VMP Note : Dosage Form relates to the VMP and not an Active Ingredient described in the group of fields that make up B.2.2.	V 2.0

96	B.2.3	Lot Number(s)	D024734	Optional, if no data use nullFlavor="NI"	Text up to 35 characters	**Pre-validation** 1) Text beyond the expected length will cause an **ERROR** 2) if date specified and date is not a valid date then, **ERROR**
						
						Business rules Repeat for as many Lot Numbers are applicable
						
						Note: The Lot Number and Expiration Date are a pair of values and it is possible to have one without the other.
							Example 1 – Lot Number and Expiration Date
							`<productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">`
							    `<id extension="1" />`
							    `<existenceTime xsi:type="IVL_TS">`
							        `<low value="20051208" />`
							    `</existenceTime>`
							    `<lotNumberText mediaType="text/plain">D024734</lotNumberText>`
							    `<expirationTime value="20060405" />`
							`</productInstanceInstance>`
							
							Example 2 – No Lot Number or Expiration Date information
							`<productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">`
							    `<id extension="1"/>`
							    `<lotNumberText nullFlavor="NI"/>`
							    `<expirationTime nullFlavor="NI"/>`
							`</productInstanceInstance>`
							
							Example 3 – No Lot Number information, Expiration date only
							`<productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">`
							    `<id extension="1"/>`
							    `<lotNumberText nullFlavor="NI"/>`
							    `<expirationTime value="20060405"/>`
							`</productInstanceInstance>`
							
							Example 4 – Multiple Lot Numbers: XYZ3487, USA-123479, USA-123480. See that the Lots do not have an Expiration date
							`<productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">`
							    `<id extension="1"/>`
							    `<existenceTime xsi:type="IVL_TS">`
							        `<low value="20051208"/>`
							    `</existenceTime>`
							    `<lotNumberText mediaType="text/plain">XYZ3487</lotNumberText>`
							    `<expirationTime value="20060405"/>`
							
							    `<member classCode="MBR">`
							        `<memberProductInstance classCode="MMAT" determinerCode="INSTANCE">`
							            `<id extension="2"/>`
							            `<existenceTime xsi:type="IVL_TS">`
							                `<low value="20051218"/>`
							            `</existenceTime>`
							            `<lotNumberText mediaType="text/plain">USA-123479</lotNumberText>`
							            `<expirationTime nullFlavor="NI"/>`
							        `</memberProductInstance>`
							    `</member>`
							
							    `<member classCode="MBR">`
							        `<memberProductInstance classCode="MMAT" determinerCode="INSTANCE">`
							            `<id extension="3"/>`
							            `<existenceTime xsi:type="IVL_TS">`
							                `<low value="20051218"/>`
							            `</existenceTime>`
							            `<lotNumberText mediaType="text/plain">USA-123480</lotNumberText>`
							            `<expirationTime nullFlavor="NI"/>`
							        `</memberProductInstance>`
							    `</member>`
							`</productInstanceInstance>`
									Repeat for each Lot
									
									Lot Number and Expiration Date are a pair of values that are repeatable many times for each VMP
									
									The first Lot is in `</productInstanceInstance>` and has id extension="1"
									
									each subsequent lot is provided as a `<member>`, see example with id extension="2" id extension="3" etc
										V 2.2

97 and 98	B.2.3.1	Expiration Date	20060405	Optional, if no data use nullFlavor="NI"	Date (YYYY, YYYYMM or YYYYMMDD)					

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99	B.2.4	Who Administered the VMP code	C82468	Optional, if no data use **C17998**Unknown n or nullFlavor="NI"	Code List	**Business rules** If there is a value then the code must exist in GL30 2.16.840.1.113883.13.208 else **ERROR**	`<performer typeCode="PRF">`
							`    <assignedEntity classCode="ASSIGNED">`
							`        <code code="C82468" codeSystem="2.16.840.1.113883.13.208" displayName="ANIMAL OWNER" />`
							`    </assignedEntity>`
							`</performer>`
								MCCI_IN200100UV01/PORR_IN049006UV /controlActProcess/subject/investigationE vent/component/adverseEventAssessmen t/subject1/primaryRole/subjectOf2/subst anceAdministration[id/@extension="1"]/ performer/assignedEntity/code/@code	One per VMP	V 2.0

100 and 101	B.2.5	Use According to Label (Y/N)?	No	Optional, if no data use nullFlavor="NI"
				
				Values permitted are:
				• Yes/True
				• No/False
				• NullFlavor = "UNK" or "NI"
					Boolean	**Pre-validation** XML Locator Codes**T95015** is required else **ERROR**	XPath for Use According to Label is outboundRelationship2 block within PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEven tAssessment/subject1/primaryRole/subjectOf2/substanceAdministration
							
							Example 1 – use not according to label
							`<outboundRelationship2 contextConductionInd="true" typeCode="PERT">`
							`    <observation classCode="OBS" moodCode="EVN">`
							`        <code code="T95015" codeSystem="2.16.840.13.206" displayName="Use According to Label"/>`
							`            <value value="false" xsi:type="BL"/>`
							`    </observation>`
							`</outboundRelationship2>`
							
							Example 2– use according to label
							`<outboundRelationship2 contextConductionInd="true" typeCode="PERT">`
							`    <observation classCode="OBS" moodCode="EVN">`
							`        <code code="T95015" codeSystem="2.16.840.13.206" displayName="Use According to Label"/>`
							`            <value value="true" xsi:type="BL"/>`
							`    </observation>`
							`</outboundRelationship2>`
							
							Example 3– Unknown
							`<outboundRelationship2 contextConductionInd="true" typeCode="PERT">`
							`    <observation classCode="OBS" moodCode="EVN">`
							`        <code code="T95015" codeSystem="2.16.840.13.206" displayName="Use According to Label"/>`
							`            <value xsi:type="BL" nullFlavor="UNK" />`
							`    </observation>`
							`</outboundRelationship2>`
							
							Example 4– no information
							`<outboundRelationship2 contextConductionInd="true" typeCode="PERT">`
							`    <observation classCode="OBS" moodCode="EVN">`
							`        <code code="T95015" codeSystem="2.16.840.13.206" displayName="Use According to Label"/>`
							`            <value xsi:type="BL" nullFlavor="NI" />`
							`    </observation>`
							`</outboundRelationship2>`
								MCCI_IN200100UV01/PORR_IN049006UV /controlActProcess/subject/investigationE vent/component/adverseEventAssessmen t/subject1/pri maryRole/subjectOf2/substanceAdministr ation[id/@extension="1"]/outboundRelati onship2/observation[code/@code= "T95015"]/value/	One per VMP	V 2.2

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published

102	B.2.5.1.1	Was the target species Off-Label?	Yes	Each of the 9 Explanation data fields is Conditional
				
				If B.2.5 is 'Yes' then Off-label Explanation is NOT required and all explanations are nullFlavor="NI"
				
				If B.2.5 is 'No' then provide a value for each of the Off-label explanations, if no data use nullFlavor="NI"
				
				Values permitted are:
				• Yes/True
				• No/False
				• NullFlavor = "NI"
					Boolean	**Pre-validation**
						XML Locator Code **T95016** is required, and under **T95016**, then **T95028 through to T95035** are required else **ERROR**
						
						Business rules
						1) If B.2.5 is 'Yes' then the VMP has been used correctly and explanation for Off-Label is not required and all explanations are nullFlavor="NI" else **ERROR**
						2) If B.2.5 is 'No' then the VMP has not been used correctly and explanation for Off-Label is required, at least one explanation must be set to true/Yes else **WARNING**
							Example 1 – off-label species, overdosed and off-label treatment regimen
							`<observation classCode="OBS" moodCode="EVN">`
							   `<code code="T95016" codeSystem="2.16.840.1.113883.13.206"`
							     `displayName="VICH Label Use"/>`
							   `<outboundRelationship2 contextConductionInd="true" typeCode="PERT">`
							   `<observation classCode="OBS" moodCode="EVN">`
							     `<code code="T95028" codeSystem="2.16.840.1.113883.13.206"`
							     `displayName="Species Off-Label "/>`
							     `<value value="true" xsi:type="BL"/>`
							   `</observation>`
							   `</outboundRelationship2>`
							   `<outboundRelationship2 contextConductionInd="true" typeCode="PERT">`
							     `<observation classCode="OBS" moodCode="EVN">`
							     `<code code="T95029" codeSystem="2.16.840.1.113883.13.206"`
							     `displayName="Route Off-Label"/>`
							     `<value nullFlavor="NI" xsi:type="BL"/>`
							   `</observation>`
							   `</outboundRelationship2>`
							   `<outboundRelationship2 contextConductionInd="true" typeCode="PERT">`
							     `<observation classCode="OBS" moodCode="EVN">`
							     `<code code="T95030" codeSystem="2.16.840.1.113883.13.206"`
							     `displayName="Overdosed"/>`
							     `<value value="true" xsi:type="BL"/>`
							   `</observation>`
							   `</outboundRelationship2>`
							   `<outboundRelationship2 contextConductionInd="true" typeCode="PERT">`
							     `<observation classCode="OBS" moodCode="EVN">`
							     `<code code="T95031" codeSystem="2.16.840.1.113883.13.206"`
							     `displayName="Underdosed"/>`
							     `<value nullFlavor="NI" xsi:type="BL"/>`
							   `</observation>`
							   `</outboundRelationship2>`
							   `<outboundRelationship2 contextConductionInd="true" typeCode="PERT">`
							   `<observation classCode="OBS" moodCode="EVN">`
							     `<code code="T95032" codeSystem="2.16.840.1.113883.13.206"`
							     `displayName="Treatment regimen Off-Label"/>`
							     `<value value="true" xsi:type="BL"/>`
							   `</observation>`
							   `</outboundRelationship2>`
							   `<outboundRelationship2 contextConductionInd="true" typeCode="PERT">`
							     `<observation classCode="OBS" moodCode="EVN">`
							     `<code code="T95033" codeSystem="2.16.840.1.113883.13.206"`
							     `displayName="Indication Off-Label"/>`
							     `<value nullFlavor="NI" xsi:type="BL"/>`
							   `</observation>`
							   `</outboundRelationship2>`
							   `<outboundRelationship2 contextConductionInd="true" typeCode="PERT">`
							     `<observation classCode="OBS" moodCode="EVN">`
							     `<code code="T95034" codeSystem="2.16.840.1.113883.13.206"`
							     `displayName="Storage condition Off-Label"/>`
							     `<value nullFlavor="NI"  xsi:type="BL"/>`
							   `</observation>`
							   `</outboundRelationship2>`
							   `<outboundRelationship2 contextConductionInd="true" typeCode="PERT">`
							     `<observation classCode="OBS" moodCode="EVN">`
							     `<code code="T95035" codeSystem="2.16.840.1.113883.13.206"`
							     `displayName="Product expired"/>`
							     `<value nullFlavor="NI" xsi:type="BL"/>`
							   `</observation>`
							   `</outboundRelationship2>`
							   `<outboundRelationship2 contextConductionInd="true" typeCode="PERT">`
							     `<observation classCode="OBS" moodCode="EVN">`
							     `<code code="T95036" codeSystem="2.16.840.1.113883.13.206"`
							     `displayName="Other off label issue"/>`
							     `<value nullFlavor="NI" xsi:type="BL"/>`
							   `</observation>`
							   `</outboundRelationship2>`
							`</observation>`
								MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/outboundRelationship2/observation[code/@code="T95016"]/outboundRelationship2/observation[code/@code="T95030"]/value/@value	One per VMP	V 2.0

103	B.2.5.1.2	Was the route of administration Off-Label?								
104	B.2.5.1.3	Was the animal overdosed?	Yes							
105	B.2.5.1.4	Was the animal underdosed?								
106	B.2.5.1.5	Was the treatment regimen Off-Label?	Yes							
107	B.2.5.1.6	Was the indication Off-Label?								
108	B.2.5.1.7	Was the storage condition Off-Label?								
109	B.2.5.1.8	Was the product expired?								
110	B.2.5.1.9	Was there any other Off-Label issue?								

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
111 and 112	B.3.9	Previous Exposure to the VMP (Y/N)?	Yes	Optional, if no data use nullFlavor="NI" Values permitted are: • Yes/True • No/False • NullFlavor = "UNK" or "NI"	Boolean	**Pre-validation** 1) XML Locator Code **T95024** is required else **ERROR**	Example 1 <outboundRelationship2 contextConductionInd="true" typeCode="PERT"> <observation classCode="OBS" moodCode="EVN"> <code code="**T95024**" codeSystem="2.16.840.1.113883.13.206" displayName="Previous Exposure to the VMP"/> <value xsi:type="BL" value="true" /> </observation> </outboundRelationship2> Example 2 - no data <outboundRelationship2 typeCode="PERT" contextConductionInd="true"> <observation moodCode="EVN" classCode="OBS"> <code codeSystem="2.16.840.1.113883.13.206" code="**T95024**" displayName="Previous Exposure to the VMP" /> <value xsi:type="BL" nullFlavor="NI" /> </observation> </outboundRelationship2> Example 3 – Unknown As above, except <value xsi:type="BL" nullFlavor="UNK" />	/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/outboundRelationship2/observation[code/@code="T95024"]/value/@value	One per VMP	V 2.2
113 and 114	B.3.10	Previous AE to VMP (Y/N)?	Yes	Optional, if no data use nullFlavor="NI" Values permitted are: • Yes/True • No/False • NullFlavor = "UNK" or "NI"	Boolean	**Pre-validation** 1) XML Locator Code **T95025** is required else **ERROR**	Example 1 <outboundRelationship2 contextConductionInd="true" typeCode="PERT"> <observation classCode="OBS" moodCode="EVN"> <code code="**T95025**" codeSystem="2.16.840.1.113883.13.206" displayName="Previous AE to the VMP"/> <value value="true" xsi:type="BL"/> </observation> </outboundRelationship2> Example 2 - no data <outboundRelationship2 typeCode="PERT" contextConductionInd="true"> <observation moodCode="EVN" classCode="OBS"> <code codeSystem="2.16.840.1.113883.13.206" code="**T95025**" displayName="Previous AE to the VMP" /> <value xsi:type="BL" nullFlavor="NI"/> </observation> </outboundRelationship2> Example 3 – Unknown As above, except <value xsi:type="BL" nullFlavor="UNK"/>	/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/outboundRelationship2/observation[code/@code="T95025"]/value/@value	One per VMP	V 2.2
115 and 116	B.4.1	Did AE Abate After Stopping the VMP (Y/N)?	Yes	Optional, if no data use nullFlavor="NI" Values permitted are: • Yes/True • No/False • NullFlavor = "UNK", "NA" or "NI"	Boolean	**Pre-validation** 1) XML Locator Code **T95026** is required else **ERROR**	Example 1 – AE abated after stopping the VMP <outboundRelationship2 contextConductionInd="true" typeCode="PERT"> <observation classCode="OBS" moodCode="EVN"> <code code="**T95026**" codeSystem="2.16.840.1.113883.13.206" displayName="Did AE Abate After Stopping the VMP "/> <value value="true" xsi:type="BL"/> </observation> </outboundRelationship2> Example 2 - no data As above, except <value xsi:type="BL" nullFlavor="NI" /> Example 3 – Unknown As above, except <value xsi:type="BL" nullFlavor="UNK" /> Example 4 – Not Applicable As above, except <value xsi:type="BL" nullFlavor="NA" />	/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/outboundRelationship2/observation[code/@code="T95026"]/value/@value	One per VMP	V 2.0

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published

117 and 118	B.4.2	Did AE Reappear After Reintroduction of the VMP (Y/N)?	Yes	Optional
				
				Values permitted are:
				• Yes/True
				• No/False
				NullFlavor = "UNK", "NA" or "NI"
					Boolean	**Pre-validation**
						1) XML Locator Code **T95027** is required else **ERROR**
							Example 1 – AE reappeared after reintroduction of the VMP
							\<outboundRelationship2 contextConductionInd="true" typeCode="PERT"\>
							    \<observation classCode="OBS" moodCode="EVN"\>
							        \<code code="**T95027**" codeSystem="2.16.840.1.113883.13.206" displayName="Did AE Reappear After Re-introducing the VMP"/\>
							        \<value xsi:type="BL" value="true" /\>
							    \</observation\>
							\</outboundRelationship2\>
							
							Example 2 - no data
							\<outboundRelationship2 typeCode="PERT" contextConductionInd="true"\>
							    \<observation moodCode="EVN" classCode="OBS"\>
							        \<code code="**T95027**" codeSystem="2.16.840.1.113883.13.206" displayName="Did AE Reappear After Re-introducing the VMP"/\>
							        \<value xsi:type="BL" nullFlavor="NI" /\>
							    \</observation\>
							\</outboundRelationship2\>
							
							Example 3 – Unknown
							As above, except \<value xsi:type="BL" nullFlavor="UNK" /\>
							
							Example 4 – Not Applicable
							As above, except \<value xsi:type="BL" nullFlavor="NA" /\>
								MCCI_IN200100UV01/PORR_IN049006UV /controlActProcess/subject/investigationE vent/component/adverseEventAssessmen t/subject1/pri maryRole/subjectOf2/substanceAdministr ation[id/@extension="1"]/outboundRelati onship2/observation[code/@code= "T95027"]/value/@value	One per VMP	V 2.0

Reaction data, assessment and references to other AERs and documents – B.3 (excl B.3.9 and B.3.10), B.5, B.6 and B.7

There is one <controlActProcess> block per AER.

Within the <controlActProcess> block there may be many <subjectOf2> blocks for multiple Adverse Clinical Manifestations, Linked Reports and Supplemental Documents.

	Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
	119	B.3.1	Narrative of AE	The sows and gilts were given the two medications. Two days after receiving the medicine in the feed the sows and gilts started going off feed. A closer inspection of a previous report *(report number here)*indicated some kind of foreign contaminant in the Type A medicated article bag. SUPPLEMENTAL: document number one was supplied by attending vet. Document number two was supplied by the laboratory XXXXX Ltd at the request of the attending vet. SUPPLEMENTAL DOCUMENTS: 1.Other- HL7 additional text	**Mandatory**	Text up to 20,000 characters	**Pre-validation** 1) If mandatory elements are missing then **ERROR** 2) Text beyond the expected length will cause an **ERROR**	Example <text mediaType="text/plain">The sows and gilts were given the two medications. Two days after receiving the medicine in the feed the sows and gilts started going off feed. A closer inspection of a previous report *(report number here)*indicated some kind of foreign contaminant in the Type A medicated article bag. SUPPLEMENTAL: document number one was supplied by attending vet. Document number two was supplied by the laboratory XXXXX Ltd at the request of the attending vet. SUPPLEMENTAL DOCUMENTS: 1.Other- HL7 additional text</text>	/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/text	One per AER	V 2.0

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
120	B.3.2	Adverse Clinical Manifestations code (Veddra LLT Key)	2283	Mandatory	Code List	**Pre-validation** 1) XML Locator Codes**T95020** is required else **ERROR** 2) If mandatory elements are missing then **ERROR** 3) If not a valid date then **ERROR** **Business rules** 1) A pair of values is required for LLT Key and version. There must be a Valid LLT Key and version associated with the LLT key else **ERROR** 2) LLT key is expected to be in list of VeDDRA Terms, refer to GL30VocabularyOID 2.16.840.1.113883.4.358 else **ERROR** 3) If Number of Animals is provided then Accuracy of Animals must exist as a code as in GL30VocabularyOID 2.16.840.1.113883.13.209 else **ERROR** 4) If there is a Duration specified then Duration Time Unit must exist as a code with the Category 'Time Unit' in GL30 list 2.16.840.1.113883.6.8 i.e. s, min, h, d, wk, mo, or a else **ERROR** Note: Refer to detailed business rules to explain validation rules for reaction details, for example, Date of Onset cannot be a date in the future	Example – Date of Onset 8-June-2006, product problem for 1 animal (estimated), for 5 days	Use one <subjectOf2> block adverseEventAssessment/subject1/primaryRole with XML Locator code **T95020** for: - VeDDRA Code and version (B.3.2) - Number of Animals (B.3.2.1 and.3.2.1.1) - Date of Onset (B.3.3) - Duration (B.3.5.1 and B.3.5.2) /MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/observation[code/@code="T95020"]	Repeat for each Adverse Clinical Manifestation There must be at least one Adverse Clinical Manifestation code per AER. Each Adverse Clinical Manifestations has its own <subjectOf2> block but only the first one contains the Date of Onset and Duration.	V 2.2
121		Veddra version associated with Veddra LLT Key	13							
122	B.3.2.1	Number of Animals	1	Optional, if no data use nullFlavor="NI"	Integer					
123	B.3.2.1.1	Accuracy of the Number of Animals code	C25498	Conditional Mandatory IF B.3.2.1 is specified. If no value for B.3.2.1 then use nullFlavor="NI"	Code List					

.xml snippet (cell for rows 120–123):

```
Example – Date of Onset 8-June-2006, product problem for 1 animal (estimated), for 5 days
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <code code="T95020" codeSystem="2.16.840.1.113883.13.206" displayName="Reaction"/>
        <effectiveTime xsi:type="IVL_TS">
            <low value="20060608"/>
            <width unit="d" value="5"/>
        </effectiveTime>
        <value code="2283" codeSystem="2.16.840.1.113883.4.358" codeSystemVersion="13" displayName="Product problem" xsi:type="CE"/>
        <referenceRange>
            <observationRange classCode="OBS" moodCode="EVN.CRT">
                <value value="1" xsi:type="INT"/>
                <interpretationCode code="C25498" codeSystem="2.16.840.1.113883.13.209" displayName="Estimated"/>
            </observationRange>
        </referenceRange>
    </observation>
</subjectOf2>

Example 2 – repeated Manifestations, estimated 1 Animal has died and 10 Animals are vomiting
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <code code="T95020" codeSystem="2.16.840.1.113883.13.206" displayName="Reaction"/>
        <effectiveTime xsi:type="IVL_TS">
            <low value="20060608"/>
            <width unit="d" value="5"/>
        </effectiveTime>
        <value code="984" codeSystem="2.16.840.1.113883.4.358" codeSystemVersion="7" displayName="Death" xsi:type="CE"/>
        <referenceRange>
            <observationRange classCode="OBS" moodCode="EVN.CRT">
                <value value="1" xsi:type="INT"/>
                <interpretationCode code="C25498" codeSystem="2.16.840.1.113883.13.209" displayName="Estimated"/>
            </observationRange>
        </referenceRange>
    </observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <code code="T95020" codeSystem="2.16.840.1.113883.13.206" displayName="Reaction"/>
        <value code="334" codeSystem="2.16.840.1.113883.4.358" codeSystemVersion="8" displayName="Vomiting" xsi:type="CE"/>
        <referenceRange>
            <observationRange classCode="OBS" moodCode="EVN.CRT">
                <value value="10" xsi:type="INT"/>
                <interpretationCode code="C25274" codeSystem="2.16.840.1.113883.13.209" displayName="Actual"/>
            </observationRange>
        </referenceRange>
    </observation>
</subjectOf2>

Example 3 – a Manifestation without the number of animals being specified
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <code code="T95020" codeSystem="2.16.840.1.113883.13.206" displayName="Reaction"/>
        <value code="334" codeSystem="2.16.840.1.113883.4.358" codeSystemVersion="8" displayName="Vomiting" xsi:type="CE"/>
        <referenceRange>
            <observationRange classCode="OBS" moodCode="EVN.CRT">
                <value xsi:type="INT" nullFlavor="NI"/>
                <interpretationCode nullFlavor="NI"/>
            </observationRange>
        </referenceRange>
    </observation>
</subjectOf2>
```

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
124 and 125	B.3.3	Date of Onset of AE (AE Start Date)	20060608	**Mandatory**	Date (YYYY, YYYYMM or YYYYMMDD)	See B.3.2 above	See B.3.2 above in effectiveTime	See B.3.2 above	One per AER	V 2.2

126	B.3.5.1	Duration (Time)	5	Optional, if no data use nullFlavor="NI"	Numeric, max 12 characters including a decimal point , max 4 d.p.	See B.3.2 above	See B.3.2 above in effectiveTime/width/unit and in effectiveTime/width/value
							
							Example of no information for Duration
							`<effectiveTime xsi:type="IVL_TS">`
							`    <low value="20060608"/>`
							`    <width nullFlavor="NI" />`
							`</effectiveTime>`
								See B.3.2 above	One per AER	V 2.6

127	B.3.5.1.1	Duration Time Unit code	d	Conditional Mandatory IF B.3.5.1 is specified. If no value for B.3.5.1 then use nullFlavor="NI"	Code List					

128	B.3.4	Length of Time between Exposure to VMP & Onset of AE code	C82440	Optional, if no data use **C17998** for Unknown or nullFlavor="NI"	Code List	**Pre-validation**
						XML Locator Codes**T95021** is required else **ERROR**
						
						Business rules
						Length of time between Exposure and Onset must exist as a code as in GL30VocabularyOID 2.16.840.1.113883.13.50 else **ERROR**
							Example 1 - <12 hours between Exposure to VMP & Onset of AE code
							`<subjectOf2 typeCode="SBJ">`
							`    <observation classCode="OBS" moodCode="EVN">`
							`        <code code="`**T95021**`" codeSystem="2.16.840.1.113883.13.206" displayName="Length of Time Between Exposure to VMP and Onset of AE"/>`
							`        <value code="C82440" codeSystem="2.16.840.1.113883.13.50" displayName="<12 hours" xsi:type="CE"/>`
							`    </observation>`
							`</subjectOf2>`
							
							Example 2 – no information for time between Exposure to VMP & Onset of AE code
							`<subjectOf2 typeCode="SBJ">`
							`    <observation moodCode="EVN" classCode="OBS">`
							`        <code codeSystem="2.16.840.1.113883.13.206" code="`**T95021**`" displayName="Length of Time Between Exposure to VMP and Onset of AE" />`
							`        <value xsi:type="CE" nullFlavor="NI" />`
							`    </observation>`
							`</subjectOf2>`
								Use a separate `<subjectOf2>` block adverseEventAssessment/subject1/primaryRole with XML Locator code **T95021** for Length of Time between Exposure to VMP & Onset of AE code
								
								/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/observation[code/@code="**T95021**"]/value/@code
									One per AER	V 2.0

129	B.3.6	Serious AER Reported (Y/N)?	True	**Mandatory**
				
				Values permitted are:
				• Yes/True
				• No/False
					Boolean	**Pre-validation**
						1) XML Locator Code **T95022** is required else **ERROR**
						2) If mandatory elements are missing then **ERROR**
						
						Business rules
						Unknown is NOT a valid value
							Example 1
							`<subjectOf2 typeCode="SUBJ">`
							`    <investigationCharacteristic classCode="CASE" moodCode="EVN">`
							`        <code codeSystem="2.16.840.1.113883.13.206" code="`**T95022**`" displayName="Serious AE" />`
							`        <value value="true" xsi:type="BL"/>`
							`    </investigationCharacteristic>`
							`</subjectOf2>`
								Use a separate `<subjectOf2>` block /MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf2/investigationCharacteristic[code/@code="**T95022**"]/value	One per AER	V 2.2

130 and 131	B.3.7	Treatment of AE (Y/N)?	true	Optional, if no data use nullFlavor="NI"
				
				Values permitted are:
				• Yes/True
				• No/False
				• NullFlavor = "UNK"
					Boolean	**Pre-validation**
						1) XML Locator Code **T95023** is required else **ERROR**
							Example 1 – Treatment of AER = Yes
							`<subjectOf2 typeCode="SBJ">`
							`    <observation classCode="OBS" moodCode="EVN">`
							`        <code code="`**T95023**`" codeSystem="2.16.840.1.113883.13.206" displayName="Treatment of AE"/>`
							`        <value value="true" xsi:type="BL"/>`
							`    </observation>`
							`</subjectOf2>`
							
							Example 2 – no data
							`<subjectOf2 typeCode="SBJ">`
							`    <observation moodCode="EVN" classCode="OBS">`
							`        <code codeSystem="2.16.840.1.113883.13.206" code="`**T95023**`" displayName="Treatment of AE" />`
							`        <value xsi:type="BL" nullFlavor="NI" />`
							`    </observation>`
							`</subjectOf2>`
							
							Example 3 – Treatment of AER is Unknown
							`<subjectOf2 typeCode="SBJ">`
							`    <observation moodCode="EVN" classCode="OBS">`
							`        <code codeSystem="2.16.840.1.113883.13.206" code="`**T95023**`" displayName="Treatment of AE" />`
							`        <value xsi:type="BL" nullFlavor="UNK" />`
							`    </observation>`
							`</subjectOf2>`
								Use a separate `<subjectOf2>` block adverseEventAssessment/subject1/primaryRole with XML Locator code **T95023** for Treatment of AE (Y/N)? (B.3.7)
								
								/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/observation[code/@code="**T95023**"]/value/@value
									One per AER	V 2.2

Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
132	B.3.8.1	Ongoing	3	Optional	Integer	**Pre-validation** Values are zero or positive integers **Business rules** All of these data fields are numbers of animals for each outcome to date. Refer to detailed business rules to explain validation **ERROR**s and warnings. For example, as per GL42, total number of Animals in B.3.8 should be equal to the Number of Animals Affected in B.1.2. <u>Guidance Note:</u> If the number of animals that have died is greater than zero, then there ought to be at least one VMPwith the VeDDRA term for Death in B.2.1.3	Outcome data is given as six separate<subjectOf2> blocks <subjectOf2 typeCode="SBJ"> <observation classCode="OBS" moodCode="EVN"> <code code="**C53279**" codeSystem="2.16.840.1.113883.13.206" displayName="Ongoing" /> <value value="3" xsi:type="INT" /> </observation> </subjectOf2> <subjectOf2 typeCode="SBJ"> <observation classCode="OBS" moodCode="EVN"> <code code="**C82467**" codeSystem="2.16.840.1.113883.13.206" displayName="Recovered/Normal" /> <value value="2" xsi:type="INT" /> </observation> </subjectOf2> <subjectOf2 typeCode="SBJ"> <observation classCode="OBS" moodCode="EVN"> <code code="**C49495**" codeSystem="2.16.840.1.113883.13.206" displayName="Recovered with Sequela" /> <value value="1" xsi:type="INT" /> </observation> </subjectOf2> <subjectOf2 typeCode="SBJ"> <observation classCode="OBS" moodCode="EVN"> <code code="**C28554**" codeSystem="2.16.840.1.113883.13.206" displayName="Died" /> <value value="3" xsi:type="INT" /> </observation> </subjectOf2> <subjectOf2 typeCode="SBJ"> <observation classCode="OBS" moodCode="EVN"> <code code="**C21115**" codeSystem="2.16.840.1.113883.13.206" displayName="Euthanized" /> <value nullFlavor="NI" xsi:type="INT" /> </observation> </subjectOf2> <subjectOf2 typeCode="SBJ"> <observation classCode="OBS" moodCode="EVN"> <code code="**C17998**" codeSystem="2.16.840.1.113883.13.206" displayName="Outcome Unknown" /> <value value="0" xsi:type="INT" /> </observation> </subjectOf2> <u>Note:</u> For 'no data supplied, replace the <value> with<value nullFlavor="NI" xsi:type="INT" />	Use a separate <subjectOf2> block within adverseEventAssessment/subject1/primaryRole for each Outcome xPath for 'Ongoing' is /MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/observation[code/@code="**C53279**"]/value/@value xPath for 'Recovered/Normal' is /MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/observation[code/@code="**C82467**"]/value/@value xPath for 'Recovered with Sequela' is /MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/observation[code/@code="**C49495**"]/value/@value xPath for 'Died' is /MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/observation[code/@code="**C28554**"]/value/@value xPath for 'Euthanized' is /MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/observation[code/@code="**C21115**"]/value/@value xPath for 'Outcome Unknown' is /MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/primaryRole/subjectOf2/observation[code/@code="**C17998**"]/value/@value	Each AER will have one each of **C17998** **C21115** **C28554** **C49495** **C53279** **C82467**	V 2.0
133	B.3.8.2	Recovered/Normal	2	Optional	Integer					
134	B.3.8.3	Recovered with Sequela	1	Optional	Integer					
135	B.3.8.4	Died	3	Optional	Integer					
136	B.3.8.5	Euthanized		Optional	Integer					
137	B.3.8.6	Outcome Unknown	0	Optional	Integer					

	Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
	138	B.5.1	Attending Veterinarian's Assessment of AE Code	C82490	Optional, if no data use **C17998** for Unknown or nullFlavor="NI"	Code List	**Business rules** 1) If there is a value then the code must exist as a code as in GL30 2.16.840.1.113883.13.210 else **ERROR** 2) If there is no value then value should be nullFlavor="NI" else **ERROR**	Example `<component typeCode="COMP">` `<causalityAssessment classCode="INVSTG" moodCode="EVN">` `<value code="`**C82490**`" codeSystem="2.16.840.1.113883.13.210" displayName="Possible" xsi:type="CE"/>` `<author typeCode="AUT">` `<assignedEntity classCode="ASSIGNED">` `<code code="C82470" codeSystem="2.16.840.1.113883.13.194" displayName="Veterinarian"/>` `</assignedEntity>` `</author>` `</causalityAssessment>` `</component>` Example – no data `<component typeCode="COMP">` `<causalityAssessment classCode="INVSTG" moodCode="EVN">` `<value xsi:type="CE" nullFlavor="NI" />` `<author typeCode="AUT">` `<assignedEntity classCode="ASSIGNED">` `<code codeSystem="2.16.840.1.113883.13.194"code="C82470" displayName="Veterinarian" />` `</assignedEntity>` `</author>` `</causalityAssessment>` `</component>`	/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/component/causalityAssessment[author/assignedEntity/code/@code="C82470"]	One per AER	V 2.0
	139	B.6.1	Unique AER Identification Number of Linked Report	NLD-INDGAPSY-2009-NL-01234	Optional if no data use nullFlavor="NI"	Text up to 60 characters	**Pre-validation** 1) XML Locator Code **T95037** is required else **ERROR** 2) Text beyond the expected length will cause an **ERROR**	Example 1 - a Linked Report `<subjectOf2 typeCode="SUBJ">` `<investigationCharacteristic classCode="CASE" moodCode="EVN">` `<code code="`**T95037**`" codeSystem="2.16.840.1.113883.13.206" displayName="Report Number(s) of Linked Report(s)"/>` `<value code="LTOT" codeSystem="2.16.840.1.113883.13.219" displayName="Parent – Offspring" xsi:type="CD">` `<originalText>`NLD-INDGAPSY-2009-NL-01234`</originalText>` `</value>` `</investigationCharacteristic>` `</subjectOf2>` Example 2 – more than one Linked Report Repeat the `<subjectOf2>` block as above Example 3 – no Linked Report `<subjectOf2 typeCode="SUBJ">` `<investigationCharacteristic classCode="CASE" moodCode="EVN">` `<code codeSystem="2.16.840.1.113883.13.206" code="`**T95037**`" displayName="Report Number(s) of Linked Report(s)" />` `<value xsi:type="CD" nullFlavor="NI">` `<originalText nullFlavor="NI"/>` `</value>` `</investigationCharacteristic>` `</subjectOf2>`	Use a separate `<subjectOf2>` block, within investgationEvent for each Linked Report /MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf2/investigationCharacteristic[code/@code="**T95037**"]/value	Repeat for each Linked Report At least one - even when no data, and, if required, many per AER	V 2.3
	140	B.6.1.1	Explanation for Linkage code	LTOT	Conditional Mandatory IF B.6.1 is specified, if no data use nullFlavor="NI"	Code List	**Business rules** 1) If there is a linked report then the report number must be a known report else **ERROR** 2) If there is a linked report then an explanation must be given and the explanation code must exist in GL30 2.16.840.1.113883.13.219 else **ERROR** 3) If there is no linked report then value for both report and explanation should be nullFlavor="NI" else **ERROR** _Guidance Note:_ The Unique AER Identification Number of Linked Report is for RA use only and not for MAH use.				

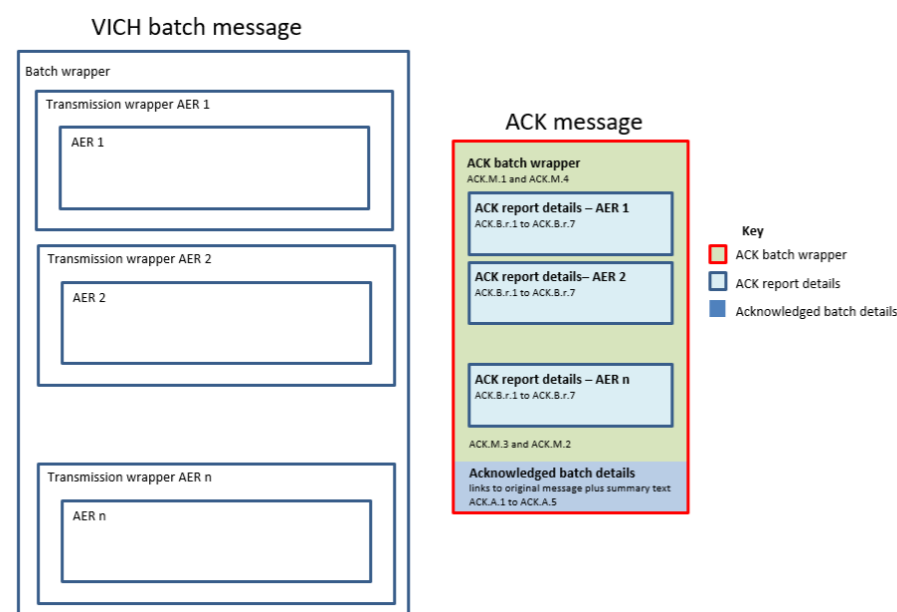|	Internal EMA Ref	GL35 Ref	EMA Name (may differ from GL42 name)	Example of data that is stored	Mandatory /Optional /Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published

	141	B.7.1	Attached Document Filename	1_Additional_info.txt	Conditional
					
					Optional, IF there is an Attached Document then both the Filename and the Type must be specified, if no data use nullFlavor="NI"
						Text up to 255 characters	**Pre-validation**
							Text beyond the expected length will cause an **ERROR**
							
							Business rules
							1) If there is an attached document then both the filename and file type must be specified else **ERROR**
							2) If there is an attached document, the filename must include a 3-character file extension that matches the document type
							3) If there is an attached document, the document type code must exist in GL30 2.16.840.1.113883.13.211 else **ERROR**
							4) If there is no value then value should be nullFlavor="NI" else **ERROR**
							
							<u>Guidance Note:</u>
							If there are attached documents, a description of the document(s) is expected to be given in B.3.1 Narrative
								Example 1 – one attached document
								\<reference typeCode="REFR">
								    \<document classCode="DOC" moodCode="EVN">
								        \<id extension="1" />
								        \<code code="C17649" codeSystem="2.16.840.1.113883.13.211" displayName="Other"/>
								        \<title>1_Additional_info.txt\</title>
								        \<text mediaType="text/plain" representation="B64">UGF0aWVudCBicmVlZDogQXNzZXNzbWVudCByZWZb246Cgo=\</text>
								    \</document>
								\</reference>
									Each linked document has a \<reference> block, each reference is identified by a unique extension number.
									
									/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/reference/document
										Repeat for each Supplemental Document
										
										At least one (even when no data), and, if required, many per AER
											Outstanding: Technical review of .xml snippets to ensure that mediaType and representation are correct. Step by Step Guide uses "text/plain" for file types and the filename extension is used to indicate the file type
											
											Note: HL7 allows compression

*	142	B.7.1.1	Attached Document Type code	C17649	Conditional
					
					Optional, IF there is an Attached Document then both the Filename and the Type must be specified, if no data use nullFlavor="NI"
						Code List		Example 2 – three Attached documents
								\<reference typeCode="REFR">
								    \<document classCode="DOC" moodCode="EVN">
								        \<id extension="1"/>
								        \<code code="C17649" codeSystem="2.16.840.1.113883.13.211" displayName="Other"/>
								        \<title>1_Additional_info.txt\</title>
								        \<text mediaType="text/plain" representation="B64">UGF0aWVudCBicmVlZDogQXNzZXNzbWVudCByZWZb246Cgo=\</text>
								    \</document>
								\</reference>
								\<reference typeCode="REFR">
								    \<document classCode="DOC" moodCode="EVN">
								        \<id extension="2"/>
								        \<code codeSystem="2.16.840.1.113883.13.211" code="C68623" displayName="Necropsy (Autopsy)"/>
								        \<title>necpicturedoc.doc\</title>
								        \<text mediaType="text/plain" representation="B64">UGF0aWVudCBicmVlZDogQXNzZXNzbWVudCByZWZb246Cgo=\</text>
								    \</document>
								\</reference>
								\<reference typeCode="REFR">
								    \<document classCode="DOC" moodCode="EVN">
								        \<id extension="3"/>
								        \<code codeSystem="2.16.840.1.113883.13.211" code="C36292" displayName="Laboratory Report"/>
								        \<title>labreport.pdf\</title>
								        \<text mediaType="text/plain" representation="B64">UGF0aWVudCBicmVlZDogQXNzZXNzbWVudCByZWZb246Cgo=\</text>
								    \</document>
								\</reference>
								
								Example 3 - no Attached documents
								\<reference typeCode="REFR">
								    \<document moodCode="EVN" classCode="DOC">
								        \<id extension="1" />
								        \<code nullFlavor="NI"/>
								        \<title nullFlavor="NI"/>
								        \<text nullFlavor="NI"/>
								    \</document>
								\</reference>			

Data element description of ACK message

Acknowledgements

The ACK message is a standardised XML acknowledgement that is created for each VICH batch message. The ACK message will contain an acknowledgement for each AER in the batch so that there is an indication of:

- successful import and loading of a valid AER, this includes AERs that generate warning messages
- import and loading of AERs that have business rule errors and are considered to be invalid
- technical errors that prevent acceptance of the batch, resulting in no AERs being imported or stored

A simplified view of the ACK message and how it corresponds to a VICH batch message is shown below:

VICH batch message

Batch wrapper

Transmission wrapper AER 1

AER 1

ACK message

Transmission wrapper AER 2

AER 2

ACK batch wrapper
ACK.M.1 and ACK.M.4

ACK report details – AER 1
ACK.B.r.1 to ACK.B.r.7

ACK report details– AER 2
ACK.B.r.1 to ACK.B.r.7

ACK report details – AER n
ACK.B.r.1 to ACK.B.r.7

ACK.M.3 and ACK.M.2

Acknowledged batch details
links to original message plus summary text
ACK.A.1 to ACK.A.5

Key
- ACK batch wrapper
- ACK report details
- Acknowledged batch details

Transmission wrapper AER n

AER n

Each VICH batch message that is received by the EMA will generate an ACK message.

The ACK message is made up of three types of attribute:

ACK.M (4 attributes) — the ACK batch wrapper, starting with a unique ACK message number and date created, and ending with the sender and receiver information

ACK.B.r. (7 attributes) — identification and valid/invalid/warning comment for each AER received

ACK.A (5 attributes) — processing summary of the VICH batch message

Acknowledgement Code scenarios

Application processing of a VICH batch message includes technical and pre-validation tests to ensure that the .xml is valid, attachments are within size limits, there are no viruses within the file etc. and only then may the message be stored and continue to business rule validation. Each ACK message represents the outcome of application processing of a VICH batch message using the Transmission ACK codes: AR, AE and AA.

If the VICH batch message passes technical and pre-validation testing then the VICH batch message is valid according to the xsd schema and each AER within the batch is processed. Each AER will generate an ACK code, either CA for valid AERs and AERs with warnings, or CR for AERs with a business rule error.

EMA processing of a VICH batch message will generate Batch ACK codes and AER ACK codes as explained in the table below.

Batch ACK code ACK.A.4 Transmission ACK Code	Scenario description	VICH batch message stored	Scenario	Technical and/or pre-validation errors?	Batch Level business rule errors? e.g. batch creation date is a future date	AER ACK code ACK.B.r.6 Acknowledgement Code for each AER Occurs once for each AER in the VICH Batch	AER stored and is assigned a Local Report Number	AER business rule errors? e.g. Species must not be null, species provided must exist in GL30 List	AER business rule warnings? e.g. if number of animals affected =1 then reproductive status should not be 'MIXED'
AR	**BATCH ERROR:** VICH batch message is rejected because invalid batch structure prevents processing and no AERs are accepted or stored. If the batch is rejected (AR) then all AER in it are automatically rejected and not stored (CR)	No	1	Yes	Not Tested	None	No	Not Tested	Not Tested
			2	Yes	Not Tested	CR	No	Not Tested	Not Tested
			3	No	Yes	CR	No	Yes or No	Yes or No
AE	VICH batch message accepted with errors (AE), all AERs are stored and at least one AER in the batch has an **ERROR** (CR). Each AER that generates a CR requires attention and needs to be resent. The batch may also contain AERs that are a **VALID MESSAGE** (CA) or **WARNING** (CA).	Yes	4	No	No	CR	Yes	Yes	Yes or No
			5	No	No	CA	Yes	No	Yes or No
AA	VICH batch message accepted, all AERs are stored as **VALID MESSAGE** or **WARNING**. All AERs are valid (CA) and the ACK message will contain details of any business rule warnings.	Yes	6	No	No	CA	Yes	No	Yes or No

ACK batch wrapper – attributes belonging to the ACK message

A system generated ACK message number and transmission date appears at the start of the ACK message and sender and receiver identifiers appear at the end, following the AER attributes.

Internal EMA Ref	ACK Ref	EMA Name	Example of data in the ACK message	Always present/ Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
184	ACK.M.1	Batch Number	EU-EC-M-20000010149-ACK	**Always present**	Text up to 100 characters	A unique system generated ACK Message Identifier. When the creator of this ACK message is the EMA, this value is ACK.A.2 (see below) plus a suffix of '-ACK'.	Example – Acknowledgement for EU-EC-M-20000010145 <id root="2.16.840.1.113883.3.989.2.1.3.20" extension="EU-EC-M-20000010149-ACK"/> Note: In the case of a BATCH ERROR, it is not possible to store the VICH batch message and there is no Batch Number generated, this is indicated by EU-EC-M-XMLVALACK-INVALID-ACK <id root="2.16.840.1.113883.3.989.2.1.3.20" extension="EU-EC-M-XMLVALACK-INVALID-ACK"/>	/MCCI_IN200101UV01/id/@extension	One per ACK message at start of file	V 2.5
185	ACK.M.4	Batch Transmission Date	20201112164237	**Always present**	Date (YYYYMMDDHHMMSS) where YYYYMMDDHHMMSS is UTC using 24 hour clock	System generated during processing of the VICH batch message, time is UTC and +/-ZZZZ time zone is not present when the creator of this ACK message is the EMA .	Example - This acknowledgement generated on 12-Nov-2020 at 16:42 <creationTime value="20201112164237"/>	/MCCI_IN200101UV01/creationTime	One per ACK message at start of file	V 2.5
186	ACK.M.3	Batch Receiver Identifier	ACMEGACO	**Always present**	Text up to 60 characters	The intended recipient of this ACK message, equivalent to B.8.1.2.1 Batch Sender - Organisation Identifier in the original message	Example <receiver typeCode="RCV"> <device classCode="DEV" determinerCode="INSTANCE"> <id root="2.16.840.1.113883.3.989.2.1.3.18" extension="ACMEGACO"/> </device> </receiver>	/MCCI_IN200101UV01/receiver/device/id/@extension	One per ACK message at end of file	V 2.5
187	ACK.M.2	Batch Sender Identifier	EVVETPROD	**Always present**	Text up to 60 characters	The creator of this ACK message, equivalent to B.8.1.3.1 Batch Receiver - Identifier in the original message	Example <sender typeCode="SND"> <device classCode="DEV" determinerCode="INSTANCE"> <id root="2.16.840.1.113883.3.989.2.1.3.17" extension="EVVETPROD"/> </device> </sender>	/MCCI_IN200101UV01/sender/device/id/@extension	One per ACK message at end of file	V 2.5

ACK report details – attributes to identify and summarise the original AER

Note that attributes ACK.B.r.1 thru 7 do not appear in sequential order within the ACK message. If there have been errors that prevent the batch being accepted and individual reports being processed, ACK report details may not be present.

Internal EMA Ref	ACK Ref	EMA Name	Example of data in the ACK message	Always present/ Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published

173	ACK.B.r.2	Local Report Number	EU-EC-20000010202	Conditional, IF AER is stored i.e. IF ACK.A.4 Transmission ACK Code is 'AE' or 'AA'	Text up to 100 characters	System generated unique AER ID, assigned when and if AER is valid and can be stored	Example – report is valid and unique report number generated
							`<id root="2.16.840.1.113883.3.989.2.1.3.19" extension="EU-EC-20000010202"/>`
							
							Example – report is not valid and cannot be stored
							`<id nullFlavour="NA">`
								/MCCI_IN200101UV01/MCCI_IN000002UV01/id/@extension	Occurs once within 'ACK report details' i.e. between each `<MCCI_IN000002UV01>` and `<MCCI_IN000002UV01>`	V 2.5

174	ACK.B.r.3	Report Sender Identifier	ACMEGACO	Always present	Text up to 60 characters	The intended recipient of this ACK message, equivalent to B.8.1.2.1 Batch Sender - Organisation Identifier in the original message	Example
							`<receiver typeCode="RCV">`
							　`<device classCode="DEV" determinerCode="INSTANCE">`
							　　`<id root="2.16.840.1.113883.3.989.2.1.3.16" extension=" ACMEGACO "/>`
							　`</device>`
							`</receiver>`
								/MCCI_IN200101UV01/MCCI_IN000002UV01/receiver/device/id/@extension	Occurs once within 'ACK report details'	V 2.5

175	ACK.B.r.4	Report Receiver Identifier	EVVETPROD	Always present	Text up to 60 characters	The creator of this ACK message. ACK.B.r.4 is equivalent to B.8.2.3.1 Message Receiver - Identifier in the original message	Example
							`<sender typeCode="SND">`
							　`<device classCode="DEV" determinerCode="INSTANCE">`
							　　`<id root="2.16.840.1.113883.3.989.2.1.3.15" extension="EVVETPROD"/>`
							　`</device>`
							`</sender>`
								/MCCI_IN200101UV01/MCCI_IN000002UV01/sender/device/id/@extension	Occurs once within 'ACK report details'	V 2.5

176	ACK.B.r.5	Created On	20200127114439	Always present	Date (YYYYMMDDHHMMSS) where YYYYMMDDHHMMSS is UTC using 24 hour clock	The date and time when this AER was created, time is UTC and time zone is not present. ACK.B.r.5 is equivalent to B.8.2.4 Date of Message Creation in the original message	Example – message created 27-Jan-2020 at 11:44 am UTC
							`<attentionLine>`
							　`<keyWordText code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.24" codeSystemVersion="2.0" displayName="dateOfIcsrMessageCreation"/>`
							　`<value xsi:type="TS" value="20200127114439"/>`
							`</attentionLine>`
								/MCCI_IN200101UV01/MCCI_IN000002UV01/attentionLine/value/@value	Occurs once within 'ACK report details'	V 2.5

177	ACK.B.r.6	Acknowledgement Code	CA	Always present	2 character text code	System generated code to explain outcome of AER processing as in the table above.	Example 1- valid AER (with or without warnings)
							`<acknowledgement typeCode="CA">`
							
							Example 2 – AER is invalid and will only be stored when there are no Batch Level errors
							`<acknowledgement typeCode="CR">`
								/MCCI_IN200101UV01/MCCI_IN000002UV01/acknowledgement/@typeCode	Occurs once within 'ACK report details'	V 2.5

172	ACK.B.r.1	Message Identifier	SampleMessageWithWarning-90205	Always present	Text up to 100 characters	ACK.B.r.1 is equivalent to B.8.2.1.2 Message Identifier in the original message	Example
							`<targetMessage>`
							　`<id root="2.16.840.1.113883.3.989.2.1.3.1" extension="SampleMessageWithWarning-90205"/>`
							`</targetMessage>`
								/MCCI_IN200101UV01/MCCI_IN000002UV01/acknowledgement/targetMessage/@extension	Occurs once, near the end of 'ACK report details'	V 2.5

178	ACK.B.r.7	Validation Comment	adverse event report loaded; Validated against 3.00 business rules;
			
			Comments: Parsing process: Correct report;
			
			Classification: new: EU-EC-20000010203
				Always present	Text up to 2000 characters	System generated comment(s) to explain the processing of an AER i.e. explains the reason for the code given in ACK.B.r..6 above	Example 1 – a valid AER ('CA') with no errors
							`<acknowledgementDetail>`
							　`<text> adverse event report loaded; Validated against 3.00 business rules;`
							　`Comments: Parsing process: Correct report;`
							　`Classification: new: EU-EC-20000010203 </text>`
							`</acknowledgementDetail>`
							
							Example 2 – a valid AER ('CA') with a business rule warning
							`<text>adverse event report loaded; Validated against 3.00 business rules;`
							　`Comments: Parsing process: Report with warnings;`
							`The AER should contain valid Off label use answers based on the Off label use for the Target Species;`
							　`Classification: old: EU-EC-20000010202 </text>`
							
							Example 3 – an invalid AER ('CA') that is stored even though it has business rule errors
							`<text> adverse event report not loaded; Validated against 0.3.0.136 business rules;`
							　`Comments: Parsing process: Report with errors and warnings;`
							`errors:`
							`[[R150][B.2.1.2][150]]: The field Registration Identifier - B.2.1.2 exceeds the maximum allowed length(length <= 50 characters. )warnings:`
							`[[R148][vmp,B.2.1][148]]: The field Registered Name or Brand Name - B.2.1 could not be matched against product and substance information database;`
							　`Classification: Report with error`
							`</text>`
								/MCCI_IN200101UV01/MCCI_IN000002UV01/acknowledgement/acknowledgementDetail/text	Occurs once, at the end of 'ACK report details'	V 2.5

Acknowledged batch details – attributes to identify and summarise the VICH batch message

ACK.A.1 thru 5 appear at the end of the ACK message, although not in sequential reference number order.

Internal EMA Ref	ACK Ref	EMA Name	Example of data in the ACK message	Always present/ Conditional	Datatype	EMA Comment	.xml snippet	xPath (element or start of node as applicable)	Explanation for Repeating Groups	Version Published
180	ACK.A.2	Local Message Number	EU-EC-M-20000010149	Always present	Text up to 100 characters	System generated Internal Batch ID assigned by EMA	Example – AER is stored <attentionLine> <keyWordText code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.24" codeSystemVersion="2.0" displayName="acknowledgementLocalMessageNumber"/> <value xsi:type="II" root="2.16.840.1.113883.3.989.2.1.3.21" extension="EU-EC-M-20000010149"/> </attentionLine> Note: there is no Local Message Number when the batch is invalid and AER cannot be stored <value xsi:type="II" root="2.16.840.1.113883.3.989.2.1.3.21" extension="EU-EC-M-XMLVALACK-INVALID"/>	/MCCI_IN200101UV01/attentionLine[keyWordText/@code='2']/value/@extension	One per ACK message at end of file	V 2.5
181	ACK.A.3	Acknowledged Batch Transmission Date	20200127114439	Always present	Date (YYYYMMDDHHMMSS) where YYYYMMDDHHMMSS is UTC using 24 hour clock	The date and time when the VICH batch message was created, time is UTC and time zone is not present. ACK.A.3 is equivalent to B.8.1.4 date of Batch Creation in the original VICH batch message	Example - batch created 27-Jan-2020 at 11:44 am UTC <attentionLine> <keyWordText code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.24" codeSystemVersion="2.0" displayName="dateOfIcsrBatchTransmission"/> <value xsi:type="TS" value="20200127114439"/> </attentionLine>	/MCCI_IN200101UV01/attentionLine[keyWordText/@code='3']/value/@value	One per ACK message at end of file	V 2.5
182	ACK.A.4	Transmission ACK Code	AE	Always present	2 character text code	System generated summary code to explain outcome of batch processing as in table above	Example <acknowledgement typeCode="AE">	/MCCI_IN200101UV01/acknowledgement/@	One per ACK message at end of file	V 2.5
179 *	ACK.A.1	Acknowledged Batch Number	SampleMessageWithWarning-5502	Always present	Text up to 100 characters	ACK.A.1 is equivalent to B.8.1.1.2 Batch Number/Identifier - name in the original VICH batch message	Example <targetBatch> <id root="2.16.840.1.113883.3.989.2.1.3.22" extension="SampleMessageWithWarning-5502"/> </targetBatch>	/MCCI_IN200101UV01/acknowledgement/targetBatch/id/@extension	One per ACK message at end of file	V 2.5
183	ACK.A.5	Batch Validation Error	Batch message processed with errors	Always present	Text up to 250 characters	System generated summary comment to explain the processing of the VICH batch message i.e. explains the reason for the code given in ACK.A.4 above	Example – all AERs in the batch are valid ('AA') <acknowledgementDetail> <text>Batch message processed without errors</text> </acknowledgementDetail> Example – at least one error in batch ('AE' or 'AR' errors) <acknowledgementDetail> <text>Batch message processed with errors</text> </acknowledgementDetail> Example – batch level business rule error ('AR') <acknowledgementDetail> <text>Batch message processed with errors: [[P108][B.8.1.4][108]]: Batch creation time must be expressed in the correct date format</text> </acknowledgementDetail>	/MCCI_IN200101UV01/acknowledgement/acknowledgementDetail/text	One per ACK message at end of file	V 2.5

ACK message attributes – comparison with guidance published by Canadian Regulatory Authorities

There are 16 attributes, 8 are generated by 'the process' and the rest have data that is provided by the original VICH batch message.

		ACK Ref	Name in Canadian Document	EMA Name	Description	Source of the data value	Data value generated by processing
1.		ACK.M.1	Acknowledgement Batch Number	Batch Number	System generated Internal Batch ID + '-ACK' assigned by EMA		Yes
2.		ACK.M.2	Acknowledgement Batch Sender Identifier	Batch Sender Identifier	Value corresponds to the **Batch Receiver – Identifier** in the batch wrapper of the VICH batch message, for example, for messages sent to EMA, this will be EVVETPROD	B.8.1.3.1	
3.		ACK.M.3	Acknowledgement Batch Receiver Identifier	Batch Receiver Identifier	The intended recipient of the ACK message, value corresponds to the **Batch Sender – Organisation Identifier** in the batch wrapper of the VICH batch message	B.8.1.2.1	
4.		ACK.M.4	Acknowledgement Date of Batch Transmission	Batch Transmission Date	System generated date that EMA processed the message		Yes
5.		ACK.B.r.1	ICSR Message Number	Message Identifier	Value corresponds to **Message Identifier** in the transmission wrapper for the AER in the VICH batch message	B.8.2.1.2	
6.		ACK.B.r.2	Local Report Number	Local Report Number	System generated Internal AER ID assigned by EMA		Yes
7.		ACK.B.r.3	ICSR Message ACK Receiver	Report Sender Identifier	The intended recipient of the ACK message, then value corresponds to **Message Sender – Organisation Identifier** in the transmission wrapper for the AER in the VICH batch message	B.8.2.2.1	
8.		ACK.B.r.4	ICSR Message ACK Sender	Report Receiver Identifier	Value corresponds to **Message Receiver – Identifier** in the transmission wrapper for the AER in the VICH batch message, for example, for messages sent to EMA, this will be EVVETPROD	B.8.2.3.1	
9.		ACK.B.r.5	Date of ICSR Message Creation	Created On	Value corresponds to **Date of Message Creation** in the transmission wrapper for the AER in the VICH batch message	B.8.2.4	
10.		ACK.B.r.6	Acknowledgement Code for a ICSR Message	Acknowledgement Code	System generated code to explain the processing of an AER		Yes
11.		ACK.B.r.7	Error / Warning Message or Comment	Validation Comment	System generated comment(s) to explain the processing of an AER		Yes
12.		ACK.A.1	ICSR Batch Number	Acknowledged Batch Number	Value corresponds to **Batch Number/Identifier Name** in the batch wrapper of the VICH batch message	B.8.1.1.2	
13.		ACK.A.2	Acknowledgement Local Message Number	Local Message Number	System generated Internal Batch ID assigned by EMA		Yes
14.		ACK.A.3	Date of ICSR Batch Transmission	Acknowledged Batch Transmission Date	Value corresponds to **Date of Batch Creation** in the batch wrapper of the VICH batch message	B.8.1.4	
15.		ACK.A.4	Transmission Acknowledgement Code	Transmission ACK Code	System generated summary code to explain the processing of the VICH batch message		Yes
16.		ACK.A.5	Batch Validation Error	Batch Validation Error	System generated summary comment to explain the processing of the VICH batch message		Yes

Key

	ACK batch wrapper attributes occur once in each ACK message
	ACK report details occur once for each AER in the VICH batch message
	Acknowledged batch details occur once at the end of the ACK message

Sample .xml files accompanying this annex

File	VICH Batch Message Filename	Short Description	Scenario	ACK Filename	Comment
See below	VICH_EU_Sample_AER.xml	A representative sample – superceded by SampleMessageValidReport.xml			
1	VICH_EU_Sample_AER_mandatory.xml	Mandatory fields only			
2	VICH_EU_Sample_With_All_Values.xml	All fields with values, many of the snippets used in 'Example 1' of the .xml snippet column are taken from this file			
3	MultipleVMPsAndRoutes.xml	Multiple VMPs and Route of Exposure, illustrates use of id extension to link data fields to VMP			
4, 5	SampleMessage_TechnicalError.xml	An acknowledgement for a batch that is rejected due to technical errors	1	ack_SampleMessage_TechnicalError.xml	xml has xsd validation error **BATCH ERROR** AR - no AER ACKs
6, 7	SampleMessageFailPre-Validation.xml	An acknowledgement for an report in a batch that fails pre-validation and is unable to be converted to the domain model	2	ack_SampleMessageFailPre-Validation.xml	xml failed in pre-validation **BATCH ERROR** AR, CR
8, 9	SampleMessage_BatchLevelError.xml	An acknowledgement for a report in a batch that fails Batch Level Validation	3	ack_SampleMessage_BatchLevelError.xml	xml fails Batch Business Rules **BATCH ERROR** AR, CR
10, 11	SampleMessageWithBizRuleError.xml	An acknowledgement for an report that is invalid due to failing business rules ACMEGACO-173771397952-NL20270_77708804773 **AE - CR**	4	ack_SampleMessageWithBizRuleError.xml	AER is stored with business rule errors **ERROR** ACK Codes AE, CR business rule error
12, 13	SampleMessage_MultipleReports_OneBizruleErr.xml	An acknowledgement for a valid batch report for ICSRs with a mixture of statuses (one accepted, one warning, one rejected) **AE - CR, CA and CA** ACMEGACO-Firstreport-NLD20270_777004773 has business rule error **CR** ACMEGACO-Secondreport-NLD20270_777004773 has business rule warnings **CA** ACMEGACO-Thridreport-NLD20270_777004773 has with no errors or warnings **CA**	5	ack_SampleMessage_MultipleReports_OneBizruleErr.xml	xml has three reports one is valid, one is valid with warnings and one is invalid, all are stored **3 MESSAGES; ERROR, WARNING, VALID MESSAGE** AE, CR business rule error, CA with warning, CA
14, 15	SampleMessageValidReport.xml	A representative sample used for many of the sample snippets in the Annex to the implementation guide together with the acknowledgement for a valid report that is accepted without warnings ACMEGACO-173771397952-NL2020_004774 stored as AER Id EU-EC-20000010203	6	ack_SampleMessageValidAck.xml	AER is valid and stored, no errors in Batch or AERs **VALID MESSAGE** AA, CA
16, 17	SampleMessageWithWarning.xml	An acknowledgement for a valid report that is accepted with warnings ACMEGACO-173771397952-NL20270_777004773 updated i.e. 'old' AER Id EU-EC-20000010202	6	ack_SampleMessage_WithWarnings.xml	AER is valid and stored but has warnings **WARNING** AA, CA

End of document.