

International Cooperation on Harmonization of Technical
Requirements for Registration of Veterinary Medicinal Products
(VICH)

Electronic Submission of Animal Adverse Events

**Electronic Transmission Implementation Specifications
VICH Step By Step Document**

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1 Introduction

The purpose of this document is to provide step by step directions to assist users, reporters, and technical staff in completing a well formed Veterinary Medicinal Product (VMP) Adverse Event Reports (AER) message that is compliant with the ISO 27953-1 schema.

1.1 VICH GL42

The International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) has established a standard set of definitions to describe the data elements that need to be submitted for compliant adverse event reports (AERs). These data elements can be found in VICH GL42. This document provides a translation and mapping of GL42 compliant adverse event report's data elements into the ISO 27953-1 version XML message.

This document describes Marketing Authorization Holder (MAH) to Regulatory Authority (RA) message. Section 6 of this document also provides examples for RA to RA, RA to MAH, and MAH to MAH messages. MAHs will send a message compliant with the RA systems, adherent to GL35, this document and the relevant Regional Annexes.

1.2 AER Documents

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

Table 1-1 AER Documents

Title	Description
VICH GL42 - PHARMACOVIGILANCE OF VETERINARY MEDICINAL PRODUCTS: Data Elements for Submission of Adverse Event Reports (AERS)	Establishes a standard set of definitions to describe the data elements that need to be submitted for compliant adverse event reports
VICH GL 35 - PHARMACOVIGILANCE OF VETERINARY MEDICINAL PRODUCTS: Electronic Standards for Transfer of Data	Establishes a standard to construct a single electronic message to transmit AERs to all regions
VICH Electronic Transmission Implementation Specifications VICH Validation Procedure Document and Regional Annexes	Validation procedures for compliant VMP AERs
VICH GL 30 - PHARMACOVIGILANCE OF VETERINARY MEDICINAL PRODUCTS: Controlled Lists of Terms	A listing of the vocabularies for use in the AER message
VICH Electronic Transmission Implementation Specifications VICH Step By Step Document and Regional Annexes	Step by step document for implementation of ISO 27953-1 schema compliant message

1.3 Document Structure

This document is structured to follow GL42 and GL35 and Regional Annexes. Each AER data element is discussed with a description of the element along with its structure. XPath examples are included along with sample XML snippets. The sample XML snippets have a defined format that includes the following:

- Defined AER data element names and element reference values
- codeSystem OIDs that must be used
- Variable sample data (Indicated by the use of italics within the snippet)

1.4 Structure of AER Submission Message

The electronic AER submission structure is based on the ISO 27953-1 schema. Each submission must follow this model. The complete set of messages is to be bounded by a single *Batch Submission* wrapper. Each individual message is bounded by a *Transmission* and a *Control Act* wrapper.

Figure 1-1 Sample AER Submission Format

Batch Wrapper

Transmission Wrapper Message 1

Control Act Wrapper

Payload

Transmission Wrapper Message 2

Control Act Wrapper

Payload

.....

Transmission Wrapper Message n

Control Act Wrapper

Payload

The following figure depicts a sample valid XML Batch electronic submission.

Figure 1-2 Sample XML AER Batch Submission

```
<MCCI_IN200100UV01 xmlns="urn:hl7-org:v3" xmlns:mif="urn:hl7-org:v3/mif"
    xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
    xsi:schemaLocation="urn:hl7-org:v3
        MCCI_IN200100UV01.xsd" ITSVVersion="XML_1.0">
<id root="SubmittingOrganizationID" extension="ABCDrug-20100328-batch-12345"/>
<creationTime value="20120516102030+0300"/>
.....
<versionCode code="VICHAER1.0.0"/>
.....
<PORR_IN049006UV xsi:type="PORR_IN049006UV.MCCI_MT000100UV01.Message">
    <id root="2.16.840.1.156.3.150" extension="Batch-155-392"/>
    <creationTime value="20120515102030+0300"/>
    .....
    <interactionId/>
    <profileId root="2.16.840.1.113883.13.207"
        extension="AES.FDA.VICHGL42.M.V1.ACOUNT.AE"/>
    .....
    <controlActProcess moodCode="EVN" classCode="CACT">
        <subject typeCode="SUBJ">
            <investigationEvent moodCode="EVN" classCode="INVSTG">
                .....
                </investigationEvent>
            </subject>
        </controlActProcess >
    </PORR_IN049006UV>
    .....
    <PORR_IN049006UV xsi:type="PORR_IN049006UV.MCCI_MT000100UV01.Message">
        .....
    </PORR_IN049006UV>
    .....
</MCCI_IN200100UV01>
```

All adverse event electronic transmissions sent must follow this structure to be accepted for review. Not following this standard and structure will result in the submission being rejected and not being reviewed.

1.5 Exceptions to Be Noted

Please note that in this document, the XPaths for the data elements are based on an individual **AER** message (as depicted in the *Figure 1-1, Message 1*) without the batch wrapper included in the XPath. Please add /MCCI_IN200100UV01 in the XPath for the batch wrapper.

For example, the XPath to get “Type of Submission” in an individual AER message without batch wrapper is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf2/investigationCharacteristic[code/@code="T95003"]/value/@code
```

In a batch message, the XPath to get “Type of Submission” is:

```
/MCCI_IN200100UV01/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf2/investigati
onCharacteristic[code/@code="T95003"]/value/@code
```

Also note that, in the HL7 messages of this implementation, the standard date format is YYYYMMDD. However, for some “date” data elements, for example “Expiration Date”, a partial date value may be accepted, i.e. date value with only year, or with only year and month, is acceptable. In these cases, the accepted date format could be YYYYMMDD, YYYYMM, or YYYY. Please refer to the VICH Validation Procedure Document for specific date data element for detailed information.

In addition, two “date” data elements, Date of Batch Creation (B.8.1.4) and Date of Message Creation (B.8.2.4) are required to contain the timestamp information. These two dates are required to be in the format of YYYYMMDDHHMMSS+/-ZZZZ, where YYYYMMDDHHMMSS contains the local time including the hour, minute, and second information (HHMMSS), while +/-ZZZZ is the positive or negative offsets (in hour and minute) of local time from UTC (Coordinated Universal Time, a time standard and one of the successors to Greenwich Mean Time (GMT))

The following characters have special meaning in XML, and in general it is suggested to replace them with their corresponding entity reference when using them.

Entity Reference	Character	
<	<	less than
>	>	greater than
&	&	ampersand
'	'	apostrophe
"	"	quotation mark

For example, to use code C82440 (<12 hours) in the Vocabulary List for “Length of Time Between Exposure to VMP and Onset of AE”, reporter needs to replace the “<” character with “<,” as shown in the example below:

```
<value xsi:type="CE" codeSystem="2.16.840.1.113883.13.50" code="C82440" displayName="&lt;12 hours"/>
```

1.6 Special Handling of Element Fields (Null Flavors)

The sender should map every data element into the AER message, whether or not it is a required data element or an optional data element. For data elements that can have repeated values, e.g., multiple lot numbers and VedDRA terms, the message does not include a repeated value of nullFlavor “NI” to indicate that there are “no additional values”.

All the data elements should be mapped into the AER message. For optional fields, if the data are unknown, senders should use the “NI” (No Information) for null flavor, as referenced in the example below. A sample showing a fully compliant data element is shown and then a fully compliant data element demonstrating a null flavor is shown.

Fully Compliant XML Snippet

```
<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>

```

Fully Compliant Null Flavor XML Snippet

```

<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" nullFlavor="NI"/>
    </observation>
</subjectOf2>

```

If "Unknown" or a similar code is in a published vocabulary list for that particular data element (mandatory or optional) the assigned code and the accompanying term together with the codeSystem OID should be used, instead of using the null flavor.

All mandatory and optional elements of the AER message must be coded with an actual value or a null flavor selection specific to the associated data element.

Please note that, null flavor should not be used together with an actual value for the same data element.

The following table documents the null flavor handling for each element type.

Table 1-2 Null Flavor Element Data Rules

Element Type	Null Flavor Rule
Mandatory Coded Element	Submitters should use a valid value from the vocabulary list.
Optional Coded Element	Should use the null flavor specified for the element when a valid value is not known. 'Unknown' may be included in vocabulary lists.
Mandatory Text Field Element	Submitters should use a valid value. Use of a null flavor is NOT permitted.
Optional Text Field Element	Should use null flavors when a valid value is not known. 'NI – No Information' is the default null flavor for this data type.
Mandatory Numeric Field Element	Should contain a valid value. Null flavor use is NOT permitted. Zero may be a valid value (unless otherwise specified by specific business rules).
Optional Numeric Field Element	Should use a null flavor when a valid value is not known. 'NI – No Information' is the default null flavor for this data type.
Mandatory Date Field Element	Should contain a valid date. Null flavor use is NOT permitted.
Optional Date Field Element	Should use a null flavor when a valid date is not known. 'NI – No Information' is the default null flavor for this data type.
Optional Text Element Related to Coded Element	Should use a null flavor when a valid value is not known. 'NI – No Information' is the default null flavor for this element type.
Boolean Field Elements –	Boolean elements have a number of null flavor terms and conditions

Element Type	Null Flavor Rule
Mandatory or Optional	for when a null flavor can be used. The allowable null flavors are "NA", "NI", and "UNK".

1.7 XML Locator Codes

The ISO 27953-1 schema uses a defined set of “observation” classes to capture specific data elements in the AER message. In order to differentiate each “observation” class, we have extended this functionality with a list of locator codes to locate the specific data element within the AER message. The *XML Locator Code* vocabulary is a listing of these “Observation” locators.

The following table contains the list of locator codes.

Table 1-3 XML Locator Codes

Code	Term
C17998	Outcome Unknown
C21115	Euthanized
C28554	Died
C49495	Recovered With Sequela
C53279	Ongoing
C82467	Recovered / Normal
T95001	MAH
T95002	Sourcereport
T95003	Type Of Submission
T95004	Type Of Information In Report
T95005	Number Of Animals Affected
T95006	Assessment of Health Status Prior to the Exposure to Product
T95007	Are Animals Crossbred
T95008	Breed Components
T95009	RA
T95010	Female Physiological Status
T95011	Weight
T95012	Age
T95013	ATCvet Code
T95015	Use According To Label
T95016	VICH Label Use
T95017	Number Of Defective Items
T95018	Number Of Items Returned
T95019	ORA District Field Office
T95020	Reaction
T95021	Length Of Time Between Exposure To VMP And Onset Of AE
T95022	Serious AE
T95023	Treatment Of AE

Code	Term
T95024	Previous Exposure To The VMP
T95025	Previous AE To The VMP
T95026	Did AE Abate After Stopping the VMP
T95027	Did AE Reappear After Re-Introduction of the VMP
T95028	Species Off-Label
T95029	Route Off-Label
T95030	Overdosed
T95031	Underdosed
T95032	Treatment regimen Off-Label
T95033	Indication Off-Label
T95034	Storage condition Off-Label
T95035	Product expired
T95036	Other off label issue
T95037	Report number(s) of linked report(s)

1.8 Rules Concerning Handling Responses Within Elements

The Adverse Events Processing system will validate and process all AER element responses using the following data format rules:

- Leading and trailing white space (blanks) will be trimmed for each element value
- White space within an element value will be considered part of the element value
- Case will not be significant nor considered when validating element values

1.9 Vocabulary Reference List of Values

The vocabulary lists to be used for coding AER messages are described in the documents referenced in Section 1.2 AER Documents. The processing systems use these vocabularies to validate the information within the AER message.

1.10 MAH to RA Message

The example snippets included in the body of this document for Section 2 Administrative and Identification Information is for a MAH to RA message. Section 2 also can be used for a RA to MAH, RA to RA, and a MAH to MAH message (see Section 6 below).

1.11 Disclaimer

For any ISO 27953-1 version AER messages that are submitted for evaluation and review, please note that the applications and systems will only capture and process the data elements that are explicitly described in this document. Any other data elements and/or information that are included within the submitted messages but are not explicitly described within this document will be ignored and not processed.

2 Administrative and Identification Information – GL42

Section A

2.1 Regulatory Authority (RA) – GL42 Section A.1 (A.1.1 – A.1.6)

Information: This is the Regulatory Authority (RA) to which this AER is to be initially submitted based on which RA has the authority to regulate the product. The sender should enter the “RA Name”, “RA Street Address”, “RA City”, “RA State/County”, “RA Mail/Zip Code”, and “RA Country” (3 character code ISO 3166). The codeSystem OID is that for “Locator Codes”, and the XML Locator Code to be used is “T95009”.

The information required for this section can be found in *RA Identifier Code* vocabulary list. The example of US FDA CVM is as follows:

Table 2-1 Regulatory Authority Information

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

ICSR Location: RA information is located in the message payload <primaryInformationRecipient> section of an <investigationEvent> within the <controlActEvent> element.

XML Details: RA information is captured using <assignedEntity> element as shown in the sample code below. Note that for “RA Address”, data elements are captured in <addr> element.

Senders should use the <code> element of <assignedEntity> to specify the role played by the recipient. In this case, set the code value to “T95009”, and set the codeSystem value to the OID for “Locator Codes” (2.16.840.1.113883.13.206). The code value for a MAH to RA transmission should be the “RA” value in the code list.

Note that an OID is not required for address information. For “RA Country” data, an ISO 3166 3-Character Country Code shall be used.

The XPath's to get the “RA Name” and the “RA Country” code in an AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf1/controlActEvent/primaryInformationRecipient/assignedEntity[code/@code="T95009"]/representedOrganization/name
```

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf1/controlActEvent/primaryInformationRecipient/assignedEntity[code/@code="T95009"]/addr/country
```

A sample XML snippet for “RA Name” in an AER message is shown below. Note that this example uses a US address (the actual address for FDA/CVM). For foreign addresses using province, simply map the province data into <state> element.

```
<controlActEvent classCode="CACT" moodCode="EVN">
  <primaryInformationRecipient typeCode="PRCP">
    <assignedEntity classCode="ASSIGNED">
      <code codeSystem="2.16.840.1.113883.13.206" code="T95009" displayName="RA"/>
      <addr use="WP">
        <streetAddressLine>7500 Standish Place (HFV-199), Room 403</streetAddressLine>
        <city>Rockville</city>
        <state>MD</state>
        <postalCode>20855</postalCode>
        <country>USA</country>
      </addr>
      <representedOrganization determinerCode="INSTANCE" classCode="ORG">
        <name>Food and Drug Administration Center for Veterinary Medicine</name>
      </representedOrganization>
    </assignedEntity>
  </primaryInformationRecipient>
</controlActEvent>
```

2.2 Marketing Authorization Holder (MAH) (Sender) – GL42 Section A.2 (A.2.1 - A.2.2.6)

Information: This is the AER “Sender” information. In this example, this is the MAH responsible for sending the AE information to the RA who is responsible for regulating the VMP.

Sender information consists of three parts: “MAH Information”, “Person Acting on Behalf of MAH” (optional), and “Sender Category”.

ICSR Location: MAH (Sender) information is located in the AER message payload <author> section of <investigationEvent> within the <controlActEvent> element, adjacent to the RA (A.1) node.

XML Details: The MAH part of the “Sender Information” should provide the business name, street address, city, state/county/province, mail/zip code, and country of the submitting organization. As with the RA information, the MAH information is captured using <assignedEntity> element. The “Person Acting on Behalf of MAH” is captured in <contactParty> child element. The codeSystem OID is for “Locator Codes” and the code value for a MAH to RA transmission should be the “MAH” value in the code list.

The telecom values for email addresses, phone and fax numbers in AER messages should follow the following rules to be a valid:

Table 2-2 Telecom Entry Format Rules

Telecom Entry Rules
Each telecom value must include the type of telecom entry. The element type choices must be one of the following: "FAX:", "MAILTO:", and "TEL:". Any other choice will result in the AER being rejected.
If the validation rules allow and all telecom entries are not known then the complete telecom entry can use a single "NI – No Information" nullFlavor. It is not required to list each telecom entry with a nullFlavor. Example: <code><telecom nullFlavor="NI"/></code>

The XPath's to locate the "MAH Information", "Sender Information", and "Sender Category" in an AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf1/controlActEvent/author/assignedEntity/representedOrganization/name
```

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf1/controlActEvent/author/assignedEntity/representedOrganization/contactParty/contactPerson/name
```

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf1/controlActEvent/author/assignedEntity/representedOrganization/contactParty/telecom[starts-with(@value, "TEL")]/@value
```

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf1/controlActEvent/author/assignedEntity/code/@code
```

A sample XML snippet for "Sender Category", "MAH Information" and "Sender Information" in an AER message is:

```

<author typeCode="AUT">
  <assignedEntity classCode="ASSIGNED">
    <code codeSystem="2.16.840.1.113883.13.206" code="T95001" displayName="MAH"/>
    <addr use="WP">
      <streetAddressLine>555 Prosperity Place</streetAddressLine>
      <city>Woodbury</city>
      <state>TN</state>
      <postalCode>12345</postalCode>
      <country>USA</country>
    </addr>
    <representedOrganization determinerCode="INSTANCE" classCode="ORG">
      <name>GAP Industries</name>
      <contactParty classCode="CON">
        <telecom value="TEL:+1-615-5551110-10"/>
        <telecom value="FAX:+1-616-5559090"/>
        <telecom value="MAILTO:someone@apple.com"/>
      <contactPerson determinerCode="INSTANCE" classCode="PSN">
        <name>
          <prefix>Dr</prefix>
          <given>John</given>
          <family>Smith</family>
        </name>
      </contactPerson>
    </representedOrganization>
  </assignedEntity>
</author>

```

```

</contactParty>
</representedOrganization>
</assignedEntity>
</author>
```

2.3 Person(s) Involved in AER (Reporter) – GL42 Section A.3 (A.3.1 – A.3.2.12)

Information: This section contains information on the Reporter(s) who originally reported the AE (to the sender). A “Primary Reporter” is required. Only one “Other Reporter” can be entered in the AER message.

ICSR Location: Reporter information is captured in the AER message payload using a couple of child elements of <investigationEvent>, <outboundRelationship> which wraps the <relatedInvestigation> node that contains reporter information.

XML Details: Since the <outboundRelationship> element in AER message can be used for other information related to AER investigation event, when the “Reporter Information” element is selected, reporters should use the code (“T95002”) for “Sourcereport” to identify that this <outboundRelationship> element contains “Reporter Information”. To differentiate “Primary Reporter” from “Other Reporter”, a <priorityNumber> child element is used. For the “Primary Reporter”, it should be valued as “1”. For the “Other Reporter”, it should be valued as “2”.

Reporters should use <participation> node that contains <assignedEntity> to capture the “Reporter’s Information”. Use <assignedPerson>’s child element <asIdentifiedEntity> to capture the “Business Name” information of the reporter if needed (as the value of <name> element under <assigningOrganization>). If “Business Name” value is not available then use the null flavor “NI”, as shown in the snippet below.

“Reporter Category” shall be set in <code> element where the code value should be set to one of the codes listed in *Reporter Categories* vocabulary list.

The XPath to get the “Primary Reporter’s” “Last Name” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/outboundRelationship[priorityNumber/@value=1]/relatedInvestigation[code/@code="T95002"]/participation/assignedEntity/assignedPerson/name/family
```

The XPath to get the “Reporter Telephone” number of the “Primary Reporter” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/outboundRelationship[priorityNumber/@value=1]/relatedInvestigation[code/@code="T95002"]/participation/assignedEntity/telecom[starts-with(@value, "TEL")]/@value
```

The following is a sample XML snippet for “Primary Reporter” in an AER message. Note that the same snippet could be for “Other Reporter” if the second line in the snippet is replaced with <priorityNumber value="2"/>.

```
<investigationEvent classCode="INVSTG" moodCode="EVN">
....
```

```

<outboundRelationship typeCode="SPRT">
  <priorityNumber value="1"/>
  <relatedInvestigation classCode="INVSTG" moodCode="EVN">
    <code codeSystem="2.16.840.1.113883.13.206" code="T95002" displayName="Sourcereport"/>
    <effectiveTime value="20091005"/>
    <participation typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code codeSystem="2.16.840.1.113883.13.194" code="C82470" displayName="Veterinarian"/>
        <addr use="WP">
          <streetAddressLine>1st Old Street </streetAddressLine>
          <city>SmallTown</city>
          <state>AZ</state>
          <postalCode>12345</postalCode>
          <country>USA</country>
        </addr>
        <telecom value="TEL:+1-888-1234567"/>
        <telecom value="FAX:+1-888-1234789"/>
        <telecom value="MAILTO:vet1@example.com"/>
      <assignedPerson determinerCode="INSTANCE" classCode="PSN">
        <name>
          <family>Peterson</family>
          <given>Glenn</given>
        </name>
        <asIdentifiedEntity classCode="IDENT">
          <assigningOrganization determinerCode="INSTANCE" classCode="ORG">
            <name>Prehistoric Pets Clinic</name>
          </assigningOrganization>
        </asIdentifiedEntity>
      </assignedPerson>
    </assignedEntity>
  </participation>
  </relatedInvestigation>
</outboundRelationship>
</investigationEvent>

```

2.4 AER Information (Investigation/Report Information) – GL42 Section

A.4 (A.4.1 – A.4.4.3)

Information: This section contains general information about the AER, including:

- A.4.1 Unique Adverse Event Report Identification Number
- A.4.2 Original Receive Date
- A.4.3 Date of Current Submission
- A.4.4 Type of Report
 - A.4.4.1 Type of Submission
 - A.4.4.2 Reason for Nullification
 - A.4.4.3 Type of Information in Report

2.4.1 Unique Adverse Event Report Identification Number – GL42 Section A.4.1

Information: The “Unique Adverse Event Report Identification Number” is Sender’s (Case) Safety Report Unique Identifier. It contains the 3-Character ISO 3166 Country Code, the 8-

Character Sender Identifier Code, and a number or number/letter combination that is unique within the Sender organization.

ICSR Location: This information is located in the AER message payload <id> section of <investigationEvent> within the <controlActProcess> element. The id root must be hard coded as “1.2.3.4”. The “extension” attribute captures the Unique Adverse Event Report Identification Number.

XML Details: The XPath to get the “Unique Adverse Event Report Identification Number” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/id/@extension
```

A sample XML snippet for “Unique Adverse Event Report Identification Number” in an AER message is:

```
<investigationEvent moodCode="EVN" classCode="INVSTG">
    <id root="1.2.3.4" extension="USA-GAPINDSY-2012-US-14973"/>
    .....
</investigationEvent>
```

2.4.2 Original Receive Date – GL42 Section A.4.2

Information: This is the date the initial report was received from the primary reporter by the MAH or RA.

ICSR Location: This information is located in the AER message payload <outboundRelationship> section of <investigationEvent>, specifically inside the <relatedInvestigation> child element. Note that this <relatedInvestigation> element is located in the same <outboundRelationship> element where the “Primary Reporter” element is located.

XML Details: “YYYYMMDD” is the date format to be used for this data element, i.e. the HL7 “Point in Time” (TS) literal form, which is a simple calendar form. To get the day, month, and year data, the reporter needs to parse the date value.

The XPath to get the “Original Receive Date” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/outboundRelationship[priorityNumber/@value=1]
]RELATEDINVESTIGATION[code/@code="T95002"]]/effectiveTime/@value
```

A sample XML snippet for “Original Receive Date” in an AER message is:

```
<outboundRelationship typeCode="SPRT">
    <priorityNumber value="1"/>
    <relatedInvestigation moodCode="EVN" classCode="INVSTG">
        <code codeSystem="2.16.840.1.113883.13.206" code="T95002" displayName="Sourcereport"/>
        <effectiveTime value="20120128"/>
        .....
    </relatedInvestigation>
</outboundRelationship>
```

2.4.3 Date of Current Submission – GL42 Section A.4.3

Information: This is the date that the current AER was submitted to the RA.

ICSR Location: This information is located in the AER message payload <availabilityTime> element of <investigationEvent>.

XML Details: The XPath to get the “Date of Current Submission” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/availabilityTime/@value
```

A sample XML snippet for “Date of Current Submission” in an AER message is:

```
<investigationEvent classCode="INVSTG" moodCode="EVN">
    .....
    <availabilityTime value="20110517"/>
    .....
</investigationEvent>
```

2.4.4 Type of Report – GL42 Section A.4.4

Information: This information contains “Type of Submission”, and if this is a nullification report then this element contains, “Reason for Nullification Report”. It also contains “Type of Information in Report”.

2.4.4.1 Type of Submission

ICSR Location: “Type of Submission” information is located in the AER message payload <subjectOf2> section of <investigationEvent> within a <investigationCharacteristic> node.

XML Details: The <code> element describes the data element from GL42 (see sample XML snippet below). In this example, it is the Type of Submission data element. The OID for <code> codeSystem attribute is the OID of the *XML Locator Codes* vocabulary (2.16.840.1.113883.13.206). The <code> code attribute is “T95003” and displayName attribute value is “Type of Submission”, which come from this vocabulary. The <value> codeSystem attribute is the OID (2.16.840.1.113883.13.195) of the *Type of Submission* vocabulary. The <value> code attribute is “C68624” and displayName attribute “EXPEDITED”, which come from the *Type of Submission* vocabulary.

2.4.4.2 Reason for Nullification

ICSR Location: Same as “Type of Submission”.

XML Details: For the element “Reason of Nullification Report”, the information is captured using a <originalText> element, a child node of <value> element that captures the “Type of Submission” value. “Reason of Nullification” shall be entered only when the code value for “Type of Submission” is “C68625”, i.e. “NULLIFICATION”.

The XPath to get “Type of Submission” in the AER message is:

/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf2/investigationCharacteristic[code/@code="T95003"]/value/@code

A sample XML snippet for the “Type of Submission” in an AER message is:

```
<investigationEvent moodCode="EVN" classCode="INVSTG">
    .....
    <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="C68624"
                displayName="EXPEDITED">
                <originalText nullFlavor="NI"/>
            </value>
        </investigationCharacteristic>
    </subjectOf2>
    .....
</investigationEvent>
```

The XPath to get to the “Reason for Nullification” in the AER message is:

/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf2/investigationCharacteristic[code/@code="T95003"]/value/originalText

A sample XML snippet for “Reason for Nullification” in an AER message is:

```
<investigationEvent moodCode="EVN" classCode="INVSTG">
    .....
    <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="NULLIFICATION">
                <originalText>This is the text for the reason</originalText>
            </value>
        </investigationCharacteristic>
    </component4>
    .....
</investigationEvent>
```

2.4.4.3 Type of Information in Report

ICSR Location: Same as “Type of Submission”.

XML Details: Same as “Type of Submission”, “Type of Information in Report” is captured in a `<investigationCharacteristic>` element, but using the XML Locator Code “T95004” to identify the node. The actual data value is set to one of the codes listed in *Type of Information* vocabulary.

The XPath to get “Type of Information in Report” in the AER message is:

/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf2/investigationCharacteristic[code/@code="T95004"]/value/@code

A sample XML snippet for “Type of Information in Report” in an AER message is:

```
<investigationEvent moodCode="EVN" classCode="INVSTG">
    .....
    <subjectOf2 typeCode="SUBJ">
        <investigationCharacteristic classCode="CASE" moodCode="EVN">
            <code codeSystem="2.16.840.1.113883.13.206" code="T95004"
                  displayName="Type of Information in Report"/>
            <value xsi:type="CE" codeSystem="2.16.840.1.113883.13.196" code="C82452"
                  displayName="Both Safety And Lack Of Expected Effectiveness"/>
        </investigationCharacteristic>
    </subjectOf2>
    .....
</investigationEvent>
```

3 Description of AE – GL42 Section B

3.1 Animal Data – GL42 Section B.1 (B.1.1 – B.1.9.3.1)

Information: This information is for the animal data.

ICSR Location: These data elements are provided in the appropriate sections and subsections of AER message payload, within the <primaryRole> node inside the <subject1> tag of the <adverseEventAssessment> section.

The Animal Data Elements are described below.

3.1.1 Number of Animals Treated – GL42 Section B.1.1

Information: Number of Animals Treated With VMP

ICSR Location: This data is captured using a <quantity> element inside the <player2> node. The <player2> node is located inside the <primaryRole> and <subject1> element tags.

XML Details: The XPath to get “Number of Animals Treated” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/player2/quantity/@value
```

A sample XML snippet for “Number of Animals Treated” in an AER message is:

```
<component typeCode="COMP">  
  <adverseEventAssessment classCode="INVSTG" moodCode="EVN">  
    <subject1 typeCode="SBJ">  
      <primaryRole classCode="INVSBJ">  
        <player2 determinerCode="INSTANCE" classCode="ANM">  
          .....  
          <quantity xsi:type="PQ" value="3"/>  
          .....  
        </player2>  
      </primaryRole>  
    </subject1>  
  </adverseEventAssessment>  
</component>
```

3.1.2 Number of Animals Affected – GL42 Section B.1.2

Information: This is the number of animals adversely affected by the VMP(s).

ICSR Location: This information is captured as an observation using a <observation> element inside a <subjectOf2> node.

XML Details: The XPath to get the “Number of Animals Affected” in the AER message is:

/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/observation[code/@code="T95005"]/value/@value

The `<code>` element describes the data element from GL42 (see sample XML snippet below). In this example, it is the Number of Animals Affected data element. The OID for `<code>` codeSystem attribute is the OID of the *XML Locator Codes* vocabulary (2.16.840.1.113883.13.206). The `<code>` code attribute is “T95005” and displayName attribute value is “Number of Animals Affected”, which come from this vocabulary. The `<value>` value attribute is the number of animals affected, which is “3”.

```
<primaryRole classCode="INVSBJ">
  <subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
      <code codeSystem="2.16.840.1.113883.13.206" code="T95005"
            displayName="Number of Animals Affected"/>
      <value xsi:type="INT" value="3"/>
    </observation>
  </subjectOf2>
  .....
</primaryRole>
```

3.1.2.1 Attending Veterinarian's Assessment of Health Status Prior to VMP – GL42 Section B.1.2.1

Information: This is the attending Veterinarian’s assessment of the health status of the animal(s) involved in the AE prior to their exposure to the VMP.

ICSR Location: This information is captured as an observation using a `<observation>` element inside a `<subjectOf2>` node.

XML Details: Users should use a proper code to ensure `<subjectOf2>` contains “Attending Veterinarian’s Assessment”. The reporter must also use a coded value for the actual assessment value. The list of codes and values are shown in *Vet Health Status Assessment* vocabulary list.

The `<code>` element describes the data element from GL42 (see sample XML snippet below). In this example, it is the Attending Veterinarian’s Assessment of Health Status Prior to VMP data element. The OID for `<code>` codeSystem attribute is the OID of the *XML Locator Codes* vocabulary (2.16.840.1.113883.13.206). The `<code>` code attribute is “T95006” and displayName attribute value is “Assessment of Health Status Prior to the Exposure to Product”, which come from this vocabulary. The `<value>` codeSystem attribute is the OID of the *Vet Health Status Assessment* vocabulary (2.16.840.1.113883.13.197). The `<value>` code attribute is “C82488” and displayName attribute “EXCELLENT”, which come from the *Vet Health Status Assessment* vocabulary. The author of the assessment, Veterinarian” is described in the `<author>` element. The OID for `<code>` codeSystem attribute is the OID of the *Reporter Categories* vocabulary (2.16.840.1.113883.13.194). The `<code>` code attribute is “C82470” and displayName attribute “Veterinarian”, which come from the *Reporter Categories* vocabulary.

The XPath to get the “Attending Veterinarian’s Assessment” in the AER message is:

/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/observation[code/@code="T95006" and
author/assignedEntity/code/@code="C82470"]/value/@value

A sample XML snippet for “Attending Veterinarian's Assessment” in an AER message is:

```
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <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" codeSystem="2.16.840.1.113883.13.197" code="C82488"
          displayName="EXCELLENT"/>
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code codeSystem="2.16.840.1.113883.13.194" code="C82470" displayName="Veterinarian"/>
      </assignedEntity>
    </author>
  </observation>
</subjectOf2>
```

3.1.3 Species – GL42 Section B.1.3

Information: The species is the species of the animal affected by the VMP.

ICSR Location: Species data is captured in the <primaryRole> in <adverseEventAssessment>

XML Details: This data are provided in code attribute value in the <code> element of <player2> element. The codeSystem OID is “2.16.840.1.113883.4.341” is for the *Species* vocabulary list. In the following sample snippet, the <code> code attribute is “CTT” and displayName attribute value is “Cattle”, which come from this *Species* vocabulary.

The XPath to get the “Species” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/player2/code/@code
```

A sample XML snippet for “Species” in an AER message is:

```
<component typeCode="COMP">
  <adverseEventAssessment classCode="INVSTG" moodCode="EVN">
    <subject1 typeCode="SBJ">
      <primaryRole classCode="INVSBJ">
        <player2 classCode="ANM" determinerCode="INSTANCE">
          <code codeSystem="2.16.840.1.113883.4.341" code="CTT" displayName="Cattle"/>
          .....
        </player2>
      </primaryRole>
    </subject1>
  </adverseEventAssessment>
</component>
```

3.1.4 Breed (Breed Group) – GL42 Section B.1.4

Information: This is the breed(s) of the animal(s) associated with the species chosen in B.1.3. The VICH codes and values for breed are shown in *Breeds* vocabulary list. The codeSystem OID for the *Breeds* vocabulary list is “2.16.840.1.113883.4.342”.

ICSR Location: Breed information is captured as an observation(s) using <subjectOf2> node(s).

XML Details: Breed information in an AER message may be purebred and/or crossbred. Up to two breed <observation> nodes can be used, one for purebred and/or the other for crossbred. Both cases are modeled similarly.

For purebred, the information is captured as one single observation. The Observation Type Code (T95007) indicates that this observation is about animal breed. In order to differentiate between the purebred and crossbreed information, the question is asked “Are Animals Crossbred”. The observation value is a Boolean value, with “True” indicating crossbred, and “False” that indicates purebred. The OID for <code> codeSystem attribute is the OID of the *XML Locator Codes* vocabulary (2.16.840.1.113883.13.206). The <code> code attribute is “T95007” and displayName attribute value is “Are Animals Crossbred”, which come from this vocabulary.

The actual breed information for the purebred case is then captured in a single or multiple child observations using a list of <inboundRelationship> nodes. The <code> element describes the data element from GL42. In this example, it is the Breed data element. The OID for <code> codeSystem attribute is the OID of the *XML Locator Codes* vocabulary (2.16.840.1.113883.13.206). The <code> code attribute is “T95008” and displayName attribute value is “Breed Components”, which come from this vocabulary. The <value> codeSystem attribute is the OID of the *Breed* vocabulary (2.16.840.1.113883.4.342). The <value> code attribute is “Pig33” and displayName attribute “Duroc”, which come from the *Breed* vocabulary.

The XPath to get the purebred information in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/observation[code/@code="T95007" and value/@value=false()]/inboundRelationship  
/observation/value/@code
```

A sample XML snippet for capturing the purebred information with multiple purebred animals (2) in an AER message follows:

```
<subjectOf2 typeCode="SBJ">  
  <observation classCode="OBS" moodCode="EVN">  
    <code codeSystem="2.16.840.1.113883.13.206" code="T95007"  
          displayName="Are Animals Crossbred"/>  
    <value xsi:type="BL" value="false"/>  
  
    <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>
```

```

</inboundRelationship>

</observation>
</subjectOf2>
```

For crossbred, similar to purebred, use the observation type <code> to indicate that this observation is for breed information, but in this case the Boolean value is set to ‘True’ to indicate that the observation is for crossbred.

The XPath for crossbred information that will get the list of breeds’ component is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/observation[code/@code="T95007" and value/@value=true()]/inboundRelationship
/observation/value/@code
```

The breed components for the crossbred are captured using a list of nested observations inside the <sourceOf2> nodes. These observations are handled similar to pure breed observations.

A sample XML snippet for crossbred information including multiple animal breeds (3) in an AER message is:

```

<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <code codeSystem="2.16.840.1.113883.13.206" code="T95007"
          displayName="Are Animals Crossbred"/>
    <value xsi:type="BL" value="true"/>

    <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>
    <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="Pig88"
              displayName="Other"/>
      </observation>
    </inboundRelationship>
  </observation>
</subjectOf2>
```

In the following are snippets that illustrate the mapping of breed data in AER message for several common situations.

Case 1: One animal involved - The reporter knows that the animal is crossbred but does not know the breeds of the animal. (There are no purebred animals reported.) In the case of a crossbred animal, the breed that you would report is the generic crossbred code (for example, DOG88).

```
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <!-- ***** B.1.4 Breed - pure breed-->
    <code codeSystem="2.16.840.1.113883.13.206" code="T95007" displayName="Are Animals Crossbred"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <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" nullFlavor="NI"/>
      </observation>
    </inboundRelationship>
  </observation>
</subjectOf2>

<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <!-- ***** B.1.4 Breed - crossbred-->
    <code codeSystem="2.16.840.1.113883.13.206" code="T95007" displayName="Are Animals Crossbred"/>
    <value xsi:type="BL" value="true"/>
    <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="DOG88"
              displayName="Crossbred Canine/Dog"/>
      </observation>
    </inboundRelationship>
  </observation>
</subjectOf2>
```

Case 2: One animal involved - The reporter knows that the animal is purebred but does not know the breed of the animal. (There are no crossbred animals reported.) In the case of a purebred animal, when there is no breed reported, one would use the nullFlavor "NI".

```
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <!-- ***** B.1.4 Breed - purebred-->
    <code codeSystem="2.16.840.1.113883.13.206" code="T95007" displayName="Are Animals Crossbred"/>
    <value xsi:type="BL" value="false"/>
    <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" nullFlavor="NI"/>
      </observation>
    </inboundRelationship>
  </observation>
</subjectOf2>

<subjectOf2 typeCode="SBJ">
```

```

<observation classCode="OBS" moodCode="EVN">
    <!-- **** B.1.4 Breed - crossbred-->
    <code codeSystem="2.16.840.1.113883.13.206" code="T95007" displayName="Are Animals Crossbred"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <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" nullFlavor="NI"/>
        </observation>
    </inboundRelationship>
</observation>
</subjectOf2>

```

Case 3: At least 2 animals - The reporter knows that one animal is purebred and one is crossbred but does not know the breed of the animals.

```

<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <!-- **** B.1.4 Breed - pure breed-->
        <code codeSystem="2.16.840.1.113883.13.206" code="T95007" displayName="Are Animals Crossbred"/>
        <value xsi:type="BL" value="false"/>
        <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" nullFlavor="NI"/>
            </observation>
        </inboundRelationship>
    </observation>
</subjectOf2>

<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <!-- **** B.1.4 Breed - crossbred-->
        <code codeSystem="2.16.840.1.113883.13.206" code="T95007" displayName="Are Animals Crossbred"/>
        <value xsi:type="BL" value="true"/>
        <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="DOG88"
                      displayName="Crossbred Canine/Dog"/>
            </observation>
        </inboundRelationship>
    </observation>
</subjectOf2>

```

Case 4: Breed Unknown - The reporter does not know whether the animals are purebred or crossbred. This snippet can be used for a human case.

```

<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <!-- **** B.1.4 Breed - pure breed-->
        <code codeSystem="2.16.840.1.113883.13.206" code="T95007" displayName="Are Animals Crossbred"/>
        <value xsi:type="BL" nullFlavor="NI"/>
        <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" nullFlavor="NI"/>
</observation>
</inboundRelationship>
</observation>
</subjectOf2>

<subjectOf2 typeCode="SBJ">
<observation classCode="OBS" moodCode="EVN">
<!-- ***** B.1.4 Breed - crossbred-->
<code codeSystem="2.16.840.1.113883.13.206" code="T95007" displayName="Are Animals Crossbred"/>
<value xsi:type="BL" nullFlavor="NI"/>
<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" nullFlavor="NI"/>
</observation>
</inboundRelationship>
</observation>
</subjectOf2>

```

Case 5: One animal - The reporter knows that the animal is crossbred but only knows one of the breeds of the animal.

```

<subjectOf2 typeCode="SBJ">
<observation classCode="OBS" moodCode="EVN">
<!-- ***** B.1.4 Breed - pure breed-->
<code codeSystem="2.16.840.1.113883.13.206" code="T95007" displayName="Are Animals Crossbred"/>
<value xsi:type="BL" nullFlavor="NI"/>
<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" nullFlavor="NI"/>
</observation>
</inboundRelationship>
</observation>
</subjectOf2>

<subjectOf2 typeCode="SBJ">
<observation classCode="OBS" moodCode="EVN">
<!-- ***** B.1.4 Breed - crossbred-->
<code codeSystem="2.16.840.1.113883.13.206" code="T95007" displayName="Are Animals Crossbred"/>
<value xsi:type="BL" value="true"/>
<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="DOG256"
displayName="Retriever - Labrador"/>
</observation>
</inboundRelationship>
</observation>
</subjectOf2>

```

3.1.5 Gender, Reproductive Status, and Female Physiological Status – GL42

Section B.1.5 - B.1.7

Information: It captures the gender, reproductive status, and physiological status data based on the animal reported.

ICSR Location: These data elements are all captured inside <primaryRole> element. “Gender” and “Reproductive Status” codes are both located inside child node <player2>. “Female Physiological Status” is captured using an observation inside child node <subjectOf2>.

XML Details: “Gender” and “Reproductive Status” are both captured inside <player2>. For gender status, the code value and displayNames are taken from *Gender* vocabulary list.

For “Reproductive Status”, reporters should use the code value and displayNames that are found in *Reproductive Status* vocabulary list.

For “Female Physiological Status”, an observation is used to capture this information. The allowed code values and displayNames are found in *Female Physiological Status* vocabulary list.

The XPath to get the “Gender” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/player2/administrativeGenderCode/@code
```

The XPath to get the “Reproductive Status” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/player2/genderStatusCode/@code
```

The XPath to get the “Female Physiological Status” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/observation[code/@code="T95010"]/value/@code
```

A sample XML snippet for “Gender”, “Reproductive Status” and “Female Physiological Status” in an AER message is:

```
<adverseEventAssessment classCode="INVSTG" moodCode="EVN">  
  <subject1 typeCode="SBJ">  
    <primaryRole classCode="INVSBJ">  
      <player2 classCode="ANM" determinerCode="INSTANCE">  
        .....  
        <!-- The following administrativeGenderCode is the Gender of the animals. -->  
        <administrativeGenderCode codeSystem="2.16.840.1.113883.13.198" code="C16576"  
          displayName="FEMALE"/>  
        <!-- The following genderStatusCode is the Reproductive Status of the animals. -->  
        <genderStatusCode codeSystem="2.16.840.1.113883.13.199" code="C62399"  
          displayName="INTACT"/>  
      </player2>  
      <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>
.....
</primaryRole>
</subject1>
<adverseEventAssessment>
```

3.1.6 Weight & Age – GL42 Section B.1.8 and B.1.9

Information: The reporter should enter the numerical minimum weight in kilograms (kg) extended to 3 decimals.

ICSR Location: Weight and Age information are captured using two observations inside <subjectOf2> elements.

XML Details: For both the “Weight” and “Age” data elements, a method code needs to be set. The value should be one of the codes and code values shown in *Precision Categories* vocabulary list. Both “Weight” and “Age” should use data type IVL_PQ, and use low for the Minimum Weight and Age values and high for the Maximum Weight and Age values.

For “Age” data, units of measurements must be one of the following valid values: s, min, h, d, wk, mo, or a (year).

For both “Weight” and “Age” data, if there is only one value, use the <low> element.

The XPath's to get the code and value of “Weight” in the AER message is:

```

/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/observation[code/@code="T95011"]/methodCode/@code

/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/observation[code/@code="T95011"]/value/low/@value

/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/observation[code/@code="T95011"]/value/low/@unit

/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/observation[code/@code="T95011"]/value/high/@value

/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/observation[code/@code="T95011"]/value/high/@unit
```

The XPath's to get the code and value of “Age” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/observation[code/@code="T95012"]/methodCode/@code
```

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/observation[code/@code="T95012"]/value/low/@value  
  
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/observation[code/@code="T95012"]/value/low/@unit  
  
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/observation[code/@code="T95012"]/value/high/@value  
  
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/observation[code/@code="T95012"]/value/high/@unit
```

A sample XML snippet for Weight and Age in an AER message is:

```
<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 value="125" unit="kg"/>  
      <high value="225" unit="kg"/>  
    </value>  
    <methodCode codeSystem="2.16.840.1.113883.13.200" code="C44473" displayName="MEASURED"/>  
  </observation>  
</subjectOf2>  
  
<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 value="7" unit="mo"/>  
      <high value="3" unit="a"/>  
    </value>  
    <methodCode codeSystem="2.16.840.1.113883.13.200" code="C25498" displayName="ESTIMATED "/>  
  </observation>  
</subjectOf2>
```

Note that for any of these data elements, if only one value is available, use <low> element of the IVL_PQ data type to capture the data, and use a null flavor for the <high> element.

In the following is sample snippet for Weight and Age when GL42 data elements B.1.8.1 and/or B.1.9.1 value is Unknown.

```
<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 codeSystem="2.16.840.1.113883.13.200" code="C17998" displayName="Unknown"/>  
  </observation>  
</subjectOf2>  
  
<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>

```

3.2 VMP(s) Data and Usage – GL42 Section B.2 (B.2.1 – B.2.6.5)

Information: This section contains information about the VMP(s) that are indicated in the reported AE, and the usage of the VMP(s).

3.2.1 Registered or Brand Name – GL42 Section B.2.1

Information: The reporter should provide the complete “Registered or Brand Name” for their approved VMP(s) involved in the adverse event.

ICSR Location: “Registered or Brand Name” information is captured as product information within an observation, inside <substanceAdministration>, uses a <kindOfProduct> node.

XML Details: “Registered or Brand Name” should be complete and entered as a text field. Since multiple VMP(s) could be used, in order to provide the needed references, a <substanceAdministration> id is used. Note that this id is only expected to be used within the context of a single AER. ***The importance of the “Extension” is to link the same product information throughout the xml message. This extension should be unique for a product but not necessarily sequential within the message.***

The XPath to get the “Registered or Brand Name” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind/kindOfProduct/name
```

A sample XML snippet for Brand Name in an AER message is:

```

<subjectOf2 typeCode="SBJ">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="1.2.3.4" extension="1"/>
    .....
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        .....
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
          .....
          <name xsi:type="TN">DEXABRAND</name>
          .....
        </kindOfProduct>
        .....
      </instanceOfKind>
    </consumable>
    .....

```

```
</substanceAdministration>
</subjectOf2>
```

3.2.1.1 Product Code – GL42 Section B.2.1.1

Information: This information is the VMP's Product Code.

ICSR Location: Product Code information is captured in the same product information node as B.2.1 "Brand Name" within an observation.

XML Details: Product code is entered as the code value text inside the <consumable> element. For more details, refer to the Regional Annexes.

The XPath to get the "Product Code" in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind/kindOfProduct/code/
@code
```

A sample XML snippet for "Product Code" in an AER message is:

```
<subjectOf2 typeCode="SBJ">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="1.2.3.4" extension="1"/>
    .....
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        .....
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
          <code codeSystem="2.16.840.1.113883.6.69" code="01234-*444/>
        .....
        </kindOfProduct>
        .....
      </instanceOfKind>
    </consumable>
    .....
  </substanceAdministration>
</subjectOf2>
```

3.2.1.2 Registration Identifier – GL42 Section B.2.1.2

Information: This is the "Registration Identifier" of the VMP.

ICSR Location: The "Registration Identifier" is captured inside <kindOfProduction> node's child element <asManufacturedProduct>, using an <approval> class. It is next to the data element B.2.1.4 Company or MAH.

XML Details: The XPath to get the "Registration Identifier" in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind/kindOfProduct/asMa
nufacturedProduct/subjectOf/approval/id/@extension
```

A sample XML snippet for “Registration Identifier” in an AER message is:

```
<subjectOf2 typeCode="SBJ">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="1.2.3.4" extension="I"/>
    .....
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        .....
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
          .....
          <asManufacturedProduct classCode="MANU">
            <manufacturerOrganization classCode="ORG" determinerCode="INSTANCE">
              <name>Safe Animal Health</name>
            </manufacturerOrganization>
            <subjectOf typeCode="SBJ">
              <approval classCode="CNTRCT" moodCode="EVN">
                <id extension="USA-USFDACVM-N141321"/>
              </approval>
            </subjectOf>
          </asManufacturedProduct>
          .....
        </kindOfProduct>
        .....
      </instanceOfKind>
    </consumable>
    .....
  </substanceAdministration>
</subjectOf2>
```

3.2.1.3 Anatomical Therapeutic Chemical Vet (ATCvet) Code – GL42 Section B.2.1.3

Information: The MAH should provide the “ATCvet Code” for their VMP(s).

ICSR Location: Sibling node of B.2.1.2 Registration Identifier, but inside a <asSpecializedKind> element.

XML Details: “ATCvet Code” is captured using the <name> element value inside the <asSpecializedKind> node. The <code> element should be used to indicate that this name value is for the ATCvet code.

The XPath to get the “ATCvet Code” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind/kindOfProduct/asSpe  
cializedKind/generalizedMaterialKind[code/@code="T95013"]/name
```

A sample XML snippet for “ATCvet Code” in an AER message is:

```
<subjectOf2 typeCode="SBJ">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="1.2.3.4" extension="I"/>
    .....
```

```

<consumable typeCode="CSM">
  <instanceOfKind classCode="INST">
    .....
    <kindOfProduct classCode="MMAT" determinerCode="KIND">
      .....
      <asSpecializedKind classCode="GEN">
        <generalizedMaterialKind classCode="MMAT" determinerCode="KIND">
          <code codeSystem= "2.16.840.1.113883.13.206" code="T95013"
            displayName="ATCvet Code"/>
          <name xsi:type="TN">QH02AB02</name>
        </generalizedMaterialKind>
      </asSpecializedKind>
      .....
    </kindOfProduct>
    .....
  </instanceOfKind>
</consumable>
.....
</substanceAdministration>
</subjectOf2>

```

3.2.1.4 Company or MAH – GL42 Section B.2.1.4

Information: This is the name of the “Company or MAH” owning the VMP(s) involved in the AE.

ICSR Location: This data is captured in <asManufacturedProduct> node, inside its <manufacturerOrganization> child element.

XML Details: This information is captured as free text.

The XPath to get “Company” or “MAH” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind/kindOfProduct/asMa  
nufacturedProduct/manufacturerOrganization/name
```

A sample XML snippet for “Company” or “MAH” in an AER message is:

```

<subjectOf2 typeCode="SBJ">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="1.2.3.4" extension="1"/>
    .....
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        .....
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
          .....
          <asManufacturedProduct classCode="MANU">
            <manufacturerOrganization classCode="ORG" determinerCode="INSTANCE">
              <name>Safe Animal Health</name>
            </manufacturerOrganization>
            .....
          </asManufacturedProduct>
        </kindOfProduct>
      </instanceOfKind>
    </consumable>
  </substanceAdministration>
</subjectOf2>

```

```

<asSpecializedKind classCode="GEN">
.....
</asSpecializedKind>
.....
</kindOfProduct>
.....
</instanceOfKind>
</consumable>
.....
</substanceAdministration>
</subjectOf2>

```

3.2.1.5 MAH Assessment – GL42 Section B.2.1.5

Information: This is the assessment conducted by the MAH for the association between the use of the VMP and the AE.

ICSR Location: Located in a <causalityAssessment> element inside a <adverseEventAssessment> node.

XML Details: The XPath to get “MAH Assessment” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/component/causalityAssessment[author/assignedEntity/code/@code="T95001"]/value/originalText
```

A sample XML snippet for “MAH Assessment” in an AER message is shown below. Note that since the causality assessment is for each VMP, a <productUseReference> element is used to link the assessment to a particular VMP using the internal <id> to indicate the specific VMP. If multiple VMPs are used, multiple <causalityAssessment> nodes can be used with <author> being MAH, one for each VMP.

```

<adverseEventAssessment classCode="INVSTG" moodCode="EVN">
.....
<component typeCode="COMP">
  <causalityAssessment classCode="INVSTG" moodCode="EVN">
    <value xsi:type="CE">
      <originalText>4000 chars here</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="I"/>
      </productUseReference>
    </subject2>
  </causalityAssessment>
</component>
<component typeCode="COMP">
  <causalityAssessment classCode="INVSTG" moodCode="EVN">
    <value xsi:type="CE">

```

```

<originalText>4000 chars here</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="2"/>
    </productUseReference>
</subject2>
</causalityAssessment>
</component>
.....
</adverseEventAssessment>
```

Please refer to Regional Annexes for regional specific needs concerning MAH Assessment.

3.2.1.6 RA Assessment – GL42 Section B.2.1.6 and B.2.1.6.1

Information: This is the assessment conducted by the RA for the association between the use of the VMP and the AE based on a *RA Assessment Categories* vocabulary list. The RA can also provide an optional explanation relating to assessment.

ICSR Location: Same as “MAH Assessment”, but in another <causalityAssessment> element.

XML Details: Same as “MAH Assessment”, except that the <author> assignedEntity has a code value for “RA”, instead of “MAH”. For the explanation text element use the <text> child element. The assessment codes and values are taken from the *RA Assessment Categories* vocabulary list.

Note that, same as “MAH Assessment”, the “RA Assessment” is tied to VMP. In the case of multiple products used, multiple <causalityAssessment> nodes should be used, one for each product.

The XPath to get “RA Assessment” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/component/
causalityAssessment[author/assignedEntity/code/@code="T95009"]/value/@code
```

A sample XML snippet for “RA Assessment” in an AER message is:

```
<adverseEventAssessment classCode="INVSTG" moodCode="EVN">
.....
<component typeCode="COMP">
    <causalityAssessment classCode="INVSTG" moodCode="EVN">
<text>The reason for RA's causality assessment can put here. </text>
<value xsi:type="CE" codeSystem="2.16.840.1.113883.13.201" code="C54154"
        displayName="Probable"/>
    <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="I"/>
  </productUseReference>
</subject2>

</causalityAssessment>
</component>
.....
</adverseEventAssessment>
```

3.2.1.7 Route of Exposure (Route of Administration) – GL42 Section B.2.1.7

Information: This information is for the route of exposure for the VMP(s). The codes and values for “Route of Exposure” are shown in *Route of Exposure* vocabulary list.

ICSR Location: Located in the context of a substance administration instance. For repeated route of exposure to same VMP, use the recursive `<outboundRelationship2>` element in substance administration element to provide further information.

XML Details: Multiple route of exposure information could be provided, using a list of nested `<substanceAdministration>` nodes. Note that the `<id>` element inside `<substanceAdministration>` is used. This `<id>` is used to internally refer to a specific VMP, so that if a data element such as Route of Exposure or Causality Assessment needs to associate with a specific VMP, the report can use this id to link to a specific VMP when multiple VMP(s) are involved in the AE being reported.

The following XPath is to be used in the AER message when a single “Route of Exposure” is reported for a product.

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/routeCode/@code
```

When additional usage of the VMP is recorded (e.g., when one or more of the following elements have been changed for the VMP usage: route of exposure, dosage, interval of administration, and date of exposures), the first “Route of Exposure” for a product is specified in the XPath above and the remaining routes of exposure for that product are captured as “outboundRelationship2” using the XPath below.

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/outboundRelationship2/substanceAdministration/r  
outeCode/@code
```

A sample XML snippet for “Route of Exposure” in an AER message is:

```

<subjectOf2 typeCode="SBJ">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="1.2.3.4" extension="I"/>
    .....
    <routeCode codeSystem="2.16.840.1.113883.13.202" code="C38288" displayName="Oral">
    </routeCode>
```

```

.....
<!--For repeated route of exposure, use multiple outboundRelationship2 -->
<outboundRelationship2 typeCode="SEQL" contextConductionInd="true">
    <substanceAdministration classCode="SBADM" moodCode="EVN">
        <id root="1.2.3.4" extension="1"/>
        .....
        <routeCode codeSystem="2.16.840.1.113883.13.202" code="C38284" displayName="Nasal">
        </routeCode>
        .....
    </substanceAdministration>
</outboundRelationship2>
.....
</substanceAdministration>
</subjectOf2>

```

Please refer to Section 3.2.1.9 for a more complete example snippet for complex VMP usages.

3.2.1.7.1 Dose Administration per Unit – GL42 Section B.2.1.7.1 - B.2.1.7.2

Information: This data element collects the actual dose administered. This is not the label indicated dose.

ICSR Location: This information is captured right next to “Route of Exposure”, in a <doseCheckQuantity> element.

XML Details: The “Dose Administration per Unit” data element consists of two parts. The Numerator and Denominator information each consist of a “value” and “unit”. The unit is captured using coded value. The “unit” code value can be taken from one of three vocabularies. The *Units of Measurement* vocabulary list has a codeSystem OID of “2.16.840.1.113883.6.8”. The *Units of Presentation* vocabulary list has a codeSystem OID of “2.16.840.1.113883.13.203”. The *Dose Denominator Qualifiers* vocabulary list has a codeSystem OID of “2.16.840.1.113883.13.204”. Depending on which vocabulary list is used to report the “Unit” the matching codeSystem OID must be also reported.

The XPath to get the value and unit of Numerator in “Dose Administration per Unit” in the AER message are:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/doseCheckQuantity/numerator/@value
```

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/doseCheckQuantity/numerator/translation/@code
```

Replace “numerator” with “denominator” to get the XPath for value and unit of Denominator.

The XPath to get the Numerator value for “Repeated Exposure” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/outboundRelationship2/substanceAdministration/
doseCheckQuantity/numerator/@value
```

A sample XML snippet for “Dose Administration per Unit” that references the *Units of Presentation* vocabulary list with a codeSystem OID of “2.16.840.1.113883.13.203” in the numerator; and the *Dose Denominator Qualifiers* vocabulary list with an OID of “2.16.840.1.113883.13.204” in the denominator is shown below.

```

<subjectOf2 typeCode="SBJ">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="1.2.3.4" extension="1"/>
    .....
    <routeCode codeSystem="2.16.840.1.113883.13.202" code="C79137" displayName="Intramammary">
    </routeCode>

    <doseCheckQuantity>
      <numerator xsi:type="PQ" value="2">
        <translation codeSystem="2.16.840.1.113883.13.203" code="C48549" displayName="Tube"/>
      </numerator>
      <denominator xsi:type="PQ" value="1">
        <translation codeSystem="2.16.840.1.113883.13.204" code="C94851" displayName="Quarter"/>
      </denominator>
    </doseCheckQuantity>

    .....
    <!--For repeated route of exposure, use multiple outboundRelationship2 -->
    <outboundRelationship2 typeCode="SEQL" contextConductionInd="true">
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <id root="1.2.3.4" extension="1"/>
        .....
        <routeCode codeSystem="2.16.840.1.113883.13.202" code="C79137" displayName="Intramammary">
        </routeCode>

        <doseCheckQuantity>
          <numerator xsi:type="PQ" value="1">
            <translation codeSystem="2.16.840.1.113883.13.203" code="C48549" displayName="Tube"/>
          </numerator>
          <denominator xsi:type="PQ" value="1">
            <translation codeSystem="2.16.840.1.113883.13.204" code="C94851" displayName="Quarter"/>
          </denominator>
        </doseCheckQuantity>

        .....
      </substanceAdministration>
    </outboundRelationship2>
    .....
  </substanceAdministration>
</subjectOf2>
```

3.2.1.7.2 Interval of Administration – GL42 Section B.2.1.7.1.3

Information: This is the frequency of administration of the VMP(s) involved in the AE. For example, a tablet is given “once per day” from August 1, 2006 to February 10, 2007.

ICSR Location: They are located next to “Route of Exposure” and “Dose per Administration”.

XML Details: “Interval of Administration” is captured using an `<effectiveTime>` node. Use the `<low>` element for “Date of First Exposure”, and the `<high>` element for “Date of Last Exposure”. The `<period>` element is used for the “Interval of Administration”. Repeated exposures are handled the same way as “Route of Administration”, using multiple `<outboundRelationship2>` nodes.

The XPath's to locate the “Interval of Administration” value and unit in the AER message are:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/effectiveTime/comp/period/@value
```

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/effectiveTime/comp/period/@unit
```

The XPath's to locate the “Date of First Exposure” and the “Date of Last Exposure” in the AER message are:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/effectiveTime/comp/low/@value
```

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/effectiveTime/comp/high/@value
```

For “Interval of Administration”, the units of measurements must be one of the following valid values: s, min, h, d, wk, mo, or a (year).

A sample XML snippet for “Interval of Administration”, “Date of First Exposure” and “Date of Last Exposure” in an AER message is:

```
<subjectOf2 typeCode="SBJ">  
  <substanceAdministration classCode="SBADM" moodCode="EVN">  
    <id root="1.2.3.4" extension="1"/>  
    <effectiveTime xsi:type="SXPRTS">  
      <comp xsi:type="IVL_TS">  
        <low value="20060601"/>  
        <high value="20060602"/>  
      </comp>  
      <comp xsi:type="PIVL_TS" operator="A">  
        <period value="8" unit="h"/>  
      </comp>  
    </effectiveTime>  
    <routeCode codeSystem="2.16.840.1.113883.13.202" code="C38288" displayName="Oral">  
    </routeCode>  
    .....  
    <!--For repeated route of exposure, use multiple outboundRelationship2-->  
    <outboundRelationship2 typeCode="SEQL" contextConductionInd="true">  
      <substanceAdministration classCode="SBADM" moodCode="EVN">  
        <id root="1.2.3.4" extension="1"/>  
        <effectiveTime xsi:type="SXPRTS">  
          <comp xsi:type="IVL_TS">  
            <low value="20060602"/>  
            <high value="20060603"/>  
          </comp>  
          <comp xsi:type="PIVL_TS" operator="A">
```

```

<period value="I" unit="d"/>
</comp>
</effectiveTime>
<routeCode codeSystem="2.16.840.1.113883.13.202" code="C38288" displayName="Oral">
</routeCode>
.....
</substanceAdministration>
</outboundRelationship2>
.....
</substanceAdministration>
</subjectOf2>

```

3.2.1.8 Dosage Form – GL42 Section B.2.2.2

Information: Dosage Forms of the VMP(s) that is involved in the AER.

ICSR Location: This information is captured in AER message next to “Brand Name”, in element <formCode> of <kindOfProduct> within <consumable> element.

XML Details: The code value should be one of the codes from the *Dosage Forms* vocabulary list (codeSystem OID = “2.16.840.1.113883.13.205”).

The XPath to get the “Dosage Form” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind/kindOfProduct/form
Code/@code
```

A sample XML snippet for “Dosage Form” in an AER message is:

```

<subjectOf2 typeCode="SBJ">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="1.2.3.4" extension="I"/>
    .....
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        .....
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
          .....
          <name xsi:type="TN">DEXABRAND</name>
          <formCode codeSystem="2.16.840.1.113883.13.205" code="C42998" displayName="TABLET">
            </formCode>
          .....
        </kindOfProduct>
        .....
      </instanceOfKind>
    </consumable>
    .....
  </substanceAdministration>
</subjectOf2>

```

3.2.1.9 VMP Usage Example

The following section is a complete example that demonstrates VMP usages that involve two drugs. Each drug has multiple values in “Route of Administration”, “Dosage Levels”, multiple “Intervals of Administration”, “Date of First Exposure” and “Date of Last Exposure”.

Example: A data mapping of multiple drugs involved in the AER into the HL7 message. The examples of drug usages are illustrated below:

Drug#1: Spectramast DC (ATCvet Code: QJ51DD90; Dosage Form: Suspension)

Table 3-1 Usage of Sample Drug 1

Route	Dosage	Interval of Admin	Date of Exposures
Intramammary	1 Tube per 1 Quarter	12 Hours	05/30/2006-06/05/2006
Intramammary	1 Tube per 1 Quarter	1 Day	06/06/2006-06/15/2006

Drug#2: Dexamethasone (ATCvet Code: QA01AC02; Dosage Form: Solution)

Table 3-2 Usage of Sample Drug 2

Route	Dosage	Interval of Admin	Date of Exposures
Oral	10 ml per animal	8 Hours	06/01/2006-06/01/2006
Oral	30 ml per animal	1 Day	06/02/2006-06/02/2006
Oral	30 ml per animal	18 Hours	06/03/2006-06/05/2006
Intramuscular	5 ml per animal	1 Day	06/06/2006-06/10/2006

A sample XML snippet for the drug usage examples shown above:

```
<adverseEventAssessment classCode="INVSTG" moodCode="EVN">
  <subject1 typeCode="SBJ">
    <primaryRole classCode="INVSBJ">
      .....
      <!-- First Drug -->
      <subjectOf2 typeCode="SBJ">
        <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="20060530"/>
              <high value="20060605"/>
            </comp>
            <comp xsi:type="PIVL_TS">
              <period value="12" unit="h"/>
            </comp>
          </effectiveTime>
          <routeCode codeSystem="2.16.840.1.113883.13.202" code="C79137"
                    displayName="Intramammary">
            </routeCode>
            <doseCheckQuantity>
              <numerator xsi:type="PQ" value="1">
                <translation codeSystem="2.16.840.1.113883.13.203" code="C48549" displayName="Tube"/>
              </numerator>
              <denominator xsi:type="PQ" value="1">
                <translation codeSystem="2.16.840.1.113883.13.204" code="C94851" displayName="Quarter"/>
              </denominator>
            </doseCheckQuantity>
          </substanceAdministration>
        </subjectOf2>
      </primaryRole>
    </subject1>
  </adverseEventAssessment>
```

```

</denominator>
</doseCheckQuantity>
<consumable typeCode="CSM">
  <instanceOfKind classCode="INST">
    .....
    <kindOfProduct classCode="MMAT" determinerCode="KIND">
      <code codeSystem="2.16.840.1.113883.6.69" code="01234-*444"/>
      <name xsi:type="TN">Spectramast DC</name>
      <formCode codeSystem="2.16.840.1.113883.13.205" code="C42994"
                displayName="SUSPENSION">

    </formCode>

    <asManufacturedProduct classCode="MANU">
      <manufacturerOrganization classCode="ORG" determinerCode="INSTANCE">
        <name>Safe Animal Health</name>
      </manufacturerOrganization>
      <subjectOf typeCode="SBJ">
        <approval classCode="CNTRCT" moodCode="EVN">
          <id extension="USA-USFDACVM-N141321"/>
        .....
        </approval>
      </subjectOf>
    </asManufacturedProduct>

    <asSpecializedKind classCode="GEN">
      <generalizedMaterialKind classCode="MMAT" determinerCode="KIND">
        <code codeSystem="2.16.840.1.113883.13.206" code="T95013"
              displayName="ATCvet Code"/>
        <name xsi:type="TN">QJ51DD90</name>
      </generalizedMaterialKind>
    </asSpecializedKind>
    .....
  </kindOfProduct>
  .....
</instanceOfKind>
</consumable>

<outboundRelationship2 typeCode="SEQL" contextConductionInd="true">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="1.2.3.4" extension="I"/>
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="IVL_TS">
        <low value="20060606"/>
        <high value="20060615"/>
      </comp>
      <comp xsi:type="PIVL_TS">
        <period value="1" unit="d"/>
      </comp>
    </effectiveTime>
    <routeCode codeSystem="2.16.840.1.113883.13.202" code="C79137"
               displayName="Intramammary">
  </routeCode>
  <doseCheckQuantity>
    <numerator xsi:type="PQ" value="1">
      <translation codeSystem="2.16.840.1.113883.13.203" code="C48549" displayName="Tube"/>

```

```

</numerator>
<denominator xsi:type="PQ" value="I">
    <translation codeSystem="2.16.840.1.113883.13.204" code="C94851"
               displayName="Quarter"/>
</denominator>
</doseCheckQuantity>

</substanceAdministration>
</outboundRelationship2>
.....
</substanceAdministration>
</subjectOf2>

<!-- Second Drug -->
<subjectOf2 typeCode="SBJ">
    <substanceAdministration classCode="SBADM" moodCode="EVN">
        <id root="1.2.3.4" extension="2"/>
        <effectiveTime xsi:type="SXR_TS">
            <comp xsi:type="IVL_TS">
                <low value="20060601"/>
                <high value="20060601"/>
            </comp>
            <comp xsi:type="PIVL_TS">
                <period value="8" unit="h"/>
            </comp>
        </effectiveTime>
        <routeCode codeSystem="2.16.840.1.113883.13.202" code="C38288" displayName="Oral">
        </routeCode>
        <doseCheckQuantity>
            <numerator xsi:type="PQ" value="10">
                <translation codeSystem="2.16.840.1.113883.6.8" code="mL" displayName="mL"/>
            </numerator>
            <denominator xsi:type="PQ" value="I">
                <translation codeSystem="2.16.840.1.113883.13.204" code="C14182" displayName="Animal"/>
            </denominator>
        </doseCheckQuantity>
        <consumable typeCode="CSM">
            <instanceOfKind classCode="INST">
                .....
                <kindOfProduct classCode="MMAT" determinerCode="KIND">
                    <code codeSystem="2.16.840.1.113883.6.69" code="01234-*555"/>
                    <name xsi:type="TN">Dexamethasone</name>
                    <formCode codeSystem="2.16.840.1.113883.13.205" code="C42986"
                             displayName="SOLUTION">
                </formCode>

                <asManufacturedProduct classCode="MANU">
                    <manufacturerOrganization classCode="ORG" determinerCode="INSTANCE">
                        <name>Another Safe Animal Health Inc</name>
                    </manufacturerOrganization>
                    <subjectOf typeCode="SBJ">
                        <approval classCode="CNTRCT" moodCode="EVN">
                            <id extension="USA-USFDACVM-N141321"/>
                            .....
                        </approval>
                    </subjectOf>
                </asManufacturedProduct>
            </kindOfProduct>
        </consumable>
    </substanceAdministration>
</subjectOf2>

```

```

</asManufacturedProduct>

<asSpecializedKind classCode="GEN">
  <generalizedMaterialKind classCode="MMAT" determinerCode="KIND">
    <code codeSystem="2.16.840.1.113883.13.206" code="T95013"
          displayName="ATCvet Code"/>
    <name xsi:type="TN"> QA01AC02</name>
  </generalizedMaterialKind>
</asSpecializedKind>
.....
</kindOfProduct>
.....
</instanceOfKind>
</consumable>

<outboundRelationship2 typeCode="SEQL" contextConductionInd="true">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="1.2.3.4" extension="2"/>
    <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>

<outboundRelationship2 typeCode="SEQL" contextConductionInd="true">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="1.2.3.4" extension="2"/>
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="IVL_TS">
        <low value="20060603"/>
        <high value="20060605"/>
      </comp>
      <comp xsi:type="PIVL_TS">
        <period value="18" unit="h"/>
      </comp>
    </effectiveTime>
    <routeCode codeSystem="2.16.840.1.113883.13.202" code="C38288" displayName="Oral">
    </routeCode>
  </substanceAdministration>
</outboundRelationship2>

```

```

<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="I">
    <translation codeSystem="2.16.840.1.113883.13.204" code="C14182"
      displayName="Animal"/>
  </denominator>
</doseCheckQuantity>
</substanceAdministration>
</outboundRelationship2>

<outboundRelationship2 typeCode="SEQL" contextConductionInd="true">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="1.2.3.4" extension="2"/>
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="IVL_TS">
        <low value="20060606"/>
        <high value="20060610"/>
      </comp>
      <comp xsi:type="PIVL_TS">
        <period value="I" unit="d"/>
      </comp>
    </effectiveTime>
    <routeCode codeSystem="2.16.840.1.113883.13.202" code="C28161"
      displayName="INTRAMUSCULAR">
    </routeCode>
    <doseCheckQuantity>
      <numerator xsi:type="PQ" value="5">
        <translation codeSystem="2.16.840.1.113883.6.8" code="mL" displayName="mL"/>
      </numerator>
      <denominator xsi:type="PQ" value="I">
        <translation codeSystem="2.16.840.1.113883.13.204" code="C14182"
          displayName="Animal"/>
      </denominator>
    </doseCheckQuantity>
  </substanceAdministration>
</outboundRelationship2>
.....
</substanceAdministration>
</subjectOf2>

.....
</primaryRole>
</subject1>
</adverseEventAssessment>

```

3.2.2 Active Ingredient(s) – GL42 Section B.2.2

Information: This section captures the active ingredients, the strength of the active ingredient, and the dosage form of the reported VMP.

3.2.2.1 Active Ingredient(s) – GL42 Section B.2.2.1

Information: Mandatory for MAH product(s). For all non-MAH products, this is optional if B.2.1 Registered or Brand Name is provided.

ICSR Location: This information is captured in AER message next to “Brand Name”, in element <ingredient> inside <kindOfProduct> within a <consumable> node.

XML Details: If more than one active ingredient needs to be included, use a list of <ingredient> elements. Ingredient strength is reported as a ratio of the two quantities. Both the numerator and denominator information needs to be included. Use the *Units of Measurement* vocabulary list for numerator code and term values and either the *Units of Measurement* or the *Units of Presentation* vocabulary lists for denominator code and term values. For more details concerning the Active Ingredient Code, refer to the Regional Annexes.

The XPath to get the “Active Ingredients Name” is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind/kindOfProduct/ingre  
dient/ingredientSubstance/name
```

The XPath to get the “Strength” (value and unit), the numerator part in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind/kindOfProduct/ingre  
dient/quantity/numerator/@value
```

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind/kindOfProduct/ingre  
dient/quantity/numerator/translation/@code
```

Substitute “numerator” with “denominator” in the above XPath’s for the denominator part of the “Strength” data.

The XPath to get the “Active Ingredients” code in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind/kindOfProduct/ingre  
dient/ingredientSubstance/code/@code
```

A sample XML snippet for “Active Ingredients” in an AER message is:

```
<subjectOf2 typeCode="SBJ">  
  <substanceAdministration classCode="SBADM" moodCode="EVN">  
    <id root="1.2.3.4" extension="1"/>  
    .....  
    <consumable typeCode="CSM">  
      <instanceOfKind classCode="INST">  
        .....  
        <kindOfProduct classCode="MMAT" determinerCode="KIND">  
          .....  
          <ingredient classCode="INGR">  
            <quantity>
```

```

<numerator xsi:type="PQ" value="5">
    <translation codeSystem="2.16.840.1.113883.6.8" code="mL" displayName="mL"/>
</numerator>
<denominator xsi:type="PQ" value="1">
    <translation codeSystem="2.16.840.1.113883.6.8" code="L" displayName="L"/>
</denominator>
</quantity>
<ingredientSubstance determinerCode="KIND" classCode="MMAT">
    <code codeSystem="2.16.840.1.113883.4.9" code="7S5I7G3JQL"/>
    <name xsi:type="TN">DEXAMETHASONE</name>
</ingredientSubstance>
</ingredient>
.....
</kindOfProduct>
.....
</instanceOfKind>
</consumable>
.....
</substanceAdministration>
</subjectOf2>

```

Please note, if the strength unit is unknown, reporter shall use the actual code for unknown (C17998) which is provided in the vocabulary list mentioned above. A sample snippet for unknown strength unit is provided below.

```

<ingredient classCode="INGR">
    <!-- active ingredient -->
    <quantity>
        <numerator xsi:type="PQ" value="1">
            <translation codeSystem="2.16.840.1.113883.6.8" code="C17998" displayName="Unknown"/>
        </numerator>
        <denominator xsi:type="PQ" value="1">
            <translation codeSystem="2.16.840.1.113883.6.8" code="C17998" displayName="Unknown"/>
        </denominator>
    </quantity>
    <ingredientSubstance determinerCode="KIND" classCode="MMAT">
        <code codeSystem="2.16.840.1.113883.4.9" code="7S111G1XYZ"/>
        <name xsi:type="TN">The-Ingredient-Name</name>
    </ingredientSubstance>
</ingredient>

```

3.2.3 Lot Number and Expiration Date – GL42 Section B.2.3, B.2.3.1

Information: This section includes information about the Lot Number and Expiration Date of the reported VMP.

ICSR Location: Inside a particular product instance of a product.

XML Details: These data elements are captured inside the <instanceOfKind> element of the <consumable> element that represents the drug product. “Expiration Date” is captured in <expirationTime>. “Lot Number” is captured within the text element <lotNumberText>.

The XPath to get the “Lot Number” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind/productInstanceInsta  
nce/lotNumberText
```

The XPath to get the “Expiration Date” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind/productInstanceInsta  
nce/expirationTime/@value
```

A sample XML snippet for “Lot Number” and “Expiration Date” in an AER message is:

```
<subjectOf2 typeCode="SBJ">  
  <substanceAdministration classCode="SBADM" moodCode="EVN">  
    <id root="1.2.3.4" extension="1"/>  
    .....  
    <consumable typeCode="CSM">  
      <instanceOfKind classCode="INST">  
        <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">  
          <id extension="1"/>  
          <existenceTime xsi:type="IVL_TS">  
            <low value="20051208"/>  
          </existenceTime>  
          <lotNumberText mediaType="text/plain">GAP3487 FOR USA-123479</lotNumberText>  
          <expirationTime value="20060405"/>  
        </productInstanceInstance>  
        .....  
      </instanceOfKind>  
    </consumable>  
    .....  
  </substanceAdministration>  
</subjectOf2>
```

Note that for “Expiration Date” a partial date value, i.e. date value with only year, or with only year and month, is acceptable. Please refer to VICH Validation Procedure Document for more details.

For multiple lots of one drug product, use multiple <member> elements of <productInstanceInstance> element, one for each lot. Following is an example of two lots for one drug product.

```

<subjectOf2 typeCode="SBJ">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="1.2.3.4" extension="I"/>
    .....
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
          <id extension="I"/>
          <existenceTime xsi:type="IVL_TS">
            <low value="20051208"/>
          </existenceTime>
          <lotNumberText mediaType="text/plain">GAP3488 FOR USA-123479</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">GAP3489 FOR USA-123479</lotNumberText>
              <expirationTime value="20060415"/>
            </memberProductInstance>
          </member>
        </productInstanceInstance>
        .....
      </instanceOfKind>
    </consumable>
    .....
  </substanceAdministration>
</subjectOf2>

```

3.2.4 Who Administered the VMP (Administered or Performed by) – GL42 Section B.2.4

Information: The category of the person who administered the VMP involved in the AE.

ICSR Location: Captured using a <performer> element, inside a substance administration class.

XML Details: Use the *Administrators of VMP* vocabulary list for the code attribute.

The XPath to get the “Who Administered the VMP” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/performer/assignedEntity/code/@code
```

A sample XML snippet for “Who Administered the VMP” in an AER message is:

```

<subjectOf2 typeCode="SBJ">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="1.2.3.4" extension="I"/>

```

```

.....
<performer typeCode="PRF">
  <assignedEntity classCode="ASSIGNED">
    <code codeSystem="2.16.840.1.113883.13.208" code="C82468" displayName="ANIMAL OWNER"/>
  </assignedEntity>
</performer>
.....
</substanceAdministration>
</subjectOf2>
```

3.2.5 Use According to Label – GL42 Section B.2.5

Information: Information on whether the VMP was used according to its label recommendations. If off-label use was employed then provide an explanation.

ICSR Location: Next to the data element for “Who Administered the VMP”, but captured using an observation class inside of `<outboundRelationship2>` elements where the reporter can provide additional related information.

XML Details: Two `<outboundRelationship2>` nodes should be used for label use information. One node is used to capture if the VMP was used according to the label. The other node is used to capture the explanation if the VMP was indeed used off-label. For the `<outboundRelationship2>` node that is used for capturing the off-label use explanation, a list of nine nested `<outboundRelationship2>` nodes is used to capture the off-label use explanation. One is used for each Off-Label use reason.

If “False (no)” is chosen for “Use According to Label”, the reporter must provide an explanation by selecting the appropriate VICH label use code. If “True (yes)” is chosen for “Use According to Label”, the reporter still needs to use the nine nested `<outboundRelationship2>` nodes for the off label use explanation, however all the values should be set to use nullflavor “NI”.

The XPath to get “Use According to Label” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/outboundRelationship2/observation[code/@code=
"T95015"]/value/@value
```

The XPath to get “Explanation for Label Use” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/
outboundRelationship2/observation[code/@code="T95016"]/outboundRelationship2/observation[code/@code="T950
30"]/value/@value
```

A sample XML snippet for “Use According to Label” and “Explanation for Off-Label Use” in an AER message is provided below. Please note that, for the nine “Explanation for Off-Label Use” elements, the data type is Boolean (BL) type. However, the only acceptable Boolean value is “True”. The only acceptable null flavor is “NI”.

```
<subjectOf2 typeCode="SBJ">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="1.2.3.4" extension="1"/>
```

```

.....
<outboundRelationship2 typeCode="PERT" contextConductionInd="true">
  <observation classCode="OBS" moodCode="EVN">
    <code codeSystem="2.16.840.1.113883.13.206" code="T95015"
          displayName="Use According to Label"/>
    <value xsi:type="BL" value="false"/>
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT" contextConductionInd="true">
  <observation classCode="OBS" moodCode="EVN">
    <code codeSystem="2.16.840.1.113883.13.206" code="T95016"
          displayName="VICH Label Use"/>

  <outboundRelationship2 typeCode="PERT" contextConductionInd="true">
    <observation moodCode="EVN" classCode="OBS">
      <code codeSystem="2.16.840.1.113883.13.206" code="T95028"
            displayName="Species Off-Label"/>
      <value xsi:type="BL" value="true"/>
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT" contextConductionInd="true">
    <observation moodCode="EVN" classCode="OBS">
      <code codeSystem="2.16.840.1.113883.13.206" code="T95029"
            displayName="Route Off-Label"/>
      <value xsi:type="BL" nullFlavor="NI"/>
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT" contextConductionInd="true">
    <observation moodCode="EVN" classCode="OBS">
      <code codeSystem="2.16.840.1.113883.13.206" code="T95030" displayName="Overdosed"/>
      <value xsi:type="BL" value="true"/>
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT" contextConductionInd="true">
    <observation moodCode="EVN" classCode="OBS">
      <code codeSystem="2.16.840.1.113883.13.206" code="T95031" displayName="Underdosed"/>
      <value xsi:type="BL" nullFlavor="NI"/>
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT" contextConductionInd="true">
    <observation moodCode="EVN" classCode="OBS">
      <code codeSystem="2.16.840.1.113883.13.206" code="T95032"
            displayName="Treatment regimen Off-Label"/>
      <value xsi:type="BL" nullFlavor="NI"/>
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT" contextConductionInd="true">
    <observation moodCode="EVN" classCode="OBS">
      <code codeSystem="2.16.840.1.113883.13.206" code="T95033"
            displayName="Indication Off-Label"/>
      <value xsi:type="BL" nullFlavor="NI"/>
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT" contextConductionInd="true">
    <observation moodCode="EVN" classCode="OBS">
      <code codeSystem="2.16.840.1.113883.13.206" code="T95034"
            displayName="Reason Off-Label"/>
      <value xsi:type="BL" nullFlavor="NI"/>
    </observation>
  </outboundRelationship2>

```

```

        displayName="Storage condition Off-Label"/>
        <value xsi:type="BL" nullFlavor="NI"/>
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT" contextConductionInd="true">
    <observation moodCode="EVN" classCode="OBS">
        <code codeSystem="2.16.840.1.113883.13.206" code="T95035"
            displayName="Product expired"/>
        <value xsi:type="BL" nullFlavor="NI"/>
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT" contextConductionInd="true">
    <observation moodCode="EVN" classCode="OBS">
        <code codeSystem="2.16.840.1.113883.13.206" code="T95036"
            displayName="Other off label issue"/>
        <value xsi:type="BL" nullFlavor="NI"/>
    </observation>
</outboundRelationship2>
</observation>
</outboundRelationship2>
.....
</substanceAdministration>
</subjectOf2>

```

3.3 Adverse Event Data – GL42 Section B.3 (B.3.1 – B.3.10)

This section contains information about the adverse event being reported.

3.3.1 Narrative of AE – GL42 Section B.3.1

Information: This data element captures the narrative description of the sequence of the adverse event.

ICSR Location: It is captured inside the `<text>` element of the investigative event.

XML Details: Required.

The XPath to get “Narrative of AE” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/text
```

A sample XML snippet for “Narrative of AE” in an AER message is:

```

<investigationEvent moodCode="EVN" classCode="INVSTG">
    .....
    <text mediaType="text/plain">
The sows and gilts were given the two medications. Two days after receiving the
chlorotetracycline penicillin combination in the feed the sows and gilts started going
off feed. A closer inspection of GAP7777 FOR USA-124578 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 ABC Labs, Inc. at the request of the attending vet.

```

```
</text>
.....
</investigationEvent>
```

3.3.2 Adverse Clinical Manifestations (AER Term Name) – GL42 Section B.3.2

Information: Adverse clinical manifestations observed in the AE.

ICSR Location: It is captured in the reaction that triggers the investigation event.

XML Details: The VeDDRA medical terminology code shall be used for this data element. The “code” and the associated “displayName” will be the lowest level key value (LLT Key) entry. The reporter is also required to indicate the version of the VeDDRA table used by storing the version number in the “codeSystemVersion” element attribute.

The <code> element describes the data element from GL42 (see sample XML snippet below). In this example, it is the adverse clinical manifestations data element. The OID for <code> codeSystem attribute is the OID of the *XML Locator Codes* vocabulary (2.16.840.1.113883.13.206). The code attribute value is “T95020” and displayName attribute value is “Reaction”, which come from this vocabulary. The <value> codeSystem attribute is the OID of the *VeDDRA Terms* vocabulary (2.16.840.1.113883.4.358). The <value> code attribute is “984” and displayName attribute “Death”, which come from the *VeDDRA Terms* vocabulary. The codeSystemVersion is the version of the *VeDDRA Terms* vocabulary associated with this code (7).

The <observationRange> node is used to capture the number of animals (10) associated with the adverse clinical manifestation. The OID for <interpretationCode> codeSystem attribute is the OID for the *Accuracy of No. of Animals* vocabulary list (2.16.840.1.113883.13.209). The code attribute is “C25498” and displayName attribute value is “Estimated”, which come from this vocabulary.

The XPath to get “Adverse Clinical Manifestations” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri-
maryRole/subjectOf2/observation[code/@code="T95020"]/value/@code
```

The number of animals affected is mapped using a reference observation inside clinical manifestation observation. The XPath to get “Number of Animals Affected per Adverse Clinical Manifestations” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri-
maryRole/subjectOf2/observation[code/@code="T95020"]/referenceRange/observationRange/value/@value
```

The XPath to get the “Accuracy of the Number of Animals” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri-
maryRole/subjectOf2/observation[code/@code="T95020"]/referenceRange/observationRange/interpretationCode/@co-
de
```

If multiple clinical signs need to be reported in the AER message, repeat the <subjectOf2> node that contains the observation, one for each clinical sign.

A sample XML snippet for “Adverse Clinical Manifestations” in an AER message is:

```
<adverseEventAssessment classCode="INVSTG" moodCode="EVN">
  <subject1 typeCode="SBJ">
    <primaryRole classCode="SBJ">
      .....
      <subjectOf2 typeCode="SBJ">
        <observation classCode="OBS" moodCode="EVN">
          <code codeSystem="2.16.840.1.113883.13.206" code="T95020" displayName="Reaction"/>
          .....
          <value xsi:type="CE" codeSystem="2.16.840.1.113883.4.358"
                codeSystemVersion="7" code="984" displayName="Death"/>
        <referenceRange>
          <observationRange classCode="OBS" moodCode="EVN.CRT">
            <value xsi:type="INT" value="10" />
            <interpretationCode codeSystem="2.16.840.1.113883.13.209" code="C25498"
                               displayName="Estimated"/>
          </observationRange>
        </referenceRange>
      </observation>
    </subjectOf2>
    <subjectOf2 typeCode="SBJ">
      <observation classCode="OBS" moodCode="EVN">
        <code codeSystem="2.16.840.1.113883.13.206" code="T95020" displayName="Reaction"/>
        .....
        <value xsi:type="CE" codeSystem="2.16.840.1.113883.4.358"
              codeSystemVersion="8" code="334" displayName="Vomiting"/>
      <referenceRange>
        <observationRange classCode="OBS" moodCode="EVN.CRT">
          <value xsi:type="INT" nullFlavor="NI"/>
          <interpretationCode nullFlavor="NI"/>
        </observationRange>
      </referenceRange>
    </observation>
  </subjectOf2>
  .....
  </primaryRole>
</subject1>
</adverseEventAssessment>
```

3.3.3 Date of Onset of AE (AE Start Date) – GL42 Section B.3.3

Information: This is the date of the first clinical manifestation of the AE.

ICSR Location: The element is located in the adverse event assessment class, mapped as an observation.

XML Details: The information is captured using a <effectiveTime> element. The <low> value is the date of onset of the AE, and the <width> is the duration of AE. For the “AE Duration Time Units” element, the <unit> of measurement must be one of the following valid values: s, min, h, d, wk, mo, or a (year).

The XPath to get “Date of Onset of AE” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/observation[code/@code="T95020"]/effectiveTime/low/@value
```

A sample XML snippet for “Date of Onset of AE” in an AER message is:

```
<adverseEventAssessment classCode="INVSTG" moodCode="EVN">  
  <subject1 typeCode="SBJ">  
    <primaryRole classCode="SBJ">  
      .....  
      <subjectOf2 typeCode="SBJ">  
        <observation classCode="OBS" moodCode="EVN">  
          <code codeSystem="2.16.840.1.113883.13.206" code="T95020" displayName="Reaction"/>  
          <effectiveTime xsi:type="IVL_TS">  
            <low value="20060608"/>  
            <width value="5" unit="d"/>  
          </effectiveTime>  
  
        </observation>  
      </subjectOf2>  
  
      .....  
    </primaryRole>  
  </subject1>  
</adverseEventAssessment>
```

3.3.4 Length of Time between Exposure to VMP and Onset of AE – GL42 Section B.3.4

Information: Length of time refers to the time difference between the exposure to VMP and onset of AE.

ICSR Location: This data element is captured in an observation of the investigative subject, inside a <subjectOf2> element.

XML Details: A code value should be used for “Length of Time between Exposure to VMP and Onset of AE”. The code should correspond to one of the length of time contained in *Exposure and Onset Time* vocabulary list.

The XPath to get “Length of Time Between Exposure to VMP and Onset of AE” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/observation[code/@code="T95021"]/value/@code
```

A sample XML snippet for “Length of Time Between Exposure to VMP and Onset of AE” in an AER message is:

```
<subjectOf2 typeCode="SBJ">  
  <observation classCode="OBS" moodCode="EVN">  
    <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" codeSystem="2.16.840.1.113883.13.50" code="C82440"
          displayName="&lt;12 hours"/>
</observation>
</subjectOf2>
```

3.3.5 Duration of AE – GL42 Section B.3.5, B.3.5.1, B.3.5.1.1

Information: This is the duration of the AE, in the actual or approximate length of time the AE lasted.

ICSR Location: The element is located in the adverse event assessment class, mapped as an observation.

XML Details: The information is captured using a <effectiveTime> element. The <low> value is the date of onset of the AE, and the <width> is the duration of AE. For the “AE Duration Time Units” element, the <unit> of measurement must be one of the following valid values: s, min, h, d, wk, mo, or a (year).

The XPath to get the “AE Duration – value” in an AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/observation[code/@code="T95020"]/effectiveTime/width/@value
```

The XPath to get the “AE Duration Time Units” in an AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/observation[code/@code="T95020"]/effectiveTime/width/@unit
```

A sample XML snippet for “Duration of AE” in an AER message is:

```

<adverseEventAssessment statusCode="INVSTG" moodCode="EVN">
    <subject1 typeCode="SBJ">
        <primaryRole statusCode="SBJ">
            .....
            <subjectOf2 typeCode="SBJ">
                <observation statusCode="OBS" moodCode="EVN">
                    <code codeSystem="2.16.840.1.113883.13.206" code="T95020" displayName="Reaction"/>
                    <effectiveTime xsi:type="IVL_TS">
                        <low value="20060608"/>
                        <width value="5" unit="d"/>
                    </effectiveTime>

                </observation>
            </subjectOf2>
            .....
        </primaryRole>
    </subject1>
</adverseEventAssessment>
```

3.3.6 Serious AER (Serious AE as Reported) – GL42 Section B.3.6

Information: This data element indicates whether the AER is being reported as a serious AE.

ICSR Location: This data element is captured as an observation, inside an <investigationCharacteristic> class, as a reference of the investigation event.

XML Details: HL7 Boolean values will be used.

The XPath to get “Seriousness of AE” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf2/investigationCharacteristic[code/@code="T95022"]/value/@value
```

A sample XML snippet for “Seriousness of AE” in an AER message is:

```
<subjectOf2 typeCode="SUBJ">
  <investigationCharacteristic classCode="CASE" moodCode="EVN">
    <code codeSystem="2.16.840.1.113883.13.206" code="T95022" displayName="Serious AE"/>
    <value xsi:type="BL" value="true"/>
  </investigationCharacteristic>
</subjectOf2>
```

3.3.7 Treatment of AE – GL42 Section B.3.7

Information: This data element indicates whether the human or animal involved in the AE was treated for the AE.

ICSR Location: This data element is located inside a <subjectOf2> observation of the adverse event assessment subject class.

XML Details: “Treatment of AE” is captured as an observation, using <code> node for observation type, and using the <value> node for the actual observation value. HL7 Boolean values and the HL7 null flavor will be used.

The XPath to get “Treatment of AE” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri
maryRole/subjectOf2/observation[code/@code="T95023"]/value/@value
```

A sample XML snippet for “Treatment of AE” in an AER message is:

```
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <code codeSystem="2.16.840.1.113883.13.206" code="T95023" displayName="Treatment of AE"/>
    <value xsi:type="BL" value="true"/>
  </observation>
</subjectOf2>
```

3.3.8 Outcomes to Date – GL42 Section B.3.8 (B.3.8.1 – B.3.8.6)

Information: This provides a number of possible outcome categories for the animal(s) affected in the adverse event. These categories are: Ongoing, Recovered/Normal, Recovered with Sequela, Died, Euthanized, Unknown (Outcome Unknown).

ICSR Location: These data elements are captured using a list of observations of investigative subject.

XML Details: Six observation nodes are used. One is used for each outcome category to capture this information.

The XPath to get “Ongoing” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/observation[code/@code="C53279"]/value/@value
```

Use the same XPath for other “Outcomes to Date” data elements (“Recovered/Normal”, “Recovered with Sequela”, “Died”, “Euthanized” and “Outcome Unknown”) by simply replacing the observation code value in XPath predicate.

A sample XML snippet for “Outcomes to Date” data elements (“Recovered/Normal”, “Recovered with Sequela”, “Died”, “Euthanized” and “Outcome Unknown”) in an AER message is:

```
<subjectOf2 typeCode="SBJ">  
  <observation moodCode="EVN" classCode="OBS">  
    <code codeSystem="2.16.840.1.113883.13.206" code="C53279"  
          displayName="Ongoing"/>  
    <value xsi:type="INT" value="2"/>  
  </observation>  
</subjectOf2>  
  
<subjectOf2 typeCode="SBJ">  
  <observation moodCode="EVN" classCode="OBS">  
    <code codeSystem="2.16.840.1.113883.13.206" code="C82467"  
          displayName="Recovered/Normal"/>  
    <value xsi:type="INT" value="2"/>  
  </observation>  
</subjectOf2>  
  
<subjectOf2 typeCode="SBJ">  
  <observation moodCode="EVN" classCode="OBS">  
    <code codeSystem="2.16.840.1.113883.13.206" code="C49495"  
          displayName="Recovered with Sequela"/>  
    <value xsi:type="INT" value="1"/>  
  </observation>  
</subjectOf2>  
  
<subjectOf2 typeCode="SBJ">  
  <observation moodCode="EVN" classCode="OBS">  
    <code codeSystem="2.16.840.1.113883.13.206" code="C28554"  
          displayName="Died"/>  
    <value xsi:type="INT" value="3"/>  
  </observation>  
</subjectOf2>
```

```

<subjectOf2 typeCode="SBJ">
  <observation moodCode="EVN" classCode="OBS">
    <code codeSystem="2.16.840.1.113883.13.206" code="C21115"
          displayName="Euthanized"/>
    <value xsi:type="INT" value="1"/>
  </observation>
</subjectOf2>

<subjectOf2 typeCode="SBJ">
  <observation moodCode="EVN" classCode="OBS">
    <code codeSystem="2.16.840.1.113883.13.206" code="C17998"
          displayName="Outcome Unknown"/>
    <value xsi:type="INT" value="0"/>
  </observation>
</subjectOf2>

```

3.3.9 Previous Exposure to the VMP – GL42 Section B.3.9

Information: This relates to previous exposures to the VMP that occurred before the reported “Date of First Exposure” given in this report.

ICSR Location: Located in an observation of investigative subject, inside the substance administration process node.

XML Details: Using `<code>` to identify that the observation is for this data element, use `<value>` to provide the actual data. HL7 Boolean values and the HL7 null flavor will be used.

The XPath to get “Previous Exposure to VMP” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri-
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/outboundRelationship2/observation[code/@code=-
"T95024"]/value/@value
```

A sample XML snippet for “Previous Exposure to VMP” in an AER message is:

```

<subjectOf2 typeCode="SBJ">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="1.2.3.4" extension="1"/>
    .....
    <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" value="true"/>
      </observation>
    </outboundRelationship2>
    .....
  </substanceAdministration>
</subjectOf2>

```

3.3.10 Previous AE to VMP – GL42 Section B.3.10

Information: This field refers only to clinical manifestations that occurred during the previous exposure mentioned in B.3.9 above.

ICSR Location: Same as B.3.9, except that this data element is in another observation element.

XML Details: Same as B.3.9, except that in the observation type <code> node, the code attribute value should be the code that identifies this data element. HL7 Boolean values and the HL7 null flavor will be used.

The XPath to get “Previous AE to VMP” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/outboundRelationship2/observation[code/@code=  
"T95025"]/value/@value
```

A sample XML snippet for “Previous AE to VMP” in an AER message is:

```
<subjectOf2 typeCode="SBJ">  
  <substanceAdministration classCode="SBADM" moodCode="EVN">  
    <id root="1.2.3.4" extension="1"/>  
    .....  
    <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" value="false"/>  
      </observation>  
    </outboundRelationship2>  
    .....  
  </substanceAdministration>  
</subjectOf2>
```

3.4 Dechallenge - Rechallenge Information – GL42 Section B.4 (B.4.1 – B.4.2)

Information: The information in this section relates to affected animal(s). This set of fields will be used for cases where dechallenge or rechallenge occur.

3.4.1 Did AE Abate After Stopping the VMP – GL42 Section B.4.1

3.4.2 Did AE Reappear After Re-introduction of the VMP – GL42 Section B.4.2

ICSR Location: Same as B.3.10, data elements in B.4.1 and B.4.2 are captured in observations. There is one observation for each data element. The code value in <code> that identifies the observation type is different for 3.4.1 and 3.4.2. HL7 Boolean values and the HL7 null flavor will be used.

XML Details: Same as B.3.10. Note the difference in code value in the predicates.

The XPath to get “Did AE Abate After Stopping the VMP” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/outboundRelationship2/observation[code/@code= "T95026"]/value/@value
```

The XPath to get “Did AE Reappear After Re-introduction of the VMP” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/subject1/pri  
maryRole/subjectOf2/substanceAdministration[id/@extension="1"]/outboundRelationship2/observation[code/@code= "T95027"]/value/@value
```

A sample XML snippet for “Did AE Abate After Stopping the VMP” and ”Did AE Reappear After Re-introduction of the VMP“ in an AER message is:

```
<subjectOf2 typeCode="SBJ">  
  <substanceAdministration classCode="SBADM" moodCode="EVN">  
    <id root="1.2.3.4" extension="I"/>  
    .....  
    <outboundRelationship2 typeCode="PERT" contextConductionInd="true">  
      <observation moodCode="EVN" classCode="OBS">  
        <code codeSystem="2.16.840.1.113883.13.206" code="T95026"  
          displayName="Did AE Abate After Stopping the VMP "/>  
        <value xsi:type="BL" value="false"/>  
      </observation>  
    </outboundRelationship2>  
  
    <outboundRelationship2 typeCode="PERT" contextConductionInd="true">  
      <observation moodCode="EVN" classCode="OBS">  
        <code codeSystem="2.16.840.1.113883.13.206" code="T95027"  
          displayName="Did AE Reappear After Re-introduction of the VMP"/>  
        <value xsi:type="BL" nullFlavor="NA"/>  
      </observation>  
    </outboundRelationship2>  
    .....  
  </substanceAdministration>  
</subjectOf2>
```

3.5 Assessment of AE – GL42 Section B.5

Information: This is the assessment of the attending veterinarian regarding the association between the VMP and the AE.

ICSR Location: Located in a causality assessment class instance that is associated with the adverse event assessment that triggers the investigation event.

XML Details: This data element must use the coded value. A list of values is shown in *Attending Veterinarian’s Causality Assessment* vocabulary list.

The XPath to get the “Assessment of AE” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/component/adverseEventAssessment/component/  
causalityAssessment[author/assignedEntity/code/@code="C82470"]/value/@code
```

A sample XML snippet for “Assessment of AE” in an AER message is:

```
<component typeCode="COMP">
  <causalityAssessment classCode="INVSTG" moodCode="EVN">
    <value xsi:type="CE" codeSystem="2.16.840.1.113883.13.210" code="C82490" displayName="Possible"/>
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code codeSystem="2.16.840.1.113883.13.194" code="C82470" displayName="Veterinarian"/>
      </assignedEntity>
    </author>
  </causalityAssessment>
</component>
```

3.6 Report Number(s) of Linked Report(s) – Section GL42 B.6 (B.6.1 – B.6.1.1)

Information: This section lists the “Report Number(s) of Linked Report(s)” information on a specific AER to be submitted to the RA.

ICSR Location: Located inside the investigationCharacteristic that is close to data element such as A.4.4.1 Type of Submission.

XML Details: This data element is captured in an `<investigationCharacteristic>` node, an XML Locator Code (T95037) is used to identify that this is the node for “Linked Report Number”. The value of linked report number is captured as a text value. The explanation for the link type is captured as a coded value from the *Explanation for Linkage* vocabulary list. If more than one linked report number needs to be reported, a list of such `<investigationCharacteristic>` nodes can be used, one for each linked report.

The XPath to get the “Report Number of Linked Report” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf2/investigationCharacteristic[code/@code="T95037"]/value/originalText
```

The XPath to get the Type of Link for a linked report in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf2/investigationCharacteristic[code/@code="T95037"]/value/@code
```

A sample XML snippet for “Number(s) of Linked Report(s)” in an AER message is:

```
<subjectOf2 typeCode="SUBJ">
  <investigationCharacteristic moodCode="EVN" classCode="CASE">
    <code codeSystem="2.16.840.1.113883.13.206" code="T95037"
          displayName="Report number(s) of linked report(s)"/>
    <value xsi:type="CD" codeSystem="2.16.840.1.113883.13.219" code="LTPO"
          displayName="Parent - Offspring">
      <originalText>USA-FDASENDR-2009-US-01234</originalText>
    </value>
  </investigationCharacteristic>
</subjectOf2>
```

```

<subjectOf2 typeCode="SUBJ">
  <investigationCharacteristic moodCode="EVN" classCode="CASE">
    <code codeSystem="2.16.840.1.113883.13.206" code="T95037"
          displayName="Report number(s) of linked report(s)"/>
    <value xsi:type="CD" codeSystem="2.16.840.1.113883.13.219" code="LTPO"
          displayName="Parent – Offspring">
      <originalText>USA-FDASENDR-2010-US-04321</originalText>
    </value>
  </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
  <investigationCharacteristic moodCode="EVN" classCode="CASE">
    <code codeSystem="2.16.840.1.113883.13.206" code="T95037"
          displayName="Report number(s) of linked report(s)"/>
    <value xsi:type="CD" codeSystem="2.16.840.1.113883.13.219" code="LTSP"
          displayName="Same Patient">
      <originalText>USA-FDASENDR-2009-US-05678</originalText>
    </value>
  </investigationCharacteristic>
</subjectOf2>

```

3.7 Supplemental Documents – Section GL42 B.7

Information: This section lists the “Supplemental Documents” information on a specific AER to be submitted to the RA. Please note that “Supplemental Documents” should be embedded in the AER message file, and binary “Supplemental Documents” should be embedded as Base-64 encoded data.

Each “Supplemental Document” is mapped into the `<document>` node inside the `<reference>` element that is associated with the investigation event. In the case that multiple supplemental documents need to be attached, reporters can use multiple `<reference>` nodes in the AER message, one for each “Supplemental Document”. Reporters should use a unique `<id>` element to specify each document.

3.7.1 Attached Document Filename – GL42 Section B.7.1

Information: This is the proper name of the “Supplemental Document”. The filename must contain the 3-character file extension of the acceptable file kind.

ICSR Location: This element is located within the `<title>` element within the `<document>` node.

XML Details: The XPath to get to the “Supplemental Document Filename” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/reference/document/title
```

3.7.2 Attached Document Type – GL42 Section B.7.1.1

Information: VICH has defined the types of “Supplemental Document(s)” that it will accept. The list of acceptable document type is in the *Attached Document Type* vocabulary list.

ICSR Location: This element is located within the `<code>` element of the `<document>` node. The *Attached Document Type* vocabulary list should be used for this data element.

XML Details: The XPath to get the “Supplemental Document Type” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/reference/document/code/@code
```

3.7.3 Supplemental Document Data

Information: The “Supplemental Document” itself should be embedded inside the <text> element of the <document> node. Binary “Supplemental Documents”, for example a graphic GIF file, should be Base-64 encoded.

ICSR Location: This element is located within the <text> element of the <document> node; “B64” should be used as the attribute value.

XML Details: The XPath to get to the “Supplemental Document Data” in the AER message is:

```
/PORR_IN049006UV/controlActProcess/subject/investigationEvent/reference/document/text
```

A sample XML snippet for a “Supplemental Document”, including an “Attached Document Filename”, “Attached Document Type”, and a “Supplemental Document Data” is shown in the following XML snippet.

```
<investigationEvent classCode="INVSTG" moodCode="EVN">
    .....
    <reference typeCode="REFR">
        <document classCode="DOC" moodCode="EVN">
            <id extension="1"/>
            <code codeSystem="2.16.840.1.113883.13.211" code="C68623"
                displayName="Necropsy (Autopsy)"/>
            <title>necpicture.jpg</title>
            <text mediaType="text/plain" representation="B64">
R0IGODlhZABqALMAAFrMYr/BvIKOVJKOg2xZUKmenMfDw8tgWJpVUbaxsPb19v///+bm5tfX1wAAAAAAAC
wAAAAAZABqAAAE/3DJSau9mCrGWhkFlOpF2TSMkq1s674rk4x0TRB1ETQq7P/AS6gmOhPRxuu0Ag6nyzGC
EmtVmFqHa7MByK1rCV8OWagwUjTsw2FhG9s5ylQCRxtIF+gNjTvmfDHOEGQ12
                ..... more Base-64 data .....
            </text>
        </document>
    </reference>

    <reference typeCode="REFR">
        <document classCode="DOC" moodCode="EVN">
            <id extension="2"/>
            <code codeSystem="2.16.840.1.113883.13.211" code="C36292"
                displayName="Laboratory Report"/>
            <title>labreport.pdf</title>
            <text mediaType="text/plain" representation="B64">
JVBERi0xLjQNJeLjz9MNCjYgMCBvYmo8PC9IWzQ3NiAxMzMNdL0xpbnVhcmI6ZWQgMS9FIDE3OTAvTCA1N
jg5L04gMS9PIDkvVCA1NTIzPj4NZW5kb2JqDSAgICAgICAgICAgICAgICAgICAgICAgICAgICAgICAgDQp4cmVmDQo2I
DkNCjAwMDAwMDAwMTYgMDAwMDAzbgb0KMDAwMDAwMDYwOSAwMDA
                ..... more Base-64 data .....
            </text>
        </document>
    </reference>
    .....
```

</investigationEvent>

4 AER Wrapper Information

This group of data elements contains information that is captured in one of the ISO 27953-1 schema wrappers.

4.1 Batch Wrapper (Section B.8.1 – B.8.1.6)

This section contains data elements that will be captured within the batch wrapper of the report.

4.1.1 Batch Number/Identifier (B.8.1.1.1 – B.8.1.1.2)

Information: The “Batch Number/Identifier” information identifies the collection of reports in this batch as a complete submission message. The concatenation of Batch Number/Identifier Root and Extension uniquely identifies each batch of reports. It is the sender’s responsibility to define and assign this identifier, as each batch submission should have a unique identifier. A “Batch Number/Identifier” should be supplied even if only one AER is within the batch.

ICSR Location: This information is located in the Batch Wrapper. It is captured in the `<id>` element.

XML Details: The “Batch Identifier” of this batch transmission of AER reports is captured in the extension attribute of `<id>` element. The `<id>` root attribute (Batch Number/Identifier - Root) should be populated with the submitting organization’s unique “sender identifier”. The `<id>` extension attribute (Batch Number/Identifier - Extension) is a unique tracking number within the sender system assigned to a specific batch file transmitted by the sender. The form and format of this element is up to the creator of the batch.

The XPath to get “Batch ID” in the AER message is:

```
/MCCI_IN200100UV01/id/@extension
```

A sample XML snippet for “Batch ID” in the AER message is:

```
<MCCI_IN200100UV01>
  <id root="SubmittingOrganizationID" extension="ABCDrag-20100328-batch-12345"/>
</MCCI_IN200100UV01>
```

4.1.2 Batch Sender (B.8.1.2.1 – B.8.1.2.8)

Information: This information identifies the sender who is responsible for any technical communications between receiver and sender regarding the batch transmission of the AER message.

ICSR Location: This information is located in the Batch Wrapper. It is captured in the batch sender class.

XML Details: The sender could provide an ID and contact information inside `<sender>` node.

The XPath to get “Batch Sender” in the AER report is:

/MCCI_IN200100UV01/sender

A sample XML snippet for “Batch ID” in the AER message is:

```
<MCCI_IN200100UV01>
<sender>
  <device determinerCode="INSTANCE" classCode="DEV">
    <id/>
    <asAgent classCode="AGNT">
      <representedOrganization determinerCode="INSTANCE" classCode="ORG">
        <id root="batch-sender-identifier-id" extension="sender organization name"/>
        <notificationParty classCode="CON">
          <id/>
          <telecom value="TEL:+1-123-4567890"/>
          <telecom value="FAX:+1-123-456789"/>
          <telecom value="MAILTO:someone@example.com"/>
        <contactPerson>
          <id/>
          <name>
            <prefix>Ms</prefix>
            <given>Jane</given>
            <family>Doe</family>
          </name>
        </contactPerson>
      </notificationParty>
    </representedOrganization>
  </asAgent>
  </device>
</sender>
</MCCI_IN200100UV01>
```

4.1.3 Batch Receiver (B.8.1.3.1 – B.8.1.3.2)

Information: The “Batch Receiver” information identifies the receiver of the batch message.

ICSR Location: This information is located in the Batch Wrapper. It is captured in the <receiver> class.

XML Details: The “Batch Receiver” of this batch transmission of AER reports is captured in the <receiver> element. Currently, only an id is needed. The id value should be able to uniquely identify the receiver.

The XPath to get “Batch Receiver” ID in the AER message is:

/MCCI_IN200100UV01/receiver/device/asAgent/representedOrganization/id

A sample XML snippet for “Batch Receiver” in the AER message is:

```
< MCCI_IN200100UV01>
<receiver>
  <device determinerCode="INSTANCE" classCode="DEV">
    <id/>
    <asAgent classCode="AGNT">
      <representedOrganization determinerCode="INSTANCE" classCode="ORG">
```

```
<id root="batch-receiver-identifier-id" extension="receiver organization name"/>
  </representedOrganization>
  </asAgent>
  </device>
</receiver>
</MCCI_IN200100UV01>
```

4.1.4 Date of Batch Creation (B.8.1.4)

Information: The “Date of Batch Creation” indicates the date the batch report is created.

ICSR Location: This information is located in the Batch Wrapper. It is captured in the <creationTime> element.

XML Details: The “Message Date” is captured using a simple TS data format. Please refer to the Validation Procedure Document for more details regarding the date/time format and time zone.

The XPath to get “Message Date” in the ISCR message is:

```
/MCCI_IN200100UV01/creationTime/@value
```

A sample XML snippet for “Message Date” in an AER message is:

```
< MCCI_IN200100UV01 .....>
  .....
  <creationTime value="20071016102030+0300"/>
  .....
</MCCI_IN200100UV01>
```

4.1.5 VICH AER Version Number (B.8.1.5)

Information: The “VICH AER Version Number” indicates the AER Message Version and Release Number on which this batch is based.

ICSR Location: This information is located in the Batch Wrapper. It is captured in the <versionCode> element.

XML Details: Submitters should use the VICH AER version code. The initial version code is “VICHAER1.0.0”.

The XPath to get “Version Information” in the AER message is:

```
/MCCI_IN200100UV01/versionCode/@code
```

A sample XML snippet for “Version Information” in an AER message is:

```
<MCCI_IN200100UV01>
  <versionCode code="VICHAER1.0.0"/>
</MCCI_IN200100UV01>
```

4.2 Transmission Wrapper (Section B.8.2 – B.8.2.8)

This section contains data elements that will be captured with in the transmission wrapper of the report

4.2.1 Message Number (B.8.2.1.1 – B.8.2.1.2)

Information: The “Message Number” information identifies the message. The concatenation of Message Number Root and Extension uniquely identifies each message. The message creator should ensure that this uniquely assigned identifier will never be used in another message. It is the sender’s responsibility to define and assign this number, as each message should have a unique number.

ICSR Location: This information is located in the HL7 Transmission Wrapper. It is captured in the <id> of each message inside the batch being transmitted.

XML Details: The reporter should provide an ID inside <id> node. The <id> root attribute (Message Number - Root) is the submitting organization’s unique “sender identifier”. The <id> extension attribute (Message Number - Extension) contains the uniquely assigned message identifier for the specified message (this is not the Unique Adverse Event Report Identification Number). This field format is up to the creator of the message. The message creator should ensure that this uniquely assigned identifier will never be used in another message.

The XPath to get the “Message Number” information in the AER message is:

```
/MCCI_IN200100UV01/PORR_IN049006UV/id/@extension
```

A sample XML snippet for “Message Number” in an AER message is:

```
<MCCI_IN200100UV01>
  <PORR_IN049006UV xsi:type="PORR_IN049006UV.MCCI_MT000100UV01.Message">
    <id root="senders-safety-report-identifier-oid" extension="identifier"/>
  </PORR_IN049006UV>
</MCCI_IN200100UV01>
```

4.2.2 Message Sender (B.8.2.2.1 - B.8.2.2.8)

Information: These data elements contain the organization name of the message sender who is defined as the Pharmacovigilance Contact Person in charge of the AER message.

ICSR Location: This information is located in the HL7 Transmission Wrapper. It is captured in the transmission wrapper sender class.

XML Details: The reporter should provide the person’s title, first name, last name, telephone number, optional fax number, and e-mail address.

The XPath to get the “Pharmacovigilance Contact Person” in the AER message is:

```
/MCCI_IN200100UV01/PORR_IN049006UV/sender
```

A sample XML snippet for Pharmacovigilance Contact Person is:

```

<MCII_IN200100UV01>
<PORR_IN049006UV xsi:type="PORR_IN049006UV.MCII_MT000100UV01.Message">
  <sender typeCode="SND">
    <device determinerCode="INSTANCE" classCode="DEV">
      <id/>
      <asAgent classCode="AGNT">
        <representedOrganization determinerCode="INSTANCE" classCode="ORG">
          <id root="message-sender-identifier-id" extension="sender organization name"/>
          <notificationParty classCode="CON">
            <id/>
            <contactPerson>
              <id/>
              <name>
                <prefix>Dr</prefix>
                <given>Tom</given>
                <family>Brown</family>
              </name>
              <telecom value="TEL:+1-123-4567890"/>
              <telecom value="FAX:+1-123-4567891"/>
              <telecom value="MAILTO:someone@example.com"/>
            </contactPerson>
            </notificationParty>
          </representedOrganization>
          </asAgent>
        </device>
      </sender>
    </PORR_IN049006UV>
  </MCII_IN200100UV01>

```

4.2.3 Message Receiver (B.8.2.3 – B.8.2.3.1)

Information: The “Message Receiver Root” is a field that contains the receiver of the AER message, e.g., the MAH unique ID or RA unique ID.

ICSR Location: This information is located in the HL7 Transmission Wrapper. It is captured in the receiver class.

XML Details: The reporter should provide an ID inside <receiver> node. The “Message Receiver Root” is a field that contains the “message-receiver-identifier-id” of the message receiver.

The XPath to get the “Message Sender Identifier Telecom” information in the AER message is:

```
/MCII_IN200100UV01/PORR_IN049006UV/receiver
```

A sample XML snippet for “Message Sender Identifier” in an AER message is:

```

<MCII_IN200100UV01>
<PORR_IN049006UV xsi:type="PORR_IN049006UV.MCII_MT000100UV01.Message">
  <receiver typeCode="RCV">
    <device determinerCode="INSTANCE" classCode="DEV">
      <id/>
      <asAgent classCode="AGNT">
        <representedOrganization determinerCode="INSTANCE" classCode="ORG">

```

```

<id root="message-receiver-identifier-id"/>
</representedOrganization>
</asAgent>
</device>
</receiver>
</PORR_IN049006UV>
</MCCI_IN200100UV01>

```

4.2.4 Date of Message Creation (B.8.2.4)

Information: This is the date on which the message inside the batch was created. This date may be the same as the date of batch creation.

ICSR Location: This information is located in the HL7 Transmission Wrapper. It is captured in the <creationTime> in each message in the batch.

XML Details: The reporter should provide a date using a simple TS data format inside <creationTime> node. Please refer to the Validation Procedure Document for more details regarding the date/time format and time zone.

The XPath to get the “Date of Message Creation” information in the AER message is:

```
/MCCI_IN200100UV01/PORR_IN049006UV/creationTime/@value
```

A sample XML snippet for “Date of Message Creation” in an AER message is:

```

<MCCI_IN200100UV01>
<PORR_IN049006UV xsi:type="PORR_IN049006UV.MCCI_MT000100UV01.Message">
  <creationTime value="20120120102030+0300"/>
</PORR_IN049006UV>
</MCCI_IN200100UV01>

```

4.2.5 Report Identifier (B.8.2.5)

Information: This field is used for the sender to identify additional information that may be used to process the information into their IT systems. Refer to Regional Annexes for additional information.

ICSR Location: This information is located in the AER message Transmission Wrapper. It is captured in an <attentionLine> node.

XML Details: Note that since multiple <attentionLine> nodes are used for different information, users shall use an identification code in <keyWordText> element to identify this date element.

The XPath to get “Report Identifier” in the AER message is:

```
/MCCI_IN200100UV01/PORR_IN049006UV/attentionLine[keyWordText="Report Identifier"]/value
```

A sample XML snippet for “Report Identifier” in an AER message is:

```

<MCCI_IN200100UV01>
<PORR_IN049006UV xsi:type="PORR_IN049006UV.MCCI_MT000100UV01.Message">

```

```

<attentionLine>
  <keyWordText>Report Identifier</keyWordText>
  <value xsi:type="ST">NI23123</value>
</attentionLine>
</PORR_IN049006UV>
</MCCI_IN200100UV01>

```

For regions where “Report Identifier” is not required, use the following snippet:

```

<MCCI_IN200100UV01>
<PORR_IN049006UV xsi:type="PORR_IN049006UV.MCCI_MT000100UV01.Message">
  <attentionLine>
    <keyWordText>Report Identifier</keyWordText>
    <value xsi:type="ST" nullFlavor="NI"/>
  </attentionLine>
</PORR_IN049006UV>
</MCCI_IN200100UV01>

```

4.2.6 Domestic vs. Foreign Report Category (B.8.2.6)

Information: The “Domestic vs Foreign Report Category” indicates if the specified AER is a domestic or foreign report relative to the receiver. Refer to Regional Annexes for additional information.

ICSR Location: This information is located in the AER message Transmission Wrapper. It is captured in an <attentionLine> node.

XML Details: Note that since multiple <attentionLine> nodes are used for different information, a code must be used in <keyWordText> node to identify this data element. Users should use the values from the *Domestic vs. Foreign Report Categories* vocabulary list.

The XPath to get “Domestic vs Foreign Report Category” in the AER message is:

```
/MCCI_IN200100UV01/PORR_IN049006UV/attentionLine[keyWordText="Domestic vs Foreign Report Category"]/value
```

A sample XML snippet for “Domestic vs Foreign Report Category” in an AER message is:

```

<MCCI_IN200100UV01>
<PORR_IN049006UV xsi:type="PORR_IN049006UV.MCCI_MT000100UV01.Message">
  <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>
</PORR_IN049006UV>
</MCCI_IN200100UV01>

```

For regions where “Domestic vs Foreign Report Category” is not required, use the following snippet:

```

<MCCI_IN200100UV01>
<PORR_IN049006UV xsi:type="PORR_IN049006UV.MCCI_MT000100UV01.Message">
  <attentionLine>

```

```
<keyWordText>Domestic vs Foreign Report Category</keyWordText>
<value xsi:type="SC" nullFlavor="NI"/>
</attentionLine>
</PORR_IN049006UV>
</MCCL_IN200100UV01>
```

4.2.7 Profile Identifier (B.8.2.7)

Information: The “Profile Identifier (Profile ID) Code” contains details about the type of report contained in this message payload. When creating the message, the value for this field should be from the Profile Identifier Vocabulary list. Refer to Regional Annexes for additional information.

ICSR Location: This information is located in the AER message Transmission Wrapper. It is captured in the <profileId> node. The actual value is set in its extension attribute.

XML Details: The XPath and snippet for the data element are below.

The XPath to get the “Profile ID” element within the AER message is:

```
/MCCL_IN200100UV01/PORR_IN049006UV/profileId/@extension
```

A sample XML snippet for “Profile ID” in an AER message is:

```
< MCCL_IN200100UV01>
<PORR_IN049006UV xsi:type="PORR_IN049006UV.MCCL_MT000100UV01.Message">
<profileId root="2.16.840.1.113883.13.207"
           extension="AES.FDA.VICHGL42.M.V1.ACOUNT.AE"/>
</PORR_IN049006UV>
</MCCL_IN200100UV01>
```

For regions where “Profile ID” is not required, use the following snippet:

```
< MCCL_IN200100UV01>
<PORR_IN049006UV xsi:type="PORR_IN049006UV.MCCL_MT000100UV01.Message">
<profileId nullFlavor="NI"/>
</PORR_IN049006UV>
</MCCL_IN200100UV01>
```

5 List of Abbreviations

Abbreviation	Description
AE	Adverse Event
AER	Adverse Event Report
ATC Vet Code	Anatomical Therapeutic Chemical classification system for veterinary medicinal products
CVM	Center for Veterinary Medicine
EMA	European Medicines Agency
FDA	US Food and Drug Administration
HL7	Health Level 7 Organization
ICSR	HL7 Individual Case Safety Report format
ISO	International Standards Organization
MAH	Marketing Authorization Holder
OID	Object Identifier
Payload	The XML message organizational structure that contains the AER
RA	Regulatory Authority
VICH	International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products
VMP	Veterinary Medicinal Product
XML	Extensible Markup Language
XPath	An XML method to locate specific elements within an XML document

6 RA to MAH, RA to RA, and MAH to MAH Snippets

Example for a case sent from a RA to a MAH

In this case the receiver section in the XML is Section VICH A.1 RA. The sender (author) section in the XML is Section VICH A.2 MAH

```

<subjectOf1 typeCode="SUBJ">
  <controlActEvent classCode="CACT" moodCode="EVN">
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code codeSystem="2.16.840.1.113883.13.193" code="T95009" displayName="RA"/>
        <addr use="WP">
          <streetAddressLine> 7 Westferry Circus Canary Wharf </streetAddressLine>
          <city>London</city>
          <state/>
          <postalCode>E14 4HB </postalCode>
          <country>GBR</country>
        </addr>
        <representedOrganization determinerCode="INSTANCE" classCode="ORG">
          <name>European Medicines Agency </name>
          <contactParty classCode="CON">
            <telecom value="TEL:+44-20-7418-8400"/>
            <telecom value="FAX:+44-20-7418-8599"/>
            <telecom value="MAILTO:tom.brown@ema.europa.eu"/>
          <contactPerson determinerCode="INSTANCE" classCode="PSN">
            <name>
              <prefix>Dr</prefix>
              <given>Tom</given>
              <family>Brown</family>
            </name>
          </contactPerson>
          <contactParty>
            <representedOrganization>
              <name>
                <prefix>Dr</prefix>
                <given>Tom</given>
                <family>Brown</family>
              </name>
            </contactPerson>
            <contactParty>
              <representedOrganization>
                <name>
                  <prefix>Dr</prefix>
                  <given>Tom</given>
                  <family>Brown</family>
                </name>
              </contactPerson>
            </contactParty>
          </representedOrganization>
        </assignedEntity>
      </author>
      <primaryInformationRecipient typeCode="PRCP">
        <assignedEntity classCode="ASSIGNED">
          <code codeSystem="2.16.840.1.113883.13.193" code="T95001" displayName="MAH"/>
          <addr use="WP">
            <streetAddressLine> Building MON 6700 </streetAddressLine>
            <city>Leverkusen</city>
            <state>NRW</state>
            <postalCode>51368</postalCode>
            <country>DEU</country>
          </addr>
          <representedOrganization determinerCode="INSTANCE" classCode="ORG">
            <name>Company Animal Health GmbH</name>
          </representedOrganization>
        </assignedEntity>
      </primaryInformationRecipient>
    </controlActEvent>
  </subjectOf1>

```

Example for a case sent from a RA to a RA

In this case the receiver section in the XML is Section VICH A.1 RA. The sender (author) section in the XML is also RA, Section VICH A.1 RA.

```

<subjectOf1 typeCode="SUBJ">
  <controlActEvent classCode="CACT" moodCode="EVN">
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code codeSystem="2.16.840.1.113883.13.193" code="T95009" displayName="RA"/>
        <addr use="WP">
          <streetAddressLine> 7 Westferry Circus Canary Wharf </streetAddressLine>
          <city>London</city>
          <state/>
          <postalCode>E14 4HB </postalCode>
          <country>GBR</country>
        </addr>
        <representedOrganization determinerCode="INSTANCE" classCode="ORG">
          <name>European Medicines Agency </name>
          <contactParty classCode="CON">
            <telecom value="TEL:+44-20-7418-8400"/>
            <telecom value="FAX:+44-20-7418-8599"/>
            <telecom value="MAILTO:tom.brown@ema.europa.eu"/>
            <contactPerson determinerCode="INSTANCE" classCode="PSN">
              <name>
                <prefix>Dr</prefix>
                <given>Tom</given>
                <family>Brown</family>
              </name>
              </contactPerson>
            </contactParty>
          </representedOrganization>
        </assignedEntity>
      </author>
      <primaryInformationRecipient typeCode="PRCP">
        <assignedEntity classCode="ASSIGNED">
          <code codeSystem="2.16.840.1.113883.13.193" code="T95009" displayName="RA"/>
          <addr use="WP">
            <streetAddressLine>Paul-Ehrlich-Strasse </streetAddressLine>
            <city>Langen</city>
            <state>Hessen</state>
            <postalCode>63225</postalCode>
            <country>DEU</country>
          </addr>
          <representedOrganization determinerCode="INSTANCE" classCode="ORG">
            <name>Paul-Ehrlich-Institut</name>
          </representedOrganization>
        </assignedEntity>
      </primaryInformationRecipient>
    </controlActEvent>
  </subjectOf1>

```

Example for a case sent from a MAH to a MAH

In this case the receiver section in the XML is Section VICH A.1 MAH. In this case the sender (author) section in the XML is also RA Section VICH A.1 MAH

```

<subjectOf1 typeCode="SUBJ">
  <controlActEvent classCode="CACT" moodCode="EVN">
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code codeSystem="2.16.840.1.113883.13.193" code="T95001" displayName="MAH"/>
        <addr use="WP">
          <streetAddressLine> B Street 123 </streetAddressLine>
          <city>London</city>
          <state/>
          <postalCode>E14 4HB </postalCode>
          <country>GBR</country>
        </addr>
        <representedOrganization determinerCode="INSTANCE" classCode="ORG">
          <name>Company Pet Health GmbH </name>
          <contactParty classCode="CON">
            <telecom value="TEL:+44-20-1234-5678"/>
            <telecom value="FAX:+44-20-1234-8765"/>
            <telecom value="MAILTO:john.doe@companypethealth.com"/>
            <contactPerson determinerCode="INSTANCE" classCode="PSN">
              <name>
                <prefix>Dr</prefix>
                <given>John</given>
                <family>Doe</family>
              </name>
              </contactPerson>
            </contactParty>
          </representedOrganization>
        </assignedEntity>
      </author>
      <primaryInformationRecipient typeCode="PRCP">
        <assignedEntity classCode="ASSIGNED">
          <code codeSystem="2.16.840.1.113883.13.193" code="T95001" displayName="MAH"/>
          <addr use="WP">
            <streetAddressLine> Building 1234 </streetAddressLine>
            <city>Leverkusen</city>
            <state>NRW</state>
            <postalCode>51368</postalCode>
            <country>DEU</country>
          </addr>
          <representedOrganization determinerCode="INSTANCE" classCode="ORG">
            <name>Company Animal Health GmbH</name>
          </representedOrganization>
        </assignedEntity>
      </primaryInformationRecipient>
    </controlActEvent>
  </subjectOf1>

```