#214

Pharmacovigilance of Veterinary Medicinal Products Electronic Standards for Transfer of Data

VICH GL35

Guidance for Industry

This version of the guidance replaces the version made available December 2014. The document has been revised to update information and harmonize with the March 2023 revision of VICH GL35 to the extent consistent with FDA regulations.

Submit comments on this guidance at any time. Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All written comments should be identified with the Docket No. FDA-2011-D-0588.

For further information regarding this document, contact the Division of Pharmacovigilance and Surveillance (HFV-240), Office of Surveillance and Compliance, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl, Rockville, MD 20855, Email: CVMAESupport@fda.hhs.gov.

Additional copies of this guidance document may be requested from the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville, MD 20855, and may be viewed on the Internet at https://www.fda.gov/animal-veterinary, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or http://www.regulations.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine
January 2024

International Cooperation on Harmonisation of Technical Requirements
for Registration of Veterinary Medicinal Products

VICH GL35 (R1) (PHARMACOVIGILANCE: ESTD)
March 2023
Revision 1 at Step 9
For Implementation at Step 7

PHARMACOVIGILANCE OF VETERINARY MEDICINAL PRODUCTS: ELECTRONIC STANDARDS FOR TRANSFER OF DATA (REVISION 1)

Revision at Step 9

Adopted at Step 7 of the VICH Process by the VICH Steering Committee
in March 2023
for implementation by March 2024

This Guideline has been developed and revised by the appropriate VICH Expert Working Group in accordance with the VICH Process. At Step 7 of the Process the final draft is recommended for adoption to the regulatory bodies of the European Union, Japan and USA.

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Contains Nonbinding Recommendations

Pharmacovigilance of Veterinary Medicinal Products: Electronic Standards for Transfer of Data[1]

Guidance for Industry

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

The objective of this guidance is to provide recommended standards to construct a single Adverse Event Report (AER) electronic message to transmit GL42 contents to all member regions and Product Problem Reports (PPR) to FDA for veterinary medicinal products.

The need to transfer and disseminate information quickly, accurately and easily between Regulatory Authorities (RA) and Marketing Authorization Holders (MAH) on a worldwide scope is especially pertinent to the notification and assimilation of information for pharmacovigilance. Whereas the recommended definition of the pharmacovigilance information has been set forth within GL42, this GL35 guidance defines the recommended electronic standards for transfer of data. GL35 and associated documents described below, "Electronic Submission of Animal Adverse Events Electronic Transmission Implementation Specifications VICH Validation Procedure Document (USFDACVM Regional Annex)" and "Electronic Submission of Animal Adverse Events Electronic Transmission Implementation Specifications VICH Step By Step Document (USFDACVM Regional Annex)," should be used to develop the electronic system.[2]

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Scope of Electronic Standards for Information Exchange

The scope of recommended electronic standards for exchange of veterinary pharmacovigilance data between VICH RAs and MAHs includes but is not limited to:

- Recommendation to ensure secure transmission

[1] This guidance, to the extent consistent with FDA regulations, harmonizes with the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) guideline document, "Pharmacovigilance of Veterinary Medicinal Products Electronic Standards for Transfer of Data (Revision 1)" (VICH GL35(R1)), but has some FDA-specific application.

[2] Contact CVMAESupport@fda.hhs.gov for these documents.

- Definition of the electronic message structure
- Relationships (cardinality) between the data elements
- Recommended additional vocabularies for electronic transmission and implementation of GL42
- Business and schema validation rules and field descriptors specification for the data defined in GL35 and GL42.

III. Recommendations to Ensure Secure Transmission

Regional exchange of pharmacovigilance information preferably occurs through a Gateway that follows the ICH M2 Gateway recommendation for the Electronic Standards for the Transfer of Regulatory Information (ESTRI-Gateway) in order to provide for an automated and secure way of transmission including all aspects of confidentiality, authentication, integrity and non-repudiation of all transactions in pharmacovigilance. MAHs should adhere to the RAs gateway specifications.

IV. Definition of the Electronic Message Structure

The message format is XML.

The technical document entitled "Electronic Submission of Animal Adverse Events - Electronic Transmission Implementation Specifications VICH Step By Step Document (USFDACVM Regional Annex)" (herein known as the FDA Step By Step Document) was developed to be in line with ISO 27953-1. The adverse event processing system of each MAH and RA should be compliant with GL35 and the FDA Step By Step Document including the Regional Annexes.

The purpose of the FDA Step By Step Document is to provide directions to assist users, reporters, and technical staff in completing a well-formed electronic message for AER and PPR for veterinary medicinal products. The GL42 document has recommended a standard set of definitions to describe the data elements that should be submitted for compliant AERs and PPRs. The FDA Step By Step Document provides a translation and mapping of GL42 compliant adverse event and product problem elements into an electronic message. The GL42 data elements comprise the "payload" of the message.

These submissions are intended to be sent electronically to the receivers through their Electronic Submissions Gateway (ESG), and upon receipt they will be processed by the receiver unique systems. In addition to the "payload" information, the electronic message also contains "wrapper" information (also known as envelope information).

The structure of the wrapper is specified in GL35 and the FDA Step By Step Document. It contains the data elements recommended in GL35 and the XML structure as set forth in the FDA Step By Step Document.

V. Relationships (Cardinality) Between the Data Elements

The recommended relationships (cardinality) between the data elements are set forth in GL35. The data model diagrams are found in Annex A to GL35.

VI. Electronic Submission of Animal Adverse Events and Product Problems Electronic Transmission Implementation Specifications FDA Validation Procedure Document

The technical document entitled "Electronic Submission of Animal Adverse Events - Electronic Transmission Implementation Specifications VICH Validation Procedure Document (USFDACVM Regional Annex)" (herein known as the FDA Validation Procedure Document) describes the schema and business validation rules that will be performed on the AER and PPR message. The purpose of the FDA Validation Procedure Document is to provide directions to assist users, reporters, and technical staff in the successful validation of the electronic message for AER and PPR for veterinary medicinal products.

VII. Electronic Submission of Animal Adverse Events and Product Problems Electronic Transmission Implementation Specifications FDA Step By Step Document

The FDA Step By Step Document describes the mapping of the data elements listed in GL42 and GL35 into the AER and PPR XML message that is ISO 27953-1 schema compliant.

VIII. Wrapper Data Elements

The following are the data elements to be included in the batch and transmission wrappers of the message.

Section B.8.1 Batch Wrapper

The batch wrapper is established in line with ISO 27953-1 specification.

Section B.8.1.1 Batch Number/Identifier

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 or PPR is within the batch.

Section B.8.1.1.1 Batch Number/Identifier – Root

This is the submitting organization's unique "sender identifier." This data element identifies the sender of the AER or PPR message, e.g., the MAH unique ID or RA unique ID.

Section B.8.1.1.2 Batch Number/Identifier – Extension

The "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.

Section B.8.1.2 Batch Sender

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

Section B.8.1.2.1 Batch Sender – Root

This is the submitting organization's unique "sender identifier." This data element identifies the sender of the AER or PPR message, e.g., the MAH unique ID or RA unique ID.

Section B.8.1.2.2 Batch Sender – Extension

The "Batch Sender Extension" is the organization name.

Section B.8.1.2.3 Batch Sender – Title

The "Batch Sender Title" is a field that contains the title of the sender who is responsible for any corresponding communications regarding the transmission batch.

Section B.8.1.2.4 Batch Sender – Last name

The "Batch Sender Last name" is a field that contains the last name of the sender who is responsible for any corresponding communications regarding the transmission batch.

Section B.8.1.2.5 Batch Sender – First name

The "Batch Sender First name" is a field that contains the first name of the sender who is responsible for any corresponding communications regarding the transmission batch.

Section B.8.1.2.6 Batch Sender – Telephone

The "Batch Sender Telephone" is a field that contains the telephone number of the sender who is responsible for any corresponding communications regarding the transmission batch.

Section B.8.1.2.7 Batch Sender – Fax

The "Batch Sender Fax" is a field that contains the fax number of the sender who is responsible for any corresponding communications regarding the transmission batch.

Section B.8.1.2.8 Batch Sender – e-mail

The "Batch Sender e-mail" is a field that contains the e-mail address of the sender (or an equally functional group e-mail address) who is responsible for any corresponding communications regarding the transmission batch.

Section B.8.1.3 Batch Receiver

The "Batch Receiver" information identifies the receiver of the batch message.

Section B.8.1.3.1 Batch Receiver – Root

This is the submitting organization's unique "receiver identifier". This data element identifies the receiver of the AER or PPR message, e.g., the MAH unique ID or RA unique ID.

Section B.8.1.3.2 Batch Receiver – Extension

The "Batch Receiver Extension" is a field that contains the organization name.

Section B.8.1.4 Date of Batch Creation

The "Date of Batch Creation" indicates the date the batch report is created.

Section B.8.1.5 VICH AER Version Number

The "VICH AER Version Number" indicates the AER Message Version and Release Number on which this batch is based.

Section B.8.2 Transmission Wrapper

Section B.8.2.1 Message Number

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.

Section B.8.2.1.1 Message Number – Root

The "Message Number Root" is the submitting organization's unique "sender identifier". This data element identifies the sender of the AER or PPR message, e.g., the MAH unique ID or RA unique ID.

Section B.8.2.1.2 Message Number – Extension

The "Message Number – Extension" is a field that contains the uniquely assigned message identifier for the specified message (this is not the Unique Adverse Event Report Identification Number). Each submitted message should have a unique identifier assigned regardless of the Type of Submission. This field format is up to the creator of the message.

Section B.8.2.2 Message Sender)

Section B.8.2.2.1 Message Sender – Root

This is the submitting organization's unique "sender identifier". This data element identifies the sender of the AER or PPR message, e.g., the MAH unique ID or RA unique ID.

Section B.8.2.2.2 Message Sender – Extension

The "Message Sender Extension" is a field that contains the organization name of the message sender who is defined as the Pharmacovigilance Contact Person in charge of the AER or PPR message.

Section B.8.2.2.3 Message Sender – Title

The "Message Sender Title" is a field that contains the title of the message sender who is defined as the Pharmacovigilance Contact Person in charge of the AER or PPR message.

Section B.8.2.2.4 Message Sender – Last name

The "Message Sender Last name" is a field that contains the last name of the message sender who is defined as the Pharmacovigilance Contact Person in charge of the AER or PPR message.

Section B.8.2.2.5 Message Sender – First name

The "Message Sender First name" is a field that contains the first name of the message sender who is defined as the Pharmacovigilance Contact Person in charge of the AER or PPR message.

Section B.8.2.2.6 Message Sender – Telephone

The "Message Sender Telephone" is a field that contains the telephone number of the message sender who is defined as the Pharmacovigilance Contact Person in charge of the AER or PPR message.

Section B.8.2.2.7 Message Sender – Fax

The "Message Sender Fax" is a field that contains the fax number of the message sender who is defined as the Pharmacovigilance Contact Person in charge of the AER or PPR message.

Section B.8.2.2.8 Message Sender – e-mail

The "Message Sender e-mail" is a field that contains the e-mail address of the message sender (or an equally functional group e-mail address) who is defined as the Pharmacovigilance Contact Person in charge of the AER or PPR message.

Section B.8.2.3 Message Receiver

Section B.8.2.3.1 Message Receiver – Root

The "Message Receiver Root" is a field that contains the receiver of the AER or PPR message, e.g., the MAH unique ID or RA unique ID.

Section B.8.2.4 Date of Message Creation

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

Section B.8.2.5 Report Identifier

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

Section B.8.2.6 Domestic vs Foreign Report Category

The "Domestic vs Foreign Report Category" indicates if the specified AER or PPR is a domestic or foreign report relative to the receiver.

Section B.8.2.7 Profile Identifier

The "Profile Identifier (Profile ID) Code" contains details about the type of report contained in this message payload. When creating this message, the value for this field should be from the Profile Identifier Vocabulary list.

Field Descriptions

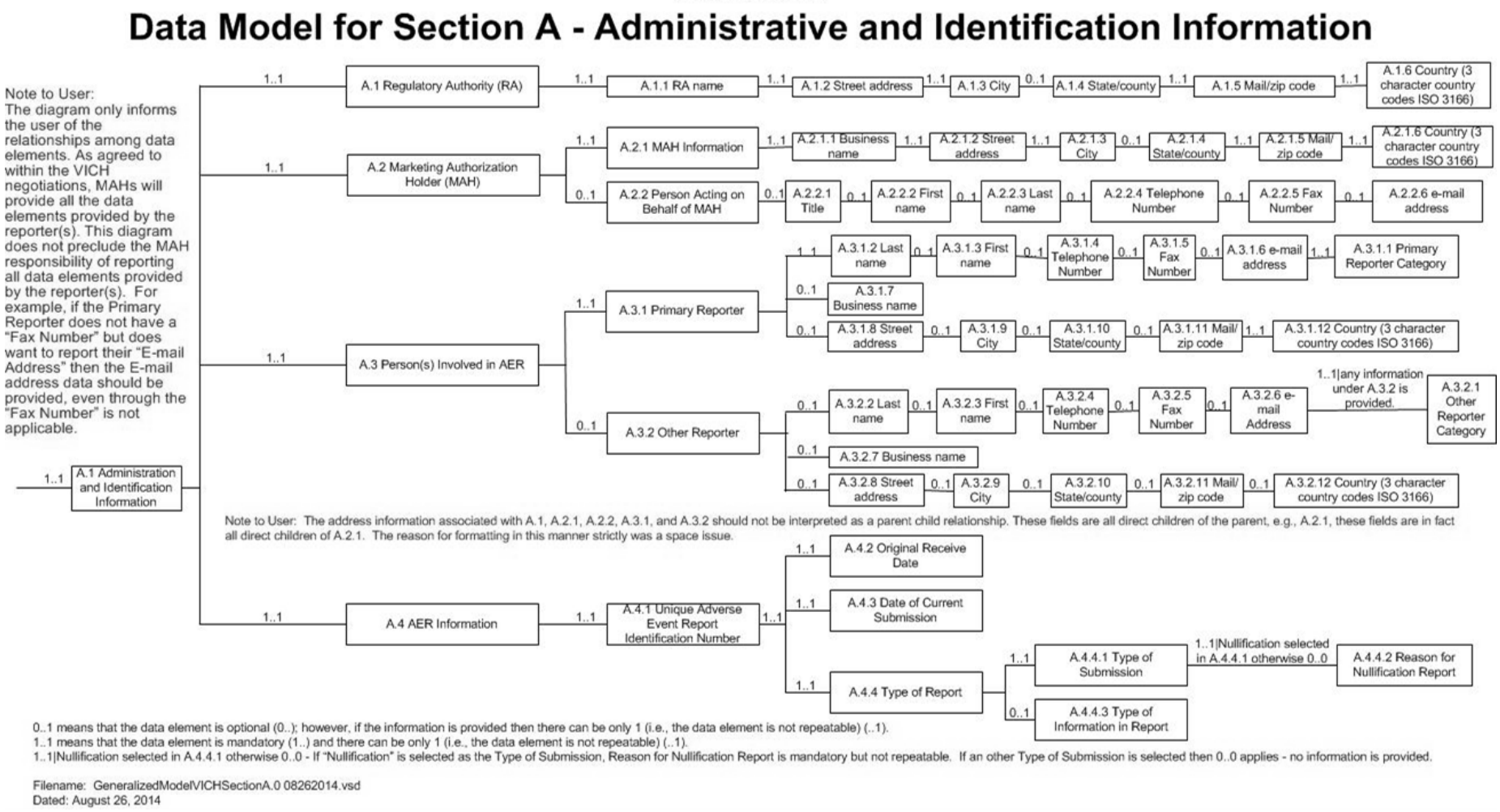
Presented in Annex C are the field lengths and data types for all the wrapper data elements that will serve as the basis for the message.

Corrigendum

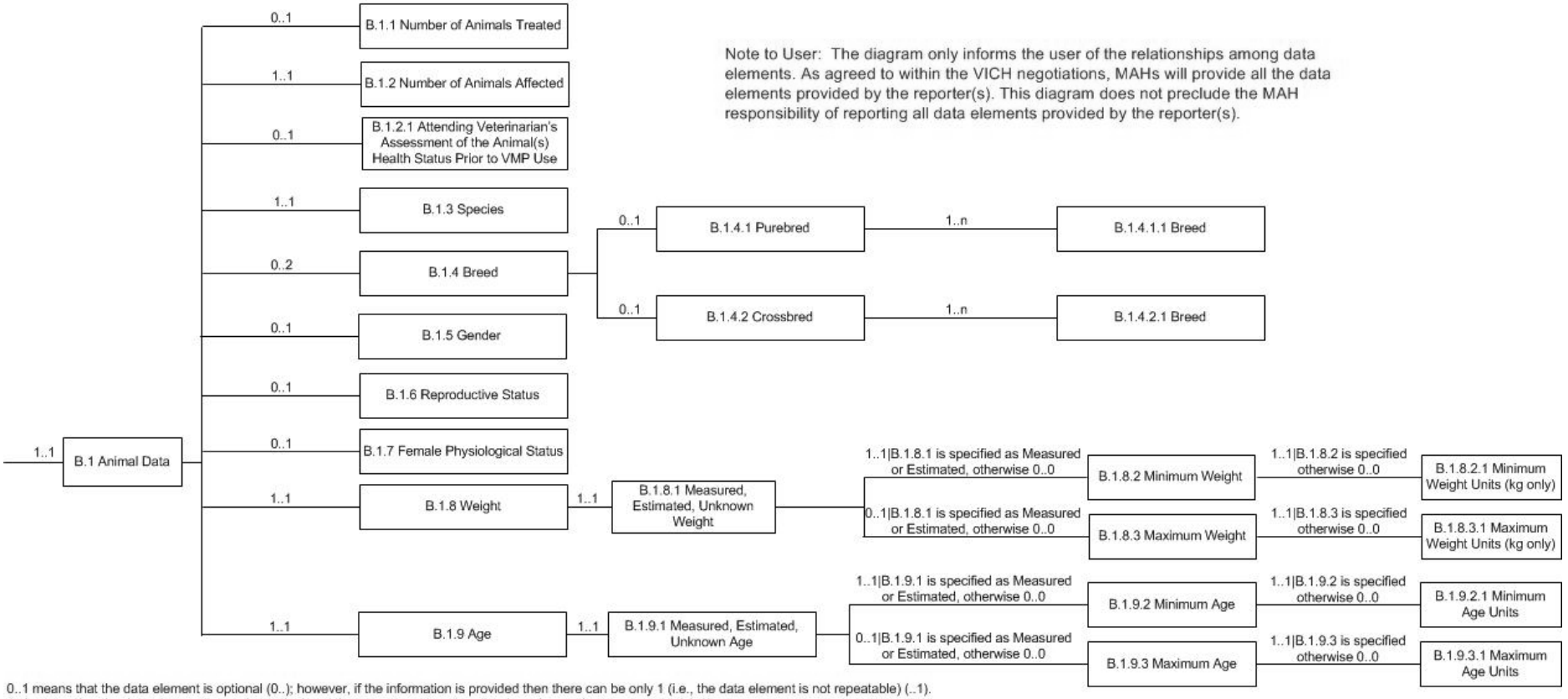
Annex A and B (Sections B.2, B.3, and B.4) have been updated to be consistent with the Electronic Transmission Implementation Specification VICH Step By Step Document (Version 1.0.2 – November 05, 2014). The VICH Step By Step Document links B.3.9 Previous Exposure to the VMP, B.3.10 Previous AE to the VMP, B.4.1 Did AE Abate After Stopping the VMP, and B.4.2 Did the AE Reappear After Stopping the VMP to Section B.2 VMPs Data and Usage, i.e., to the product information.

Please note that the number system was not updated to reflect the number system of B.2. The working group determined that if the number system was updated then substantial updates would be necessary for GL42 and the Step By Step Document, as well as RA specific documents.

Annex A. Data Model



Data Model for Section B.1 - Animal Data

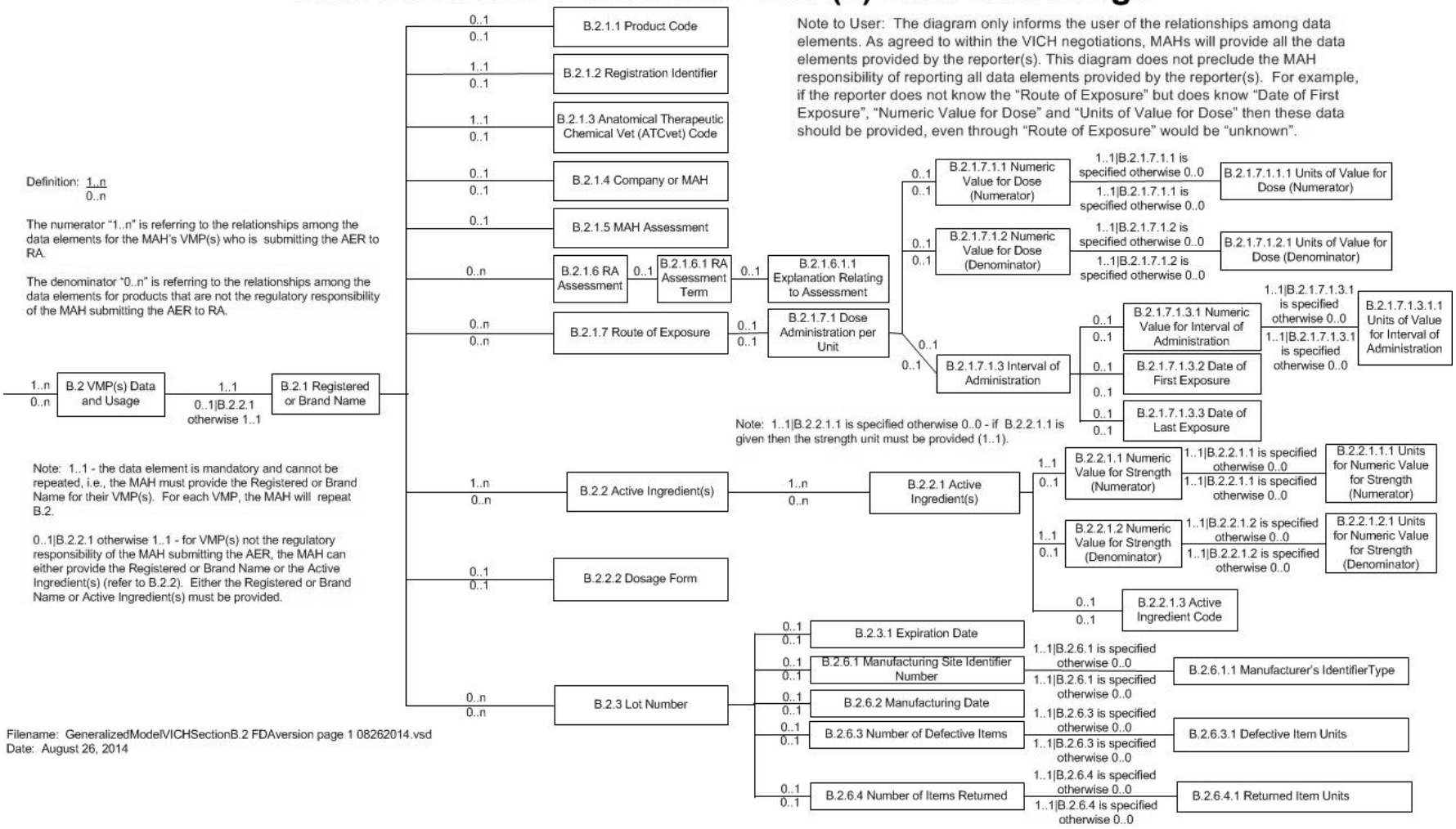


0..1 means that the data element is optional (0..); however, if the information is provided then there can be only 1 (i.e., the data element is not repeatable) (..1).
1..1 means that the data element is mandatory (1..) and there can be only 1 (i.e., the data element is not repeatable) (..1).
1..1|B.1.8.1 is specified as Measured or Estimated, otherwise 0..0 - The data element minimum weight is mandatory but not repeatable if B.1.8.1 is specified as Measured or Estimated or 0..0 if unknown is specified - no information is provided.
1..1|B.1.9.2 is specified otherwise 0..0 - The data element age units is mandatory but not repeatable if B.1.9.2, minimum age is specified or 0..0 if unknown is specified in B.1.9.1 - no information is provided.

NOTE: For B.1.4 Breed – 0..2 means that both purebreds and crossbreds can be expressed in the model. B.1.4.1 and B.1.4.2 are indicators of purebred or crossbred. B.1.4.1.1 and B.1.4.2.1 indicates the actual name of the breeds involved.

Filename: GeneralizedModelVICHSectionB.1 08262014.vsd
Date: August 26, 2014

Data Model for Section B.2 VMP(s) Data and Usage



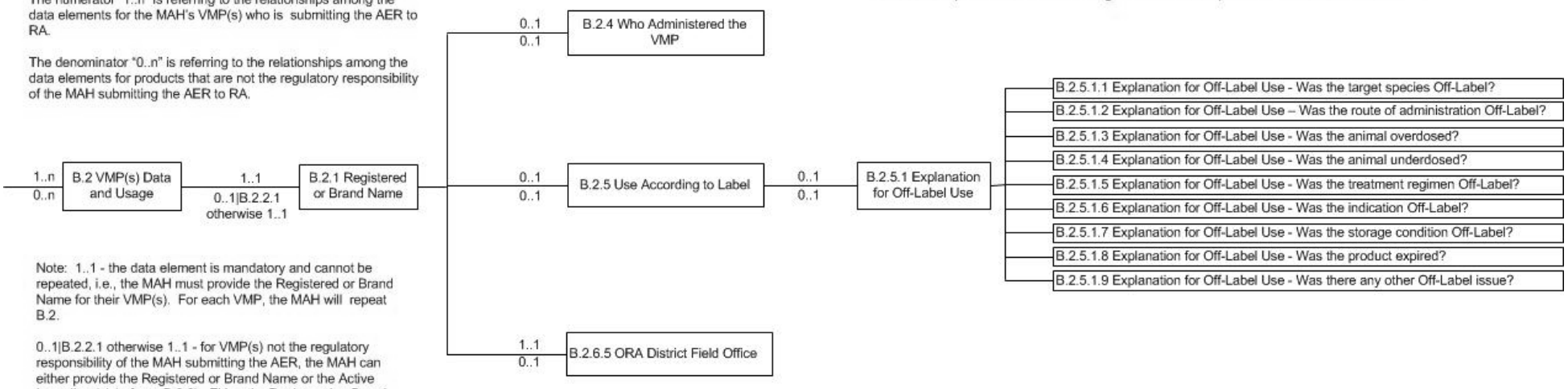
Data Model for Section B.2 VMP(s) Data and Usage (Continued)

Note to User: The diagram only informs the user of the relationships among data elements. As agreed to within the VICH negotiations, MAHs will provide all the data elements provided by the reporter(s). This diagram does not preclude the MAH responsibility of reporting all data elements provided by the reporter(s). For example, if the reporter does not know the "Route of Exposure" but does know "Date of First Exposure", "Numeric Value for Dose" and "Units of Value for Dose" then these data should be provided, even through "Route of Exposure" would be "unknown".

Definition: 1..n / 0..n

The numerator "1..n" is referring to the relationships among the data elements for the MAH's VMP(s) who is submitting the AER to RA.

The denominator "0..n" is referring to the relationships among the data elements for products that are not the regulatory responsibility of the MAH submitting the AER to RA.

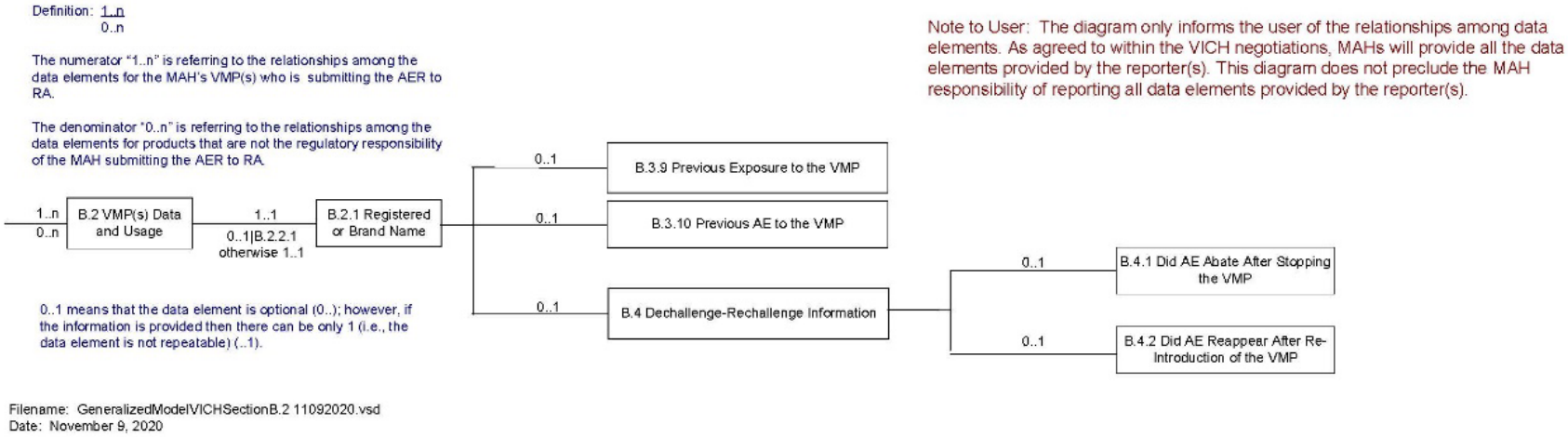


Note: 1..1 - the data element is mandatory and cannot be repeated, i.e., the MAH must provide the Registered or Brand Name for their VMP(s). For each VMP, the MAH will repeat B.2.

0..1|B.2.2.1 otherwise 1..1 - for VMP(s) not the regulatory responsibility of the MAH submitting the AER, the MAH can either provide the Registered or Brand Name or the Active Ingredient(s) (refer to B.2.2). Either the Registered or Brand Name or Active Ingredient(s) must be provided.

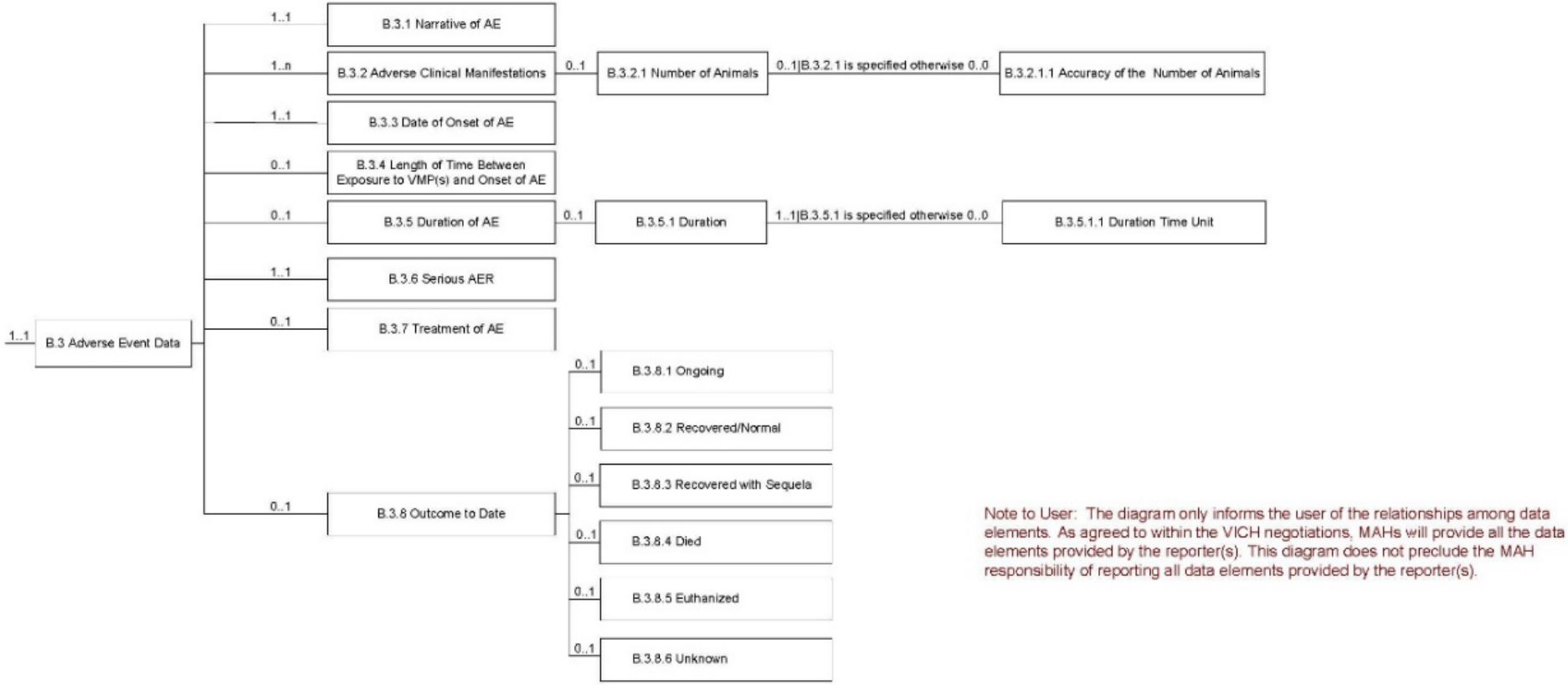
Filename: GeneralizedModelVICHSectionB.2 FDAversion page 2 08262014.vsd
Date: August 26, 2014

Draft Data Model for Section B.2 VMP(s) Data and Usage (Continued)



Filename: GeneralizedModelVICHSectionB.2 11092020.vsd
Date: November 9, 2020

Draft Data Model for Section B.3 - Adverse Event Data

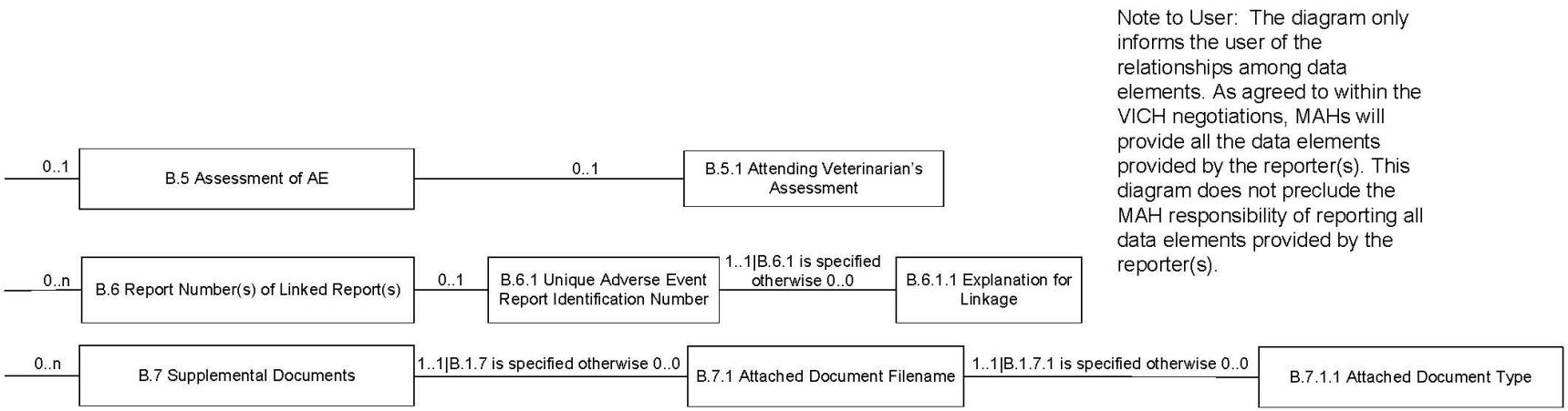


Note to User: The diagram only informs the user of the relationships among data elements. As agreed to within the VICH negotiations, MAHs will provide all the data elements provided by the reporter(s). This diagram does not preclude the MAH responsibility of reporting all data elements provided by the reporter(s).

0..1 means that the data element is optional (0..); however, if the information is provided then there can be only 1 (i.e., the data element is not repeatable) (..1).
1..1 means that the data element is mandatory (1..) and there can be only 1 (i.e., the data element is not repeatable) (..1).
1..1|B.3.5.1 is specified otherwise 0..0 - This data element of time unit is mandatory if B.3.5.1, duration, is specified or 0..0 meaning no information is necessary if duration is not specified.

GeneralizedModelVICHSectionB.3 11092020.vsd
Dated: November 9, 2020

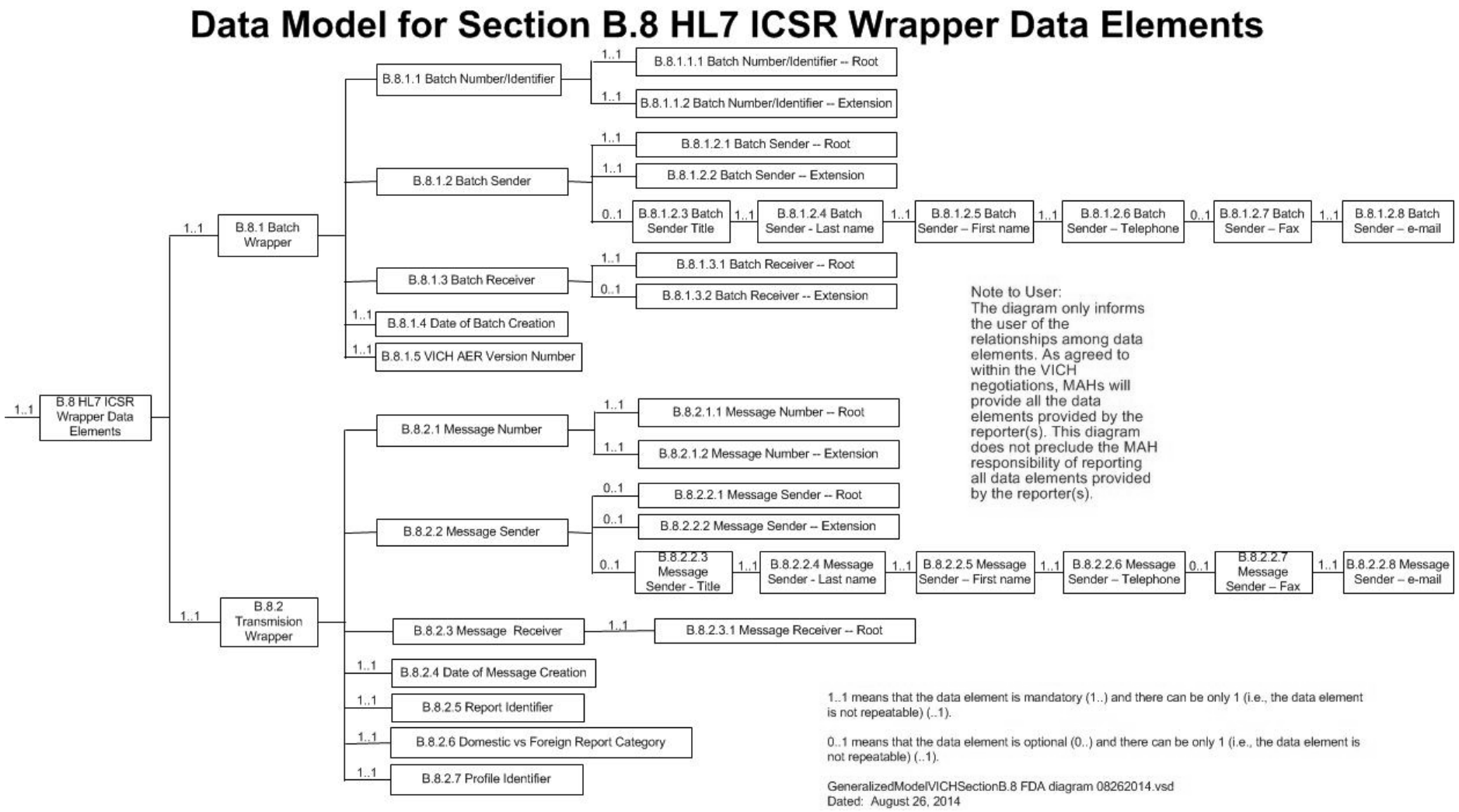
Data Model for Sections B.5 Assessment of AE, B.6 Report Number(s) of Linked Report(s), and B.7 Supplemental Documents



Note to User: The diagram only informs the user of the relationships among data elements. As agreed to within the VICH negotiations, MAHs will provide all the data elements provided by the reporter(s). This diagram does not preclude the MAH responsibility of reporting all data elements provided by the reporter(s).

0..1 means that the data element is optional (0..); however, it the information is provided then there can be only 1 (i.e., the data element is not repeatable) (..1).
0..n means that the data element is optional (0..) and the information data element can be repeated (..n).
1..1 means that the data element is mandatory (1..) and there can be only 1 (i.e., the data element is not repeatable) (..1).

GeneralizedModelVICHSectionB.4 5 6 7 11082020.vsd
Dated: November 11, 2020


Data Model for Section B.8 HL7 ICSR Wrapper Data Elements
1..1 B.8 HL7 ICSR Wrapper Data Elements
1..1 B.8.1 Batch Wrapper
1..1 B.8.2 Transmision Wrapper
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1..1 B.8.1.1.2 Batch Number/Identifier -- Extension
B.8.1.2 Batch Sender
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1..1 B.8.1.2.2 Batch Sender -- Extension
0..1 B.8.1.2.3 Batch Sender Title
1..1 B.8.1.2.4 Batch Sender - Last name
1..1 B.8.1.2.5 Batch Sender – First name
1..1 B.8.1.2.6 Batch Sender – Telephone
0..1 B.8.1.2.7 Batch Sender – Fax
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0..1 B.8.1.3.2 Batch Receiver -- Extension
1..1 B.8.1.4 Date of Batch Creation
1..1 B.8.1.5 VICH AER Version Number
B.8.2.1 Message Number
1..1 B.8.2.1.1 Message Number -- Root
1..1 B.8.2.1.2 Message Number -- Extension
B.8.2.2 Message Sender
0..1 B.8.2.2.1 Message Sender -- Root
0..1 B.8.2.2.2 Message Sender -- Extension
0..1 B.8.2.2.3 Message Sender - Title
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1..1 B.8.2.5 Report Identifier
1..1 B.8.2.6 Domestic vs Foreign Report Category
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Note to User:
The diagram only informs the user of the relationships among data elements. As agreed to within the VICH negotiations, MAHs will provide all the data elements provided by the reporter(s). This diagram does not preclude the MAH responsibility of reporting all data elements provided by the reporter(s).
1..1 means that the data element is mandatory (1..) and there can be only 1 (i.e., the data element is not repeatable) (..1).
0..1 means that the data element is optional (0..) and there can be only 1 (i.e., the data element is not repeatable) (..1).
GeneralizedModelVICHSectionB.8 FDA diagram 08262014.vsd
Dated: August 26, 2014

Annex B. Field Length and Data Type by GL42 Data Elements

GL 42 Section Title	GL42 Section Number	Field Length (maximum length – characters)	Data Type
Administrative and Identification Information – Section A			
Regulatory Authority (RA)	A.1		
RA name	A.1.1	100	Open ended text
Street address	A.1.2	100	Open ended text
City	A.1.3	50	Open ended text
State/county	A.1.4	USA State – 15 County – 80	Code List Open ended text
Mail/zip code	A.1.5	35	Open ended text
Country (3-character country codes ISO 3166)	A.1.6	15	Code List
Marketing Authorization Holder (MAH) (Sender) – Section A.2			
MAH Information	A.2.1		
Business name	A.2.1.1	100	Open ended text
Street address	A.2.1.2	100	Open ended text
City	A.2.1.3	50	Open ended text
State/county	A.2.1.4	USA State – 15 County – 80	Code List Open ended text
Mail/zip code	A.2.1.5	35	Open ended text
Country (3-character country codes ISO 3166)	A.2.1.6	15	Code List
Person Acting on Behalf of MAH	A.2.2		
Title	A.2.2.1	50	Open ended text
First name	A.2.2.2	50	Open ended text
Last name	A.2.2.3	50	Open ended text
Telephone Number	A.2.2.4	20	Open ended text
Fax Number	A.2.2.5	20	Open ended text
e-mail address	A.2.2.6	100	Open ended text
Person(s) Involved in AER (Reporter) – Section A.3			
Primary Reporter	A.3.1		
Primary Reporter Category	A.3.1.1	15 (code) 80 (code description/ term)	Code List

GL 42 Section Title	GL42 Section Number	Field Length (maximum length – characters)	Data Type
Last name	A.3.1.2	50	Open ended text
First name	A.3.1.3	50	Open ended text
Telephone Number	A.3.1.4	20	Open ended text
Fax Number	A.3.1.5	20	Open ended text
e-mail address	A.3.1.6	100	Open ended text
Business name	A.3.1.7	100	Open ended text
Street address	A.3.1.8	100	Open ended text
City	A.3.1.9	50	Open ended text
State/county	A.3.1.10	USA State – 15 County – 80	Code List Open ended text
Mail/zip code	A.3.1.11	35	Open ended text
Country (3-character country codes ISO 3166)	A.3.1.12	15	Code List
Other Reporter	A.3.2		
Other Reporter Category	A.3.2.1	15 (code) 80 (code description/ term)	Code List
Last name	A.3.2.2	50	Open ended text
First name	A.3.2.3	50	Open ended text
Telephone Number	A.3.2.4	20	Open ended text
Fax Number	A.3.2.5	20	Open ended text
e-mail address	A.3.2.6	100	Open ended text
Business name	A.3.2.7	100	Open ended text
Street address	A.3.2.8	100	Open ended text
City	A.3.2.9	50	Open ended text
State/county	A.3.2.10	USA State – 15 County – 80	Code List Open ended text
Mail/zip code	A.3.2.11	35	Open ended text
Country (3-character country codes ISO 3166)	A.3.2.12	15	Code List
AER Information (Sender Investigation/Report Information) – Section A.4			
Unique Adverse Event Report Identification Number	A.4.1	60	Open ended text

GL 42 Section Title	GL42 Section Number	Field Length (maximum length – characters)	Data Type
Original Receive Date	A.4.2	19	Date (YYYYMMDD)
Date of Current Submission	A.4.3	19	Date (YYYYMMDD)
Type of Report – Section A.4.4			
Type of Submission	A.4.4.1	15 (code) 80 (code description/ term)	Code List
Reason for Nullification Report	A.4.4.2	200	Open ended text
Type of Information in Report	A.4.4.3	15 (code) 80 (code description/ term)	Code List
Description of the AE – Section B			
Animal Data – Section B.1			
Number of Animals Treated	B.1.1	12	Integer
Number of Animals Affected	B.1.2	12	Integer
Attending Veterinarian's Assessment of Animal Health Status Prior to VMP	B.1.2.1	15 (code) 80 (code description/ term)	Code List
Species	B.1.3	15 (code) 160 (code description/ term)	Code List
Breed	B.1.4.1.1 Breed (Purebred) and B.1.4.2.1 Breed (Crossbred)	15 (code) 250 (code description/ term)	Code List
Gender	B.1.5	15 (code) 80 (code description/ term)	Code List
Reproductive Status	B.1.6	15 (code) 80 (code description/ term)	Code List

GL 42 Section Title	GL42 Section Number	Field Length (maximum length – characters)	Data Type
Female Physiological Status	B.1.7	15 (code) 80 (code description/ term)	Code List
Weight – Section B.1.8			
Measured, Estimated, Unknown Weights	B.1.8.1	15 (code) 80 (code description/ term)	Code List
Minimum Weight in Kilograms	B.1.8.2	12	Numeric (nnnnnnnn.nnn) [1]
Minimum Weight Unit	B.1.8.2.1	kg	
Maximum Weight in Kilograms	B.1.8.3	12	Numeric (nnnnnnnn.nnn) [1]
Maximum Weight Unit	B.1.8.3.1	kg	
Age – Section B.1.9			
Measured, Estimated, Unknown Age	B.1.9.1	15 (code) 80 (code description/ term)	Code List
Minimum Age	B.1.9.2	12	Numeric (nnnnnnnnn.nn) [2]
Minimum Age Units	B.1.9.2.1	15	Code List
Maximum Age	B.1.9.3	12	Numeric (nnnnnnnnn.nn) [2]
Maximum Age Units	B.1.9.3.1	15	Code List
VMP Data and Usage – Section B.2			
Registered or Brand Name	B.2.1	200	Open ended text
Product Code	B.2.1.1	50	Open ended text
Registration Identifier	B.2.1.2	50	Open ended text
Anatomical Therapeutic Chemical Vet (ATCvet) Code	B.2.1.3	10	Open ended text
Company or MAH	B.2.1.4	100	Open ended text
MAH Assessment	B.2.1.5	4000	Open ended text

[1] The decimal point is floating but can't exceed 3 decimals or total of 12 characters (which includes the decimal point).

[2] The decimal point is floating but can't exceed 2 decimals or total of 12 characters (which includes the decimal point).

GL 42 Section Title	GL42 Section Number	Field Length (maximum length – characters)	Data Type
RA Assessment	B.2.1.6		
RA Assessment Term	B.2.1.6.1	15 (code) 80 (code description/ term)	Code List
Explanation Relating to Assessment	B.2.1.6.1.1	4000	Open ended text
Previous Exposure to the VMP	B.3.9	5	Boolean/Null Flavor
Previous AE to VMP	B.3.10	5	Boolean/Null Flavor
B.4 Dechallenge-Rechallenge Information - Did AE Abate After Stopping the VMP?	B.4.1	5	Boolean/Null Flavor
B.4 Dechallenge-Rechallenge Information - Did AE Reappear After Re-introduction of the VMP?	B.4.2	5	Boolean/Null Flavor
Route of Exposure & Dosage Information – Section B.2.1.7 & Section B.2.2			
Route of Exposure	B.2.1.7	15 (code) 80 (code description/ term)	Code List
Dose Per Administration	B.2.1.7.1		
Numeric Value for Dose (Numerator)	B.2.1.7.1.1	12	Numeric (nnnnnnn.nnnn) [3]
Units of Value for Dose (Numerator)	B.2.1.7.1.1.1	15 (code) 80 (code description/ term)	Code List
Numeric Value for Dose (Denominator)	B.2.1.7.1.2	12	Numeric (nnnnnnn.nnnn) [3]
Units of Value for Dose (Denominator)	B.2.1.7.1.2.1	15 (code) 80 (code description/ term)	Code List
Interval of Administration	B.2.1.7.1.3		
Numeric Value for Interval of Administration	B.2.1.7.1.3.1	12	Integer

[3] The decimal point is floating but can't exceed 4 decimals or total of 12 characters (which includes the decimal point).

GL 42 Section Title	GL42 Section Number	Field Length (maximum length – characters)	Data Type
Units of Value for the Interval of Administration	B.2.1.7.1.3.1.1	15 (code) 80 (code description/term)	Code List
Date of First Exposure	B.2.1.7.1.3.2	19	Date (YYYY, YYYYMM, or YYYYMMDD)
Date of Last Exposure	B.2.1.7.1.3.3	19	Date (YYYY, YYYYMM, or YYYYMMDD)
Active Ingredient(s)	B.2.2		
Active Ingredient(s)	B.2.2.1	200	Open ended text
Numeric Value for Strength (Numerator)	B.2.2.1.1	12	Numeric (nnnnnnn.nnnn) [3]
Units for Numeric Value for Strength (Numerator)	B.2.2.1.1.1	15 (code) 80 (code description/ term)	Code List
Numeric Value for Strength (Denominator)	B.2.2.1.2	12	Numeric (nnnnnnn.nnnn) [3]
Units for Numeric Value for Strength (Denominator)	B.2.2.1.2.1	15 (code) 80 (code description/ term)	Code List
Active Ingredient Code	B.2.2.1.3	15	Code List
Dosage Form	B.2.2.2	15 (code) 80 (code description/ term)	Code List
Lot Number(s)	B.2.3	35	Open ended text
Expiration Date	B.2.3.1	19	Date (YYYY, YYYYMM, or YYYYMMDD)
Who Administered the VMP	B.2.4	15 (code) 80 (code description/ term)	Code List
Use According to Label	B.2.5	5	Boolean/Null Flavor
Explanation for Off-Label Use	B.2.5.1		

GL 42 Section Title	GL42 Section Number	Field Length (maximum length – characters)	Data Type
Was the target species Off-Label?	B.2.5.1.1	5	Yes/No Information [4]
Was the route of administration Off-Label?	B.2.5.1.2	5	Yes/No Information [4]
Was the animal overdosed?	B.2.5.1.3	5	Yes/No Information [4]
Was the animal underdosed?	B.2.5.1.4	5	Yes/No Information [4]
Was the treatment regimen Off-Label?	B.2.5.1.5	5	Yes/No Information [4]
Was the indication Off-Label?	B.2.5.1.6	5	Yes/No Information [4]
Was the storage condition Off-Label?	B.2.5.1.7	5	Yes/No Information [4]
Was the product expired?	B.2.5.1.8	5	Yes/No Information [4]
Was there any other Off-Label issue?	B.2.5.1.9	5	Yes/No Information [4]
Manufacturing/Product Defect Information – Section B.2.6			
Manufacturing Site Identifier Number	B.2.6.1	50	Open ended text
Manufacturer's Identifier Type	B.2.6.1.1	50	OID for DUNS or FEI Number
Manufacturing Date	B.2.6.2	19	Date (YYYYMMDD)
Number of Defective Items	B.2.6.3	12	Integer
Defective Item Unit	B.2.6.3.1	15 (code) 80 (code description/ term)	Code list
Number of Items Returned	B.2.6.4	12	Integer
Returned Item Units	B.2.6.4.1	15 (code) 80 (code description/ term)	Code list
ORA District Field Office	B.2.6.5	15 (code) 80 (code description/ term)	Code list

[4] "Yes" will be presented "True" in the message using a Boolean snippet. "No Information" will be presented in the message using a null Flavor snippet.

GL 42 Section Title	GL42 Section Number	Field Length (maximum length – characters)	Data Type
Adverse Event Data – Section B.3			
Narrative of AE	B.3.1	20,000	Open ended text
Adverse Clinical Manifestations	B.3.2	15 (code) 250 (code description/ term)	Code List
Number of Animal	B.3.2.1	12	Integer
Accuracy of the Number of Animals	B.3.2.1.1	15 (code) 80 (code description/ term)	Code List
Date of Onset of AE/PP found date	B.3.3	19	Date (YYYY, YYYYMM, or YYYYMMDD)
Length of Time between Exposure to VMP & Onset of AE	B.3.4	15 (code) 80 (code description/ term)	Code List
Duration of AE	B.3.5		
Duration	B.3.5.1	12	Numeric (nnnnnnn.nnnn) [3]
Duration Time Units	B.3.5.1.1	15 (code) 80 (code description/ term)	Code List
Serious AER	B.3.6	5	Boolean
Treatment of AE	B.3.7	5	Boolean/Null Flavor
Outcome to Date	B.3.8		
Ongoing	B.3.8.1	12	Integer
Recovered/Normal	B.3.8.2	12	Integer
Recovered with Sequela	B.3.8.3	12	Integer
Died	B.3.8.4	12	Integer
Euthanized	B.3.8.5	12	Integer
Unknown	B.3.8.6	12	Integer
Veterinary Assessment of AE – Section B.5			
Attending Veterinarian's Assessment of AE	B.5.1	15 (code) 80 (code description/ term)	Code List

GL 42 Section Title	GL42 Section Number	Field Length (maximum length – characters)	Data Type
Report Number(s) of Linked Report(s) – Section B.6			
Unique Adverse Event Report Identification Number	B.6.1	60	Open ended text
Explanation for Linkage	B.6.1.1	15 (code) 80 (code description/ term)	Code List
Supplemental Documents -- Section B.7			
Attached Document Filename	B.7.1	255	Open ended text
Attached Document Type	B.7.1.1	15 (code) 80 (code description/ term)	Code List

Annex C. Field Length and Data Type for GL35 HL7 Wrapper Data Elements

GL35 Section Title	GL35 Section Number	Field Length (maximum length – characters)	Data Type
HL7 ICSR Wrapper Data Elements -- *Section B.8*			
Batch Wrapper	B.8.1		
Batch Number/Identifier	B.8.1.1		
Batch Number/Identifier – Root	B.8.1.1.1	60	Open ended text
Batch Number/Identifier – Extension	B.8.1.1.2	100	Open ended text
Batch Sender	B.8.1.2		
Batch Sender – Root	B.8.1.2.1	60	Open ended text
Batch Sender – Extension	B.8.1.2.2	100	Open ended text
Batch Sender – Title	B.8.1.2.3	50	Open ended text
Batch Sender – Last name	B.8.1.2.4	50	Open ended text
Batch Sender – First name	B.8.1.2.5	50	Open ended text
Batch Sender – Telephone	B.8.1.2.6	20	Open ended text
Batch Sender – Fax	B.8.1.2.7	20	Open ended text
Batch Sender – e-mail	B.8.1.2.8	100	Open ended text
Batch Receiver	B.8.1.3		
Batch Receiver – Root	B.8.1.3.1	60	Open ended text
Batch Receiver – Extension	B.8.1.3.2	100	Open ended text
Date of Batch Creation	B.8.1.4	19	YYYYMMDDHHMMSS+/-ZZZZ ***NOTE: HHMMSS represents hours, minutes, and seconds, and +/-ZZZZ represents GMT offset*
VICH AER Version Number	B.8.1.5	15	Open ended text
Transmission Wrapper	B.8.2		
Message Number –	B.8.2.1		
Message Number – Root	B.8.2.1.1	60	Open ended text
Message Number – Extension	B.8.2.1.2	100	Open ended text
Message Sender	B.8.2.2		
Message Sender – Root	B.8.2.2.1	60	Open ended text
Message Sender – Extension	B.8.2.2.2	100	Open ended text
Message Sender – Title	B.8.2.2.3	50	Open ended text

GL35 Section Title	GL35 Section Number	Field Length (maximum length – characters)	Data Type
Message Sender – Last name	B.8.2.2.4	50	Open ended text
Message Sender – First name	B.8.2.2.5	50	Open ended text
Message Sender – Telephone	B.8.2.2.6	20	Open ended text
Message Sender – Fax	B.8.2.2.7	20	Open ended text
Message Sender – e-mail	B.8.2.2.8	100	Open ended text
Message Receiver	B.8.2.3		
Message Receiver – Root	B.8.2.3.1	60	Open ended text
Date of Message Creation	B.8.2.4	19	YYYYMMDDHHMMSS+/-ZZZZ ***NOTE: HHMMSS represents hours, minutes, and seconds, and +/-ZZZZ represents GMT offset*
Report Identifier	B.8.2.5	7	Open ended text
Domestic vs Foreign Report Category	B.8.2.6	15 (code) 80 (code description/ term)	Code List
Profile Identifier	B.8.2.7	60	Open ended text