"Yaku-Sei-Yaku-Shin" 薬生薬審発" Notification No. 0207-1
"Yaku-Sei-An" 薬生安発" Notification No. 0207-1
Reiwa 4 (2022), February 7

To: The Director General of each Prefectural Health Administration Division

Director, Pharmaceutical Evaluation and Management Division, Pharmaceutical Sciences and Consumer Affairs Division, the Ministry of Health, Labour and Welfare
(Omission of MHLW seal)

Director, Pharmaceutical Safety Division, Pharmaceutical and Consumer Affairs Bureau, the Ministry of Health, Labour and Welfare
(Omission of MHLW seal)

Partial Amendments to Postmarketing Adverse Reaction Reporting and Study Adverse Reaction Reporting in Response to E2B (R3) Implementation Guide

Regarding the handling of Postmarketing Adverse Reaction Reporting (Reported adverse reactions are defined in Article 68, 10, Paragraph 1 of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices (Notification No. 145 of 1960. Hereafter referred to as the "Act".). However, this does not apply to periodic reports of unknown or non-serious adverse drug reactions as stipulated in Article 228 20, Paragraph 1, Item 3 of the Ordinance for Enforcement of the Act on Securing Quality, Efficacy and Safety of Drugs and Medical Devices (Ordinance of the Ministry of Health and Welfare No. 1 of 1961). and Study Adverse Reaction Reporting (Refers to reports of adverse reactions, etc. related to clinical trials as specified in Article 80 (2) (6) of the Act.) in accordance with the E2B (R3) Implementation Guide presented in (Joint Notification No. 0708-5 and Notification No. 0708-1, by the Director of the Evaluation and Licensing Division and the Director of the Safety Division, Pharmaceutical and Food Safety Bureau, the Ministry of Health, Labour and Welfare, dated July 8, 2013), Joint Notification of the Evaluation and Licensing Division, No. 0831 No. 12, and No. 0831 No. 3, by the Director of the Evaluation and Licensing Division, Pharmaceutical Affairs and Consumer Affairs Bureau, the Ministry of Health, Labour and Welfare, dated August 31, 2020. Partially revised on July 30, 2021.) It has just been shown by.

We have recently decided to revise the handling of these items as follows, and we ask that you be aware of this and give due consideration to informing your subordinates.

The revised information is provided in the Attachment.

Notice

Applicable sections	New	Old
J2.14.i in Exhibit 4. Description of Expectedness (Labelled and Un-Labelled) items	This Item, since they are associated with adverse drug reactions/adverse events (MedDRA codes), unknown (Un-labeled) or known (Labelled) information should be assigned to each adverse drug reaction. If there is only one suspected drug to be reported in the report, enter unknown if the adverse drug reaction is Unknown (Un-labelled) or known if it is predictable. If there is more than one suspected drug to be reported in the report, leave this field blank. **If the above measures cannot be taken, even if there are only one or more suspected drugs, leave the J2.14.i field blank and enter information about the Expectedness as Unknown (Un-Labelled)/Known (Labelled) status of all suspected drugs in the J2.11 field.** As for the Expectedness of adverse drug reactions, it should be judged whether it can be predicted from the latest Investigator's Brochure, etc., if the suspected drug is an investigational product, or from documents containing the latest scientific knowledge if it is an investigational product other than the investigational product. For the criterion of Expectedness, see (1) in "8. Other Precautions for Reporting Adverse Drug Reactions in Clinical Trials" attached to this notice.	This Item, since they are associated with adverse drug reactions/adverse events (MedDRA codes), unknown (Un-labeled) or known (Labelled) information should be assigned to each adverse drug reaction. If there is only one suspected drug to be reported in the report, enter unknown if the adverse drug reaction is Unknown (Un-labelled) or known if it is predictable. If there is more than one suspected drug to be reported in the report, leave this field blank. As for the Expectedness of adverse drug reactions, it should be judged whether it can be predicted from the latest Investigator's Brochure, etc., if the suspected drug is an investigational product, or from documents containing the latest scientific knowledge if it is an investigational product other than the investigational product. For the criterion of Expectedness, see (1) in "8. Other Precautions for Reporting Adverse Drug Reactions in Clinical Trials" attached to this notice.

Attachment

"Yaku-Sei-Yaku-Shin" 薬生薬審発" No. 0831 No.12
"Yaku-Sei-An" 薬生安発" No. 0831 No.3
Reiwa 2 (2020), August 31
(Partially amended) Reiwa 3 (2021), July 30
(Partially amended) Reiwa 4 (2022), February 7

To: The Director General of each Prefectural Health Administration Division

Director, Pharmaceutical Evaluation and Management Division, Pharmaceutical Sciences and Consumer Affairs Division, the Ministry of Health, Labour and Welfare
(Omission of MHLW seal)

Director, Pharmaceutical Safety Division, Pharmaceutical and Consumer Affairs Bureau, the Ministry of Health, Labour and Welfare
(Omission of MHLW seal)

Post-marketing adverse reaction reports and clinical trial adverse reaction reports in accordance with the E2B (R3) Implementation Guide

Post-marketing adverse drug reaction reports based on the E2B (R3) implementation guide presented in (Joint Notification No. 0708-5 and Notification No. 0708-1, by the Director of the Evaluation and Licensing Division and the Director of the Safety Division, Pharmaceutical and Food Safety Bureau, the Ministry of Health, Labour and Welfare, dated July 8, 25. Hereafter referred to as "E2B (R3) Implementation Guide Notice".) (Adverse drug reactions prescribed in Article 68, 10, Paragraph 1 of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, etc. (Act No. 145 of Showa 35. Hereafter referred to as the "Act".)

However, periodic reports of unknown or non-serious adverse drug reactions prescribed in Article 228, 20, Paragraph 1, Item 3 of the Ordinance for Enforcement of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, etc. (Ordinance of the Ministry of Health and Welfare No. 1 of 36. Hereafter referred to as the "Article".) are excluded.

And the handling of reports on adverse reactions in clinical trials (Refers to reports of adverse reactions, etc. related to clinical trials as specified in Article 80 (2) (6) of the Act.) have been shown in the section entitled (Joint Notification No. 0331-6 and Notification No. 0331-1, by the Director of the Evaluation and Licensing Division and the Director of the Safety Division, Pharmaceutical Affairs and Consumer Affairs Division, the Ministry of Health, Labour and Welfare, dated March 31, 29. Hereafter referred to as the "Heisei-29 E2B (R3) Joint Notice of 2-Directors (二課長通知 "2-Kacho Notification".).

With the enforcement of the Act for Partial Revision of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices (Act No. 63 of 2019) and the Act for Partial Revision of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices, etc. With the enforcement of the Ministerial Ordinance on Maintenance of Relevant Ministerial Ordinances (MHLW Ordinance No. 155 of 2020)

Accordingly, we have decided to revise the handling of these ordinances as follows.

We ask that you give due consideration to informing your subordinates.

The Heisei-29 E2B (R3) Joint 2-Director (2-Kacho) Notice will be discontinued after August 31, 2022.

Notify

1. Reporting Methods

(1) Post-marketing adverse reaction reports of drugs, and research reports or clinical trial adverse reactions reports of drugs, quasi-drugs and cosmetics (Report prescribed in Article 228, 20 Paragraph (1), Items (1) and (2) and Paragraph (5), Item(2)- (□) or Article 273, Paragraph (1) and (2) of the Regulations. To: The Director General of each Prefectural Health Administration Division

In order to promote e-government toward the realization of efficient government, the acceptance of reports by electronic data processing systems has been promoted in accordance with the Act on the Use of Information and Communications Technology in Administrative Procedures (Act No. 151 of 2002), etc., and the management of adverse reaction reports in an electronic format and in a database contributes to prompt safety measures. If reporting by electronic data processing systems is difficult due to unavoidable circumstances, reporting by electronic data processing systems can be made in accordance with (2) or (3), but we request your cooperation in moving to electronic data processing systems as much as possible.

① Reporting by electronic data processing systems

The matters listed in Attachments 1 and 2 shall be recorded in XML format corresponding to the E2B (R3) Implementation Guide Notice and Attachment 3 and reported to the Institute by electronic data processing systems.

② CD, etc. Reports

A CD-R (ROM) or DVD-R (ROM) (Hereafter referred to as "CD, etc.".) recording the matters listed in Attachments 1 and 2 in an XML format corresponding to the E2B (R3) Implementation Guide Notice and Attachment 3, as well as a document stating the name, address, date of report and other necessary matters of the reporter (a part of the original copy and a part of the duplicate copy if you wish to return the duplicate copy) shall be submitted to the Institute.

③ Paper report

"Partial Amendments to "Reporting of Adverse Drug Reactions" and "Reporting of Adverse Drug Reactions to the Pharmaceuticals and Medical Devices Agency"" (Yaku-Sei Notification No. 0331 No. 4 of Director of the Pharmaceutical and Community Health Bureau, the Ministry of Health, Labour and Welfare, dated March 31, 28) (Yaku-Shoku Notification No. 1002 No. 20 of the Ministry of Health, Labour and Welfare Pharmaceutical and Food Safety dated, 26 10.

Director-General of the Pharmaceutical and Food Safety Bureau Notification. Hereafter referred to as the "Post-marketing Director's Notification".) Attached Form or "Report of Adverse Drug Reactions to the Pharmaceuticals and Medical Devices Agency"

(Yaku-Sei Notification No. 0831 No. 8 of the Director of the Pharmaceutical and Community Health Bureau, the Ministry of Health, Labour and Welfare, dated August 31, 2020) Submit to the Agency a written report (one copy of the original and one copy of the duplicate if you wish to return the duplicate) containing the necessary information specified in the attached form and a CD, etc. in which the matters listed in Attachments 1 and 2 are recorded in XML format corresponding to the E2B (R3) Implementation Guide Notice and Attachment 3.

However, if it is difficult to submit the report and the CD, etc. at the same time due to unavoidable circumstances, it may be possible to submit the CD, etc. separately but as soon as possible.

(2) In the case of reports of adverse reactions to quasi-drugs and cosmetics (reports specified in Article 228, 20, Paragraph 5, Items 1 and 2 (a) of the Regulations)

As a general rule, reports shall be made according to (1) or (2), but if reporting according to (1) or (2) is difficult due to unavoidable circumstances, reports according to (3) may be made.

① Reporting by Electronic Data Processing System

The matters listed in Attachments 1 and 2 shall be recorded in XML format corresponding to the E2B (R3) Implementation Guide Notice and Attachment 3 and reported to the Pharmaceuticals and Medical Devices Agency (Hereafter referred to as the "PMDA".) by electronic data processing system.

② mail report

The matters listed in Attachments 1 and 2 shall be recorded in an XML format corresponding to the E2B (R3) Implementation Guide Notice and Attachment 3, attached to an e-mail, and submitted to an e-mail address separately specified by the Institute, together with a written report (one copy of the original and one copy of the duplicate, if you wish to return the duplicate) describing the necessary matters specified in the Attachment Form (Yaku-Sei Notification No. 0331-7 of Director of the Pharmaceutical and Community Health Bureau, the Ministry of Health, Labour and Welfare, dated March 31, 2017. Hereafter referred to as the "2017 Notice by the Director General of the Cosmetics Bureau".) to the Institute.

③ Paper report

Submit a written report (one copy of the original and one copy of the duplicate, if you wish to return the duplicate) containing the necessary information specified in the form attached to the notification form of the Director of the Bureau of External Products and Cosmetics in Heisei 29, as well as a CD, etc., in which the matters listed in the attached Exhibits 1 and 2 are recorded in an XML format corresponding to the E2B (R3) Implementation Guide notification and the attached Exhibit 3, to the Agency(PMDA).

2. However, if it is difficult to submit the report and the CD, etc. at the same time due to unavoidable circumstances, it is acceptable to submit the CD, etc. separately, but as soon as possible. Handling of the reports in 2 (1) ② of the Attachment to the Post-marketing Director's Notice

With regard to the first report by fax, etc., pursuant to the provisions of 2 (1) ② of the Attachment to the Post-marketing Director's Notice (Hereafter referred to as "Immediate Report"), if the content of the report satisfies the "mandatory items" listed in Attachment 1 and 2, the regular first report by the electronic data processing system set forth in 1 (1) ① may be made an immediate report.

3. Attention should be paid to the information in the Attachment notification report.

4. Timing of application

This notice is effective September 1, 2020 (Reiwa 2). However, for those who have submitted notification of their clinical trial plans in accordance with the previous rules in accordance with the "Handling of Notification of Clinical Trial Plans for Drugs by Persons Who Intend to Request Clinical Trials" (Yaku-Sei-Yaku-Shin Notification No. 10 0831 of the Evaluation and Licensing Division, Pharmaceutical and Pharmacological Evaluation and Licensing Division, the Ministry of Health, Labour and Welfare, dated August 31, 2020), the clinical trial adverse reaction reports should be submitted in accordance with the previous rules.

別添 Attachment

Notes on reporting

1. Reporting Classification (Report Type)

Each reporting classification shall be as follows:

AA = Domestic Infectious Disease Case Report (post-marketing) (Related to Article 228, 20 Paragraph 1, Item 1 (ヘ) and (ト) of the Regulation): [Local infection case report (PM)]

AB = National Adverse Drug Reaction Case Reports (post-marketing) (Related to Article 228, 20, Paragraph 1, Item 1, (イ), (ロ), (ハ), (ニ) and (ホ) of the Regulation and Item 2, (イ) of the same paragraph) : [Local adverse reaction case report (PM)]

AC = Foreign infectious disease case report (post-marketing) (Related to Article 228, 20 Paragraph 1, Item 1, (ト) of the Regulation) : [Overseas infection case report (PM)]

AD = Foreign adverse reaction case report (post-marketing) (Related to Article 228, 20 Paragraph 1, Item 1 (ロ) and (ハ) of the Regulation) : [Overseas adverse reaction case report (PM)]

AE = Infectious disease research report (post-marketing) (Related to Article 228, 20 Paragraph 1, Item 2 (ロ) of the Regulation) : [Research report for infection (PM)]

AF = Adverse drug reaction study report (post-marketing) (Related to Article 228, 20 Paragraph 1, Item 2 (ロ) of the Regulations) : [Research report for adverse reaction (PM)]

AG = Report on measures such as suspension of production, collection and disposal in foreign countries (post-marketing) (Related to Article 228, 20 Paragraph 1, Item 1 (チ) of the Regulations) : [Measures-taken Report (PM)]

BA = Quasi-drug adverse drug reaction reports (post-marketing) (Related to Article 228, 20 Item 5, Items 1 and 2 (イ) of the Regulation) : [Quasi-drug research report (PM)]

BB = Reports of adverse reactions to cosmetics (post-marketing) (Related to Article 228, 20 Paragraph 5, Item 1 and Item 2, (イ) of the Regulation) : [Cosmetics Research report (PM)]

BC = Quasi-drug Research Report (post-marketing) (Related to Article 228, 20 Paragraph 5, Item 2 (ロ) of the Regulation) : [Quasi-drug research report (PM)]

BD = Cosmetics Research Report (post-marketing) (Related to Article 228, 20 Paragraph 5, Item 2 (ロ) of the Regulation) : [Cosmetics Research report (PM)]

DA = Domestic Infectious Disease Case Reports (clinical trial) (Related to Article 273, Paragraph 1, Item 1 and 2 of the Regulation) : [Local infection case report (CT)]

DB = Domestic adverse reaction case report (clinical trial) (Related to Article 273, Paragraph 1, Item 1 and 2 of the regulation) : [Local adverse reaction case report (CT)]

DC = Foreign Infectious Disease Case Report (clinical trial) (Related to Article 273 Paragraph 1, Item 1 and 2 and Paragraph 2, item 1 and 2 (イ) (ロ) of the Regulation) : [Overseas adverse reaction case report (CT)]

DD = Foreign adverse reaction case report (clinical trial) (Related to Article 273 Paragraph 1, Item 1 and 2 and Paragraph 2, item 1 and 2 (イ) (ロ) of the Regulation) : [Research report for infection (CT)]

DE = Infectious disease research report (clinical trial) (related to Article 273, Paragraph 2, Item 2 (ニ) of the Regulation)

DF = Adverse drug reaction research report (clinical trial) (Related to Article 273, Paragraph 2, Item 2 (ニ) of the Regulation) : [Research report for adverse reaction (CT)]

DG = Report on measures taken in foreign countries, such as suspension of production, collection, and disposal (clinical trial) (Related to Article 273, Paragraph 2, Item 2 (ハ) of the Regulation)

Withdrawal (Nullification) = "Withdrawal report" in each report

2. Definition of Terms

(1) Post-marketing adverse reaction reports

Post-marketing adverse drug reaction reports are a general term for Reporting Classification as “AA, AB, AC, AD, AE, AF, AG, BA, BB, BC and BD”.

(2) Reports of adverse drug reactions in clinical trials

Clinical Study adverse drug reaction reports are a general term for reporting categories DA, DB, DC, DD, DE, DF and DG.

(3) J Item

Items included in the report that are listed in Exhibit 4.

(4) E2B Items

Items included in the report that are listed in Chapter 3.4 of "Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSR)," Attachment 1 of the E2B (R3) Implementation Guide Notice.

(5) Acknowledgement Message Items

An acknowledgement message is a message that the Institute responds to the sender after receiving a report, and refers to the items listed in Exhibit 6 and Attachment 1 of the E2B (R3) Implementation Guide Notification, Chapter 4.2 of the Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSR).

(6) Identification number

This is a unique number assigned to the reporting of post-marketing adverse reactions, etc. and to the reporting of clinical trial adverse reactions, etc., and an acknowledgment message item "ACK.B.r.2 Regional Report Number" is included.

(7) Withdrawal report

This term refers to the withdrawal of a report by stating the identification number of the report in "J2.1b identification number (number)" and stating necessary items such as "C11.1 Report Nullification / Amendment " and "C.1.11.2 Reasons for Report Nullification / Amendment " in cases such as erroneously reporting "C.1.1 Sender's (case) Safety Report Unique Identifier" etc.

(8) Reporter

Refers to a primary source. A primary source is a person who reports information on adverse reactions, etc., and includes medical professionals, authors of literature, users, lawyers, etc. If more than one source exists, the person who first reports the fact to the sender is the primary source for regulatory purposes. Primary sources should be distinguished from senders.

(9) Sender

The organization that transmits (reports) adverse drug reaction information to the Pharmaceuticals and Medical Devices Agency refers to an individual Marketing Authorisation Holder, foreign special approval holder, or sponsor.

3. J Item and E2B Items

For the input types, allowable values, J Item and E2B items to be included in the report, see (1) to (4) below, and use Exhibits 1 and 2.

(1) Character code and input type/allowable value

The character code to be used is UTF-8.

The input type is one of the following "NUM," "TXT," "Date (minimum precision)," "List," or "Code listing" Boolean "or" UUID ", and the allowable values vary depending on the input type. The input types and allowable values used for each item are shown in the input types and allowable values columns in Exhibit 1 and Exhibit 2.

Note that when “<",">” and “&” are used, they are referred to as “<”, “>” and “&” can be represented by substituting the following:

ア. NUM

Integers are used for floating-point number representation. Only the characters "0 ~ 9,..., E, +, -" are allowed.

The permissible value column in Exhibits 1 and 2 indicates the number of characters that can be entered, not the data size in XML.

イ. TXT

Use kanji, hiragana, katakana, alphanumeric characters, Greek letters, special symbols and spaces. However, if a kanji character that is not currently used has a new typeface in the common use kanji, it should be written in a new typeface.

The permissible value column in Exhibits 1 and 2 indicates the number of characters that can be entered, not the data size in XML.

ウ. Date (minimum precision)

Used in the form of Date/Time types (CCYMMDDhhmmss.UUUU [+ | -ZZzz]). CCYY denotes the year, MM denotes the month, DD denotes the day, hh denotes the hour, mm denotes the minute, ss denotes the second, UUUU denotes the millisecond, and [+ | -ZZzz] denotes the time difference from Coordinated Universal Time, with + denoting times earlier than Coordinated Universal Time and + denoting times later after one.

The entries in the Value Allowed column of Exhibit 1 and Exhibit 2 are the minimum precision of the dates that must be entered.

エ. List

Select from specific values to use.

Null flavor is a selectable value in the Value Allowed column of Exhibits 1 and 2.

オ. Code List

Use codes defined by the Health Level Seven (Health Level Seven. Hereafter referred to as "HL7"), an international organization that creates standards for the exchange of medical information.

The codes used for J Items are shown in Exhibit 5.

カ. Boolean

Used for binary values of yes and no. When writing XML, use [yes] = “true” and [no] = “false”.

The values indicated in the Value Allowed column in Exhibits 1 and 2 are actually usable values. However, for some Element id, only one of true and false can be used.

キ. UUID

Enter an ID in UUID format.

The permissible value column in Exhibits 1 and 2 indicates the number of characters that can be entered, not the data size in XML.

ク. Null Flavor (null flavor)

A code defined by HL7 that allows a null value to have a certain meaning. When used for J Items, select from the null flavors shown in Exhibit 5. The null flavor indicates the reason for the blank and, in principle, is not considered to have given a value, but there are exceptions, so please refer to Exhibits 1 and 2 for details.

(2) Object Identifier (OID)

The OIDs used in J Items are listed in XPath in Exhibit 4.

(3) Necessary items, items that need to be described in conjunction with other items, compliance items, and non-reportable items As indicated in the report classification column in Exhibit 1 and Exhibit 2, each item is described below (ア). to (エ). The subject falls under any of the preceding items or an item that can be abbreviated (■).

ア. Items that must be described (required items (◎)

In the AA, AB, AC, AD, BA, BB, DA, DB, DC and DD reporting categories, "D.1 Patient (name or initials)" is a required item. In addition, in the AA, AB, AC, AD, DA, DB, DC and DD reporting categories, at least one of the items for identifying patients (Of the E2B items, "D.1 Patient (name or initials)," "D.1.1.1 through D.1.1.4 Patient medical record numbers and their sources," "D.2.1 Date of Birth," "D.2.2 Age at onset of reaction/event," "D.2.2.1a and D.2.2.1b Gestational age at onset of adverse reaction/event in fetus," "D.2.3 Patient age group (as expressed by reporter)" and "D.5 Gender") should be entered. For entry of these items, see Exhibit 2.

イ. b. Items that require entry depending on the content of other items (Items that need to be entered in conjunction with other items (□))

Whether or not other items are entered, and the values listed are items that require entry depending on the conditions of the description guidelines.

ウ. Items to be entered as much as possible (compliance items (▲))

Compliance items can be reported even if they are not listed, but if they are not listed, they are deemed to be unknown. Therefore, efforts should be made to collect information and report as much as possible.

If a withdrawal report is made based on additional information, compliance items should read "Unnecessary but listed items that do not result in an error (However, if the data type is incorrect, an error is assumed.)."

エ. Items that should not be included (non-reportable items (X))

A report is not accepted if it is listed in the non-reportable section. In addition, if null flavor is listed, it is treated as if data were entered and no report is accepted.

(4) XPath *[see Note-2]*

J Items describe XML according to XPath shown in Exhibit 4. E2B items describe XML according to XPath shown in Appendix I (G) of Appendix 1 "Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSR)" of the E2B (R3) Implementation Guide Notice.

4. Descriptions and Methods for Individual Case Safety Reports

When reporting cases of infections (AA, AC, DA and DC of the reporting classification and their withdrawal (Nullification) and cases of adverse reactions (AB, AD, BA, BB, DB and DD in the happy report classification and their withdrawal), the items specified in Exhibits 1 and 2 should be included. When entering items, refer to Exhibit 4 for J Items and E2B (R3) Implementation Guide Notice for E2B items, and note the following:

Note-2: The "XPath Information" for each element item has been removed from this document. If formal XPath information is required, refer to the original Regulatory information from the MHLW/PMDA Notifications.

(1) Setting a reporting deadline

When setting a reporting deadline, the date on which information was received should be set as 00 days, and if the reporting deadline falls on a non-business day of the Institute, the next business day should be set as the reporting deadline. In the case of information in foreign countries, the reporting deadline should be set as the date on which the information was received in Japan, rather than the local time (date) in the country of the primary source.

(2) When reporting infectious disease case reports and adverse reaction case reports in a single case

For domestic cases, select "J2.1 an Identification Number (Reporting Classification)" for "AA" and "DA" for "AA," and for foreign cases, select "J2.1 an Identification Number (Reporting Classification)" and "AC" and "DC" for "AC."

(3) When reporting additional information on reports of adverse drug reactions in foreign clinical trials after the approval date

The information should be reported as a "post-marketing adverse drug reaction report (initial report)."

(4) Sender

If the sender is a corporation, the name of its representative should be listed in "Sender's name (C.3.3.3)" and "Sender's last name (C.3.3.5)" and the address of its principal facility should be listed in (C.3.4.1 to C.3.4.5).

(5) Post-marketing (excluding quasi-drug adverse reaction reports and cosmetic adverse reaction reports)

ア. Does this case meet the criteria for emergency reporting in the relevant country? (C.1.7)

Write "yes" for a 15-day report and "no" for a 30-day report.

The deadline for reporting can be changed from a 15-day report to a 30-day report in a follow-up report because the deadline is determined when the information is available.

イ. Adverse reactions/events (E items)

(ア) Adverse reactions/events (E.i.2.1b)

Enter the MedDRA code corresponding to the name of the adverse reaction.

(イ) (b) Adverse reactions/adverse events deemed important by the reporter (E.i.3.1) and severity criteria for each adverse event (E.i.3.2)

Judgment is made on the responsibility of the sender based on the severity assessment described (provided) in the adverse reaction report from the reporter. All of the cases judged by the reporter to be serious are classified as serious, but if the case is judged to be serious by the sender even if the case is judged not to be serious by the reporter, the case should be described and reported as serious.

ウ. Drug information (G-element)

Listed in order of the company's suspected drugs, other suspected drugs, and other drugs. If there is more than one drug, list in order of the earliest start date. In the case of foreign infectious disease case reports (post-marketing) and foreign adverse drug reaction case reports (post-marketing), if materials with case information are attached to the ICSR file for reporting, it is acceptable to enter only suspected drugs, including other companies' products.

(ア) Blinding status of the study drug (G.k.2.5)

When reporting adverse drug reactions, etc. in post-marketing clinical studies, etc. of an own company’s drug, reports should be made before the “Unblinding” of the suspected drug even if the drug is “Blinded”. In this case, this item should be reported as "true".

(イ) Drug dosage form (G.K.4.r.9.1)

It should be written in half-width English letters in accordance with Exhibit 7, List of Dosage Forms.

(ウ) ID of administration route (G.K.4.r.10.2b)/ID of administration route to parent (G.K.4.r.11.2b)

In accordance with Appendix I (F) of the Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSR) in the Attachment to the E2B (R3) Implementation Guide Notification, these should be entered in half-width (single byte) numerals.

(エ) Other information related to pharmaceuticals (G.k.11)

When reporting foreign infectious disease case reports and foreign I) reaction case reports, enter "TIKEN" in half-width English letters if a clinical study is being conducted for the purpose of making partial changes to the approved items related to the addition or deletion of indications for the dosage and administration of the pharmaceutical already approved for marketing in Japan.

(6) Clinical trials

ア. Does this case meet the criteria for emergency reporting in the country? (C.1.7)

Enter "yes" for a 7-day report and "no" for a 15-day report.

イ. b) Effects/adverse events (E items)

(ア) Effects/adverse events (E.i.2.1b)

The MedDRA code corresponding to the action name should be provided.

(イ) Adverse drug reactions/events deemed important by the reporter (E.i.3.1) and severity criteria for each adverse event (E.i.3.2)

Based on the severity assessment described (provided) in the adverse drug reaction report from the reporter, the sender's responsibility is to revise the report. All of the reports judged to be serious by the reporter should be classified as serious, but all of the reports judged to be serious by the reporter but judged to be serious by the sender should be described and reported as serious.

ウ. Drug Information (G Item)

Drugs used in the study and other drugs recognized by the attending physician as the suspected drug (Including anesthetics, blood transfusion, etc.) and other drugs used during the period of use of the suspected drug should be described.

Reporting categories DA and DB should be described in order of the suspected drug and drugs other than the suspected drug. Then, if there are multiple suspected drugs, they should be listed in order of the investigational drug, investigational drugs other than the investigational drug, and other drugs, and if there are multiple drugs of the same position, they should be listed in order of the drug with the earlier start date. As a general rule, reporting categories DC and DD should be listed in the above order.

For drugs other than the suspect drug, the investigational drug, investigational drugs other than the investigational drug, and other drugs may be listed in any order, but as a general rule, they should be listed in order from the earliest start date.

(ア) Name of drug reported by the primary source (G.k.2.2)

Information on the investigational drug should be provided if the report is from a double-blind study and the suspected drug could not be identified as either the investigational drug or the control drug before unblinding. Additional reports should also be provided based on information obtained after unblinding.

If information obtained after unblinding reveals that the suspected drug is a “Placebo” and there is no more suspected drug to be reported, a withdrawal (Nullification) report should be made.

(イ) Drug dosage form (G.K.4.r.9.1)

It should be written in half-width English letters in accordance with Exhibit 7: List of Dosage Forms.

(ウ) ID of administration route (G.K.4.r.10.2b)/ID of administration route to parent (G.K.4.r.11.2b)

In accordance with Appendix I (F) of the Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSR) in the Attachment to the E2B (R3) Implementation Guide Notification, these should be entered in half-width numerals.

(7) Quasi-drug adverse reaction reports and cosmetic adverse reaction reports

ア. Severity, etc. (J2.26.i)

It is the sender's responsibility to revise the report based on the severity assessment provided in the adverse reaction report from the reporter. All cases judged to be serious by the reporter are classified as serious, but even if the reporter judged the case to be not serious, if the sender judged it to be serious, it should be described and reported as serious.

イ. Does this case meet the criteria for emergency reporting in the country? (C.1.7)

Write "yes" for a 15-day report and "no" for a 30-day report.

The deadline for reporting can be changed from a 15-day report to a 30-day report in a follow-up report because the deadline is determined when the information is available.

ウ. Adverse reactions/events (E.i.2.1b)

MedDRA codes corresponding to adverse drug reactions should be specified by selecting appropriate terms from Exhibit 8, Quasi-drug Adverse Drug Reaction Codes.

エ. Product Information (G Item)

For suspected products, the company's suspected product most likely to be related to the adverse drug reaction should be listed as the first suspected product, followed by the suspected product in the order of relationship to the onset of the adverse drug reaction, regardless of the company's product or the products of other companies.

5. Use of ISO/HL7 standards

As shown in the attachment to the E2B (R3) Implementation Guide Notice, E2B items and message specifications for electronic data processing system reporting are defined in terms of the International Organization for Standardization (International Organization for Standardization: ISO) and the standard developed by HL7, ISO/HL7 27953-2: 2011 Health informatics-Individual case safety reports (ICSRs) in pharmacovigilance-Part 2: Human pharmaceutical reporting requirements for ICSR (Hereafter referred to as "ISO/HL7 27953-2 Standard".). Similarly, J items referring to this standard are used with permission from the issuer. The ISO/HL7 27953-2 standard is copyrighted jointly by ISO and HL7 and its unauthorized copying, reproduction and reproduction are prohibited.

6. Use of the MedDRA

The provision of MedDRA and maintenance of listed terms are implemented by the JMO Division of the Pharmaceutical and Medical Devices Regulatory Science Foundation, based on an agreement reached at the International Conference on Harmonization of Drug Regulations (Hereafter referred to as "ICH".). In selecting MedDRA terms, reference should be made to the MedDRA TERM SELECTION: POINTS TOCONSIDERJ (PTC) compiled as part of the ICH activities.

(1) Items using MedDRA terms and hierarchy used

See the E2B (R3) Implementation Guide Notice for items using MedDRA terms and the hierarchy of MedDRA term choices.

(2) MedDRA Term Choices

MedDRA terms should be chosen based on medical judgment as the most appropriate term.

ア. Name of adverse drug reaction

(ア) Domestic cases

Select a term with an English currency flag of “Y”.

(イ) Foreign cases

If a case was transmitted from a foreign country and is listed in the "Adverse reactions/events reported by the primary source in the native language (E.i.1.1a)" it is acceptable to report the case with the contents of the report intact.

Select a term with an English currency flag of Y.

7. Details and methods of entries in research reports and foreign action reports

When conducting research reports (AE, AF, BC, BD, DE and DF of the reporting classification and their withdrawal (Nullification)) and foreign action reports (AG and DG of the reporting classification and their withdrawal (Nullification)), the items specified in Exhibits 1 and 2 should be entered. For how to enter each item, refer to Exhibit 4 for J Items and E2B (R3) Implementation Guide Notice for E2B items, and note the following:

(1) Setting reporting deadlines

When setting reporting deadlines, the date of information acquisition should be set as 00 days, and if the reporting deadline falls on a non-business day of the Institute, the next business day should be set as the reporting deadline. In the case of information in foreign countries, the reporting deadline should be set as the date of information acquisition in Japan, not the local time (date) in the country of the primary source.

(2) Sender

If the sender is a corporation, the name of its representative should be listed in "Sender's name (C.3.3.3)" and "Sender's last name (C.3.3.5)" and the address of its principal facility should be listed in (C.3.4.1 to C.3.4.5).

(3) Post-marketing

ア. Identification of case safety reports (C.1 Item)

(ア) Type of report (C.1.3)

In a research report, if a survey of pharmacoepidemiology is to be reported, it should be indicated as "reports from studies," and if a literature review article, etc. is to be reported, it should be indicated as "others."

イ. The literature for bow I (C.4 Item)

(ア) Citations (reference Literature) (C.4.r.1)

"Citations (reference Literature) (C.4.r.1) shall read "Publication of research reports or measures in foreign countries (C.4.r.1)."

1) Research Report

Citations (reference Literature) should be provided in accordance with the Vancouver Convention (It's known as the "Vancouver style".) as proposed by the International Committee of Medical Journal Editors (International Committee of Medical Journal Editors).
The convention format, including special cases, should be referred to in the following documents.

If the International Committee of Medical Journal Editors "Recommendations for the conduct, reporting, editing and publication of academic research for publication in medical journals" information is Unpublished in its own materials, a statement to that effect (such as "Unpublished") should be included, along with the title, the reporter, the organization or laboratory to which the reporter belongs, the year of implementation, etc.
If the information comes from a website, enter its URL, etc. If the information comes from other sources, specify the source.

2) Report on Foreign Measures

Identical actions taken by regulators in multiple countries may be reported as a single report. In doing so, the state of publication in the representative country should be listed first and, using repetition, the state of publication in the other countries should be listed second and later.

If the same measure is taken in another country at a later date, the state of publication in that country should be additionally reported. In doing so, the state of publication of that additional report in the representative country should be noted immediately after the previous report. If there is more than one country in which the additional report was published, the state of publication of the other countries should be noted using repetition.

If citations should be noted, refer to 1) above.

ウ. Drug information (G Items)

Describe the drugs to be reported. Describe all products if more than one product is covered.

(ア) Approval/Application Number (G.k.3.1)

Enter the approval number of the reportable drug, etc.

In the cosmetics research report, the prefecture code (CSS standard) of the jurisdiction prefecture and the date of submission of the cosmetics marketing notification should be described. If there was an approval number, the date of approval should be described.

エ. Description of case summary and other information (H item)

(ア) Descriptive information of the case, including clinical course, treatment procedure, outcome and other relevant information (H.1)

"Descriptive case information, including clinical course, treatment, outcome and other relevant information (H.1)" should read "The research report is a summary of measures taken in foreign countries (H.1)."

1) Research Report

Summaries of studies/research results, opinions of authors, etc. should be briefly described. For reports on significant changes in incidence trends, the period in which the incidence is related, analysis method, interpretation of results, etc. should be described.

2) Report on Foreign Measures

A brief summary of the nature of the measures and the views of the regulatory authorities should be included.

(イ) The sender's opinion (H.4)

The sender's opinion should be stated.

(4) Clinical trials

ア. Identification of case safety reports (C.1 Item)

(ア) Type of report (C.1.3)

In a research report, if a survey of pharmacoepidemiology is to be reported, it should be indicated as "reports from studies," and if a literature review article, etc. is to be reported, it should be indicated as "others."

イ. Citations (reference Literature) (C.4 items)

(ア) Citations (reference Literature) (C.4.r.1)

"Citations (reference Literature) (C.4.r.1)" shall read "Publication of research reports or measures in foreign countries (C.4.r.1)."

1) Research Report

Citations (reference Literature) should be provided in accordance with the Vancouver Convention (It's known as the "Vancouver style".) as proposed by the International Committee of Medical Journal Editors (International Committee of Medical Journal Editors).

The convention format, including special cases, should be referred to in the following documents.

If the International Committee of Medical Journal Editors "Recommendations for the conduct, reporting, editing and publication of academic research for publication in medical journals" information is Unpublished in its own materials, a statement to that effect (such as "Unpublished") should be included, along with the title, the reporter, the organization or laboratory to which the reporter belongs, the year of implementation, etc.

If the information comes from a website, enter its URL, etc. If the information comes from other sources, specify the source.

2) Report on Foreign Measures

Identical actions taken by regulators in multiple countries may be reported as a single report. In doing so, the state of publication in the representative country should be listed first and, using repetition, the state of publication in the other countries should be listed second and later.

If the same measure is taken in another country at a later date, the state of publication in that country should be additionally reported. In doing so, the state of publication of that additional report in the representative country should be noted immediately after the previous report. If there is more than one country in which the additional report was published, the state of publication of the other countries should be noted using repetition.

If citations should be noted, refer to 1) above.

ウ. Drug information (G Item)

The investigational new drugs to be reported should be described.

(ア) Drug names reported by primary sources (G.k.2.2)

4. (6) ウ shall apply.

(イ) Approval number (G.k.3.1)

At least one investigational product that has an approval number in Japan should be listed.

エ. Description of case summary and other information (H item)

(ア) Descriptive information of the case, including clinical course, treatment procedure, outcome and other relevant information (H.1)

"Descriptive case information (H.1), including clinical course, treatment, outcome and other relevant information" shall read "Summary of research reports or measures taken in foreign countries (H.1)."

1) Research Report

Summaries of studies/research results, opinions of authors, etc. should be briefly described. For reports on significant changes in developmental trends, the period in which the frequency of occurrence is related (phase of development), methods of analysis, interpretation of results, etc. should be described.

2) Report on Foreign Measures

A brief summary of the nature of the measures and the views of the regulatory authorities should be included.

(イ) The sender's opinion (H.4)

The sender's opinion should be stated.

8. Other precautions for reporting adverse reactions in clinical trials

The following points should also be kept in mind when reporting Adverse Drug Reactions.

(1) Expectedness criteria, etc.

Expectedness criteria, etc., should be calculated based on the following:

ア. Investigational drug should be calculated based on the adverse events described in the latest Investigator's Brochure. However, if a person who intends to sponsor a clinical trial is conducting a clinical trial using multiple Investigational drug and is unable to prepare the Investigator's Brochure because the drug is used in combination with an investigational drug that the person intends to market, but is marketed by another company, etc., the drug is an active ingredient that has already been approved in Japan, and the person who intends to sponsor a clinical trial should be allowed to reduce the cost based on the document describing the latest scientific findings of the investigational drug (Attached documents and interview forms are for academic papers, etc.) in lieu of the Investigator's Brochure for the investigational drug. In addition, for investigational drugs other than the investigational drug, the cost should be reduced based on the document describing the latest scientific findings.

イ. The time point considered "predictable/ Expected (Labelled)" should be the date of preparation or revision of the latest Investigator's Brochure or document containing the latest scientific findings.

However, if the sponsor's protocol stipulates that documents notifying the medical institution of cases of adverse reactions etc. should be kept as a separate volume of the Investigator's Brochure or document containing the latest scientific findings, the date of preparation of the notification document can be regarded as the date of revision of the Investigator's Brochure or document containing the latest scientific findings.

The sponsor should fully understand the occurrence trends, such as the number and frequency of the occurrence of the case of an adverse reaction, etc., and appropriately revise whether the occurrence trends can be predicted from the document containing the latest scientific findings in the Investigational Drug Brochure so that there are no errors.

ウ. Even if the latest Investigational Drug Brochure is contained in the document containing the latest scientific findings, the occurrence trends, such as the number and frequency of occurrence, that do not match the contents of the document should be regarded as "Unknown (Un-labelled)."

エ. For investigational products, if no clinical study has been conducted for the application for partial changes in the approved information, such as an additional indication, for the product in the application, the Expectedness should be determined from the adverse events described in the summary of application materials.

オ. For investigational products, the predictability of a clinical trial with the same ingredients as the product for which an application is being filed should be determined based on the adverse events described in the Investigational Product Description in the Application Data Summary and the Investigational Product Description.

カ. For investigational products, long-term treatment studies, etc. continue even after the approval application, and if the long-term treatment studies, etc. are completed before the approval, the basis for judging the predictability will be switched from the Investigational New Drug Summary to the Application Data Summary on the day the completion notification of the long-term treatment study, etc. is submitted.

(2) Causality

Causality should be treated as follows in clinical trial reports.

ア. Cases in which both the investigator and the sponsor deny a causal relationship are subject to favorable reporting.

イ. Cases in foreign countries where the patient is based on information from a person other than a healthcare professional, such as the patient's family member, are not subject to reporting if the sponsor determines that a causal relationship can be denied.

(3) Other matters related to reporting of adverse reactions in clinical trials

ア. Drugs that are already approved in Japan, or in clinical trials for the purpose of applying for partial changes to approved matters, etc., must complete all clinical trials related to the drug concerned, and in the case of preparing or applying for partial changes to approved matters, clinical trials, etc., must immediately report the foreign action report within the reporting deadline when measures, etc., that are considered to affect the content of the application are taken for drugs of the same ingredient marketed in Japan.

イ. Handling of special reporting targets

(ア) Handling of exacerbations of target diseases

① In clinical trials in which fatal or some other serious outcome is used as an efficacy indicator, serious adverse events that are medically difficult to distinguish from exacerbations of target diseases are treated as disease-related events only if a data monitoring committee has been established, and are excluded from emergency reporting as events that are not normally subject to emergency reporting. However, if the data monitoring committee determines, based on accumulated data, that investigational drugs may increase the risk of such a serious outcome, it should be reported promptly.

② When submitting a protocol notification, a document containing the following should be provided: If these matters are described in the protocol, it is not necessary to prepare new documents.

1) Summary of the subject, study drug (The intended indications are efficacy, mechanism of action, development status in Japan and abroad, etc.)
2) Summary of the subject study plan (In the case of a clinical trial conducted in Japan, the number of notifications and the date of notification should also include the expected date of notification.)
3) Scope of events to be treated as disease-related events and rationale for the scope of setting
4) Where similar arrangements have been made with foreign regulatory authorities, details of such arrangements
5) Role of the Data Monitoring Committee

(イ) Handling of adverse reactions caused by narcotics used for non-medical purposes

① Adverse reactions caused by the use of narcotic drugs for non-medical purposes, such as drug abuse, are not subject to emergency reporting only if they are determined in advance between the sponsor of the clinical trial and the Review Planning Division of the Review Management Department of the Agency (PMDA) as events not subject to the usual emergency reporting. However, this does not apply in the event of an unapproved domestic ingredient or an Unknown (Un-labelled).

② A document describing the following should be prepared as a submission for the arrangement, and the Review Planning Division of the Review Management Department of the Institute should be contacted.

1) Outline of the subject, experimental drug (The intended indications are efficacy, mechanism of action, development status in Japan and abroad, etc.)
2) Outline of the subject clinical trial plan (In the case of a clinical trial conducted in Japan, the number of notifications and the date of notification should also include the expected date of notification.)
3) Data related to the use of drugs outside the immediate medical area of drug abuse, etc. and the occurrence of adverse reactions, etc.
4) Scope of events to be handled outside the scope of emergency reporting and the basis for the scope of settings
5) Where similar arrangements have been made with foreign regulatory authorities, the details of such arrangements

ウ. Treatment of the mandatory reporting period

(ア) Mandatory reporting period

① The mandatory reporting period for an investigational drug shall be any period from the first submission of a notification to the submission of a development notification for the investigational drug until approval is obtained. If the submission of a clinical trial notification is not required, it shall be one of the periods from the start date of the study period specified in the clinical trial protocol for the investigational drug to the notification in writing (form free) to the Review Planning Division, Review Management Department (PMDA), that the investigational drug is to be developed until approval is obtained.

② The mandatory reporting period for investigational new drugs other than the investigational drug shall be one of the periods from the date of submission of the notification for the clinical trial using the investigational new drug to the submission of the completion notification for the clinical trial and until the approval of the investigational drug in the clinical trial is obtained. If the submission of a clinical trial notification is not required, the reporting period shall be one of the periods from the start date of the period stated in the clinical trial protocol using the investigational new drug to the completion date of the period until the approval of the investigational drug in the clinical trial is obtained, and until the submission of the development notification for the investigational drug is notified in writing (form free) to the Review Planning Division, Review Management Department of the Organization (PMDA).

(イ) When the development is interrupted for a long period of time, etc.

① When the development is expected to be judged for a long period of time, or when it is expected to take a long time to prepare the answers to the inquiry after the expert consultation, the applicant may notify the Review Planning Division of the Review Management Department of the Agency in writing to that effect and withhold the report until the development is resumed until the submission of the answers to the inquiry. In addition, efforts should be made to collect safety information even when the report of adverse drug reactions (Excluding research reports and foreign action reports.) is withheld, and the information should be reflected in the Investigator's Brochure and the protocol when the development is resumed. In addition, necessary documents should be submitted to the Review Planning Division of the Review Management Department of the Agency when the reporting of adverse drug reactions is resumed with the resumption of development (PMDA).

② Application for Reservation

A document describing the following should be prepared and submitted to the Review Planning Division, Review Management Department (PMDA).

1) The title of the document should be "Application for Withholding Report of Adverse Drug Reactions/Infectious Diseases."

2) The trial ingredient symbol should be included, and the generic name should also be written in parentheses.
3) The number of times that clinical trial notices should be submitted and the date of initial notification of the clinical trial plan should be included.
4) The intended indication should include the effect.
5) Describe the development phase of the clinical trial to be controlled.
6) Describe the specific reason for withholding the report.
7) The following statements should be included: "Efforts will continue to be made to collect information on adverse reactions, etc," "When resuming development, report adverse reactions collected during the period when development was suspended," and "Contact the Review Planning Division of the Review Management Department of the Agency in advance if development (PMDA) is to be resumed."
8) Describe the name and contact information of the person in charge.
9) The address should be "President of the Pharmaceuticals and Medical Devices Agency."

(ウ) Submission when resuming development

When resuming development, release the reservations and (I) resume reporting of effects, etc. In doing so, prepare a document describing the following and submit it to the Review Planning Division of the Review Management Department of the Agency.

① The title should be "Application for Releasing Reservation to Report Adverse Drug Reactions and Infectious Diseases" and state the reason for the reservation, the period of the reservation, and the reason for the release of the reservation.

② Form 1 and Form 2 and the Clinical Trial Safety Update Report (DSUR) in the section entitled (Notification No. 14 0831 of the Evaluation and Licensing Division, Pharmaceutical and Pharmacological Evaluation and Licensing Division, the Ministry of Health, Labour and Welfare, dated August 31, 2020) should be submitted.

③ The Investigator's Brochure, etc., prepared based on the information collected during the retention period should be the protocol and the revised portion of the application data summary should be the corresponding portion.

エ. e. For reporting categories DA, DB, DC and DD, all suspected drugs should be reported in one report, even when multiple investigational drugs are used and each is a suspected drug.

Reporting categories DE, DF, and DG should be reported for each investigational ingredient symbol of the main investigational drug.

オ. For a drug that has already been approved in Japan, when a person other than the person approved for the drug is acting as the in-country supervisor of the clinical trial and is conducting a clinical trial for the application of partial changes in the indication and dosage and administration, and information is shared appropriately between the two parties, it is acceptable for the person approved to submit a case report of an effect, etc. However, in advance, a written agreement between the sponsor and the person approved for the reporting of foreign adverse reaction case reports and matters related to information sharing should be prepared and submitted to the Review Planning Division of the Review Management Department of the Organization (PMDA).

In addition, the person approved for the drug should enter "TIKEN" in half-width English characters in the "G.K.11 Other Pharmaceutical Information" column when submitting post-marketing adverse reaction reports for the drug.

カ. If multiple clinical trials are being conducted in Japan by different clinical trial sponsors for the drug in question, it is acceptable to submit a national adverse reaction case report for each trial to the regulatory authorities. However, even in such cases, information should be shared appropriately between the two parties.

the Ministry of Health, Labour and Welfare System Management Data J Item)

別紙１： Exhibit 1

Post-market	AA	Domestic Infectious Disease Case Report (post-market)
	AB	Domestic adverse reaction case reports (post-marketing)
	AC	Foreign infection case reports (post-marketing)
	AD	Foreign adverse reaction case reports (post-marketing)
	AE	Infectious disease research reports (post-marketing)
	AF	Adverse drug reaction research reports (post-marketing)
	AG	Reports on measures taken in foreign countries, such as suspension of production, recall and disposal (post-marketing)
	BA	Quasi-drug adverse drug reaction case report
	BB	Cosmetic adverse drug reaction case report
	BC	Quasi-drug research report
	BD	Cosmetic research report
Clinical trial	DA	Domestic infection case report (clinical trial)
	DB	Domestic adverse reaction case report (clinical trial)
	DC	Foreign infectious disease case report (clinical trial)
	DD	Foreign adverse reaction case report (clinical trial)
	DE	Infectious disease research report (clinical trial)
	DF	Adverse drug reaction research reports (clinical trials)
	DG	Reports on measures taken in foreign countries, such as suspension of production, recall and disposal (clinical trials)

Input Condition Symbols

◎	Required Items.
□	Items that may need to be entered depending on the
▲	Items to be entered whenever possible.
■	Items that can be abbreviated.
×	Items that should not be entered

Light blue part: updated in E2B(R3) Guideline on Reiwa 4. 24-June.
Refer to the “Partial Amendments to Postmarketing Adverse Reaction Reporting and Study Adverse Reaction Reporting in Response to E2B (R3) Implementation Guide on 4-Jun-2022”

Element id (R3)	Element Name (R3)	Reporting Classification Uncompleted Report																		Reporting Classification Completed Report																		Withdrawal (Nullificatio		Supplement to entry conditions	Value Allowed related				ACK code: upper 8 digits)					
		Post-marketing											Clinical Trial							Post-marketing										Clinical Trial																					
		AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	DA	DB	DC	DD	DE	DF	DG	AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	DA	DB	DC	DD	DE	DF	DG	PM	CS		Input type	Acceptable value	NullFlavor	Supplement	Item			Sequence number		ACK Supplemental Description
																																												Parent	Child	
J2	J-Item	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–		–			2	00	0	00	00	
J2.1a	Identification Number Reporting Classification)	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	Special notes on additional reporting from R2: Enter the value of old J. 4 a after changing it to the appropriate value of J 2.1 a.	Code List	CL_J2.1a			2	01	0	00	00	
J2.1a[Ver]	Identification number (reporting	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	5			2	02	0	00	00	
J2.1b	Identification number number)	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	Special notes on initial report: Do not enter this data item when reporting as an initial report. Determine whether to make an initial report or an additional report based on the presence or absence of input.)	NUM	8		Enter eight digits, even if the first character starts with zero.	2	03	0	00	00	
J2.2.1	Initial date of reporting	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		Date (minimum precision)	CCYYMMDD			2	04	0	00	00	
J2.2.2	Comments on the reporting date	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	▲	▲	Special notes on initial report: If C. 1.4 and J 2.2.1 are different in the initial report, they should be entered. Comparisons between Hong C. 1.4 and J 2.2.1 should be made with accuracy up to CCYYMMD D.	TXT	10000			2	05	0	00	00	
J2.3	Immediate reporting flag	□	□	□	X	X	X	□	X	X	X	X	X	X	X	X	X	X	X	□	□	□	X	X	X	□	X	X	X	X	X	X	X	X	X	X	▲	▲		Code List	CL_J2.3			2	06	0	00	00	
J2.3[Ver]	Immediate report flag - CodeSystemVersion	□	□	□	X	X	X	□	X	X	X	X	X	X	X	X	X	X	X	□	□	□	X	X	X	□	X	X	X	X	X	X	X	X	X	X	▲	▲		TXT	5			2	07	0	00	00	
J2.7.1	Completion, Incomplete Classification	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		List	active completed			2	08	0	00	00	
J2.7.2	Unfinished Comments	□	□	■	■	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	■	■	□	□	□	□	□	□	□	□	□	□	□	□	□	▲	▲	Even if it is possible to make a brief statement, the explanation should be made available in the event of an inquiry from the PMDA.	TXT	10000		When making a brief statement, enter "Omitted."	2	09	0	00	00	
J2.8.1	Unreported Flags	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲	Special notes on initial report: Do not enter this data item when reporting as an initial report.	Code List	CL_J2.8.1			2	10	0	00	00	
J2.8.1[Ver]	Non-reporting flag - CodeSystemVersion	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		TXT	5			2	11	0	00	00	
J2.8.2	Reasons not covered by the report	□	□	■	■	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	■	■	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲	Even if it is possible to make a brief statement, the explanation should be made available in the event of an inquiry from the PMDA.	TXT	10000		When making a brief statement, enter "Omitted."	2	12	0	00	00	
J2.9	Retrospective investigation of infectious	◎	X	◎	X	X	X	X	X	X	X	X	◎	X	◎	X	X	X	X	◎	X	◎	X	X	X	X	X	X	X	X	◎	X	◎	X	X	X	X	▲	▲		TXT	10000			2	13	0	00	00	
J2.10	Future measures	▲	▲	■	■	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	◎	◎	■	■	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲	Brief description is allowed, but only if the reporting deadline is 30 days (except for cases determined to be known based on descriptions in Other adverse reactions) or for AC or AD.	TXT	10000		For abbreviated descriptions, enter "No special mention."	2	14	0	00	00	
J2.11	Other References, etc.	▲	▲	■	■	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	◎	◎	■	■	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲	Brief description is allowed, but only if the reporting deadline is 30 days (except for cases determined to be known based on descriptions in Other adverse reactions) or for AC or AD.	TXT	10000		For abbreviated entries, enter "already included in package insert," etc.	2	15	0	00	00	
J2.12	Study ingredient symbol	X	X	X	X	X	X	X	X	X	X	X	◎	◎	◎	◎	◎	◎	◎	X	X	X	X	X	X	X	X	X	X	X	◎	◎	◎	◎	◎	◎	◎	▲	▲		TXT	70			2	16	0	00	00	
J2.13	Outline of the trial Repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–		–			2	17	0	00	00	
J2.13.r.1	Number of notifications	X	X	X	X	X	X	X	X	X	X	X	▲	▲	▲	▲	▲	▲	▲	X	X	X	X	X	X	X	X	X	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲		NUM	2			2	18	0	01～	00	
J2.13.r.2	Target disease	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□	□	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□	□	▲	▲		TXT	1000			2	19	0	01～	00	
J2.13.r.3	Development Minister	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□	□	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□	□	▲	▲		Code List	CL_J2.13.r.3			2	20	0	01～	00	
J2.13.r.3[Ver]	Development phase - CodeSystemVersion	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□	□	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□	□	▲	▲		TXT	5			2	21	0	01～	00	
J2.13.r.4	Presence or absence of cases on medication	X	X	X	X	X	X	X	X	X	X	X	◎	◎	◎	◎	◎	◎	◎	X	X	X	X	X	X	X	X	X	X	X	◎	◎	◎	◎	◎	◎	◎	▲	▲		Boolean	TRUE/FALSE			2	22	0	01～	00	
J2.16	Key points of the report	X	X	X	X	◎	◎	◎	X	X	◎	◎	X	X	X	X	◎	◎	◎	X	X	X	X	◎	◎	◎	X	X	X	X	◎	◎	◎	◎	◎	◎	◎	▲	▲		TXT	500			2	23	0	00	00	
J2.18.1	Recipient organization name	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲		TXT	100		Enter "Pharmaceuticals and Medical Devices Agency." as "PMDA"	2	24	0	00	00	
J2.18.2	Recipient Title	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲		TXT	100		Enter "Chairperson."	2	25	0	00	00	
J2.18.3	Recipient surname	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲		TXT	100		Enter the last name of the	2	26	0	00	00	
J2.18.4	Recipient name	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲		TXT	100		Enter the name of the director of	2	27	0	00	00	
J2.19	Remark 1	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	▲	▲		TXT	10000			2	28	0	00	00	
J2.20	Remark 2	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	▲	▲		TXT	10000			2	29	0	00	00	
J2.21	Remark 3	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	▲	▲		TXT	10000			2	30	0	00	00	
J2.22	Remark 4	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	▲	▲		TXT	10000			2	31	0	00	00	
C.2.r.2	Address and telephone number of reporter	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–		–			3	33	0	01～	00	

the Ministry of Health, Labour and Welfare System Management Data Item J-Item)

別紙１： Exhibit 1

Element id (R3)	Element Name (R3)	Reporting Classification Uncompleted Report																		Reporting Classification Completed Report																		Withdrawal (Nullificatio		Supplement to entry conditions	Value Allowed Related				ACK Code (upper 8 digits)				
		Post-marketing										Clinical Trial								Post-marketing										Clinical Trial								PM	CS		Input type	Value Allowed	NullFlavor	Supplement	Item			Sequence number		ACK Supplemental Description
		AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	DA	DB	DC	DD	DE	DF	DG	AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	DA	DB	DC	DD	DE	DF	DG								Parent	Child	
J2.29.r	Source of information	X	X	X	X	X	X	X	◎	◎	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	◎	◎	X	X	X	X	X	X	X	X	▲	▲		Code List	CL_J2.29.r			3	42	1	01～	00	
J2.29.r[Ver]	Source 1 CodeSystemVersion	X	X	X	X	X	X	X	◎	◎	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	◎	◎	X	X	X	X	X	X	X	X	▲	▲		TXT	5			3	43	2	01～	00	
J2.27.r	Date Flags	X	X	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	▲	▲		Code List	CL_J2.27.r			2	44	1	01～	00	
J2.27.r[Ver]	date flag CodeSystemVersion	X	X	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	▲	▲		TXT	5			2	44	2	01～	00	
C.4.r	Citation Repeat as needed)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			3	64	0	01～	00	
J2.15.r	State of publication	X	X	X	X	◎	◎	◎	X	X	◎	◎	X	X	X	X	◎	◎	◎	X	X	X	X	◎	◎	◎	X	X	◎	◎	X	X	X	X	◎	◎	◎	▲	▲		Code List	ISO 3166-1(alpha_2)+EU		Some reporting classifications do not allow "EU." For details, please refer to "Rules for checking items on the SKW site."	2	32	0	01～ 99	00	
J2.17.r	Classification of tests/studies	X	X	X	X	◎	◎	X	X	X	◎	◎	X	X	X	X	◎	◎	X	X	X	X	X	◎	◎	X	X	X	◎	◎	X	X	X	X	◎	◎	X	▲	▲		List	1 2			2	33	0	01～	00	
D.2.2	Age at onset of reaction/event	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			4	09	0	00	00	
J2.28	Pregnancy or not	X	X	X	X	X	X	X	▲	▲	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	▲	▲	X	X	X	X	X	X	X	X	▲	▲		Code List	CL_J2.28	UNK,NA,ASKU,NASK		4	19	1	00	00	
J2.28[Ver]	Pregnancy Status - CodeSystemVersion	X	X	X	X	X	X	X	▲	▲	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	▲	▲	X	X	X	X	X	X	X	X	▲	▲		TXT	5			4	19	2	00	00	
E.i	Adverse reactions/events Repeat as needed)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			5	00	0	01～	00	
J2.14.i	unknown known	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	X	X	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲	If there is only one suspected drug, entry is mandatory.	Code List	CL_J2.14.i			2	34	0	01～ 99	00	
J2.14.i[Ver]	Unknown one CodeSystemVersion	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	X	X	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	5			2	35	0	01～	00	
J2.26.i	Seriousness, etc.	X	X	X	X	X	X	X	◎	◎	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	◎	◎	X	X	X	X	X	X	X	X	▲	▲		Code List	CL_J2.26.i			2	35	1	01～	00	
J2.26.i[Ver]	Severity etc. -CodeSystemVersion	X	X	X	X	X	X	X	◎	◎	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	◎	◎	X	X	X	X	X	X	X	X	▲	▲		TXT	5			2	35	2	01～	00	
G	Pharmaceuticals	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			7	00	0	00	00	
G.k	Drug information Repeat as needed)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			7	01	0	01～	00	
J2.4.k	Status classification of new drugs, etc.	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲	"◎" must be entered at least once in a repetition. Not all repetitions require input.) Also, if the reporting classification is clinical trial, the entry must be made in the first repetition.	Code List	CL_J2.4.k			2	36	0	01～ 99	00	
J2.4.k[Ver]	Status classification of new drugs, etc. -	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲		TXT	5			2	37	0	01～	00	
J2.5.k	Risk Categories, etc. for Over-the-Counter	□	□	□	□	□	□	□	X	X	X	X	▲	▲	▲	▲	▲	▲	▲	□	□	□	□	□	□	□	X	X	X	X	▲	▲	▲	▲	▲	▲	▲		Code List	CL_J2.5.k			2	38	0	01～	00	
J2.5.k[Ver]	Risk Categories for Over-the-Counter Drugs, etc. - CodeSystemVersion	□	□	□	□	□	□	□	X	X	X	X	▲	▲	▲	▲	▲	▲	▲	□	□	□	□	□	□	□	X	X	X	X	▲	▲	▲	▲	▲	▲	▲		TXT	5			2	39	0	01～ 99	00	
J2.6.k	Access to OTC drugs	□	□	□	□	□	□	□	X	X	X	X	▲	▲	▲	▲	▲	▲	▲	□	□	□	□	□	□	□	X	X	X	X	▲	▲	▲	▲	▲	▲	▲		Code List	CL_J2.6.k	ASKU,UNK		2	40	0	01～ 99	00	
J2.6.k[Ver]	Access to OTC drugs - CodeSystemVersion	□	□	□	□	□	□	□	X	X	X	X	▲	▲	▲	▲	▲	▲	▲	□	□	□	□	□	□	□	X	X	X	X	▲	▲	▲	▲	▲	▲	▲		TXT	5			2	41	0	01～ 99	00	
G.k.2	Drug identification																				–																			-			7	11	0	01～	00	
J2.23.k	Nickname	X	X	X	X	X	X	X	▲	▲	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	▲	▲	X	X	X	X	X	X	X	X	▲	▲		TXT	100			7	12	1	01～	00	
J2.24.k	Product type	X	X	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	▲	▲		Code List	CL_J2.24.k			7	12	2	01～	00	
J2.24.k[Ver]	Product type - CodeSystemVersion	X	X	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	▲	▲		TXT	5			7	12	3	01～	00	
G.k.2.3.r	Ingredient/Specific ingredient identifier and content Repeat as needed)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–						7	13	0	01～ 99	01～ 99	Represent parent = k child = r.
J2.25.k.r	Classification of ingredients	X	X	X	X	X	X	X	□	□	□	□	X	X	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	X	X	X	X	X	X	▲	▲		Code List	CL_J2.25.k.r			7	14	1	01～ 99	01～ 99	Represent parent = k child = r.
J2.25.k.r[Ver]	Component Division - CodeSystemVersion	X	X	X	X	X	X	X	□	□	□	□	X	X	X	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	X	X	X	X	X	X	▲	▲		TXT	5			7	14	2	01～ 99	01～ 99	Represent parent = k child = r.

別紙 2： Exhibit 2

Individual case safety report data item E2B (R3) item)

Based on the "ICH E2B Implementation Working Group: Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs)
E2B(R3) Data Elements and Message Specification Version 5.02, 10 November 2016"

Input Condition Symbols

◎	Required Items.
□	Items that may need to be entered depending on the
▲	Items to be entered whenever possible.
■	Items that can be abbreviated.
×	Items that should not be entered

Data Item (R3)	Element Name (R3)	Reporting Classification Uncompleted Report																			Reporting Classification Completed Report																			Withdrawal (Nullification)		Supplement to entry conditions	Value Allowed Related				ACK Code (upper 8 digits)					
		Post-marketing											Clinical Trial								post-marketing											Clinical Trial																								
		AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	DA	DB	DC	DD	DE	DF	DG	AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	DA	DB	DC	DD	DE	DF	DG	PM	CS		Input type	Value Allowed	NullFlavor	Supplemental	Item			Sequence number		ACK Supplemental Description
																																														Parent	Parent	
N.1	ICH ICSR Transmission Identification (batch wrapper)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–		-			1	00	0	00	00	
N.1.1	Types of Messages in	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲		Code List	E2B_CL1			1	01	0	00	00	
N.1.1[Ver]	Types of Messages in Batch - CodeSystemVersion	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲		TXT	5			1	02	0	00	00	
N.1.2	Batch number	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	100		Enter a company-specific case report number.	1	03	0	00	00	
N.1.3	Batch Sender Identifier	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	60		Enter the Sender ID.	1	04	0	00	00	
N.1.4	Batch Recipient Identifier	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	60		Type "PMDA"	1	05	0	00	00	
N.1.5	Date of the Batch Transmission	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		Date (minimum precision)	CCYYMMDDhhmmss			1	06	0	00	00	
N.2.r	ICH ICSR Message Header (message wrapper) (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–		-			1	07	0	0000～	9999	The last four digits of the eight digits are tied to the string without separating them into parent and child.
N.2.r.1	Message Identifier	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	100		C. 1.1 Enter the safety report identifier.	1	08	0	0000～	9999	The last four digits of the eight digits are tied to the string without separating them into parent and child.
N.2.r.2	Message Sender Identifier	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	60		Enter the Sender ID.	1	09	0	0000～	9999	The last four digits of the eight digits are tied to the string without separating them into parent and child.
N.2.r.3	Message Receiver Identifier	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	60		Type "PMDA"	1	10	0	0000～	9999	The last four digits of the eight digits are tied to the string without separating them into parent and child.
N.2.r.4	Date of Message Creation	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		Date (minimum precision)	CCYYMMDDhhmmss			1	11	0	0000～	9999	The last four digits of the eight digits are tied to the string without separating them into parent and child.
C.1	Identification of the Case Safety Report	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–		-			3	00	0	00	00	
C.1.1	Sender's (case) Safety Report Unique Identifier	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	Special notes on initial report: Enter a safety report identifier that has not been used in the past.	TXT	100		Primary source country code - sender identifier - company specific case report number '.	3	01	0	00	00	
C.1.2	Date of Creation	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		Date (minimum precision)	CCYYMMDDhhmmss			3	02	0	00	00	
C.1.3	Type of Report	◎	◎	◎	◎	◎	◎	◎	X	X	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	X	X	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲		Code List	E2B_CL2			3	03	0	00	00	
C.1.3[Ver]	Type of Report - CodeSystemVersion	◎	◎	◎	◎	◎	◎	◎	X	X	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	X	X	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲		TXT	5			3	04	0	00	00	
C.1.4	Date Report Was First Received from Source	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲		Date (minimum precision)	CCYYMMDD			3	05	0	00	00	
C.1.5	Date of Most Recent Information for This Report	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲		Date (minimum precision)	CCYYMMDD			3	06	0	00	00	
C.1.6	Additional Available Documents Held by Sender	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–		-			3	07	0	00	00	
C.1.6.1	Are Additional Documents Available?	◎	◎	◎	◎	□	□	□	◎	◎	□	□	◎	◎	◎	◎	□	□	□	◎	◎	◎	◎	□	□	□	◎	◎	□	□	◎	◎	◎	◎	□	□	□	▲	▲	If the reporting category is AE-AG, BC, BD or DE-DG, the information should be entered when the package insert is attached.	Boolean	TRUE/FALSE			3	08	0	00	00	
C.1.6.1.r	Documents Held by Sender (repeat as	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–		-			3	09	0	01～	00	
C.1.6.1.r.1	Documents Held by Sender	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	▲	▲	If non-cited documents such as electrocardiograms, X-rays, CIOMS, MedWatch, etc. and package inserts are to be attached, C.1.6.1 should be set to true. C.1.6.1.r.1 should be filled in and C.1.6.1.r.2 should be accompanied by data.	TXT	2000			3	10	0	01～99	00	
C.1.6.1.r.2	Included Documents	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲			Types of media		Enter text or B 64 encoded attachment data. *Example statement: <text mediaType='application/pdf representation='B64'> (Binary data) </text>	3	11	0	01～99	00	
C.1.7	Does This Case Fulfil the Local Criteria for an Expedited Report?	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲	Special notes on the initial report: If the initial report of AC does not contain any adverse event information for which Ei. 3.2 is true, true is not entered.	Boolean	TRUE/FALSE		The use of NullFlavor NI is also prohibited because we do not assume cases where A.1.9 is not reported in R2.	3	12	0	00	00	
C.1.8	Worldwide Unique Case Identification	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–		-			3	13	0	00	00	
C.1.8.1	Worldwide Unique Case Identification Number	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	100			3	14	0	00	00	
C.1.8.2	First Sender of This Case	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		Code List	E2B_CL3			3	15	0	00	00	
C.1.8.2[Ver]	First Sender of This Case - CodeSystemVersion	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	5			3	16	0	00	00	
C.1.9	Other Case Identifiers	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–		-			3	17	0	00	00	
C.1.9.1	Other Case Identifiers in Previous Transmission	◎	◎	◎	◎	◎	◎	◎	X	X	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	X	X	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲		Boolean	TRUE	NI		3	18	0	00	00	

Individual case safety report data item E2B (R3) item)

別紙 2： Exhibit 2

Element id (R3)	Element Name (R3)	Reporting Classification Uncompleted Report																		Reporting Classification Completed Report																		Withdrawal (Nullificatio		Supplement to entry conditions	Value Allowed related				ACK Code (upper 8 digits)				
		Post-marketing											Clinical Trial							Post-marketing									Clinical Trial																						
		AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	DA	DB	DC	DD	DE	DF	DG	AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	DA	DB	DC	DD	DE	DF	DG	PM	CS		Input type	Value Allowed	NullFlavor	Supplemental	Item			Sequence number		ACK Supplemental Description
																																													Parent	Child	
C.1.9.1.r	Other Case Identifiers (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			3	19	0	01～	00	
C.1.9.1.r.1	Other Case Identifiers in Previous	□	□	□	□	□	□	□	X	X	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	X	X	□	□	□	□	□	□	□	□	▲	▲		TXT	100			3	20	0	01～	00	
C.1.9.1.r.2	Case Identifier	□	□	□	□	□	□	□	X	X	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	X	X	□	□	□	□	□	□	□	□	▲	▲		TXT	100			3	21	0	01～	00	
C.1.10.r	Identification Number of the Report Linked to This Report (repeat as necessary)	▲	▲	▲	▲	▲	▲	▲	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲		TXT	100			3	22	0	01～	00	
C.1.11	Report Nullification / Amendment	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			3	23	0	00	00	
C.1.11.1	Report Nullification/Amendment	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	◎	◎	Special notes on initial report: Do not enter this data item when reporting as an initial report.	Code List	E2B_CL5			3	24	0	00	00	
C.1.11.1[Ver]	Report Nullification/Amendment CodeSystemVersion	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	◎	◎		TXT	5			3	25	0	00	00	
C.1.11.2	Reason for Nullification/Amendment	□	□	■	■	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	■	■	□	□	□	□	□	□	□	□	□	□	□	□	□	◎	◎	Even if it is possible to make a brief statement, the explanation should be made available in the event of an inquiry from the PMDA.	TXT	2000		When making a brief statement, enter "Omitted."	3	26	0	00	00	
C.2.r	Primary Source(s) (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			3	27	0	01～	00	
C.2.r.1	Reporter's Name	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			3	28	0	01～	00	
C.2.r.1.1	Reporter's Title	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		TXT	50	MSKU,UNK,ASKU,NASK		3	29	0	01～99	00	
C.2.r.1.2	Reporter's Given Name	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		TXT	60	MSK,ASKU,NASK		3	30	0	01～99	00	
C.2.r.1.3	Reporter's Middle Name	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		TXT	60	MSK,ASKU,NASK		3	31	0	01～99	00	
C.2.r.1.4	Reporter's Family Name	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		TXT	60	MSK,ASKU,NASK		3	32	0	01～99	00	
C.2.r.2	Reporter's Address and Telephone	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–						3	33	0	01～	00	
C.2.r.2.1	Reporter's Organisation	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		TXT	60	MSK,ASKU,NASK		3	34	0	01～99	00	
C.2.r.2.2	Reporter's Department	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		TXT	60	MSK,ASKU,NASK		3	35	0	01～99	00	
C.2.r.2.3	Reporter's Street	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		TXT	100	MSK,ASKU,NASK		3	36	0	01～99	00	
C.2.r.2.4	Reporter's City	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		TXT	35	MSK,ASKU,NASK		3	37	0	01～99	00	
C.2.r.2.5	Reporter's State or Province	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		TXT	40	MSK,ASKU,NASK		3	38	0	01～99	00	
C.2.r.2.6	Reporter's Postcode	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		TXT	15	MSK,ASKU,NASK		3	39	0	01～99	00	
C.2.r.2.7	Reporter's Telephone	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		TXT	33	MSK,ASKU,NASK		3	40	0	01～99	00	
C.2.r.3	Reporter's Country Code	□	□	□	□	◎	◎	◎	X	X	◎	◎	□	□	□	□	◎	◎	◎	□	□	□	□	◎	◎	◎	X	X	◎	◎	□	□	□	□	◎	◎	◎	▲	▲	Research Report (AE AF DE DF BC BD) and Action Report (AGDG) should be noted below. C2.r.3 must be entered. Only once in a repetition.) •NullFlavor shall not be used	Code List	ISO_3166-1(alpha_2)+EU	MSK,UNK,ASKU,NASK		3	41	0	01～99	00	
C.2.r.4	Qualification	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL6	UNK		3	42	0	01～	00	
C.2.r.4[Ver]	Qualification - CodeSystemVersion	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	5			3	43	0	01～	00	
C.2.r.5	Primary Source for Regulatory Purposes	◎	◎	◎	◎	X	X	X	X	X	X	X	◎	◎	◎	◎	X	X	X	◎	◎	◎	◎	X	X	X	X	X	X	X	◎	◎	◎	◎	X	X	X	▲	▲	Used only once in a repetition.	List	1			3	44	0	01～99	00	
C.3	Information on Sender of Case Safety Report	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–						3	45	0	00	00	
C.3.1	Sender Type	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		Code List	E2B_CL7			3	46	0	00	00	
C.3.1[Ver]	Sender type - CodeSystemVersion	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	5			3	47	0	00	00	
C.3.2	Sender's Organisation	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	100		Enter the Sender ID.	3	48	0	00	00	
C.3.3	Person Responsible for Sending the Report	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–						3	49	0	00	00	
C.3.3.1	Sender's Department	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		TXT	60		Enter the sender's department.	3	50	0	00	00	
C.3.3.2	Sender's Title	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	50		Enter "Representative Information - Job Title."	3	51	0	00	00	
C.3.3.3	Sender's Given Name	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	60		Enter "Representative Information - First Name."	3	52	0	00	00	
C.3.3.4	Sender's Middle Name	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲		TXT	60		Enter "Representative Information - Intermediate Name."	3	53	0	00	00	
C.3.3.5	Sender's Family Name	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	60		Enter "Representative Information - Last Name."	3	54	0	00	00	
C.3.4	Sender's Address, Fax, Telephone and E-mail Address	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			3	55	0	00	00	
C.3.4.1	Sender's Street Address	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	100		Enter the Representative's Location.	3	56	0	00	00	
C.3.4.2	Sender's City	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	35		Enter the Representative's Location.	3	57	0	00	00	
C.3.4.3	Sender's State or Province	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	40		Enter the Representative Location.	3	58	0	00	00	
C.3.4.4	Sender's Postcode	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	15			3	59	0	00	00	
C.3.4.5	Sender's Country Code	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		Code List	ISO_3166-			3	60	0	00	00	
C.3.4.6	Sender's Telephone	▲	▲	▲	▲	▲	▲	▲	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲		TXT	33		Main telephone number '.	3	61	0	00	00	
C.3.4.7	Sender's Fax	▲	▲	▲	▲	▲	▲	▲	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲		TXT	33		Enter the "Representative Fax Number."	3	62	0	00	00	
C.3.4.8	Sender's E-mail Address	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		TXT	100			3	63	0	00	00	
C.4.r	Literature Reference(s) (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			3	64	0	01～	00	
C.4.r.1	Literature Reference(s)	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	▲	▲		TXT	500	ASKU,NASK		3	65	0	01～99	00	

Individual case safety report data item E2B (R3) item)

別紙 2： Exhibit 2

Element id (R3)	Element Name (R3)	Reporting Classification Uncompleted Report: Post-marketing AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	Clinical Trial DA	DB	DC	DD	DE	DF	DG	Reporting Classification Completed Report: Post-marketing AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	Clinical Trial DA	DB	DC	DD	DE	DF	DG	Withdrawal (Nullificatio PM	CS	Supplement to entry conditions	Value Allowed related: Input type	Value Allowed	NullFlavor	Supplemental	ACK Code (upper 8 digits): Item			Sequence number: Parent	Child	ACK Supplemental Description
C.4.r.2	Included Documents	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲		Types of media		Enter text., or B 64 encoded attachment data. *Example statement: <text mediaType='application/pdf representation='B64'> (Binary data) </text>	3	66	0	01 99	～00	
C.5	Study Identification	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–		-			3	67	0	00	00	
C.5.1.r	Study Registration (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–		-			3	68	0	01	～00	
C.5.1.r.1	Study Registration Number	▲	▲	▲	▲	▲	▲	▲	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲		TXT	50	ASKU,NASK		3	69	0	01 99	～00	
C.5.1.r.2	Study Registration Country	▲	▲	▲	▲	▲	▲	▲	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲		Code List	ISO_3166-1(alpha_2)+EU	ASKU,NASK		3	70	0	01 99	～00	
C.5.2	Study Name	▲	▲	▲	▲	▲	▲	▲	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲		TXT	2000	ASKU,NASK		3	71	0	00	00	
C.5.3	Sponsor Study Number	▲	▲	▲	▲	▲	▲	▲	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲		TXT	50	ASKU,NASK		3	72	0	00	00	
C.5.4	Study Type Where Reaction(s) / Event(s)	□	□	□	□	□	□	□	X	X	□	□	□	□	□	□	□	□	□	□	□	□	□	□	X	X	□	□	□	□	□	□	□	□	□	□	▲	▲		Code List	E2B_CL8			3	73	0	00	00	
C.5.4[Ver]	Study Type Where Reaction(s) / Event(s) Were Observed - CodeSvstemVersion	□	□	□	□	□	□	□	X	X	□	□	□	□	□	□	□	□	□	□	□	□	□	□	X	X	□	□	□	□	□	□	□	□	□	□	▲	▲		TXT	5			3	74	0	00	00	
D	Patient Characteristics	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			4	00	0	00	00	
D.1	Patient (name or initials)	◎	◎	◎	◎	X	X	X	◎	◎	X	X	◎	◎	◎	◎	X	X	X	◎	◎	◎	◎	X	X	X	◎	◎	X	X	◎	◎	◎	◎	X	X	X	▲	▲		TXT	60	MSK,ASKU,NASK,UNK		4	01	0	00	00	
D.1.1	Patient Medical Record Number(s) and Source(s) of the Record Number (if allowable)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			4	02	0	00	00	
D.1.1.1	Patient Medical Record Number(s) and Source(s) of the Record Number (GP Medical Record Number)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲	No input except NullFlavor	TXT	20	MSK		4	03	0	00	00	
D.1.1.2	Patient Medical Record Number(s) and Source(s) of the Record Number (Specialist Record Number)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲	No input except NullFlavor	TXT	20	MSK		4	04	0	00	00	
D.1.1.3	Patient Medical Record Number(s) and Source(s) of the Record Number (Hospital Record Number)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲	No input except NullFlavor	TXT	20	MSK		4	05	0	00	00	
D.1.1.4	Patient Medical Record Number(s) and Source(s) of the Record Number	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲	No input except NullFlavor	TXT	20	MSK		4	06	0	00	00	
D.2	Age Information	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			4	07	0	00	00	
D.2.1	Date of Birth	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲	No input except NullFlavor	Date (minimum precision)	CCYYMMDD	MSK		4	08	0	00	00	
D.2.2	Age at Time of Onset of Reaction / Event	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			4	09	0	00	00	
D.2.2a	Age at Time of Onset of Reaction / Event	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		NUM	5			4	10	0	00	00	
D.2.2b	Age at Time of Onset of Reaction / Event (unit)	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL26b		Limited UCUM: 10 a	4	11	0	00	00	
D.2.2.1a	Gestation Period When Reaction / Event Was Observed in the Foetus (number)	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		NUM	3			4	12	0	00	00	
D.2.2.1b	Gestation Period When Reaction/Event Was Observed in the Foetus (unit)	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL26g		Limited UCUM: trimester}	4	13	0	00	00	
D.2.3	Patient Age Group (as per reporter)	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL9			4	14	0	00	00	
D.2.3[Ver]	Patient Age Group (as per reporter) - CodeSvstemVersion	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		TXT	5			4	15	0	00	00	
D.3	Body Weight (kg)	▲	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲		NUM	6			4	16	0	00	00	
D.4	Height (cm)	▲	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲		NUM	3			4	17	0	00	00	
D.5	Sex	□	□	□	□	X	X	X	▲	▲	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	▲	▲	X	X	□	□	□	□	X	X	X	▲	▲		List	12	UNK,ASKU,NASK,MSK	Foreign cases (AC AD DC DD) are prohibited from using MSK.	4	18	0	00	00	
D.6	Last Menstrual Period Date	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Date (minimum precision)	CCYY	MSK	Foreign cases (AC AD DC DD) are prohibited from using MSK	4	19	0	00	00	
D.7	Relevant Medical History and Concurrent Conditions (not including reaction / event)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			4	20	0	00	00	
D.7.1.r	Structured Information on Relevant Medical History (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			4	21	0	01 99	～00	
D.7.1.r.1a	MedDRA Version for Medical History	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		TXT	4		MedDRA Version '. Only "numbers' and "." are available.	4	22	0	01 99	～00	
D.7.1.r.1b	Medical History (disease / surgical procedure / etc.) (MedDRA code)	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		NUM	8			4	23	0	01 99	～00	
D.7.1.r.2	Start Date	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Date (minimum precision)	CCYY	ASKU,NASK,MSK	Foreign cases (AC AD DC DD) are prohibited from using MSK	4	24	0	01 99	～00	
D.7.1.r.3	Continuing	▲	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Boolean	TRUE/FALSE	ASKU,NASK, MSK,UNK	Foreign cases (AC AD DC DD) are prohibited from using MSK.	4	25	0	01 99	～00	
D.7.1.r.4	End Date	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Date (minimum precision)	CCYY	ASKU, NASK, MSK	Foreign cases (AC AD DC DD) are prohibited from using MSK	4	26	0	01 99	～00	
D.7.1.r.5	Comments	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		TXT	2000			4	27	0	01	～00	
D.7.1.r.6	Family History	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Boolean	TRUE			4	28	0	01	～00	
D.7.2	Text for Relevant Medical History and Concurrent Conditions (not including reaction / event)	▲	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲		TXT	10000	UNK,ASKU,NASK,MSK	Foreign cases (AC AD DC DD) are prohibited from using MSK.	4	29	0	00	00	
D.7.3	Concomitant Therapies	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Boolean	TRUE			4	30	0	00	00	
D.8.r	Relevant Past Drug History (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			4	31	0	01 99	～00	
D.8.r.1	Name of Drug as Reported	□	□	□	□	X	X	X	▲	▲	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	▲	▲	X	X	□	□	□	□	X	X	X	▲	▲		TXT	250	NA		4	32	0	01	～00	
D.8.r.2a	MPID Version Date/Number	X	X	□	□	X	X	X	X	X	X	X	X	X	□	□	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	X	□	□	X	X	X	▲	▲		TXT	250		Tentative until IDMP	4	33	0	01	～00	
D.8.r.2b	Medicinal Product Identifier (MPID)	X	X	□	□	X	X	X	X	X	X	X	X	X	□	□	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	X	□	□	X	X	X	▲	▲		TXT	250		Tentative until IDMP	4	34	0	01	～00	
D.8.r.3a	PhPID Version Date/Number	X	X	□	□	X	X	X	X	X	X	X	X	X	□	□	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	X	□	□	X	X	X	▲	▲		TXT	250		Tentative until IDMP	4	35	0	01	～00	
D.8.r.3b	Pharmaceutical Product Identifier (PhPID)	X	X	□	□	X	X	X	X	X	X	X	X	X	□	□	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	X	□	□	X	X	X	▲	▲		TXT	250		Tentative until IDMP	4	36	0	01	～00	
D.8.r.4	Start Date	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Date (minimum precision)	CCYY	ASKU,NASK,MSK	Foreign cases (AC AD DC DD) are prohibited from using MSK	4	37	0	01 99	～00	

Individual case safety report data item E2B (R3) item)

別紙 2： Exhibit 2

Element id (R3)	Element Name (R3)	Reporting Classification Uncompleted Report: Post-marketing AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	Clinical Trial DA	DB	DC	DD	DE	DF	DG	Reporting Classification Completed Report: Post-marketing AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	Clinical Trial DA	DB	DC	DD	DE	DF	DG	Withdrawal (Nullificatio PM	CS	Supplemental information about input conditions	Input type	Value Allowed	NullFlavor	Supplemental	ACK Code (upper 8 digits) Item			Sequence number Parent	Child	ACK Supplemental Description
D.8.r.5	End Date	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Date (minimum precision)	CCYY	ASKU,NASKMSK	Foreign cases (AC AD DC DD) are prohibited from using MSK.	4	38	0	01～99	00	
D.8.r.6a	MedDRA Version for Indication	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	4		MedDRA Version '. Only "numbers' and "." are available.	4	39	0	01～99	00	
D.8.r.6b	Indication (MedDRA code)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		NUM	8			4	40	0	01～	00	
D.8.r.7a	MedDRA Version for Reaction	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		TXT	4		MedDRA Version '. Only "numbers' and "." are available.	4	41	0	01～99	00	
D.8.r.7b	Reaction (MedDRA code)	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		NUM	8			4	42	0	01～	00	
D.9	In Case of Death	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–						4	43	0	00	00	
D.9.1	Date of Death	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	□	□	□	□	X	X	X	X	X	X	▲	▲		Date (minimum precision)	CCYY	ASKU,NASKMSK	Foreign cases (AC AD DC DD) are prohibited from using MSK.	4	44	0	00	00	
D.9.2.r	Reported Cause(s) of Death (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			4	45	0	01～99	00	
D.9.2.r.1a	MedDRA Version for Reported Cause(s) of Death	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	4		MedDRA Version '. Only "numbers' and "." are available.	4	46	0	01～99	00	
D.9.2.r.1b	Reported Cause(s) of Death (MedDRA code)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		NUM	8			4	47	0	01～	00	
D.9.2.r.2	Reported Cause(s) of Death (free text)	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		TXT	250			4	48	0	01～	00	
D.9.3	Was Autopsy Done?	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		Boolean	TRUE/FALSE	UNK,ASKU,NASK		4	49	0	00	00	
D.9.4.r	Autopsy-determined Cause(s) of Death	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			4	50	0	01～	00	
D.9.4.r.1a	MedDRA Version for Autopsy-determined Cause(s) of Death	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	4		MedDRA Version '. Only "numbers' and "." are available.	4	51	0	01～99	00	
D.9.4.r.1b	Autopsy-determined Cause(s) of Death	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		NUM	8			4	52	0	01～	00	
D.9.4.r.2	Autopsy-determined Cause(s) of Death (free	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		TXT	250			4	53	0	01～	00	
D.10	For a Parent-Child / Foetus Report, Information Concerning the Parent	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			4	54	0	00	00	
D.10.1	Parent Identification	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		TXT	60	MSK,UNK,ASKU,ASK		4	55	0	00	00	
D.10.2	Parent Age Information	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			4	56	0	00	00	
D.10.2.1	Date of Birth of Parent	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X		Date (minimum precision)	CCYY	MSK,ASKU,NASK		4	57	0	00	00	
D.10.2.2	Age of Parent	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			4	58	0	00	00	
D.10.2.2a	Age of Parent (number)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		NUM	3			4	59	0	00	00	
D.10.2.2b	Age of Parent (unit)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL26a		Limited UCUM: 10 a	4	60	0	00	00	
D.10.3	Last Menstrual Period Date of Parent	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Date (minimum precision)	CCYY	ASKU,NASK,MSK	Foreign cases (AC AD DC DD) are prohibited from using MSK.	4	61	0	00	00	
D.10.4	Body Weight (kg) of Parent	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		NUM	6			4	62	0	00	00	
D.10.5	Height (cm) of Parent	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		NUM	3			4	63	0	00	00	
D.10.6	Sex of Parent	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		List	12	UNK,ASKU,NASK,MSK	Foreign cases (AC AD DC DD) are prohibited from using MSK.	4	64	0	00	00	
D.10.7	Relevant Medical History and Concurrent Conditions of Parent	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			4	65	0	00	00	
D.10.7.1.r	Structured Information of Parent (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			4	66	0	01～99	00	
D.10.7.1.r.1a	MedDRA Version for Medical History	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	4		MedDRA Version '. Only "numbers' and "." are available.	4	67	0	01～99	00	
D.10.7.1.r.1b	Medical History (disease / surgical procedure / etc.) (MedDRA code)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		NUM	8			4	68	0	01～	00	
D.10.7.1.r.2	Start Date	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Date (minimum precision)	CCYY	ASKU,NASK,MSK	Foreign cases (AC AD DC DD) are prohibited from using MSK.	4	69	0	01～99	00	
D.10.7.1.r.3	Continuing	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Boolean	TRUE/FALSE	ASKU,NASK,MSK,UNK	Foreign cases (AC AD DC DD) are prohibited from using MSK.	4	70	0	01～99	00	
D.10.7.1.r.4	End Date	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Date (minimum precision)	CCYY	ASKU,NASK,MSK	Foreign cases (AC AD DC DD) are prohibited from using MSK.	4	71	0	01～99	00	
D.10.7.1.r.5	Comments	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		TXT	2000			4	72	0	01～99	00	
D.10.7.2	Text for Relevant Medical History and	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		TXT	10000			4	73	0	00	00	
D.10.8.r	Relevant Past Drug History of Parent (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–						4	74	0	01～99	00	
D.10.8.r.1	Name of Drug as Reported	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		TXT	250			4	75	0	01～	00	
D.10.8.r.2a	MPID Version Date/Number	X	X	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	X	X	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	250		Tentative until IDMP specifications are finalized	4	76	0	01～99	00	
D.10.8.r.2b	Medicinal Product Identifier (MPID)	X	X	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	X	X	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	250		Tentative until IDMP specifications are	4	77	0	01～	00	
D.10.8.r.3a	PhPID Version Date/Number	X	X	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	X	X	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	250		Tentative until IDMP specifications are	4	78	0	01～	00	
D.10.8.r.3b	Pharmaceutical Product Identifier (PhPID)	X	X	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	X	X	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	250		Tentative until IDMP specifications are	4	79	0	01～	00	
D.10.8.r.4	Start Date	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Date (minimum precision)	CCYY	ASKU,NASK,MSK	Foreign cases (AC AD DC DD) are prohibited from using MSK.	4	80	0	01～99	00	
D.10.8.r.5	End Date	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Date (minimum precision)	CCYY	ASKU,NASK,MSK	Foreign cases (AC AD DC DD) are prohibited from using MSK.	4	81	0	01～99	00	
D.10.8.r.6a	MedDRA Version for Indication	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	4		MedDRA Version '. Only "numbers' and "." are available.	4	82	0	01～99	00	
D.10.8.r.6b	Indication (MedDRA code)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		NUM	8			4	83	0	01～	00	
D.10.8.r.7a	MedDRA Version for Reaction	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	4		MedDRA Version '. Only "numbers' and "." are available.	4	84	0	01～99	00	
D.10.8.r.7b	Reactions (MedDRA code)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		NUM	8			4	85	0	01～	00	
E.i	Reaction(s)/Event(s) (repeat as necessary)																																														5	00	0	01～	00	
E.i[EID]	Reaction(s)/Event(s) (repeat as necessary) [EID]	◎	◎	◎	◎	X	X	X	◎	◎	X	X	◎	◎	◎	◎	X	X	X	◎	◎	◎	◎	X	X	X	◎	◎	X	X	◎	◎	◎	◎	X	X	X	□	□		UUID	40		Enter values that are unique in the report.	5	01	0	01～99	00	
E.i.1	Reaction / Event as Reported by the Primary Source	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–						5	02	0	01～99	00	
E.i.1.1a	Reaction / Event as Reported by the Primary Source in Native Language	□	□	■	■	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	■	■	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲	Only MedDRA-coded terms may be entered.	TXT	250			5	03	0	01～99	00	
E.i.1.1b	Reaction / Event as Reported by the Primary Source Language	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲	Only MedDRA-coded terms may be entered. Required if entered in E.i.1.1a.	Code List	ISO 639-2 RA(alpha-3)			5	04	0	01～99	00	

Individual Case Safety Report Data Item E2B (R3) Item)

別紙 2： Exhibit 2

Data Item (R3)	Element Name (R3)	Reporting Classification Uncompleted Report																		Reporting Classification Completed Report																		Withdrawal (Nullificatio		Supplement to entry conditions	Value Allowed related				ACK Code (upper 8 digits)					
		Post-marketing											Clinical Trial							post-marketing											Clinical Trial																					
		AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	DA	DB	DC	DD	DE	DF	DG	AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	DA	DB	DC	DD	DE	DF	DG	PM	CS		Input type	Value Allowed	NullFlavor	Supplemental	Item			Sequence number		ACK Supplemental Description
																																													Parent	Child	
E.i.1.2	Reaction / Event as Reported by the Primary Source for Translation	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲	Only terms coded in MedDRA may be prefilled. Input required unless E.i.1.lb is jpn eng or null.	TXT	250			5	05	0	01 ～ 99	00	
E.i.2.1a	MedDRA Version for Reaction / Event	◎	◎	◎	◎	X	X	X	□	□	X	X	◎	◎	◎	◎	X	X	X	◎	◎	◎	◎	X	X	X	□	□	X	X	◎	◎	◎	◎	X	X	X	▲	▲		TXT	4		MedDRA Version '. Only "numbers' and "." are available.	5	06	0	01 ～ 99	00	
E.i.2.1b	Reaction / Event (MedDRA code)	◎	◎	◎	◎	X	X	X	□	□	X	X	◎	◎	◎	◎	X	X	X	◎	◎	◎	◎	X	X	X	□	□	X	X	◎	◎	◎	◎	X	X	X	▲	▲		NUM	8			5	07	0	01 ～	00	
E.i.3.1	Term Highlighted by the Reporter	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL10			5	08	0	01 ～	00	
E.i.3.1[Ver]	Term Highlighted by the Reporter CodeSystemVersion	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	5			5	09	0	01 ～ 99	00	
E.i.3.2	Seriousness Criteria at Event Level	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			5	10	0	01 ～	00	
E.i.3.2a	Results in Death	◎	◎	◎	◎	X	X	X	X	X	X	X	◎	◎	◎	◎	X	X	X	◎	◎	◎	◎	X	X	X	X	X	X	X	◎	◎	◎	◎	X	X	X	▲	▲		Boolean	TRUE	NI		5	11	0	01 ～	00	
E.i.3.2b	Life Threatening	◎	◎	◎	◎	X	X	X	X	X	X	X	◎	◎	◎	◎	X	X	X	◎	◎	◎	◎	X	X	X	X	X	X	X	◎	◎	◎	◎	X	X	X	▲	▲		Boolean	TRUE	NI		5	12	0	01 ～	00	
E.i.3.2c	Caused / Prolonged Hospitalisation	◎	◎	◎	◎	X	X	X	X	X	X	X	◎	◎	◎	◎	X	X	X	◎	◎	◎	◎	X	X	X	X	X	X	X	◎	◎	◎	◎	X	X	X	▲	▲		Boolean	TRUE	NI		5	13	0	01 ～	00	
E.i.3.2d	Disabling / Incapacitating	◎	◎	◎	◎	X	X	X	X	X	X	X	◎	◎	◎	◎	X	X	X	◎	◎	◎	◎	X	X	X	X	X	X	X	◎	◎	◎	◎	X	X	X	▲	▲		Boolean	TRUE	NI		5	14	0	01 ～	00	
E.i.3.2e	Congenital Anomaly / Birth Defect	◎	◎	◎	◎	X	X	X	X	X	X	X	◎	◎	◎	◎	X	X	X	◎	◎	◎	◎	X	X	X	X	X	X	X	◎	◎	◎	◎	X	X	X	▲	▲		Boolean	TRUE	NI		5	15	0	01 ～	00	
E.i.3.2f	Other Medically Important Condition	◎	◎	◎	◎	X	X	X	X	X	X	X	◎	◎	◎	◎	X	X	X	◎	◎	◎	◎	X	X	X	X	X	X	X	◎	◎	◎	◎	X	X	X	▲	▲		Boolean	TRUE	NI		5	16	0	01 ～	00	
E.i.4	Date of Start of Reaction / Event	▲	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Date (minimum precision)	CCYY	ASKU,NASK,MSK	Foreign cases (AC AD DC DD) are prohibited from using MSK.	5	17	0	01 ～ 99	00	
E.i.5	Date of End of Reaction / Event	▲	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Date (minimum precision)	CCYY	ASKU,NASK,MSK	Foreign cases (AC AD DC DD) are prohibited from using MSK.	5	18	0	01 ～ 99	00	
E.i.6a	Duration of Reaction / Event (number)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		NUM	5			5	19	0	01 ～	00	
E.i.6b	Duration of Reaction / Event (unit)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL26e		Restricted UCUM	5	20	0	01 ～	00	
E.i.7	Outcome of Reaction / Event at the Time of Last Observation	◎	◎	◎	◎	X	X	X	◎	◎	X	X	◎	◎	◎	◎	X	X	X	◎	◎	◎	◎	X	X	X	◎	◎	X	X	◎	◎	◎	◎	X	X	X	▲	▲		Code List	E2B_CL11			5	21	0	01 ～ 99	00	
E.i.7[Ver]	Outcome of Reaction / Event at the Time of Last Observation - CodeSystemVersion	◎	◎	◎	◎	X	X	X	◎	◎	X	X	◎	◎	◎	◎	X	X	X	◎	◎	◎	◎	X	X	X	◎	◎	X	X	◎	◎	◎	◎	X	X	X	▲	▲		TXT	5			5	22	0	01 ～ 99	00	
E.i.8	Medical Confirmation by Healthcare Professional	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Boolean	TRUE/FALSE			5	23	0	01 ～ 99	00	
E.i.9	Identification of the Country Where the Reaction / Event Occurred	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Code List	ISO_3166-			5	24	0	01 ～ 99	00	
F.r	Results of Tests and Procedures Relevant to the Investigation of the Patient (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			6	00	0	0000 ～	9999	Do not separate into parent and child, but tie the last four digits within the eight digits to the.
F.r.1	Test Date	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		Date (minimum precision)	CCYY	UNK		6	01	0	0000 ～	9999	Do not separate into parent and child, but tie the last four digits within the eight digits to the.
F.r.2	Test Name																				–																					-			6	02	0	01 ～	00	
F.r.2.1	Test Name (free text)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	250			6	03	0	0000 ～	9999	Do not separate into parent and child, but tie the last four digits within the eight digits to the.
F.r.2.2a	MedDRA Version for Test Name	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	4		MedDRA Version '. Numbers are available '.' Earlier.)	6	04	0	0000 ～	9999	Do not separate into parent and child, but tie the last four digits within the eight digits to the.
F.r.2.2b	Test Name (MedDRA code)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		NUM	8			6	05	0	0000 ～	9999	Do not separate into parent and child, but tie the last four digits within the eight digits to the.
F.r.3	Test Result	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			6	06	0	01 ～	00	
F.r.3.1	Test Result (code)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL12			6	07	0	0000 ～	9999	Do not separate into parent and child, but tie the last four digits of the eight digits to the.
F.r.3.1[Ver]	Test Result (code) - CodeSystemVersion	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	5			6	08	0	0000 ～	9999	Do not separate into parent and child, but tie the last four digits within the eight digits to the.
F.r.3.2	Test Result (value / qualifier)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		NUM	50	NINF, PINF	Qualifiers are determined by the XML description format.	6	09	0	0000 ～	9999	Do not separate into parent and child, but tie the last four digits within the eight digits to the.
F.r.3.3	Test Result (unit)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	50		It should be written in standard UCUM format. Reference OID: 2.16.840.1.113883.6.8)	6	10	0	0000 ～	9999	Do not separate into parent and child, but tie the last four digits within the eight digits to the.
F.r.3.4	Result Unstructured Data (free text)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	2000			6	11	0	0000 ～	9999	Do not separate into parent and child, but tie the last four digits within the eight digits to the.
F.r.4	Normal Low Value	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		NUM	50			6	12	0	0000 ～	9999	Do not separate into parent and child, but tie the last four digits within the eight digits to the.
F.r.4[Unit]	Normal Low Value (units)	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		TXT	50		The Unit attribute need not be specified. If specified, enter the unit as in F.r.3.3.	6	13	0	0000 ～	9999	Do not separate into parent and child, but tie the last four digits within the eight digits to the.
F.r.5	Normal High Value	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		NUM	50			6	14	0	0000 ～	9999	Do not separate into parent and child, but tie the last four digits within the eight digits to the.
F.r.5[Unit]	Normal High Value (units)	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		TXT	50		The Unit attribute need not be specified. If specified, enter the unit as in F.r.3.3.	6	15	0	0000 ～	9999	Do not separate into parent and child, but tie the last four digits of the eight digits to.
F.r.6	Comments (free text)	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		TXT	2000			6	16	0	0000 ～	9999	Do not separate into parent and child, but tie the last four digits within the eight digits to the.
F.r.7	More Information Available	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Boolean	TRUE/FALSE			6	17	0	0000 ～	9999	Do not separate into parent and child, but tie the last four digits within the eight digits to the.
G	Drug(s) Information	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			7	00	0	00	00	
G.k	Drug(s) Information (Repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			7	01	0	01～	00	
G.k[MPID]	Drug(s) Information (MPID)	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	□	□		UUID	40		Enter values that are unique in the report.	7	02	0	01～ 99	00	

Individual case safety report data item E2B (R3) item)

別紙 2： Exhibit 2

Element id (R3)	Element Name (R3)	Reporting Classification Uncompleted Report																		Reporting Classification Completed Report																		Withdrawal (Nullificatio		Supplement to entry conditions	Value Allowed Related				ACK Code (upper 8 digits)				
		Post-marketing										Clinical Trial								Post-marketing								Clinical Trial								PM	CS		Input type	Value Allowed	NullFlavor	Supplement	Item			Sequence number Parent	Sequence number Child	ACK Supplemental Description
		AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	DA	DB	DC	DD	DE	DF	DG	AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	DA	DB	DC	DD	DE	DF	DG										
G.k.1	Characterisation of Drug Role	◎	◎	◎	◎	X	X	X	◎	◎	X	X	◎	◎	◎	◎	X	X	X	◎	◎	◎	◎	X	X	X	◎	◎	X	X	◎	◎	◎	◎	X	X	X	□	□	Special notes at the time of withdrawal (Nullification) reporting: If the reporting category is AA-AD, BA, BB, DA-DD, the company's drug (What Has Input in J2.4.k?) that has a G.k.1 of 1 or 3 is used at least once at the time of withdrawal (Nullification) reporting.	Code List	E2B_CL13			7	03	0	01～99	00	
G.k.1[Ver]	Characterisation of Drug Role – CodeSystemVersion	◎	◎	◎	◎	X	X	X	◎	◎	X	X	◎	◎	◎	◎	X	X	X	◎	◎	◎	◎	X	X	X	◎	◎	X	X	◎	◎	◎	◎	X	X	X	□	□		TXT	5			7	04	0	01～99	00	
G.k.1[MPID]	Characterisation of Drug Role (MPID)	◎	◎	◎	◎	X	X	X	◎	◎	X	X	◎	◎	◎	◎	X	X	X	◎	◎	◎	◎	X	X	X	◎	◎	X	X	◎	◎	◎	◎	X	X	X	□	□		UUID	40		Enter values that are unique in the report.	7	05	0	01～99	00	Note that sequence numbers may not be
G.k.2.1	Medicinal Product Unique Identifier / Pharmaceutical Product Unique Identifier	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			7	06	0	01～99	00	
G.k.2.1.1a	MPID Version Date / Number	X	X	□	□	X	X	X	X	X	X	X	X	X	□	□	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	□	□	X	X	X	▲	▲		TXT	250		Tentative until IDMP specifications	7	07	0	01～	00	
G.k.2.1.1b	Medicinal Product Identifier (MPID)	X	X	□	□	X	X	X	X	X	X	X	X	X	□	□	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	□	□	X	X	X	▲	▲		TXT	250		Tentative until IDMP specifications	7	08	0	01～	00	
G.k.2.1.2a	PhPID Version Date/Number	X	X	□	□	X	X	X	X	X	X	X	X	X	□	□	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	□	□	X	X	X	▲	▲		TXT	250		Tentative until IDMP specifications	7	09	0	01～	00	
G.k.2.1.2b	Pharmaceutical Product Identifier (PhPID)	X	X	□	□	X	X	X	X	X	X	X	X	X	□	□	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	□	□	X	X	X	▲	▲		TXT	250		Tentative until IDMP specifications	7	10	0	01～	00	
G.k.2	Drug Identification	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			7	11	0	01～	00	
G.k.2.2	Medicinal Product Name as Reported by the Primary Source	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲	In the case of AC and AD, if case information is attached to the report, it is acceptable to enter only suspected drugs, including other companies' products.	TXT	250			7	12	0	01～99	00	
G.k.2.3.r	Substance / Specified Substance Identifier and Strength (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			7	13	0	01～99	01～99	Represent parent = k child = r.
G.k.2.3.r.1	Substance / Specified Substance Name	□	□	□	□	□	□	□	□	▲	□	□	□	□	□	□	□	□	□	□	□	□	□	□	▲	□	□	□	□	□	□	□	□	□	□	□	▲	▲		TXT	250			7	14	0	01～	01～	Represent parent = k
G.k.2.3.r.2a	Substance/Specified Substance TermID Version Date/Number	X	X	□	□	X	X	X	X	X	X	X	X	X	□	□	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	□	□	X	X	X	▲	▲		TXT	250		Tentative until IDMP specifications are finalized	7	15	0	01～99	01～99	Represent parent = k child = r.
G.k.2.3.r.2b	Substance/Specified Substance TermID	X	X	□	□	X	X	X	X	X	X	X	X	X	□	□	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	□	□	X	X	X	▲	▲		TXT	250		Tentative until IDMP specifications	7	16	0	01～	01～	Represent parent = k
G.k.2.3.r.3a	Strength (number)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		NUM	10			7	17	0	01～	01～	Represent parent = k
G.k.2.3.r.3b	Strength (unit)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL25		Restricted UCUM	7	18	0	01～	01～	Represent parent = k
G.k.2.4	Identification of the Country Where the Drug Was Obtained	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Code List	ISO_3166-			7	19	0	01～99	00	
G.k.2.5	Investigational Product Blinded	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Boolean	TRUE			7	20	0	01～	00	
G.k.3	Holder and Authorisation / Application Number of Drug	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			7	21	0	01～99	00	
G.k.3.1	Authorisation / Application Number	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲		TXT	35			7	22	0	01～	00	
G.k.3.2	Country of Authorisation / Application	□	□	□	□	□	□	□	X	X	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	X	X	□	□	□	□	□	□	□	□	□	▲	▲		Code List	ISO_3166-			7	23	0	01～	00	
G.k.3.3	Name of Holder / Applicant	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲		TXT	60			7	24	0	01～	00	
G.k.4.r	Dosage and Relevant Information (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			7	25	0	01～99	01～99	Represent parent = k child = r.
G.k.4.r.1a	Dose (number)	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		NUM	8			7	26	0	01～	01～	Represent parent = k
G.k.4.r.1b	Dose (unit)	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL25		Limited UCUM: [DF]	7	27	0	01～	01～	Represent parent = k
G.k.4.r.2	Number of Units in the Interval	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		NUM	4			7	28	0	01～	01～	Represent parent = k
G.k.4.r.3	Definition of the Time Interval Unit	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL26c		Restricted UCUM: {cyclical} {unnecessary},[total]	7	29	0	01～99	01～99	Represent parent = k child = r.
G.k.4.r.4	Date and Time of Start of Drug	▲	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Date (minimum precision)	CCYY	ASKU,NASK,MSK	Foreign cases (AC AD DC DD) are prohibited from using MSK	7	30	0	01～99	01～99	Represent parent = k child = r.
G.k.4.r.5	Date and Time of Last Administration	▲	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲		Date (minimum precision)	CCYY	ASKU,NASK,MSK	Foreign cases (AC AD DC DD) are prohibited from using MSK	7	31	0	01～99	01～99	Represent parent = k child = r.
G.k.4.r.6a	Duration of Drug Administration (number)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		NUM	5			7	32	0	01～99	01～99	Represent parent = k child = r.
G.k.4.r.6b	Duration of Drug Administration (unit)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL26e		Limited UCUM	7	33	0	01～	01～	Represent parent = k
G.k.4.r.7	Batch / Lot Number	□	▲	▲	▲	X	X	X	X	X	X	X	◎	▲	▲	▲	X	X	X	□	▲	▲	▲	X	X	X	X	X	X	X	◎	▲	▲	▲	X	X	X	▲	▲		TXT	35			7	34	0	01～	01～	Represent parent = k
G.k.4.r.8	Dosage Text	▲	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲		TXT	2000			7	35	0	01～	01～	Represent parent = k
G.k.4.r.9	Pharmaceutical Dose Form																																								-			7	36	0	01～	01～	Represent parent = k
G.k.4.r.9.1	Pharmaceutical Dose Form (free text)	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		TXT	60	UNK,ASKU,NASK		7	37	0	01～99	01～99	Represent parent = k child = r.
G.k.4.r.9.2a	Pharmaceutical Dose Form TermID Version	X	X	□	□	X	X	X	X	X	X	X	X	X	□	□	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	□	□	X	X	X	▲	▲		TXT	250		Tentative until IDMP specifications	7	38	0	01～	01～	Represent parent = k
G.k.4.r.9.2b	Pharmaceutical Dose Form TermID	X	X	□	□	X	X	X	X	X	X	X	X	X	□	□	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	□	□	X	X	X	▲	▲		TXT	250		Tentative until IDMP specifications	7	39	0	01～	01～	Represent parent = k
G.k.4.r.10	Route of Administration																																							-			7	40	0	01～	01～	Represent parent = k
G.k.4.r.10.1	Route of Administration (free text)	▲	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	▲	▲		TXT	60	UNK,ASKU,NASK		7	41	0	01～99	01～99	Represent parent = k child = r.
G.k.4.r.10.2a	Route of Administration TermID Version Date / Number	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	5		IDMP Tentative Specifications Until Available E2B CL 14 version listed)	7	42	0	01～99	01～99	Represent parent = k child = r.
G.k.4.r.10.2b	Route of Administration TermID	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL14		IDMP Tentative Specifications Until Available	7	43	0	01～99	01～99	Represent parent = k child = r.
G.k.4.r.11	Parent Route of Administration (in case of a parent child / foetus report)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			7	44	0	01～99	01～99	Represent parent = k child = r.
G.k.4.r.11.1	Parent Route of Administration (free text)	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		TXT	60	UNK,ASKU,NASK		7	45	0	01～99	01～99	Represent parent = k child = r.
G.k.4.r.11.2a	Parent Route of Administration TermID Version Date / Number	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	5		IDMP Tentative Specifications Until Available E2B CL 14 version listed)	7	46	0	01～99	01～99	Parent = k Child = r.
G.k.4.r.11.2b	Parent Route of Administration TermID	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL14		IDMP Tentative Specifications Until Available	7	47	0	01～99	01～99	Parent = k Child = r.
G.k.5a	Cumulative Dose to First Reaction (number)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		NUM	10			7	48	0	01～	00	
G.k.5b	Cumulative Dose to First Reaction (unit)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL25		Limited UCUM: [DF]	7	49	0	01～	00	
G.k.6a	Gestation Period at Time of Exposure (number)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		NUM	3			7	50	0	01～99	00	
G.k.6b	Gestation Period at Time of Exposure (unit)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL26g		Limited UCUM: {trimester}	7	51	0	01～	00	
G.k.7.r	Indication for Use in Case (repeat as necessary)																																							-			7	52	0	01～99	01～99	Represent parent = k child = r.
G.k.7.r.1	Indication as Reported by the Primary Source	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	X	X	X	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		TXT	250	UNK,ASKU,NASK		7	53	0	01～99	01～99	Represent parent = k child = r.
G.k.7.r.2a	MedDRA Version for Indication	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	4		MedDRA Version '. Only "numbers' and "." are available.	7	54	0	01～99	01～99	Represent parent = k child = r.
G.k.7.r.2b	Indication (MedDRA code)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		NUM	8			7	55	0	01～	01～	Represent parent = k
G.k.8	Action(s) Taken with Drug	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲	In the case of in-house drugs (What Has Input in J2.4.k?), it is mandatory to report completion.	Code List	E2B_CL15			7	56	0	01～99	00	
G.k.8[Ver]	Action(s) Taken with Drug - CodeSystemVersion	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	5			7	57	0	01～99	00	
G.k.9	Drug-reaction(s) / Event(s) Matrix (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			7	58	0	01～99	00	
G.k.9.i.3.1	Time Interval between Beginning of Drug Administration and Start of Reaction / Event	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			7	59	0	01～99	01～99	Parent = k Child = i.

Individual Case Safety Report Data Item E2B (R3) Item)

別紙 2： Exhibit 2

Element id (R3)	Element Name (R3)	Reporting Classification Uncompleted Report																		Reporting Classification Completed Report																		Withdrawal (Nullificatio		Supplement to entry conditions	Value Allowed related				ACK load (upper 8 digits)					
		After market											Clinical Trial							Post-marketing										Clinical Trial																	
		AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	DA	DB	DC	DD	DE	DF	DG	AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	DA	DB	DC	DD	DE	DF	DG	PM	CS		Input type	Value Allowed	NullFlavor	Supplemental	Item			Sequence number		ACK Supplementary Explanation
																																													Parent	Child	
G.k.9.i.3.1[EID]	Subject reaction/adverse event (reference ID)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□		UUID	40		Enter values that are unique in the report.	7	60	0	01～99	01～99	Parent = k Child = i. Note that due to the configuration of Hong XM L, sequence numbers may not be obtained.
G.k.9.i.3.1a	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		NUM	5			7	61	0	01～99	01～99	Parent = k Child = i.
G.k.9.i.3.1b	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL26e		Limited UCUM	7	62	0	01～99	01～99	Parent = k Child = i.
G.k.9.i.3.2	Time Interval between Last Dose of Drug and Start of Reaction / Event (Repeat as needed)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			7	63	0	01～99	01～99	Parent = k Child = i.
G.k.9.i.3.2[EID]	Target reaction/adverse event (reference ID)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□		UUID	40		Enter values that are unique in the report.	7	64	0	01～99	01～99	Parent = k Child = i. Note that due to the configuration of Hong XM L, sequence numbers may not be obtained.
G.k.9.i.3.2a	Time Interval between Last Dose of Drug and Start of Reaction / Event (number)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		NUM	5			7	65	0	01～99	01～99	Parent = k Child = i.
G.k.9.i.3.2b	Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL26e		Limited UCUM	7	66	0	01～99	01～99	Parent = k Child = i.
G.k.9.i.4	Did Reaction Recur on Re-administration?	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL16			7	67	0	01～99	01～99	Parent = k Child = i.
G.k.9.i.4[Ver]	Did Reaction Recur on Re-administration? - CodeSystemVersion	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	▲	▲		TXT	5			7	68	0	01～99	01～99	Parent = k Child = i.
G.k.9.i.4[EID]	Target reaction/adverse event (reference ID)	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	□	□	X	X	□	□	□	□	X	X	X	□	□		UUID	40		Enter values that are unique in the report.	7	69	0	01～99	01～99	Parent = k Child = i. Note that due to the configuration of Hong XM L, sequence numbers may not be obtained.
G.k.10.r	Additional Information on Drug (coded) (repeat as necessary)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		Code List	E2B_CL17			7	70	0	01～99	01～99	Represent parent = k child = r.
G.k.10.r[Ver]	Additional Information on Drug (coded) (repeat as necessary) - CodeSystemVersion	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	5			7	71	0	01～99	01～99	Represent parent = k child = r.
G.k.11	Additional Information on Drug (free text)	▲	▲	▲	▲	▲	▲	▲	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲	▲	▲	▲	▲	▲	X	X	X	X	▲	▲	▲	▲	X	X	X	▲	▲		TXT	2000			7	72	0	01～99	00	
G.k.9.i	Drug-reaction(s) / Event(s) Matrix (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			7	73	0	01～99	01～99	Parent = k Child = i.
G.k.9.i.1	Reaction(s) / Event(s) Assessed	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			N/A		Not an item entered by the user. Also, Xpath is not provided, so it should not be checked.	7	74	0	01～99	01～99	Parent = k Child = i.
G.k.9.i.2.r	Assessment of Relatedness of Drug to Reaction(s) / Event(s) (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			7	75	0	01～99	01～99	Parent = k Child = i. r does not represent ACK □ -do.
G.k.9.i.2.r[EID]	Drug under evaluation (reference ID for reaction/adverse event)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□		UUID	40		Enter values that are unique in the report.	7	76	0	01～99	01～99	Parent = k Child = i. r does not represent ACK □ -do. Note that due to the configuration of Hong XM L, sequence numbers may not be
G.k.9.i.2.r[GID]	Adverse reactions/events to be evaluated (ID for drug information reference)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□		UUID	40		Enter values that are unique in the report.	7	77	0	01～99	01～99	Parent = k Child = i. r does not represent ACK □ -do. Note that due to the configuration of Hong XM L, sequence numbers may not be
G.k.9.i.2.r.1	Source of Assessment	□	□	▲	▲	X	X	X	X	X	X	X	□	□	▲	▲	X	X	X	□	□	▲	▲	X	X	X	X	X	X	X	□	□	▲	▲	X	X	X	▲	▲		TXT	60			7	78	0	01～99	01～99	Parent = k Child = i. r does not represent ACK □ -do.
G.k.9.i.2.r.2	Method of Assessment	□	□	▲	▲	X	X	X	X	X	X	X	□	□	▲	▲	X	X	X	□	□	▲	▲	X	X	X	X	X	X	X	□	□	▲	▲	X	X	X	▲	▲		TXT	60			7	79	0	01～99	01～99	Parent = k Child = i. r does not represent ACK □ -do.
G.k.9.i.2.r.3	Result of Assessment	□	□	▲	▲	X	X	X	X	X	X	X	□	□	▲	▲	X	X	X	□	□	▲	▲	X	X	X	X	X	X	X	□	□	▲	▲	X	X	X	▲	▲		TXT	60			7	80	0	01～99	01～99	Parent = k Child = i. r does not represent ACK □ -do.
H	Narrative Case Summary and Other Information	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			8	00	0	00	00	
H.1	Case Narrative Including Clinical Course, Therapeutic Measures, Outcome and Additional Relevant Information	▲	▲	■	■	◎	◎	◎	▲	▲	◎	◎	▲	▲	▲	▲	◎	◎	◎	◎	◎	■	■	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲	Brief description is allowed, but only if the reporting deadline is 30 days (except for cases determined to be known based on descriptions in Other adverse reactions) or for AC or AD.	TXT	100000		For abbreviated descriptions, enter "see attached data," etc.	8	01	0	00	00	
H.2	Reporter's Comments	▲	▲	■	■	X	X	X	▲	▲	X	X	▲	▲	▲	▲	X	X	X	◎	◎	■	■	X	X	X	◎	◎	X	X	◎	◎	◎	◎	X	X	X	▲	▲	Brief description is allowed, but only if the reporting deadline is 30 days (except for cases determined to be known based on descriptions in Other adverse reactions) or for AC or AD.	TXT	20000		For abbreviated descriptions, enter "see attached data," etc.	8	02	0	00	00	
H.3.r	Sender's Diagnosis (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			8	03	0	01～99	00	
H.3.r.1a	MedDRA Version for Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	4		MedDRA Version '. Only "numbers' and "." are available.	8	04	0	01～99	00	
H.3.r.1b	Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event (MedDRA code)	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		NUM	8			8	05	0	01～99	00	
H.4	Sender's Comments	▲	▲	■	■	▲	▲	▲	▲	▲	▲	▲	◎	◎	◎	◎	◎	◎	◎	◎	◎	■	■	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲	Brief description is allowed, but only if the reporting deadline is 30 days (except for cases determined to be known based on descriptions in Other adverse reactions) or for AC or AD.	TXT	20000		For abbreviated entries, enter "See attachment" or the like.	8	06	0	00	00	
H.5.r	Case Summary and Reporter's Comments in Native Language (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			8	07	0	01～99	00	
H.5.r.1a	Case Summary and Reporter's Comments Text	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		TXT	100000			8	08	0	01～99	00	
H.5.r.1b	Case Summary and Reporter's Comments Language	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	□	□	□	□	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲		Code List	ISO_639-2_RA(alpha-			8	09	0	01～99	00	

Symbols and notes

•Reporting Classification

Post-marketing	AA	Domestic Infectious Disease Case Report Post-marketing)
	AB	Domestic Adverse Drug Reaction Case Report Post-marketing)
	AC	Foreign infection case reports (post-marketing)
	AD	Foreign adverse reaction case reports (post-marketing)
	AE	Infectious Disease Study Report Post-marketing)
	AF	Adverse Drug Reaction Study Report Post-marketing)
	AG	Measures such as discontinuation, recall, and disposal in foreign countries Reporting Post-marketing)
	BA	Quasi-drug adverse reaction case report
	BB	Cosmetic adverse reaction case report
	BC	Quasi-drug research report
	BD	Cosmetic research report
Clinical trial	DA	Domestic infectious disease case report clinical trial)
	DB	domestic adverse reaction case report study)
	DC	Foreign infectious disease case report (clinical trial)
	DD	Foreign adverse reaction case report (clinical trial)
	DE	Infectious Disease Research Reporting Trial)
	DF	Adverse Drug Reaction Research Report Trial)
	DG	Measures such as discontinuation, recall, and disposal in foreign countries Reporting Trial)

•Input Condition Symbol

◎	Required Items
□	Items that may need to be entered depending on the contents of other items
▲	Items to be entered whenever possible
■	Items that can be abbreviated
X	Items that should not be stated

Note-3: Exhibit 5 has been deleted, not translated.

別紙６：Exhibit 6

Individual Case Safety Report, etc. Confirmation Response (ACK) Message Element id

Explanation of Symbols in Entries
◎= Entries to be Entered
◊ = Entries to be Entered in the Event of an Error

Common to all reporting categories

Data item number	Data item name	Description	Input Type	Value Allowed	E2B item number resulting in identical value
ACK.M.1	Acknowledgement batch number	◎	TXT	100	
ACK.M. 2	Acknowledgement batch sender identifier	◎	TXT	60	N.1.4
ACK.M. 3	Acknowledgement batch recipient identifier	◎	TXT	60	N.1.3
ACK.M. 4	Confirmation response date for batch transmission	◎	Date	CCYYMMDDhhmmss +0900	
ACK.A.1	ICSR batch number	◎	TXT	100	N.1.2
ACK.A.2	Acknowledgement Region Message Number	◎	TXT	100	
ACK.A.3	ICSR batch transmission date	◎	Date (lowest precision)	CCYYMMDDhhmmss	N.1.5
ACK.A.4	Transmission Acknowledgement Code	◎	List	AA, AE, AR	
ACK.A.5	batch validation error	◊	TXT	250	
ACK.B.r.1	ICSR message number	◎	TXT	100	N.2.r.1,C.1.1
ACK.B.r.2	Regional report number	◎	TXT	100	
ACK.B.r.3	ICSR Message Acknowledgement Recipient	◎	TXT	60	N.2.r.2
ACK.B.r.4	ICSR Message Acknowledgement Sender	◎	TXT	60	N.2.r.3
ACK.B.r.5	ICSR message creation date	◎	Date (lowest precision)	CCYYMMDDhhmmss	N.2.r.4, C.1.2
ACK.B.r.6	ICSR Message Acknowledgement Code	◎	List	CA, CR	
ACK.B.r.7	Error/Warning message or opinion	◊	TXT	250	

別紙７： Exhibit 7

List of dosage forms

Classification	State character PMDA 3-digit Code	description
oral drug	TAB	Tablets tablet (Includes tablets with the usual skin, sugar-coated tablets, sublingual tablets and oral tablets. However, extended-release tablets "SRT" and vaginal tablets "IMP" are not included.)
	CAP	Capsule capsule (However, extended-release capsules "SRC" are not included.)
	GRA	Granulate
	POW	Powder Powder "Does not contain "DPO" dusting powder"
	FGR	Fine granules fine grain
	SYR	Syrup syrup (including dry syrup)
	ENT	Enteric-coated tablet Enteric-coated tablet Enteric solvent
	SRC	Sustained-release capsule Sustained release capsule
	CTS	Cachet Cashew (including oblat pouch)
	CTB	Chewable tablet Masticating lock
	DRO	Drops (for oral use) Drop
	PIL	Pill pills (not including tablets)
	SOL	Oral liquid oral liquids (including all orally administered liquid formulations but excluding syrup 'SYR')
	LOZ	Troche and Lozenge Confectionery tablets (Lozenges, candy, etc.)
	SRT	Sustained-release tablet Sustained release tablets
	SRG	Sustained-release granules Sustained release granules
	POR	Preparation for oral use(NOS) Oral dosage form not clear (*) ・Note that multiple dosage forms such as tablets and granules are available in the market for oral dosage form, and when it is not clear which one is available, "POR" is used instead of "XXX."
Injectable dosage form	INJ	Injection Injections (Including those dissolved before use. Also includes trans central intravenous nutrition)
External preparations	DPO	Powder for external use Spray powder (dusting powder)
	LOT	Lotion (not for ophthalmic use) Lotion (except ophthalmic lotion)
	OIT	Ointment and Cream Ointment/Cream
	SHP	Shampoo Shampoo
	SPR	Spray (not inhalation) Spray (except inhalants)
	LIQ	Liquid for external use Topical liquid (including liniment)
	TAP	Poultice or Patch Tape (including poultice)
	AER	Aerosol for inhalation Aerosols (limited to inhaled metered-dose aerosols). Exterior aerosols "SPR")
	EDR	Ear drops Ear drops
	EED	Ear drops Eye drops

	EOI	Ophthalmic ointment/cream Eye drops ointment
	NDR	Nasal drops (including nasal spray) Nasal drops (including nasal spray)
	INH	Inhalant Inhalers (Inhalation anesthetics, including inhalation spray)
	INS	Gas for inhalation Gas inhalers (nitrous oxide, etc.)
	SPC	Spincap Spin cap
	MWH	Mouth wash Antitusant
	SUP	Suppository Anal suppository
	IMP	Vaginal suppository Insertion agent (Vaginal suppository, vaginal tablet, etc.)
	ENM	Enema Enema
	JEL	Jelly Jelly
	EXT	Preparation for external use(NOS) Topical preparation without clear dosage form
Other	INF	Injection for infusion Infusions (Peritoneal perfusate, etc.)
	XXX	Unknown

別紙８：Exhibit 8

Quasi-drug adverse reaction code

Code value	**E.i.2.1b Adverse drug reactions/events**
800001	Application site redness
800002	Application site rash
800003	Application site acne
800004	Application site pruritus
800005	Application site irritation
800006	Application site swelling
800007	Application site drying
800008	Application site exfoliation
800009	Application site pain
800010	Application site blisters
800011	Application site pigmentation changes
800012	Application site vitiligo
800013	Application site dermatitis
800014	Application site hair loss
800015	Application site heat
800016	Application site cold
900001	Hair discoloration
900002	hair disorder
900003	eye redness
900004	eye irritation
900005	eye abnormalities
900006	redness
900007	Rash
900008	Pruritus
900009	Swelling
900010	Edema
900011	Pain
900012	Blisters
900013	discoloration
900014	vitiligo
900015	heat
900016	cold

900017	Nausea
900018	Vomiting
900019	Liver dysfunction
900020	Stomachache
900021	abdominal pain
900022	diarrhea
900023	constipation
900024	choking sensation
900025	headache
900026	dizziness
900027	malaise
900028	anaphylaxis
900029	palpitations
900030	fever
900031	decreased blood pressure
900032	food allergy
900033	nasal discharge
900034	nasal congestion
900035	contact dermatitis