“Yaku-Sei-Yaku-shin“ 薬生薬発 ”Notification No. 0624 No. 4
“Yaku-Sei-An” 薬生安発” Notification No. 0624 No. 1
Reiwa 4 (2022), June 24

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

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 (Act 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 response to the Implementation Guide for Electronic Transmission of Individual Case Safety Reports, which was compiled based on an agreement reached at the International Conference on Harmonization of Drug Regulations, has just been presented in the section entitled Postmarketing Adverse Reaction Reporting and Study Adverse Reaction Reporting in Response to E2B (R3) Implementation Guide (Joint Notification No. 0831 No. 12 and Notification No. 0831 No. 3, by the Director of the Evaluation and Management Division and the Director of the Safety Division, Pharmaceutical Affairs and Consumer Affairs Division, the Ministry of Health, Labour and Welfare, dated August 31, 2020. Hereafter referred to as "E2B Director Notice".).

We have recently reviewed the matters described in the Postmarketing Adverse Reaction Reporting for drugs, quasi-drugs, and cosmetics, and have decided to revise 別紙: 1 Exhibits 1 and 別紙 2 : Exhibit 2 attached to the “E2B 二課長通知 2-Kacho Notification” as attached.

This notification is effective from July 1, 2022 (Reiwa 4).

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 contents of other items.
▲	Items to be entered whenever possible.
■	Items that can be abbreviated.
×	Items that should not be entered

Yellow part: Partially updated in E2B(R3) Guideline on Reiwa 4. 24-June (this guideline)
Refer to the OLD Exhibit1/2 at “Postmarketing Adverse Reaction Reporting and Study Adverse Reaction Reporting in Response to E2B (R3) Implementation Guide on 7-Feb-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	Value Allowed	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 To be entered after changing the value of old J.4a to the appropriate value of J2.1a.	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)	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	This data item should not be entered when reporting as an initial report. (Whether the report is an initial report or an additional report is judged by 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 J2.2.1 are different in the initial report, enter them. >The comparison between C.1.4 and J2.2.1 is 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	▲	▲	This data item should not be entered 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	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	◎	◎	◎	◎	◎	◎	◎	▲	▲	-- (Deleted)	TXT	10000		For abbreviated descriptions, enter "No special mention."	2	14	0	00	00	
J2.11	Other References, etc.	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	◎	◎	◎	◎	◎	◎	◎	▲	▲	-- (Deleted)	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	X	◎	◎	◎	◎	◎	◎	◎	▲	▲		TXT	500			2	23	0	00	00	
J2.18.1	Recipient organization name	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲		TXT	100		Enter "Pharmaceuticals and Medical Devices Agency."	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	▲	▲		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	▲	▲		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	▲	▲		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	▲	▲		TXT	10000			2	31	0	00	00	
C.2.r.2	Address and telephone number of reporter	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			3	33	0	01～	00	
J2.29.r		X	X	X	X	X	X	X	◎	◎	X	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]		X	X	X	X	X	X	X	◎	◎	X	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		X	X	X	X	X	X	X	□	□	X	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			3	44	1	01～	00	
J2.27.r[Ver]		X	X	X	X	X	X	X	□	□	X	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	44	2	01～	00	
C.4.r		–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			3	64	0	01～	00	

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

別紙１： Exhibit 1

Reporting Classification Uncompleted Report

Element id (R3)	Element Name (R3)	Post-marketing AA	AB	AC	AD	AE	AF	AG	BA	BB	BC	BD	Clinical Trial DA	DB	DC	DD	DE	DF	DG
J2.15.r	State of publication	X	X	X	X	◎	◎	◎	X	X	◎	◎	X	X	X	X	◎	◎	◎
J2.17.r	Classification of tests/studies	X	X	X	X	◎	◎	X	X	X	◎	◎	X	X	X	X	◎	◎	X
D.2.2	Age at onset of reaction/event	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
J2.28	Pregnancy or not	X	X	X	X	X	X	X	▲	▲	X	X	X	X	X	X	X	X	X
J2.28[Ver]	Pregnancy Status - CodeSystemVersion	X	X	X	X	X	X	X	▲	▲	X	X	X	X	X	X	X	X	X
E.i	Adverse reactions/events Repeat as needed)																		
J2.14.i	unknown known	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	X	X	X
J2.14.i[Ver]	Unknown one CodeSystemVersion	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	X	X	X
J2.26.i	Seriousness, etc.	X	X	X	X	X	X	X	◎	◎	X	X	X	X	X	X	X	X	X
J2.26.i[Ver]	Severity etc. -CodeSystemVersion	X	X	X	X	X	X	X	◎	◎	X	X	X	X	X	X	X	X	X
G	Pharmaceuticals	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
G.k	Drug information Repeat as needed)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
J2.4.k	Status classification of new drugs, etc.	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎
J2.4.k[Ver]	Status classification of new drugs, etc. -	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎
J2.5.k	Risk Categories, etc. for Over-the-Counter	□	□	□	□	□	□	□	X	X	X	X	▲	▲	▲	▲	▲	▲	▲
J2.5.k[Ver]	Risk Categories for Over-the-Counter Drugs, etc. - CodeSystemVersion	□	□	□	□	□	□	□	X	X	X	X	▲	▲	▲	▲	▲	▲	▲
J2.6.k	Access to OTC drugs	□	□	□	□	□	□	□	X	X	X	X	▲	▲	▲	▲	▲	▲	▲
J2.6.k[Ver]	Access to OTC drugs - CodeSystemVersion	□	□	□	□	□	□	□	X	X	X	X	▲	▲	▲	▲	▲	▲	▲
G.k.2	Drug identification	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
J2.23.k	Nickname	X	X	X	X	X	X	X	▲	▲	X	X	X	X	X	X	X	X	X
J2.24.k	Product type	X	X	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	X
J2.24.k[Ver]	Product type - CodeSystemVersion	X	X	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	X
G.k.2.3.r	Ingredient/Specific ingredient identifier and content Repeat as needed)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
J2.25.k.r	Classification of ingredients	X	X	X	X	X	X	X	□	□	□	□	X	X	X	X	X	X	X
J2.25.k.r[Ver]	Component Division - CodeSystemVersion	X	X	X	X	X	X	X	□	□	□	□	X	X	X	X	X	X	X

Reporting Classification Completed Report

Element id (R3)	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
J2.15.r	X	X	X	X	◎	◎	◎	X	X	◎	◎	X	X	X	X	◎	◎	◎	▲	▲
J2.17.r	X	X	X	X	◎	◎	X	X	X	◎	◎	X	X	X	X	◎	◎	X	▲	▲
D.2.2	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
J2.28	X	X	X	X	X	X	X	▲	▲	X	X	X	X	X	X	X	X	X	▲	▲
J2.28[Ver]	X	X	X	X	X	X	X	▲	▲	X	X	X	X	X	X	X	X	X	▲	▲
E.i		–																		
J2.14.i	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲
J2.14.i[Ver]	X	X	X	X	X	X	X	X	X	X	X	□	□	□	□	X	X	X	▲	▲
J2.26.i	X	X	X	X	X	X	X	◎	◎	X	X	X	X	X	X	X	X	X	▲	▲
J2.26.i[Ver]	X	X	X	X	X	X	X	◎	◎	X	X	X	X	X	X	X	X	X	▲	▲
G	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
G.k	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
J2.4.k	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲
J2.4.k[Ver]	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲
J2.5.k	□	□	□	□	□	□	□	X	X	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲
J2.5.k[Ver]	□	□	□	□	□	□	□	X	X	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲
J2.6.k	□	□	□	□	□	□	□	X	X	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲
J2.6.k[Ver]	□	□	□	□	□	□	□	X	X	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲
G.k.2	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
J2.23.k	X	X	X	X	X	X	X	▲	▲	X	X	X	X	X	X	X	X	X	▲	▲
J2.24.k	X	X	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	X	▲	▲
J2.24.k[Ver]	X	X	X	X	X	X	X	□	□	X	X	X	X	X	X	X	X	X	▲	▲
G.k.2.3.r	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
J2.25.k.r	X	X	X	X	X	X	X	□	□	□	□	X	X	X	X	X	X	X	▲	▲
J2.25.k.r[Ver]	X	X	X	X	X	X	X	□	□	□	□	X	X	X	X	X	X	X	▲	▲

Element id (R3)	Supplement to entry conditions	Value Allowed Related: Input type	Value Allowed	NullFlavor	Supplement	ACK Code (upper 8 digits): Item			Sequence number Parent	Child	ACK Supplemental Description
J2.15.r		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		List	1,2			2	33	0	01～	00	
D.2.2			-			4	09	0	00	00	
J2.28		Code List	CL_J2.28	UNK,NA,ASKU,NASK		4	19	1	00	00	
J2.28[Ver]		TXT	5			4	19	2	00	00	
E.i			-			5	00	0	01～	00	
J2.14.i	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]		TXT	5			2	35	0	01～	00	
J2.26.i		Code List	CL_J2.26.i			2	35	1	01～	00	
J2.26.i[Ver]		TXT	5			2	35	2	01～	00	
G			-			7	00	0	00	00	
G.k			-			7	01	0	01～	00	
J2.4.k	◎" 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]		TXT	5			2	37	0	01～	00	
J2.5.k		Code List	CL_J2.5.k			2	38	0	01～	00	
J2.5.k[Ver]		TXT	5			2	39	0	01～99	00	
J2.6.k		Code List	CL_J2.6.k	ASKU,UNK		2	40	0	01～99	00	
J2.6.k[Ver]		TXT	5			2	41	0	01～99	00	
G.k.2			-			7	11	0	01～	00	
J2.23.k		TXT	100			7	12	1	01～	00	
J2.24.k		Code List	CL_J2.24.k			7	12	2	01～	00	
J2.24.k[Ver]		TXT	5			7	12	3	01～	00	
G.k.2.3.r			-			7	13	0	01～99	01～99	Represent parent = k child = r
J2.25.k.r		Code List	CL_J2.25.k.r			7	14	1	01～99	01～99	Represent parent = k child = r
J2.25.k.r[Ver]		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: 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 (Nullification) 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
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			3	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	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		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 necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–							3	09	0	01～99	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 B64 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 E.i.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	

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	Other Case Identifiers in Previous	◎	◎	◎	◎	◎	◎	◎	X	X	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	X	X	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲		Boolean	TRUE	NI		3	18	0	00	00	
C.1.9.1.r	Other Case Identifiers in Previous (repeat as necessary)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			3	19	0	01～99	00	
C.1.9.1.r.1	Other Case Identifiers in Previous	□	□	□	□	□	□	□	X	X	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	X	X	□	□	□	□	□	□	□	□	▲	▲		TXT	100			3	20	0	01～99	00	
C.1.9.1.r.2	Case Identifier	□	□	□	□	□	□	□	X	X	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	X	X	□	□	□	□	□	□	□	□	▲	▲		TXT	100			3	21	0	01～99	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	01～99	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	01～99	00	
C.2.r.1	Reporter's Name	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			3	28	0	01～99	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	MSK,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	01～99	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	01～99	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	01～99	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_3166-1(alpha_2)			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	01～99	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																		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.4.r.2	Included Documents	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲			Types of media		Enter text., or B64 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 ～ 99	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 (Investigation 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: 10a	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,MSKK	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 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 ～ 99	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 ～ 99	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 ～ 99	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 ～ 99	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 ～ 99	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 ～ 99	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 ～ 99	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	Value Allowed related: 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,NASK,MSK	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,NASK,MSK	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,NASK		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～	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～	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	X	□	□	X	X	X	▲	▲		TXT	250		Tentative until IDMP specifications are finalized	4	76	0	01～	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	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	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	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～	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.1.1b 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. only “numbers” and “.”are available.	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: 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 PM	CS	Supplement to entry conditions	Value Allowed Related: Input type	Value Allowed	NullFlavor	Supplement	ACK Code (upper 8 digits): Item			Sequence number: Parent	Child	ACK Supplemental Description
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 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 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 are finalized	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 are finalized	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 are finalized	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 are finalized	7	10	0	01～	00	
G.k.2	Drug Identification	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–			-			7	11	0	01～99	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 are finalized	7	16	0	01～99	01～99	Represent parent = k child = r.
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	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	X	▲	▲		Code List	E2B_CL25		Limited 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_3166-1			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_3166-1			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	□	□	□	▲	▲		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	□	□	□	▲	▲		Code List	E2B_CL25		Limited UCUM Code (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	□	□	□	▲	▲		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	□	□	□	▲	▲		Code List	E2B_CL26c		Restricted UCUM（Cyclical) (as necessary), (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	▲	▲	▲	▲	▲		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	▲	▲	▲	▲	▲		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	X	X	▲	▲		NUM	5			7	32	0	01～	01～	Represent parent = k
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	X	X	▲	▲		Code List	E2B_CL26e		Limited UCUM Code	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	▲	▲	▲	▲	▲		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	▲	▲	▲	▲	▲		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	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	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	▲	▲	▲	▲	▲		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 CL14 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 CL14 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 Code (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 Code (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 own company's drugs (What has Input in J2.4k?), at the time of completion report, it shall be mandatory as ◎.	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		Supplement to entry conditions	Value Allowed related				ACK load (upper 8 digits)					
		After market											Clinical Trial							Post-marketing										Clinical Trial										PM	CS		Input type	Acceptable value	NullFlavor	Supplemental	Item			Sequence number		ACK Supplementary Explanation
		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	
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
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
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～	01～	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
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～	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
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
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-3)			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