

厚生労働省システム管理用データ項目

■報告分類

市販後	AA	国内感染症例報告(市販後)	
	AB	国内副作用症例報告(市販後)	
	AC	外国感染症例報告(市販後)	
	AD	外国副作用症例報告(市販後)	
	AE	感染症研究報告(市販後)	
	AF	副作用研究報告(市販後)	
	AG	外国における製造等の中止、回収、廃棄等の措置報告(市販後)	
	BC	医薬部外品研究報告(記載方法はAPIに準ずる)	
	BD	化粧品研究報告(記載方法はAPIに準ずる)	
	治験	DA	国内感染症例報告(治験)
		DB	国内副作用症例報告(治験)
		DC	外国感染症例報告(治験)
		DU	外国副作用症例報告(治験)
		DE	感染症研究報告(治験)
		DF	副作用研究報告(治験)
DG		外国における製造等の中止、回収、廃棄等の措置報告(治験)	

■入力条件記号

◎	必ず記載する項目
□	他の項目の記載内容によって入力が必要になる項目
▲	可能な限り記載する項目
X	記載してはならない項目

データ項目 (R3)	表題 (R3)	報告分類 - 未完了報告																報告分類 - 完了報告																取下		入力条件に関する補足	許容値関連				ACKコード(L&R桁)																
		市販後								治験								市販後								治験								市	治		入力照別	許容値	NullFlavor	補足	項目	順序番号	ACK補足説明														
		AA	AB	AC	AD	AE	AF	AG	BC	BD	DA	DB	DC	DD	DE	DF	DG	AA	AB	AC	AD	AE	AF	AG	BC	BD	DA	DB	DC	DD	DE	DF	DG																								
J2	J項目	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎																				
J2.1a	識別番号(報告分類)	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	【R2からの追加報告時の特記事項】 旧J.4aの値をJ.2.1aの該当する値に変更した上で入力すること。	コードリスト	CL_J2.1a															
J2.1a[Ver]	識別番号(報告分類) - codeSystemVersion	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎		TXT	5															
J2.1b	識別番号(番号)	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	【初回報告時の特記事項】 初回報告として、報告する場合は本データ項目は入力しないこと。(入力有無により初回報告か追加報告かを判断する。)	NUM	8															
J2.2.1	報告起算日	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲		日付(最低精度)	CCYYMMDD															
J2.2.2	報告起算日に関するコメント	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	▲	▲	【初回報告時の特記事項】 初回報告において、G.1.4とJ2.2.1が異なる場合、入力すること。 ※G.1.4とJ2.2.1の比較は、CCYYMMDDまでの精度で行う。	TXT	10000															
J2.3	即時報告フラグ	□	□	□	X	X	X	□	X	X	X	X	X	X	X	X	□	□	□	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	▲	▲		コードリスト	CL_J2.3																
J2.3[Ver]	即時報告フラグ - 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																
J2.7.1	完了、未完了区分	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎				リスト	active,completed															
J2.7.2	未完了に関するコメント	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	□	▲	▲		TXT	10000															
J2.8.1	報告対象外フラグ	□	□	□	X	X	X	□	X	X	X	□	□	□	X	X	X	□	□	□	X	X	X	X	X	□	□	□	X	X	X	X	X	X	X	X	▲	▲	【初回報告時の特記事項】 初回報告として、報告する場合は本データ項目は入力しないこと。	コードリスト	CL_J2.8.1																
J2.8.1[Ver]	報告対象外フラグ - 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																
J2.8.2	報告対象外の理由	□	□	□	X	X	X	□	X	X	X	□	□	□	X	X	X	□	□	□	X	X	X	X	X	□	□	□	X	X	X	X	X	X	X	X	▲	▲		TXT	10000																
J2.9	感染症の通知調査	◎	X	◎	X	X	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																
J2.10	今後の対応	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲		TXT	10000																
J2.11	その他参考事項等	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲		TXT	10000																
J2.12	治験成分記号	X	X	X	X	X	X	X	◎	◎	◎	◎	◎	◎	◎	X	X	X	X	X	X	X	X	X	X	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	▲	▲		TXT	70																
J2.13	治験の概要(必要に応じ繰り返し)																				
J2.13.r.1	届出回数	X	X	X	X	X	X	X	X	▲	▲	▲	▲	▲	▲	▲	X	X	X	X	X	X	X	X	X	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲	▲		NUM	2																
J2.13.r.2	対象疾患	X	X	X	X	X	X	X	X	□	□	□	□	□	□	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□	□	□	□	□	□	□	▲	▲		TXT	1000																
J2.13.r.3	開発相	X	X	X	X	X	X	X	X	□	□	□	□	□	□	X	X	X	X	X	X	X	X	X	□	□	□	□	□	□	□	□	□	□	□	□	▲	▲		コードリスト	CL_J2.13.r.3																

厚生労働省システム管理用データ項目

別紙1

Table with columns: データ項目 (R3), 表題 (R3), 報告分類 - 未完了報告 (市販後, 治験), 報告分類 - 完了報告 (市販後, 治験), 取下 (市, 治), 入力条件に関する補足, 許容値関連 (入力種別, 許容値, NullFlayer, 補足), ACKコード(L16桁) (項目, 順序番号, 親子, ACK補足説明). Rows include items like J2.13.r.3, J2.13.r.4, J2.16, J2.18.1, J2.18.2, J2.18.3, J2.18.4, J2.19, J2.20, J2.21, J2.22, C.4.r, J2.15.r, J2.17.r, E.i, J2.14.i, J2.14.l[Ver], G, G.k, J2.4.k, J2.4.k[Ver], J2.5.k, J2.5.k[Ver], J2.6.k, J2.6.k[Ver].

個別症例安全性報告データ項目

Table with columns for data item (R3), title (R3), report status (uncompleted/finished), input condition, data type, code list, and ACK code. Includes rows for sender information (C.3.1-3.4), references (C.4.r), and trial information (C.5).

個別症例安全性報告データ項目

Table with columns for Data Item (R3), Category (R3), Report Status (Incomplete/Completed), Market Status (Pre-market/Post-market), Treatment Status (Pre-treatment/Post-treatment), Input Conditions, Data Type, Value, and ACK Code (R3). Rows include items like D.9.2.r.2 (Reported death), D.9.3 (New test implemented), D.9.4.r (Death due to test), D.9.4.r.1a (Death due to MedDRA version), D.9.4.r.1b (Death due to MedDRA code), D.9.4.r.2 (Death due to test (free text)), D.10 (Parent/Child report), D.10.1 (Parent ID), D.10.2 (Parent age), D.10.2.1 (Parent birth date), D.10.2.2 (Parent age), D.10.2.2a (Parent age (count)), D.10.2.2b (Parent age (unit)), D.10.3 (Parent last visit date), D.10.4 (Parent weight), D.10.5 (Parent height), D.10.6 (Parent gender), D.10.7 (Parent related treatment and symptoms), D.10.7.1.r (Parent structured information), D.10.7.1.r.1a (Parent related treatment and symptoms (MedDRA version)), D.10.7.1.r.1b (Parent related treatment and symptoms (disease/handwritten/other (MedDRA code))), D.10.7.1.r.2 (Start date), D.10.7.1.r.3 (Continuation), D.10.7.1.r.4 (End date), D.10.7.1.r.5 (Remarks), D.10.7.2 (Parent related treatment and symptoms (narrative)), D.10.8.r (Parent related past drug use), D.10.8.r.1 (Drug name), D.10.8.r.2a (MPID version date/number), D.10.8.r.2b (Drug product code), D.10.8.r.3a (PhPID version date/number), D.10.8.r.3b (Drug code), D.10.8.r.4 (Start date), D.10.8.r.5 (End date), D.10.8.r.6a (Reason for use (MedDRA version)), D.10.8.r.6b (Reason for use (MedDRA code)), D.10.8.r.7a (Side effect (MedDRA version)), D.10.8.r.7b (Side effect (MedDRA code)), and E.i (Side effect/serious event).

個別症例安全性報告データ項目

Table with columns for Data Item (R3), Title (R3), Report Status (Incomplete/Completed), City/Treatment, Input Conditions, Data Type, and ACK Code. Includes rows for E.I. (Adverse Events) and F.r. (Medical Review).

個別症例安全性報告データ項目

別紙2

データ項目 (R3)	表題 (R3)	報告分類 - 未完了報告														報告分類 - 完了報告														取下		入力条件に関する補足	許容値関連				ACKコード(LB#時)								
		市販後							治験							市販後							治験							市	治		入力種別	許容値	NullFlavor	補足	項目	順序番号		ACK補足説明					
		AA	AB	AC	AD	AE	AF	AG	BC	BD	DA	DB	DC	DD	DE	DF	DG	AA	AB	AC	AD	AE	AF	AG	BC	BD	DA	DB	DC									DD	DE		DF	DG	順	子	
G.k.9.i.4	再投与で副作用は再発したか?	□	□	□	□	×	×	×	×	×	□	□	□	□	×	×	×	□	□	□	□	×	×	×	×	□	□	□	□	×	×	×	×	▲	▲	コードリスト	E2B_CL16			7	67	0	01'99	01'99	親=、子=を教す
G.k.9.i.4[Ver]	再投与で副作用は再発したか? - codeSystemVersion	□	□	□	□	×	×	×	×	×	□	□	□	□	×	×	×	□	□	□	□	×	×	×	×	□	□	□	□	×	×	×	×	▲	▲	TXT	5			7	88	0	01'99	01'99	親=、子=を教す
G.k.9.i.4[EID]	対象とする副作用/有害事象 [副作用/有害事象参照用ID]	▲	▲	▲	▲	×	×	×	×	×	▲	▲	▲	▲	×	×	×	▲	▲	▲	▲	×	×	×	×	▲	▲	▲	▲	×	×	×	×	▲	▲	UUID	40	報告内でユニークな値を入力する。		7	69	0	01'99	01'99	親=、子=を教す ※XMLの構成上順序番号は取得できない場合があるので注意。
G.k.10.r	医薬品に関するその他の情報(コード化)(必要に応じ繰り返す)	□	□	□	□	×	×	×	×	×	□	□	□	□	×	×	×	□	□	□	□	×	×	×	×	□	□	□	□	×	×	×	×	▲	▲	コードリスト	E2B_CL17			7	70	0	01'99	01'99	親=、子=を教す。
G.k.10.r[Ver]	医薬品に関するその他の情報(コード化)(必要に応じ繰り返す)codeSystemVersion	□	□	□	□	×	×	×	×	×	□	□	□	□	×	×	×	□	□	□	□	×	×	×	×	□	□	□	□	×	×	×	×	▲	▲	TXT	5			7	71	0	01'99	01'99	親=、子=を教す。
G.k.11	医薬品に関するその他の情報(自由記述)	▲	▲	▲	▲	×	×	×	×	×	▲	▲	▲	▲	×	×	×	▲	▲	▲	▲	×	×	×	×	▲	▲	▲	▲	×	×	×	×	▲	▲	TXT	2000			7	72	0	01'99	00	
G.k.9.i	医薬品と副作用/有害事象のマトリックス (必要に応じ繰り返す)	-	-			7	73	0	01'99	01'99	親=、子=を教す
G.k.9.i.1	評価対象の副作用/有害事象	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	N/A		ユーザが入力する項目ではない。また、XPathが用意されていないため、チェック対象外とする。		7	74	0	01'99	01'99	親=、子=を教す	
G.k.9.i.2.r	医薬品と副作用/有害事象の因果関係(必要に応じ繰り返す)	-	-			7	75	0	01'99	01'99	親=、子=を教す。rはACKコードでは表さない。
G.k.9.i.2.r[EID]	評価対象の医薬品 [副作用/有害事象参照用ID]	□	□	▲	▲	×	×	×	×	×	□	□	▲	▲	×	×	×	×	□	□	▲	▲	×	×	×	□	□	▲	▲	×	×	×	×	▲	▲	UUID	40	報告内でユニークな値を入力する。		7	76	0	01'99	01'99	親=、子=を教す。rはACKコードでは表さない。 ※XMLの構成上順序番号は取得できない場合があるので注意。
G.k.9.i.2.r[GID]	評価対象の副作用/有害事象 [医薬品情報参照用ID]	□	□	▲	▲	×	×	×	×	×	□	□	▲	▲	×	×	×	×	□	□	▲	▲	×	×	×	□	□	▲	▲	×	×	×	×	▲	▲	UUID	40	報告内でユニークな値を入力する。		7	77	0	01'99	01'99	親=、子=を教す。rはACKコードでは表さない。 ※XMLの構成上順序番号は取得できない場合があるので注意。
G.k.9.i.2.r.1	評価の情報源	□	□	▲	▲	×	×	×	×	×	□	□	▲	▲	×	×	×	×	□	□	▲	▲	×	×	×	□	□	▲	▲	×	×	×	×	▲	▲	TXT	60			7	78	0	01'99	01'99	親=、子=を教す。rはACKコードでは表さない。
G.k.9.i.2.r.2	評価方法	□	□	▲	▲	×	×	×	×	×	□	□	▲	▲	×	×	×	×	□	□	▲	▲	×	×	×	□	□	▲	▲	×	×	×	×	▲	▲	TXT	60			7	79	0	01'99	01'99	親=、子=を教す。rはACKコードでは表さない。
G.k.9.i.2.r.3	評価結果	□	□	▲	▲	×	×	×	×	×	□	□	▲	▲	×	×	×	×	□	□	▲	▲	×	×	×	□	□	▲	▲	×	×	×	×	▲	▲	TXT	60			7	80	0	01'99	01'99	親=、子=を教す。rはACKコードでは表さない。
H	症例概要及びその他の情報の記述	-	-			8	00	0	00	00	
H.1	臨床経過、治療措置、転帰及びその他の関連情報を含む症例の記述情報	▲	▲	▲	▲	◎	◎	◎	◎	◎	▲	▲	▲	▲	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	TXT	100000	照録(報告期限が30日の場合(「その他の副作用」に記載があることを前提に既知と判断した場合を除く。))又は外国医薬品の副作用によると疑われるものの場合に限る。		8	01	0	00	00	
H.2	報告者の意見	▲	▲	▲	▲	×	×	×	×	×	▲	▲	▲	▲	×	×	×	×	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	TXT	20000	照録(報告期限が30日の場合(「その他の副作用」に記載があることを前提に既知と判断した場合を除く。))又は外国医薬品の副作用によると疑われるものの場合に限る。		8	02	0	00	00	
H.3.r	送信者による診断名(必要に応じ繰り返す)	-	-			8	03	0	01'99	00	
H.3.r.1a	送信者による診断名/症候群及び/又は副作用/有害事象の再分類のMedDRAバージョン	□	□	□	□	×	×	×	×	×	□	□	□	□	×	×	×	×	□	□	□	□	×	×	×	□	□	□	□	×	×	×	×	▲	▲	TXT	4	「MedDRAバージョン」を入力する。(利用できるのは「数字」「のみ。)		8	04	0	01'99	00	
H.3.r.1b	送信者による診断名/症候群及び/又は副作用/有害事象の再分類(MedDRAコード)	□	□	□	□	×	×	×	×	×	□	□	□	□	×	×	×	×	□	□	□	□	×	×	×	□	□	□	□	×	×	×	×	▲	▲	NUM	8			8	05	0	01'99	00	
H.4	送信者の意見	▲	▲	▲	▲	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	◎	TXT	20000	照録(報告期限が30日の場合(「その他の副作用」に記載があることを前提に既知と判断した場合を除く。))又は外国医薬品の副作用によると疑われるものの場合に限る。		8	06	0	00	00	
H.5.r	母国語で記載された症例概要及び報告者の意見(必要に応じ繰り返す)	-	-			8	07	0	01'99	00	
H.5.r.1a	症例概要及び報告者の意見に関する記述情報	□	□	□	□	×	×	×	×	×	□	□	□	□	×	×	×	×	□	□	□	□	×	×	×	□	□	□	□	×	×	×	×	▲	▲	TXT	100000			8	08	0	01'99	00	
H.5.r.1b	症例概要及び報告者の意見の記載言語	□	□	□	□	×	×	×	×	×	□	□	□	□	×	×	×	×	□	□	□	□	×	×	×	□	□	□	□	×	×	×	×	▲	▲	コードリスト	ISO_639-2_RA(alpha-3)			8	09	0	01'99	00	

XML 参照インスタンス (個別症例安全性報告)

```

<?xml version="1.0" encoding="UTF-8"?>
<MCCI_IN200100UV01 ITSVersion="XML_1.0" xsi:schemaLocation="urn:hl7-org:v3 MCCI_IN200100UV01.xsd" xmlns="urn:hl7-org:v3"
xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
  <id extension="N.1.2" root="2.16.840.1.113883.3.989.2.1.3.22"/>
  <!-- N.1.2: Batch Number -->
  <creationTime value="20101214151617"/>
  <!-- N.1.5: Date of Batch Transmission -->
  <responseModeCode code="D"/>
  <interactionId extension="MCCI_IN200100UV01" root="2.16.840.1.113883.1.6"/>
  <name code="N.1.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.1" codeSystemVersion="1.01"/>
  <!-- N.1.1: Type of Messages in Batch -->
  <!-- Message #1 -->
  <PORR_IN049016UV>
    <id extension="N.2.r.1" root="2.16.840.1.113883.3.989.2.1.3.1"/>
    <!-- N.2.r.1: Message Identifier -->
    <creationTime value="20101214151617"/>
    <!-- N.2.r.4: Date of Message Creation -->
    <interactionId extension="PORR_IN049016UV" root="2.16.840.1.113883.1.6"/>
    <processingCode code="P"/>
    <processingModeCode code="T"/>
    <acceptAckCode code="AL"/>
    <receiver typeCode="RCV">
      <device classCode="DEV" determinerCode="INSTANCE">
        <id extension="N.2.r.3" root="2.16.840.1.113883.3.989.2.1.3.12"/>
        <!-- N.2.r.3: Message Receiver Identifier -->
      </device>
    </receiver>
    <sender typeCode="SND">
      <device classCode="DEV" determinerCode="INSTANCE">
        <id extension="N.2.r.2" root="2.16.840.1.113883.3.989.2.1.3.11"/>
        <!-- N.2.r.2: Message Sender Identifier -->
      </device>
    </sender>
    <controlActProcess classCode="CACT" moodCode="EVN">
      <code code="PORR_TE049016UV" codeSystem="2.16.840.1.113883.1.18"/>
      <!-- HL7 Trigger Event ID -->
      <effectiveTime value="20101214151617"/>
      <!-- C.1.2: Date of Creation -->
      <subject typeCode="SUBJ">
        <investigationEvent classCode="INVSTG" moodCode="EVN">
          <id extension="C.1.1" root="2.16.840.1.113883.3.989.2.1.3.1"/>
          <!-- C.1.1: Sender's (case) Safety Report Unique Identifier -->
          <id extension="C.1.8.1" root="2.16.840.1.113883.3.989.2.1.3.2"/>
          <!-- C.1.8.1: Worldwide Unique Case Identification Number -->
          <id extension="J2.1b" root="2.16.840.1.113883.3.989.5.1.3.2.3.1"/>
          <!-- @@@J2.1b: 識別番号 (番号) -->
          <code code="PAT_ADV_EVNT" codeSystem="2.16.840.1.113883.5.4"/>
          <text>H.1</text>
          <!-- H.1: Case Narrative Including Clinical Course, Therapeutic Measures, Outcome and Additional Relevant
Information -->
          <statusCode code="active"/>
          <!-- @@@J2.7.1 完了、未完了区分 -->
          <effectiveTime>
            <low value="20090101"/>
            <!-- C.1.4: Date Report Was First Received from Source -->
          </effectiveTime>
          <availabilityTime value="20090101"/>
          <!-- C.1.5: Date of Most Recent Information for This Report -->
          <reference typeCode="REFR">
            <document classCode="DOC" moodCode="EVN">
              <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" codeSystemVersion="1.0"

```

```

displayName="documentsHeldBySender"/>
  <title>C.1.6.1.r.1</title>
  <!-- C.1.6.1.r.1: Documents Held by Sender (repeat as necessary) #1 -->
  <text mediaType="application/pdf" representation="B64">C.1.6.1.r.2</text>
  <!-- C.1.6.1.r.2: Included Documents #1 -->
</document>
</reference>
<reference typeCode="REFR">
  <document classCode="DOC" moodCode="EVN">
    <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" codeSystemVersion="1.0"
displayName="documentsHeldBySender"/>
    <title>C.1.6.1.r.1</title>
    <!-- C.1.6.1.r.1: Documents Held by Sender (repeat as necessary) #2 -->
    <text mediaType="image/jpeg" representation="B64" compression="DF">C.1.6.1.r.2</text>
    <!-- C.1.6.1.r.2: Included Documents #2 -->
  </document>
</reference>
<reference typeCode="REFR">
  <document classCode="DOC" moodCode="EVN">
    <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" codeSystemVersion="1.0"
displayName="literatureReference"/>
    <title>J2.17.r</title>
    <!-- @@@J2.17.r 試験/研究の分類 #1 -->
    <text mediaType="application/pdf" representation="B64">C.4.r.2</text>
    <!-- C.4.r.2: Included Documents #1 -->
    <bibliographicDesignationText>C.4.r.1</bibliographicDesignationText>
    <!-- C.4.r.1: Literature Reference(s) #1 -->
    <participation typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <representedOrganization classCode="ORG" determinerCode="INSTANCE">
          <asLocatedEntity classCode="LOCE">
            <location classCode="COUNTRY" determinerCode="INSTANCE">
              <code code="J2.15.r" codeSystem="1.0.3166.1.2.2"/>
              <!-- @@@J2.15.r 公表国 #1 -->
            </location>
          </asLocatedEntity>
        </representedOrganization>
      </assignedEntity>
    </participation>
  </document>
</reference>
<reference typeCode="REFR">
  <document classCode="DOC" moodCode="EVN">
    <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.27" codeSystemVersion="1.0"
displayName="literatureReference"/>
    <title>J2.17.r</title>
    <!-- @@@J2.17.r 試験/研究の分類 #2 -->
    <text mediaType="application/pdf" representation="B64">C.4.r.2</text>
    <!-- C.4.r.2: Included Documents #2 -->
    <bibliographicDesignationText>C.4.r.1</bibliographicDesignationText>
    <!-- C.4.r.1: Literature Reference(s) #2 -->
    <participation typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <representedOrganization classCode="ORG" determinerCode="INSTANCE">
          <asLocatedEntity classCode="LOCE">
            <location classCode="COUNTRY" determinerCode="INSTANCE">
              <code code="J2.15.r" codeSystem="1.0.3166.1.2.2"/>
              <!-- @@@J2.15.r 公表国 #2 -->
            </location>
          </asLocatedEntity>
        </representedOrganization>
      </assignedEntity>
    </participation>
  </document>
</reference>
<component typeCode="COMP">
  <adverseEventAssessment classCode="INVSTG" moodCode="EVN">
    <subject1 typeCode="SBJ">
      <primaryRole classCode="INVSBJ">

```

```

<player1 classCode="PSN" determinerCode="INSTANCE">
  <name>D.1</name>
  <!-- D.1: Patient (name or initials) -->
  <administrativeGenderCode code="D.5" codeSystem="1.0.5218"/>
  <!-- D.5 Sex -->
  <birthTime value="20090101"/>
  <!-- D.2.1: Date of Birth -->
  <deceasedTime value="20090101"/>
  <!-- D.9.1: Date of Death -->
  <asIdentifiedEntity classCode="IDENT">
    <id extension="D.1.1.1" root="2.16.840.1.113883.3.989.2.1.3.7"/>
    <!-- D.1.1.1: Patient Medical Record Number(s) and Source(s) of the Record Number (GP Medical
Record Number) -->
    <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" codeSystemVersion="1.0"
displayName="GP"/>
  </asIdentifiedEntity>
  <asIdentifiedEntity classCode="IDENT">
    <id extension="D.1.1.2" root="2.16.840.1.113883.3.989.2.1.3.8"/>
    <!-- D.1.1.2: Patient Medical Record Number(s) and Source(s) of the Record Number (Specialist
Record Number) -->
    <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" codeSystemVersion="1.0"
displayName="Specialist"/>
  </asIdentifiedEntity>
  <asIdentifiedEntity classCode="IDENT">
    <id extension="D.1.1.3" root="2.16.840.1.113883.3.989.2.1.3.9"/>
    <!-- D.1.1.3: Patient Medical Record Number(s) and Source(s) of the Record Number (Hospital Record
Number) -->
    <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" codeSystemVersion="1.0"
displayName="Hospital Record"/>
  </asIdentifiedEntity>
  <asIdentifiedEntity classCode="IDENT">
    <id extension="D.1.1.4" root="2.16.840.1.113883.3.989.2.1.3.10"/>
    <!-- D.1.1.4: Patient Medical Record Number(s) and Source(s) of the Record Number (Investigation
Number) -->
    <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.4" codeSystemVersion="1.0"
displayName="Investigation"/>
  </asIdentifiedEntity>
  <role classCode="PRS">
    <code code="PRN" codeSystem="2.16.840.1.113883.5.111"/>
    <associatedPerson classCode="PSN" determinerCode="INSTANCE">
      <name>D.10.1</name>
      <!-- D.10.1: Parent Identification -->
      <administrativeGenderCode code="D.10.6" codeSystem="1.0.5218"/>
      <!-- D.10.6: Sex of Parent -->
      <birthTime value="20090101"/>
      <!-- D.10.2.1: Date of Birth of Parent -->
    </associatedPerson>
    <subjectOf2 typeCode="SBJ">
      <observation classCode="OBS" moodCode="EVN">
        <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="age"/>
        <value xsi:type="PQ" value="10" unit="D.10.2.2b"/>
        <!-- D.10.2.2a: Age of Parent (number) -->
        <!-- D.10.2.2b: Age of Parent (unit) -->
      </observation>
    </subjectOf2>
    <subjectOf2 typeCode="SBJ">
      <observation classCode="OBS" moodCode="EVN">
        <code code="22" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="lastMenstrualPeriodDate"/>
        <value xsi:type="TS" value="20090101"/>
        <!-- D.10.3: Last Menstrual Period Date of Parent -->
      </observation>
    </subjectOf2>
    <subjectOf2 typeCode="SBJ">
      <observation classCode="OBS" moodCode="EVN">
        <code code="7" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="bodyWeight"/>
        <value xsi:type="PQ" value="50" unit="kg"/>

```

```

        <!-- D.10.4: Body Weight (kg) of Parent -->
    </observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <code code="17" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="height"/>
        <value xsi:type="PQ" value="160" unit="cm"/>
        <!-- D.10.5: Height (cm) of Parent -->
    </observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <organizer classCode="CATEGORY" moodCode="EVN">
        <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" codeSystemVersion="1.0"
displayName="relevantMedicalHistoryAndConcurrentConditions"/>
        <component typeCode="COMP">
            <observation classCode="OBS" moodCode="EVN">
                <code code="D.10.7.1.r.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.10.7.1.r.1a"/>
                <!-- D.10.7.1.r.1a: MedDRA Version for Medical History #1 -->
                <!-- D.10.7.1.r.1b: Medical History (disease / surgical procedure/ etc.) (MedDRA code) #1 -
->
                <effectiveTime xsi:type="IVL_TS">
                    <low value="20090101"/>
                    <!-- D.10.7.1.r.2: Start Date #1 -->
                    <high value="20090101"/>
                    <!-- D.10.7.1.r.4: End Date #1 -->
                </effectiveTime>
                <outboundRelationship2 typeCode="COMP">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="comment"/>
                        <value xsi:type="ED">D.10.7.1.r.5</value>
                        <!-- D.10.7.1.r.5: Comments #1 -->
                    </observation>
                </outboundRelationship2>
                <inboundRelationship typeCode="REFR">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="13" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="continuing"/>
                        <value xsi:type="BL" value="true"/>
                        <!-- D.10.7.1.r.3: Continuing #1 -->
                    </observation>
                </inboundRelationship>
            </component>
        </component typeCode="COMP">
            <observation classCode="OBS" moodCode="EVN">
                <code code="D.10.7.1.r.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.10.7.1.r.1a"/>
                <!-- D.10.7.1.r.1a: MedDRA Version for Medical History #2 -->
                <!-- D.10.7.1.r.1b: Medical History (disease / surgical procedure/ etc.) (MedDRA code) #2 -
->
                <effectiveTime xsi:type="IVL_TS">
                    <low value="20090101"/>
                    <!-- D.10.7.1.r.2: Start Date #2 -->
                    <high value="20090101"/>
                    <!-- D.10.7.1.r.4: End Date #2 -->
                </effectiveTime>
                <outboundRelationship2 typeCode="COMP">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="comment"/>
                        <value xsi:type="ED">D.10.7.1.r.5</value>
                        <!-- D.10.7.1.r.5: Comments #2 -->
                    </observation>
                </outboundRelationship2>
                <inboundRelationship typeCode="REFR">
                    <observation classCode="OBS" moodCode="EVN">

```

```

        <code code="13" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="continuing"/>
        <value xsi:type="BL" value="true"/>
        <!-- D.10.7.1.r.3: Continuing #2 -->
    </observation>
</inboundRelationship>
</observation>
</component>
<component typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
        <code code="18" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="historyAndConcurrentConditionText"/>
        <value xsi:type="ED">D.10.7.2</value>
        <!-- D.10.7.2: Text for Relevant Medical History and Concurrent Conditions of Parent -->
    </observation>
</component>
</organizer>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <organizer classCode="CATEGORY" moodCode="EVN">
        <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" codeSystemVersion="1.0"
displayName="drugHistory"/>
        <component typeCode="COMP">
            <substanceAdministration classCode="SBADM" moodCode="EVN">
                <effectiveTime xsi:type="IVL_TS">
                    <low value="20090101"/>
                    <!-- D.10.8.r.4: Start Date #1 -->
                    <high value="20090101"/>
                    <!-- D.10.8.r.5: End Date #1 -->
                </effectiveTime>
                <consumable typeCode="CSM">
                    <instanceOfKind classCode="INST">
                        <kindOfProduct classCode="MMAT" determinerCode="KIND">
                            <code code="D.10.8.r.2b" codeSystem="TBD-MPID" codeSystemVersion="D.10.8.r.2a"/>
                            <!-- D.10.8.r.2a: MPID Version Date / Number #1 -->
                            <!-- D.10.8.r.2b: Medicinal Product Identifier (MPID) #1 -->
                            <name>D.10.8.r.1</name>
                            <!-- D.10.8.r.1: Name of Drug as Reported #1 -->
                        </kindOfProduct>
                    </instanceOfKind>
                </consumable>
                <outboundRelationship2 typeCode="RSON">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="indication"/>
                        <value xsi:type="CE" code="D.10.8.r.6b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.10.8.r.6a"/>
                        <!-- D.10.8.r.6a: MedDRA Version for Indication #1 -->
                        <!-- D.10.8.r.6b: Indication (MedDRA code) #1 -->
                    </observation>
                </outboundRelationship2>
                <outboundRelationship2 typeCode="CAUS">
                    <observation classCode="OBS" moodCode="EVN">
                        <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
                        <value xsi:type="CE" code="D.10.8.r.7b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.10.8.r.7a"/>
                        <!-- D.10.8.r.7a: MedDRA Version for Reaction #1 -->
                        <!-- D.10.8.r.7b: Reactions (MedDRA code) #1 -->
                    </observation>
                </outboundRelationship2>
            </substanceAdministration>
        </component>
    </component typeCode="COMP">
        <substanceAdministration classCode="SBADM" moodCode="EVN">
            <effectiveTime xsi:type="IVL_TS">
                <low value="20090101"/>
                <!-- D.10.8.r.4: Start Date #2 -->
                <high value="20090101"/>
            </effectiveTime>
        </substanceAdministration>
    </component typeCode="COMP">

```



```

    <!-- D.10.8.r.5: End Date #2 -->
  </effectiveTime>
  <consumable typeCode="CSM">
    <instanceOfKind classCode="INST">
      <kindOfProduct classCode="MMAT" determinerCode="KIND">
        <code code="D.10.8.r.3b" codeSystem="TBD-PhPID" codeSystemVersion="D.10.8.r.3a"/>
        <!-- D.10.8.r.3a: PhPID Version Date / Number #2 -->
        <!-- D.10.8.r.3b: Pharmaceutical Product Identifier (PhPID) #2 -->
        <name>D.10.8.r.1</name>
        <!-- D.10.8.r.1: Name of Drug as Reported #2 -->
      </kindOfProduct>
    </instanceOfKind>
  </consumable>
  <outboundRelationship2 typeCode="RSON">
    <observation classCode="OBS" moodCode="EVN">
      <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="indication"/>
      <value xsi:type="CE" code="D.10.8.r.6b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.10.8.r.6a"/>
      <!-- D.10.8.r.6a: MedDRA Version for Indication #2 -->
      <!-- D.10.8.r.6b: Indication (MedDRA code) #2 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="CAUS">
    <observation classCode="OBS" moodCode="EVN">
      <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
      <value xsi:type="CE" code="D.10.8.r.7b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.10.8.r.7a"/>
      <!-- D.10.8.r.7a: MedDRA Version for Reaction #2 -->
      <!-- D.10.8.r.7b: Reactions (MedDRA code) #2 -->
    </observation>
  </outboundRelationship2>
</substanceAdministration>
</component>
</organizer>
</subjectOf2>
</role>
</player1>
<subjectOf1 typeCode="SBJ">
  <researchStudy classCode="CLNTRL" moodCode="EVN">
    <id extension="C.5.3" root="2.16.840.1.113883.3.989.2.1.3.5"/>
    <!-- C.5.3: Sponsor Study Number -->
    <code code="C.5.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.8" codeSystemVersion="1.0"/>
    <!-- C.5.4: Study Type Where Reaction(s) / Event(s) Were Observed -->
    <title>C.5.2</title>
    <!-- C.5.2: Study Name -->
    <authorization typeCode="AUTH">
      <studyRegistration classCode="ACT" moodCode="EVN">
        <id extension="C.5.1.r.1" root="2.16.840.1.113883.3.989.2.1.3.6"/>
        <!-- C.5.1.r.1: Study Registration Number #1 -->
        <author typeCode="AUT">
          <territorialAuthority classCode="TERR">
            <governingPlace classCode="COUNTRY" determinerCode="INSTANCE">
              <code code="C.5.1.r.2" codeSystem="1.0.3166.1.2.2"/>
              <!-- C.5.1.r.2: Study Registration Country #1 -->
            </governingPlace>
          </territorialAuthority>
        </author>
      </studyRegistration>
    </authorization>
    <authorization typeCode="AUTH">
      <studyRegistration classCode="ACT" moodCode="EVN">
        <id extension="C.5.1.r.1" root="2.16.840.1.113883.3.989.2.1.3.6"/>
        <!-- C.5.1.r.1 Study Registration Number #2 -->
        <author typeCode="AUT">
          <territorialAuthority classCode="TERR">
            <governingPlace classCode="COUNTRY" determinerCode="INSTANCE">
              <code code="C.5.1.r.2" codeSystem="1.0.3166.1.2.2"/>

```

```

        <!-- C.5.1.r.2: Study Registration Country #2 -->
        </governingPlace>
        </territorialAuthority>
        </author>
        </studyRegistration>
        </authorization>
        </researchStudy>
        </subjectOf1>
        <subjectOf2 typeCode="SBJ">
          <observation classCode="OBS" moodCode="EVN">
            <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="age"/>
            <value xsi:type="PQ" value="10" unit="D.2.2b"/>
            <!-- D.2.2a: Age at Time of Onset of Reaction / Event (number) -->
            <!-- D.2.2b: Age at Time of Onset of Reaction / Event (unit) -->
          </observation>
        </subjectOf2>
        <subjectOf2 typeCode="SBJ">
          <observation classCode="OBS" moodCode="EVN">
            <code code="16" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="gestationPeriod"/>
            <value xsi:type="PQ" value="10" unit="D.2.2.1b"/>
            <!-- D.2.2.1a: Gestation Period When Reaction / Event Was Observed in the Foetus (number) -->
            <!-- D.2.2.1b: Gestation Period When Reaction / Event Was Observed in the Foetus (unit) -->
          </observation>
        </subjectOf2>
        <subjectOf2 typeCode="SBJ">
          <observation classCode="OBS" moodCode="EVN">
            <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="ageGroup"/>
            <value xsi:type="CE" code="D.2.3" codeSystem="2.16.840.1.113883.3.989.2.1.1.9"
codeSystemVersion="1.0"/>
            <!-- D.2.3: Patient Age Group (as per reporter) -->
          </observation>
        </subjectOf2>
        <subjectOf2 typeCode="SBJ">
          <observation classCode="OBS" moodCode="EVN">
            <code code="7" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="bodyWeight"/>
            <value xsi:type="PQ" value="48.2" unit="kg"/>
            <!-- D.3: Body Weight (kg) -->
          </observation>
        </subjectOf2>
        <subjectOf2 typeCode="SBJ">
          <observation classCode="OBS" moodCode="EVN">
            <code code="17" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="height"/>
            <value xsi:type="PQ" value="152" unit="cm"/>
            <!-- D.4: Height (cm) -->
          </observation>
        </subjectOf2>
        <subjectOf2 typeCode="SBJ">
          <observation classCode="OBS" moodCode="EVN">
            <code code="22" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="lastMenstrualPeriodDate"/>
            <value xsi:type="TS" value="20090101"/>
            <!-- D.6: Last Menstrual Period Date -->
          </observation>
        </subjectOf2>
        <subjectOf2 typeCode="SBJ">
          <organizer classCode="CATEGORY" moodCode="EVN">
            <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" codeSystemVersion="1.0"
displayName="relevantMedicalHistoryAndConcurrentConditions"/>
            <component typeCode="COMP">
              <observation classCode="OBS" moodCode="EVN">
                <code code="D.7.1.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.7.1.r.1a"/>
                <!-- D.7.1.r.1a: MedDRA Version for Medical History #1 -->
                <!-- D.7.1.r.1b: Medical History (disease / surgical procedure / etc.) (MedDRA code) #1 -->
                <effectiveTime xsi:type="IVL_TS">

```

```

        <low value="20090101"/>
        <!-- D.7.1.r.2: Start Date #1 -->
        <high value="20090101"/>
        <!-- D.7.1.r.4: End Date #1 -->
    </effectiveTime>
    <outboundRelationship2 typeCode="COMP">
        <observation classCode="OBS" moodCode="EVN">
            <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="comment"/>
            <value xsi:type="ED">D.7.1.r.5</value>
            <!-- D.7.1.r.5: Comments #1 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="EXPL">
        <observation classCode="OBS" moodCode="EVN">
            <code code="38" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="familyHistory"/>
            <value xsi:type="BL" value="true"/>
            <!-- D.7.1.r.6: Family History #1 -->
        </observation>
    </outboundRelationship2>
    <inboundRelationship typeCode="REFR">
        <observation classCode="OBS" moodCode="EVN">
            <code code="13" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="continuing"/>
            <value xsi:type="BL" value="true"/>
            <!-- D.7.1.r.3: Continuing #1 -->
        </observation>
    </inboundRelationship>
</observation>
</component>
<component typeCode="COMP">
    <observation classCode="OBS" moodCode="EVN">
        <code code="D.7.1.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.7.1.r.1a"/>
        <!-- D.7.1.r.1a: MedDRA Version for Medical History #2 -->
        <!-- D.7.1.r.1b: Medical history (disease / surgical procedure / etc.) (MedDRA code) #2 -->
        <effectiveTime xsi:type="IVL_TS">
            <low value="20090101"/>
            <!-- D.7.1.r.2: Start Date #2 -->
            <high value="20090101"/>
            <!-- D.7.1.r.4: End Date #2 -->
        </effectiveTime>
        <outboundRelationship2 typeCode="COMP">
            <observation classCode="OBS" moodCode="EVN">
                <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="comment"/>
                <value xsi:type="ED">D.7.1.r.5</value>
                <!-- D.7.1.r.5: Comments #2 -->
            </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="EXPL">
            <observation classCode="OBS" moodCode="EVN">
                <code code="38" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="familyHistory"/>
                <value xsi:type="BL" value="true"/>
                <!-- D.7.1.r.6: Family History #2 -->
            </observation>
        </outboundRelationship2>
        <inboundRelationship typeCode="REFR">
            <observation classCode="OBS" moodCode="EVN">
                <code code="13" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="continuing"/>
                <value xsi:type="BL" value="true"/>
                <!-- D.7.1.r.3: Continuing #2 -->
            </observation>
        </inboundRelationship>
    </observation>
</component>
</component typeCode="COMP">

```

```

      <observation classCode="OBS" moodCode="EVN">
        <code code="18" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="historyAndConcurrentConditionText"/>
        <value xsi:type="ED">D.7.2</value>
        <!-- D.7.2: Text for Relevant Medical History and Concurrent Conditions (not including reaction
/ event) -->
      </observation>
    </component>
    <component typeCode="COMP">
      <observation classCode="OBS" moodCode="EVN">
        <code code="11" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="concomitantTherapy"/>
        <value xsi:type="BL" value="true"/>
        <!-- D.7.3: Concomitant Therapies -->
      </observation>
    </component>
  </organizer>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <organizer classCode="CATEGORY" moodCode="EVN">
    <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" codeSystemVersion="1.0"
displayName="drugHistory"/>
    <component typeCode="COMP">
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <effectiveTime xsi:type="IVL_TS">
          <low value="20090101"/>
          <!-- D.8.r.4: Start Date #1 -->
          <high value="20090101"/>
          <!-- D.8.r.5: End Date #1 -->
        </effectiveTime>
        <consumable typeCode="CSM">
          <instanceOfKind classCode="INST">
            <kindOfProduct classCode="MMAT" determinerCode="KIND">
              <code code="D.8.r.2b" codeSystem="TBD-MPID" codeSystemVersion="D.8.r.2a"/>
              <!-- D.8.r.2a: MPID Version Date / Number #1 -->
              <!-- D.8.r.2b: Medicinal Product Identifier (MPID) #1 -->
              <name>D.8.r.1</name>
              <!-- D.8.r.1: Name of Drug as Reported #1 -->
            </kindOfProduct>
          </instanceOfKind>
        </consumable>
        <outboundRelationship2 typeCode="RSON">
          <observation classCode="OBS" moodCode="EVN">
            <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="indication"/>
            <value xsi:type="CE" code="D.8.r.6b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.8.r.6a"/>
            <!-- D.8.r.6a: MedDRA Version for Indication #1 -->
            <!-- D.8.r.6b: Indication (MedDRA code) #1 -->
          </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="CAUS">
          <observation classCode="OBS" moodCode="EVN">
            <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
            <value xsi:type="CE" code="D.8.r.7b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.8.r.7a"/>
            <!-- D.8.r.7a: MedDRA Version for Reaction #1 -->
            <!-- D.8.r.7b: Reaction (MedDRA code) #1 -->
          </observation>
        </outboundRelationship2>
      </substanceAdministration>
    </component>
  <component typeCode="COMP">
    <substanceAdministration classCode="SBADM" moodCode="EVN">
      <effectiveTime xsi:type="IVL_TS">
        <low value="20090101"/>
        <!-- D.8.r.4: Start Date #2 -->
        <high value="20090101"/>

```

```

        <!-- D.8.r.5: End Date #2 -->
    </effectiveTime>
    <consumable typeCode="CSM">
        <instanceOfKind classCode="INST">
            <kindOfProduct classCode="MMAT" determinerCode="KIND">
                <code code="D.8.r.3b" codeSystem="TBD-PhPID" codeSystemVersion="D.8.r.3a"/>
                <!-- D.8.r.3a: PhPID Version Date / Number -->
                <!-- D.8.r.3b: Pharmaceutical Product Identifier (PhPID) #2 -->
                <name>D.8.r.1</name>
                <!-- D.8.r.1: Name of Drug as Reported #2 -->
            </kindOfProduct>
        </instanceOfKind>
    </consumable>
    <outboundRelationship2 typeCode="RSON">
        <observation classCode="OBS" moodCode="EVN">
            <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="indication"/>
            <value xsi:type="CE" code="D.8.r.6b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.8.r.6a"/>
            <!-- D.8.r.6a: MedDRA Version for Indication #2 -->
            <!-- D.8.r.6b: Indication (MedDRA code) #2 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="CAUS">
        <observation classCode="OBS" moodCode="EVN">
            <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
            <value xsi:type="CE" code="D.8.r.7b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.8.r.7a"/>
            <!-- D.8.r.7a: MedDRA Version for Reaction #2 -->
            <!-- D.8.r.7b: Reaction (MedDRA code) #2 -->
        </observation>
    </outboundRelationship2>
</substanceAdministration>
</component>
</organizer>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <code code="32" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reportedCauseOfDeath"/>
        <value xsi:type="CE" code="D.9.2.r.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.9.2.r.1a">
            <!-- D.9.2.r.1a: MedDRA Version for Reported Cause(s) of Death #1 -->
            <!-- D.9.2.r.1b: Reported Cause(s) of Death (MedDRA code) #1 -->
            <originalText>D.9.2.r.2</originalText>
            <!-- D.9.2.r.2: Reported Cause(s) of Death (free text) #1 -->
        </value>
    </observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <code code="32" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reportedCauseOfDeath"/>
        <value xsi:type="CE" code="D.9.2.r.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.9.2.r.1a">
            <!-- D.9.2.r.1a: MedDRA Version for Reported Cause(s) of Death #2 -->
            <!-- D.9.2.r.1b: Reported Cause(s) of Death (MedDRA code) #2 -->
            <originalText>D.9.2.r.2</originalText>
            <!-- D.9.2.r.2: Reported Cause(s) of Death (free text) #2 -->
        </value>
    </observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <code code="5" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="autopsy"/>
        <value xsi:type="BL" value="true"/>
        <!-- D.9.3 Was Autopsy Done? -->

```

```

    <outboundRelationship2 typeCode="DRIV">
      <observation classCode="OBS" moodCode="EVN">
        <code code="8" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="causeOfDeath"/>
        <value xsi:type="CE" code="D.9.4.r.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.9.4.r.1a">
          <!-- D.9.4.r.1a: MedDRA Version for Autopsy-determined Cause(s) of Death #1 -->
          <!-- D.9.4.r.1b Autopsy-determined Cause(s) of Death (MedDRA code) #1 -->
          <originalText>D.9.4.r.2</originalText>
          <!-- D.9.4.r.2: Autopsy-determined Cause(s) of Death (free text) #1 -->
        </value>
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="DRIV">
      <observation classCode="OBS" moodCode="EVN">
        <code code="8" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="causeOfDeath"/>
        <value xsi:type="CE" code="D.9.4.r.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="D.9.4.r.1a">
          <!-- D.9.4.r.1a: MedDRA Version for Autopsy-determined Cause(s) of Death #2 -->
          <!-- D.9.4.r.1b Autopsy-determined Cause(s) of Death (MedDRA code) #2 -->
          <originalText>D.9.4.r.2</originalText>
          <!-- D.9.4.r.2: Autopsy-determined Cause(s) of Death (free text) #2 -->
        </value>
      </observation>
    </outboundRelationship2>
  </observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
    <effectiveTime xsi:type="IVL_TS">
      <low value="20090101"/>
      <!-- E.i.4: Date of Start of Reaction / Event #1 -->
      <high value="20090102"/>
      <!-- E.i.5: Date of End of Reaction / Event #1 -->
    </effectiveTime>
    <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="E.i.2.1a">
      <!-- E.i.2.1a: MedDRA Version for Reaction / Event #1 -->
      <!-- E.i.2.1b: Reaction / Event (MedDRA code) #1 -->
      <originalText language="E.i.1.1b">E.i.1.1a</originalText>
      <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #1 -->
      <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #1 -->
    </value>
    <location typeCode="LOC">
      <locatedEntity classCode="LOCE">
        <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
          <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
          <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #1 -->
        </locatedPlace>
      </locatedEntity>
    </location>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reactionForTranslation"/>
        <value xsi:type="ED">E.i.1.2</value>
        <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #1 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="termHighlightedByReporter"/>
        <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"
codeSystemVersion="1.0"/>

```

```

      <!-- E.i.3.1: Term Highlighted by the Reporter #1 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInDeath"/>
      <value xsi:type="BL" value="true"/>
      <!-- E.i.3.2a: Results in Death #1 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="isLifeThreatening"/>
      <value xsi:type="BL" nullFlavor="NI"/>
      <!-- E.i.3.2b: Life Threatening #1 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="requiresInpatientHospitalization"/>
      <value xsi:type="BL" value="true"/>
      <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #1 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInPersistentOrSignificantDisability"/>
      <value xsi:type="BL" nullFlavor="NI"/>
      <!-- E.i.3.2d: Disabling / Incapacitating #1 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="congenitalAnomalyBirthDefect"/>
      <value xsi:type="BL" nullFlavor="NI"/>
      <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #1 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="otherMedicallyImportantCondition"/>
      <value xsi:type="BL" value="true"/>
      <!-- E.i.3.2f: Other Medically Important Condition #1 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="outcome"/>
      <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"
codeSystemVersion="1.0"/>
      <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #1 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="medicalConfirmationByHealthProfessional"/>
      <value xsi:type="BL" value="true"/>
      <!-- E.i.8: Medical Confirmation by Healthcare Professional #1 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">

```

```

      <observation classCode="OBS" moodCode="EVN">
        <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="未知·既知"/>
        <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.0"/>
        <!-- @@@J2.14.i 未知·既知 #1 -->
      </observation>
    </outboundRelationship2>
  </subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
    <effectiveTime xsi:type="IVL_TS">
      <low value="20090101"/>
      <!-- E.i.4: Date of Start of Reaction / Event #2 -->
      <width value="24" unit="E.i.6b"/>
      <!-- E.i.6a: Duration of Reaction / Event (number) #2 -->
      <!-- E.i.6b: Duration of Reaction / Event (unit) #2 -->
    </effectiveTime>
    <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="E.i.2.1a">
      <!-- E.i.2.1a: MedDRA Version for Reaction / Event #2 -->
      <!-- E.i.2.1b: Reaction / Event (MedDRA code) #2 -->
      <originalText language="E.i.1.1b">E.i.1.1a</originalText>
      <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #2 -->
      <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #2 -->
    </value>
    <location typeCode="LOC">
      <locatedEntity classCode="LOCE">
        <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
          <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
          <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #2 -->
        </locatedPlace>
      </locatedEntity>
    </location>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reactionForTranslation"/>
        <value xsi:type="ED">E.i.1.2</value>
        <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #2 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="termHighlightedByReporter"/>
        <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"
codeSystemVersion="1.0"/>
        <!-- E.i.3.1: Term Highlighted by the Reporter #2 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInDeath"/>
        <value xsi:type="BL" value="true"/>
        <!-- E.i.3.2a: Results in Death #2 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="isLifeThreatening"/>
        <value xsi:type="BL" nullFlavor="NI"/>
        <!-- E.i.3.2b: Life Threatening #2 -->
      </observation>
    </outboundRelationship2>
  </subjectOf2>

```



```

    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="requiresInpatientHospitalization"/>
      <value xsi:type="BL" value="true"/>
      <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #2 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInPersistentOrSignificantDisability"/>
      <value xsi:type="BL" nullFlavor="NI"/>
      <!-- E.i.3.2d: Disabling / Incapacitating #2 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="congenitalAnomalyBirthDefect"/>
      <value xsi:type="BL" nullFlavor="NI"/>
      <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #2 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="otherMedicallyImportantCondition"/>
      <value xsi:type="BL" value="true"/>
      <!-- E.i.3.2f: Other Medically Important Condition #2 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="outcome"/>
      <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"
codeSystemVersion="1.0"/>
      <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #2 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="medicalConfirmationByHealthProfessional"/>
      <value xsi:type="BL" value="true"/>
      <!-- E.i.8: Medical Confirmation by Healthcare Professional #2 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="未知·既知"/>
      <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.0"/>
      <!-- @@@J2.14.i 未知·既知 #2 -->
    </observation>
  </outboundRelationship2>
</observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="3a8626cb-9f1b-4ea8-8a0f-e0ff34430adf"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
    <effectiveTime xsi:type="IVL_TS">
      <width value="24" unit="E.i.6b"/>
    </effectiveTime>
  </observation>

```

```

        <!-- E. i. 6a: Duration of Reaction / Event (number) #3 -->
        <!-- E. i. 6b: Duration of Reaction / Event (unit) #3 -->
        <high value="20101201"/>
        <!-- E. i. 5: Date of End of Reaction / Event #3 -->
    </effectiveTime>
    <value xsi:type="CE" code="E. i. 2. 1b" codeSystem="2. 16. 840. 1. 113883. 6. 163"
codeSystemVersion="E. i. 2. 1a">
        <!-- E. i. 2. 1a: MedDRA Version for Reaction / Event #3 -->
        <!-- E. i. 2. 1b: Reaction / Event (MedDRA code) #3 -->
        <originalText language="E. i. 1. 1b">E. i. 1. 1a</originalText>
        <!-- E. i. 1. 1a: Reaction / Event as Reported by the Primary Source in Native Language #3 -->
        <!-- E. i. 1. 1b: Reaction / Event as Reported by the Primary Source Language #3 -->
    </value>
    <location typeCode="LOC">
        <locatedEntity classCode="LOCE">
            <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
                <code code="E. i. 9" codeSystem="1. 0. 3166. 1. 2. 2"/>
                <!-- E. i. 9: Identification of the Country Where the Reaction / Event Occurred #3 -->
            </locatedPlace>
        </locatedEntity>
    </location>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="30" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 19" codeSystemVersion="1. 1"
displayName="reactionForTranslation"/>
            <value xsi:type="ED">E. i. 1. 2</value>
            <!-- E. i. 1. 2: Reaction / Event as Reported by the Primary Source for Translation #3 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="37" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 19" codeSystemVersion="1. 1"
displayName="termHighlightedByReporter"/>
            <value xsi:type="CE" code="E. i. 3. 1" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 10"
codeSystemVersion="1. 0"/>
            <!-- E. i. 3. 1: Term Highlighted by the Reporter #3 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="34" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 19" codeSystemVersion="1. 1"
displayName="resultsInDeath"/>
            <value xsi:type="BL" value="true"/>
            <!-- E. i. 3. 2a: Results in Death #3 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="21" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 19" codeSystemVersion="1. 1"
displayName="isLifeThreatening"/>
            <value xsi:type="BL" nullFlavor="NI"/>
            <!-- E. i. 3. 2b: Life Threatening #3 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="33" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 19" codeSystemVersion="1. 1"
displayName="requiresInpatientHospitalization"/>
            <value xsi:type="BL" value="true"/>
            <!-- E. i. 3. 2c: Caused / Prolonged Hospitalisation #3 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="35" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 19" codeSystemVersion="1. 1"
displayName="resultsInPersistentOrSignificantDisability"/>
            <value xsi:type="BL" nullFlavor="NI"/>
            <!-- E. i. 3. 2d: Disabling / Incapacitating #3 -->
        </observation>
    </outboundRelationship2>

```

```

</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="congenitalAnomalyBirthDefect"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #3 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="25" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="otherMedicallyImportantCondition"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.3.2f: Other Medically Important Condition #3 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="outcome"/>
    <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"
codeSystemVersion="1.0"/>
    <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #3 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="medicalConfirmationByHealthProfessional"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.8: Medical Confirmation by Healthcare Professional #3 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="未知·既知"/>
    <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.0"/>
    <!-- @J2.14.i 未知·既知 #3 -->
  </observation>
</outboundRelationship2>
</observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="IVL_TS">
        <low value="20090101"/>
        <!-- E.i.4: Date of Start of Reaction / Event #4 -->
        <high value="20101201"/>
        <!-- E.i.5: Date of End of Reaction / Event #4 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <width value="24" unit="E.i.6b"/>
        <!-- E.i.6a: Duration of Reaction / Event (number) #4 -->
        <!-- E.i.6b: Duration of Reaction / Event (unit) #4 -->
      </comp>
    </effectiveTime>
    <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="E.i.2.1a">
      <!-- E.i.2.1a: MedDRA Version for Reaction / Event #4 -->
      <!-- E.i.2.1b: Reaction / Event (MedDRA code) #4 -->
      <originalText language="E.i.1.1b">E.i.1.1a</originalText>
      <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #4 -->
    </value>
  </observation>
</subjectOf2>

```

```

    <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #4 -->
  </value>
  <location typeCode="LOC">
    <locatedEntity classCode="LOCE">
      <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
        <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
        <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #4 -->
      </locatedPlace>
    </locatedEntity>
  </location>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reactionForTranslation"/>
      <value xsi:type="ED">E.i.1.2</value>
      <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #4 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="termHighlightedByReporter"/>
      <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"
codeSystemVersion="1.0"/>
      <!-- E.i.3.1: Term Highlighted by the Reporter #4 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInDeath"/>
      <value xsi:type="BL" value="true"/>
      <!-- E.i.3.2a: Results in Death #4 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="isLifeThreatening"/>
      <value xsi:type="BL" nullFlavor="NI"/>
      <!-- E.i.3.2b: Life Threatening #4 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="requiresInpatientHospitalization"/>
      <value xsi:type="BL" value="true"/>
      <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #4 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInPersistentOrSignificantDisability"/>
      <value xsi:type="BL" nullFlavor="NI"/>
      <!-- E.i.3.2d: Disabling / Incapacitating #4 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="congenitalAnomalyBirthDefect"/>
      <value xsi:type="BL" nullFlavor="NI"/>
      <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #4 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">

```

```

                <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="otherMedicallyImportantCondition"/>
                <value xsi:type="BL" value="true"/>
                <!-- E.i.3.2f: Other Medically Important Condition #4 -->
            </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
                <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="outcome"/>
                <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"
codeSystemVersion="1.0"/>
                <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #4 -->
            </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
                <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="medicalConfirmationByHealthProfessional"/>
                <value xsi:type="BL" value="true"/>
                <!-- E.i.8: Medical Confirmation by Healthcare Professional #4 -->
            </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="PERT">
            <observation classCode="OBS" moodCode="EVN">
                <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="未知·既知"/>
                <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.0"/>
                <!-- @J2.14.i 未知·既知 #4 -->
            </observation>
        </outboundRelationship2>
    </observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <id root="1071064c-cf10-4a3b-83c1-34f9ddb7ea6d"/>
        <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
        <effectiveTime xsi:type="IVL_TS">
            <low value="20090101"/>
            <!-- E.i.4: Date of Start of Reaction / Event #5 -->
        </effectiveTime>
        <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="E.i.2.1a">
            <!-- E.i.2.1a: MedDRA Version for Reaction / Event #5 -->
            <!-- E.i.2.1b: Reaction / Event (MedDRA code) #5 -->
            <originalText language="E.i.1.Ib">E.i.1.1a</originalText>
            <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #5 -->
            <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #5 -->
        </value>
        <location typeCode="LOC">
            <locatedEntity classCode="LOCE">
                <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
                    <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
                    <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #5 -->
                </locatedPlace>
            </locatedEntity>
        </location>
    </subjectOf2>
</outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
        <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reactionForTranslation"/>
        <value xsi:type="ED">E.i.1.2</value>
        <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #5 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">

```

```

        <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="termHighlightedByReporter"/>
        <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"
codeSystemVersion="1.0"/>
        <!-- E.i.3.1:Term Highlighted by the Reporter #5 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
        <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInDeath"/>
        <value xsi:type="BL" value="true"/>
        <!-- E.i.3.2a: Results in Death #5 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
        <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="isLifeThreatening"/>
        <value xsi:type="BL" nullFlavor="NI"/>
        <!-- E.i.3.2b: Life Threatening #5 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
        <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="requiresInpatientHospitalization"/>
        <value xsi:type="BL" value="true"/>
        <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #5 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
        <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInPersistentOrSignificantDisability"/>
        <value xsi:type="BL" nullFlavor="NI"/>
        <!-- E.i.3.2d: Disabling / Incapacitating #5 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
        <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="congenitalAnomalyBirthDefect"/>
        <value xsi:type="BL" nullFlavor="NI"/>
        <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #5 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
        <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="otherMedicallyImportantCondition"/>
        <value xsi:type="BL" value="true"/>
        <!-- E.i.3.2f: Other Medically Important Condition #5 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
        <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="outcome"/>
        <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"
codeSystemVersion="1.0"/>
        <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #5 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
        <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="medicalConfirmationByHealthProfessional"/>
        <value xsi:type="BL" value="true"/>

```

```

      <!-- E.i.8: Medical Confirmation by Healthcare Professional #5 -->
    </observation>
  </outboundRelationship2>
  <outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
      <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="未知·既知"/>
      <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.0"/>
      <!-- @J2.14.i 未知·既知 #5 -->
    </observation>
  </outboundRelationship2>
</observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="1f927283-10b6-4334-9d43-e925640fb18f"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
    <effectiveTime xsi:type="IVL_TS">
      <high value="20090101"/>
      <!-- E.i.4: Date of Start of Reaction / Event #6 -->
    </effectiveTime>
    <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="E.i.2.1a">
      <!-- E.i.2.1a: MedDRA Version for Reaction / Event #6 -->
      <!-- E.i.2.1b: Reaction / Event (MedDRA code) #6 -->
      <originalText language="E.i.1.1b">E.i.1.1a</originalText>
      <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #6 -->
      <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #6 -->
    </value>
    <location typeCode="LOC">
      <locatedEntity classCode="LOCE">
        <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
          <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
          <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #6 -->
        </locatedPlace>
      </locatedEntity>
    </location>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reactionForTranslation"/>
        <value xsi:type="ED">E.i.1.2</value>
        <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #6 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="termHighlightedByReporter"/>
        <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"
codeSystemVersion="1.0"/>
        <!-- E.i.3.1: Term Highlighted by the Reporter #6 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInDeath"/>
        <value xsi:type="BL" value="true"/>
        <!-- E.i.3.2a: Results in Death #6 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="isLifeThreatening"/>
        <value xsi:type="BL" nullFlavor="NI"/>

```

```

        <!-- E.i.3.2b: Life Threatening #6 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
        <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="requiresInpatientHospitalization"/>
        <value xsi:type="BL" value="true"/>
        <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #6 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
        <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInPersistentOrSignificantDisability"/>
        <value xsi:type="BL" nullFlavor="NI"/>
        <!-- E.i.3.2d: Disabling / Incapacitating #6 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
        <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="congenitalAnomalyBirthDefect"/>
        <value xsi:type="BL" nullFlavor="NI"/>
        <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #6 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
        <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="otherMedicallyImportantCondition"/>
        <value xsi:type="BL" value="true"/>
        <!-- E.i.3.2f: Other Medically Important Condition #6 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
        <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="outcome"/>
        <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"
codeSystemVersion="1.0"/>
        <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #6 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
        <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="medicalConfirmationByHealthProfessional"/>
        <value xsi:type="BL" value="true"/>
        <!-- E.i.8: Medical Confirmation by Healthcare Professional #6 -->
    </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
    <observation classCode="OBS" moodCode="EVN">
        <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="未知·既知"/>
        <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.0"/>
        <!-- @J2.14.i 未知·既知 #6 -->
    </observation>
</outboundRelationship2>
</observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <id root="e0342969-38be-423f-b6bb-ce14bc279d8e"/>
        <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
        <effectiveTime xsi:type="IVL_TS">

```



```

        <width value="24" unit="E.i.6b"/>
        <!-- E.i.6a: Duration of Reaction / Event (number) #7 -->
        <!-- E.i.6b: Duration of Reaction / Event (unit) #7 -->
    </effectiveTime>
    <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="E.i.2.1a">
        <!-- E.i.2.1a: MedDRA Version for Reaction / Event #7 -->
        <!-- E.i.2.1b: Reaction / Event (MedDRA code) #7 -->
        <originalText language="E.i.1.1b">E.i.1.1a</originalText>
        <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #7 -->
        <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #7 -->
    </value>
    <location typeCode="LOC">
        <locatedEntity classCode="LOCE">
            <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
                <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
                <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #7 -->
            </locatedPlace>
        </locatedEntity>
    </location>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reactionForTranslation"/>
            <value xsi:type="ED">E.i.1.2</value>
            <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #7 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="termHighlightedByReporter"/>
            <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"
codeSystemVersion="1.0"/>
            <!-- E.i.3.1: Term Highlighted by the Reporter #7 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInDeath"/>
            <value xsi:type="BL" value="true"/>
            <!-- E.i.3.2a: Results in Death #7 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="isLifeThreatening"/>
            <value xsi:type="BL" nullFlavor="NI"/>
            <!-- E.i.3.2b: Life Threatening #7 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="requiresInpatientHospitalization"/>
            <value xsi:type="BL" value="true"/>
            <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #7 -->
        </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInPersistentOrSignificantDisability"/>
            <value xsi:type="BL" nullFlavor="NI"/>
            <!-- E.i.3.2d: Disabling / Incapacitating #7 -->
        </observation>
    </outboundRelationship2>

```

```

    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="congenitalAnomalyBirthDefect"/>
        <value xsi:type="BL" nullFlavor="NI"/>
        <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #7 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="otherMedicallyImportantCondition"/>
        <value xsi:type="BL" value="true"/>
        <!-- E.i.3.2f: Other Medically Important Condition #7 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="outcome"/>
        <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"
codeSystemVersion="1.0"/>
        <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #7 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="medicalConfirmationByHealthProfessional"/>
        <value xsi:type="BL" value="true"/>
        <!-- E.i.8: Medical Confirmation by Healthcare Professional #7 -->
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">
        <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="未知・既知"/>
        <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.0"/>
        <!-- @J2.14.i 未知・既知 #7 -->
      </observation>
    </outboundRelationship2>
  </observation>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="a15be092-8070-426d-af04-6863263443e0"/>
    <code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reaction"/>
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="IVL_TS">
        <low value="20090101"/>
        <!-- E.i.4: Date of Start of Reaction / Event #8 -->
        <width value="24" unit="E.i.6b"/>
        <!-- E.i.6a: Duration of Reaction / Event (number) #8 -->
        <!-- E.i.6b: Duration of Reaction / Event (unit) #8 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <high value="20101201"/>
        <!-- E.i.5: Date of End of Reaction / Event #8 -->
      </comp>
    </effectiveTime>
    <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="E.i.2.1a">
      <!-- E.i.2.1a: MedDRA Version for Reaction / Event #8 -->
      <!-- E.i.2.1b: Reaction / Event (MedDRA code) #8 -->
      <originalText language="E.i.1.1b">E.i.1.1a</originalText>
      <!-- E.i.1.1a: Reaction / Event as Reported by the Primary Source in Native Language #8 -->
      <!-- E.i.1.1b: Reaction / Event as Reported by the Primary Source Language #8 -->
    </value>
  </observation>
</subjectOf2>

```

```

</value>
<location typeCode="LOC">
  <locatedEntity classCode="LOCE">
    <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
      <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
      <!-- E.i.9: Identification of the Country Where the Reaction / Event Occurred #8 -->
    </locatedPlace>
  </locatedEntity>
</location>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="reactionForTranslation"/>
    <value xsi:type="ED">E.i.1.2</value>
    <!-- E.i.1.2: Reaction / Event as Reported by the Primary Source for Translation #8 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="termHighlightedByReporter"/>
    <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10"
codeSystemVersion="1.0"/>
    <!-- E.i.3.1:Term Highlighted by the Reporter #8 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInDeath"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.3.2a: Results in Death #8 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="isLifeThreatening"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <!-- E.i.3.2b: Life Threatening #8 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="requiresInpatientHospitalization"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.3.2c: Caused / Prolonged Hospitalisation #8 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="resultsInPersistentOrSignificantDisability"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <!-- E.i.3.2d: Disabling / Incapacitating #8 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="congenitalAnomalyBirthDefect"/>
    <value xsi:type="BL" nullFlavor="NI"/>
    <!-- E.i.3.2e: Congenital Anomaly / Birth Defect #8 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"

```

```

displayName="otherMedicallyImportantCondition"/>
  <value xsi:type="BL" value="true"/>
  <!-- E.i.3.2f: Other Medically Important Condition #8 -->
</observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="outcome"/>
    <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11"
codeSystemVersion="1.0"/>
    <!-- E.i.7: Outcome of Reaction / Event at the Time of Last Observation #8 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="medicalConfirmationByHealthProfessional"/>
    <value xsi:type="BL" value="true"/>
    <!-- E.i.8: Medical Confirmation by Healthcare Professional #8 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="11" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="未知・既知"/>
    <value xsi:type="CE" code="J2.14.i" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.8"
codeSystemVersion="1.0"/>
    <!-- @J2.14.i 未知・既知 #8 -->
  </observation>
</outboundRelationship2>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <organizer classCode="CATEGORY" moodCode="EVN">
    <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" codeSystemVersion="1.0"
displayName="testsAndProceduresRelevantToTheInvestigation"/>
    <component typeCode="COMP">
      <observation classCode="OBS" moodCode="EVN">
        <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
          <!-- F.r.2.2a: MedDRA Version for Test Name #1 -->
          <!-- F.r.2.2b: Test Name (MedDRA code) #1 -->
          <originalText>F.r.2.1</originalText>
          <!-- F.r.2.1: Test Name (free text) #1 -->
        </code>
        <effectiveTime value="20090101"/>
        <!-- F.r.1: Test Date #1 -->
        <value xsi:type="IVL_PQ">
          <center value="10" unit="mg/dl"/>
          <!-- F.r.3.2: Test Result (value / qualifier) #1 -->
          <!-- F.r.3.3: Test Result (unit) #1 -->
        </value>
        <interpretationCode code="F.r.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.12"
codeSystemVersion="1.0"/>
        <!-- F.r.3.1: Test Result (code) #1 -->
        <referenceRange typeCode="REFV">
          <observationRange classCode="OBS" moodCode="EVN.CRT">
            <value xsi:type="PQ" value="40" unit="mg/dl"/>
            <!-- F.r.4: Normal Low Value #1 -->
            <interpretationCode code="L" codeSystem="2.16.840.1.113883.5.83"/>
          </observationRange>
        </referenceRange>
        <referenceRange typeCode="REFV">
          <observationRange classCode="OBS" moodCode="EVN.CRT">
            <value xsi:type="PQ" value="110" unit="mg/dl"/>
            <!-- F.r.5: Normal High Value #1 -->
            <interpretationCode code="H" codeSystem="2.16.840.1.113883.5.83"/>
          </observationRange>
        </referenceRange>
      </component>
    </organizer>
  </subjectOf2>
</subjectOf2>

```

```

<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="comment"/>
    <value xsi:type="ED">F.r.6</value>
    <!-- F.r.6: Comments (free text) #1 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="25" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="moreInformationAvailable"/>
    <value xsi:type="BL" value="true"/>
    <!-- F.r.7: More Information Available #1 -->
  </observation>
</outboundRelationship2>
</observation>
</component>
<component typeCode="COMP">
  <observation classCode="OBS" moodCode="EVN">
    <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
      <!-- F.r.2.2a: MedDRA Version for Test Name #2 -->
      <!-- F.r.2.2b: Test Name (MedDRA code) #2 -->
      <originalText>F.r.2.1</originalText>
      <!-- F.r.2.1: Test Name (free text) #2 -->
    </code>
    <effectiveTime value="20090101"/>
    <!-- F.r.1: Test Date #2 -->
    <value xsi:type="IVL_PQ">
      <low nullFlavor="NINF"/>
      <high value="10" unit="mg/dl" inclusive="false"/>
    </value>
    <!-- F.r.3.2: Test Result (value / qualifier) #2 -->
    <!-- F.r.3.3: Test Result (unit) #2 -->
    <!-- LT 10 mg/dl #2 -->
  </observation>
</component>
<component typeCode="COMP">
  <observation classCode="OBS" moodCode="EVN">
    <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
      <!-- F.r.2.2a: MedDRA Version for Test Name #3 -->
      <!-- F.r.2.2b: Test Name (MedDRA code) #3 -->
      <originalText>F.r.2.1</originalText>
      <!-- F.r.2.1: Test Name (free text) #3 -->
    </code>
    <effectiveTime value="20090101"/>
    <!-- F.r.1: Test Date #3 -->
    <value xsi:type="IVL_PQ">
      <low nullFlavor="NINF"/>
      <high value="10" unit="mg/dl" inclusive="true"/>
    </value>
    <!-- F.r.3.2: Test Result (value / qualifier) #3 -->
    <!-- F.r.3.3: Test Result (unit) #3 -->
    <!-- LE 10 mg/dl #3 -->
  </observation>
</component>
<component typeCode="COMP">
  <observation classCode="OBS" moodCode="EVN">
    <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
      <!-- F.r.2.2a: MedDRA Version for Test Name #4 -->
      <!-- F.r.2.2b: Test Name (MedDRA code) #4 -->
      <originalText>F.r.2.1</originalText>
      <!-- F.r.2.1: Test Name (free text) #4 -->
    </code>
    <effectiveTime value="20090101"/>
    <!-- F.r.1: Test Date #4 -->
    <value xsi:type="IVL_PQ">
      <low value="10" unit="mg/dl" inclusive="false"/>
      <high nullFlavor="PINF"/>
    </value>
  </observation>
</component>

```

```

    </value>
    <!-- F.r.3.2: Test Result (value / qualifier) #4 -->
    <!-- F.r.3.3: Test Result (unit) #4 -->
    <!-- GT 10 mg/dl #4 -->
  </observation>
</component>
<component typeCode="COMP">
  <observation classCode="OBS" moodCode="EVN">
    <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
      <!-- F.r.2.2a: MedDRA Version for Test Name #5 -->
      <!-- F.r.2.2b: Test Name (MedDRA code) #5 -->
      <originalText>F.r.2.1</originalText>
      <!-- F.r.2.1: Test Name (free text) #5 -->
    </code>
    <effectiveTime value="20090101"/>
    <!-- F.r.1: Test Date #5 -->
    <value xsi:type="IVL_PQ">
      <low value="10" unit="mg/dl" inclusive="true"/>
      <high nullFlavor="PINF"/>
    </value>
    <!-- F.r.3.2: Test Result (value / qualifier) #5 -->
    <!-- F.r.3.3: Test Result (unit) #5 -->
    <!-- GE 10 mg/dl #5 -->
  </observation>
</component>
<component typeCode="COMP">
  <observation classCode="OBS" moodCode="EVN">
    <code code="F.r.2.2b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="F.r.2.2a">
      <!-- F.r.2.2a: MedDRA Version for Test Name #6 -->
      <!-- F.r.2.2b: Test Name (MedDRA code) #6 -->
      <originalText>F.r.2.1</originalText>
      <!-- F.r.2.1: Test Name (free text) #6 -->
    </code>
    <effectiveTime value="20090101"/>
    <!-- F.r.1: Test Date #6 -->
    <value xsi:type="ED">F.r.3.4</value>
    <!-- F.r.3.4: Result Unstructured Data (free text) #6 -->
  </observation>
</component>
</organizer>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <organizer classCode="CATEGORY" moodCode="EVN">
    <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.20" codeSystemVersion="1.0"
displayName="drugInformation"/>
    <!-- G.k Drug(s) Information (repeat as necessary) #1 -->
    <component typeCode="COMP">
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
        <consumable typeCode="CSM">
          <instanceOfKind classCode="INST">
            <kindOfProduct classCode="MMAT" determinerCode="KIND">
              <code code="G.k.2.1.1b" codeSystem="TBD-MPID" codeSystemVersion="G.k.2.1.1a"/>
              <!-- G.k.2.1.1a: MPID Version Date / Number #1 -->
              <!-- G.k.2.1.1b: Medicinal Product Identifier (MPID) #1 -->
              <name>G.k.2.2</name>
              <!-- G.k.2.2: Medicinal Product Name as Reported by the Primary Source #1 -->
              <asManufacturedProduct classCode="MANU">
                <subjectOf typeCode="SBJ">
                  <approval classCode="CNTRCT" moodCode="EVN">
                    <id extension="G.k.3.1" root="2.16.840.1.113883.3.989.2.1.3.4"/>
                    <!-- G.k.3.1: Authorisation / Application Number #1 -->
                    <holder typeCode="HLD">
                      <role classCode="HLD">
                        <playingOrganization classCode="ORG" determinerCode="INSTANCE">
                          <name>G.k.3.3</name>
                          <!-- G.k.3.3: Name of Holder / Applicant #1 -->
                        </playingOrganization>
                      </role>
                    </approval>
                  </subjectOf>
                </asManufacturedProduct>
              </name>
            </kindOfProduct>
          </instanceOfKind>
        </consumable>
      </substanceAdministration>
    </component>
  </organizer>
</subjectOf2>

```

```

</holder>
<author typeCode="AUT">
  <territorialAuthority classCode="TERR">
    <territory classCode="NAT" determinerCode="INSTANCE">
      <code code="G. k. 3. 2" codeSystem="1. 0. 3166. 1. 2. 2"/>
      <!-- G. k. 3. 2: Country of Authorisation / Application #1 -->
    </territory>
  </territorialAuthority>
</author>
<pertinentInformation typeCode="PERT">
  <policy classCode="POLICY" moodCode="EVN">
    <code code="J2. 5. k" codeSystem="2. 16. 840. 1. 113883. 3. 989. 5. 1. 3. 2. 1. 4"
codeSystemVersion="1. 0"/>
    <!-- @J2. 5. k: 一般用医薬品等のリスク区分等 #1 -->
  </policy>
</pertinentInformation>
</approval>
</subjectOf>
<subjectOf typeCode="SBJ">
  <characteristic classCode="OBS" moodCode="EVN">
    <code code="1" codeSystem="2. 16. 840. 1. 113883. 3. 989. 5. 1. 3. 2. 1. 10"
codeSystemVersion="1. 0" displayName="新医薬品等の状況区分"/>
    <value xsi:type="CE" code="J2. 4. k" codeSystem="2. 16. 840. 1. 113883. 3. 989. 5. 1. 3. 2. 1. 3"
codeSystemVersion="1. 0"/>
    <!-- @J2. 4. k: 新医薬品等の状況区分 #1 -->
  </characteristic>
</subjectOf>
</asManufacturedProduct>
<asSpecializedKind classCode="GEN">
  <generalizedMaterialKind classCode="MAT" determinerCode="KIND">
    <code>
      <originalText>J2. 12</originalText>
      <!-- @J2. 12: 治験成分記号 -->
    </code>
  </generalizedMaterialKind>
</asSpecializedKind>
<ingredient classCode="ACTI">
  <quantity>
    <numerator value="10" unit="G. k. 2. 3. r. 3b"/>
    <!-- G. k. 2. 3. r. 3a: Strength (number) #1-1 -->
    <!-- G. k. 2. 3. r. 3b: Strength (unit) #1-1 -->
    <denominator value="1"/>
  </quantity>
  <ingredientSubstance classCode="MMAT" determinerCode="KIND">
    <code code="G. k. 2. 3. r. 2b" codeSystem="TBD-Substance"
codeSystemVersion="G. k. 2. 3. r. 2a"/>
    <!-- G. k. 2. 3. r. 2a: Substance / Specified Substance TermID Version Date / Number #1-1
-->
    <!-- G. k. 2. 3. r. 2b: Substance / Specified Substance TermID #1-1 -->
    <name>G. k. 2. 3. r. 1</name>
    <!-- G. k. 2. 3. r. 1: Substance / Specified Substance Name #1-1 -->
  </ingredientSubstance>
</ingredient>
<ingredient classCode="ACTI">
  <quantity>
    <numerator value="10" unit="G. k. 2. 3. r. 3b"/>
    <!-- G. k. 2. 3. r. 3a: Strength (number) #1-2 -->
    <!-- G. k. 2. 3. r. 3b: Strength (unit) #1-2 -->
    <denominator value="1"/>
  </quantity>
  <ingredientSubstance classCode="MMAT" determinerCode="KIND">
    <code code="G. k. 2. 3. r. 2b" codeSystem="TBD-Substance"
codeSystemVersion="G. k. 2. 3. r. 2a"/>
    <!-- G. k. 2. 3. r. 2a: Substance / Specified Substance TermID Version Date / Number #1-2
-->
    <!-- G. k. 2. 3. r. 2b: Substance / Specified Substance TermID #1-2 -->
    <name>G. k. 2. 3. r. 1</name>
    <!-- G. k. 2. 3. r. 1: Substance / Specified Substance Name #1-2 -->
  </ingredientSubstance>

```

```

</ingredient>
</kindOfProduct>
<subjectOf typeCode="SBJ">
  <productEvent classCode="ACT" moodCode="EVN">
    <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.18" codeSystemVersion="1.0"
displayName="retailSupply"/>
    <performer typeCode="PRF">
      <assignedEntity classCode="ASSIGNED">
        <representedOrganization classCode="ORG" determinerCode="INSTANCE">
          <addr>
            <country>G.k.2.4</country>
            <!-- G.k.2.4: Identification of the Country Where the Drug Was Obtained #1 -->
          </addr>
        </representedOrganization>
      </assignedEntity>
    </performer>
  </productEvent>
</subjectOf>
<subjectOf typeCode="SBJ">
  <observationEvent classCode="OBS" moodCode="EVN">
    <code code="2" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10"
codeSystemVersion="1.0" displayName="一般用医薬品の入手経路"/>
    <value xsi:type="CE" code="J2.6.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.5"
codeSystemVersion="1.0"/>
    <!-- @@@J2.6.k: 一般用医薬品の入手経路 #1 -->
  </observationEvent>
</subjectOf>
</instanceOfKind>
</consumable>
<outboundRelationship1 typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
  <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #1, Reaction #1 -->
  <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit) Drug #1, Reaction #1 -->
  <actReference classCode="OBS" moodCode="EVN">
    <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
  </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAE">
  <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
  <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number) Drug #1, Reaction #1 -->
  <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit) Drug #1, Reaction #1 -->
  <actReference classCode="OBS" moodCode="EVN">
    <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
  </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
  <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #1, Reaction #2 -->
  <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit) Drug #1, Reaction #2 -->
  <actReference classCode="OBS" moodCode="EVN">
    <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
  </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAE">
  <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
  <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number) Drug #1, Reaction #2 -->
  <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit) Drug #1, Reaction #2 -->
  <actReference classCode="OBS" moodCode="EVN">
    <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
  </actReference>
</outboundRelationship1>

```



```

<outboundRelationship1 typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
  <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #1, Reaction #3 -->
  <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit) Drug #1, Reaction #3 -->
  <actReference classCode="OBS" moodCode="EVN">
    <id root="3a8626cb-9f1b-4ea8-8a0f-e0ff34430adf"/>
  </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAE">
  <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
  <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number) Drug #1, Reaction #3 -->
  <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit) Drug #1, Reaction #3 -->
  <actReference classCode="OBS" moodCode="EVN">
    <id root="3a8626cb-9f1b-4ea8-8a0f-e0ff34430adf"/>
  </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
  <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #1, Reaction #4 -->
  <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit) Drug #1, Reaction #4 -->
  <actReference classCode="OBS" moodCode="EVN">
    <id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
  </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAE">
  <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
  <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number) Drug #1, Reaction #4 -->
  <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit) Drug #1, Reaction #4 -->
  <actReference classCode="OBS" moodCode="EVN">
    <id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
  </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
  <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #1, Reaction #5 -->
  <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit) Drug #1, Reaction #5 -->
  <actReference classCode="OBS" moodCode="EVN">
    <id root="1071064c-cf10-4a3b-83c1-34f9ddb7ea6d"/>
  </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAE">
  <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
  <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number) Drug #1, Reaction #5 -->
  <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit) Drug #1, Reaction #5 -->
  <actReference classCode="OBS" moodCode="EVN">
    <id root="1071064c-cf10-4a3b-83c1-34f9ddb7ea6d"/>
  </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
  <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #1, Reaction #6 -->
  <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit) Drug #1, Reaction #6 -->
  <actReference classCode="OBS" moodCode="EVN">
    <id root="1f927283-10b6-4334-9d43-e925640fb18f"/>
  </actReference>

```

```

        </outboundRelationship1>
        <outboundRelationship1 typeCode="SAE">
          <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
          <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number) Drug #1, Reaction #6 -->
          <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit) Drug #1, Reaction #6 -->
          <actReference classCode="OBS" moodCode="EVN">
            <id root="1f927283-10b6-4334-9d43-e925640fb18f"/>
          </actReference>
        </outboundRelationship1>
        <outboundRelationship1 typeCode="SAS">
          <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
          <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #1, Reaction #7 -->
          <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit) Drug #1, Reaction #7 -->
          <actReference classCode="OBS" moodCode="EVN">
            <id root="e0342969-38be-423f-b6bb-ce14bc279d8e"/>
          </actReference>
        </outboundRelationship1>
        <outboundRelationship1 typeCode="SAE">
          <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
          <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number) Drug #1, Reaction #7 -->
          <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit) Drug #1, Reaction #7 -->
          <actReference classCode="OBS" moodCode="EVN">
            <id root="e0342969-38be-423f-b6bb-ce14bc279d8e"/>
          </actReference>
        </outboundRelationship1>
        <outboundRelationship1 typeCode="SAS">
          <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
          <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #1, Reaction #8 -->
          <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit) Drug #1, Reaction #8 -->
          <actReference classCode="OBS" moodCode="EVN">
            <id root="a15be092-8070-426d-af04-6863263443e0"/>
          </actReference>
        </outboundRelationship1>
        <outboundRelationship1 typeCode="SAE">
          <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
          <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number) Drug #1, Reaction #8 -->
          <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit) Drug #1, Reaction #8 -->
          <actReference classCode="OBS" moodCode="EVN">
            <id root="a15be092-8070-426d-af04-6863263443e0"/>
          </actReference>
        </outboundRelationship1>
        <outboundRelationship2 typeCode="PERT">
          <observation classCode="OBS" moodCode="EVN">
            <code code="6" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="blinded"/>
            <value xsi:type="BL" value="true"/>
            <!-- G.k.2.5: Investigational Product Blinded #1 -->
          </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="COMP">
          <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #1-1 -->
          <substanceAdministration classCode="SBADM" moodCode="EVN">
            <text>G.k.4.r.8</text>
            <!-- G.k.4.r.8: Dosage Text #1-1 -->
            <effectiveTime xsi:type="SXPR_TS">
              <comp xsi:type="PIVL_TS">
                <period value="10" unit="G.k.4.r.3"/>
                <!-- G.k.4.r.2: Number of Units in the Interval #1-1 -->
                <!-- G.k.4.r.3: Definition of the Time Interval Unit #1-1 -->
              </comp>
            </effectiveTime>
          </substanceAdministration>
        </outboundRelationship2>

```

```

</comp>
<comp xsi:type="IVL_TS" operator="A">
  <low value="20090101"/>
  <!-- G.k.4.r.4: Date and Time of Start of Drug #1-1 -->
  <high value="20090101"/>
  <!-- G.k.4.r.5: Date and Time of Last Administration #1-1 -->
</comp>
<comp xsi:type="IVL_TS" operator="A">
  <width value="4" unit="G.k.4.r.6b"/>
  <!-- G.k.4.r.6a: Duration of Drug Administration (number) #1-1 -->
  <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #1-1 -->
</comp>
</effectiveTime>
<routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
  <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #1-1 -->
  <!-- G.k.4.r.10.2b: Route of Administration TermID #1-1 -->
  <originalText>G.k.4.r.10.1</originalText>
  <!-- G.k.4.r.10.1: Route of Administration (free text) #1-1 -->
</routeCode>
<doseQuantity value="10" unit="G.k.4.r.1b"/>
<!-- G.k.4.r.1a Dose (number) #1-1 -->
<!-- G.k.4.r.1b: Dose (unit) #1-1 -->
<consumable typeCode="CSM">
  <instanceOfKind classCode="INST">
    <productInstance classCode="MMAT" determinerCode="INSTANCE">
      <lotNumberText>G.k.4.r.7</lotNumberText>
      <!-- G.k.4.r.7: Batch / Lot Number #1-1 -->
    </productInstance>
    <kindOfProduct classCode="MMAT" determinerCode="KIND">
      <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
      <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #1-1 -->
      <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #1-1 -->
      <originalText>G.k.4.r.9.1</originalText>
      <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #1-1 -->
    </formCode>
    </kindOfProduct>
  </instanceOfKind>
</consumable>
<inboundRelationship typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
    <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
    <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #1-1
-->
    <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #1-1 -->
    <originalText>G.k.4.r.11.1</originalText>
    <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #1-1 -->
  </value>
</observation>
</inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #1-2 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #1-2 -->
    <effectiveTime xsi:type="SXPRTS">
      <comp xsi:type="PIVL_TS">
        <period value="10" unit="G.k.4.r.3"/>
        <!-- G.k.4.r.2: Number of Units in the Interval #1-2 -->
        <!-- G.k.4.r.3: Definition of the Time Interval Unit #1-2 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <low value="20090101"/>

```

```

        <!-- G.k.4.r.4: Date and Time of Start of Drug #1-2 -->
        <high value="20090101"/>
        <!-- G.k.4.r.5: Date and Time of Last Administration #1-2 -->
    </comp>
</effectiveTime>
<routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
    <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #1-2 -->
    <!-- G.k.4.r.10.2b: Route of Administration TermID #1-2 -->
    <originalText>G.k.4.r.10.1</originalText>
    <!-- G.k.4.r.10.1: Route of Administration (free text) #1-2 -->
</routeCode>
<doseQuantity value="10" unit="G.k.4.r.1b"/>
<!-- G.k.4.r.1a Dose (number) #1-2 -->
<!-- G.k.4.r.1b: Dose (unit) #1-2 -->
<consumable typeCode="CSM">
    <instanceOfKind classCode="INST">
        <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
            <lotNumberText>G.k.4.r.7</lotNumberText>
            <!-- G.k.4.r.7: Batch / Lot Number #1-2 -->
        </productInstanceInstance>
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
            <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
                <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #1-2 -->
                <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #1-2 -->
                <originalText>G.k.4.r.9.1</originalText>
                <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #1-2 -->
            </formCode>
        </kindOfProduct>
    </instanceOfKind>
</consumable>
    <inboundRelationship typeCode="REFR">
        <observation classCode="OBS" moodCode="EVN">
            <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
            <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
                <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #1-2
-->
                <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #1-2 -->
                <originalText>G.k.4.r.11.1</originalText>
                <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #1-2 -->
            </value>
        </observation>
    </inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
    <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #1-3 -->
    <substanceAdministration classCode="SBADM" moodCode="EVN">
        <text>G.k.4.r.8</text>
        <!-- G.k.4.r.8: Dosage Text #1-3 -->
        <effectiveTime xsi:type="SXPR_TS">
            <comp xsi:type="PIVL_TS">
                <period value="10" unit="G.k.4.r.3"/>
                <!-- G.k.4.r.2: Number of Units in the Interval #1-3 -->
                <!-- G.k.4.r.3: Definition of the Time Interval Unit #1-3 -->
            </comp>
            <comp xsi:type="IVL_TS" operator="A">
                <low value="20090101"/>
                <!-- G.k.4.r.4: Date and Time of Start of Drug #1-3 -->
                <width value="4" unit="G.k.4.r.6b"/>
                <!-- G.k.4.r.6a: Duration of Drug Administration (number) #1-3 -->
                <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #1-3 -->
            </comp>
        </effectiveTime>
    </substanceAdministration>
</outboundRelationship2>
</routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">

```

```

<!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #1-3 -->
<!-- G.k.4.r.10.2b: Route of Administration TermID #1-3 -->
<originalText>G.k.4.r.10.1</originalText>
<!-- G.k.4.r.10.1: Route of Administration (free text) #1-3 -->
</routeCode>
<doseQuantity value="10" unit="G.k.4.r.1b"/>
<!-- G.k.4.r.1a Dose (number) #1-3 -->
<!-- G.k.4.r.1b: Dose (unit) #1-3 -->
<consumable typeCode="CSM">
  <instanceOfKind classCode="INST">
    <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
      <lotNumberText>G.k.4.r.7</lotNumberText>
      <!-- G.k.4.r.7: Batch / Lot Number #1-3 -->
    </productInstanceInstance>
    <kindOfProduct classCode="MMAT" determinerCode="KIND">
      <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
      <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #1-3 -->
      <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #1-3 -->
      <originalText>G.k.4.r.1</originalText>
      <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #1-3 -->
    </formCode>
  </kindOfProduct>
</instanceOfKind>
</consumable>
<inboundRelationship typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
    <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
    <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #1-3
-->
    <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #1-3 -->
    <originalText>G.k.4.r.11.1</originalText>
    <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #1-3 -->
  </value>
</observation>
</inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #1-4 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #1-4 -->
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="PIVL_TS">
        <period value="10" unit="G.k.4.r.3"/>
        <!-- G.k.4.r.2: Number of Units in the Interval #1-4 -->
        <!-- G.k.4.r.3: Definition of the Time Interval Unit #1-4 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <width value="4" unit="G.k.4.r.6b"/>
        <!-- G.k.4.r.6a: Duration of Drug Administration (number) #1-4 -->
        <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #1-4 -->
        <high value="20090101"/>
        <!-- G.k.4.r.5: Date and Time of Last Administration #1-4 -->
      </comp>
    </effectiveTime>
    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
    <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #1-4 -->
    <!-- G.k.4.r.10.2b: Route of Administration TermID #1-4 -->
    <originalText>G.k.4.r.10.1</originalText>
    <!-- G.k.4.r.10.1: Route of Administration (free text) #1-4 -->
  </routeCode>
  <doseQuantity value="10" unit="G.k.4.r.1b"/>
  <!-- G.k.4.r.1a Dose (number) #1-4 -->

```

```

<!-- G.k.4.r.1b: Dose (unit) #1-4 -->
<consumable typeCode="CSM">
  <instanceOfKind classCode="INST">
    <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
      <lotNumberText>G.k.4.r.7</lotNumberText>
      <!-- G.k.4.r.7: Batch / Lot Number #1-4 -->
    </productInstanceInstance>
    <kindOfProduct classCode="MMAT" determinerCode="KIND">
      <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
      <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #1-4 -->
      <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #1-4 -->
      <originalText>G.k.4.r.9.1</originalText>
      <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #1-4 -->
    </formCode>
    </kindOfProduct>
  </instanceOfKind>
</consumable>
<inboundRelationship typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="2B" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
    <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
      <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #1-4
-->
      <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #1-4 -->
      <originalText>G.k.4.r.11.1</originalText>
      <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #1-4 -->
    </value>
  </observation>
</inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #1-5 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #1-5 -->
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="IVL_TS">
        <low value="20090101"/>
        <!-- G.k.4.r.4: Date and Time of Start of Drug #1-5 -->
        <high value="20090101"/>
        <!-- G.k.4.r.5: Date and Time of Last Administration #1-5 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <width value="4" unit="G.k.4.r.6b"/>
        <!-- G.k.4.r.6a: Duration of Drug Administration (number) #1-5 -->
        <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #1-5 -->
      </comp>
    </effectiveTime>
    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
      <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #1-5 -->
      <!-- G.k.4.r.10.2b: Route of Administration TermID #1-5 -->
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #1-5 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #1-5 -->
    <!-- G.k.4.r.1b: Dose (unit) #1-5 -->
  </substanceAdministration>
</outboundRelationship2>
<consumable typeCode="CSM">
  <instanceOfKind classCode="INST">
    <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
      <lotNumberText>G.k.4.r.7</lotNumberText>
      <!-- G.k.4.r.7: Batch / Lot Number #1-5 -->
    </productInstanceInstance>
    <kindOfProduct classCode="MMAT" determinerCode="KIND">

```

```

codeSystemVersion="G.k.4.r.9.2a"
    <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
    <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #1-5 -->
    <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #1-5 -->
    <originalText>G.k.4.r.9.1</originalText>
    <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #1-5 -->
    </formCode>
    </kindOfProduct>
    </instanceOfKind>
    </consumable>
    <inboundRelationship typeCode="REFR">
    <observation classCode="UBS" moodCode="EVN">
    <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
    displayName="parentRouteOfAdministration"/>
    <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
    codeSystemVersion="G.k.4.r.11.2a"
    <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #1-5
    -->
    <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #1-5 -->
    <originalText>G.k.4.r.11.1</originalText>
    <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #1-5 -->
    </value>
    </observation>
    </inboundRelationship>
    </substanceAdministration>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="COMP">
    <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #1-6 -->
    <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #1-6 -->
    <effectiveTime xsi:type="SXPRTS">
    <comp xsi:type="PIVL_TS">
    <period value="10" unit="G.k.4.r.3"/>
    <!-- G.k.4.r.2: Number of Units in the Interval #1-6 -->
    <!-- G.k.4.r.3: Definition of the Time Interval Unit #1-6 -->
    </comp>
    <comp xsi:type="IVL_TS" operator="A">
    <low value="20090101"/>
    <!-- G.k.4.r.4: Date and Time of Start of Drug #1-6 -->
    <width value="4" unit="G.k.4.r.6b"/>
    <!-- G.k.4.r.6a: Duration of Drug Administration (number) #1-6 -->
    <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #1-6 -->
    </comp>
    <comp xsi:type="IVL_TS" operator="A">
    <high value="20090101"/>
    <!-- G.k.4.r.5: Date and Time of Last Administration #1-6 -->
    </comp>
    </effectiveTime>
    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
    codeSystemVersion="G.k.4.r.10.2a"
    <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #1-6 -->
    <!-- G.k.4.r.10.2b: Route of Administration TermID #1-6 -->
    <originalText>G.k.4.r.10.1</originalText>
    <!-- G.k.4.r.10.1: Route of Administration (free text) #1-6 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #1-1 -->
    <!-- G.k.4.r.1b: Dose (unit) #1-1 -->
    <consumable typeCode="CSM">
    <instanceOfKind classCode="INST">
    <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
    <lotNumberText>G.k.4.r.7</lotNumberText>
    <!-- G.k.4.r.7: Batch / Lot Number #1-1 -->
    </productInstanceInstance>
    <kindOfProduct classCode="MMAT" determinerCode="KIND">
    <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
    codeSystemVersion="G.k.4.r.9.2a"
    <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #1-6 -->

```

```

        <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #1-6 -->
        <originalText>G.k.4.r.9.1</originalText>
        <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #1-6 -->
        </formCode>
    </kindOfProduct>
</instanceOfKind>
</consumable>
<inboundRelationship typeCode="REFR">
    <observation classCode="OBS" moodCode="EVN">
        <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
        <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
            <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #1-6
-->
            <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #1-6 -->
            <originalText>G.k.4.r.11.1</originalText>
            <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #1-6 -->
            </value>
        </observation>
    </inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
    <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #1-7 -->
    <substanceAdministration classCode="SBADM" moodCode="EVN">
        <text>G.k.4.r.8</text>
        <!-- G.k.4.r.8: Dosage Text #1-7 -->
        <effectiveTime xsi:type="SXPR_TS">
            <comp xsi:type="IVL_TS">
                <low value="20090101"/>
                <!-- G.k.4.r.4: Date and Time of Start of Drug #1-7 -->
                <width value="4" unit="G.k.4.r.6b"/>
                <!-- G.k.4.r.6a: Duration of Drug Administration (number) #1-7 -->
                <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #1-7 -->
            </comp>
            <comp xsi:type="IVL_TS" operator="A">
                <high value="20090101"/>
                <!-- G.k.4.r.5: Date and Time of Last Administration #1-7 -->
            </comp>
        </effectiveTime>
        <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
            <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #1-7 -->
            <!-- G.k.4.r.10.2b: Route of Administration TermID #1-7 -->
            <originalText>G.k.4.r.10.1</originalText>
            <!-- G.k.4.r.10.1: Route of Administration (free text) #1-7 -->
        </routeCode>
        <doseQuantity value="10" unit="G.k.4.r.1b"/>
        <!-- G.k.4.r.1a Dose (number) #1-7 -->
        <!-- G.k.4.r.1b: Dose (unit) #1-7 -->
        <consumable typeCode="CSM">
            <instanceOfKind classCode="INST">
                <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
                    <lotNumberText>G.k.4.r.7</lotNumberText>
                    <!-- G.k.4.r.7: Batch / Lot Number #1-7 -->
                </productInstanceInstance>
                <kindOfProduct classCode="MMAT" determinerCode="KIND">
                    <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
                        <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #1-7 -->
                        <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #1-7 -->
                        <originalText>G.k.4.r.9.1</originalText>
                        <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #1-7 -->
                    </formCode>
                </kindOfProduct>
            </instanceOfKind>
        </consumable>
    </outboundRelationship2>

```



```

        <observation classCode="OBS" moodCode="EVN">
          <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
          <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
            <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #1-7
-->
            <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #1-7 -->
            <originalText>G.k.4.r.11.1</originalText>
            <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #1-7 -->
          </value>
        </observation>
      </inboundRelationship>
    </substanceAdministration>
  </outboundRelationship2>
<outboundRelationship2 typeCode="SUMM">
  <observation classCode="OBS" moodCode="EVN">
    <code code="14" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="cumulativeDoseToReaction"/>
    <value xsi:type="PQ" value="10" unit="G.k.5b"/>
    <!-- G.k.5a: Cumulative Dose to First Reaction (number) #1 -->
    <!-- G.k.5b: Cumulative Dose to First Reaction (unit) #1 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="16" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="gestationPeriod"/>
    <value xsi:type="PQ" value="10" unit="G.k.6b"/>
    <!-- G.k.6a: Gestation Period at Time of Exposure (number) #1 -->
    <!-- G.k.6b: Gestation Period at Time of Exposure (unit) #1 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="recurrenceOfReaction"/>
    <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
codeSystemVersion="1.0"/>
    <!-- G.k.9.i.4: Did Reaction Recur on Re-administration? Drug #1, Reaction #1 -->
    <outboundRelationship1 typeCode="REFR">
      <actReference classCode="OBS" moodCode="EVN">
        <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
      </actReference>
    </outboundRelationship1>
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="recurrenceOfReaction"/>
    <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
codeSystemVersion="1.0"/>
    <!-- G.k.9.i.4: Did Reaction Recur on Re-administration? Drug #1, Reaction #2 -->
    <outboundRelationship1 typeCode="REFR">
      <actReference classCode="OBS" moodCode="EVN">
        <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
      </actReference>
    </outboundRelationship1>
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="codedDrugInformation"/>
    <value xsi:type="CE" code="G.k.10.r" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"
codeSystemVersion="1.0"/>
    <!-- G.k.10.r: Additional Information on Drug (coded) (repeat as necessary) #1-1 -->
  </observation>

```

```

        </outboundRelationship2>
        <outboundRelationship2 typeCode="REFR">
          <observation classCode="OBS" moodCode="EVN">
            <code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
            displayName="codedDrugInformation"/>
            <value xsi:type="CE" code="G.k.10.r" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"
            codeSystemVersion="1.0"/>
            <!-- G.k.10.r: Additional Information on Drug (coded) (repeat as necessary) #1-2 -->
          </observation>
        </outboundRelationship2>
        <outboundRelationship2 typeCode="REFR">
          <observation classCode="OBS" moodCode="EVN">
            <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
            displayName="additionalInformation"/>
            <value xsi:type="ST">G.k.11</value>
            <!-- G.k.11: Additional Information on Drug (free text) #1 -->
          </observation>
        </outboundRelationship2>
        <inboundRelationship typeCode="RSON">
          <observation classCode="OBS" moodCode="EVN">
            <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
            displayName="indication"/>
            <value xsi:type="CE" code="G.k.7.r.2b" codeSystem="2.16.840.1.113883.6.163"
            codeSystemVersion="G.k.7.r.2a">
              <!-- G.k.7.r.2a: MedDRA Version for Indication #1-1 -->
              <!-- G.k.7.r.2b: Indication (MedDRA code) #1-1 -->
              <originalText>G.k.7.r.1</originalText>
              <!-- G.k.7.r.1: Indication as Reported by the Primary Source #1-1 -->
            </value>
            <performer typeCode="PRF">
              <assignedEntity classCode="ASSIGNED">
                <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
                displayName="sourceReporter"/>
              </assignedEntity>
            </performer>
          </observation>
        </inboundRelationship>
        <inboundRelationship typeCode="RSON">
          <observation classCode="OBS" moodCode="EVN">
            <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
            displayName="indication"/>
            <value xsi:type="CE" code="G.k.7.r.2b" codeSystem="2.16.840.1.113883.6.163"
            codeSystemVersion="G.k.7.r.2a">
              <!-- G.k.7.r.2a: MedDRA Version for Indication #1-2 -->
              <!-- G.k.7.r.2b: Indication (MedDRA code) #1-2 -->
              <originalText>G.k.7.r.1</originalText>
              <!-- G.k.7.r.1: Indication as Reported by the Primary Source #1-2 -->
            </value>
            <performer typeCode="PRF">
              <assignedEntity classCode="ASSIGNED">
                <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
                displayName="sourceReporter"/>
              </assignedEntity>
            </performer>
          </observation>
        </inboundRelationship>
        <inboundRelationship typeCode="CAUS">
          <act classCode="ACT" moodCode="EVN">
            <code code="G.k.8" codeSystem="2.16.840.1.113883.3.989.2.1.1.15" codeSystemVersion="1.0"/>
            <!-- G.k.8: Action(s) Taken with Drug #1 -->
          </act>
        </inboundRelationship>
      </substanceAdministration>
    </component>
    <!-- G.k Drug(s) Information (repeat as necessary) #2 -->
    <component typeCode="COMP">
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9"/>
        <consumable typeCode="CSM">

```

```

<instanceOfKind classCode="INST">
  <kindOfProduct classCode="MMAT" determinerCode="KIND">
    <code code="G.k.2.1.2b" codeSystem="TBD-PhPID" codeSystemVersion="G.k.2.1.2a"/>
    <!-- G.k.2.1.2a: PhPID Version Date / Number #2 -->
    <!-- G.k.2.1.2b: Pharmaceutical Product Identifier (PhPID) #2 -->
    <name>G.k.2.2</name>
    <!-- G.k.2.2: Medicinal Product Name as Reported by the Primary Source #2 -->
    <asManufacturedProduct classCode="MANU">
      <subjectOf typeCode="SBJ">
        <approval classCode="CNTRCT" moodCode="EVN">
          <id extension="G.k.3.1" root="2.16.840.1.113883.3.989.2.1.3.4"/>
          <!-- G.k.3.1: Authorisation / Application Number #2 -->
          <holder typeCode="HLD">
            <role classCode="HLD">
              <playingOrganization classCode="ORG" determinerCode="INSTANCE">
                <name>G.k.3.3</name>
                <!-- G.k.3.3: Name of Holder / Applicant #2 -->
              </playingOrganization>
            </role>
          </holder>
          <author typeCode="AUT">
            <territorialAuthority classCode="TERR">
              <territory classCode="NAT" determinerCode="INSTANCE">
                <code code="G.k.3.2" codeSystem="1.0.3166.1.2.2"/>
                <!-- G.k.3.2: Country of Authorisation / Application #2 -->
              </territory>
            </territorialAuthority>
          </author>
          <pertinentInformation typeCode="PERT">
            <policy classCode="POLICY" moodCode="EVN">
              <code code="J2.5.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.4"
codeSystemVersion="1.0"/>
              <!-- @@@J2.5.k: 一般用医薬品等のリスク区分等 #2 -->
            </policy>
          </pertinentInformation>
        </approval>
      </subjectOf>
      <subjectOf typeCode="SBJ">
        <characteristic classCode="OBS" moodCode="EVN">
          <code code="1" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10"
codeSystemVersion="1.0" displayName="新医薬品等の状況区分"/>
          <value xsi:type="CE" code="J2.4.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.3"
codeSystemVersion="1.0"/>
          <!-- @@@J2.4.k: 新医薬品等の状況区分 #2 -->
        </characteristic>
      </subjectOf>
    </asManufacturedProduct>
    <ingredient classCode="ACTI">
      <quantity>
        <numerator value="10" unit="G.k.2.3.r.3b"/>
        <!-- G.k.2.3.r.3a: Strength (number) #2-1 -->
        <!-- G.k.2.3.r.3b: Strength (unit) #2-1 -->
        <denominator value="1"/>
      </quantity>
      <ingredientSubstance classCode="MMAT" determinerCode="KIND">
        <code code="G.k.2.3.r.2b" codeSystem="TBD-Substance"
codeSystemVersion="G.k.2.3.r.2a"/>
        <!-- G.k.2.3.r.2a: Substance / Specified Substance TermID Version Date / Number #2-1
-->
        <!-- G.k.2.3.r.2b Substance / Specified Substance TermID #2-1 -->
        <name>G.k.2.3.r.1</name>
        <!-- G.k.2.3.r.1: Substance / Specified Substance Name #2-1 -->
      </ingredientSubstance>
    </ingredient>
    <ingredient classCode="ACTI">
      <quantity>
        <numerator value="10" unit="G.k.2.3.r.3b"/>
        <!-- G.k.2.3.r.3a: Strength (number) #2-2 -->
        <!-- G.k.2.3.r.3b: Strength (unit) #2-2 -->

```

```

        <denominator value="1"/>
    </quantity>
    <ingredientSubstance classCode="MMAT" determinerCode="KIND">
        <code code="G.k.2.3.r.2b" codeSystem="TBD-Substance"
codeSystemVersion="G.k.2.3.r.2a"/>
    <!-- G.k.2.3.r.2a: Substance / Specified Substance TermID Version Date/Number #2-2 -->
    <!-- G.k.2.3.r.2b Substance / Specified Substance TermID #2-2 -->
    <name>G.k.2.3.r.1</name>
    <!-- G.k.2.3.r.1: Substance / Specified Substance Name #2-2 -->
    </ingredientSubstance>
</ingredient>
</kindOfProduct>
<subjectOf typeCode="SBJ">
    <productEvent classCode="ACT" moodCode="EVN">
        <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.18" codeSystemVersion="1.0"
displayName="retailSupply"/>
    <performer typeCode="PRF">
        <assignedEntity classCode="ASSIGNED">
            <representedOrganization classCode="ORG" determinerCode="INSTANCE">
                <addr>
                    <country>G.k.2.4</country>
                    <!-- G.k.2.4: Identification of the Country Where the Drug Was Obtained #2 -->
                </addr>
            </representedOrganization>
        </assignedEntity>
    </performer>
</productEvent>
</subjectOf>
    <subjectOf typeCode="SBJ">
        <observationEvent classCode="OBS" moodCode="EVN">
            <code code="2" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10"
codeSystemVersion="1.0" displayName="一般用医薬品の入手経路"/>
            <value xsi:type="CE" code="J2.6.k" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.5"
codeSystemVersion="1.0"/>
            <!-- @@@J2.6.k: 一般用医薬品の入手経路 #2 -->
        </observationEvent>
    </subjectOf>
</instanceOfKind>
</consumable>
<outboundRelationship1 typeCode="SAS">
    <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
    <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #2, Reaction #1 -->
    <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit) Drug #2, Reaction #1 -->
    <actReference classCode="OBS" moodCode="EVN">
        <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
    </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAE">
    <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
    <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number) Drug #2, Reaction #1 -->
    <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit) Drug #2, Reaction #1 -->
    <actReference classCode="OBS" moodCode="EVN">
        <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
    </actReference>
</outboundRelationship1>
<outboundRelationship1 typeCode="SAS">
    <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
    <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #2, Reaction #2 -->
    <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit) Drug #2, Reaction #2 -->
    <actReference classCode="OBS" moodCode="EVN">
        <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
    </actReference>

```

```

</outboundRelationship>
<outboundRelationship typeCode="SAE">
  <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
  <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number) Drug #2, Reaction #2 -->
  <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit) Drug #2, Reaction #2 -->
  <actReference classCode="OBS" moodCode="EVN">
    <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
  </actReference>
</outboundRelationship>
<outboundRelationship typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
  <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #2, Reaction #3 -->
  <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit) Drug #2, Reaction #3 -->
  <actReference classCode="OBS" moodCode="EVN">
    <id root="3a8626cb-9f1b-4ea8-8a0f-e0ff34430adf"/>
  </actReference>
</outboundRelationship>
<outboundRelationship typeCode="SAE">
  <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
  <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number) Drug #2, Reaction #3 -->
  <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit) Drug #2, Reaction #3 -->
  <actReference classCode="OBS" moodCode="EVN">
    <id root="3a8626cb-9f1b-4ea8-8a0f-e0ff34430adf"/>
  </actReference>
</outboundRelationship>
<outboundRelationship typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
  <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #2, Reaction #4 -->
  <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit) Drug #2, Reaction #4 -->
  <actReference classCode="OBS" moodCode="EVN">
    <id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
  </actReference>
</outboundRelationship>
<outboundRelationship typeCode="SAE">
  <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
  <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number) Drug #2, Reaction #4 -->
  <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit) Drug #2, Reaction #4 -->
  <actReference classCode="OBS" moodCode="EVN">
    <id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/>
  </actReference>
</outboundRelationship>
<outboundRelationship typeCode="SAS">
  <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
  <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #2, Reaction #5 -->
  <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit) Drug #2, Reaction #5 -->
  <actReference classCode="OBS" moodCode="EVN">
    <id root="1071064c-cf10-4a3b-83c1-34f9ddb7ea6d"/>
  </actReference>
</outboundRelationship>
<outboundRelationship typeCode="SAE">
  <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
  <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number) Drug #2, Reaction #5 -->
  <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit) Drug #2, Reaction #5 -->
  <actReference classCode="OBS" moodCode="EVN">
    <id root="1071064c-cf10-4a3b-83c1-34f9ddb7ea6d"/>
  </actReference>

```

```

        </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAS">
        <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
        <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #2, Reaction #6 -->
        <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit) Drug #2, Reaction #6 -->
        <actReference classCode="OBS" moodCode="EVN">
            <id root="1f927283-10b6-4334-9d43-e925640fb18f"/>
        </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAE">
        <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
        <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number) Drug #2, Reaction #6 -->
        <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit) Drug #2, Reaction #6 -->
        <actReference classCode="OBS" moodCode="EVN">
            <id root="1f927283-10b6-4334-9d43-e925640fb18f"/>
        </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAS">
        <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
        <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #2, Reaction #7 -->
        <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit) Drug #2, Reaction #7 -->
        <actReference classCode="OBS" moodCode="EVN">
            <id root="e0342969-38be-423f-b6bb-ce14bc279d8e"/>
        </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAE">
        <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
        <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number) Drug #2, Reaction #7 -->
        <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit) Drug #2, Reaction #7 -->
        <actReference classCode="OBS" moodCode="EVN">
            <id root="e0342969-38be-423f-b6bb-ce14bc279d8e"/>
        </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAS">
        <pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
        <!-- G.k.9.i.3.1a: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (number) Drug #2, Reaction #8 -->
        <!-- G.k.9.i.3.1b: Time Interval between Beginning of Drug Administration and Start of
Reaction / Event (unit) Drug #2, Reaction #8 -->
        <actReference classCode="OBS" moodCode="EVN">
            <id root="a15be092-8070-426d-af04-6863263443e0"/>
        </actReference>
    </outboundRelationship1>
    <outboundRelationship1 typeCode="SAE">
        <pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
        <!-- G.k.9.i.3.2a: Time Interval between Last Dose of Drug and Start of Reaction / Event
(number) Drug #2, Reaction #8 -->
        <!-- G.k.9.i.3.2b: Time Interval between Last Dose of Drug and Start of Reaction / Event
(unit) Drug #2, Reaction #8 -->
        <actReference classCode="OBS" moodCode="EVN">
            <id root="a15be092-8070-426d-af04-6863263443e0"/>
        </actReference>
    </outboundRelationship1>
    <outboundRelationship2 typeCode="PERT">
        <observation classCode="OBS" moodCode="EVN">
            <code code="6" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="blinded"/>
            <value xsi:type="BL" value="true"/>
            <!-- G.k.2.5: Investigational Product Blinded #2 -->
        </observation>

```

```

</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r : Dosage and Relevant Information (repeat as necessary) #2-1 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-1 -->
    <effectiveTime xsi:type="IVL_TS">
      <low value="20090101"/>
      <!-- G.k.4.r.4: Date and Time of Start of Drug #2-1 -->
      <high value="20090101"/>
      <!-- G.k.4.r.5: Date and Time of Last Administration #2-1 -->
    </effectiveTime>
    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
      <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-1 -->
      <!-- G.k.4.r.10.2b: Route of Administration TermID #2-1 -->
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-1 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-1 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-1 -->
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
          <lotNumberText>G.k.4.r.7</lotNumberText>
          <!-- G.k.4.r.7: Batch / Lot Number #2-1 -->
        </productInstanceInstance>
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
          <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
            <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-1 -->
            <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-1 -->
            <originalText>G.k.4.r.9.1</originalText>
            <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-1 -->
          </formCode>
        </kindOfProduct>
      </instanceOfKind>
    </consumable>
    <inboundRelationship typeCode="REFR">
      <observation classCode="OBS" moodCode="EVN">
        <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
        <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
          <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-1
-->
          <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-1 -->
          <originalText>G.k.4.r.11.1</originalText>
          <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-1 -->
        </value>
      </observation>
    </inboundRelationship>
  </substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #2-2 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-2 -->
    <effectiveTime xsi:type="IVL_TS">
      <low value="20090101"/>
      <!-- G.k.4.r.4: Date and Time of Start of Drug #2-2 -->
      <width value="4" unit="G.k.4.r.6b"/>
      <!-- G.k.4.r.6a: Duration of Drug Administration (number) #2-2 -->
      <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #2-2 -->
    </effectiveTime>
    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">

```

```

      <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-2 -->
      <!-- G.k.4.r.10.2b: Route of Administration TermID #2-2 -->
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-2 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-2 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-2 -->
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
          <lotNumberText>G.k.4.r.7</lotNumberText>
          <!-- G.k.4.r.7: Batch / Lot Number #2-2 -->
        </productInstanceInstance>
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
          <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
          <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-2 -->
          <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-2 -->
          <originalText>G.k.4.r.9.1</originalText>
          <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-2 -->
        </formCode>
        </kindOfProduct>
      </instanceOfKind>
    </consumable>
    <inboundRelationship typeCode="REFR">
      <observation classCode="OBS" moodCode="EVN">
        <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
        <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
          <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-2
-->
          <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-2 -->
          <originalText>G.k.4.r.11.1</originalText>
          <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-2 -->
        </value>
      </observation>
    </inboundRelationship>
  </substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #2-3 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-3 -->
    <effectiveTime xsi:type="IVL_TS">
      <width value="4" unit="G.k.4.r.6b"/>
      <!-- G.k.4.r.6a: Duration of Drug Administration (number) #2-3 -->
      <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #2-3 -->
      <high value="20090101"/>
      <!-- G.k.4.r.5: Date and Time of Last Administration #2-3 -->
    </effectiveTime>
    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
      <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-3 -->
      <!-- G.k.4.r.10.2b: Route of Administration TermID #2-3 -->
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-3 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-3 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-3 -->
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
          <lotNumberText>G.k.4.r.7</lotNumberText>
          <!-- G.k.4.r.7: Batch / Lot Number #2-3 -->
        </productInstanceInstance>

```



```

    <kindOfProduct classCode="MMAT" determinerCode="KIND">
      <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
        <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-3 -->
        <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-3 -->
        <originalText>G.k.4.r.9.1</originalText>
        <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-3 -->
      </formCode>
    </kindOfProduct>
  </instanceOfKind>
</consumable>
<inboundRelationship typeCode="REFK">
  <observation classCode="OBS" moodCode="EVN">
    <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
    <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
      <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-3
-->
      <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-3 -->
      <originalText>G.k.4.r.11.1</originalText>
      <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-3 -->
    </value>
  </observation>
</inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #2-4 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-4 -->
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="PIVL_TS">
        <period value="10" unit="G.k.4.r.3"/>
        <!-- G.k.4.r.2: Number of Units in the Interval #2-4 -->
        <!-- G.k.4.r.3: Definition of the Time Interval Unit #2-4 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <low value="20090101"/>
        <!-- G.k.4.r.4: Date and Time of Start of Drug #2-4 -->
      </comp>
    </effectiveTime>
    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
      <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-4 -->
      <!-- G.k.4.r.10.2b: Route of Administration TermID #2-4 -->
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-4 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-4 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-4 -->
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
          <lotNumberText>G.k.4.r.7</lotNumberText>
          <!-- G.k.4.r.7: Batch / Lot Number #2-4 -->
        </productInstanceInstance>
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
          <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
            <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-4 -->
            <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-4 -->
            <originalText>G.k.4.r.9.1</originalText>
            <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-4 -->
          </formCode>
        </kindOfProduct>
      </instanceOfKind>

```

```

</consumable>
<inboundRelationship typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
    <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
      <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-4
-->
      <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-4 -->
      <originalText>G.k.4.r.11.1</originalText>
      <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-4 -->
    </value>
  </observation>
</inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #2-5 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-5 -->
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="PIVL_TS">
        <period value="10" unit="G.k.4.r.3"/>
        <!-- G.k.4.r.2: Number of Units in the Interval #2-5 -->
        <!-- G.k.4.r.3: Definition of the Time Interval Unit #2-5 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <high value="20090101"/>
        <!-- G.k.4.r.5: Date and Time of Last Administration #2-5 -->
      </comp>
    </effectiveTime>
    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
      <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-5 -->
      <!-- G.k.4.r.10.2b: Route of Administration TermID #2-5 -->
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-5 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-5 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-5 -->
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
          <lotNumberText>G.k.4.r.7</lotNumberText>
          <!-- G.k.4.r.7: Batch / Lot Number #2-5 -->
        </productInstanceInstance>
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
          <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
            <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-5 -->
            <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-5 -->
            <originalText>G.k.4.r.9.1</originalText>
            <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-5 -->
          </formCode>
        </kindOfProduct>
      </instanceOfKind>
    </consumable>
  </substanceAdministration>
</outboundRelationship2>
<inboundRelationship typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
    <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
      <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-5
-->
      <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-5 -->
    </value>
  </observation>
</inboundRelationship>

```

```

        <originalText>G.k.4.r.11.1</originalText>
        <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-5 -->
    </value>
    </observation>
  </inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #2-6 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-6 -->
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="PIVL_TS">
        <period value="10" unit="G.k.4.r.3"/>
        <!-- G.k.4.r.2: Number of Units in the Interval #2-6 -->
        <!-- G.k.4.r.3: Definition of the Time Interval Unit #2-6 -->
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <width value="4" unit="G.k.4.r.6b"/>
        <!-- G.k.4.r.6a: Duration of Drug Administration (number) #2-6 -->
        <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #2-6 -->
      </comp>
    </effectiveTime>
    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
      <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-6 -->
      <!-- G.k.4.r.10.2b: Route of Administration TermID #2-6 -->
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-6 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-6 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-6 -->
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
          <lotNumberText>G.k.4.r.7</lotNumberText>
          <!-- G.k.4.r.7: Batch / Lot Number #2-6 -->
        </productInstanceInstance>
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
          <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
            <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-6 -->
            <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-6 -->
            <originalText>G.k.4.r.9.1</originalText>
            <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-6 -->
          </formCode>
        </kindOfProduct>
      </instanceOfKind>
    </consumable>
    <inboundRelationship typeCode="REFR">
      <observation classCode="OBS" moodCode="EVN">
        <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
        <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
          <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-6
-->
          <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-6 -->
          <originalText>G.k.4.r.11.1</originalText>
          <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-6 -->
        </value>
      </observation>
    </inboundRelationship>
  </substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #2-7 -->

```

```

    <substanceAdministration classCode="SBADM" moodCode="EVN">
      <text>G.k.4.r.8</text>
      <!-- G.k.4.r.8: Dosage Text #2-7 -->
      <effectiveTime xsi:type="PIVL_TS">
        <period value="10" unit="G.k.4.r.3"/>
        <!-- G.k.4.r.2: Number of Units in the Interval #2-7 -->
        <!-- G.k.4.r.3: Definition of the Time Interval Unit #2-7 -->
      </effectiveTime>
      <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
      <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-7 -->
      <!-- G.k.4.r.10.2b: Route of Administration TermID #2-7 -->
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-7 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-7 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-7 -->
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
          <lotNumberText>G.k.4.r.7</lotNumberText>
          <!-- G.k.4.r.7: Batch / Lot Number #2-7 -->
        </productInstanceInstance>
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
          <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
          <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-7 -->
          <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-7 -->
          <originalText>G.k.4.r.9.1</originalText>
          <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-7 -->
        </formCode>
      </kindOfProduct>
    </instanceOfKind>
  </consumable>
  <inboundRelationship typeCode="REFR">
    <observation classCode="OBS" moodCode="EVN">
      <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
      <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
      <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-7
-->
      <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-7 -->
      <originalText>G.k.4.r.11.1</originalText>
      <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-7 -->
    </value>
  </observation>
</inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #2-8 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-8 -->
    <effectiveTime xsi:type="IVL_TS">
      <low value="20090101"/>
      <!-- G.k.4.r.4: Date and Time of Start of Drug #2-8 -->
    </effectiveTime>
    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
    <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-8 -->
    <!-- G.k.4.r.10.2b: Route of Administration TermID #2-8 -->
    <originalText>G.k.4.r.10.1</originalText>
    <!-- G.k.4.r.10.1: Route of Administration (free text) #2-8 -->
  </routeCode>
  <doseQuantity value="10" unit="G.k.4.r.1b"/>
  <!-- G.k.4.r.1a Dose (number) #2-8 -->

```

```

<!-- G.k.4.r.1b: Dose (unit) #2-8 -->
<consumable typeCode="CSM">
  <instanceOfKind classCode="INST">
    <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
      <lotNumberText>G.k.4.r.7</lotNumberText>
      <!-- G.k.4.r.7: Batch / Lot Number #2-8 -->
    </productInstanceInstance>
    <kindOfProduct classCode="MMAT" determinerCode="KIND">
      <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
      <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-8 -->
      <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-8 -->
      <originalText>G.k.4.r.1</originalText>
      <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-8 -->
    </formCode>
    </kindOfProduct>
  </instanceOfKind>
</consumable>
<inboundRelationship typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
    <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
      <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-8
-->
      <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-8 -->
      <originalText>G.k.4.r.11.1</originalText>
      <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-8 -->
    </value>
  </observation>
</inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r: Dosage and Relevant Information (repeat as necessary) #2-9 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-9 -->
    <effectiveTime xsi:type="IVL_TS">
      <high value="20090101"/>
      <!-- G.k.4.r.5: Date and Time of Last Administration #2-9 -->
    </effectiveTime>
    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
      <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-9 -->
      <!-- G.k.4.r.10.2b: Route of Administration TermID #2-9 -->
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-9 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-9 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-9 -->
  </substanceAdministration>
  <consumable typeCode="CSM">
    <instanceOfKind classCode="INST">
      <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
        <lotNumberText>G.k.4.r.7</lotNumberText>
        <!-- G.k.4.r.7: Batch / Lot Number #2-9 -->
      </productInstanceInstance>
      <kindOfProduct classCode="MMAT" determinerCode="KIND">
        <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
        <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-9 -->
        <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-9 -->
        <originalText>G.k.4.r.1</originalText>
        <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-9 -->
      </formCode>
      </kindOfProduct>
    </instanceOfKind>
  </consumable>

```

```

</consumable>
<inboundRelationship typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
    <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
      <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-9
-->
      <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-9 -->
      <originalText>G.k.4.r.11.1</originalText>
      <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-9 -->
    </value>
  </observation>
</inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <!-- G.k.4.r.: Dosage and Relevant Information (repeat as necessary) #2-10 -->
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <!-- G.k.4.r.8: Dosage Text #2-10 -->
    <effectiveTime xsi:type="IVL_TS">
      <width value="4" unit="G.k.4.r.6b"/>
      <!-- G.k.4.r.6a: Duration of Drug Administration (number) #2-10 -->
      <!-- G.k.4.r.6b: Duration of Drug Administration (unit) #2-10 -->
    </effectiveTime>
    <routeCode code="G.k.4.r.10.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.10.2a">
      <!-- G.k.4.r.10.2a: Route of Administration TermID Version Date / Number #2-10 -->
      <!-- G.k.4.r.10.2b: Route of Administration TermID #2-10 -->
      <originalText>G.k.4.r.10.1</originalText>
      <!-- G.k.4.r.10.1: Route of Administration (free text) #2-10 -->
    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
    <!-- G.k.4.r.1a Dose (number) #2-10 -->
    <!-- G.k.4.r.1b: Dose (unit) #2-10 -->
    <consumable typeCode="CSM">
      <instanceOfKind classCode="INST">
        <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
          <lotNumberText>G.k.4.r.7</lotNumberText>
          <!-- G.k.4.r.7: Batch / Lot Number #2-10 -->
        </productInstanceInstance>
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
          <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm"
codeSystemVersion="G.k.4.r.9.2a">
            <!-- G.k.4.r.9.2a: Pharmaceutical Dose Form TermID Version Date / Number #2-10 -->
            <!-- G.k.4.r.9.2b: Pharmaceutical Dose Form TermID #2-10 -->
            <originalText>G.k.4.r.9.1</originalText>
            <!-- G.k.4.r.9.1: Pharmaceutical Dose Form (free text) #2-10 -->
          </formCode>
        </kindOfProduct>
      </instanceOfKind>
    </consumable>
  </substanceAdministration>
</outboundRelationship2>
</outboundRelationship2 typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="28" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="parentRouteOfAdministration"/>
    <value xsi:type="CE" code="G.k.4.r.11.2b" codeSystem="2.16.840.1.113883.3.989.2.1.1.14"
codeSystemVersion="G.k.4.r.11.2a">
      <!-- G.k.4.r.11.2a: Parent Route of Administration TermID Version Date / Number #2-10
-->
      <!-- G.k.4.r.11.2b: Parent Route of Administration TermID #2-10 -->
      <originalText>G.k.4.r.11.1</originalText>
      <!-- G.k.4.r.11.1: Parent Route of Administration (free text) #2-10 -->
    </value>
  </observation>
</inboundRelationship>
</substanceAdministration>

```

```

</outboundRelationship2>
<outboundRelationship2 typeCode="SUMM">
  <observation classCode="OBS" moodCode="EVN">
    <code code="14" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="cumulativeDoseToReaction"/>
    <value xsi:type="PQ" value="10" unit="G.k.5b"/>
    <!-- G.k.5a: Cumulative Dose to First Reaction (number) #2 -->
    <!-- G.k.5b: Cumulative Dose to First Reaction (unit) #2 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="16" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="gestationPeriod"/>
    <value xsi:type="PQ" value="10" unit="G.k.6b"/>
    <!-- G.k.6a: Gestation Period at Time of Exposure (number) #2 -->
    <!-- G.k.6b: Gestation Period at Time of Exposure (unit) #2 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="recurrenceOfReaction"/>
    <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
codeSystemVersion="1.0"/>
    <!-- G.k.9.i.4: Did Reaction Recur on Re-administration? Drug #2, Reaction #1 -->
    <outboundRelationship1 typeCode="REFR">
      <actReference classCode="OBS" moodCode="EVN">
        <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
      </actReference>
    </outboundRelationship1>
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
    <code code="31" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="recurrenceOfReaction"/>
    <value xsi:type="CE" code="G.k.9.i.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.16"
codeSystemVersion="1.0"/>
    <!-- G.k.9.i.4: Did Reaction Recur on Re-administration? Drug #2, Reaction #2 -->
    <outboundRelationship1 typeCode="REFR">
      <actReference classCode="OBS" moodCode="EVN">
        <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
      </actReference>
    </outboundRelationship1>
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="codedDrugInformation"/>
    <value xsi:type="CE" code="G.k.10.r" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"
codeSystemVersion="1.0"/>
    <!-- G.k.10.r: Additional Information on Drug (coded) (repeat as necessary) #2-1 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="9" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="codedDrugInformation"/>
    <value xsi:type="CE" code="G.k.10.r" codeSystem="2.16.840.1.113883.3.989.2.1.1.17"
codeSystemVersion="1.0"/>
    <!-- G.k.10.r: Additional Information on Drug (coded) (repeat as necessary) #2-2 -->
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
    <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="additionalInformation"/>

```

```

        <value xsi:type="ST">G.k.11</value>
        <!-- G.k.11: Additional Information on Drug (free text) #2 -->
    </observation>
</outboundRelationship2>
<inboundRelationship typeCode="RSON">
    <observation classCode="OBS" moodCode="EVN">
        <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="indication"/>
        <value xsi:type="CE" code="G.k.7.r.2b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="G.k.7.r.2a">
            <!-- G.k.7.r.2a: MedDRA Version for Indication #2-1 -->
            <!-- G.k.7.r.2b: Indication (MedDRA code) #2-1 -->
            <originalText>G.k.7.r.1</originalText>
            <!-- G.k.7.r.1: Indication as Reported by the Primary Source #2-1 -->
        </value>
        <performer typeCode="PRF">
            <assignedEntity classCode="ASSIGNED">
                <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
displayName="sourceReporter"/>
            </assignedEntity>
        </performer>
    </observation>
</inboundRelationship>
<inboundRelationship typeCode="RSON">
    <observation classCode="OBS" moodCode="EVN">
        <code code="19" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="indication"/>
        <value xsi:type="CE" code="G.k.7.r.2b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="G.k.7.r.2a">
            <!-- G.k.7.r.2a: MedDRA Version for Indication #2-2 -->
            <!-- G.k.7.r.2b: Indication (MedDRA code) #2-2 -->
            <originalText>G.k.7.r.1</originalText>
            <!-- G.k.7.r.1: Indication as Reported by the Primary Source #2-2 -->
        </value>
        <performer typeCode="PRF">
            <assignedEntity classCode="ASSIGNED">
                <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
displayName="sourceReporter"/>
            </assignedEntity>
        </performer>
    </observation>
</inboundRelationship>
<inboundRelationship typeCode="CAUS">
    <act classCode="ACT" moodCode="EVN">
        <code code="G.k.8" codeSystem="2.16.840.1.113883.3.989.2.1.1.15" codeSystemVersion="1.0"/>
        <!-- G.k.8: Action(s) Taken with Drug #2 -->
    </act>
</inboundRelationship>
</substanceAdministration>
</component>
</organizer>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <organizer classCode="CATEGORY" moodCode="EVN">
        <code code="1" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.11" codeSystemVersion="1.0"
displayName="治療の概要"/>
        <component typeCode="COMP">
            <observation classCode="OBS" moodCode="EVN">
                <code code="7" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="届出回数"/>
                <value xsi:type="INT" value="1"/>
                <!-- J2.13.r.1: 届出回数 #1 -->
            </observation>
        </component>
        <component typeCode="COMP">
            <observation classCode="OBS" moodCode="EVN">
                <code code="8" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="対象疾患"/>
                <value xsi:type="ED">J2.13.r.2</value>
            </observation>
        </component>
    </organizer>
</subjectOf2>

```



```

        <!-- @J2.13.r.2: 対象疾患 #1 -->
        </observation>
    </component>
    <component typeCode="COMP">
        <observation classCode="OBS" moodCode="EVN">
            <code code="9" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="開発相"/>
            <value xsi:type="CE" code="J2.13.r.3" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.7"
codeSystemVersion="1.0"/>
        </observation>
    </component>
    <component typeCode="COMP">
        <observation classCode="OBS" moodCode="EVN">
            <code code="10" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="投薬中の症例の有無"/>
            <value xsi:type="BL" value="true"/>
        </observation>
    </component>
<!-- @J2.13.r.4: 投薬中の症例の有無 #1 -->
    </organizer>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
    <organizer classCode="CATEGORY" moodCode="EVN">
        <code code="1" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.11" codeSystemVersion="1.0"
displayName="治験の概要"/>
        <component typeCode="COMP">
            <observation classCode="OBS" moodCode="EVN">
                <code code="7" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="届出回数"/>
                <value xsi:type="INT" value="1"/>
            </observation>
        </component>
        <component typeCode="COMP">
            <observation classCode="OBS" moodCode="EVN">
                <code code="8" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="対象疾患"/>
                <value xsi:type="ED">J2.13.r.2</value>
            </observation>
        </component>
        <component typeCode="COMP">
            <observation classCode="OBS" moodCode="EVN">
                <code code="9" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="開発相"/>
                <value xsi:type="CE" code="J2.13.r.3" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.7"
codeSystemVersion="1.0"/>
            </observation>
        </component>
        <component typeCode="COMP">
            <observation classCode="OBS" moodCode="EVN">
                <code code="10" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0"
displayName="投薬中の症例の有無"/>
                <value xsi:type="BL" value="false"/>
            </observation>
        </component>
    </organizer>
</subjectOf2>
</primaryRole>
</subject1>
<component typeCode="COMP">
    <causalityAssessment classCode="OBS" moodCode="EVN">
        <code code="20" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="interventionCharacterization"/>
        <value xsi:type="CE" code="G.k.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.13"
codeSystemVersion="1.0"/>
    </causalityAssessment>
</component>

```

```

    <!-- G.k.1: Characterisation of Drug Role Drug #1 -->
    <subject2 typeCode="SUBJ">
      <productUseReference classCode="SBADM" moodCode="EVN">
        <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
      </productUseReference>
    </subject2>
  </causalityAssessment>
</component>
<component typeCode="COMP">
  <causalityAssessment classCode="OBS" moodCode="EVN">
    <code code="20" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="interventionCharacterization"/>
    <value xsi:type="CE" code="G.k.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.13"
codeSystemVersion="1.0"/>
    <!-- G.k.1: Characterisation of Drug Role Drug #2 -->
    <subject2 typeCode="SUBJ">
      <productUseReference classCode="SBADM" moodCode="EVN">
        <id root="68d6f5ce-3b3b-45c7-92dd-69e06730c3a9"/>
      </productUseReference>
    </subject2>
  </causalityAssessment>
</component>
<component typeCode="COMP">
  <causalityAssessment classCode="OBS" moodCode="EVN">
    <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="causality"/>
    <value xsi:type="ST">G.k.9.i.2.r.3</value>
    <!-- G.k.9.i.2.r.3: Result of Assessment Drug #1, Reaction #1, Assessment #1 -->
    <methodCode>
      <originalText>G.k.9.i.2.r.2</originalText>
      <!-- G.k.9.i.2.r.2: Method of Assessment Drug #1, Reaction #1, Assessment #1 -->
    </methodCode>
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code>
          <originalText>G.k.9.i.2.r.1</originalText>
          <!-- G.k.9.i.2.r.1: Source of Assessment Drug #1, Reaction #1, Assessment #1 -->
        </code>
      </assignedEntity>
    </author>
    <subject1 typeCode="SUBJ">
      <adverseEffectReference classCode="OBS" moodCode="EVN">
        <id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
      </adverseEffectReference>
    </subject1>
    <subject2 typeCode="SUBJ">
      <productUseReference classCode="SBADM" moodCode="EVN">
        <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
      </productUseReference>
    </subject2>
  </causalityAssessment>
</component>
<component typeCode="COMP">
  <causalityAssessment classCode="OBS" moodCode="EVN">
    <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="causality"/>
    <value xsi:type="ST">G.k.9.i.2.r.3</value>
    <!--G.k.9.i.2.r.3: Result of Assessment Drug #1, Reaction #2, Assessment #1 -->
    <methodCode>
      <originalText>G.k.9.i.2.r.2</originalText>
      <!--G.k.9.i.2.r.2: Method of Assessment Drug #1, Reaction #2, Assessment #1 -->
    </methodCode>
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code>
          <originalText>G.k.9.i.2.r.1</originalText>
          <!-- G.k.9.i.2.r.1: Source of Assessment Drug #1, Reaction #2, Assessment #1 -->
        </code>
      </assignedEntity>

```

```

</author>
<subject1 typeCode="SUBJ">
  <adverseEffectReference classCode="OBS" moodCode="EVN">
    <id root="2baa28d6-c9e8-4e6c-93e9-5b860b314220"/>
  </adverseEffectReference>
</subject1>
<subject2 typeCode="SUBJ">
  <productUseReference classCode="SBADM" moodCode="EVN">
    <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
  </productUseReference>
</subject2>
</causalityAssessment>
</component>
<component typeCode="COMP">
  <causalityAssessment classCode="OBS" moodCode="EVN">
    <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="causality"/>
    <value xsi:type="ST">G.k.9.i.2.r.3</value>
    <!--G.k.9.i.2.r.3: Result of Assessment Drug #2, Reaction #2, Assessment #1 -->
    <methodCode>
      <originalText>G.k.9.i.2.r.2</originalText>
      <!--G.k.9.i.2.r.2: Method of Assessment Drug #2, Reaction #2, Assessment #1 -->
    </methodCode>
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code>
          <originalText>G.k.9.i.2.r.1</originalText>
          <!-- G.k.9.i.2.r.1: Source of Assessment Drug #2, Reaction #2, Assessment #1 -->
        </code>
      </assignedEntity>
    </author>
  </causalityAssessment>
</component>
<component typeCode="COMP">
  <causalityAssessment classCode="OBS" moodCode="EVN">
    <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="causality"/>
    <value xsi:type="ST">G.k.9.i.2.r.3</value>
    <!--G.k.9.i.2.r.3: Result of Assessment Drug #2, Reaction #2, Assessment #2 -->
    <methodCode>
      <originalText>G.k.9.i.2.r.2</originalText>
      <!--G.k.9.i.2.r.2: Method of Assessment Drug #2, Reaction #2, Assessment #2 -->
    </methodCode>
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code>
          <originalText>G.k.9.i.2.r.1</originalText>
          <!-- G.k.9.i.2.r.1: Source of Assessment Drug #2, Reaction #2, Assessment #2 -->
        </code>
      </assignedEntity>
    </author>
  </causalityAssessment>
</component>
<component typeCode="COMP">
  <causalityAssessment classCode="OBS" moodCode="EVN">
    <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="causality"/>
    <value xsi:type="ST">G.k.9.i.2.r.3</value>
    <!--G.k.9.i.2.r.3: Result of Assessment Drug #2, Reaction #2, Assessment #2 -->
    <methodCode>
      <originalText>G.k.9.i.2.r.2</originalText>
      <!--G.k.9.i.2.r.2: Method of Assessment Drug #2, Reaction #2, Assessment #2 -->
    </methodCode>
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code>
          <originalText>G.k.9.i.2.r.1</originalText>
          <!-- G.k.9.i.2.r.1: Source of Assessment Drug #2, Reaction #2, Assessment #2 -->
        </code>
      </assignedEntity>
    </author>
  </causalityAssessment>
</component>
<component typeCode="COMP">
  <causalityAssessment classCode="OBS" moodCode="EVN">
    <code code="39" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="causality"/>
    <value xsi:type="ST">G.k.9.i.2.r.3</value>
    <!--G.k.9.i.2.r.3: Result of Assessment Drug #2, Reaction #2, Assessment #2 -->
    <methodCode>
      <originalText>G.k.9.i.2.r.2</originalText>
      <!--G.k.9.i.2.r.2: Method of Assessment Drug #2, Reaction #2, Assessment #2 -->
    </methodCode>
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code>
          <originalText>G.k.9.i.2.r.1</originalText>
          <!-- G.k.9.i.2.r.1: Source of Assessment Drug #2, Reaction #2, Assessment #2 -->
        </code>
      </assignedEntity>
    </author>
  </causalityAssessment>
</component>

```

```

        </productUseReference>
    </subject2>
    </causalityAssessment>
</component>
<component1 typeCode="COMP">
    <observationEvent classCode="OBS" moodCode="EVN">
        <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="comment"/>
        <value xsi:type="ED">H.2</value>
        <!-- H.2: Reporter's Comments -->
        <author typeCode="AUT">
            <assignedEntity classCode="ASSIGNED">
                <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
displayName="sourceReporter"/>
            </assignedEntity>
        </author>
    </observationEvent>
</component1>
<component1 typeCode="COMP">
    <observationEvent classCode="OBS" moodCode="EVN">
        <code code="15" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="diagnosis"/>
        <value xsi:type="CE" code="H.3.r.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="H.3.r.1a"/>
        <!-- H.3.r.1a: MedDRA Version for Sender's Diagnosis / Syndrome and / or Reclassification of Reaction /
Event #1 -->
        <!-- H.3.r.1b: Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event (MedDRA
code) #1 -->
        <author typeCode="AUT">
            <assignedEntity classCode="ASSIGNED">
                <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
displayName="sender"/>
            </assignedEntity>
        </author>
    </observationEvent>
</component1>
<component1 typeCode="COMP">
    <observationEvent classCode="OBS" moodCode="EVN">
        <code code="15" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="diagnosis"/>
        <value xsi:type="CE" code="H.3.r.1b" codeSystem="2.16.840.1.113883.6.163"
codeSystemVersion="H.3.r.1a"/>
        <!-- H.3.r.1a: MedDRA Version for Sender's Diagnosis / Syndrome and / or Reclassification of Reaction /
Event #2 -->
        <!-- H.3.r.1b: Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event (MedDRA
code) #2 -->
        <author typeCode="AUT">
            <assignedEntity classCode="ASSIGNED">
                <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
displayName="sender"/>
            </assignedEntity>
        </author>
    </observationEvent>
</component1>
<component1 typeCode="COMP">
    <observationEvent classCode="OBS" moodCode="EVN">
        <code code="10" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="comment"/>
        <value xsi:type="ED">H.4</value>
        <!-- H.4: Sender's Comments -->
        <author typeCode="AUT">
            <assignedEntity classCode="ASSIGNED">
                <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
displayName="sender"/>
            </assignedEntity>
        </author>
    </observationEvent>
</component1>
</component1 typeCode="COMP">

```

```

      <observationEvent classCode="OBS" moodCode="EVN">
        <code code="3" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
未完了に対するコメント"/>
        <value xsi:type="ED">J2.7</value>
        <!-- @@@J2.7.2: 未完了に対するコメント -->
      </observationEvent>
    </component1>
    <component1 typeCode="COMP">
      <observationEvent classCode="OBS" moodCode="EVN">
        <code code="4" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
感染症の遡及調査"/>
        <value xsi:type="ED">J2.9</value>
        <!-- @@@J2.9: 感染症の遡及調査 -->
      </observationEvent>
    </component1>
    <component1 typeCode="COMP">
      <observationEvent classCode="OBS" moodCode="EVN">
        <code code="5" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
今後の対応"/>
        <value xsi:type="ED">J2.10</value>
        <!-- @@@J2.10: 今後の対応 -->
      </observationEvent>
    </component1>
    <component1 typeCode="COMP">
      <observationEvent classCode="OBS" moodCode="EVN">
        <code code="6" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
その他参考事項等"/>
        <value xsi:type="ED">J2.11</value>
        <!-- @@@J2.11: その他参考事項等 -->
      </observationEvent>
    </component1>
    <component1 typeCode="COMP">
      <observationEvent classCode="OBS" moodCode="EVN">
        <code code="12" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
報告内容の要点"/>
        <value xsi:type="ED">J2.16</value>
        <!-- @@@J2.16: 報告内容の要点 -->
      </observationEvent>
    </component1>
    <component1 typeCode="COMP">
      <observationEvent classCode="OBS" moodCode="EVN">
        <code code="13" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
備考 1"/>
        <value xsi:type="ED">J2.19</value>
        <!-- @@@J2.19: 備考 1 -->
      </observationEvent>
    </component1>
    <component1 typeCode="COMP">
      <observationEvent classCode="OBS" moodCode="EVN">
        <code code="14" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
備考 2"/>
        <value xsi:type="ED">J2.20</value>
        <!-- @@@J2.20: 備考 2 -->
      </observationEvent>
    </component1>
    <component1 typeCode="COMP">
      <observationEvent classCode="OBS" moodCode="EVN">
        <code code="15" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
備考 3"/>
        <value xsi:type="ED">J2.21</value>
        <!-- @@@J2.21: 備考 3 -->
      </observationEvent>
    </component1>
    <component1 typeCode="COMP">
      <observationEvent classCode="OBS" moodCode="EVN">
        <code code="16" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.10" codeSystemVersion="1.0" displayName="
備考 4"/>
        <value xsi:type="ED">J2.22</value>
        <!-- @@@J2.22: 備考 4 -->
      </observationEvent>
    </component1>

```

```

        </observationEvent>
    </component1>
</adverseEventAssessment>
</component>
<component typeCode="COMP">
    <observationEvent classCode="OBS" moodCode="EVN">
        <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="additionalDocumentsAvailable"/>
        <value xsi:type="BL" value="true"/>
        <!-- C.1.6.1: Are Additional Documents Available? -->
    </observationEvent>
</component>
<component typeCode="COMP">
    <observationEvent classCode="OBS" moodCode="EVN">
        <code code="23" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="localCriteriaForExpedited"/>
        <value xsi:type="BL" value="true"/>
        <!-- C.1.7: Does This Case Fulfil the Local Criteria for an Expedited Report? -->
    </observationEvent>
</component>
<component typeCode="COMP">
    <observationEvent classCode="OBS" moodCode="EVN">
        <code code="36" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="summaryAndComment"/>
        <value xsi:type="ED" language="H.5.r.1b">H.5.r.1a</value>
        <!-- H.5.r.1a: Case Summary and Reporter's Comments Text #1 -->
        <!-- H.5.r.1b: Case Summary and Reporter's Comments Language #1 -->
        <author typeCode="AUT">
            <assignedEntity classCode="ASSIGNED">
                <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
displayName="reporter"/>
            </assignedEntity>
        </author>
    </observationEvent>
</component>
<component typeCode="COMP">
    <observationEvent classCode="OBS" moodCode="EVN">
        <code code="36" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1"
displayName="summaryAndComment"/>
        <value xsi:type="ED" language="H.5.r.1b">H.5.r.1a</value>
        <!-- H.5.r.1a: Case Summary and Reporter's Comments Text #2 -->
        <!-- H.5.r.1b: Case Summary and Reporter's Comments Language #2 -->
        <author typeCode="AUT">
            <assignedEntity classCode="ASSIGNED">
                <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.21" codeSystemVersion="1.0"
displayName="reporter"/>
            </assignedEntity>
        </author>
    </observationEvent>
</component>
<outboundRelationship typeCode="SPRT">
    <relatedInvestigation classCode="INVSTG" moodCode="EVN">
        <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" codeSystemVersion="1.0"
displayName="initialReport"/>
        <subjectOf2 typeCode="SUBJ">
            <controlActEvent classCode="CACT" moodCode="EVN">
                <author typeCode="AUT">
                    <assignedEntity classCode="ASSIGNED">
                        <code code="C.1.8.2" codeSystem="2.16.840.1.113883.3.989.2.1.1.3" codeSystemVersion="1.0"/>
                        <!-- C.1.8.2: First Sender of This Case -->
                    </assignedEntity>
                </author>
            </controlActEvent>
        </subjectOf2>
    </relatedInvestigation>
</outboundRelationship>
<outboundRelationship typeCode="SPRT">
    <relatedInvestigation classCode="INVSTG" moodCode="EVN">
        <code nullFlavor="NA"/>

```

```

    <subjectOf2 typeCode="SUBJ">
      <controlActEvent classCode="CACT" moodCode="EVN">
        <id extension="C.1.10.r" root="2.16.840.1.113883.3.989.2.1.3.2"/>
        <!-- C.1.10.r: Identification Number of the Report Which Is Linked to This Report (repeat as necessary)
#1 -->
      </controlActEvent>
    </subjectOf2>
  </relatedInvestigation>
</outboundRelationship>
<outboundRelationship typeCode="SPRT">
  <relatedInvestigation classCode="INVSTG" moodCode="EVN">
    <code nullFlavor="NA"/>
    <subjectOf2 typeCode="SUBJ">
      <controlActEvent classCode="CACT" moodCode="EVN">
        <id extension="C.1.10.r" root="2.16.840.1.113883.3.989.2.1.3.2"/>
        <!-- C.1.10.r: Identification Number of the Report Which Is Linked to this Report (repeat as necessary)
#2 -->

```

```

    </controlActEvent>
  </subjectOf2>
</relatedInvestigation>
</outboundRelationship>
<outboundRelationship typeCode="SPRT">
  <priorityNumber value="1"/>
  <!-- C.2.r.5: Primary Source for Regulatory Purposes #1 -->
  <relatedInvestigation classCode="INVSTG" moodCode="EVN">
    <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.22" codeSystemVersion="1.0"
displayName="sourceReport"/>
    <subjectOf2 typeCode="SUBJ">
      <controlActEvent classCode="CACT" moodCode="EVN">
        <author typeCode="AUT">
          <assignedEntity classCode="ASSIGNED">
            <addr>
              <streetAddressLine>C.2.r.2.3</streetAddressLine>
              <!-- C.2.r.2.3: Reporter's Street #1 -->
              <city>C.2.r.2.4</city>
              <!-- C.2.r.2.4: Reporter's City #1 -->
              <state>C.2.r.2.5</state>
              <!-- C.2.r.2.5: Reporter's State or Province #1 -->
              <postalCode>C.2.r.2.6</postalCode>
              <!-- C.2.r.2.6: Reporter's Postcode #1 -->
            </addr>
            <telecom value="tel:C.2.r.2.7"/>
            <!-- C.2.r.2.7: Reporter's Telephone #1 -->
            <assignedPerson classCode="PSN" determinerCode="INSTANCE">
              <name>
                <prefix>C.2.r.1.1</prefix>
                <!-- C.2.r.1.1: Reporter's Title #1 -->
                <given>C.2.r.1.2</given>
                <!-- C.2.r.1.2: Reporter's Given Name #1 -->
                <given>C.2.r.1.3</given>
                <!-- C.2.r.1.3: Reporter's Middle Name #1 -->
                <family>C.2.r.1.4</family>
                <!-- C.2.r.1.4: Reporter's Family Name #1 -->
              </name>
              <asQualifiedEntity classCode="QUAL">
                <code code="C.2.r.4" codeSystem="2.16.840.1.113883.3.989.2.1.1.6" codeSystemVersion="1.0"/>
                <!-- C.2.r.4: Qualification #1 -->
              </asQualifiedEntity>
              <asLocatedEntity classCode="LOCE">
                <location classCode="COUNTRY" determinerCode="INSTANCE">
                  <code code="C.2.r.3" codeSystem="1.0.3166.1.2.2"/>
                  <!-- C.2.r.3: Reporter's Country Code #1 -->
                </location>
              </asLocatedEntity>
            </assignedPerson>
            <representedOrganization classCode="ORG" determinerCode="INSTANCE">
              <name>C.2.r.2.2</name>
              <!-- C.2.r.2.2: Reporter's Department #1 -->
              <assignedEntity classCode="ASSIGNED">

```

```

        <representedOrganization classCode="ORG" determinerCode="INSTANCE">
          <name>C. 2. r. 2. 1</name>
          <!-- C. 2. r. 2. 1: Reporter's Organisation #1 -->
        </representedOrganization>
      </assignedEntity>
    </representedOrganization>
  </assignedEntity>
</author>
</controlActEvent>
</subjectOf2>
</relatedInvestigation>
</outboundRelationship>
<outboundRelationship typeCode="SPRT">
  <relatedInvestigation classCode="INVSTG" moodCode="EVN">
    <code code="2" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 22" codeSystemVersion="1. 0"
    displayName="sourceReport"/>
    <subjectOf2 typeCode="SUBJ">
      <controlActEvent classCode="CACT" moodCode="EVN">
        <author typeCode="AUT">
          <assignedEntity classCode="ASSIGNED">
            <addr>
              <streetAddressLine>C. 2. r. 2. 3</streetAddressLine>
              <!-- C. 2. r. 2. 3: Reporter's Street #2 -->
              <city>C. 2. r. 2. 4</city>
              <!-- C. 2. r. 2. 4: Reporter's City #2 -->
              <state>C. 2. r. 2. 5</state>
              <!-- C. 2. r. 2. 5: Reporter's State or Province #2 -->
              <postalCode>C. 2. r. 2. 6</postalCode>
              <!-- C. 2. r. 2. 6: Reporter's Postcode #2 -->
            </addr>
            <telecom value="tel:C. 2. r. 2. 7"/>
            <!-- C. 2. r. 2. 7: Reporter's Telephone #2 -->
          </assignedPerson classCode="PSN" determinerCode="INSTANCE">
            <name>
              <prefix>C. 2. r. 1. 1</prefix>
              <!-- C. 2. r. 1. 1: Reporter's Title #2 -->
              <given>C. 2. r. 1. 2</given>
              <!-- C. 2. r. 1. 2: Reporter's Given Name #2 -->
              <given>C. 2. r. 1. 3</given>
              <!-- C. 2. r. 1. 3: Reporter's Middle Name #2 -->
              <family>C. 2. r. 1. 4</family>
              <!-- C. 2. r. 1. 4: Reporter's Family Name #2 -->
            </name>
            <asQualifiedEntity classCode="QUAL">
              <code code="C. 2. r. 4" codeSystem="2. 16. 840. 1. 113883. 3. 989. 2. 1. 1. 6" codeSystemVersion="1. 0"/>
              <!-- C. 2. r. 4: Qualification #2 -->
            </asQualifiedEntity>
            <asLocatedEntity classCode="LOCE">
              <location classCode="COUNTRY" determinerCode="INSTANCE">
                <code code="C. 2. r. 3" codeSystem="1. 0. 3166. 1. 2. 2"/>
                <!-- C. 2. r. 3: Reporter's Country Code #2 -->
              </location>
            </asLocatedEntity>
          </assignedPerson>
        </representedOrganization classCode="ORG" determinerCode="INSTANCE">
          <name>C. 2. r. 2. 2</name>
          <!-- C. 2. r. 2. 2: Reporter's Department #2 -->
        </assignedEntity classCode="ASSIGNED">
          <representedOrganization classCode="ORG" determinerCode="INSTANCE">
            <name>C. 2. r. 2. 1</name>
            <!-- C. 2. r. 2. 1: Reporter's Organisation #2 -->
          </representedOrganization>
        </assignedEntity>
      </representedOrganization>
    </assignedEntity>
  </author>
</controlActEvent>
</subjectOf2>
</relatedInvestigation>

```



```

</outboundRelationship>
<subjectOf1 typeCode="SUBJ">
  <controlActEvent classCode="CACT" moodCode="EVN">
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code code="C.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.7" codeSystemVersion="1.0"/>
        <!-- C.3.1: Sender Type -->
        <addr>
          <streetAddressLine>C.3.4.1</streetAddressLine>
          <!-- C.3.4.1: Sender's Street Address -->
          <city>C.3.4.2</city>
          <!-- C.3.4.2: Sender's City -->
          <state>C.3.4.3</state>
          <!-- C.3.4.3: Sender's State or Province -->
          <postalCode>C.3.4.4</postalCode>
          <!-- C.3.4.4: Sender's Postcode -->
        </addr>
        <telecom value="tel:C.3.4.6"/>
        <!-- C.3.4.6: Sender's Telephone -->
        <telecom value="fax:C.3.4.7"/>
        <!-- C.3.4.7: Sender's Fax -->
        <telecom value="mailto:C.3.4.8"/>
        <!-- C.3.4.8: Sender's E-mail Address -->
        <assignedPerson classCode="PSN" determinerCode="INSTANCE">
          <name>
            <prefix>C.3.3.2</prefix>
            <!-- C.3.3.2: Sender's Title -->
            <given>C.3.3.3</given>
            <!-- C.3.3.3: Sender's Given Name -->
            <given>C.3.3.4</given>
            <!-- C.3.3.4: Sender's Middle Name -->
            <family>C.3.3.5</family>
            <!-- C.3.3.5: Sender's Family Name -->
          </name>
          <asLocatedEntity classCode="LOCE">
            <location classCode="COUNTRY" determinerCode="INSTANCE">
              <code code="C.3.4.5" codeSystem="1.0.3166.1.2.2"/>
              <!-- C.3.4.5: Sender's Country Code -->
            </location>
          </asLocatedEntity>
        </assignedPerson>
        <representedOrganization classCode="ORG" determinerCode="INSTANCE">
          <name>C.3.3.1</name>
          <!-- C.3.3.1: Sender's Department -->
          <assignedEntity classCode="ASSIGNED">
            <representedOrganization classCode="ORG" determinerCode="INSTANCE">
              <name>C.3.2</name>
              <!-- C.3.2: Sender's Organisation -->
            </representedOrganization>
          </assignedEntity>
        </representedOrganization>
      </author>
    </controlActEvent>
  </subjectOf1>
  <primaryInformationRecipient typeCode="PRCP">
    <assignedEntity classCode="ASSIGNED">
      <assignedPerson classCode="PSN" determinerCode="INSTANCE">
        <name>
          <prefix>J2.18.2</prefix>
          <!-- @J2.18.2: 受信者 肩書き -->
          <family>J2.18.3</family>
          <!-- @J2.18.3: 受信者 姓 -->
          <given>J2.18.4</given>
          <!-- @J2.18.4: 受信名 名 -->
        </name>
      </assignedPerson>
      <representedOrganization classCode="ORG" determinerCode="INSTANCE">
        <name>J2.18.1</name>
        <!-- @J2.18.1: 受信者 組織名 -->
      </representedOrganization>
    </assignedEntity>
  </primaryInformationRecipient>

```

```

    </assignedEntity>
  </primaryInformationRecipient>
</controlActEvent>
</subjectOf1>
<subjectOf1 typeCode="SUBJ">
  <controlActEvent classCode="CACT" moodCode="EVN">
    <id assigningAuthorityName="C.1.9.1.r.1" extension="C.1.9.1.r.2" root="2.16.840.1.113883.3.989.2.1.3.3"/>
    <!-- C.1.9.1.r.1: Source(s) of the Case Identifier (repeat as necessary) #1 -->
    <!-- C.1.9.1.r.2 Case Identifier(s) #1 -->
  </controlActEvent>
</subjectOf1>
<subjectOf1 typeCode="SUBJ">
  <controlActEvent classCode="CACT" moodCode="EVN">
    <id assigningAuthorityName="C.1.9.1.r.1" extension="C.1.9.1.r.2" root="2.16.840.1.113883.3.989.2.1.3.3"/>
    <!-- C.1.9.1.r.1: Source(s) of the Case Identifier (repeat as necessary) #2 -->
    <!-- C.1.9.1.r.2 Case Identifier(s) #2 -->
  </controlActEvent>
</subjectOf1>
<subjectOf2 typeCode="SUBJ">
  <investigationCharacteristic classCode="OBS" moodCode="EVN">
    <code code="1" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" codeSystemVersion="1.0"
    displayName="ichReportType"/>
    <value xsi:type="CE" code="C.1.3" codeSystem="2.16.840.1.113883.3.989.2.1.1.2" codeSystemVersion="1.0"/>
    <!-- C.1.3 Type of Report -->
  </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
  <investigationCharacteristic classCode="OBS" moodCode="EVN">
    <code code="2" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" codeSystemVersion="1.0"
    displayName="otherCaseIds"/>
    <value xsi:type="BL" value="true"/>
    <!-- C.1.9.1 Other Case Identifiers in Previous Transmissions -->
  </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
  <investigationCharacteristic classCode="OBS" moodCode="EVN">
    <code code="3" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" codeSystemVersion="1.0"
    displayName="nullificationAmendmentCode"/>
    <value xsi:type="CE" code="C.1.11.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.5" codeSystemVersion="1.0"/>
    <!-- C.1.11.1: Report Nullification / Amendment -->
  </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
  <investigationCharacteristic classCode="OBS" moodCode="EVN">
    <code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.23" codeSystemVersion="1.0"
    displayName="nullificationAmendmentReason"/>
    <value xsi:type="CE">
      <originalText>C.1.11.2</originalText>
      <!-- C.1.11.2: Reason for Nullification / Amendment -->
    </value>
  </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
  <investigationCharacteristic classCode="OBS" moodCode="EVN">
    <code code="1" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="識別
番号 (報告分類)"/>
    <value xsi:type="CE" code="J2.1a" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.1"
    codeSystemVersion="1.0"/>
    <!-- @J2.1a: 識別番号 (報告分類) -->
  </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
  <investigationCharacteristic classCode="OBS" moodCode="EVN">
    <code code="2" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="報告
起算日"/>
    <value xsi:type="TS" value="20130107"/>
    <!-- @J2.2.1: 報告起算日 -->
  </investigationCharacteristic>
</subjectOf2>

```

```

<subjectOf2 typeCode="SUBJ">
  <investigationCharacteristic classCode="OBS" moodCode="EVN">
    <code code="3" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="報告
起算日に関するコメント"/>
    <value xsi:type="ED">J2.2.2</value>
    <!-- @@@J2.2.2: 報告起算日に関するコメント -->
  </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
  <investigationCharacteristic classCode="OBS" moodCode="EVN">
    <code code="4" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="即時
報告フラグ"/>
    <value xsi:type="CE" code="J2.3" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.2" codeSystemVersion="1.0"/>
    <!-- @@@J2.3: 即時報告フラグ -->
  </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
  <investigationCharacteristic classCode="OBS" moodCode="EVN">
    <code code="5" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="報告
対象外フラグ"/>
    <value xsi:type="CE" code="J2.8.1" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.6"
codeSystemVersion="1.0"/>
    <!-- @@@J2.8.1: 報告対象外フラグ -->
  </investigationCharacteristic>
</subjectOf2>
<subjectOf2 typeCode="SUBJ">
  <investigationCharacteristic classCode="OBS" moodCode="EVN">
    <code code="6" codeSystem="2.16.840.1.113883.3.989.5.1.3.2.1.12" codeSystemVersion="1.0" displayName="報告
対象外の理由"/>
    <value xsi:type="ED">J2.8.2</value>
    <!-- @@@J2.8.2: 報告対象外の理由 -->
  </investigationCharacteristic>
</subjectOf2>
</investigationEvent>
</subject>
</controlActProcess>
</PORR_IN049016UV>
<!-- Message #1 -->
<!-- Message #2 -->
<!-- PORR_IN049016UV -->
<!-- /PORR_IN049016UV -->
<!-- Message #2 -->
<receiver typeCode="RCV">
  <device classCode="DEV" determinerCode="INSTANCE">
    <id extension="N.1.4" root="2.16.840.1.113883.3.989.2.1.3.14"/>
    <!-- N.1.4: Batch Receiver Identifier -->
  </device>
</receiver>
<sender typeCode="SND">
  <device classCode="DEV" determinerCode="INSTANCE">
    <id extension="N.1.3" root="2.16.840.1.113883.3.989.2.1.3.13"/>
    <!-- N.1.3: Batch Sender Identifier -->
  </device>
</sender>
</MCCI_IN200100UV01>

```

厚生労働省システム管理用データ項目（J項目）の属性

J2.1a 識別番号（報告分類）	
項目説明	本通知別添の「1. 報告分類」に基づく報告分類を示す。
記載方法	別紙5より該当する報告分類を選択して記載する。
データ型	2A
許容値	別紙5参照
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='1']][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.12']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.1']/@code
XPath (codeSystem Version)	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='1']][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.12']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.1']/@codeSystemVersion
J2.1b 識別番号（番号）	
項目説明	機構が付与した識別番号を示す。
記載方法	第一報については、完了報告・未完了報告の如何に関わらず、空欄とする。また、第二報以降については、機構が付与した識別番号を記載する。完了報告、未完了報告であるにかかわらず第一報報告は、本項目を空欄とすることとし、機構による識別番号の付与をもって受付完了となる。
データ型	8N
許容値	該当なし
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/id[@root='2.16.840.1.113883.3.989.5.1.3.2.3.1']][1]/@extension

J2.2.1 報告起算日	
項目説明	当該報告について、報告の起算となる日を示す。通常、規則第 228 条の 20 第 1 項若しくは第 5 項第 2 号ロ又は第 273 条第 1 項に定める事項を知った日となる。
記載方法	最低限 CCYYMMDD まで記載すること。
データ型	CCYYMMDDhhmmss.UUUU[+ -ZZzz]
許容値	日付
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.12']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='TS']/@value
J2.2.2 報告起算日に関するコメント	
項目説明	「J2.2.1 報告起算日」について、以下に示す場合等、説明が必要な場合に記載する。 <ul style="list-style-type: none"> ・ 第一報において、「C.1.4 情報源から最初に報告が入手された日」と「J2.2.1 報告起算日」が異なる場合 ・ 規則第 228 条の 20 第 1 項若しくは第 5 項第 2 号ロ又は第 273 条第 1 項に定める報告期限を超過していることを、製造販売業者又は外国特例承認取得者が把握している場合 ・ 30（又は 15）日以内の報告対象であると考えていたところ、第 1 報を報告する前に追加情報により 15（又は 7）日以内の報告の対象であることが判明した場合
記載方法	なし
データ型	10000AN
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='3'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.12']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
J2.3 即時報告フラグ	
項目説明	副作用症例報告、感染症症例報告及び外国措置報告において、即時報告の場合、本項目を記載する。
記載方法	該当する場合のみ「1=即時報告」を記載すること。

データ型	1N
許容値	1=即時報告
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.12']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.2']/@code
XPath (codeSystem Version)	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.12']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.2']/@codeSystemVersion
J2.4.k 新医薬品等の状況区分	
項目説明	全ての被疑薬のうち、自社医薬品又は自社治験薬について区分を示す。
記載方法	別紙5より適切なコード値を選択して記載する。 <ul style="list-style-type: none"> ・医療用医薬品の場合は、「1=市販直後調査中」、「2=承認2年以内」又は「5=該当なし」の中から選択し記載すること。 ・治験薬の場合は「3=未承認」又は「4=一変治験中」から選択し記載すること。 ・要指導医薬品の場合は「5=該当なし」、「6=再審査期間中（要指導）」又は「7=PMS期間中（要指導）」の中から選択し記載すること。 ・一般用医薬品、医薬部外品又は化粧品の場合は「5=該当なし」を選択し記載すること。
データ型	1N
許容値	別紙5参照

XPath	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'] [@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent [@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] [adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'] [@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ'] /subjectOf2[@typeCode='SBJ'] [organizer/code[@code='4'] [@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']] [1]/organizer[@classCode='CATEGORY'] [@moodCode='EVN']/component[@typeCode='COMP'] [substanceAdministration[id][k]/substanceAdministration [@classCode='SBADM'] [@moodCode='EVN']/consumable[@typeCode='CSM'] [1]/instanceOfKind[@classCode='INST'] /kindOfProduct[@classCode='MMAT'] [@determinerCode='KIND']/asManufacturedProduct [@classCode='MANU']/subjectOf [@typeCode='SBJ'] [characteristic[1]/characteristic [code[@code='1'] [@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']] [1] [@classCode='OBS'] [@moodCode='EVN']/value [@xsi:type='CE'] [@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.3'] /@code </pre>
XPath (codeSystem Version)	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'] [@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent [@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] [adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'] [@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ'] /subjectOf2[@typeCode='SBJ'] [organizer/code[@code='4'] [@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']] [1]/organizer[@classCode='CATEGORY'] [@moodCode='EVN']/component[@typeCode='COMP'] [substanceAdministration[id][k]/substanceAdministration [@classCode='SBADM'] [@moodCode='EVN']/consumable[@typeCode='CSM'] [1]/instanceOfKind[@classCode='INST'] /kindOfProduct[@classCode='MMAT'] [@determinerCode='KIND']/asManufacturedProduct [@classCode='MANU']/subjectOf [@typeCode='SBJ'] [characteristic[1]/characteristic [code[@code='1'] [@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']] [1] [@classCode='OBS'] [@moodCode='EVN']/value [@xsi:type='CE'] [@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.3'] /@codeSystemVersion </pre>
J2.5.k 一般用医薬品等のリスク区分等	
項目説明	<p>全ての被疑薬のうち、自社医薬品が一般用医薬品又は要指導医薬品の場合、一般用医薬品のリスク区分又は要指導医薬品若しくは薬局製造販売医薬品であることを示す。</p>
記載方法	<p>別紙5より適切なコード値を選択して記載すること。</p>

	<ul style="list-style-type: none"> ・報告時点において一般用医薬品の場合は、「01=第一類医薬品」、「02=第二類医薬品」、「2S=指定第二類医薬品」又は「03=第三類医薬品」の中から選択し記載すること。 ・報告時点において要指導医薬品の場合は、「04=要指導医薬品」を選択し記載すること。 ・報告時点において薬局製造販売医薬品の場合は、「05=薬局製造販売医薬品」を記載すること。
データ型	2AN
許容値	別紙5参照
XPath	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:h17-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'] [@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent [@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] [adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'] [@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ'] /subjectOf2[@typeCode='SBJ'] [organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']] [1]/organizer[@classCode='CATEGORY'] [@moodCode='EVN']/component[@typeCode='COMP'] [substanceAdministration/id][k]/substanceAdministration [@classCode='SBADM'] [@moodCode='EVN']/consumable[@typeCode='CSM'] [1]/instanceOfKind[@classCode='INST'] [kindOfProduct[@classCode='MMAT'] [@determinerCode='KIND']/asManufacturedProduct [@classCode='MANU']/subjectOf [@typeCode='SBJ'] [approval][1]/approval[@classCode='CNTRCT'] [@moodCode='EVN']/pertinentInformation [@typeCode='PERT'] [1]/policy[@classCode='POLICY'] [@moodCode='EVN']/code[@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.4'] /@code </pre>
XPath (codeSystem Version)	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:h17-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'] [@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent [@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] [adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'] [@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ'] /subjectOf2[@typeCode='SBJ'] [organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']] [1]/organizer[@classCode='CATEGORY'] [@moodCode='EVN']/component[@typeCode='COMP'] [substanceAdministration/id][k]/substanceAdministration [@classCode='SBADM'] [@moodCode='EVN']/consumable[@typeCode='CSM'] [1]/instanceOfKind[@classCode='INST'] [kindOfProduct[@classCode='MM </pre>

	AT'][@determinerCode='KIND']/asManufacturedProduct[@classCode='MANU']/subjectOf[@typeCode='SBJ'][approval][1]/approval[@classCode='CNTRCT'][@moodCode='EVN']/pertinentInformation[@typeCode='PERT'][1]/policy[@classCode='POLICY'][@moodCode='EVN']/code[@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.4']/@codeSystemVersion
J2.6.k 一般用医薬品等の入手経路	
項目説明	全ての被疑薬のうち、自社医薬品が一般用医薬品又は要指導医薬品の場合の入手経路を示す。
記載方法	別紙5より適切なコード値を選択して記載すること。
データ型	1A
許容値	別紙5参照
XPath (value)	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP'][substanceAdministration/id][k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/subjectOf[@typeCode='SBJ']/observationEvent[code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']][1][@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.5']/@code

XPath (null flavor)	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP']{adverseEventAssessment}[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classCode='INVSBJ']{1}/subjectOf2[@typeCode='SBJ']{organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']}[1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP']{substanceAdministration/id}[1]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM']{1}/instanceOfKind[@classCode='INST']/subjectOf[@typeCode='SBJ']/observationEvent[code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']}[1][@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.5']/@nullFlavor
XPath (codeSystem Version)	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']{1}/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP']{adverseEventAssessment}[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ']{1}/primaryRole[@classCode='INVSBJ']{1}/subjectOf2[@typeCode='SBJ']{organizer/code[@code='4'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.20']}[1]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP']{substanceAdministration/id}[k]/substanceAdministration[@classCode='SBADM'][@moodCode='EVN']/consumable[@typeCode='CSM']{1}/instanceOfKind[@classCode='INST']/subjectOf[@typeCode='SBJ']/observationEvent[code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']}[1][@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.5']/@codeSystemVersion
J2.7.1 完了、未完了区分	
項目説明	当該報告について、未完了報告又は完了報告の区分を示す。
記載方法	報告すべき事項の調査が完了していない場合は、未完了報告として報告すること。なお、完了報告後に新たな情報を入手した場合は、改めて完了報告として報告する。HL7により定義されたコードを用いて記載すること。
データ型	HL7 コード 10A
許容値	active=未完了 completed=完了

XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/statusCode/@code
J2.7.2 未完了に関するコメント	
項目説明	未完了報告の場合は、未完了報告の理由を示す。
記載方法	なし
データ型	10000AN
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][(adverseEventAssessment)[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP'][(observationEvent[code=@code='3'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10'])][1]/observationEvent[classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
J2.8.1 報告対象外フラグ	
項目説明	副作用症例報告又は感染症症例報告において、報告対象外の追加報告の場合に記載する。
記載方法	該当する場合のみ「1=報告対象外」を記載すること。
データ型	1N
許容値	1=報告対象外
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][(investigationCharacteristic/code[@code='5'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.12'])][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.6']/@code
XPath (codeSystem Version)	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent

	[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='5']][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.12']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='CE']][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.6']/@codeSystemVersion
J2.8.2 報告対象外の理由	
項目説明	副作用症例報告又は感染症症例報告において、報告対象外の追加報告を行う場合に報告対象外である理由を記載する。
記載方法	なし
データ型	10000AN
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf2[@typeCode='SUBJ'][investigationCharacteristic/code[@code='6']][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.12']][1]/investigationCharacteristic[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
J2.9 感染症の遡及調査	
項目説明	感染症症例報告の場合は、平成 24 年 3 月 6 日付け薬食発 0306 号厚生労働省医薬食品局長通知「「血液製剤等に係る遡及調査ガイドライン」の一部改正について」の別添「血液製剤等に係る遡及調査ガイドライン」により示された調査内容を記載する。
記載方法	なし
データ型	10000AN
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP'][observationEvent[code[@code='4']][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']]][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
J2.10 今後の対応	
項目説明	当該報告の副作用等に対する送信者の評価に基づく処置と今後の対応について記載

	する。
記載方法	なし
データ型	10000AN
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP'][observationEvent[code[@code='5'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']]][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
J2.11 その他参考事項等	
項目説明	その他参考となる事項を記載する。
記載方法	なし
データ型	10000AN
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP'][observationEvent[code[@code='6'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']]][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
J2.12 治験成分記号	
項目説明	治験計画届書に記載している治験成分記号を示す。
記載方法	治験計画届書を提出していない場合には、治験実施計画書に記載している開発コードを記載すること。
データ型	70AN
許容値	自由記載

XPath	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent [@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@mo odCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='4'][@codeSystem='2.16.840. 1.113883.3.989.2.1.1.20']][1]/organizer[@classCode='CATEGORY'][@moodCode='E VN']/component[@typeCode='COMP'][substanceAdministration/id]/substanceAd ministration[@classCode='SBADM'][@moodCode='EVN'][consumable/instanceOf Kind/kindOfProduct/asSpecializedKind/generalizedMaterialKind/code/originalTe xt][1]/consumable[@typeCode='CSM'][1]/instanceOfKind[@classCode='INST']/kin dOfProduct[@classCode='MMAT'][@determinerCode='KIND']/asSpecializedKind[@classCode='GEN'][1]/generalizedMaterialKind[@classCode='MAT'][@determiner Code='KIND']/code/originalText/text() </pre>
-------	--

J2.13.r.1 届出回数

項目説明	治験ごとに、治験計画届書の届出回数を記載する。
記載方法	治験計画届書を提出していない場合には、空欄とすること。
データ型	2N
許容値	該当なし

XPath	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent [@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@mo odCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ]/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840. 1.113883.3.989.5.1.3.2.1.11']][r]/organizer[@classCode='CATEGORY'][@moodCode ='EVN']/component[@typeCode='COMP']/observation[@classCode='OBS'][@mood Code='EVN'][code[@code='7'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']]/value[@xsi:type='INT']/@value </pre>
-------	---

J2.13.r.2 対象疾患

項目説明	治験ごとに、治験計画届書に記載されている対象疾患を記載する。
記載方法	治験計画届出書を提出している場合には、記載を省略することができる。なお、治験計画届書を提出していない場合には、治験実施計画書に記載している対象疾患を記載すること。同一の治験実施計画書での複数の疾患を対象とする場合は、カンマで区切

	って記載すること。
データ型	1000AN
許容値	自由記載
XPath	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent [@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@mo odCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ'] /subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840. 1.113883.3.989.5.1.3.2.1.11']]r]/organizer[@classCode='CATEGORY'][@moodCode ='EVN']/component[@typeCode='COMP']/observation[@classCode='OBS'][@mood Code='EVN'][code[@code='8'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']]/value[@xsi:type='ED']/text() </pre>
J2.13.r.3 開発相	
項目説明	治験計画届書に記載されている開発相を示す。
記載方法	治験計画届出書を提出している場合には、記載を省略することができる。なお、治験計画届書を提出していない場合には、別紙5より適切なコード値を選択して記載すること。
データ型	1N
許容値	別紙5 参照
XPath	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent [@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@mo odCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ'] /subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840. 1.113883.3.989.5.1.3.2.1.11']]r]/organizer[@classCode='CATEGORY'][@moodCode ='EVN']/component[@typeCode='COMP']/observation[@classCode='OBS'][@mood Code='EVN'][code[@code='9'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']]/value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.7']/@code </pre>

XPath (codeSystem Version)	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.11']] [r]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP']/observation[@classCode='OBS'][@moodCode='EVN'][code[@code='9'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']] /value[@xsi:type='CE'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.7'] /@codeSystemVersion
J2.13.r.4 投薬中の症例の有無	
項目説明	当該報告の治験成分を投薬中の被験者の有無を示す。
記載方法	コード値ではなく Boolean で該当者がいる場合は「true=有」を、いない場合は「false=無」を選択すること。
データ型	Boolean 10A
許容値	true=有 false=無
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment[1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ']/subjectOf2[@typeCode='SBJ'][organizer/code[@code='1'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.11']] [r]/organizer[@classCode='CATEGORY'][@moodCode='EVN']/component[@typeCode='COMP']/observation[@classCode='OBS'][@moodCode='EVN'][code[@code='10'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']] /value[@xsi:type='BL'] /@value
J2.14.i 未知・既知	
項目説明	治験の場合、当該報告の副作用等が治験薬概要書から予測できないものである場合は未知、その他の場合は既知とする。E2B 項目の E.i.2.1b 副作用／有害事象 (MedDRA コード) と関連づけられ、副作用毎に未知・既知を付与する。(予測性の判断基準は、本通知別添の「8. その他の治験副作用等報告に際しての注意事項」の (1) を参照すること。)

記載方法	コード値から選択して記載すること。
データ型	1N
許容値	1=未知 2=既知
XPath	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent [@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@mo odCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2. 16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode= 'EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='11'] [@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']][1]/observation[@classCode= 'OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.11388 3.3.989.5.1.3.2.1.8']/@code </pre>
XPath (codeSystem Version)	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent [@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@mo odCode='EVN']/subject1[@typeCode='SBJ'][1]/primaryRole[@classCode='INVSBJ ']/subjectOf2[@typeCode='SBJ'][observation[id][code[@code='29'][@codeSystem='2. 16.840.1.113883.3.989.2.1.1.19']]][i]/observation[@classCode='OBS'][@moodCode= 'EVN']/outboundRelationship2[@typeCode='PERT'][observation/code[@code='11'] [@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']][1]/observation[@classCode= 'OBS'][@moodCode='EVN']/value[@xsi:type='CE'][@codeSystem='2.16.840.1.11388 3.3.989.5.1.3.2.1.8']/@codeSystemVersion </pre>
J2.15.r. 公表国	
項目説明	研究報告及び外国措置報告において、外国において報告内容が公表されている場合、公表国を示す。
記載方法	<p>国コードから適切なコードを選択して記載すること。</p> <p>研究報告の場合、報告者/文献著者等の所属又は、試験実施場所の国を記載すること。</p> <p>また、外国措置報告の場合、措置を行った国を記載すること。</p> <p>措置報告において、複数国の規制当局によって同一の措置がなされた場合、1つの報</p>

	<p>告として報告して差し支えない。その際には代表国を1番目に記載し、繰り返しを利用して、二番目以降にその他の公表国を記載すること。</p> <p>後日、同一の措置が他国でなされた場合には、当該公表国について追加報告する。その際には、前回報告の後に続けて当該追加報告の代表国を記載すること。当該報告の公表国が複数ある場合は繰り返しを利用すること。</p> <p>なお、各国の措置内容が異なる場合は、別報告とすること。</p>
データ型	2A
許容値	ISO 3166-1 アルファ-2 の国コード、EU
XPath	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent [@classCode='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][document/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27']]/document [@classCode='DOC'][@moodCode='EVN']/participation[@typeCode='AUT']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'] [@determinerCode='INSTANCE']/asLocatedEntity[@classCode='LOCE']/location[@classCode='COUNTRY'][@determinerCode='INSTANCE']/code[@codeSystem='1.0.3166.1.2.2'] /@code </pre>
J2.16 報告内容の要点	
項目説明	研究報告及び外国措置報告において、「研究報告又は外国における措置の概要 (H.1)」に記載した内容の要点を本項目に示す。
記載方法	なし
データ型	500AN
許容値	自由記載
XPath	<pre> /MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent [@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN'] /component1[@typeCode='COMP'][observationEvent[code[@code='12'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']]][1]/observationEvent[@classCode='OBS'] [@moodCode='EVN']/value[@xsi:type='ED']/text() </pre>
J2.17.r 試験／研究の分類	
項目説明	研究報告の場合、「臨床試験／研究」又は「非臨床試験／研究」の別を示す。
記載方法	なし
データ型	1N

許容値	1=臨床試験／研究 2=非臨床試験／研究
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/reference[@typeCode='REFR'][(document/code[@code='2'][@codeSystem='2.16.840.1.113883.3.989.2.1.1.27'])][r]/document[@classCode='DOC'][@moodCode='EVN']/title/text()
J2.18.1 受信者組織名	
項目説明	ICSR の受信者の組織名を示す。
記載方法	独立行政法人医薬品医療機器総合機構と記載する。
データ型	100AN
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/primaryInformationRecipient][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/primaryInformationRecipient[@typeCode='PRCP']/assignedEntity[@classCode='ASSIGNED']/representedOrganization[@classCode='ORG'][@determinerCode='INSTANCE']/name/text()
J2.18.2 受信者職名	
項目説明	ICSR の受信者の肩書きを示す。
記載方法	理事長と記載する。
データ型	100AN
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/primaryInformationRecipient][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/primaryInformationRecipient[@typeCode='PRCP']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/prefix[1]/text()
J2.18.3 受信者姓	

項目説明	ICSR の受信者の姓を示す。
記載方法	機構の理事長の姓を記載する。
データ型	100AN
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/primaryInformationRecipient][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/primaryInformationRecipient[@typeCode='PRCP']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/family[1]/text()
J2.18.4 受信者名	
項目説明	ICSR の受信者の名を示す。
記載方法	機構の理事長の名を記載する。
データ型	100AN
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/subjectOf1[@typeCode='SUBJ'][controlActEvent/primaryInformationRecipient][1]/controlActEvent[@classCode='CACT'][@moodCode='EVN']/primaryInformationRecipient[@typeCode='PRCP']/assignedEntity[@classCode='ASSIGNED']/assignedPerson[@classCode='PSN'][@determinerCode='INSTANCE']/name/given[1]/text()
J2.19 備考 1	
項目説明	予備項目
記載方法	なし
データ型	10000AN
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:hl7-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@mo

	odCode='EVN']/component1[@typeCode='COMP'][observationEvent[code[@code='13'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
J2.20 備考 2	
項目説明	予備項目
記載方法	なし
データ型	10000AN
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:h17-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP'][observationEvent[code[@code='14'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
J2.21 備考 3	
項目説明	予備項目
記載方法	なし
データ型	10000AN
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:h17-org:v3 MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ'][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'][adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP'][observationEvent[code[@code='15'][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
J2.22 備考 4	
項目説明	予備項目
記載方法	なし
データ型	10000AN
許容値	自由記載
XPath	/MCCI_IN200100UV01[@ITSVersion='XML_1.0'][@xsi:schemaLocation='urn:h17-org:v3

MCCI_IN200100UV01.xsd']/PORR_IN049016UV[r]/controlActProcess[@classCode='CACT'][@moodCode='EVN']/subject[@typeCode='SUBJ']][1]/investigationEvent[@classCode='INVSTG'][@moodCode='EVN']/component[@typeCode='COMP'] adverseEventAssessment][1]/adverseEventAssessment[@classCode='INVSTG'][@moodCode='EVN']/component1[@typeCode='COMP'] observationEvent[code[@code='16']][@codeSystem='2.16.840.1.113883.3.989.5.1.3.2.1.10']][1]/observationEvent[@classCode='OBS'][@moodCode='EVN']/value[@xsi:type='ED']/text()
--

厚生労働省システム管理用データ項目（J項目）のコード値

コード値	J2.1a 識別番号（報告分類）	市販後／ 治験
AA	国内感染症症例報告（市販後）	市販後
AB	国内副作用症例報告（市販後）	市販後
AC	外国感染症症例報告（市販後）	市販後
AD	外国副作用症例報告（市販後）	市販後
AE	感染症研究報告（市販後）	市販後
AF	副作用研究報告（市販後）	市販後
AG	外国における製造等の中止、回収、廃棄等の措置報告（市販後）	市販後
BC	医薬部外品研究報告	市販後
BD	化粧品研究報告	市販後
DA	国内感染症症例報告（治験）	治験
DB	国内副作用症例報告（治験）	治験
DC	外国感染症症例報告（治験）	治験
DD	外国副作用症例報告（治験）	治験
DE	感染症研究報告（治験）	治験
DF	副作用研究報告（治験）	治験
DG	外国における製造等の中止、回収、廃棄等の措置報告（治験）	治験

コード値	J2.4.k 新医薬品等の状況区分	市販後／ 治験
1	市販直後調査中	市販後
2	承認2年以内	市販後
3	未承認	治験
4	一変治験中	治験
5	該当なし	市販後
6	再審査期間中（要指導）	市販後
7	PMS 期間中（要指導）	市販後

コード値	J2.5.k 一般用医薬品等のリスク区分等	市販後/ 治験
01	第一類医薬品	市販後
02	第二類医薬品	市販後
2S	指定第二類医薬品	市販後
03	第三類医薬品	市販後
04	要指導医薬品	市販後
05	薬局製造販売医薬品	市販後

コード値	J2.6.k 一般用医薬品等の入手経路	市販後/ 治験
S	薬局等の店頭での販売の場合	市販後
H	配置販売の場合	市販後
I	インターネットによる通信販売の場合	市販後
T	その他の通信販売（電話等）の場合	市販後
nullFlavor=ASKU	確認を行ったが、情報が入手できなかった場合	市販後
nullFlavor=UNK	やむを得ない理由により確認不能で、不明の場合	市販後

コード値	J2.13.r.3 開発相	市販後/ 治験
0	マイクロドーズ試験等	治験
1	第Ⅰ相	治験
2	第Ⅱ相	治験
3	第Ⅲ相	治験
4	第Ⅰ/Ⅱ相	治験
5	第Ⅱ/Ⅲ相	治験
7	申請中	治験
8	その他	治験

個別症例安全性報告等確認応答メッセージデータ項目

記載項目における記号の解説

◎＝必ず記載する項目

◇＝エラー等が発生した場合に記載される項目

全報告分類共通

データ項目番号	データ項目名	記載項目	入力種別	許容値	同一の値となるE2B項目番号
ACK. M. 1	確認応答バッチ番号	◎	TXT	100	
ACK. M. 2	確認応答バッチ送信者識別子	◎	TXT	60	N. 1. 4
ACK. M. 3	確認応答バッチ受信者識別子	◎	TXT	60	N. 1. 3
ACK. M. 4	バッチ伝送の確認応答日	◎	日付	CCYYMMDDhhmmss+0900	
ACK. A. 1	ICSRバッチ番号	◎	TXT	100	N. 1. 2
ACK. A. 2	確認応答地域メッセージ番号	◎	TXT	100	
ACK. A. 3	ICSRバッチ伝送日	◎	日付（最低精度）	CCYYMMDDhhmmss	N. 1. 5
ACK. A. 4	伝送確認応答コード	◎	リスト	AA, AE, AR	
ACK. A. 5	バッチバリデーションエラー	◇	TXT	250	
ACK. B. r. 1	ICSRメッセージ番号	◎	TXT	100	N. 2. r. 1, C. 1. 1
ACK. B. r. 2	地域報告番号	◎	TXT	100	
ACK. B. r. 3	ICSRメッセージ確認応答受信者	◎	TXT	60	N. 2. r. 2
ACK. B. r. 4	ICSRメッセージ確認応答送信者	◎	TXT	60	N. 2. r. 3
ACK. B. r. 5	ICSRメッセージ作成日	◎	日付（最低精度）	CCYYMMDDhhmmss	N. 2. r. 4, C. 1. 2
ACK. B. r. 6	ICSRメッセージの確認応答コード	◎	リスト	CA, CR	
ACK. B. r. 7	エラー／警告メッセージ又は意見	◇	TXT	250	

投与剤形一覧

分類	記載する文字	説明
経口剤	TAB	錠剤（通常の剤皮を施した錠剤、糖衣錠、舌下錠、口腔錠を含む。ただし、徐放錠「SRT」、臙錠「IMP」は含まない）
	CAP	カプセル（ただし、徐放性カプセル「SRC」は含まない）
	GRA	顆粒
	POW	散剤（ただし、外用剤の撒布粉剤「ダスティングパウダー「DPO」は含まない）
	FGR	細粒
	SYR	シロップ（ドライシロップを含む）
	ENT	腸溶剤
	SRC	徐放性カプセル
	CTS	カシュー（オブラート嚢を含む）
	CTB	咀嚼錠
	DRO	ドロップ
	PIL	丸剤（錠剤は含まない）
	SOL	内用液剤（経口投与される液体剤形のものすべて含むがシロップ「SYR」を除く）
	LOZ	菓子錠剤（トローチ、飴類等）
	SRT	徐放錠
SRG	徐放性顆粒	
POR	剤形の明確でない経口剤（*） *経口剤として、錠剤、顆粒剤等複数の剤形が市販されており、そのいずれか不明の場合は「XXX」ではなく、「POR」となることに注意すること。	
注射剤	INJ	注射剤（用時溶解のものを含む。また、経中心静脈栄養剤も含む）
外用剤	DPO	撒布粉剤（ダスティングパウダー）
	LOT	ローション（眼科用ローションを除く）
	OIT	軟膏・クリーム
	SHP	シャンプー
	SPR	スプレー（吸入剤を除く）
	LIQ	外用液剤（リニメントを含む）
	TAP	テープ剤（パップ剤を含む）
	AER	エアゾール（吸入用定量噴霧式エアゾールに限る。外皮用のエアゾールは「SPR」とすること）
	EDR	点耳剤
	EED	点眼剤

	EOI	点眼軟膏
	NDR	点鼻剤（点鼻スプレーを含む）
	INH	吸入剤（吸入麻酔剤、吸入用スプレーを含む）
	INS	ガス吸入剤（亜酸化窒素等）
	SPC	スピンキャップ
	MWH	含そう剤
	SUP	肛門坐剤
	IMP	挿入剤（膣坐剤、膣錠等）
	ENM	浣腸剤
	JEL	ゼリー
	EXT	剤形の明確でない外用剤
その他	INF	注入剤（腹膜灌流液等）
	XXX	不明