

衛生福利部食品藥物管理署

ICH E2B(R3)藥品不良反應通報系統測試

操作手冊

目錄

壹、	系統使用說明	3
一、	系統測試網址	3
二、	本系統建議開啟方式	3
三、	測試時間.....	3
四、	如何申請帳號	3
五、	帳號角色及功能	6
	(一) 管理者帳號	6
	(二) 一般使用者帳號	7
六、	通報案件方式	8
	(一) 如何通報案件	8
	(二) 如何查詢通報過案件	13
	(三) 通報案件內容有誤可以修改嗎	15
七、	E2B R3 參考範例	17
八、	E2B R3 批次上傳操作	20
貳、	相關資訊.....	23
一、	系統網址:	23
二、	技術服務聯絡資訊:	23
參、	意見回饋單	24
肆、	附件.....	25
一、	管理者帳號申請辦法暨權責聲明及申請資料表	25
二、	E2B R3 參考範例檔	28

壹、系統使用說明

一、系統測試網址

<https://e2badr.fda.gov.tw/>。

二、本系統建議開啟方式

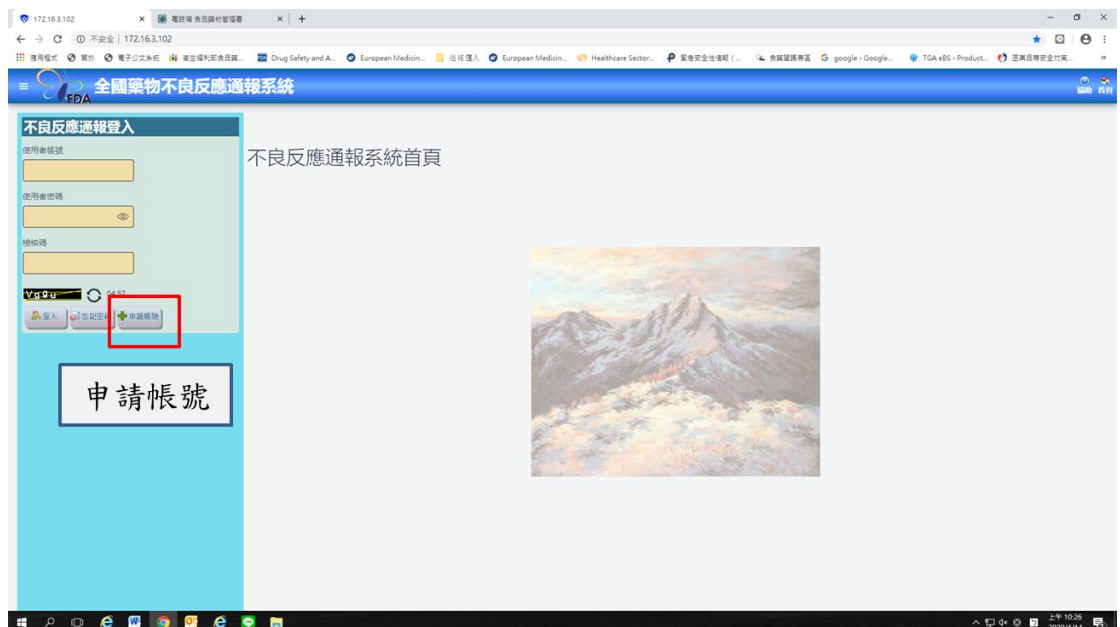
以 Google chrome/Mozilla Firefox/Microsoft Edge/Apple Safari 等瀏覽器開啟。

三、測試時間

自 109 年 6 月 1 日至 6 月 30 日止，測試時間結束後將會將其帳號密碼及通報資料全數刪除。正式資料請至現行系統(<https://adr.fda.gov.tw>)進行通報。

四、如何申請帳號

(一) 首次使用本系統，需先註冊帳號，並填寫相關資料(黃底處為必填)。填寫完畢後按下送出申請後，如成功會跳出對話框，同時使用者電子郵件信箱會收到一封預設密碼的郵件。



(二) 帳號欄位說明：

1. 登入帳號:該帳號必須為唯一，如有重複帳號，系統會在送出申請

後顯示錯誤。

2. **顯示名稱:**此僅為登入畫面後之暱稱。
3. **電子郵件:**請填寫可用之電子郵件，以利接收通報中心與您聯繫所有與通報相關事務之用(包含收件回函、退件通知、資料異動通知等)，請確認您使用的信箱將不會將通報中心伺服器寄送之郵件偵測為垃圾郵件。
4. **使用者姓:**可填寫中英文，惟請填寫真實姓名，以利後續如需與之聯繫使用。
5. **使用者名:**可填寫中英文，惟請填寫真實姓名，以利後續如需與之聯繫使用。
6. **使用者電話:**請填寫上班時間可聯絡的固定市內電話號碼及分機號碼；若無固定電話者請填寫可聯絡的電話號碼。以利後續聯繫通報相關事宜使用。
7. **人員屬性:**請填寫使用者屬性，如醫師、藥師、其他醫療人員等並勾選相關醫事機構，若勾選其他者亦請填寫醫事機構或相關單位。
8. **醫事機構:**請填寫所屬服務機構之名稱，得搜尋內建醫事機構資料庫選取，服務機構名稱選定後會自動帶入地址。

全國藥物不良反應通報系統

FDA

傳送申請 回復前一頁

登入帳號: testchen 顯示名稱: 陳先生

電子郵件: abc@gmail.com 備用電子郵件:

姓: 陳 名: 小明

電話: 0911001001

人員屬性: 醫師 藥師 其他醫療人員 其他

☒ 民眾

城市: 郵遞區號: 地址:

個人照片: 選擇檔案 將檔案拖到此處

photo_portrait.png

黃底處為必填

全國藥物不良反應通報系統

登入帳號: test100 顯示名稱: Joey

電子郵件: t0920008899@gmail.com 備用電子郵件:

姓: Chen 名: Joey

電話: 0920008899

人員屬性: 醫療人員: ☐ 醫師 ☐ 藥師 ☒ 其他醫療人員 ☐ 民眾

醫事機構: 國立臺灣大學醫學院附設醫院

台北市 中正區中山南路7、8號: 常

個人照片: 選擇檔案 將檔案拖到此處

帳號申請

帳號已申請成功, 請檢查您的電子郵件。

瞭解

藥物不良反應事件通報系統-帳號啟動

Yahoo奇摩/收件匣

5月12日 週二 於 下午2:48

這封是由全國藥物不良反應通報中心系統自動寄送的E-MAIL, 以通知您的帳號已經建立

顯示名稱: Why

帳號: Gay

密碼: nHhA.PvBiE

※電子郵件免責聲明: 本通訊及其所有附件所含之資訊均屬機密文件, 僅供指定之收件人使用, 未經寄件人許可不得揭露、複製或散布本通訊。若您並非指定之收件人, 請勿使用、保存或揭露本通訊之任何部份, 並請即通知寄件人並完全刪除本通訊。網路通訊可能含有病毒, 收件人應自行確認本郵件是否安全, 若因此造成損害, 寄件人恕不負責。 This electronic mail transmission is intended only for the named recipient. It contains information which may be privileged, confidential and exempt from disclosure under applicable law. Dissemination, distribution, or copying of this communication by anyone other than the recipient or the recipient's agent is strictly prohibited. If this electronic mail transmission is received in error, Please notify us immediately and delete the message and all attachments of it from your computer system. We shall not be liable for the improper or incomplete transmission of the information contained in this email nor for any delay in its receipt or damage to your system.

(三) 首次以預設密碼登入時, 系統會自動要求變更密碼, 輸入完成後按下送出申請。

全國藥物不良反應通報系統

變更密碼

使用者帳號: test100

舊密碼: ...

新密碼:

再次輸入新密碼:

送出申請 回首頁

密碼設定原則

- 密碼長度最少12碼
- 密碼複雜度需為大小寫文字、數字及特殊符號 (!@#\$%) 至少4選3
- 密碼最長使用期限90天
- 不得與前三次密碼相同

五、帳號角色及功能

系統測試期間並未開放此功能，僅先供使用者瞭解未來帳號角色及功能。該功能於日後正式上線時將以下列方式進行申請，並將視後續情況進行調整。

(一) 管理者帳號

1. 一個單位僅能申請 1 組管理者帳號，一般使用者帳號上限為 4 組，惟請依實際需求申請。
2. 醫療機構及藥商：請以醫療機構或公司名義連同「管理者帳號申請辦法暨權責聲明及申請資料(如附件 1)」表正式行文至全國藥物不良反應通報中心或本署。本署或委辦單位將依所提供資料於本系統建立管理者帳號。
3. 帳號申請規則：「醫療機構或公司英文簡稱+ 阿拉伯數字」（如 TDRF01），新申請帳號之 E-mail 不得與其他通報帳號重複。藥商申請時其名稱需與藥品許可證上之「申請商名稱」一致，方可收到系統副知的不良反應通報案件。
4. 帳號啟用：系統將自動發送啟動密碼至電子郵件地址，並另行以 E-mail 通知，故請確實填寫申請表資料。使用者收到啟動密碼後，請依其帳號及所提供之啟動密碼登入系統，進入系統基本資料修改功能，將相關資料填齊，並修改登入密碼。
5. 管理權責須知：
 - (1) 帳號管理及使用權責由各單位自行負責。
 - (2) 帳號密碼應由各單位及其系統使用者本人妥善保存，並在人員或職務異動時自行交接並於系統上更新相關資料（包含密碼）。
 - (3) 每三個月會提醒更新密碼，並請同時確認基本資料是否須更新，以保障其使用之權益，敬請配合。

6. 功能權限:

- (1) 可進行案件通報。
- (2) 得以查看及編輯該單位內所有使用者通報的案件。
- (3) 得以執行該單位內一般使用者帳號重啟或暫停，及檢視上線使用者情形。
- (4) 得於系統即時維護該單位資訊，包含:食品藥物管理署與藥商之緊急連絡使用資訊、醫療機構資訊維護、收到系統副知通報表資訊之副知窗口 (Email)等。

(二)一般使用者帳號

1. 帳號申請規則:請參照「如何申請帳號」。

2. 權責須知:

- (1) 該等帳號密碼應妥善保存，並在人員或職務異動時自行交接並於系統上更新相關資料（包含密碼）。
- (2) 每三個月會提醒更新密碼，並請同時確認基本資料是否須更新，以保障其使用之權益，敬請配合。

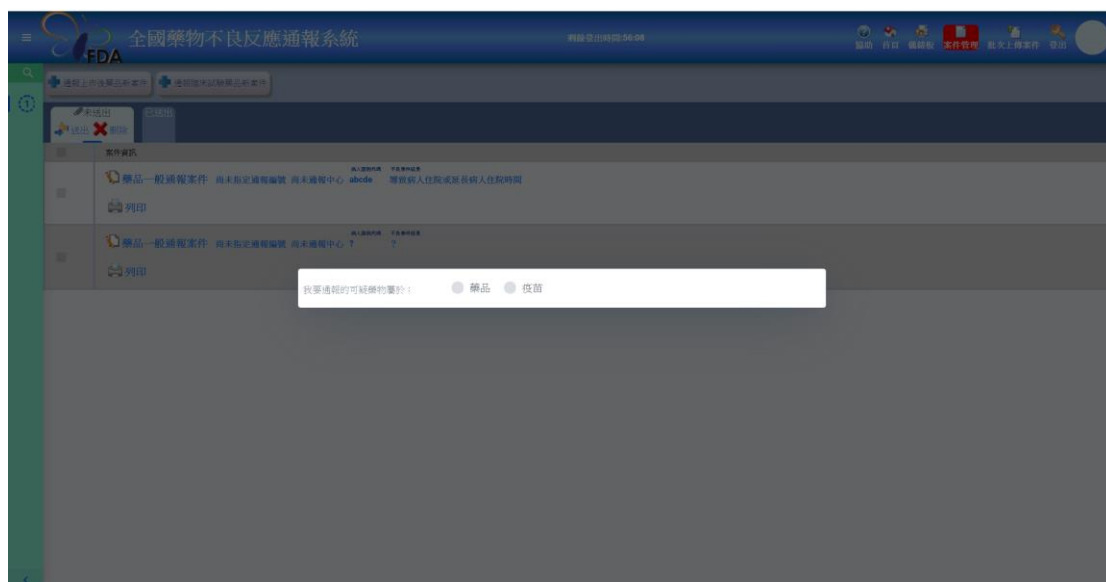
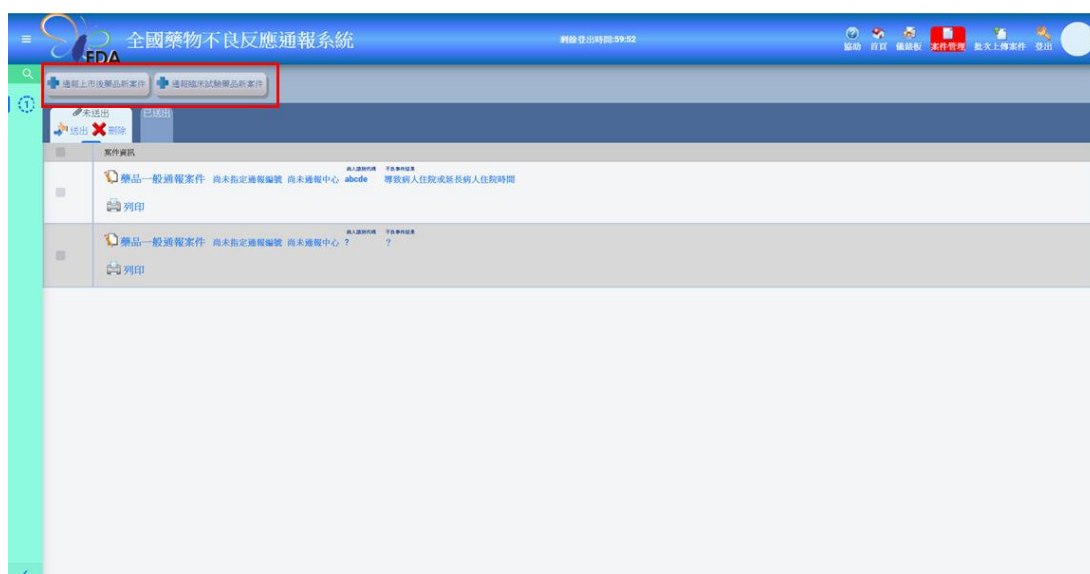
3. 功能權限:

- (1) 可進行案件通報。
- (2) 可搜尋該帳號通報過之案件。

六、通報案件方式

(一)如何通報案件

1. 針對**單一案件之線上通報者**:在登入系統後，進入案件列表，點選「通報上市後藥品新案件」、「通報臨床試驗藥品新案件」，即出現對話框，選取通報項目，即可進入案件通報編輯頁面。



全國藥物不良反應通報系統

幫助 首頁 協助報 登出 報表 報表上傳案件 登出

報表 報表查詢 報表上傳

報表代碼：

原通報單位藥別代號：

性別： ☐ 男 ☐ 女 ☐ 未知

出生日期或年齡：

體重 (kg)：

身高 (cm)：

請填寫出生日期或年齡
如選擇已知出生日期，請必能填寫出生日期
如選擇已知此次發生不良反應年齡，請必能填寫首次發生不良反應年齡
如選擇未知的年齡，請必能填寫未知的年齡
注意：性別與本報選擇不可同時為未知

通報過程中如需暫存，請直接按暫存鍵，會出現下列提醒未填寫處，按下了解鍵後，即可登出或回到列表頁。回到列表處可看見未出送案件，並可以使用列印模式，了解填寫情形，如需繼續填寫，點選上市藥品一般通報案件，即回到填寫畫面可繼續填寫。

全國藥物不良反應通報系統

幫助 首頁 協助報 登出 報表 報表上傳案件 登出

報表 報表查詢 報表上傳

報表代碼：

原通報單位藥別代號：

性別： ☐ 男 ☐ 女 ☐ 未知

出生日期或年齡：

體重 (kg)：

身高 (cm)：

請填寫出生日期或年齡

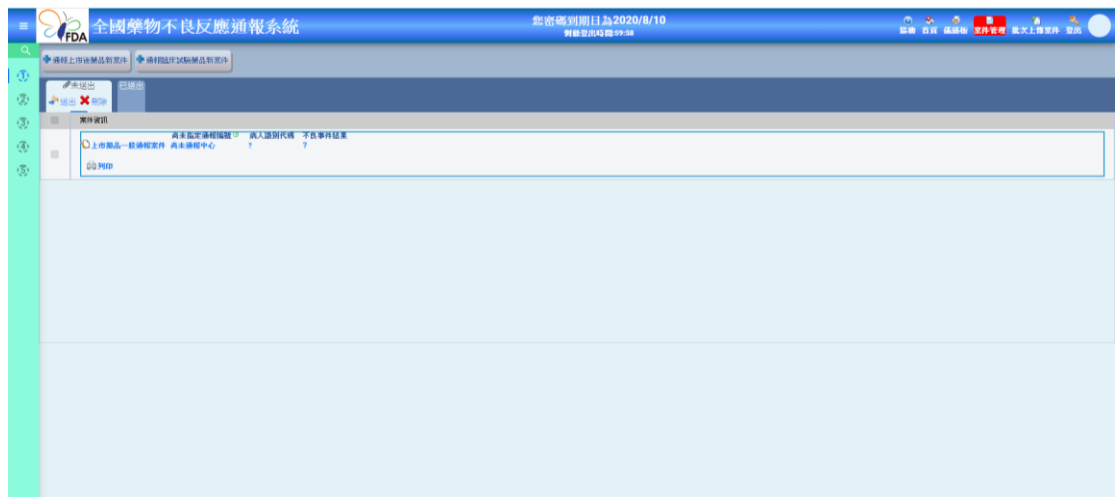
有下列驗證錯誤

藥別代碼不能空白

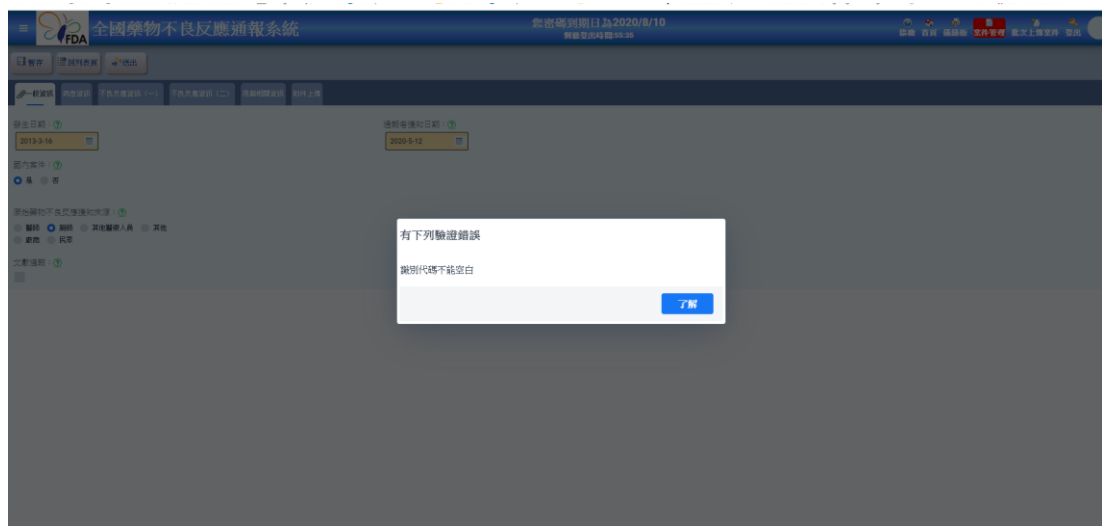
不良事件結果不能空白

案件描述不能為空白

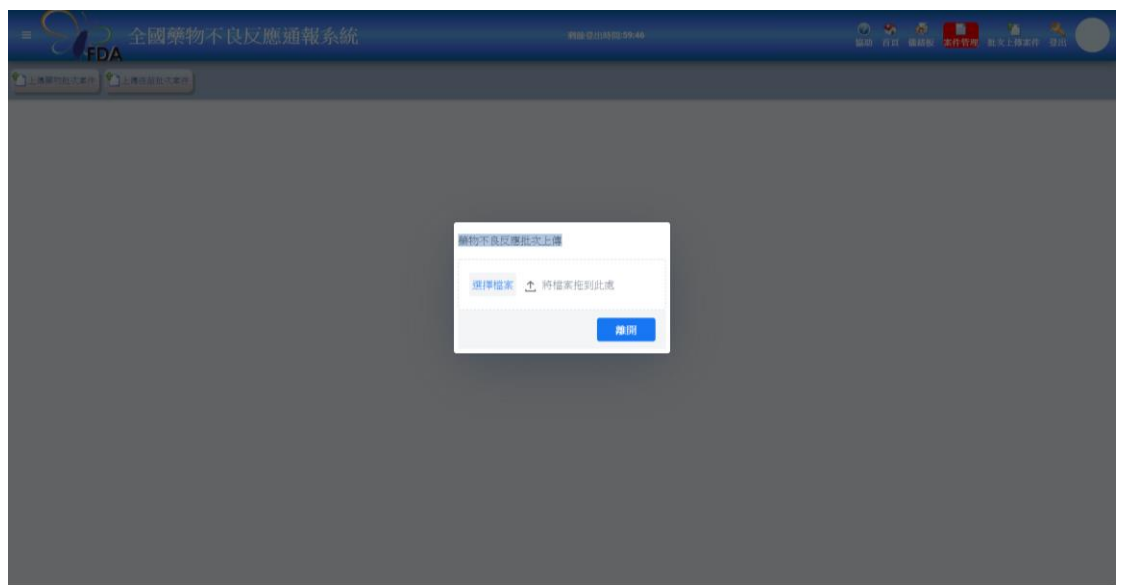
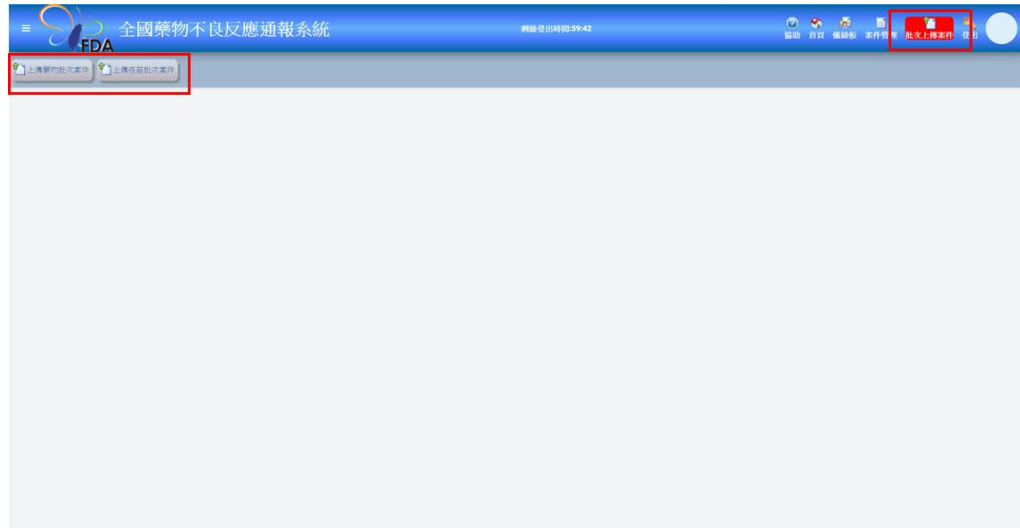
了解



填寫過程如有錯誤或必填卻未填寫處，暫存時皆會出現提醒，亦無法送出該案件。



2. 針對以 **E2B R3 格式做批次上傳者**：在登入系統後點選「批次上傳案件」，進入頁面後選取「上傳藥物批次案件」或「上傳臨床試驗批次案件」。



選擇上傳的檔案(.zip 或.xml)後，如果上傳檔案符合 E2B R3 規範，則系統會自動轉譯檔案內容如下圖供上傳者檢視。


全國藥物不良反應通報系統
新報送出時間: 59:41











C.1-Id. of ICSR

C.2-Primary Source(s)

C.3-Sender Info.

C.4-Literature Ref.

C.5-Study Id.

C.6-Patient Info.

C.7-Reaction(s)

C.8-Test Result(s)

C.9-Drug(s) Info.

C.10-Narrative

C.1.1-Sender's ID	C.1.2-Date of Creation	C.1.3-Report Type	C.1.4-First Received	C.1.5-After Recd Info.
ES-EMA-ichicor-test110	2017-9-21 12:34:4	Spontaneous report	2015-6-4	2015-6-4
C.1.6-Any Additional Documents Available*				
Yes				
C.1.6.1- Documents Held by Sender				
No data available				
C.1.7-Expedited Report?	C.1.8.1- Worldwide ID	C.1.8.2-First Sender of This Case		
	ES-EMA-ichicor-test110	Other		
C.1.9-Other Case ID(s)				
C.1.9.1-Source(s) of the Case ID(s)				
No data available				
C.1.10-ID(s) of the Linked Report				
No data available				
C.1.11-Report Notification/Amendment		C.1.11.2-Reason for Notification/Amendment		

一旦檢視無誤，則按下送出鍵，則該案件即自動送出，使用者可至案件管理中檢視送出的案件。

(二)如何查詢通報過案件

進入案件管理頁面，案件分為未送出及已送出，**未送出之案件可允許使用者修改，已送出案件則無法修改**。每一案件均可自行列印下載成 PDF 檔，如下。



FD

通報新事件

未送

送出

關閉

事件 登出

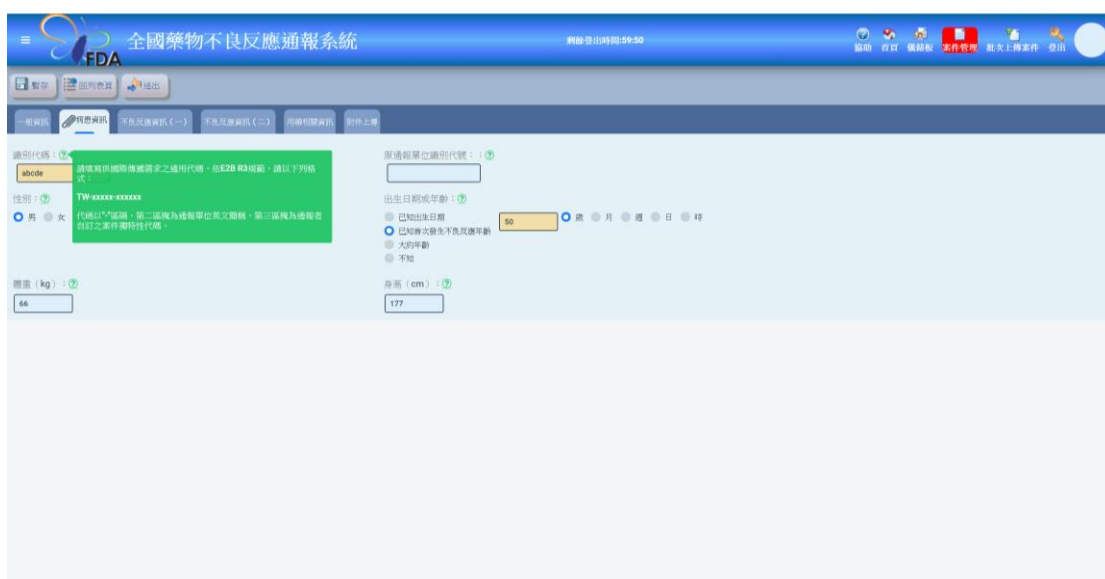
藥品不良反應通報表

個案編號 (由通報中心填寫) :

通報者姓名	null, null		
電話			
通報人員身份	☐ 醫師 ☐ 藥師 ☐ 其他醫療人員 ☐ 廠商 ☐ 民眾 ☐ 其他		
服務機構名稱	國立臺灣大學醫學院附設醫院		
服務機構地址	nullnullnull		
獲知藥品不良反應日期	109年1月22日		
獲知藥品不良反應來源	☐ 醫師 ☐ 藥師 ☐ 其他醫療人員 ☒ 廠商 ☐ 民眾 ☐ 其他		
識別代號 :	abcde	原通報單位識別代號	
性別	☒ 男 ☐ 女 體重 66.0 (公斤) 身高 177.0 (公分)		
出生日期(或年齡)	年 月 日 (或50.0歲)		
不良反應發生日期	109年1月20日		

(三)通報案件內容有誤可以修改嗎

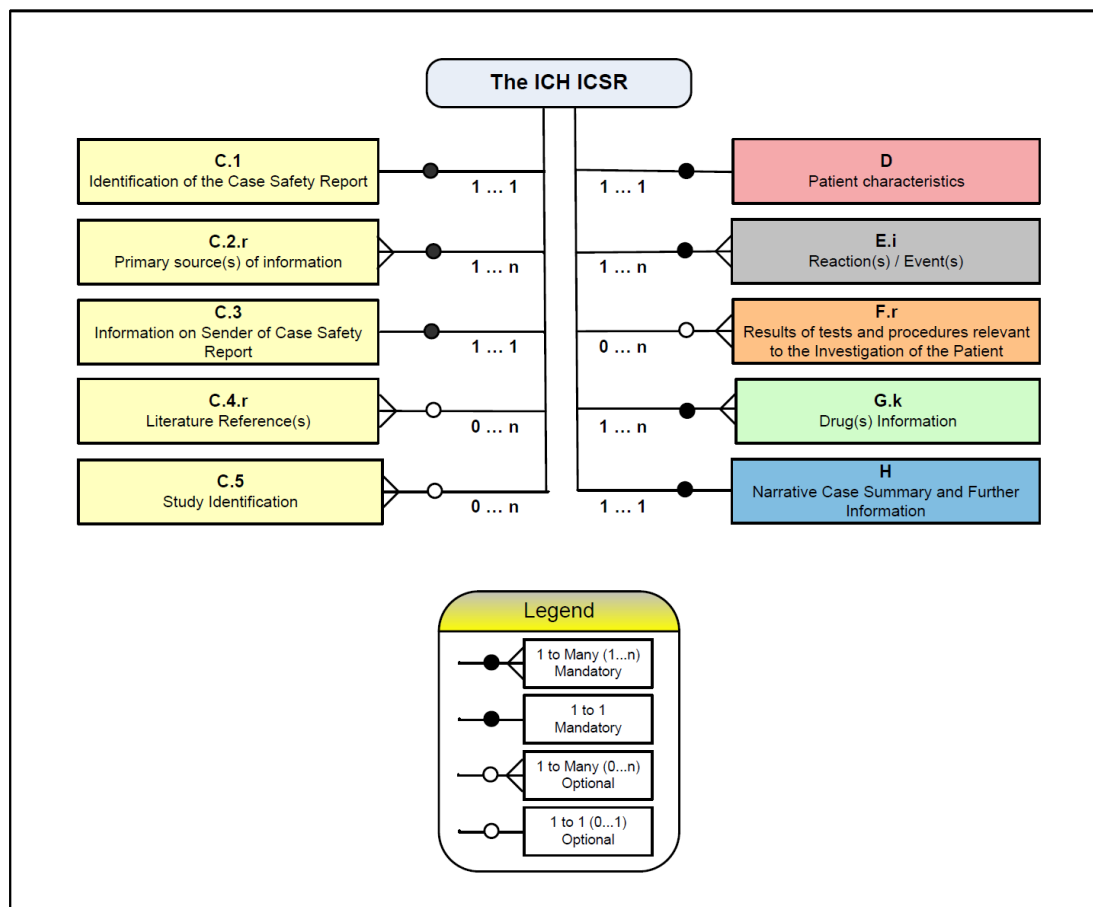
1. 點擊未送出之案件點選案件屬性則會自動跳入編輯頁面，使用者可
以在此繼續編輯。



2. 針對已送出案件如有需要更正或補充資料，則需以案件追蹤進行，
按下案件追蹤，則會將此案件內容複製至同一案件編號之未送出新
案件，供使用者編輯。

七、 E2B R3 參考範例

(一) 本系統係為依據 ICH E2B (R3)格式中有關不良反應資料交換定義所建構而來。標準命名為「**ISO / HL7 27953-2: 2011 Health informatics -- Individual case safety reports (ICSRs) in pharmacovigilance -- Part 2: Human pharmaceutical reporting requirements for ICSR**」, 參考範例如附件 2, 詳請自行至 ISO 網站參閱(<http://www.iso.org/iso/store.htm>)。ICH ICSR 關聯架構及上傳資料格式架構說明如下:



(二) TFDA 通報表與 ICH E2B R3 關聯資料對照如下:

TFDA 資料欄位	ICH E2B(R3)對應欄位	資料型態	備註
發生日期	E.i.4 - Date of Start of Reaction / Event	日期	
通報者獲知日期	C.1.4 - Date Report Was First Received from Source	日期	

是否國內案件	無	文數字	客製欄位
原始藥物不良反應獲知來源	無	文數字	客製欄位
文獻通報	無	文數字	客製欄位
識別代碼	D.1.1.2 - Patient Medical Record Number(s) and the Source(s) of the Record Number (Specialist Record Number)	文數字	
原通報單位識別代號	D.1.1.3 - Patient Medical Record Number(s) and the Source(s) of the Record Number (Hospital Record Number)	文數字	
性別	D.5 - Sex	文數字	
出生日期	D.2.1 - Date of Birth	日期	
首次發生不良反應年齡	D.2.2a/D.2.2b - Age at Time of Onset of Reaction / Event	數字	
大約年齡	D.2.3 - Patient Age Group (as per reporter)	文數字	
體重 (kg)	D.3 - Body Weight (kg)	數字	
身高 (cm)	D.4 - Height (cm)	數字	
不良事件結果	E.i.3.2 - Seriousness Criteria at Event Level	文數字	
死亡日期	D.9.1 - Date of Death	日期	
死亡原因	D.9.2.r.2 - Reported Cause(s) of Death (free text)	文數字	
案件描述	H.1 - Case Narrative Including Clinical Course, Therapeutic Measures, Outcome and Additional Relevant Information	文數字	
檢驗說明	無	文數字	客製欄位
其他相關資料	H.2 - Reporter's comments	文數字	
不良事件後續結果	E.i.7 - Outcome of Reaction / Event at the Time of Last Observation	文數字	
不良反應症狀	E.i.1.1a - Reaction / Event as Reported by the Primary Source in Native Language	文數字	
檢驗日期	F.r.1 - Test Date	日期	

檢驗項目	F.r.2.1 - Test Name (free text)	文數字	
檢驗結果	F.r.3.2 - Test Result (value/qualifier)	文數字	
檢驗結果單位	F.r.3.3 - Test Result (unit)	文數字	
檢查描述	F.r.3.4 - Result Unstructured Data (free text)	文數字	
許可字號	G.k.3.1 - Authorisation / Application Number	文數字	
學名	G.k.2.3.r.1 - Substance/ Specified Substance Name	文數字	
商品名	G.k.2.2 - Medicinal Product Name as Reported by the Primary Source	文數字	
廠商	G.k.3.3 - Name of Holder / Applicant	文數字	
含量	G.k.2.3.r.3 - Strength (number)	數字	
含量單位	G.k.2.3.r.4 - Strength (unit)	文數字	
劑型	G.k.4.r.9.1 - Pharmaceutical Dose Form (free text)	文數字	
劑量	G.k.4.r.1a - Dose (number)	數字	
劑量單位	G.k.4.r.1b - Dose (unit)	文數字	
頻率	G.k.4.r.2 - Number of Units in the Interval	數字	
頻率單位	G.k.4.r.3 - Definition of the Time Interval Unit	文數字	
起始日期	G.k.4.r.4 - Date and Time of Start of Drug	日期	
結束日期	G.k.4.r.5 - Date and Time of Last Administration	日期	
用藥原因	G.k.4.r.8 - Dosage Text	文數字	
給藥途徑	G.k.4.r.10.1 - Route of Administration (free text)	文數字	
批號	G.k.4.r.7 - Batch / Lot Number	文數字	
效期	無	文數字	客製欄位
處置情形	G.k.8 - Action(s) Taken with Drug	文數字	
再投藥是否出現 同樣反應	G.k.9.i.4 - Did Reaction Recur on Re-administration?	文數字	

八、 E2B R3 批次上傳操作

(一) 上傳檔案格式為符合 ICH E2B (R3) 批次傳遞規範之.xml 檔或包含符合前述規範之.xml 檔在內的.zip 壓縮檔。每一件不良反應案件需以表頭

<PORR_IN049016UV></PORR_IN049016UV> 包覆。

(二) 如為.zip 壓縮檔，則壓縮檔內僅可內含一個批次.xml 檔，但一個批次檔內可包含多個通報案件內容。

(三) 批次檔表頭須符合 R3 規範：

```
<?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="[ Batch Number]"
  root="2.16.840.1.113883.3.989.2.1.3.22"/>
  <creationTime value="[Date of Batch Transmission]"/>
  <responseModeCode code="D"/>
  <interactionId extension="MCCI_IN200100UV01"
  root="2.16.840.1.113883.1.6"/>
  <name code="[ Type of Messages in Batch]"
  codeSystem="2.16.840.1.113883.3.989.2.1.1.1"/>
  <PORR_IN049016UV>

    .....[單一案件訊息本體].....

  </PORR_IN049016UV>
  <PORR_IN049016UV>

    .....[ 單一案件訊息本體].....

  </PORR_IN049016UV>
  <receiver typeCode="RCV">
    <device classCode="DEV" determinerCode="INSTANCE">
      <id extension="[Batch Receiver Identifier]"
      root="2.16.840.1.113883.3.989.2.1.3.14"/>
    </device>
  </receiver>
  <sender typeCode="SND">
```

```

<device classCode="DEV" determinerCode="INSTANCE">
  <id extension="[Batch Sender Identifier]"
    root="2.16.840.1.113883.3.989.2.1.3.13"/>
</device>
</sender>
</MCCI_IN200100UV01>

```

(四) 目前系統並未提供 Batch Acknowledgement，但上傳檔案仍需遵循批次檔案的表頭格式。

(五) 檔案上傳後，系統會自行一 R3 規範擷取所有案件資訊，並以頁籤方式分別顯示個規範區塊之資訊。使用者檢核無誤後則可按送出鍵將案件送出。

全國藥物不良反應通報系統

您密碼到期日為2020/6/10
剩餘登入時間:59:27

協助 首頁 儀錶板 案件管理 批次上傳案件 登入

送出 回列表頁

C.1-Id. of ICSR	C.2.r-Primary Source(s)	C.3-Sender Info.	C.4.r-Literature Ref.	C.5-Study Id.	D-Patient Info.	E.I-Reaction(s)	F.r-Test Result(s)	G.k-Drug(s) Info.	H-Narrative
C.1.1-Sender's UID US-obsStudy-R3TESTCASE03	C.1.2-Date of Creation 2017-9-21 12:2:46	C.1.3-Report Type Report from study	C.1.4-First Received 2015-2-27	C.1.5-Most Recent Info. 2015-2-27					
C.1.6.1-Are Additional Documents Available? Yes									
C.1.6.1.r-Documents Held by Sender No data available									
C.1.7-Expedited Report? No data available	C.1.8.1-Worldwide UID US-obsStudy-R3TESTCASE03	C.1.8.2-First Sender of This Case Other							
C.1.9.1-Other Case ID(s)									
C.1.9.1.r-Source(s) of the Case ID(s) No data available									
C.1.10.r-ID(s) of the Linked Report									
C.1.10.1-Worldwide UID of the Linked Report US-obsStudy-R3TESTCASE04									
C.1.11.1-Report Nullification/Amendment									
C.1.11.2-Reason for Nullification/Amendment									

(六) 如果批次檔中內含多個案件，則系統會分別萃取案件資料顯示如下，使用者可個別案件逐一檢視資訊，待資訊無誤，則按送出即將所有案件一起送出。

全國藥物不良反應通報系統 您密碼到期日為2020/6/10 剩餘登出時間:59:51

協助 首頁 儀錶板 案件管理 批次上傳案件 登出

搜尋選項

SE-EMA-R3-TESTCASE01

US-obsStudy-R3TESTCASE04

送出 返回列表

C.1-Id. of ICSR	C.2-r-Primary Source(s)	C.3-Sender Info.	C.4-r-Literature Ref.	C.5-Study Id.	D-Patient Info.	E-I-Reaction(s)	F-r-Test Result(s)	G.k-Drug(s) Info.	H-Narrat
C.1.1-Sender's UID SE-EMA-R3-TESTCASE01	C.1.2-Date of Creation 2017-9-21 11:38:30	C.1.3-Report Type Report from study	C.1.4-First Received 2017-5-24	C.1.5-Most Recent Info. 2017-5-24					
C.1.6.1-Are Additional Documents Available? Yes									
C.1.6.1.r-Documents Held by Sender									
C.1.6.1.r.1-Documents Description ECG printout					C.1.6.1.r.2-Included Documents				
C.1.7-Expedited Report? SE-EMA-R3-TESTCASE01									
C.1.8-First Sender of This Case Other									
C.1.9.1-Other Case ID(s)									
C.1.9.1.r-Source(s) of the Case ID(s)									
C.1.9.1.r.1-Source(s) of the Case Id. Spectrum medical information ZX82					C.1.9.1.r.2-Case Id.(s)				
C.1.10.r-ID(s) of the Linked Report									
C.1.10.r.1-Worldwide UID of the Linked Report SE-MPA-1234									
C.1.11.1-Report Nullification/Amendment					C.1.11.2-Reason for Nullification/Amendment				

< 固定欄開

(七) R3 規範中規定之必填資訊必須存在，否則系統在檢核時會通報錯誤。

(八) 一旦送出成功，則系統會賦予一個中心編號，使用者可以在案件管理列表之送出頁簽中檢視。

貳、 相關資訊

一、 系統網址:

<https://e2badr.fda.gov.tw/>

二、 技術服務聯絡資訊:

info@digigenomics.com，並副知 j81313@fda.gov.tw

參、意見回饋單

問題	
建議： 結論：	
姓名： 職稱	

肆、 附件

一、管理者帳號申請辦法暨權責聲明及申請資料表

管理者帳號申請辦法暨權責聲明及申請資料

(本文件將說明於新版藥物不良反應通報系統線上通報之管理者帳號申請辦法及其管理權責。)

食品藥物管理署(以下簡稱本署)為強化線上通報系統(以下簡稱本系統)的實用性與便利性，建置新版本的系統取代舊有的通報系統。透過線上單一通報窗口之設計，使用者可選擇通報臨床試驗案件或是上市後藥物不良反應案件，同時**新建置管理者功能**。透過管理者功能，可即時更新相關聯絡資訊，維護帳號使用以及查詢該單位曾通報過之案件。

考量對於通報資料的保護及工作管理之需求，不開放直接經由線上系統申請管理者帳號。請詳閱下述帳號申請辦法及權責須知：

一、 帳號申請辦法

(一) 申請流程：

1. **提出申請：**請以醫療機構或公司名義連同申請帳號所需資料（本聲明暨申請資料表）行文至全國藥物不良反應通報中心或本署。
2. **開啟權限：**本署或全國藥物不良反應通報中心收到函文後，將依所提供資料於本系統建立通報帳號，於**本系統上線後**自動發送啟動密碼至提供帳號之電子郵件地址，並另行以 E-mail 通知，故請確實填寫申請表資料。
3. **帳號啟用：**
 - (1) 依其帳號及本系統所提供之啟動密碼登入系統。
 - (2) 進入本系統基本資料修改功能，將相關資料填齊，並修改登入密碼。

(二) 申請注意事項：

1. 醫療機構或藥商之帳號命名規則請統一以「醫療機構或公司英文簡稱+阿拉伯數字」（如 TDRF01），各帳號之 E-mail 不得重複。
2. **一個單位僅能申請 1 組管理者帳號，一般使用者帳號上限為 4 組**，惟請依實際需求申請。
3. 藥商申請時其名稱需與藥品許可證上之「申請商名稱」一致，方可收到系統

副知的不良反應通報案件。

二、 帳號管理權責須知

- (一) 帳號經中心建立發出後，帳號管理及使用權責由各單位自行負責。
- (二) 各組帳號密碼應由各單位及其系統使用者本人妥善保存，並在人員或職務異動時自行交接並於系統上更新相關資料（包含密碼）。
- (三) 本系統每三個月會提醒更新密碼，並請同時確認基本資料是否須更新，以保障其使用之權益，敬請配合。

三、 功能權限：

- 1. 可進行案件通報。
- 2. 得以查看及編輯該單位內所有使用者通報的案件。
- 3. 得以執行該單位內一般使用者帳號重啟或暫停，及檢視上線使用者情形。
- 4. 得於系統即時維護該單位資訊，如藥商得以維護食品藥物管理署與藥商之急連絡使用資訊、收到系統副知通報表資訊之副知窗口 (Email)；醫療機構得以維護其基本資訊等。

四、 依個人資料保護法應告知事項

- (一) 蒐集機關名稱：行政院衛生福利部食品藥物管理署-全國藥物不良反應通報中心。
- (二) 蒐集之目的：
 - 1. 辦理行政院衛生福利部食品藥物管理署全國藥物不良反應通報業務。
 - 2. 建立我國全國藥物不良反應通報系統帳號，以利依法通報。
 - 3. 聯繫藥物不良反應案件通報者、藥商或醫療機構聯絡窗口。
 - 4. 建立藥物安全相關資訊傳遞窗口。
- (三) 蒐集之個人資料類別：使用者姓名、出生日期、服務機構名稱、職稱、電子郵件地址、聯絡電話。
- (四) 個人資料利用之期間：於主管機關許可業務經營之存續期間內。
- (五) 個人資料利用之地區：台灣地區（包括金門、馬祖及澎湖等地區）。
- (六) 個人資料利用之對象：行政院衛生福利部食品藥物管理署及其全國藥物不良反

應通報中心。

(七) 個人資料利用之方式：1. 建立本系統帳號。2. 系統查詢及統計分析。3. 有通報案件追蹤之必要時做為聯繫通報者或藥商之用。4. 依聯絡資料發送藥物安全資訊、教育訓練課程。5. 副知藥品不良反應通報案件等。

(八) 行使個人資料權利方式：依據個人資料保護法第三條規定，可就本中心保有之個人資料得行使查詢或請求閱覽、請求製給複製本、請求補充或更正、請求停止蒐集、處理或利用、請求刪除。前項權利本中心得依「衛生福利部及所屬機關提供政府資訊收費標準」酌收必要成本費用。

(九) 您不提供個人資料所致權益之影響：無法使用全國藥物不良反應線上通報系統及獲知相關藥物安全資訊。

(十) 告知事項之諮詢：如果您對於以上條款有任何疑問，歡迎來信至 adr@tdrf.org.tw 或來電至 02-2396-0100。

管理者帳號使用者申請資料

服務機構名稱 (藥商請與藥品許可證之申請商名稱一致) _____

帳號名稱：_____ 使用者中文姓名：_____

出生日期(西元年月日)：_____ 聯絡電話：_____

電子郵件地址：_____ 服務機構地址：_____

本人已詳閱並完全瞭解本聲明之內容：☐同意 ☐不同意，簽名：_____

二、E2B R3 參考範例檔

N.1	N.1.2	N.1.2	Batch Number	2.1.3.22
N.1	N.1.5	N.1.5	Date of Batch Transmission	

N.1	N.1.1	N.1.1	Type of Messages in Batch	2.1.1.1
-----	-------	-------	---------------------------	---------

N.2	N.2.r.1	N.2.r.1	Message Identifier	2.1.3.1
N.2	N.2.r.4	N.2.r.4	Date of Message Creation	

N.2	N.2.r.3			
N.2	N.2.r.3			
N.2	N.2.r.3	N.2.r.3	Message Receiver Identifier	2.1.3.12
N.2	N.2.r.3			
N.2	N.2.r.3			
N.2	N.2.r.2			
N.2	N.2.r.2	N.2.r.2	Message Sender Identifier	2.1.3.11
N.2	N.2.r.2			
N.2	N.2.r.2			

HL7Trigger
EventID 2.16.840.1.11
3883.1.18

C	C.1.2	C.1.2	Date of Creation	
---	-------	-------	------------------	--

C	C.1.1	C.1.1	Sender's (case) Safety Report Unique Identifier	2.1.3.1
C	C.1.8.1	C.1.8.1	Worldwide Unique Case Identification Number	2.1.3.2

2.16.840.1.11
3883.5.4

H	H.1	H.1	Case Narrative Including Clinical Course, Therapeutic Measures, Outcome and Additional Relevant	
---	-----	-----	---	--

C	C.1.4			
C	C.1.4	C.1.4	Date Report Was First Received from Source	
C	C.1.4			
C	C.1.5	C.1.5	Date of Most Recent Information for	
C	C.1.6.1.r	R1		
C	C.1.6.1.r	R1		
C	C.1.6.1.r	R1		
C	C.1.6.1.r	R1	C.1.6.1.r.1, 2 C.1.6.1.r.1 Documents Held by Sender (repeat as necessary) Included Documents	2.1.1.27
C	C.1.6.1.r	R1	C.1.6.1.r.1, 2 C.1.6.1.r.2	
C	C.1.6.1.r	R1	C.1.6.1.r.1, 2	
C	C.1.6.1.r	R1	C.1.6.1.r.1, 2	
C	C.1.6.1.r	R2	C.1.6.1.r.1, 2	

```
</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"/>
  <creationTime value="20101214151617"/>
  <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"/>
  <PORR_IN049016UV>
    <id extension="N.2.r.1" root="2.16.840.1.113883.3.989.2.1.3.1"/>
    <creationTime value="20101214151617"/>
    <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"/>
      </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"/>
      </device>
    </sender>
    <controlActProcess classCode="CACT" moodCode="EVN">
      <code code="PORR_TE049016UV" codeSystem="2.16.840.1.113883.1.18"/>
      <effectiveTime value="20101214151617"/>
      <subject typeCode="SUBJ">
        <investigationEvent classCode="INVTG" moodCode="EVN">
          <id extension="C.1.1" root="2.16.840.1.113883.3.989.2.1.3.1"/>
          <id extension="C.1.8.1" root="2.16.840.1.113883.3.989.2.1.3.2"/>
          <code code="PAT_ADV_EVNT" codeSystem="2.16.840.1.113883.5.4"/>
          <text>H.1</text>
          <statusCode code="active"/>
          <effectiveTime>
            <low value="20090101"/>
          </effectiveTime>
          <availabilityTime value="20090101"/>
          <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>
              <text mediaType="application/pdf" representation="B64">C.1.6.1.r.2</text>
            </document>
          </reference>
          <reference typeCode="REFR">
```

C	C.1.6.1.r	R2	C.1.6.1.r.1, 2		
C	C.1.6.1.r	R2	C.1.6.1.r.1, 2		2.1.1.27
C	C.1.6.1.r	R2	C.1.6.1.r.1, 2	C.1.6.1.r.1	Documents Held by Sender (repeat as necessary) Included Documents
C	C.1.6.1.r	R2	C.1.6.1.r.1, 2	C.1.6.1.r.2	
C	C.1.6.1.r	R2	C.1.6.1.r.1, 2		
C	C.1.6.1.r	R2	C.1.6.1.r.1, 2		
C	C.4.r	R1	C.4.r.1, 2		
C	C.4.r	R1	C.4.r.1, 2		2.1.1.27
C	C.4.r	R1	C.4.r.1, 2	C.4.r.2	Included Documents Literature Reference(s)
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C	C.4.r	R1	C.4.r.1, 2		
C	C.4.r	R1	C.4.r.1, 2		
C	C.4.r	R2	C.4.r.1, 2		
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C	C.4.r	R2	C.4.r.1, 2	C.4.r.2	Included Documents Literature Reference(s)
C	C.4.r	R2	C.4.r.1, 2	C.4.r.1	
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C	C.4.r	R2	C.4.r.1, 2		

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D	D.9.1	D.9.1	Date of Death	
D	D.1.1.1		Patient Medical Record Number(s) and the Source(s) of the Record Number (GP Medical Record Number)	
D	D.1.1.1	D.1.1.1		2.1.3.7
D	D.1.1.1			2.1.1.4
D	D.1.1.1			
D	D.1.1.2		Patient Medical Record Number(s) and the Source(s) of the Record Number (Specialist Record Number)	
D	D.1.1.2	D.1.1.2		2.1.3.8
D	D.1.1.2			2.1.1.4
D	D.1.1.2			
D	D.1.1.3		Patient Medical Record Number(s) and Source(s) of the Record Number (Hospital Record Number)	
D	D.1.1.3	D.1.1.3		2.1.3.9
D	D.1.1.3			2.1.1.4
D	D.1.1.3			
D	D.1.1.4		Patient Medical Record Number(s) and Source(s) of the Record Number (Investigation)	
D	D.1.1.4	D.1.1.4		2.1.3.10

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D.10					
D.10					2.16.840.1.113883.3.989.2.1.1.4
D.10					3883.5.111
D.10					
D.10	D.10.1	D.10.1	Parent Identification		
D.10	D.10.6	D.10.6	Sex of Parent		1.0.5218
D.10	D.10.2.1	D.10.2.1	Date of Birth of Parent		
D.10					
D.10	D.10.2.2				
D.10	D.10.2.2				
D.10	D.10.2.2				2.1.1.19
D.10	D.10.2.2	D.10.2.2a	Age of Parent (number)	D.10.2.2b	Age of Parent (unit)
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D.10	D.10.2.2				
D.10	D.10.3				
D.10	D.10.3				
D.10	D.10.3				2.1.1.19
D.10	D.10.3	D.10.3	Last Menstrual Period Date of Parent		
D.10	D.10.3				
D.10	D.10.3				
D.10	D.10.4				
D.10	D.10.4				
D.10	D.10.4				2.1.1.19
D.10	D.10.4	D.10.4	Body Weight (kg) of Parent		
D.10	D.10.4				
D.10	D.10.4				
D.10	D.10.5				
D.10	D.10.5				
D.10	D.10.5				2.1.1.19
D.10	D.10.5	D.10.5	Height (cm) of Parent		
D.10	D.10.5				
D.10	D.10.5				
D.10					
D.10					
D.10					2.1.1.20
D.10	D.10.7.1.r	R1			
D.10	D.10.7.1.r	R1			
D.10	D.10.7.1.r	R1	D.10.7.1.r.1	D.10.7.1.r.1 MedDRA Version for Medical History	2.16.840.1.113883.6.163
D.10	D.10.7.1.r	R1	D.10.7.1.r.2, 4	Medical History (disease / surgical procedure/ etc.) (MedDRA code)	
D.10	D.10.7.1.r	R1	D.10.7.1.r.2, 4	D.10.7.1.r.2 Start Date	
D.10	D.10.7.1.r	R1	D.10.7.1.r.2, 4	D.10.7.1.r.4 End Date	
D.10	D.10.7.1.r	R1	D.10.7.1.r.2, 4		
D.10	D.10.7.1.r	R1	D.10.7.1.r.5		
D.10	D.10.7.1.r	R1	D.10.7.1.r.5		
D.10	D.10.7.1.r	R1	D.10.7.1.r.5		2.1.1.19
D.10	D.10.7.1.r	R1	D.10.7.1.r.5	D.10.7.1.r.5 Comments	
D.10	D.10.7.1.r	R1	D.10.7.1.r.5		
D.10	D.10.7.1.r	R1	D.10.7.1.r.5		
D.10	D.10.7.1.r	R1	D.10.7.1.r.3		
D.10	D.10.7.1.r	R1	D.10.7.1.r.3		
D.10	D.10.7.1.r	R1	D.10.7.1.r.3		2.1.1.19
D.10	D.10.7.1.r	R1	D.10.7.1.r.3	D.10.7.1.r.3 Continuing	
D.10	D.10.7.1.r	R1	D.10.7.1.r.3		

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D.10	D.10.7.1.r	R1				
D.10	D.10.7.1.r	R2				
D.10	D.10.7.1.r	R2				
D.10	D.10.7.1.r	R2	D.10.7.1.r.1	D.10.7.1.r.1 MedDRA Version for Medical History	D.10.7.1.r.1 Medical History (disease / surgical procedure/ etc.) (MedDRA code)	2.16.840.1.113883.6.163
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D.10	D.10.7.1.r	R2	D.10.7.1.r.2, 4	D.10.7.1.r.4 End Date		
D.10	D.10.7.1.r	R2	D.10.7.1.r.2, 4			
D.10	D.10.7.1.r	R2	D.10.7.1.r.5			
D.10	D.10.7.1.r	R2	D.10.7.1.r.5			
D.10	D.10.7.1.r	R2	D.10.7.1.r.5			2.1.1.19
D.10	D.10.7.1.r	R2	D.10.7.1.r.5	D.10.7.1.r.5 Comments		
D.10	D.10.7.1.r	R2	D.10.7.1.r.5			
D.10	D.10.7.1.r	R2	D.10.7.1.r.5			
D.10	D.10.7.1.r	R2	D.10.7.1.r.3			
D.10	D.10.7.1.r	R2	D.10.7.1.r.3			
D.10	D.10.7.1.r	R2	D.10.7.1.r.3			2.1.1.19
D.10	D.10.7.1.r	R2	D.10.7.1.r.3	D.10.7.1.r.3 Continuing		
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D.10	D.10.7.1.r	R2	D.10.7.1.r.3			
D.10	D.10.7.1.r	R2				
D.10	D.10.7.1.r	R2				
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D.10			D.10.7.2			
D.10			D.10.7.2			2.1.1.19
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D.10			D.10.7.2			
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D.10						
D.10						
D.10						
D.10						2.1.1.20
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D.10	D.10.8.r	R1				
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D.10	D.10.8.r	R1	D.10.8.r.1, 2			
D.10	D.10.8.r	R1	D.10.8.r.1, 2			
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D.10	D.10.8.r	R1	D.10.8.r.6			
D.10	D.10.8.r	R1	D.10.8.r.6			
D.10	D.10.8.r	R1	D.10.8.r.6			2.1.1.19
D.10	D.10.8.r	R1	D.10.8.r.6	D.10.8.r.6a MedDRA Version for Indication	D.10.8.r.6b Indication (MedDRA code)	2.16.840.1.113883.6.163

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D.10	D.10.8.r	R1		D.10.8.r.7				
D.10	D.10.8.r	R1		D.10.8.r.7				2.1.1.19
D.10	D.10.8.r	R1		D.10.8.r.7	D.10.8.r.7a	MedDRA Version for Reaction	D.10.8.r.7b	Reactions (MedDRA code) 2.16.840.1.113883.6.163
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D.10	D.10.8.r	R1						
D.10	D.10.8.r	R2						
D.10	D.10.8.r	R2						
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D.10	D.10.8.r	R2		D.10.8.r.4, 5	D.10.8.r.4	Start Date		
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D.10	D.10.8.r	R2		D.10.8.r.1, 2				
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D.10	D.10.8.r	R2		D.10.8.r.6				2.1.1.19
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D.10	D.10.8.r	R2		D.10.8.r.7				
D.10	D.10.8.r	R2		D.10.8.r.7				
D.10	D.10.8.r	R2		D.10.8.r.7				2.1.1.19
D.10	D.10.8.r	R2		D.10.8.r.7	D.10.8.r.7a	MedDRA Version for Reaction	D.10.8.r.7b	Reactions (MedDRA code) 2.16.840.1.113883.6.163
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D.10								
D.10								

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C	C.5.1.r	R1				
C	C.5.1.r	R1	C.5.1.r.1	C.5.1.r.1	Study Registration Number	2.1.3.6
C	C.5.1.r	R1		C.5.1.r.2		
C	C.5.1.r	R1		C.5.1.r.2		
C	C.5.1.r	R1		C.5.1.r.2		

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          <name>D.10.8.r.1</name>
        </kindOfProduct>
      </instanceOfKind>
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        <value xsi:type="CE" code="D.10.8.r.6b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.10.8.r.6a"/>
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    <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"/>
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C	C.5.1.r	R1	C.5.1.r.2			
C	C.5.1.r	R1	C.5.1.r.2			
C	C.5.1.r	R1	C.5.1.r.2			
C	C.5.1.r	R1				
C	C.5.1.r	R1				
C	C.5.1.r	R2				
C	C.5.1.r	R2				
C	C.5.1.r	R2	C.5.1.r.1	C.5.1.r.1	Study Registration Number	2.1.3.6
C	C.5.1.r	R2	C.5.1.r.2			
C	C.5.1.r	R2	C.5.1.r.2			
C	C.5.1.r	R2	C.5.1.r.2	C.5.1.r.2	Study Registration Country	1.0.3166.1.2.2
C	C.5.1.r	R2	C.5.1.r.2			
C	C.5.1.r	R2	C.5.1.r.2			
C	C.5.1.r	R2	C.5.1.r.2			
C	C.5.1.r	R2				
C	C.5.1.r	R2				

C						
C						
D			D.2.2			
D			D.2.2			
D			D.2.2			2.1.1.19
D			D.2.2	D.2.2a	Age at Time of Onset of Reaction / Event (number)	Age at Time of Onset of Reaction / Event (unit)
D			D.2.2			
D			D.2.2			
D			D.2.2.1			
D			D.2.2.1			
D			D.2.2.1			2.1.1.19
D			D.2.2.1	D.2.2.1a	Gestation Period When Reaction / Event Was Observed in the Foetus (value)	Gestation Period When Reaction / Event Was Observed in the Foetus (unit)
D			D.2.2.1			
D			D.2.2.1			
D			D.2.3			
D			D.2.3			2.1.1.19
D			D.2.3	D.2.3	Patient Age Group (as per reporter)	
D			D.2.3			2.1.1.19
D			D.2.3			
D			D.2.3			
D			D.3			
D			D.3			2.1.1.19
D			D.3	D.3	Body Weight (kg)	
D			D.3			
D			D.3			
D			D.4			
D			D.4			2.1.1.19
D			D.4	D.4	Height (cm)	
D			D.4			
D			D.4			
D			D.6			
D			D.6			
D			D.6			2.1.1.19

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<code code="4" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="ageGroup"/>
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<code code="22" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="lastMenstrualPeriodDate"/>

D			D.6	D.6	Last Menstrual Period Date		
D			D.6				
D			D.6				
D							
D						2.1.1.20	
D	D.7.1.r	R1					
D	D.7.1.r	R1					
D	D.7.1.r	R1	D.7.1.r.1	D.7.1.r.1a	MedDRA Version for Medical History	D.7.1.r.1b	Medical History (disease / surgical procedure / etc.) (MedDRA code) 2.16.840.1.1 13883.6.163
D	D.7.1.r	R1	D.7.1.r.2, 4				
D	D.7.1.r	R1	D.7.1.r.2, 4	D.7.1.r.2	Start Date		
D	D.7.1.r	R1	D.7.1.r.2, 4	D.7.1.r.4	End Date		
D	D.7.1.r	R1	D.7.1.r.2, 4				
D	D.7.1.r	R1	D.7.1.r.5				
D	D.7.1.r	R1	D.7.1.r.5				
D	D.7.1.r	R1	D.7.1.r.5	D.7.1.r.5	Comments		2.1.1.19
D	D.7.1.r	R1	D.7.1.r.5				
D	D.7.1.r	R1	D.7.1.r.5				
D	D.7.1.r	R1	D.7.1.r.6				
D	D.7.1.r	R1	D.7.1.r.6				
D	D.7.1.r	R1	D.7.1.r.6	D.7.1.r.6	Family History		2.1.1.19
D	D.7.1.r	R1	D.7.1.r.6				
D	D.7.1.r	R1	D.7.1.r.6				
D	D.7.1.r	R1	D.7.1.r.3				
D	D.7.1.r	R1	D.7.1.r.3				
D	D.7.1.r	R1	D.7.1.r.3				
D	D.7.1.r	R1	D.7.1.r.3	D.7.1.r.3	Continuing		2.1.1.19
D	D.7.1.r	R1	D.7.1.r.3				
D	D.7.1.r	R1	D.7.1.r.3				
D	D.7.1.r	R1	D.7.1.r.3				
D	D.7.1.r	R1	D.7.1.r.3				
D	D.7.1.r	R2					
D	D.7.1.r	R2					
D	D.7.1.r	R2					
D	D.7.1.r	R2	D.7.1.r.1	D.7.1.r.1a	MedDRA Version for Medical History	D.7.1.r.1b	Medical history (disease / surgical procedure / etc.) (MedDRA code) 2.16.840.1.1 13883.6.163
D	D.7.1.r	R2	D.7.1.r.2, 4				
D	D.7.1.r	R2	D.7.1.r.2, 4	D.7.1.r.2	Start Date		
D	D.7.1.r	R2	D.7.1.r.2, 4	D.7.1.r.4	End Date		
D	D.7.1.r	R2	D.7.1.r.2, 4				
D	D.7.1.r	R2	D.7.1.r.5				
D	D.7.1.r	R2	D.7.1.r.5				
D	D.7.1.r	R2	D.7.1.r.5				
D	D.7.1.r	R2	D.7.1.r.5	D.7.1.r.5	Comments		2.1.1.19
D	D.7.1.r	R2	D.7.1.r.5				
D	D.7.1.r	R2	D.7.1.r.5				
D	D.7.1.r	R2	D.7.1.r.6				
D	D.7.1.r	R2	D.7.1.r.6				
D	D.7.1.r	R2	D.7.1.r.6	D.7.1.r.6	Family History		2.1.1.19
D	D.7.1.r	R2	D.7.1.r.6				
D	D.7.1.r	R2	D.7.1.r.6				
D	D.7.1.r	R2	D.7.1.r.3				
D	D.7.1.r	R2	D.7.1.r.3				
D	D.7.1.r	R2	D.7.1.r.3				
D	D.7.1.r	R2	D.7.1.r.3				2.1.1.19

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D	D.7.1.r	R2	D.7.1.r.3			
D	D.7.1.r	R2	D.7.1.r.3			
D	D.7.1.r	R2				
D	D.7.1.r	R2				
D			D.7.2			2.1.1.19
D			D.7.2			
D			D.7.2	D.7.2	Text for Relevant Medical History and Concurrent Conditions (not including reaction / event)	
D			D.7.2			
D			D.7.2			
D			D.7.3			2.1.1.19
D			D.7.3			
D			D.7.3	D.7.3	Concomitant Therapies	
D			D.7.3			
D			D.7.3			
D						2.1.1.20
D	D.8.r	R1				
D	D.8.r	R1				
D	D.8.r	R1	D.8.r.4, 5	D.8.r.4	Start Date	
D	D.8.r	R1	D.8.r.4, 5	D.8.r.5	End Date	
D	D.8.r	R1	D.8.r.4, 5			
D	D.8.r	R1	D.8.r.1, 2			
D	D.8.r	R1	D.8.r.1, 2			
D	D.8.r	R1	D.8.r.1, 2			
D	D.8.r	R1	D.8.r.1, 2	D.8.r.2a	MPID Version Date / Number	TBD-MPID
D	D.8.r	R1	D.8.r.1, 2	D.8.r.2b	Medicinal Product Identifier (MPID)	
D	D.8.r	R1	D.8.r.1, 2	D.8.r.1	Name of Drug as Reported	
D	D.8.r	R1	D.8.r.1, 2			
D	D.8.r	R1	D.8.r.1, 2			
D	D.8.r	R1	D.8.r.6			
D	D.8.r	R1	D.8.r.6			
D	D.8.r	R1	D.8.r.6			2.1.1.19
D	D.8.r	R1	D.8.r.6	D.8.r.6a	MedDRA Version for Indication	2.16.840.1.113883.6.163
D	D.8.r	R1	D.8.r.6	D.8.r.6b	Indication (MedDRA code)	
D	D.8.r	R1	D.8.r.6			
D	D.8.r	R1	D.8.r.7			2.1.1.19
D	D.8.r	R1	D.8.r.7			2.16.840.1.113883.6.163
D	D.8.r	R1	D.8.r.7	D.8.r.7a	MedDRA Version for Reaction	
D	D.8.r	R1	D.8.r.7	D.8.r.7b	Reaction (MedDRA code)	
D	D.8.r	R1	D.8.r.7			
D	D.8.r	R1				
D	D.8.r	R1				
D	D.8.r	R2				
D	D.8.r	R2				
D	D.8.r	R2	D.8.r.4, 5			
D	D.8.r	R2	D.8.r.4, 5	D.8.r.4	Start Date	

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</outboundRelationship2>
<outboundRelationship2 typeCode="CAUS">
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<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"/>
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D	D.8.r	R2	D.8.r.1, 3					
D	D.8.r	R2	D.8.r.1, 3					
D	D.8.r	R2	D.8.r.1, 3					
D	D.8.r	R2	D.8.r.1, 3	D.8.r.3a	PhPID Version Date / Number	D.8.r.3b	Pharmaceutical Product Identifier (PhPID)	TBD-PhPID
D	D.8.r	R2	D.8.r.1, 3	D.8.r.1	Name of Drug as Reported			
D	D.8.r	R2	D.8.r.1, 3					
D	D.8.r	R2	D.8.r.1, 3					
D	D.8.r	R2	D.8.r.6					
D	D.8.r	R2	D.8.r.6					
D	D.8.r	R2	D.8.r.6					2.1.1.19
D	D.8.r	R2	D.8.r.6	D.8.r.6a	MedDRA Version for Indication	D.8.r.6b	Indication (MedDRA code)	2.16.840.1.1 13883.6.163
D	D.8.r	R2	D.8.r.6					
D	D.8.r	R2	D.8.r.6					
D	D.8.r	R2	D.8.r.7					
D	D.8.r	R2	D.8.r.7					
D	D.8.r	R2	D.8.r.7					2.1.1.19
D	D.8.r	R2	D.8.r.7	D.8.r.7a	MedDRA Version for Reaction	D.8.r.7b	Reaction (MedDRA code)	2.16.840.1.1 13883.6.163
D	D.8.r	R2	D.8.r.7					
D	D.8.r	R2						
D	D.8.r	R2						
D								
D								
D	D.9.2.r	R1	D.9.2.r.1, 2					
D	D.9.2.r	R1	D.9.2.r.1, 2					
D	D.9.2.r	R1	D.9.2.r.1, 2					2.1.1.19
D	D.9.2.r	R1	D.9.2.r.1, 2	D.9.2.r.1a	MedDRA Version for Reported Cause(s) of Death	D.9.2.r.1b	Reported Cause(s) of Death (MedDRA code)	2.16.840.1.1 13883.6.163
D	D.9.2.r	R1	D.9.2.r.1, 2	D.9.2.r.2	Reported Cause(s) of Death (free)			
D	D.9.2.r	R1	D.9.2.r.1, 2					
D	D.9.2.r	R1	D.9.2.r.1, 2					
D	D.9.2.r	R1	D.9.2.r.1, 2					
D	D.9.2.r	R2	D.9.2.r.1, 2					
D	D.9.2.r	R2	D.9.2.r.1, 2					2.1.1.19
D	D.9.2.r	R2	D.9.2.r.1, 2	D.9.2.r.1a	MedDRA Version for Reported Cause(s) of Death	D.9.2.r.1b	Reported Cause(s) of Death (MedDRA code)	2.16.840.1.1 13883.6.163
D	D.9.2.r	R2	D.9.2.r.1, 2	D.9.2.r.2	Reported Cause(s) of Death (free)			
D	D.9.2.r	R2	D.9.2.r.1, 2					
D	D.9.2.r	R2	D.9.2.r.1, 2					
D	D.9.2.r	R2	D.9.2.r.1, 2					
D								
D			D.9.3					2.1.1.19
D			D.9.3	D.9.3	WasAutopsyDone?			
D	D.9.4.r	R1	D.9.4.r.1, 2					
D	D.9.4.r	R1	D.9.4.r.1, 2					
D	D.9.4.r	R1	D.9.4.r.1, 2					2.1.1.19
D	D.9.4.r	R1	D.9.4.r.1, 2	D.9.4.r.1a	MedDRA Version for Autopsy- determined Cause(s) of Death	D.9.4.r.1b	Autopsy- determined Cause(s) of Death (MedDRA code)	2.16.840.1.1 13883.6.163

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  </instanceOfKind>
</consumable>
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    <value xsi:type="CE" code="D.8.r.6b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.8.r.6a"/>
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    <value xsi:type="CE" code="D.8.r.7b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.8.r.7a"/>
  </observation>
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</organizer>
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  <observation classCode="OBS" moodCode="EVN">
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    <value xsi:type="CE" code="D.9.2.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.9.2.r.1a">
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    <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">

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D	D.9.4.r	R1	D.9.4.r.1, 2	D.9.4.r.2	Autopsy–determined Cause(s) of Death (free text)			
D	D.9.4.r	R1	D.9.4.r.1, 2					
D	D.9.4.r	R1	D.9.4.r.1, 2					
D	D.9.4.r	R1	D.9.4.r.1, 2					
D	D.9.4.r	R2	D.9.4.r.1, 2					
D	D.9.4.r	R2	D.9.4.r.1, 2					
D	D.9.4.r	R2	D.9.4.r.1, 2		2.1.1.19			
D	D.9.4.r	R2	D.9.4.r.1, 2	D.9.4.r.1a	MedDRA Version for Autopsy–determined Cause(s) of Death Autopsy–determined Cause(s) of Death (free text)	D.9.4.r.1b	Autopsy–determined Cause(s) of Death (MedDRA code)	2.16.840.1.1 13883.6.163
D	D.9.4.r	R2	D.9.4.r.1, 2	D.9.4.r.2				
D	D.9.4.r	R2	D.9.4.r.1, 2					
D	D.9.4.r	R2	D.9.4.r.1, 2					
D	D.9.4.r	R2	D.9.4.r.1, 2					
D								
D								
E	E.i	il						
E	E.i	il						
E	E.i	il	Event ID					
E	E.i	il	2.1.1.19					
E	E.i	il	E.i.4, 5					
E	E.i	il	E.i.4, 5	E.i.4	Date of Start of Reaction / Event			
E	E.i	il	E.i.4, 5	E.i.5	Date of End of Reaction / Event			
E	E.i	il	E.i.4, 5					
E	E.i	il	E.i.2.1	E.i.2.1a	MedDRA Version for Reaction / Event	E.i.2.1b	Reaction / Event (MedDRA code)	2.16.840.1.1 13883.6.163
E	E.i	il	E.i.1.1	E.i.1.1a	Reaction / Event as Reported by the Primary Source in Native	E.i.1.1b	Reaction / Event as Reported by the Primary Source Language	
E	E.i	il						
E	E.i	il	E.i.9					
E	E.i	il	E.i.9					
E	E.i	il	E.i.9					
E	E.i	il	E.i.9	E.i.9	Identification of the Country Where the Reaction / Event Occurred			1.0.3166.1.2. 2
E	E.i	il	E.i.9					
E	E.i	il	E.i.9					
E	E.i	il	E.i.9					
E	E.i	il	E.i.1.2					
E	E.i	il	E.i.1.2					
E	E.i	il	E.i.1.2		2.1.1.19			
E	E.i	il	E.i.1.2	E.i.1.2	Reaction / Event as Reported by the Primary Source for			
E	E.i	il	E.i.1.2					
E	E.i	il	E.i.1.2					
E	E.i	il	E.i.3.1					
E	E.i	il	E.i.3.1					
E	E.i	il	E.i.3.1		2.1.1.19			
E	E.i	il	E.i.3.1	E.i.3.1	Term Highlighted by the Reporter			2.1.1.10
E	E.i	il	E.i.3.1					
E	E.i	il	E.i.3.1					
E	E.i	il	E.i.3.2a					
E	E.i	il	E.i.3.2a					

	<originalText>D.9.4.r.2</originalText>
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	</observation>
	</outboundRelationship2>
	<outboundRelationship2 typeCode="DRIV">
	<observation classCode="OBS" moodCode="EVN">
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	<value xsi:type="CE" code="D.9.4.r.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="D.9.4.r.1a">
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	</value>
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	</outboundRelationship2>
	</observation>
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	<id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>
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	<value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
	<originalText language="E.i.1.1b">E.i.1.1a</originalText>
	</value>
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	<locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
	<code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
	</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>
	</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"/>
	</observation>
	</outboundRelationship2>
	<outboundRelationship2 typeCode="PERT">
	<observation classCode="OBS" moodCode="EVN">

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E	E.i	i1	E.i.3.2a				<value xsi:type="BL" value="true"/>
E	E.i	i1	E.i.3.2a				</observation>
E	E.i	i1	E.i.3.2a				</outboundRelationship2>
E	E.i	i1	E.i.3.2b	E.i.3.2b	Life Threatening	2.1.1.19	<outboundRelationship2 typeCode="PERT">
E	E.i	i1	E.i.3.2b				<observation classCode="OBS" moodCode="EVN">
E	E.i	i1	E.i.3.2b				<code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="isLifeThreatening"/>
E	E.i	i1	E.i.3.2b				<value xsi:type="BL" nullFlavor="NI"/>
E	E.i	i1	E.i.3.2b				</observation>
E	E.i	i1	E.i.3.2b				</outboundRelationship2>
E	E.i	i1	E.i.3.2c	E.i.3.2c	Caused / Prolonged Hospitalisation	2.1.1.19	<outboundRelationship2 typeCode="PERT">
E	E.i	i1	E.i.3.2c				<observation classCode="OBS" moodCode="EVN">
E	E.i	i1	E.i.3.2c				<code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="requiresInpatientHospitalization"/>
E	E.i	i1	E.i.3.2c				<value xsi:type="BL" value="true"/>
E	E.i	i1	E.i.3.2c				</observation>
E	E.i	i1	E.i.3.2c				</outboundRelationship2>
E	E.i	i1	E.i.3.2d	E.i.3.2d	Disabling / Incapacitating	2.1.1.19	<outboundRelationship2 typeCode="PERT">
E	E.i	i1	E.i.3.2d				<observation classCode="OBS" moodCode="EVN">
E	E.i	i1	E.i.3.2d				<code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="resultsInPersistentOrSignificantDisability"/>
E	E.i	i1	E.i.3.2d				<value xsi:type="BL" nullFlavor="NI"/>
E	E.i	i1	E.i.3.2d				</observation>
E	E.i	i1	E.i.3.2d				</outboundRelationship2>
E	E.i	i1	E.i.3.2e	E.i.3.2e	Congenital Anomaly / Birth Defect	2.1.1.19	<outboundRelationship2 typeCode="PERT">
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E	E.i	i1	E.i.3.2e				<code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="congenitalAnomalyBirthDefect"/>
E	E.i	i1	E.i.3.2e				<value xsi:type="BL" nullFlavor="NI"/>
E	E.i	i1	E.i.3.2e				</observation>
E	E.i	i1	E.i.3.2e				</outboundRelationship2>
E	E.i	i1	E.i.3.2f	E.i.3.2f	Other Medically Important Condition	2.1.1.19	<outboundRelationship2 typeCode="PERT">
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E	E.i	i1	E.i.3.2f				<code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="otherMedicallyImportantCondition"/>
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E	E.i	i1	E.i.3.2f				</observation>
E	E.i	i1	E.i.3.2f				</outboundRelationship2>
E	E.i	i1	E.i.7	E.i.7	Outcome of Reaction / Event at the Time of Last Observation	2.1.1.19	<outboundRelationship2 typeCode="PERT">
E	E.i	i1	E.i.7				<observation classCode="OBS" moodCode="EVN">
E	E.i	i1	E.i.7				<code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="outcome"/>
E	E.i	i1	E.i.7				<value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11" codeSystemVersion="1.0"/>
E	E.i	i1	E.i.7				</observation>
E	E.i	i1	E.i.7				</outboundRelationship2>
E	E.i	i1	E.i.8	E.i.8	Medical Confirmation by Healthcare Professional	2.1.1.19	<outboundRelationship2 typeCode="PERT">
E	E.i	i1	E.i.8				<observation classCode="OBS" moodCode="EVN">
E	E.i	i1	E.i.8				<code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="medicalConfirmationByHealthProfessional"/>
E	E.i	i1	E.i.8				<value xsi:type="BL" value="true"/>
E	E.i	i1	E.i.8				</observation>
E	E.i	i1	E.i.8				</outboundRelationship2>
E	E.i	i1					<observation>
E	E.i	i1					</subjectOf2>
E	E.i	i2					<subjectOf2 typeCode="SBJ">
E	E.i	i2					<observation classCode="OBS" moodCode="EVN">
E	E.i	i2					<id root="2baa28d6-c9e8-4efc-93e9-5b860b314220"/>
E	E.i	i2					<code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="reaction"/>

E	E.i	i2	E.i.4, 6					
E	E.i	i2	E.i.4, 6	E.i.4	Date of Start of Reaction / Event			
E	E.i	i2	E.i.4, 6	E.i.6a	Duration of Reaction / Event (number)	E.i.6b	Duration of Reaction / Event (unit)	
E	E.i	i2	E.i.4, 6					
E	E.i	i2	E.i.2.1	E.i.2.1a	MedDRA Version for Reaction / Event	E.i.2.1b	Reaction / Event (MedDRA code)	2.16.840.1.113883.6.163
E	E.i	i2	E.i.1.1	E.i.1.1a	Reaction / Event as Reported by the Primary Source in Native	E.i.1.1b	Reaction / Event as Reported by the Primary Source in Language	
E	E.i	i2						
E	E.i	i2	E.i.9					
E	E.i	i2	E.i.9					
E	E.i	i2	E.i.9					
E	E.i	i2	E.i.9	E.i.9	Identification of the Country Where the Reaction / Event Occurred			1.0.3166.1.2.2
E	E.i	i2	E.i.9					
E	E.i	i2	E.i.9					
E	E.i	i2	E.i.9					
E	E.i	i2	E.i.1.2					
E	E.i	i2	E.i.1.2					
E	E.i	i2	E.i.1.2					2.1.1.19
E	E.i	i2	E.i.1.2	E.i.1.2	Reaction / Event as Reported by the Primary Source for			
E	E.i	i2	E.i.1.2					
E	E.i	i2	E.i.1.2					
E	E.i	i2	E.i.3.1					
E	E.i	i2	E.i.3.1					2.1.1.19
E	E.i	i2	E.i.3.1	E.i.3.1	Term Highlighted by the Reporter			2.1.1.10
E	E.i	i2	E.i.3.1					
E	E.i	i2	E.i.3.1					
E	E.i	i2	E.i.3.2a					
E	E.i	i2	E.i.3.2a					
E	E.i	i2	E.i.3.2a					2.1.1.19
E	E.i	i2	E.i.3.2a	E.i.3.2a	Results in Death			
E	E.i	i2	E.i.3.2a					
E	E.i	i2	E.i.3.2b					
E	E.i	i2	E.i.3.2b					
E	E.i	i2	E.i.3.2b					2.1.1.19
E	E.i	i2	E.i.3.2b	E.i.3.2b	Life Threatening			
E	E.i	i2	E.i.3.2b					
E	E.i	i2	E.i.3.2b					
E	E.i	i2	E.i.3.2c					
E	E.i	i2	E.i.3.2c					
E	E.i	i2	E.i.3.2c					2.1.1.19
E	E.i	i2	E.i.3.2c	E.i.3.2c	Caused / Prolonged Hospitalisation			
E	E.i	i2	E.i.3.2c					
E	E.i	i2	E.i.3.2c					
E	E.i	i2	E.i.3.2d					
E	E.i	i2	E.i.3.2d					
E	E.i	i2	E.i.3.2d					2.1.1.19
E	E.i	i2	E.i.3.2d	E.i.3.2d	Disabling / Incapacitating			
E	E.i	i2	E.i.3.2d					
E	E.i	i2	E.i.3.2d					

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    <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
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    </locatedPlace>
  </locatedEntity>
</location>
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  <observation classCode="OBS" moodCode="EVN">
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  <observation classCode="OBS" moodCode="EVN">
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    <value xsi:type="BL" nullFlavor="NI"/>
  </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"/>
  </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"/>
  </observation>
</outboundRelationship2>

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N	E	E.i	i3	E.i.1.2					</observation>
N	E	E.i	i3	E.i.1.2					</outboundRelationship2>
N	E	E.i	i3	E.i.3.1					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i3	E.i.3.1					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i3	E.i.3.1			2.1.1.19		<code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="termHighlightedByReporter"/>
N	E	E.i	i3	E.i.3.1	E.i.3.1	Term Highlighted by the Reporter	2.1.1.10		<value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10" codeSystemVersion="1.0"/>
N	E	E.i	i3	E.i.3.1					</observation>
N	E	E.i	i3	E.i.3.1					</outboundRelationship2>
N	E	E.i	i3	E.i.3.2a					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i3	E.i.3.2a					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i3	E.i.3.2a			2.1.1.19		<code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="resultsInDeath"/>
N	E	E.i	i3	E.i.3.2a	E.i.3.2a	Results in Death			<value xsi:type="BL" value="true"/>
N	E	E.i	i3	E.i.3.2a					</observation>
N	E	E.i	i3	E.i.3.2a					</outboundRelationship2>
N	E	E.i	i3	E.i.3.2b					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i3	E.i.3.2b					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i3	E.i.3.2b			2.1.1.19		<code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="isLifeThreatening"/>
N	E	E.i	i3	E.i.3.2b	E.i.3.2b	Life Threatening			<value xsi:type="BL" nullFlavor="NI"/>
N	E	E.i	i3	E.i.3.2b					</observation>
N	E	E.i	i3	E.i.3.2b					</outboundRelationship2>
N	E	E.i	i3	E.i.3.2c					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i3	E.i.3.2c					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i3	E.i.3.2c			2.1.1.19		<code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="requiresInpatientHospitalization"/>
N	E	E.i	i3	E.i.3.2c	E.i.3.2c	Caused / Prolonged Hospitalisation			<value xsi:type="BL" value="true"/>
N	E	E.i	i3	E.i.3.2c					</observation>
N	E	E.i	i3	E.i.3.2c					</outboundRelationship2>
N	E	E.i	i3	E.i.3.2d					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i3	E.i.3.2d					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i3	E.i.3.2d			2.1.1.19		<code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="resultsInPersistentOrSignificantDisability"/>
N	E	E.i	i3	E.i.3.2d	E.i.3.2d	Disabling / Incapacitating			<value xsi:type="BL" nullFlavor="NI"/>
N	E	E.i	i3	E.i.3.2d					</observation>
N	E	E.i	i3	E.i.3.2d					</outboundRelationship2>
N	E	E.i	i3	E.i.3.2e					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i3	E.i.3.2e					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i3	E.i.3.2e			2.1.1.19		<code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="congenitalAnomalyBirthDefect"/>
N	E	E.i	i3	E.i.3.2e	E.i.3.2e	Congenital Anomaly / Birth Defect			<value xsi:type="BL" nullFlavor="NI"/>
N	E	E.i	i3	E.i.3.2e					</observation>
N	E	E.i	i3	E.i.3.2e					</outboundRelationship2>
N	E	E.i	i3	E.i.3.2f					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i3	E.i.3.2f					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i3	E.i.3.2f			2.1.1.19		<code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="otherMedicallyImportantCondition"/>
N	E	E.i	i3	E.i.3.2f	E.i.3.2f	Other Medically Important Condition			<value xsi:type="BL" value="true"/>
N	E	E.i	i3	E.i.3.2f					</observation>
N	E	E.i	i3	E.i.3.2f					</outboundRelationship2>
N	E	E.i	i3	E.i.7					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i3	E.i.7					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i3	E.i.7			2.1.1.19		<code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="outcome"/>
N	E	E.i	i3	E.i.7	E.i.7	Outcome of Reaction / Event at the Time of Last Observation	2.1.1.11		<value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11" codeSystemVersion="1.0"/>
N	E	E.i	i3	E.i.7					</observation>
N	E	E.i	i3	E.i.7					</outboundRelationship2>
N	E	E.i	i3	E.i.8					<outboundRelationship2 typeCode="PERT">

[illegible]

N	E	E.i	i4	E.i.3.2b			
N	E	E.i	i4	E.i.3.2b			2.1.1.19
N	E	E.i	i4	E.i.3.2b	E.i.3.2b	Life Threatening	
N	E	E.i	i4	E.i.3.2b			
N	E	E.i	i4	E.i.3.2b			
N	E	E.i	i4	E.i.3.2c			
N	E	E.i	i4	E.i.3.2c			2.1.1.19
N	E	E.i	i4	E.i.3.2c	E.i.3.2c	Caused / Prolonged Hospitalisation	
N	E	E.i	i4	E.i.3.2c			
N	E	E.i	i4	E.i.3.2c			
N	E	E.i	i4	E.i.3.2d			
N	E	E.i	i4	E.i.3.2d			2.1.1.19
N	E	E.i	i4	E.i.3.2d	E.i.3.2d	Disabling / Incapacitating	
N	E	E.i	i4	E.i.3.2d			
N	E	E.i	i4	E.i.3.2d			
N	E	E.i	i4	E.i.3.2e			
N	E	E.i	i4	E.i.3.2e			2.1.1.19
N	E	E.i	i4	E.i.3.2e	E.i.3.2e	Congenital Anomaly / Birth Defect	
N	E	E.i	i4	E.i.3.2e			
N	E	E.i	i4	E.i.3.2e			
N	E	E.i	i4	E.i.3.2f			
N	E	E.i	i4	E.i.3.2f	E.i.3.2f	Other Medically Important Condition	2.1.1.19
N	E	E.i	i4	E.i.3.2f			
N	E	E.i	i4	E.i.3.2f			
N	E	E.i	i4	E.i.7			
N	E	E.i	i4	E.i.7			2.1.1.19
N	E	E.i	i4	E.i.7	E.i.7	Outcome of Reaction / Event at the Time of Last Observation	2.1.1.11
N	E	E.i	i4	E.i.7			
N	E	E.i	i4	E.i.7			
N	E	E.i	i4	E.i.8			
N	E	E.i	i4	E.i.8			2.1.1.19
N	E	E.i	i4	E.i.8	E.i.8	Medical Confirmation by Healthcare Professional	
N	E	E.i	i4	E.i.8			
N	E	E.i	i4	E.i.8			
N	E	E.i	i4	E.i.8			
N	E	E.i	i5				
N	E	E.i	i5				
N	E	E.i	i5			Event ID	
N	E	E.i	i5				2.1.1.19
N	E	E.i	i5	E.i.4			
N	E	E.i	i5	E.i.4	E.i.4	Date of Start of Reaction / Event	
N	E	E.i	i5	E.i.4			

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<observation classCode="OBS" moodCode="EVN">
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  <value xsi:type="BL" nullFlavor="NI"/>
</observation>
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<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"/>
  </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"/>
  </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"/>
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
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    <value xsi:type="BL" value="true"/>
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<outboundRelationship2 typeCode="PERT">
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    <code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="outcome"/>
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  </observation>
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<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
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    <value xsi:type="BL" value="true"/>
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</outboundRelationship2>
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<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"/>
    </effectiveTime>
  </observation>

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N	E	E.i	i5	E.i.2.1	E.i.2.1a	MedDRA Version for Reaction / Event	E.i.2.1b	Reaction / Event (MedDRA code)	2.16.840.1.1 13883.6.163
N	E	E.i	i5	E.i.1.1	E.i.1.1a	Reaction / Event as Reported by the Primary Source in Native	E.i.1.1b	Reaction / Event as Reported by the Primary Source Language	
N	E	E.i	i5						
N	E	E.i	i5	E.i.9					
N	E	E.i	i5	E.i.9					
N	E	E.i	i5	E.i.9					
N	E	E.i	i5	E.i.9	E.i.9	Identification of the Country Where the Reaction / Event Occurred			1.0.3166.1.2. 2
N	E	E.i	i5	E.i.9					
N	E	E.i	i5	E.i.9					
N	E	E.i	i5	E.i.9					
N	E	E.i	i5	E.i.1.2					
N	E	E.i	i5	E.i.1.2					
N	E	E.i	i5	E.i.1.2					2.1.1.19
N	E	E.i	i5	E.i.1.2	E.i.1.2	Reaction / Event as Reported by the Primary Source for			
N	E	E.i	i5	E.i.1.2					
N	E	E.i	i5	E.i.1.2					
N	E	E.i	i5	E.i.3.1					
N	E	E.i	i5	E.i.3.1					2.1.1.19
N	E	E.i	i5	E.i.3.1					
N	E	E.i	i5	E.i.3.1	E.i.3.1	Term Highlighted by the Reporter			2.1.1.10
N	E	E.i	i5	E.i.3.1					
N	E	E.i	i5	E.i.3.1					
N	E	E.i	i5	E.i.3.2a					
N	E	E.i	i5	E.i.3.2a					
N	E	E.i	i5	E.i.3.2a					2.1.1.19
N	E	E.i	i5	E.i.3.2a	E.i.3.2a	Results in Death			
N	E	E.i	i5	E.i.3.2a					
N	E	E.i	i5	E.i.3.2a					
N	E	E.i	i5	E.i.3.2b					
N	E	E.i	i5	E.i.3.2b					
N	E	E.i	i5	E.i.3.2b					2.1.1.19
N	E	E.i	i5	E.i.3.2b	E.i.3.2b	Life Threatening			
N	E	E.i	i5	E.i.3.2b					
N	E	E.i	i5	E.i.3.2c					
N	E	E.i	i5	E.i.3.2c					
N	E	E.i	i5	E.i.3.2c					2.1.1.19
N	E	E.i	i5	E.i.3.2c	E.i.3.2c	Caused / Prolonged Hospitalisation			
N	E	E.i	i5	E.i.3.2c					
N	E	E.i	i5	E.i.3.2c					
N	E	E.i	i5	E.i.3.2d					
N	E	E.i	i5	E.i.3.2d					
N	E	E.i	i5	E.i.3.2d					2.1.1.19
N	E	E.i	i5	E.i.3.2d	E.i.3.2d	Disabling / Incapacitating			
N	E	E.i	i5	E.i.3.2d					
N	E	E.i	i5	E.i.3.2d					
N	E	E.i	i5	E.i.3.2e					
N	E	E.i	i5	E.i.3.2e					
N	E	E.i	i5	E.i.3.2e					2.1.1.19
N	E	E.i	i5	E.i.3.2e	E.i.3.2e	Congenital Anomaly / Birth Defect			

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<originalText language="E.i.1.1b">E.i.1.1a</originalText>

</value>
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  <locatedEntity classCode="LOCE">
    <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
      <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
    </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>
</observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
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    <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10" codeSystemVersion="1.0"/>
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
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    <value xsi:type="BL" value="true"/>
  </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"/>
  </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"/>
  </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"/>
  </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"/>
  </observation>
</outboundRelationship2>

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N	E	E.i	i5	E.i.3.2e					
N	E	E.i	i5	E.i.3.2e					
N	E	E.i	i5	E.i.3.2f					
N	E	E.i	i5	E.i.3.2f					
N	E	E.i	i5	E.i.3.2f				2.1.1.19	
N	E	E.i	i5	E.i.3.2f	E.i.3.2f	Other Medically Important Condition			
N	E	E.i	i5	E.i.3.2f					
N	E	E.i	i5	E.i.3.2f					
N	E	E.i	i5	E.i.7					
N	E	E.i	i5	E.i.7				2.1.1.19	
N	E	E.i	i5	E.i.7					
N	E	E.i	i5	E.i.7	E.i.7	Outcome of Reaction / Event at the Time of Last Observation		2.1.1.11	
N	E	E.i	i5	E.i.7					
N	E	E.i	i5	E.i.7					
N	E	E.i	i5	E.i.8					
N	E	E.i	i5	E.i.8				2.1.1.19	
N	E	E.i	i5	E.i.8	E.i.8	Medical Confirmation by Healthcare Professional			
N	E	E.i	i5	E.i.8					
N	E	E.i	i5	E.i.8					
N	E	E.i	i5						
N	E	E.i	i5						
N	E	E.i	i6						
N	E	E.i	i6						
N	E	E.i	i6						
N	E	E.i	i6					2.1.1.19	
N	E	E.i	i6	E.i.5					
N	E	E.i	i6	E.i.5	E.i.5	Date of End of Reaction / Event			
N	E	E.i	i6	E.i.5					
N	E	E.i	i6	E.i.2.1	E.i.2.1a	MedDRA Version for Reaction / Event	E.i.2.1b	Reaction / Event (MedDRA code)	2.16.840.1.1 13883.6.163
N	E	E.i	i6	E.i.1.1	E.i.1.1a	Reaction / Event as Reported by the Primary Source in Native	E.i.1.1b	Reaction / Event as Reported by the Primary Source Language	
N	E	E.i	i6						
N	E	E.i	i6	E.i.9					
N	E	E.i	i6	E.i.9					
N	E	E.i	i6	E.i.9					
N	E	E.i	i6	E.i.9	E.i.9	Identification of the Country Where the Reaction / Event Occurred			1.0.3166.1.2. 2
N	E	E.i	i6	E.i.9					
N	E	E.i	i6	E.i.9					
N	E	E.i	i6	E.i.9					
N	E	E.i	i6	E.i.1.2					
N	E	E.i	i6	E.i.1.2					
N	E	E.i	i6	E.i.1.2				2.1.1.19	
N	E	E.i	i6	E.i.1.2	E.i.1.2	Reaction / Event as Reported by the Primary Source for			
N	E	E.i	i6	E.i.1.2					
N	E	E.i	i6	E.i.1.2					
N	E	E.i	i6	E.i.3.1					
N	E	E.i	i6	E.i.3.1					

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</observation>
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    <value xsi:type="BL" value="true"/>
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  <observation classCode="OBS" moodCode="EVN">
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    <value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11" codeSystemVersion="1.0"/>
  </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"/>
  </observation>
</outboundRelationship2>
</observation>
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<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"/>
    </effectiveTime>
    <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
      <originalText language="E.i.1.1b">E.i.1.1a</originalText>
    </value>
    <location typeCode="LOC">
      <locatedEntity classCode="LOCE">
        <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
          <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
        </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>
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">
      <observation classCode="OBS" moodCode="EVN">

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N	E	E.i	i6	E.i.3.1			2.1.1.19		<code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="termHighlightedByReporter"/>
N	E	E.i	i6	E.i.3.1	E.i.3.1	Term Highlighted by the Reporter	2.1.1.10		<value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10" codeSystemVersion="1.0"/>
N	E	E.i	i6	E.i.3.1					</observation>
N	E	E.i	i6	E.i.3.1					</outboundRelationship2>
N	E	E.i	i6	E.i.3.2a					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i6	E.i.3.2a					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i6	E.i.3.2a			2.1.1.19		<code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="resultsInDeath"/>
N	E	E.i	i6	E.i.3.2a	E.i.3.2a	Results in Death			<value xsi:type="BL" value="true"/>
N	E	E.i	i6	E.i.3.2a					</observation>
N	E	E.i	i6	E.i.3.2a					</outboundRelationship2>
N	E	E.i	i6	E.i.3.2b					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i6	E.i.3.2b					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i6	E.i.3.2b			2.1.1.19		<code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="isLifeThreatening"/>
N	E	E.i	i6	E.i.3.2b	E.i.3.2b	Life Threatening			<value xsi:type="BL" nullFlavor="NI"/>
N	E	E.i	i6	E.i.3.2b					</observation>
N	E	E.i	i6	E.i.3.2b					</outboundRelationship2>
N	E	E.i	i6	E.i.3.2c					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i6	E.i.3.2c					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i6	E.i.3.2c			2.1.1.19		<code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="requiresInpatientHospitalization"/>
N	E	E.i	i6	E.i.3.2c	E.i.3.2c	Caused / Prolonged Hospitalisation			<value xsi:type="BL" value="true"/>
N	E	E.i	i6	E.i.3.2c					</observation>
N	E	E.i	i6	E.i.3.2c					</outboundRelationship2>
N	E	E.i	i6	E.i.3.2d					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i6	E.i.3.2d					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i6	E.i.3.2d			2.1.1.19		<code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="resultsInPersistentOrSignificantDisability"/>
N	E	E.i	i6	E.i.3.2d	E.i.3.2d	Disabling / Incapacitating			<value xsi:type="BL" nullFlavor="NI"/>
N	E	E.i	i6	E.i.3.2d					</observation>
N	E	E.i	i6	E.i.3.2d					</outboundRelationship2>
N	E	E.i	i6	E.i.3.2e					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i6	E.i.3.2e					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i6	E.i.3.2e			2.1.1.19		<code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="congenitalAnomalyBirthDefect"/>
N	E	E.i	i6	E.i.3.2e	E.i.3.2e	Congenital Anomaly / Birth Defect			<value xsi:type="BL" nullFlavor="NI"/>
N	E	E.i	i6	E.i.3.2e					</observation>
N	E	E.i	i6	E.i.3.2e					</outboundRelationship2>
N	E	E.i	i6	E.i.3.2f					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i6	E.i.3.2f					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i6	E.i.3.2f			2.1.1.19		<code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="otherMedicallyImportantCondition"/>
N	E	E.i	i6	E.i.3.2f	E.i.3.2f	Other Medically Important Condition			<value xsi:type="BL" value="true"/>
N	E	E.i	i6	E.i.3.2f					</observation>
N	E	E.i	i6	E.i.3.2f					</outboundRelationship2>
N	E	E.i	i6	E.i.7					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i6	E.i.7					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i6	E.i.7			2.1.1.19		<code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="outcome"/>
N	E	E.i	i6	E.i.7	E.i.7	Outcome of Reaction / Event at the Time of Last Observation	2.1.1.11		<value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11" codeSystemVersion="1.0"/>
N	E	E.i	i6	E.i.7					</observation>
N	E	E.i	i6	E.i.7					</outboundRelationship2>
N	E	E.i	i6	E.i.8					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i6	E.i.8					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i6	E.i.8			2.1.1.19		<code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="medicalConfirmation

N	E	E.i	i6						
N	E	E.i	i6						
N	E	E.i	i7						
N	E	E.i	i7						
N	E	E.i	i7						
N	E	E.i	i7					Event ID	
N	E	E.i	i7						2.1.1.19
N	E	E.i	i7	E.i.6		Duration of Reaction / Event (number)	E.i.6b	Duration of Reaction / Event (unit)	
N	E	E.i	i7	E.i.6	E.i.6a				
N	E	E.i	i7	E.i.2.1	E.i.2.1a	MedDRA Version for Reaction / Event	E.i.2.1b	Reaction / Event (MedDRA code)	2.16.840.1.113883.6.163
N	E	E.i	i7	E.i.1.1	E.i.1.1a	Reaction / Event as Reported by the Primary Source in Native	E.i.1.1b	Reaction / Event as Reported by the Primary Source Language	
N	E	E.i	i7						
N	E	E.i	i7	E.i.9					
N	E	E.i	i7	E.i.9					
N	E	E.i	i7	E.i.9	E.i.9	Identification of the Country Where the Reaction / Event Occurred			1.0.3166.1.2.2
N	E	E.i	i7	E.i.9					
N	E	E.i	i7	E.i.9					
N	E	E.i	i7	E.i.1.2					
N	E	E.i	i7	E.i.1.2					
N	E	E.i	i7	E.i.1.2	E.i.1.2	Reaction / Event as Reported by the Primary Source for			2.1.1.19
N	E	E.i	i7	E.i.1.2					
N	E	E.i	i7	E.i.1.2					
N	E	E.i	i7	E.i.3.1	E.i.3.1	Term Highlighted by the Reporter			2.1.1.19
N	E	E.i	i7	E.i.3.1					2.1.1.10
N	E	E.i	i7	E.i.3.1					
N	E	E.i	i7	E.i.3.1					
N	E	E.i	i7	E.i.3.2a					
N	E	E.i	i7	E.i.3.2a					
N	E	E.i	i7	E.i.3.2a	E.i.3.2a	Results in Death			2.1.1.19
N	E	E.i	i7	E.i.3.2a					
N	E	E.i	i7	E.i.3.2a					
N	E	E.i	i7	E.i.3.2b					
N	E	E.i	i7	E.i.3.2b					
N	E	E.i	i7	E.i.3.2b	E.i.3.2b	Life Threatening			2.1.1.19
N	E	E.i	i7	E.i.3.2b					
N	E	E.i	i7	E.i.3.2b					
N	E	E.i	i7	E.i.3.2c					
N	E	E.i	i7	E.i.3.2c					
N	E	E.i	i7	E.i.3.2c					2.1.1.19
N	E	E.i	i7	E.i.3.2c	E.i.3.2c	Caused / Prolonged Hospitalisation			
N	E	E.i	i7	E.i.3.2c					
N	E	E.i	i7	E.i.3.2c					
N	E	E.i	i7	E.i.3.2d					

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</observation>
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<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
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    <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>
    <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
      <originalText language="E.i.1.1b">E.i.1.1a</originalText>
    </value>
    <location typeCode="LOC">
      <locatedEntity classCode="LOCE">
        <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
          <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
        </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>
      </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"/>
      </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"/>
      </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"/>
      </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"/>
      </observation>
    </outboundRelationship2>
    <outboundRelationship2 typeCode="PERT">

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N	E	E.i	i7	E.i.3.2d	E.i.3.2d	Disabling / Incapacitating		2.1.1.19	<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i7	E.i.3.2d					<code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="resultsInPersistentOrSignificantDisability"/>
N	E	E.i	i7	E.i.3.2d					<value xsi:type="BL" nullFlavor="NI"/>
N	E	E.i	i7	E.i.3.2d					</observation>
N	E	E.i	i7	E.i.3.2d	</outboundRelationship2>	<outboundRelationship2 typeCode="PERT">			<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i7	E.i.3.2e	E.i.3.2e	Congenital Anomaly / Birth Defect		2.1.1.19	<code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="congenitalAnomalyBirthDefect"/>
N	E	E.i	i7	E.i.3.2e					<value xsi:type="BL" nullFlavor="NI"/>
N	E	E.i	i7	E.i.3.2e					</observation>
N	E	E.i	i7	E.i.3.2e					</outboundRelationship2>
N	E	E.i	i7	E.i.3.2f	E.i.3.2f	Other Medically Important Condition		2.1.1.19	<outboundRelationship2 typeCode="PERT">
N	E	E.i	i7	E.i.3.2f					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i7	E.i.3.2f					<code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="otherMedicallyImportantCondition"/>
N	E	E.i	i7	E.i.3.2f					<value xsi:type="BL" value="true"/>
N	E	E.i	i7	E.i.3.2f	</observation>	</outboundRelationship2>			<outboundRelationship2 typeCode="PERT">
N	E	E.i	i7	E.i.7	E.i.7	Outcome of Reaction / Event at the Time of Last Observation		2.1.1.19	<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i7	E.i.7					<code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="outcome"/>
N	E	E.i	i7	E.i.7					<value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11" codeSystemVersion="1.0"/>
N	E	E.i	i7	E.i.7					</observation>
N	E	E.i	i7	E.i.7	</outboundRelationship2>	<outboundRelationship2 typeCode="PERT">			<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i7	E.i.8	E.i.8	Medical Confirmation by Healthcare Professional		2.1.1.19	<code code="24" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="medicalConfirmationByHealthProfessional"/>
N	E	E.i	i7	E.i.8					<value xsi:type="BL" value="true"/>
N	E	E.i	i7	E.i.8					</observation>
N	E	E.i	i7	E.i.8					</outboundRelationship2>
N	E	E.i	i7	E.i.8	</observation>	</subjectOf2>			<subjectOf2 typeCode="SBJ">
N	E	E.i	i8						<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i8						<id root="3a8626cb-9f1b-4ea8-8a0f-e0ff34430ad"/>
N	E	E.i	i8						<code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="reaction"/>
N	E	E.i	i8	E.i.5, 6	E.i.6a	Duration of Reaction / Event (number)	E.i.6b	Duration of Reaction / Event (unit)	<effectiveTime xsi:type="IVL_TS">
N	E	E.i	i8	E.i.5, 6					<width value="24" unit="E.i.6b"/>
N	E	E.i	i8	E.i.5, 6					<high value="20101201"/>
N	E	E.i	i8	E.i.5, 6					</effectiveTime>
N	E	E.i	i8	E.i.2.1	E.i.2.1a	MedDRA Version for Reaction / Event	E.i.2.1b	Reaction / Event (MedDRA code)	<value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
N	E	E.i	i8	E.i.1.1	E.i.1.1a	Reaction / Event as Reported by the Primary Source in Native	E.i.1.1b	Reaction / Event as Reported by the Primary Source Language	<originalText language="E.i.1.1b">E.i.1.1a</originalText>
N	E	E.i	i8						</value>
N	E	E.i	i8	E.i.9	E.i.9	Identification of the Country Where the Reaction / Event Occurred		1.0.3166.1.2.2	<location typeCode="LOC">
N	E	E.i	i8	E.i.9					<locatedEntity classCode="LOCE">
N	E	E.i	i8	E.i.9					<locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
N	E	E.i	i8	E.i.9					<code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
N	E	E.i	i8	E.i.9					</locatedPlace>

N	E	E.i	i8		E.i.9				</locatedEntity>
N	E	E.i	i8		E.i.9				</location>
N	E	E.i	i8		E.i.1.2				<outboundRelationship2 typeCode="PERT">
N	E	E.i	i8		E.i.1.2				<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i8		E.i.1.2	2.1.1.19			<code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="reactionForTranslation"/>
N	E	E.i	i8	E.i.1.2	Reaction / Event as Reported by the Primary Source for				<value xsi:type="ED">E.i.1.2</value>
N	E	E.i	i8		E.i.1.2				</observation>
N	E	E.i	i8		E.i.1.2				</outboundRelationship2>
N	E	E.i	i8		E.i.3.1				<outboundRelationship2 typeCode="PERT">
N	E	E.i	i8		E.i.3.1	2.1.1.19			<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i8		E.i.3.1				<code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="termHighlightedByReporter"/>
N	E	E.i	i8	E.i.3.1	Term Highlighted by the Reporter	2.1.1.10			<value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10" codeSystemVersion="1.0"/>
N	E	E.i	i8		E.i.3.1				</observation>
N	E	E.i	i8		E.i.3.1				</outboundRelationship2>
N	E	E.i	i8		E.i.3.2a				<outboundRelationship2 typeCode="PERT">
N	E	E.i	i8		E.i.3.2a	2.1.1.19			<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i8		E.i.3.2a				<code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="resultsInDeath"/>
N	E	E.i	i8	E.i.3.2a	Results in Death				<value xsi:type="BL" value="true"/>
N	E	E.i	i8		E.i.3.2a				</observation>
N	E	E.i	i8		E.i.3.2a				</outboundRelationship2>
N	E	E.i	i8		E.i.3.2b				<outboundRelationship2 typeCode="PERT">
N	E	E.i	i8		E.i.3.2b	2.1.1.19			<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i8		E.i.3.2b				<code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="isLifeThreatening"/>
N	E	E.i	i8	E.i.3.2b	Life Threatening				<value xsi:type="BL" nullFlavor="NI"/>
N	E	E.i	i8		E.i.3.2b				</observation>
N	E	E.i	i8		E.i.3.2b				</outboundRelationship2>
N	E	E.i	i8		E.i.3.2c				<outboundRelationship2 typeCode="PERT">
N	E	E.i	i8		E.i.3.2c	2.1.1.19			<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i8		E.i.3.2c				<code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="requiresInpatientHospitalization"/>
N	E	E.i	i8	E.i.3.2c	Caused / Prolonged Hospitalisation				<value xsi:type="BL" value="true"/>
N	E	E.i	i8		E.i.3.2c				</observation>
N	E	E.i	i8		E.i.3.2c				</outboundRelationship2>
N	E	E.i	i8		E.i.3.2d				<outboundRelationship2 typeCode="PERT">
N	E	E.i	i8		E.i.3.2d	2.1.1.19			<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i8		E.i.3.2d				<code code="35" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="resultsInPersistentOrSignificantDisability"/>
N	E	E.i	i8	E.i.3.2d	Disabling / Incapacitating				<value xsi:type="BL" nullFlavor="NI"/>
N	E	E.i	i8		E.i.3.2d				</observation>
N	E	E.i	i8		E.i.3.2d				</outboundRelationship2>
N	E	E.i	i8		E.i.3.2e				<outboundRelationship2 typeCode="PERT">
N	E	E.i	i8		E.i.3.2e	2.1.1.19			<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i8		E.i.3.2e				<code code="12" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="congenitalAnomalyBirthDefect"/>
N	E	E.i	i8	E.i.3.2e	Congenital Anomaly / Birth Defect				<value xsi:type="BL" nullFlavor="NI"/>
N	E	E.i	i8		E.i.3.2e				</observation>
N	E	E.i	i8		E.i.3.2e				</outboundRelationship2>
N	E	E.i	i8		E.i.3.2f				<outboundRelationship2 typeCode="PERT">
N	E	E.i	i8		E.i.3.2f	2.1.1.19			<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i8		E.i.3.2f				<code code="26" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="otherMedicallyImportantCondition"/>
N	E	E.i	i8	E.i.3.2f	Other Medically Important Condition				<value xsi:type="BL" value="true"/>
N	E	E.i	i8		E.i.3.2f				</observation>
N	E	E.i	i8		E.i.3.2f				</outboundRelationship2>
N	E	E.i	i8		E.i.7				<outboundRelationship2 typeCode="PERT">
N	E	E.i	i8		E.i.7	2.1.1.19			<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i8		E.i.7				<code code="27" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="outcome"/>

N	E	E.i	i8	E.i.7	E.i.7	Outcome of Reaction / Event at the Time of Last Observation			2.1.1.11	
N	E	E.i	i8	E.i.7						
N	E	E.i	i8	E.i.7						
N	E	E.i	i8	E.i.8						
N	E	E.i	i8	E.i.8					2.1.1.19	
N	E	E.i	i8	E.i.8	E.i.8	Medical Confirmation by Healthcare Professional				
N	E	E.i	i8	E.i.8						
N	E	E.i	i8	E.i.8						
N	E	E.i	i8							
N	E	E.i	i9							
N	E	E.i	i9							
N	E	E.i	i9			Event ID				
N	E	E.i	i9						2.1.1.19	
N	E	E.i	i9							
N	E	E.i	i9	E.i.4, 5, 6						
N	E	E.i	i9	E.i.4, 5, 6	E.i.4	Date of Start of Reaction / Event				
N	E	E.i	i9	E.i.4, 5, 6	E.i.5	Date of End of Reaction / Event				
N	E	E.i	i9	E.i.4, 5, 6						
N	E	E.i	i9	E.i.4, 5, 6						
N	E	E.i	i9	E.i.4, 5, 6	E.i.6a	Duration of Reaction / Event (number)	E.i.6b	Duration of Reaction / Event (unit)		
N	E	E.i	i9	E.i.4, 5, 6						
N	E	E.i	i9							
N	E	E.i	i9	E.i.2.1	E.i.2.1a	MedDRA Version for Reaction / Event	E.i.2.1b	Reaction / Event (MedDRA code)	2.16.840.1.113883.6.163	
N	E	E.i	i9	E.i.1.1	E.i.1.1a	Reaction / Event as Reported by the Primary Source in Native	E.i.1.1b	Reaction / Event as Reported by the Primary Source Language		
N	E	E.i	i9							
N	E	E.i	i9	E.i.9						
N	E	E.i	i9	E.i.9						
N	E	E.i	i9	E.i.9						
N	E	E.i	i9	E.i.9	E.i.9	Identification of the Country Where the Reaction / Event Occurred			1.0.3166.1.2.2	
N	E	E.i	i9	E.i.9						
N	E	E.i	i9	E.i.9						
N	E	E.i	i9	E.i.9						
N	E	E.i	i9	E.i.1.2						
N	E	E.i	i9	E.i.1.2						
N	E	E.i	i9	E.i.1.2					2.1.1.19	
N	E	E.i	i9	E.i.1.2	E.i.1.2	Reaction / Event as Reported by the Primary Source for				
N	E	E.i	i9	E.i.1.2						
N	E	E.i	i9	E.i.1.2						
N	E	E.i	i9	E.i.3.1						
N	E	E.i	i9	E.i.3.1					2.1.1.19	
N	E	E.i	i9	E.i.3.1	E.i.3.1	Term Highlighted by the Reporter			2.1.1.10	
N	E	E.i	i9	E.i.3.1						
N	E	E.i	i9	E.i.3.1						
N	E	E.i	i9	E.i.3.2a						

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<value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11" codeSystemVersion="1.0"/>
</observation>
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  <observation classCode="OBS" moodCode="EVN">
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    <value xsi:type="BL" value="true"/>
  </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"/>
        <high value="20101201"/>
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <width value="24" unit="E.i.6b"/>
      </comp>
    </effectiveTime>
    <value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
      <originalText language="E.i.1.1b">E.i.1.1a</originalText>
    </value>
    <location typeCode="LOC">
      <locatedEntity classCode="LOCE">
        <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
          <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
        </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>
      </observation>
    </outboundRelationship2>
  </subjectOf2 typeCode="SBJ">
    <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"/>
    </observation>
  </outboundRelationship2>
</outboundRelationship2 typeCode="PERT">

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N	E	E.i	i9	E.i.3.2a		
N	E	E.i	i9	E.i.3.2a		2.1.1.19
N	E	E.i	i9	E.i.3.2a	E.i.3.2a	Results in Death
N	E	E.i	i9	E.i.3.2a		
N	E	E.i	i9	E.i.3.2a		
N	E	E.i	i9	E.i.3.2b		
N	E	E.i	i9	E.i.3.2b		2.1.1.19
N	E	E.i	i9	E.i.3.2b	E.i.3.2b	Life Threatening
N	E	E.i	i9	E.i.3.2b		
N	E	E.i	i9	E.i.3.2b		
N	E	E.i	i9	E.i.3.2c		
N	E	E.i	i9	E.i.3.2c		2.1.1.19
N	E	E.i	i9	E.i.3.2c	E.i.3.2c	Caused / Prolonged Hospitalisation
N	E	E.i	i9	E.i.3.2c		
N	E	E.i	i9	E.i.3.2c		
N	E	E.i	i9	E.i.3.2d		
N	E	E.i	i9	E.i.3.2d		2.1.1.19
N	E	E.i	i9	E.i.3.2d	E.i.3.2d	Disabling / Incapacitating
N	E	E.i	i9	E.i.3.2d		
N	E	E.i	i9	E.i.3.2d		
N	E	E.i	i9	E.i.3.2e		
N	E	E.i	i9	E.i.3.2e		2.1.1.19
N	E	E.i	i9	E.i.3.2e	E.i.3.2e	Congenital Anomaly / Birth Defect
N	E	E.i	i9	E.i.3.2e		
N	E	E.i	i9	E.i.3.2e		
N	E	E.i	i9	E.i.3.2f		
N	E	E.i	i9	E.i.3.2f		2.1.1.19
N	E	E.i	i9	E.i.3.2f	E.i.3.2f	Other Medically Important Condition
N	E	E.i	i9	E.i.3.2f		
N	E	E.i	i9	E.i.3.2f		
N	E	E.i	i9	E.i.7		
N	E	E.i	i9	E.i.7		2.1.1.19
N	E	E.i	i9	E.i.7	E.i.7	Outcome of Reaction / Event at the Time of Last Observation
N	E	E.i	i9	E.i.7		2.1.1.11
N	E	E.i	i9	E.i.7		
N	E	E.i	i9	E.i.7		
N	E	E.i	i9	E.i.8		
N	E	E.i	i9	E.i.8		2.1.1.19
N	E	E.i	i9	E.i.8	E.i.8	Medical Confirmation by Healthcare Professional
N	E	E.i	i9	E.i.8		
N	E	E.i	i9	E.i.8		
N	E	E.i	i9	E.i.8		
N	E	E.i	i10			
N	E	E.i	i10			
N	E	E.i	i10			Event ID

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<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"/>
</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"/>
  </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"/>
  </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"/>
  </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"/>
  </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"/>
  </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"/>
  </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"/>
  </observation>
</outboundRelationship2>
</subjectOf2>
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <id root="1071064c-cf10-4a3b-83c1-34f9ddb7ca6d"/>

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N	E	E.i	i10						2.1.1.19
N	E	E.i	i10	E.i.4					
N	E	E.i	i10	E.i.4	E.i.4	Date of Start of Reaction / Event			
N	E	E.i	i10	E.i.4					
N	E	E.i	i10	E.i.2.1	E.i.2.1a	MedDRA Version for Reaction / Event	E.i.2.1b	Reaction / Event (MedDRA code)	2.16.840.1.113883.6.163
N	E	E.i	i10	E.i.1.1	E.i.1.1a	Reaction / Event as Reported by the Primary Source in Native	E.i.1.1b	Reaction / Event as Reported by the Primary Source Language	
N	E	E.i	i10						
N	E	E.i	i10	E.i.9					
N	E	E.i	i10	E.i.9					
N	E	E.i	i10	E.i.9					
N	E	E.i	i10	E.i.9	E.i.9	Identification of the Country Where the Reaction / Event Occurred			1.0.3166.1.2.2
N	E	E.i	i10	E.i.9					
N	E	E.i	i10	E.i.9					
N	E	E.i	i10	E.i.9					
N	E	E.i	i10	E.i.1.2					
N	E	E.i	i10	E.i.1.2					
N	E	E.i	i10	E.i.1.2					2.1.1.19
N	E	E.i	i10	E.i.1.2	E.i.1.2	Reaction / Event as Reported by the Primary Source for			
N	E	E.i	i10	E.i.1.2					
N	E	E.i	i10	E.i.1.2					
N	E	E.i	i10	E.i.3.1					
N	E	E.i	i10	E.i.3.1					2.1.1.19
N	E	E.i	i10	E.i.3.1	E.i.3.1	Term Highlighted by the Reporter			2.1.1.10
N	E	E.i	i10	E.i.3.1					
N	E	E.i	i10	E.i.3.1					
N	E	E.i	i10	E.i.3.2a					
N	E	E.i	i10	E.i.3.2a					
N	E	E.i	i10	E.i.3.2a					2.1.1.19
N	E	E.i	i10	E.i.3.2a	E.i.3.2a	Results in Death			
N	E	E.i	i10	E.i.3.2a					
N	E	E.i	i10	E.i.3.2a					
N	E	E.i	i10	E.i.3.2b					
N	E	E.i	i10	E.i.3.2b					
N	E	E.i	i10	E.i.3.2b					2.1.1.19
N	E	E.i	i10	E.i.3.2b	E.i.3.2b	Life Threatening			
N	E	E.i	i10	E.i.3.2b					
N	E	E.i	i10	E.i.3.2b					
N	E	E.i	i10	E.i.3.2c					
N	E	E.i	i10	E.i.3.2c					
N	E	E.i	i10	E.i.3.2c					2.1.1.19
N	E	E.i	i10	E.i.3.2c	E.i.3.2c	Caused / Prolonged Hospitalisation			
N	E	E.i	i10	E.i.3.2c					
N	E	E.i	i10	E.i.3.2c					
N	E	E.i	i10	E.i.3.2d					
N	E	E.i	i10	E.i.3.2d					
N	E	E.i	i10	E.i.3.2d					2.1.1.19
N	E	E.i	i10	E.i.3.2d	E.i.3.2d	Disabling / Incapacitating			
N	E	E.i	i10	E.i.3.2d					
N	E	E.i	i10	E.i.3.2d					
N	E	E.i	i10	E.i.3.2e					

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  <low value="20090101"/>
</effectiveTime>
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  <originalText language="E.i.1.1b">E.i.1.1a</originalText>
</value>
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  <locatedEntity classCode="LOCE">
    <locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
      <code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
    </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>
  </observation>
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  <observation classCode="OBS" moodCode="EVN">
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    <value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10" codeSystemVersion="1.0"/>
  </observation>
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<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
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    <value xsi:type="BL" value="true"/>
  </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"/>
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
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  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">
  <observation classCode="OBS" moodCode="EVN">
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    <value xsi:type="BL" nullFlavor="NI"/>
  </observation>
</outboundRelationship2>
<outboundRelationship2 typeCode="PERT">

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N	E	E.i	i10	E.i.3.2e	E.i.3.2e	Congenital Anomaly / Birth Defect	2.1.1.19		
N	E	E.i	i10	E.i.3.2e					
N	E	E.i	i10	E.i.3.2e					
N	E	E.i	i10	E.i.3.2e					
N	E	E.i	i10	E.i.3.2f					
N	E	E.i	i10	E.i.3.2f	E.i.3.2f	Other Medically Important Condition	2.1.1.19		
N	E	E.i	i10	E.i.3.2f					
N	E	E.i	i10	E.i.3.2f					
N	E	E.i	i10	E.i.7					
N	E	E.i	i10	E.i.7					
N	E	E.i	i10	E.i.7	E.i.7	Outcome of Reaction / Event at the Time of Last Observation	2.1.1.19		
N	E	E.i	i10	E.i.7					
N	E	E.i	i10	E.i.7					
N	E	E.i	i10	E.i.7					
N	E	E.i	i10	E.i.7					
N	E	E.i	i10	E.i.8	E.i.8	Medical Confirmation by Healthcare Professional	2.1.1.19		
N	E	E.i	i10	E.i.8					
N	E	E.i	i10	E.i.8					
N	E	E.i	i10	E.i.8					
N	E	E.i	i10	E.i.8					
N	E	E.i	i10	E.i.8					
N	E	E.i	i10	E.i.8					
N	E	E.i	i10	E.i.8					
N	E	E.i	i11						
N	E	E.i	i11						
N	E	E.i	i11		Event ID				
N	E	E.i	i11		2.1.1.19				
N	E	E.i	i11	E.i.5	E.i.5	Date of End of Reaction / Event			
N	E	E.i	i11	E.i.5					
N	E	E.i	i11	E.i.5					
N	E	E.i	i11	E.i.2.1	E.i.2.1a	MedDRA Version for Reaction / Event	E.i.2.1b	Reaction / Event (MedDRA code)	2.16.840.1.1 13883.6.163
N	E	E.i	i11	E.i.1.1	E.i.1.1a	Reaction / Event as Reported by the Primary Source in Native	E.i.1.1b	Reaction / Event as Reported by the Primary Source Language	
N	E	E.i	i11						
N	E	E.i	i11	E.i.9	E.i.9	Identification of the Country Where the Reaction / Event Occurred			1.0.3166.1.2. 2
N	E	E.i	i11	E.i.9					
N	E	E.i	i11	E.i.9					
N	E	E.i	i11	E.i.9					
N	E	E.i	i11	E.i.9					
N	E	E.i	i11	E.i.1.2	E.i.1.2	Reaction / Event as Reported by the Primary Source for			2.1.1.19
N	E	E.i	i11	E.i.1.2					
N	E	E.i	i11	E.i.1.2					
N	E	E.i	i11	E.i.1.2					
N	E	E.i	i11	E.i.1.2					

	<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"/>
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	<outboundRelationship2 typeCode="PERT">
	<observation classCode="OBS" moodCode="EVN">
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	<value xsi:type="BL" value="true"/>
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	</outboundRelationship2>
	<outboundRelationship2 typeCode="PERT">
	<observation classCode="OBS" moodCode="EVN">
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	<value xsi:type="CE" code="E.i.7" codeSystem="2.16.840.1.113883.3.989.2.1.1.11" codeSystemVersion="1.0"/>
	</observation>
	</outboundRelationship2>
	<outboundRelationship2 typeCode="PERT">
	<observation classCode="OBS" moodCode="EVN">
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	<value xsi:type="BL" value="true"/>
	</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"/>
	</effectiveTime>
	<value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
	</value>
	<originalText language="E.i.1.1b">E.i.1.1a</originalText>
	</value>
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	<locatedEntity classCode="LOCE">
	<locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
	<code code="E.i.9" codeSystem="1.0.3166.1.2.2"/>
	</locatedPlace>
	</locatedEntity>
	</location>
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	<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>

N	E	E.i	i11	E.i.1.2		
N	E	E.i	i11	E.i.1.2		
N	E	E.i	i11	E.i.3.1		
N	E	E.i	i11	E.i.3.1		
N	E	E.i	i11	E.i.3.1	E.i.3.1	Term Highlighted by the Reporter
N	E	E.i	i11	E.i.3.1		2.1.1.19
N	E	E.i	i11	E.i.3.1		2.1.1.10
N	E	E.i	i11	E.i.3.1		
N	E	E.i	i11	E.i.3.1		
N	E	E.i	i11	E.i.3.2a		
N	E	E.i	i11	E.i.3.2a		
N	E	E.i	i11	E.i.3.2a	E.i.3.2a	Results in Death
N	E	E.i	i11	E.i.3.2a		2.1.1.19
N	E	E.i	i11	E.i.3.2a		
N	E	E.i	i11	E.i.3.2b		
N	E	E.i	i11	E.i.3.2b		
N	E	E.i	i11	E.i.3.2b	E.i.3.2b	Life Threatening
N	E	E.i	i11	E.i.3.2b		2.1.1.19
N	E	E.i	i11	E.i.3.2b		
N	E	E.i	i11	E.i.3.2b		
N	E	E.i	i11	E.i.3.2c		
N	E	E.i	i11	E.i.3.2c		
N	E	E.i	i11	E.i.3.2c	E.i.3.2c	Caused / Prolonged Hospitalisation
N	E	E.i	i11	E.i.3.2c		2.1.1.19
N	E	E.i	i11	E.i.3.2c		
N	E	E.i	i11	E.i.3.2c		
N	E	E.i	i11	E.i.3.2d		
N	E	E.i	i11	E.i.3.2d		
N	E	E.i	i11	E.i.3.2d	E.i.3.2d	Disabling / Incapacitating
N	E	E.i	i11	E.i.3.2d		2.1.1.19
N	E	E.i	i11	E.i.3.2d		
N	E	E.i	i11	E.i.3.2d		
N	E	E.i	i11	E.i.3.2e		
N	E	E.i	i11	E.i.3.2e		
N	E	E.i	i11	E.i.3.2e	E.i.3.2e	Congenital Anomaly / Birth Defect
N	E	E.i	i11	E.i.3.2e		2.1.1.19
N	E	E.i	i11	E.i.3.2e		
N	E	E.i	i11	E.i.3.2e		
N	E	E.i	i11	E.i.3.2f		
N	E	E.i	i11	E.i.3.2f		
N	E	E.i	i11	E.i.3.2f	E.i.3.2f	Other Medically Important Condition
N	E	E.i	i11	E.i.3.2f		2.1.1.19
N	E	E.i	i11	E.i.3.2f		
N	E	E.i	i11	E.i.3.2f		
N	E	E.i	i11	E.i.7		
N	E	E.i	i11	E.i.7		
N	E	E.i	i11	E.i.7	E.i.7	Outcome of Reaction / Event at the Time of Last Observation
N	E	E.i	i11	E.i.7		2.1.1.19
N	E	E.i	i11	E.i.7		2.1.1.11
N	E	E.i	i11	E.i.7		
N	E	E.i	i11	E.i.7		
N	E	E.i	i11	E.i.8		
N	E	E.i	i11	E.i.8		
N	E	E.i	i11	E.i.8		2.1.1.19

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<outboundRelationship2 typeCode="PERT">
<observation classCode="OBS" moodCode="EVN">
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<value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10" codeSystemVersion="1.0"/>
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<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"/>
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<value xsi:type="BL" nullFlavor="NI"/>
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<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"/>
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<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"/>
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</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"/>
</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"/>
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</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"/>
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</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"/>

N	E	E.i	i11		E.i.8	E.i.8	Medical Confirmation by Healthcare Professional			<value xsi:type="BL" value="true"/>
N	E	E.i	i11		E.i.8					</observation>
N	E	E.i	i11		E.i.8					</outboundRelationship2>
N	E	E.i	i11							</observation>
N	E	E.i	i11							</subjectOf2>
N	E	E.i	i12							<subjectOf2 typeCode="SBJ">
N	E	E.i	i12							<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i12							<id root="c0342969-38be-423f-b6bb-ce14bc279d8e"/>
N	E	E.i	i12							<code code="29" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="reaction"/>
N	E	E.i	i12							<effectiveTime xsi:type="IVL_TS">
N	E	E.i	i12		E.i.6					<width value="24" unit="E.i.6b"/>
N	E	E.i	i12		E.i.6	E.i.6a	Duration of Reaction / Event (number)	E.i.6b	Duration of Reaction / Event (unit)	</effectiveTime>
N	E	E.i	i12		E.i.2.1	E.i.2.1a	MedDRA Version for Reaction / Event	E.i.2.1b	Reaction / Event (MedDRA code)	<value xsi:type="CE" code="E.i.2.1b" codeSystem="2.16.840.1.113883.6.163" codeSystemVersion="E.i.2.1a">
N	E	E.i	i12		E.i.1.1	E.i.1.1a	Reaction / Event as Reported by the Primary Source in Native	E.i.1.1b	Reaction / Event as Reported by the Primary Source Language	<originalText language="E.i.1.1b">E.i.1.1a</originalText>
N	E	E.i	i12							</value>
N	E	E.i	i12		E.i.9					<location typeCode="LOC">
N	E	E.i	i12		E.i.9					<locatedEntity classCode="LOCE">
N	E	E.i	i12		E.i.9					<locatedPlace classCode="COUNTRY" determinerCode="INSTANCE">
N	E	E.i	i12		E.i.9	E.i.9	Identification of the Country Where the Reaction / Event Occurred			<code code="E.i.9" codeSystem="1.03166.1.2.2"/>
N	E	E.i	i12		E.i.9					</locatedPlace>
N	E	E.i	i12		E.i.9					</locatedEntity>
N	E	E.i	i12		E.i.9					</location>
N	E	E.i	i12		E.i.1.2					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i12		E.i.1.2					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i12		E.i.1.2					<code code="30" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="reactionForTranslation"/>
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N	E	E.i	i12		E.i.1.2					</observation>
N	E	E.i	i12		E.i.1.2					</outboundRelationship2>
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N	E	E.i	i12		E.i.3.1					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i12		E.i.3.1					<code code="37" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="termHighlightedByReporter"/>
N	E	E.i	i12		E.i.3.1	E.i.3.1	Term Highlighted by the Reporter			<value xsi:type="CE" code="E.i.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.10" codeSystemVersion="1.0"/>
N	E	E.i	i12		E.i.3.1					</observation>
N	E	E.i	i12		E.i.3.1					</outboundRelationship2>
N	E	E.i	i12		E.i.3.2a					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i12		E.i.3.2a					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i12		E.i.3.2a					<code code="34" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="resultsInDeath"/>
N	E	E.i	i12		E.i.3.2a	E.i.3.2a	Results in Death			<value xsi:type="BL" value="true"/>
N	E	E.i	i12		E.i.3.2a					</observation>
N	E	E.i	i12		E.i.3.2a					</outboundRelationship2>
N	E	E.i	i12		E.i.3.2b					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i12		E.i.3.2b					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i12		E.i.3.2b					<code code="21" codeSystem="2.16.840.1.113883.3.989.2.1.1.19" codeSystemVersion="1.1" displayName="isLifeThreatening"/>
N	E	E.i	i12		E.i.3.2b	E.i.3.2b	Life Threatening			<value xsi:type="BL" nullFlavor="NI"/>
N	E	E.i	i12		E.i.3.2b					</observation>
N	E	E.i	i12		E.i.3.2b					</outboundRelationship2>
N	E	E.i	i12		E.i.3.2c					<outboundRelationship2 typeCode="PERT">
N	E	E.i	i12		E.i.3.2c					<observation classCode="OBS" moodCode="EVN">
N	E	E.i	i12		E.i.3.2c					<code code="33" codeSystem="2.16.840.1.113883.3.989.2.1.1.

N	E	E.i	i12	E.i.3.2c	E.i.3.2c	Caused / Prolonged Hospitalisation		
N	E	E.i	i12	E.i.3.2c				
N	E	E.i	i12	E.i.3.2c				
N	E	E.i	i12	E.i.3.2d				
N	E	E.i	i12	E.i.3.2d				
N	E	E.i	i12	E.i.3.2d			2.1.1.19	
N	E	E.i	i12	E.i.3.2d	E.i.3.2d	Disabling / Incapacitating		
N	E	E.i	i12	E.i.3.2d				
N	E	E.i	i12	E.i.3.2d				
N	E	E.i	i12	E.i.3.2e				
N	E	E.i	i12	E.i.3.2e			2.1.1.19	
N	E	E.i	i12	E.i.3.2e	E.i.3.2e	Congenital Anomaly / Birth Defect		
N	E	E.i	i12	E.i.3.2e				
N	E	E.i	i12	E.i.3.2e				
N	E	E.i	i12	E.i.3.2f				
N	E	E.i	i12	E.i.3.2f			2.1.1.19	
N	E	E.i	i12	E.i.3.2f	E.i.3.2f	Other Medically Important Condition		
N	E	E.i	i12	E.i.3.2f				
N	E	E.i	i12	E.i.3.2f				
N	E	E.i	i12	E.i.7				
N	E	E.i	i12	E.i.7			2.1.1.19	
N	E	E.i	i12	E.i.7				
N	E	E.i	i12	E.i.7	E.i.7	Outcome of Reaction / Event at the Time of Last Observation	2.1.1.11	
N	E	E.i	i12	E.i.7				
N	E	E.i	i12	E.i.7				
N	E	E.i	i12	E.i.8				
N	E	E.i	i12	E.i.8			2.1.1.19	
N	E	E.i	i12	E.i.8				
N	E	E.i	i12	E.i.8	E.i.8	Medical Confirmation by Healthcare Professional		
N	E	E.i	i12	E.i.8				
N	E	E.i	i12	E.i.8				
N	E	E.i	i12					
F								
F								
F							2.1.1.20	
F	F.r	R1						
F	F.r	R1						
F	F.r	R1	F.r.2.1, 2	F.r.2.2a	MedDRA Version for Test Name	F.r.2.2b	Test Name (MedDRA code)	2.16.840.1.113883.6.163
F	F.r	R1	F.r.2.1, 2	F.r.2.1	Test Name (free text)			
F	F.r	R1	F.r.2.1, 2					
F	F.r	R1	F.r.1	F.r.1	Test Date			
F	F.r	R1	F.r.3.2, 3					
F	F.r	R1	F.r.3.2, 3	F.r.3.2	Test Result (value / qualifier)	F.r.3.3	Test Result (unit)	
F	F.r	R1	F.r.3.2, 3					
F	F.r	R1	F.r.3.1	F.r.3.1	Test Result (code)			2.1.1.12
F	F.r	R1	F.r.4					
F	F.r	R1	F.r.4					

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<outboundRelationship2 typeCode="PERT">
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    <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"/>
  </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"/>
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  <organizer classCode="CATEGORY" moodCode="EVN">
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    <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">
          <originalText>F.r.2.1</originalText>
        </code>
        <effectiveTime value="20090101"/>
        <value xsi:type="IVL_PQ">
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        </value>
        <interpretationCode code="F.r.3.1" codeSystem="2.16.840.1.113883.3.989.2.1.1.12" codeSystemVersion="1.0"/>
        <referenceRange typeCode="REFV">
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F	F.r	R1	F.r.4	F.r.4	Normal Low Value				2.16.840.1.113883.5.83
F	F.r	R1	F.r.4						
F	F.r	R1	F.r.4						
F	F.r	R1	F.r.4						
F	F.r	R1	F.r.5						
F	F.r	R1	F.r.5	F.r.5	Normal High Value				2.16.840.1.113883.5.83
F	F.r	R1	F.r.5						
F	F.r	R1	F.r.5						
F	F.r	R1	F.r.5						
F	F.r	R1	F.r.6						
F	F.r	R1	F.r.6						
F	F.r	R1	F.r.6	F.r.6	Comments (free text)				2.1.1.19
F	F.r	R1	F.r.6						
F	F.r	R1	F.r.6						
F	F.r	R1	F.r.7						
F	F.r	R1	F.r.7						
F	F.r	R1	F.r.7	F.r.7	More Information Available				2.1.1.19
F	F.r	R1	F.r.7						
F	F.r	R1	F.r.7						
F	F.r	R1	F.r.7						
F	F.r	R1	F.r.7						
F	F.r	R1	F.r.7						
F	F.r	R1	F.r.7						
F	F.r	R2							
F	F.r	R2							
F	F.r	R2	F.r.2.1, 2	F.r.2.2a	MedDRA Version for Test Name	F.r.2.2b	Test Name (MedDRA code)		2.16.840.1.113883.6.163
F	F.r	R2	F.r.2.1, 2	F.r.2.1	Test Name (free text)				
F	F.r	R2	F.r.2.1, 2						
F	F.r	R2	F.r.1	F.r.1	Test Date				
F	F.r	R2	F.r.3.2, 3						
F	F.r	R2	F.r.3.2, 3						
F	F.r	R2	F.r.3.2, 3	F.r.3.2	Test Result (value / qualifier)			LT 10 mg/dl	
F	F.r	R2	F.r.3.2, 3						
F	F.r	R2	F.r.3.2, 3						
F	F.r	R2	F.r.3.2, 3						
F	F.r	R3							
F	F.r	R3							
F	F.r	R3	F.r.2.1, 2	F.r.2.2a	MedDRA Version for Test Name	F.r.2.2b	Test Name (MedDRA code)		2.16.840.1.113883.6.163
F	F.r	R3	F.r.2.1, 2	F.r.2.1	Test Name (free text)				
F	F.r	R3	F.r.2.1, 2						
F	F.r	R3	F.r.1	F.r.1	Test Date				
F	F.r	R3	F.r.3.2, 3						
F	F.r	R3	F.r.3.2, 3						
F	F.r	R3	F.r.3.2, 3	F.r.3.2	Test Result (value / qualifier)			LE 10 mg/dl	
F	F.r	R3	F.r.3.2, 3						
F	F.r	R3	F.r.3.2, 3						
F	F.r	R3	F.r.3.2, 3						
F	F.r	R4							
F	F.r	R4							
F	F.r	R4	F.r.2.1, 2	F.r.2.2a	MedDRA Version for Test Name	F.r.2.2b	Test Name (MedDRA code)		2.16.840.1.113883.6.163
F	F.r	R4	F.r.2.1, 2	F.r.2.1	Test Name (free text)				
F	F.r	R4	F.r.2.1, 2						
F	F.r	R4	F.r.1	F.r.1	Test Date				

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<observationRange classCode="OBS" moodCode="EVN.CRT">
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</observationRange>
</referenceRange>
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</observation>
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</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">
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<value xsi:type="IVL_PQ">
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<observation classCode="OBS" moodCode="EVN">
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<originalText>F.r.2.1</originalText>
</code>
<effectiveTime value="20090101"/>

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F	F.r	R4	F.r.3.2, 3						
F	F.r	R4	F.r.3.2, 3						
F	F.r	R4	F.r.3.2, 3	F.r.3.2	Test Result (value / qualifier)			GT 10 mg/dl	
F	F.r	R4	F.r.3.2, 3						
F	F.r	R4							
F	F.r	R5							
F	F.r	R5							
F	F.r	R5	F.r.2.1, 2	F.r.2.2a	MedDRA Version for Test Name	F.r.2.2b	Test Name (MedDRA code)	2.16.840.1.1 13883.6.163	
F	F.r	R5	F.r.2.1, 2	F.r.2.1	Test Name (free text)				
F	F.r	R5	F.r.2.1, 2						
F	F.r	R5	F.r.1	F.r.1	Test Date				
F	F.r	R5	F.r.3.2, 3						
F	F.r	R5	F.r.3.2, 3						
F	F.r	R5	F.r.3.2, 3	F.r.3.2	Test Result (value / qualifier)			GE 10 mg/dl	
F	F.r	R5	F.r.3.2, 3						
F	F.r	R5							
F	F.r	R5							
F	F.r	R6							
F	F.r	R6							
F	F.r	R6	F.r.2.1, 2	F.r.2.2a	MedDRA Version for Test Name	F.r.2.2b	Test Name (MedDRA code)	2.16.840.1.1 13883.6.163	
F	F.r	R6	F.r.2.1, 2	F.r.2.1	Test Name (free text)				
F	F.r	R6	F.r.2.1, 2						
F	F.r	R6	F.r.1	F.r.1	Test Date				
F	F.r	R6	F.r.3.4	F.r.3.4	Result Unstructured Data (free text)				
F	F.r	R6							
F	F.r	R6							

F

F

G

G

G 2.1.1.20

G	G.k	k1							
G	G.k	k1							
G	G.k	k1						Drug ID	
G	G.k	k1							
G	G.k	k1							
G	G.k	k1	G.k.2.1.1	G.k.2.1.1a	MPID Version Date / Number	G.k.2.1.1b	Medicinal Product Identifier (MPID)	TBD-MPID	
G	G.k	k1	G.k.2.2	G.k.2.2	Medicinal Product Name as Reported by the Primary Source				
G	G.k	k1							
G	G.k	k1							
G	G.k	k1	G.k.3.1	G.k.3.1	Authorization / Application			2.1.3.4	
G	G.k	k1	G.k.3.3						
G	G.k	k1	G.k.3.3						
G	G.k	k1	G.k.3.3	G.k.3.3	Name of Holder / Applicant				
G	G.k	k1	G.k.3.3						
G	G.k	k1	G.k.3.3						
G	G.k	k1	G.k.3.3						
G	G.k	k1	G.k.3.2						

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</component>
<component typeCode="COMP">
  <observation classCode="OBS" moodCode="EVN">
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      <originalText>F.r.2.1</originalText>
    </code>
    <effectiveTime value="20090101"/>
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      <low value="10" unit="mg/dl" inclusive="true"/>
      <high nullFlavor="PINF"/>
    </value>
  </observation>
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<component typeCode="COMP">
  <observation classCode="OBS" moodCode="EVN">
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    </code>
    <effectiveTime value="20090101"/>
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  </observation>
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</subjectOf2>
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  <organizer classCode="CATEGORY" moodCode="EVN">
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    <component typeCode="COMP">
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <id root="3c91b4d5-e039-4a7a-9c30-67671b0ef9e4"/>
        <consumable typeCode="CSM">
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            <kindOfProduct classCode="MMAT" determinerCode="KIND">
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            </kindOfProduct>
            <name>G.k.2.2</name>
          </instanceOfKind>
          <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"/>
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                    <playingOrganization classCode="ORG" determinerCode="INSTANCE">
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                    </playingOrganization>
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                <author typeCode="AUT">
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G	G.k	k1	G.k.9.i	i1	G.k.9.i.3.1									<outboundRelationship1 typeCode="SAE">
G	G.k	k1	G.k.9.i	i1	G.k.9.i.3.2									
G	G.k	k1	G.k.9.i	i1	G.k.9.i.3.2	G.k.9.i.3.2a	Time Interval between Last Dose of Drug and Start of Reaction / Event (number)	G.k.9.i.3.2b	Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)					<pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
G	G.k	k1	G.k.9.i	i1	G.k.9.i.3.2									<actReference classCode="OBS" moodCode="EVN">
G	G.k	k1	G.k.9.i	i1	G.k.9.i.3.2					Event ID				<id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/> </actReference>
G	G.k	k1	G.k.9.i	i1	G.k.9.i.3.2									</outboundRelationship1>
G	G.k	k1	G.k.9.i	i2	G.k.9.i.3.1									<outboundRelationship1 typeCode="SAS">
G	G.k	k1	G.k.9.i	i2	G.k.9.i.3.1	G.k.9.i.3.1a	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number)	G.k.9.i.3.1b	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit)					<pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
G	G.k	k1	G.k.9.i	i2	G.k.9.i.3.1									<actReference classCode="OBS" moodCode="EVN">
G	G.k	k1	G.k.9.i	i2	G.k.9.i.3.1					Event ID				<id root="2baa28d6-c9e8-4ec6-93c9-5b860b314220"/> </actReference>
G	G.k	k1	G.k.9.i	i2	G.k.9.i.3.1									</outboundRelationship1>
G	G.k	k1	G.k.9.i	i2	G.k.9.i.3.2									<outboundRelationship1 typeCode="SAE">
G	G.k	k1	G.k.9.i	i2	G.k.9.i.3.2	G.k.9.i.3.2a	Time Interval between Last Dose of Drug and Start of Reaction / Event (number)	G.k.9.i.3.2b	Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)					<pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
N	G	G.k	k1	i2	G.k.9.i.3.2									<actReference classCode="OBS" moodCode="EVN">
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N	G	G.k	k1	i2	G.k.9.i.3.2									</outboundRelationship1>
N	G	G.k	k1	i3	G.k.9.i.3.1									<outboundRelationship1 typeCode="SAS">
N	G	G.k	k1	i3	G.k.9.i.3.1	G.k.9.i.3.1a	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number)	G.k.9.i.3.1b	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit)					<pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
N	G	G.k	k1	i3	G.k.9.i.3.1									<actReference classCode="OBS" moodCode="EVN">
N	G	G.k	k1	i3	G.k.9.i.3.1					Event ID				<id root="3a8626cb-9f1b-4ca8-8a0f-e0ff34430ad"/> </actReference>
N	G	G.k	k1	i3	G.k.9.i.3.1									</outboundRelationship1>
N	G	G.k	k1	i3	G.k.9.i.3.2									<outboundRelationship1 typeCode="SAE">
N	G	G.k	k1	i3	G.k.9.i.3.2	G.k.9.i.3.2a	Time Interval between Last Dose of Drug and Start of Reaction / Event (number)	G.k.9.i.3.2b	Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)					<pauseQuantity value="10" unit="G.k.9.i.3.2b"/>
N	G	G.k	k1	i3	G.k.9.i.3.2									<actReference classCode="OBS" moodCode="EVN">
N	G	G.k	k1	i3	G.k.9.i.3.2					Event ID				<id root="3a8626cb-9f1b-4ca8-8a0f-e0ff34430ad"/> </actReference>
N	G	G.k	k1	i3	G.k.9.i.3.2									</outboundRelationship1>
N	G	G.k	k1	i4	G.k.9.i.3.1									<outboundRelationship1 typeCode="SAS">
N	G	G.k	k1	i4	G.k.9.i.3.1	G.k.9.i.3.1a	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number)	G.k.9.i.3.1b	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit)					<pauseQuantity value="10" unit="G.k.9.i.3.1b"/>
N	G	G.k	k1	i4	G.k.9.i.3.1									<actReference classCode="OBS" moodCode="EVN">
N	G	G.k	k1	i4	G.k.9.i.3.1					Event ID				<id root="2e99840f-08b4-499c-80ff-dd8415f4f8a5"/> </actReference>
N	G	G.k	k1	i4	G.k.9.i.3.1									</outboundRelationship1>
N	G	G.k	k1	i4	G.k.9.i.3.2									<outboundRelationship1 typeCode="SAE">

N	G	G.k	k1	G.k.9.i i4	G.k.9.i.3.2	G.k.9.i.3.2a	Time Interval between Last Dose of Drug and Start of Reaction / Event (number)	G.k.9.i.3.2b	Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)	
N	G	G.k	k1	G.k.9.i i4	G.k.9.i.3.2					
N	G	G.k	k1	G.k.9.i i4	G.k.9.i.3.2					Event ID
N	G	G.k	k1	G.k.9.i i4	G.k.9.i.3.2					
N	G	G.k	k1	G.k.9.i i4	G.k.9.i.3.2					
N	G	G.k	k1	G.k.9.i i5	G.k.9.i.3.1					
N	G	G.k	k1	G.k.9.i i5	G.k.9.i.3.1	G.k.9.i.3.1a	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number)	G.k.9.i.3.1b	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit)	
N	G	G.k	k1	G.k.9.i i5	G.k.9.i.3.1					
N	G	G.k	k1	G.k.9.i i5	G.k.9.i.3.1					Event ID
N	G	G.k	k1	G.k.9.i i5	G.k.9.i.3.1					
N	G	G.k	k1	G.k.9.i i5	G.k.9.i.3.1					
N	G	G.k	k1	G.k.9.i i5	G.k.9.i.3.2					
N	G	G.k	k1	G.k.9.i i5	G.k.9.i.3.2	G.k.9.i.3.2a	Time Interval between Last Dose of Drug and Start of Reaction / Event (number)	G.k.9.i.3.2b	Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)	
N	G	G.k	k1	G.k.9.i i5	G.k.9.i.3.2					Event ID
N	G	G.k	k1	G.k.9.i i5	G.k.9.i.3.2					
N	G	G.k	k1	G.k.9.i i5	G.k.9.i.3.2					
N	G	G.k	k1	G.k.9.i i6	G.k.9.i.3.1					
N	G	G.k	k1	G.k.9.i i6	G.k.9.i.3.1	G.k.9.i.3.1a	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number)	G.k.9.i.3.1b	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit)	
N	G	G.k	k1	G.k.9.i i6	G.k.9.i.3.1					
N	G	G.k	k1	G.k.9.i i6	G.k.9.i.3.1					Event ID
N	G	G.k	k1	G.k.9.i i6	G.k.9.i.3.1					
N	G	G.k	k1	G.k.9.i i6	G.k.9.i.3.1					
N	G	G.k	k1	G.k.9.i i6	G.k.9.i.3.2					
N	G	G.k	k1	G.k.9.i i6	G.k.9.i.3.2	G.k.9.i.3.2a	Time Interval between Last Dose of Drug and Start of Reaction / Event (number)	G.k.9.i.3.2b	Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)	
N	G	G.k	k1	G.k.9.i i6	G.k.9.i.3.2					Event ID
N	G	G.k	k1	G.k.9.i i6	G.k.9.i.3.2					
N	G	G.k	k1	G.k.9.i i6	G.k.9.i.3.2					
N	G	G.k	k1	G.k.9.i i6	G.k.9.i.3.2					
N	G	G.k	k1	G.k.9.i i7	G.k.9.i.3.1					
N	G	G.k	k1	G.k.9.i i7	G.k.9.i.3.1	G.k.9.i.3.1a	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number)	G.k.9.i.3.1b	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit)	
N	G	G.k	k1	G.k.9.i i7	G.k.9.i.3.1					
N	G	G.k	k1	G.k.9.i i7	G.k.9.i.3.1					Event ID
N	G	G.k	k1	G.k.9.i i7	G.k.9.i.3.1					
N	G	G.k	k1	G.k.9.i i7	G.k.9.i.3.1					
N	G	G.k	k1	G.k.9.i i7	G.k.9.i.3.2					
N	G	G.k	k1	G.k.9.i i7	G.k.9.i.3.2	G.k.9.i.3.2a	Time Interval between Last Dose of Drug and Start of Reaction / Event (number)	G.k.9.i.3.2b	Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)	
N	G	G.k	k1	G.k.9.i i7	G.k.9.i.3.2					Event ID
G	G.k	G.k	k1	G.k.9.i i7	G.k.9.i.3.2					
G	G.k	G.k	k1	G.k.9.i i7	G.k.9.i.3.2					
G	G.k	G.k	k1	G.k.9.i i7	G.k.9.i.3.2					

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</outboundRelationship1>
<outboundRelationship1 typeCode="SAE">

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<pauseQuantity value="10" unit="G.k.9.i.3.1b"/>

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</actReference>
</outboundRelationship1>
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G	G.k	k1	G.k.4.r R2								
G	G.k	k1	G.k.4.r	R2	G.k.4.r.8	G.k.4.r.8	Dosage Text				
G	G.k	k1	G.k.4.r R2								
G	G.k	k1	G.k.4.r	R2	G.k.4.r.2,3,4,5						
G	G.k	k1	G.k.4.r	R2	G.k.4.r.2,3,4,5	G.k.4.r.2	Number of Units in the Interval	G.k.4.r.3	Definition of the Time Interval Unit		
G	G.k	k1	G.k.4.r	R2	G.k.4.r.2,3,4,5						
G	G.k	k1	G.k.4.r	R2	G.k.4.r.2,3,4,5						
G	G.k	k1	G.k.4.r	R2	G.k.4.r.2,3,4,5	G.k.4.r.4	Date and Time of Start of Drug				
G	G.k	k1	G.k.4.r	R2	G.k.4.r.2,3,4,5	G.k.4.r.5	Date and Time of Last				
G	G.k	k1	G.k.4.r	R2	G.k.4.r.2,3,4,5						
G	G.k	k1	G.k.4.r	R2							
G	G.k	k1	G.k.4.r	R2	G.k.4.r.10.1,5	G.k.4.r.10.2	Route of Administration TermID Version Date / Number Route of Administration (free text)	G.k.4.r.10.2	Route of Administration TermID		
G	G.k	k1	G.k.4.r	R2	G.k.4.r.10.1,5	G.k.4.r.10.1	Administration (free text)		2.1.1.14		
G	G.k	k1	G.k.4.r	R2	G.k.4.r.10.1,5						
G	G.k	k1	G.k.4.r	R2	G.k.4.r.1	G.k.4.r.1a	Dose(number)	G.k.4.r.1b	Dose (unit)		
G	G.k	k1	G.k.4.r	R2							
G	G.k	k1	G.k.4.r	R2							
G	G.k	k1	G.k.4.r	R2	G.k.4.r.7						
G	G.k	k1	G.k.4.r	R2	G.k.4.r.7	G.k.4.r.7	Batch / Lot Number				
G	G.k	k1	G.k.4.r	R2	G.k.4.r.7						
G	G.k	k1	G.k.4.r	R2	G.k.4.r.9.1,2						
G	G.k	k1	G.k.4.r	R2	G.k.4.r.9.1,2	G.k.4.r.9.2a	Pharmaceutical Dose Form TermID Version Date / Number Pharmaceutical Dose Form (free text)	G.k.4.r.9.2b	Pharmaceutical Dose Form TermID		
G	G.k	k1	G.k.4.r	R2	G.k.4.r.9.1,2	G.k.4.r.9.1	Dose Form (free text)		TBD-DoseForm		
G	G.k	k1	G.k.4.r	R2	G.k.4.r.9.1,2						
G	G.k	k1	G.k.4.r	R2	G.k.4.r.9.1,2						
G	G.k	k1	G.k.4.r	R2							
G	G.k	k1	G.k.4.r	R2							
G	G.k	k1	G.k.4.r	R2	G.k.4.r.11.1,2				2.1.1.19		
G	G.k	k1	G.k.4.r	R2	G.k.4.r.11.1,2						
G	G.k	k1	G.k.4.r	R2	G.k.4.r.11.1,2						
G	G.k	k1	G.k.4.r	R2	G.k.4.r.11.1,5	G.k.4.r.11.2	Parent Route of Administration TermID Version Date / Number Parent Route of Administration (free text)	G.k.4.r.11.2	Parent Route of Administration TermID		
G	G.k	k1	G.k.4.r	R2	G.k.4.r.11.1,5	G.k.4.r.11.1	Administration (free text)		2.1.1.14		
G	G.k	k1	G.k.4.r	R2	G.k.4.r.11.1,2						
N	G	G.k	G.k.4.r	R2	G.k.4.r.11.1,2						
N	G	G.k	G.k.4.r	R2	G.k.4.r.11.1,2						
N	G	G.k	G.k.4.r	R2	G.k.4.r.11.1,2						
N	G	G.k	G.k.4.r	R2							
N	G	G.k	G.k.4.r	R2							
N	G	G.k	G.k.4.r	R3							
N	G	G.k	G.k.4.r	R3							
N	G	G.k	G.k.4.r	R3	G.k.4.r.8	G.k.4.r.8	Dosage Text				
N	G	G.k	G.k.4.r	R3							
N	G	G.k	G.k.4.r	R3	G.k.4.r.2,3,4,6						
N	G	G.k	G.k.4.r	R3	G.k.4.r.2,3,4,6	G.k.4.r.2	Number of Units in the Interval	G.k.4.r.3	Definition of the Time Interval Unit		
N	G	G.k	G.k.4.r	R3	G.k.4.r.2,3,4,6						
N	G	G.k	G.k.4.r	R3	G.k.4.r.2,3,4,6	G.k.4.r.4	Date and Time of Start of Drug				
N	G	G.k	G.k.4.r	R3	G.k.4.r.2,3,4,6	G.k.4.r.6a	Duration of Drug Administration (number)	G.k.4.r.6b	Duration of Drug Administration (unit)		

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<substanceAdministration classCode="SBADM" moodCode="EVN">
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  <effectiveTime xsi:type="SXPR_TS">
    <comp xsi:type="PIVL_TS">
      <period value="10" unit="G.k.4.r.3"/>
    </comp>
    <comp xsi:type="IVL_TS" operator="A">
      <low value="20090101"/>
      <high value="20090101"/>
    </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">
    <originalText>G.k.4.r.10.1</originalText>
  </routeCode>
  <doseQuantity value="10" unit="G.k.4.r.1b"/>
  <consumable typeCode="CSM">
    <instanceOfKind classCode="INST">
      <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
        <lotNumberText>G.k.4.r.7</lotNumberText>
      </productInstanceInstance>
      <kindOfProduct classCode="MMAT" determinerCode="KIND">
        <formCode code="G.k.4.r.9.2b" codeSystem="TBD-DoseForm" codeSystemVersion="G.k.4.r.9.2a">
          <originalText>G.k.4.r.9.1</originalText>
        </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">
        <originalText>G.k.4.r.11.1</originalText>
      </value>
    </observation>
  </inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <text>G.k.4.r.8</text>
    <effectiveTime xsi:type="SXPR_TS">
      <comp xsi:type="PIVL_TS">
        <period value="10" unit="G.k.4.r.3"/>
      </comp>
      <comp xsi:type="IVL_TS" operator="A">
        <low value="20090101"/>
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    </effectiveTime>
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</outboundRelationship2>
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N	G	G.k	k1	G.k.4.r R3 G.k.4.r.2,3,4,6						
N	G	G.k	k1	G.k.4.r R3						
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.10.1, 2	G.k.4.r.10.2	Route of Administration TermID Version Date / Number Route of Administration (free text)	G.k.4.r.10.2 Administration TermID	2.1.1.14
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.10.1, 2	G.k.4.r.10.1	Route of Administration (free text)		
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.10.1, 2				
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.1	G.k.4.r.1a	Dose(number)	G.k.4.r.1b	Dose (unit)
N	G	G.k	k1	G.k.4.r	R3					
N	G	G.k	k1	G.k.4.r	R3					
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.7				
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.7	G.k.4.r.7	Batch / Lot Number		
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.7				
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.9.1, 2				
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.9.1, 2	G.k.4.r.9.2a	Pharmaceutical Dose Form TermID Version Date / Number Pharmaceutical Dose Form (free text)	G.k.4.r.9.2b Pharmaceutical Dose Form TermID	TBD— DoseForm
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.9.1, 2	G.k.4.r.9.1			
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.9.1, 2				
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.9.1, 2				
N	G	G.k	k1	G.k.4.r	R3					
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.11.1, 2				
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.11.1, 2				
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.11.1, 2				2.1.1.19
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.11.1, 2	G.k.4.r.11.2	Parent Route of Administration TermID Version Date / Number Parent Route of Administration (free text)	G.k.4.r.11.2 Administration TermID	2.1.1.14
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.11.1, 2	G.k.4.r.11.1			
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.11.1, 2				
N	G	G.k	k1	G.k.4.r	R3	G.k.4.r.11.1, 2				
N	G	G.k	k1	G.k.4.r	R3					
N	G	G.k	k1	G.k.4.r	R3					
N	G	G.k	k1	G.k.4.r	R4					
N	G	G.k	k1	G.k.4.r	R4					
N	G	G.k	k1	G.k.4.r	R4	G.k.4.r.8	G.k.4.r.8	Dosage Text		
N	G	G.k	k1	G.k.4.r	R4					
N	G	G.k	k1	G.k.4.r	R4	G.k.4.r.2,3,5,6				
N	G	G.k	k1	G.k.4.r	R4	G.k.4.r.2,3,5,6	G.k.4.r.2	Number of Units in the Interval	G.k.4.r.3 Definition of the Time Interval Unit	
N	G	G.k	k1	G.k.4.r	R4	G.k.4.r.2,3,5,6				
N	G	G.k	k1	G.k.4.r	R4	G.k.4.r.2,3,5,6				
N	G	G.k	k1	G.k.4.r	R4	G.k.4.r.2,3,5,6	G.k.4.r.6a	Duration of Drug Administration (number) Date and Time of Last	G.k.4.r.6b Duration of Drug Administration (unit)	
N	G	G.k	k1	G.k.4.r	R4	G.k.4.r.2,3,5,6	G.k.4.r.5			
N	G	G.k	k1	G.k.4.r	R4	G.k.4.r.2,3,5,6				
N	G	G.k	k1	G.k.4.r	R4					
N	G	G.k	k1	G.k.4.r	R4	G.k.4.r.10.1, 2	G.k.4.r.10.2	Route of Administration TermID Version Date / Number Route of Administration (free text)	G.k.4.r.10.2 Administration TermID	2.1.1.14
N	G	G.k	k1	G.k.4.r	R4	G.k.4.r.10.1, 2	G.k.4.r.10.1			
N	G	G.k	k1	G.k.4.r	R4	G.k.4.r.10.1, 2				
N	G	G.k	k1	G.k.4.r	R4	G.k.4.r.1	G.k.4.r.1a	Dose(number)	G.k.4.r.1b	Dose (unit)
N	G	G.k	k1	G.k.4.r	R4					
N	G	G.k	k1	G.k.4.r	R4					

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</comp>
</effectiveTime>

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</routeCode>
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      <lotNumberText>G.k.4.r.7</lotNumberText>
    </productInstanceInstance>
    <kindOfProduct classCode="MMAT" determinerCode="KIND">
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      </formCode>
    </kindOfProduct>
  </instanceOfKind>
</consumable>
<inboundRelationship typeCode="REFR">
  <observation classCode="OBS" moodCode="EVN">
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      <originalText>G.k.4.r.1.1</originalText>
    </value>
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</inboundRelationship>
</substanceAdministration>
</outboundRelationship2>
<outboundRelationship2 typeCode="COMP">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
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    <effectiveTime xsi:type="SXPR_TS">
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        <period value="10" unit="G.k.4.r.3"/>
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      <comp xsi:type="TVL_TS" operator="A">
        <width value="4" unit="G.k.4.r.6b"/>
        <high value="20090101"/>
      </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">
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    </routeCode>
    <doseQuantity value="10" unit="G.k.4.r.1b"/>
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[illegible]

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  </formCode>
</kindOfProduct>
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    </value>
  </observation>
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substanceAdministration>
outboundRelationship2>
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substanceAdministration classCode="SBADM" moodCode="EVN">
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    <low value="20090101"/>
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  </comp>
  <comp xsi:type="IVL_TS" operator="A">
    <width value="4" unit="G.k.4.r.6b"/>
  </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">
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</routeCode>
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<consumable typeCode="CSM">
  <instanceOfKind classCode="INST">
    <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
      <lotNumberText>G.k.4.r.7</lotNumberText>
    </productInstanceInstance>
    <kindOfProduct classCode="MMAT" determinerCode="KIND">
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        <originalText>G.k.4.r.9.1</originalText>
      </formCode>
    </kindOfProduct>
  </instanceOfKind>
</consumable>

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N	G	G.k	k1	G.k.4.r	R5	G.k.4.r.9.1, 2				
N	G	G.k	k1	G.k.4.r	R5					
N	G	G.k	k1	G.k.4.r	R5					
N	G	G.k	k1	G.k.4.r	R5	G.k.4.r.11.1, 2				
N	G	G.k	k1	G.k.4.r	R5	G.k.4.r.11.1, 2				
N	G	G.k	k1	G.k.4.r	R5	G.k.4.r.11.1, 2				2.1.1.19
N	G	G.k	k1	G.k.4.r	R5	G.k.4.r.11.1, 2	G.k.4.r.11.2	Parent Route of Administration TermID Version Date / Number Parent Route of Administration (free text)	G.k.4.r.11.2	Parent Route of Administration TermID 2.1.1.14
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G	G.k	G.k	k1	G.k.4.r	R5	G.k.4.r.11.1, 2				
G	G.k	G.k	k1	G.k.4.r	R5	G.k.4.r.11.1, 2				
G	G.k	G.k	k1	G.k.4.r	R5	G.k.4.r.11.1, 2				
G	G.k	G.k	k1	G.k.4.r	R5					
G	G.k	G.k	k1	G.k.4.r	R5					
G	G.k	G.k	k1			G.k.5				
G	G.k	G.k	k1			G.k.5				
G	G.k	G.k	k1			G.k.5				2.1.1.19
G	G.k	G.k	k1			G.k.5	G.k.5a	Cumulative Dose to First Reaction (number)	G.k.5b	Cumulative Dose to First Reaction (unit)
G	G.k	G.k	k1			G.k.5				
G	G.k	G.k	k1			G.k.5				
G	G.k	G.k	k1			G.k.6				
G	G.k	G.k	k1			G.k.6				
G	G.k	G.k	k1			G.k.6				2.1.1.19
G	G.k	G.k	k1			G.k.6	G.k.6a	Gestation Period at Time of Exposure (number)	G.k.6b	Gestation Period at Time of Exposure (unit)
G	G.k	G.k	k1			G.k.6				
G	G.k	G.k	k1			G.k.6				
G	G.k	G.k	k1	G.k.9.i	i1	G.k.9.i.4				
G	G.k	G.k	k1	G.k.9.i	i1	G.k.9.i.4				
G	G.k	G.k	k1	G.k.9.i	i1	G.k.9.i.4				2.1.1.19
G	G.k	G.k	k1	G.k.9.i	i1	G.k.9.i.4	G.k.9.i.4	Did Reaction Recur on Re-administration?		2.1.1.16
G	G.k	G.k	k1	G.k.9.i	i1	G.k.9.i.4				
G	G.k	G.k	k1	G.k.9.i	i1	G.k.9.i.4				
G	G.k	G.k	k1	G.k.9.i	i1	G.k.9.i.4				
G	G.k	G.k	k1	G.k.9.i	i1	G.k.9.i.4				
G	G.k	G.k	k1	G.k.9.i	i1	G.k.9.i.4				
G	G.k	G.k	k1	G.k.9.i	i1	G.k.9.i.4				
G	G.k	G.k	k1	G.k.9.i	i2	G.k.9.i.4				
G	G.k	G.k	k1	G.k.9.i	i2	G.k.9.i.4				
G	G.k	G.k	k1	G.k.9.i	i2	G.k.9.i.4				2.1.1.19
G	G.k	G.k	k1	G.k.9.i	i2	G.k.9.i.4	G.k.9.i.4	Did Reaction Recur on Re-administration?		2.1.1.16
G	G.k	G.k	k1	G.k.9.i	i2	G.k.9.i.4				
G	G.k	G.k	k1	G.k.9.i	i2	G.k.9.i.4				
G	G.k	G.k	k1	G.k.9.i	i2	G.k.9.i.4				
G	G.k	G.k	k1	G.k.9.i	i2	G.k.9.i.4				
G	G.k	G.k	k1	G.k.9.i	i2	G.k.9.i.4				
G	G.k	G.k	k1	G.k.9.i	i2	G.k.9.i.4				
G	G.k	G.k	k1	G.k.9.i	i2	G.k.9.i.4				
G	G.k	G.k	k1	G.k.10.r	R1	G.k.10.r				
G	G.k	G.k	k1	G.k.10.r	R1	G.k.10.r				
G	G.k	G.k	k1	G.k.10.r	R1	G.k.10.r				2.1.1.19

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G	G.k	k1	G.k.10.r R1	G.k.10.r	G.k.10.r	Additional Information on Drug (coded)	2.1.1.17
G	G.k	k1	G.k.10.r R1	G.k.10.r			
G	G.k	k1	G.k.10.r R1	G.k.10.r			
G	G.k	k1	G.k.10.r R2	G.k.10.r			
G	G.k	k1	G.k.10.r R2	G.k.10.r			
G	G.k	k1	G.k.10.r R2	G.k.10.r			2.1.1.19
G	G.k	k1	G.k.10.r R2	G.k.10.r	G.k.10.r	Additional Information on Drug (coded)	2.1.1.17
G	G.k	k1	G.k.10.r R2	G.k.10.r			
G	G.k	k1	G.k.10.r R2	G.k.10.r			
G	G.k	k1		G.k.11			
G	G.k	k1		G.k.11			
G	G.k	k1		G.k.11			2.1.1.19
G	G.k	k1		G.k.11	G.k.11	Additional Information on Drug (free text)	
G	G.k	k1		G.k.11			
G	G.k	k1		G.k.11			
G	G.k	k1	G.k.7.r R1	G.k.7.r.1, 2			
G	G.k	k1	G.k.7.r R1	G.k.7.r.1, 2			
G	G.k	k1	G.k.7.r R1	G.k.7.r.1, 2			2.1.1.19
G	G.k	k1	G.k.7.r R1	G.k.7.r.1, 2	G.k.7.r.2a	MedDRA Version for Indication Indication as Reported by the Primary Source	2.16.840.1.1 13883.6.163
G	G.k	k1	G.k.7.r R1	G.k.7.r.1, 2	G.k.7.r.1		
G	G.k	k1	G.k.7.r R1	G.k.7.r.1, 2			
G	G.k	k1	G.k.7.r R1	G.k.7.r.1, 2			
G	G.k	k1	G.k.7.r R1	G.k.7.r.1, 2			2.1.1.21
G	G.k	k1	G.k.7.r R1	G.k.7.r.1, 2			
G	G.k	k1	G.k.7.r R1	G.k.7.r.1, 2			
G	G.k	k1	G.k.7.r R1	G.k.7.r.1, 2			
G	G.k	k1	G.k.7.r R2	G.k.7.r.1, 2			
G	G.k	k1	G.k.7.r R2	G.k.7.r.1, 2			
G	G.k	k1	G.k.7.r R2	G.k.7.r.1, 2			2.1.1.19
G	G.k	k1	G.k.7.r R2	G.k.7.r.1, 2	G.k.7.r.2a	MedDRA Version for Indication Indication as Reported by the Primary Source	2.16.840.1.1 13883.6.163
G	G.k	k1	G.k.7.r R2	G.k.7.r.1, 2	G.k.7.r.1		
G	G.k	k1	G.k.7.r R2	G.k.7.r.1, 2			
G	G.k	k1	G.k.7.r R2	G.k.7.r.1, 2			
G	G.k	k1	G.k.7.r R2	G.k.7.r.1, 2			2.1.1.21
G	G.k	k1	G.k.7.r R2	G.k.7.r.1, 2			
G	G.k	k1	G.k.7.r R2	G.k.7.r.1, 2			
G	G.k	k1	G.k.7.r R2	G.k.7.r.1, 2			
G	G.k	k1	G.k.8				
G	G.k	k1	G.k.8				
G	G.k	k1	G.k.8	G.k.8	Action(s) Taken with Drug		2.1.1.15
G	G.k	k1	G.k.8				
G	G.k	k1	G.k.8				
G	G.k	k1					
G	G.k	k2					
G	G.k	k2					
G	G.k	k2				Drug ID	
G	G.k	k2					

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[illegible]

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G	G.k	k2		G.k.2.4						</representedOrganization>	
G	G.k	k2		G.k.2.4						</assignedEntity>	
G	G.k	k2		G.k.2.4						</performer>	
G	G.k	k2		G.k.2.4						</productEvent>	
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G	G.k	k2	G.k.9.i	i1	G.k.9.i.3.1					</outboundRelationship1>	
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G	G.k	k2	G.k.9.i	i1	G.k.9.i.3.2					<id root="154eb889-958b-45f2-a02f-42d4d6f4657f"/>	
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G	G.k	k2	G.k.9.i	i1	G.k.9.i.3.2					</outboundRelationship1>	
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G	G.k	k2	G.k.9.i	i2	G.k.9.i.3.1	G.k.9.i.3.1a	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number)	G.k.9.i.3.1b	Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit)	<pauseQuantity value="10" unit="G.k.9.i.3.1b"/>	
G	G.k	k2	G.k.9.i	i2	G.k.9.i.3.1					<actReference classCode="OBS" moodCode="EVN">	
G	G.k	k2	G.k.9.i	i2	G.k.9.i.3.1					<id root="2baa28d6-c9e8-4efc-93e9-5b860b314220"/>	
G	G.k	k2	G.k.9.i	i2	G.k.9.i.3.1					</actReference>	
G	G.k	k2	G.k.9.i	i2	G.k.9.i.3.1					</outboundRelationship1>	
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G	G.k	k2	G.k.9.i	i2	G.k.9.i.3.2	G.k.9.i.3.2a	Time Interval between Last Dose of Drug and Start of Reaction / Event (number)	G.k.9.i.3.2b	Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)	<pauseQuantity value="10" unit="G.k.9.i.3.2b"/>	
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N	G	G.k	k2	G.k.9.i	i3	G.k.9.i.3.1			
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N	G	G.k	k2	G.k.9.i	i3	G.k.9.i.3.2	G.k.9.i.3.2a Time Interval between Last Dose of Drug and Start of Reaction / Event (number)	G.k.9.i.3.2b Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)	
N	G	G.k	k2	G.k.9.i	i3	G.k.9.i.3.2			Event ID
N	G	G.k	k2	G.k.9.i	i3	G.k.9.i.3.2			
N	G	G.k	k2	G.k.9.i	i3	G.k.9.i.3.2			
N	G	G.k	k2	G.k.9.i	i3	G.k.9.i.3.2			
N	G	G.k	k2	G.k.9.i	i4	G.k.9.i.3.1			
N	G	G.k	k2	G.k.9.i	i4	G.k.9.i.3.1	G.k.9.i.3.1a Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number)	G.k.9.i.3.1b Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit)	
N	G	G.k	k2	G.k.9.i	i4	G.k.9.i.3.1			Event ID
N	G	G.k	k2	G.k.9.i	i4	G.k.9.i.3.1			
N	G	G.k	k2	G.k.9.i	i4	G.k.9.i.3.1			
N	G	G.k	k2	G.k.9.i	i4	G.k.9.i.3.2			
N	G	G.k	k2	G.k.9.i	i4	G.k.9.i.3.2	G.k.9.i.3.2a Time Interval between Last Dose of Drug and Start of Reaction / Event (number)	G.k.9.i.3.2b Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)	
N	G	G.k	k2	G.k.9.i	i4	G.k.9.i.3.2			Event ID
N	G	G.k	k2	G.k.9.i	i4	G.k.9.i.3.2			
N	G	G.k	k2	G.k.9.i	i4	G.k.9.i.3.2			
N	G	G.k	k2	G.k.9.i	i4	G.k.9.i.3.2			
N	G	G.k	k2	G.k.9.i	i5	G.k.9.i.3.1			
N	G	G.k	k2	G.k.9.i	i5	G.k.9.i.3.1	G.k.9.i.3.1a Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number)	G.k.9.i.3.1b Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit)	
N	G	G.k	k2	G.k.9.i	i5	G.k.9.i.3.1			Event ID
N	G	G.k	k2	G.k.9.i	i5	G.k.9.i.3.1			
N	G	G.k	k2	G.k.9.i	i5	G.k.9.i.3.1			
N	G	G.k	k2	G.k.9.i	i5	G.k.9.i.3.1			
N	G	G.k	k2	G.k.9.i	i5	G.k.9.i.3.2			
N	G	G.k	k2	G.k.9.i	i5	G.k.9.i.3.2	G.k.9.i.3.2a Time Interval between Last Dose of Drug and Start of Reaction / Event (number)	G.k.9.i.3.2b Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)	
N	G	G.k	k2	G.k.9.i	i5	G.k.9.i.3.2			Event ID
N	G	G.k	k2	G.k.9.i	i5	G.k.9.i.3.2			
N	G	G.k	k2	G.k.9.i	i5	G.k.9.i.3.2			
N	G	G.k	k2	G.k.9.i	i5	G.k.9.i.3.2			
N	G	G.k	k2	G.k.9.i	i6	G.k.9.i.3.1			
N	G	G.k	k2	G.k.9.i	i6	G.k.9.i.3.1	G.k.9.i.3.1a Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number)	G.k.9.i.3.1b Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit)	
N	G	G.k	k2	G.k.9.i	i6	G.k.9.i.3.1			Event ID
N	G	G.k	k2	G.k.9.i	i6	G.k.9.i.3.1			
N	G	G.k	k2	G.k.9.i	i6	G.k.9.i.3.1			
N	G	G.k	k2	G.k.9.i	i6	G.k.9.i.3.2			
N	G	G.k	k2	G.k.9.i	i6	G.k.9.i.3.2	G.k.9.i.3.2a Time Interval between Last Dose of Drug and Start of Reaction / Event (number)	G.k.9.i.3.2b Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)	
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N	G	G.k	k2	G.k.9.i i7	G.k.9.i.3.1		
N	G	G.k	k2	G.k.9.i i7	G.k.9.i.3.1	G.k.9.i.3.1a Time Interval between Beginning of Drug Administration and Start of Reaction / Event (number)	G.k.9.i.3.1b Time Interval between Beginning of Drug Administration and Start of Reaction / Event (unit)
N	G	G.k	k2	G.k.9.i i7	G.k.9.i.3.1		Event ID
N	G	G.k	k2	G.k.9.i i7	G.k.9.i.3.1		
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N	G	G.k	k2	G.k.9.i i7	G.k.9.i.3.2		
N	G	G.k	k2	G.k.9.i i7	G.k.9.i.3.2	G.k.9.i.3.2a Time Interval between Last Dose of Drug and Start of Reaction / Event (number)	G.k.9.i.3.2b Time Interval between Last Dose of Drug and Start of Reaction / Event (unit)
G	G.k	k2		G.k.9.i i7	G.k.9.i.3.2		Event ID
G	G.k	k2		G.k.9.i i7	G.k.9.i.3.2		
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G	G.k	k2		G.k.2.5			2.1.1.19
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G	G.k	k2		G.k.2.5	G.k.2.5	Investigational Product Blinded	
G	G.k	k2		G.k.2.5			
G	G.k	k2		G.k.4.r R1			
G	G.k	k2		G.k.4.r R1			
G	G.k	k2		G.k.4.r R1	G.k.4.r.8	G.k.4.r.8	Dosage Text
G	G.k	k2		G.k.4.r R1			
G	G.k	k2		G.k.4.r R1	G.k.4.r.4, 5	G.k.4.r.4	Date and Time of Start of Drug
G	G.k	k2		G.k.4.r R1	G.k.4.r.4, 5	G.k.4.r.5	Date and Time of Last
G	G.k	k2		G.k.4.r R1			
G	G.k	k2		G.k.4.r R1	G.k.4.r.10.1, 2	G.k.4.r.10.2	Route of Administration TermID Version Date / Number Route of Administration (free text)
G	G.k	k2		G.k.4.r R1	G.k.4.r.10.1, 2		1.1.14
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G	G.k	k2		G.k.4.r R1		G.k.4.r.1b	Dose (unit)
G	G.k	k2		G.k.4.r R1			
G	G.k	k2		G.k.4.r R1	G.k.4.r.7		
G	G.k	k2		G.k.4.r R1	G.k.4.r.7	G.k.4.r.7	Batch / Lot Number
G	G.k	k2		G.k.4.r R1	G.k.4.r.7		
G	G.k	k2		G.k.4.r R1	G.k.4.r.9.1, 2		
G	G.k	k2		G.k.4.r R1	G.k.4.r.9.1, 2	G.k.4.r.9.2a Pharmaceutical Dose Form TermID Version Date / Number Pharmaceutical Dose Form (free text)	G.k.4.r.9.2b Pharmaceutical Dose Form TermID
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G	G.k	k2		G.k.4.r R1	G.k.4.r.9.1, 2		
G	G.k	k2		G.k.4.r R1	G.k.4.r.9.1, 2		
G	G.k	k2		G.k.4.r R1			
G	G.k	k2		G.k.4.r R1			
G	G.k	k2		G.k.4.r R1	G.k.4.r.11.1, 2		
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N	G	G.k	k2	G.k.4.r	R5	G.k.4.r.11.1, 2					
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N	G	G.k	k2	G.k.4.r	R5	G.k.4.r.11.1, 2; G.k.4.r.11.2	Parent Route of Administration TermID Version Date / Number Parent Route of Administration (free text)	G.k.4.r.11.2	Parent Route of Administration TermID		1.1.14
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N	G	G.k	k2	G.k.4.r	R5	G.k.4.r.11.1, 2					
N	G	G.k	k2	G.k.4.r	R5	G.k.4.r.11.1, 2					
N	G	G.k	k2	G.k.4.r	R5						
N	G	G.k	k2	G.k.4.r	R5						
N	G	G.k	k2	G.k.4.r	R6						
N	G	G.k	k2	G.k.4.r	R6						
N	G	G.k	k2	G.k.4.r	R6	G.k.4.r.8	G.k.4.r.8	Dosage Text			
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N	G	G.k	k2	G.k.4.r	R6	G.k.4.r.2,3,6	G.k.4.r.2	Number of Units in the Interval	G.k.4.r.3	Definition of the Time Interval Unit	
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N	G	G.k	k2	G.k.4.r	R6	G.k.4.r.2,3,6	G.k.4.r.6a	Duration of Drug Administration (number)	G.k.4.r.6b	Duration of Drug Administration (unit)	
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N	G	G.k	k2	G.k.4.r	R6						
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N	G	G.k	k2	G.k.4.r	R6	G.k.4.r.10.1, 2; G.k.4.r.10.1	Administration (free text)				
N	G	G.k	k2	G.k.4.r	R6	G.k.4.r.10.1, 2					
N	G	G.k	k2	G.k.4.r	R6	G.k.4.r.1	G.k.4.r.1a	Dose(number)	G.k.4.r.1b	Dose (unit)	
N	G	G.k	k2	G.k.4.r	R6						
N	G	G.k	k2	G.k.4.r	R6						
N	G	G.k	k2	G.k.4.r	R6	G.k.4.r.7					
N	G	G.k	k2	G.k.4.r	R6	G.k.4.r.7	G.k.4.r.7	Batch / Lot Number			
N	G	G.k	k2	G.k.4.r	R6	G.k.4.r.7					
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N	G	G.k	k2	G.k.4.r	R6	G.k.4.r.9.1, 2	G.k.4.r.9.2a	Pharmaceutical Dose Form TermID Version Date / Number Pharmaceutical Dose Form (free text)	G.k.4.r.9.2b	Pharmaceutical Dose Form TermID	TBD–DoseForm
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N	G	G.k	k2	G.k.4.r	R6	G.k.4.r.9.1, 2					
N	G	G.k	k2	G.k.4.r	R6						
N	G	G.k	k2	G.k.4.r	R6						
N	G	G.k	k2	G.k.4.r	R6	G.k.4.r.11.1, 2					
N	G	G.k	k2	G.k.4.r	R6	G.k.4.r.11.1, 2					
N	G	G.k	k2	G.k.4.r	R6	G.k.4.r.11.1, 2					2.1.1.19
N	G	G.k	k2	G.k.4.r	R6	G.k.4.r.11.1, 2; G.k.4.r.11.2	Parent Route of Administration TermID Version Date / Number Parent Route of Administration (free text)	G.k.4.r.11.2	Parent Route of Administration TermID		1.1.14
N	G	G.k	k2	G.k.4.r	R6	G.k.4.r.11.1, 2; G.k.4.r.11.1	Administration (free text)				
N	G	G.k	k2	G.k.4.r	R6	G.k.4.r.11.1, 2					
N	G	G.k	k2	G.k.4.r	R6	G.k.4.r.11.1, 2					

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N	G	G.k	k2	G.k.4.r	R7						
N	G	G.k	k2	G.k.4.r	R7						
N	G	G.k	k2	G.k.4.r	R7	G.k.4.r.8	G.k.4.r.8	Dosage Text			
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N	G	G.k	k2	G.k.4.r	R7	G.k.4.r.2, 3					
N	G	G.k	k2	G.k.4.r	R7	G.k.4.r.10.1, 1	G.k.4.r.10.2	Route of Administration TermID Version Date / Number Route of Administration (free text)	G.k.4.r.10.2	Route of Administration TermID	1.1.14
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N	G	G.k	k2	G.k.4.r	R7						
N	G	G.k	k2	G.k.4.r	R7						
N	G	G.k	k2	G.k.4.r	R7	G.k.4.r.7					
N	G	G.k	k2	G.k.4.r	R7	G.k.4.r.7	G.k.4.r.7	Batch / Lot Number			
N	G	G.k	k2	G.k.4.r	R7	G.k.4.r.7					
N	G	G.k	k2	G.k.4.r	R7	G.k.4.r.9.1, 2					
N	G	G.k	k2	G.k.4.r	R7	G.k.4.r.9.1, 2	G.k.4.r.9.2a	Pharmaceutical Dose Form TermID Version Date / Number Pharmaceutical Dose Form (free text)	G.k.4.r.9.2b	Pharmaceutical Dose Form TermID	
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N	G	G.k	k2	G.k.4.r	R7						
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N	G	G.k	k2	G.k.4.r	R7						
N	G	G.k	k2	G.k.4.r	R8						
N	G	G.k	k2	G.k.4.r	R8						
N	G	G.k	k2	G.k.4.r	R8	G.k.4.r.8	G.k.4.r.8	Dosage Text			
N	G	G.k	k2	G.k.4.r	R8	G.k.4.r.4					
N	G	G.k	k2	G.k.4.r	R8	G.k.4.r.4	G.k.4.r.4	Date and Time of Start of Drug			
N	G	G.k	k2	G.k.4.r	R8	G.k.4.r.4					
N	G	G.k	k2	G.k.4.r	R8	G.k.4.r.10.1, 1	G.k.4.r.10.2	Route of Administration TermID Version Date / Number Route of Administration (free text)	G.k.4.r.10.2	Route of Administration TermID	1.1.14
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N	G	G.k	k2	G.k.4.r	R8	G.k.4.r.10.1, 2					
N	G	G.k	k2	G.k.4.r	R8	G.k.4.r.1	G.k.4.r.1a	Dose(number)	G.k.4.r.1b	Dose (unit)	
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[illegible]

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N	G	G.k	k2	G.k.4.r	R9					</outboundRelationship2>
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N	G	G.k	k2	G.k.4.r	R10	G.k.4.r.1	G.k.4.r.1a Dose (number)	G.k.4.r.1b Dose (unit)		<doseQuantity value="10" unit="G.k.4.r.1b"/>
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N	G	G.k	k2	G.k.4.r	R10	G.k.4.r.11.1, 'G.k.4.r.11.1	Administration (free text)			<originalText>G.k.4.r.11.1</originalText>
N	G	G.k	k2	G.k.4.r	R10	G.k.4.r.11.1, 2				</value>
G	G.k	k2	G.k.4.r	R10	G.k.4.r.11.1, 2					</observation>
G	G.k	k2	G.k.4.r	R10	G.k.4.r.11.1, 2					</inboundRelationship>
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G	G.k	k2	G.k.4.r	R10						</outboundRelationship2>
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G	G.k	k2		G.k.5						</outboundRelationship2>

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G	G.k	k2	G.k.6						
G	G.k	k2	G.k.6					2.1.1.19	
G	G.k	k2	G.k.6	G.k.6a	Gestation Period at Time of Exposure (number)	G.k.6b	Gestation Period at Time of Exposure (unit)		
G	G.k	k2	G.k.6						
G	G.k	k2	G.k.6						
G	G.k	k2	G.k.9.i	i1	G.k.9.i.4				
G	G.k	k2	G.k.9.i	i1	G.k.9.i.4				
G	G.k	k2	G.k.9.i	i1	G.k.9.i.4			2.1.1.19	
G	G.k	k2	G.k.9.i	i1	G.k.9.i.4	G.k.9.i.4	Did Reaction Recur on Re- administration?	2.1.1.16	
G	G.k	k2	G.k.9.i	i1	G.k.9.i.4				
G	G.k	k2	G.k.9.i	i1	G.k.9.i.4				
G	G.k	k2	G.k.9.i	i1	G.k.9.i.4				Event ID
G	G.k	k2	G.k.9.i	i1	G.k.9.i.4				
G	G.k	k2	G.k.9.i	i1	G.k.9.i.4				
G	G.k	k2	G.k.9.i	i2	G.k.9.i.4				
G	G.k	k2	G.k.9.i	i2	G.k.9.i.4				
G	G.k	k2	G.k.9.i	i2	G.k.9.i.4			2.1.1.19	
G	G.k	k2	G.k.9.i	i2	G.k.9.i.4	G.k.9.i.4	Did Reaction Recur on Re- administration?	2.1.1.16	
G	G.k	k2	G.k.9.i	i2	G.k.9.i.4				
G	G.k	k2	G.k.9.i	i2	G.k.9.i.4				
G	G.k	k2	G.k.9.i	i2	G.k.9.i.4				
G	G.k	k2	G.k.9.i	i2	G.k.9.i.4				
G	G.k	k2	G.k.9.i	i2	G.k.9.i.4				
G	G.k	k2	G.k.10.r	R1	G.k.10.r				
G	G.k	k2	G.k.10.r	R1	G.k.10.r				
G	G.k	k2	G.k.10.r	R1	G.k.10.r			2.1.1.19	
G	G.k	k2	G.k.10.r	R1	G.k.10.r	G.k.10.r	Additional Information on Drug (coded)	2.1.1.17	
G	G.k	k2	G.k.10.r	R1	G.k.10.r				
G	G.k	k2	G.k.10.r	R1	G.k.10.r				
G	G.k	k2	G.k.10.r	R2	G.k.10.r				
G	G.k	k2	G.k.10.r	R2	G.k.10.r				
G	G.k	k2	G.k.10.r	R2	G.k.10.r			2.1.1.19	
G	G.k	k2	G.k.10.r	R2	G.k.10.r	G.k.10.r	Additional Information on Drug (coded)	2.1.1.17	
G	G.k	k2	G.k.10.r	R2	G.k.10.r				
G	G.k	k2	G.k.10.r	R2	G.k.10.r				
G	G.k	k2	G.k.11						
G	G.k	k2	G.k.11						
G	G.k	k2	G.k.11					2.1.1.19	
G	G.k	k2	G.k.11	G.k.11			Additional Information on Drug (free text)		
G	G.k	k2	G.k.11						
G	G.k	k2	G.k.11						
G	G.k	k2	G.k.7.r	R1	G.k.7.r.1, 2				
G	G.k	k2	G.k.7.r	R1	G.k.7.r.1, 2				
G	G.k	k2	G.k.7.r	R1	G.k.7.r.1, 2			2.1.1.19	
G	G.k	k2	G.k.7.r	R1	G.k.7.r.1, 2	G.k.7.r.2a	MedDRA Version for Indication Indication as Reported by the Primary Source	2.16.840.1.1 13883.6.163	
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G	G.k	k2	G.k.7.r	R1	G.k.7.r.1, 2				
G	G.k	k2	G.k.7.r	R1	G.k.7.r.1, 2			2.1.1.21	
G	G.k	k2	G.k.7.r	R1	G.k.7.r.1, 2				
G	G.k	k2	G.k.7.r	R1	G.k.7.r.1, 2				
G	G.k	k2	G.k.7.r	R1	G.k.7.r.1, 2				
G	G.k	k2	G.k.7.r	R1	G.k.7.r.1, 2				
G	G.k	k2	G.k.7.r	R2	G.k.7.r.1, 2				
G	G.k	k2	G.k.7.r	R2	G.k.7.r.1, 2				
G	G.k	k2	G.k.7.r	R2	G.k.7.r.1, 2			2.1.1.19	
G	G.k	k2	G.k.7.r	R2	G.k.7.r.1, 2	G.k.7.r.2a	MedDRA Version for Indication as Reported by the Primary Source	G.k.7.r.2b	Indication (MedDRA code)
								2.16.840.1.113883.6.163	
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G	G.k	k2	G.k.7.r	R2	G.k.7.r.1, 2				
G	G.k	k2	G.k.7.r	R2	G.k.7.r.1, 2				
G	G.k	k2	G.k.7.r	R2	G.k.7.r.1, 2			2.1.1.21	
G	G.k	k2	G.k.7.r	R2	G.k.7.r.1, 2				
G	G.k	k2	G.k.7.r	R2	G.k.7.r.1, 2				
G	G.k	k2	G.k.7.r	R2	G.k.7.r.1, 2				
G	G.k	k2			G.k.8				
G	G.k	k2			G.k.8				
G	G.k	k2			G.k.8	G.k.8	Action(s) Taken with Drug		2.1.1.15
G	G.k	k2			G.k.8				
G	G.k	k2			G.k.8				
G	G.k	k2							
G	G.k	k2							

G
G
G
G

G	G.k.1	k1		G.k.1					
G	G.k.1	k1		G.k.1					
G	G.k.1	k1		G.k.1					2.1.1.19
G	G.k.1	k1		G.k.1	G.k.1	Characterization of Drug Role			2.1.1.13
G	G.k.1	k1		G.k.1					
G	G.k.1	k1		G.k.1				drug ID	
G	G.k.1	k1		G.k.1					
G	G.k.1	k1		G.k.1					
G	G.k.1	k1		G.k.1					
G	G.k.1	k1		G.k.1					
G	G.k.1	k2		G.k.1					
G	G.k.1	k2		G.k.1					
G	G.k.1	k2		G.k.1					2.1.1.19
G	G.k.1	k2		G.k.1	G.k.1	Characterization of Drug Role			2.1.1.13
G	G.k.1	k2		G.k.1					
G	G.k.1	k2		G.k.1					
G	G.k.1	k2		G.k.1				drug ID	
G	G.k.1	k2		G.k.1					
G	G.k.1	k2		G.k.1					
G	G.k.1	k2		G.k.1					
G	G.k.9.i.2.r	k1, i1, r1							
G	G.k.9.i.2.r	k1, i1, r1							

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G	G.k.9.i.2.r	k1, i1, r1	G.k.9.i.2.r.3	Result of Assessment
G	G.k.9.i.2.r	k1, i1, r1	G.k.9.i.2.r.2	
G	G.k.9.i.2.r	k1, i1, r1	G.k.9.i.2.r.2	Method of Assessment
G	G.k.9.i.2.r	k1, i1, r1	G.k.9.i.2.r.2	
G	G.k.9.i.2.r	k1, i1, r1	G.k.9.i.2.r.1	
G	G.k.9.i.2.r	k1, i1, r1	G.k.9.i.2.r.1	
G	G.k.9.i.2.r	k1, i1, r1	G.k.9.i.2.r.1	Source of Assessment
G	G.k.9.i.2.r	k1, i1, r1	G.k.9.i.2.r.1	
G	G.k.9.i.2.r	k1, i1, r1	G.k.9.i.2.r.1	
G	G.k.9.i.2.r	k1, i1, r1	G.k.9.i.2.r.1	
G	G.k.9.i.2.r	k1, i1, r1		
G	G.k.9.i.2.r	k1, i1, r1		
G	G.k.9.i.2.r	k1, i1, r1		Event ID
G	G.k.9.i.2.r	k1, i1, r1		
G	G.k.9.i.2.r	k1, i1, r1		
G	G.k.9.i.2.r	k1, i1, r1		drug ID
G	G.k.9.i.2.r	k1, i1, r1		
G	G.k.9.i.2.r	k1, i1, r1		
G	G.k.9.i.2.r	k1, i2, r1		
G	G.k.9.i.2.r	k1, i2, r1		
G	G.k.9.i.2.r	k1, i2, r1		2.1.1.19
G	G.k.9.i.2.r	k1, i2, r1	G.k.9.i.2.r.3	Result of Assessment
G	G.k.9.i.2.r	k1, i2, r1	G.k.9.i.2.r.2	
G	G.k.9.i.2.r	k1, i2, r1	G.k.9.i.2.r.2	Method of Assessment
G	G.k.9.i.2.r	k1, i2, r1	G.k.9.i.2.r.2	
G	G.k.9.i.2.r	k1, i2, r1	G.k.9.i.2.r.1	
G	G.k.9.i.2.r	k1, i2, r1	G.k.9.i.2.r.1	
G	G.k.9.i.2.r	k1, i2, r1	G.k.9.i.2.r.1	Source of Assessment
G	G.k.9.i.2.r	k1, i2, r1	G.k.9.i.2.r.1	
G	G.k.9.i.2.r	k1, i2, r1	G.k.9.i.2.r.1	
G	G.k.9.i.2.r	k1, i2, r1	G.k.9.i.2.r.1	
G	G.k.9.i.2.r	k1, i2, r1		
G	G.k.9.i.2.r	k1, i2, r1		
G	G.k.9.i.2.r	k1, i2, r1		Event ID
G	G.k.9.i.2.r	k1, i2, r1		
G	G.k.9.i.2.r	k1, i2, r1		
G	G.k.9.i.2.r	k1, i2, r1		drug ID
G	G.k.9.i.2.r	k1, i2, r1		
G	G.k.9.i.2.r	k1, i2, r1		
G	G.k.9.i.2.r	k1, i2, r1		
G	G.k.9.i.2.r	k2, i2, r1		
G	G.k.9.i.2.r	k2, i2, r1		
G	G.k.9.i.2.r	k2, i2, r1		2.1.1.19
G	G.k.9.i.2.r	k2, i2, r1	G.k.9.i.2.r.3	Result of Assessment
G	G.k.9.i.2.r	k2, i2, r1	G.k.9.i.2.r.2	
G	G.k.9.i.2.r	k2, i2, r1	G.k.9.i.2.r.2	Method of Assessment

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G	G.k.9.i.2.r	k2, i2, r1	G.k.9.i.2.r.1		
G	G.k.9.i.2.r	k2, i2, r1	G.k.9.i.2.r.1		
G	G.k.9.i.2.r	k2, i2, r1	G.k.9.i.2.r.1	G.k.9.i.2.r.1	Source of Assessment
G	G.k.9.i.2.r	k2, i2, r1	G.k.9.i.2.r.1		
G	G.k.9.i.2.r	k2, i2, r1	G.k.9.i.2.r.1		
G	G.k.9.i.2.r	k2, i2, r1	G.k.9.i.2.r.1		
G	G.k.9.i.2.r	k2, i2, r1	G.k.9.i.2.r.1		
G	G.k.9.i.2.r	k2, i2, r1			Event ID
G	G.k.9.i.2.r	k2, i2, r1			
G	G.k.9.i.2.r	k2, i2, r1			drug ID
G	G.k.9.i.2.r	k2, i2, r1			
G	G.k.9.i.2.r	k2, i2, r1			
G	G.k.9.i.2.r	k2, i2, r2			
G	G.k.9.i.2.r	k2, i2, r2			
G	G.k.9.i.2.r	k2, i2, r2		2.1.1.19	
G	G.k.9.i.2.r	k2, i2, r2	G.k.9.i.2.r.3	G.k.9.i.2.r.3	Result of Assessment
G	G.k.9.i.2.r	k2, i2, r2	G.k.9.i.2.r.2		
G	G.k.9.i.2.r	k2, i2, r2	G.k.9.i.2.r.2	G.k.9.i.2.r.2	Method of Assessment
G	G.k.9.i.2.r	k2, i2, r2	G.k.9.i.2.r.2		
G	G.k.9.i.2.r	k2, i2, r2	G.k.9.i.2.r.1		
G	G.k.9.i.2.r	k2, i2, r2	G.k.9.i.2.r.1		
G	G.k.9.i.2.r	k2, i2, r2	G.k.9.i.2.r.1	G.k.9.i.2.r.1	Source of Assessment
G	G.k.9.i.2.r	k2, i2, r2	G.k.9.i.2.r.1		
G	G.k.9.i.2.r	k2, i2, r2	G.k.9.i.2.r.1		
G	G.k.9.i.2.r	k2, i2, r2	G.k.9.i.2.r.1		
G	G.k.9.i.2.r	k2, i2, r2			Event ID
G	G.k.9.i.2.r	k2, i2, r2			
G	G.k.9.i.2.r	k2, i2, r2			drug ID
G	G.k.9.i.2.r	k2, i2, r2			
G	G.k.9.i.2.r	k2, i2, r2			
G	G.k.9.i.2.r	k2, i2, r2			
G	G.k.9.i.2.r	k2, i2, r2			
H			H.2		
H			H.2		
H			H.2	2.1.1.19	
H			H.2	H.2	Reporter's Comments
H			H.2		
H			H.2		
H			H.2	2.1.1.21	
H			H.2		
H			H.2		
H			H.2		
H			H.2		

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  </adverseEffectReference>
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  </productUseReference>
</subject2>
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    <value xsi:type="ED">H.2</value>
  </observationEvent>
  <author typeCode="AUT">
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    </assignedEntity>
  </author>
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H	H.3.r	R1	H.3.r.1				
H	H.3.r	R1	H.3.r.1				2.1.1.19
H	H.3.r	R1	H.3.r.1	H.3.r.1a	MedDRA Version for Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event	H.3.r.1b	2.16.840.1.113883.6.163
H	H.3.r	R1	H.3.r.1				
H	H.3.r	R1	H.3.r.1				
H	H.3.r	R1	H.3.r.1				2.1.1.21
H	H.3.r	R1	H.3.r.1				
H	H.3.r	R1	H.3.r.1				
H	H.3.r	R1	H.3.r.1				
H	H.3.r	R2	H.3.r.1				
H	H.3.r	R2	H.3.r.1				
H	H.3.r	R2	H.3.r.1				2.1.1.19
H	H.3.r	R2	H.3.r.1	H.3.r.1a	MedDRA Version for Sender's Diagnosis / Syndrome and / or Reclassification of Reaction / Event	H.3.r.1b	2.16.840.1.113883.6.163
H	H.3.r	R2	H.3.r.1				
H	H.3.r	R2	H.3.r.1				
H	H.3.r	R2	H.3.r.1				2.1.1.21
H	H.3.r	R2	H.3.r.1				
H	H.3.r	R2	H.3.r.1				
H	H.3.r	R2	H.3.r.1				
H			H.4				
H			H.4				
H			H.4				2.1.1.19
H			H.4	H.4	Sender's Comments		
H			H.4				
H			H.4				
H			H.4				2.1.1.21
H			H.4				
H			H.4				
H			H.4				
C			C.1.6.1				
C			C.1.6.1				
C			C.1.6.1				2.1.1.19
C			C.1.6.1	C.1.6.1	Are Additional Documents Available?		
C			C.1.6.1				
C			C.1.6.1				
C			C.1.7				
C			C.1.7				
C			C.1.7				2.1.1.19
C			C.1.7	C.1.7	Does this Case Fulfill the Local Criteria for an Expedited Report?		
C			C.1.7				
C			C.1.7				
H	H.5.r	R1	H.5.r.1				
H	H.5.r	R1	H.5.r.1				

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  </observationEvent>
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  </author>
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H	H.5.r	R1	H.5.r.1				
H	H.5.r	R1	H.5.r.1				
H	H.5.r	R1	H.5.r.1				2.1.1.21
H	H.5.r	R1	H.5.r.1				
H	H.5.r	R1	H.5.r.1				
H	H.5.r	R1	H.5.r.1				
H	H.5.r	R2	H.5.r.1				
H	H.5.r	R2	H.5.r.1				2.1.1.19
H	H.5.r	R2	H.5.r.1	H.5.r.1a	Case Summary and Reporter's Comments Text	H.5.r.1b	Case Summary and Reporter's Comments Language
H	H.5.r	R2	H.5.r.1				
H	H.5.r	R2	H.5.r.1				
H	H.5.r	R2	H.5.r.1				2.1.1.21
H	H.5.r	R2	H.5.r.1				
H	H.5.r	R2	H.5.r.1				
C			C.1.8.2				
C			C.1.8.2				
C			C.1.8.2				2.1.1.22
C			C.1.8.2				
C			C.1.8.2				
C			C.1.8.2				
C			C.1.8.2	C.1.8.2	First Sender of this Case		2.1.1.3
C			C.1.8.2				
C			C.1.8.2				
C			C.1.8.2				
C			C.1.8.2				
C			C.1.8.2				
C	C.1.10.r	R1	C.1.10.r				
C	C.1.10.r	R1	C.1.10.r				
C	C.1.10.r	R1	C.1.10.r				
C	C.1.10.r	R1	C.1.10.r				
C	C.1.10.r	R1	C.1.10.r	C.1.10.r	Identification Number of the Report Which Is Linked to this Report		2.1.3.2
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C	C.1.10.r	R1	C.1.10.r				
C	C.1.10.r	R1	C.1.10.r				
C	C.1.10.r	R2	C.1.10.r				
C	C.1.10.r	R2	C.1.10.r				
C	C.1.10.r	R2	C.1.10.r				
C	C.1.10.r	R2	C.1.10.r				
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C	C.1.10.r	R2	C.1.10.r		
C	C.2.r	R1			
C	C.2.r	R1	C.2.r.5	C.2.r.5	Primary Source for Regulatory Purposes
C	C.2.r	R1			
C	C.2.r	R1			2.1.1.22
C	C.2.r	R1			
C	C.2.r	R1			
C	C.2.r	R1			
C	C.2.r	R1			
C	C.2.r	R1	C.2.r.2.3, 4, 5, 6		
C	C.2.r	R1	C.2.r.2.3, 4, 5 C.2.r.2.3		Reporter's Street
C	C.2.r	R1	C.2.r.2.3, 4, 5 C.2.r.2.4		Reporter's City
C	C.2.r	R1	C.2.r.2.3, 4, 5 C.2.r.2.5		Reporter's State or Province
C	C.2.r	R1	C.2.r.2.3, 4, 5 C.2.r.2.6		Reporter's Postcode
C	C.2.r	R1	C.2.r.2.3, 4, 5, 6		
C	C.2.r	R1	G.2.r.2.7	G.2.r.2.7	Reporter's Telephone
C	C.2.r	R1			
C	C.2.r	R1	C.2.r.1.1, 2, 3, 4		
C	C.2.r	R1	C.2.r.1.1, 2, 3 C.2.r.1.1		Reporter's Title
C	C.2.r	R1	C.2.r.1.1, 2, 3 C.2.r.1.2		Reporter's Given Name
C	C.2.r	R1	C.2.r.1.1, 2, 3 C.2.r.1.3		Reporter's Middle Name
C	C.2.r	R1	C.2.r.1.1, 2, 3 C.2.r.1.4		Reporter's Family Name
C	C.2.r	R1	C.2.r.1.1, 2, 3, 4		
C	C.2.r	R1	C.2.r.4		
C	C.2.r	R1	C.2.r.4	C.2.r.4	Qualification
C	C.2.r	R1	C.2.r.4		2.1.1.6
C	C.2.r	R1	C.2.r.3		
C	C.2.r	R1	C.2.r.3		
C	C.2.r	R1	C.2.r.3	G.2.r.3	Reporter's Country Code
C	C.2.r	R1	C.2.r.3		1.0.3166.1.2.2
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C	C.2.r	R1			
C	C.2.r	R1			
C	C.2.r	R1	C.2.r.2.2	C.2.r.2.2	Reporter's Department
C	C.2.r	R1	C.2.r.2.1		
C	C.2.r	R1	C.2.r.2.1		
C	C.2.r	R1	C.2.r.2.1	C.2.r.2.1	Reporter's Organisation
C	C.2.r	R1	C.2.r.2.1		
C	C.2.r	R1	C.2.r.2.1		
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C	C.2.r	R1			
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C	C.2.r	R1			
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C	C.2.r	R2			
C	C.2.r	R2			

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C			C.3.3.2, 3, 4, C.3.3.4	Sender's Middle Name		
C			C.3.3.2, 3, 4, C.3.3.5	Sender's Family Name		
C			C.3.3.2, 3, 4, 5			
C			C.3.4.5			
C			C.3.4.5			
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C			C.3.4.5			

C						
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C			C.3.2			
C			C.3.2			
C			C.3.2	C.3.2	Sender's Organisation	
C			C.3.2			
C			C.3.2			

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C	C.1.9.1.r	R2	C.1.9.1.r.1, 2			
C	C.1.9.1.r	R2	C.1.9.1.r.1, 2	C.1.9.1.r.1	Source(s) of the Case Identifier	C.1.9.1.r.2 Case Identifier(s) 2.1.3.3
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C	C.1.9.1.r	R2	C.1.9.1.r.1, 2			

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C			C.1.3			
C			C.1.3			
C			C.1.3	C.1.3	TypeofReport	2.1.1.23 2.1.1.2
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C			C.1.3			

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C			C.1.9.1			
C			C.1.9.1			2.1.1.23
C			C.1.9.1	C.1.9.1	OtherCaseIdentifiersinPreviousTransmissions	
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C			C.1.9.1			

C			C.1.11.1			
C			C.1.11.1			
C			C.1.11.1			2.1.1.23
C			C.1.11.1	C.1.11.1	Report Nullification /	2.1.1.5
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C			C.1.11.2			

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C				
C				
C				
C				
N.1	N.1.4			
N.1	N.1.4			
N.1	N.1.4	N.1.4	Batch Receiver Identifier	2.1.3.14
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N.1	N.1.3			
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