

```

<!--
INDIVIDUAL CASE SAFETY REPORT
XML DOCUMENT TYPE DEFINITION VERSION 2.1
-->

<!-- ===== -->
<!-- Entities -->
<!-- ===== -->
<!-- Use the lang attribute to indicate the language of an elements
      content via an ISO 639 language Code.
-->
<!ENTITY % lang.att "lang CDATA #IMPLIED">
<!-- Standard Character Entities to escape SGML special characters.
      When "<", ">", and "&" occur in text, they should be replaced
      by "&lt;", "&gt;", and "&amp;" respectively.
-->
<!-- Less Than "<" -->
<!ENTITY lt "&#38;#60;">
<!-- Greater Than ">" -->
<!ENTITY gt "&#62;">
<!-- Ampersand "&" -->
<!ENTITY amp "&#38;#38;">
<!-- ===== -->
<!-- Elements and Attributes -->
<!-- ===== -->
<!ELEMENT ichicsr (ichicsrmessageheader, safetyreport+)>
<!ATTLIST ichicsr
      lang CDATA #REQUIRED
>
<!-- M.1 ICH ICSR Message Header Information -->
<!ELEMENT ichicsrmessageheader (messagetype, messageformatversion,
messageformatrelease, messagenumb, messagesenderidentifier,
messagereceiveridentifier, messagedateformat, messagedate)>
<!ATTLIST ichicsrmessageheader
      %lang.att;
>
<!--
Field ref:  M.1.1
Field title:      Message Type
Field name: messagetype
Field length:    16AN
Field values:    icshr
-->
<!ELEMENT messagetype (#PCDATA)>
<!ATTLIST messagetype
      %lang.att;
>
<!--
Field ref:  M.1.2
Field title:      Message Format Version
Field name: messageformatversion
Field length:    3AN
Field values:
Comment :   In Step 4 ICSR DTD version 2.1, this field will have value "2".
-->
<!ELEMENT messageformatversion (#PCDATA)>
<!ATTLIST messageformatversion

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```
        %lang.att;
>
<!--
Field ref:  M.1.3
Field title:      Message Format Release
Field name: messageformatrelease
Field length:    3AN
Comment :   In Step 4 ICSR DTD version 2.1, this field will have value "1".
-->
<!ELEMENT messageformatrelease (#PCDATA)>
<!ATTLIST messageformatrelease
        %lang.att;
>
<!--
Field ref:  M.1.4
Field title:      Message Number
Field name: messagenumb
Field length:    100AN
Comment :   This field is important for the efficient tracking of Reports. Since
the SafetyReportID field is optional, the identification and acknowledgement of
safety reports must be done on the basis of the Message Number an the position
of each Safety Report in a Message.
Comment :   The Message Number is specific to one transmission between one
Sender and one Receiver.
-->
<!ELEMENT messagenumb (#PCDATA)>
<!ATTLIST messagenumb
        %lang.att;
>
<!--
Field ref:  M.1.5
Field title:      Message Sender Identifier
Field name: messagesenderidentifier
Field length:    60AN
Comment :   This field is of primary importance for efficient tracking of Safety
Reports. It permits a Receiver to define a Thread of Reports related to a Case
and to analyse the sequence of follow-ups. It is also required for the
acknowledgement of Reports.
Comment :   It should be a coded value agreed between correspondents through an
Interchange Agreement. Message not having pre-agreed values in this field should
be rejected.
-->
<!ELEMENT messagesenderidentifier (#PCDATA)>
<!ATTLIST messagesenderidentifier
        %lang.att;
>
<!--
Field ref:  M.1.6
Field title:      Message Receiver Identifier
Field name: messagereceiveridentifier
Field length:    60AN
-->
<!ELEMENT messagereceiveridentifier (#PCDATA)>
<!ATTLIST messagereceiveridentifier
        %lang.att;
>
<!--
```

Field ref: M.1.7.a  
Field title: Message Date Format  
Field name: messagedateformat  
Field length: 3N  
Field values: 204=CCYYMMDDHHMMSS  
-->  
<!ELEMENT messagedateformat (#PCDATA)>  
<!ATTLIST messagedateformat  
 %lang.att;  
>  
<!--

Field ref: M.1.7.b  
Field title: Message Date  
Field name: messagedate  
Field length: 14N  
-->  
<!ELEMENT messagedate (#PCDATA)>  
<!ATTLIST messagedate  
 %lang.att;  
>

<!-- Individual Case Safety Report(s) Specifications -->  
<!--

Entity ref: A.1

Entity title: SAFETY REPORT

Entity name: safetyreport

Comment : The following fields are specific to the Report and should be considered as a Report Header: safetyreportid, safetyreportversion, transmissiondateformat, transmissiondate, receivedateformat, receivedate, sender, receiver. A Sender may change the contents of these fields without altering the contents of the Report associated to a Case. In this case, the Sender acts as a Relay.

Comment : Any change in the other fields generates a new Report. The Sender acts as an Author.

Comment : At present, there is no way to identify when the Sender acts as Relay or as Author, the ReceiptDate being insufficient for this purpose. This would require that the Sender would highlight the fields added, deleted or modified from a Report they received. This function was discussed by the ICH M2 EWG and may be introduced in the future as part of the message specification. The Receiver must compare subsequent Reports within one thread and between threads.

Comment : The relational model of the Safety Report is described in the following figure:

Comment : One and only one of the following fields should be populated:

A.1.10.1 - National regulatory authority's case report number

A.1.10.2 - Company's case report number

A.1.10.3 - Other sender's case report number

Comment : While the Case Number (A.1.10) is used to identify a Case and is fixed by the Case Author, the Report Identifier is used to facilitate the communication between two correspondents: Sender and Receiver. Being the safetyreportid and safetyreportversion optional fields, the Sender may choose among the following identification policies:

a.- not to specify safetyreportid. In this case, the reference to the report is done on the basis of the messagenumber and the position of the Report in the

Message (the third report in the message. The acknowledgement will follow this identification policy).

b.- to specify the Report Number (safetyreportid) but not to specify the Report Version (safetyreportversion). The Report Number is the number given by the Sender to the report, as opposed to the Case Number, given by the original Case author. As indicated by the ICH E2B EWG, the ReceiptDate may be used to locate the report in the sequence of follow-ups related to a Case, or more specifically to a Thread.

c.- to specify the Report Number (safetyreportid) and the Report Version (safetyreportversion). This may be done by Case authors not interested in keeping the historic but interested in keeping track of the number of follow-ups transmitted.

Comment : A possible flow of reports is described in the following picture. The fact that the Case Number (CN) remains the same makes it possible to recognise that the three reports respond to the same Case (MN: message number, RN: report number, LRN: Local Report Number, CN: case number).

-->

```
<!ELEMENT safetyreport (safetyreportversion?, safetyreportid,
primarysourcecountry?, occurcountry?, transmissiondateformat?,
transmissiondate?, reporttype?, serious?, seriousnessdeath?,
seriousnesslifethreatening?, seriousnesshospitalization?, seriousnessdisabling?,
seriousnesscongenitalanomaly?, seriousnessother?, receivedateformat?,
receivedate?, receiptdateformat?, receiptdate?, additionaldocument?,
documentlist?, fulfillexpeditecriteria?, authoritynumb?, companynumb?,
duplicate?, casenullification?, nullificationreason?, medicallyconfirm?,
(reportduplicate*, linkedreport*, primarysource+, sender, receiver, patient))>
```

```
<!ATTLIST safetyreport
```

```
    %lang.att;
```

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>
```

```
<!--
```

```
Entity ref:
```

```
Entity title:      REPORT DUPLICATE
```

```
Entity name:       reportduplicate
```

```
Comment : This repeatable entity will be present whenever duplicate is set to "yes".
```

```
Comment : A possible scenario for the use of reportduplicate is the following (MN: message number, RN: report number, CN: case number):
```

-->

```
<!ELEMENT reportduplicate (duplicatesource?, duplicatenumb?)>
```

```
<!ATTLIST reportduplicate
```

```
    %lang.att;
```

```
>
```

```
<!--
```

```
Entity ref:
```

```
Entity title:      LINKED REPORT
```

```
Entity name:       linkedreport
```

-->

```
<!ELEMENT linkedreport (linkreportnumb?)>
```

```
<!ATTLIST linkedreport
```

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    %lang.att;
```

```
>
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```
<!-- A.2 Primary source(s) of information -->
```

```
<!--
```

```
Entity ref: A.2
```

```
Entity title:      PRIMARY SOURCE
```

```
Entity name:       primarysource
```

```
Comment : The following fields must be populated:
```

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    A.2.1.1d reporterfamilyname
    A.2.1.2a reporterorganization
    A.2.1.2d reportercity
    A.2.1.3 reportercountry
    A.2.1.4 reporterqualification
-->
<!ELEMENT primarysource (reportertitle?, reportergivenname?, reportermiddlename?,
reporterfamilyname?, reporterorganization?, reporterdepartment?,
reporterstreet?, reportercity?, reporterstate?, reporterpostcode?,
reportercountry?, qualification?, literaturereference?, studyname?,
sponsorstudynumb?, observestudytype?)>
<!ATTLIST primarysource
    %lang.att;
>
<!-- A.3.1 Sender -->
<!--
Entity ref: A.3.1
Entity title:      SENDER
Entity name:       sender
Comment :   It has been discussed if Sender refers to the first sender or to the
last sender.
The reasons in favour of being the first sender include the following:
-the sender is already indicated at the message header level. -the additional
administrative information should be available in the data base of addresses of
the receiver.
-the sender block does not allow for a coded value: sender id identification
required for controlled transmission of safety reports.
-if the sender is the last sender, this require consistency checking for all the
reports in one message.
The reasons in favour of being the last sender include the following:
-there may be difference correspondents within the same sender organisation for
difference reports.
-spontaneous reporting may be done by non-registered correspondents.
-->
<!ELEMENT sender (sendertype?, senderorganization?, senderdepartment?,
sendertitle?, sendergivenname?, sendermiddlename?, senderfamilyname?,
senderstreetaddress?, sendercity?, senderstate?, senderpostcode?,
sendercountrycode?, sendertel?, sendertelextension?, sendertelcountrycode?,
senderfax?, senderfaxextension?, senderfaxcountrycode?, senderemailaddress?)>
<!ATTLIST sender
    %lang.att;
>
<!-- A.3.2 Receiver -->
<!--
Entity ref: A.3.2
Entity title:      RECEIVER
Entity name:       receiver
-->
<!ELEMENT receiver (receivertype?, receiverorganization?, receiverdepartment?,
receivertitle?, receivergivenname?, receivermiddlename?, receiverfamilyname?,
receiverstreetaddress?, receivercity?, receiverstate?, receiverpostcode?,
receivercountrycode?, receivertel?, receivertelextension?,
receivertelcountrycode?, receiverfax?, receiverfaxextension?,
receiverfaxcountrycode?, receiveremailaddress?)>
<!ATTLIST receiver
    %lang.att;
>

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<!-- B.1 Patient characteristics -->
<!--
Entity ref: B.1
Entity title:      PATIENT
Entity name:       patient
Comment :         There must be one and only one Patient entity in one Safety Report.
Comment :         At least one of the following fields must be populated:
B.1.1 - Patient initials
B.1.1.1a - GP medical record number
B.1.1.1b - Specialist record number
B.1.1.1c - Hospital record number
B.1.1.1d - Patient investigation number
B.1.2.1 - Date of Birth
B.1.2.2a - Age value at time of onset reaction/event
B.1.2.3 - Patient age group
B.1.5 - Sex
-->
<!ELEMENT patient (patientinitial?, patientgpmmedicalrecordnumb?,
patientspecialistrecordnumb?, patienthospitalrecordnumb?,
patientinvestigationnumb?, patientbirthdateformat?, patientbirthdate?,
patientonsetage?, patientonsetageunit?, gestationperiod?, gestationperiodunit?,
patientagegroup?, patientweight?, patientheight?, patientsex?,
lastmenstrualdateformat?, patientlastmenstrualdate?, patientmedicalhistorytext?,
resultstestsprocedures?, (medicalhistoryepisode*, patientpastdrugtherapy*,
patientdeath?, parent?, reaction+, test*, drug+, summary?))>
<!ATTLIST patient
        %lang.att;
>
<!-- B.1.7 Relevant medical history and concurrent -->
<!--
Entity ref: B.1.7
Entity title:      RELEVANT MEDICAL HISTORY EPISODE
Entity name:       medicalhistoryepisode
-->
<!ELEMENT medicalhistoryepisode (patientepisodenamemeddraversion?,
patientepisodename?, patientmedicalstartdateformat?, patientmedicalstartdate?,
patientmedicalcontinue?, patientmedicalenddateformat?, patientmedicalenddate?,
patientmedicalcomment?)>
<!ATTLIST medicalhistoryepisode
        %lang.att;
>
<!-- B.1.8 Relevant past drug history -->
<!--
Entity ref: B.1.8
Entity title:      RELEVANT PAST DRUG HISTORY
Entity name:       patientpastdrugtherapy
-->
<!ELEMENT patientpastdrugtherapy (patientdrugname?, patientdrugstartdateformat?,
patientdrugstartdate?, patientdrugenddateformat?, patientdrugenddate?,
patientindicationmeddraversion?, patientdrugindication?,
patientdrugreactionmeddraversion?, patientdrugreaction?)>
<!ATTLIST patientpastdrugtherapy
        %lang.att;
>
<!-- B.1.9 In case of death: -->
<!--
Entity ref: B.1.9

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Entity title:      PATIENT DEATH
Entity name:       patientdeath
Comment :   This entity contains the fields and entities relevant to the case in
with death took place.
-->
<!ELEMENT patientdeath (patientdeathdateformat?, patientdeathdate?,
patientautopsyyesno?, (patientdeathcause*, patientautopsy*))>
<!ATTLIST patientdeath
        %lang.att;
>
<!--
Entity ref:
Entity title:      CAUSE OF PATIENT DEATH
Entity name:       patientdeathcause
-->
<!ELEMENT patientdeathcause (patientdeathreportmeddraversion?,
patientdeathreport?)>
<!ATTLIST patientdeathcause
        %lang.att;
>
<!--
Entity ref:
Entity title:      PATIENT AUPTOPSY
Entity name:       patientautopsy
-->
<!ELEMENT patientautopsy (patientdetermautopsmeddraversion?,
patientdetermineautopsy?)>
<!ATTLIST patientautopsy
        %lang.att;
>
<!-- B.1.10 For a parent-child / fetus report, information concerning the
parent: -->
<!--
Entity ref: B.1.10
Entity title:      PARENT
Entity name:       parent
Comment :   Information concerning the parent for a parent-child / fetus report.
-->
<!ELEMENT parent (parentidentification?, parentbirthdateformat?,
parentbirthdate?, parentage?, parentageunit?, parentlastmenstrualdateformat?,
parentlastmenstrualdate?, parentweight?, parentheight?, parentsex?,
parentmedicalrelevanttext?, (parentmedicalhistoryepisode*,
parentpastdrugtherapy*))>
<!ATTLIST parent
        %lang.att;
>
<!-- B.1.10.7 Relevant medical history and concurrent conditions of parent -->
<!--
Entity ref: B.1.10.7
Entity title:      RELEVANT MEDICAL HISTORY
Entity name:       parentmedicalhistoryepisode
-->
<!ELEMENT parentmedicalhistoryepisode (parentmdepisodemeddraversion?,
parentmedicalepisodename?, parentmedicalstartdateformat?,
parentmedicalstartdate?, parentmedicalcontinue?, parentmedicalenddateformat?,
parentmedicalenddate?, parentmedicalcomment?)>
<!ATTLIST parentmedicalhistoryepisode

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```

        %lang.att;
>
<!-- B.1.10.8 Relevant past drug history -->
<!--
Entity ref: B.1.10.8
Entity title:      PARENT PAST DRUG THERAPY
Entity name:       parentpastdrugtherapy
Comment :    Relevant past drug history.
-->
<!ELEMENT parentpastdrugtherapy (parentdrugname?, parentdrugstartdateformat?,
parentdrugstartdate?, parentdrugenddateformat?, parentdrugenddate?,
parentdrugindicationmeddraversion?, parentdrugindication?,
parentdrugreactionmeddraversion?, parentdrugreaction?)>
<!ATTLIST parentpastdrugtherapy
        %lang.att;
>
<!-- B.2 Reaction(s) / Event(s) -->
<!--
Entity ref: B.2
Entity title:      REACTION
Entity name:       reaction
Comment :    The following field must be populated:
B.2.i.2 - Reaction term
This field should be a valid MedDRA 2.1 or superior LLT
-->
<!ELEMENT reaction (primarysource?reaction?, reactionmeddraversionllt?,
reactionmeddrallt?, reactionmeddraversionpt?, reactionmeddrapt?,
termhighlighted?, reactionstartdateformat?, reactionstartdate?,
reactionenddateformat?, reactionenddate?, reactionduration?,
reactiondurationunit?, reactionfirsttime?, reactionfirsttimeunit?,
reactionlasttime?, reactionlasttimeunit?, reactionoutcome?)>
<!ATTLIST reaction
        %lang.att;
>
<!-- B.3 Results of tests and procedures relevant to the investigation of the
patient: -->
<!--
Entity ref: B.3
Entity title:      TEST
Entity name:       test
Comment :    Results of tests and procedures relevant to the investigation of the
patient.
-->
<!ELEMENT test (testdateformat?, testdate?, testname?, testresult?, testunit?,
lowtestrange?, hightestrange?, moreinformation?)>
<!ATTLIST test
        %lang.att;
>
<!--
Entity ref: B.4
Entity title:      DRUG
Entity name:       drug
Comment :    The following field should be populated:
B.4.k.2.1- Proprietary medicinal product name
-->
<!ELEMENT drug (drugcharacterization?, medicinalproduct?, obtaindrugcountry?,
drugbatchnumb?, drugauthorizationnumb?, drugauthorizationcountry?,

```



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drugauthorizationholder?, drugstructuredosagenumb?, drugstructuredosageunit?,
drugseparatedosagenumb?, drugintervaldosageunitnumb?,
drugintervaldosagedefinition?, drugcumulativedosagenumb?,
drugcumulativedosageunit?, drugdosagetext?, drugdosageform?,
drugadministrationroute?, drugparadministration?, reactiongestationperiod?,
reactiongestationperiodunit?, drugindicationmeddraversion?, drugindication?,
drugstartdateformat?, drugstartdate?, drugstartperiod?, drugstartperiodunit?,
druglastperiod?, druglastperiodunit?, drugenddateformat?, drugenddate?,
drugtreatmentduration?, drugtreatmentdurationunit?, actiondrug?,
drugrecurreadadministration?, drugadditional?, (activesubstance*, drugrecurrence*,
drugreactionrelatedness*)>
<!ATTLIST drug
    %lang.att;
>
<!--
Entity ref:
Entity title:    ACTIVE SUBSTANCE
Entity name:     activesubstance
-->
<!ELEMENT activesubstance (activesubstancename)>
<!ATTLIST activesubstance
    %lang.att;
>
<!--
Entity ref:
Entity title:    DRUG RECURRENCE
Entity name:     drugrecurrence
-->
<!ELEMENT drugrecurrence (drugrecuraactionmeddraversion?, drugrecuraaction)>
<!ATTLIST drugrecurrence
    %lang.att;
>
<!-- B.4.k.18 Relatedness of drug to reaction / event -->
<!--
Entity ref: B.4.k.18
Entity title:    RELATEDNESS OF DRUG TO REACTION / EVENT
Entity name:     drugreactionrelatedness
-->
<!ELEMENT drugreactionrelatedness (drugreactionassesmeddraversion?,
drugreactionasses?, drugassessmentsource?, drugassessmentmethod?, drugresult?)>
<!ATTLIST drugreactionrelatedness
    %lang.att;
>
<!-- B.5 Narrative case summary and further information: -->
<!--
Entity ref: B.5
Entity title:    NARRATIVE CASE SUMMARY
Entity name:     summary
-->
<!ELEMENT summary (narrativeincludeclinical?, reportercomment?,
senderdiagnosismeddraversion?, senderdiagnosis?, sendercomment?)>
<!ATTLIST summary
    %lang.att;
>
<!--
Block name:
Block ref:    A.1

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Block title:      REPORT IDENTIFICATION
-->
<!--
Field ref:
Field title:      Safety report version
Field name: safetyreportversion
Field length:     2AN
Comment : This field is optional. Receivers may re-create the version number
for a Report in a particular Thread on the basis of the Receipt Date (InfoDate).
-->
<!ELEMENT safetyreportversion (#PCDATA)>
<!ATTLIST safetyreportversion
        %lang.att;
>
<!--
Field ref:
Field title:      Safety report id identifier
Field name: safetyreportid
Field length:     100AN
Comment : This field contains the Report Number (report Id identifier) given
by a sender to a report. Contrary to the Case Number, that is given by the
creator of the Case and remains unchanged all through the life cycle of the
Case, and to the Message Number, that is given by the message sender and is
specific to one transmission between the Sender and one Receiver, the Report
Number is given by the Sender to one Report and is sent to as many
correspondents as required. All the receivers of the Report will refer to it by
the same number (or alternatively by the Message number and the sequential
position of the Report in the message).
Comment : At present, this field is optional. However, all the Senders should
have a consistent numbering system for reports.
Comment : Senders may choose by generating a new Report Number when data is
added or modified in the Report or by keeping the same Report Number and
increasing the Report Version.
-->
<!ELEMENT safetyreportid (#PCDATA)>
<!ATTLIST safetyreportid
        %lang.att;
>
<!-- A.1.1 Identification of the country of the primary -->
<!--
Field ref: A.1.1
Field title: Identification of the country of the primary.
Field name: primarysourcecountry
Field length: 2A
Field values: ISO3166
-->
<!ELEMENT primarysourcecountry (#PCDATA)>
<!ATTLIST primarysourcecountry
        %lang.att;
>
<!-- A.1.2 Identification of the country where the reaction / event occurred -->
<!--
Field ref: A.1.2
Field title: Identification of the country where the reaction / event
occurred
Field name: occurcountry
Field length: 2A

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```
Field values:      ISO3166
-->
<!ELEMENT occurcountry (#PCDATA)>
<!ATTLIST occurcountry
      %lang.att;
>
<!-- A.1.3a Date of this transmission format -->
<!--
Field ref:  A.1.3a
Field title:      Date format
Field name: transmissiondateformat
Field length:     3N
Field values:     102:CCYYMMDD
-->
<!ELEMENT transmissiondateformat (#PCDATA)>
<!ATTLIST transmissiondateformat
      %lang.att;
>
<!-- A.1.3b Date of this transmission -->
<!--
Field ref:  A.1.3b
Field title:      Date of this transmission
Field name: transmissiondate
Field length:     8N
Field values:     102:CCYYMMDD
Comment :   Must be indicated according to the date format.
-->
<!ELEMENT transmissiondate (#PCDATA)>
<!ATTLIST transmissiondate
      %lang.att;
>
<!-- A.1.4 Type of report -->
<!--
Field ref:  A.1.4
Field title:      Type of report
Field name: reporttype
Field length:     1N
Field values:
1=Spontaneous
2=Report from study
3=Other
4=Not available to sender (unknown)
-->
<!ELEMENT reporttype (#PCDATA)>
<!ATTLIST reporttype
      %lang.att;
>
<!-- A.1.5.1 Serious -->
<!--
Field ref:  A.1.5.1
Field title:      Serious
Field name: serious
Field length:     1N
Field values:
1=Yes
2=No
-->
```

```
<!ELEMENT serious (#PCDATA)>
<!ATTLIST serious
    %lang.att;
>
<!-- A.1.5.2 Seriousness criteria -->
<!--
Block ref: A.1.5.2
Block title:     SERIOUSNESS CRITERIA
Block name:
-->
<!--
Field ref: A.1.5.2a
Field title:     Results in death
Field name: seriousnessdeath
Field length:    1N
Field values:
1=Yes
2=No
-->
<!ELEMENT seriousnessdeath (#PCDATA)>
<!ATTLIST seriousnessdeath
    %lang.att;
>
<!--
Field ref: A.1.5.2b
Field title:     Life threatening
Field name: seriousnesslifethreatening
Field length:    1N
Field values:
1=Yes
2=No
-->
<!ELEMENT seriousnesslifethreatening (#PCDATA)>
<!ATTLIST seriousnesslifethreatening
    %lang.att;
>
<!--
Field ref: A.1.5.2c
Field title:     Caused/prolonged hospitalization
Field name: seriousnesshospitalization
Field length:    1N
Field values:
1=Yes
2=No
-->
<!ELEMENT seriousnesshospitalization (#PCDATA)>
<!ATTLIST seriousnesshospitalization
    %lang.att;
>
<!--
Field ref: A.1.5.2d
Field title:     Disabling/Incapacitating
Field name: seriousnessdisabling
Field length:    1N
Field values:
1=Yes
2=No
```

```

-->
<!ELEMENT seriousnessdisabling (#PCDATA)>
<!ATTLIST seriousnessdisabling
    %lang.att;
>
<!--
Field ref: A.1.5.2e
Field title: Congenital anomaly/birth defect
Field name: seriousnesscongenitalanomaly
Field length: 1N
Field values:
1=Yes
2=No
-->
<!ELEMENT seriousnesscongenitalanomaly (#PCDATA)>
<!ATTLIST seriousnesscongenitalanomaly
    %lang.att;
>
<!--
Field ref: A.1.5.2f
Field title: Other medically important condition
Field name: seriousnessother
Field length: 1N
Field values:
1=Yes
2=No
-->
<!ELEMENT seriousnessother (#PCDATA)>
<!ATTLIST seriousnessother
    %lang.att;
>
<!-- A.1.6a Date report was first received from source format -->
<!--
Field ref: A.1.6a
Field title: Date report was first received from source format
Field name: receivedateformat
Field length: 3N
Field values: 102=CCYYMMDD
-->
<!ELEMENT receivedateformat (#PCDATA)>
<!ATTLIST receivedateformat
    %lang.att;
>
<!-- A.1.6b Date report was first received from source -->
<!--
Field ref: A.1.6b
Field title: Date report was first received from source
Field name: receivedate
Field length: 8N
-->
<!ELEMENT receivedate (#PCDATA)>
<!ATTLIST receivedate
    %lang.att;
>
<!-- A.1.7a Date of receipt of the most recent information for this report -->
<!--
Field ref: A.1.7a

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```
Field title:      Date of receipt of the most recent information format
Field name: receiptdateformat
Field length:     3N
Field values:     102=CCYYMMDD
-->
<!ELEMENT receiptdateformat (#PCDATA)>
<!ATTLIST receiptdateformat
        %lang.att;
>
<!-- A.1.7b Date of receipt of the most recent information for this report -->
<!--
Field ref:  A.1.7b
Field title:      Date of receipt of the most recent information
Field name: receiptdate
Field length:     8N
Field values:     102=CCYYMMDD
Comment :  Mandatory field.
-->
<!ELEMENT receiptdate (#PCDATA)>
<!ATTLIST receiptdate
        %lang.att;
>
<!-- A.1.8.1 Are additional documents available -->
<!--
Field ref:  A.1.8.1
Field title:      Are additional documents available?
Field name: additionaldocument
Field length:     1N
Field values:
1=Yes
2=No
-->
<!ELEMENT additionaldocument (#PCDATA)>
<!ATTLIST additionaldocument
        %lang.att;
>
<!-- A.1.8.2 List of documents held by sender -->
<!--
Field ref:  A.1.8.2
Field title:      List of documents held by sender
Field name: documentlist
Field length:     100AN
-->
<!ELEMENT documentlist (#PCDATA)>
<!ATTLIST documentlist
        %lang.att;
>
<!-- A.1.9 Does this case fulfill the local criteria for an expedited report -->
<!--
Field ref:  A.1.9
Field title:      Does this case fulfill the local criteria for an expedited
report?
Field name: fulfillexpeditecriteria
Field length:     1N
Field values:
1=Yes
2=No
```

```

-->
<!ELEMENT fulfillexpeditecriteria (#PCDATA)>
<!ATTLIST fulfillexpeditecriteria
    %lang.att;
>
<!--
The A.1.10 - Report Identification Numbers must be populated as per the
following user guidance:

A.1.10.1 and A.1.10.2 are the identifiers given by a national regulatory
authority and by a company or other organisation, respectively. The contents of
A.1.10.1 or A.1.10.2 should be populated only once, and all of these three items
should remain unchanged for any transmissions subsequent to the original
transmission. That is to say, these fields must only be populated once by the
originator of the first transmission. Companies or other organisations should
ensure a single international report number (A.1.10.2) to facilitate the unique
identification of a report that may have been sent to many places and subject to
multiple transmissions. The contents of the fields A.1.10.1 and/or A.1.10.2
should first list A.1.1 - Identification of the country of primary source and
secondly list A.3.1.2 - Sender Identifier, Sender Organization, and lastly, the
company international case report number, delimited by hyphens.

For example, a report transmitted by a US company to a regulatory authority
would populate A.1.10.2 with "US-Company Name-12345", where "12345" is the
company's unique case report number. In the event that the regulatory authority
transmitted this ICSR to another regulatory authority, A.1.10.2 would remain the
same. The regulatory authority would not populate A.1.10.1.

If the situation occurs where multiple reports are received about the same case,
such as a report from a physician and a report from another company, the
information may be merged. One number will be maintained as the case number in
its original field and the second number will be listed as a suspected
duplicate.
-->
<!-- A.1.10.1 National regulatory authority's case report number -->
<!--
Field ref:  A.1.10.1
Field title:      National regulatory authority's case report number
Field name:  authoritynumb
Field length:    100AN
-->
<!ELEMENT authoritynumb (#PCDATA)>
<!ATTLIST authoritynumb
    %lang.att;
>
<!-- A.1.10.2 Company's case report number -->
<!--
Field ref:  A.1.10.2
Field title:      Company's case report number
Field name:  companynumb
Field length:    100AN
-->
<!ELEMENT companynumb (#PCDATA)>
<!ATTLIST companynumb
    %lang.att;
>
<!-- A.1.11 Suspected duplicate -->

```

```

<!--
Field ref: A.1.11
Field title: Suspected duplicate : Are there duplicates?
Field name: duplicate
Field length: 1N
Field values: 1=YES
-->
<!ELEMENT duplicate (#PCDATA)>
<!ATTLIST duplicate
    %lang.att;
>
<!-- A.1.11.1 Source of the duplicate -->
<!--
Field ref: A.1.11.1
Field title: Source of the duplicate
Field name: duplicatesource
Field length: 50AN
-->
<!ELEMENT duplicatesource (#PCDATA)>
<!ATTLIST duplicatesource
    %lang.att;
>
<!-- A.1.11.2 Case report number of the suspected duplicate -->
<!--
Field ref: A.1.11.2
Field title: Case report number of the suspected duplicate
Field name: duplicatenumb
Field length: 100AN
Field values:
-->
<!ELEMENT duplicatenumb (#PCDATA)>
<!ATTLIST duplicatenumb
    %lang.att;
>
<!-- A.1.12 Identification number of the report which is linked to this report -
->
<!--
Field ref: A.1.12
Field title: Identification number of the report which is linked to this
report
Field name: linkreportnumb
Field length: 100AN
Field values:
-->
<!ELEMENT linkreportnumb (#PCDATA)>
<!ATTLIST linkreportnumb
    %lang.att;
>
<!-- A.1.13 Report nullification -->
<!--
Field ref: A.1.13
Field title: Report nullification
Field name: casenullification.
Field length: 1N
Field values: 1=YES
-->
<!ELEMENT casenullification (#PCDATA)>

```



```
<!ATTLIST casenullification
    %lang.att;
>
<!-- A.1.13.1 Reason for nullification -->
<!--
Field ref: A.1.13.1
Field title: Reason for nullification
Field name: nullificationreason
Field length: 200AN
Field values:
-->
<!ELEMENT nullificationreason (#PCDATA)>
<!ATTLIST nullificationreason
    %lang.att;
>
<!-- A.1.14 Was the case medically confirmed, if not initially from health
professional? -->
<!--
Field ref: A.1.14
Field title: Was the case medically confirmed, if not initially from health
professional?
Field name: medicallyconfirm
Field length: 1N
Field values:
1=Yes
2=No
-->
<!ELEMENT medicallyconfirm (#PCDATA)>
<!ATTLIST medicallyconfirm
    %lang.att;
>
<!-- A.2.1.1a Reporter identifier -->
<!--
Field ref: A.2.1.1a
Field title: Reporter's title
Field name: reportertitle
Field length: 10AN
Field values:
-->
<!ELEMENT reportertitle (#PCDATA)>
<!ATTLIST reportertitle
    %lang.att;
>
<!-- A.2.1.1b Reporter identifier -->
<!--
Field ref: A.2.1.1b
Field title: Reporter's given name
Field name: reportergivenname
Field length: 35AN
-->
<!ELEMENT reportergivenname (#PCDATA)>
<!ATTLIST reportergivenname
    %lang.att;
>
<!-- A.2.1.1c Reporter identifier -->
<!--
Field ref: A.2.1.1c
```

```
Field title:      Reporter's middle name
Field name: reportermiddlename
Field length:    15AN
-->
<!ELEMENT reportermiddlename (#PCDATA)>
<!ATTLIST reportermiddlename
        %lang.att;
>
<!-- A.2.1.1d Reporter identifier -->
<!--
Field ref:  A.2.1.1d
Field title:      Reporter's family name
Field name: reporterfamilyname
Field length:    35AN
Field values:
-->
<!ELEMENT reporterfamilyname (#PCDATA)>
<!ATTLIST reporterfamilyname
        %lang.att;
>
<!-- A.2.1.2a Reporter's address -->
<!--
Field ref:  A.2.1.2a
Field title:      Reporter's organization
Field name: reporterorganization
Field length:    60AN
Field values:
-->
<!ELEMENT reporterorganization (#PCDATA)>
<!ATTLIST reporterorganization
        %lang.att;
>
<!-- A.2.1.2b Reporter's address -->
<!--
Field ref:  A.2.1.2.b
Field title:      Reporter's department
Field name: reporterdepartment
Field length:    60AN
Field values:
-->
<!ELEMENT reporterdepartment (#PCDATA)>
<!ATTLIST reporterdepartment
        %lang.att;
>
<!-- A.2.1.2c Reporter's address -->
<!--
Field ref:  A.2.1.2.c
Field title:      Reporter's street
Field name: reporterstreet
Field length:    60AN
Field values:
-->
<!ELEMENT reporterstreet (#PCDATA)>
<!ATTLIST reporterstreet
        %lang.att;
>
<!-- A.2.1.2d Reporter's address -->
```

```
<!--
Field ref: A.2.1.2.d
Field title: Reporter's city
Field name: reportercity
Field length: 35AN
Field values:
-->
<!ELEMENT reportercity (#PCDATA)>
<!ATTLIST reportercity
    %lang.att;
>
<!-- A.2.1.2e Reporter's address -->
<!--
Field ref: A.2.1.2.e
Field title: Reporter's state or province
Field name: reporterstate
Field length: 40AN
Field values:
-->
<!ELEMENT reporterstate (#PCDATA)>
<!ATTLIST reporterstate
    %lang.att;
>
<!-- A.2.1.2f Reporter's address -->
<!--
Field ref: A.2.1.2.f
Field title: Reporter's post code
Field name: reporterpostcode
Field length: 15AN
Field values:
-->
<!ELEMENT reporterpostcode (#PCDATA)>
<!ATTLIST reporterpostcode
    %lang.att;
>
<!-- A.2.1.3 Country -->
<!--
Field ref: A.2.1.3
Field title: Reporter's country
Field name: reportercountry
Field length: 2A
Field values: ISO3166
-->
<!ELEMENT reportercountry (#PCDATA)>
<!ATTLIST reportercountry
    %lang.att;
>
<!-- A.2.1.4 Qualification -->
<!--
Field ref: A.2.1.4
Field title: Reporter's qualification
Field name: qualification
Field length: 1N
Field values:
1=Physician7
2=Pharmacist
3=Other Health Professional
```

```
4=Lawyer
5=Consumer or other non health professional
-->
<!ELEMENT qualification (#PCDATA)>
<!ATTLIST qualification
    %lang.att;
>
<!-- A.2.2 Literature reference(s) -->
<!--
Field ref: A.2.2
Field title: Literature reference(s)
Field name: literaturereference
Field length: 500AN
Field values:
-->
<!ELEMENT literaturereference (#PCDATA)>
<!ATTLIST literaturereference
    %lang.att;
>
<!-- A.2.3.1 Study name -->
<!--
Field ref: A.2.3.1
Field title: Study name
Field name: studyname
Field length: 100AN
Field values:
-->
<!ELEMENT studyname (#PCDATA)>
<!ATTLIST studyname
    %lang.att;
>
<!-- A.2.3.2 Sponsor study number -->
<!--
Field ref: A.2.3.2
Field title: Sponsor study number
Field name: sponsorstudynumb
Field length: 35AN
Field values:

-->
<!ELEMENT sponsorstudynumb (#PCDATA)>
<!ATTLIST sponsorstudynumb
    %lang.att;
>
<!-- A.2.3.3 Study type in which the reactions / events were observed -->
<!--
Field ref: A.2.3.3
Field title: Study type in which the reactions / events were observed
Field name: observestudytype
Field length: 1N
Field values:
1=Clinical trials
2=Individual patient use
3=Other studies
-->
<!ELEMENT observestudytype (#PCDATA)>
<!ATTLIST observestudytype
```

```

        %lang.att;
>
<!-- A.3.1.1 Sender type -->
<!--
Field ref: A.3.1.1
Field title: Sender type
Field name: sendertype
Field length: 1N
Field values:
1=Pharmaceutical Company
2=Regulatory Authority
3=Health professional
4=Regional Pharmacovigilance Center
5=WHO Collaborating Center for International Drug Monitoring
6=Other
-->
<!ELEMENT sendertype (#PCDATA)>
<!ATTLIST sendertype
        %lang.att;
>
<!-- A.3.1.2 Sender organization -->
<!--
Field ref: A.3.1.2
Field title: Sender's organization
Field name: senderorganization
Field length: 60AN
Field values:
Comment : Mandatory field. The contents of this field must be previously
agreed and specified in the Interchange Agreement.-->
<!ELEMENT senderorganization (#PCDATA)>
<!ATTLIST senderorganization
        %lang.att;
>
<!-- A.3.1.3a Person responsible for sending the report -->
<!--
Field ref: A.3.1.3a
Field title: Sender's department
Field name: senderdepartment
Field length: 60AN
Field values:
-->
<!ELEMENT senderdepartment (#PCDATA)>
<!ATTLIST senderdepartment
        %lang.att;
>
<!-- A.3.1.3b Person responsible for sending the report -->
<!--
Field ref: A.3.1.3b
Field title: Sender's title
Field name: sendertitle
Field length: 10AN
Field values:
-->
<!ELEMENT sendertitle (#PCDATA)>
<!ATTLIST sendertitle
        %lang.att;
>

```

```
<!-- A.3.1.3c Person responsible for sending the report -->
<!--
Field ref: A.3.1.3c
Field title: Sender's given name
Field name: sendergivenname
Field length: 35AN
Field values:
-->
<!ELEMENT sendergivenname (#PCDATA)>
<!ATTLIST sendergivenname
    %lang.att;
>
<!-- A.3.1.3d Person responsible for sending the report -->
<!--
Field ref: A.3.1.3d
Field title: Sender's middle name
Field name: sendermiddlename
Field length: 15AN
Field values:
-->
<!ELEMENT sendermiddlename (#PCDATA)>
<!ATTLIST sendermiddlename
    %lang.att;
>
<!-- A.3.1.3e Person responsible for sending the report -->
<!--
Field ref: A.3.1.3e
Field title: Sender's family name
Field name: senderfamilyname
Field length: 35AN
Field values:
-->
<!ELEMENT senderfamilyname (#PCDATA)>
<!ATTLIST senderfamilyname
    %lang.att;
>
<!-- A.3.1.4a Address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.1.4a
Field title: Sender's street address
Field name: senderstreetaddress
Field length: 40AN
Field values:
-->
<!ELEMENT senderstreetaddress (#PCDATA)>
<!ATTLIST senderstreetaddress
    %lang.att;
>
<!-- A.3.1.4b Address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.1.4b
Field title: Sender's city
Field name: sendercity
Field length: 35AN
Field values:
-->
<!ELEMENT sendercity (#PCDATA)>
```

```
<!ATTLIST sendercity
    %lang.att;
>
<!-- A.3.1.4c Address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.1.4c
Field title: Sender's state or province
Field name: senderstate
Field length: 40AN
Field values:
-->
<!ELEMENT senderstate (#PCDATA)>
<!ATTLIST senderstate
    %lang.att;
>
<!-- A.3.1.4d Address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.1.4d
Field title: Sender's post code
Field name: senderpostcode
Field length: 15AN
Field values:
-->
<!ELEMENT senderpostcode (#PCDATA)>
<!ATTLIST senderpostcode
    %lang.att;
>
<!-- A.3.1.4e Address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.1.4e
Field title: Sender's country code
Field name: sendercountrycode
Field length: 2A
Field values: ISO3166
-->
<!ELEMENT sendercountrycode (#PCDATA)>
<!ATTLIST sendercountrycode
    %lang.att;
>
<!-- A.3.1.4f Address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.1.4f
Field title: Sender's telephone
Field name: sendertel
Field length: 10AN
Field values:
-->
<!ELEMENT sendertel (#PCDATA)>
<!ATTLIST sendertel
    %lang.att;
>
<!-- A.3.1.4g Address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.1.4g
Field title: Sender's telephone extension
Field name: sendertelextension
Field length: 5AN
```

```
Field values:
-->
<!ELEMENT sendertelextension (#PCDATA)>
<!ATTLIST sendertelextension
    %lang.att;
>
<!-- A.3.1.4h Address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.1.4h
Field title: Sender's telephone country code
Field name: sendertelcountrycode
Field length: 3AN
Field values:
-->
<!ELEMENT sendertelcountrycode (#PCDATA)>
<!ATTLIST sendertelcountrycode
    %lang.att;
>
<!-- A.3.1.4i Address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.1.4i
Field title: Sender's fax
Field name: senderfax
Field length: 10AN
Field values:
-->
<!ELEMENT senderfax (#PCDATA)>
<!ATTLIST senderfax
    %lang.att;
>
<!-- A.3.1.4j Address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.1.4j
Field title: Sender's fax extension
Field name: senderfaxextension
Field length: 5AN
Field values:
-->
<!ELEMENT senderfaxextension (#PCDATA)>
<!ATTLIST senderfaxextension
    %lang.att;
>
<!-- A.3.1.4k Address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.1.4k
Field title: Sender's fax country code
Field name: senderfaxcountrycode
Field length: 3AN
Field values:
-->
<!ELEMENT senderfaxcountrycode (#PCDATA)>
<!ATTLIST senderfaxcountrycode
    %lang.att;
>
<!-- A.3.1.4l Address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.1.4l
```



```
Field title:      Sender's email address
Field name: senderemailaddress
Field length:    100AN
Field values:
-->
<!ELEMENT senderemailaddress (#PCDATA)>
<!ATTLIST senderemailaddress
        %lang.att;
>
<!-- A.3.2.1 Receiver type -->
<!--
Field ref:  A.3.2.1
Field title:      Receiver type
Field name: receivertype
Field length:    1N
Field values:
1=Pharmaceutical Company
2=Regulatory Authority
4=Regional Pharmacovigilance Center
5=WHO Collaborating Center for International Drug Monitoring
6=Other
-->
<!ELEMENT receivertype (#PCDATA)>
<!ATTLIST receivertype
        %lang.att;
>
<!-- A.3.2.2a Receiver identifier -->
<!--
Field ref:  A.3.2.2a
Field title:      Receiver's organization
Field name: receiverorganization
Field length:    60AN
Field values:
-->
<!ELEMENT receiverorganization (#PCDATA)>
<!ATTLIST receiverorganization
        %lang.att;
>
<!-- A.3.2.2b Receiver identifier -->
<!--
Field ref:  A.3.2.2b
Field title:      Receiver's department
Field name: receiverdepartment
Field length:    60AN
Field values:
-->
<!ELEMENT receiverdepartment (#PCDATA)>
<!ATTLIST receiverdepartment
        %lang.att;
>
<!-- A.3.2.2c Receiver identifier -->
<!--
Field ref:  A.3.2.2c
Field title:      Receiver's title
Field name: receivertitle
Field length:    10AN
Field values:
```

```
-->
<!ELEMENT receivertitle (#PCDATA)>
<!ATTLIST receivertitle
    %lang.att;
>
<!-- A.3.2.2d Receiver identifier -->
<!--
Field ref: A.3.2.2d
Field title: Receiver's given name
Field name: receivergivenname
Field length: 35AN
Field values:
-->
<!ELEMENT receivergivenname (#PCDATA)>
<!ATTLIST receivergivenname
    %lang.att;
>
<!-- A.3.2.2e Receiver identifier -->
<!--
Field ref: A.3.2.2e
Field title: Receiver's middle name
Field name: receivermiddlename
Field length: 15AN
Field values:
-->
<!ELEMENT receivermiddlename (#PCDATA)>
<!ATTLIST receivermiddlename
    %lang.att;
>
<!-- A.3.2.2f Receiver identifier -->
<!--
Field ref: A.3.2.2f
Field title: Receiver's family name
Field name: receiverfamilyname
Field length: 35AN
Field values:
-->
<!ELEMENT receiverfamilyname (#PCDATA)>
<!ATTLIST receiverfamilyname
    %lang.att;
>
<!-- A.3.2.3a Receiver's address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.2.3a
Field title: Receiver's street address
Field name: receiverstreetaddress
Field length: 40AN
Field values:
-->
<!ELEMENT receiverstreetaddress (#PCDATA)>
<!ATTLIST receiverstreetaddress
    %lang.att;
>
<!-- A.3.2.3b Receiver's address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.2.3b
Field title: Receiver's city
```

```
Field name: receivercity
Field length: 35AN
Field values:
-->
<!ELEMENT receivercity (#PCDATA)>
<!ATTLIST receivercity
    %lang.att;
>
<!-- A.3.2.3c Receiver's address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.2.3c
Field title: Receiver's state or province
Field name: receiverstate
Field length: 40AN
Field values:
-->
<!ELEMENT receiverstate (#PCDATA)>
<!ATTLIST receiverstate
    %lang.att;
>
<!-- A.3.2.3d Receiver's address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.2.3d
Field title: Receiver's post code
Field name: receiverpostcode
Field length: 15AN
Field values:
-->
<!ELEMENT receiverpostcode (#PCDATA)>
<!ATTLIST receiverpostcode
    %lang.att;
>
<!-- A.3.2.3e Receiver's address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.2.3e
Field title: Receiver's country code
Field name: receivercountrycode
Field length: 2A
Field values: ISO3166
-->
<!ELEMENT receivercountrycode (#PCDATA)>
<!ATTLIST receivercountrycode
    %lang.att;
>
<!-- A.3.2.3f Receiver's address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.2.3f
Field title: Receiver's telephone
Field name: receivertel
Field length: 10AN
Field values:
-->
<!ELEMENT receivertel (#PCDATA)>
<!ATTLIST receivertel
    %lang.att;
>
<!-- A.3.2.3g Receiver's address, fax, telephone and E-mail address -->
```

```
<!--  
  
Field ref: A.3.2.3g  
Field title: Receiver's telephone extension  
Field name: receivertelextension  
Field length: 5AN  
Field values:  
-->  
<!ELEMENT receivertelextension (#PCDATA)>  
<!ATTLIST receivertelextension  
    %lang.att;  
>  
<!-- A.3.2.3h Receiver's address, fax, telephone and E-mail address -->  
<!--  
Field ref: A.3.2.3h  
Field title: Receiver's telephone country code  
Field name: receivertelcountrycode  
Field length: 3AN  
Field values:  
-->  
<!ELEMENT receivertelcountrycode (#PCDATA)>  
<!ATTLIST receivertelcountrycode  
    %lang.att;  
>  
<!-- A.3.2.3i Receiver's address, fax, telephone and E-mail address -->  
<!--  
Field ref: A.3.2.3i  
Field title: Receiver's fax  
Field name: receiverfax  
Field length: 10AN  
Field values:  
-->  
<!ELEMENT receiverfax (#PCDATA)>  
<!ATTLIST receiverfax  
    %lang.att;  
>  
<!-- A.3.2.3j Receiver's address, fax, telephone and E-mail address -->  
<!--  
Field ref: A.3.2.3j  
Field title: Receiver's fax extension  
Field name: receiverfaxextension  
Field length: 5AN  
Field values:  
-->  
<!ELEMENT receiverfaxextension (#PCDATA)>  
<!ATTLIST receiverfaxextension  
    %lang.att;  
>  
<!-- A.3.2.3k Receiver's address, fax, telephone and E-mail address -->  
<!--  
Field ref: A.3.2.3k  
Field title: Receiver's fax country code  
Field name: receiverfaxcountrycode  
Field length: 3AN  
Field values:  
-->  
<!ELEMENT receiverfaxcountrycode (#PCDATA)>
```

```
<!ATTLIST receiverfaxcountrycode
    %lang.att;
>
<!-- A.3.2.31 Receiver's address, fax, telephone and E-mail address -->
<!--
Field ref: A.3.2.31
Field title: Receiver's e-mail address
Field name: receiveremailaddress
Field length: 100AN
Field values:
-->
<!ELEMENT receiveremailaddress (#PCDATA)>
<!ATTLIST receiveremailaddress
    %lang.att;
>
<!-- B.1.1 Patient initials -->
<!--
Field ref: B.1.1
Field title: Patient initials
Field name: patientinitial
Field length: 10AN
Field values:
-->
<!ELEMENT patientinitial (#PCDATA)>
<!ATTLIST patientinitial
    %lang.att;
>
<!-- B.1.1.1a Patient medical record number(s) and source(s) -->
<!--
Field ref: B.1.1.1a
Field title: GP medical record number
Field name: patientgpmedicalrecordnumb
Field length: 20AN
Field values:
-->
<!ELEMENT patientgpmedicalrecordnumb (#PCDATA)>
<!ATTLIST patientgpmedicalrecordnumb
    %lang.att;
>
<!-- B.1.1.1b Patient medical record number(s) and source(s) -->
<!--
Field ref: B.1.1.1b
Field title: Specialist record number
Field name: patientspecialistrecordnumb
Field length: 20AN
Field values:
-->
<!ELEMENT patientspecialistrecordnumb (#PCDATA)>
<!ATTLIST patientspecialistrecordnumb
    %lang.att;
>
<!-- B.1.1.1c Patient medical record number(s) and source(s) -->
<!--
Field ref: B.1.1.1c
Field title: Hospital record number
Field name: patienthospitalrecordnumb
Field length: 20AN
```

```
Field values:
-->
<!ELEMENT patienthospitalrecordnumb (#PCDATA)>
<!ATTLIST patienthospitalrecordnumb
    %lang.att;
>
<!-- B.1.1.1d Patient medical record number(s) and source(s) -->
<!--
Field ref: B.1.1.1d
Field title: Investigation number
Field name: patientinvestigationnumb
Field length: 20AN
Field values:
-->
<!ELEMENT patientinvestigationnumb (#PCDATA)>
<!ATTLIST patientinvestigationnumb
    %lang.att;
>
<!-- B.1.2.1a Date of birth format -->
<!--
Field ref: B.1.2.1a
Field title: Date of birth format
Field name: patientbirthdateformat
Field length: 3N
Field values: 102=CCYYMMDD
-->
<!ELEMENT patientbirthdateformat (#PCDATA)>
<!ATTLIST patientbirthdateformat
    %lang.att;
>
<!-- B.1.2.1b Date of birth -->
<!--
Field ref: B.1.2.1b
Field title: Date of birth
Field name: patientbirthdate
Field length: 8N
Field values: 102=CCYYMMDD
-->
<!ELEMENT patientbirthdate (#PCDATA)>
<!ATTLIST patientbirthdate
    %lang.att;
>
<!-- B.1.2.2a Age at time of onset of reaction / event -->
<!--
Field ref: B.1.2.2a
Field title: Age at time of onset of reaction/event value
Field name: patientonsetage
Field length: 5N
Field values:
-->
<!ELEMENT patientonsetage (#PCDATA)>
<!ATTLIST patientonsetage
    %lang.att;
>
<!-- B.1.2.2b Age at time of onset of reaction / event unit -->
<!--
Field ref: B.1.2.2b
```

```
Field title:      Age at time of onset of reaction/event unit
Field name: patientonsetageunit
Field length:     3N
Field values:
800=Decade
801=Year
802=Month
803=Week
804=Day
805=Hour
-->
<!ELEMENT patientonsetageunit (#PCDATA)>
<!ATTLIST patientonsetageunit
        %lang.att;
>
<!-- B.1.2.2.1a Gestation period when reaction / event was observed in the fetus
-->
<!--
Field ref:  B.1.2.2.1a
Field title:      Gestation period when reaction/event was observed in the fetus
Field name: gestationperiod
Field length:     3N
Field values:
-->
<!ELEMENT gestationperiod (#PCDATA)>
<!ATTLIST gestationperiod
        %lang.att;
>
<!-- B.1.2.2.1b Gestation period when reaction / event was observed in the fetus
unit -->
<!--
Field ref:  B.1.2.2.1b
Field title:      Gestation period unit
Field name: gestationperiodunit
Field length:     3N
Field values:
802=Month
803=Week
804=Day
810=Trimester
-->
<!ELEMENT gestationperiodunit (#PCDATA)>
<!ATTLIST gestationperiodunit
        %lang.att;
>
<!-- B.1.2.3 Patient age group -->
<!--
Field ref:  B.1.2.3
Field title:      Patient age group
Field name: patientagegroup
Field length:     1N
Field values:
1=Neonate
2=Infant
3=Child
4=Adolescent
5=Adult
```

```
6=Elderly
-->
<!ELEMENT patientagegroup (#PCDATA)>
<!ATTLIST patientagegroup
    %lang.att;
>
<!-- B.1.3 Weight (kg) -->
<!--
Field ref: B.1.3
Field title: Weight (kg)
Field name: patientweight
Field length: 6N
Field values:
-->
<!ELEMENT patientweight (#PCDATA)>
<!ATTLIST patientweight
    %lang.att;
>
<!-- B.1.4 Height (cm) -->
<!--
Field ref: B.1.4
Field title: Height (cm)
Field name: patientheight
Field length: 3N
Field values:
-->
<!ELEMENT patientheight (#PCDATA)>
<!ATTLIST patientheight
    %lang.att;
>
<!-- B.1.5 Sex -->
<!--
Field ref: B.1.5
Field title: Sex
Field name: patientsex
Field length: 1N
Field values: (ISO 5218)
1=Male
2=Female
9=Not specified
0=Unknown
-->
<!ELEMENT patientsex (#PCDATA)>
<!ATTLIST patientsex
    %lang.att;
>
<!-- B.1.6a Last menstrual period date format -->
<!--
Field ref: B.1.6a
Field title: Last menstrual period date format
Field name: lastmenstrualdateformat
Field length: 3N
Field values:
102=CCYYMMDD
610=CCYYMM
602=CCYY
-->
```



```
<!ELEMENT lastmenstrualdateformat (#PCDATA)>
<!ATTLIST lastmenstrualdateformat
    %lang.att;
>
<!-- B.1.6b Last menstrual period date -->
<!--
Field ref: B.1.6b
Field title: Last menstrual period date
Field name: patientlastmenstrualdate
Field length: 8N
Field values:
-->
<!ELEMENT patientlastmenstrualdate (#PCDATA)>
<!ATTLIST patientlastmenstrualdate
    %lang.att;
>
<!-- B.1.7.1a.1 MedDRA version -->
<!-- B.1.7.1a.1 Structured information -->
<!--
Field ref: B.1.7.1a.1
Field title: MedDRA version for Medical History
Field name: patientepisodenamemeddraversion
Field length: 8AN
Field values:
-->
<!ELEMENT patientepisodenamemeddraversion (#PCDATA)>
<!ATTLIST patientepisodenamemeddraversion
    %lang.att;
>
<!-- B.1.7.1a.2 Structured information -->
<!--
Field ref: B.1.7.1a.2
Field title: Disease/surgical procedure
Field name: patientepisodename
Field length: 100AN
Field values:
-->
<!ELEMENT patientepisodename (#PCDATA)>
<!ATTLIST patientepisodename
    %lang.att;
>
<!-- B.1.7.1b Start date format -->
<!--
Field ref: B.1.7.1b
Field title: Start date format
Field name: patientmedicalstartdateformat
Field length: 3N
Field values:
102=CCYYMMDD
610=CCYYMM
602=CCYY
-->
<!ELEMENT patientmedicalstartdateformat (#PCDATA)>
<!ATTLIST patientmedicalstartdateformat
    %lang.att;
>
<!-- B.1.7.1c Start date -->
```

```
<!--
Field ref: B.1.7.1c
Field title: Start date
Field name: patientmedicalstartdate
Field length: 8N
Field values:
-->
<!ELEMENT patientmedicalstartdate (#PCDATA)>
<!ATTLIST patientmedicalstartdate
    %lang.att;
>
<!-- B.1.7.1d Continuing -->
<!--
Field ref: B.1.7.1d
Field title: Continuing
Field name: patientmedicalcontinue
Field length: 1N
Field values:
1=Yes
2=No
3=Unknown
-->
<!ELEMENT patientmedicalcontinue (#PCDATA)>
<!ATTLIST patientmedicalcontinue
    %lang.att;
>
<!-- B.1.7.1e End date format -->
<!--
Field ref: B.1.7.1e
Field title: End date format
Field name: patientmedicalenddateformat
Field length: 3N
Field values:
102=CCYYMMDD
610=CCYYMM
602=CCYY
-->
<!ELEMENT patientmedicalenddateformat (#PCDATA)>
<!ATTLIST patientmedicalenddateformat
    %lang.att;
>
<!-- B.1.7.1f End date -->
<!--
Field ref: B.1.7.1f
Field title: End date
Field name: patientmedicalenddate
Field length: 8N
Field values:
-->
<!ELEMENT patientmedicalenddate (#PCDATA)>
<!ATTLIST patientmedicalenddate
    %lang.att;
>
<!-- B.1.7.1g Comments -->
<!--
Field ref: B.1.7.1g
Field title: Comments
```

```
Field name: patientmedicalcomment
Field length: 100AN
Field values:
-->
<!ELEMENT patientmedicalcomment (#PCDATA)>
<!ATTLIST patientmedicalcomment
    %lang.att;
>
<!-- B.1.7.2 Text for relevant medical history and concurrent conditions -->
<!--
Field ref: B.1.7.2
Field title: Text for relevant medical history and concurrent conditions
Field name: patientmedicalhistorytext
Field length: 10000AN
Field values:
-->
<!ELEMENT patientmedicalhistorytext (#PCDATA)>
<!ATTLIST patientmedicalhistorytext
    %lang.att;
>
<!-- B.1.8a Name of drug -->
<!--
Field ref: B.1.8a
Field title: Name of drug
Field name: patientdrugname
Field length: 70AN
Field values:
-->
<!ELEMENT patientdrugname (#PCDATA)>
<!ATTLIST patientdrugname
    %lang.att;
>
<!-- B.1.8b Start date format -->
<!--
Field ref: B.1.8b
Field title: Start date format
Field name: patientdrugstartdateformat
Field length: 3N
Field values:
102=CCYYMMDD
610=CCYYMM
602=CCYY

-->
<!ELEMENT patientdrugstartdateformat (#PCDATA)>
<!ATTLIST patientdrugstartdateformat
    %lang.att;
>
<!-- B.1.8c Start date -->
<!--
Field ref: B.1.8c
Field title: Start date
Field name: patientdrugstartdate
Field length: 8N
Field values:
Comment :
-->
```

```
<!ELEMENT patientdrugstartdate (#PCDATA)>
<!ATTLIST patientdrugstartdate
    %lang.att;
>
<!-- B.1.8d End date format -->
<!--
Field ref: B.1.8d
Field title: End date format
Field name: patientdrugenddateformat
Field length: 3N
Field values:
102=CCYYMMDD
610=CCYYMM
602CCYY
-->
<!ELEMENT patientdrugenddateformat (#PCDATA)>
<!ATTLIST patientdrugenddateformat
    %lang.att;
>
<!-- B.1.8e End date -->
<!--
Field ref: B.1.8e
Field title: End date
Field name: patientdrugenddate
Field length: 8N
Field values:
-->
<!ELEMENT patientdrugenddate (#PCDATA)>
<!ATTLIST patientdrugenddate
    %lang.att;
>
<!-- B.1.8f.1 MedDRA version for indication -->
<!--
Field ref: B.1.8f.1
Field title: MedDRA version for indication
Field name: patientindicationmeddraversion
Field length: 8N
Field values:
-->
<!ELEMENT patientindicationmeddraversion (#PCDATA)>
<!ATTLIST patientindicationmeddraversion
    %lang.att;
>
<!-- B.1.8f Indication -->
<!--
Field ref: B.1.8f
Field title: Indication
Field name: patientdrugindication
Field length: 100AN
Field values:
-->
<!ELEMENT patientdrugindication (#PCDATA)>
<!ATTLIST patientdrugindication
    %lang.att;
>
<!-- B.1.8g.1 MedDRA version for reaction -->
<!--
```

```
Field ref: B.1.8g.1
Field title: MedDRA version for reaction
Field name: patientdrgreactionmeddraversion
Field length: 8AN
Field values:
-->
<!ELEMENT patientdrgreactionmeddraversion (#PCDATA)>
<!ATTLIST patientdrgreactionmeddraversion
    %lang.att;
>
<!-- B.1.8g Reaction -->
<!--
Field ref: B.1.8g
Field title: Reaction
Field name: patientdrugreaction
Field length: 100AN
Field values:
-->
<!ELEMENT patientdrugreaction (#PCDATA)>
<!ATTLIST patientdrugreaction
    %lang.att;
>
<!-- B.1.9.1a Date of death format -->
<!--
Field ref: B.1.9.1a
Field title: Date of death format
Field name: patientdeathdateformat
Field length: 3N
Field values:
102=CCYYMMDD
610=CCYYMM
602=CCYY
-->
<!ELEMENT patientdeathdateformat (#PCDATA)>
<!ATTLIST patientdeathdateformat
    %lang.att;
>
<!-- B.1.9.1b Date of death -->
<!--
Field ref: B.1.9.1b
Field title: Date of death
Field name: patientdeathdate
Field length: 8N
Field values:
-->
<!ELEMENT patientdeathdate (#PCDATA)>
<!ATTLIST patientdeathdate
    %lang.att;
>
<!-- B.1.9.2.a MedDRA version -->
<!--
Field ref: B.1.9.2.a
Field title: MedDRA version for reported cause(s) of death
Field name: patientdeathreportmeddraversion
Field length: 8N
Field values:
-->
```

```

<!ELEMENT patientdeathreportmeddraversion (#PCDATA)>
<!ATTLIST patientdeathreportmeddraversion
    %lang.att;
>
<!-- B.1.9.2.b Reported cause of death -->
<!--
Field ref: B.1.9.2.b
Field title: Reported cause of death
Field name: patientdeathreport
Field length: 100AN
Field values:
Comment : Field controlled by MedDRA LLT 2.1 or superior.
-->
<!ELEMENT patientdeathreport (#PCDATA)>
<!ATTLIST patientdeathreport
    %lang.att;
>
<!-- B.1.9.3 Was autopsy done? -->
<!--
Field ref: B.1.9.3
Field title: Was autopsy done?
Field name: patientautopsyyesno
Field length: 1N
Field values:
1=Yes
2=No
3=Unknown
-->
<!ELEMENT patientautopsyyesno (#PCDATA)>
<!ATTLIST patientautopsyyesno
    %lang.att;
>
<!-- B.1.9.4.a MedDRA version -->
<!--
Field ref: B.1.9.4.a
Field title: MedDRA version for autopsy-determined cause(s) of death
Field name: patientdetermautopsmeddraversion
Field length: 8AN
Field values:
-->
<!ELEMENT patientdetermautopsmeddraversion (#PCDATA)>
<!ATTLIST patientdetermautopsmeddraversion
    %lang.att;
>
<!-- B.1.9.4.b Autopsy-determined causes(s) of death -->
<!--
Field ref: B.1.9.4.b
Field title: Autopsy-determined causes(s) of death
Field name: patientdetermineautopsy
Field length: 100AN
Field values:
Comment : Field controlled by MedDRA LLT 2.1 or superior.
-->
<!ELEMENT patientdetermineautopsy (#PCDATA)>
<!ATTLIST patientdetermineautopsy
    %lang.att;
>

```

```

<!-- B.1.10.1 Parent identification -->
<!--
Field ref: B.1.10.1
Field title: Parent identification
Field name: parentidentification
Field length: 10AN
Field values:
-->
<!ELEMENT parentidentification (#PCDATA)>
<!ATTLIST parentidentification
    %lang.att;
>
<!-- B.1.10.2.1a Date of birth of parent format -->
<!--
Field ref: B.1.10.2.1a
Field title: Date of birth of parent format
Field name: parentbirthdateformat
Field length: 3N
Field values: 102=CCYYMMDD
-->
<!ELEMENT parentbirthdateformat (#PCDATA)>
<!ATTLIST parentbirthdateformat
    %lang.att;
>
<!-- B.1.10.2.1b Date of birth of parent -->
<!--
Field ref: B.1.10.2.1b
Field title: Date of birth of parent
Field name: parentbirthdate
Field length: 8N
Field values:
-->
<!ELEMENT parentbirthdate (#PCDATA)>
<!ATTLIST parentbirthdate
    %lang.att;
>
<!-- B.1.10.2.2a Age of parent -->
<!--
Field ref: B.1.10.2.2a
Field title: Age of parent value
Field name: parentage
Field length: 2N
Field values:
-->
<!ELEMENT parentage (#PCDATA)>
<!ATTLIST parentage
    %lang.att;
>
<!-- B.1.10.2.2b Age of parent unit -->
<!--
Field ref: B.1.10.2.2b
Field title: Age of parent unit
Field name: parentageunit
Field length: 3N
Field values: 801=Year
-->
<!ELEMENT parentageunit (#PCDATA)>

```

```

<!ATTLIST parentageunit
    %lang.att;
>
<!-- B.1.10.3a Last menstrual period format -->
<!--
Field ref: B.1.10.3a
Field title: Last menstrual period date format
Field name: parentlastmenstrualdateformat
Field length: 3N
Field values: 102=CCYYMMDD
-->
<!ELEMENT parentlastmenstrualdateformat (#PCDATA)>
<!ATTLIST parentlastmenstrualdateformat
    %lang.att;
>
<!-- B.1.10.3b Last menstrual period -->
<!--
Field ref: B.1.10.3b
Field title: Last menstrual period date
Field name: parentlastmenstrualdate
Field length: 8N
Field values: 102=CCYYMMDD
-->
<!ELEMENT parentlastmenstrualdate (#PCDATA)>
<!ATTLIST parentlastmenstrualdate
    %lang.att;
>
<!-- B.1.10.4 Weight (kg) of parent -->
<!--
Field ref: B.1.10.4
Field title: Weight (kg) of parent
Field name: parentweight
Field length: 6N
Field values:
-->
<!ELEMENT parentweight (#PCDATA)>
<!ATTLIST parentweight
    %lang.att;
>
<!-- B.1.10.5 Height (cm) of parent -->
<!--
Field ref: B.1.10.5
Field title: Height (cm) of parent
Field name: parentheight
Field length: 3N
Field values:
-->
<!ELEMENT parentheight (#PCDATA)>
<!ATTLIST parentheight
    %lang.att;
>
<!-- B.1.10.6 Sex of parent -->
<!--
Field ref: B.1.10.6
Field title: Sex of parent
Field name: parentsex
Field length: 1N

```



```
Field values:      (ISO5218)
1=Male
2=Female
9=Not Specified
0=Unknown
-->
<!ELEMENT parentsex (#PCDATA)>
<!ATTLIST parentsex
    %lang.att;
>
<!-- B.1.10.7.1a.1 MedDRA version -->
<!--
Field ref:  B.1.10.7.1a.1
Field title:      MedDRA version for parent medical history
Field name: parentmdepidemeddraversion
Field length:      8AN
Field values:
-->
<!ELEMENT parentmdepidemeddraversion (#PCDATA)>
<!ATTLIST parentmdepidemeddraversion
    %lang.att;
>
<!-- B.1.10.7.1a.2 Structured information -->
<!--
Field ref:  B.1.10.7.1a.2
Field title:      Disease / surgical procedure
Field name: parentmedicalepisodename
Field length:      100AN
Field values:
Comment :   Field controlled by MedDRA LLT 2.1 or superior.
-->
<!ELEMENT parentmedicalepisodename (#PCDATA)>
<!ATTLIST parentmedicalepisodename
    %lang.att;
>
<!-- B.1.10.7.1b Start date format -->
<!--
Field ref:  B.1.10.7.1b
Field title:      Start date format
Field name: parentmedicalstartdateformat
Field length:      3N
Field values:
102=CCYYMMDD
610=CCYYMM
602=CCYY
-->
<!ELEMENT parentmedicalstartdateformat (#PCDATA)>
<!ATTLIST parentmedicalstartdateformat
    %lang.att;
>
<!-- B.1.10.7.1c Start date -->
<!--
Field ref:  B.1.10.7.1c
Field title:      Start date
Field name: parentmedicalstartdate
Field length:      8N
Field values:
```

```
-->
<!ELEMENT parentmedicalstartdate (#PCDATA)>
<!ATTLIST parentmedicalstartdate
    %lang.att;
>
<!-- B.1.10.7.1d Continuing -->
<!--
Field ref: B.1.10.7.1d
Field title: Continuing
Field name: parentmedicalcontinue
Field length: 1N
Field values:
1=Yes
2=No
3=Unknown
-->
<!ELEMENT parentmedicalcontinue (#PCDATA)>
<!ATTLIST parentmedicalcontinue
    %lang.att;
>
<!-- B.1.10.7.1e End date format -->
<!--
Field ref: B.1.10.7.1e
Field title: End date format
Field name: parentmedicalenddateformat
Field length: 3N
Field values:
102=CCYYMMDD
610=CCYYMM
602=CCYY
-->
<!ELEMENT parentmedicalenddateformat (#PCDATA)>
<!ATTLIST parentmedicalenddateformat
    %lang.att;
>
<!-- B.1.10.7.1f End date -->
<!--
Field ref: B.1.10.7.1f
Field title: End date
Field name: parentmedicalenddate
Field length: 8N
Field values:
-->
<!ELEMENT parentmedicalenddate (#PCDATA)>
<!ATTLIST parentmedicalenddate
    %lang.att;
>
<!-- B.1.10.7.1g Comments -->
<!--
Field ref: B.1.10.7.1g
Field title: Comments
Field name: parentmedicalcomment
Field length: 100AN
Field values:
-->
<!ELEMENT parentmedicalcomment (#PCDATA)>
<!ATTLIST parentmedicalcomment
```

```
        %lang.att;
>
<!-- B.1.10.7.2 Text for relevant medical history and concurrent conditions (not
including reaction / event) of parent -->
<!--
Field ref: B.1.10.7.2
Field title: Text for relevant medical history and concurrent conditions
(not including reaction / event) of parent
Field name: parentmedicalrelevanttext
Field length: 10000AN
Field values:
-->
<!ELEMENT parentmedicalrelevanttext (#PCDATA)>
<!ATTLIST parentmedicalrelevanttext
        %lang.att;
>
<!-- B.1.10.8a Name of drug as -->
<!--
Field ref: B.1.10.8a
Field title: Name of drug
Field name: parentdrugname
Field length: 70AN
Field values:
-->
<!ELEMENT parentdrugname (#PCDATA)>
<!ATTLIST parentdrugname
        %lang.att;
>
<!-- B.1.10.8b Start date format -->
<!--
Field ref: B.1.10.8b
Field title: Start date format
Field name: parentdrugstartdateformat
Field length: 3N
Field values:
102=CCYYMMDD
610=CCYYMM
602=CCYY
-->
<!ELEMENT parentdrugstartdateformat (#PCDATA)>
<!ATTLIST parentdrugstartdateformat
        %lang.att;
>
<!-- B.1.10.8c Start date -->
<!--
Field ref: B.1.10.8c
Field title: Start date
Field name: parentdrugstartdate
Field length: 8N
Field values:
-->
<!ELEMENT parentdrugstartdate (#PCDATA)>
<!ATTLIST parentdrugstartdate
        %lang.att;
>
<!-- B.1.10.8d End date format -->
<!ELEMENT parentdrugenddateformat (#PCDATA)>
```

```
<!ATTLIST parentdrugenddateformat
    %lang.att;
>
<!--
Field ref: B.1.10.8d
Field title: End date format
Field name: parentdrugenddateformat
Field length: 3N
Field values:
102=CCYYMMDD
610=CCYYMM
602=CCYY
-->
<!-- B.1.10.8e End date -->
<!--
Field ref: B.1.10.8e
Field title: End date
Field name: parentdrugenddate
Field length: 8N
Field values:
-->
<!ELEMENT parentdrugenddate (#PCDATA)>
<!ATTLIST parentdrugenddate
    %lang.att;
>
<!-- B.1.10.8f.1 MedDRA version for indication -->
<!--
Field ref: B.1.10.8f.1
Field title: MedDRA version for indication
Field name: parentdrgindicationmeddraversion
Field length: 8AN
Field values:
-->
<!ELEMENT parentdrgindicationmeddraversion (#PCDATA)>
<!ATTLIST parentdrgindicationmeddraversion
    %lang.att;
>
<!-- B.1.10.8f Indication -->
<!--
Field ref: B.1.10.8f
Field title: Indication
Field name: parentdrugindication
Field length: 100AN
Field values:
-->
<!ELEMENT parentdrugindication (#PCDATA)>
<!ATTLIST parentdrugindication
    %lang.att;
>
<!-- B.1.10.8g.1 MedDRA version for indication -->
<!--
Field ref: B.1.10.8g.1
Field title: MedDRA version for reaction
Field name: parentdrgreactionmeddraversion
Field length: 100AN
Field values:
-->
```

```
<!ELEMENT parentdrugreactionmeddraversion (#PCDATA)>
<!ATTLIST parentdrugreactionmeddraversion
    %lang.att;
>
<!-- B.1.10.8g Reactions (if any and known) -->
<!--
Field ref: B.1.10.8g
Field title: Reactions (if any and known)
Field name: parentdrugreaction
Field length: 100AN
Field values:
-->
<!ELEMENT parentdrugreaction (#PCDATA)>
<!--
Field ref: B.2.i.1
Field title: Reaction / event as reported by primary
Field name: primarysourcereaction
Field length: 100AN
Field values:
-->
<!ATTLIST parentdrugreaction
    %lang.att;
>
<!-- B.2.i.1 Reaction / event as reported by primary -->
<!--
Field ref: B.2.i.1
Field title: Reaction / event as reported by primary
Field name: primarysourcereaction
Field length: 100AN
Field values:
-->
<!ELEMENT primarysourcereaction (#PCDATA)>
<!ATTLIST primarysourcereaction
    %lang.att;
>
<!-- B.2.i.1.a MedDRA version for reaction/event term LLT -->
<!--
Field ref: B.2.i.1.a
Field title: MedDRA version for reaction/event term LLT
Field name: reactionmeddraversionllt
Field length: 8AN
Field values:
-->
<!ELEMENT reactionmeddraversionllt (#PCDATA)>
<!ATTLIST reactionmeddraversionllt
    %lang.att;
>
<!-- B.2.i.1.b MedDRA LLT for reaction/event term -->
<!--
Field ref: B.2.i.1.b
Field title: Reaction/event in MedDRA terminology (LLT)
Field name: reactionmeddrallt
Field length: 200AN
Field values:
-->
<!ELEMENT reactionmeddrallt (#PCDATA)>
<!ATTLIST reactionmeddrallt
```

```

        %lang.att;
>
<!-- B.2.i.2.a MedDRA version for reaction/event term PT -->
<!--
Field ref: B.2.i.2.a
Field title: MedDRA version for reaction/event term PT
Field name: reactionmeddraversionpt
Field length: 8AN
Field values:
-->
<!ELEMENT reactionmeddraversionpt (#PCDATA)>
<!ATTLIST reactionmeddraversionpt
        %lang.att;
>
<!-- B.2.i.2.b MedDRA PT for reaction/event term -->
<!--
Field ref: B.2.i.2.b
Field title: Reaction/event MedDRA term (PT)
Field name: reactionmeddrapt
Field length: 200AN
Field values:
-->
<!ELEMENT reactionmeddrapt (#PCDATA)>
<!ATTLIST reactionmeddrapt
        %lang.att;
>
<!-- B.2.i.3 Term highlighted by the reporter -->
<!--
Field ref: B.2.i.3
Field title: Term highlighted by the reporter
Field name: termhighlighted
Field length: 1N
Field values:
1=Yes, highlighted by the reporter, NOT serious
2=No, not highlighted by the reporter, NOT serious
3=Yes, highlighted by the reporter, SERIOUS
4=No, not highlighted by the reporter, SERIOUS

-->
<!ELEMENT termhighlighted (#PCDATA)>
<!ATTLIST termhighlighted
        %lang.att;
>
<!-- B.2.i.4a Date of start of reaction / event format -->
<!--
Field ref: B.2.i.4a
Field title: Date of start of reaction/event format
Field name: reactionstartdateformat
Field length: 3N
Field values:
102=CCYYMMDD
203=CCYYMMDDHHMM
610=CCYYMM
602=CCYY
-->
<!ELEMENT reactionstartdateformat (#PCDATA)>
<!ATTLIST reactionstartdateformat

```

```

        %lang.att;
>
<!-- B.2.i.4b Date of start of reaction / event -->
<!--
Field ref: B.2.i.4b
Field title: Date of start of reaction/event
Field name: reactionstartdate
Field length: 12N
Field values:
-->
<!ELEMENT reactionstartdate (#PCDATA)>
<!ATTLIST reactionstartdate
        %lang.att;
>
<!-- B.2.i.5a Date of end of reaction / event format -->
<!--
Field ref: B.2.i.5a
Field title: Date of end of reaction/event format
Field name: reactionenddateformat
Field length: 3N
Field values:
102=CCYYMMDD
203=CCYYMMDDHHMM
610=CCYYMM
602=CCYY
-->
<!ELEMENT reactionenddateformat (#PCDATA)>
<!ATTLIST reactionenddateformat
        %lang.att;
>
<!-- B.2.i.5b Date of end of reaction / event -->
<!--
Field ref: B.2.i.5b
Field title: Date of end of reaction/event
Field name: reactionenddate
Field length: 12N
Field values:
-->
<!ELEMENT reactionenddate (#PCDATA)>
<!ATTLIST reactionenddate
        %lang.att;
>
<!-- B.2.i.6a Duration of reaction / event -->
<!--
Field ref: B.2.i.6a
Field title: Duration of reaction/event value
Field name: reactionduration
Field length: 5N
Field values:
-->
<!ELEMENT reactionduration (#PCDATA)>
<!ATTLIST reactionduration
        %lang.att;
>
<!-- B.2.i.6b Duration of reaction / event unit -->
<!--
Field ref: B.2.i.6b

```

```
Field title:      Duration of reaction/event unit
Field name: reactiondurationunit
Field length:    3N
Field values:
801=Year
802=Month
803=Week
804=Day
805=Hour
806=Minute
807=Second
-->
<!ELEMENT reactiondurationunit (#PCDATA)>
<!ATTLIST reactiondurationunit
    %lang.att;
>
<!-- B.2.i.7.1a Time interval between beginning of suspect drug administration
and start of reaction / event -->
<!--
Field ref:  B.2.i.7.1a
Field title:      Time interval between beginning of suspect drug administration
and start of reaction/event
Field name: reactionfirsttime
Field length:    5N
Field values:
-->
<!ELEMENT reactionfirsttime (#PCDATA)>
<!ATTLIST reactionfirsttime
    %lang.att;
>
<!-- B.2.i.7.1b Time interval between beginning of suspect drug administration
and start of reaction / event unit -->
<!--
Field ref:  B.2.i.7.1b
Field title:      Time interval unit between beginning of suspect drug
administration and start of reaction/event
Field name: reactionfirsttimeunit
Field length:    3N
Field values:
801=Year
802=Month
803=Week
804=Day
805=Hour
806=Minute
807=Second
-->
<!ELEMENT reactionfirsttimeunit (#PCDATA)>
<!ATTLIST reactionfirsttimeunit
    %lang.att;
>
<!-- B.2.i.7.2a Time interval between last dose and start of reaction / event --
>
<!--
Field ref:  B.2.i.7.2a
Field title:      Time interval between last dose and start of reaction/event
Field name: reactionlasttime
```



```
Field length:      5N
Field values:
-->
<!ELEMENT reactionlasttime (#PCDATA)>
<!ATTLIST reactionlasttime
      %lang.att;
>
<!-- B.2.i.7.2b Time interval between last dose and start of reaction / event
unit -->
<!--
Field ref:  B.2.i.7.2b
Field title:      Time interval between last dose and start of reaction/event
unit
Field name: reactionlasttimeunit
Field length:      3N
Field values:
801=Year
802=Month
803=Week
804=Day
805=Hour
806=Minute
807=Second
-->
<!ELEMENT reactionlasttimeunit (#PCDATA)>
<!ATTLIST reactionlasttimeunit
      %lang.att;
>
<!-- B.2.i.8 Outcome of reaction / event at the time of last observation -->
<!--
Field ref:  B.2.i.8
Field title:      Outcome of reaction / event at the time of last observation
Field name: reactionoutcome
Field length:      1N
Field values:
1=recovered/resolved
2=recovering/resolving
3=not recovered/not resolved
4=recovered/resolved with sequel
5=fatal
6=unknown
-->
<!ELEMENT reactionoutcome (#PCDATA)>
<!ATTLIST reactionoutcome
      %lang.att;
>
<!-- B.3.1a Date format -->
<!--
Field title:      Date format
Field name: testdateformat
Field ref:  B.3.1a
Field length:      3N
Field values:      102=CCYYMMDD; 610=CCYYMM; 602=CCYY
-->
<!ELEMENT testdateformat (#PCDATA)>
<!ATTLIST testdateformat
      %lang.att;
```

```
>
<!-- B.3.1b Date -->
<!--
Field ref: B.3.1b
Field title: Test date
Field name: testdate
Field length: 8N
Field values:
-->
<!ELEMENT testdate (#PCDATA)>
<!ATTLIST testdate
    %lang.att;
>
<!-- B.3.1c Test -->
<!--
Field ref: B.3.1c
Field title: Test
Field name: testname
Field length: 70AN
Field values:
-->
<!ELEMENT testname (#PCDATA)>
<!ATTLIST testname
    %lang.att;
>
<!-- B.3.1d Result -->
<!--
Field ref: B.3.1d
Field title: Result
Field name: testresult
Field length: 50AN
Field values:
-->
<!ELEMENT testresult (#PCDATA)>
<!ATTLIST testresult
    %lang.att;
>
<!-- B.3.1e Unit -->
<!--
Field ref: B.3.1e
Field title: Test unit
Field name: testunit
Field length: 35AN
Field values:
-->
<!ELEMENT testunit (#PCDATA)>
<!ATTLIST testunit
    %lang.att;
>
<!-- B.3.1.1 Normal low range -->
<!--
Field ref: B.3.1.1
Field title: Normal low range
Field name: lowtestrange
Field length: 10AN
Field values:
-->
```

```
<!ELEMENT lowtestrange (#PCDATA)>
<!ATTLIST lowtestrange
    %lang.att;
>
<!-- B.3.1.2 Normal high range -->
<!--
Field ref: B.3.1.
Field title: Normal high range
Field name: hightestrange
Field length: 10AN
Field values:
-->
<!ELEMENT hightestrange (#PCDATA)>
<!ATTLIST hightestrange
    %lang.att;
>
<!-- B.3.1.3 More information available (Y/N) -->
<!--
Field ref: B.3.1.3
Field title: More information available (Y/N)
Field name: moreinformation
Field length: 1N
Field values:
1=Yes
2=No
-->
<!ELEMENT moreinformation (#PCDATA)>
<!ATTLIST moreinformation
    %lang.att;
>
<!-- B.3.2 Results of tests and procedures relevant to the investigation of the
patient -->
<!--
Field ref: B.3.2
Field title: Results of tests and procedures relevant to the investigation
of the patient
Field name: resultstestsprocedures
Field length: 2000AN
Field values:
-->
<!ELEMENT resultstestsprocedures (#PCDATA)>
<!ATTLIST resultstestsprocedures
    %lang.att;
>
<!-- B.4.k.1 Characterization of drug -->
<!--
Field ref: B.4.k.1
Field title: Characterization of drug
Field name: drugcharacterization
Field length: 1N
Field values:
1=Suspect
2=Concomitant
3=Interacting
-->
<!ELEMENT drugcharacterization (#PCDATA)>
<!ATTLIST drugcharacterization
```

```
        %lang.att;
>
<!-- B.4.k.2.1 Proprietary medicinal product name -->
<!--
Field ref: B.4.k.2.1
Field title: Proprietary medicinal product name
Field name: medicinalproduct
Field length: 70AN
Field values:
Comment : Mandatory field. This field should be populated according to the EMP
Product Dictionary or the WHO Drug Dictionary.
-->
<!ELEMENT medicinalproduct (#PCDATA)>
<!ATTLIST medicinalproduct
        %lang.att;
>
<!-- B.4.k.2.2 Active drug substance names -->
<!--
Field ref: B.4.k.2.2
Field title: Active drug substance name
Field name: activesubstancename
Field length: 70AN
Field values:
-->
<!ELEMENT activesubstancename (#PCDATA)>
<!ATTLIST activesubstancename
        %lang.att;
>
<!-- B.4.k.2.2 Identification of the country where the drug was obtained -->
<!--
Field ref: B.4.k.2.3
Field title: Identification of the country where the drug was obtained
Field name: obtaindrugcountry
Field length: 2A
Field values: ISO3166
-->
<!ELEMENT obtaindrugcountry (#PCDATA)>
<!ATTLIST obtaindrugcountry
        %lang.att;
>
<!-- B.4.k.3 Batch / lot number -->
<!--
Field ref: B.4.k.3
Field title: Batch / lot number
Field name: drugbatchnumb
Field length: 35AN
Field values:
-->
<!ELEMENT drugbatchnumb (#PCDATA)>
<!ATTLIST drugbatchnumb
        %lang.att;
>
<!-- B.4.k.4.1 Authorization / application number -->
<!--
Field ref: B.4.k.4.1
Field title: Authorization / application number
Field name: drugauthorizationnumb
```

```
Field length:      35AN
Field values:
-->
<!ELEMENT drugauthorizationnumb (#PCDATA)>
<!ATTLIST drugauthorizationnumb
        %lang.att;
>
<!-- B.4.k.4.2 Country of authorization / application -->
<!--
Field ref:  B.4.k.4.2
Field title:      Country of authorization / application
Field name: drugauthorizationcountry
Field length:    2A
Field values:    ISO3166
-->
<!ELEMENT drugauthorizationcountry (#PCDATA)>
<!ATTLIST drugauthorizationcountry
        %lang.att;
>
<!-- B.4.k.4.3 Name of holder/applicant -->
<!--
Field ref:  B.4.k.4.3
Field title:      Name of drug authorization holder
Field name: drugauthorizationholder
Field length:    60AN
Field values:
-->
<!ELEMENT drugauthorizationholder (#PCDATA)>
<!ATTLIST drugauthorizationholder
        %lang.att;
>
<!-- B.4.k.5.1 Dose (number) -->
<!--
Field ref:  B.4.k.5.1
Field title:      Dose (number)
Field name: drugstructuredosagenumb
Field length:    8N
Field values:
-->
<!ELEMENT drugstructuredosagenumb (#PCDATA)>
<!ATTLIST drugstructuredosagenumb
        %lang.att;
>
<!-- B.4.k.5.2 Dose (unit) -->
<!--
Field ref:  B.4.k.5.2
Field title:      Dose (unit)
Field name: drugstructuredosageunit
Field length:    3N
Field values:
001=kg kilogram(s)
002=G gram(s)
003=Mg milligram(s)
004=µg microgram(s)
005=ng nanogram(s)
006=pg picogram(s)
007=mg/kg milligram(s)/kilogram
```

008= $\mu\text{g}/\text{kg}$  microgram(s)/kilogram  
 009= $\text{mg}/\text{m}^2$  milligram(s)/sq. meter  
 010= $\mu\text{g}/\text{m}^2$  microgram(s)/ sq. Meter  
 011=l litre(s)  
 012=ml millilitre(s)  
 013= $\mu\text{l}$  microlitre(s)  
 014=Bq becquerel(s)  
 015=GBq gigabecquerel(s)  
 016=MBq megabecquerel(s)  
 017=Kbq kilobecquerel(s)  
 018=Ci curie(s)  
 019=MCi millicurie(s)  
 020= $\mu\text{Ci}$  microcurie(s)  
 021=NCi nanocurie(s)  
 022=Mol mole(s)  
 023=Mmol millimole(s)  
 024= $\mu\text{mol}$  micromole(s)  
 025=Iu international unit(s)  
 026=Kiu iu(1000s)  
 027=Miu iu(1,000,000s)  
 028=iu/kg iu/kilogram  
 029=Meq milliequivalent(s)  
 030=% percent  
 031=Gtt drop(s)  
 032=DF dosage form  
 -->  
 <!ELEMENT drugstructuredosageunit (#PCDATA)>  
 <!ATTLIST drugstructuredosageunit  
     %lang.att;  
 >  
 <!-- B.4.k.5.3 Number of separate -->  
 <!--  
 Field ref: B.4.k.5.4  
 Field title: Number of units in the interval  
 Field name: drugintervaldosageunitnumb  
 Field length: 3N  
 Field values:  
 -->  
 <!ELEMENT drugseparatedosagenumb (#PCDATA)>  
 <!ATTLIST drugseparatedosagenumb  
     %lang.att;  
 >  
 <!-- B.4.k.5.4 Number of units in the interval -->  
 <!ELEMENT drugintervaldosageunitnumb (#PCDATA)>  
 <!ATTLIST drugintervaldosageunitnumb  
     %lang.att;  
 >  
 <!-- B.4.k.5.5 Definition of the interval -->  
 <!--  
 Field ref: B.4.k.5.5  
 Field title: Definition of the interval  
 Field name: drugintervaldosagedefinition  
 Field length: 3AN  
 Field values:  
 801=Year  
 802=Month  
 803=Week

```
804=Day
805=Hour
806=Minute
-->
<!ELEMENT drugintervaldosagedefinition (#PCDATA)>
<!ATTLIST drugintervaldosagedefinition
    %lang.att;
>
<!-- B.4.k.5.6 Cumulative dose to first reaction (number) -->
<!--
Field ref: B.4.k.5.6
Field title: Cumulative dose to first reaction (number)
Field name: drugcumulativedosagenumb
Field length: 10N
Field values:
-->
<!ELEMENT drugcumulativedosagenumb (#PCDATA)>
<!ATTLIST drugcumulativedosagenumb
    %lang.att;
>
<!-- B.4.k.5.7 Cumulative dose to first reaction (unit) -->
<!--
Field ref: B.4.k.5.7
Field title: Cumulative dose to first reaction (unit)
Field name: drugcumulativedosageunit
Field length: 3AN
Field values:
-->
<!ELEMENT drugcumulativedosageunit (#PCDATA)>
<!ATTLIST drugcumulativedosageunit
    %lang.att;
>
<!-- B.4.k.6 Dosage text -->
<!--
Field ref: B.4.k.6
Field title: Dosage text
Field name: drugdosagetext
Field length: 100AN
Field values:
-->
<!ELEMENT drugdosagetext (#PCDATA)>
<!ATTLIST drugdosagetext
    %lang.att;
>
<!-- B.4.k.7 Pharmaceutical form (Dosage form) -->
<!--
Field ref: B.4.k.7
Field title: Pharmaceutical form (Dosage form)
Field name: drugdosageform
Field length: 50AN
Field values: Field controlled by the List of Standard Terms.
-->
<!ELEMENT drugdosageform (#PCDATA)>
<!ATTLIST drugdosageform
    %lang.att;
>
<!-- B.4.k.8 Route of administration -->
```

<!--

Field ref: B.4.k.8

Field title: Route of administration

Field name: drugadministrationroute

Field length: 3N

Field values:

001=Auricular (otic)

002=Buccal

003=Cutaneous

004=Dental

005=Endocervical

006=Endosinusial

007=Endotracheal

008=Epidural

009=Extra-amniotic

010=Hemodialysis

011=Intra corpus cavernosum

012=Intra-amniotic

013=Intra-arterial

014=Intra-articular

015=Intra-uterine

016=Intracardiac

017=Intracavernous

018=Intracerebral

019=Intracervical

020=Intracisternal

021=Intracorneal

022=Intracoronary

023=Intradermal

024=Intradiscal (intraspinal)

025=Intrahepatic

026=Intralesional

027=Intralymphatic

028=Intramedullar (bone marrow)

029=Intrameningeal

030=Intramuscular

031=Intraocular

032=Intrapericardial

033=Intraperitoneal

034=Intrapleural

035=Intrasynovial

036=Intratumor

037=Intrathecal

038=Intrathoracic

039=Intratracheal

040=Intravenous bolus

041=Intravenous drip

042=Intravenous (not otherwise specified)

043=Intravesical

044=Iontophoresis

045=Nasal

046=Occlusive dressing technique

047=Ophthalmic

048=Oral

049=Oropharyngeal

050=Other

051=Parenteral



```
052=Periarticular
053=Perineural
054=Rectal
055=Respiratory (inhalation)
056=Retrobulbar
057=Subconjunctival
058=Subcutaneous
059=Subdermal
060=Sublingual
061=Topical
062=Transdermal
063=Transmammary
064=Transplacental
065=Unknown
066=Urethral
067=Vaginal
-->
<!ELEMENT drugadministrationroute (#PCDATA)>
<!ATTLIST drugadministrationroute
    %lang.att;
>
<!-- B.4.k.9 Parent route of administration (in case of a parent child / fetus
report) -->
<!--
Field ref: B.4.k.9
Field title: Parent route of administration (in case of a parent child /
fetus report)
Field name: drugparadministration
Field length: 3N
Field values:
001=Auricular (otic)
002=Buccal
003=Cutaneous
004=Dental
005=Endocervical
006=Endosinusial
007=Endotracheal
008=Epidural
009=Extra-amniotic
010=Hemodialysis
011=Intra corpus cavernosum
012=Intra-amniotic
013=Intra-arterial
014=Intra-articular
015=Intra-uterine
016=Intracardiac
017=Intracavernous
018=Intracerebral
019=Intracervical
020=Intracisternal
021=Intracorneal
022=Intracoronary
023=Intradermal
024=Intradiscal (intraspinal)
025=Intrahepatic
026=Intralesional
027=Intralymphatic
```

028=Intramedullar (bone marrow)  
029=Intrameningeal  
030=Intramuscular  
031=Intraocular  
032=Intrapericardial  
033=Intraperitoneal  
034=Intrapleural  
035=Intrasynovial  
036=Intratumor  
037=Intrathecal  
038=Intrathoracic  
039=Intratracheal  
040=Intravenous bolus  
041=Intravenous drip  
042=Intravenous (not otherwise specified)  
043=Intravesical  
044=Iontophoresis  
045=Nasal  
046=Occlusive dressing technique  
047=Ophthalmic  
048=Oral  
049=Oropharyngeal  
050=Other  
051=Parenteral  
052=Periarticular  
053=Perineural  
054=Rectal  
055=Respiratory (inhalation)  
056=Retrobulbar  
057=Sunconjunctival  
058=Subcutaneous  
059=Subdermal  
060=Sublingual  
061=Topical  
062=Transdermal  
063=Transmammary  
064=Transplacental  
065=Unknown  
066=Urethral  
067=Vaginal  
-->  
<!ELEMENT drugparadministration (#PCDATA)>  
<!ATTLIST drugparadministration  
    %lang.att;  
>  
<!-- B.4.k.10a Gestation period at time of exposure -->  
<!--  
Field ref: B.4.k.10a  
Field title: Gestation period at time of exposure  
Field name: reactiongestationperiod  
Field length: 3N  
Field values:  
-->  
<!ELEMENT reactiongestationperiod (#PCDATA)>  
<!ATTLIST reactiongestationperiod  
    %lang.att;  
>

```
<!-- B.4.k.10b Gestation period at time of exposure unit -->
<!--
Field ref: B.4.k.10b
Field title: Gestation period unit
Field name: reactiongestationperiodunit
Field length: 3N
Field values:
802=Month
803=Week
804=Day
810=Trimester
-->
<!ELEMENT reactiongestationperiodunit (#PCDATA)>
<!ATTLIST reactiongestationperiodunit
    %lang.att;
>
<!-- B.4.k.11a MedDRA version for indication -->
<!--
Field ref: B.4.k.11a
Field title: MedDRA version for indication
Field name: drugindicationmeddraversion
Field length: 8AN
Field values:
-->
<!ELEMENT drugindicationmeddraversion (#PCDATA)>
<!ATTLIST drugindicationmeddraversion
    %lang.att;
>
<!-- B.4.k.11b Indication for use in the case -->
<!--
Field ref: B.4.k.11b
Field title: Indication for use in the case
Field name: drugindication
Field length: 100AN
Field values:
Comment : Field controlled by MedDRA LLT 2.1 or superior.
-->
<!ELEMENT drugindication (#PCDATA)>
<!ATTLIST drugindication
    %lang.att;
>
<!-- B.4.k.12a Date of start of drug format -->
<!--
Field ref: B.4.k.12a
Field title: Date of start of drug format
Field name: drugstartdateformat
Field length: 3N
Field values:
102=CCYYMMDD
610=CCYYMM
602=CCYY
-->
<!ELEMENT drugstartdateformat (#PCDATA)>
<!ATTLIST drugstartdateformat
    %lang.att;
>
<!-- B.4.k.12b Date of start of drug -->
```

```

<!--
Field ref: B.4.k.12b
Field title: Date of start of drug
Field name: drugstartdate
Field length: 8N
Field values:
-->
<!ELEMENT drugstartdate (#PCDATA)>
<!ATTLIST drugstartdate
    %lang.att;
>
<!-- B.4.k.13.1a Time interval between beginning of drug administration and
start of reaction / event -->
<!--
Field ref: B.4.k.13.1a
Field title: Time interval between beginning of drug administration and
start of reaction/event
Field name: drugstartperiod
Field length: 5N
Field values:
-->
<!ELEMENT drugstartperiod (#PCDATA)>
<!ATTLIST drugstartperiod
    %lang.att;
>
<!-- B.4.k.13.1b Time interval between beginning of drug administration and
start of reaction / event unit -->
<!--
Field ref: B.4.k.13.1b
Field title: Time interval between beginning of drug administration and
start of reaction/event unit
Field name: drugstartperiodunit
Field length: 3N
Field values:
801=Year
802=Month
803=Week
804=Day
805=Hour
806=Minute
807=Second
-->
<!ELEMENT drugstartperiodunit (#PCDATA)>
<!ATTLIST drugstartperiodunit
    %lang.att;
>
<!-- fB.4.k.13.2a Time interval between last dose of drug and start of reaction
/ event -->
<!--
Field ref: B.4.k.12.2a
Field title: Time interval between last dose of drug and start of
reaction/event
Field name: druglastperiod
Field length: 5N
Field values:
-->
<!ELEMENT druglastperiod (#PCDATA)>

```

```

<!ATTLIST druglastperiod
    %lang.att;
>
<!-- B.4.k.13.2b Time interval between last dose of drug and start of reaction /
event unit -->
<!--
Field ref: B.4.k.13.2b
Field title: Time interval between last dose of drug and start of
reaction/event unit
Field name: druglastperiodunit
Field length: 3N
Field values:
801=Year
802=Month
803=Week
804=Day
805=Hour
806=Minute
807=Second
-->
<!ELEMENT druglastperiodunit (#PCDATA)>
<!ATTLIST druglastperiodunit
    %lang.att;
>
<!-- B.4.k.14a Date of last administration format -->
<!--
Field ref: B.4.k.14a
Field title: Date of last administration format
Field name: drugenddateformat
Field length: 3N
Field values:
102=CCYYMMDD
610=CCYYMM
602=CCYY
-->
<!ELEMENT drugenddateformat (#PCDATA)>
<!ATTLIST drugenddateformat
    %lang.att;
>
<!-- B.4.k.14b Date of last administration -->
<!--
Field ref: B.4.k.14b
Field title: Date of last administration
Field name: drugenddate
Field length: 8N
Field values:
-->
<!ELEMENT drugenddate (#PCDATA)>
<!ATTLIST drugenddate
    %lang.att;
>
<!-- B.4.k.15a Duration of drug administration unit -->
<!--
Field ref: B.4.k.15a
Field title: Treatment duration
Field name: drugtreatmentduration
Field length: 5N

```

```
Field values:
-->
<!ELEMENT drugtreatmentduration (#PCDATA)>
<!ATTLIST drugtreatmentduration
    %lang.att;
>
<!-- B.4.k.15b Duration of drug administration unit -->
<!--
Field ref: B.4.k.15b
Field title: Treatment duration unit
Field name: drugtreatmentdurationunit
Field length: 3N
Field values:
801=Year
802=Month
803=Week
804=Day
805=Hour
806=Minute
-->
<!ELEMENT drugtreatmentdurationunit (#PCDATA)>
<!ATTLIST drugtreatmentdurationunit
    %lang.att;
>
<!-- B.4.k.16 Action(s) taken with drug -->
<!--
Field ref: B.4.k.16
Field title: Action(s) taken with drug
Field name: actiondrug
Field length: 1N
Field values:
1=Drug withdrawn
2=Dose reduced
3=Dose increased
4=Dose not changed
5=Unknown
6=Not applicable
-->
<!ELEMENT actiondrug (#PCDATA)>
<!ATTLIST actiondrug
    %lang.att;
>
<!-- B.4.k.17.1 Did reaction recur on readministration? -->
<!--
Field ref: B.4.k.17.1
Field title: Did reaction recur on readministration?
Field name: drugrecurreadministration
Field length: 1N
Field values:
1=Yes
2=No
3=Unknown
-->
<!ELEMENT drugrecurreadministration (#PCDATA)>
<!ATTLIST drugrecurreadministration
    %lang.att;
>
```

```
<!-- B.4.k.17.2a MedDRA version for reaction/event recurred-->
<!--
Field ref: B.4.k.17.2a
Field title: MedDRA version for reaction(s)/event(s) recurred
Field name: drugrecuractionmeddraversion
Field length: 8AN
Field values:
-->
<!ELEMENT drugrecuractionmeddraversion (#PCDATA)>
<!ATTLIST drugrecuractionmeddraversion
    %lang.att;
>
<!-- B.4.k.17.2b If yes, which reaction / event recurred? -->
<!--
Field ref: B.4.k.17.2b
Field title: If yes, which reaction / event recurred?
Field name: drugrecuraction
Field length: 100AN
Field values:
Comment : Field controlled by MedDRA LLT 2.1 or superior.
-->
<!ELEMENT drugrecuraction (#PCDATA)>
<!ATTLIST drugrecuraction
    %lang.att;
>
<!-- B.4.k.18.1a MedDRA version for reaction assessed -->
<!--
Field ref: B.4.k.18.1a
Field title: MedDRA version for Reaction assessed
Field name: drugreactionassesmeddraversion
Field length: 8AN
Field values:
-->
<!ELEMENT drugreactionassesmeddraversion (#PCDATA)>
<!ATTLIST drugreactionassesmeddraversion
    %lang.att;
>
<!-- B.4.k.18.1b Reaction assessed -->
<!--
Field ref: B.4.k.18.1b
Field title: Reaction assessed
Field name: drugreactionasses
Field length: 100AN
Field values:
-->
<!ELEMENT drugreactionasses (#PCDATA)>
<!ATTLIST drugreactionasses
    %lang.att;
>
<!-- B.4.k.18.2 Source of assessment -->
<!--
Field ref: B.4.k.18.2
Field title: Source of assessment
Field name: drugassessmentsource
Field length: 60AN
Field values:
-->
```

```
<!ELEMENT drugassessmentsource (#PCDATA)>
<!ATTLIST drugassessmentsource
    %lang.att;
>
<!-- B.4.k.18.3 Method of assessment -->
<!--
Field ref: B.4.k.18.3
Field title: Method of assessment
Field name: drugassessmentmethod
Field length: 35AN
Field values:
-->
<!ELEMENT drugassessmentmethod (#PCDATA)>
<!ATTLIST drugassessmentmethod
    %lang.att;
>
<!-- B.4.k.18.4 Result -->
<!--
Field ref: B.4.k.18.4
Field title: Assessment result
Field name: drugresult
Field length: 35AN
Field values:
-->
<!ELEMENT drugresult (#PCDATA)>
<!ATTLIST drugresult
    %lang.att;
>
<!-- B.4.k.19 Additional information on drug -->
<!--
Field ref: B.4.k.19
Field title: Additional information on drug
Field name: drugadditional
Field length: 100AN
Field values:
-->
<!ELEMENT drugadditional (#PCDATA)>
<!ATTLIST drugadditional
    %lang.att;
>
<!-- B.5.1 Case narrative including clinical course, therapeutic measures,
outcome and additional relevant information -->
<!--
Field ref: B.5.1
Field title: Case narrative including clinical course, therapeutic
measures, outcome and additional relevant information
Field name: narrativeincludeclinical
Field length: 20000AN
Field values:
-->
<!ELEMENT narrativeincludeclinical (#PCDATA)>
<!ATTLIST narrativeincludeclinical
    %lang.att;
>
<!-- B.5.2 Reporter's comments -->
<!--
Field ref: B.5.2
```



Field title: Reporter's comments  
Field name: reportercomment  
Field length: 210AN  
Field values:  
-->  
<!ELEMENT reportercomment (#PCDATA)>  
<!ATTLIST reportercomment  
%lang.att;  
>  
<!-- B.5.3a MedDRA version for senders diagnosis or syndrome -->  
<!--  
Field ref: B.5.3a  
Field title: B.5.3a MedDRA version for senders diagnosis or syndrome  
Field name: senderdiagnosismeddraversion  
Field length: 8AN  
Field values:  
Comment : Field controlled by MedDRA LLT 2.1 or superior.  
-->  
<!ELEMENT senderdiagnosismeddraversion (#PCDATA)>  
<!ATTLIST senderdiagnosismeddraversion  
%lang.att;  
>  
<!-- B.5.3 Sender's diagnosis / syndrome and / or reclassification of reaction /  
event -->  
<!--  
Field ref: B.5.3  
Field title: Sender's diagnosis / syndrome and / or reclassification of  
reaction / event  
Field name: senderdiagnosis  
Field length: 210AN  
Field values:  
Comment : Field controlled by MedDRA LLT 2.1 or superior.  
-->  
<!ELEMENT senderdiagnosis (#PCDATA)>  
<!ATTLIST senderdiagnosis  
%lang.att;  
>  
<!-- B.5.4 Sender's comments -->  
<!--  
Field ref: B.5.4  
Field title: Sender's comments  
Field name: sendercomment  
Field length: 2000AN  
Field values:  
-->  
<!ELEMENT sendercomment (#PCDATA)>  
<!ATTLIST sendercomment  
%lang.att;  
>