<!DOCTYPE ichicsr [ 
<!-- PUBLIC "-//ICHM2//DTD ICH ICSR Vers. 2.1//EN" "ich-icsr-v2.1.dtd" -->
<!--
Individual Case Safety Report Document Type Definition

This DTD is issued by the ICH M2 group and is public domain in nature.

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No commercial distribution is allowed.

The ICH is not responsible for any damage or financial loss resulting from use of this DTD. This version is tentative in nature and changes are expected. This DTD is subject to the ICH M2 change control procedures.

Version 1.0, Release 1.0, October 17, 1997

1998-04-21 Modifications made by JPMA
1. Changed "resultstestsprocedures" to "resultstestsprocedures?".

2. Spelling correction "seriousnesslifethreatning" to "seriousnesslifethreatening".

3. Spelling correction "seriousnesscongenitalanomali" to "seriousnesscongenitalanomali".

4. Changed ELEMENT "parentmedicalstructure" to "parentmedicalepisodename".

1998-09-27 Modifications made by FDA
5. Added lang attribute to ichicsr as #REQUIRED using a %lang.att entity.

6. Added lang attribute to all other elements as #IMPLIED.

7. Removed all unordered "&" connectors and replaced with the ordered connector "," to be compatible with XML.

8. Changed the names of elements under "ichicsrmessagheader" to comply with group decisions.

9. Removed all "old" elements.

10. Removed all sequence number entities.

11. Added Standard SGML character entities &lt; , &gt; , &amp; so that markup can be escaped as necessary.

12. Removed the %act.rec; and %ope.rec; internal entities, thus removing all support for the "(app | rep | del )" construct.

13. Root element of DTD is now "ichicsr" which allows one "ichicsrmessagheader" followed by "safetyreport+".

14. The relationship between "drug" and "activesubstance" is now one to zero or many.
Version 2.0, Release 1.0, Date to be decided

Version 2.1, Release 1.0, agreed November 2000
Documentation of changes made in version 2.0 to version 2.1 should be completed for implementation.
Safety Report Version (ICH ICSR M2 Data Processing element) is not an E2BM data element, but rather should be used for technical transmission purposes.
Date of final release of Version 2.1 February 1, 2001

After San Diego ICH 5, this DTD was fixed to be final version for Version 2.1.

-->

<!-- TECHNICAL NOTE

ICH ICSR SGML Declaration

To correctly parse an ICH ICSR SGML message requires the selection of the correct SGML declaration, along with this DTD, and the ICH ICSR SGML instance. This technical note provides guidance on which of several SGML declarations included with the ICH ICSR application to select based on the language and character set used within the ICH ICSR SGML instance. The method by which an SGML parser is told to use a specific declaration is parser specific. The three most common methods are -

1. Tell the parser via the command line which declaration to use.
2. Tell the parser via a specific environment variable which declaration to use.
3. If the parser supports SGML Open catalogs, within the catalog file is a command that can tell the parser which declaration to use. SGML catalog files are an industry standard way to tell a parser how to find all of the pieces (declaration, DTD, SGML document instance) needed to successfully parse.

To cover all of the languages necessary to support the ICH ICSR application, ISO 10646 (UNICODE) would have to be used. If this were the case, then only one SGML declaration would be needed to support all ICH ICSR languages. Because UNICODE support is not available in all popular computer application programs, the ICH M2 EWG has recommended that a variety of character sets be used at this time, instead of a single UNICODE character encoding. For each of these different character encodings a different SGML declaration needs to be generated and used.

Five SGML declarations are included with the ICH ICSR distribution. They are described briefly below.

ich-icsr-latin1.dcl - This SGML declaration supports the ISO 8859-1 (Latin 1) character set. This character set supports English, and most Western European languages.

ich-icsr-latin7.dcl - This SGML declaration supports the ISO 8859-7 (Latin 7) character set. This character set supports Greek.
ich-icsr-sjis.dcl - This SGML declaration supports the Shift JIS character set for encoding Japanese.

ich-icsr-utf8.dcl - This SGML declaration supports the ISO 10646 (UNICODE) UTF-8 character set. This character set supports almost all of the world's currently written languages.

ich-icsr-mult.dcl - This SGML declaration will support all of the currently defined ICHICSR languages, and it doesn't require the use of UNICODE. It is however a "hack" that relies on a fortuitous characteristic of the languages currently being used within the ICH ICSR SGML application.

This hack works because the character set documented within an SGML declaration is for the benefit of both the SGML parser and the programmer who implements the SGML application. The programmer needs detailed knowledge of all the characters being used to correctly code an application. The parser only really needs to know about some of the characters. In particular it needs to know which characters signify an SGML event. For instance that the "<" character starts an SGML open tag, and the "</" character sequence starts an SGML close tag. All told, the parser needs to know very little. Because of the particular combination of character sets being used within the ICH ICSR application, an SGML declaration can be defined that tells the parser just what it needs to know and still work across all of the different character sets. The catch is that this SGML declaration doesn't tell the programmer all that she or he needs to know to correctly code the rest of the application. If this declaration is used, the programmer will have to get this detailed information from another source.

-->

<!-- Entities -->
<!-- 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;">  

<!-- Supported '"quot;' to address the CCR # 2913 -->

<!-- quot """ -->
<!ENTITY quot "&#34;">
<!-- mdash -->
<!ENTITY mdash "&#8212;"/>

<!-- tilde -->
<!ENTITY tilde "&#732;"/>

<!-- trade -->
<!ENTITY trade "&#8482;"/>

<!-- scaron -->
<!ENTITY scaron "&#353;"/>

<!-- rsaquo -->
<!ENTITY rsaquo "&#8250;"/>

<!-- oelig -->
<!ENTITY oelig "&#339;"/>

<!-- Yuml -->
<!ENTITY Yuml "&#376;"/>

<!-- nbsp -->
<!ENTITY nbsp "&#160;"/>

<!-- iexcl "¡" -->
<!ENTITY iexcl "&#161;"/>

<!-- cent "¢" -->
<!ENTITY cent "&#162;"/>

<!-- pound "£" -->
<!ENTITY pound "&#163;"/>

<!-- curren "¤" -->
<!ENTITY curren "&#164;"/>

<!-- yen "¥" -->
<!ENTITY yen "&#165;"/>

<!-- brvbar "¦" -->
<!ENTITY brvbar "&#166;"/>

<!-- sect "§" -->
<!ENTITY sect "&#167;"/>

<!-- uml "¨" -->
<!ENTITY uml "&#168;"/>

<!-- copy "©" -->
<!ENTITY copy "&#169;"/>

<!-- ordf "ª" -->
<!ENTITY ordf "&#170;"/>

<!-- laquo "«" -->
<!ENTITY laquo "&#171;"/>
<!-- aring "å" -->
<!ENTITY aring "&#229;";>

<!-- aelig "æ" -->
<!ENTITY aelig "&#230;";>

<!-- ccedil "ç" -->
<!ENTITY ccedil "&#231;";>

<!-- egrave "è" -->
<!ENTITY egrave "&#232;";>

<!-- eacute "é" -->
<!ENTITY eacute "&#233;";>

<!-- ecirc "ê" -->
<!ENTITY ecirc "&#234;";>

<!-- euml "ë" -->
<!ENTITY euml "&#235;";>

<!-- igrave "ì" -->
<!ENTITY igrave "&#236;";>

<!-- iacute "í" -->
<!ENTITY iacute "&#237;";>

<!-- icirc "î" -->
<!ENTITY icirc "&#238;";>

<!-- iuml "ï" -->
<!ENTITY iuml "&#239;";>

<!-- eth "ð" -->
<!ENTITY eth "&#240;";>

<!-- ntilde "ñ" -->
<!ENTITY ntilde "&#241;";>

<!-- ograve "ò" -->
<!ENTITY ograve "&#242;";>

<!-- oacute "ó" -->
<!ENTITY oacute "&#243;";>

<!-- ocirc "ô" -->
<!ENTITY ocirc"&#244;";>

<!-- otilde "ö" -->
<!ENTITY otilde "&#245;";>

<!-- ouml "ö" -->
<!ENTITY ouml "&#246;";>

<!-- divide "÷" -->
<!ENTITY divide "&#247;";>
<!ENTITY oslash "ø" -->
<!ENTITY oslash "&#248;"uellement -->

<!ENTITY ugrave "ù" -->
<!ENTITY ugrave "&#249;"uellement -->

<!ENTITY uacute "ú" -->
<!ENTITY uacute "&#250;"uellement -->

<!ENTITY ucirc "û" -->
<!ENTITY ucirc "&#251;"alement -->

<!ENTITY uuml "ü" -->
<!ENTITY uuml "&#252;"alement -->

<!ENTITY yacute "ý" -->
<!ENTITY yacute "&#253;"alement -->

<!ENTITY thorn "þ" -->
<!ENTITY thorn "&#254;"alement -->

<!ENTITY yuml "ï" -->
<!ENTITY yuml "&#255;"alement -->

<!-- M.1 ICH ICSR Message Header Information -->

<!ELEMENT ichicsr - - (ichicsrmessageheader, safetyreport+)>
<!ATTLIST ichicsr
  lang CDATA #REQUIRED -->

</!-- Elements and Attributes -->
</!-- Elements and Attributes -->

</!-- Elements and Attributes -->

<!-- M.1.1 Message Type -->
<!ELEMENT messagetype - - (#PCDATA) >
<!ATTLIST messagetype
  %lang.att; -->

</!-- Elements and Attributes -->
</!-- Elements and Attributes -->

</!-- Elements and Attributes -->
<!-- M.1.2 Message Format Version -->
<!ELEMENT messageformatversion [([#PCDATA]) ]>
<!ATTLIST messageformatversion %lang.att;>

<!-- M.1.3 Message Format Release -->
<!ELEMENT messageformatrelease [([#PCDATA]) ]>
<!ATTLIST messageformatrelease %lang.att;>

<!-- M.1.4 Message Number -->
<!ELEMENT messagenumb [([#PCDATA]) ]>
<!ATTLIST messagenumb %lang.att;>

<!-- M.1.5 Message Sender Identifier -->
<!ELEMENT messagesenderidentifier [([#PCDATA]) ]>
<!ATTLIST messagesenderidentifier %lang.att;>

<!-- M.1.6 Message Receiver Identifier -->
<!ELEMENT messagereceiveridentifier [([#PCDATA]) ]>
<!ATTLIST messagereceiveridentifier %lang.att;>

<!-- M.1.7a Message Date Format -->
<!ELEMENT messagedateformat [([#PCDATA]) ]>
<!ATTLIST messagedateformat %lang.att;>

<!-- M.1.7b Message Date -->
<!ELEMENT messagedate [([#PCDATA]) ]>
<!ATTLIST messagedate %lang.att;>

<!-- Individual Case Safety Report(s) Specifications -->
<!-- A.1 Identification of the case safety report -->

<!ELEMENT safetyreport [([#PCDATA]) ]>
<!ATTLIST safetyreport %lang.att;>

(safetyreportversion?,
safetyreportid ,
primarysourcecountry?,
occurrencountry?,
transmissiondateformat?,
transmissiondate?,
reporttype?,
senior?,
senioritydeath?,
senioritylifethreatening?,
seniorityhospitalization?,
seriousnessdisabling?,
seriousnesscongenitalanomaly?,
seriousnessother?,
receivedateformat?,
receivedate?,
receiptdateformat,
receiptdate,
additionaldocument?,
documentlist?,
fulfillexpeditecriteria?,
authorynumb?,
companynumb?,
duplicate?,
casenullification?,
nullificationreason?,
medicallyconfirm?,
(reportduplicate*,
linkedreport*,
primarysource+,
sender,
receiver,
patient))>
<!ATTLIST safetyreport
%lang.att;>

<!ELEMENT reportduplicate  - -
(duplicatesource?,
duplicatenumb?)>
<!ATTLIST reportduplicate
%lang.att;>

<!ELEMENT linkedreport  - -
(linkreportnumb?)>
<!ATTLIST linkedreport
%lang.att;>

<!-- A.2 Primary source(s) of information -->
<!ELEMENT primarysource  - -
(reportertitle?,
reportergivename?,
reportermiddlename?,
reporterfamilyname?,
reporterorganization?,
reporterdepartment?,
reporterstreet?,
reportercity?,
reporterstate?,
reporterpostcode?,
reportercountry?,
qualification?,
literaturereference?,
studyname?,
sponsorstudynumb?,
observestudytype?)>
<!ATTLIST primarysource
<ATTLIST patient
%lang.att;
>
<!-- B.1.7 Relevant medical history and concurrent -->
<!ELEMENT medicalhistoryepisode - -
  (patientepisodenedameddraversion?,
   patientepisodename?,
   patientmedicalstartdateformat?,
   patientmedicalstartdate?,
   patientmedicalcontinue?,
   patientmedicalenddateformat?,
   patientmedicalenddate?,
   patientmedicalcomment?)>
<ATTLIST medicalhistoryepisode
%lang.att;
>
<!-- B.1.8 Relevant past drug history -->
<!ELEMENT patientpastdrugtherapy - -
  (patientdrugname?,
   patientdrugstartdateformat?,
   patientdrugstartdate?,
   patientdrugenddateformat?,
   patientdrugenddate?,
   patientindicationmeddraversion?,
   patientdrugindication?,
   patientdrgreactionmeddraversion?,
   patientdrugreaction?)>
<ATTLIST patientpastdrugtherapy
%lang.att;
<!-- B.1.9 In case of death: -->
<!ELEMENT patientdeath - -
  (patientdeathdateformat?,
   patientdeathdate?,
   patientautopsyyesno?,
   (patientdeathcause*,
    patientautopsy*))>
<!ATTLIST patientdeath
  %lang.att;>

<!ELEMENT patientdeathcause - -
  (patientdeathreportmeddraversion?,
   patientdeathreport?)>
<!ATTLIST patientdeathcause
  %lang.att;>

<!ELEMENT patientautopsy - -
  (patientdetermautopsmeddraversion?,
   patientdetermineautopsy?)>
<!ATTLIST patientautopsy
  %lang.att;>

<!-- B.1.10 For a parent-child / fetus report, information concerning the parent: -->
<!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 -->
<!ELEMENT parentmedicalhistoryepisode - -
  (parentmedicalstartdateformat?,
   parentmedicalepisodename?,
   parentmedicalstartdate?,
   parentmedicalcontinue?,
   parentmedicalenddateformat?,
   parentmedicalenddate?)>
<!ATTLIST parentmedicalcomment?
%lang.att;
>

<!-- B.1.10.8 Relevant past drug history -->
<!ELEMENT parentpastdrugtherapy - -
(pastdrugname?,
  pastdrugstartdateformat?,
  pastdrugstartdate?,
  pastdrugenddateformat?,
  pastdrugenddate?,
  pastdrgindicationmeddraversion?,
  pastdrgindication?,
  pastdrgreactionmeddraversion?,
  pastdrgreaction?)>
<!ATTLIST parentpastdrugtherapy
%lang.att;
>

<!-- B.2 Reaction(s) / Event(s) -->
<!ELEMENT reaction - -
(primarysourcereaction?,
  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: -->
<!ELEMENT test - -
(testdateformat?,
  testdate?,
  testname?,
  testresult?,
  testunit?,
  lowtestrange?,
  hightestrange?,
  moreinformation?)>
<!ATTLIST test
%lang.att;
<!-- A.1.4 Type of report -->
<!ELEMENT reporttype - - (#PCDATA)>
<!ATTLIST reporttype
%lang.att;
>

<!-- A.1.5.1 Serious -->
<!ELEMENT serious - - (#PCDATA)>
<!ATTLIST serious
%lang.att;
>

<!-- A.1.5.2 Seriousness criteria -->
<!ELEMENT seriousnessdeath - - (#PCDATA)>
<!ATTLIST seriousnessdeath
%lang.att;
>
<!ELEMENT seriousnesslifethreatening - - (#PCDATA)>
<!ATTLIST seriousnesslifethreatening
%lang.att;
>
<!ELEMENT seriousnesshospitalization - - (#PCDATA)>
<!ATTLIST seriousnesshospitalization
%lang.att;
>
<!ELEMENT seriousnessdisabling - - (#PCDATA)>
<!ATTLIST seriousnessdisabling
%lang.att;
>
<!ELEMENT seriousnesscongenitalanomaly - - (#PCDATA)>
<!ATTLIST seriousnesscongenitalanomaly
%lang.att;
>
<!ELEMENT seriousnessother - - (#PCDATA)>
<!ATTLIST seriousnessother
%lang.att;
>

<!-- A.1.6a Date report was first received from source format -->
<!ELEMENT receivedateformat - - (#PCDATA)>
<!ATTLIST receivedateformat
%lang.att;
>

<!-- A.1.6b Date report was first received from source -->
<!ELEMENT receivedate - - (#PCDATA)>
<!ATTLIST receivedate
%lang.att;
>

<!-- A.1.7a Date of receipt of the most recent information for this report -->
<!ELEMENT receiptdateformat - - (#PCDATA)>
<!ATTLIST receiptdateformat
%lang.att;
>
<!-- A.1.7b Date of receipt of the most recent information for this report -->
<!ELEMENT receiptdate  - -     (#PCDATA)>
<!ATTLIST receiptdate
%lang.att;>

<!-- A.1.8.1 Are additional documents available -->
<!ELEMENT additionaldocument  - -     (#PCDATA)>
<!ATTLIST additionaldocument
%lang.att;>

<!-- A.1.8.2 List of documents held by sender -->
<!ELEMENT documentlist          - -     (#PCDATA)>
<!ATTLIST documentlist
%lang.att;>

<!-- A.1.9 Does this case fulfill the local criteria for an expedited report -->
<!ELEMENT fulfillexpeditecriteria  - -   (#PCDATA)>
<!ATTLIST fulfillexpeditecriteria
%lang.att;>

<!--
The A.1.10 - The worldwide unique case identification number must be populated as per the following user guidance:

Only A.1.10.1 or A.1.10.2 should be used. No case should ever have more than one of these items completed. The contents of whichever item is used should remain unchanged for any transmissions subsequent to the original transmission. When a regulator is the initial sender A.1.10.1 should be used. When an entity other than a regulator is the initial sender, A.1.10.2 should be used. When a sender has not previously received a valid E2B/M2 report electronically, the identifiers (content and format) in A.1.0.1 and A.1.10.1 or A.1.10.2 should be identical. Retransmitters should use their own sender's (case) safety report unique identifier (A.1.0.1), but not change A.1.10.1 or A.1.10.2. Examples are available in attachment 3 of the E2BM document.

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 Regulatory authority's case report number -->
<!-- B.1.10.2.2b Age of parent unit -->
<!ELEMENT parentageunit - - (#PCDATA)>
<!ATTLIST parentageunit
 %lang.att;
>

<!-- B.1.10.3a Last menstrual period format -->
<!ELEMENT parentlastmenstrualdateformat - - (#PCDATA)>
<!ATTLIST parentlastmenstrualdateformat
 %lang.att;
>

<!-- B.1.10.3b Last menstrual period -->
<!ELEMENT parentlastmenstrualdate - - (#PCDATA)>
<!ATTLIST parentlastmenstrualdate
 %lang.att;
>

<!-- B.1.10.4 Weight (kg) of parent -->
<!ELEMENT parentweight - - (#PCDATA)>
<!ATTLIST parentweight
 %lang.att;
>

<!-- B.1.10.5 Height (cm) of parent -->
<!ELEMENT parentheight - - (#PCDATA)>
<!ATTLIST parentheight
 %lang.att;
>

<!-- B.1.10.6 Sex of parent -->
<!ELEMENT parentsex - - (#PCDATA)>
<!ATTLIST parentsex
 %lang.att;
>

<!-- B.1.10.7.1a.2 Structured information -->
<!ELEMENT parentmedicalepisodename - - (#PCDATA)>
<!ATTLIST parentmedicalepisodename
 %lang.att;
>

<!-- B.1.10.7.1b Start date format -->
<!ELEMENT parentmedicalstartdateformat - - (#PCDATA)>
<!ATTLIST parentmedicalstartdateformat
 %lang.att;
>

<!-- B.1.10.7.1c Start date -->
<!ELEMENT parentmedicalstartdate - - (#PCDATA)>
<!ATTLIST parentmedicalstartdate
 %lang.att;
>

<!-- B.1.10.7.1d Continuing -->
<!ELEMENT parentmedicalcontinue - - (#PCDATA)>
<!ATTLIST parentmedicalcontinue
 %lang.att;
<!-- B.1.10.7.1e End date format -->
<!ELEMENT parentmedicalenddateformat - - (#PCDATA)>
<!ATTLIST parentmedicalenddateformat %lang.att;>

<!-- B.1.10.7.1f End date -->
<!ELEMENT parentmedicalenddate - - (#PCDATA)>
<!ATTLIST parentmedicalenddate %lang.att;>

<!-- B.1.10.7.1g Comments -->
<!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 -->
<!ELEMENT parentmedicalrelevanttext - - (#PCDATA)>
<!ATTLIST parentmedicalrelevanttext %lang.att;>

<!-- B.1.10.8a Name of drug as -->
<!ELEMENT parentdrugname - - (#PCDATA)>
<!ATTLIST parentdrugname %lang.att;>

<!-- B.1.10.8b Start date format -->
<!ELEMENT parentdrugstartdateformat - - (#PCDATA)>
<!ATTLIST parentdrugstartdateformat %lang.att;>

<!-- B.1.10.8c Start date -->
<!ELEMENT parentdrugstartdate - - (#PCDATA)>
<!ATTLIST parentdrugstartdate %lang.att;>

<!-- B.1.10.8d End date format -->
<!ELEMENT parentdrugenddateformat - - (#PCDATA)>
<!ATTLIST parentdrugenddateformat %lang.att;>

<!-- B.1.10.8e End date -->
<!ELEMENT parentdrugenddate - - (#PCDATA)>
<!ATTLIST parentdrugenddate %lang.att;>

<!-- B.1.10.8f.2 Indication -->
<!ELEMENT parentdrugindication - - (#PCDATA)>
<!-- B.2.i.7.1a Time interval between beginning of suspect drug administration and start of reaction / event -->
<!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 -->
<!ELEMENT reactionfirsttimeunit - -     (#PCDATA)>
<!ATTLIST reactionfirsttimeunit
%lang.att;>

<!-- B.2.i.7.2a Time interval between last dose and start of reaction / event -->
<!ELEMENT reactionlasttime     - -     (#PCDATA)>
<!ATTLIST reactionlasttime
%lang.att;>

<!-- B.2.i.7.2b Time interval between last dose and start of reaction / event unit -->
<!ELEMENT reactionlasttimeunit - -     (#PCDATA)>
<!ATTLIST reactionlasttimeunit
%lang.att;>

<!-- B.2.i.8 Outcome of reaction / event at the time of last observation -->
<!ELEMENT reactionoutcome      - -     (#PCDATA)>
<!ATTLIST reactionoutcome
%lang.att;>

<!-- B.3.1a Date format -->
<!ELEMENT testdateformat        - -     (#PCDATA)>
<!ATTLIST testdateformat
%lang.att;>

<!-- B.3.1b Date -->
<!ELEMENT testdate              - -     (#PCDATA)>
<!ATTLIST testdate
%lang.att;>

<!-- B.3.1c Test -->
<!ELEMENT testname              - -     (#PCDATA)>
<!ATTLIST testname
%lang.att;>

<!-- B.3.1d Result -->
<!ELEMENT testresult            - -     (#PCDATA)>
<!ATTLIST testresult
%lang.att;>
<!ATTLIST parentdrgreactionmeddraversion
  %lang.att;>

<!ELEMENT parentdrgreactionmeddraversion
  %lang.att;
>
<!ELEMENT parentdrgindicationmeddraversion
  %lang.att;>

<!ELEMENT drugindicationmeddraversion
  %lang.att;>

<!ELEMENT patientdrgreactionmeddraversion
  %lang.att;>

<!ELEMENT drugreactionassesmeddraversion
  %lang.att;>

<!ELEMENT reactionmeddraversionpt
  %lang.att;>

<!ELEMENT reactionmeddrapt
  %lang.att;>

<!ELEMENT reactionmeddraversionllt
  %lang.att;>

<!ELEMENT reactionmeddrallt
  %lang.att;>

<!ATTLIST parentdrgreactionmeddraversion
  %lang.att;>

<!-- B.1.10.8f.1 MedDRA version for indication -->
<!ELEMENT parentdrgindicationmeddraversion
  %lang.att;>

<!-- Added in version V2.1 -->
<!ATTLIST parentdrgindicationmeddraversion
  %lang.att;>

!important B.4.k.11a MedDRA version for indication -->
<!ELEMENT drugindicationmeddraversion
  %lang.att;>

<!-- Added in version V2.1 -->
<!ATTLIST drugindicationmeddraversion
  %lang.att;>

<!-- B.1.8g.1 MedDRA version for reaction -->
<!ELEMENT patientdrgreactionmeddraversion
  %lang.att;>

<!-- Added in version V2.1 -->
<!ATTLIST patientdrgreactionmeddraversion
  %lang.att;>

<!-- B.4.k.18.1a MedDRA version for reaction assessed -->
<!ELEMENT drugreactionassesmeddraversion
  %lang.att;>

<!-- Added in version V2.1 -->
<!ATTLIST drugreactionassesmeddraversion
  %lang.att;>

<!-- B.2.i.2a MedDRA version for reaction/event term PT -->
<!ELEMENT reactionmeddraversionpt
  %lang.att;>

<!-- Added in version V2.1 -->
<!ATTLIST reactionmeddraversionpt
  %lang.att;>

<!-- B.2.i.2b MedDRA PT for reaction/event term -->
<!ELEMENT reactionmeddrapt
  %lang.att;>

<!-- Added in version V2.1 -->
<!ATTLIST reactionmeddrapt
  %lang.att;>

<!-- B.2.i.1a MedDRA version for reaction/event term LLT -->
<!ELEMENT reactionmeddraversionllt
  %lang.att;>

<!-- Added in version V2.1 -->
<!ATTLIST reactionmeddraversionllt
  %lang.att;>

<!-- B.2.i.1b MedDRA LLT for reaction/event term -->
<!ELEMENT reactionmeddrallt
  %lang.att;>

<!-- Added in version V2.1 -->
<!ATTLIST reactionmeddrallt
  %lang.att;>