Schema **adverseEvents.xsd**

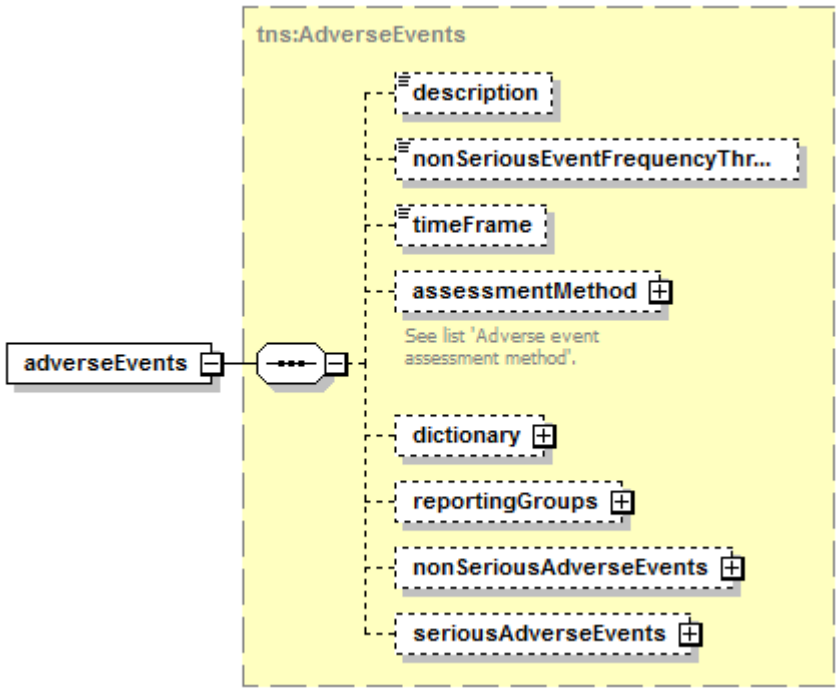
schema location: **adverseEvents.xsd**
attributeFormDefault:

elementFormDefault: **unqualified**
targetNamespace: **http://eudract.ema.europa.eu/schema/clinical_trial_result/adverse_events**

Elements
adverseEvents

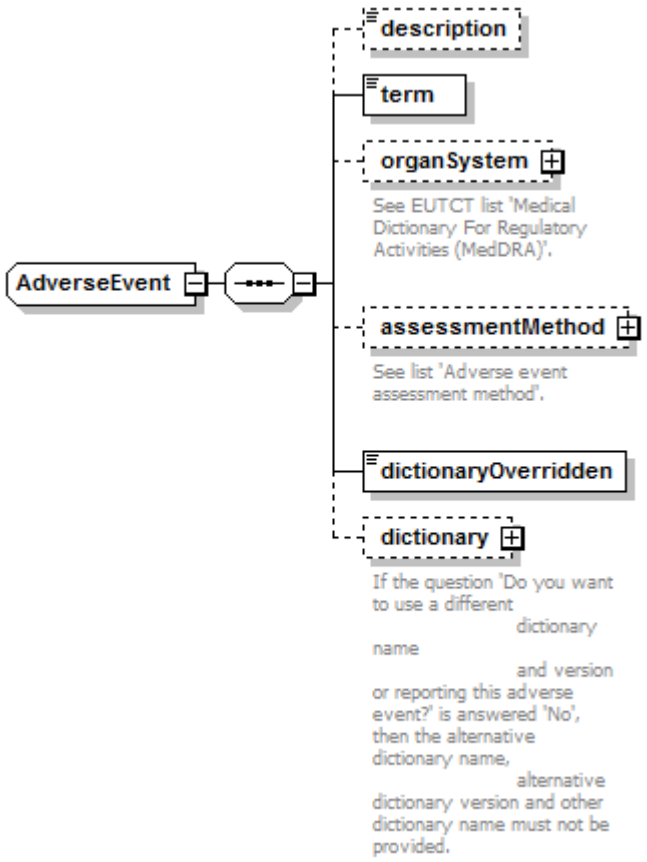
Complex types
AdverseEvent
AdverseEventReportingGroup
AdverseEvents
ControlledTerm
DictionaryDetails
EudractTerm
fatalities
NonSeriousAdverseEvent
ReportingGroupAdverseEventValues
ReportingGroupNonSeriousAdverseEventValues
ReportingGroupSeriousAdverseEventValues
SeriousAdverseEvent

element **adverseEvents**

diagram	
namespace	http://eudract.ema.europa.eu/schema/clinical_trial_result/adverse_events
type	**tns:AdverseEvents**

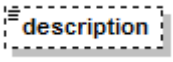
properties	content complex
children	**description** **nonSeriousEventFrequencyThreshold** **timeFrame** **assessmentMethod** **dictionary** **reportingGroups** **nonSeriousAdverseEvents** **seriousAdverseEvents**
source	<xs:element name="adverseEvents" type="tns:AdverseEvents"/>

complexType **AdverseEvent**

diagram	
namespace	http://eudract.ema.europa.eu/schema/clinical_trial_result/adverse_events
properties	abstract true
children	**description** **term** **organSystem** **assessmentMethod** **dictionaryOverridden** **dictionary**
used by	complexTypes **NonSeriousAdverseEvent** **SeriousAdverseEvent**
source	<xs:complexType name="AdverseEvent" abstract="true"> <xs:sequence> <xs:element name="description" minOccurs="0"> <xs:simpleType> <xs:restriction base="xs:string"> <xs:maxLength value="250"/> </xs:restriction> </xs:simpleType> </xs:element> <xs:element name="term"> <xs:simpleType>

```
        <xs:restriction base="xs:string">
          <xs:minLength value="2"/>
          <xs:maxLength value="100"/>
        </xs:restriction>
      </xs:simpleType>
    </xs:element>
    <xs:element name="organSystem" type="tns:ControlledTerm" minOccurs="0">
      <xs:annotation>
        <xs:documentation>See EUTCT list 'Medical Dictionary For Regulatory Activities (MedDRA)'.
                </xs:documentation>
      </xs:annotation>
    </xs:element>
    <xs:element name="assessmentMethod" type="tns:EudractTerm" minOccurs="0">
      <xs:annotation>
        <xs:documentation xml:lang="en">See list 'Adverse event assessment method'.
                </xs:documentation>
      </xs:annotation>
    </xs:element>
    <xs:element name="dictionaryOverridden" type="xs:boolean" default="false"/>
    <xs:element name="dictionary" type="tns:DictionaryDetails" minOccurs="0">
      <xs:annotation>
        <xs:documentation xml:lang="en">If the question 'Do you want to use a different
                    dictionary name
                    and version or reporting this adverse event?' is answered 'No', then the alternative
dictionary name,
                    alternative dictionary version and other dictionary name must not be provided.
                </xs:documentation>
      </xs:annotation>
    </xs:element>
  </xs:sequence>
</xs:complexType>
```

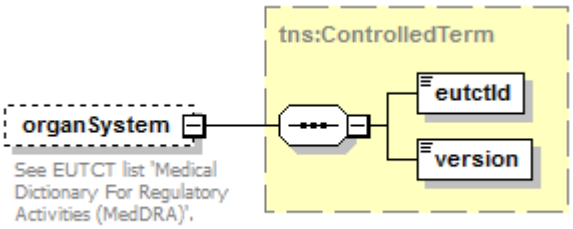
element **AdverseEvent/description**

diagram	
type	restriction of **xs:string**
properties	minOcc 0 maxOcc 1 content simple
facets	Kind Value Annotation maxLength 250
source	<xs:element name="description" minOccurs="0"> <xs:simpleType> <xs:restriction base="xs:string"> <xs:maxLength value="250"/> </xs:restriction> </xs:simpleType> </xs:element>

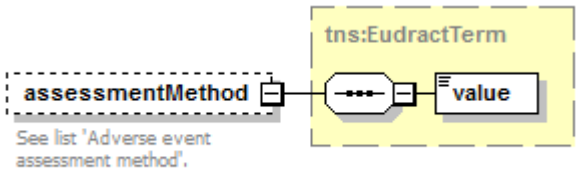
element **AdverseEvent/term**

diagram	
type	restriction of **xs:string**
properties	content simple
facets	Kind Value Annotation minLength 2 maxLength 100
source	<xs:element name="term"> <xs:simpleType> <xs:restriction base="xs:string"> <xs:minLength value="2"/> <xs:maxLength value="100"/> </xs:restriction> </xs:simpleType> </xs:element>

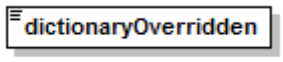
element **AdverseEvent/organSystem**

diagram	
type	**tns:ControlledTerm**
properties	minOcc 0 maxOcc 1 content complex
children	**eutctId** **version**
annotation	documentation See EUTCT list 'Medical Dictionary For Regulatory Activities (MedDRA)'.
source	<xs:element name="organSystem" type="tns:ControlledTerm" minOccurs="0"> <xs:annotation> <xs:documentation>See EUTCT list 'Medical Dictionary For Regulatory Activities (MedDRA)'. </xs:documentation> </xs:annotation> </xs:element>

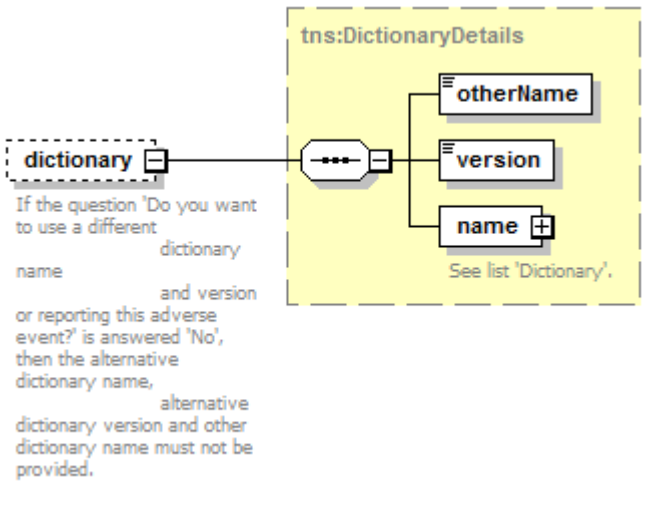
element **AdverseEvent/assessmentMethod**

diagram	
type	**tns:EudractTerm**
properties	minOcc 0 maxOcc 1 content complex
children	**value**
annotation	documentation See list 'Adverse event assessment method'.
source	<xs:element name="assessmentMethod" type="tns:EudractTerm" minOccurs="0"> <xs:annotation> <xs:documentation xml:lang="en">See list 'Adverse event assessment method'. </xs:documentation> </xs:annotation> </xs:element>

element **AdverseEvent/dictionaryOverridden**

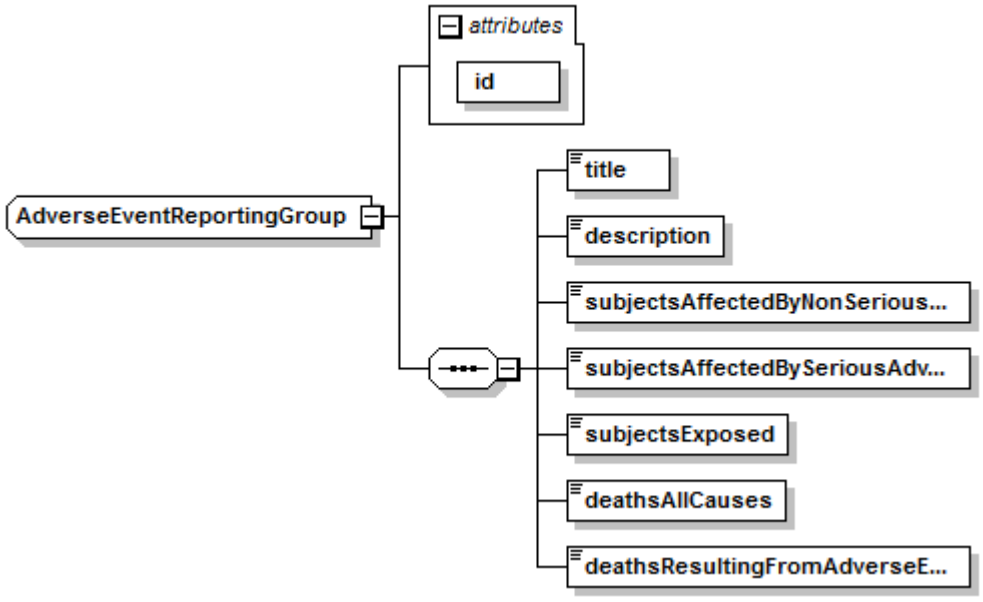
diagram	
type	**xs:boolean**
properties	content simple default false
source	<xs:element name="dictionaryOverridden" type="xs:boolean" default="false"/>

element **AdverseEvent/dictionary**

diagram	

type	**tns:DictionaryDetails**
properties	minOcc 0 maxOcc 1 content complex
children	**otherName version name**
annotation	documentation If the question 'Do you want to use a different dictionary name and version or reporting this adverse event?' is answered 'No', then the alternative dictionary name, alternative dictionary version and other dictionary name must not be provided.
source	<xs:element name="dictionary" type="tns:DictionaryDetails" minOccurs="0"> <xs:annotation> <xs:documentation xml:lang="en">If the question 'Do you want to use a different dictionary name and version or reporting this adverse event?' is answered 'No', then the alternative dictionary name, alternative dictionary version and other dictionary name must not be provided. </xs:documentation> </xs:annotation> </xs:element>

complexType **AdverseEventReportingGroup**

diagram	
namespace	http://eudract.ema.europa.eu/schema/clinical_trial_result/adverse_events
children	**title description subjectsAffectedByNonSeriousAdverseEvents subjectsAffectedBySeriousAdverseEvents subjectsExposed deathsAllCauses deathsResultingFromAdverseEvents**
used by	element **AdverseEvents/reportingGroups/reportingGroup**
attributes	Name: id; Type: **xs:ID**; Use: required; Default: ; Fixed: ; Annotation:
source	<xs:complexType name="AdverseEventReportingGroup"> <xs:sequence> <xs:element name="title">

```
      <xs:simpleType>
        <xs:restriction base="xs:string">
          <xs:minLength value="2"/>
          <xs:maxLength value="62"/>
        </xs:restriction>
      </xs:simpleType>
    </xs:element>
    <xs:element name="description" nillable="true">
      <xs:simpleType>
        <xs:restriction base="xs:string">
          <xs:maxLength value="999"/>
        </xs:restriction>
      </xs:simpleType>
    </xs:element>
    <xs:element name="subjectsAffectedByNonSeriousAdverseEvents" nillable="true">
      <xs:simpleType>
        <xs:restriction base="xs:int">
          <xs:minInclusive value="0"/>
          <xs:maxInclusive value="99999999"/>
        </xs:restriction>
      </xs:simpleType>
    </xs:element>
    <xs:element name="subjectsAffectedBySeriousAdverseEvents" nillable="true">
      <xs:simpleType>
        <xs:restriction base="xs:int">
          <xs:minInclusive value="0"/>
          <xs:maxInclusive value="99999999"/>
        </xs:restriction>
      </xs:simpleType>
    </xs:element>
    <xs:element name="subjectsExposed" nillable="true">
      <xs:simpleType>
        <xs:restriction base="xs:int">
          <xs:minInclusive value="1"/>
          <xs:maxInclusive value="99999999"/>
        </xs:restriction>
      </xs:simpleType>
    </xs:element>
    <xs:element name="deathsAllCauses" nillable="true">
      <xs:simpleType>
        <xs:restriction base="xs:int">
          <xs:minInclusive value="0"/>
        </xs:restriction>
      </xs:simpleType>
    </xs:element>
    <xs:element name="deathsResultingFromAdverseEvents" nillable="true">
      <xs:simpleType>
        <xs:restriction base="xs:int">
          <xs:minInclusive value="0"/>
        </xs:restriction>
      </xs:simpleType>
    </xs:element>
  </xs:sequence>
  <xs:attribute name="id" type="xs:ID" use="required"/>
</xs:complexType>
```

attribute **AdverseEventReportingGroup/@id**

type	**xs:ID**
properties	use required
source	<xs:attribute name="id" type="xs:ID" use="required"/>

element **AdverseEventReportingGroup/title**

diagram	
type	restriction of **xs:string**
properties	content simple
facets	Kind Value Annotation minLength 2 maxLength 62
source	<xs:element name="title"> <xs:simpleType> <xs:restriction base="xs:string"> <xs:minLength value="2"/> <xs:maxLength value="62"/> </xs:restriction> </xs:simpleType> </xs:element>

element **AdverseEventReportingGroup/description**

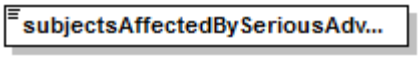
diagram	
type	restriction of **xs:string**
properties	content simple nillable true
facets	Kind Value Annotation maxLength 999
source	<xs:element name="description" nillable="true"> <xs:simpleType> <xs:restriction base="xs:string"> <xs:maxLength value="999"/> </xs:restriction> </xs:simpleType> </xs:element>

element **AdverseEventReportingGroup/subjectsAffectedByNonSeriousAdverseEvents**

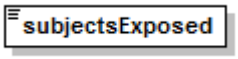
diagram	

type	restriction of **xs:int**
properties	content simple nillable true
facets	Kind Value Annotation minInclusive 0 maxInclusive 99999999
source	<xs:element name="subjectsAffectedByNonSeriousAdverseEvents" nillable="true"> <xs:simpleType> <xs:restriction base="xs:int"> <xs:minInclusive value="0"/> <xs:maxInclusive value="99999999"/> </xs:restriction> </xs:simpleType> </xs:element>

element **AdverseEventReportingGroup/subjectsAffectedBySeriousAdverseEvents**

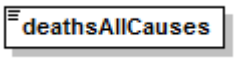
diagram	
type	restriction of **xs:int**
properties	content simple nillable true
facets	Kind Value Annotation minInclusive 0 maxInclusive 99999999
source	<xs:element name="subjectsAffectedBySeriousAdverseEvents" nillable="true"> <xs:simpleType> <xs:restriction base="xs:int"> <xs:minInclusive value="0"/> <xs:maxInclusive value="99999999"/> </xs:restriction> </xs:simpleType> </xs:element>

element **AdverseEventReportingGroup/subjectsExposed**

diagram	
type	restriction of **xs:int**
properties	content simple nillable true
facets	Kind Value Annotation minInclusive 1 maxInclusive 99999999
source	<xs:element name="subjectsExposed" nillable="true"> <xs:simpleType> <xs:restriction base="xs:int"> <xs:minInclusive value="1"/> <xs:maxInclusive value="99999999"/> </xs:restriction>

```
  </xs:simpleType>
</xs:element>
```

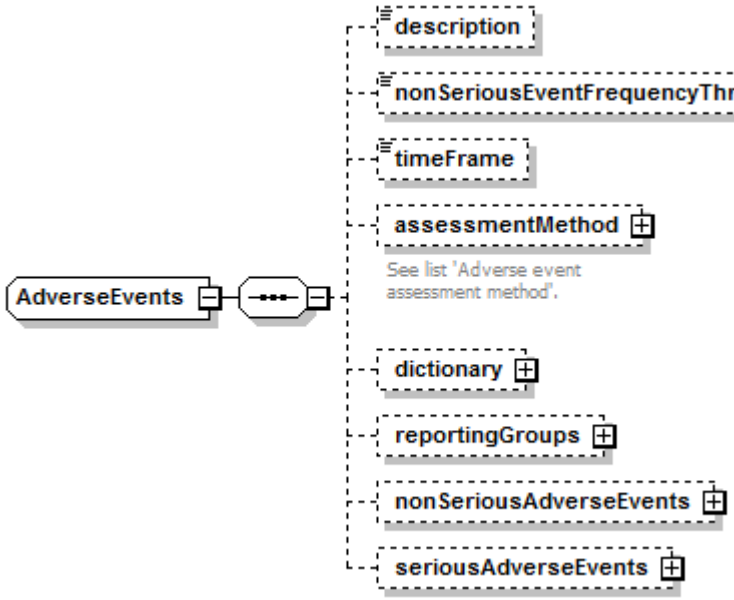
element **AdverseEventReportingGroup/deathsAllCauses**

diagram	
type	restriction of **xs:int**
properties	content simple nillable true
facets	Kind Value Annotation minInclusive 0
source	<xs:element name="deathsAllCauses" nillable="true"> <xs:simpleType> <xs:restriction base="xs:int"> <xs:minInclusive value="0"/> </xs:restriction> </xs:simpleType> </xs:element>

element **AdverseEventReportingGroup/deathsResultingFromAdverseEvents**

diagram	
type	restriction of **xs:int**
properties	content simple nillable true
facets	Kind Value Annotation minInclusive 0
source	<xs:element name="deathsResultingFromAdverseEvents" nillable="true"> <xs:simpleType> <xs:restriction base="xs:int"> <xs:minInclusive value="0"/> </xs:restriction> </xs:simpleType> </xs:element>

complexType **AdverseEvents**

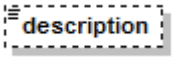
diagram	
namespace	http://eudract.ema.europa.eu/schema/clinical_trial_result/adverse_events
children	**description** **nonSeriousEventFrequencyThreshold** **timeFrame** **assessmentMethod** **dictionary** **reportingGroups** **nonSeriousAdverseEvents** **seriousAdverseEvents**
used by	element **adverseEvents**

source

```
<xs:complexType name="AdverseEvents">
 <xs:sequence>
  <xs:element name="description" minOccurs="0">
   <xs:simpleType>
    <xs:restriction base="xs:string">
     <xs:maxLength value="350"/>
    </xs:restriction>
   </xs:simpleType>
  </xs:element>
  <xs:element name="nonSeriousEventFrequencyThreshold" minOccurs="0">
   <xs:simpleType>
    <xs:restriction base="xs:decimal">
     <xs:minInclusive value="0.00"/>
     <xs:maxInclusive value="5.00"/>
    </xs:restriction>
   </xs:simpleType>
  </xs:element>
  <xs:element name="timeFrame" minOccurs="0">
   <xs:simpleType>
    <xs:restriction base="xs:string">
     <xs:minLength value="1"/>
     <xs:maxLength value="255"/>
    </xs:restriction>
   </xs:simpleType>
  </xs:element>
  <xs:element name="assessmentMethod" type="tns:EudractTerm" minOccurs="0">
   <xs:annotation>
    <xs:documentation xml:lang="en">See list 'Adverse event assessment method'.
          </xs:documentation>
```

```
      </xs:annotation>
    </xs:element>
    <xs:element name="dictionary" type="tns:DictionaryDetails" minOccurs="0"/>
    <xs:element name="reportingGroups" minOccurs="0">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="reportingGroup" type="tns:AdverseEventReportingGroup"
minOccurs="0" maxOccurs="unbounded"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <xs:element name="nonSeriousAdverseEvents" minOccurs="0">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="nonSeriousAdverseEvent" type="tns:NonSeriousAdverseEvent"
minOccurs="0" maxOccurs="unbounded"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <xs:element name="seriousAdverseEvents" minOccurs="0">
      <xs:complexType>
        <xs:sequence>
          <xs:element name="seriousAdverseEvent" type="tns:SeriousAdverseEvent" minOccurs="0"
maxOccurs="unbounded"/>
        </xs:sequence>
      </xs:complexType>
    </xs:element>
  </xs:sequence>
</xs:complexType>
```

element **AdverseEvents/description**

diagram	
type	restriction of **xs:string**
properties	minOcc 0 maxOcc 1 content simple
facets	Kind Value Annotation maxLength 350

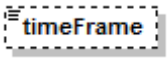
source	`<xs:element name="description" minOccurs="0">`
	`  <xs:simpleType>`
	`  <xs:restriction base="xs:string">`
	`  <xs:maxLength value="350"/>`
	`  </xs:restriction>`
	`  </xs:simpleType>`
	`</xs:element>`

element **AdverseEvents/nonSeriousEventFrequencyThreshold**

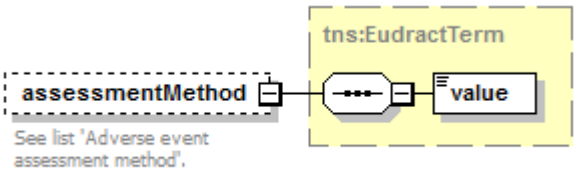
diagram	

type	restriction of **xs:decimal**
properties	minOcc 0 maxOcc 1 content simple
facets	Kind Value Annotation minInclusive 0.00 maxInclusive 5.00
source	<xs:element name="nonSeriousEventFrequencyThreshold" minOccurs="0"> <xs:simpleType> <xs:restriction base="xs:decimal"> <xs:minInclusive value="0.00"/> <xs:maxInclusive value="5.00"/> </xs:restriction> </xs:simpleType> </xs:element>

element **AdverseEvents/timeFrame**

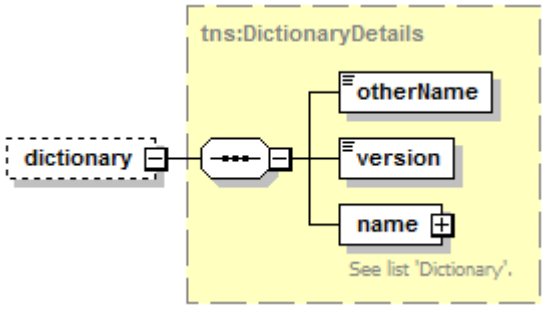
diagram	
type	restriction of **xs:string**
properties	minOcc 0 maxOcc 1 content simple
facets	Kind Value Annotation minLength 1 maxLength 255
source	<xs:element name="timeFrame" minOccurs="0"> <xs:simpleType> <xs:restriction base="xs:string"> <xs:minLength value="1"/> <xs:maxLength value="255"/> </xs:restriction> </xs:simpleType> </xs:element>

element **AdverseEvents/assessmentMethod**

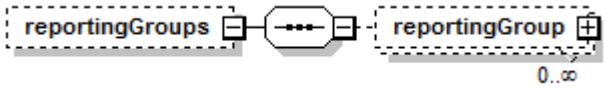
diagram	
type	**tns:EudractTerm**
properties	minOcc 0 maxOcc 1 content complex
children	**value**
annotation	documentation See list 'Adverse event assessment method'.

source	<xs:element name="assessmentMethod" type="tns:EudractTerm" minOccurs="0"> <xs:annotation> <xs:documentation xml:lang="en">See list 'Adverse event assessment method'. </xs:documentation> </xs:annotation> </xs:element>

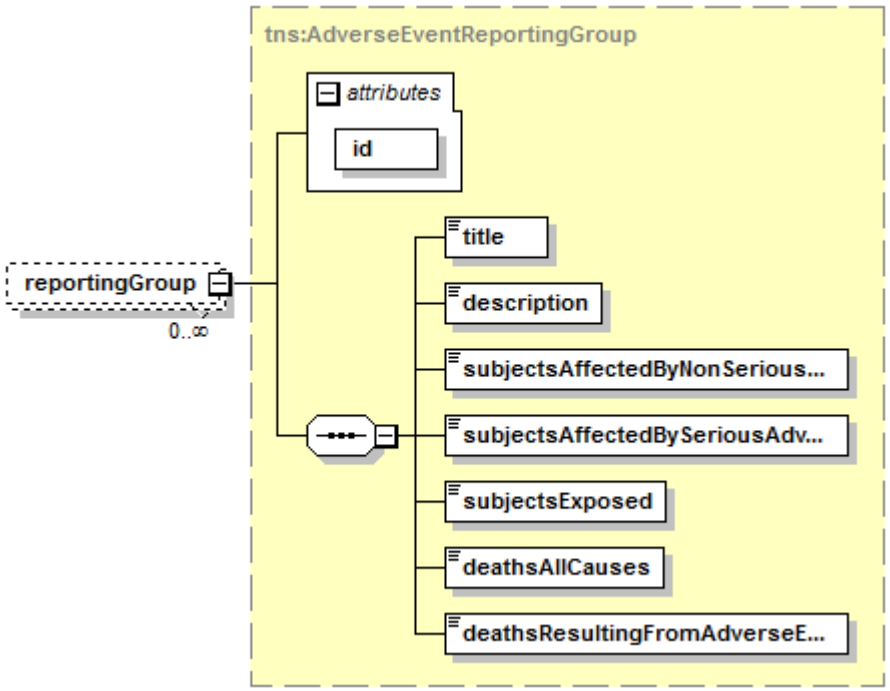
element **AdverseEvents/dictionary**

diagram	
type	**tns:DictionaryDetails**
properties	minOcc 0 maxOcc 1 content complex
children	**otherName version name**
source	<xs:element name="dictionary" type="tns:DictionaryDetails" minOccurs="0"/>

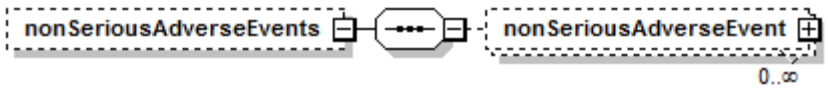
element **AdverseEvents/reportingGroups**

diagram	
properties	minOcc 0 maxOcc 1 content complex
children	**reportingGroup**
source	<xs:element name="reportingGroups" minOccurs="0"> <xs:complexType> <xs:sequence> <xs:element name="reportingGroup" type="tns:AdverseEventReportingGroup" minOccurs="0" maxOccurs="unbounded"/> </xs:sequence> </xs:complexType> </xs:element>

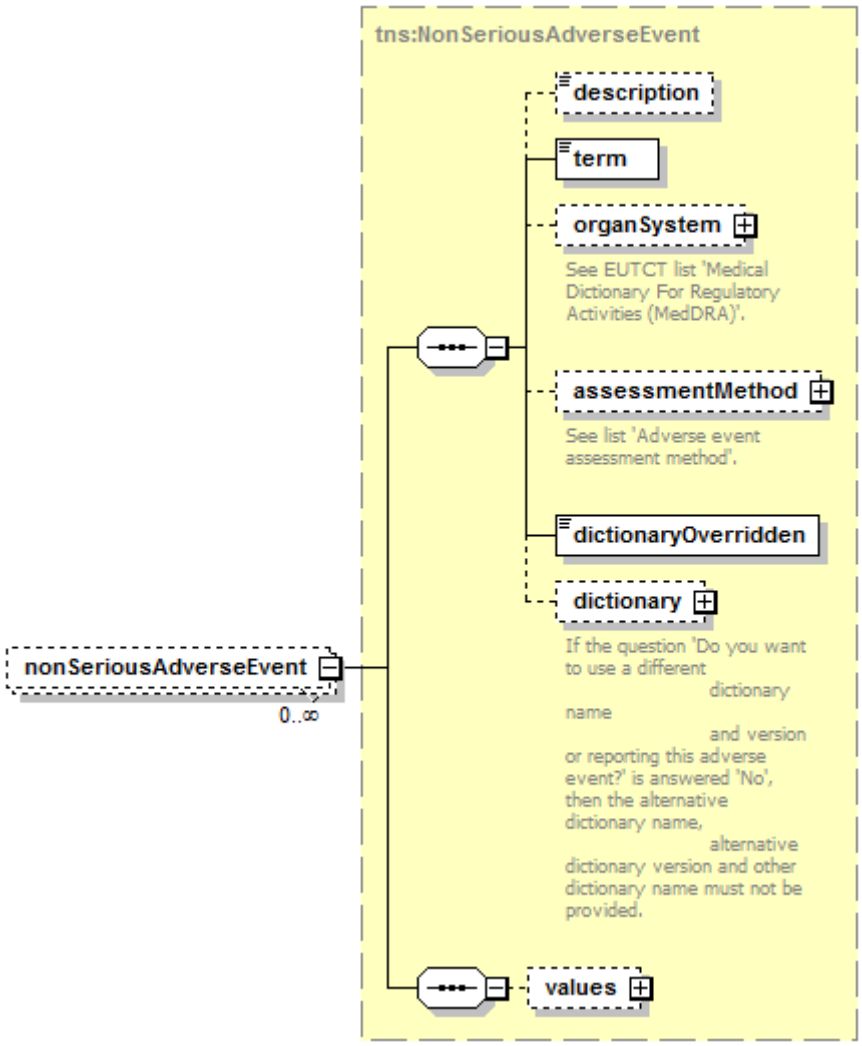
element **AdverseEvents/reportingGroups/reportingGroup**

diagram	
type	**tns:AdverseEventReportingGroup**
properties	minOcc 0 maxOcc unbounded content complex
children	**title description subjectsAffectedByNonSeriousAdverseEvents subjectsAffectedBySeriousAdverseEvents subjectsExposed deathsAllCauses deathsResultingFromAdverseEvents**
attributes	Name: id; Type: **xs:ID**; Use: required; Default: ; Fixed: ; Annotation:
source	<xs:element name="reportingGroup" type="tns:AdverseEventReportingGroup" minOccurs="0" maxOccurs="unbounded"/>

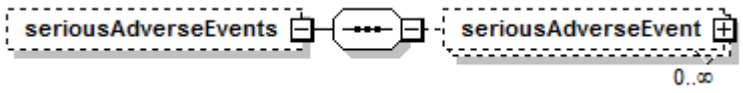
element **AdverseEvents/nonSeriousAdverseEvents**

diagram	
properties	minOcc 0 maxOcc 1 content complex
children	**nonSeriousAdverseEvent**
source	<xs:element name="nonSeriousAdverseEvents" minOccurs="0"> <xs:complexType> <xs:sequence> <xs:element name="nonSeriousAdverseEvent" type="tns:NonSeriousAdverseEvent" minOccurs="0" maxOccurs="unbounded"/> </xs:sequence> </xs:complexType> </xs:element>

element **AdverseEvents/nonSeriousAdverseEvents/nonSeriousAdverseEvent**

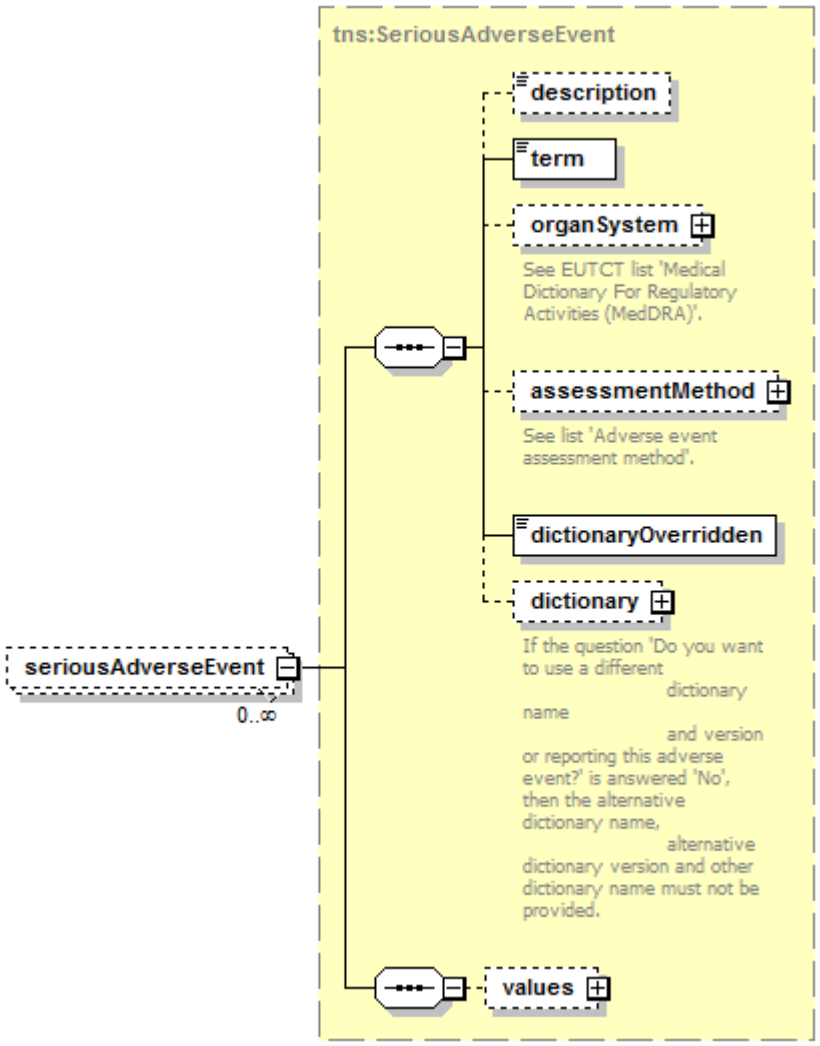
diagram	
type	tns:NonSeriousAdverseEvent
properties	minOcc 0 maxOcc unbounded content complex
children	description term organSystem assessmentMethod dictionaryOverridden dictionary values
source	<xs:element name="nonSeriousAdverseEvent" type="tns:NonSeriousAdverseEvent" minOccurs="0" maxOccurs="unbounded"/>

element **AdverseEvents/seriousAdverseEvents**

diagram	
properties	minOcc 0 maxOcc 1

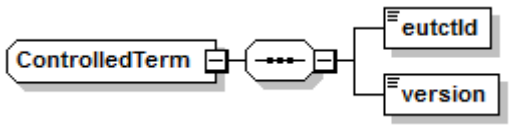
	content complex
children	**seriousAdverseEvent**
source	<xs:element name="seriousAdverseEvents" minOccurs="0"> <xs:complexType> <xs:sequence> <xs:element name="seriousAdverseEvent" type="tns:SeriousAdverseEvent" minOccurs="0" maxOccurs="unbounded"/> </xs:sequence> </xs:complexType> </xs:element>

element **AdverseEvents/seriousAdverseEvents/seriousAdverseEvent**

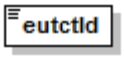
diagram	
type	**tns:SeriousAdverseEvent**
properties	minOcc 0 maxOcc unbounded content complex
children	**description term organSystem assessmentMethod dictionaryOverridden dictionary values**

source	<xs:element name="seriousAdverseEvent" type="tns:SeriousAdverseEvent" minOccurs="0" maxOccurs="unbounded"/>

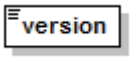
complexType **ControlledTerm**

diagram	
namespace	http://eudract.ema.europa.eu/schema/clinical_trial_result/adverse_events
children	**eutctId** **version**
used by	element **AdverseEvent/organSystem**
source	<xs:complexType name="ControlledTerm"> <xs:sequence> <xs:element name="eutctId" type="xs:long"/> <xs:element name="version" type="xs:short"/> </xs:sequence> </xs:complexType>

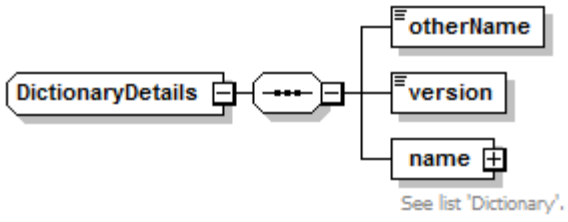
element **ControlledTerm/eutctId**

diagram	
type	**xs:long**
properties	content simple
source	<xs:element name="eutctId" type="xs:long"/>

element **ControlledTerm/version**

diagram	
type	**xs:short**
properties	content simple
source	<xs:element name="version" type="xs:short"/>

complexType **DictionaryDetails**

diagram	

namespace	http://eudract.ema.europa.eu/schema/clinical_trial_result/adverse_events
children	**otherName version name**
used by	elements **AdverseEvents/dictionary AdverseEvent/dictionary**
source	<xs:complexType name="DictionaryDetails"> <xs:sequence> <xs:element name="otherName" nillable="true"> <xs:simpleType> <xs:restriction base="xs:string"> <xs:maxLength value="20"/> </xs:restriction> </xs:simpleType> </xs:element> <xs:element name="version" nillable="true"> <xs:simpleType> <xs:restriction base="xs:string"> <xs:maxLength value="10"/> </xs:restriction> </xs:simpleType> </xs:element> <xs:element name="name" type="tns:EudractTerm" nillable="true"> <xs:annotation> <xs:documentation xml:lang="en">See list 'Dictionary'.</xs:documentation> </xs:annotation> </xs:element> </xs:sequence> </xs:complexType>

element **DictionaryDetails/otherName**

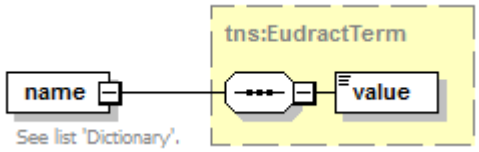
diagram	
type	restriction of **xs:string**
properties	content simple nillable true
facets	Kind Value Annotation maxLength 20
source	<xs:element name="otherName" nillable="true"> <xs:simpleType> <xs:restriction base="xs:string"> <xs:maxLength value="20"/> </xs:restriction> </xs:simpleType> </xs:element>

element **DictionaryDetails/version**

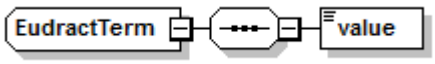
diagram	
type	restriction of **xs:string**

properties	content simple nillable true
facets	Kind Value Annotation maxLength 10
source	<xs:element name="version" nillable="true"> <xs:simpleType> <xs:restriction base="xs:string"> <xs:maxLength value="10"/> </xs:restriction> </xs:simpleType> </xs:element>

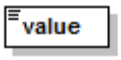
element **DictionaryDetails/name**

diagram	
type	**tns:EudractTerm**
properties	content complex nillable true
children	**value**
annotation	documentation See list 'Dictionary'.
source	<xs:element name="name" type="tns:EudractTerm" nillable="true"> <xs:annotation> <xs:documentation xml:lang="en">See list 'Dictionary'.</xs:documentation> </xs:annotation> </xs:element>

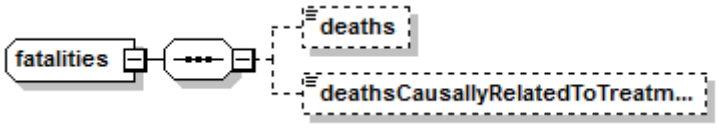
complexType **EudractTerm**

diagram	
namespace	http://eudract.ema.europa.eu/schema/clinical_trial_result/adverse_events
children	**value**
used by	elements **AdverseEvents/assessmentMethod** **AdverseEvent/assessmentMethod** **DictionaryDetails/name**
source	<xs:complexType name="EudractTerm"> <xs:sequence> <xs:element name="value" nillable="false"> <xs:simpleType> <xs:restriction base="xs:string"> <xs:minLength value="1"/> </xs:restriction> </xs:simpleType> </xs:element> </xs:sequence> </xs:complexType>

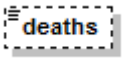
element **EudractTerm/value**

diagram	
type	restriction of **xs:string**
properties	content simple nillable false
facets	Kind Value Annotation minLength 1
source	<xs:element name="value" nillable="false"> <xs:simpleType> <xs:restriction base="xs:string"> <xs:minLength value="1"/> </xs:restriction> </xs:simpleType> </xs:element>

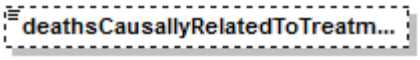
complexType **fatalities**

diagram	
namespace	http://eudract.ema.europa.eu/schema/clinical_trial_result/adverse_events
children	**deaths** **deathsCausallyRelatedToTreatment**
used by	element **ReportingGroupSeriousAdverseEventValues/fatalities**
source	<xs:complexType name="fatalities"> <xs:sequence> <xs:element name="deaths" minOccurs="0"> <xs:simpleType> <xs:restriction base="xs:int"> <xs:minInclusive value="0"/> <xs:maxInclusive value="99999999"/> </xs:restriction> </xs:simpleType> </xs:element> <xs:element name="deathsCausallyRelatedToTreatment" minOccurs="0"> <xs:simpleType> <xs:restriction base="xs:int"> <xs:minInclusive value="0"/> <xs:maxInclusive value="99999999"/> </xs:restriction> </xs:simpleType> </xs:element> </xs:sequence> </xs:complexType>

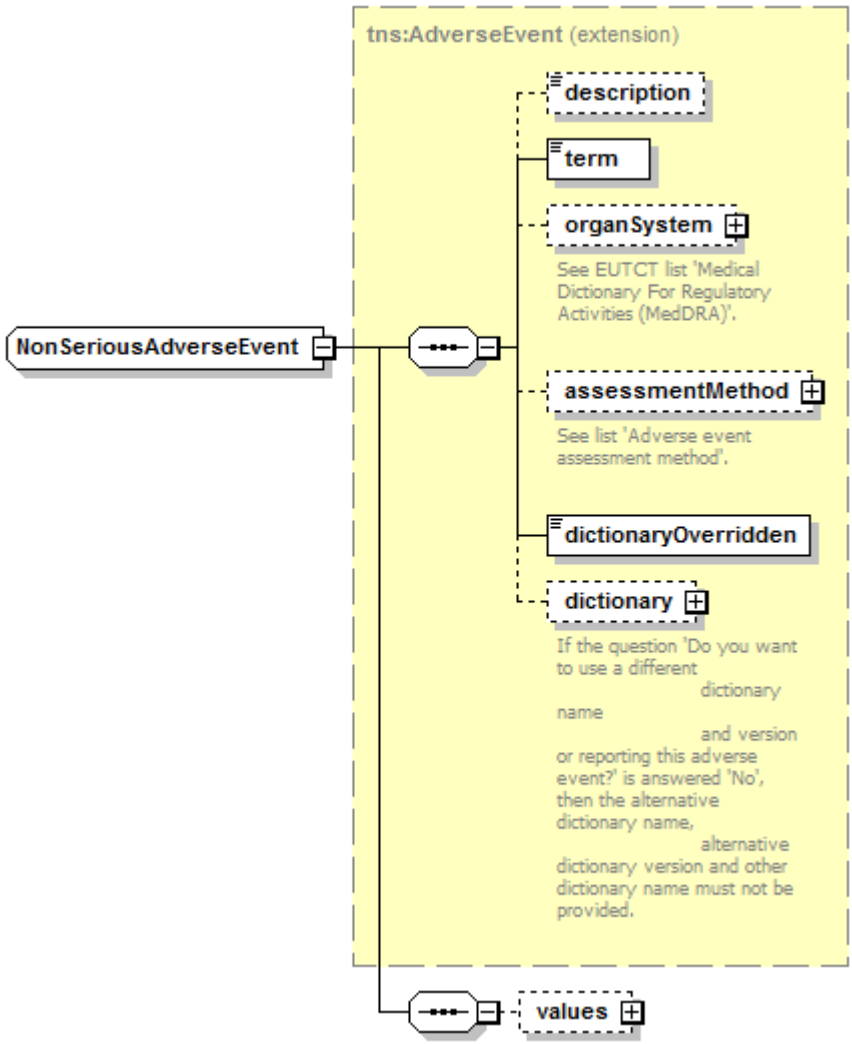
element **fatalities/deaths**

diagram	
type	restriction of **xs:int**
properties	minOcc 0 maxOcc 1 content simple
facets	Kind / Value / Annotation minInclusive 0 maxInclusive 99999999
source	<xs:element name="deaths" minOccurs="0"> <xs:simpleType> <xs:restriction base="xs:int"> <xs:minInclusive value="0"/> <xs:maxInclusive value="99999999"/> </xs:restriction> </xs:simpleType> </xs:element>

element **fatalities/deathsCausallyRelatedToTreatment**

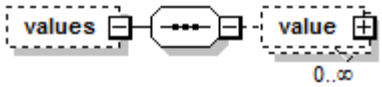
diagram	
type	restriction of **xs:int**
properties	minOcc 0 maxOcc 1 content simple
facets	Kind / Value / Annotation minInclusive 0 maxInclusive 99999999
source	<xs:element name="deathsCausallyRelatedToTreatment" minOccurs="0"> <xs:simpleType> <xs:restriction base="xs:int"> <xs:minInclusive value="0"/> <xs:maxInclusive value="99999999"/> </xs:restriction> </xs:simpleType> </xs:element>

complexType **NonSeriousAdverseEvent**

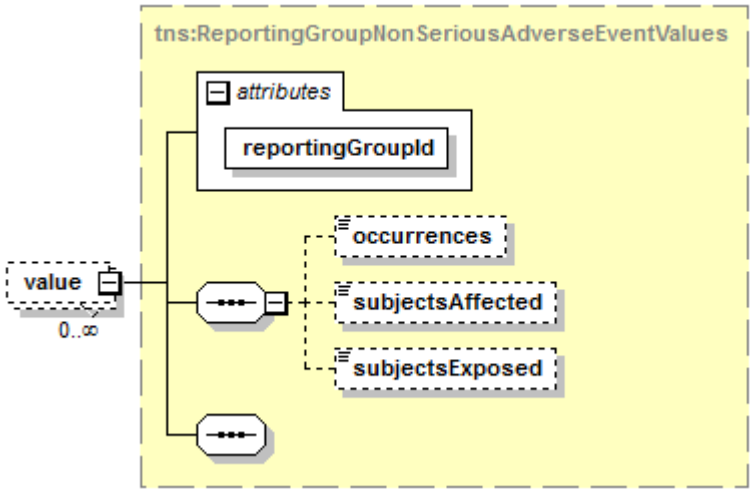
diagram	
namespace	http://eudract.ema.europa.eu/schema/clinical_trial_result/adverse_events
type	extension of **tns:AdverseEvent**
properties	base tns:AdverseEvent
children	**description term organSystem assessmentMethod dictionaryOverridden dictionary values**
used by	element **AdverseEvents/nonSeriousAdverseEvents/nonSeriousAdverseEvent**
source	<xs:complexType name="NonSeriousAdverseEvent"> <xs:complexContent> <xs:extension base="tns:AdverseEvent"> <xs:sequence> <xs:element name="values" minOccurs="0"> <xs:complexType> <xs:sequence> <xs:element name="value" type="tns:ReportingGroupNonSeriousAdverseEventValues" minOccurs="0" maxOccurs="unbounded"/> </xs:sequence> </xs:complexType> </xs:element>

```
    </xs:sequence>
   </xs:extension>
  </xs:complexContent>
</xs:complexType>
```

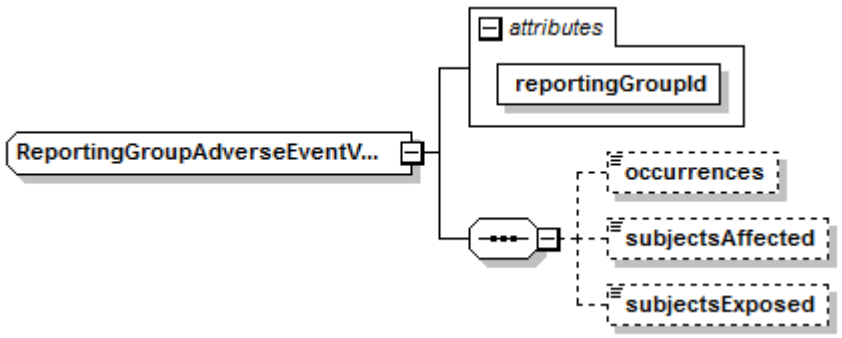
element **NonSeriousAdverseEvent/values**

diagram	
properties	minOcc 0 maxOcc 1 content complex
children	**value**
source	<xs:element name="values" minOccurs="0"> <xs:complexType> <xs:sequence> <xs:element name="value" type="tns:ReportingGroupNonSeriousAdverseEventValues" minOccurs="0" maxOccurs="unbounded"/> </xs:sequence> </xs:complexType> </xs:element>

element **NonSeriousAdverseEvent/values/value**

diagram	
type	**tns:ReportingGroupNonSeriousAdverseEventValues**
properties	minOcc 0 maxOcc unbounded content complex
children	**occurrences** **subjectsAffected** **subjectsExposed**
attributes	Name: reportingGroupId; Type: **xs:IDREF**; Use: required; Default; Fixed; Annotation
source	<xs:element name="value" type="tns:ReportingGroupNonSeriousAdverseEventValues" minOccurs="0" maxOccurs="unbounded"/>

complexType **ReportingGroupAdverseEventValues**

diagram	
namespace	http://eudract.ema.europa.eu/schema/clinical_trial_result/adverse_events
properties	abstract true
children	**occurrences** **subjectsAffected** **subjectsExposed**
used by	complexTypes **ReportingGroupNonSeriousAdverseEventValues** **ReportingGroupSeriousAdverseEventValues**

attributes

Name	Type	Use	Default	Fixed	Annotation
reportingGroupId	**xs:IDREF**	required			

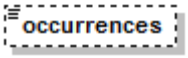
source

```
<xs:complexType name="ReportingGroupAdverseEventValues" abstract="true">
 <xs:sequence>
  <xs:element name="occurrences" minOccurs="0">
   <xs:simpleType>
    <xs:restriction base="xs:int">
     <xs:minInclusive value="0"/>
     <xs:maxInclusive value="99999999"/>
    </xs:restriction>
   </xs:simpleType>
  </xs:element>
  <xs:element name="subjectsAffected" minOccurs="0">
   <xs:simpleType>
    <xs:restriction base="xs:int">
     <xs:minInclusive value="0"/>
     <xs:maxInclusive value="99999999"/>
    </xs:restriction>
   </xs:simpleType>
  </xs:element>
  <xs:element name="subjectsExposed" minOccurs="0">
   <xs:simpleType>
    <xs:restriction base="xs:int">
     <xs:minInclusive value="1"/>
     <xs:maxInclusive value="99999999"/>
    </xs:restriction>
   </xs:simpleType>
  </xs:element>
 </xs:sequence>
 <xs:attribute name="reportingGroupId" type="xs:IDREF" use="required"/>
</xs:complexType>
```

attribute **ReportingGroupAdverseEventValues/@reportingGroupId**

type	**xs:IDREF**
properties	use required
source	<xs:attribute name="reportingGroupId" type="xs:IDREF" use="required"/>

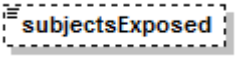
element **ReportingGroupAdverseEventValues/occurrences**

diagram	
type	restriction of **xs:int**
properties	minOcc 0 maxOcc 1 content simple
facets	Kind Value Annotation minInclusive 0 maxInclusive 99999999
source	<xs:element name="occurrences" minOccurs="0"> <xs:simpleType> <xs:restriction base="xs:int"> <xs:minInclusive value="0"/> <xs:maxInclusive value="99999999"/> </xs:restriction> </xs:simpleType> </xs:element>

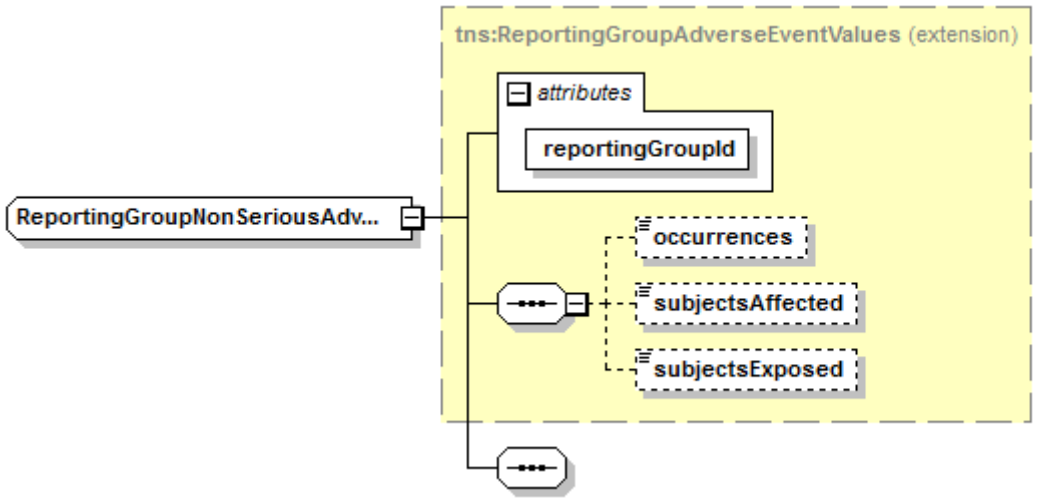
element **ReportingGroupAdverseEventValues/subjectsAffected**

diagram	
type	restriction of **xs:int**
properties	minOcc 0 maxOcc 1 content simple
facets	Kind Value Annotation minInclusive 0 maxInclusive 99999999
source	<xs:element name="subjectsAffected" minOccurs="0"> <xs:simpleType> <xs:restriction base="xs:int"> <xs:minInclusive value="0"/> <xs:maxInclusive value="99999999"/> </xs:restriction> </xs:simpleType> </xs:element>

element **ReportingGroupAdverseEventValues/subjectsExposed**

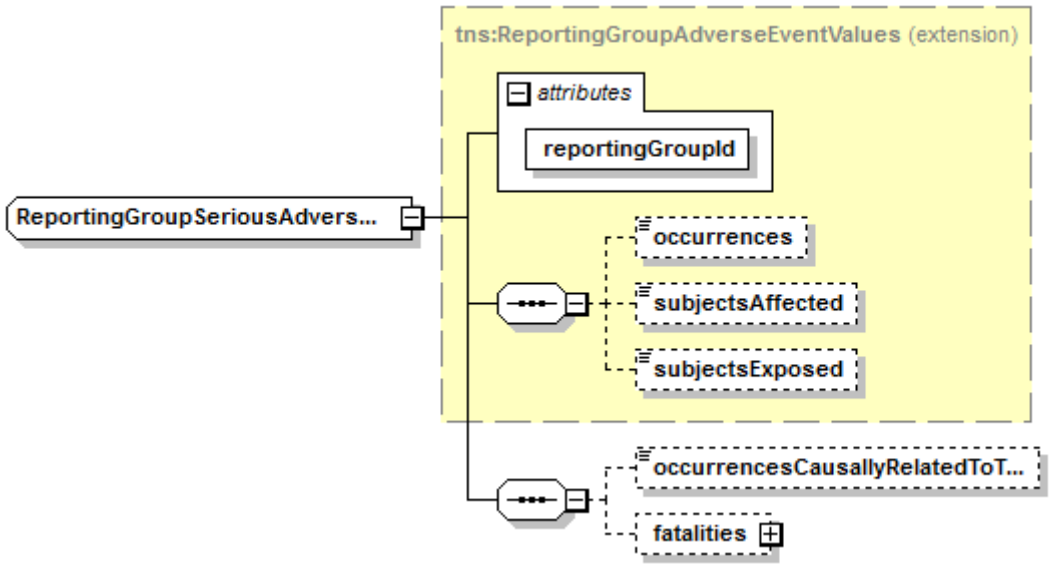
diagram	
type	restriction of **xs:int**
properties	minOcc 0 maxOcc 1 content simple
facets	Kind / Value / Annotation minInclusive 1 maxInclusive 99999999
source	<xs:element name="subjectsExposed" minOccurs="0"> <xs:simpleType> <xs:restriction base="xs:int"> <xs:minInclusive value="1"/> <xs:maxInclusive value="99999999"/> </xs:restriction> </xs:simpleType> </xs:element>

complexType **ReportingGroupNonSeriousAdverseEventValues**

diagram	
namespace	http://eudract.ema.europa.eu/schema/clinical_trial_result/adverse_events
type	extension of **tns:ReportingGroupAdverseEventValues**
properties	base tns:ReportingGroupAdverseEventValues
children	**occurrences** **subjectsAffected** **subjectsExposed**
used by	element **NonSeriousAdverseEvent/values/value**
attributes	Name / Type / Use / Default / Fixed / Annotation reportingGroupId **xs:IDREF** required
source	<xs:complexType name="ReportingGroupNonSeriousAdverseEventValues"> <xs:complexContent> <xs:extension base="tns:ReportingGroupAdverseEventValues"> <xs:sequence/> </xs:extension>

```
  </xs:complexContent>
</xs:complexType>
```

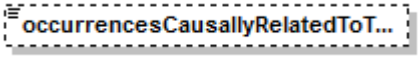
complexType **ReportingGroupSeriousAdverseEventValues**

diagram	
namespace	http://eudract.ema.europa.eu/schema/clinical_trial_result/adverse_events
type	extension of **tns:ReportingGroupAdverseEventValues**
properties	base tns:ReportingGroupAdverseEventValues
children	**occurrences** **subjectsAffected** **subjectsExposed** **occurrencesCausallyRelatedToTreatment** **fatalities**
used by	element **SeriousAdverseEvent/values/value**
attributes	Name: reportingGroupId; Type: **xs:IDREF**; Use: required; Default; Fixed; Annotation

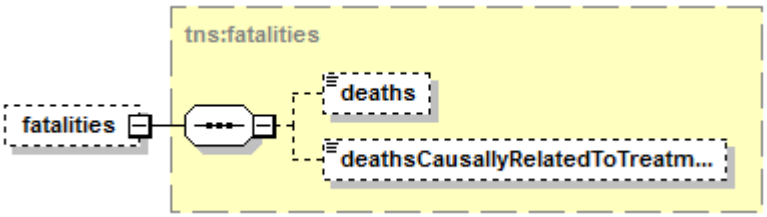
source

```
<xs:complexType name="ReportingGroupSeriousAdverseEventValues">
 <xs:complexContent>
  <xs:extension base="tns:ReportingGroupAdverseEventValues">
   <xs:sequence>
    <xs:element name="occurrencesCausallyRelatedToTreatment" minOccurs="0">
     <xs:simpleType>
      <xs:restriction base="xs:int">
       <xs:minInclusive value="0"/>
       <xs:maxInclusive value="99999999"/>
      </xs:restriction>
     </xs:simpleType>
    </xs:element>
    <xs:element name="fatalities" type="tns:fatalities" minOccurs="0"/>
   </xs:sequence>
  </xs:extension>
 </xs:complexContent>
</xs:complexType>
```

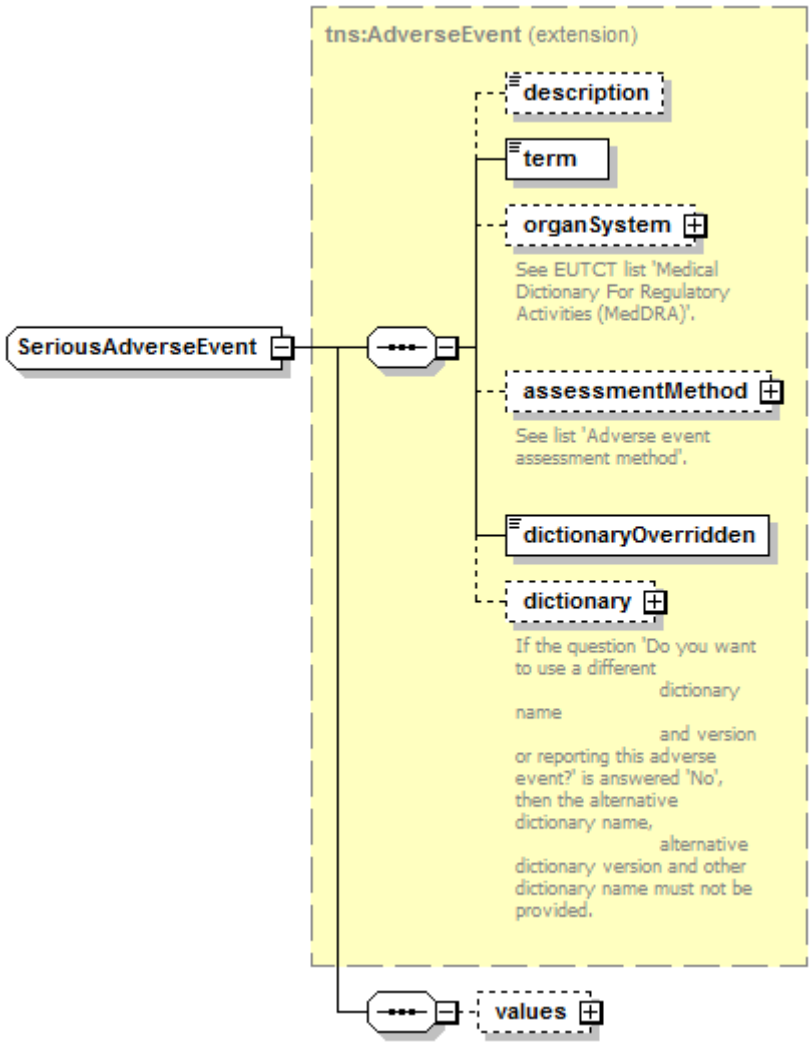
element **ReportingGroupSeriousAdverseEventValues/occurrencesCausallyRelatedToTreatment**

diagram	
type	restriction of **xs:int**
properties	minOcc 0 maxOcc 1 content simple
facets	Kind / Value / Annotation minInclusive 0 maxInclusive 99999999
source	<xs:element name="occurrencesCausallyRelatedToTreatment" minOccurs="0"> <xs:simpleType> <xs:restriction base="xs:int"> <xs:minInclusive value="0"/> <xs:maxInclusive value="99999999"/> </xs:restriction> </xs:simpleType> </xs:element>

element **ReportingGroupSeriousAdverseEventValues/fatalities**

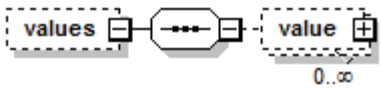
diagram	
type	**tns:fatalities**
properties	minOcc 0 maxOcc 1 content complex
children	**deaths** **deathsCausallyRelatedToTreatment**
source	<xs:element name="fatalities" type="tns:fatalities" minOccurs="0"/>

complexType **SeriousAdverseEvent**

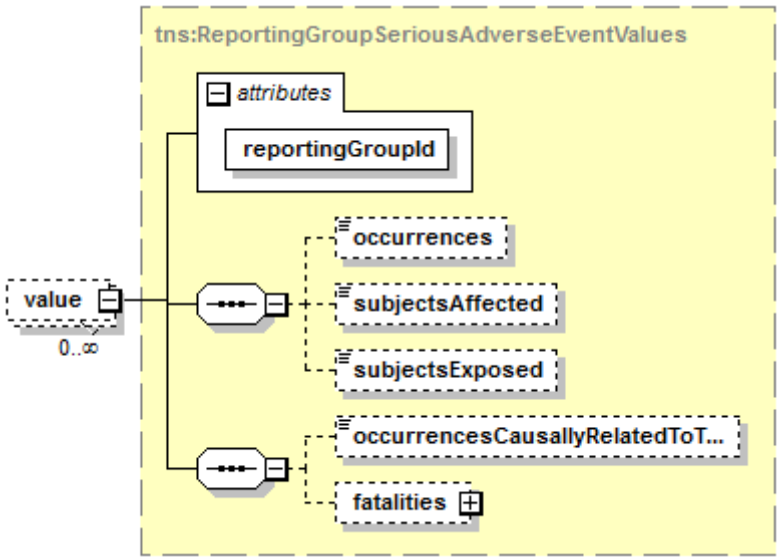
diagram	
namespace	http://eudract.ema.europa.eu/schema/clinical_trial_result/adverse_events
type	extension of **tns:AdverseEvent**
properties	base tns:AdverseEvent
children	**description term organSystem assessmentMethod dictionaryOverridden dictionary values**
used by	element **AdverseEvents/seriousAdverseEvents/seriousAdverseEvent**
source	<xs:complexType name="SeriousAdverseEvent"> <xs:complexContent> <xs:extension base="tns:AdverseEvent"> <xs:sequence> <xs:element name="values" minOccurs="0"> <xs:complexType> <xs:sequence> <xs:element name="value" type="tns:ReportingGroupSeriousAdverseEventValues" minOccurs="0" maxOccurs="unbounded"/> </xs:sequence> </xs:complexType> </xs:element>

	</xs:sequence> </xs:extension> </xs:complexContent> </xs:complexType>

element **SeriousAdverseEvent/values**

diagram	
properties	minOcc 0 maxOcc 1 content complex
children	**value**
source	<xs:element name="values" minOccurs="0"> <xs:complexType> <xs:sequence> <xs:element name="value" type="tns:ReportingGroupSeriousAdverseEventValues" minOccurs="0" maxOccurs="unbounded"/> </xs:sequence> </xs:complexType> </xs:element>

element **SeriousAdverseEvent/values/value**

diagram	
type	**tns:ReportingGroupSeriousAdverseEventValues**
properties	minOcc 0 maxOcc unbounded content complex
children	**occurrences** **subjectsAffected** **subjectsExposed** **occurrencesCausallyRelatedToTreatment** **fatalities**
attributes	Name: reportingGroupId; Type: **xs:IDREF**; Use: required; Default; Fixed; Annotation
source	<xs:element name="value" type="tns:ReportingGroupSeriousAdverseEventValues" minOccurs="0"

	maxOccurs="unbounded"/>

XML Schema documentation generated by **XMLSpy** Schema Editor **http://www.altova.com/xmlspy**