1 Namespace: "http://www.pharmml.org/2013/03/TrialDesign"

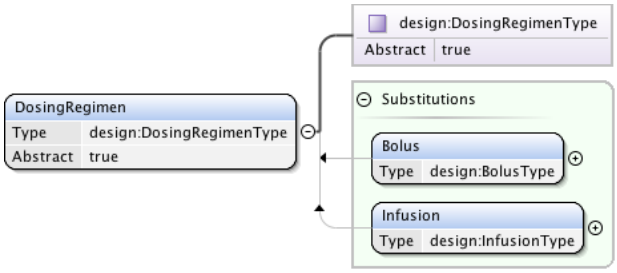
1.1 Schema(s)

1.1.1 Main schema `trialDesign.xsd`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Defines trial design section of PharmML.

1.2 Element(s)

1.2.1 Element `design:DosingRegimen`

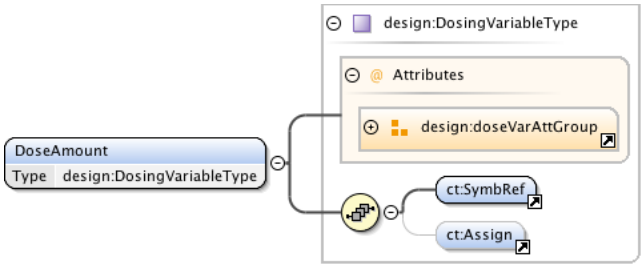
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Specifies dosing regimen.
Diagram	
Type	design:DosingRegimenType
Substitution Group	• design:Bolus • design:Infusion

1.2.2 Element `design:Washout`

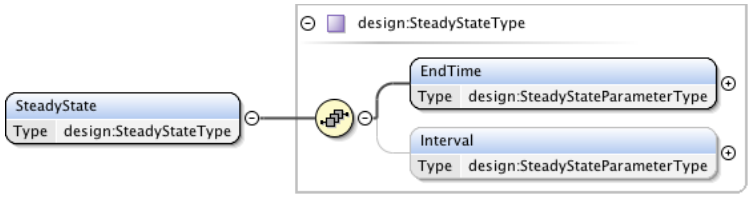
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Specifies a washout epoch, where variables are reset to their initial values.
Diagram	
Type	design:WashoutType

1.2.3 Element `design:BolusType /design:DoseAmount`

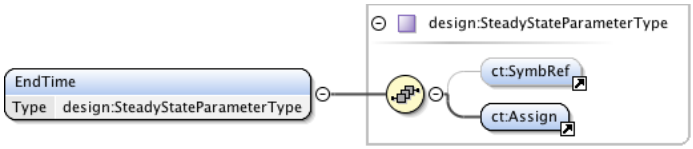
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Dosing information.

Diagram	
Type	design:DosingVariableType
Attributes	**QName** **Type** **Use** **inputType** design:DoseInputTypeType required Specifies the type of dosing. Is it assigned to a variable or is it an input to a system of ODEs.

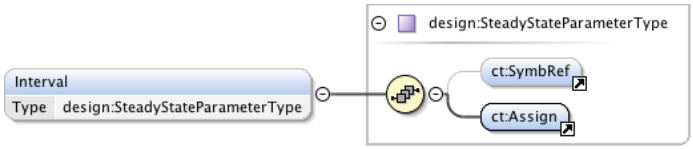
1.2.4 Element `design:BolusType /design:SteadyState`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Steady state bolus dosing.
Diagram	
Type	design:SteadyStateType

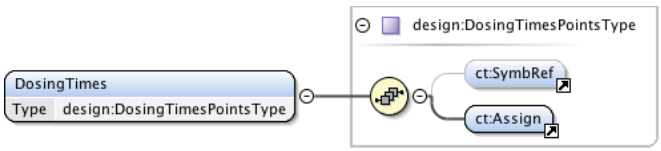
1.2.5 Element `design:SteadyStateType /design:EndTime`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	The last dosing time.
Diagram	
Type	design:SteadyStateParameterType

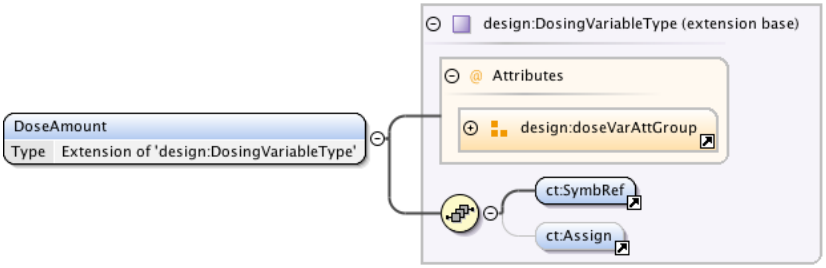
1.2.6 Element `design:SteadyStateType /design:Interval`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	The dosing period.
Diagram	
Type	design:SteadyStateParameterType

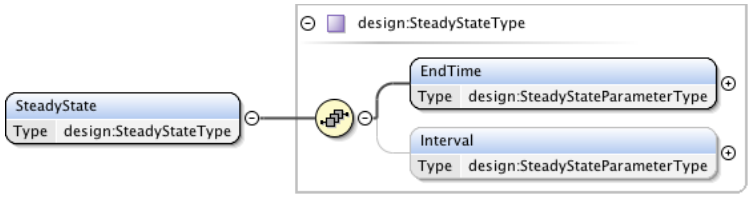
1.2.7 Element `design:BolusType /design:DosingTimes`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	The dosing times.
Diagram	
Type	design:DosingTimesPointsType

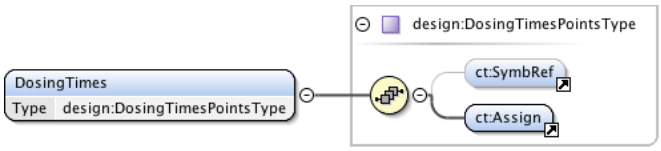
1.2.8 Element `design:InfusionType /design:DoseAmount`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Dosing information.
Diagram	
Type	extension of design:DosingVariableType
Attributes	**QName** **Type** **Use** **inputType** design:DoseInputTypeType required Specifies the type of dosing. Is it assigned to a variable or is it an input to a system of ODEs.

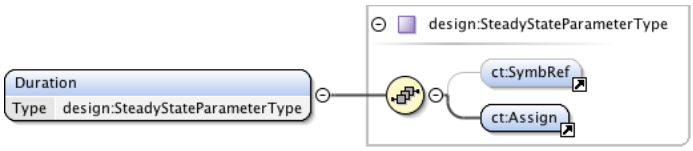
1.2.9 Element `design:InfusionType /design:SteadyState`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Steady state infusion dosing.
Diagram	
Type	design:SteadyStateType

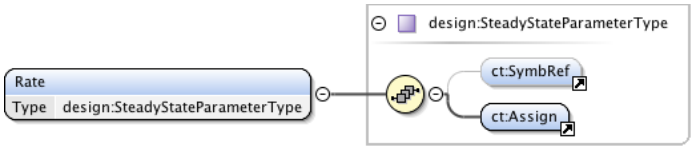
1.2.10 Element `design:InfusionType /design:DosingTimes`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	The dosing times.
Diagram	
Type	design:DosingTimesPointsType

1.2.11 Element `design:InfusionType /design:Duration`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	The duration of the infusion.
Diagram	
Type	design:SteadyStateParameterType

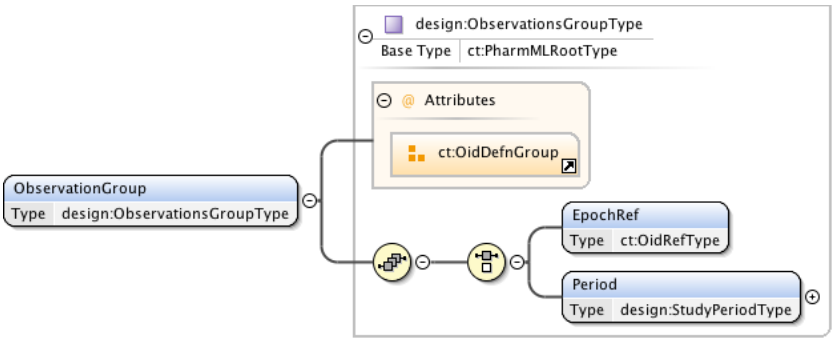
1.2.12 Element `design:InfusionType /design:Rate`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Diagram	
Type	design:SteadyStateParameterType

1.2.13 Element `design:StudyEventType /design:ArmRef`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	In effect defines the population of subjects that this event happens to.
Diagram	
Type	OidRefType

1.2.14 Element `design:ObservationsType /design:ObservationGroup`

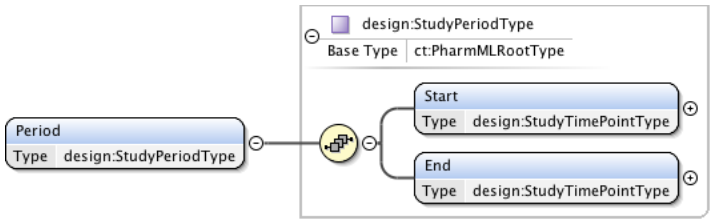
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Diagram	
Type	design:ObservationsGroupType

1.2.15 Element `design:ObservationsGroupType /design:EpochRef`

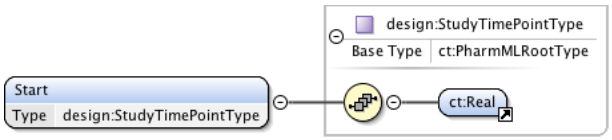
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Refers to the epoch during which this group of observations occurred.

Diagram	
Type	OidRefType

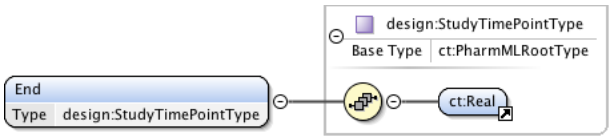
1.2.16 Element `design:ObservationsGroupType /design:Period`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Defines the time period within the study during which this group of observations occurred.
Diagram	
Type	design:StudyPeriodType

1.2.17 Element `design:StudyPeriodType /design:Start`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	The start time of the period.
Diagram	
Type	design:StudyTimePointType

1.2.18 Element `design:StudyPeriodType /design:End`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	The end time of the period.
Diagram	
Type	design:StudyTimePointType

1.2.19 Element `design:Order`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Specifies the order of elements in the trial structure.
Diagram	
Type	IntValueType

1.2.20 Element design:CellDefnType /design:EpochRef

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Refers to the epoch in which this cell occurrs.
Diagram	
Type	OidRefType

1.2.21 Element design:CellDefnType /design:ArmRef

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Refers to the arm in which this cell occurs.
Diagram	
Type	OidRefType

1.2.22 Element design:CellDefnType /design:SegmentRef

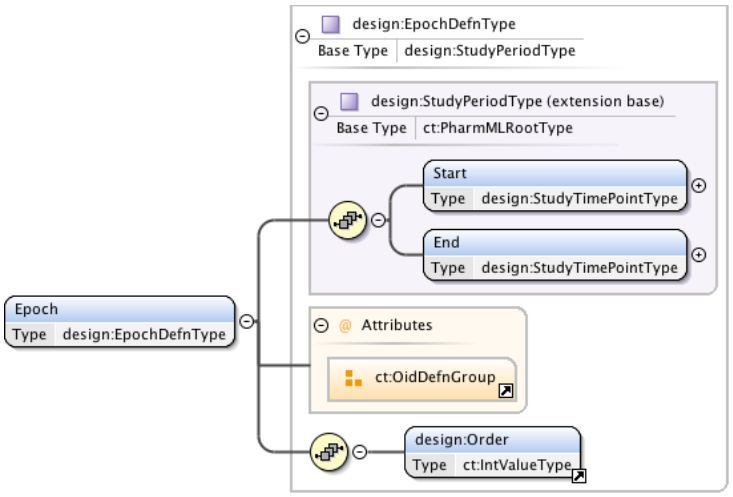
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Refers to a Segment which is used in this Cell (segments can be referred to by more than one cell.
Diagram	
Type	OidRefType

1.2.23 Element design:SegmentDefnType /design:ActivityRef

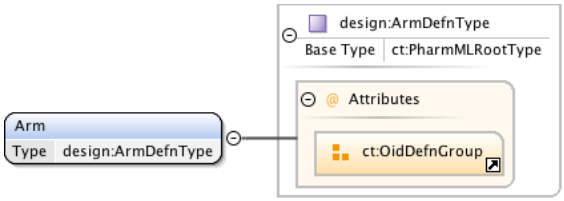
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Refers to an activity carried out in the segment of the study.
Diagram	
Type	OidRefType

1.2.24 Element design:TrialStructureType /design:Epoch

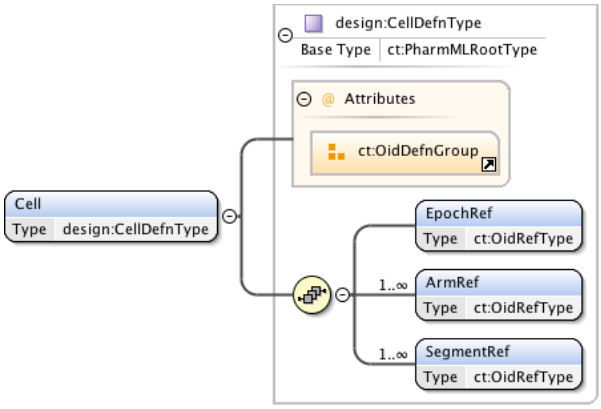
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Defines an epoch in the study.

Diagram	
Type	design:EpochDefnType

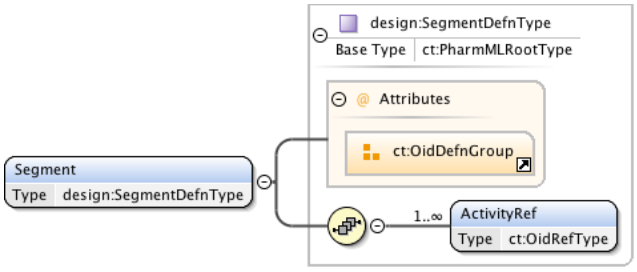
1.2.25 Element `design:TrialStructureType /design:Arm`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Defines an arm of the study.
Diagram	
Type	design:ArmDefnType

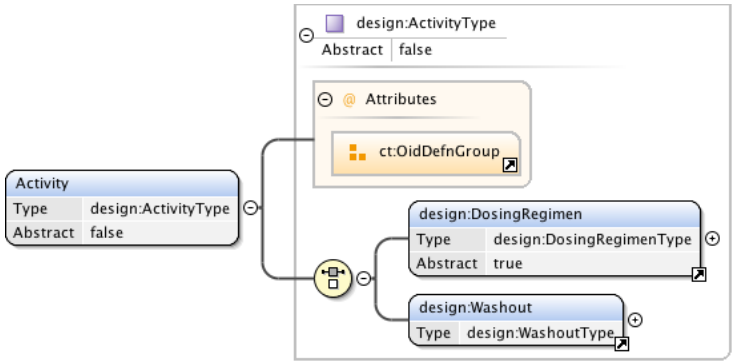
1.2.26 Element `design:TrialStructureType /design:Cell`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Defines a cell in the study.
Diagram	
Type	design:CellDefnType

1.2.27 Element `design:TrialStructureType /design:Segment`

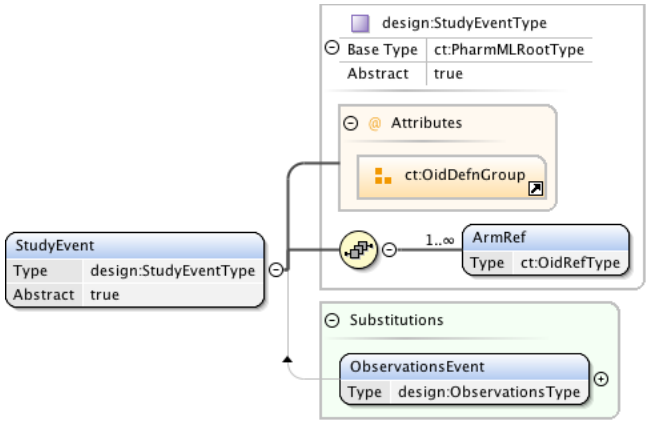
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Defines a segment of the study.
Diagram	
Type	design:SegmentDefnType

1.2.28 Element `design:Activity`

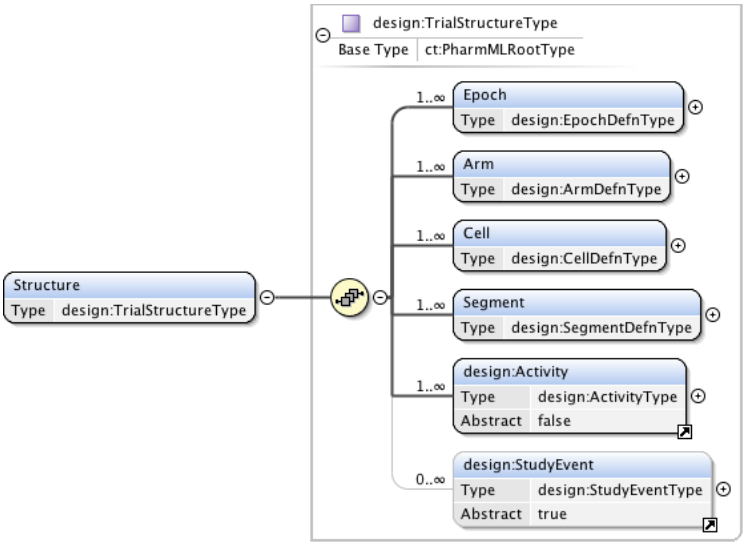
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Specifies an activity in the trial structure.
Diagram	
Type	design:ActivityType

1.2.29 Element `design:StudyEvent`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	An abstract element for all study events. There is only one element inheriting from this so this be superfluous in the future.

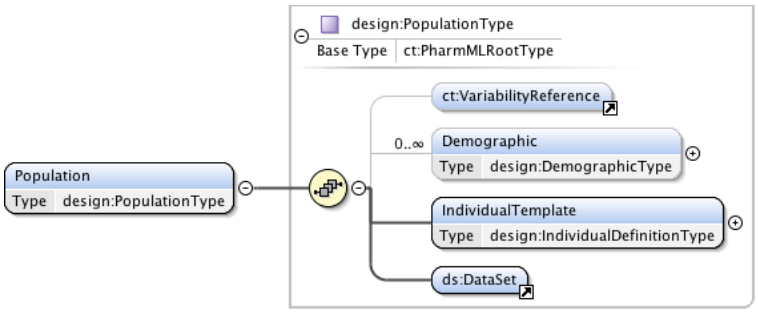
Diagram	
Type	design:StudyEventType
Substitution Group	• design:ObservationsEvent

1.2.30 Element `design:TrialDesignType /design:Structure`

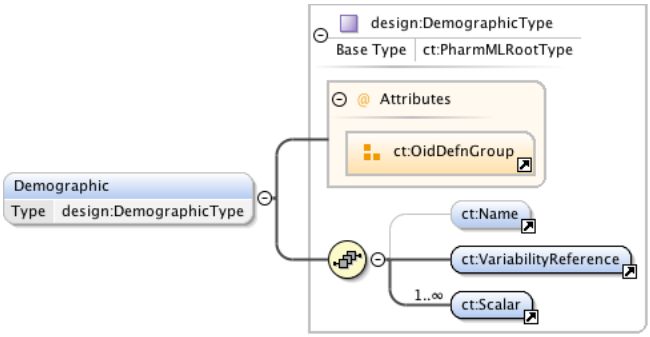
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Defines the structure of the study.
Diagram	
Type	design:TrialStructureType

1.2.31 Element `design:TrialDesignType /design:Population`

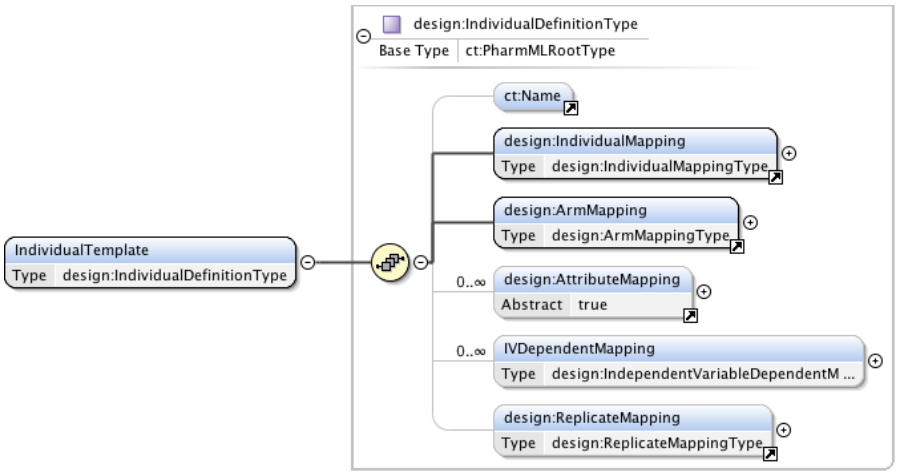
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Defines the population of the study.

Diagram	
Type	design:PopulationType

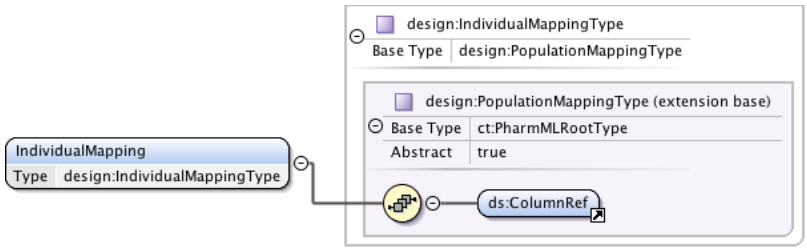
1.2.32 Element `design:PopulationType /design:Demographic`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Defines a property of the individuals in the study that is not a covariate, but is important in the design of the study.
Diagram	
Type	design:DemographicType

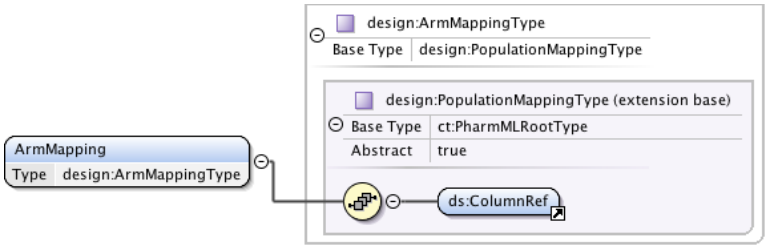
1.2.33 Element `design:PopulationType /design:IndividualTemplate`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Defines a template of information about the subjects in the study.
Diagram	
Type	design:IndividualDefinitionType

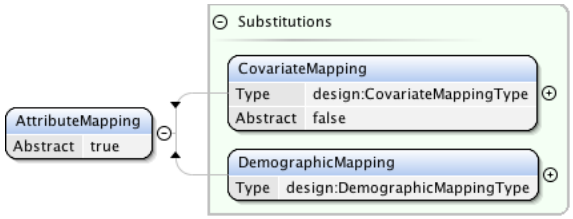
1.2.34 Element `design:IndividualMapping`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Maps the individual to the dataset.
Diagram	
Type	design:IndividualMappingType

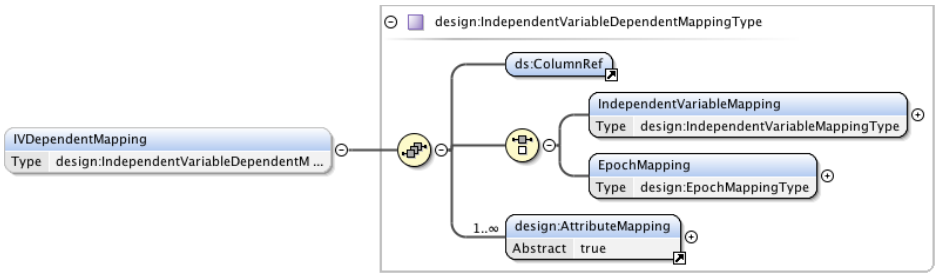
1.2.35 Element `design:ArmMapping`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Maps the arm to the dataset.
Diagram	
Type	design:ArmMappingType

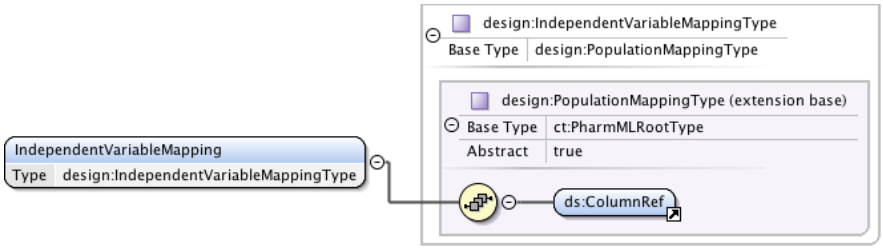
1.2.36 Element `design:AttributeMapping`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Maps attributes to the dataset.
Diagram	
Substitution Group	• design:CovariateMapping • design:DemographicMapping

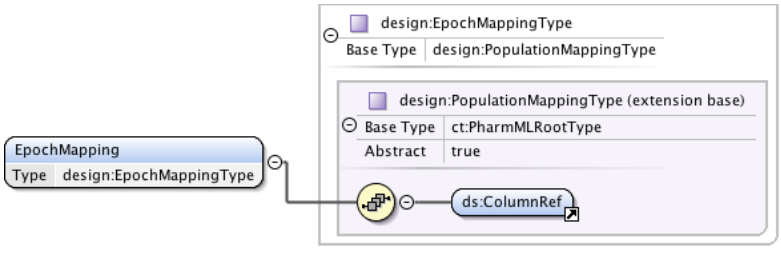
1.2.37 Element `design:IndividualDefinitionType /design:IVDependentMapping`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Defines the indepedent (usually time) variable dependent mapping to the dataset.
Diagram	
Type	design:IndependentVariableDependentMappingType

1.2.38 Element `design:IndependentVariableDependentMappingType /design:IndependentVariableMapping`

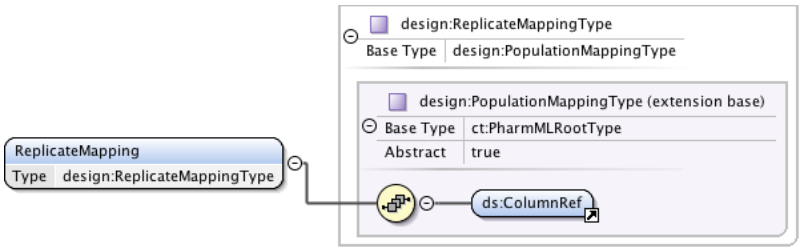
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Maps the independent variable (most often time) to a column in the dataset.
Diagram	
Type	design:IndependentVariableMappingType

1.2.39 Element `design:IndependentVariableDependentMappingType /design:EpochMapping`

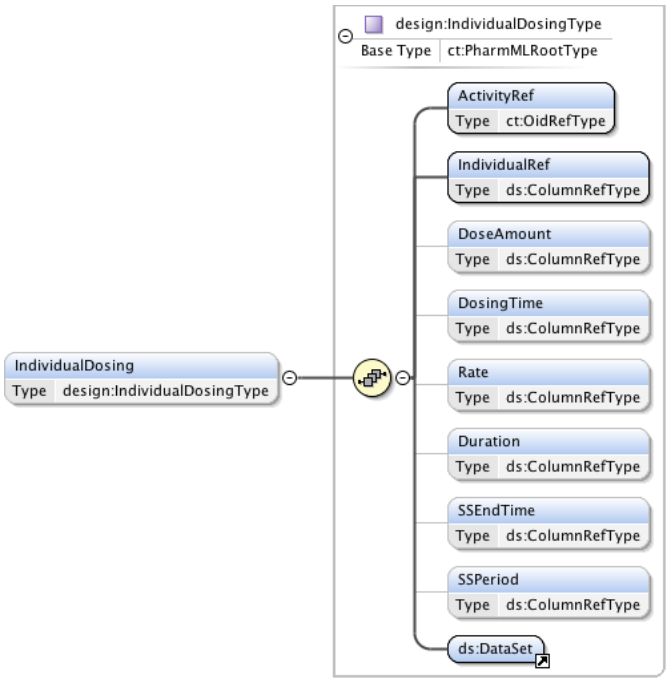
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Maps the epoch to a column in the dataset. The epoch defines the time period in which this property applies.
Diagram	
Type	design:EpochMappingType

1.2.40 Element `design:ReplicateMapping`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Mapping to replicates in the dataset.

Diagram	
Type	design:ReplicateMappingType

1.2.41 Element `design:TrialDesignType /design:IndividualDosing`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Provides time dependent dosing information for each individual in the study.
Diagram	
Type	design:IndividualDosingType

1.2.42 Element `design:IndividualDosingType /design:ActivityRef`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Refers to the activity describing the dosing regimen being instantiated here.
Diagram	
Type	OidRefType

1.2.43 Element `design:IndividualDosingType /design:IndividualRef`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Refers to the subject in the study that this dosing regimen is applied to.

Diagram	
Type	ColumnRefType

1.2.44 Element design:IndividualDosingType /design:DoseAmount

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Specifies the amount of dose.
Diagram	
Type	ColumnRefType

1.2.45 Element design:IndividualDosingType /design:DosingTime

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Specifies the dosing time.
Diagram	
Type	ColumnRefType

1.2.46 Element design:IndividualDosingType /design:Rate

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Specifies the rate of infusion.
Diagram	
Type	ColumnRefType

1.2.47 Element design:IndividualDosingType /design:Duration

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Specifies the duration of infusion.
Diagram	
Type	ColumnRefType

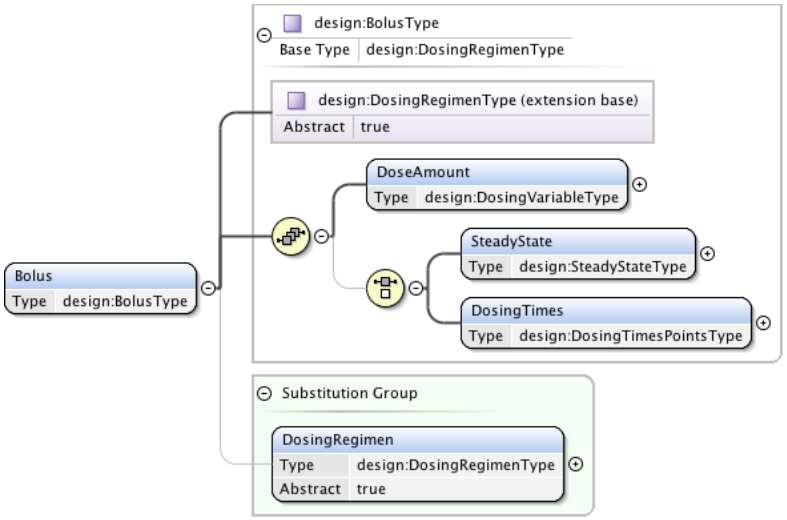
1.2.48 Element design:IndividualDosingType /design:SSEndTime

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Specifies the last dosing time in steady state dosing.
Diagram	
Type	ColumnRefType

1.2.49 Element design:IndividualDosingType /design:SSPeriod

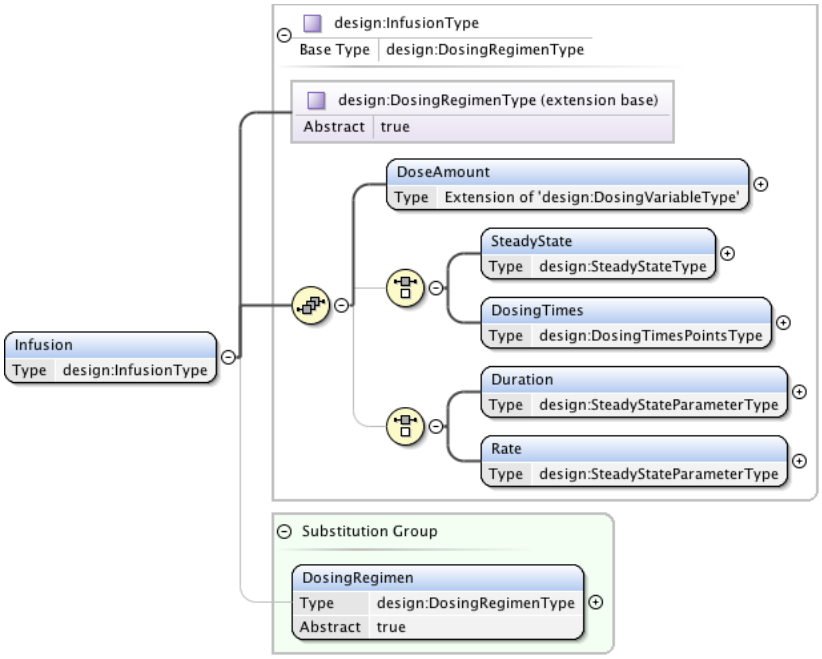
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Specifies the period in steady state dosing.
Diagram	
Type	ColumnRefType

1.2.50 Element `design:Bolus`

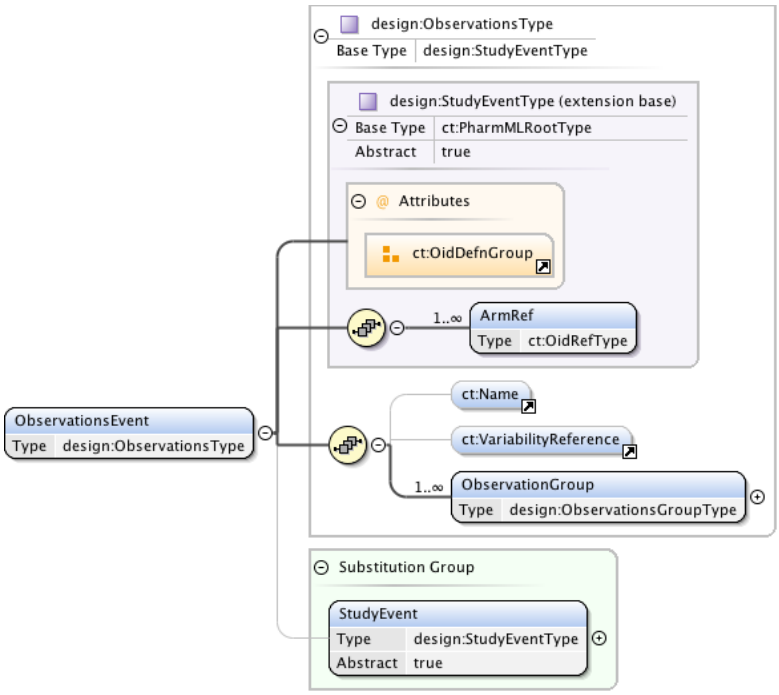
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Specifies a bolus dosing regiment.
Diagram	
Type	design:BolusType
Substitution Group Affiliation	• design:DosingRegimen

1.2.51 Element `design:Infusion`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Specifies a infusion dosing regiment.

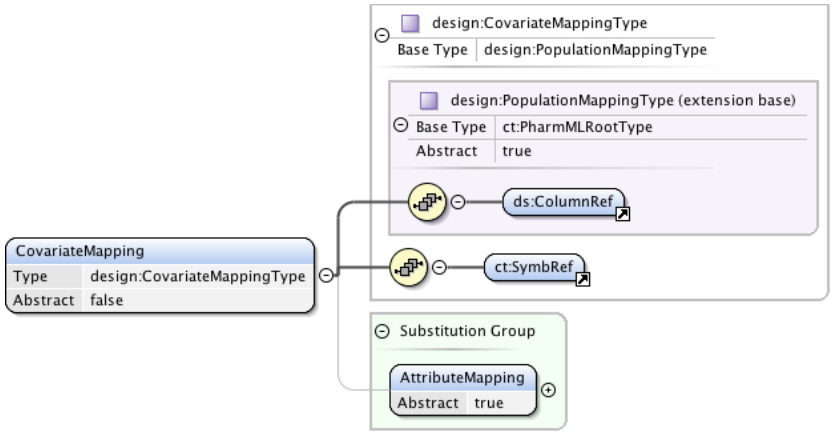
Diagram	
Type	design:InfusionType
Substitution Group Affiliation	• design:DosingRegimen

1.2.52 Element `design:ObservationsEvent`

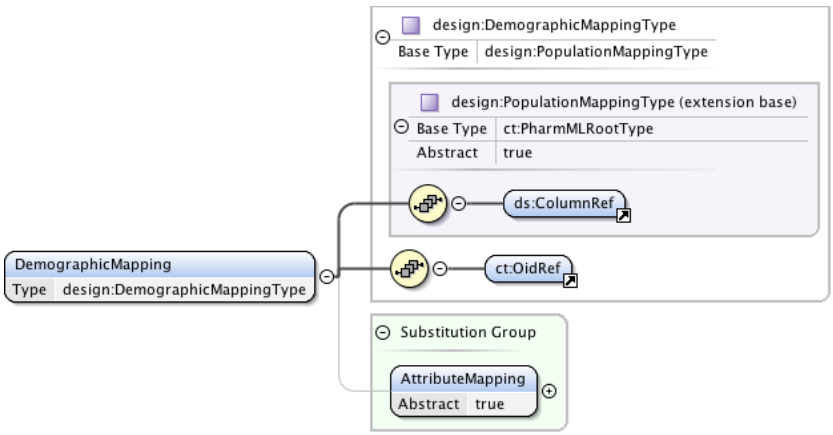
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Defines an observations event in the study,
Diagram	
Type	design:ObservationsType

Substitution Group Affiliation	• design:StudyEvent

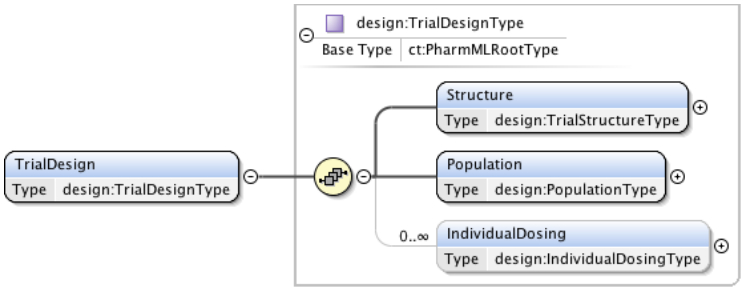
1.2.53 Element `design:CovariateMapping`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Mapping to covariates in the dataset.
Diagram	
Type	design:CovariateMappingType
Substitution Group Affiliation	• design:AttributeMapping

1.2.54 Element `design:DemographicMapping`

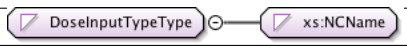
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Mapping to demographics in the dataset.
Diagram	
Type	design:DemographicMappingType
Substitution Group Affiliation	• design:AttributeMapping

1.2.55 Element `design:TrialDesign`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Defines the trial design. Top level element of this schema.
Diagram	
Type	design:TrialDesignType

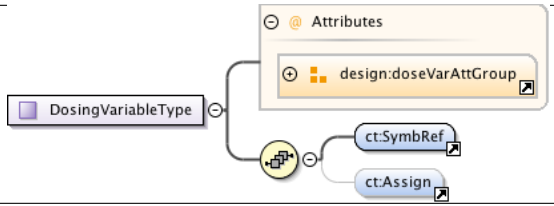
1.3 Simple Type(s)

1.3.1 Simple Type `design:DoseInputTypeType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Defines the dosing input type.
Diagram	
Type	restriction of xs:NCName
Facets	enumeration `dose` — Dose is assigned to a dosing variable. enumeration `target` — Dose is an input to a system of ODEs.

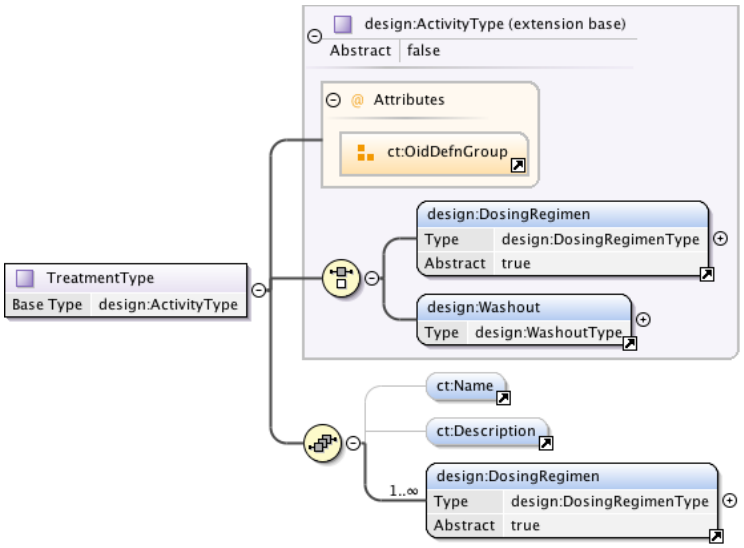
1.4 Complex Type(s)

1.4.1 Complex Type `design:DosingVariableType`

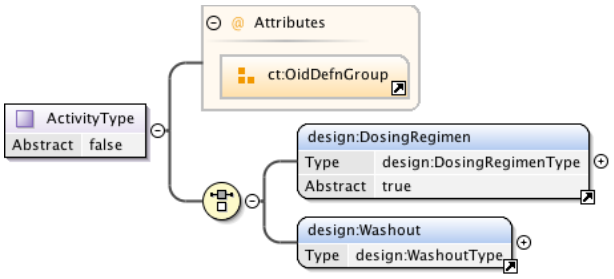
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	The type that specifies a dosing variable.
Diagram	
Attributes	**QName** **inputType** — **Type** design:DoseInputTypeType — **Use** required Specifies the type of dosing. Is it assigned to a variable or is it an input to a system of ODEs.

1.4.2 Complex Type `design:TreatmentType`

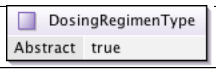
Namespace	http://www.pharmml.org/2013/03/TrialDesign

Annotations	Describes a treatment, by which we mean one or more regimens that can be appied to a subject.
Diagram	
Type	extension of design:ActivityType

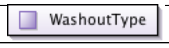
1.4.3 Complex Type `design:ActivityType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	An activity that occurs during dosing.
Diagram	

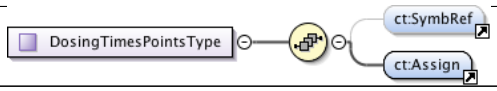
1.4.4 Complex Type `design:DosingRegimenType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Defines a dosing regimen type.
Diagram	

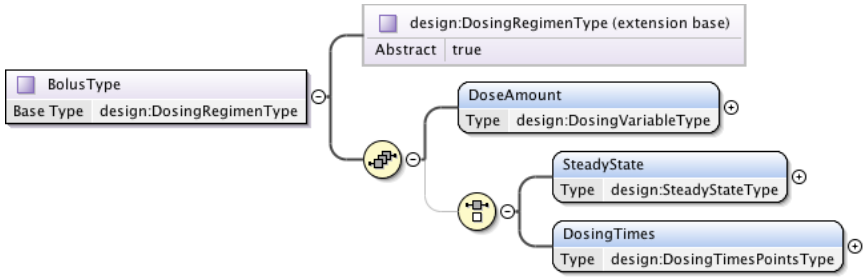
1.4.5 Complex Type `design:WashoutType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	A type that defines a washout epoch. When this applies the system is reinitialised.
Diagram	

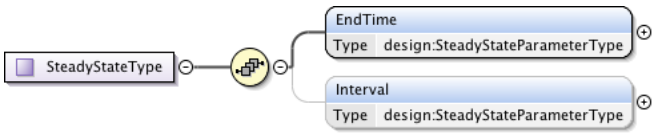
1.4.6 Complex Type `design:DosingTimesPointsType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Defines the dosing timepoints.
Diagram	

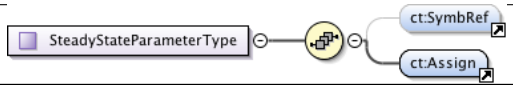
1.4.7 Complex Type `design:BolusType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Type the defines bolus dosing.
Diagram	
Type	extension of design:DosingRegimenType

1.4.8 Complex Type `design:SteadyStateType`

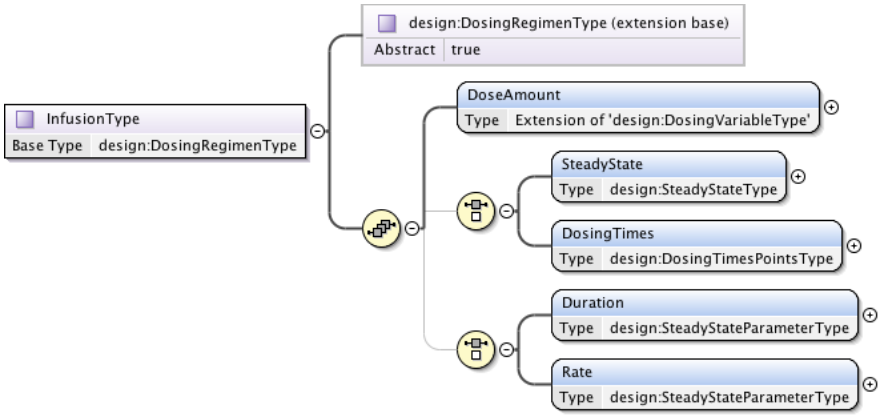
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Type that specifies steady state dosing.
Diagram	

1.4.9 Complex Type `design:SteadyStateParameterType`

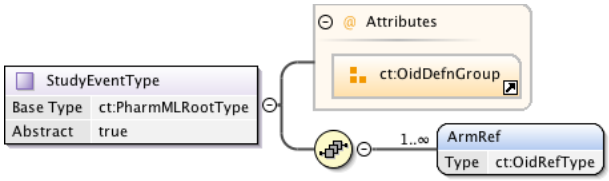
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Type that defines a paremeter used by steady state dosing.
Diagram	

1.4.10 Complex Type `design:InfusionType`

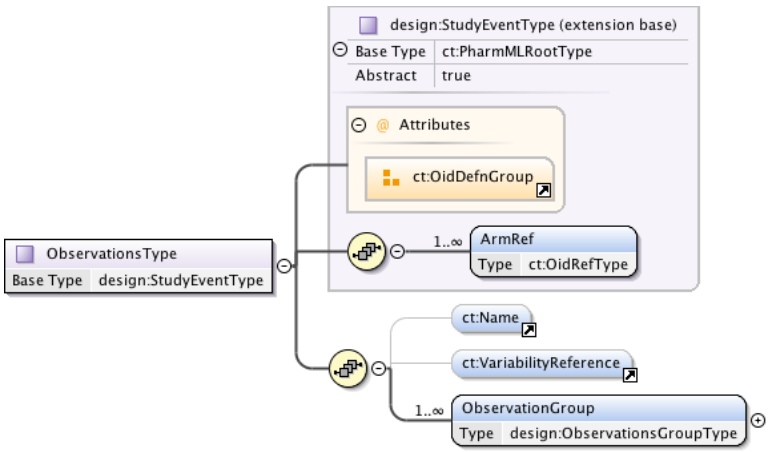
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Type the defines infusion dosing.

Diagram	
Type	extension of design:DosingRegimenType

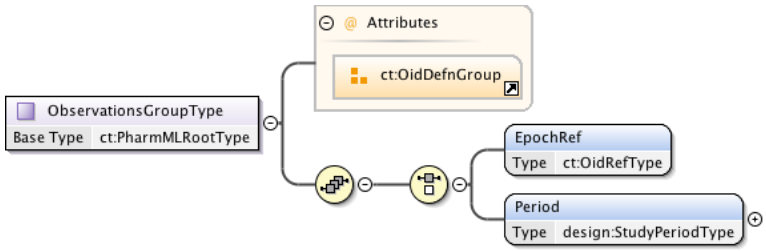
1.4.11 Complex Type `design:StudyEventType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	A type defining a study event (a CDISC term). In our case such events are observations take during the study.
Diagram	
Type	extension of PharmMLRootType

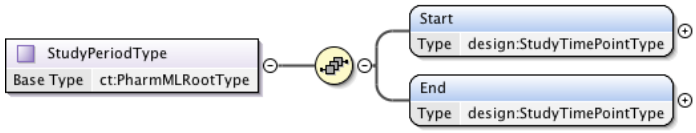
1.4.12 Complex Type `design:ObservationsType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	A type defining the set of observations taken from a set of subjects.
Diagram	
Type	extension of design:StudyEventType

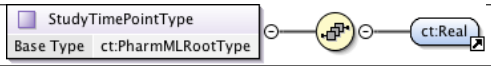
1.4.13 Complex Type `design:ObservationsGroupType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	A type defining the timepoint in a study.
Diagram	
Type	extension of PharmMLRootType

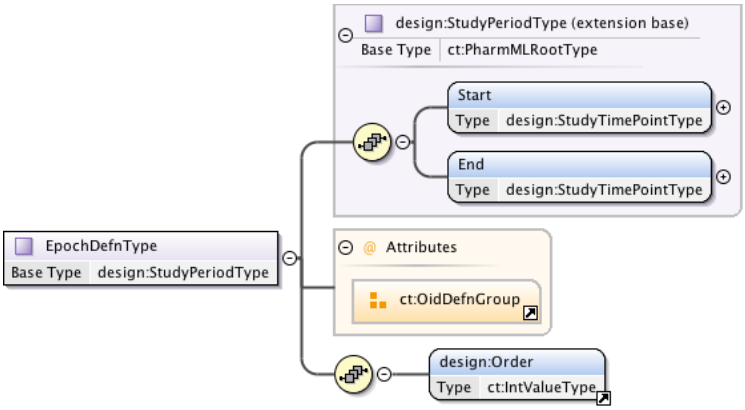
1.4.14 Complex Type `design:StudyPeriodType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	A type defining the time period in a study.
Diagram	
Type	extension of PharmMLRootType

1.4.15 Complex Type `design:StudyTimePointType`

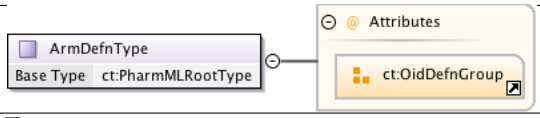
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	A type defining the timepoint in a study.
Diagram	
Type	extension of PharmMLRootType

1.4.16 Complex Type `design:EpochDefnType`

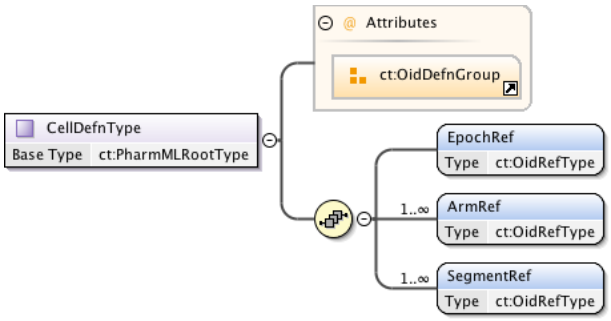
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Type that defines an epoch of the study.
Diagram	

Type	extension of design:StudyPeriodType

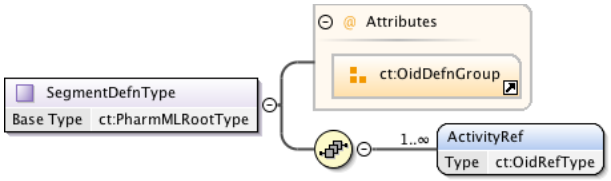
1.4.17 Complex Type `design:ArmDefnType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Type defining an arm of the study.
Diagram	
Type	extension of PharmMLRootType

1.4.18 Complex Type `design:CellDefnType`

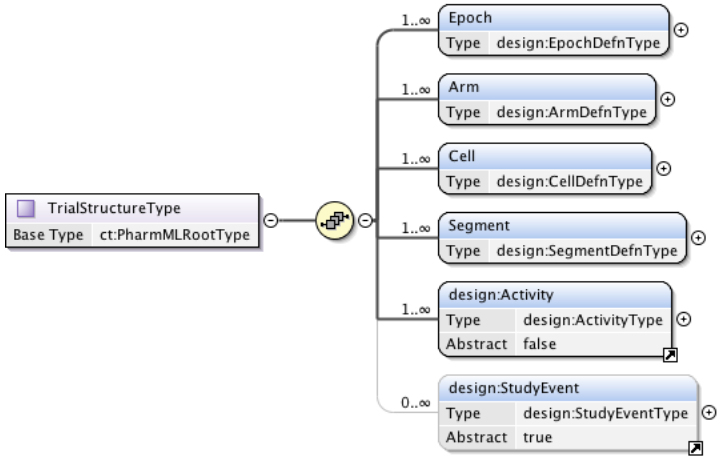
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Type defining a Cell in the study.
Diagram	
Type	extension of PharmMLRootType

1.4.19 Complex Type `design:SegmentDefnType`

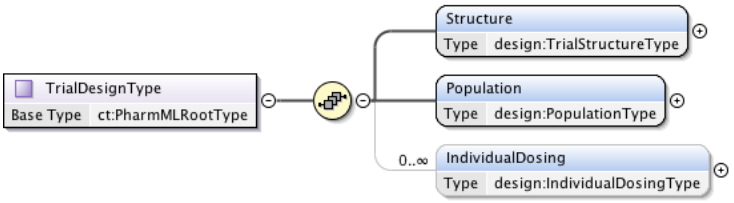
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Type defining a segment of the study.
Diagram	
Type	extension of PharmMLRootType

1.4.20 Complex Type `design:TrialStructureType`

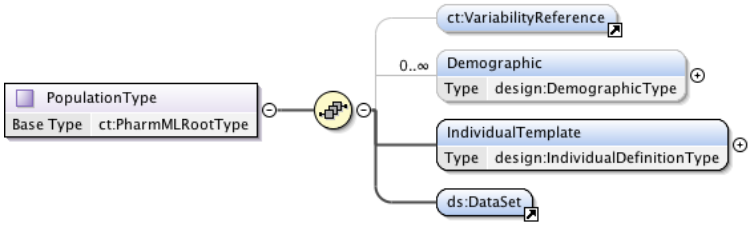
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Type that defines the structure of the study.

Diagram	
Type	extension of PharmMLRootType

1.4.21 Complex Type `design:TrialDesignType`

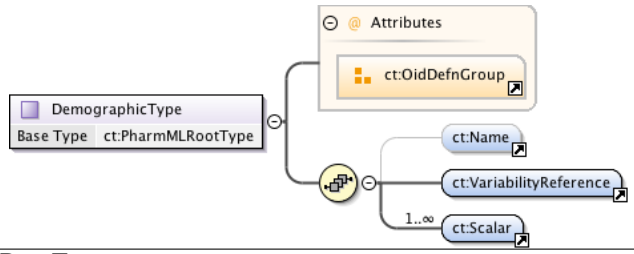
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	A type that defines the design of the study.
Diagram	
Type	extension of PharmMLRootType

1.4.22 Complex Type `design:PopulationType`

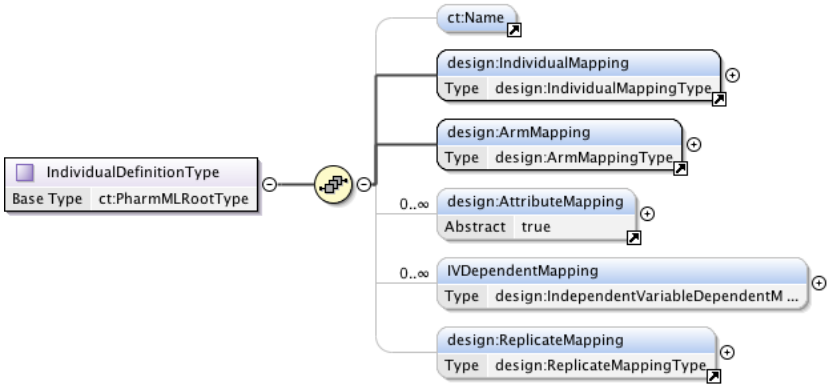
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	Type defining the population of subjects in the study.
Diagram	
Type	extension of PharmMLRootType

1.4.23 Complex Type `design:DemographicType`

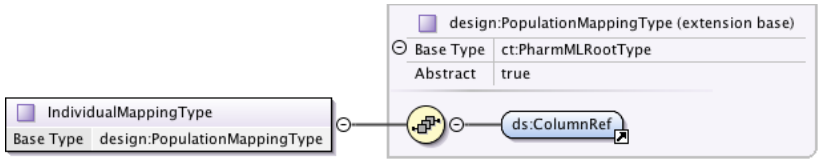
Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	The type defining a demographic attribute of the subject.

Diagram	
Type	extension of PharmMLRootType

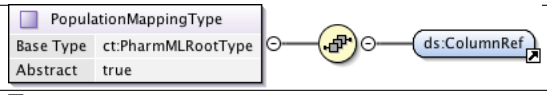
1.4.24 Complex Type `design:IndividualDefinitionType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	A type defining a template definition of the individuals in the study.
Diagram	
Type	extension of PharmMLRootType

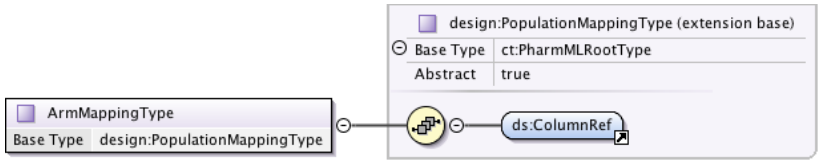
1.4.25 Complex Type `design:IndividualMappingType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	A type defining the mapping of the individual identifier to the dataset.
Diagram	
Type	extension of design:PopulationMappingType

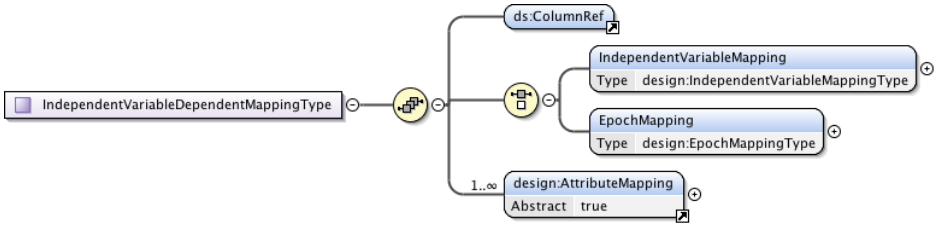
1.4.26 Complex Type `design:PopulationMappingType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	A type defining the mapping from a property of the individual template the the dataset defining each individual.
Diagram	
Type	extension of PharmMLRootType

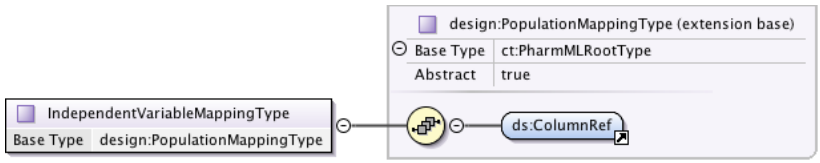
1.4.27 Complex Type `design:ArmMappingType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	A type defining the mapping of the arm to the dataset.
Diagram	
Type	extension of design:PopulationMappingType

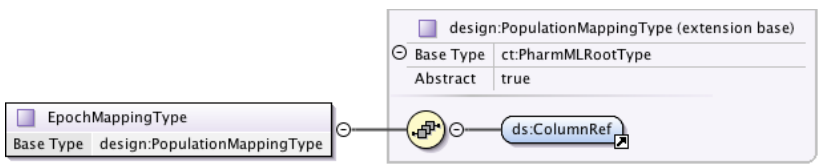
1.4.28 Complex Type `design:IndependentVariableDependentMappingType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	A type defining the mapping of indendent variable dependent properties.
Diagram	

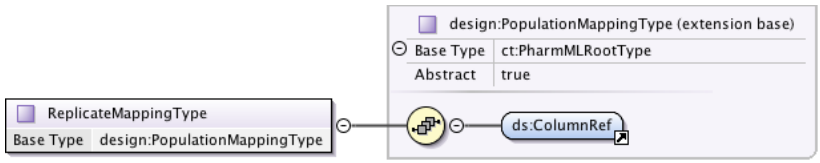
1.4.29 Complex Type `design:IndependentVariableMappingType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	A type defining the independent variable mapping.
Diagram	
Type	extension of design:PopulationMappingType

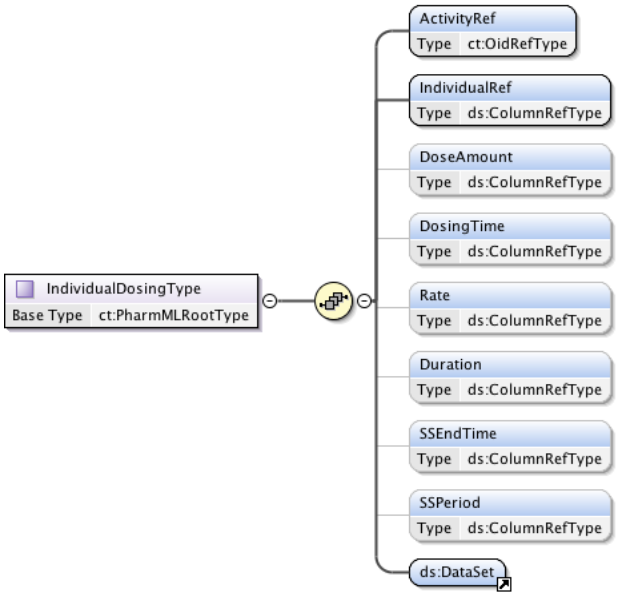
1.4.30 Complex Type `design:EpochMappingType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	A type defining a mapping from the epoch to values in the column of a dataset.
Diagram	
Type	extension of design:PopulationMappingType

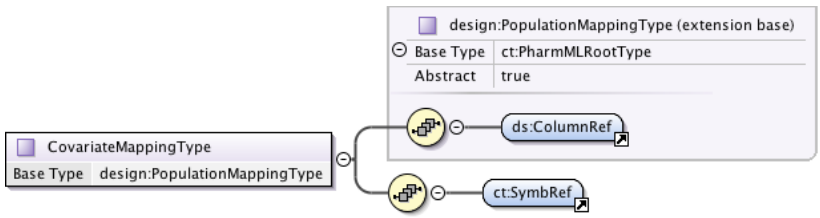
1.4.31 Complex Type `design:ReplicateMappingType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	A type defining the mapping of values specified in a column of a dataset that defines the number time the values in this row should be repeated. This is a convenient way of defining groups of individuals with the same properties, without enumerating each individual explicitly.
Diagram	
Type	extension of design:PopulationMappingType

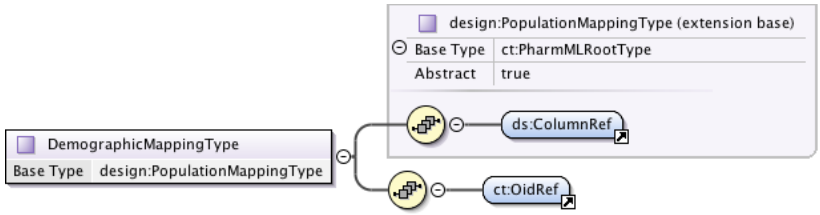
1.4.32 Complex Type `design:IndividualDosingType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Diagram	
Type	extension of PharmMLRootType

1.4.33 Complex Type `design:CovariateMappingType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	A type defining the mapping of a covariate to the values sepcified in a column of the dataset.
Diagram	
Type	extension of design:PopulationMappingType

1.4.34 Complex Type `design:DemographicMappingType`

Namespace	http://www.pharmml.org/2013/03/TrialDesign
Annotations	A type defining the mapping of a demographic attribute to the values sepcified in a column of the dataset.
Diagram	
Type	extension of design:PopulationMappingType