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<?xml version="1.0" encoding="UTF-8" standalone="yes" ?>
<!-- XML Schema for the results portion of clinical trial data to be -->
<!-- uploaded into the Protocol Registration System (PRS). -->
<!-- -->
<!-- ClinicalTrials.gov -->
<!-- National Library of Medicine, National Institutes of Health -->
<!-- Schema Version: 2008.10.28 -->
<!-- -->
<!-- This schema is subject to change without notice. -->
<!-- -->
<!-- In general, the tag names and comments within this document relate -->
<!-- to fields on the data entry screens and those have links into the -->
<!-- data element definitions document for full definitions. -->
<!-- -->
<!-- One good way of understanding the XML format is to create a record -->
<!-- interactively in the PRS and then download the XML for inspection. -->
<!-- You can then step through the screens while also examining the XML. -->
<!-- -->
<!-- NOTES: -->
<!-- 1. Most elements are noted as type string, although business rules -->
<!-- require that many of these elements be numbers. -->
<!-- There are also cases where the string needs to be one of an -->
<!-- enumerated set of strings. -->
<!-- -->
<!-- 2. Relationship by reference (ID and IDREF) -->
<!-- These are "pointers" between related row and column information. -->
<!-- * ID values must be unique within the scope of a single document -->
<!-- * Each IDREF value must match some ID value in the same document -->
<!-- -->
- <xs:schema attributeFormDefault="unqualified" elementFormDefault="unqualified" version="1.0" targetNamespace="http://clinicaltrials.
gov/rrs" xmlns:tns="http://clinicaltrials.gov/rrs" xmlns:xs="http://www.w3.org/2001/XMLSchema">
  <xs:element name="result" type="tns:Result" />
  - <xs:complexType name="Result">
    - <xs:sequence>
      <xs:element name="baseline" type="tns:Baseline" />
      <xs:element name="certainAgreement" type="tns:CertainAgreement" />
      <xs:element name="limitationsAndCaveats" type="tns:LimitationsAndCaveats" />
    - <xs:element name="outcomeMeasures">
      - <xs:complexType>
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- <xs:sequence>
  <xs:element name="outcomeMeasure" type="tns:OutcomeMeasure" minOccurs="0"
    maxOccurs="unbounded" />
</xs:sequence>
</xs:complexType>
</xs:element>
<xs:element name="participantFlow" type="tns:ParticipantFlow" />
<xs:element name="pointOfContact" type="tns:PointOfContact" />
<xs:element name="reportedEvents" type="tns:ReportedEvents" />
</xs:sequence>
</xs:complexType>
- <xs:complexType name="Baseline">
  - <xs:sequence>
    - <xs:element name="baselineMeasures">
      - <xs:complexType>
        - <xs:sequence>
          <xs:element name="baselineMeasure" type="tns:BaselineMeasure" minOccurs="0"
            maxOccurs="unbounded" />
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    - <xs:element name="baselineReportingGroups">
      - <xs:complexType>
        - <xs:sequence>
          <xs:element name="baselineReportingGroup" type="tns:BaselineReportingGroup" minOccurs="0"
            maxOccurs="unbounded" />
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <xs:element name="totalBaselineReportingGroup" type="tns:TotalBaselineReportingGroup" />
  </xs:sequence>
</xs:complexType>
- <xs:complexType name="BaselineMeasure">
  - <xs:complexContent>
    - <xs:extension base="tns:Measure">
      - <xs:sequence>
        <xs:element name="otherTitle" type="xs:string" minOccurs="0" />
        <!-- for study specific characteristic -->
      </xs:sequence>
    </xs:extension>
  </xs:complexContent>
</xs:complexType>
```

```
- <xs:complexType name="Measure" abstract="true">
  - <xs:sequence>
    <xs:element name="dispersionType" type="xs:string" minOccurs="0" />
    <!-- measure of dispersion -->
    - <xs:element name="measureCategories">
      - <xs:complexType>
        - <xs:sequence>
          <xs:element name="measureCategory" type="tns:MeasureCategory" minOccurs="0"
            maxOccurs="unbounded" />
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <xs:element name="measureDescription" type="xs:string" minOccurs="0" />
    <xs:element name="parameterType" type="xs:string" />
    <!-- measure type -->
    <xs:element name="title" type="xs:string" minOccurs="0" />
    <xs:element name="unitOfMeasure" type="xs:string" minOccurs="0" />
  </xs:sequence>
</xs:complexType>
- <xs:complexType name="MeasureCategory">
  - <xs:sequence>
    - <xs:element name="reportedValues">
      - <xs:complexType>
        - <xs:sequence>
          <xs:element name="reportedValue" type="tns:ReportedValue" minOccurs="0" maxOccurs="unbounded" />
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <xs:element name="title" type="xs:string" minOccurs="0" />
  </xs:sequence>
</xs:complexType>
<!-- Baseline Characteristic Data, Outcome Data (per Data Elements
Definitions) -->

<!--
-->
<!-- When Measure parameter type is
Number: -->
<!-- * parameterValue is a single number that describes the
observation -->
<!-- * dispersion elements are not
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applicable -->
<!--
Otherwise,
-->
<!-- * choice of Measure parameter type (Mean, Median, etc.) determines the semantics of
parameterValue -->
<!-- * if Measure dispersion type is StandardDeviation then dispersionSpread is to be
specified; -->
<!-- otherwise, dispersionLowerLimit and dispersionUpperLimit should be
provided -->

<!--
-->
- <xs:complexType name="ReportedValue">
- <xs:sequence>
  <xs:element name="reportingGroupId" type="xs:IDREF" />
  <xs:element name="dispersionLowerLimit" type="xs:string" minOccurs="0" />
  <xs:element name="dispersionSpread" type="xs:string" minOccurs="0" />
  <xs:element name="dispersionUpperLimit" type="xs:string" minOccurs="0" />
  <xs:element name="parameterValue" type="xs:string" minOccurs="0" />
</xs:sequence>
</xs:complexType>
- <xs:complexType name="BaselineReportingGroup">
- <xs:complexContent>
  - <xs:extension base="tns:MeasureReportingGroup">
    <xs:sequence />
  </xs:extension>
</xs:complexContent>
</xs:complexType>
- <xs:complexType name="MeasureReportingGroup" abstract="true">
- <xs:sequence>
  <xs:element name="description" type="xs:string" minOccurs="0" />
  <!-- number of baseline participants, number of participants analyzed (outcome) -->
  <xs:element name="subjectsAnalyzed" type="xs:string" minOccurs="0" />
  <xs:element name="title" type="xs:string" minOccurs="0" />
</xs:sequence>
  <xs:attribute name="id" type="xs:ID" use="required" />
</xs:complexType>
- <xs:complexType name="TotalBaselineReportingGroup">
- <xs:complexContent>
  - <xs:extension base="tns:BaselineReportingGroup">
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<xs:sequence />
</xs:extension>
</xs:complexContent>
</xs:complexType>
- <xs:complexType name="CertainAgreement">
  - <xs:sequence>
    <xs:element name="otherDetails" type="xs:string" minOccurs="0" />
    <xs:element name="piSponsorEmployee" type="xs:string" minOccurs="0" />
    <!-- "" (empty) for None | LTE60 for Less than or equal to 60 days | GT60 for Greater than 60
days | OTHER -->
    <xs:element name="restrictionType" type="xs:string" minOccurs="0" />
    <xs:element name="restrictiveAgreement" type="xs:string" minOccurs="0" />
    <!-- results disclosure restriction -->
  </xs:sequence>
</xs:complexType>
- <xs:complexType name="LimitationsAndCaveats">
  - <xs:sequence>
    <xs:element name="description" type="xs:string" minOccurs="0" />
  </xs:sequence>
</xs:complexType>
- <xs:complexType name="OutcomeMeasure">
  - <xs:complexContent>
    - <xs:extension base="tns:Measure">
      - <xs:sequence>
        <xs:element name="anticipatedResultPostingDate" type="tns:Date" minOccurs="0" />
        <xs:element name="measureType" type="xs:string" />
        <!-- outcome measure type -->
        - <xs:element name="outcomeMeasureAnalyses">
          - <xs:complexType>
            - <xs:sequence>
              <!-- statistical analysis -->
              <xs:element name="measureAnalysis" type="tns:OutcomeMeasureAnalysis" minOccurs="0"
maxOccurs="unbounded" />
            </xs:sequence>
          </xs:complexType>
        </xs:element>
        - <xs:element name="outcomeReportingGroups">
          - <xs:complexType>
            - <xs:sequence>
              <xs:element name="outcomeReportingGroup" type="tns:OutcomeReportingGroup" minOccurs="0"
maxOccurs="unbounded" />
            </xs:sequence>
          </xs:complexType>
        </xs:element>
      </xs:sequence>
    </xs:extension>
  </xs:complexContent>
</xs:complexType>
```

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    </xs:complexType>
  </xs:element>
  <xs:element name="populationAnalysisDescription" type="xs:string" minOccurs="0" />
  <xs:element name="reportingStatus" type="xs:string" minOccurs="0" />
  <xs:element name="safetyIssue" type="xs:string" minOccurs="0" />
  <xs:element name="timeFrame" type="xs:string" minOccurs="0" />
</xs:sequence>
</xs:extension>
</xs:complexContent>
</xs:complexType>
- <xs:complexType name="Date">
  - <xs:sequence>
    <xs:element name="month" type="xs:string" minOccurs="0" />
    <xs:element name="year" type="xs:string" minOccurs="0" />
  </xs:sequence>
</xs:complexType>
- <xs:complexType name="OutcomeMeasureAnalysis">
  - <xs:sequence>
    - <xs:element name="outcomeReportingGroups">
      <!-- comparison group selection -->
      - <xs:complexType>
        - <xs:sequence>
          <xs:element name="outcomeReportingGroupId" type="xs:IDREF" minOccurs="0" maxOccurs="unbounded" />
        >
      </xs:sequence>
    </xs:complexType>
  </xs:element>
  <xs:element name="ciLowerLimit" type="xs:string" minOccurs="0" />
  <xs:element name="ciPctValue" type="xs:string" minOccurs="0" />
  <!-- % confidence interval -->
  <xs:element name="ciUpperLimit" type="xs:string" minOccurs="0" />
  <xs:element name="dispersionType" type="xs:string" minOccurs="0" />
  <xs:element name="dispersionValue" type="xs:string" minOccurs="0" />
  <xs:element name="estimateComment" type="xs:string" minOccurs="0" />
  <!-- comment for parameter dispersion -->
  <xs:element name="groupDescription" type="xs:string" minOccurs="0" />
  <!-- comment for comparison group selection -->
  <xs:element name="nonInferiorityTestComment" type="xs:string" minOccurs="0" />
  <xs:element name="otherMethodName" type="xs:string" minOccurs="0" />
  <xs:element name="otherTypeName" type="xs:string" minOccurs="0" />
  <!-- if parameter estimated is Other -->
  <xs:element name="parameterType" type="xs:string" />

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<!-- parameter estimated -->
  <xs:element name="parameterValue" type="xs:string" minOccurs="0" />
<!-- estimated value -->
  <xs:element name="pValue" type="xs:string" minOccurs="0" />
  <xs:element name="pValueComment" type="xs:string" minOccurs="0" />
  <xs:element name="statisticalMethod" type="xs:string" minOccurs="0" />
  <xs:element name="statisticalTestComment" type="xs:string" minOccurs="0" />
<!-- comment for statistical method -->
  <xs:element name="testedNonInferiority" type="xs:string" minOccurs="0" />
</xs:sequence>
</xs:complexType>
- <xs:complexType name="OutcomeReportingGroup">
  - <xs:complexContent>
    - <xs:extension base="tns:MeasureReportingGroup">
      <xs:sequence />
    </xs:extension>
  </xs:complexContent>
</xs:complexType>
- <xs:complexType name="ParticipantFlow">
  - <xs:sequence>
    - <xs:element name="participantFlowGroups">
      - <xs:complexType>
        - <xs:sequence>
          <xs:element name="flowGroup" type="tns:ParticipantFlowGroup" minOccurs="0" maxOccurs="unbounded" />
        >
      </xs:sequence>
    </xs:complexType>
  </xs:element>
  - <xs:element name="periods">
    - <xs:complexType>
      - <xs:sequence>
        <xs:element name="period" type="tns:Period" minOccurs="0" maxOccurs="unbounded" />
      </xs:sequence>
    </xs:complexType>
  </xs:element>
  <xs:element name="preAssignmentDescription" type="xs:string" minOccurs="0" />
  <xs:element name="recruitmentDetails" type="xs:string" minOccurs="0" />
</xs:sequence>
</xs:complexType>
- <xs:complexType name="ParticipantFlowGroup">
  - <xs:sequence>
    <xs:element name="description" type="xs:string" minOccurs="0" />
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    <xs:element name="title" type="xs:string" minOccurs="0" />
  </xs:sequence>
  <xs:attribute name="id" type="xs:ID" use="required" />
</xs:complexType>
- <xs:complexType name="Period">
  - <xs:sequence>
    <xs:element name="completedMilestone" type="tns:CompletedMilestone" />
    - <xs:element name="dropWithdrawReasons">
      - <xs:complexType>
        - <xs:sequence>
          <!-- reason not completed -->
          <xs:element name="dropWithdrawReason" type="tns:DropWithdrawReason" minOccurs="0"
            maxOccurs="unbounded" />
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    - <xs:element name="milestones">
      - <xs:complexType>
        - <xs:sequence>
          <xs:element name="milestone" type="tns:MiscMilestone" minOccurs="0" maxOccurs="unbounded" />
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <xs:element name="startedMilestone" type="tns:StartedMilestone" />
    <xs:element name="title" type="xs:string" minOccurs="0" />
  </xs:sequence>
</xs:complexType>
- <xs:complexType name="CompletedMilestone">
  - <xs:complexContent>
    - <xs:extension base="tns:Milestone">
      <xs:sequence />
    </xs:extension>
  </xs:complexContent>
</xs:complexType>
- <xs:complexType name="Milestone" abstract="true">
  - <xs:sequence>
    - <xs:element name="milestoneAchievements">
      - <xs:complexType>
        - <xs:sequence>
          <xs:element name="milestoneAchievement" type="tns:MilestoneAchievement" minOccurs="0"
            maxOccurs="unbounded" />
        </xs:sequence>
      </xs:complexType>
    </xs:element>
  </xs:sequence>
</xs:complexType>
```



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</xs:complexType>
</xs:element>
</xs:sequence>
</xs:complexType>
- <xs:complexType name="MilestoneAchievement">
  - <xs:sequence>
    <xs:element name="reportingGroupId" type="xs:IDREF" />
    <xs:element name="comment" type="xs:string" minOccurs="0" />
    <xs:element name="subjectsAchieve" type="xs:string" minOccurs="0" />
    <!-- number -->
  </xs:sequence>
</xs:complexType>
- <xs:complexType name="StartedMilestone">
  - <xs:complexContent>
    - <xs:extension base="tns:Milestone">
      <xs:sequence />
    </xs:extension>
  </xs:complexContent>
</xs:complexType>
- <xs:complexType name="MiscMilestone">
  - <xs:complexContent>
    - <xs:extension base="tns:Milestone">
      - <xs:sequence>
        <xs:element name="titleOther" type="xs:string" minOccurs="0" />
        <!-- milestone title -->
      </xs:sequence>
    </xs:extension>
  </xs:complexContent>
</xs:complexType>
<!-- reason not completed -->
- <xs:complexType name="DropWithdrawReason">
  - <xs:sequence>
    - <xs:element name="dropWithdrawReasonDetails">
      - <xs:complexType>
        - <xs:sequence>
          <xs:element name="reasonDetail" type="tns:DropWithdrawReasonDetail" minOccurs="0"
            maxOccurs="unbounded" />
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <xs:element name="otherReasonName" type="xs:string" minOccurs="0" />
    <xs:element name="reasonType" type="xs:string" />
  </xs:sequence>
</xs:complexType>
```

```
</xs:sequence>
</xs:complexType>
- <xs:complexType name="DropWithdrawReasonDetail">
  - <xs:sequence>
    <xs:element name="reportingGroupId" type="xs:IDREF" />
    <xs:element name="subjectsAffected" type="xs:string" minOccurs="0" />
    <!-- untitled (per reason and arm) -->
  </xs:sequence>
</xs:complexType>
- <xs:complexType name="PointOfContact">
  - <xs:sequence>
    <xs:element name="email" type="xs:string" minOccurs="0" />
    <xs:element name="organizationName" type="xs:string" minOccurs="0" />
    <xs:element name="phoneExtension" type="xs:string" minOccurs="0" />
    <xs:element name="phoneNumber" type="xs:string" minOccurs="0" />
    <xs:element name="title" type="xs:string" minOccurs="0" />
    <!-- name or official title -->
  </xs:sequence>
</xs:complexType>
<!-- adverse events -->
- <xs:complexType name="ReportedEvents">
  - <xs:sequence>
    <xs:element name="frequencyReportingThreshold" type="xs:string" minOccurs="0" />
    - <xs:element name="frequentAdverseEvents">
      <!-- other adverse events -->
      - <xs:complexType>
        - <xs:sequence>
          <xs:element name="frequentEvent" type="tns:FrequentAdverseEvent" minOccurs="0"
            maxOccurs="unbounded" />
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    - <xs:element name="interventionGroups">
      - <xs:complexType>
        - <xs:sequence>
          <xs:element name="interventionGroup" type="tns:InterventionGroup" minOccurs="0"
            maxOccurs="unbounded" />
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    - <xs:element name="seriousAdverseEvents">
      - <xs:complexType>
```

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- <xs:sequence>
  <xs:element name="seriousEvent" type="tns:SeriousAdverseEvent" minOccurs="0"
    maxOccurs="unbounded" />
</xs:sequence>
</xs:complexType>
</xs:element>
</xs:sequence>
</xs:complexType>
<!-- other adverse event -->
- <xs:complexType name="FrequentAdverseEvent">
  - <xs:complexContent>
    - <xs:extension base="tns:AdverseEvent">
      <xs:sequence />
    </xs:extension>
  </xs:complexContent>
</xs:complexType>
- <xs:complexType name="AdverseEvent" abstract="true">
  - <xs:sequence>
    - <xs:element name="adverseEventStats">
      - <xs:complexType>
        - <xs:sequence>
          <xs:element name="eventStats" type="tns:AdverseEventStats" minOccurs="0" maxOccurs="unbounded" />
        </xs:sequence>
      </xs:complexType>
    </xs:element>
    <xs:element name="assessmentType" type="xs:string" minOccurs="0" />
    <xs:element name="organSystemName" type="xs:string" minOccurs="0" />
    <xs:element name="sourceVocabulary" type="xs:string" minOccurs="0" />
    <xs:element name="term" type="xs:string" minOccurs="0" />
  </xs:sequence>
</xs:complexType>
<!-- Adverse Event Data (per Data Elements Definitions) -->
- <xs:complexType name="AdverseEventStats">
  - <xs:sequence>
    <xs:element name="reportingGroupId" type="xs:IDREF" />
    <xs:element name="numEvents" type="xs:string" minOccurs="0" />
    <xs:element name="numSubjectsAffected" type="xs:string" minOccurs="0" />
    <xs:element name="numSubjects" type="xs:string" minOccurs="0" />
    <!-- # participants at risk -->
  </xs:sequence>
</xs:complexType>
- <xs:complexType name="SeriousAdverseEvent">
```

```
- <xs:complexContent>
  - <xs:extension base="tns:AdverseEvent">
    <xs:sequence />
  </xs:extension>
</xs:complexContent>
</xs:complexType>
- <xs:complexType name="InterventionGroup">
  - <xs:sequence>
    <xs:element name="description" type="xs:string" minOccurs="0" />
    <xs:element name="numSubjectsFrequentEvents" type="xs:string" minOccurs="0" />
    <!-- total # affected by other AE -->
    <xs:element name="numSubjectsSeriousEvents" type="xs:string" minOccurs="0" />
    <!-- total # affected by serious AE -->
    <xs:element name="title" type="xs:string" minOccurs="0" />
  </xs:sequence>
  <xs:attribute name="id" type="xs:ID" use="required" />
</xs:complexType>
</xs:schema>
```