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<?xml version="1.0" encoding="UTF-8" ?>
<!DOCTYPE Study (View Source for full doctype...)>
- <!--
  This XML Example is intended to provide a very small, valid
  example of a CDISC study.
-->
- <Study>
- <GlobalVariables>
  <StudyName>HarrisonA</StudyName>
  <StudyDescription>Phase II initial efficacy</StudyDescription>
  <ProtocolName>B00-2136</ProtocolName>
</GlobalVariables>
- <BasicDefinitions>
  <!-- One language: English -->
  <Language Name="en" ID="Language.001" />
  <!-- One locale: North America -->
  <Locale Name="North America" ID="Locale.001" />
  <!-- Two time zones: Eastern Standard Time and Eastern Daylight Time
  -->
  <TimeZone ID="TimeZone.001" Name="EST" BaseOffset="-5" />
  <TimeZone ID="TimeZone.002" Name="EDT" BaseOffset="-4" />
</BasicDefinitions>
<!-- Beginning of metadata definitions ... -->
- <MetaDataVersion ID="MetaDataVersion.001" Name="Release 1">
- <StudyProtocol>
  <StudyEventRef StudyEventID="VISIT_1" />
  <StudyEventRef StudyEventID="VISIT_2" />
</StudyProtocol>
- <!--
  There are 2 study events defined, corresponding to Visit 1 and Visit 2. On
  "Demog and Vitals" signing unit is used, while on Visit 2, the "Vitals Only
  is used.
  -->
- <StudyEvent ID="VISIT_1" Name="Visit1">
  <FormRef FormID="PAGE_1" />
</StudyEvent>
- <StudyEvent ID="VISIT_2" Name="Visit2">
  <FormRef FormID="PAGE_2" />
</StudyEvent>
- <!--
  There are 2 signing units defined: one to collect demographics AND vitals
  and one to collect just vitals.
  -->
- <Form Name="Demog and Vitals" ID="PAGE_1">
  <ItemGroupRef ItemGroupID="DEMOG" />
  <ItemGroupRef ItemGroupID="VITALS" />
</Form>
- <Form Name="Vitals Only" ID="PAGE_2">
  <ItemGroupRef ItemGroupID="VITALS" />
</Form>
<!-- There are 2 item groups (ItemGroup): Demographics and Vitals -->
- <!--
  The demographics item group contains 7 item references (ItemRef's)
  corresponding to Patient ID, Patient Initials, Sex, Date of Birth,
  Sponsor Patient ID, Weight(lb) and Weight(kg)
  -->

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- <ItemGroup Name="Demographics" ID="DEMOG">
  <ItemRef ItemID="PT" />
  <ItemRef ItemID="INITIALS" />
  <ItemRef ItemID="SEX" />
  <ItemRef ItemID="DOB" />
  <ItemRef ItemID="SPONSOR_PTID" />
  <ItemRef ItemID="WEIGHT_LB" />
  <ItemRef ItemID="WEIGHT_KG" />
</ItemGroup>
- <!--
  The vitals item group contains 6 item references (ItemRef's)
  corresponding to the Patient ID, Visit Name,
  Systolic Blood Pressure, Diastolic Blood Pressure,
  Sponsor Patient ID, and Occurrence Number (of repeat measurement)
-->
- <ItemGroup ID="VITALS" Name="Vital Signs">
  <ItemRef ItemID="PT" />
  <ItemRef ItemID="VISITNAME" />
  <ItemRef ItemID="SBP" />
  <ItemRef ItemID="DBP" />
  <ItemRef ItemID="SPONSOR_PTID" />
  <ItemRef ItemID="OCCUR_NUM" />
</ItemGroup>
- <!--
  There are 12 items defined: Patient ID, Initials, Date of Birth, Sex,
  Systolic Blood Pressure, Diastolic Blood Pressure, Visit Name, Sponsor Pati
  Visit Number (not currently used), Occurrence Number, Weight(lb) and Weight
-->
<Item ID="PT" Name="PT" DataType="text" />
<Item ID="INITIALS" Name="Initials" DataType="text" />
<Item ID="DOB" Name="Date of Birth" DataType="date" />
<Item ID="SEX" Name="Sex" DataType="text" CodeListID="CodeList.001" />
<Item ID="SBP" Name="Systolic Blood Pressure" DataType="integer" />
<Item ID="DBP" Name="Diastolic Blood Pressure" DataType="integer" />
<Item ID="VISITNAME" Name="Visit" DataType="text" />
<Item ID="SPONSOR_PTID" Name="Sponsor Patient ID" DataType="text" />
<Item ID="VISITNUM" Name="Numeric Version of Visit"
  DataType="integer" />
<Item ID="OCCUR_NUM" Name="Occurrence Number" DataType="integer" />
<Item ID="WEIGHT_LB" Name="Weight in pounds" DataType="float" />
<Item ID="WEIGHT_KG" Name="Weight in kilograms" DataType="float" />
<!-- There is a single codelist for Sex with entries for "m" and "f"
-->
- <CodeList ID="CodeList.001" Name="Sex">
- <CodeListItem ID="CodeListItem.001" CodedValue="m">
  - <Decode>
    <TranslatedText LanguageID="Language.001"
      LocaleID="Locale.001">Male</TranslatedText>
  </Decode>
</CodeListItem>
- <CodeListItem ID="CodeListItem.002" CodedValue="f">
  - <Decode>
    <TranslatedText LanguageID="Language.001"
      LocaleID="Locale.001">Female</TranslatedText>
  </Decode>
</CodeListItem>
</CodeList>

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- <!--
  Since structure and content of Presentation have not
  yet been defined, we have inserted an empty Presentation element.
-->
  <Presentation />
</MetaDataVersion>
<!-- Beginning of administrative data ... -->
- <AdminData>
  <!-- There is 1 user: John Doe -->
  - <User ID="User.001" Name="JohnDoe">
    <FirstName>John</FirstName>
    <LastName>Doe</LastName>
  </User>
  <!-- There is 1 location: General Hospital (a site) -->
  - <Location LocationType="Site" ID="Location.001" Name="General Hospital"
    TimeZoneID="TimeZone.001">
    <MetaDataVersionRef MetaDataVersionID="MetaDataVersion.001" />
  </Location>
  <!-- There is 1 SignatureDef (electronic signature for data entry) --
  >
  - <SignatureDef ID="SignatureDef.001" Methodology="Electronic">
    <Meaning>Entry</Meaning>
    <LegalReason>Signer accepts responsibility for initial data
      entry</LegalReason>
  </SignatureDef>
</AdminData>
<!-- Beginning of clinical data (using nested representation) ... -->
- <HierData>
  <!-- HierPatientData element for the first (and only) patient in this
  example -->
  - <HierPatientData Patientid="B00-2136-001" EnrollDate="1999-06-02" Sex="F"
    Initials="AMH" DOB="1947-07-16" RandDate="1999--06-02">
    <PatientKey>P001</PatientKey>
    <!-- HierStudyEventData element for Visit 1 for this patient -->
    - <HierStudyEventData>
      <StudyEventKey StudyEventID="VISIT_1" />
      <!-- HierFormData element for the Demog and Vitals form
      collected on Visit 1 (Original) -->
      - <HierFormData>
        <FormKey FormID="PAGE_1" />
        <!-- HierItemGroupData element for the Demographics part of
        the form -->
        - <HierItemGroupData>
          <ItemGroupKey ItemGroupID="DEMOG" />
          - <HierItemData>
            <ItemKey ItemID="PT" />
            <Value>P001</Value>
          </HierItemData>
          - <HierItemData>
            <ItemKey ItemID="INITIALS" />
            <Value>AMH</Value>
          </HierItemData>
          - <HierItemData>
            <ItemKey ItemID="SEX" />
            <Value>f</Value>
          </HierItemData>

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- <HierItemData>
  <ItemKey ItemID="DOB" />
  <Value>1947-07-16</Value>
</HierItemData>
- <HierItemData>
  <ItemKey ItemID="SPONSOR_PTID" />
  <Value>B00-2136-001</Value>
</HierItemData>
- <HierItemData>
  <ItemKey ItemID="WEIGHT_LB" />
  <Value>150.00</Value>
</HierItemData>
- <HierItemData>
  <ItemKey ItemID="WEIGHT_KG" />
  <Value>68.18</Value>
</HierItemData>
</HierItemGroupData>
<!-- HierItemGroupData element for the Vitals part of the
form -->
- <HierItemGroupData>
  <ItemGroupKey ItemGroupID="VITALS" />
- <HierItemData>
  <ItemKey ItemID="PT" />
  <Value>P001</Value>
</HierItemData>
- <HierItemData>
  <ItemKey ItemID="VISITNAME" />
  <Value>Visit1</Value>
</HierItemData>
- <HierItemData>
  <ItemKey ItemID="SBP" />
  <Value>120</Value>
</HierItemData>
- <HierItemData>
  <ItemKey ItemID="DBP" />
  <Value>80</Value>
</HierItemData>
- <HierItemData>
  <ItemKey ItemID="SPONSOR_PTID" />
  <Value>B00-2136-001</Value>
</HierItemData>
- <HierItemData>
  <ItemKey ItemID="OCCUR_NUM" />
  <Value>1</Value>
</HierItemData>
</HierItemGroupData>
<!-- Electronic signature for this form -->
- <Signature>
  <UserRef UserID="User.001" />
  <LocationRef LocationID="Location.001" />
  <SignatureDefRef SignatureDefID="SignatureDef.001" />
  <DateTimeStamp>2000-02-07T17:15:42Z</DateTimeStamp>
</Signature>
</HierFormData>
<!-- HierFormData element for the Demog and Vitals form

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collected on Visit 1 (Modified)  -->
- <HierFormData>
  <FormKey FormID="PAGE_1" />
  <!-- HierItemGroupData element for the Demographics part of
the form -->
- <HierItemGroupData>
  <ItemGroupKey ItemGroupID="DEMOG" />
</HierItemGroupData>
<!-- HierItemGroupData element for the Vitals part of the
form -->
- <HierItemGroupData>
  <ItemGroupKey ItemGroupID="VITALS" />
  - <HierItemData>
    <ItemKey ItemID="SBP" />
    <Value>130</Value>
  </HierItemData>
</HierItemGroupData>
<!-- Electronic signature for this form -->
- <Signature>
  <UserRef UserID="User.001" />
  <LocationRef LocationID="Location.001" />
  <SignatureDefRef SignatureDefID="SignatureDef.001" />
  <DateTimeStamp>2000-02-08T18:44:28Z</DateTimeStamp>
</Signature>
</HierFormData>
</HierStudyEventData>
<!-- HierStudyEventData element for Visit 2 for the patient -->
- <HierStudyEventData>
  <StudyEventKey StudyEventID="VISIT_2" />
  <!-- HierFormData element for the Vitals Only form collected on
Visit 2 -->
- <HierFormData>
  <FormKey FormID="PAGE_2" />
  <!-- Data for 3 repeats of Vitals item group on this form --
>
- <HierItemGroupData>
  <ItemGroupKey ItemGroupID="VITALS"
    ItemGroupRepeatKey="1" />
  - <HierItemData>
    <ItemKey ItemID="PT" />
    <Value>P001</Value>
  </HierItemData>
  - <HierItemData>
    <ItemKey ItemID="VISITNAME" />
    <Value>Visit2</Value>
  </HierItemData>
  - <HierItemData>
    <ItemKey ItemID="SBP" />
    <Value>130</Value>
  </HierItemData>
  - <HierItemData>
    <ItemKey ItemID="DBP" />
    <Value>90</Value>
  </HierItemData>
  - <HierItemData>

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        <ItemKey ItemID="SPONSOR_PTID" />
        <Value>B00-2136-001</Value>
    </HierItemData>
- <HierItemData>
    <ItemKey ItemID="OCCUR_NUM" />
    <Value>1</Value>
</HierItemData>
</HierItemGroupData>
- <HierItemGroupData>
    <ItemGroupKey ItemGroupID="VITALS"
        ItemGroupRepeatKey="2" />
- <HierItemData>
    <ItemKey ItemID="PT" />
    <Value>P001</Value>
</HierItemData>
- <HierItemData>
    <ItemKey ItemID="VISITNAME" />
    <Value>Visit2</Value>
</HierItemData>
- <HierItemData>
    <ItemKey ItemID="SBP" />
    <Value>125</Value>
</HierItemData>
- <HierItemData>
    <ItemKey ItemID="DBP" />
    <Value>86</Value>
</HierItemData>
- <HierItemData>
    <ItemKey ItemID="SPONSOR_PTID" />
    <Value>B00-2136-001</Value>
</HierItemData>
- <HierItemData>
    <ItemKey ItemID="OCCUR_NUM" />
    <Value>2</Value>
</HierItemData>
</HierItemGroupData>
- <HierItemGroupData>
    <ItemGroupKey ItemGroupID="VITALS"
        ItemGroupRepeatKey="3" />
- <HierItemData>
    <ItemKey ItemID="PT" />
    <Value>P001</Value>
</HierItemData>
- <HierItemData>
    <ItemKey ItemID="VISITNAME" />
    <Value>Visit2</Value>
</HierItemData>
- <HierItemData>
    <ItemKey ItemID="SBP" />
    <Value>122</Value>
</HierItemData>
- <HierItemData>
    <ItemKey ItemID="DBP" />
    <Value>84</Value>
</HierItemData>

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- <HierItemData>
  <ItemKey ItemID="SPONSOR_PTID" />
  <Value>B00-2136-001</Value>
</HierItemData>
- <HierItemData>
  <ItemKey ItemID="OCCUR_NUM" />
  <Value>3</Value>
</HierItemData>
</HierItemGroupData>
<!-- Electronic signature for this form -->
- <Signature>
  <UserRef UserID="User.001" />
  <LocationRef LocationID="Location.001" />
  <SignatureDefRef SignatureDefID="SignatureDef.001" />
  <DateTimeStamp>2000-02-07T17:18:48Z</DateTimeStamp>
</Signature>
</HierFormData>
</HierStudyEventData>
</HierPatientData>
</HierData>
</Study>

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