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The ODM Extension for Trial Design - Status

- Developed by Jan Kratky and Peter Villiers
- Currently in beta
- Reviewed / tested by the ODM Team
- Publication expected end 2010
- Scope: Design, not Execution
The ODM Extension for Trial Design - Contents

- Trial Summary and Parameters
- Inclusion / Exclusion Criteria
- Structural Elements: Arms, Epochs, Cells, Segments
- Activities
- Workflows between Activities
- Timings between Activities
Trial Summary and Parameters

<sdm:Summary>
  <!-- Indication -->
  <sdm:Parameter
    OID="PARM.001" Term="Indication" ShortName="INDIC">
    <sdm:Value>ASTHMA</sdm:Value>
  </sdm:Parameter>
  <!-- Age Span -->
  <sdm:Parameter
    OID="PARM.002" Term="Age span" ShortName="AGESPAN">
    <sdm:Value>Adult (18-65)</sdm:Value>
    <sdm:Value>Elderly (&gt;65)</sdm:Value>
  </sdm:Parameter>
  ...
</sdm:Summary>

Information may go into SDTM domain TS
Inclusion / Exclusion Criteria

<sdm:InclusionExclusionCriteria>
  <sdm:Criterion OID="CRIT00" Category="INCLUSION"
      ConditionOID="COND.AGE" Name="age condition" />
</sdm:InclusionExclusionCriteria>

<ConditionDef Name="Minimum Age" OID="COND.AGE">
  <Description>
    <TranslatedText xml:lang="en">Over Age 21</TranslatedText>
  </Description>
  <!-- 'computer-executable' -->
  <FormalExpression Context="xpath">Age &gt; 21</FormalExpression>
</ConditionDef>
Structural Elements: Arms, Epochs, Cells, Segments

Generated using the XML4Pharma ODM Study Designer R2010
Cells and Segments

- A **Cell** is a crossing between an **Arm** and an **Epoch**
- A **Cell** can contain one or more **Segments**
- **Segments** are the basic building blocks:
  - Can contain Activities
  - There can be no gaps between segments

Remark that in ODM, Segments and Activities are **reusable**
(Definition – Reference mechanism)
Activities

• Different types:
  – Study Start
  – Study Finish
  – Non-data-collection (e.g. intervention)
  – Data Collection
  – Scheduling
    • “milestones”

• An Activity can (but is not required to) use a Form
Workflows

- Entry & Exit Criteria for
  - Epochs
  - Cells
  - Segments
  - StudyEvents (visits)
  - Activities
  - ... using the ODM ConditionDef
    - Human-readable
    - Machine-executable
Workflows

- (Conditional) transitions between Activities
Workflow

• Does not describe timings between Activities
  – “Separation of concerns”
• Can be easily translated / transformed into more common machine-executable instruction sets such as:
  – BPEL
  – Windows Workflow Foundation
  – XPDL, YAWL, ...
Timings

- Essentially between Activities
- Absolute or relative timings
- Time Windows
  - +1 day, -2 days window
  - “within the same month”
The proof of the pudding is in the eating

• Can we use the ODM extension to set up a caBIG Patient Study Calendar?
The caBIG Patient Study Calendar

- Web application (open source)
- Sets up a study calendar for a group of patients
- Claimed to be an implementation of PRM v.1.0
The proof of the pudding is in the interoperability

- PSC knows epochs, segments, activities
- Has XML export and import

- Segments have one or more Periods
- Periods have a time “duration”
- Activity Timings are relative to start of Period
- Smallest time unit is “day”
  - No order of Activities within a day
- Uses GUIDs
ODM for PSC import

• 1 Segment = 1 Period

• Add “scheduling” activities to each Segment
  – Segment Start + Segment Finish
  – Add a Timing between these two “scheduling activities” => Period duration

• Define other “normal” activities

• Add timings for each activity relative to start-of-segment “scheduling” activity
- Start- and end “scheduling” activity allow to define a segment duration
- All other activities get a timing relative to “start-of-segment” “scheduling” activity
ODM for PSC import: the process

Implemented in the XML4Pharma ODM Study Designer R2010
Import into PSC: the result
The (bright) future
Tools used

- XML4Pharma ODM StudyDesigner R2010
  - Extended for ODM-SDM (prototype)
  - Extended for PSC-XML generation
  
    www.xml4pharma.com/CDISC_Products/ODMDesigner.html

- CaBIG Patient Study Calendar v.2.6
  
    https://cabig.nci.nih.gov/tools/PatientStudyCalendar
Conclusions

• The (prototype) ODM extension for trial design is in pretty good shape

• Some improvements still need to be made

• Some extra testing is necessary

• Allows to generate a caBIG Patient Study Calendar
  - But only when a strict procedure is followed
Conclusions

- PRM is the basis for the ODM-extension
- PRM is a “domain analysis model” (DAM)
  - Not an implementation model
- Different implementations of PRM are not necessarily interoperable!
  - DAM allows different interpretations
  - DAM does not contain any “how to”
- Transformations possible for
  - Subject search systems, Workflow engines
  - SDTM, FDA messages, ClinicalTrials.gov, ...