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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 Q4 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>
  <sdm:Parameter
    OID="PARM.IND" ShortName="Indication" OrderNumber="1">
    <sdm:Term>Indication</sdm:Term>
    <sdm:Value>ASTHMA</sdm:Value>
  </sdm:Parameter>
  <sdm:Parameter
    OID="PARM.AGEMAX" ShortName="Maximum Age"
    OrderNumber="2">
    <sdm:Term>Agemax</sdm:Term>
    <sdm:Value>65</sdm:Value>
  </sdm:Parameter>
  ...
</sdm:Summary>

Information will 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
- 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

Generated using the XML4Pharma ODM Study Designer R2010
Workflows

- 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

1. Create ODM with Study Extension
2. Add Arms, Epochs, Segments, Activities
3. Add Timings
4. Add "Scheduling" Activities (start/end) for each Segment
5. Check suitability for PSC
   - Not suitable
   - Suitable
6. Transform to PSC-XML using XSLT Stylesheet
7. Add GUIDs
8. Save as PSC-XML
9. Import into PSC web application
Import into PSC: the result
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”