The CDISC ODM Extension for Study Design / Protocol

Eligibility Criteria and Workflows

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The ODM-SDM Extension

- Study Parameters
- Inclusion / Exclusion criteria
- Structure: Arms, Epochs, Cells, Segments, Activities
- Workflow (between Activities)
- Timings
Inclusion / Exclusion Criteria

- `<sdm:InclusionExclusionCriteria>`
  - `<sdm:InclusionCriteria>`
    - `<sdm:Criterion ConditionOID="COND.MIN_AGE" Name="Inclusion criterion for age"> OID="CRIT.MIN_AGE" /></sdm:Criterion>
    - `<sdm:Criterion ConditionOID="COND.ALZHEIMER_DISEASE" Name="Inclusion criterion: subject has AD"> OID="CRIT.ALZHEIMER_DISEASE" /></sdm:Criterion>
    - `<sdm:Criterion ConditionOID="COND.MMSE_10-23" Name="Inclusion criterion: MMSE between 10 and 23"> OID="CRIT.MMSE_10-23" /></sdm:Criterion>
    - `<sdm:Criterion ConditionOID="COND.HACHINSKI" Name="Inclusion criterion: Hachinski score <= 4"> OID="CRIT.HACHINSKI" /></sdm:Criterion>
    - `<sdm:Criterion ConditionOID="COND.CNS_1_YEAR" Name="Inclusion criterion: CNS in past year compatible with AD"> OID="CRIT.CNS_1_YEAR" /></sdm:Criterion>
  </sdm:InclusionCriteria>
  `<sdm:ExclusionCriteria>`
    - `<sdm:Criterion ConditionOID="COND.MAX_AGE" Name="Exclusion criterion for age"> OID="CRIT.MAX_AGE" /></sdm:Criterion>
  </sdm:ExclusionCriteria>
</sdm:InclusionExclusionCriteria>

- `<ConditionDef Name="Condition Hachinski Ischemic Scale score of <= 4"> OID="COND.HACHINSKI">`
Using formal expressions for Eligibility Criteria

- allow to add machine-readable code to criteria
- can be Java, C#, SQL, ...

allows e.g.
- search for eligible patients in databases, social networks ...
In a study designer ...
Workflows in study designs
Entry / Exit criteria for epochs, cells and segments

- e.g. "treatment epoch may only be started when all IE criteria have been fulfilled"
- additional conditions can be added
  - e.g. "subject did not have any antidepressants in the last week"
Transformations realized so far

- Workflow/Timing
  -> caBIG Patient Study Calendar (PSC)

- Workflow -> BPMN2 xml
Transformation to PSC-XML import into PSC
Transformation to BPMN2-XML