

## DATABASE SCHEMA SDR-REFERENCE IMPLEMENTATION

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{
  "clinicalStudy": {
    "studyId": "7682150a-079d-4732-acea-7d761546c32b",
    "studyTitle": "Study Number One",
    "studyType": "INTERVENTIONAL",
    "studyPhase": "PHASE_1_TRIAL",
    "studyStatus": "this is a study status",
    "studyTag": "1.0Draft",
    "studyIdentifiers": [
      {
        "id": "4ac4d0d2-dcb8-43a5-9ad3-0a4eece92008",
        "orgCode": "2.16.840.1.113883.3.1077",
        "name": "ClinicalTrials.gov",
        "idType": "REGISTRY_STUDY"
      },
      {
        "id": "7e2136bc-1359-4874-9cfe-3c8223e4f632",
        "orgCode": "2.16.840.1.113883.3.1077",
        "name": "ClinicalTrials.gov",
        "idType": "SPONSOR_ID"
      },
      {
        "id": "3979732f-2a97-46cb-abb1-a9d1d0a3c885",
        "orgCode": "2.16.842.1.113844.3.1088",
        "name": "ClinicalTrials.gov",
        "idType": "SPONSOR_ID"
      }
    ],
    "currentSections": [
      {
        "id": "300fafcb-4b1f-4c8b-9988-dfd23b1b2d9a",
        "sectionType": "STUDY_INDICATIONS",
        "studyIndications": [
          {
            "id": "3c36a671-5a7a-4a4a-a5dc-5eec59bba5ca",
            "description": "Alzheimer's disease",
            "coding": [
              {
                "code": "26929004",
                "codeSystem": "SNOMED-CT",
                "codeSystemVersion": "4.0.6.4",
                "decode": "Alzheimer's disease (disorder)"
              }
            ]
          }
        ]
      }
    ],
    {
      "id": "c4e5bc13-d633-4d70-a905-c438b0f66ff4",
      "sectionType": "STUDY_DESIGNS",
      "studyDesigns": [
        {
          "currentSections": [
            {

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    "id": "80175728-71a9-43d3-af09-d4f9a0d49db8",
    "sectionType": "STUDY_POPULATIONS",
    "studyPopulations": [
      {
        "Id": "f20c4547-816e-44a4-9c8a-22c9d024a8a2",
        "description": "healthy volunteers of age between 18 and 65"
      }
    ]
  },
  {
    "id": "b0fa4e3e-a98e-434f-a3d3-c4140ef54982",
    "sectionType": "PLANNED_WORKFLOWS",
    "plannedWorkflows": [
      {
        "id": "c8151ff7-6d19-4714-88e7-4954e1673ce6",
        "description": "Planned Workflow for DeprecatedStudy ACME001",
        "startPoint": {
          "id": "22bc092e-2492-49eb-a97d-169f923ebe47",
          "type": "SCREENING",
          "subjectStatusGrouping": "In Screening",
          "startDate": "2022-JAN-01",
          "endDate": "2022-JAN-31"
        },
        "endPoint": {
          "id": "011ed0a9-f88f-4c35-b74a-4a6f26501fe5",
          "type": "SCREENING",
          "subjectStatusGrouping": "In Screening",
          "startDate": "2022-JAN-01",
          "endDate": "2022-JAN-31"
        },
        "workflowItemMatrix": {
          "id": "30c683b5-1d28-49f9-92be-9a0abd73f00b",
          "matrix": [
            {
              "id": "bd837e65-3fc8-4794-a0e1-753d0c1e5680",
              "items": [
                {
                  "id": "bb8e4f98-881e-402c-bfae-ac14662eb683",
                  "description": "go to next when subject has systolic blood pressure below 130 mmHg",
                  "fromPointInTime": {
                    "id": "712634b0-8be7-496b-a673-f06e6ba0d7d8",
                    "type": "SCREENING",
                    "subjectStatusGrouping": "In Screening",
                    "startDate": "2022-JAN-01",
                    "endDate": "2022-JAN-31"
                  },
                  "toPointInTime": {
                    "id": "64d80b47-8630-4df5-abe4-91db7eeda0af",
                    "type": "SCREENING",
                    "subjectStatusGrouping": "In Screening",
                    "startDate": "2022-JAN-01",
                    "endDate": "2022-JAN-31"
                  }
                }
              ]
            }
          ]
        }
      }
    ]
  }
]

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"activity": {
  "id": "bb9e930e-59ac-4d60-8cbc-7d0829690080",
  "description": "description",
  "definedProcedures": [
    {
      "procedureCode": "testCode"
    }
  ],
  "studyDataCollection": [
    {
      "id": "6a52e1d3-f812-4980-9cbb-13043ca85a6b",
      "name": "Systolic Blood Pressure",
      "description": "Measurement of systolic blood pressure in
sitting position in either mm or cm Mercury column",
      "eCRFLink": "https://library.cdisc.org/api/mdr/cdashig/2-
1/domains/VS"
    }
  ]
},
"encounter": {
  "id": "03f65c8e-9131-4a22-bcb0-dc6bb5d5712d",
  "name": "test visit",
  "description": "visit description",
  "contactMode": "IN_PERSON",
  "environmentalSetting": "CLINIC",
  "startRule": {
    "id": "e7bb0435-e3d3-4db4-bced-7d1516e356ab",
    "description": "start rule",
    "coding": [
      {
        "code": "xyz",
        "codeSystem": "test system",
        "codeSystemVersion": "1.0",
        "decode": "the decode string"
      }
    ]
  },
  "endRule": {
    "id": "436dcee7-58e4-40e3-ada8-f8651c659162",
    "description": "end rule",
    "coding": [
      {
        "code": "xyz",
        "codeSystem": "test system",
        "codeSystemVersion": "1.0",
        "decode": "the decode string"
      }
    ]
  },
  "epoch": {
    "id": "661430c0-6e04-4e9f-9f03-473eff7f2004",
    "epochType": "SCREENING",
    "name": "First treatment epoch",
    "description": "First treatment epoch with low dose",

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        "sequenceInStudy": 1
    }
},
"previousItemsInSequence": [],
"nextItemsInSequence": [
    "34773d2b-1080-49fe-888a-6e6aef6d8b75"
]
},
{
    "id": "34773d2b-1080-49fe-888a-6e6aef6d8b75",
    "description": "go to next when subject has systolic blood press
ure below 130 mmHg",
    "fromPointInTime": {
        "id": "7c7cc0dc-7e8e-4b08-99f2-f27b7ddd64bd",
        "type": "SCREENING",
        "subjectStatusGrouping": "In Screening",
        "startDate": "2022-JAN-01",
        "endDate": "2022-JAN-31"
    },
    "toPointInTime": {
        "id": "7abcb038-e1d5-4fc1-8935-86877c69d935",
        "type": "SCREENING",
        "subjectStatusGrouping": "In Screening",
        "startDate": "2022-JAN-01",
        "endDate": "2022-JAN-31"
    },
    "activity": {
        "id": "9fe667a9-b9f1-4fdc-9895-df2898f61e4d",
        "description": "description",
        "definedProcedures": [
            {
                "procedureCode": "testCode"
            }
        ],
        "studyDataCollection": [
            {
                "id": "e6a73164-4875-45f3-85be-90fa7ead768f",
                "name": "Systolic Blood Pressure",
                "description": "Measurement of systolic blood pressure in
sitting position in either mm or cm Mercury column",
                "eCRFLink": "https://library.cdisc.org/api/mdr/cdashig/2-
1/domains/VS"
            }
        ]
    },
    "encounter": {
        "id": "facf77b2-4cba-4468-bc39-e0a27c9db29b",
        "name": "test visit",
        "description": "visit description",
        "contactMode": "IN_PERSON",
        "environmentalSetting": "CLINIC",
        "startRule": {
            "id": "c9540ba7-df4d-4d51-8855-19a376c80576",
            "description": "start rule",

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        "coding": [
            {
                "code": "xyz",
                "codeSystem": "test system",
                "codeSystemVersion": "1.0",
                "decode": "the decode string"
            }
        ],
        "endRule": {
            "id": "53f81205-93f3-4196-904f-01fccb5be293",
            "description": "end rule",
            "coding": [
                {
                    "code": "xyz",
                    "codeSystem": "test system",
                    "codeSystemVersion": "1.0",
                    "decode": "the decode string"
                }
            ]
        },
        "epoch": {
            "id": "439421cb-bb60-419c-9dd8-93a15cdd8843",
            "epochType": "SCREENING",
            "name": "First treatment epoch",
            "description": "First treatment epoch with low dose",
            "sequenceInStudy": 1
        },
        "previousItemsInSequence": [
            "bb8e4f98-881e-402c-bfae-ac14662eb683"
        ],
        "nextItemsInSequence": []
    }
}
]
},
{
    "id": "6209c1e2-2453-47da-9b74-35b222eafe71",
    "sectionType": "STUDY_CELLS",
    "studyCells": [
        {
            "id": "74949168-fddc-4366-8277-2397c1a53aa2",
            "studyElements": [
                {
                    "id": "d2ac4030-2e58-427a-be8f-3ae6f76837cd",
                    "name": "washout after treatment element",
                    "description": "This element is for washout after treatment with either active ingredient or placebo",
                    "startRule": {

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        "id": "a44a22a6-9b78-4d0b-8ac8-be9134effba5",
        "description": "Textual description of the rule",
        "coding": [
            {
                "code": "test transition rule in Python",
                "codeSystem": "Python",
                "codeSystemVersion": "1.0",
                "decode": "???"
            }
        ]
    },
    "endRule": {
        "id": "c5bea8cf-07e6-4412-b32f-2c904cc00021",
        "description": "Textual description of the rule",
        "coding": [
            {
                "code": "test transition rule in Perl",
                "codeSystem": "Perl",
                "codeSystemVersion": "1.0",
                "decode": "???"
            }
        ]
    }
},
"studyArm": {
    "id": "2b8b7e2d-2654-449f-8fa3-8c48a8f14dc2",
    "description": "200mg Ibuprofen active comparator arm",
    "studyArmType": "ACTIVE_COMPARATOR_ARM",
    "studyOriginType": "INTERNAL",
    "studyArmOrigin": "HISTORICAL",
    "name": "My Comparator Arm"
},
"studyEpoch": {
    "id": "ebce7d5d-a0d4-460b-8182-c2b174da0907",
    "epochType": "SCREENING",
    "name": "First treatment epoch",
    "description": "First treatment epoch with low dose",
    "sequenceInStudy": 2
}
}
],
},
{
    "id": "9d8f6879-479b-4fda-bce8-30681e9d8dba",
    "sectionType": "INVESTIGATIONAL_INTERVENTIONS",
    "investigationalInterventions": [
        {
            "id": "a665e616-06c6-4188-9d47-f32ba61ec923",
            "description": "Ibuprofen 200mg",
            "interventionType": null,
            "interventionModel": "SEQUENTIAL",
            "status": "A Status",
            "coding": [

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        {
          "code": "26929004",
          "codeSystem": "SNOMED-CT",
          "codeSystemVersion": "4.0.6.4",
          "decode": "Alzheimer's disease (disorder)"
        }
      ]
    }
  ],
  "studyDesignId": "bb8ec54e-4970-403c-bd90-09fe2cee7b7a",
  "trialIntentType": "TrialIntentType",
  "trialType": "TrialType"
}
],
{
  "id": "d668e61a-eb7e-48db-8f66-0520c467aa1a",
  "sectionType": "OBJECTIVES",
  "objectives": [
    {
      "description": "Example trial objective",
      "id": "05ad8ec6-0a7e-47f3-9c9a-5fafc08466d4",
      "level": "PRIMARY",
      "endpoints": [
        {
          "description": "Cumulative incidence of virus detection in sputum samples among participants up to...",
          "purpose": "EFFICACY",
          "id": "76bdb66b-fd68-4a96-abab-e9084ba2f546",
          "outcomeLevel": "PRIMARY"
        }
      ]
    }
  ]
}
]
}
}
}

```