



OpenStudyBuilder - A USDM compatible SDR solution

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A dedicated module enables OpenStudyBuilder to convert our metadata into the Unified Study Definition Model (USDM) and exposes the result through compliant API endpoint



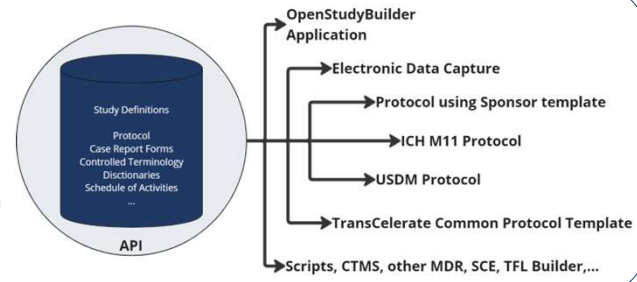
OpenStudyBuilder Solution

- A Clinical Metadata Repository the Neo4j graph database
- An API layer with full Audit Trail features and USDM compatibility
- The OpenStudyBuilder Application (web application)



OpenStudyBuilder as a multisource system

- Protocol harmonization through standards
- Full connectivity to any kind of systems through APIs - including USDM compatibility
- Maintenance of standards, like CRFs standardization and utilization in downstream EDC system



DDF endpoints

GET /ddf/v3/studyDefinitions/{study_uid} Return an entire study in DDF USDM format

State before:
• Study must exist

State after:
• no change

Possible errors:
• Invalid study-uid

Parameters

Name Description

study_uid **required** string (path)
The unique uid of the study.

Study_000001

Execute Clear

The API Endpoint to produce USDM

```
{
  "id": "f822f9ae-9283-4495-b363-953cf351311a",
  "description": null,
  "label": "New short title",
  "versions": [
    {
      "id": "3ed85ac4-f784-48aa-bcae-283753214220",
      "versionIdentifier": "None",
      "rationale": "",
      "studyType": {
        "id": "508813bc-c0de-4f68-8e12-fb79dab1f0bc",
        "codeSystem": "openstudybuilder.org",
        "codeSystemVersion": "",
        "instanceType": "Code"
      },
      "studyPhase": {
        "id": "3cb7f916-dda1-4368-89ba-b7674fba3acc",
        "standardCode": {
          "id": "428e7a71-bc83-4b32-8821-6760fc46d71e",
          "codeSystem": "openstudybuilder.org",
          "codeSystemVersion": "",
          "instanceType": "Code"
        },
        "standardCodeAliases": [],
        "instanceType": "AliasCode"
      }
    }
  ]
}
```

- Single metadata source for key deliverables in digital protocol linked to USDM
- Standardization through controlled terminology, dictionaries, templates
- Metadata driven creation of structured protocol content

Digital Data Flow Adaptor in OpenStudyBuilder

Study Structure (CDISC DEV-0)

#	Epoch name	Epoch type	Epoch subtype	Start rule	End rule	Description	Number of visits	Assigned
1	Screening	Screening	Screening	ICF submitted	ICF signed	Screening epoch (up to 1)	1	●
2	Treatment	Treatment	Treatment	RDM ok	OSIRIS complete	Treatment epoch without dosing escalation	9	●
3	Followup	Pilot Treatment	Followup	Treatment ok	Last follow-up ok	Follow-up epoch to follow the subject	1	●

API

```
{
  "id": "StudyElement_000001",
  "instanceType": "StudyElement",
  "id": "f822f9ae-9283-4495-b363-953cf351311a",
  "label": "StudyElement_000001",
  "codeSystem": "openstudybuilder.org",
  "codeSystemVersion": "",
  "instanceType": "Code",
  "studyPhase": {
    "id": "3cb7f916-dda1-4368-89ba-b7674fba3acc",
    "standardCode": {
      "id": "428e7a71-bc83-4b32-8821-6760fc46d71e",
      "codeSystem": "openstudybuilder.org",
      "codeSystemVersion": "",
      "instanceType": "Code"
    },
    "standardCodeAliases": [],
    "instanceType": "AliasCode"
  },
  "description": null,
  "rationale": "",
  "epochs": [
    {
      "id": "StudyEpoch_000001",
      "name": "Screening",
      "label": null,
      "description": "Screening epoch to start",
      "type": "Screening",
      "id": "508813bc-c0de-4f68-8e12-fb79dab1f0bc",
      "codeSystem": "openstudybuilder.org",
      "codeSystemVersion": "",
      "instanceType": "Code",
      "description": null,
      "rationale": "Screening",
      "id": "3cb7f916-dda1-4368-89ba-b7674fba3acc",
      "codeSystem": "openstudybuilder.org",
      "codeSystemVersion": "",
      "instanceType": "Code"
    }
  ]
}
```



Open Source

- OpenStudyBuilder is shared as open source under COSA by Novo Nordisk
- Collaborate with TransCelerate as a Digital Data Flow (DDF) compatible solution
- Collaborate with CDISC, e.g. for Biomedical Concept Development & Enhancements

