HealthTech
Partners 42

Using APIs in OSB

Getting started With OSB APIs

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Presentation objectives

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1. Discover the OpenStudyBuilder (OSB) APIs
2. Learn how to access and use OSB APIs
3. Find practical use cases and examples leveraging OSB APIs
4. Understand the limitations of the current APIs
5. Learn about the new upcoming Consumer APIs

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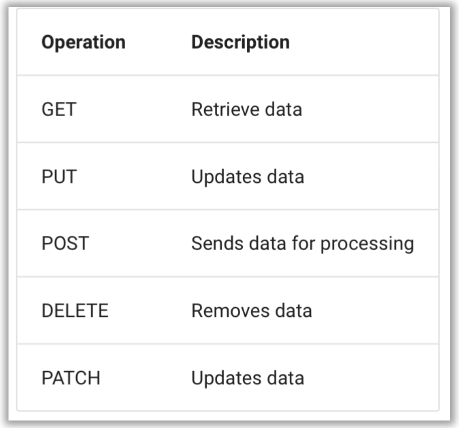
API Overview

a. Accessing the APIs

- One strength of the OpenStudyBuilder is that it uses the powerful and simplified REST protocol for its APIs[Application Programming Language].
- These APIs provide a seamless way of integrating OSB with other systems or software, making communication and exchange of information easy.
- This essentially means that most processes can be managed or accessed through any language by making use of the specific APIs. This can be accessed through Python, R and even SAS.
- The APIs documentation is available here
- They include GET, POST, PATCH, DELETE request endpoints that allow to retrieve, delete, or update data in OSB, giving developers and sponsors tools to customize OSB and facilitate seamless automation.



Operation	Description
GET	Retrieve data
PUT	Updates data
POST	Sends data for processing
DELETE	Removes data
PATCH	Updates data

API Overview

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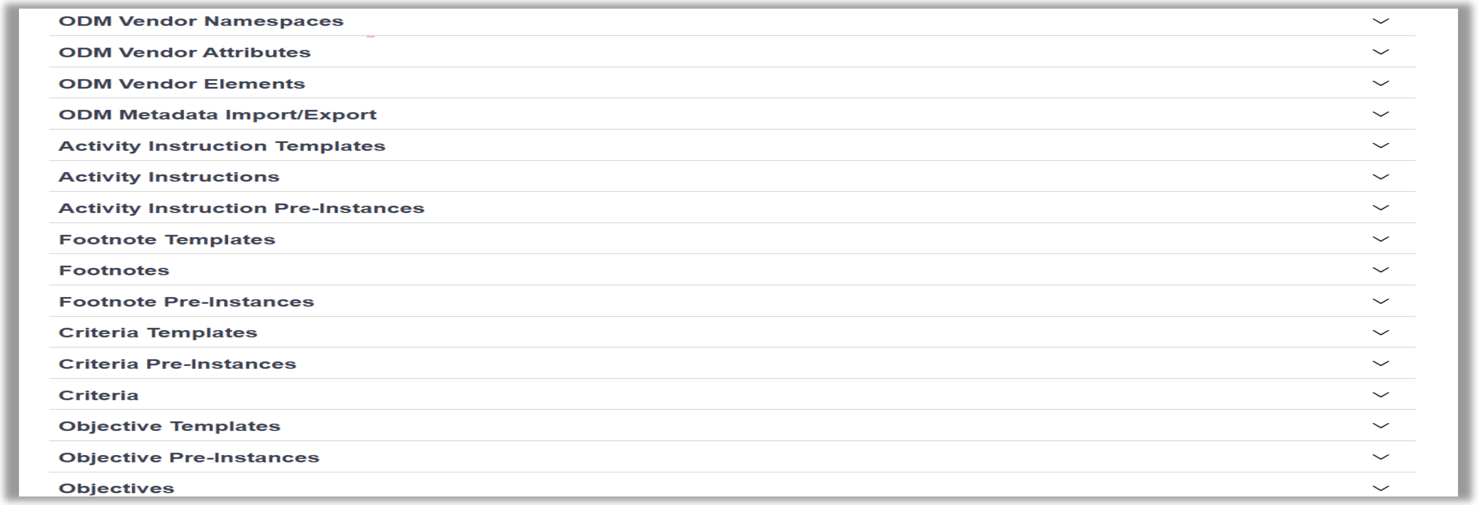
b. What are the existing APIs?

It is easy to access the Swagger API documentation and even execute some calls directly from the documentation webpage.

All the solutions offered currently by OSB (handling studies, libraries, and defining protocol automation) can be called independently of the web application, using API calls.

A (partial) representation of what is currently available as APIs is as shown below


ODM Vendor Namespaces
ODM Vendor Attributes
ODM Vendor Elements
ODM Metadata Import/Export
Activity Instruction Templates
Activity Instructions
Activity Instruction Pre-Instances
Footnote Templates
Footnotes
Footnote Pre-Instances
Criteria Templates
Criteria Pre-Instances
Criteria
Objective Templates
Objective Pre-Instances
Objectives

API Overview

c. How to use the APIs

The APIs can be:

- ✓ **Called** using Python, R or SAS
- ✓ **Used** to download files from OSB or access data in JSON format.

The next few slides will show some uses cases of API in relation to getting information from OSB using python.

Get authorized

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Before you can connect with OSB, you need to get authorized

1. The client application (similar to the StudyBuilder UI) contacts its Authentication Identity Provider to receive a valid OAuth 2, JWT, access token.
2. The client application then initiates an authorization code flow by passing the access token and the requested role (among the available roles) through the header of the call, along with the permission for the granted roles.
3. Once OSB approves access, the client application receives an authorization token along with a refresh token.

Please see the Authorization module documentation for further details.

Example 1: Getting the Controlled Terminology from OSB

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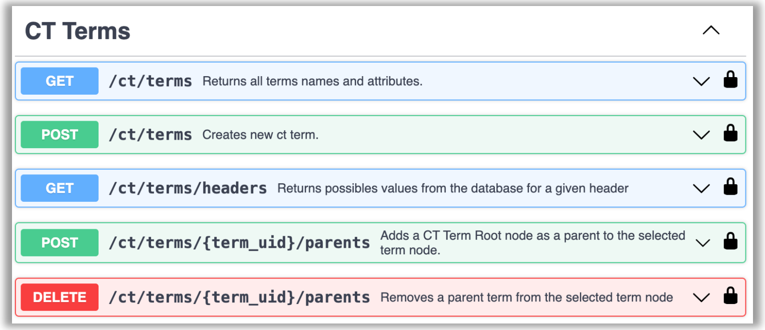
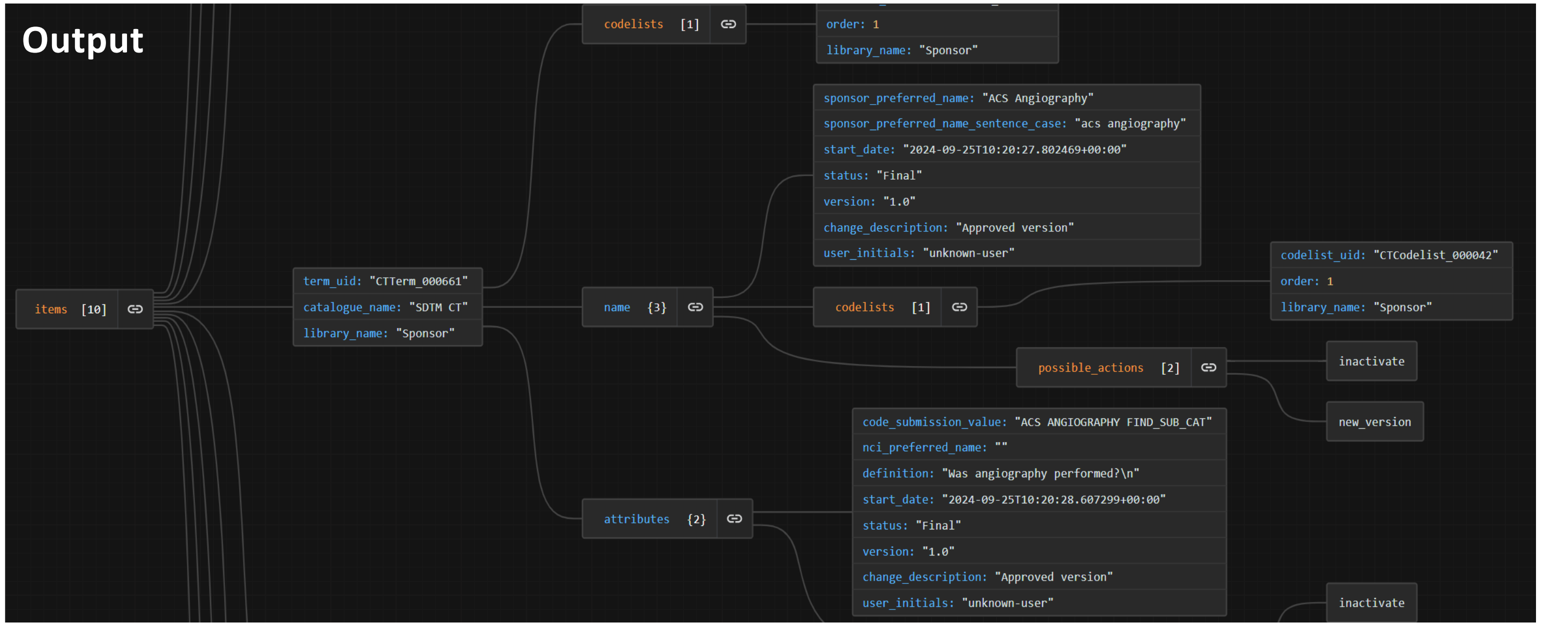


CT Terms

GET	`/ct/terms`	Returns all terms names and attributes.
POST	`/ct/terms`	Creates new ct term.
GET	`/ct/terms/headers`	Returns possibles values from the database for a given header
POST	`/ct/terms/{term_uid}/parents`	Adds a CT Term Root node as a parent to the selected term node.
DELETE	`/ct/terms/{term_uid}/parents`	Removes a parent term from the selected term node

```
import requests

# API endpoint and key for ct terms
API_URL = "http://osb/api/ct/terms"
headers = {'accept': 'application/json'}
# Making the API request
response =
requests.get(API_URL,headers=headers)
data=response.json()
```



Output

```
items [10]

term_uid: "CTTerm_000661"
catalogue_name: "SDTM CT"
library_name: "Sponsor"

codelists [1]
    order: 1
    library_name: "Sponsor"

name {3}
    sponsor_preferred_name: "ACS Angiography"
    sponsor_preferred_name_sentence_case: "acs angiography"
    start_date: "2024-09-25T10:20:27.802469+00:00"
    status: "Final"
    version: "1.0"
    change_description: "Approved version"
    user_initials: "unknown-user"

    codelists [1]
        codelist_uid: "CTCodelist_000042"
        order: 1
        library_name: "Sponsor"

    possible_actions [2]
        inactivate
        new_version

attributes {2}
    code_submission_value: "ACS ANGIOGRAPHY FIND_SUB_CAT"
    nci_preferred_name: ""
    definition: "Was angiography performed?\n"
    start_date: "2024-09-25T10:20:28.607299+00:00"
    status: "Final"
    version: "1.0"
    change_description: "Approved version"
    user_initials: "unknown-user"

        inactivate
```

Example 2: Getting the list of studies defined in OSB

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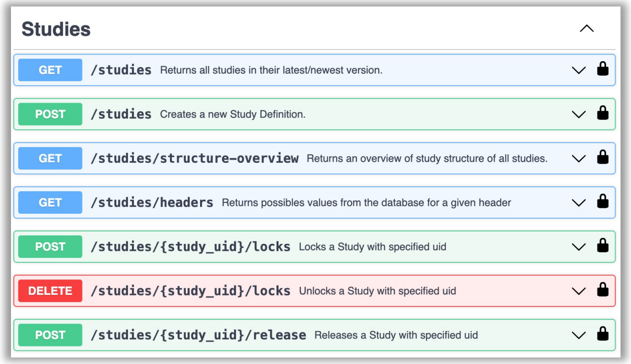


Studies

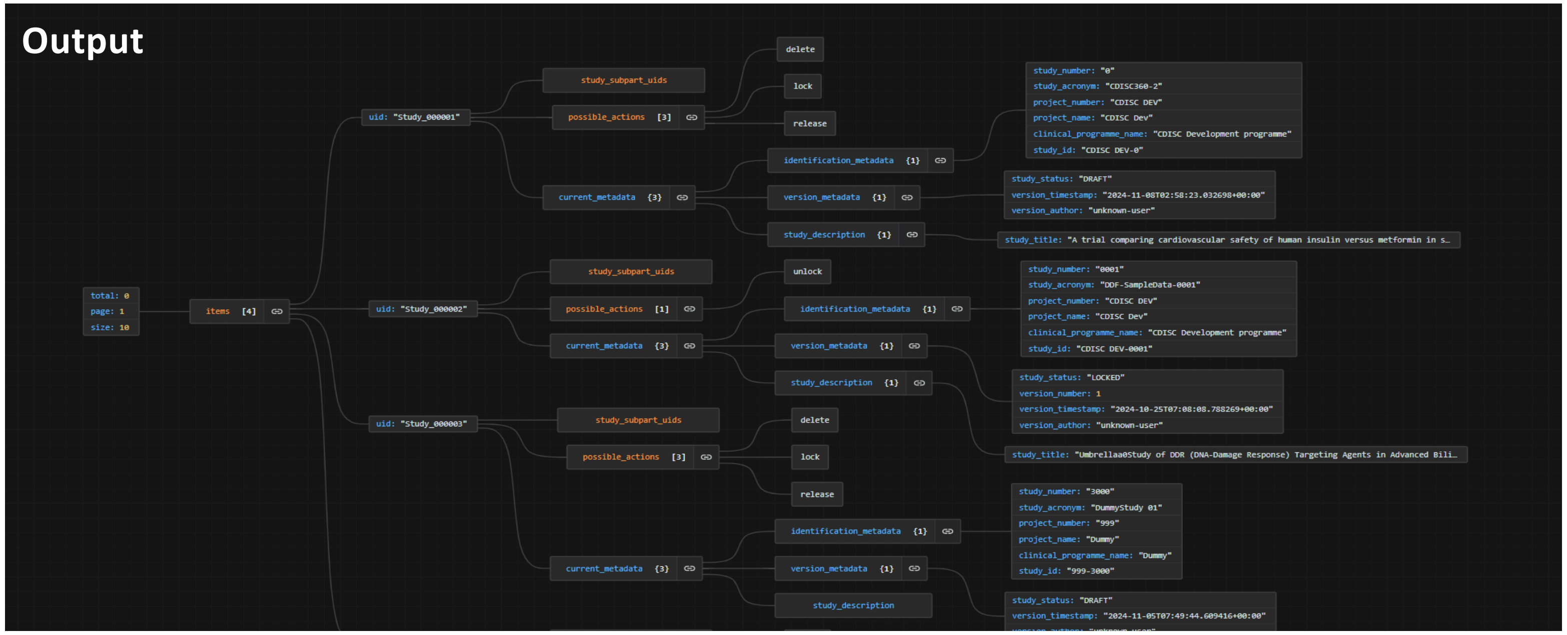
- GET `/studies` Returns all studies in their latest/newest version.
- POST `/studies` Creates a new Study Definition.
- GET `/studies/structure-overview` Returns an overview of study structure of all studies.
- GET `/studies/headers` Returns possibles values from the database for a given header
- POST `/studies/{study_uid}/locks` Locks a Study with specified uid
- DELETE `/studies/{study_uid}/locks` Unlocks a Study with specified uid
- POST `/studies/{study_uid}/release` Releases a Study with specified uid

```
import requests

# API endpoint and key for studies
API_URL = "http://osb/api/studies"
headers = {'accept': 'application/json'}
# Making the API request
response =
requests.get(API_URL,headers=headers)

data=response.json()
```

Output



```
total: 0
page: 1
size: 10
items [4]
  uid: "Study_000001"
    study_subpart_uids
    possible_actions [3]
      delete
      lock
      release
    current_metadata {3}
      identification_metadata {1}
        study_number: "0"
        study_acronym: "CDISC360-2"
        project_number: "CDISC DEV"
        project_name: "CDISC Dev"
        clinical_programme_name: "CDISC Development programme"
        study_id: "CDISC DEV-0"
      version_metadata {1}
        study_status: "DRAFT"
        version_timestamp: "2024-11-08T02:58:23.032698+00:00"
        version_author: "unknown-user"
      study_description {1}
        study_title: "A trial comparing cardiovascular safety of human insulin versus metformin in s…
  uid: "Study_000002"
    study_subpart_uids
    possible_actions [1]
      unlock
    current_metadata {3}
      identification_metadata {1}
        study_number: "0001"
        study_acronym: "DDF-SampleData-0001"
        project_number: "CDISC DEV"
        project_name: "CDISC Dev"
        clinical_programme_name: "CDISC Development programme"
        study_id: "CDISC DEV-0001"
      version_metadata {1}
        study_status: "LOCKED"
        version_number: 1
        version_timestamp: "2024-10-25T07:08:08.788269+00:00"
        version_author: "unknown-user"
      study_description {1}
        study_title: "Umbrellaa0Study of DDR (DNA-Damage Response) Targeting Agents in Advanced Bili…
  uid: "Study_000003"
    study_subpart_uids
    possible_actions [3]
      delete
      lock
      release
    current_metadata {3}
      identification_metadata {1}
        study_number: "3000"
        study_acronym: "DummyStudy 01"
        project_number: "999"
        project_name: "Dummy"
        clinical_programme_name: "Dummy"
        study_id: "999-3000"
      version_metadata {1}
        study_status: "DRAFT"
        version_timestamp: "2024-11-05T07:49:44.609416+00:00"
      study_description
```

Example 3: Retrieving the SOA[1] for one study

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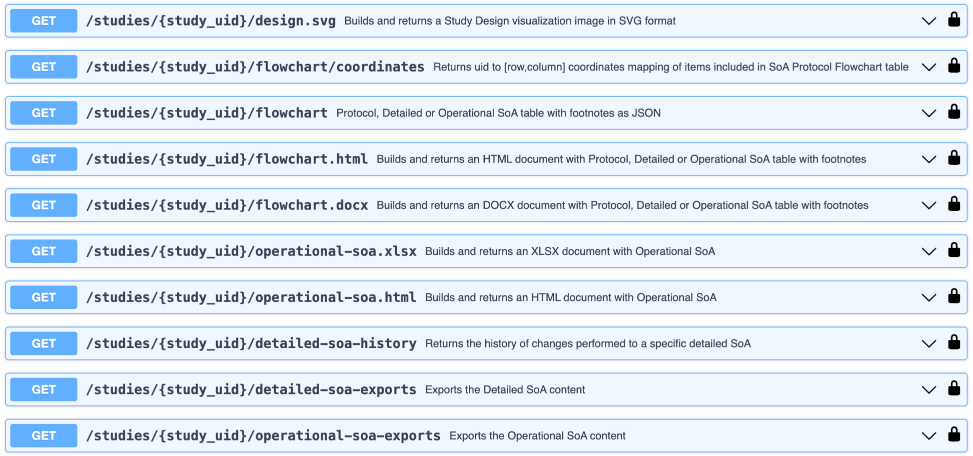


GET /studies/{study_uid}/design.svg Builds and returns a Study Design visualization image in SVG format

GET /studies/{study_uid}/flowchart/coordinates Returns uid to [row,column] coordinates mapping of items included in SoA Protocol Flowchart table

GET /studies/{study_uid}/flowchart Protocol, Detailed or Operational SoA table with footnotes as JSON

GET /studies/{study_uid}/flowchart.html Builds and returns an HTML document with Protocol, Detailed or Operational SoA table with footnotes

GET /studies/{study_uid}/flowchart.docx Builds and returns an DOCX document with Protocol, Detailed or Operational SoA table with footnotes

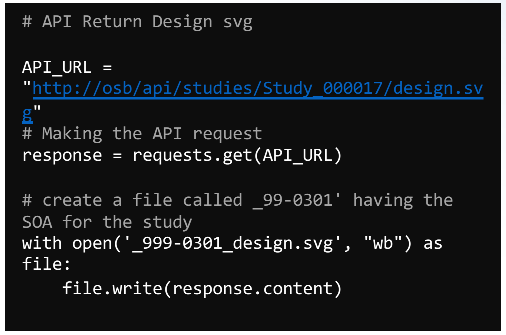
GET /studies/{study_uid}/operational-soa.xlsx Builds and returns an XLSX document with Operational SoA

GET /studies/{study_uid}/operational-soa.html Builds and returns an HTML document with Operational SoA

GET /studies/{study_uid}/detailed-soa-history Returns the history of changes performed to a specific detailed SoA

GET /studies/{study_uid}/detailed-soa-exports Exports the Detailed SoA content

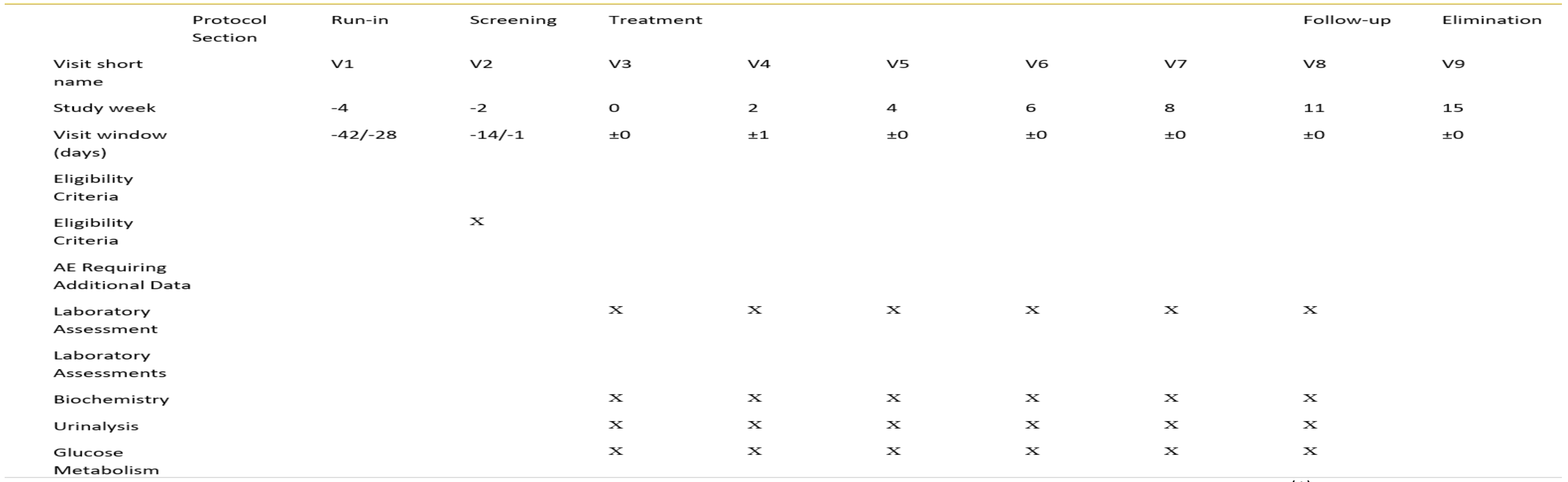
GET /studies/{study_uid}/operational-soa-exports Exports the Operational SoA content



```
# API Return Design svg

API_URL =
"http://osb/api/studies/Study_000017/design.sv
g"
# Making the API request
response = requests.get(API_URL)

# create a file called _99-0301' having the
SOA for the study
with open('_999-0301_design.svg', "wb") as
file:
    file.write(response.content)
```



Protocol Section	Run-in	Screening	Treatment					Follow-up	Elimination
Visit short name	V1	V2	V3	V4	V5	V6	V7	V8	V9
Study week	-4	-2	0	2	4	6	8	11	15
Visit window (days)	-42/-28	-14/-1	±0	±1	±0	±0	±0	±0	±0
Eligibility Criteria									
Eligibility Criteria		X							
AE Requiring Additional Data									
Laboratory Assessment			X	X	X	X	X	X	
Laboratory Assessments									
Biochemistry			X	X	X	X	X	X	
Urinalysis			X	X	X	X	X	X	
Glucose Metabolism			X	X	X	X	X	X	

[1] SOA: Schedule of Activities

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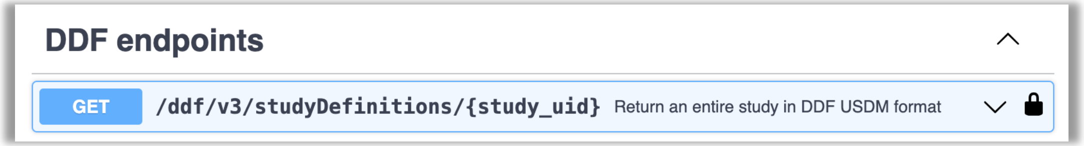
Example 4: Retrieving the USDM of a study



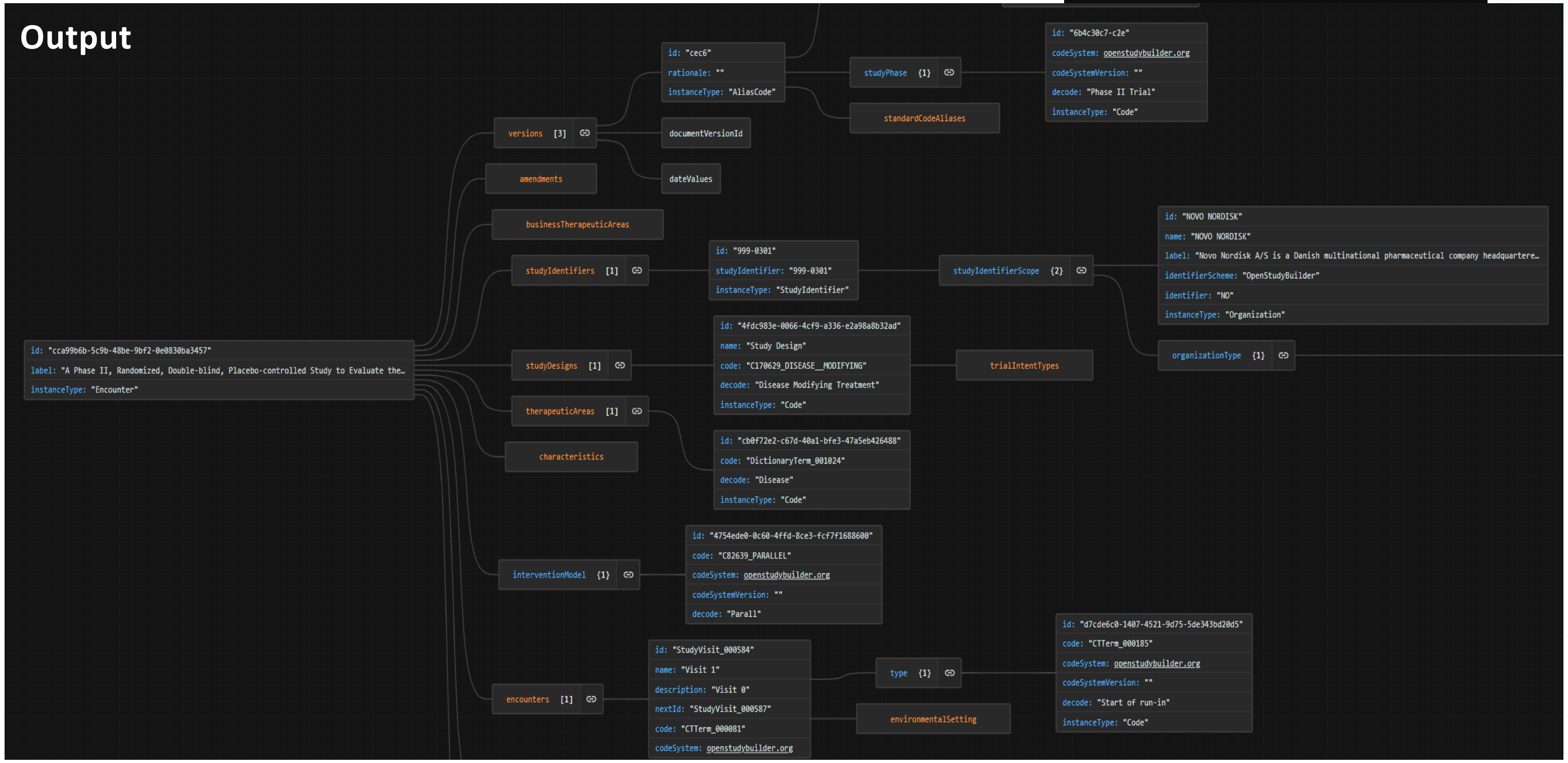
DDF endpoints

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

```
import requests

# API endpoint for DDF USDM
API_URL =
"http://osb/api//ddf/v3/studyDefinitions/S
tudy_000017"
headers = {'accept': 'application/json'}
# Making the API request
response = requests.get(API_URL)

data=response.json()
```



Output

```
id: "cca99b6b-5c9b-48be-9bf2-0e0830ba3457"
label: "A Phase II, Randomized, Double-blind, Placebo-controlled Study to Evaluate the…
instanceType: "Encounter"

versions [3]
    id: "cec6"
    rationale: ""
    instanceType: "AliasCode"
        studyPhase {1}
            id: "6b4c30c7-c2e"
            codeSystem: openstudybuilder.org
            codeSystemVersion: ""
            decode: "Phase II Trial"
            instanceType: "Code"
        standardCodeAliases
    documentVersionId
    dateValues
amendments
businessTherapeuticAreas
studyIdentifiers [1]
    id: "999-0301"
    studyIdentifier: "999-0301"
    instanceType: "StudyIdentifier"
        studyIdentifierScope {2}
            id: "NOVO NORDISK"
            name: "NOVO NORDISK"
            label: "Novo Nordisk A/S is a Danish multinational pharmaceutical company headquartere…
            identifierScheme: "OpenStudyBuilder"
            identifier: "NO"
            instanceType: "Organization"
            organizationType {1}
studyDesigns [1]
    id: "4fdc983e-0066-4cf9-a336-e2a98a8b32ad"
    name: "Study Design"
    code: "C170629_DISEASE__MODIFYING"
    decode: "Disease Modifying Treatment"
    instanceType: "Code"
        trialIntentTypes
therapeuticAreas [1]
    id: "cb0f72e2-c67d-40a1-bfe3-47a5eb426488"
    code: "DictionaryTerm_001024"
    decode: "Disease"
    instanceType: "Code"
characteristics
interventionModel {1}
    id: "4754ede0-0c60-4ffd-8ce3-fcf7f1688600"
    code: "C82639_PARALLEL"
    codeSystem: openstudybuilder.org
    codeSystemVersion: ""
    decode: "Parall"
encounters [1]
    id: "StudyVisit_000584"
    name: "Visit 1"
    description: "Visit 0"
    nextId: "StudyVisit_000587"
    code: "CTTerm_000081"
    codeSystem: openstudybuilder.org
        type {1}
            id: "d7cde6c0-1407-4521-9d75-5de343bd20d5"
            code: "CTTerm_000185"
            codeSystem: openstudybuilder.org
            codeSystemVersion: ""
            decode: "Start of run-in"
            instanceType: "Code"
        environmentalSetting
```

Example 5: Audit trail

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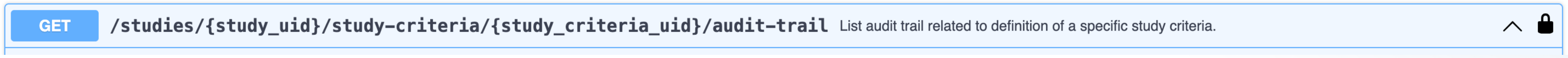
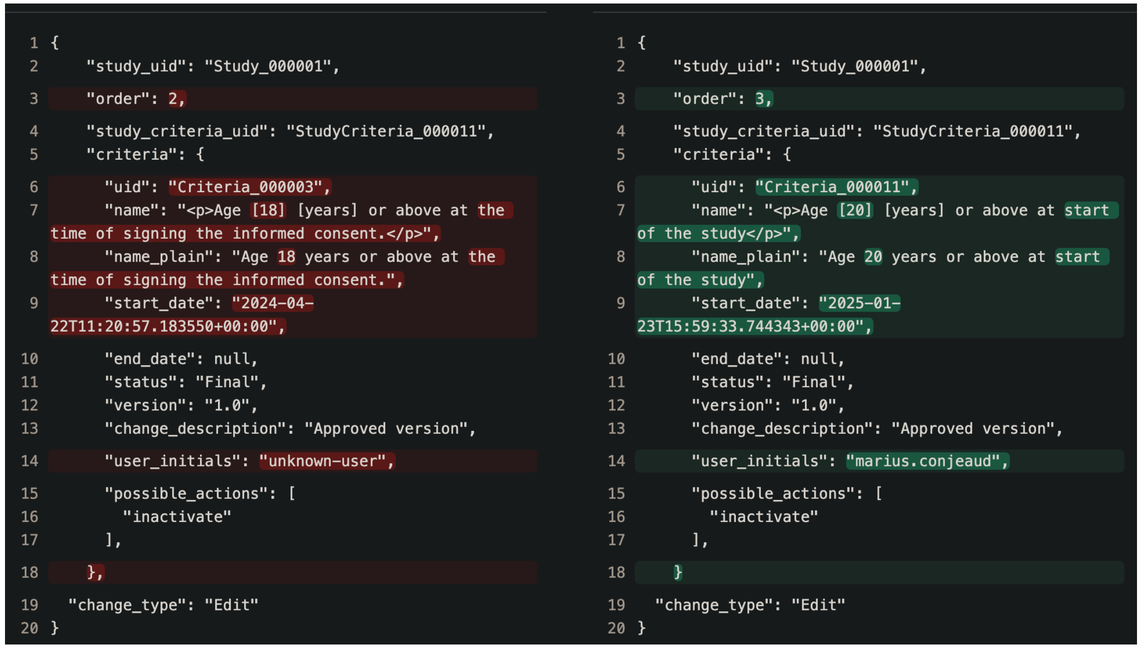


GET `/studies/{study_uid}/study-criteria/{study_criteria_uid}/audit-trail` List audit trail related to definition of a specific study criteria.

Output

The output will be a list of all **changes** for a given object. Each element in that list will contain the object itself as it was in the corresponding version, and information about the change itself ("Create"/"Edit"/"Delete", user_initials, etc...).

The screenshot below shows a diff of the last version and an intermediate one (simplified)



```
{
    "study_uid": "Study_000001",
    "order": 2,
    "study_criteria_uid": "StudyCriteria_000011",
    "criteria": {
      "uid": "Criteria_000003",
      "name": "<p>Age [18] [years] or above at the time of signing the informed consent.</p>",
      "name_plain": "Age 18 years or above at the time of signing the informed consent.",
      "start_date": "2024-04-22T11:20:57.183550+00:00",
      "end_date": null,
      "status": "Final",
      "version": "1.0",
      "change_description": "Approved version",
      "user_initials": "unknown-user",
      "possible_actions": [
        "inactivate"
      ],
    },
  "change_type": "Edit"
}
```

```
{
    "study_uid": "Study_000001",
    "order": 3,
    "study_criteria_uid": "StudyCriteria_000011",
    "criteria": {
      "uid": "Criteria_000011",
      "name": "<p>Age [20] [years] or above at start of the study</p>",
      "name_plain": "Age 20 years or above at start of the study",
      "start_date": "2025-01-23T15:59:33.744343+00:00",
      "end_date": null,
      "status": "Final",
      "version": "1.0",
      "change_description": "Approved version",
      "user_initials": "marius.conjeaud",
      "possible_actions": [
        "inactivate"
      ],
    }
  "change_type": "Edit"
}
```

API Limitations and future improvements

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1. Outputting a complete document version of the requires a lot of API calls.
2. More specific Consumer APIs are under development, simplifying the API structure for downstream users.
3. API versioning is planned for the Consumer API, but not for the “main” API.
4. Some endpoints are slow, and performance testing is not yet industrialized.

THANK YOU