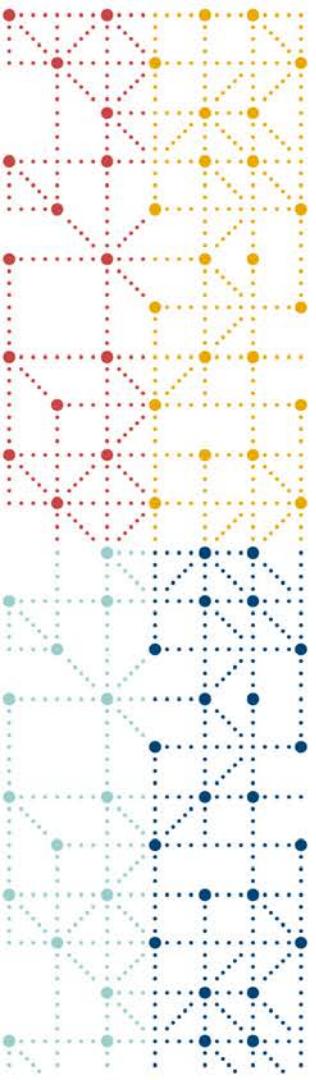


PharmaSUG Japan: CDISC Library Update

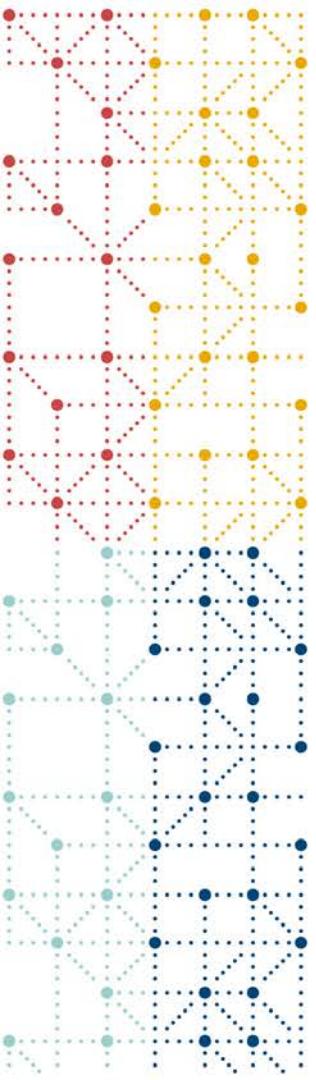
Presented by CDISC Data Science Team
October 24, 2019





Agenda

1. CDISC Library High-Level Technical Overview
2. CDISC Library Demo



CDISC Library High-Level Technical Overview

Technology Snapshot



CDISC Library, an
Resource Description
standards metadata

W3C

M3: Meta-Meta-Model

RDF

chitecture using the
deliver CDISC
processes.

CDISC Library pro
controlled termino
the single, trusted
creating, maintain

ISO

M2: Meta-Model

ISO 11179

d CDISC standards and
lards. CDISC Library is
presents a new way of

In non-technical te
will continue to pr

CDISC

M1: Model

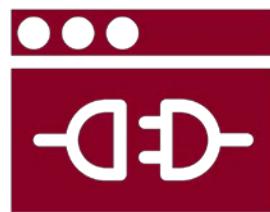
Data Standards

ptive for the future. It
ial needs.

M0: Model Runtime

Trial Data

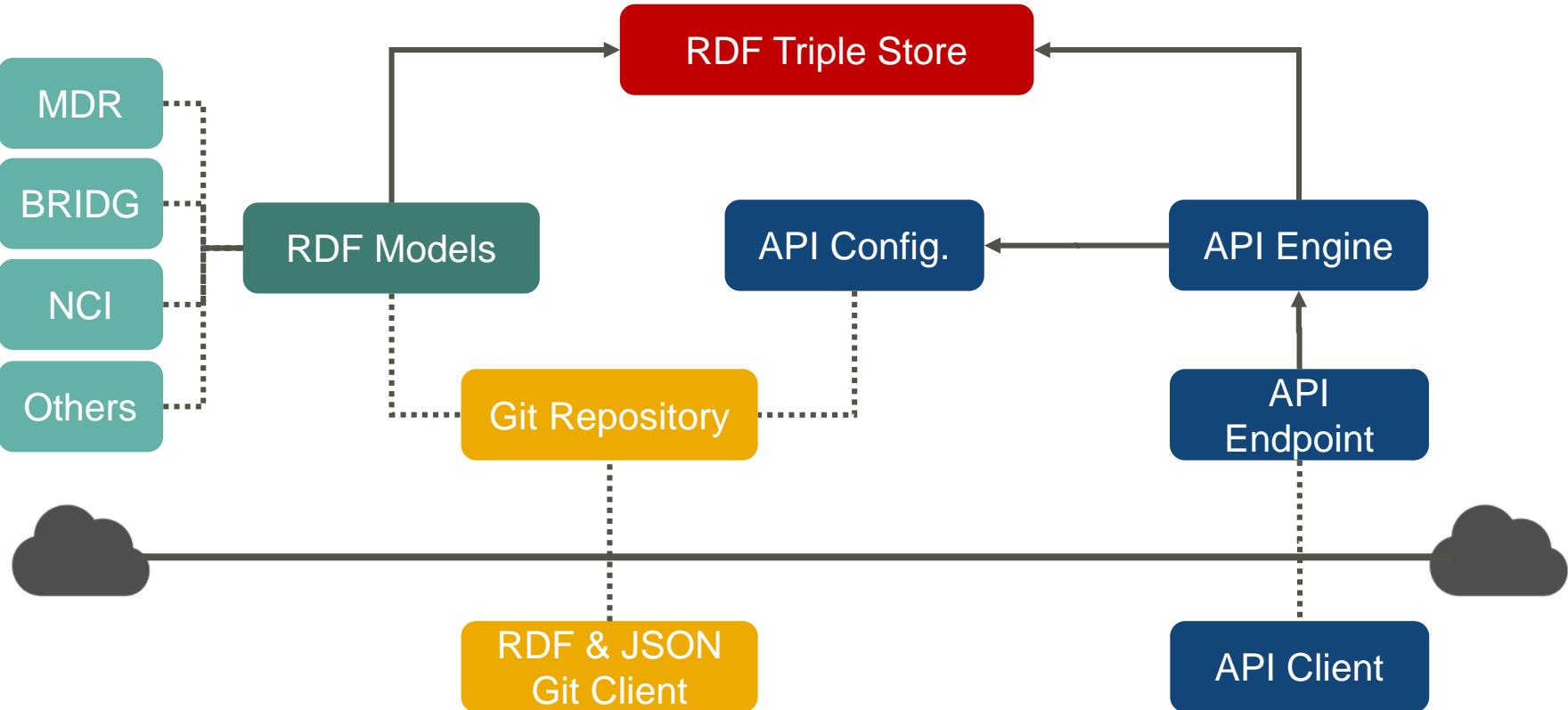
Accessibility Possibilities



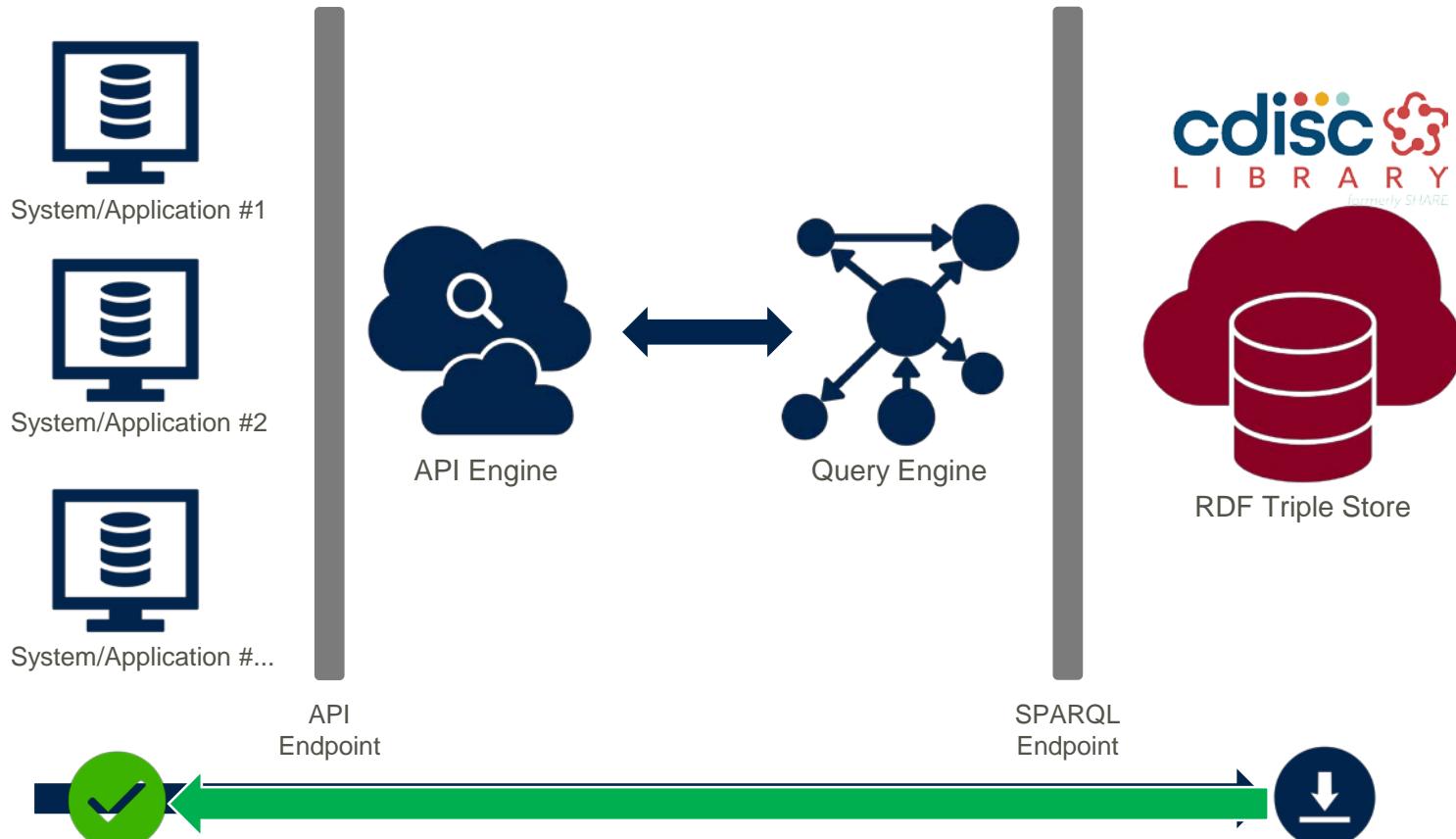
API & UI



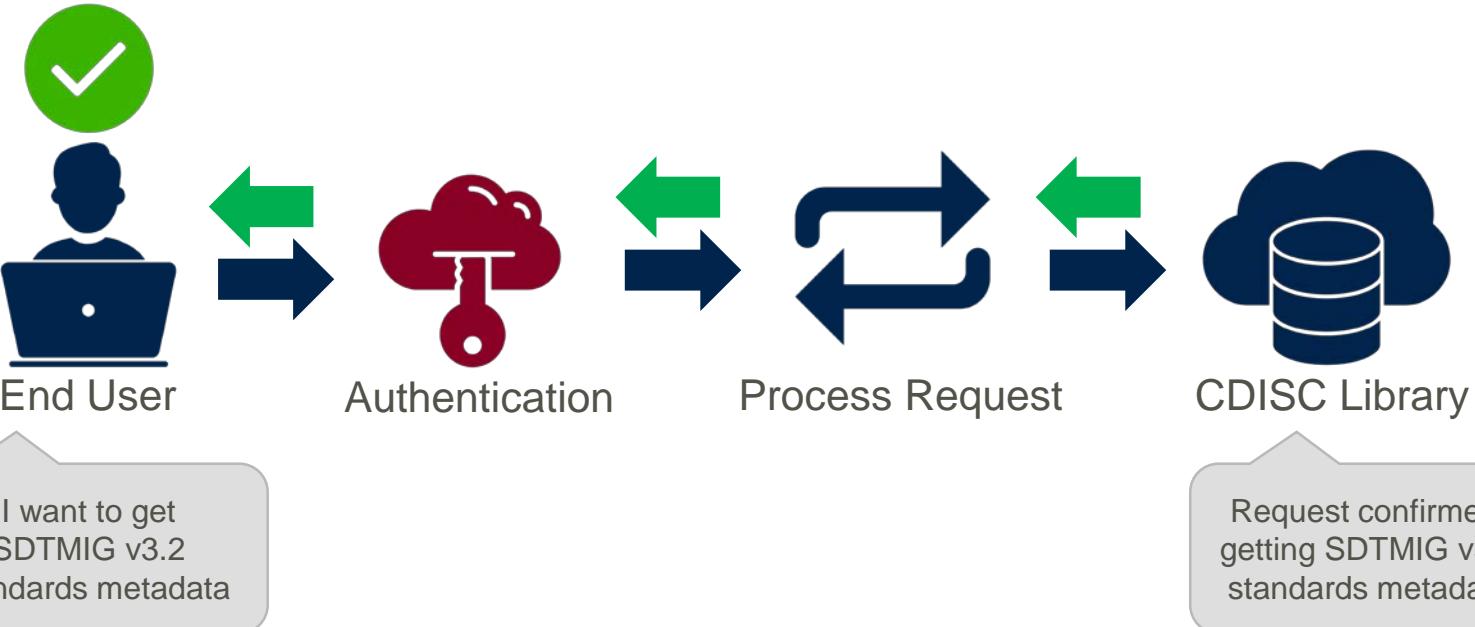
API System Diagram



API Access Overview



API Access Overview (cont.)



API Endpoint's

SDTM Implementation Guide (SDTMIG)

GET /mdr/sdtmig/{version} Get SDTMIG Product



GET /mdr/sdtmig/{version}/classes Get SDTMIG Class List



GET /mdr/sdtmig/{version}/classes/{class} Get SDTMIG Class



GET /mdr/sdtmig/{version}/classes/{class}/datasets Get SDTMIG Class Dataset List



GET /mdr/sdtmig/{version}/datasets Get SDTMIG Dataset List



GET /mdr/sdtmig/{version}/datasets/{dataset} Get SDTMIG Dataset



GET /mdr/sdtmig/{version}/datasets/{dataset}/variables Get SDTMIG Dataset Variable List



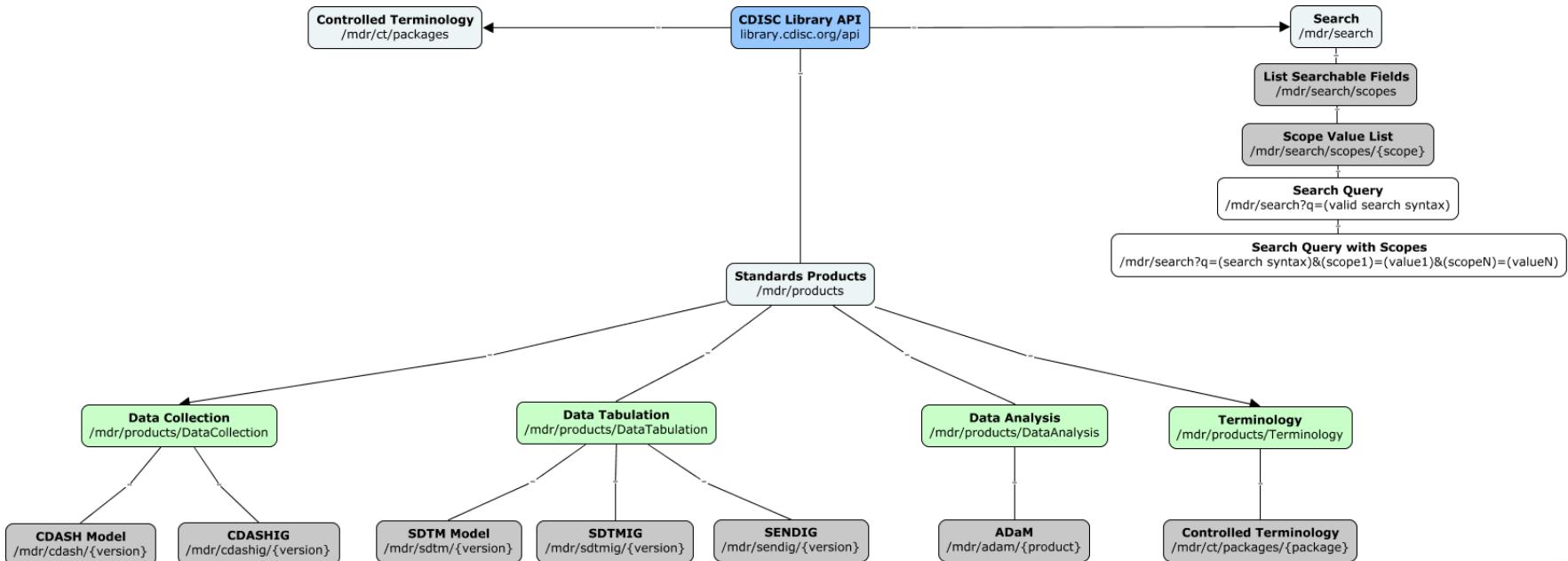
GET /mdr/sdtmig/{version}/datasets/{dataset}/variables/{var} Get SDTMIG Dataset Variable



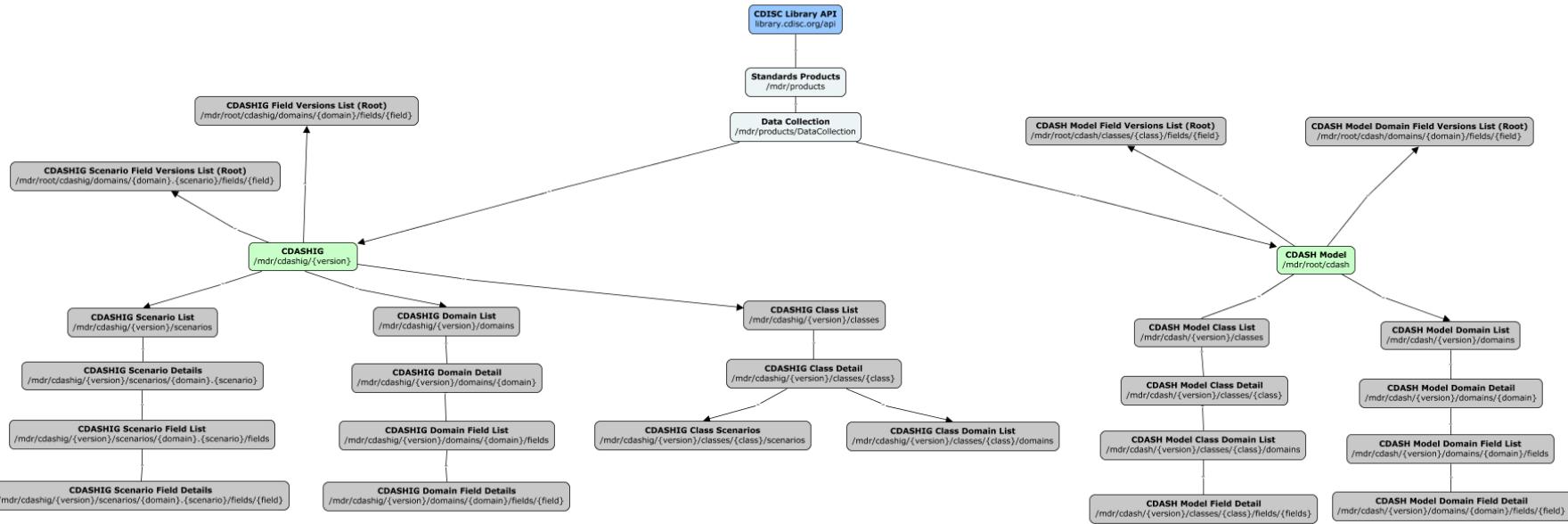
GET /mdr/root/sdtmig/datasets/{dataset}/variables/{var} Get Root SDTMIG Dataset Variable



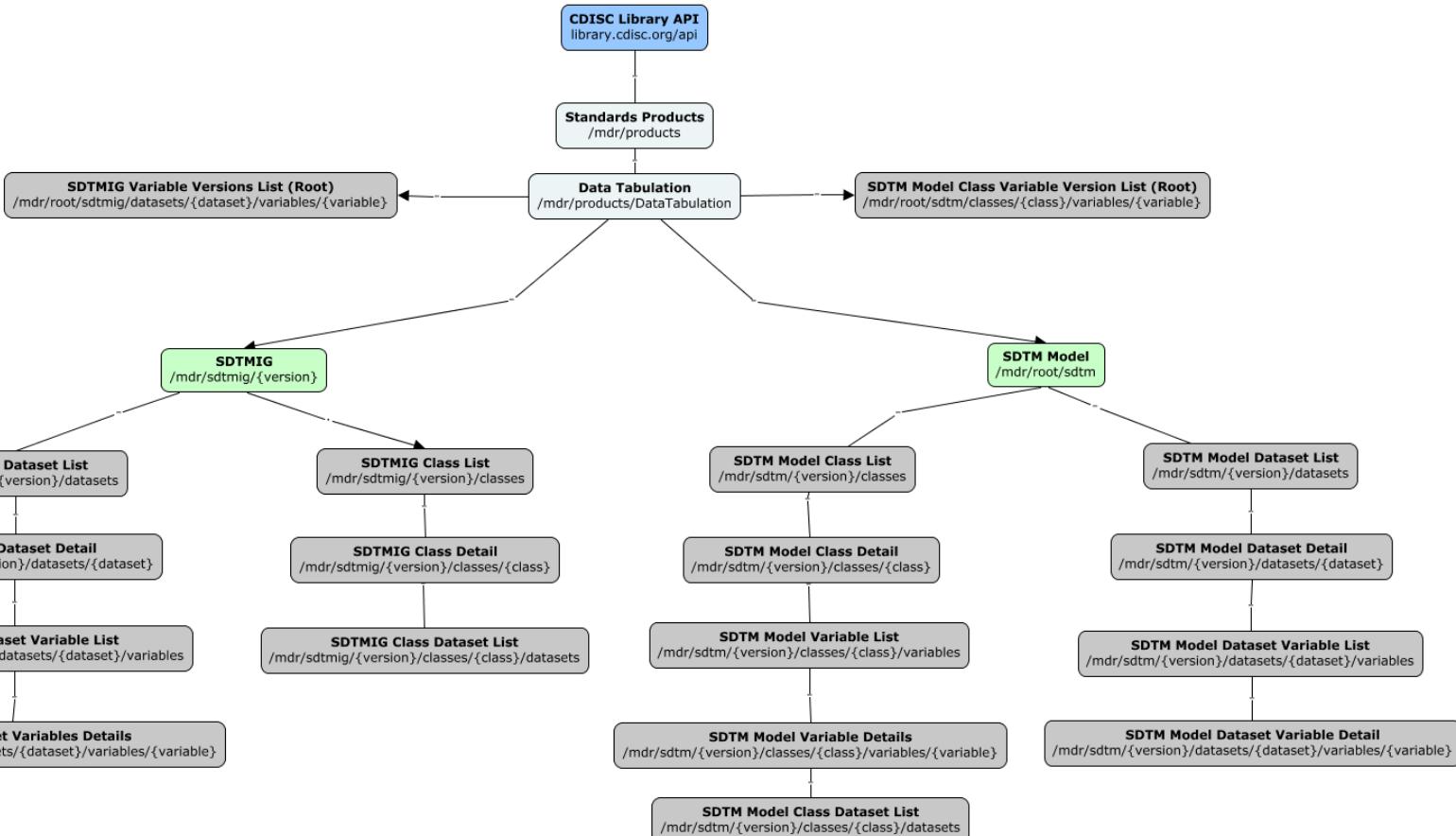
API Taxonomy: Top Level



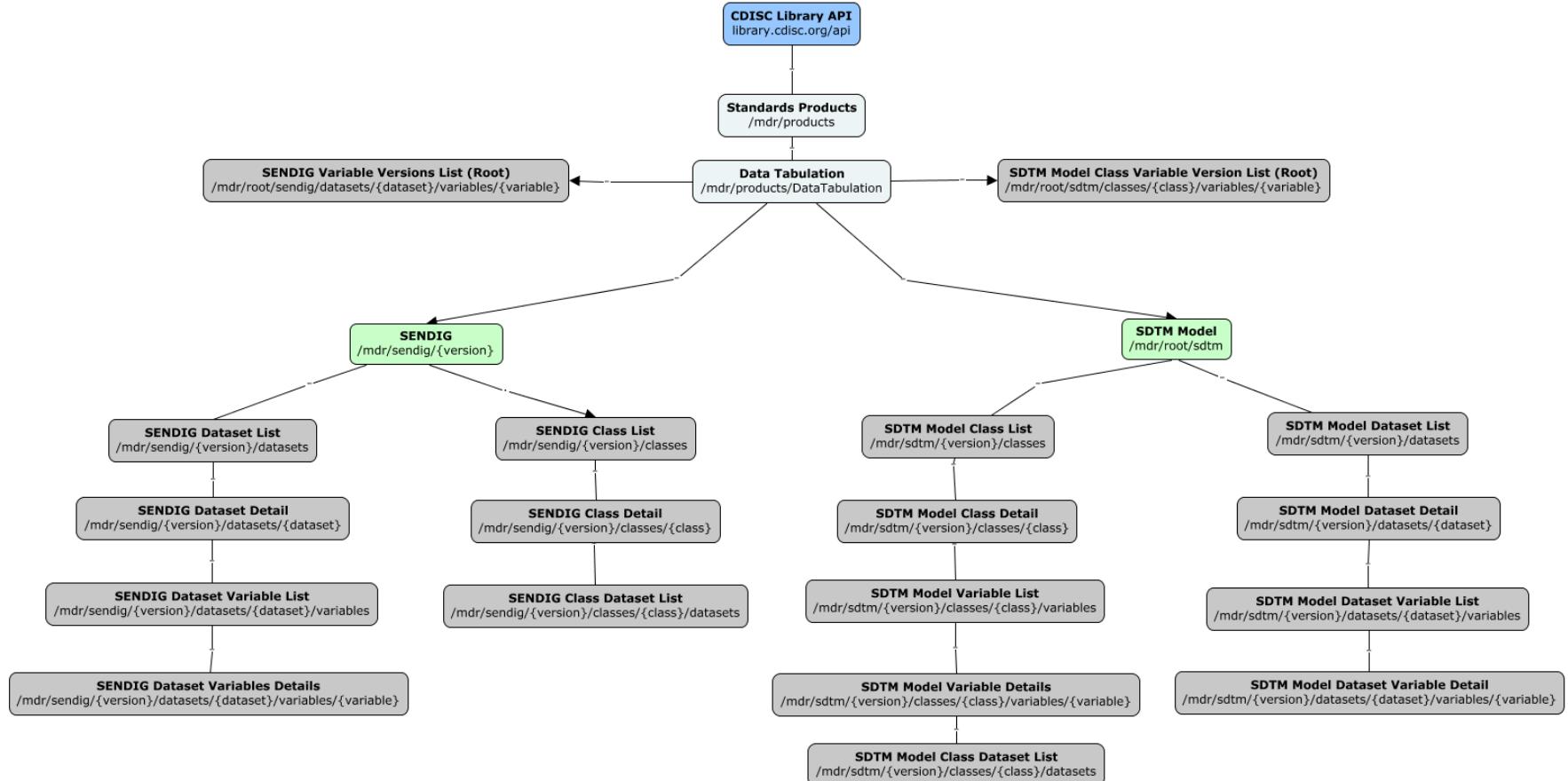
API Taxonomy: CDASH/CDASHIG



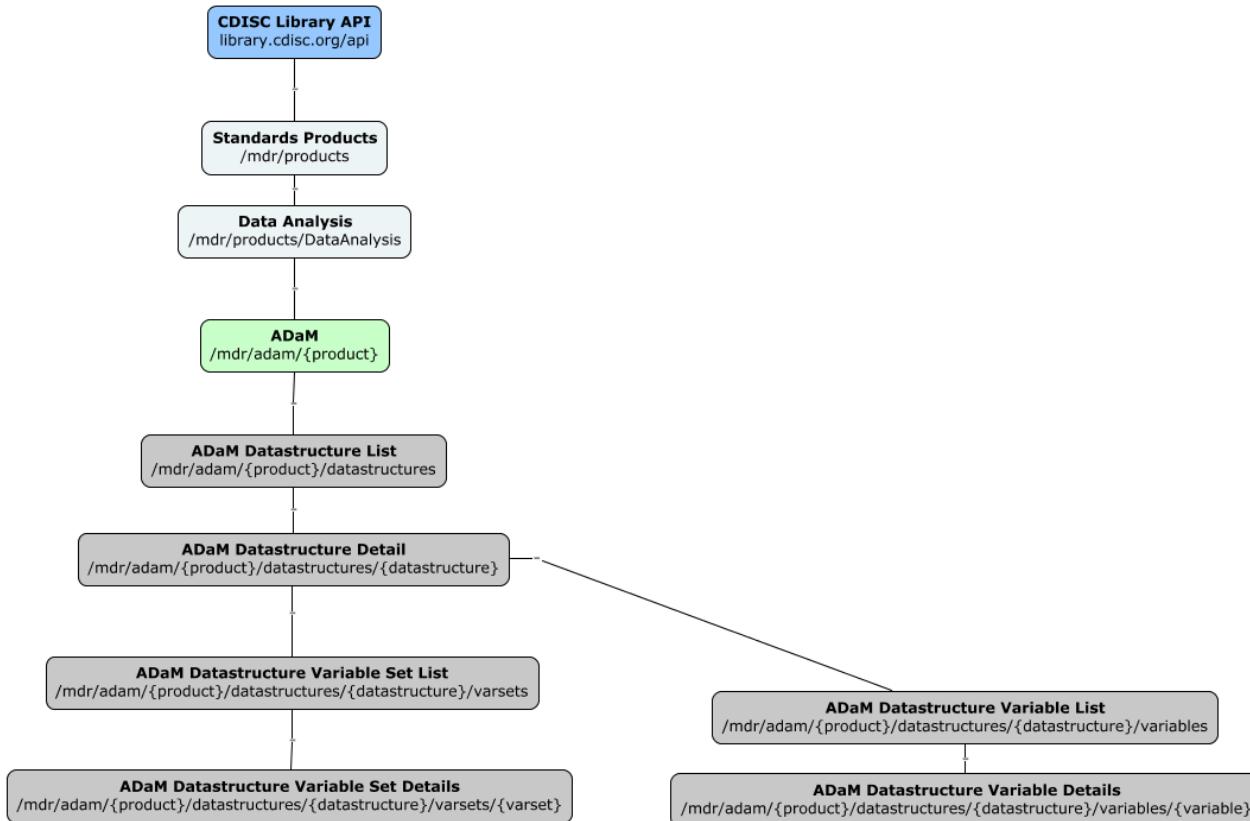
API Taxonomy: SDTM/SDTMIG



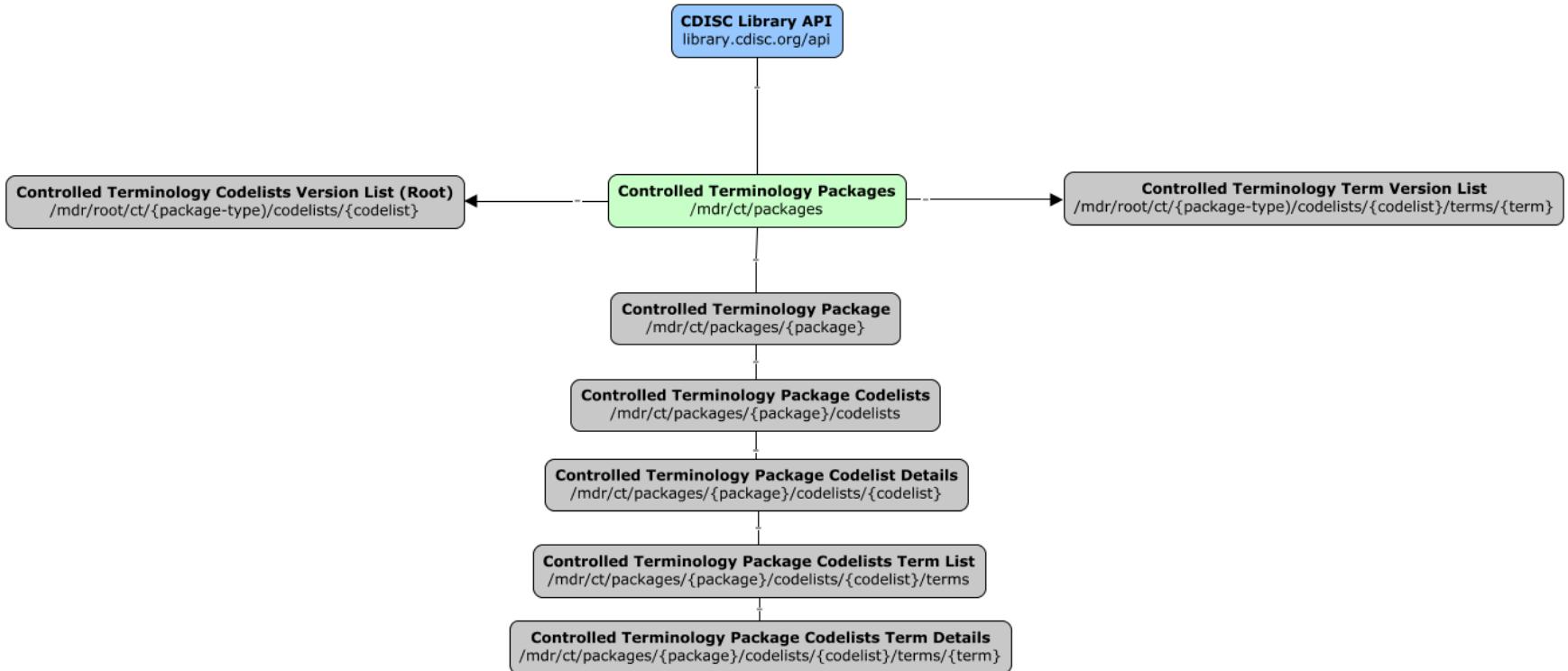
API Taxonomy: SDTM/SENDIG



API Taxonomy: ADaM



API Taxonomy: CT



API via Postman Illustration

The screenshot shows the Postman application interface. At the top, there is a header with 'GET' selected, a URL field containing 'https://library.cdisc.org/api/mdr/sdtmig/3-2', and a 'Send' button. Below the header, there are tabs for 'Params', 'Authorization', 'Headers (2)', and 'Body'. A dark blue callout bubble is overlaid on the interface, containing the following text:

Example of XML Request & Retrieval

What ways can CDISC Library API be accessed?

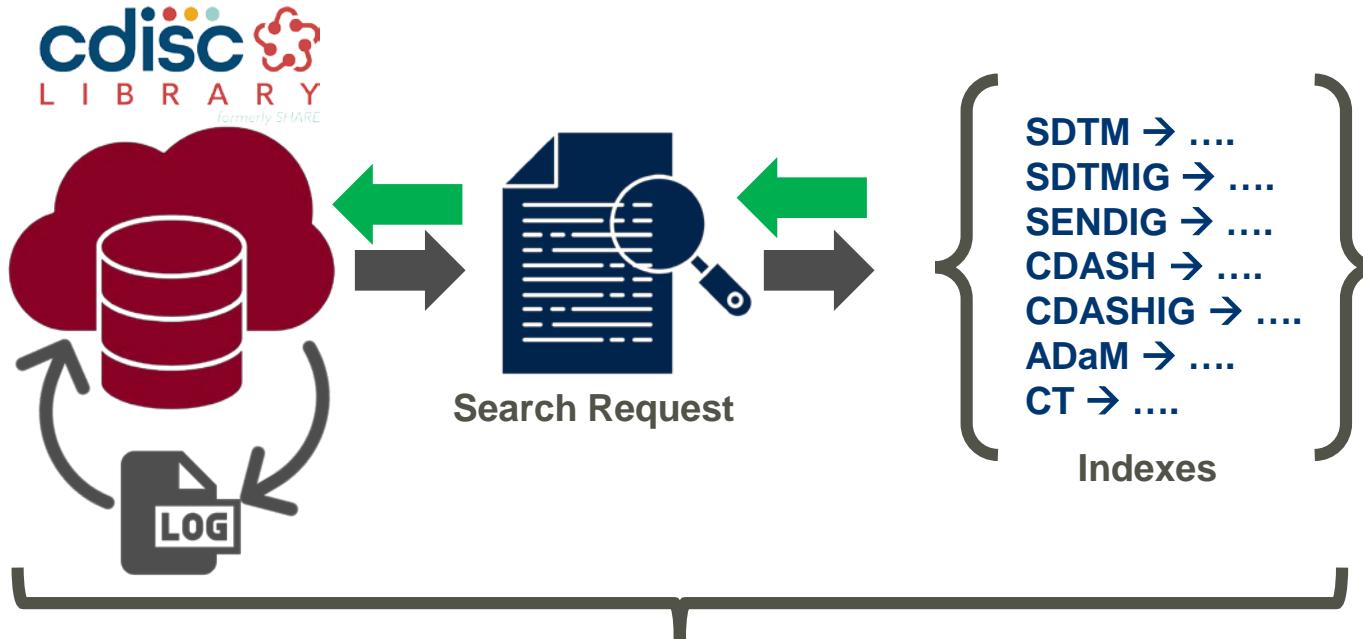
- **API Tools:** Postman, Insomnia, SoapUI, Katalon, etc.
- **Systems:** MDRs, CDMS, CTMS, EDCs, etc.
- **Applications:** Validators, Editors, ETLs, etc.
- **Macros/Code:** SAS, Python, Julia, R, Go, Rust, XML, etc.
- **Web Browser:** FireFox, Chrome, IE, Opera, Brave, Safari, etc.

And possibly others not described above

```
22      <nref>/MDR/sdtmig/3-1-3</nref>
23      <title>Study Data Tabulation Model Implementation Guide: Human Clinical Trials Version 3.1.3 (Final)</title>
24      <type>Implementation Guide</type>
25      </priorVersion>
26      </_links>
27      <class>
28      <ordinal>1</ordinal>
```

At the bottom right of the Postman interface, there are buttons for 'Build', 'Browse', and other settings.

ElasticSearch

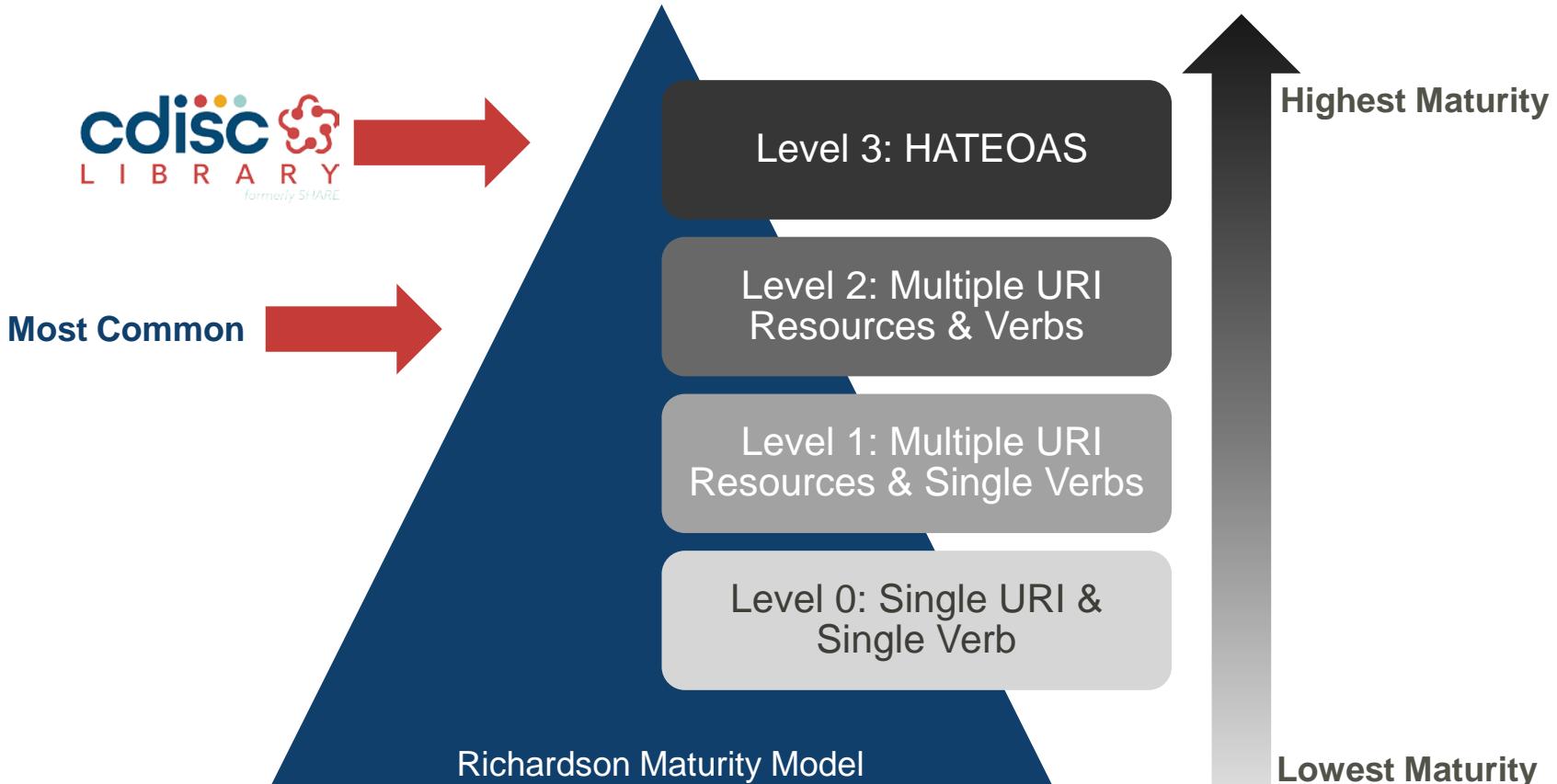


ElasticSearch (cont.)

- **Words:** (race AND ethnicity) OR age
- **Phrases:** “One record” OR “per subject”
- **Specify Field:** Label=“Study Identifier”
- **Wildcard:** AGE* OR *DTC
- **RegEx:** Description: /s?dtmig(ath[en]if)/
- **Proximity (Edit Distance of 3):** “supplemental”^3
- **Date Range:** date:[2019-09-09 TO 2020-01-09]
- **Date Before:** date:{* TO 2020-01-09}
- **Number Range:** ordinal:[6 TO 10]
- **Number Range Exclusive:** ordinal:[1 TO 5}
- **Number Ranges Unbounded:** ordinal:>8

And more...

Hypermedia



Hypermedia (cont.)

```
"ordinal": "10",
"name": "AE",
"label": "Adverse Events",
"definition": {
    "ordinal": "28",
    "name": "AEACN",
    "label": "Action Taken with Study Treatment",
    "description": "Describes changes to the study treatment as a result of the event. AEACN is used for actions unrelated to dose adjustments of study treatment. Examples of AEACN include: DOSE REDUCED, DOSE INCREASED, DOSE NOT CHANGED, UNKNOWN or NOT APPLICABLE.",
    "role": "Record Qualifier",
    "simpleDatatype": "Char",
    "core": "Exp",
    "_links": {
        "self": {
            "href": "/mdr/sdtmig/3-2/datasets/AE/variables/AEACN",
            "title": "Action Taken with Study Treatment",
            "type": "SDTM Dataset Variable"
        },
        "codelist": [
            {
                "type": "Class"
            }
        ]
    },
    "priorVersion": {
        "href": "/mdr/sdtmig/3-1-3/datasets/AE",
        "title": "Adverse Events",
        "type": "SDTM Dataset"
    }
}
```

ient or subjects th
nt. (Source: CDISC

2 (Final)",

Hypermedia (cont.)

Computer science

From Wikipedia, the free encyclopedia

"Computer sciences" redirects here. For the American corporation, see [Computer Sciences Corporation](#).

Computer science is the study of processes that interact with data and that can be represented as data in the form of programs. It enables the use of algorithms to manipulate, store, and communicate digital information. A computer scientist studies the theory of computation and the practice of designing software systems.^[1]

Its fields can be divided into theoretical and practical disciplines. Computational complexity theory is highly abstract, while computer graphics emphasizes real-world applications. Programming language theory considers approaches to the description of computational processes, while computer programming itself involves the use of programming languages and complex systems. Human–computer interaction considers the challenges in making computers useful, usable, and accessible.

Not to be confused with [information science](#).

Data science is a multi-disciplinary field that uses scientific methods, processes, algorithms and systems to extract knowledge and insights from data in various forms, both structured and unstructured,^{[1][2]} similar to [data mining](#).

Data science is a "concept to unify statistics, data analysis, machine learning and their related methods" in order to "understand and analyze actual phenomena" with data.^[3] It employs techniques and theories drawn from many fields within the context of [mathematics](#), [statistics](#), [information science](#), and [computer science](#).

Turing award winner Jim Gray imagined data science as a "fourth paradigm" of science (empirical, theoretical, computational and now data-driven) and asserted that "everything about science is changing because of the impact of information technology" and the [data deluge](#).^{[4][5]}

In 2012, when [Harvard Business Review](#) called it "The Sexiest Job of the 21st Century",^[6] the term "data science" became a [buzzword](#). It is now often used interchangeably with earlier concepts like [business analytics](#),^[7] [business intelligence](#), [predictive modeling](#), and [statistics](#). Even the suggestion that data science is sexy was paraphrasing Hans Rosling, featured in a 2011 BBC documentary^[8] with the quote, "Statistics is now the sexiest subject around."^[8] Nate Silver referred to data science as a sexed up term for statistics.^[9] In many cases, earlier approaches and solutions are now simply rebranded as "data science" to be more attractive, which can cause the term to become "dilute[d] beyond usefulness".^[10] While many university programs now offer a data science degree, there exists no consensus on a definition or suitable curriculum contents.^[7] To its discredit, however, many data-science and [big-data](#) projects fail to deliver useful results, often as a result of poor management and utilization of resources.^{[11][12][13][14]}



Machine learning and data mining



Problems

[show]

Supervised learning (classification · regression)

[show]

Clustering

[show]

Dimensionality reduction

[show]

Structured prediction

[show]

Anomaly detection

[show]

Evolution of Media Types

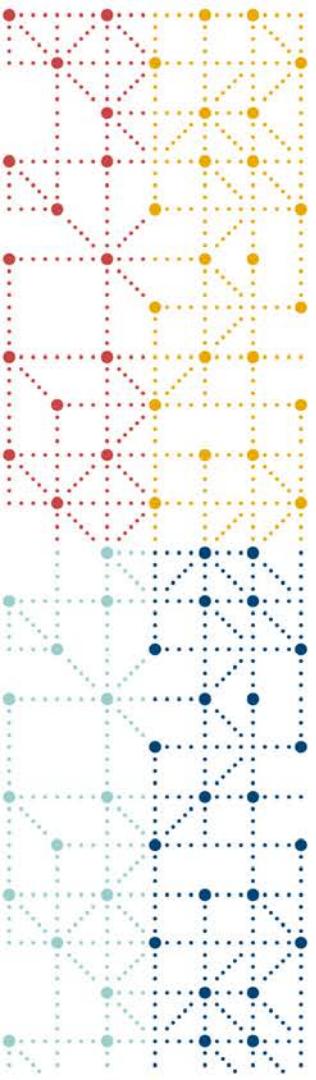
SDTMIG DDM (Demographics) as JSON

Variable Name	Variable Label	Definition	Core
STUDYID	Study ID	"ordinal": "1", "name": "STUDYID", "label": "Study ID", "description": "Unique identifier for the study.", "role": "Identifier", "simpleDatatype": "Char", "core": "Req", "valueList": [It is the
DONORID	Donor ID	"ordinal": "2", "name": "DONORID", "label": "Domain Abbreviation", "description": "Two-character abbreviation for the domain.", "role": "Identifier", "simpleDatatype": "Char", "core": "Req", "valueList": [Req
USUARID	User ID	"ordinal": "3", "name": "USUARID", "label": "User ID", "description": "Unique identifier for the user.", "role": "Identifier", "simpleDatatype": "Char", "core": "Req", "valueList": [Req
SUBJID	Subject ID	"ordinal": "4", "name": "SUBJID", "label": "Subject ID", "description": "Unique identifier for the subject.", "role": "Identifier", "simpleDatatype": "Char", "core": "Req", "valueList": [Req
RFSTUDYID	Reference Study ID	"ordinal": "5", "name": "RFSTUDYID", "label": "Reference Study ID", "description": "Unique identifier for the reference study.", "role": "Identifier", "simpleDatatype": "Char", "core": "Exp", "valueList": [Exp
RFENDTC	Reference End Date/Time	"ordinal": "6", "name": "RFENDTC", "label": "Subject Reference End Date/Time", "description": "Reference End Date/time for the subject in ISO 8601 character format. Usually equivalent to the date/time in the record.", "role": "Record Qualifier", "simpleDatatype": "Char", "core": "Exp", "describedValueDomain": "ISO 8601", "links": {	have failures or Exp
RFXSITEID	Reference Site ID	"ordinal": "7", "name": "RFXSITEID", "label": "Subject Reference Site ID", "description": "Reference Site ID for the subject.", "role": "Record Qualifier", "simpleDatatype": "Char", "core": "Exp", "valueList": [Exp

What future media types can we expect?

- **ODM-XML** (Operational Data Model as XML)
- **YAML** (YAML Ain't Markup Language)
- **JSON-LD** (JavaScript Object Notation for Linked Data)
- **TOML** (Tom's Obvious, Minimal Language)
- **CSON** (CoffeeScript Object Notation)

Maybe others....



CDISC Library Demo

- Sample RDF Graph in CDISC Library
- Hypermedia Representation from REST API
- Navigation within Data Standards Browser



TechniCon | 2020

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17 January - Asia/Pacific Rim

27 January - EMEA

29 January - Americas

<https://www.cdisc.org/2020-cdisc-technicon>



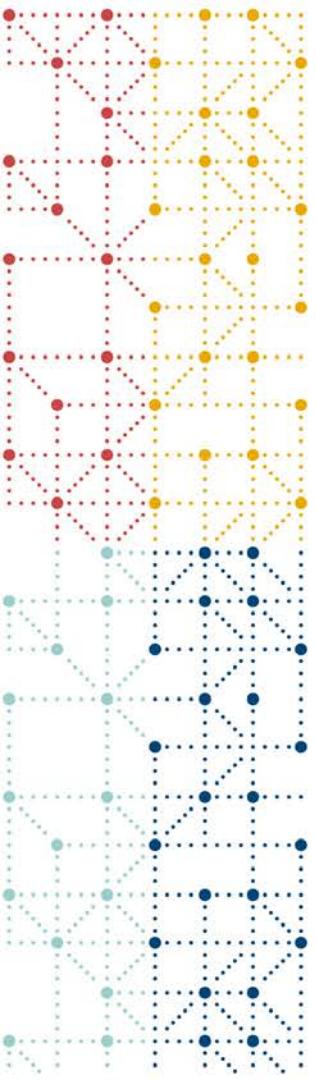
Access CDISC Library now!

CDISC Membership Inquiry: <https://www.cdisc.org/register>

CDISC Library: <https://www.cdisc.org/cdisc-library>



#CDISCLibrary | #ClearDataClearImpact



Thank You!

