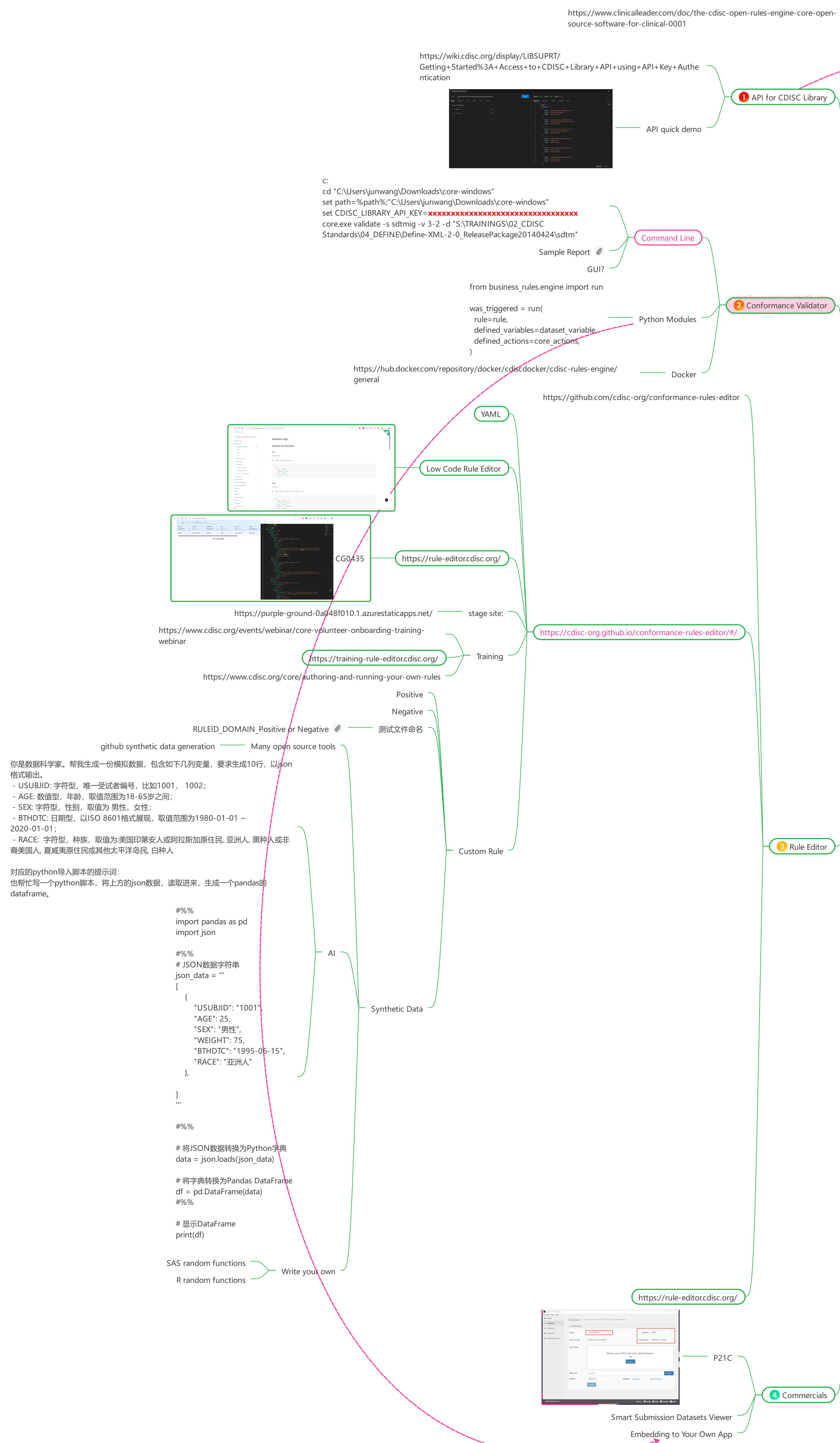
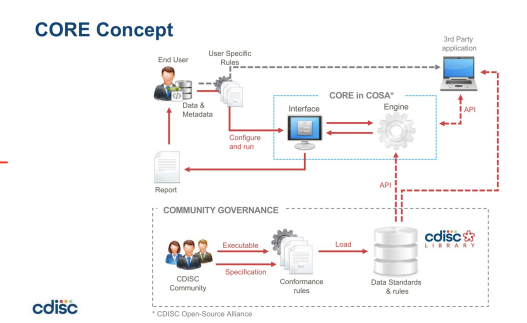




CDISC CORE

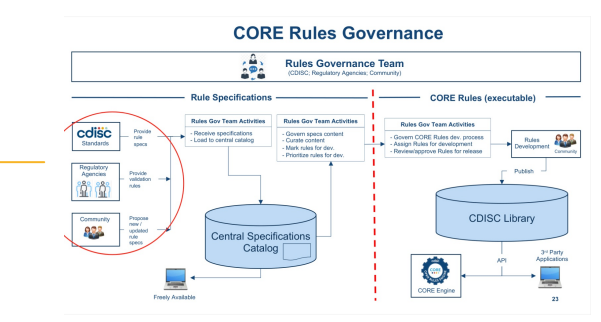


- Best Practise on Conformance Rule — 项目中持续检查
- Conformance Rules stored in — CDISC Library
 - https://www.cdisc.org/cdisc-library
 - https://library.cdisc.org/browser/#/
https://library.cdisc.org/browser/#/mdr/sdtmig/3-4/classes/GeneralObservations
 - https://api.developerlibrary.cdisc.org/api-details#api=cdisc-library-api&operation=api-products-rule-get
- Concept



Conformance Rules

- CDISC
 - SDTM — https://www.cdisc.org/standards/foundational/sdtmig/sdtmig-and-sdtmig-conformance-rules-v2-0
 - ADaM — https://www.cdisc.org/standards/foundational/adam/adam-conformance-rules-v5-0
- FDA
 - https://www.fda.gov/industry/fda-data-standards-advisory-board/study-data-standards-resources
 - Business Rules (May 2019) — https://www.fda.gov/media/116935/download?attachment
 - Validator Rules (Dec 2022) — https://www.fda.gov/media/103587/download?attachment
- PMDA
 - https://www.pmda.go.jp/english/review-services/reviews/0002.html
 - Study Data Validation Rules (Mar 2024) — https://www.pmda.go.jp/files/000267621.zip
 - CDISC Data Validation Software (2311.0, Validation Rule v5.0)
- NMPA?
- Commercials
 - P21
 - XML4Pharma
 - Smart Submission Datasets Viewer
http://www.xml4pharma.com/Smart_Submission_Dataset_Viewor/
- CDISC CORE
 - 主站点 https://www.cdisc.org/core
 - https://github.com/cdisc-org/cdisc-rules-engine
 - MIT License
 - 一统江湖
 - Progress (Apr 2023)
- Open Source
 - OpenChecks — https://github.com/PhIRDA/openchecks
 - OpenRules — XML4Pharma
- Rule Categories
 - CTxxxx, SDxxxx, SExxxx



Rules Development Progress

Rule ID	Rule Name	Version	Status	Owner	Created	Last Modified
CT0001	CT0001	1.0	Completed	CDISC	2019-01-01	2019-01-01
CT0002	CT0002	1.0	Completed	CDISC	2019-01-01	2019-01-01
CT0003	CT0003	1.0	Completed	CDISC	2019-01-01	2019-01-01
CT0004	CT0004	1.0	Completed	CDISC	2019-01-01	2019-01-01
CT0005	CT0005	1.0	Completed	CDISC	2019-01-01	2019-01-01
CT0006	CT0006	1.0	Completed	CDISC	2019-01-01	2019-01-01
CT0007	CT0007	1.0	Completed	CDISC	2019-01-01	2019-01-01
CT0008	CT0008	1.0	Completed	CDISC	2019-01-01	2019-01-01
CT0009	CT0009	1.0	Completed	CDISC	2019-01-01	2019-01-01
CT0010	CT0010	1.0	Completed	CDISC	2019-01-01	2019-01-01

