Define2Validate - Validate CDISC Dataset-XML with corresponding Define-XML metadata

Key message: We developed an **open-source tool** that validates Dataset-XML against the rules or metadata defined in Define-XML.

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Background

Define-XML defines the metadata of CDISC dataset. However, though there are some tools to validate dataset against SDTM standards or regulatory validation rules, there is still **no reference tool** to validate datasets against the metadata and business rules that is defined by corresponding **Define-XML**.

Objective

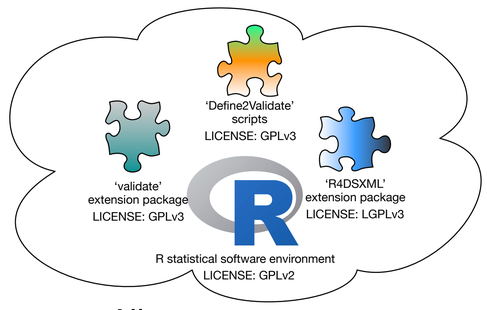
To prove the concept of validating dataset against the metadata defined in Define-XML, we developped an open-source tool to validate datasets against corresponding Define-XML.

Methods

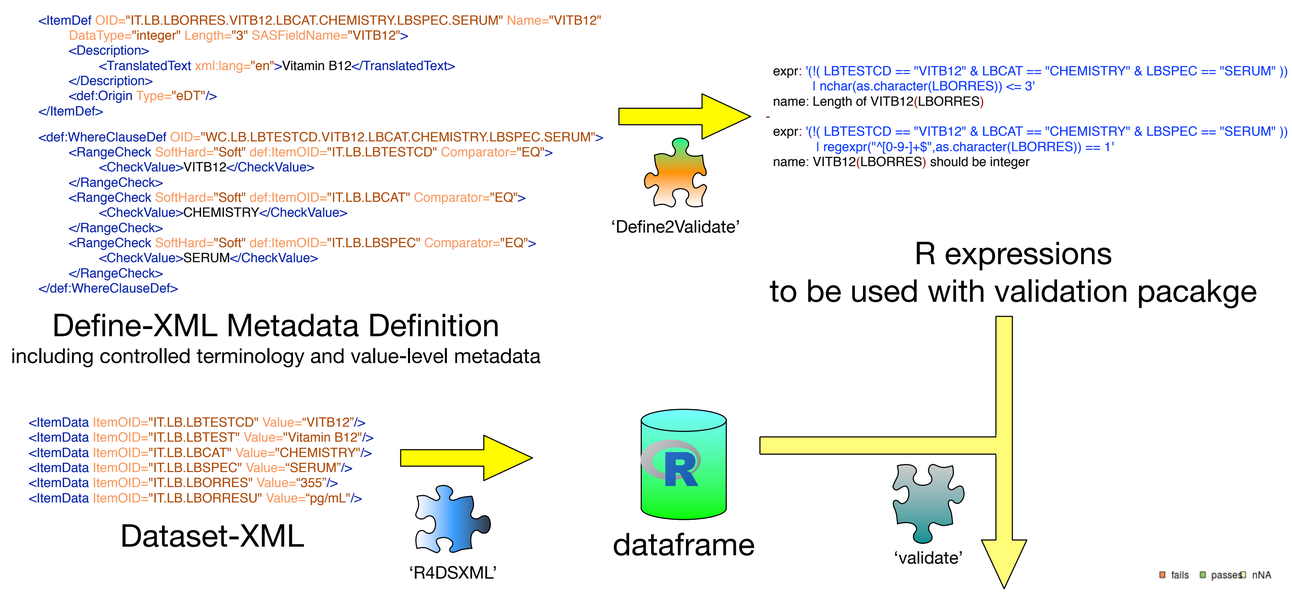
We implemented a validation tool on the R statistical programming environment[1]. We named the tool as “Define2Validate”. To read the content of Define-XML and Dataset-XML, we adopted a R package “R4DSXML” written by Ippei Akiya[2]. Define2Validate reads Define-XML, then converts the rules to which the dataset conforms into a set of R expressions. To perform tests against the dataset with the expressions, we adopted a R package “validate” written by Mark van der Loo[3]. We also adopted a R package “testthat” written by Hadley Wickham[4] to implement Define2Validate. All tools are licensed under open-source licenses.

Results

With Define2Validate, we could validate the dataset against the metadata defined in Define-XML and generate a report of conformance. Though currently not all business rules are implemented in Define2Validate, it supports variable-level metadata, value-level metadata, and controlled terminology.



All components are **open source software**



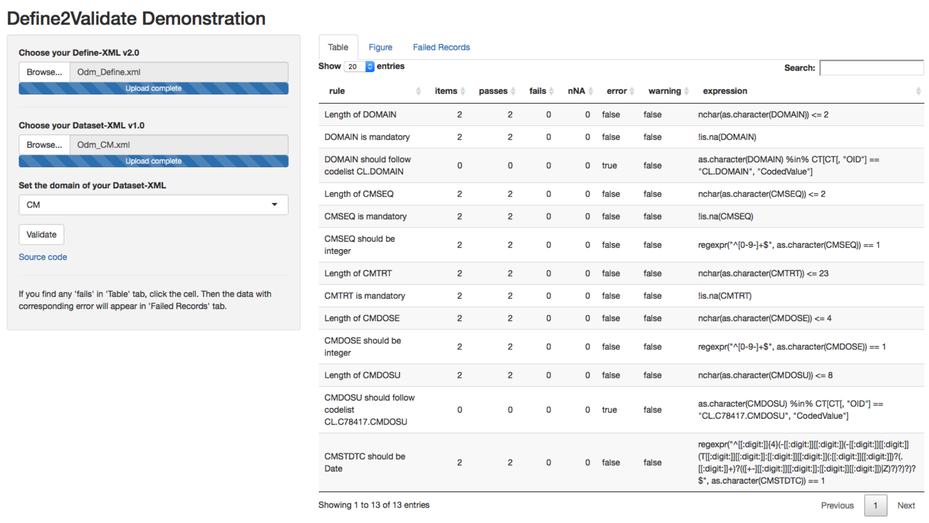
validation report

Source code:

`https://github.com/mokjpn/Define2Validate`

Live demonstration available:

`https://cuda.umin.ac.jp/s/Define2ValidateDemo/`



Discussion

Define-XML stores metadata to which the dataset should conform. The metadata should be defined at the very early stage of planning a clinical trial. However, currently there is no reference tool to validate the data against the metadata defined in Define-XML. Thus not so many investigators writes Define-XML at the beginning of trials. Indeed, some investigators “generate” Define-XML to match the actual dataset after the data collection. That practice might spoil some philosophy of data and metadata standards. Our tool would help researchers to validate the data against the pre-defined metadata which is described in Define-XML.

References

1. R Core Team (2016). R: A language and environment for statistical computing. R Foundation for Statistical Computing,Vienna, Austria. URL https://www.R-project.org/.
2. Ippei Akiya(2016). R4DSXML package. https://github.com/DataDrivenInc/R4DSXML
3. Mark van der Loo(2016).validation package. https://CRAN.R-project.org/package=validate
4. Hadley Wickham(2016). testthat package. https://CRAN.R-project.org/package=testthat

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