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An interactive platform for integrating and editing metadata to generate Define-XML

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Peng LI

May 25



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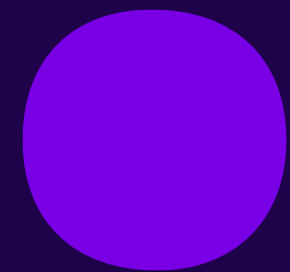


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Agenda

- Overview
- Integrate Multi-source Metadata
- Reverse Data Flow
- Metadata Management
- Hybrid Translation Model
- CDISC Compliance
- Demo

01 Overview

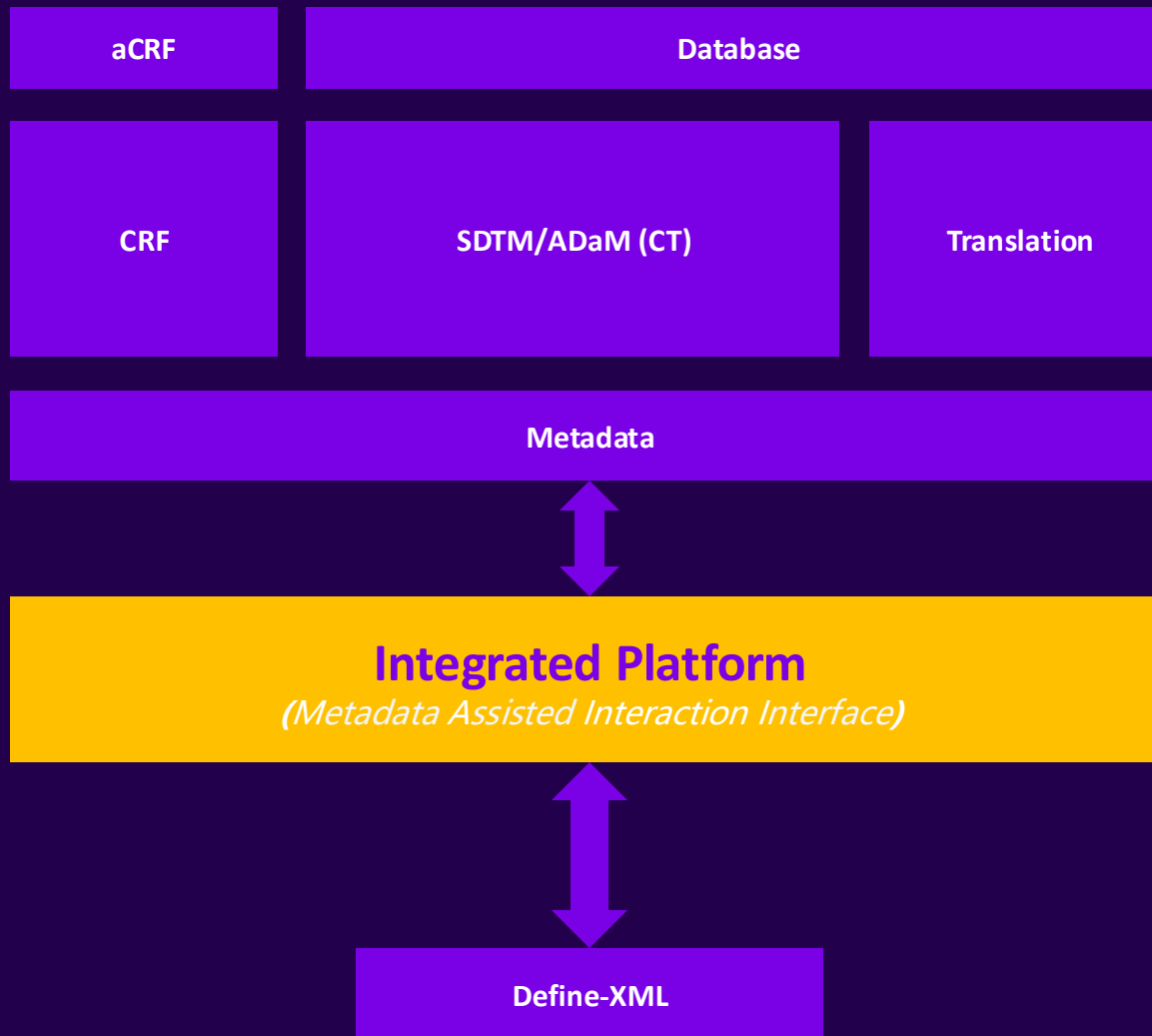


Background

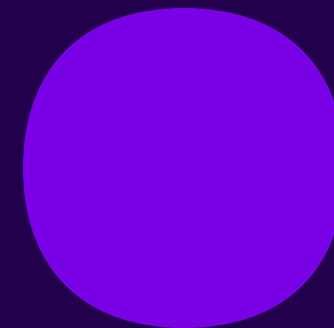
- Low-coupled, parallel, modular programming helps improve submission efficiency.
- Define-XML is difficult to update.
- Multi-language submission.
- More friendly metadata management mode.



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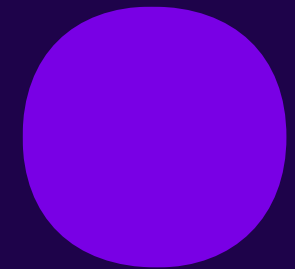
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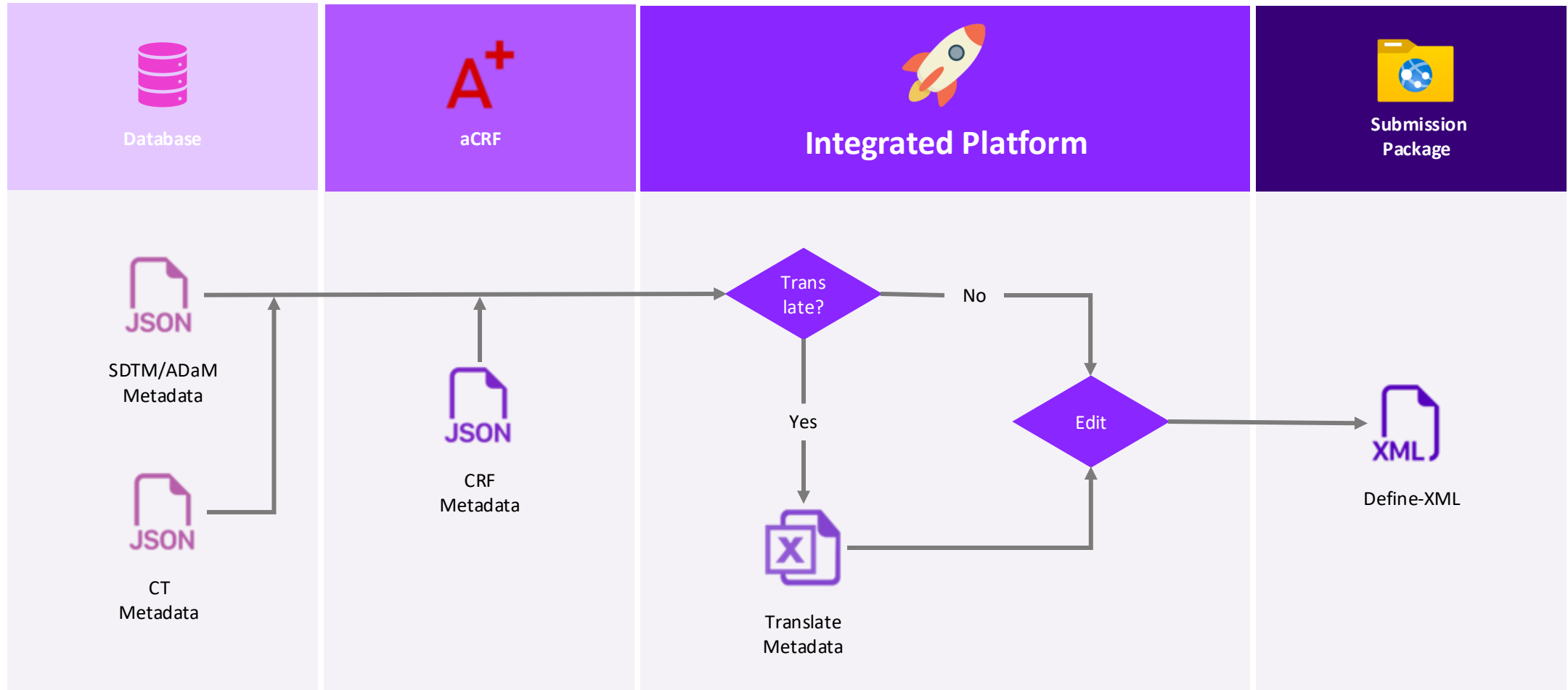
Features of the platform

- An interactive platform based on the concept of low coupling and **modular** design, aiming to provide more stable, high-quality and efficient **submission** support.
- Realizes the **integration**, **editing** and **management** of multi-source **metadata**.
- Used to generate, translate and update **Define-XML**.

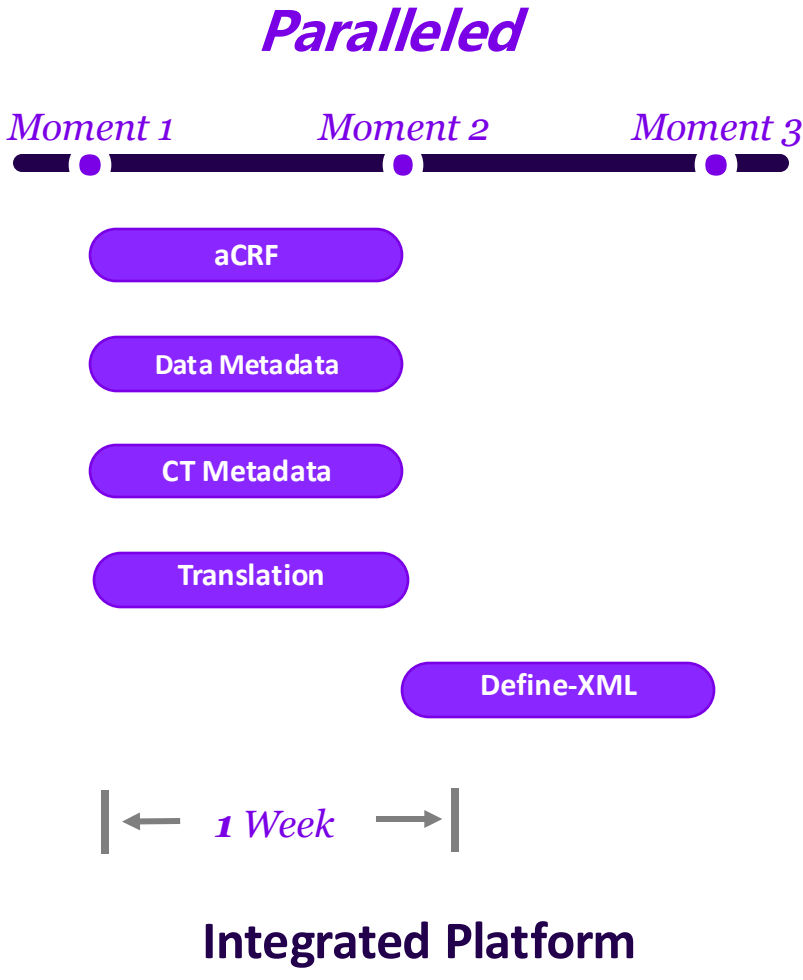
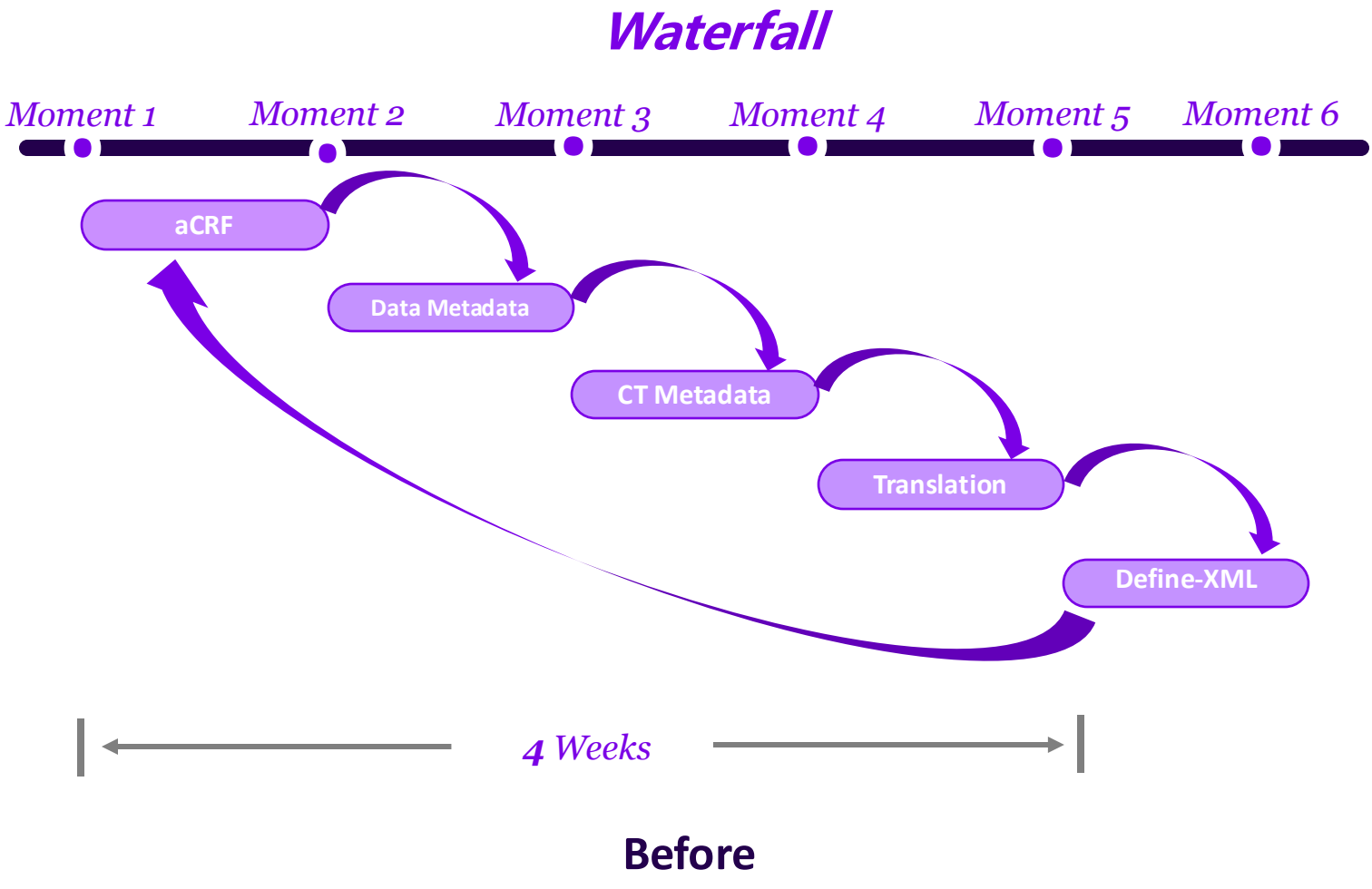
02 Integrate Multi-source Metadata



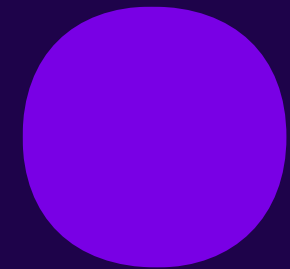
In-house Study



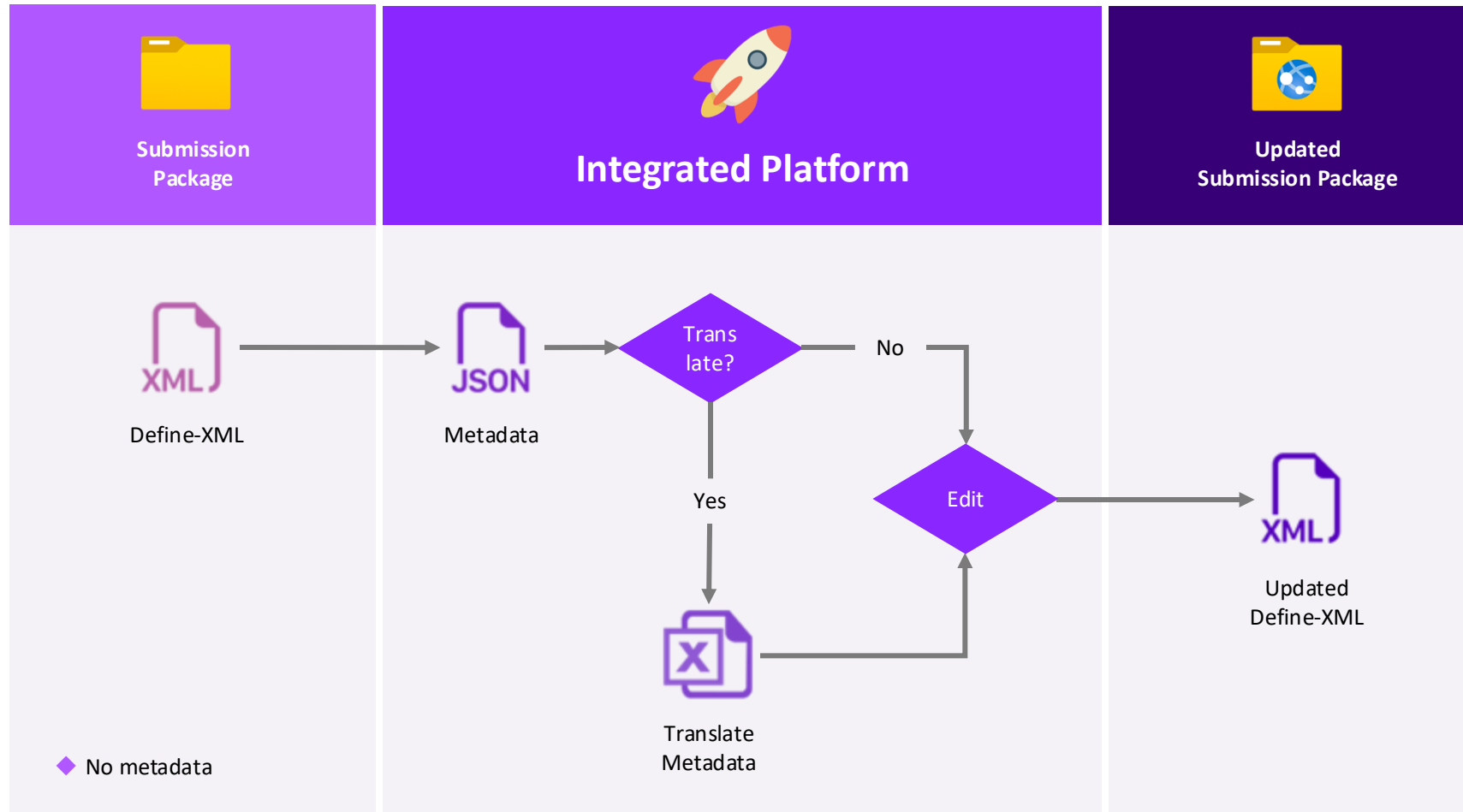
Compare with Before



03 Reverse Data Flow

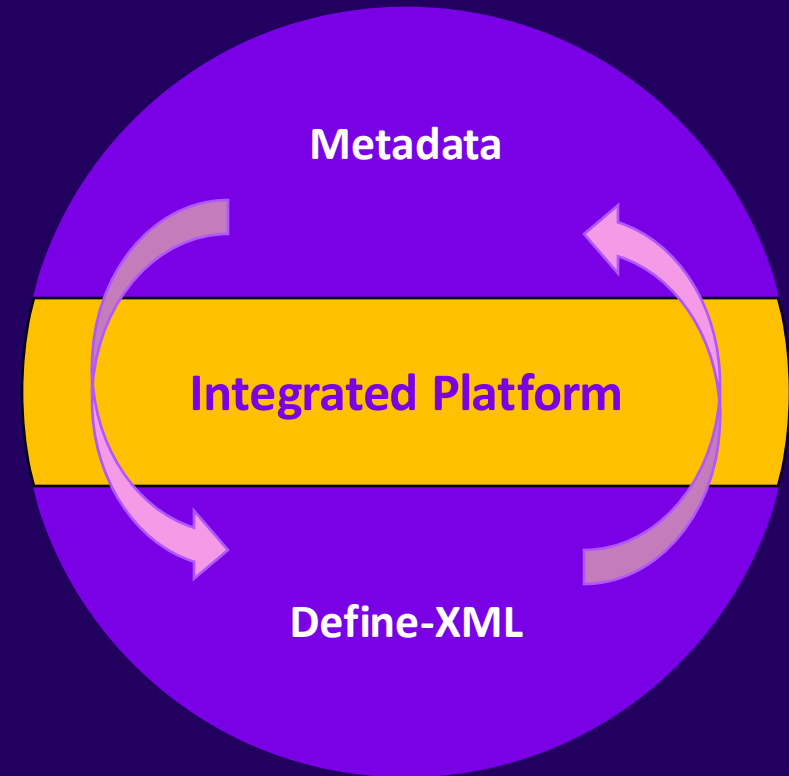


Outsourced Study

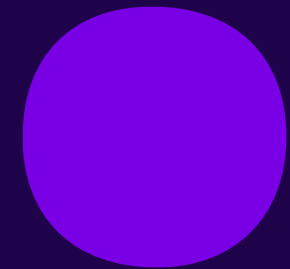


Data Loop

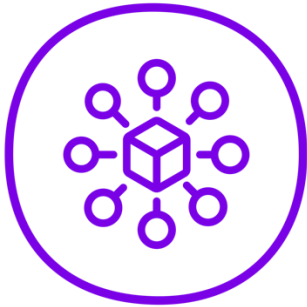
- It realizes two-ways data flow and data loop.
- Deal with more complex submission scenarios.
 - ✓ Undertake all outsourced study.
 - ✓ Multi-country and multi-language submission.
- It is beneficial for us to build the data lake.



04 Metadata Management



Metadata Management



Integrator

Integrate metadata from multiple sources.



Visual Editor

Manipulate all the attributes in the metadata.



Version Controller

Ensure traceability and reproducibility of metadata.

Dashboard

STUDYID

C: / USERS / E0459206 / ONEDRIVE - SANOFI / DOCUMENTS / MELODIE / PROJECTS

msdtm file input

mcrf file input

Reference Excel Metadata file input

xml file input

CREATE METADATA

CREATE DEFINE XML

OPEN PATH

LanguageEnglish

Metadata ModeDOT

STUDY

METADATA

STANDARDS

DOCUMENTS

METHOD

WHERE CLAUSE

CT

EXTERNAL CT

SHARE COMMENTS

ADD NEW DOMAIN

CONSISTENCY

Select

Select Dataset

Dataset Label

Standard

Class

Purpose

Dataset Structure

Key Variables

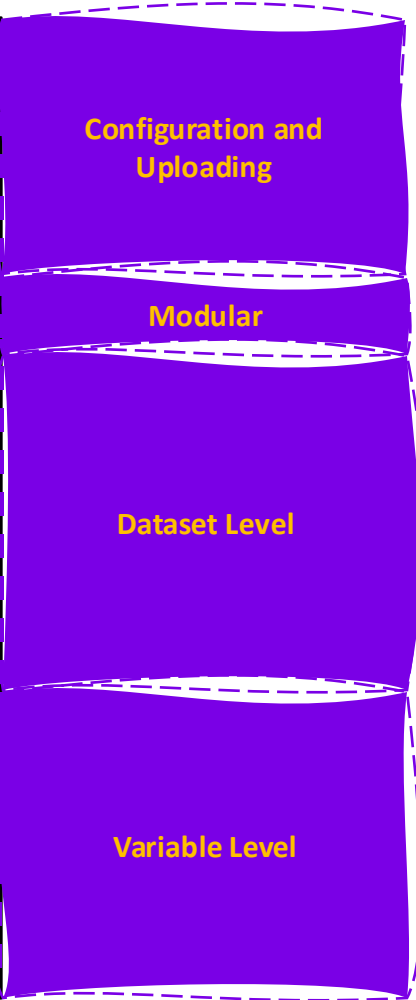
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Define Comments

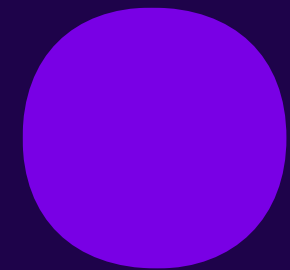
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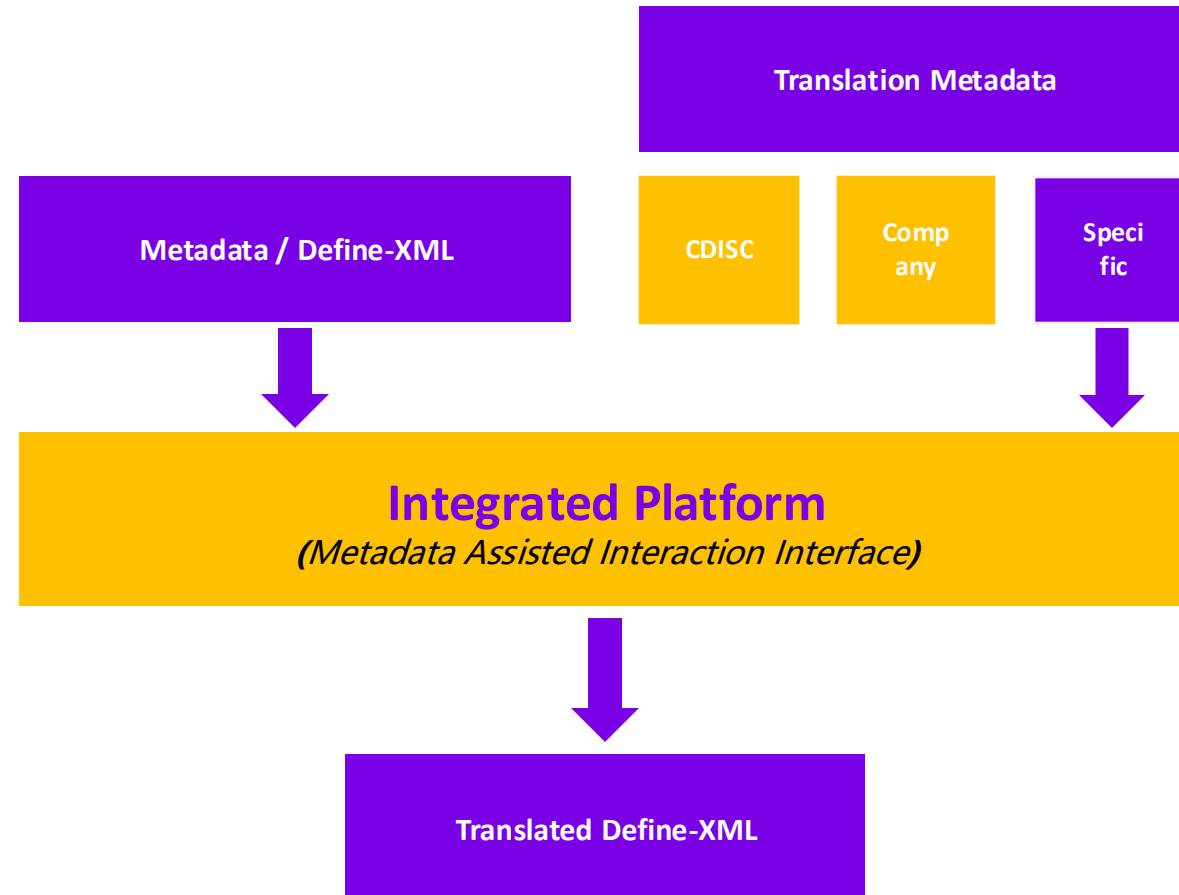


05 Hybrid Translation Model



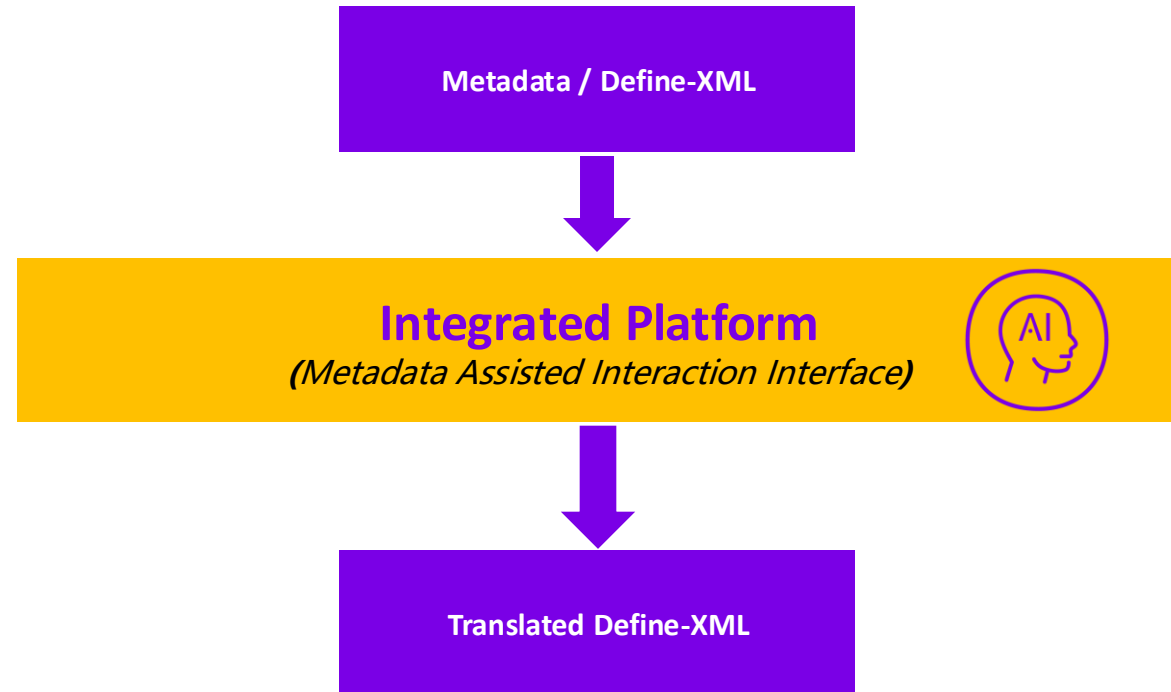
Manual

- Metadata for translation is required.
- This integrated platform performs integration operations only.
- Create the translation library.

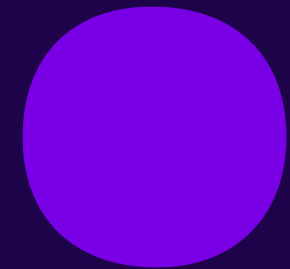


AI + Manual

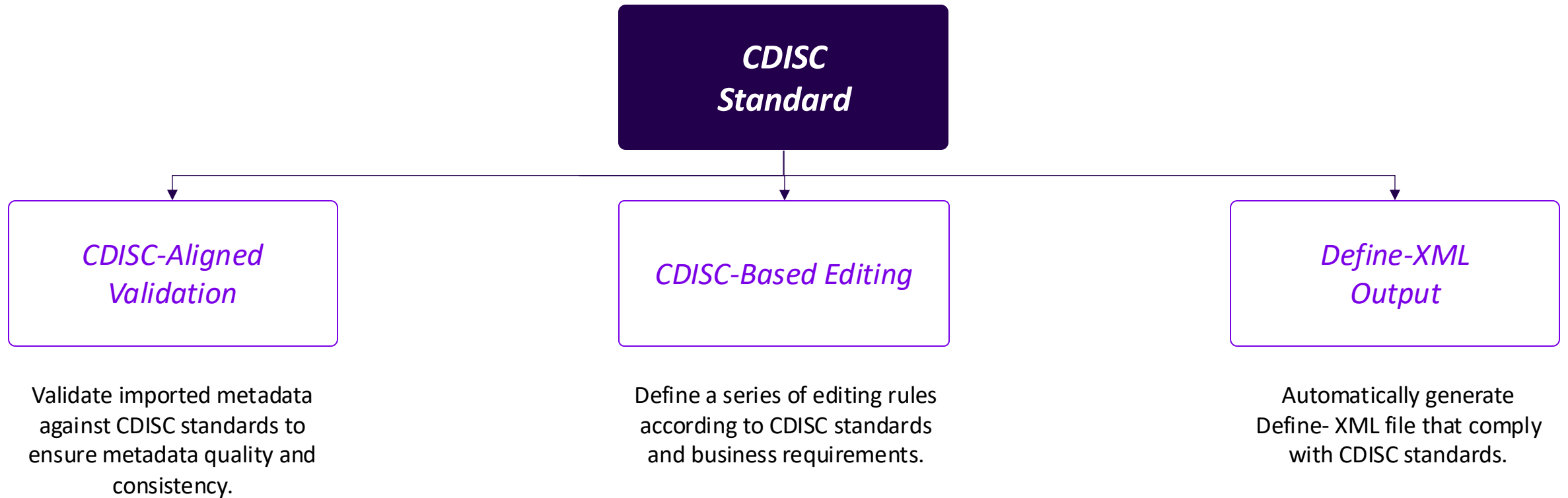
- Context-awareness skills to improve accuracy and consistency of translations.
- Analyzes semantic relationships, professional terminology, industry background and other information in the text to generate more accurate and contextual translations.
- Manual review and proofreading by professional translators.



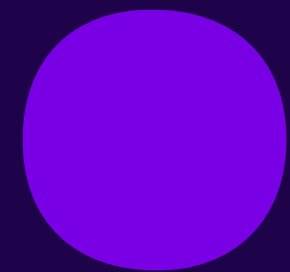
06 CDISC Compliance



CDISC Compliance



07 Demo



Demo: Upload and update Define-XML

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- Demo: Integrate and translate multi-source metadata**
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Thank *you!*

Time for feedback

For further questions, please contact marco.li@sanofi.com

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