



MINT+ Automation and Digitization of SDTM specification

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Standard Data Tabulation Model (SDTM)

Key Facts

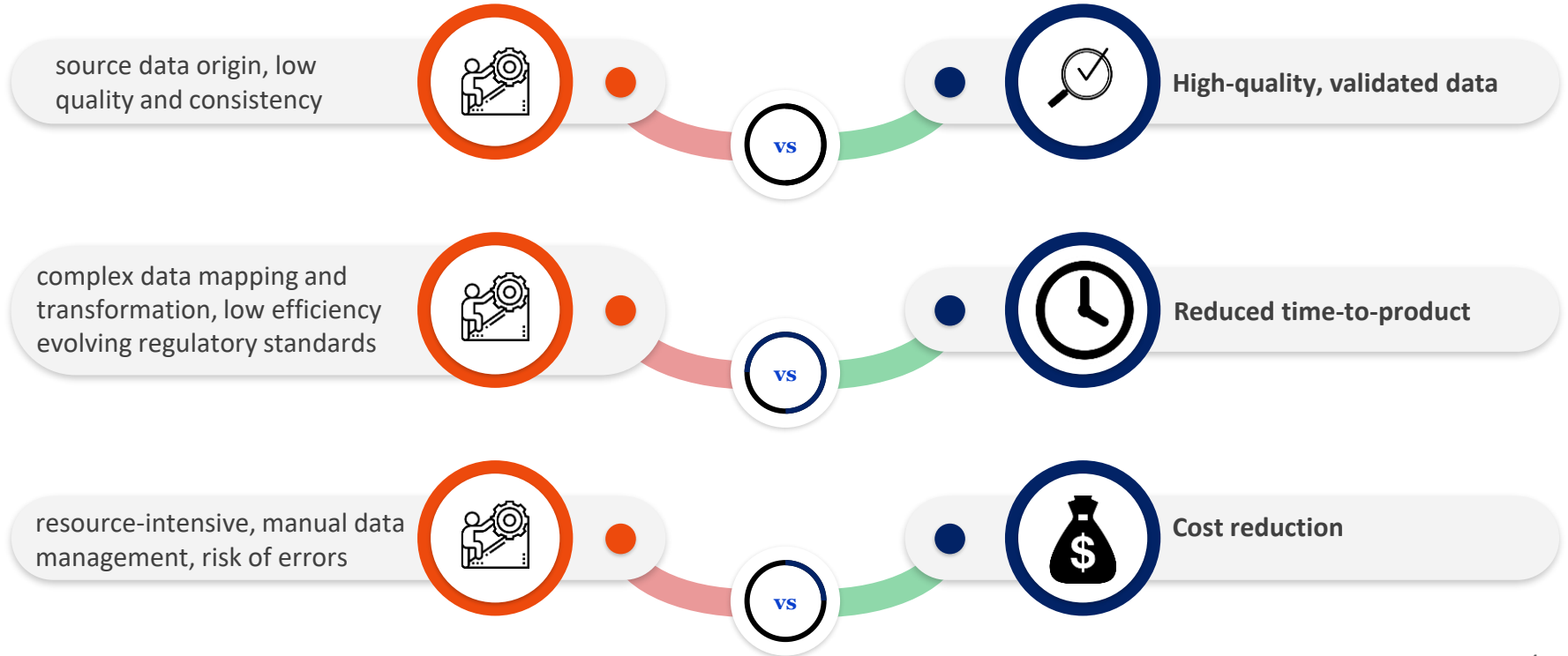
- ① model used for organizing data collected in clinical trials
- ① developed by CDISC – the Clinical Data Interchange Standards Consortium
- ① enforces industry-wide standardization of domains, datasets, variables
- ① required format when submitting to:
 - US Food and Drug Administration (FDA)
 - UK Medicines and Healthcare products Regulatory Agency (MHRA)
 - Pharmaceuticals and Medical Devices Agency (PMDA) in Japan

Identifiers		Qualifier	Topic	Qualifier	Timing
USUBJID	MHSEQ	MHCAT	MHTERM	MHSEV*	VISITNUM
1912	1	Nervous System Medical History	Neuralgia	MILD	3
1912	2	Nervous System Medical History	Epilepsy	MILD	3
1912	3	Respiratory System Medical History	Laryngitis	SEVERE	3

* Codelist: Severity Response (NCI Code: C165643)

Example Medical History (MH) domain with variable roles

Automation challenges & opportunities



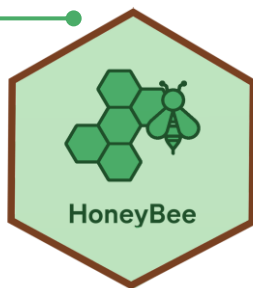


OAK Garden aims to automate the study SDTMv deliverables



Semantic model
in GDSR

Part of
GDSR



Content upload
to GDSR
(Java program)

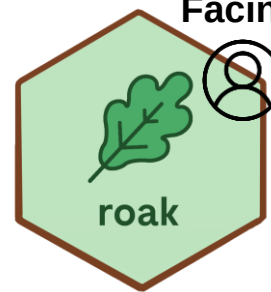


SDTMv Spec
Creator
(Web App)

User
Facing

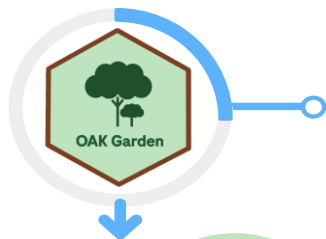


SDTMv Spec
Repository
(DocumentDB)

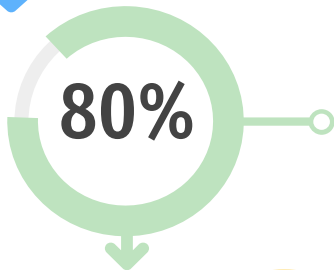


Data
transformation
engine
(R package)

User
Facing



Driven by **metadata & Global Data Standards**,
OAK Garden can



Automate ~80% of study SDTM(v)
domains with a concept of
Reusable Algorithms (In a typical Roche study)

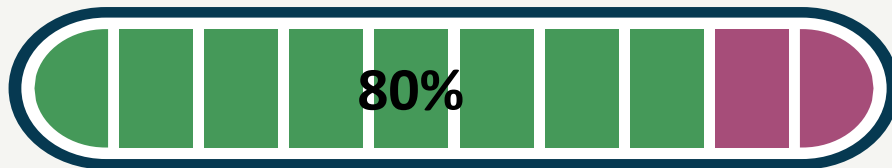


In a typical Roche study
Expect ~**20% programming and manual
work** to enable full automation in your study

What can be automated?



Standards in the study can be automated



If a study has 80% standard mappings (eCRF & Non-CRF), those can be automated.

Less automation in TAs where Data collection standards don't exist.

Based on the past data (since 2019), average standard adherence in a Roche study is **~80%**.

What has to be programmed or configured?



- **Complex Non- Standards in the study**
- **Certain SDTM domains - SE, SV, RELREC, TDDs & EPOCH**
- **Known bugs in automation of standards**



~20% of study SDTMv deliverables require some kind of programming effort.



- ❖ Non-standard SDTMv mappings & Algorithms
 - Most Non-standards can be automated using existing Algorithms and can be re-used from previous studies.
- ❖ Some standard mappings that need user input (20_NEED_USER_INPUT Algorithm)

SDTM automation



Automates creation of :

- ❖ Study SDTMv spec
- ❖ Study Controlled Terminology
- ❖ Study VLM
- ❖ SDTM Define.xml



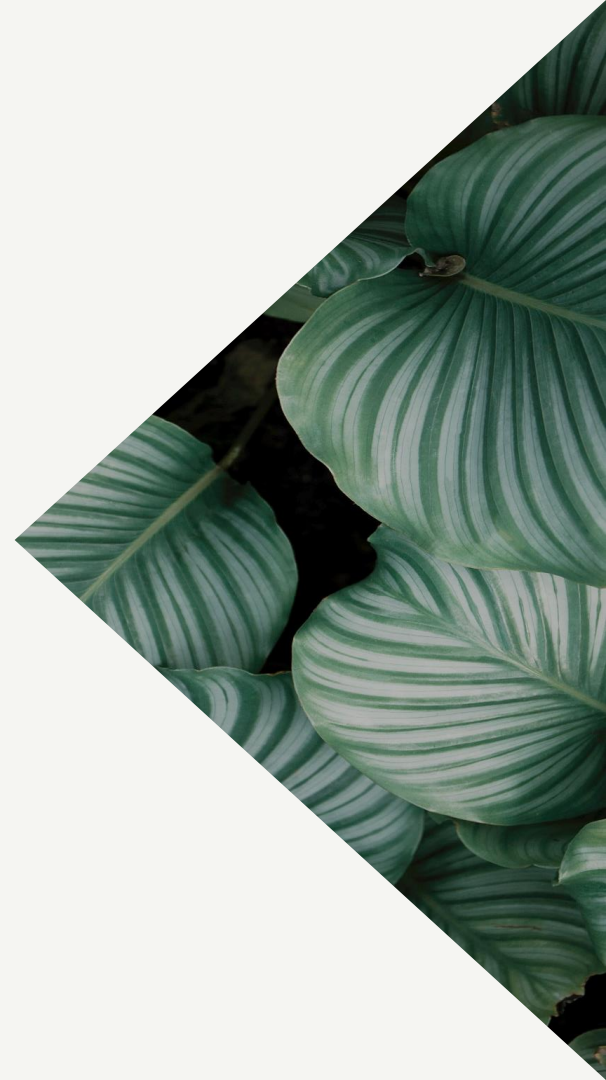
Automates creation of:

- ❖ SDTM(v) datasets
- ❖ SDTM(v) to SDTM
- ❖ XPT file creation





MINT+



Frontend

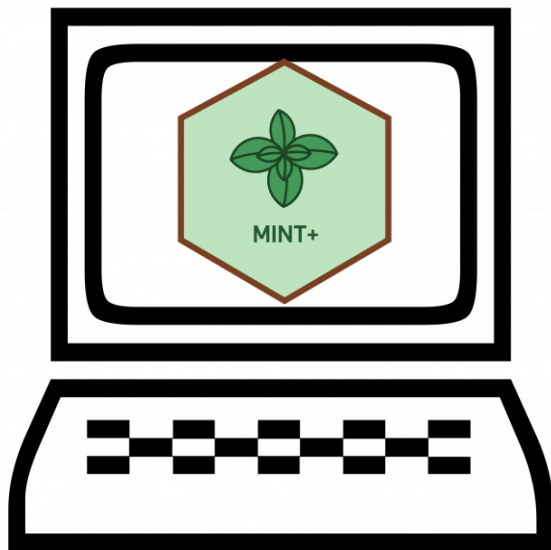
Backend

Storage

React UI

R packages

Amazon DocumentDB



*data processing
& business logic*



Web API



*document
store*

MINT+ Functionalities

Digital study SDTMv Specification



Create and access your study SDTM specification online.

Interactive UI



Add Non-standards mappings & Algorithms for Non-standards.

Locking Feature



Helps prevent override each other's work.

Draft/QA/PROD Workflow



Manage specifications to help the development process.

Store & Reuse



Every user action is stored in the underlying DB - Saffron Amazon DocumentDB.

Molecule level consistency



Easily search Non-standard mapping across studies.

A hand is holding a large, green, heart-shaped leaf with prominent veins. The leaf is covered in numerous small, clear water droplets. The hand is positioned at the bottom left, with fingers gently gripping the leaf's stem. The background is a soft, out-of-focus light gray. A semi-transparent white rectangular box is overlaid on the right side of the image, containing the word "Demo!" in a bold, black, sans-serif font.

Demo!

A close-up photograph of a person's hand holding a large, dark green leaf. The leaf is covered in numerous small, clear water droplets, suggesting it has been recently watered or is in a humid environment. The hand is positioned at the bottom left, with fingers gently gripping the leaf's stem. A semi-transparent white rectangular box is centered over the middle of the image, containing the text "Thank you!" in a bold, black, sans-serif font. The background is a soft, out-of-focus light gray, providing a clean and minimalist aesthetic.

Thank you!

Doing now what patients need next