



SPA MDR CDR SCE

RIP – Inconsistent Metadata
Specifications with RAP (R And Python).
Generate Specs Faster and Detect Early
Errors to Speed Up Submissions.

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Authors

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Kairav Tarmaster is from Surat (the city of the sun) in western India, where he lives in a big joint family with his parents & brother's family, a concept unique to Indian culture. Kairav is a subject matter expert in Metadata Management and Digital Data Flow with 18 years of experience in the clinical trials domain.

Kairav is a Director of Product Management for multiple solutions like Metadata Repository, Structured Study Design and Structured Protocol Authoring, and Data Transformation Module at Sycamore Informatics. He works with Sycamore Informatics to digitally transform and manage change with software products and services to mega, and mid-size pharma and CROs.

He lives by the motto - Live and Let Live !!!



Agenda

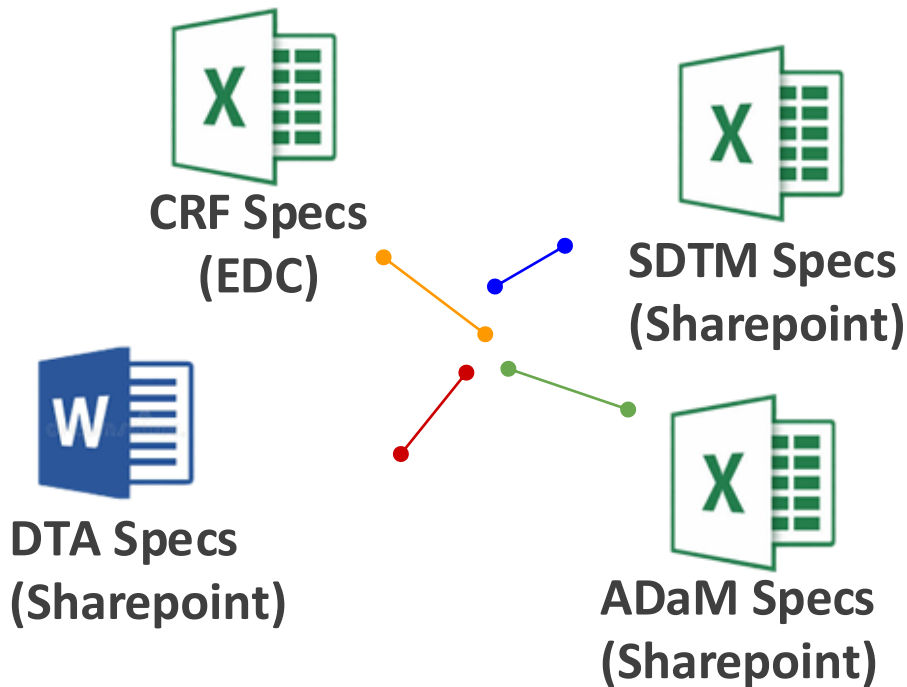
- CHALLENGES AND PAIN POINTS IN METADATA MANAGEMENT
- SOLUTION
 - GENERATE METADATA USING RULES
 - VALIDATE METADATA USING RULES
 - WHERE & WHEN TO EXECUTE RULES
 - MANAGE R AND PYTHON PACKAGES AND VERSIONING
- IMPLEMENTING METADATA AUTOMATION - KEY CONSIDERATIONS
- OTHER GENAI & METADATA RULES USE CASES
- SUMMARY



Challenges



No
Automation



BORING!

Disparate Sources for Metadata Management



Uh Oh - Problems !!!



Solution



**Metadata
Repository
(MDR)**

- Centralized repository & single source of truth
 - Clinical Data Standards Governance
 - Study Conformance and Compliance to Standards and Rules



Gen AI

- R / Python with Gen AI
 - Metadata Generation & Validation
 - Integrations with clinical trial systems
 - Local LLMs



Generate Metadata !!!



Gen AI Prompt

Design a CRF to understand Protein Binding in subjects between 10 to 20 years of age, administered with HPV Vaccine to prevent Cervical Cancer

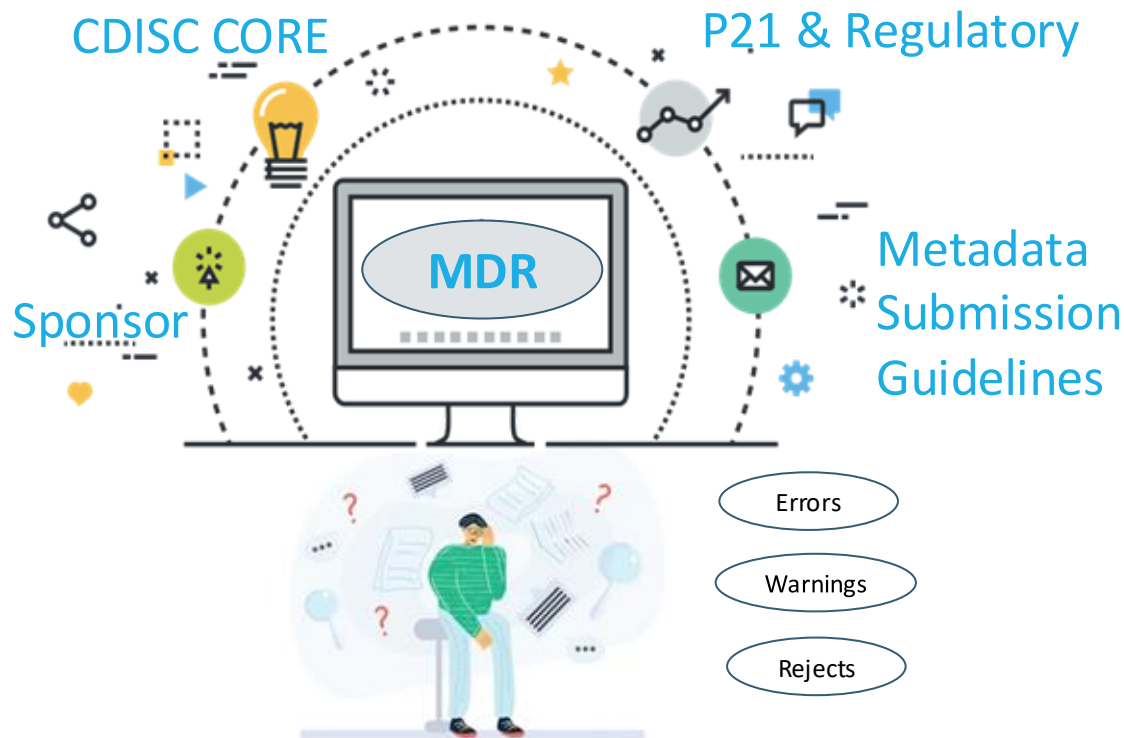
Example Rules to Generate Metadata

Rule Number	Rule Description	Rule Owner
MG.CRF.Rule01	When an Item on a Form uses a Codelist, its length should be the maximum of the EDC Display Value of all the Code Terms.	Data Collection
MG.CRF.Rule02	When an Item on a Form uses a Codelist, the user interface control should be driven by the number of Code Terms.	Data Collection
MG.CRF.Rule03	My organization should follow CDASH Naming conventions for Item OIDs.	Data Collection

Demo



Validate Metadata !!!

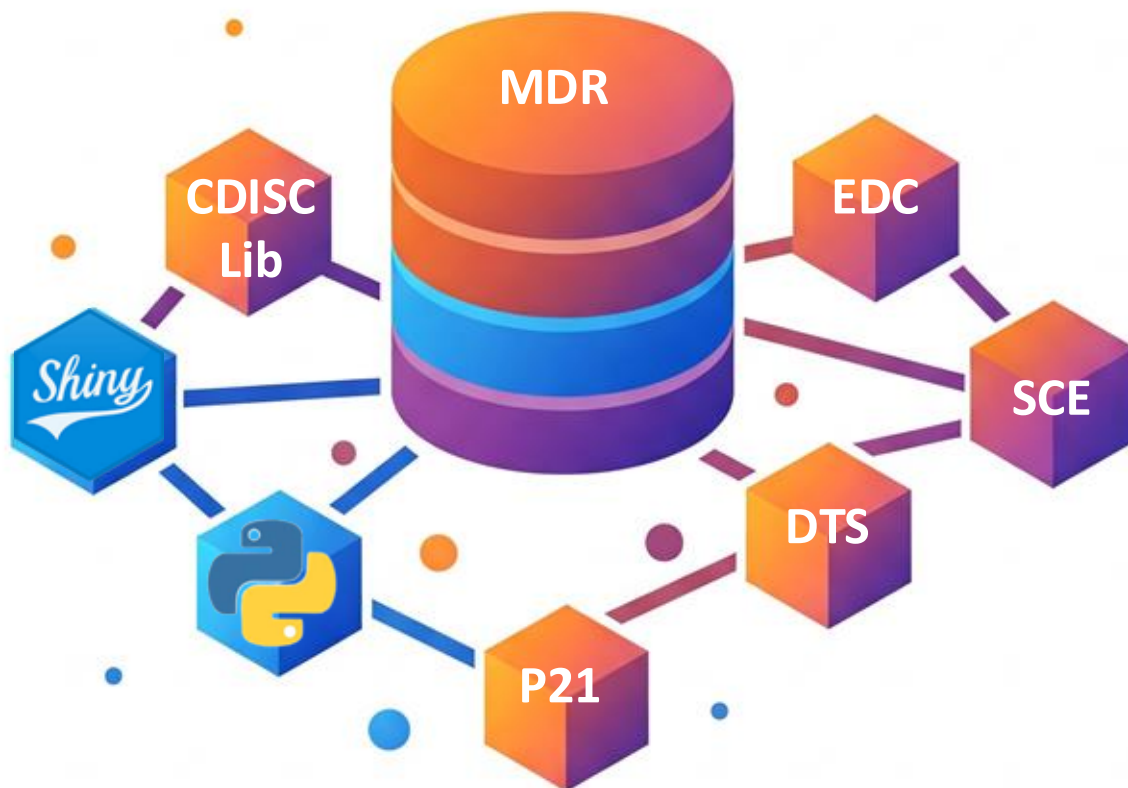


Example Rules to Validate Metadata

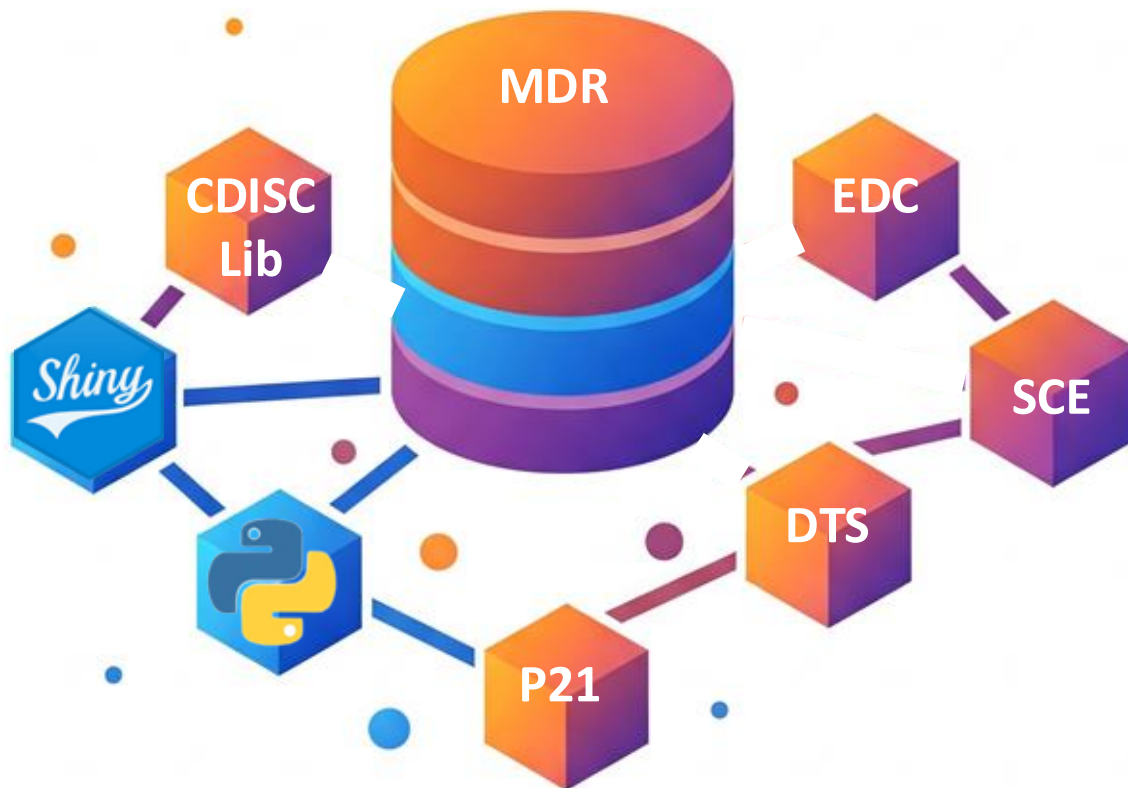
Rule Number	Rule Description	Rule Owner
MV.SDTM.Rule01	For a derived SDTM variable, i.e., when Origin = Derived, the variable must have a Method Definition.	Data Submission
MV.SDTM.Rule02	For an SDTM variable with Origin = CRF, the variable must have Page Numbers specified.	Data Submission
MV.SDTM.Rule03	For an SDTM variable mapped to a CRF variable, i.e., when Origin = CRF, the SDTM Mapping specification must mention the Form.Item, where Form.Item is the 2-level convention for specifying mappings. For an SDTM variable with an assigned value, i.e., when Origin = Assigned, the SDTM Mapping specification must mention a constant value in double quotes "value."	Data Submission



Execution - Where?



Execution - When?



So Many Packages & Versions



**Different outcome with each version -
Which package version I used in study X?**



pytorch 2.3.1



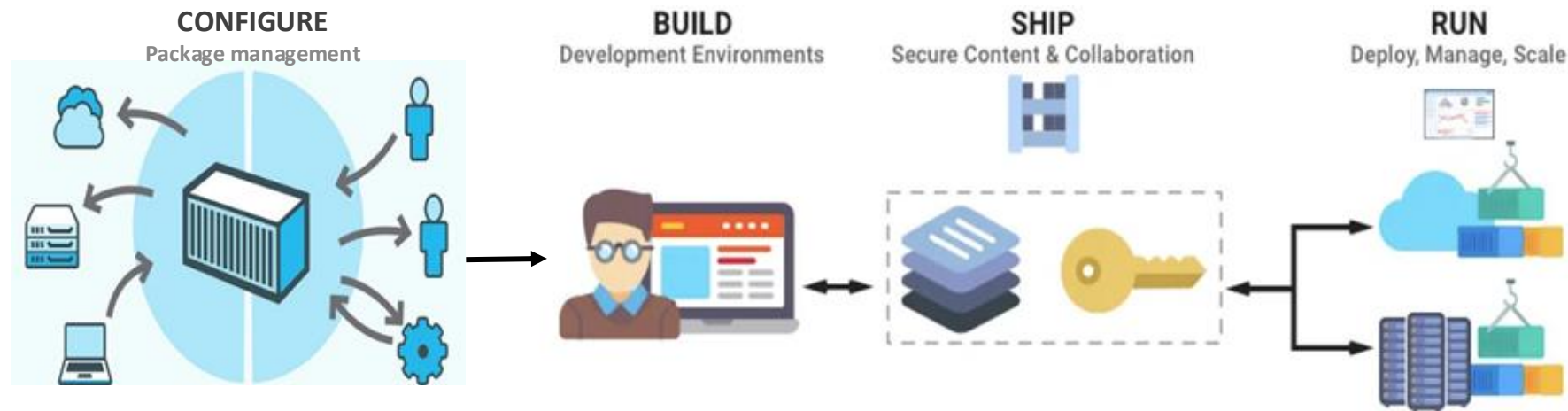
pytorch 2.4.0



pytorch 2.5.0
(dev20240901)



So Many Packages & Versioning - Problem Solved



Other Gen AI and Metadata Rules Use Cases

- Compare study specifications across MDR and EDC, CTMS, etc to ensure they are in sync
- Read Protocol to generate standard based study specifications and T Domains
- Get an early head-start to generate CSR with AI and rule-based Clinical Content Reuse from other study documents



Implementing Metadata Automations - Key Considerations



Reproducibility & Traceability



Integrations capabilities



Balancing cost & ROI



Data privacy & security



Change management



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Thank You
