



CDISC India Day

AI/ML Applications in Clinical Data Workflows





CDISC India Day

From Hours to Minutes: Automating SDRG and ADRG Creation with Gen-DRG

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Speakers



Deepika R
Program Lead
Zifo

Clinical data standards and statistical programming leader with experience in regulatory submission and CDISC implementation with around 6 years of experience.

Demonstrated ability to deliver high-quality, compliant, and efficient clinical programming solutions across multiple therapeutic areas while maintaining strong customer relationships and ensuring consistency.

Expertise:

Development / Review of SDTM, ADaM, Tables, Listings, Define.xml, aCRF, Pinnacle Validation, Reviewer's guide



Agenda

1. Abstract
2. Challenges with Existing Solutions
3. Gen-DRG Workflow
4. Tool Walkthrough
5. Advantages of Gen-DRG
6. ADRG walkthrough and Highlights
7. Gen-DRG 2.0





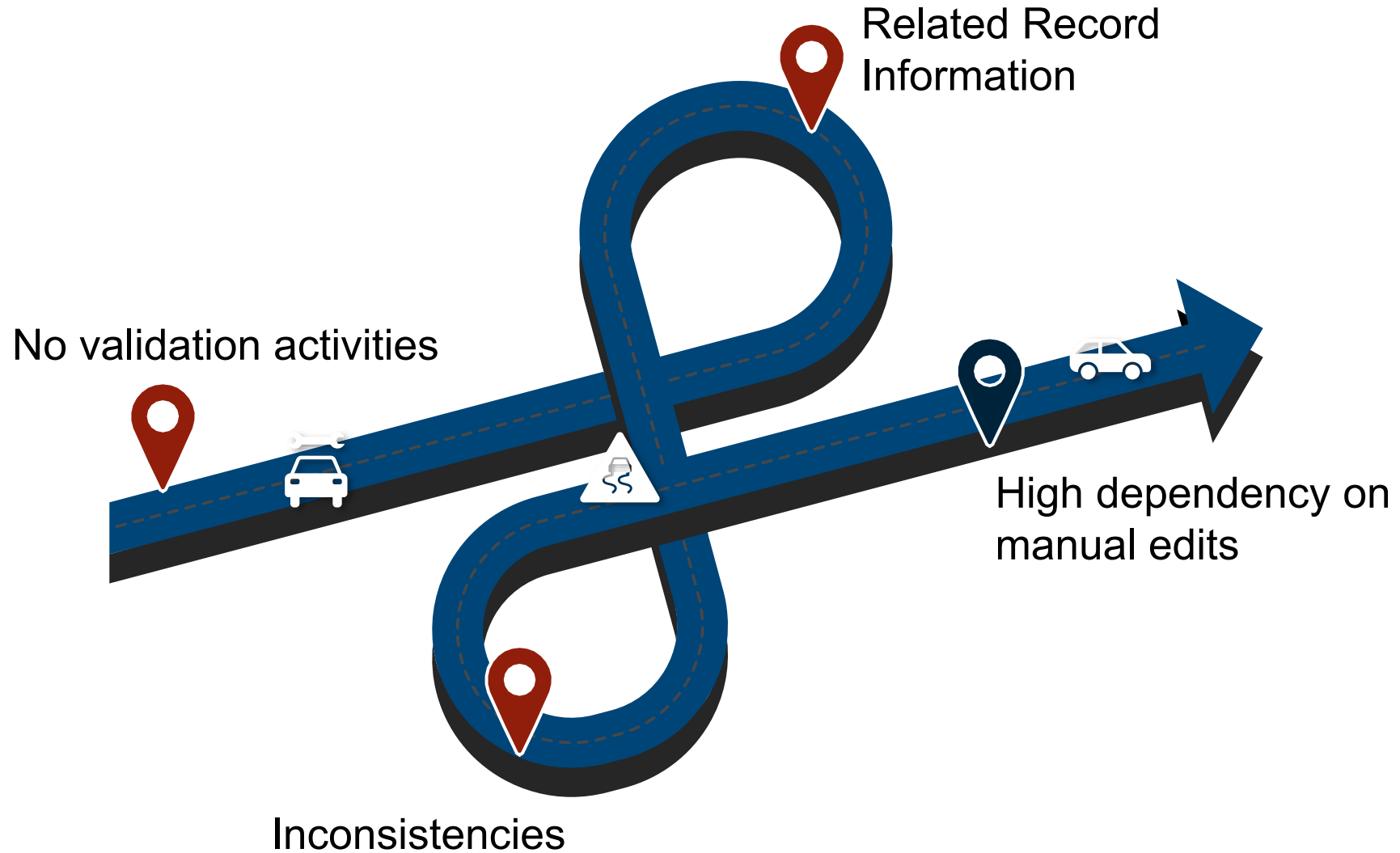
Abstract

Ever spent hours creating SDRGs and ADRGs, only to end up compiling same references, analyses, acronyms, and reviewer comments repeatedly? Reviewer guides are important for navigating submission packages but putting them together usually takes a lot of time and effort.

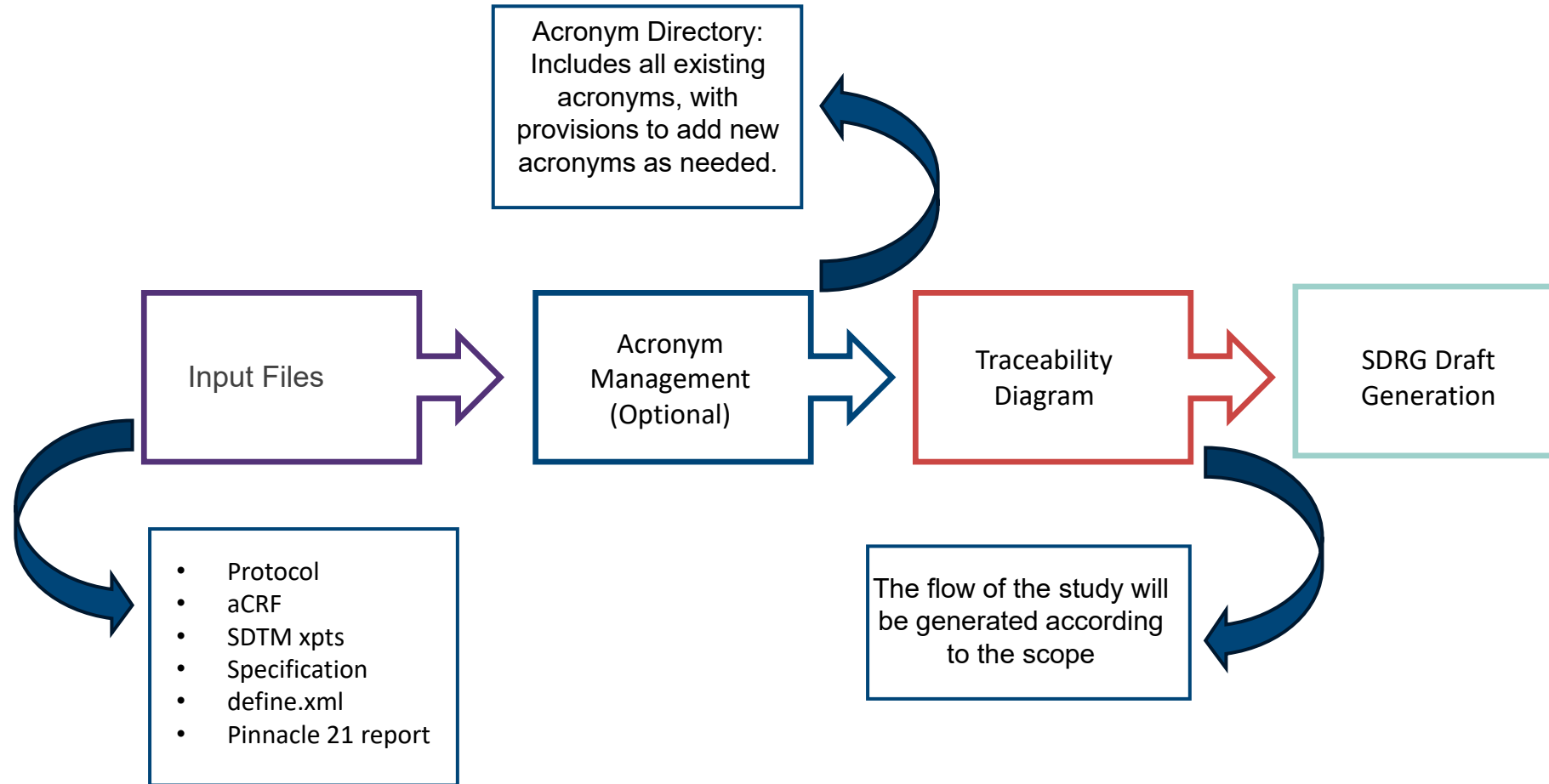
To solve this problem, we created Gen-DRG, an R Shiny app that makes it easier to draft SDRGs and ADRGs from different sources like Pinnacle SDTM specs, define.xml files, annotated CRFs, XPT datasets, and documents with reviewer comments. Gen-DRG can automatically create about 75–80% of a reviewer guide in just 3–4 minutes, cutting manual work by around 75%. Some highlights are its ability to generate acronym lists that meet FDA and PMDA standards, let users edit drafts as needed, and fill in missing QNAMs automatically. In our presentation, we will show how Gen-DRG speeds up reviewer guide creation and helps improve quality, consistency, and readiness for regulatory review.



Challenges with Existing Solutions



Gen-SDRG Workflow



Implementation Demo - SDRG

csdrg Creator

Create

Validate

Upload the zip file which has xpts and aCRF

Browse... No file selected

Choose latest Specification file created

Upload No file selected

Choose SDTM Define file

Upload No file selected

Choose latest Pinnacle file

Upload No file selected

Upload the protocols as zip file

Upload No file selected

Specify the Inclusion section number

Specify the Exclusion section number

Add the Acronyms that need to be filled in SDRG (For Section 1.2 (Optional))

Add the Acronyms from Repository

Add any other required Acronyms for this section

Acronym

Translation if known

Add Row

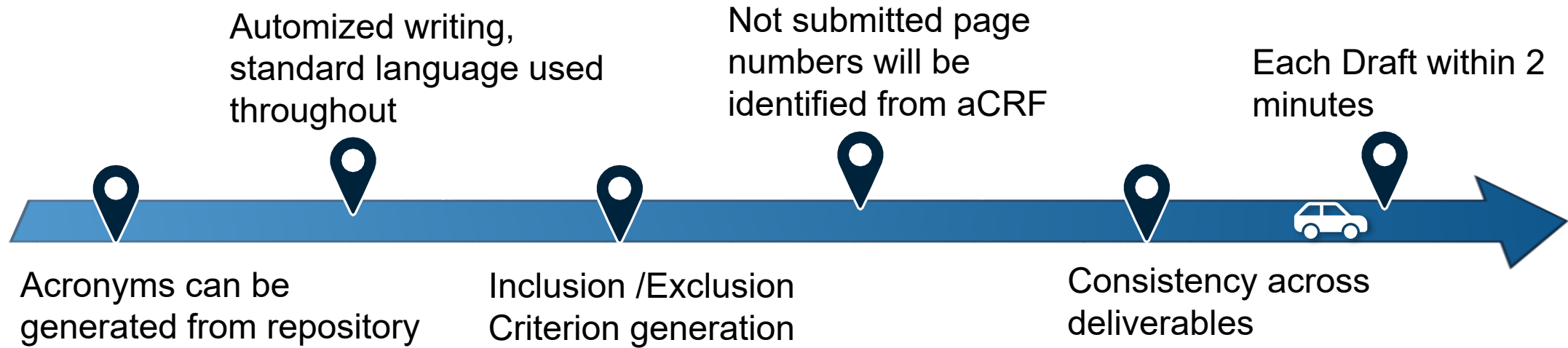
Show Acronyms Table

Choose the Scope of the Project (Note: This will be used for Flow Diagram in Section 3.2)

☐ SDTM Alone

☐ SDTM and ADaM

Advantages of Gen-DRG



Implementation Demo - ADRG

ADRG Creator

adrg

Validate

Enter Study Folder Path (e.g., C:/Users/ABC-001)

Upload the zip file which has xpts (Include TS.xpt)

Browse...

No file selected

Upload Study Tracker (Applicable when TLFs in scope)

Upload

No file selected

Choose latest Specification file created

Upload

No file selected

Choose latest Pinnacle file

Upload

No file selected

Add the Acronyms that need to be filled in ADRG (For Section 1.2 (Optional))

Add the Acronyms from Repository

Add any other required Acronyms for this section

Acronym

Translation if known

Add Row

Show Acronyms Table

Choose the regulatory body for Submission

☐ FDA

☐ PMDA

Create ADRG

Download ADRG

Download Error Log

cdisc®

What's Next?

01

Development Enhancement



- Smart Acronym mapping
- Consistency across RGs
- Optimized Eligibility criteria for multiple protocol versions ...

02

GEN-DRG as Reviewer



- Tense Validation
- Sequential Section numbering
- Alignment and Font Checker ...

03

Major leap



nSDRG ...

References

- FDA. Study Data Technical Conformance Guide: Technical Specifications Document. March 2018.
<https://www.fda.gov/media/88173/download>
- PHUSE. Analysis Data Reviewer's Guide (ADRG) Package. PHUSE Advance Hub.
<https://advance-phuse.atlassian.net/wiki/spaces/WEL/pages/26804660/Analysis+Data+Reviewer+s+Guide+ADRG+Package>
- Clinical Career Path. define.xml, ADRG & SDRG: The Submission Documentation Explained.
<https://clinicalcareerpath.com/define-xml-adrg-sdrg/>



Thank You!





Questions?





“Let machines handle the repetitive, so people can focus on creativity, innovation, and making a difference.”

