

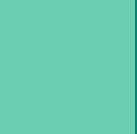
Paper ML27

Enhancing Clinical Study Report Authoring with Generative AI: Lessons Learned on TLF Formatting and Metadata Integration in Merck's iRAP Tool.

Madhusudhan Reddy Papasani, Elisabeth Pyle
Merck & Co., Inc., Rahway, NJ, USA



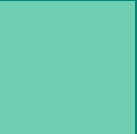
Agenda



Applying Gen AI Technology @ Merck



Merck's Gen AI Journey: Authoring Projects



iRAP (Intelligent Research Authoring Portal): a Tech Hub



CSR writing-Inputs



TLF Standardization checklist



Conclusion

Applying Gen AI Technology @ Merck

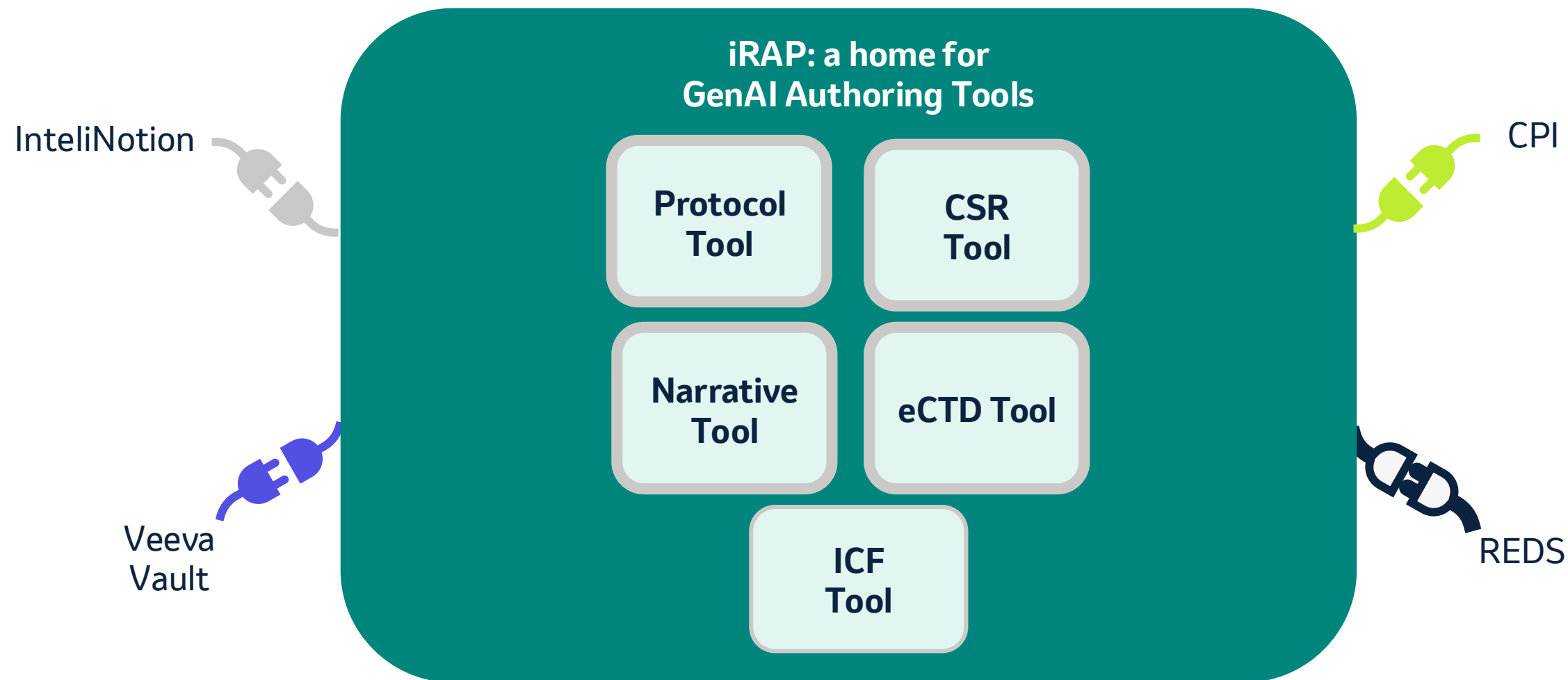
- ❑ GenAI technology is **rapidly advancing** and is transforming the businesses.
- ❑ Merck **embraces this technology** to remain competitive in the industry.
- ❑ Leverage GenAI tools can help increase our efficiency, **enabling us to deliver** on the anticipated portfolio expansion.



Merck's Gen AI Journey: Authoring Projects

Protocols	Clinical Study Reports	Patient Safety Narratives	eCTD
Objective: Create first drafts of prioritized protocol sections (~60% of a protocol document, NOT including Section 9) and the application of pre-approved library components Status: Several early adopter programs currently in progress	Objective: Create first drafts of CSRs incorporating TLFs Status: Several early adopter CSRs are currently in progress. 1 complete! Developed capacity for authoring of data summaries in specific situations; continuing to expand this capability	Objective: Create batches of narrative shells and clinical courses of events in parallel using study data Status: Transition to full adoption in progress	Objective: Create first drafts of clinical modules (2.5, 2.7.3, 2.7.4) incorporating TLFs Status: Several early adopter programs currently in progress

iRAP (Intelligent Research Authoring Portal): a Tech Hub



CSR writing - Inputs

Tables, Listings, and Figures	Data Meta File	Protocol	Standard CSR templet
• Tables and Figures in DOCX format • Listings in pdf format	• Structured Metadata for TLFs: DM files capture key details—file names, titles, type, layout, and linkage—enabling seamless integration of immutable TLFs into CSRs without source file access. • Ensures compatibility with iRAP-CSR, streamlining authoring and supporting accurate placement of TLFs in CSR body and appendices.	• Protocol in PDF format to get the study details	• Standard CSR template to populate the content

TLF Standardization checklist

DELIVERY FOLDER ORGANIZATION

- Store all immutable tables (that are in the docx format-the content can't be changed) and figures for the CSR in a single folder within the clinical production area (immutable-tbls).
- Include all waves of TLFs in the same folder as they become available, including patient-reported outcome (PRO) tables.
- Only tables and figures designated for the CSR body (Sections 10–14) should appear in the immutable table folder in **DOCX format**.
- Listings designated for the CSR appendix Section 16 should be placed in the csr-appendices folder in **PDF format**. The iRAP CSR tool does not currently accommodate listings in Sections 10–14.

DM FILE FORMAT

- Create one comprehensive DM file named **dm.xlsx** (case-sensitive) that includes TLFs from all waves.
- Only one DM file per CSR is allowed.
- Ensure file names in the DM file match those in the Delivery folder.
- Exclude listings designated for Section 16 and any temporary files (prefix ~\$).
- Exclude files that contain multiple tables in a single document.

CONTENT PROTECTION

- Apply content protection to all tables in DOCX files using the immutable table process.

TLF Standardization checklist-Continued

SENSITIVITY LABEL REMOVAL

- Ensure TLF DOCX files do not contain sensitivity labels (e.g., Public, Proprietary, Confidential). Users must avoid applying labels when closing files.

IMAGE FORMAT

- Use **PNG or JPG** formats for figures in DOCX files. WMF and EMF formats are not compatible.
- Standard graphic macros default to PNG; if figures are created outside these macros, specify PNG or JPG explicitly.

TLF FORMATTING CHECKS

- Ensure TLF titles in DOCX files:
 - Do not have leading/trailing new lines or excessive white spaces.
 - Are contained within a single paragraph (including subtitles).
 - Citations should also be in a single paragraph.
- One leading whitespace in the title is acceptable.
- Avoid additional spaces or line breaks that could cause formatting issues.

Conclusion

GenAI Accelerates CSR Authoring: Automates initial draft creation, enabling teams to focus on interpretation and clinical insights.

iRAP CSR + Standardization = Efficiency: Seamless integration of TLFs and DM files ensures accuracy and scalability.

Checklist is Key: Clear formatting and metadata guidelines reduce errors and support consistent, compliant outputs.

Adherence Drives Success: Following standards is essential to fully leverage GenAI and meet growing portfolio demands.

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Thank you

