

SMART CSRT

Clinical Study Report Automation using ML/NLP

THE PROBLEM

Clinical Study Report:

- It is a document, typically very long, providing much detail about the methods and results. A CSR is a scientific document addressing efficacy and safety.
- Creating Clinical Study Report (CSR) is highly manual and time consuming.
- The content of CSR is constructed from Protocol, CRF, SAP, Safety narratives, in-text tables ,TLFs and medical writer's interpretation of study results.
- No automotive way to handle Errors and multiple iterations

WHY AUTOMATION ?

- 60%-80% of Manual effort can be saved with creating a template using the ML/NLP tool.
- Effective use and reuse of the template for an organization or Therapeutic area or Compound.
- The ML Prediction algorithm along with NLP is used to identify/effectively used to read the texts from other PDF documents such as Protocol, SAP, CRF & etc.,
- The CSR Template will be created based on ICH -E3 guidelines
- The medical writers can focus more on discussion points and interpretation of study results.

BLANK CSR TEMPLATE

1. TITLE PAGE
2. STUDY SYNOPSIS
3. TABLE OF CONTENTS
4. LIST OF ABBREVIATIONS & DEFINITION OF TERMS
5. ETHICS AND REGULATORY APPROVAL
6. INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE
7. INTRODUCTION
8. STUDY OBJECTIVES
9. INVESTIGATIONAL PLAN
10. STUDY POPULATION
11. RESULTS
12. SAFETY EVALUATION
13. DISCUSSION AND OVERALL CONCLUSIONS
14. TABLES, FIGURES AND GRAPHS
15. REFERENCES
16. APPENDICES

ICH E3(INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION ON PHARMACEUTICALS FOR HUMAN USE)

- ICH E3, provides recommendation of CSR structure , organization and content.
- Symbiance.AI elected to follow ICH E3 for CSR to build CSR Template tool.
- **Section 1-15 (CSR Body)**
 - ❑ **Section 1-9 -:** Planned aspects of the study (ie, Protocol, SAP)
 - ❑ **Section 10-15 -:** Study outcome (ie, results, analysis, and interpretation)
 - Section 10 = Study Objectives
 - Section 11 = Efficacy
 - Section 12 = Safety
 - Section 13 = Discussion/Conclusion
 - Section 14 = Tables & Figures
 - Section 15 = Reference
- **Section 16 (CSR Appendices)**
 - Section 16.1 = Study information
 - Section 16.2 = Subject Data Listings

TABLES, LISTINGS & FIGURES

All files to be bookmarked with Full Table Title

❑ **Section 14** = Tables, Figures and Graphs Referred to but Not Included in the Text

- Section 14.1 - Demographic Data
- Section 14.2 - Efficacy Data
- Section 14.3 - Safety Data

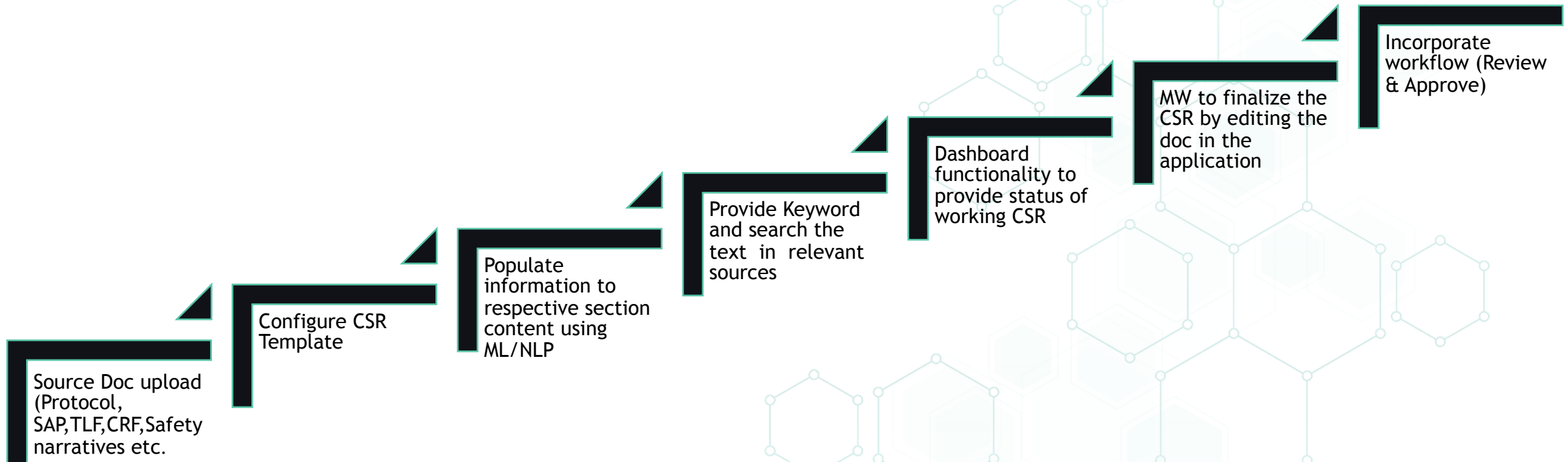
Note: Per eCTD, Section 14 is part of the CSR body

❑ **Section 16.2** = Subject Data Listings

- Appendix 16.2.1 Discontinued Subjects
- Appendix 16.2.2 Protocol Deviations
- Appendix 16.2.3 Subjects Excluded From Analyses
- Appendix 16.2.4 Demography Data
- Appendix 16.2.5 Compliance and/or Drug Concentration Data
- Appendix 16.2.6 Efficacy Data
- Appendix 16.2.7 Adverse Event Listing
- Appendix 16.2.8 Listing of Individual Laboratory Measurements by Subject

Note: Per eCTD, each appendix is a separate document from the CSR body (ie, Sections 1-15)

STEPS



PROCESS

Inputs to Generate CSR word Template

Protocol



SAP



CRF



Narratives



TLF

In-text tables

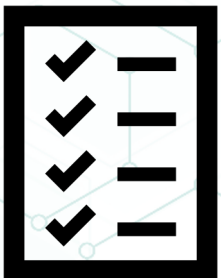


CSR Template with populated required information using ML/AI



Final CSR Additional information provided by clinical writers

MW input & summary



CONCLUSION

- Blank CSR Template Generation in a word format
- Populating required content from protocol, SAP, In-text Tables & TLF in the blank CSR Template
- ICH guidelines - E3 compliance
- Using ML 60-80% of information from other source documents is populated and generated in CSRT by saving medical writers time.



QUESTIONS ??