



ZYLiQ
ACCELERATE MEDICAL WRITING



AI application for authoring Clinical Study Report
(ZYLiQ) – SD01

What are we trying to solve?

Clinical Study Report

- ❑ Creating Clinical Study Report (CSR) is highly manual and time consuming.
- ❑ The content of CSR is constructed from Protocol, SAP, Safety narratives, in-text tables and medical writer's interpretation of study results.
- ❑ No automative way to handle Manual Errors and multiple iterations

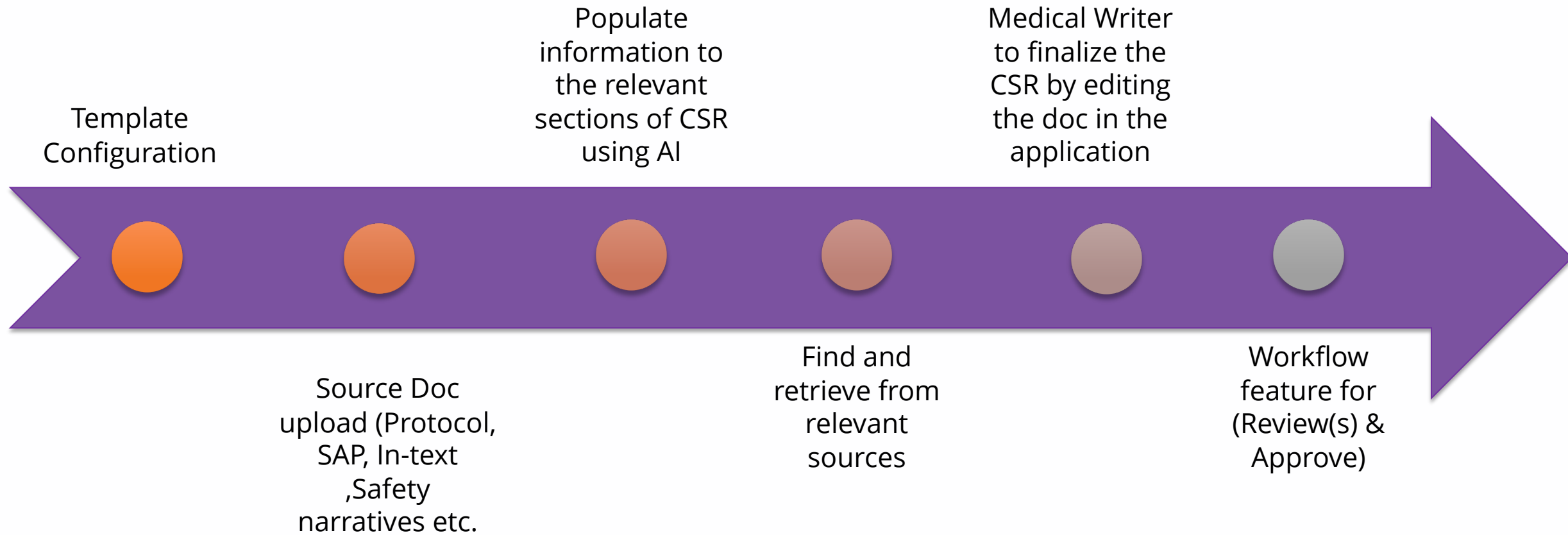
Why automation ?

- ❑ The goal is to bring 65-75% of efficiency by automating CSR writing, MW can focus on the Interpretation and discussion points.
- ❑ Effective use and reuse of the template for an organization or therapeutic area or compound.
- ❑ The ML prediction algorithm along with NLP/NLG is used to identify/effectively used to read/write the texts from other documents such as Protocol, SAP, In-text Table & etc.,
- ❑ The CSR Template will be created based on ICH –E3 guidelines

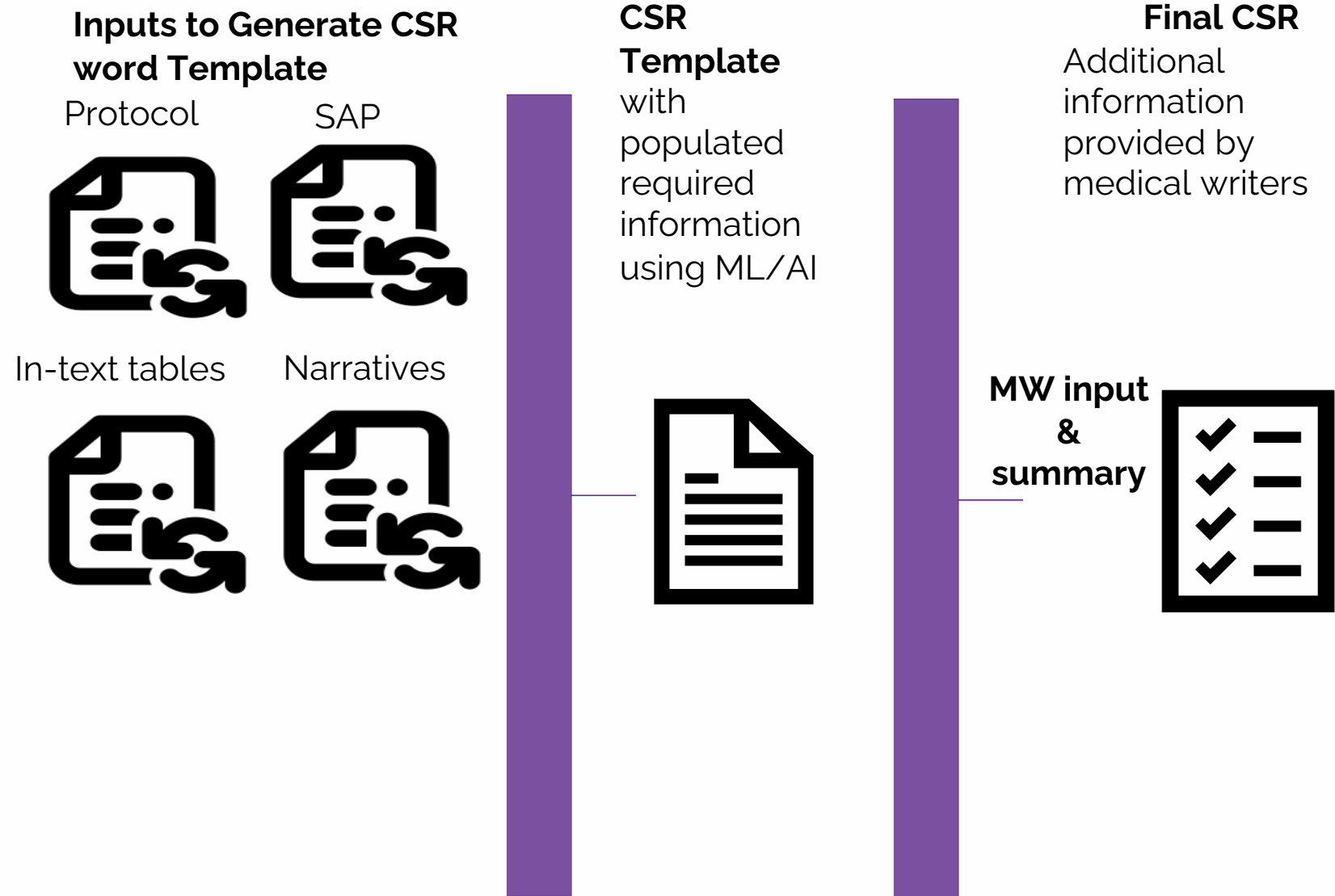
Blank CSR Template

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

ZYLiQ Steps



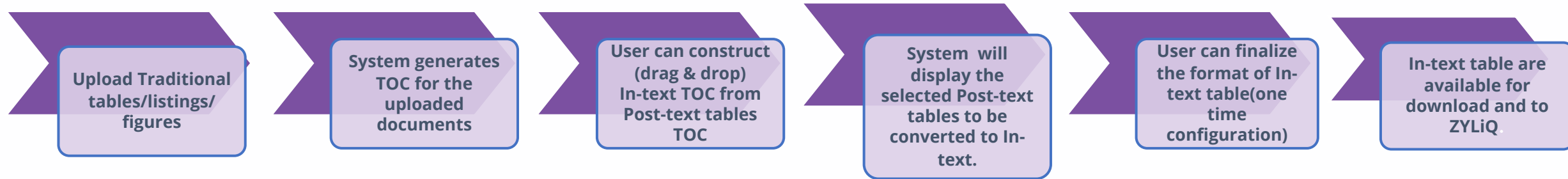
Process



ZYLiQ Highlights

- ❑ MW can add or modify the content by **section within the system.**
- ❑ Multi-Authoring (can have more than one authors for same study)
- ❑ Conversion of post-text TLF to In-text tables
- ❑ ZYLiQ editor functions as MS word and have the same look and feel.
- ❑ Traceability Report(source file to final CSR mapping), Audit Log & Version History
- ❑ Workflow integration(Author(s), Reviewer(s) & Approver)
- ❑ Narrative writing from Patient profiles/ Subject Listing .
- ❑ In-text table interpretation in simple English.
- ❑ Automatic Tense conversion (Present/future tense to past tense)

Converting Post-text tables to In-text tables





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Thank you!!

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