

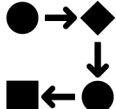
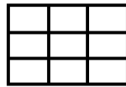


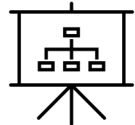
Single Day Event

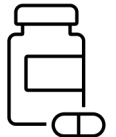
Leverage AI in Clinical data and study reports generation
Ramesh /Divya, Symbiance



LEVERAGING AI IN CLINICAL DATA AND STUDY REPORTS GENERATION

1. Standardization of clinical data  

2. Analysis & Reporting  

3. Clinical Study Report  

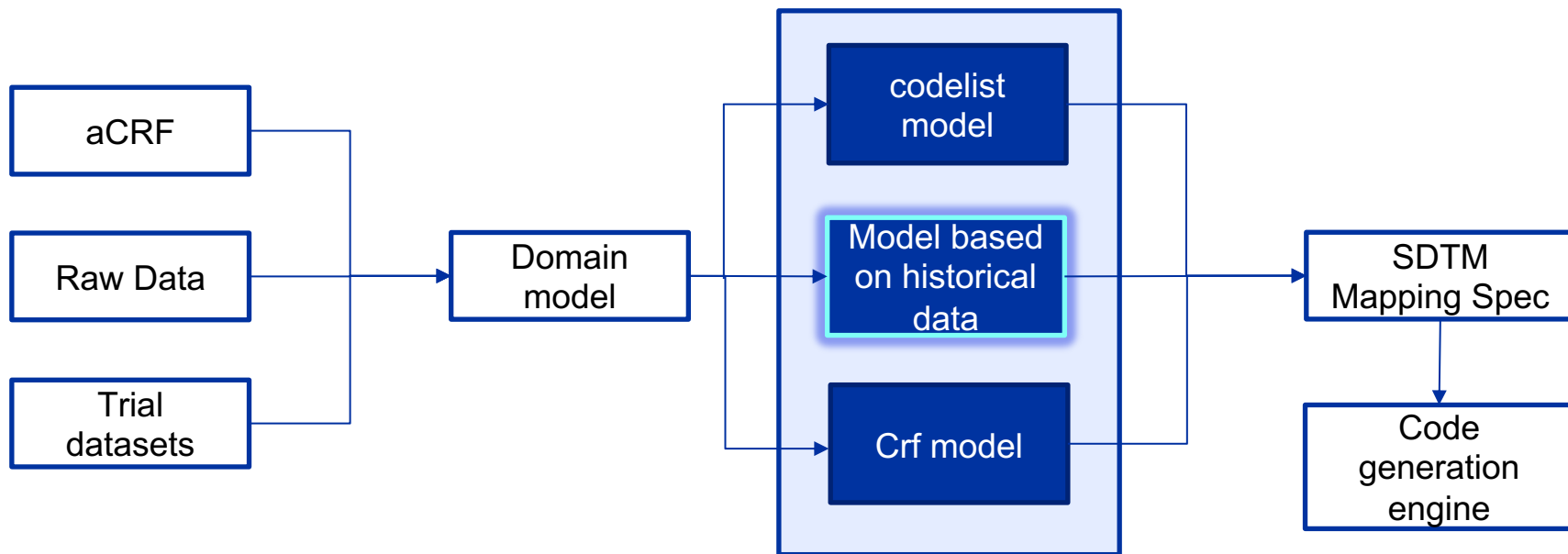


STANDARDIZATION OF CLINICAL DATA

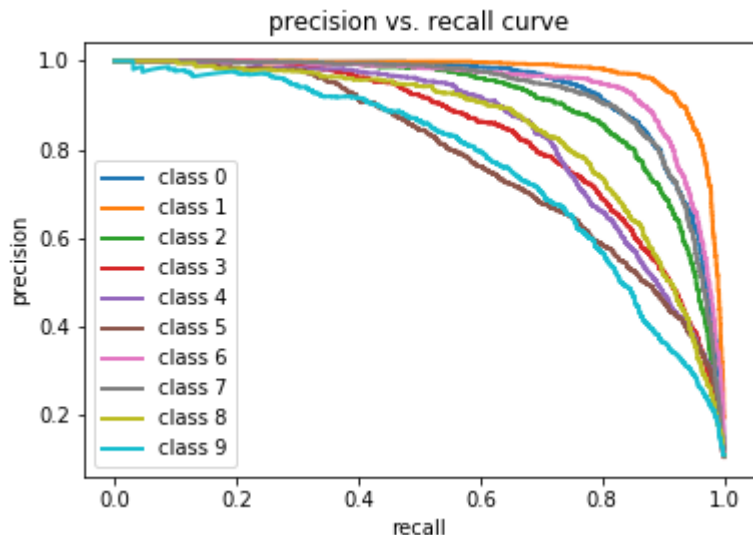
Objective

- Map raw variables to appropriate Sdtm variables with high precision by using ensemble of multiple models
- Reduce programmers effort by automating the repetitive work
- Build model which could retrain itself from feedback

Transforming raw data to SDTM



Augment model reliability



Note: illustrated sample of precision recall curves for multiclass classification

- Threshold is identified individually for each domain using Precision Recall curves
- Precision is maintained high by choosing the appropriate threshold value.



ANALYSIS & REPORTING

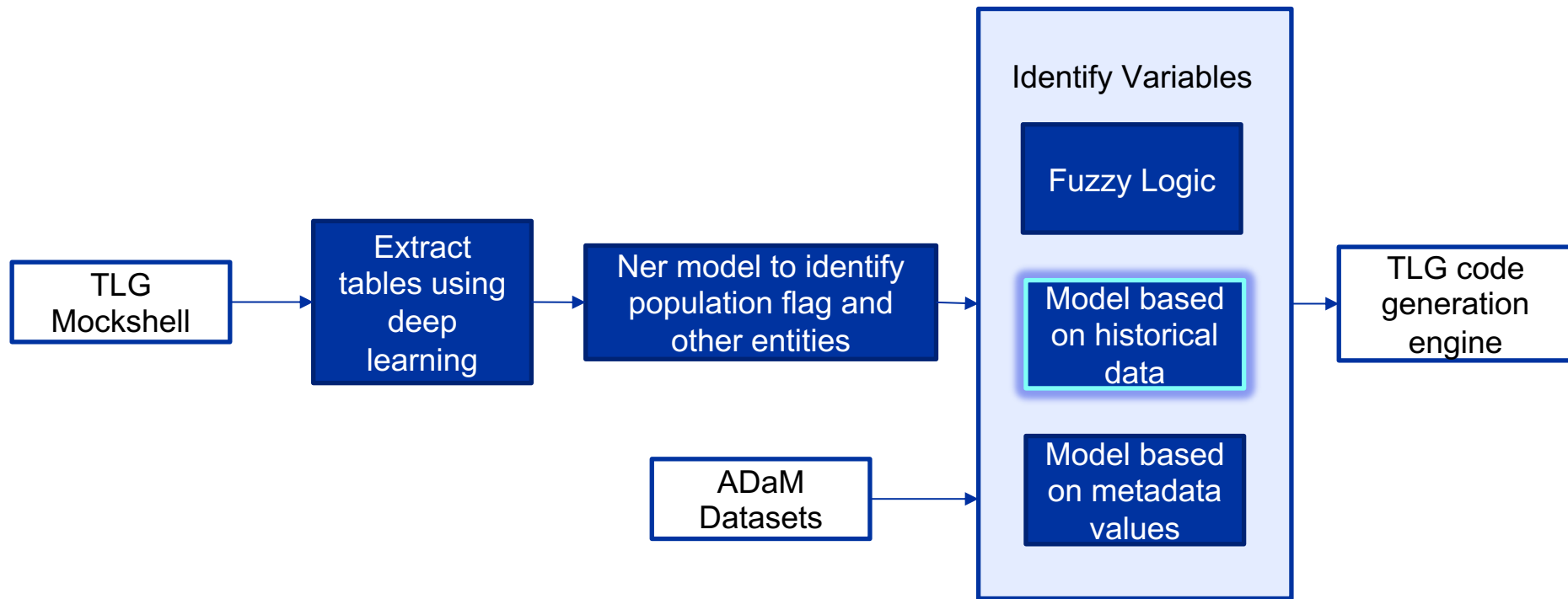
Objective

- Mockshell -> Tables, listings and figures
- Identify table structure, tag population flag, annotate categories and subcategories and construct TLF from parsed/mapped information.



ANALYSIS & REPORTING

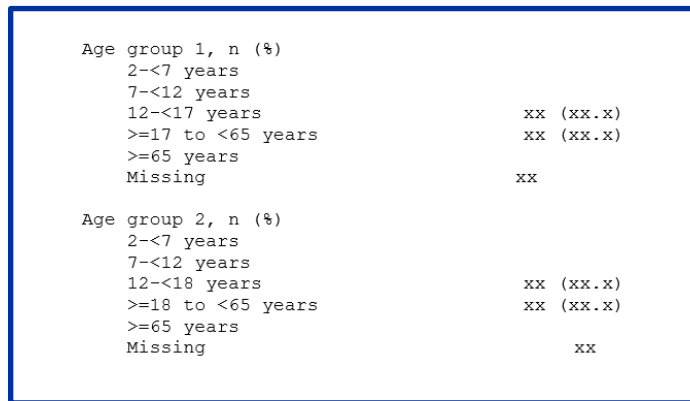
ADaM dataset to TLG





ANALYSIS & REPORTING

Fuzzy logic to match subcategories



Unique values from
ADaM Datasets

Fuzzy
Logic

Mockshell Value	Dataset Value From AGEGRP01
2-<7 years	2 to 7 years
7-<12 years	7 to 12 years
12-<17 years	12 to 17 years
>=17 to <65 years	17 to 65 years
>=65 years	Above 65 years



WHY DID WE FIND AI ASSISTANCE?

- ❖ The CSR's inputs and outputs are both unstructured data (pdf/word documents).
- ❖ Creating a Clinical Study Report (CSR) describes the clinical study's end points, data collection, and safety and efficacy analysis.
- ❖ CSR authoring is a time-consuming and laborious process, so the goal is to increase 60-70% efficiency by automating the CSR writing so that MW can focus on the interpretation and discussion points.
- ❖ The content of CSR is constructed from Protocol, SAP, Safety narratives, In-text tables and medical writer's interpretation of study results.
- ❖ The ML prediction algorithm, in conjunction with NLP/NLG, is used to identify/effectively read/write texts from other documents such as Protocol, SAP, In-text Tables, and so on.
- ❖ The CSR Template will be created in accordance with the ICH -E3 guidelines.

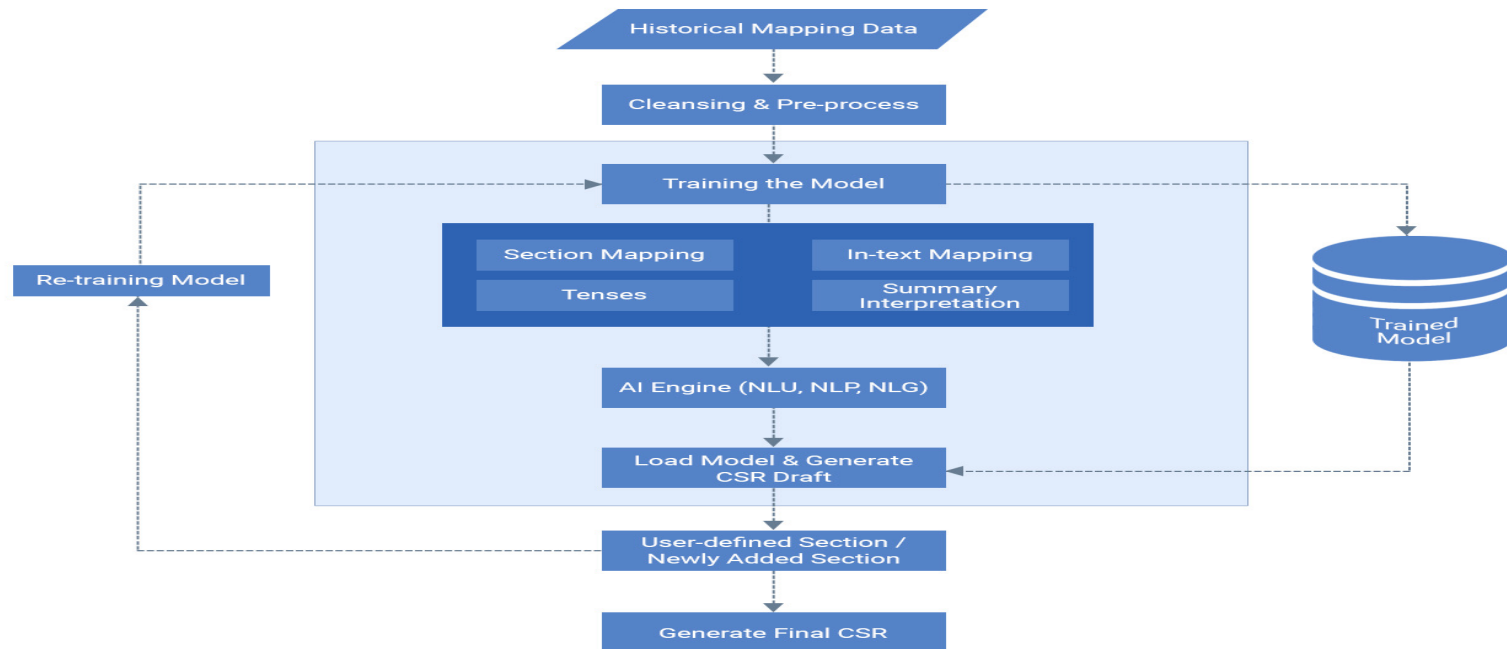


WHERE DID WE FIND AI ASSISTANCE?

- ❖ Extracting data from source documents (PDF/Word, formatting and special symbols, subscript & superscripts and diagrams)
- ❖ Summarizing large paragraphs using NLU & NLG for CSR synopsis
- ❖ Reading the data from the unstructured TLFs & table details extraction of data and interpretation in simple English
- ❖ Tense conversion
- ❖ Section mapping

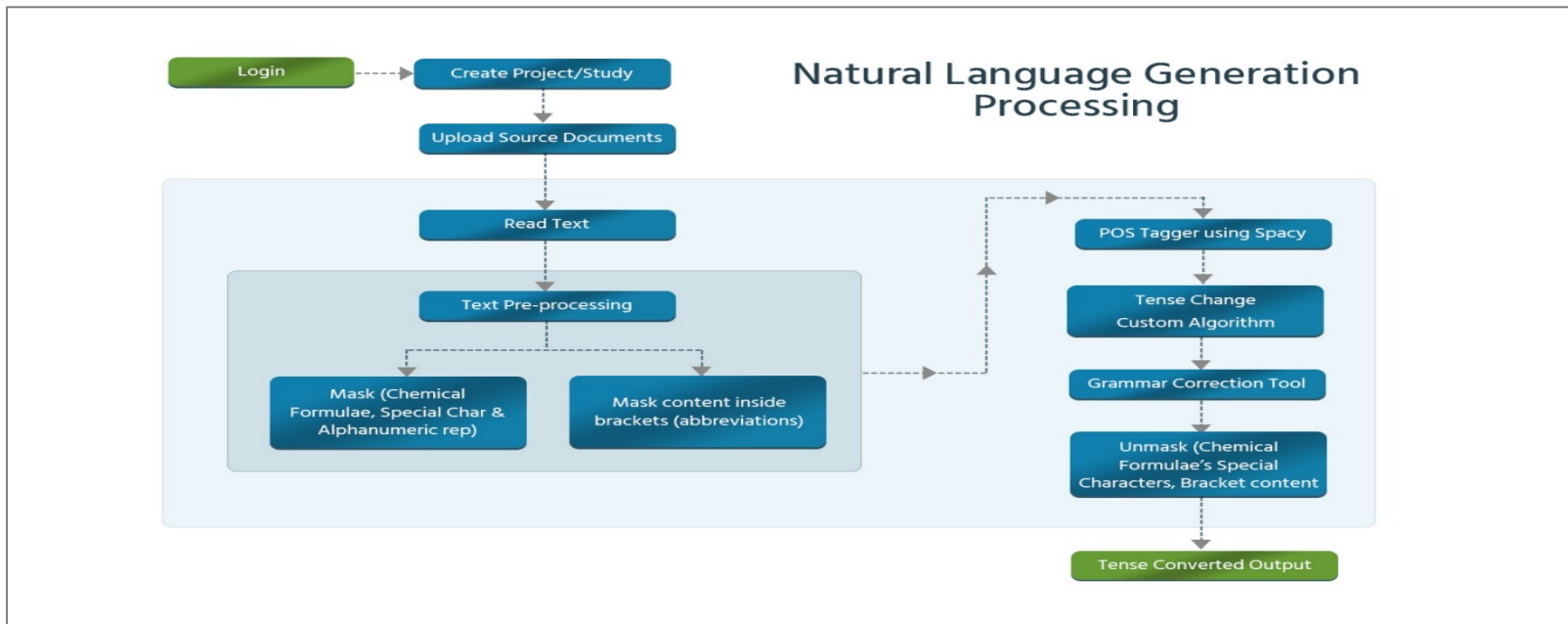


HOW IS ARTIFICIAL INTELLIGENCE USED?





NLG TENSE SHIFT AI





TLF – DATA TO TEXT INFERENCE





The Global Healthcare Data Science Community

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Social Media

- @phusetwitta
- /phusebook
- /phusetube
- /company/phuse