



Single Day Event

Leveraging AI techniques in clinical data submission processes

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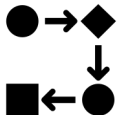
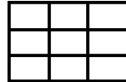
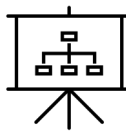


AI's Techniques & it's Usage

Machine Learning & Deep Learning (ML & DL)	Natural Language Processing (NLP)	Natural language Generation (NLG)
• Risk and trend Prediction are valuable outcomes of ML that is a vital factor to save time and money. • ML capability reduces manual redundant work and saves huge time	• Helps to identify and map relationship between data entities • Extraction of unstructured data and converting it into meaningful insights	• System articulation and augmentation from extracted/analysed data • NLG based human machine interface offers better info communication



Leveraging AI in Multiple Functions

1. Standardization of clinical data  
2. Analysis & Reporting  
3. Clinical Study Report  



Standardization of clinical data

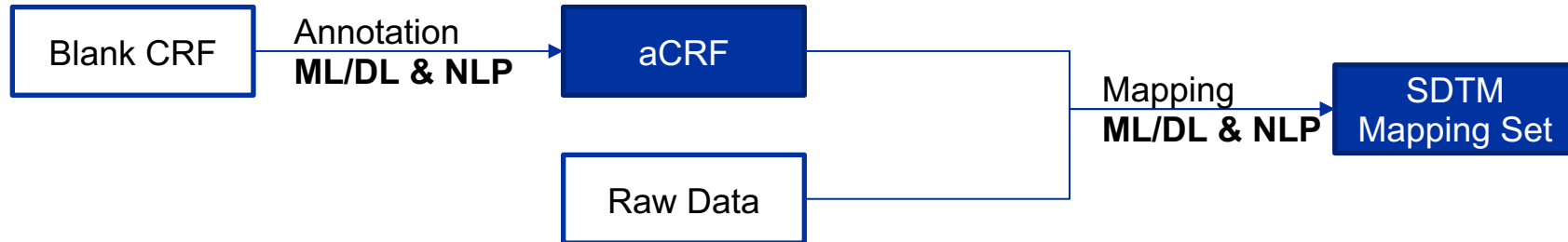
- **Clinical Report Form (CRF) annotation**
 - Domain and variable prediction based on trained data
 - Training based on therapeutical area
 - Reusability of Newly trained form
 - Training system based on annotated CRF (aCRF) to reduce redundant manual efforts



Standardization of clinical data

Transforming raw data to SDTM

- SDTM Domain mapping using Prediction logic and historical data
- SDTM variable Mapping using Prediction logic and historical data
- Variable derivation identification based on study similarity and therapeutical area



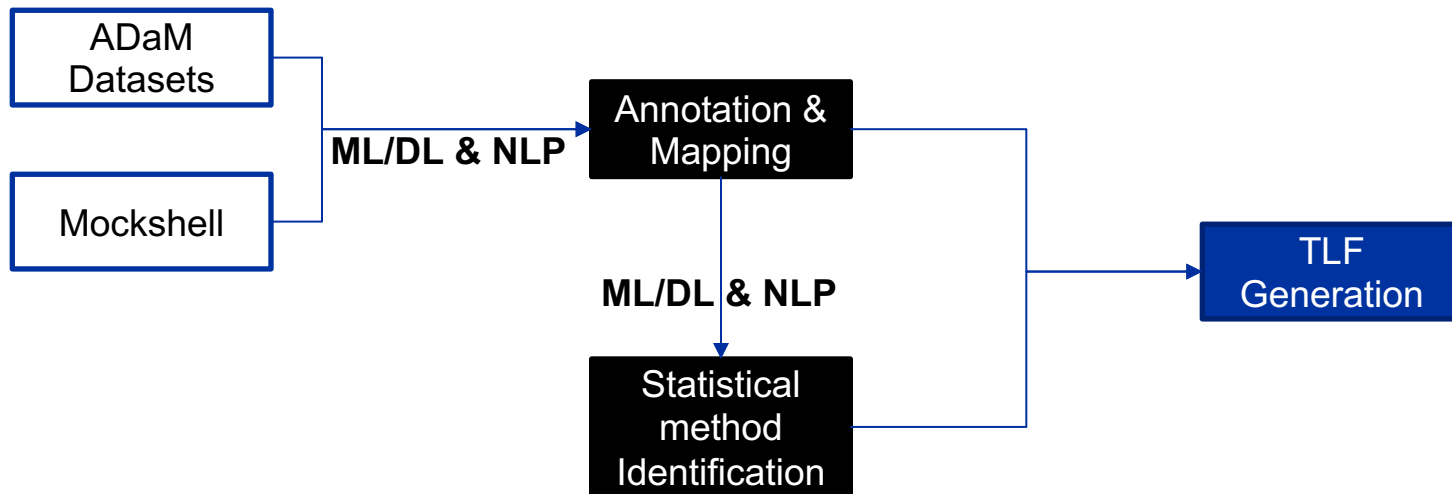
Legends

Input

Outcome



Analysis & Reporting



Legends

Input

Process

Outcome

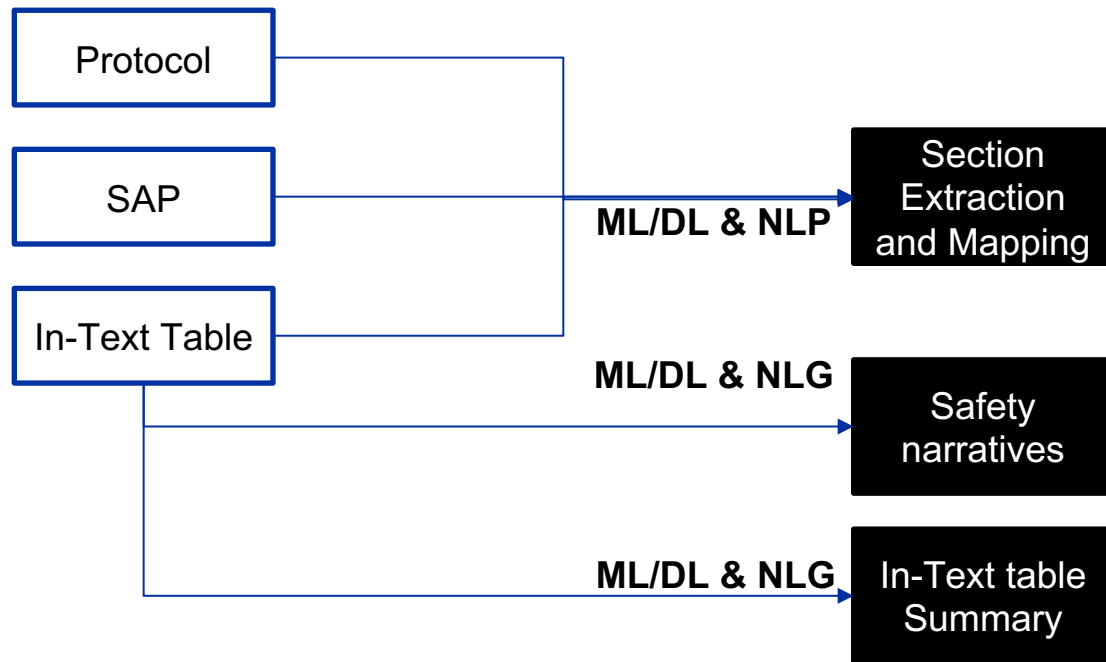


Clinical Study Report

ML / DL & NLP	NLG
Section Extraction - Extraction of relevant sections can be done from source documents such as protocol and SAP based on ICH- E3 guidelines Section Mapping - Extracted sections' contents can be placed under appropriate titles	In-text Table Summary NLG can be used to generate the summary of any in-text table Safety Narrative To Generate safety narrative text from the Serious adverse Events Listing present in in-text table



Clinical Study Report



Thank You!



Ai BioStats



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Data Science Community**

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