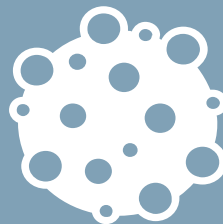




Global Reach



Speed & Delivery



Therapeutic Knowledge



Creative Solutions

Artificial Intelligence in Clinical Trials

Silvester Patil

Manager of Programming, Biostatistics and Programming

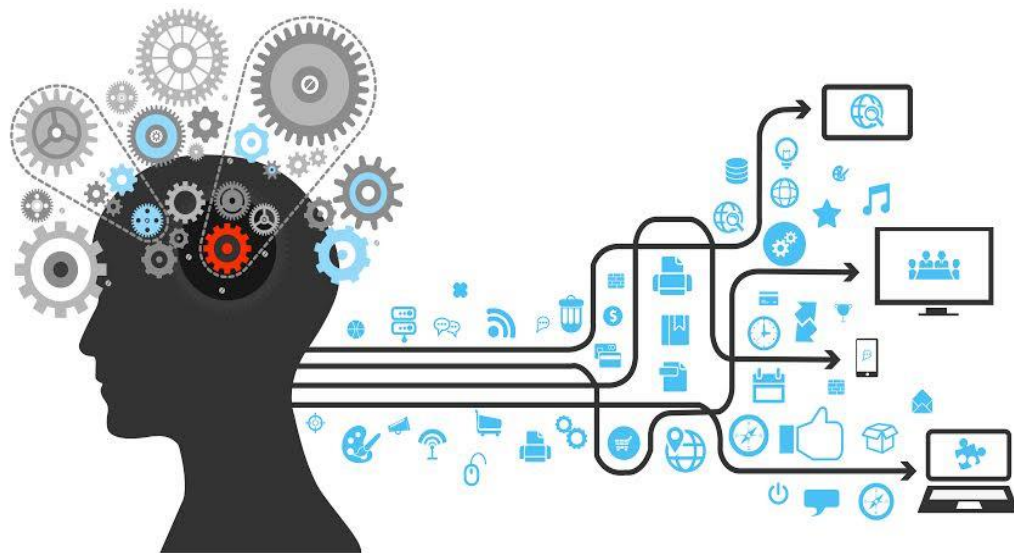


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Agenda

- + Introduction (Brief about AI)
- + Regulatory Writing with the help of AI
- + SDTM Mapping using Machine Learning Technique
- + Summary
- + Q&A



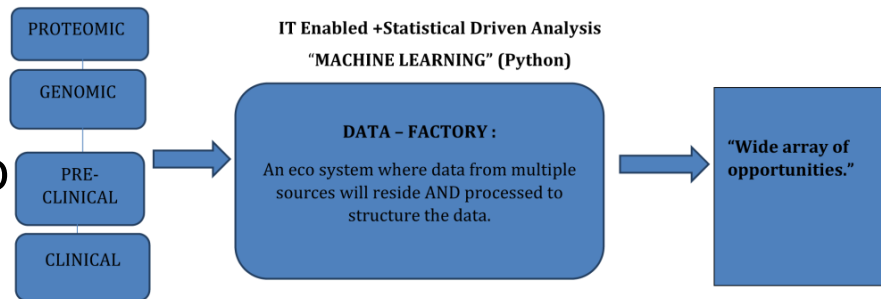
Introduction

+ Artificial Intelligence:

- It is the next gen technologies of exploring data.
- The intelligent machines that work and react like humans.

+ Machine Learning:

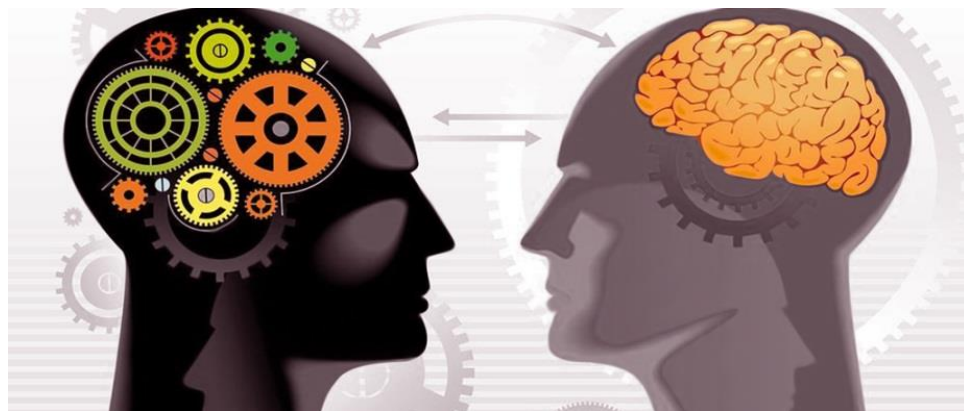
- Provides computers to learn by itself without being explicitly programmed.
- Focuses on the development of computer programs that can change when exposed to new data.



E.g. Data Flow from multiple sources and processed using specific algorithms

Introduction (contd.)

- + In regulatory writing, AI will help understand the context of information in study documents and will interpret where it belongs in each study report section.
- + In SDTM Mapping, Machine Learning algorithms and patterns will help to derive and predict possible mappings from EDC to SDTM datasets.



Regulatory Writing using AI technology

- + Pharmaceutical companies make use of structured authoring to streamline document writing.
- + With the use of AI we can achieve as below:
 - Moving to contextual based understanding rather than relying on a structured content.
 - Adjust approaches based on smart and learning objects.
 - Automatically Interpret the type of input data to develop the appropriate output reports.



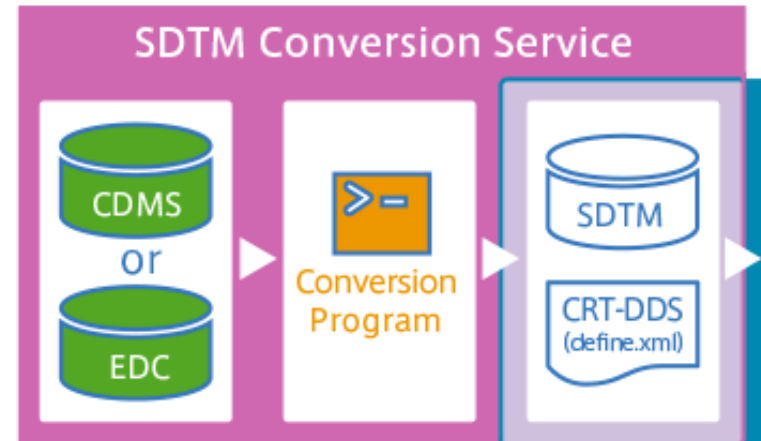
Regulatory Writing using AI technology

- + Efforts in writing a CSR involves identifying information in study documents and putting it in right tense.
- + AI will help speed up the process of CSR writing by taking information from study documents and putting it into the right places in the CSR.
- + The benefits of such approach include:
 - Smarter data interpretation
 - Faster data manipulation
 - More efficient and cost effective generation of the outputs



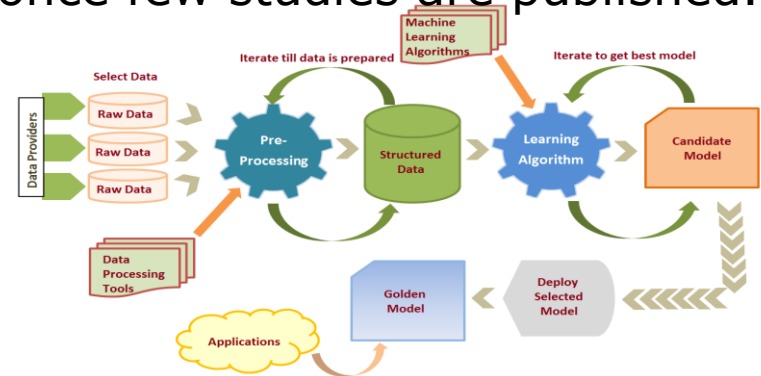
SDTM Mapping using Machine Learning

- + In our industry, mapping raw data to CDSIC standards is one of the most challenging process.
- + Reusing the information from previously mapped studies and building upon that knowledge is the important part of mapping.
- + Every organization follow a different process to create the SDTM domains.



SDTM Mapping using Machine Learning

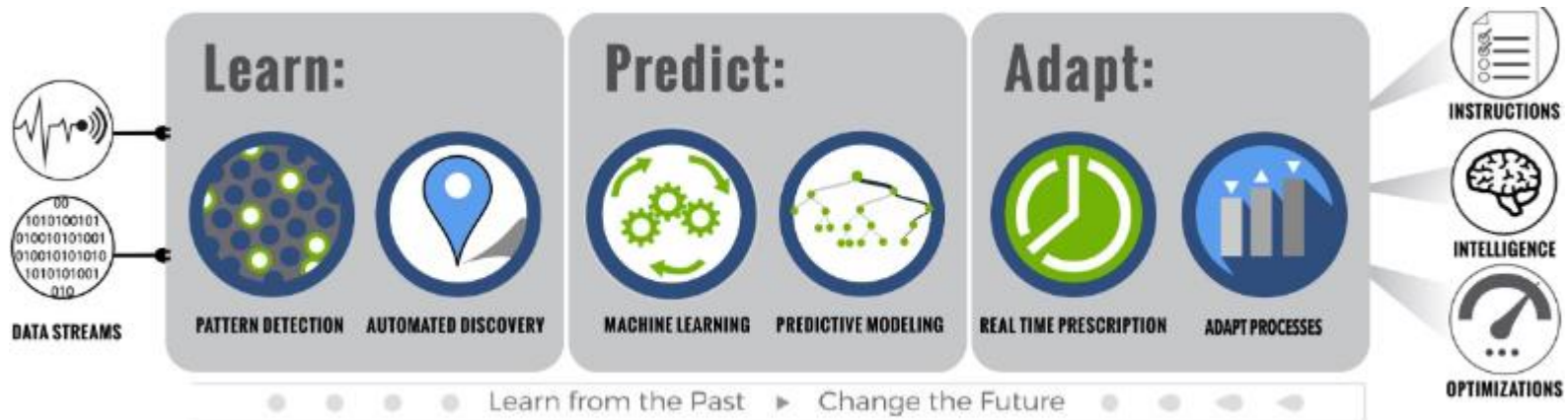
- + The approach is to have a web-based tool that provides a user friendly interface for mapping raw datasets to SDTM domains.
- + The tool provides users to:
 - Manually assign the data to target variables if working on first study.
 - Make use of smart-mapping and auto-mapping features to populate variable mappings in each domain once few studies are published.
 - Generate mapping specification
 - Allow users to generate SAS program shell for each domain (This won't be a validated code)



SDTM Mapping using Machine Learning

+ This Machine Learning technique will lead to:

- Improvements in Quality
- Efficiency
- Consistency
- Time Reduction



Summary

- + In regulatory writing, moving from structured way to contextual based approach.
- + AI will help automate more than 50% of time spent writing CSRs where the Medical writers can focus more on the parts of the CSR that require higher level scientific interpretation.
- + Tool based mapping of SDTMs based on below components:
 - Initial study setup (Enter required study information)
 - Raw data standards and Controlled Terminology
 - Variable Mapping and create SDTM specifications
 - Generate SAS program shells
- + The idea behind using this technology is not human versus machine, it is human and machine versus the problem. With AI, you will accomplish more in less time with quality.

Q&A

References:

- Images - <https://images.google.com/>
- <https://www.youtube.com/watch?v=mJeNghZXtMo>
- <https://www.youtube.com/watch?v=cKxRvEZd3Mw>
- https://www.sas.com/en_us/services/offerings/results-as-a-service.html
- <https://www.certara.com/2017/04/21/how-ai-tech-is-changing-regulatory-writing/?ap%5B0%5D=RW>
- <http://medcraveonline.com/BBIJ/BBIJ-05-00135.php>

THANK YOU

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