Society for Clinical Data Management
DATA DRIVEN

Theme:
Capabilities | Collaboration |
Change on the way to Clinical Data Science

SCDM Live

India conference

2nd - 3rd December 2022
Radisson Blu Hotel, Bengaluru

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DAY 2 : 03-DEC-2022

Parallel Track – 4 (2.00 PM to 3.30 PM IST)

Unveiling the impact of AI initiatives in Clinical Data Management

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Session Chair and Speakers

Santosh Karthikeyan
Session Chair

Kedar Deshpande
Speaker

Ayush Mittal
Speaker

Soumya Veerla
Speaker

Abhishek Kadam
Speaker

Shreyans Patel
Speaker

Agenda

S. No.	Agenda	Duration
1	Slido – Have your say	15 mins
2	AI influencing Quality and Efficiency – Kedar & Ayush	20 mins
3	AI Assisted Data Review for Significant Efficiency & Accuracy - Soumya	20 mins
4	Under the Hood, AI Empowers CDM – Abhishek & Shreyans	20 mins
5	Q&A	10 mins

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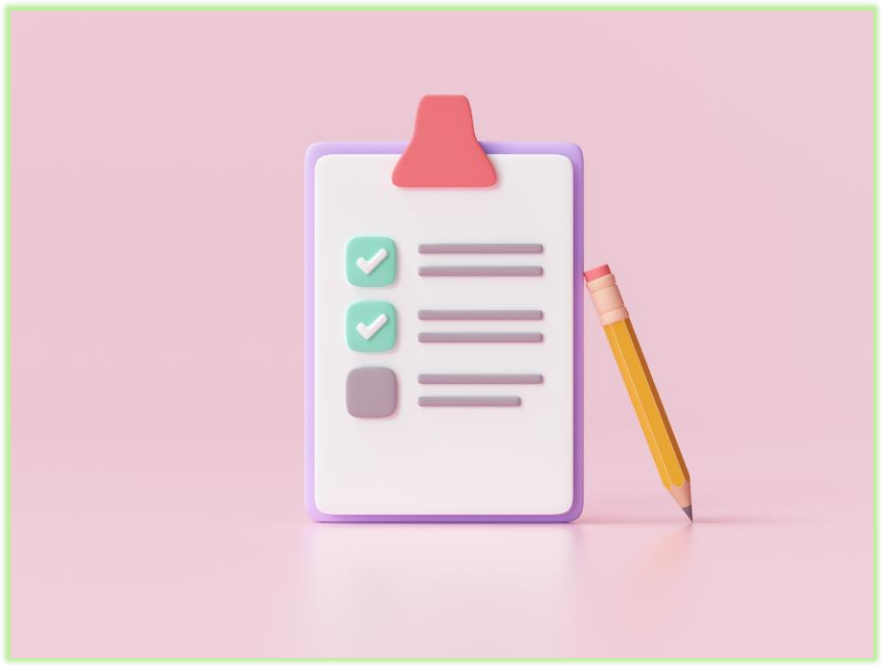
Have your say



Please open https://www.slido.com in your web browser and provide the code **#SCDMINDIA** or scan the below QR code

Presentation (Kedar & Ayush)

AI influencing Quality and Efficiency

Artificial Intelligence (AI) can enhance clinical trials and augment human efforts by enabling quick and easy access to data and documents. AI powered tools and solutions can fully adapt to user needs and can automate, accelerate, and optimize processes in clinical trials.

The availability of an AI-enabled tool that allows users to upload, select, search, compare, and download required information from clinical trial documents can bring much-needed change and cause a revolution in the clinical research field.

Problem Statement

Pharma, CRO, BPO and Tech companies are required to generate number of delivery ready artifacts that requires vetting by multiple stakeholders.

Historical Data Store

- ✓ Absence of organized and centralized historical data.
- ✓ Reference for a new project with similar endpoints and success factors.
- ✓ Need analytical insights to drive decision making

Time Investment

- ✓ Large number of regulatory compliant, submission ready documents.
- ✓ High Expense. Profitability impact.

Dependency

- ✓ Readiness of upstream documents and processes on downstream activities.
- ✓ Manual approach to creation of EDC objects like CRFs and edit checks.

Review/Approval

- ✓ Systematic approach to review and approval.
- ✓ Accelerate finalization of artifacts.

AI Framework for Clinical Trials domain

- ✓ **NLP enabled** protocol content ingestion
- ✓ **AI/ML powered** tool that learns and matures.
- ✓ **Knowledge store** integrated with external data sources like CTGov.

- ✓ **Ontology** driven knowledge graph
- ✓ Locate projects with identical end points and success factors.
- ✓ Analytical data driven decisions.

- ✓ Building EDC and documents with no development overhead
- ✓ Transformational approach. Substantial time savings.

- ✓ **Auto-mapping** source to target structures
- ✓ **Systematic generation** of modelling scripts

- ✓ Automated creation of ready to use content for **targeted individuals/groups** e.g. Medical writers, Bios, CRF designers.

- ✓ **User Friendly Interface/ Enhanced User Experience**
- ✓ Easy to use, responsive.
- ✓ Create objects within seconds.
- ✓ GxP Compliant validated system

- ✓ Content Management with workflows
- ✓ Content creation and content prediction with **auto text generation models using NLG**
- ✓ Paraphrasing, text suggestion, text completion

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Proposed Framework

Data Sources

- CTGov
- Structured Data Sources
- Documents
- Video/Images

Workflows
Role based access
Approvals
Notifications
Collaborations

Process Flow

Upload Protocol → ML/ NLP/ NLG → Extract Contents → Database Storage → Ontology → Knowledge Graph

Review Checklist — Protocol Analytics — Library — Download Contents

Machine Learning Layer

Document Parser	Ontology Builder	Text Generation	Semantic Mapping	Active learning
Encoder-Decoder	Graph Neural Network	Transformers	Transformers	Transformers

eCRF Generation
- ✓ eCRF design
- ✓ EDC upload able file

Edit Check originator
- ✓ Edit Check Specification Creation
- ✓ Attach Edit Check Program

SDTM
- ✓ SDTM Annotation
- ✓ SDTM Mapping Specification
- ✓ SAS Program

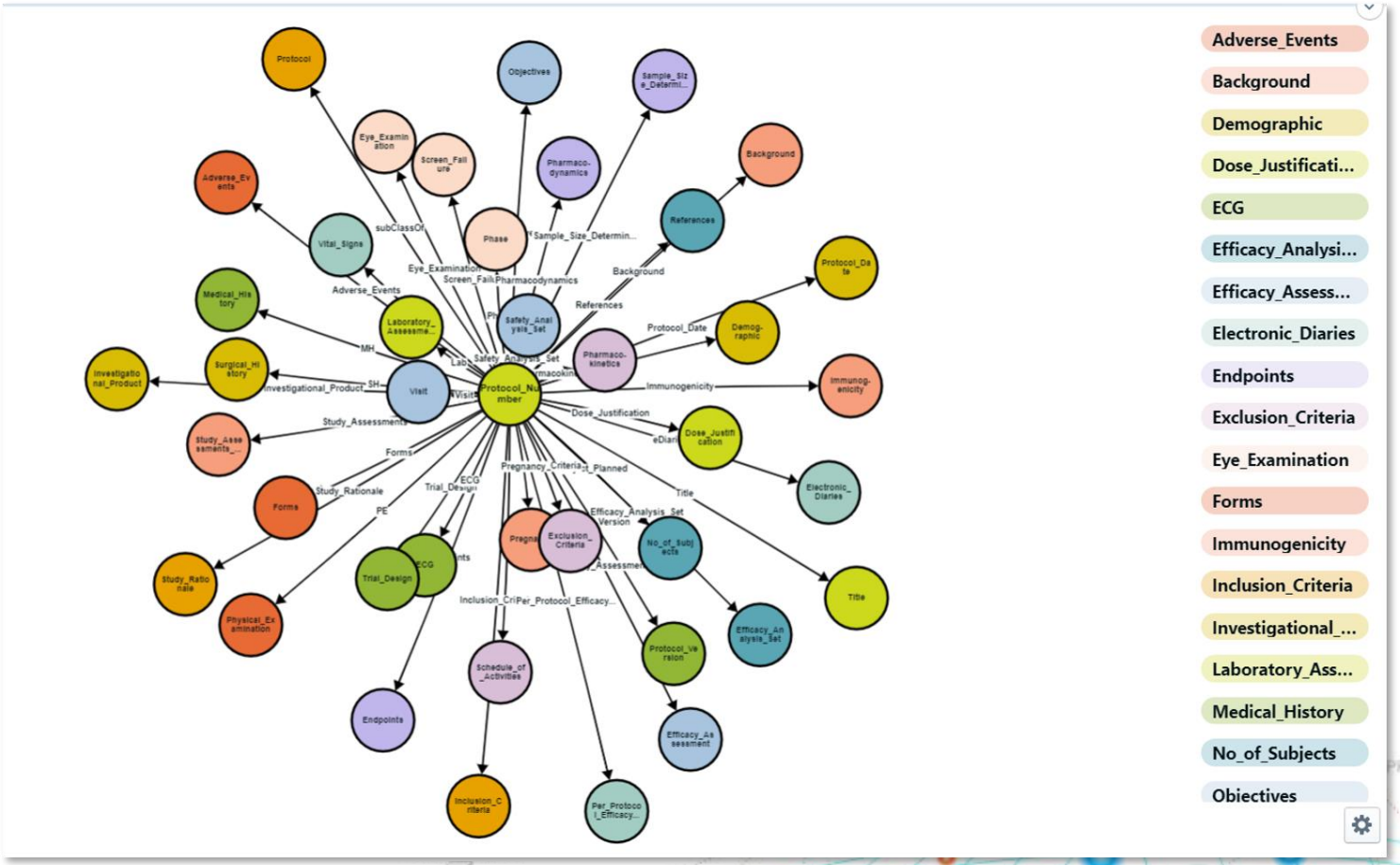
Dummy Data
- ✓ Dummy EDC dataset

Test Case Generation
- ✓ Test Case Generation for edit check testing.
- ✓ Test Case Automation

Analytics
- ✓ Protocol Analytics
- ✓ Site Intelligence
- ✓ Statistical Analysis

Documents
- ✓ Regulatory Documents
- ✓ CSRs/SAPs/Protocols
- ✓ Manuscripts/Publications

Knowledge Store



- Exhaustive Knowledge Store is Key.
- Some examples we captured in this framework:
  - Documents
  - ECRFs
  - Insights
  - Medical Codes
  - Objectives
  - Endpoints
  - Time & Event Schedule
  - CTGov Data
  - CDISC
  - Exclusion Inclusion Criteria

Knowledge Store

Granularity

ML Modelling

Document-Net

Self-supervised pre-training

Masked Language Models

Transformers (Multi-modal)

Word Embeddings + Image Representation

Building Knowledge Store

Graph Neural Network

Matching Networks

Encoder-Decoder Architectures

Semantic Mappers

Text & Analytics Generation

Transformers (Multi-modal)

Wide and Deep Neural Networks

Diffusion Language Models

Active Learning

Embedding Stores

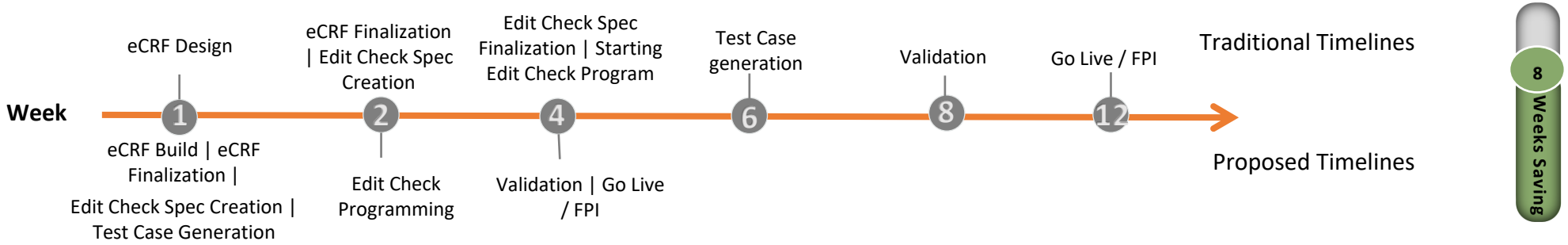
Intelligent Semantic Cache

Feedback driven explore-exploit network

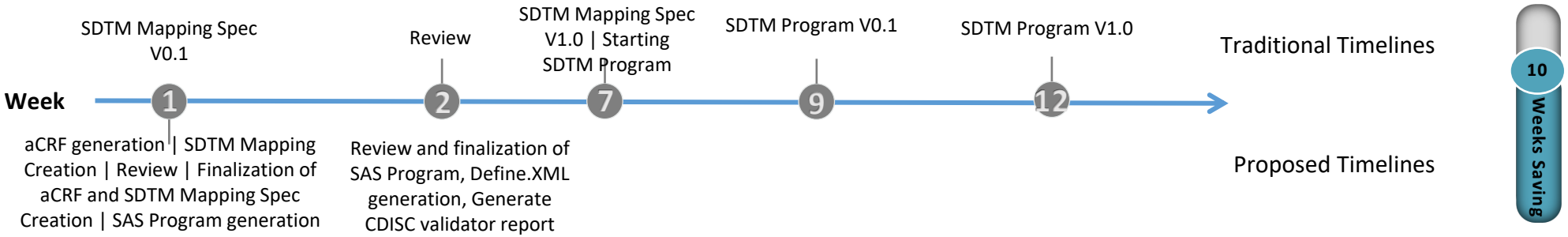
Leap Forward

1 Study Protocol

2 Study Build



3 SDTM



Conclusion

- As competition in the market for products and services intensifies, companies are looking to automation as a solution in their quest to reduce operational costs.
- A lot of manual effort can be saved by digitally accessing the clinical study documents like protocols, supported by NL queries, NLG, ML and Knowledge Graphs.
- The combination of AI-powered tools and the wonder of the human brain has the potential to revolutionize the way documents, analytics and other artifacts are generated today in the clinical research field.
- Proposed framework can significantly reduce time required for generating high quality deliverables.

Presentation (Soumya)

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AI Assisted Data Review for Significant Efficiency & Accuracy

Soumya Veerla
Senior Manager, Data Management
ICON PLC

Do you know?

GPAI | THE GLOBAL PARTNERSHIP ON ARTIFICIAL INTELLIGENCE

Aims to bridge the gap between theory and practice on AI by supporting cutting-edge research and applied activities on AI-related priorities.

GPAI brings together engaged minds and expertise from science, industry, civil society, governments, international organizations and academia to **foster international cooperation**.

29 countries

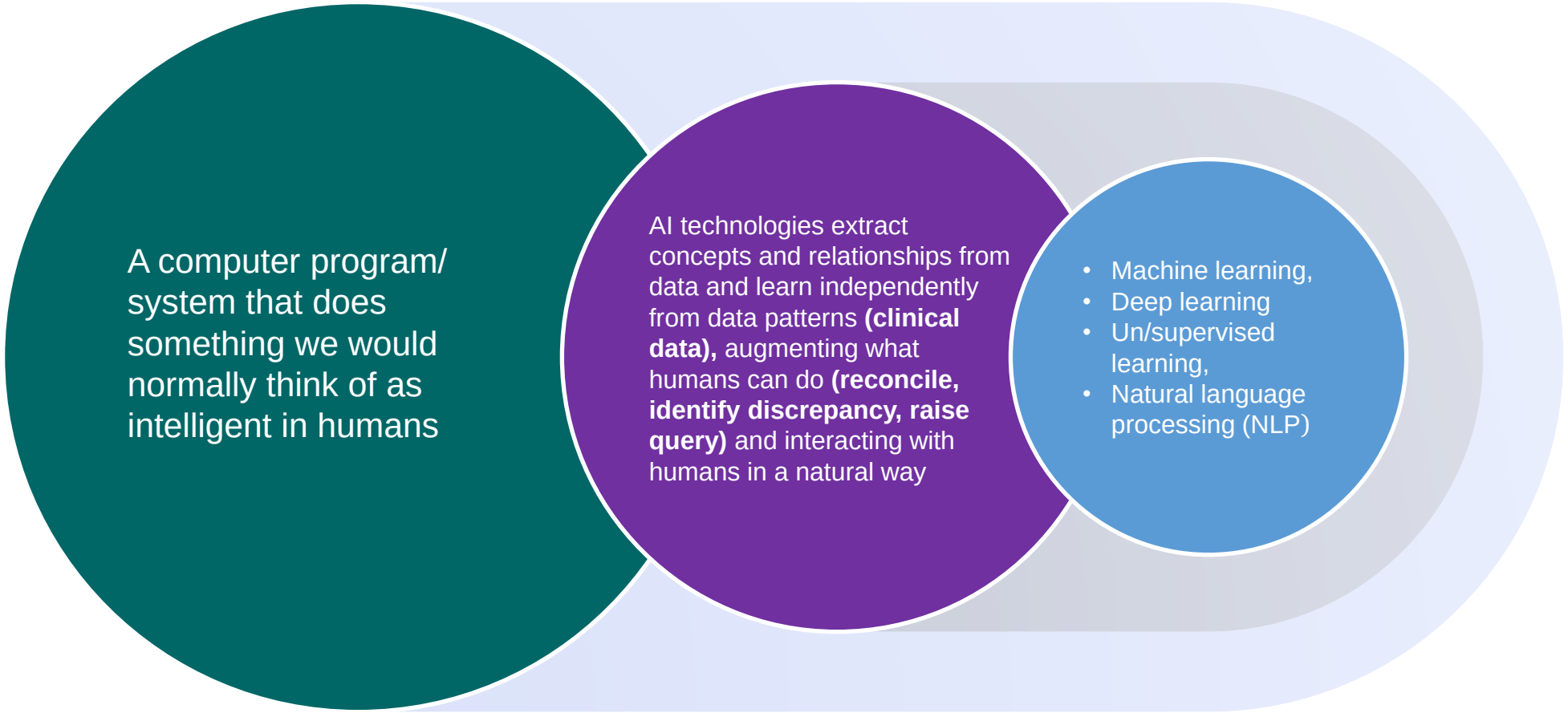
Members

29 international partners have joined together to guide the responsible development and use of artifical intelligence, grounded in human rights, inclusion, diversity, innovation and economic growth:

- Argentina
- Australia
- Belgium
- Brazil
- Canada
- Czech Republic
- Denmark
- France
- Germany
- India
- Ireland
- Israel
- Italy
- Japan
- Republic of Korea
- Mexico
- Netherlands
- New Zealand
- Poland
- Senegal
- Serbia
- Singapore
- Slovenia
- Spain
- Sweden
- Türkiye
- United Kingdom
- United States
- European Union

Chair 2023?

AI Overview


A computer program/ system that does something we would normally think of as intelligent in humans
AI technologies extract concepts and relationships from data and learn independently from data patterns **(clinical data),** augmenting what humans can do **(reconcile, identify discrepancy, raise query)** and interacting with humans in a natural way
• Machine learning,
• Deep learning
• Un/supervised learning,
• Natural language processing (NLP)

Journey – AI in Data Review

1. Can we automate?

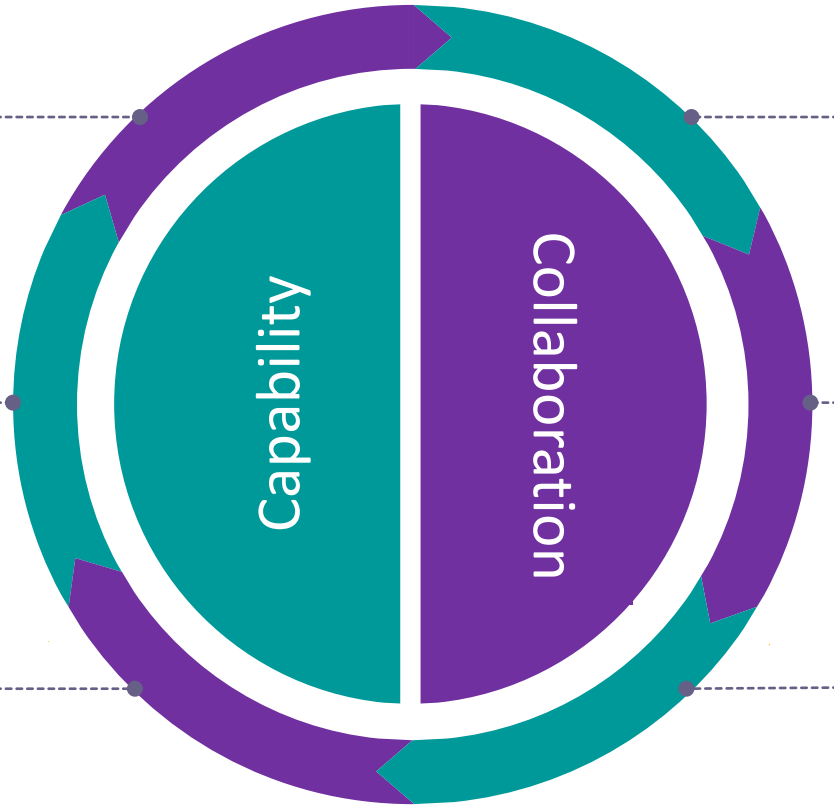
Manual review of clinical data listings which need critical thinking and human cognitive decision making

2. Which listsings to choose?

High volume & Impact
Maximum time & effort
Generic- across all studies, TA, Phase

3. Explore Solution?

Did not go for off the shelf product available in market



4. Solution?

Idea was to innovate & create inhouse scalable product

5. Solution Finalized?

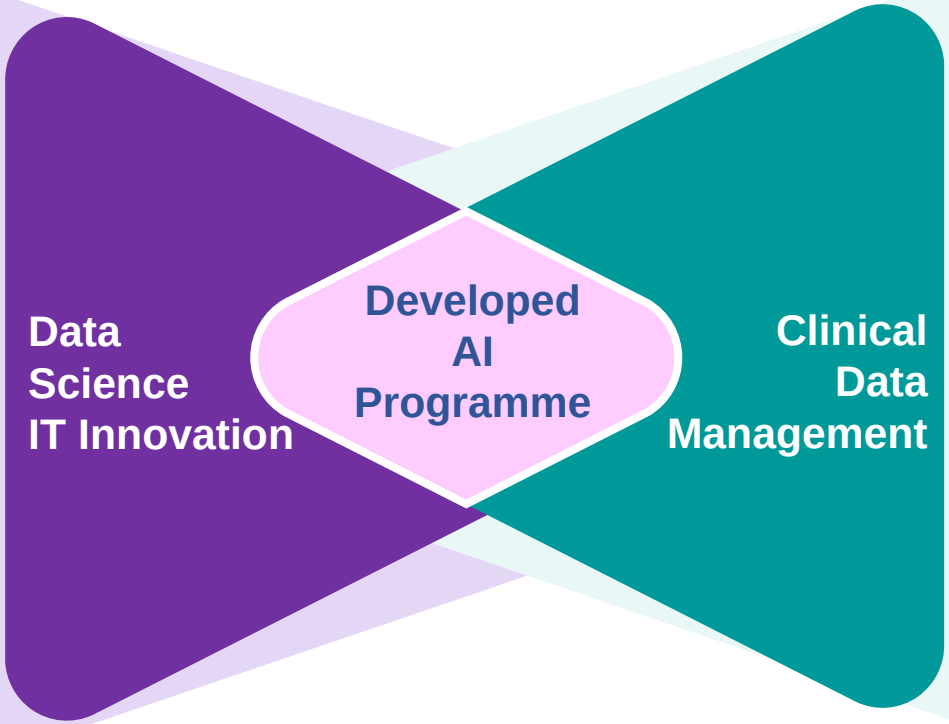
AI programme with Python, machine learning, combination of NLP & rules-based pattern matching

6. Proof Of Concept (POC)

CM-AE-MH Review
3 studies

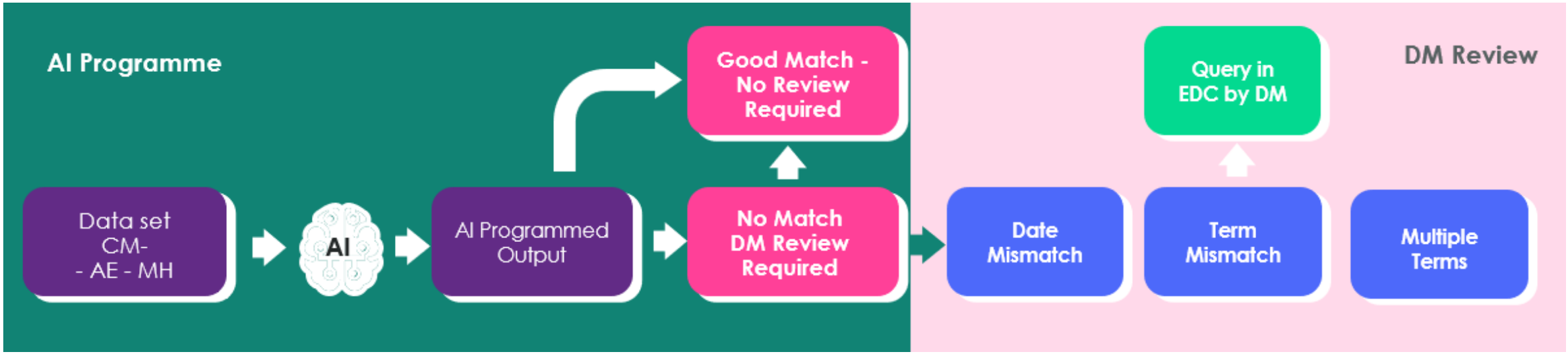
AI Development

- Artificial Intelligence, mainly NLP developed to review Con Med, Medical History & Adverse Event.
- Combination of NLP & rules-based pattern matches indication from CON Med to Adverse event or medical history along with corresponding dates.
- Continuous update of programme from user feedback



- AI assisted in identifying each of the records which needs action or no action as per match.
- AI out put Action required and no action required was reviewed 100% manually to check accuracy and efficiency of program.
- After each round of review feedback was provided to development team.
- Program started learning and correcting itself giving higher percentage of accuracy with every new round of review.

AI Assisted Data Review Process



AI output:

Good Match – No review required: When there is no discrepancy
No Match DM review required: When there is discrepancy in date or term

AI Output

Subject ID	Medication Name	CM Start	CM End	Indication	AE Term	AE Start	AE End	AI Output	AI Output
XXXX	CALCITONIN	7-Mar-22	7-Mar-22	HYPERCALCEMIA	HYPERCALCEMIA	7-Mar-22	9-Mar-22	Good Match	
XXXX	VOMEX	14-May-21	19-May-21	NAUSEA	NAUSEA	13-May-21	17-May-21	Good Match	
XXXX	LORAZEPAM	22-Oct-22		ANXIETY	ANXIETY	19-Oct-22	23-Oct-22	Good Match	
XXXX	PARACETAMOLE	29-Oct-21	29-Oct-21	flu	Flu	30-Oct-21	4-Nov-21	No Match	Date Mismatch
XXXX	FENTANYL	27-Aug-22	27-Aug-22	ANESTHESIA FOR PCN REPLACEMENT	RENAL AND URINARY DISORDERS- OTHER; PCN DISLODGED	27-Aug-22	30-Aug-22	No Match	Term Mismatch
XXXX	AMOXICILLE + CLAVULANIC ACID	21-Dec-21		fever:tachycardia	Fever	21-Dec-21		No Match	Multiple Terms

Subject ID	Medication Name	CM Start	CM End	Indication	MH Term	MH Start	MH End	AI Output	AI Output
XXXX	LORAZEPAM	14-Jul-20		ANXIETY	ANXIETY	18-Jun-20		Good Match	
XXXX	ENDONE	UN UNK 2020		arthritis	ARTHRITIS	UN UNK 2020		Good Match	
XXXX	OZEMPIC	UN-Jan-21	1-Nov-21	diabetes	DIABETES	UN UNK 2015		Good Match	
XXXX	RABEPRAZOLE	21-Jul-19		GERD	HYPERTENSION	UN UNK 2016		No Match	Term Mismatch
XXXX	BISOPROLOL	UN-Aug-18	11-Jul-22	ischemic Heart Disease:peripheral Artery Disease	ischemic Heart Disease	UN-Aug-18		No Match	Multiple Terms
XXXX	LEVETIRACETAM	25-Sep-22		aphasia	APHASIA	7-Apr-22	7-Apr-22	No Match	Date Mismatch

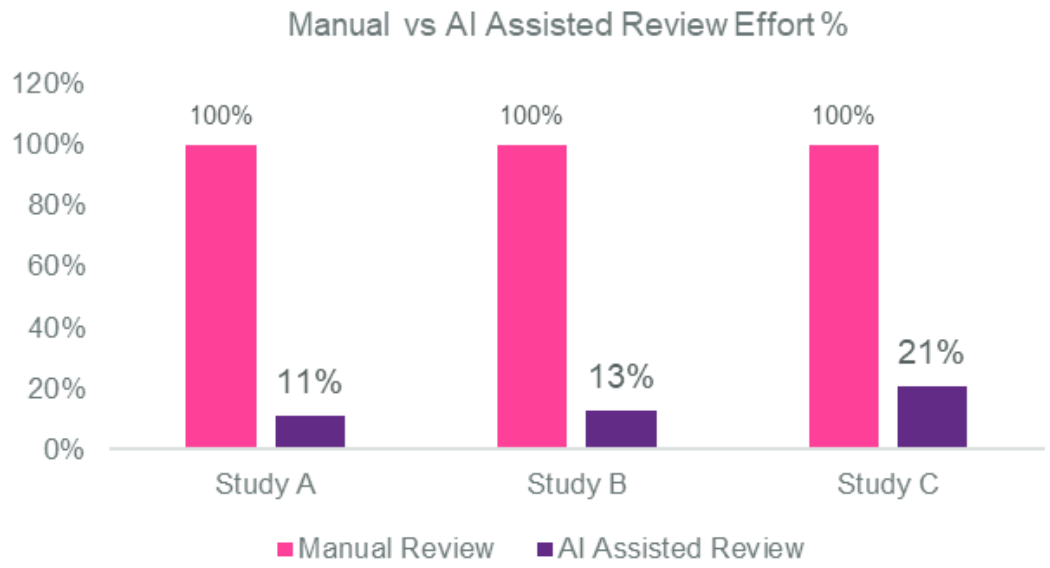
POC Outcome

Manual Review

100% Effort – 0% Efficiency
High turn around

AI Assisted Review

15% Effort - 85 % Efficiency
Quick turn around



Conclusion

Training

Develop new capabilities
Data Manager to Data Science

Governance

Monitor metrics
Return on investment
Documentation

Communication

Keep Team informed
New way of work
Opportunities

Future Development

Projects in pipeline
Prepared for future of work

NLP has the ability interpreting multiple data points – symptoms, medications, start & stop dates from various listings and transforms it into algorithm to identify actions required in case of discrepancy and no action required when data is reconciled, similar to critical thinking and human cognitive decision making. ML after each review updates algorithm to make it robust.
We are persuaded with the outcome of POC and the project is in the implementation phase.
The program developed can be easily implemented across all studies.

Presentation (Abhishek & Shreyans)

Under the hood, AI empowers CDM !!!

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Presenter:

Abhishek Kadam, Associate Director, Novartis

Shreyans Patel, Associate Director, Novartis

Unveiling the Case of Nora and John

Nora is a Data Manager and has a deeper experience of implementing AI/ML solutions in her studies for data management activities.

John, study data manager is new to AI/ML concepts and wants to understand how these concepts can impact his way of working.

Let's see what John learns from Nora about Impact of AI/ML on Clinical Data Management

Impact of AI on CDM

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Current Application of AI in CDM

Identify KRIs, KPIs

CTTI – CTQs

Risks to Milestones

LSTM, SVM

Data Visualization Tools, Integrations

Dashboards, System Alerts

Audit Trails, Real World Evidence, eSource data

Isolation Forest

Anomalies, Data Patterns, Outliers

CRFs, Fields, Edit Checks, Manual Checks

Apriori Algorithm

Time & Event Structure, Similarity Algorithms

Key Decision Makers

Identify issue, write query Post Query

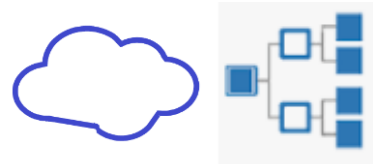
BEFORE FPFV

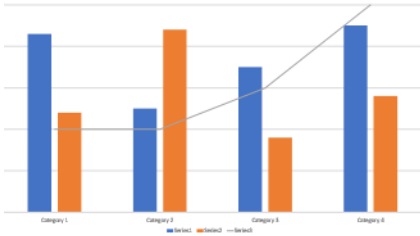
- Risk Based Database Set-up
- Setting Up Enterprise Tools
- Database Elements Recommender
- Extract Protocol Information

Literature & Specifications Mining + Virtual Site Assistant for EDC

AFTER FPFV

- Predictive KRIs & KPIs For Milestones
- Big Data Reviews
- Risk Data Review Insights, Trends & Patterns
- AI Based Query Generation & Closure





CLINICAL TRIALS TRANSFORMATION INITIATIVE

SVM – Support Vector Machine, LSTM – Long Short Term Memory

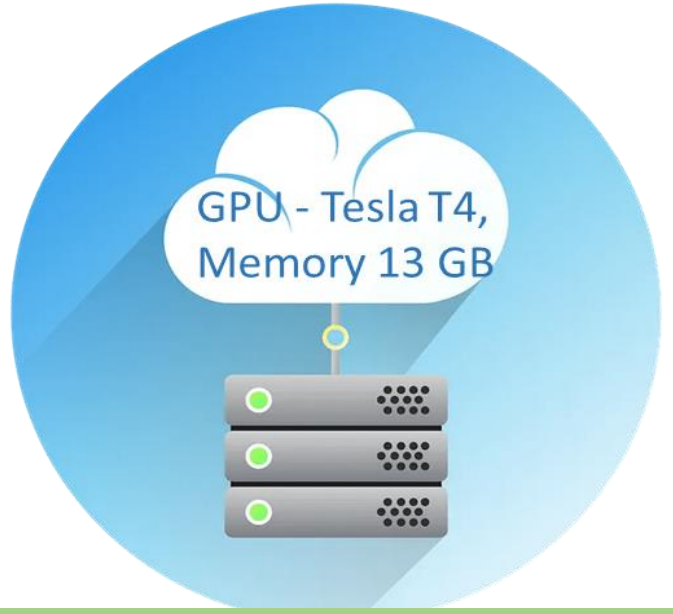
Impact on Infrastructure & Technology

Let's go through how AI demands better infrastructure and technology....

Impact on Infrastructure & Technology

Training NLP Model in Regular Laptop vs on Cloud Sever with required GPUs

8 hrs. for approx. 3 million records



5 min. for approx. 3 million records

NLP – Natural Language Processing

Impact on Infrastructure & Technology

One stop shop for all these infrastructure needs is a emerging impact of AI ML on clinical data management infrastructure.

01 Ecosystem

Technology, Integrated systems

Integration of AI tools with DM tools
Technology stack with AI/ML and Data science work – TensorFlow, Keras etc.
Code maintenance through GIT or similar platforms
Prototying environments and sandboxes, IDEs like PyCharm, R-Studios, Streamlit, etc.

02 Compute Engines

GPUs, Clouds

For scalable solutions
Distributed file system and RDDs to work on big data
GPUs for high compute power and processing of big data

03 Platforms

Cloud service providers

Leveraging the state-of-the-art platforms created for AI ML development
Platforms enabling ML Ops and Low code evnironments

04 Tools

IDEs, Visualization

Commercial off the shelf solutions can be utilized for programming and visualization

Data Engineering and Data Privacy

After this infrastructure, in my study, Can I merge X-Ray Images, MRI recordings and sensor data with CRF datasets for Data Review by AI ?

Data Refresh Data refresh strategies to overcome latency issues in data availability

Data Unification Enriching data by unifying different data sources

Data Pipeline Ingest & transform structured & unstructured big data for the use of AI/ML Algorithms

Data Privacy De-identification of personal information & ensuring model to remain unbiased

Sure! Consider these Data Engineering and Data Privacy aspects. Close collaboration between these team is a key!!

Skill Development – AI & Data Science

Now let us see how Clinical Data Management skill sets are influenced by application of AI in CDM!

Skill Development – AI & Data Science

A Mix of Life Science + Data Science Experts will be required in DM!!

Aspects	Details
New Skill Sets/ Reskilling in Data Management	Programming – Python, R etc. Tools Knowledge – Analytics tools and Low code tools IDEs – PyCharm, VS Code etc.
Training Curriculum	Coding with Python or R Basic Data Science Concepts – Supervised vs Unsupervised, Deep Learning Interpreting Visualization – Histograms, Scatter Plots
Recruitment Strategy	Team - A mix of Data Science and DM Experts
New Roles & Career Development	Evolution of Clinical Data Scientist, Data Analyst, Data Translator, Data Engineers in CDM

Collaborating with partners

FSP Partners

Provide resources skilled in Data Science, AI and AI enabled tools

Technology Partners

Niche partners who have capabilities to support AI/ML Journey.

Recruitment Partners

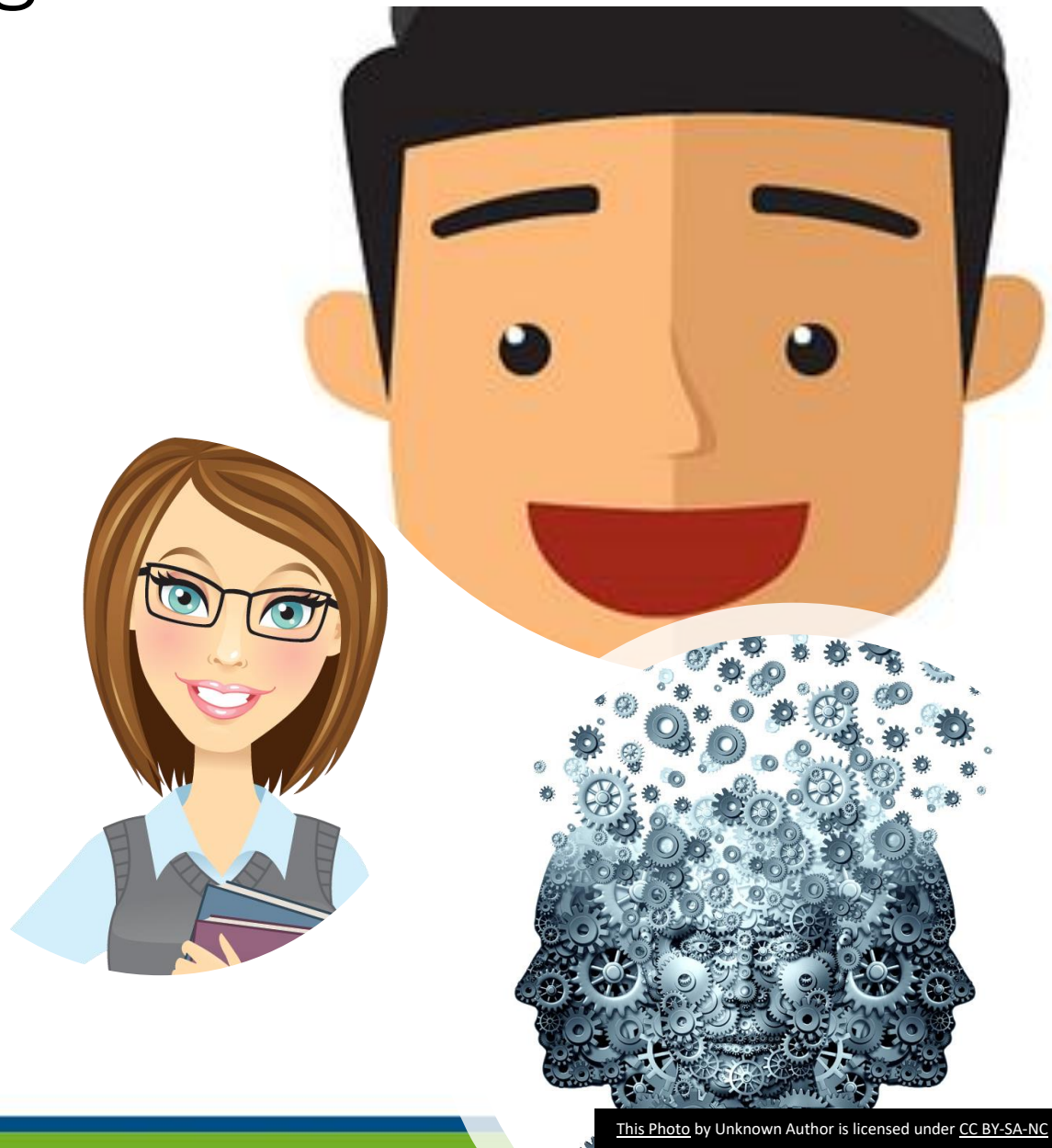
Recruiting & retaining niche talent in shorter duration of time

Training Partners

Specialized trainers for delivering Niche content in AI/ML Data Science Trainings in simplified /customized manner

Impact on Regulations & Processes

Finally, AI has an impact on the CDM process and regulations. Let us see how!



Impact on Regulations and Processes

Impact on Regulations

New FDA regulations for validating SaMDs

EU & other regional Data Privacy Guidelines

Functional Impact

Creation of New Process Maps

Getting away from 100 % Data Cleaning

Additional Data Scrutiny on Audit Trials, RWE data etc.

Impact on Decisions

Responsibility with Machines & Accountability with Humans

Reliance on Algorithm outputs for decision making

Use of differential privacy by technology giants

Emergence of the AI enabled query management

Human in the loop systems assisting decisions

Conclusion

AI + INFRASTRUCTURE + SKILLS + PROCESS = SUCCESS

“AI is probably the most important thing humanity has ever worked on. I think of it as something more profound than electricity or fire.” – Sundar Pichai.

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Q&A

Thank You