Society for Clinical Data Management
DATA DRIVEN

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

SCDM Live

India conference

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Radisson Blu Hotel, Bengaluru

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

Current Application of AI in CDM

Identify KRIs, KPIs

CTTI – CTQs

Data Visualization Tools, Integrations

Dashboards, System Alerts

CRFs, Fields, Edit Checks, Manual Checks

Apriori Algorithm

Time & Event Structure, Similarity Algorithms

Key Decision Makers

LSTM, SVM

Risks to Milestones

Audit Trails, Real World Evidence, eSource data

Isolation Forest

Anomalies, Data Patterns, Outliers

Identify issue, write query Post Query

Risk Based Database Set-up

Setting Up Enterprise Tools

Database Elements Recommender

Extract Protocol Information

BEFORE FPFV

Literature & Specifications Mining + Virtual Site Assistant for EDC

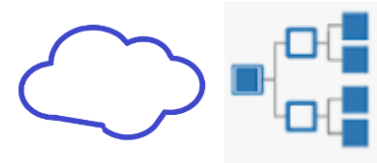
AFTER FPFV

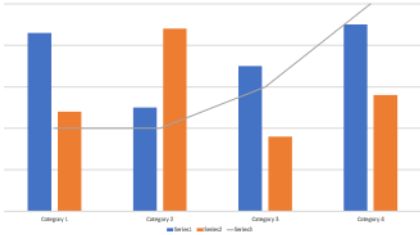
Predictive KRIs & KPIs For Milestones

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

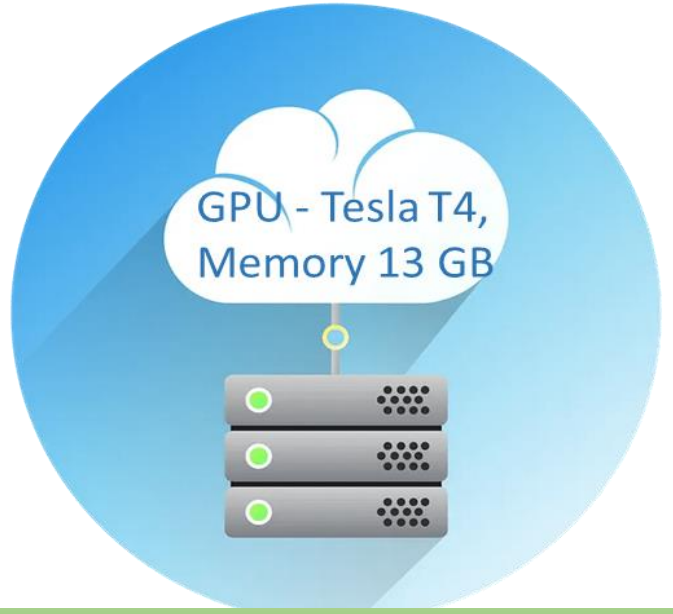
Impact on Infrastructure & Technology

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.

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

IDEs, Visualization

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

01 Ecosystem

02 Compute Engines

03 Platforms

04 Tools

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.

Cloud service providers

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

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!

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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!

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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 like apple, Facebook etc.

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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Thank you