



Society for Clinical Data Management  
DATA DRIVEN

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

# SCDM **Live**

## India conference

2<sup>nd</sup> - 3<sup>rd</sup> December 2022  
Radisson Blu Hotel, Bengaluru

# Under the Hood, AI Empowers CDM !!!

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# 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**



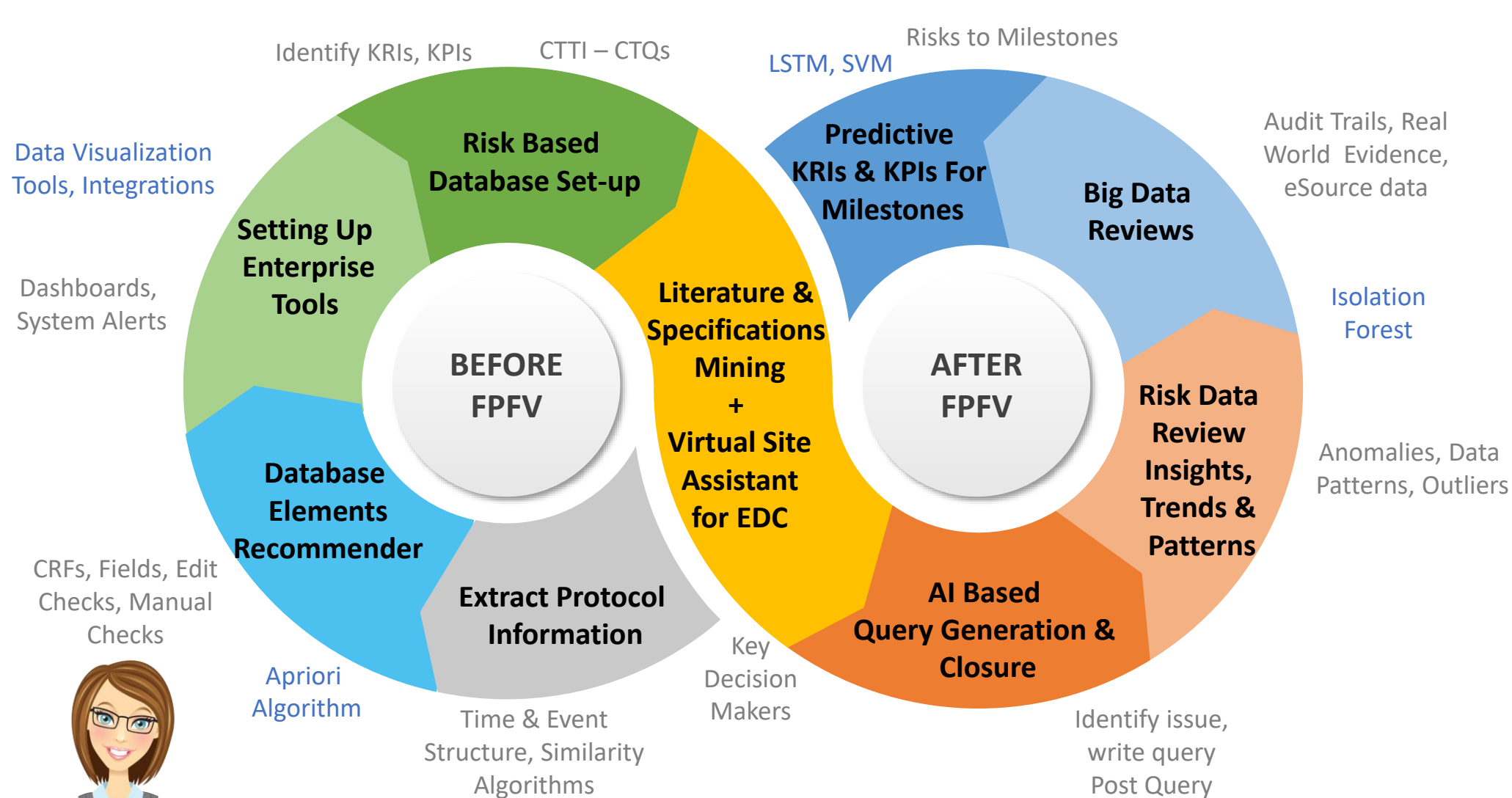
# Impact of AI on CDM

Let me explain you where the industry in using these technologies in Clinical Data Management.....





# Current Application of AI in CDM



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



# Impact on Infrastructure & Technology

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

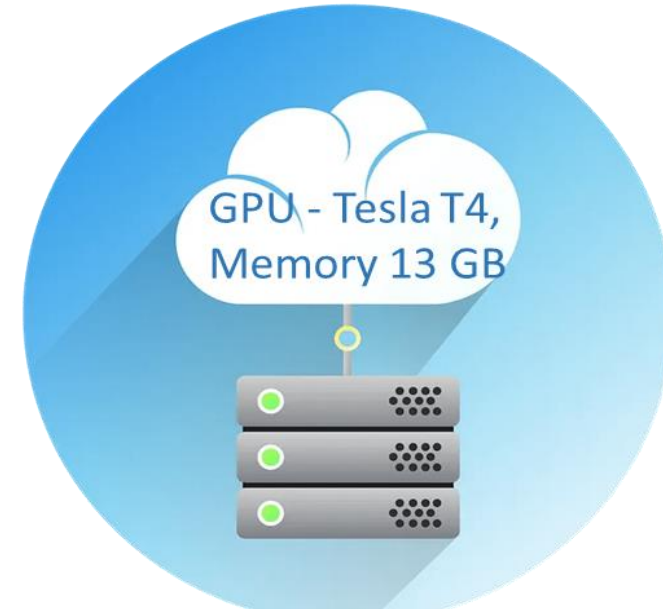


# Impact on Infrastructure & Technology

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

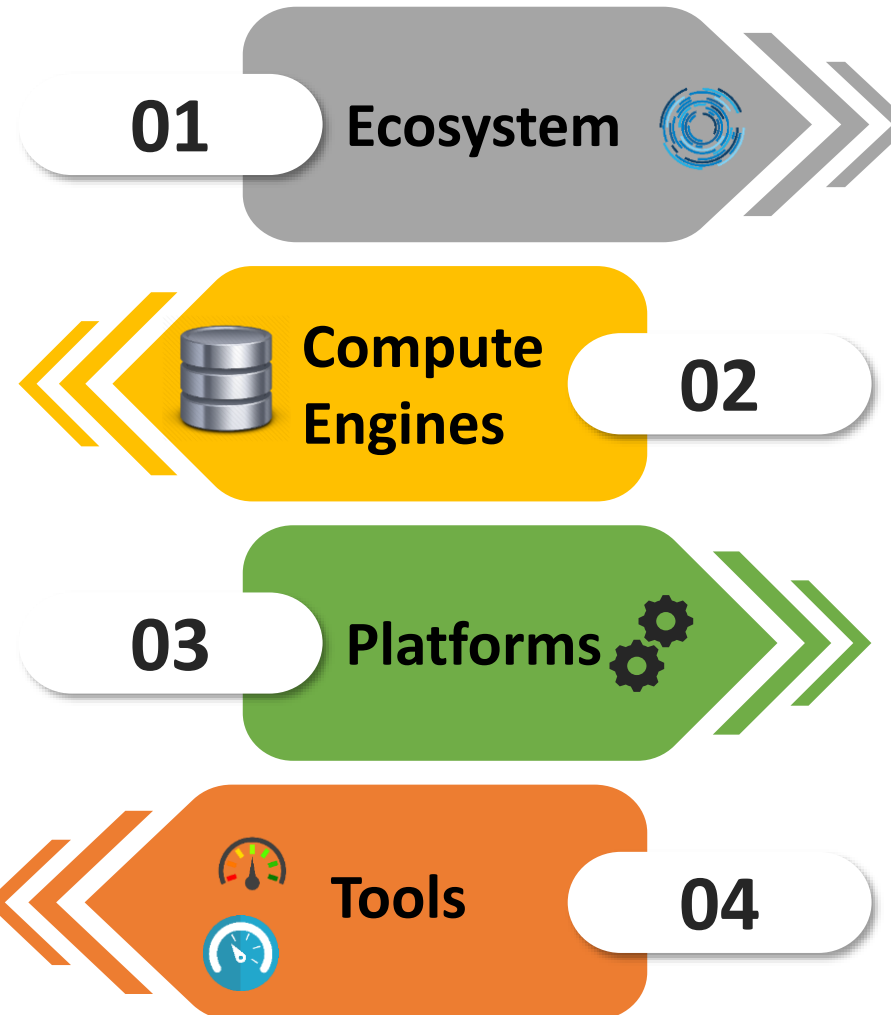
One stop shop for all these infrastructure needs is a emerging impact of AI ML on clinical data management infrastructure.

## 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



## 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  
Prototyping 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 environments



# 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



## Recruitment Partners

Recruiting & retaining niche talent in shorter duration of time



## Technology Partners

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



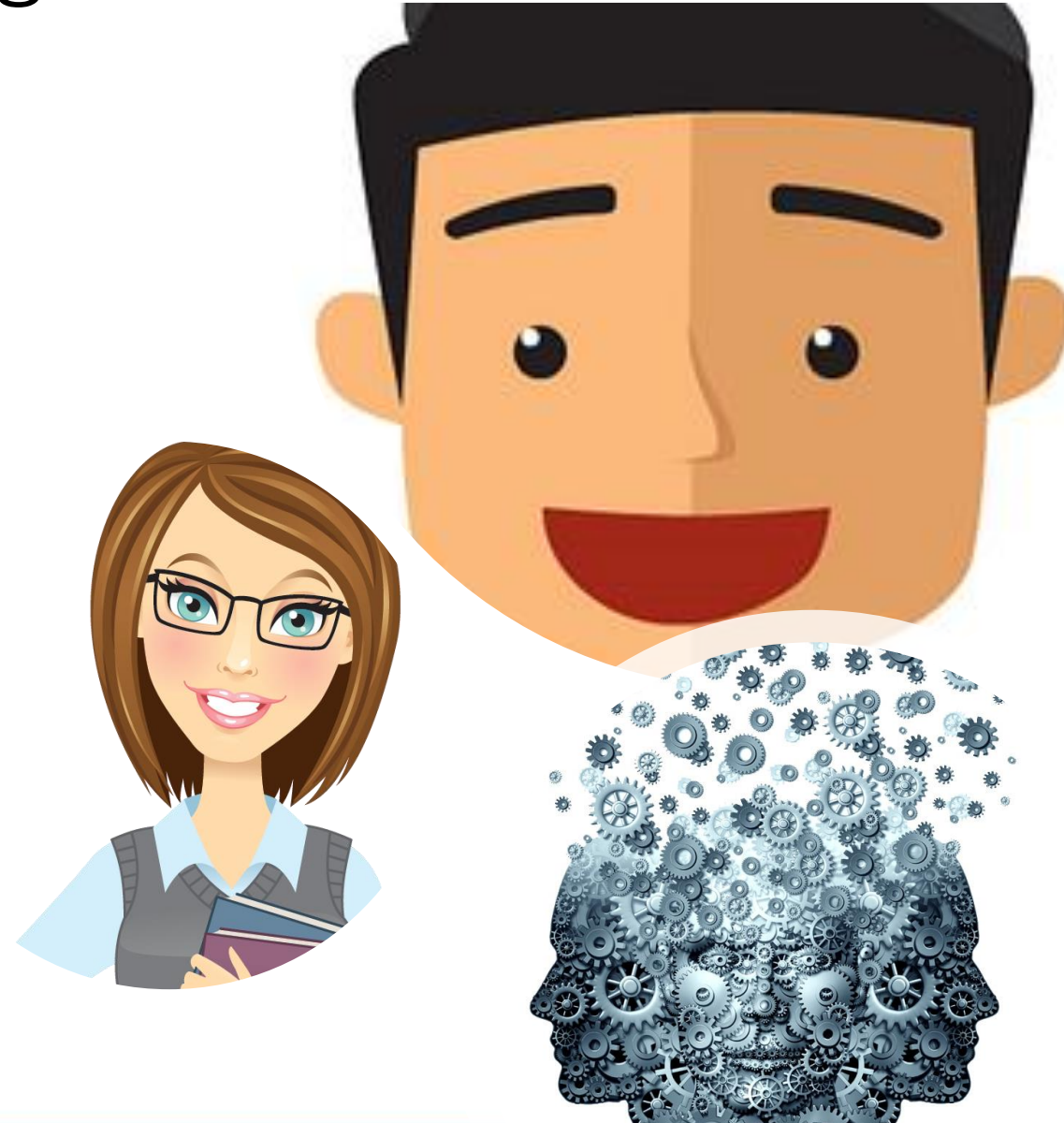
## Training Partners

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!



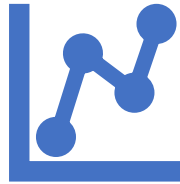
# Impact on Regulations and Processes



## Impact on Regulations

New FDA regulations for validating SaMDs  
EU & other regional Data Privacy Guidelines

Use of differential privacy by  
technology giants like apple,  
Facebook etc.



## Functional Impact

Creation of New Process Maps  
Getting away from 100 % Data Cleaning  
Additional Data Scrutiny on Audit Trials, RWE  
data etc.

Emergence of the AI enabled  
query management



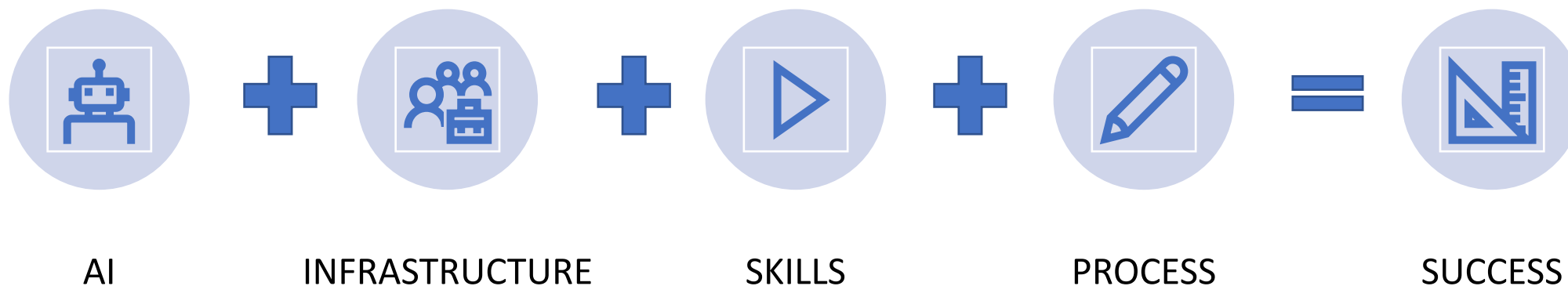
## Impact on Decisions

Responsibility with Machines &  
Accountability with Humans  
Reliance on Algorithm outputs for decision  
making

Human in the loop systems  
assisting decisions



# Conclusion



*“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.*

# References

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# Thank you