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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
Let me explain you where the industry in using these technologies in Clinical Data Management......
Current Application of AI in CDM

**Before FPFV**
- Setting Up Enterprise Tools
- CRFs, Fields, Edit Checks, Manual Checks
- Database Elements Recommender
- Extract Protocol Information
- Time & Event Structure, Similarity Algorithms
- Identify issue, write query for EDC
- Apriori Algorithm

**After FPFV**
- LSTM, SVM
- Literature & Specifications Mining + Virtual Site Assistant for EDC
- Key Decision Makers
- Identify KRIs, KPIs, CTTI – CTQs
- Predictive KRIs & KPIs For Milestones
- Audit Trails, Real World Evidence, eSource data
- Isolation Forest
- Risk Data Review Insights, Trends & Patterns
- Anomalies, Data Insights, Patterns, Outliers

**Tools and Integrations**
- Data Visualization
- Dashboards, System Alerts

**Milestones**
- Setting Up Enterprise Tools
- CRFs, Fields, Edit Checks, Manual Checks
- Database Elements Recommender
- Extract Protocol Information
- Time & Event Structure, Similarity Algorithms
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**AI Based Query Generation & Closure**
- SVM – Support Vector Machine, LSTM – Long Short Term Memory
Let’s go through how AI demands better infrastructure and technology....
Training NLP Model in Regular Laptop vs on Cloud Server with required GPUs

8 hrs. for approx. 3 million records

5 min. for approx. 3 million records

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

**Ecosystem (01)**
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.

**Compute Engines (02)**
Cloud service providers
Leveraging the state-of-the-art platforms created for AI ML development
Platforms enabling ML Ops and Low code environments

**Platforms (03)**
GPU, Clouds
For scalable solutions
Distributed file system and RDDs to work on big data
GPUs for high compute power and processing of big data

**Tools (04)**
IDEs, Visualization
Commercial off the shelf solutions can be utilized for programming and visualization
Sure! Consider these Data Engineering and Data Privacy aspects. Close collaboration between these teams is a key!!

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?
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!!

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

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

**Technology Partners**
Niche partners who have capabilities to support AI/ML Journey.
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 like apple, Facebook etc.

Emergence of the AI enabled query management

Human in the loop systems assisting decisions
“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

• The automation of CDM Driven activities (Version #1), SCDM Innovation Committee –CDS Topic Brief

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• https://www.ctti-clinicaltrials.org/projects/quality-design


• Artificial Intelligence (AI) in Clinical Trials Market is (globenewswire.com)
Thank you