Society for Clinical Data Management
DATA DRIVEN

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

Technology & Regulatory Considerations

SCDM Live

India conference

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

Workshop - Smart Data Review and early insights in era of Clinical Data Sciences

Facilitator - 1

Raghuram Thata has over 24+ years of experience across ITES, Pharma & CRO industries. He specializes in setting up Clinical Data Sciences business | has built large teams in Data Management, Statistical Programming, Statistics, Medical writing and submissions| has turned around engagements that have deteriorating relationship| Provides solutions for large, complex opportunities, builds BPaaS services |develops AI/ML/RPA, analytics |is passionate about giving back to community, speaks at SCDM, PHUSE and ISCR |

Raghu is currently Sr. Director, Global Head of Programming @ IQVIA and has teams across 7 countries| Raghu is Bachelors in Statistics from Bangalore University and Masters in Computer Applications from Bharathidasan University|

Facilitators 2

Inder Sachdeva is a distinguished industry leader in clinical R&D space with 20+ years of experience. He has worked in both Pharma and Clinical Research Organizations thus holds a good command over either side perspectives of sponsor as well as service provider.

Inder currently hold the role of Portfolio Delivery Leader & CDS Practice Leader at Cognizant Technology Solutions. By education Inder is a Pharmacist, Post Graduate in Pharmaceutical Management and further specialized Diplomas in Clinical Trials, Contract Research and Intellectual Property Rights. Inder has been a change leader and supporter of continued evolution of clinical R&D roles

Facilitator 3

Dr. Jayathirtha comes with two-decade of Pharmaceutical/ Clinical Research experience. He worked in leading Pharmaceutical and Clinical Research & Technology Organizations, such as Veeva, Oracle Health Sciences, in clinical R&D space. He is a recipient of India's premier national R&D - Council for Scientific and Industrial Research Fellowship. Published several research papers in International and National Scientific journals.

Dr. Jay is a Ph. D in Pharmaceutical Sciences and currently - CDM, Offering Lead at TCS

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Smart Data Review and early insights in era of Clinical Data Sciences

Agenda - 08:00 to 10:00 AM

First half – 60 min

- Workshop objective - Raghuram Thata
- Introduction to Clinical Data Sciences - Inder Sachdeva
- Need for Smart Data Review and early insights - Dr. Jayathirtha Gopalakrishna
- Day in life of a Clinical Data Scientist - Priyanka Samel

Second half – 60 min

- Group activity (30 min) 4 groups – People |Process |Technology |Regulatory
- Group read out (5 min/group) Group leads to present
- Closure (10 min) Raghu, Jay, Inder

Groups

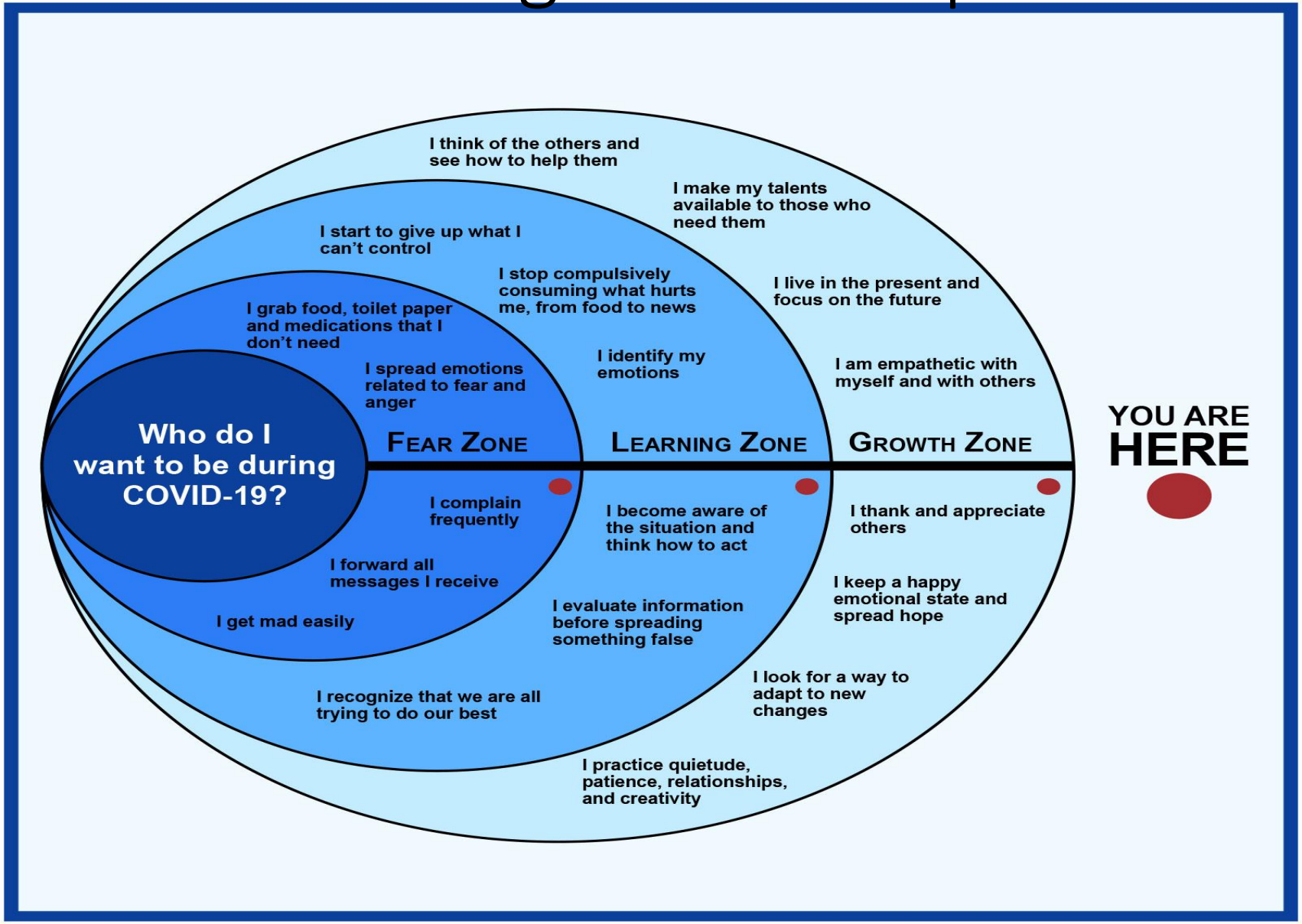
People	Process	Technology	Regulatory
Lead – Raghavendra Shivallingappa	**Lead - Amey Choutai**	**Lead - Jyothi Kotha**	**Lead - Prakash Tupe**
Eithasab Ahmed	Jalpa Ajmera	Rishabh Bansal	Dilip Barai
Namarata Belekar	Anindita Bhattacharjee	Vaishali Chandra	Nishant Chaudhari
Diksha Chavan	Vardha Desai	Kedar Deshpande	Tania Ganguli
Meeta Gavade	Subhrajit Ghose	Pooja Gowlikar	Rajeshwari H
Sachin Heralagi	Sundar HM	Dinesh Kumar Jothi	Rajesh Kumar Karthikeyan
Atik Khan	Prasanna Kumar	Sri Geevan Kumar	Anitha Kumari
Priyadharshini Lobow	Eswar M	Nirali Mehta	Sreeparna Mitra
Saifudheen M Musthafa	Shakir Omair M	Remya Sudhir More	Lohith Mullanda
Hanumantharao Mundra	Nishanth Nalan	Haseena PV	Kuldeep Raju
Swati Rananaware	Win Samuel	Elizabeth Samuel	Sreenivasa Shamarao
Saket Sharma	Poornima Shreyas K	Meena Shrihari	Frederic Sibeaud
Shwetha Siddappa	Vijay Sindhe	Sushil Singh	Sushil Kumar Singh
Seema Singh	Ganesh Srinivasan	Sivasamy Subramanian	Ankitha Swapnil
Sridhar Tirandas	Megha TM	Dhanashree Tulsulkar- K	Appalla Venkata Prabhakar

Poll question

In 1 word or a small phrase – pl let us know

What are your expectations from today's workshop?

During COVID 19 pandemic



- Work from home is a new normal
- Decentralized approach
- Clinical Data Sciences – smart review from being value ad to main stream
- Paved path to several innovations to address 4 V's – velocity, veracity, variety, volume

Source: Ohio Christian University

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Clinical Data Sciences
Inder Sachdeva

Poll question

Is our CDM business ready to face another long BCP situation/disruption that we recently witnessed due to COVID?

- Yes
- No
- May be

Acknowledgements

The content in this presentation is from the SCDM Materials (Reflection Papers, Topic Briefs & Position Paper/s). Sincere Thanks to SCDM Innovation committee on bringing out these phenomenal contributions

Thanks to SCDM India Leadership on this opportunity to present my views

Thanks to Cognizant Teams on supporting the content preparation and views

Impact of Pandemic on Clinical R&D Industry

Data Security

Accessing data through out of office environment

New tools to oversee data leakage

Remote Working

Self governed planning

Self governed QC

Self governed Training & Development

Great Attrition Wave

Moving jobs without moving

Managing attrition versus *Managing Impact of Attrition*

Employee Employer Relationship

Significantly impacted bond between Employee and Employer

Manager-Reportee Relationship

Business Resilience

Preparing for next pandemic

Risk based DM

Contingency Planning

Dealing with the 5 Vs

CDM is different from CDS?

[(40) Society for Clinical Data Management (SCDM): Videos | LinkedIn]

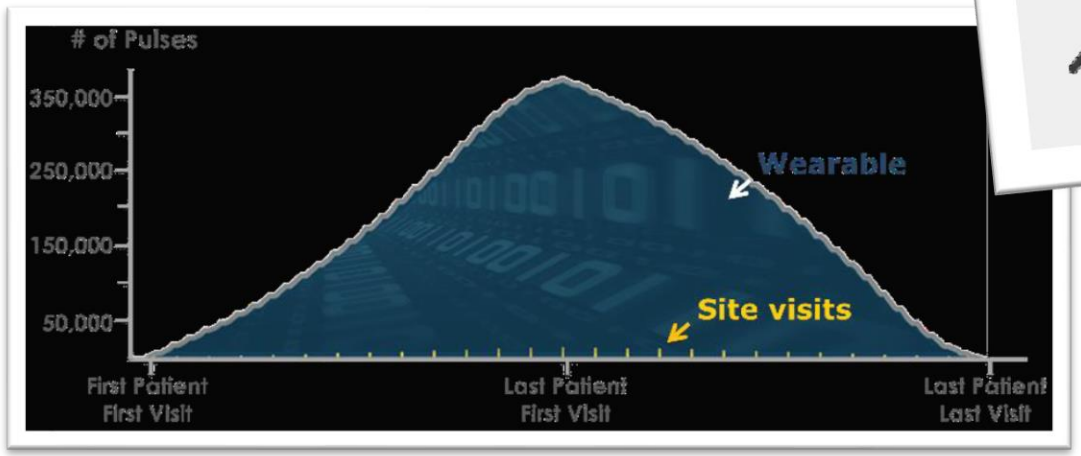
Clinical data science is NOT data science. #CDS is an evolution of clinical data management, and it should never be confused with the general discipline of data science.

Head of Clinical Technology Strategy & Operations, Abbvie

Global Head, Clinical Data Management, Sanofi

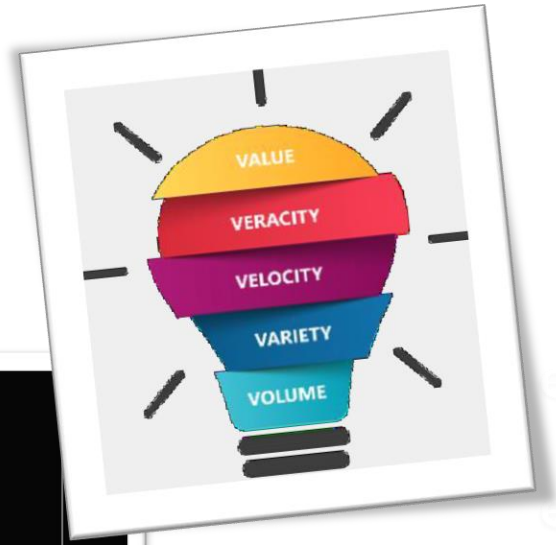
https://scdm.org/

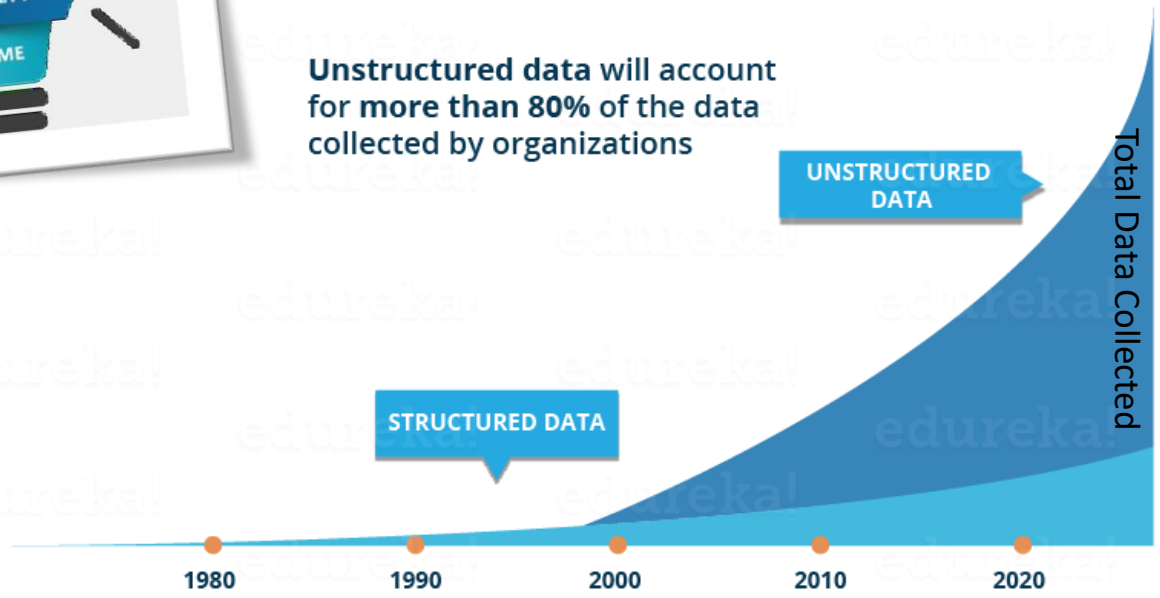
Why we Need Data Science approach to CDM



Volume of actigraphy data generated by wearables (in blue) vs data generated from site visits (in orange).

The protocol requires 260 patients to be treated for 6 months. Wearable device set to ***transmit data every minute***, thus would generate a reading more than ***68 million times***. In comparison, pulse would only be generated ***3,380 times*** through site visits, assuming ***patient's visits every 2 weeks***.





Unlike data in the traditional systems which was mostly structured, today most of the data is unstructured or semi-structured. By 2020, more than 80 % of the data will be unstructured.

Reference: The Evolution of Clinical Data Management to Clinical Data Science (Part 2) Society for Clinical Data Management Reflection Paper

Ref: www.edureka.co

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SCDM CDS (Clinical Data Scientist) Role Evolution

- SCDM innovation committee has rolled out 3 reflection papers in 2019 and 2020 going through how CDM is evolving to CDS, technology playing a huge part in it and how the skills of today's Data Managers need to evolve to meet the expectations of CDS role.

  A lot has changed since the last 3 reflection papers, thus SCDM innovation committee recently released a Topic Brief on The CDM Role evolution which puts a thorough framework around the whole evolution process.


The Evolution of Clinical Data Management to Clinical Data Science

A Reflection Paper on the impact of the Clinical Research industry trends on Clinical Data Management

4 June 2019

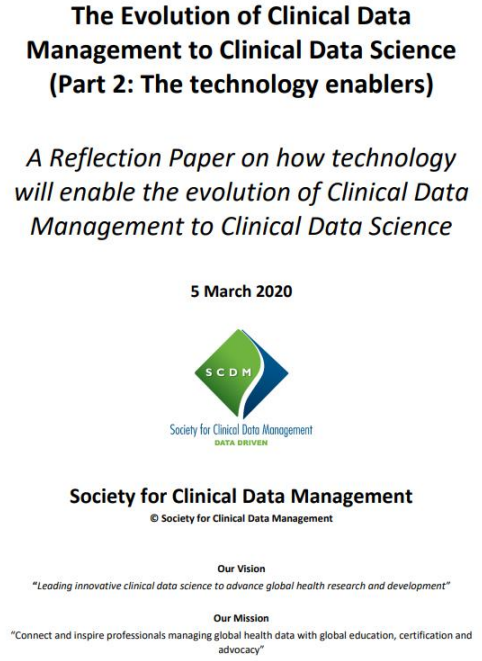
Society for Clinical Data Management

Our Vision

"Leading innovative clinical data science to advance global health research and development"

Our Mission

"Connect and inspire professionals managing global health data with global education, certification and advocacy"


The Evolution of Clinical Data Management to Clinical Data Science (Part 2: The technology enablers)

A Reflection Paper on how technology will enable the evolution of Clinical Data Management to Clinical Data Science

5 March 2020

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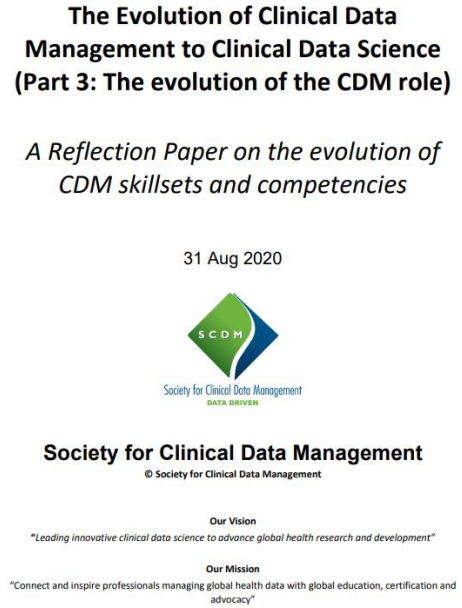
The Evolution of Clinical Data Management to Clinical Data Science (Part 3: The evolution of the CDM role)

A Reflection Paper on the evolution of CDM skillsets and competencies

31 Aug 2020

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Society for Clinical Data Management

The CDM Role Evolution

Version 1 (August 2022)

Authors

- Catherine Célingant, Executive Director, Data Monitoring & Management – Oncology, Pfizer
- Patrick Nadolny, Global head, Clinical Data Management, Sanofi
- Inder Sachdeva, Portfolio Delivery Leader, Clinical Data Sciences & Safety, Cognizant
- Ian Shafer, Principal, PwC

Reviewers and Contributors

- Sanjay Bhardwaj, Head of Clinical Technology Strategy & Operations, Abbvie
- Jérémy Nadolny, Sr Business Associate, Trial Operations
- Demetris Zambas, Global Head, Data Monitoring & Management, Pfizer

The Society for Clinical Data Management (SCDM) would like to acknowledge the many volunteers who have contributed to the development of the SCDM reflection papers used as the primary basis for this topic brief.

Methodology

The SCDM Innovation Committee seeks to provide thought-leadership to our industry and support the SCDM vision of "*leading innovative clinical data science to advance global health research and development*". To that end, the SCDM Innovation Committee strives to demystify Clinical Data Science (CDS) and support the development of all Clinical Data Management (CDM) professionals, from subject matter experts (SMEs) working on clinical studies to CDM leaders setting the direction of their organizations.

The SCDM Innovation Committee is publishing topic briefs intended to serve as orientation guides on specific areas which are contributing directly or indirectly to the evolution of CDM into CDS. The content of those topic briefs is primarily an extract from the previously published SCDM Reflection Papers which collectively provide a cohesive and comprehensive overview of CDS from the point of view of industry leaders. Due to the recent emergence of the CDS discipline and the absence of a comprehensive literature base regarding CDS within the Drug Development industry, this content was gathered from industry leaders through a consensus-based methodology. As CDS matures and technology evolves, we anticipate that literature on this topic will blossom.

https://scdm.org/clinical-data-science

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Conceptualizing the CDS (Clinical Data Scientist) Role

This reflection paper clearly illustrated the necessity for CDM to keep pace with the Clinical Research industry evolution and anticipate the downstream impact on the overall CDM and health development processes down to the study level. The rise of big and complex data stream, the availability of innovative technol ogies, the maturity of Artificial Intelligence, the adoption of new study designs and the evolutions of regulations are already starting to reshape what CDM mea ns today.

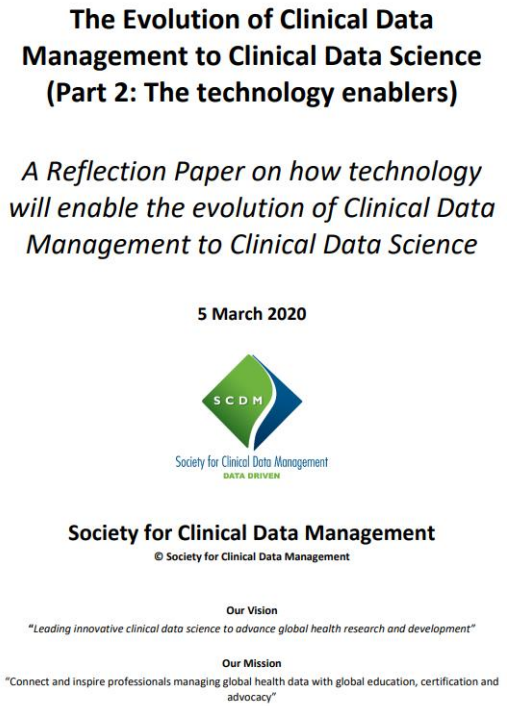
We are entering an exciting era w here quality by design, critical thin king, risk-based and fit for purpos e approaches will prevail. In this d ata and patient centric framework , CDM will play a strategic role in ensuring the reliability of the trial results and support the transform ation that Clinical Research needs.

The rising complexity of the CDM Role

https://scdm.org/clinical-data-science

Role of Technology

CDM must ensure the veracity of data coming from a variety of sources with high volume and high velocity. Technology must allow Clinical Data Scientists, supported by Virtual Clinical Data Managers, to ultimately extract the full value of clinical research and health care data. The 5Vs data journey from collection to value generation. In such a context, technology must become the enabler to a true and scalable change allowing CDM to meet the demand of clinical research while remaining compliant to increasing regulatory requirements. In conclusion, technology is the key enabler of our evolution to CDS. CDM organizations should consider the elements outlined in this paper, as well in those in the first SCDM reflection paper (Part 1), to set their organization's vision and its corresponding roadmap to success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5 March 2020

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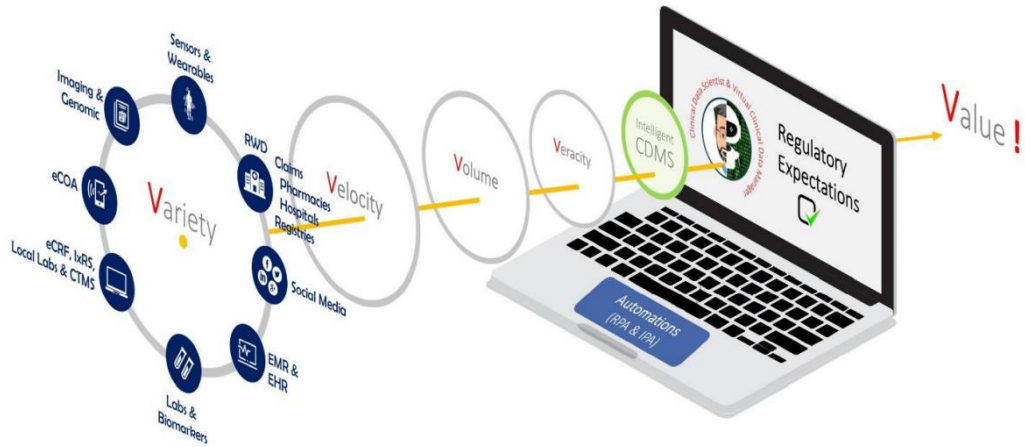

https://scdm.org/clinical-data-science

CDS (Clinical Data Scientist) Role Evolution

The Evolution of Clinical Data Management to Clinical Data Science (Part 3: The evolution of the CDM role)

A Reflection Paper on the evolution of CDM skillsets and competencies

31 Aug 2020

Society for Clinical Data Management

The evolution from CDM to CDS summarized in this paper results from evolving regulations, technologies, and clinical research approaches. This represents a major shift in focus, not only for CDM but for all clinical research stakeholders.

Summary of the CDM focus	Summary of the CDS focus
Achieve data integrity	Achieve data quality
Quality controls	Quality by Design
Focused on logical thinking (Output)	Focused on critical thinking (Outcome)
Randomized controlled trials	Adaptive and master protocols
Focused on site generated data	Focused on eSource data from DCTs
Standard processes across studies (one size-fits-all)	Risk-based processes tailored for each study (focus on what matters)
Low volume of data and sources	High volume of data and sources
Simple data flows	Complex data flows
Vendor management	Vendor oversight
Data cleaning	Data review, tagging, exclusion and curation
Project Management	Cross-functional leadership
Clinical research standard	Clinical research and healthcare standards
Clinical research data	Clinical research and healthcare data
Traditional programming (SQL, C#, SAS, etc.)	ML (Python, R, etc.)
Standard data interrogation (e.g., SQL)	Advanced data interrogation (e.g., non-SQL)

While taking different pathways, many CDM leaders will gradually evolve their organization toward their own tailored CDS future. To initiate such a change management endeavor, they must clearly define their own ultimate destination and value proposition for their organization considering the evolution of the industry toward a digital and patient centric future.

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Recent key changes in Clinical R&D Domain

Number of DCT Trials and component of DCT in each trial has increased significantly.

Variety, Veracity and Volume of data as part of trials have increased significantly.

Difference between RWE and Clinical Trial data is thinning continuously

Analytics and technology will take a bigger lead in trials of future.

CDM roles rolling onto CDS

Ever stronger need to build processes and trial designs to be more business resilient

CDM Vs CDS Framework

Best Practices	Soft Skills
Data Management Plan Paper CRF and EDC Lifecycle Vendor Selection and Management External Data Management Assuring and Measuring Quality Patient-Reported Outcomes Medical Coding	Attention to details Logical thinking Adaptability Ability to articulate complex concepts Ability to work with cross-functional teams Ability to troubleshoot complex data trends
Core Competencies Areas	**Foundational Knowledge**
Design Programming Data Processing Project Management	Clinical Development Methodology Regulations Software Development Life Cycle (SDLC) Audit Methodologies Standard Models and Terminologies Workflow Management

Fig 1. The traditional CDM role framework

This represents a major shift in focus, not only for CDM but for all clinical research stakeholders. For CDM itself, this leads to the **evolution of its competencies, foundational knowledge, best practices, and soft skills** requiring the following expectations to be added on top of the existing CDM.

The evolution from CDM to CDS summarized in this topic brief results from **evolving regulations**, **technologies**, and **clinical research approaches**.

Best Practices	Soft Skills
Risk-based CDM approaches *(Incl. Operational feasibility, QbD and CtQs)* Advanced Clinical Data Reviews *(incl. Story telling visualizations, systematic errors detection, Data Tagging, Exclusion and Curation)* Implementation of the 5Vs of Clinical Data *(Incl. Secondary data assets such a synthetic control arms and complex data Integrations)* Automation of CDM Activities *(Incl. Robotic and Intelligent Process Automation)*	Critical thinking Influential leadership Pragmatism Ability to manage ambiguities Ability to make and own decisions
Core competencies Areas	**Foundational Knowledge**
Risk Management Vendor Oversight Patient Centric Technologies Deployment Process Management RPA and ML Based SDLC Advanced data exploration and interrogations *(e.g., non-SQL, R, Python)*	New protocol designs (e.g., Master, Adaptive) DCT approaches[11] Risk-Based methodologies and regulations Health Care Data (RWD/RWE), Standard Models and Terminologies Emerging Data Structures (e.g., Sensors) Automation and Artificial Intelligence concepts

Fig 2. CDS role framework

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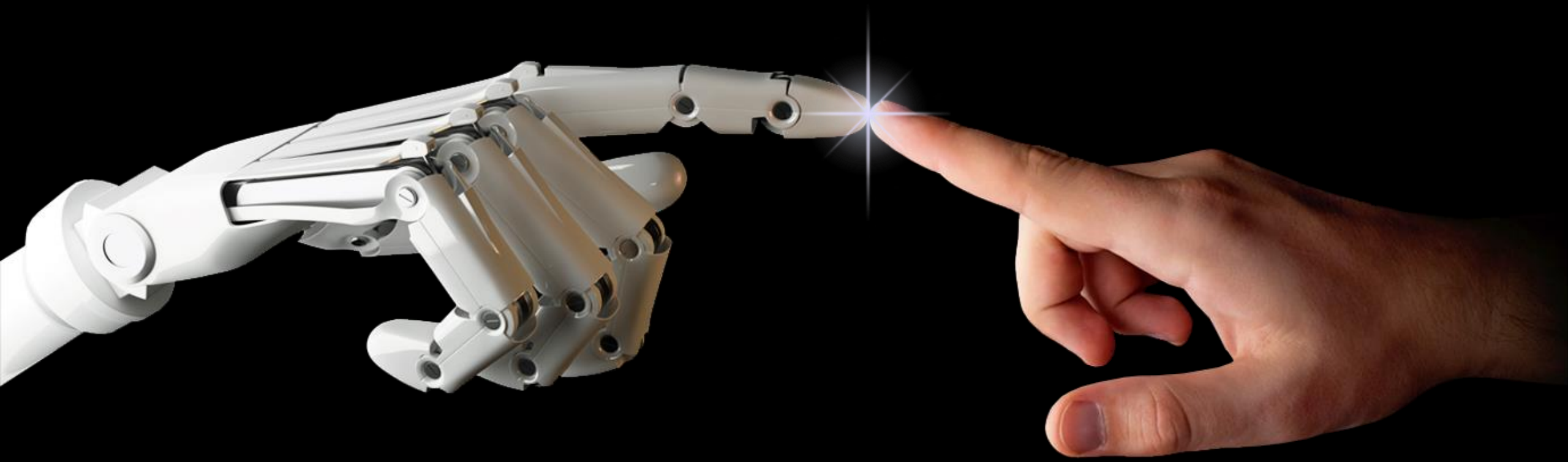
DIGITAL, with **HUMAN** is the new Normal



Appendix

Variety, Frequency, Speed, Type..

Head	Conventional Trials	DCT/eSource Trials
Variety	EDC centric including local labs and PK External data mostly limited to IxRS, central labs and eCOA	Scope expanded to regular, imaging, video, sensors and wearables (i.e., sequenced data), structured and unstructured data
Velocity	Days, weeks and months Data entered in eCRF days after patient's visits	Real time data RESTful APIs providing interoperability between computer systems
Veracity	Manual/scientific Reviews Mainly confirmed through SDV and queries (100% error free)	AI-driven automation of issue detection and resolution Real time Data visualizations tool for 100% error free
Value	Focused on regulatory submissions	Focused on regulatory submissions Continuous data insights on patients (e.g., safety, behavior, etc.)

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Need for Smart Data Review and early insights

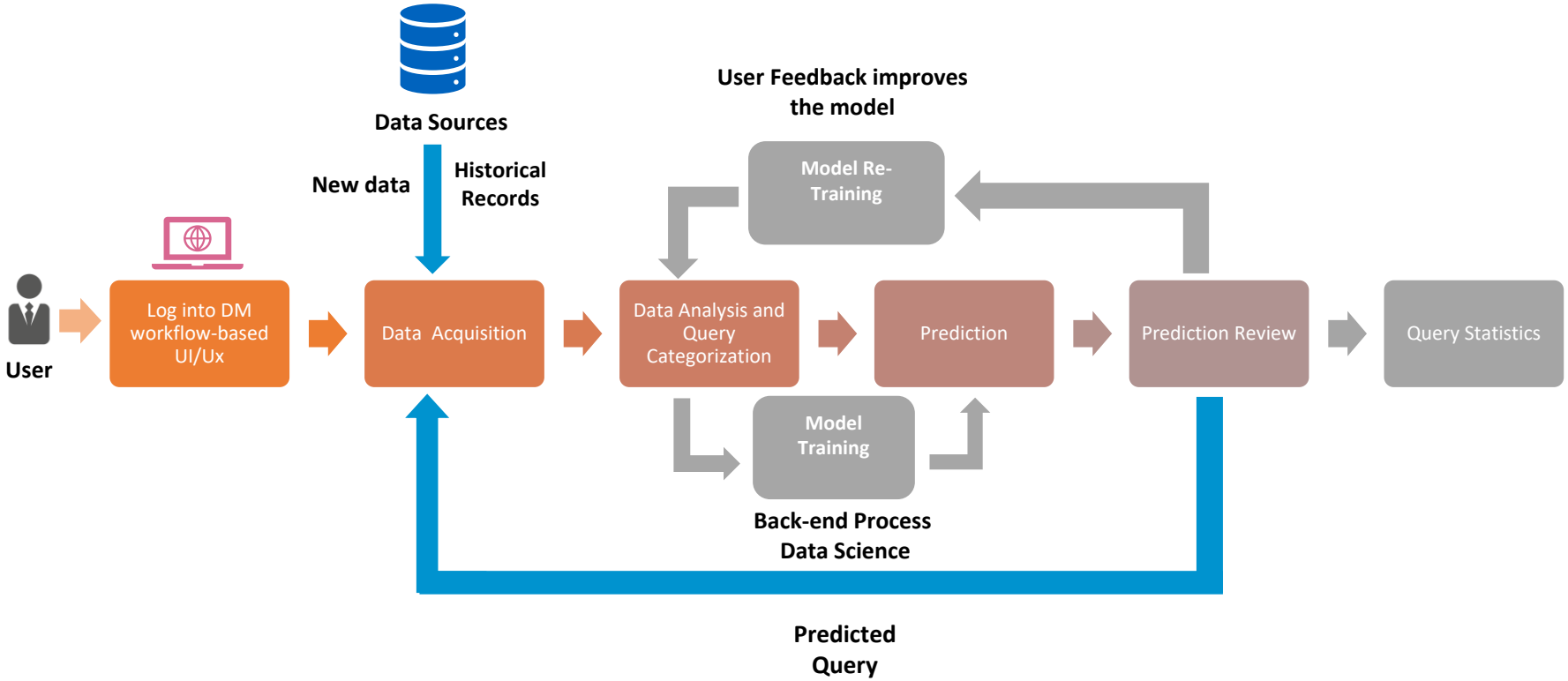
Dr. Jayathirtha Gopalkrishna

Current Challenges

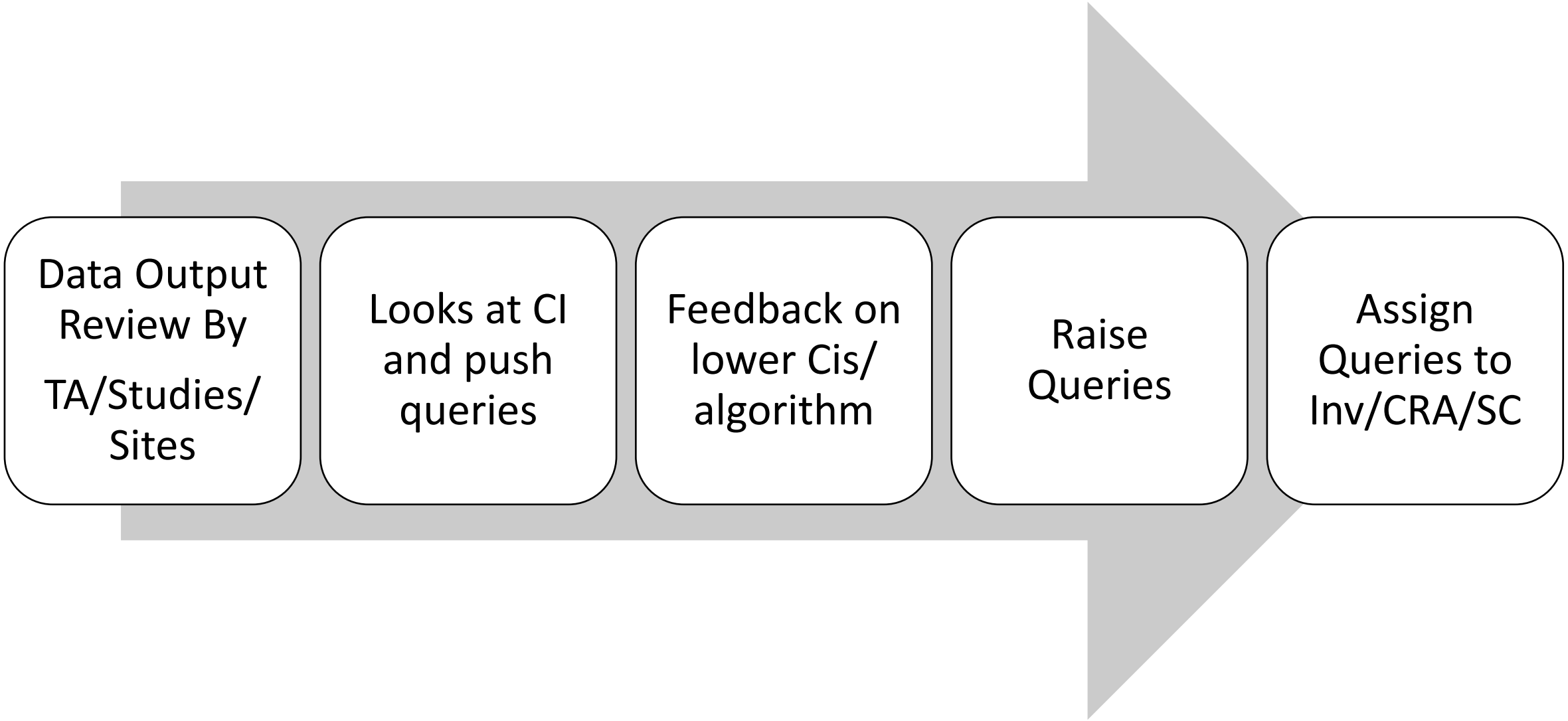
Objectives:

- ❑ Reduce Technology dependencies
- ❑ Disconnected to Connected
- ❑ Standardize
- ❑ Enhance Efficiency & Consistency

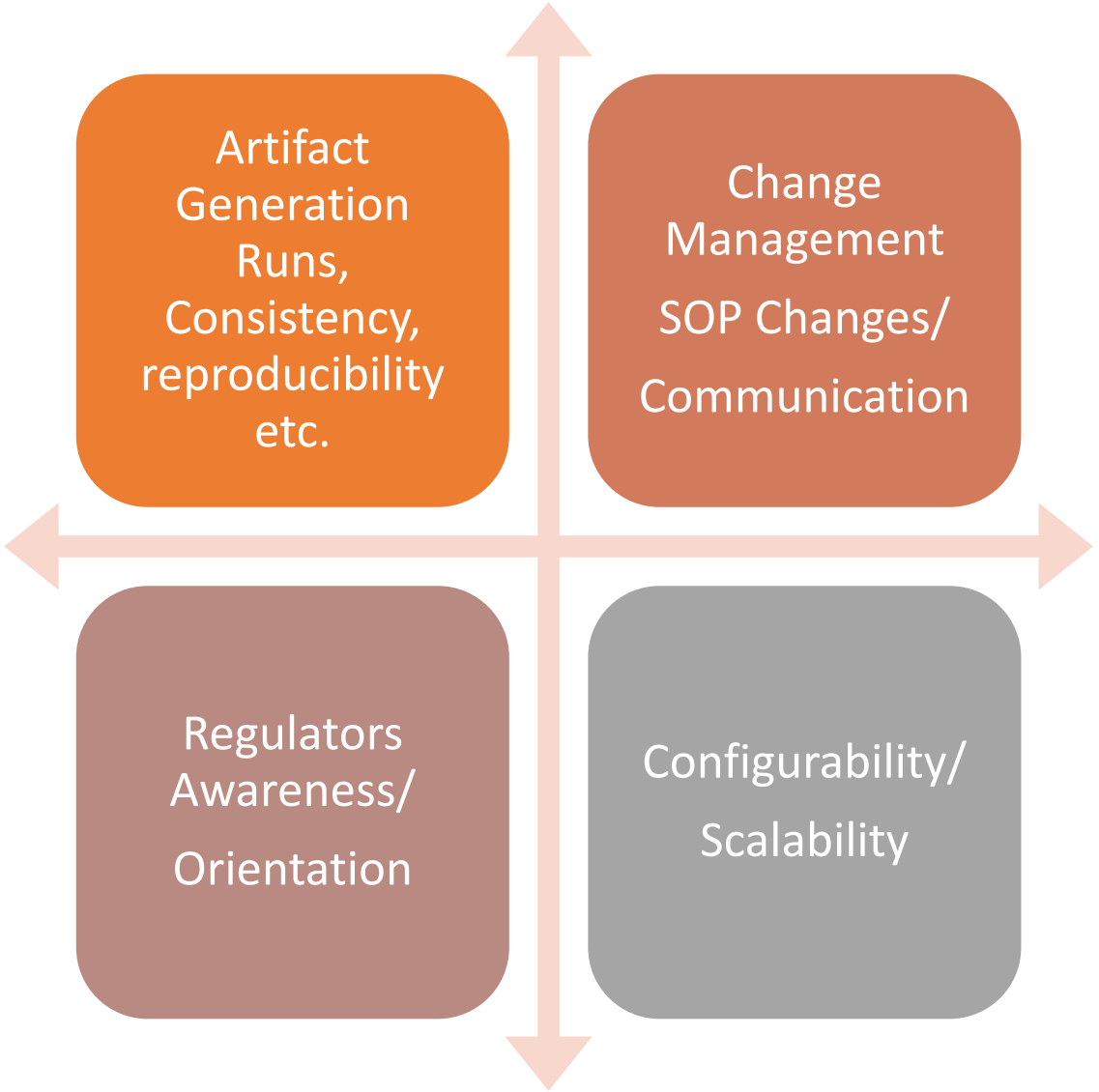
High Level Architecture



Typical Process Flow



Regulatory Considerations



Case Study

Business Problem

Reduce labor cost, reduce cycle time for DB lock and improve accuracy of queries
(Onco, I&I, Neuro, Vaccines)

Customer Inputs

1. EDC Data, Query data and metadata for completed & ongoing studies
2. SMEs, DM, Data Scientist & Clinical Programmers
3. Ground truth (limited data) and guidance on the nature of queries

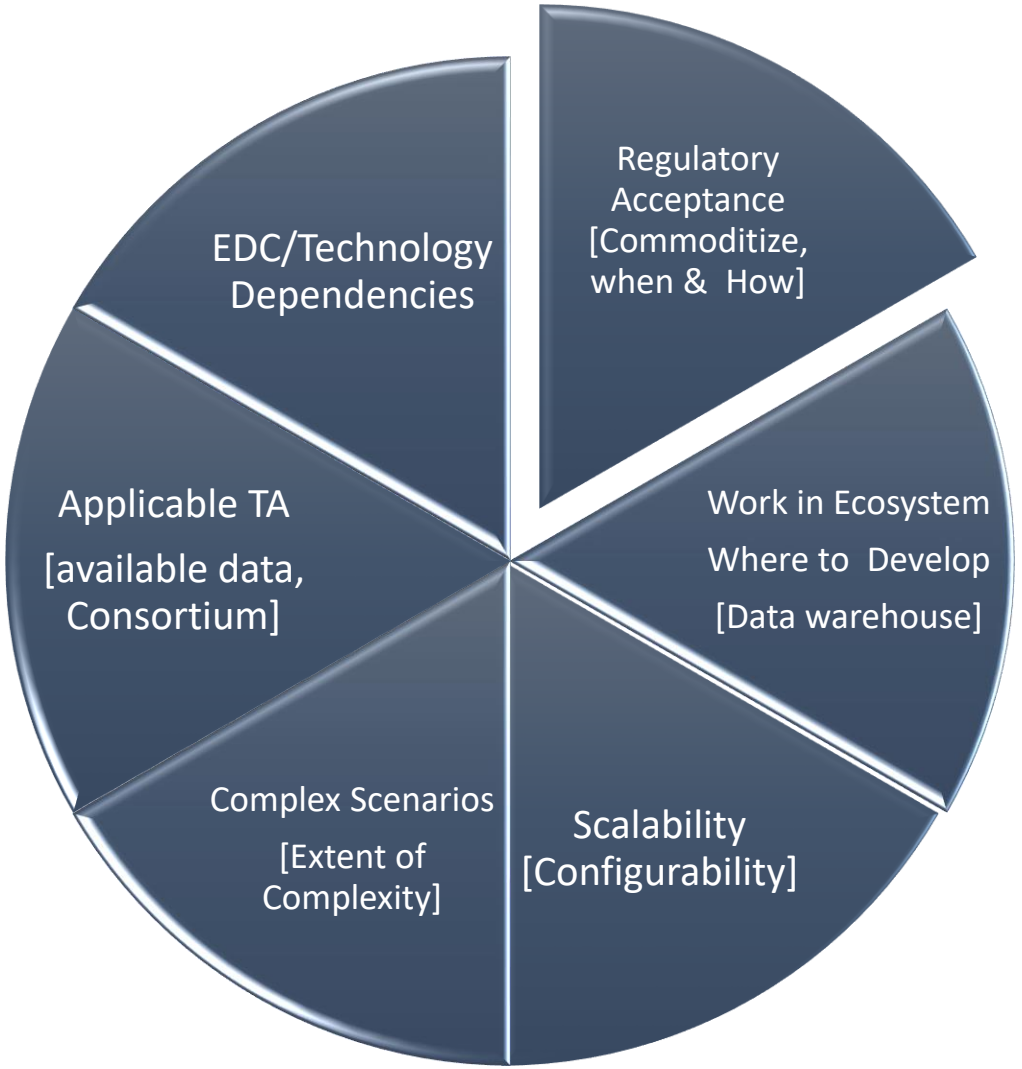
Timelines

14-16 weeks to demonstrate the outcome

Output

1. From 13 oncology studies, selected **193,147** manual queries for Learning distinct patterns of data queries
2. **Neural Network** was trained on GOOD and CRITICAL queries
3. Multiple patterns were identified however, focus was to successfully predict **10** Categories (5 AE, 5 CM) from clinical data which accounted for ~ 30% of total # Queries
4. Data Discrepancies were awarded IDs, standard descriptions, standard queries with data specific tags
5. Achieved ~ **90%** Accuracy multiple iterations with human-in- loop
6. Reduction in time/effort in identification of manual query by ~40%

Key Considerations



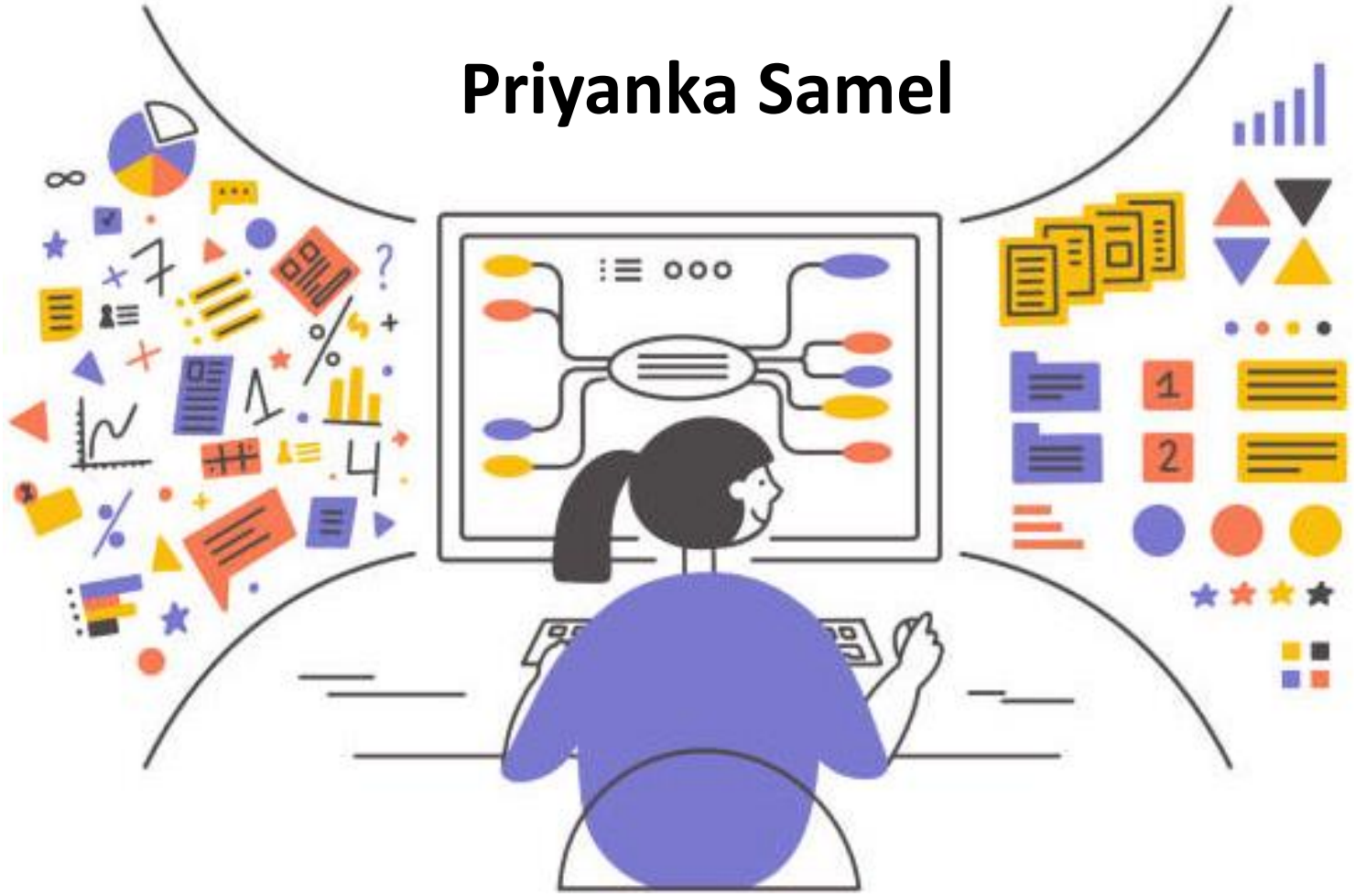
Poll Question

Is the role Clinical Data Scientist different than that of Clinical Data Manager?

- Different
- Same
- Overlapping

CDS- my journey

Priyanka Samel



Clinical Data Scientist – KRIs
day in life of a CDS

Accountability of **Data Integrity** and **Data Quality**	To share insights about missing data
	Look for Data Trends and overall health of data
	Identify anomalies, issues, outliers
	No data issues in P21 when nearing the timeline
	Edit check specification robustness (for completeness and accuracy, identify missing checks)
	Identify data issues closed without proper resolution
	Identification of dormant check/ which never fired
	Query response cycle time to de-risk timely availability of Data

Group activity

30 minutes - Brainstorm within your groups –
People | Process | Technology | Regulatory

What are your top 5 considerations to promote **Smart Data Review** for **Early Data Insights** from

a) People perspective
b) Process perspective
c) Technology perspective
d) Regulatory perspective

Provide ~5 responses for your assigned group only

Eg: if you are assigned to people group; pl provide 5 considerations from people perspective only

Enter your responses on flip chart; Group Lead to present

Groups

People	Process	Technology	Regulatory
Lead – Raghavendra Shivallingappa	**Lead - Amey Choutai**	**Lead - Jyothi Kotha**	**Lead - Prakash Tupe**
Eithasab Ahmed	Jalpa Ajmera	Rishabh Bansal	Dilip Barai
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Seema Singh	Ganesh Srinivasan	Sivasamy Subramanian	Ankitha Swapnil
Sridhar Tirandas	Megha TM	Dhanashree Tulsulkar- K	Appalla Venkata Prabhakar

Conclusion

Raghu, Jay, Inder

Thank you