How leadership, statistics and new insights can bring data management closer to data science

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Disclaimer

The views expressed in this presentation are solely my own and do not reflect the views of my employer, colleagues, or the conference organizers.

Outline - *How to connect the dots*

Leadership
- Empower and connect teams
- Competency development & Change Management

Statistics
- Learning from the scientific approach in drug development
- Build in-house analytical competencies

New Insights
- Build a Data Scientist hub
- Evolve our current organization

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Perspectives from a “Biostatistics” leader

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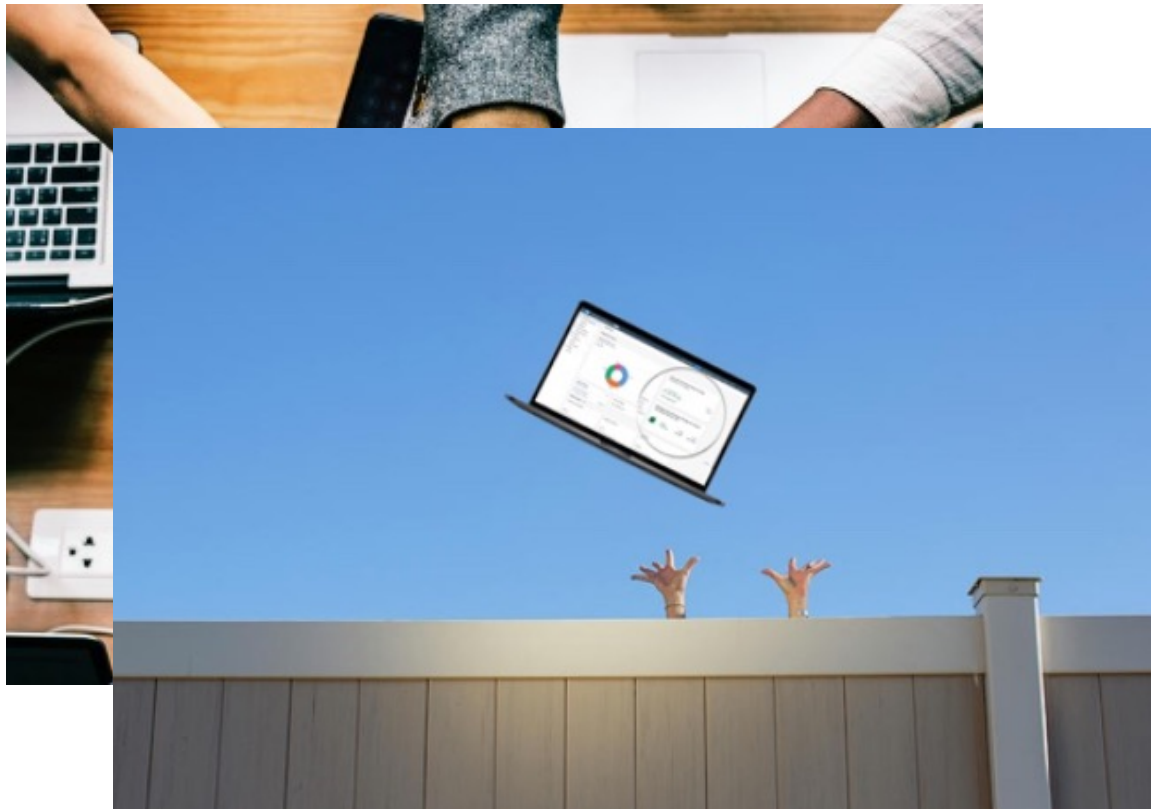
The complexity of Clinical Data Management

How Biostatistics should receive data from CDM



- High complexity of the Clinical Data Management process & system landscape – **an eye opener!**
- Organizational understanding on both sides of the ”fence”
- Understanding of implications with e.g., non-standard data flow
- Importance of setting the direction - connecting the teams
- Increased focus on a competency development and change management

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Scientific deliverables with increased insight

- Study deliveries without surprises across the trial data value chain - accountability, agreements and clear expectations
- Focus on design, critical data and technical feasibility
- Empower teams to take decisions, connect roles and teams
- Joint understanding and increased insights to the scientific objective

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What can we learn from Biostatistics?

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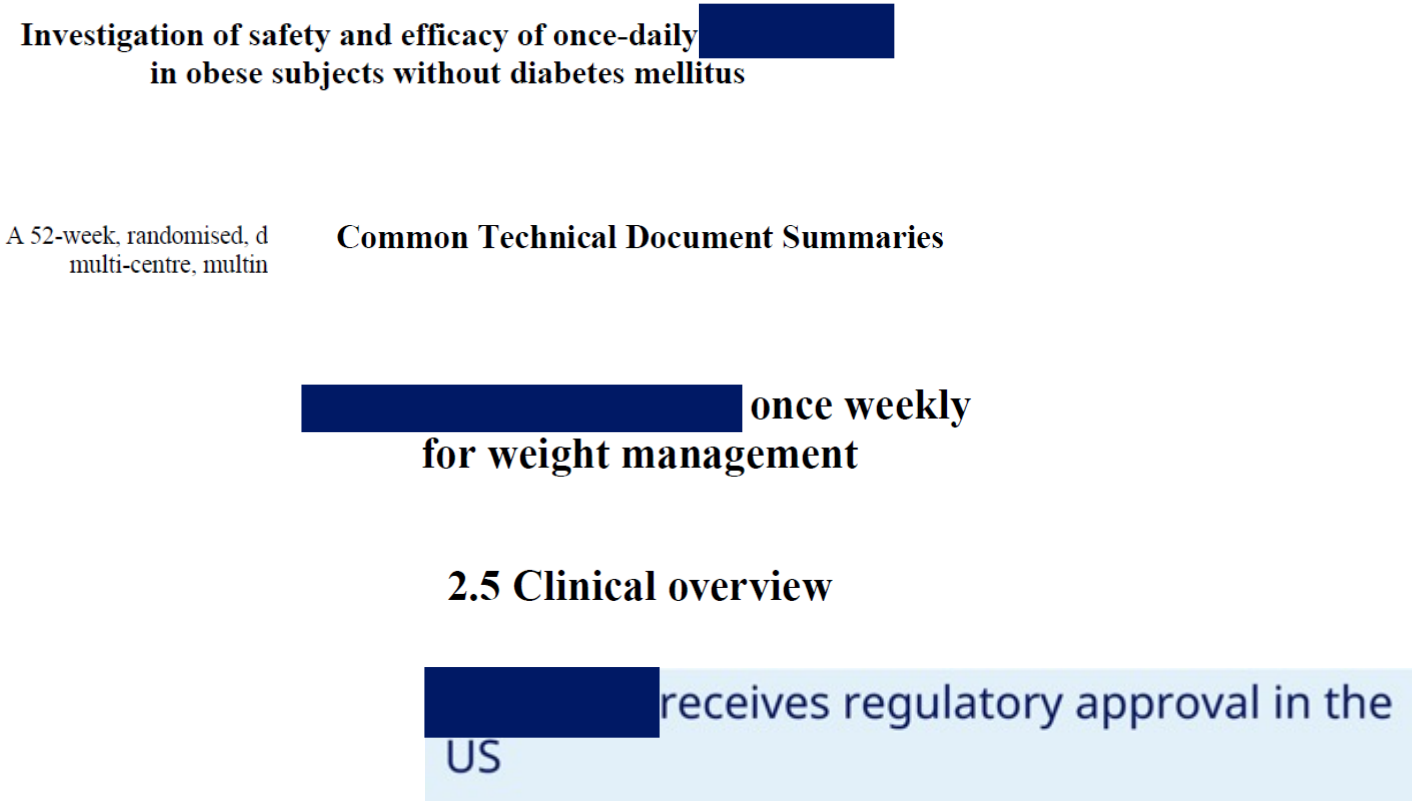
Statistical perspectives

The understanding of drug development across the clinical program



A broader understanding of data science is crucial for ….

- The Product Development Plan can be directly linked to Clinical Data Management operational activities
- Clinical Data Management can significantly influence the Global Project Teams
- Gaining deeper insights into the importance of quality is essential

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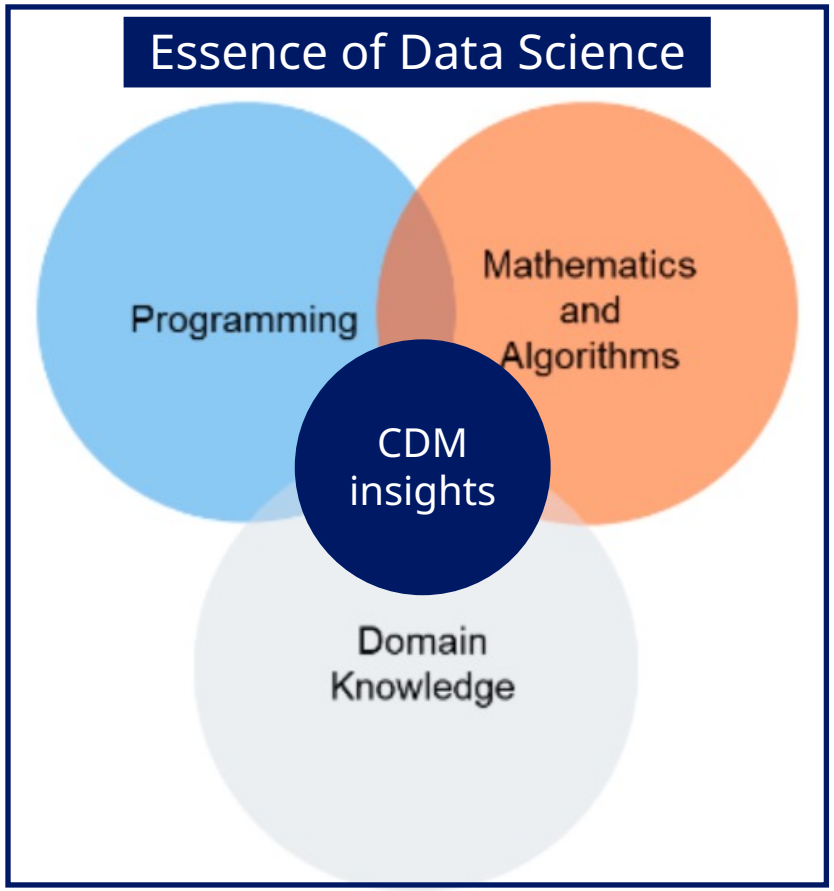
Understand your science based on your data

- Increase your focus on applying multidimensional visualizations
- Leave the listings behind and embark on advanced plots and dashboards
- Expand the focus on “Why is Quality important?” beyond RBQM for increased insights into the clinical assessments and statistical analyses
- Maintain a continuous focus on enabling data-driven decisions
- Embrace the “detail-oriented colleagues” – advocate for the risk-based approach across the data flow
- Increase the data literacy as part of the competency development journey



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New insights & reflections

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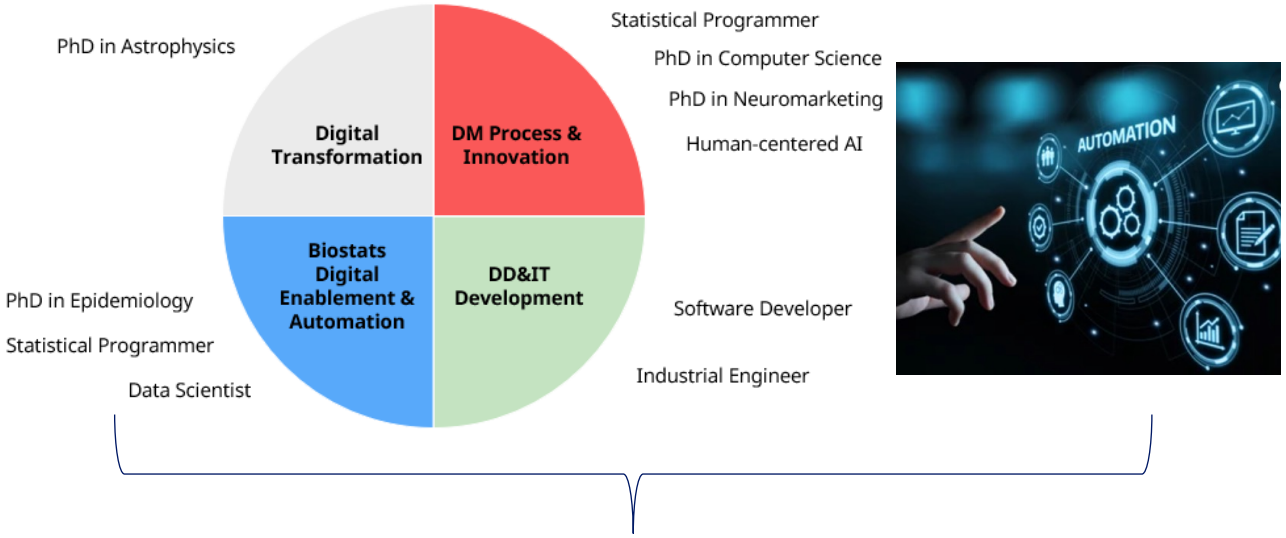
Grow new competencies by inclusion and development

Include new skills to Clinical Data Management community by inviting Data Scientist into the organization with objective to apply analytical problem-solving, programming skills, and focus on data science methodology.



Statistical analyses, Generative AI, Machine Learning

- Establishment of a Data Science Automation Group partly anchored in Clinical Data Operations & Insights
- Data Scientists to join the problem solving for the operational teams
- Using science to solve operational challenges
- Working across the global organization to connect our analytical insights and avoid silo thinking

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Data Science Methodologies – Analytical insights for Clinical Data Management Operations

- Gain deeper understanding of the multiple data sources (new immature data vendors) with new data types, changing type of data (e.g., omics), new systems, access without compromising data integrity and to allow data driven decisions
- Build expertise within methodologies of ML, AI, Multidimensional statistics and to build an analysis platform for analyzing data in “real-time”
- Examples of projects & ideas from NN CDOI Data Science team:
  - Anomaly detection using machine learning models for the likelihood that a data point should be queried
  - Analyses of using historical data to improve our approach to data cleaning
  - Generative AI for automatic coding of free text
  - Initiatives to empower the Clinical Data Management community including an Open-Source programming community, Visualizations, Dashboards and new ways of assessing the data flow

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Summary

Hope you got ideas to strength the link between Clinical Data Management and Data Science …

via reflections on how leadership, statistics and new insights can help this

Questions ?

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