

# Welcome & Plenary Session 1

## Up-Skilling Data Managers for the Future Panel

Presented by:

**Maria Craze** - Executive Director, Merck & Co., Inc. (USA)

**Mike Jagielski** - CEO & President, KCR

**Christopher Lamplugh** - Associate Vice President, Merck & Co., Inc. (USA)

**Catherine Celingant** - Senior Director, Pfizer Inc.

**Jennifer Duff** - Senior Partner, Watson Health Consulting for Life Sciences at IBM



# Agenda



Introduction to the Panel



Panelist Discussion



Audience Q & A/Discussion (Live or Via Slido)



Panelist Discussion



Audience Q & A/Discussion (Live or via Slido)



Closing Remarks



# Introduction to Session Chair: Maria Craze

- Currently the Head/Executive Director of Global Data Operations @ MSD (Merck & Co., Inc. (New Jersey, USA). Global Data Operations is a team of over 850 staff responsible for effectively and efficiently providing data collection and validation tool specifications, UAT of those tools as well as the in-life data validation and encoding of all late-stage clinical trial data.
- Maria's career at MSD started 20 years ago in the data entry department. Over this career Maria has held many CDM roles ranging from CDM to lead CDM, Project Manager to Subject matter expert as well as several leadership roles.
- Maria also serves the Pharma industry in the area of CDM by contributing to many conferences, organizations and committees. Maria is currently on the Board of Trustees' Executive Committee of the SCDM and participates in DIA and eClinical Forum. She is a repeat presenter at ACDM as well.

# Introduction to the Panel: Mike Jagielski



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Mike Jagielski is President & CEO of KCR, a contract research organization operating internationally. KCR is a mid-size full service CRO with 500+ employees.

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He plays a significant role in advocating for a patient-centric approach in clinical studies. Mr. Mike Jagielski stepped in as President and CEO of KCR in 2013.

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He has over 20 years of experience in the global clinical trial operations industry. Prior to joining KCR, Mr. Jagielski worked for MSD (Merck & Co, Inc. (NJ, USA) for over 15 years, holding managerial positions across many different countries and regions.

# Introduction to the Panel: Christopher Lamplugh



- Christopher Lamplugh is the Associate Vice President and Head of Global Clinical Data Management & Standards @ MSD. (aka Merck & Co., Inc, New Jersey, USA) providing Clinical Data Management Services for both early and late-stage trials, including data standards, IRT, COA, PV Case Processing, and other technical business enablement responsibilities. He has been in multiple leadership roles throughout his 18 year career with the company.
- Chris also led the creation, expansion and operationalization of MSD's Data Management Center Model across numerous locations.
- Prior to his CDM career, Chris worked for General Electric for a decade in the area of Sales Management and Sales Force Effectiveness and Quality.
- Chris is a Certified Six Sigma Black Belt and is active in several industry forums; such as, SCDM, DIA and multiple user groups and professional working groups.

# Introduction to the Panel: Catherine Celingant



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Catherine Celingant celebrates 30+ years in the Pharma/ Clinical Research Industry. Her experience includes Data Management, Clinical Informatics, and Medical Operations across several influential companies such as Millennium (Takeda), Genetics Institute (Wyeth) and Accenture.

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Catherine is currently Executive Director @ Pfizer, Inc. in Data Management & Monitoring; she is responsible for the timely and high-quality data management deliverables for the Oncology portfolio and is currently co-leading a cross-functional initiative to implement risk-based data review across the Data Management and Clinical organizations.

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Catherine is a member and participant in many industry forums and teams; including efforts by Transcelerate, eClinical Forum, SCDM and PhRMA EDC. She has presented in such forums as SCDM, DIA, SCOPE and PhRMA (just to name a few).

# Introduction to the Panel: Jennifer Duff



Jennifer Duff has over 23 years of experience in the Life Sciences industry with specialization in enabling and scaling industry-leading services and technology solutions with clients. She is the eClinical & Customer Solutions Leader for IBM Watson Health Life Sciences where Jennifer is focused on enabling the next generation of eClinical and clinical development solutions for leaders across the Life Sciences industry. Jennifer leads a global team of experts specializing in eClinical and clinical development technology solutions and is responsible for defining and leading Watson Health's Life Sciences eClinical and clinical development strategy.

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Over her career, Jennifer has collaborated with teams across the Life Sciences industry, from large to mid-sized companies, as well as many of the major technology providers.

~~Jennifer has an MBA in Biotechnology and Healthcare~~ Management. She is passionate about challenging industry norms and seeking powerful, novel solutions that drive business growth and deliver improved outcomes for Life Sciences clients and the patients they serve.



What 1 Word would you use to describe the Data Manager of the Future?

- English Responses Please
- Use the Slido

# Question Set Options: Set 1



Prior to talking about the upskilling of CDM for the future... What do you believe is the **scope** of Data Management in the future?



Some describe a Data Scientist as being responsible to develop a clinical data strategy for a clinical development program. How would you describe a Data Scientist to compliment or even contradict this description?



How do you think new tools; automation, analytics , statistical, ML/AI, etc. will change the roles and responsibilities of the Data Manager?



What role do you believe the Data Manager (or Data Scientist) of the future plays in Outsourced Trials?

# Question Set Options: Set 1 (page 2)



What new skills will Data Managers need to be able to effectively communicate to tech based data acquirers (e.g. digital data capture technologies) in order to get the required data in an appropriate format and on time?



How does our approach to training data managers need to change and evolve to keep up with change?



Are organizations moving Data Managers into new roles such as Central or Remote Monitoring? If so, how are/should they deal with new skill training?

# Audience Q & A



# Question Set Options: Set 2



When thinking of recruiting for the data manager of the future what are the key skills and competencies you think will be most valuable?



As Data Managers evolve from data cleaners and collectors to data brokers and data analysts, should we be thinking about formal programs available in Universities to support skills changes?

# Question Set Options: Set 2 (cont'd)



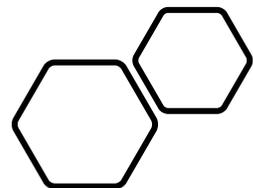
How can the future data manager focus on understanding truly cross functional study delivery to optimize data collection?  
Who are their partners, customers, stakeholders and how do they relate and collaborate?



As a more patient centric approach, including decentralized trials) is certainly a big part of future clinical trial execution, what role does the data manager of the future play in these types of trials?



Data Managers now need significant skills in; understanding protocols to identify which vendors can deliver the required data, managing vendors and managing timelines & budgets. What are the most effective methods to help them make that transition?



Audience Q & A





What 1 Word would you use to describe most important SKILL the data manager of the future will need?

- English Responses Please
- Use the Slido

# Closing Remarks from Each Panelist



THANK YOU