The Role of the Statistician and Statistical Programmer in Real-world Data Analysis

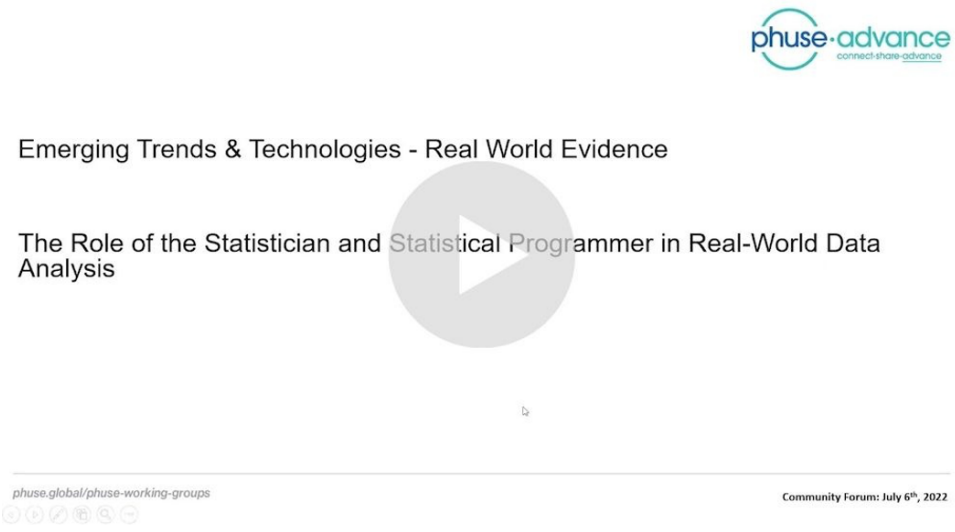
Emerging Trends & Technologies: The Role of the Statistician and Statistical Programmer in Real-world Data Analysis

Use of real-world data in regulatory submissions is growing. Real-world data provides unique insights which can be used for informed decision-making, resulting in faster drug approval. However, the nature of real-world data is quite different from that of clinical trial data. While the latter can be controlled at all stages, from collecting to reporting, this is not the case for real-world data. This imposes many challenges including pre-study alignment with regulatory agencies regarding validity of the data used. How does this affect the roles and corresponding responsibilities of various cross-functional clinical team members?

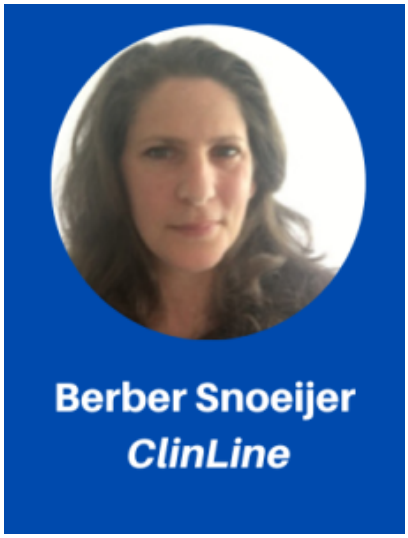
This event took place 6 July 2022 and started with a 30-minute presentation focused on the changes necessary to use real-world data. The event is followed by a forum discussion on how this affects the role of the statistical programmer and the statistician. Visit the online Disqus forum to be part of the discussion!

Catch up Here!

This Community Forum took place on 6 July 2022. Catch up by viewing the recording.
Do you have a question for the presenters? Please submit it to the online Disqus forum posted below!

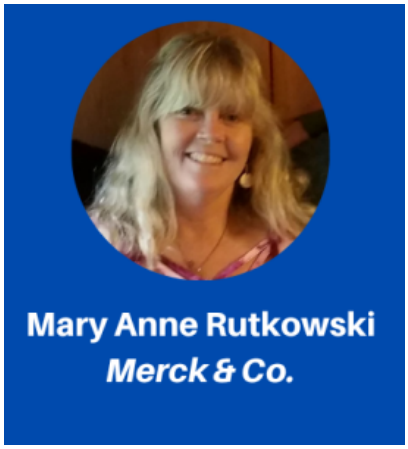


Presenter	Bio



Berber Snoeijer, *ClinLine*

Berber Snoeijer started in clinical research in 1997 as a biometrician and has since then worked with clinical data in different functions. In 2001 she started a CRO – Biometric Support – aimed at the data management, data analysis and reporting of clinical trials. In 2011 she started as an R&D manager dedicated to investigating and utilising the potential of real-world data from electronic health records. This resulted in many different solutions including a full reporting system to give feedback information to clinical research professionals. Berber is experienced with software and database engineering, process engineering and improving efficient utilisation and interaction of people based on management drivers. Nowadays, she uses these skills and knowledge to help life science companies assess, design and improve business solutions and processes at smaller and larger scales.



Mary Anne Rutkowski, *Merck & Co*

Mary Anne Rutkowski is currently a Principal Scientist at Merck & Co in a Statistical Programming department, where her team provides high-quality programming analysis and reporting deliverables using real-world-data for non-interventional studies. She has been at Merck for over 30 years and during her first 25 years she had many roles, most of which were in programming groups that used clinical trial data for regulatory submissions or claims data for marketing analysis. Mary Anne recently joined the PHUSE Real-World Evidence Working Group. She has a bachelor's degree in engineering, a master's degree in computer science and a master's degree in business administration.

Sangeeta Bhattacharya, *Johnson & Johnson*

Sangeeta Bhattacharya is the Statistical Programming and Analysis Head for Immunology and Medical Affairs at Janssen Research & Development. For the last 24 years, Sangeeta has led large high-performing global teams of statistical programmers/analysts in various pharmaceutical companies. At Janssen, Sangeeta is also responsible for sponsoring and setting the data engineering strategy, to pioneer data wrangling and visualisation skills in support of analysis of novel trial designs. Sangeeta has been involved in PHUSE in various capacities including Stream Chair, Working Group Lead and PHUSE Board member. She has a master's in biostatistics with a minor in epidemiology from the School of Public Health, University of Texas.