Designing Your RWD Study: Is Your Data Fit for Purpose?

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This was our third Community Forum of the year and included three insightful presentations from Jonathan, Elizabeth and Andy. Jonathan kicked off the Forum with a broad overview of study design considerations when using real-world data in regulatory submissions. His gentle introduction to some of the biases common to studies using real-world data prompted interesting questions on how to handle these biases and how to evaluate databases for such biases. Elizabeth's presentation followed and got more specific, with a dive into externally controlled study designs. She guided the attendees through the industry's experience with these study designs so far, particularly in terms of getting regulatory approval, to see what we could learn in terms of getting data that is fit for purpose. Last but not least, we got more technical, with Andy's presentation on the FHIR[1] standard, where he talked about how FHIR may be used as part of an ETL[2] procedure to replace the manual EDC[3] from EHRs[4] traditionally done in clinical trials – an exciting idea that is very applicable to RWD and surely worth a second viewing or two! Thanks to Mary Anne for organising and leading the Forum, to Jonathan, Elizabeth and Andy for presenting, and to the attendees for their participation. We look forward to hosting the next Community Forum in October – please watch this space! [1] Fast Healthcare Interoperability Resources [2] Extract, Transform, Load [3] Electronic Data Capture [4] Electronic Health Records The recording for this Community Forum is available now at the bottom of this page and the slides are available here.

Catch up here!
This Community Forum took place 6 July 2023. Catch up by viewing the recording. Got a question for the presenters? Submit it to the online Disqus forum posted below!


Presenter	**Bio**

Andy Richardson, *Zenetar*

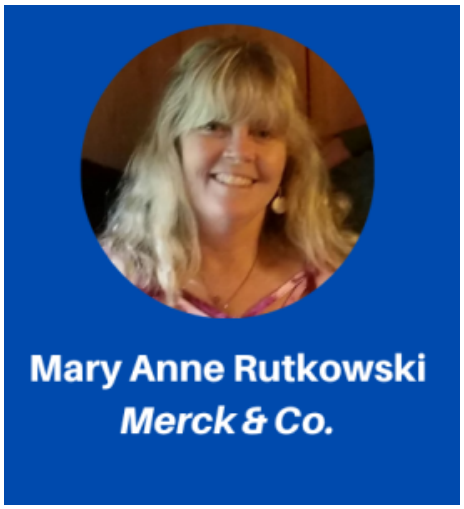
Andy Richardson is an independent clinical standards and data management consultant with Zenetar, with more than 30 years' CRO and pharma experience. His principal interests are in operational data efficiency and currently in the use of the HL7 FHIR standards in support of clinical research. Andy is an active PHUSE Working Group member and is a key member of the HL7 Vulcan SOA and related projects. He holds degrees in pharmacology from Sunderland (BSc) and Leicester (PhD) and is an LSHTM tutor.

Elizabeth Merrall, *Janssen Research and Development*

Elizabeth Merrall is an Associate Director in Biostatistics at Janssen Vaccines and has been working in the industry for nearly 12 years. She is a keen follower of methodological developments, particularly in the area of real-world data, and participates in both the PHUSE and PSI real-world data special interest groups. Elizabeth holds a PhD in Medical Statistics from the University of Cambridge, a master's from the University of Southampton and an undergraduate degree from Imperial College London (UK).

Jonathan Assayag, *Pfizer*

Jonathan Assayag is Global Director RWE Scientist Oncology at Pfizer in the evidence RWE generation department. He supports oncology deliverables using real-world data for non-interventional studies. He has been at Pfizer for over six years and prior to this role he worked in medical affairs at Pfizer Canada. Jonathan recently joined the PHUSE Real World Evidence Working Group. He has an MSc and PhD in Pharmacoepidemiology and is also an adjunct faculty at McGill University in the Faculty of Medicine.



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.