Experiences with Adapting RWD to CDISC Submission Standards

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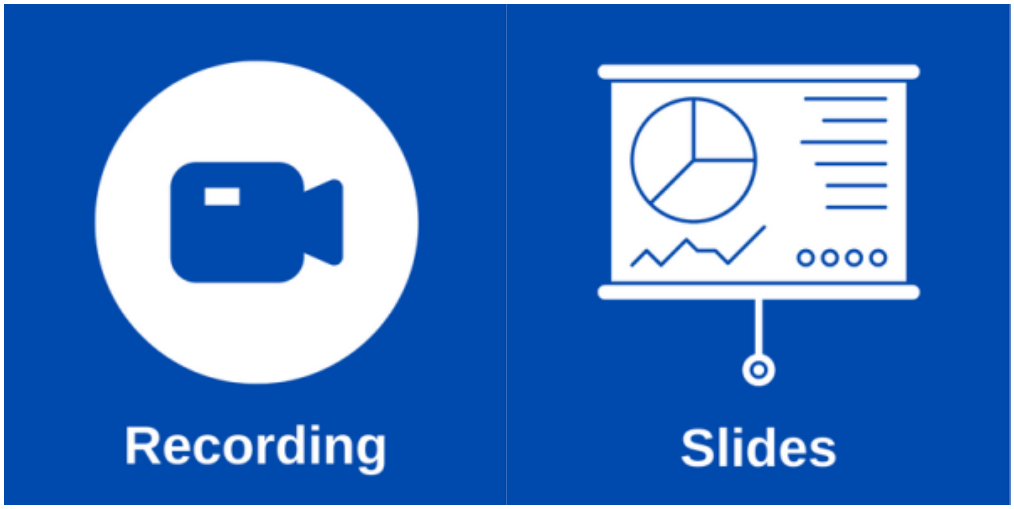
This was our fourth and final Community Forum of the year and it was a lively event. It included two insightful presentations from Lauren, as well as Sandy and Christine, who shared their experiences of adapting RWD into CDISC submission standards. This was followed by a sum-up from the regulatory perspective by Jeff, and plenty of discussions – which participants and late-viewers are welcome to continue here online. Lauren set the scene nicely with an overview of the challenges and focused on two of these relevant to her experiences in oncology, but likely equally applicable to others: missing data elements and source-to-target mapping. Sandy and Christine followed with their wide-ranging experiences of a phase 4 observational study of vaccine effectiveness – the need for RWD, and how these data were linked with the clinical subject data via tokenisation, CDISC mapping challenges and considerations for submission data package components. Jeff rounded off the forum with his invaluable commentary, recognising the various gaps in the current standards for submitting RWD and common issues identified by Lauren, Sandy and Christine; how the key issues may be addressed in the short-term and what are the possible solutions in the long-term. Thanks to Lauren, Sandy, Christine and Jeff for presenting their experiences, to Elizabeth and Mary Anne for organising and leading the Forum, to Alexandra from PhUSE for making sure everything ran smoothly behind the scenes and, last but not least, to the attendees for their active participation. We look forward to hosting the next Community Forum in January – please watch this space! This event took place on **5 October**

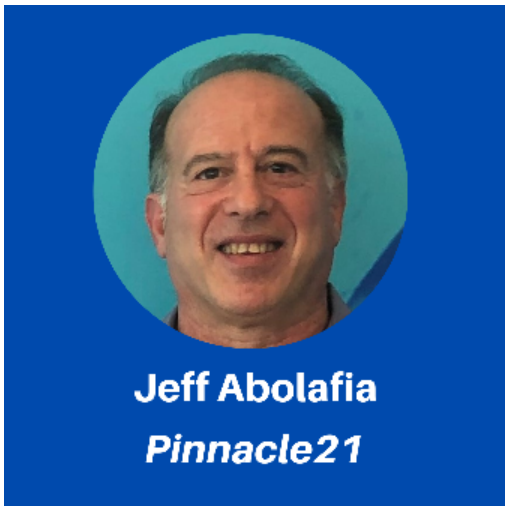
Catch up here!
This Community Forum took place 5 October 2023. Catch up by viewing the recording or reading the slides Got a question for the presenters? Submit it to the online Disqus forum posted below!



Presenter	Bio

Lauren Green, *Amgen*

Lauren Green is a Biostatistical Programming Senior Manager at Amgen, where she provides leadership to the US-based oncology therapeutic area pipeline programming team. As the programming lead, she supports the execution of oncology-related real-world evidence observational studies and collaborates closely with epidemiologists and product leads in their respective spaces. In her career, Lauren has led additional efforts in the evaluation of real-world data aimed at improving the quality, safety and value of healthcare, publishing papers in emergency medicine, internal medicine and medical education. Her main interests include dissecting the challenges of real-world data (RWD) and the unprecedented opportunity it provides in preventative medicine and population health.



Jeff Abolafia, *Pinnacle 21*

Jeff Abolafia is currently Director of Product Innovation at Pinnacle 21 and supports multiple offices at the FDA. Previously, Jeff held the position of Chief Strategist of Data Standards and was a member of the faculty in the Department of Biostatistics at the University of North Carolina. He has been involved with public health research and data standards for over 30 years. Jeff co-founded the RTP CDISC User's Group and is a member of the CDISC ADaM and Analysis Results teams and several PHUSE Real World Evidence Working Group Projects. His areas of interest include regulatory submissions, real-world evidence, mobile health, data standards and bioinformatics.

Christine Rossin, *Pfizer*

Christine Rossin is currently the Senior Director of Electronic Submissions in Statistical Data Sciences and Analytics at Pfizer. In the three years in her role, she has expanded the eSub group from a single position into a global team of eSub specialists, who ensure quality and technical conformance for all data packages dispatched to agencies. Christine has also made numerous improvements in the cross- functional collaborations needed to deliver conformant eSub data packages efficiently. As a result of the critical importance of Pfizer's COVID-19 vaccine development, she established a new working model of embedding a specialized eSub team into statistical programming teams for high-priority programs. Christine brings a deep level of experience into her work as she has been in the pharmaceutical industry for over 24 years, including 13 years at Roche and 5 years previously at Pfizer. When not working, Christine spends her free time cooking with her husband, traveling as a new empty-nester and watching NJ Devils or Pittsburgh Penguins NHL teams (or any level of hockey)!

Sandra VanPelt Nguyen, *Pfizer*

Sandy VanPelt Nguyen has been working in clinical research for over 20 years and has been involved with PHUSE since 2015. She currently co-leads the Best Practices in Data Standards Governance Implementation project and supports the Clinical Integrated Study Data and Analysis Data Reviewer's Guide and Submitting Real World Data projects. Sandy works at Pfizer as a Director in the Submissions and Standards team, focused on end-to-end data standards implementation, governance and optimisation.