# Submitting Real-world Data Community Forum


**Submitting Real-world Data**

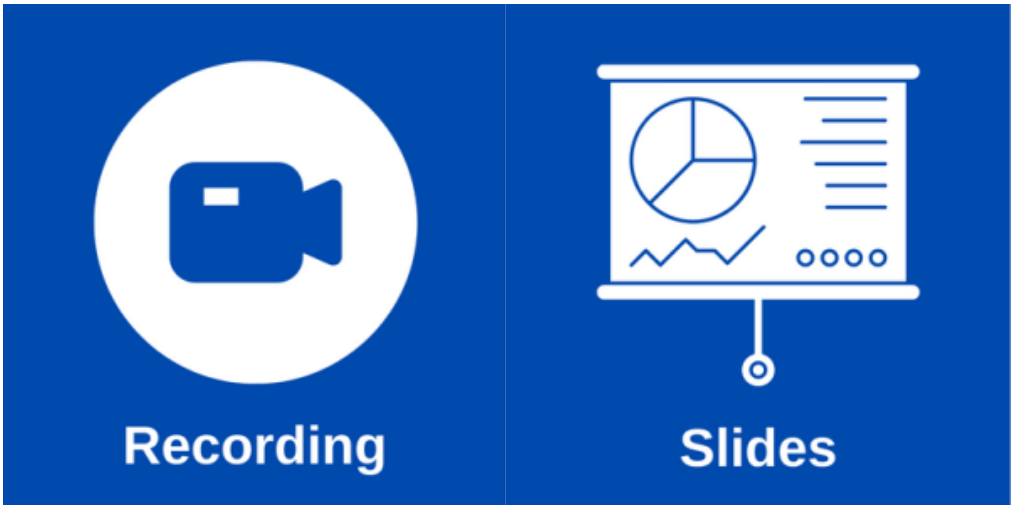
There has been a rapid increase in the use of Real-world Data (RWD) to support marketing applications. In 2020, over 75% of NDAs and BLAs submitted to the FDA included an RWD study to support safety and/or efficacy claims. Use of such data poses several challenges in terms of bias, traceability, transparency and clinical data compliance to current submission standards. Submission of such data to regulatory authorities also poses challenges, and sponsors need to plan such submissions properly.

This Community Forum hosted by the Emerging Trends & Technologies Working Group will present an overview of current regulatory guidance and their interpretations. Presenters Parag Shiralkar (*Sumptuous Data Sciences*) and Jeff Abolafia (*Pinnacle 21*) will discuss the approach to planning the submission of RWD to regulatory bodies. As part of the planning, interpretation and use of regulatory guidance, issues, gaps and challenges will be investigated, as well as possible resolutions and recommendations, for submitting RWD.

Informative presentations will be alternated with Q&A sessions, followed by an online Disqus forum to continue the conversation on this subject and exchange experiences and ideas post event!

**Catch up here!**

This Community Forum took place on 18 January 2023. Catch up by viewing the recording or reading the slides.
Do you have a question for the presenters? Please submit it to the online Disqus forum posted below!




| Presenter | Bio |
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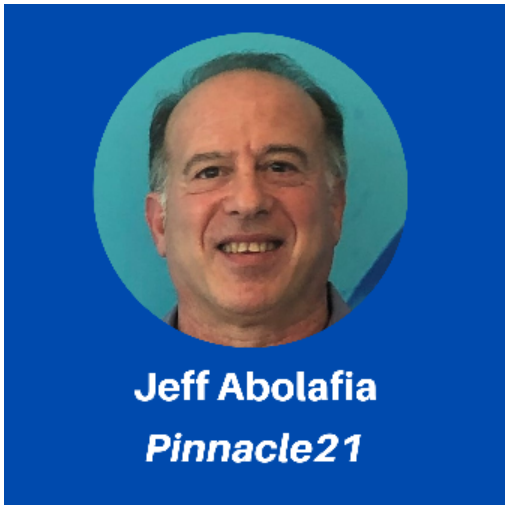
**Parag Shiralkar, *Sumptuous Data Sciences***

Parag Shiralkar has over 18 years of experience in the pharmaceutical and biotech industry. He has taken operational, managerial and executive leadership roles in the functions of data operations, biostatistics and statistical programming. In his tenure, Parag has worked on almost all aspects of data operations and analysis involved in clinical trial data used in the context of the drug development process. He has led the execution of statistical programming activities for various regulatory submissions in the Immunology, Rare Disease, Infectious Disease and Oncology therapeutic areas. Parag's current career interests include framework for appropriate use of Real World Data (RWD) for clinical as well as medical research, risk-managed use of open-source technologies and application of AI/ML in the statistical reporting environment. He has completed master's degrees in biostatistics and in business administration. Parag is President of Sumptuous Data Sciences and is based out of New Jersey, USA.




**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.

| Resources |
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| Submission Standards for RWD: The Good, The Bad and The Ugly |