Speaker Introduction

Shweta Daga *is an Executive Regulatory & Quality Leader with over 14 years of successful experience in the regulated industry including Regulatory Affairs, Quality Assurance and Systems and Clinical Affairs regulations.*

She specializes in designing and implementing creative and compliant US/OUS regulatory strategies for faster patient access to novel medical devices including SiMD, SaMD, e-Commerce, Digital Health, Natural Health, and Drug/Device Combination products

Shweta is currently part of MDIC Medical Device Extended Reality Workgroup as one of the industry representative.

Shweta is also currently leading regulatory engineering, compliance and operations functions at Align Technology Inc. as Director of Regulatory Affairs.

In her free time, she likes running, dancing, sidewalk chalking, and of-course reading and interpreting lots of regulations.

Can be reached at sdaga@rwb.llc for any questions.)

The Importance of Patient Perspective & early patient engagement for evaluating the benefits and risks of Medical Extended Reality Devices

Shweta Daga, Director Regulatory Affairs at Align technology

Speaker's Disclaimers

- **Shweta Daga** do not have any financial conflicts to disclose.
- This presentation or session is not meant to offer medical, legal accounting, regulatory, compliance or reimbursement advice and is not intended to establish a regulatory state of art requirement.
- Please consult professionals in these areas if you have related concerns.
- Please refer to applicable country specific regulations directly for most up to date regulatory requirements.
- The speaker is not promoting any service, product or organization.

Background

- Augmented Reality (AR) and Virtual Reality (VR) Medical Devices are accelerating the use of immersive technologies for healthcare consumers.
- AR/ VR in healthcare has opened new opportunities for Health Care Professionals and is a promising technology from a modern health organization perspective.
- AR/ VR developments and use in target pediatric and cognitive impaired population are moving rapidly and so are the unique challenges due to the novel attributes of digital health visualization, tracking techniques, embedded software and unknowns in the pre-market evaluation space. Hence, these technologies require patient perspective and early engagement for a seamless transition more than regular digital health technologies.
- AR/ VR devices have the potential to be used in the surgical space and **s**ome other healthcare use cases of AR/ VR devices include but are not limited to 1) understand patients' condition better, 2) relieve pain, 3) provide surgery simulators for training medical practitioners, 4) train surgeons for actual surgeries, 5) educational training for medical students and teaching medical centers, and 5) Diagnosis and treatment of health conditions of patients

“User-centered design” for AR/VR Devices

- AR/VR Devices require a “user-centered design” specially considering that the target patient population is inclusive of pediatric and cognitive impaired patients.
- AR/VR devices are novel technologies and come with a key challenge associated with these devices directly related to “use” and “user” driven risks in addition to risks coming from hardware including display technologies, physical environment and software failure modes.
- To evaluate these risks as a patient centered device, there is a need to clearly define pre-market and post –market evaluations that are inclusive of patient early engagement.
- Patient-centered design during device development can occur at any point during the AR/VR devices development process. Early patient engagement for pre-market evaluation may be incorporated as equal partners with the designers at the beginning of a project instead of patient input obtained via usability testing only during the final stages of design.
- The AR/ VR devices design process shall also include the needs of the environment and other users in the ecosystem like family members or guardians.

Reference: Brinbaum F. et al. **Patient engagement and the design of digital health.** Acad Emerg Med. 2015 Jun; 22(6): 754–756

Real-World Data, Privacy and AR/VR Device Designs

- AR/VR devices come with unique user privacy challenges due to the scope, scale, and sensitivity of the information collected by these devices.
- The immersive nature of AR/VR makes it difficult to mitigate risks by applying current privacy policies and practices from other digital health technologies.
- AR/ VR devices require new ways to manage transparency, choice, and security.
- Post market evaluation of AR/ VR devices can benefit significantly from a dedicated Real-world data collection program as the patient feedback can provide critical design improvements or identify future device generations that cannot be done in a pre-market set up.

Reference: Dick E.; Balancing User Privacy and Innovation in Augmented and Virtual Reality; 04 March 2021

Any Questions?

For future questions, I can be reached at **sdaga@rwb.llc**

)