

Summary of the Day and Closing Thoughts



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Summary of the Day and Closing Thoughts

Session 1: Selection of patient-reported symptomatic adverse event items is critical to informing tolerability, and can be improved with patient input and use of free-text items

Session 2: Timing of patient-reported outcomes can substantially impact results, particularly when assessing therapies with varying administration schedules and washouts.

Session 3: An overall side-effect bother item is an important piece of the tolerability puzzle.

Session 4: Project Patient Voice was a collaboration between patients, FDA, industry, and academic thought leaders to create a usable repository of patient-reported symptomatic adverse events.

Session 5: Patients and providers find Project Patient Voice valuable, helpful and useful, but there are areas for improvement for version 2.0.

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Acknowledgements

FDA Project Patient Voice Development Team

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Rick Pazdur

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Special thanks to our excellent panelists and all the patients who have provided invaluable feedback along the way.

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