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# A Practical Approach To

**John Ringwood Atkins**

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**A Practical Approach to Quantitative Validation of Patient-Reported Outcomes** Andrew G. Bushmakin,Joseph C. Cappelleri,2022-10-31 A Simulation Based Guide Using SAS In A

Practical Approach to Quantitative Validation of Patient Reported Outcomes two distinguished researchers with 50 years of collective research experience and hundreds of publications on patient centered research deliver a detailed and comprehensive exposition on the critical steps required for quantitative validation of patient reported outcomes PROs The book provides an incisive and instructional explanation and discussion on major aspects of psychometric validation

methodology on PROs especially relevant for medical applications sponsored by the pharmaceutical industry where SAS is the primary software and evaluated in regulatory and other healthcare environments Central topics include test retest

reliability exploratory and confirmatory factor analyses construct and criterion validity responsiveness and sensitivity

interpretation of PRO scores and findings and meaningful within patient change and clinical important difference The

authors provide step by step guidance while walking readers through how to structure data prior to a PRO analysis and demonstrate how to implement analyses with simulated examples grounded in real life scenarios Readers will also find A

thorough introduction to patient reported outcomes including their definition development and psychometric validation

Comprehensive explorations of the validation workflow including discussions of clinical trials as a data source for validation and the validation workflow for single and multi item scales In depth discussions of key concepts related to a validation of a measurement scale Special attention is given to the US Food and Drug Administration FDA guidance on development and validation of the PROs which lay the foundation and inspiration for the analytic methods executed A Practical Approach to

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