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Leif Simmatis

Postdoctoral Researcher,
University of Toronto

I'm excited to use the Study Builder to help my colleagues and I focus efforts on developing speech technologies by following a standardized, robust workflow for validation. By providing a thorough and actionable framework, the VNDCM framework and the Study Builder fill a critical need for theoretical approaches to validation and real, tangible guidelines that will help inform and instruct those working in this space.

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Libby Floden

Biostatistician, Head of
Endpoints, Evinova

I am thrilled to be able to leverage this scientifically principled validation approach for novel digital measures. This is a valuable resource for accelerating the acceptance of patient-centric endpoints in drug development.

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Chen Chen

Senior Research Fellow,
Lee Kong Chian School of
Medicine Singapore

As a researcher working on validating novel digital measures, I encounter challenges due to a lack of systematic approaches and a limited understanding of appropriate analytical tools. As a result, researchers in the field have continued accumulating evidence while regulators remain hesitant to endorse new products.

I was pleased to be involved in research comparing the statistical properties of simple correlation analysis and more powerful techniques like confirmatory factor analysis, particularly in recovering latent relationships between novel digital measures and reference measures that lack direct correspondence. I anticipate leveraging the insights from simulation studies and the accompanying toolkit to inform the development of robust analysis plans to evaluate novel digital clinical measures in future research.