VivoSense is an agile end-to-end scientific solutions company developing novel digital endpoints from wearable sensor data. We are focused on healthcare research & delivery, clinical trials and patient wellness. Our hypothesis-driven framework provides analytical and clinical validation leading to FDA approval.

"The fact that these tools were collaboratively developed by a diverse group of experts with various stakes has made it an invaluable resource that we can confidently reference."

The Problem
Pharmaceutical clients frequently approach us with a specific use case - they want to use a specific sensor in a specific clinical population to measure a specific endpoint.

Prior to the Measurement Dossier and the V3 framework published by DiMe, the large majority of these conversations were uphill battles, with clients not fully understanding why or when additional validation is required.

The Impact
✓ Operational efficiency
✓ Clear communication with pharma clients

The Resource
We use the Measurement Dossier to help guide internal R&D decisions and recommendations to external clients. Part of our job at VivoSense is to evaluate the state of existing analytical and clinical validity evidence relevant for the specific use case, identify any missing pieces and make recommendations on how to most effectively move forward with the project or conduct additional validation activities.

The Measurement Dossier directly and concisely outlines the level of evidentiary requirements needed for digital clinical measures throughout the drug development process.