The Family of Health Centers of San Diego is dedicated to providing affordable, high-quality health care to everyone, with a special commitment to uninsured, low-income and the underserved.

We were keen to deploy the Withings ecosystem and the Apple Watch measure of Heart Rate Variability (HRV) for use in pharma/NIH studies. However, analytic validation of these digital measurement tools had not been completed. As such, these tools with enormous promise were being excluded from clinical trials.

Using DiMe’s V3 Framework, we worked with the Digital Strategy team at our industry collaborators to target the evaluation of analytical validity of digital measurement products. Our goal was to establish which tools were fit-for-purpose for our industry partner’s pre-defined trial population and protocols.

In this case study, we report the use of the V3 Framework in studies evaluating connected scales, thermometers, sleep pads, and blood pressure monitors manufactured by Withings. Note: For Apple Watch, we focused on heart rate variability (HRV) only.

It helped our team to describe the phase of work we are engaged in vis-a-vis building trust in digital clinical measures.

Our first application of the V3 framework brought us together with the team funding this and ongoing work.

Robust and independent evaluation of the analytical validity of BioMets is necessary in order to extract their full potential to better understand and improve human health.

— Job Godino, Scientific Director of Laura Rodriguez Research Institute