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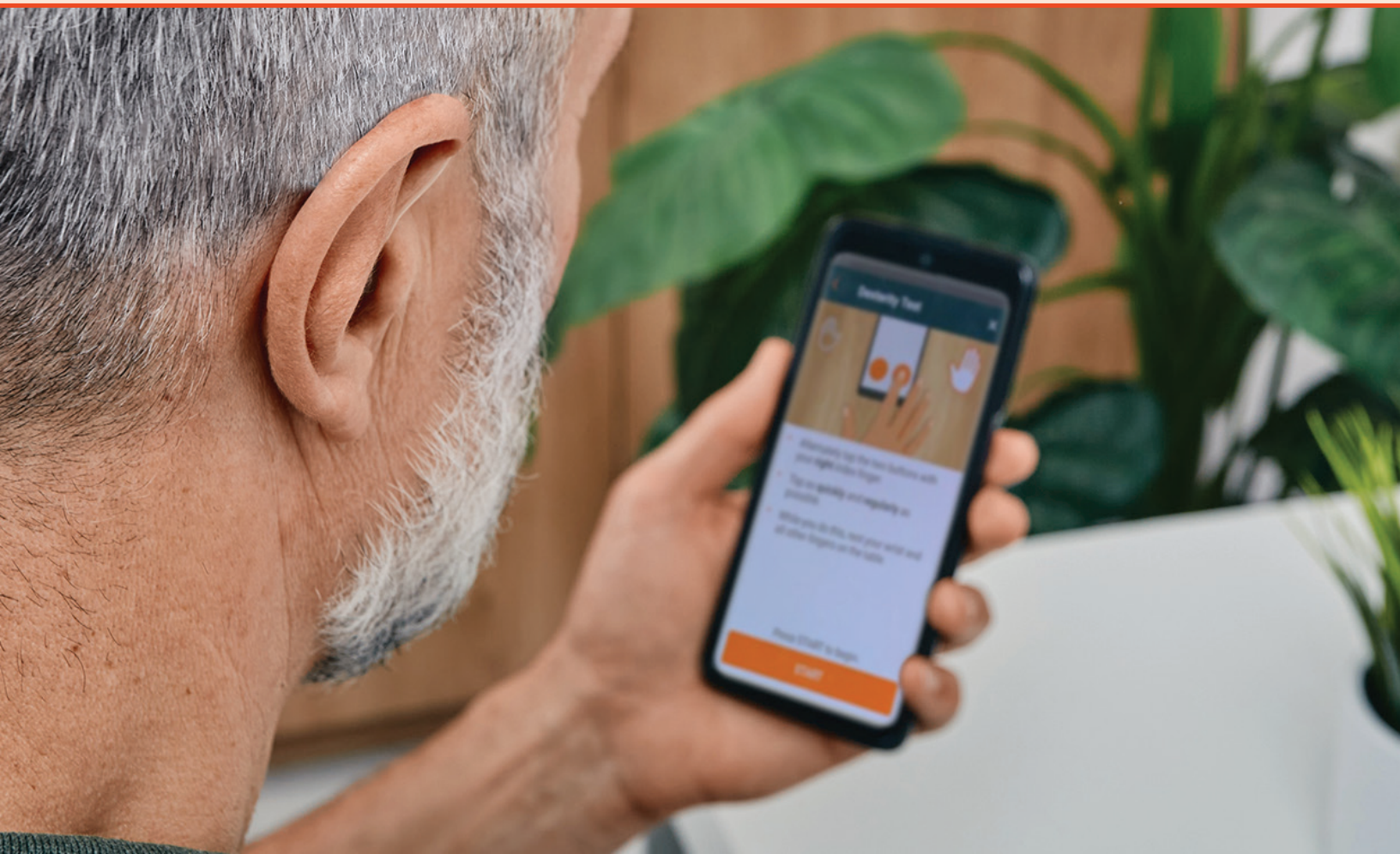
Roche

Roche Digital Biomarker Solution demonstrates adherence, user satisfaction, and initial evidence of clinical validity

in clinical trial for Parkinson's disease.[1]



Digital biomarkers can help address the challenges of clinical outcome assessments

Clinical outcome assessments can present challenges in clinical trials, particularly for Parkinson's disease studies.[2-4] Current measurement standards lack sensitivity to subtle changes and are affected by poor inter- and intra-rater reliability. Such challenges can lead to more patients needed in trials, longer trial durations, and inconclusive trial results.

Digital tools, such as smartphones or wearables, can measure and collect health information – or "digital biomarkers" – from patients. Digital biomarkers are becoming more important to clinical trials because they allow researchers and clinicians to objectively collect patient data remotely and at high frequency without the need for an in-person or even virtual visit with a provider.

Remote and at-home digital measurement of a person's movements and activities in lieu of relying on the patient's memory may yield more meaningful insights – and greater precision – as researchers evaluate the efficacy of treatments. Because the data are objective and collected more frequently, researchers can assess treatment response and disease progression more accurately and quickly than by relying on in-clinic assessments alone.

Digital measurement offers benefits

Frequency

How often measurement is repeated

Daily measurement can capture fluctuating symptoms

Resolution

Smallest increment that can be measured

High precision sensor measurement may reveal clinically meaningful differences and avoid floor/ceiling effects

Accuracy

Closeness of measurement to actual value

Sensors can directly measure the behaviors and physiological characteristics of interest

Reliability

Consistency of measurement

Sensors can provide highly consistent measurements of everyday behaviors

Ecological validity

Generalisability of measurement to real-life

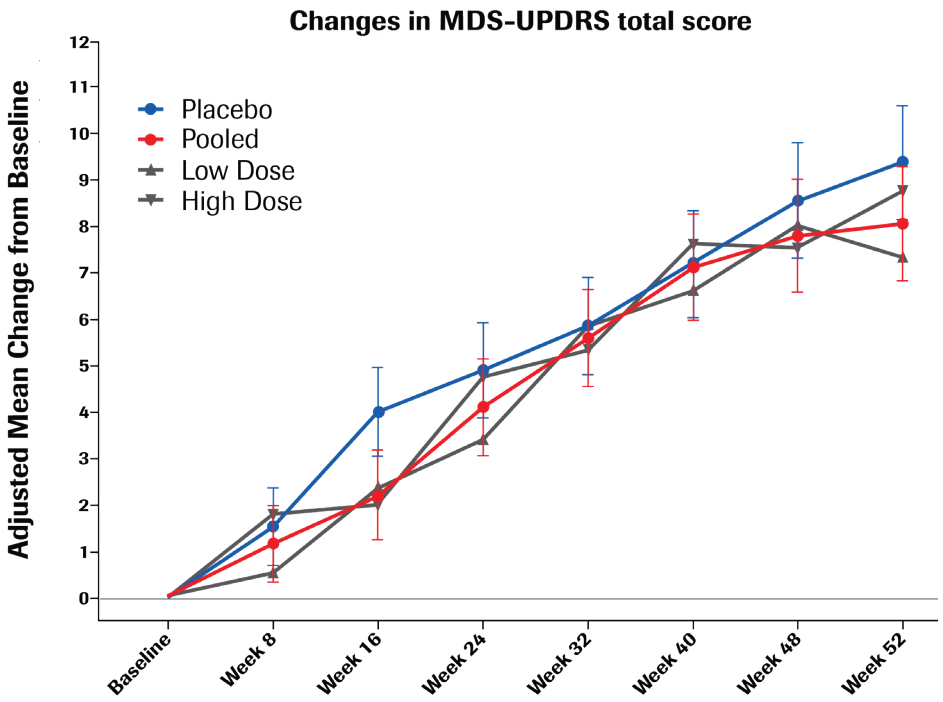
Patients can perform tasks at home and are measured during their typical, daily activities

Sensitive and objective measurements have been proven in a large phase 2 Parkinson's disease clinical trial.[5]

The PASADENA clinical trial for early-stage Parkinson's disease, involving 316 enrolled participants, consisted of a 52-week, double-blind, placebo-controlled treatment period, followed by a 52-week extension period during which all participants received active treatment but remained blinded to dose allocation. Smartphone and smartwatch sensors (e.g. accelerometer) sampled data throughout the day from assigned active tests and/or passive digital motor behaviors.[5]

The primary endpoint of this study did not demonstrate a measurable impact on Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) scores, which are indicative of the level of progression of Parkinson's disease.[2]

Primary endpoint



Pooled: -1.30, 80% CI=(-3.18, 0.58); -14.0%
Low dose: -2.02, 80% CI=(-4.21, 0.18); -21.5%
High dose: -0.62, 80% CI=(-2.82, 1.58); -6.6%

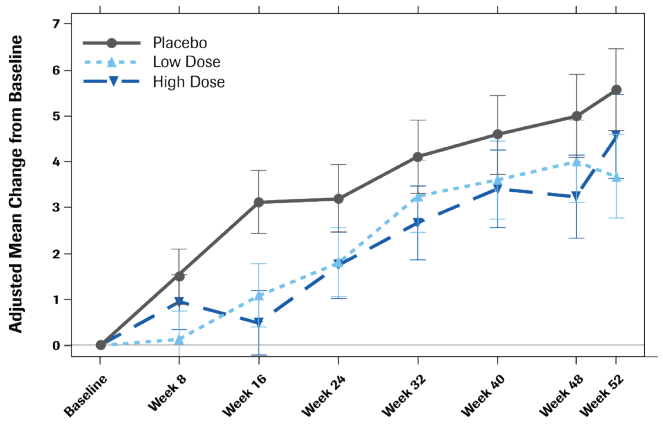
Exploratory Endpoint: Change in MDS-UPDRS Part III score from baseline

Analysis of exploratory endpoints, including MDS-UPDRS Part III sub-scores (motor components of the total UPDRS score) and the digital motor composite scores (composite of features from the motor active tests and passive monitoring), showed a significant 25% deviation from a normal progression in the treated arms.

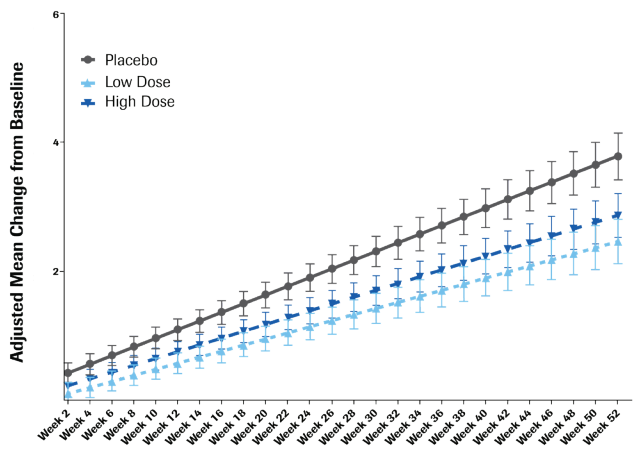
The data suggest that the digital measurements are sensitive enough to detect a divergence of the incremental slope of disease progression between the placebo and therapeutic arm, similar to what is measured by the MDS-UPDRS part III sub-score.[5]

These results were used to inform decisions regarding future trial investments and release of the Roche Digital Biomarker Solution to clinical trial sponsors and the life sciences industry.

Exploratory endpoints



Pooled: -1.44, 80% CI=(-2.83,- 0.06); -25%
Low dose: -1.88, 80% CI=(-3.49, -0.27); -34%
High dose: -1.02, 80% CI=(-2.64, 0.61); -18%



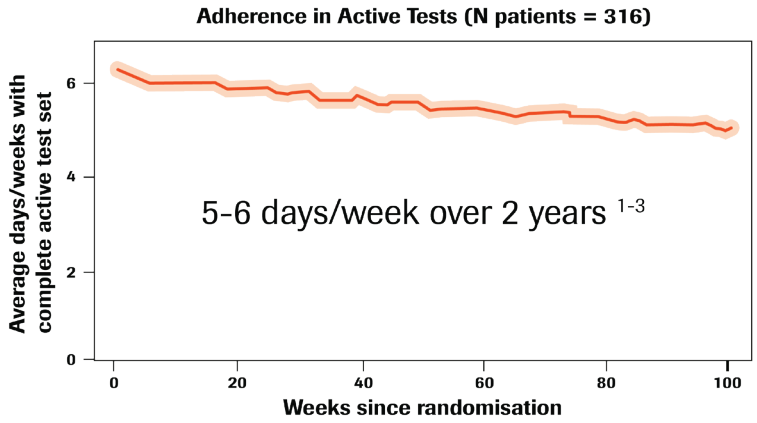
Pooled: -0.030, 80% CI=(-0.050,- 0.010); -25%
Low dose: -0.040, 80% CI=(-0.063, -0.017); -30.3%
High dose: -0.029, 80% CI=(-0.052, -0.006); -21.5%

These results coming from exploratory endpoints provided greater confidence in the potential efficacy of the treatment and were used to inform decisions regarding future trial investments.

Data show positive patient adherence and satisfaction

Evidence from the PASADENA study suggests patients who use Roche's Digital Biomarker Solution demonstrated high satisfaction and good adherence to daily testing. The digital biomarkers demonstrated good reliability and initial evidence of clinical validity over two years.

- Good adherence to daily testing in clinical trials: 5-6 days/week over 2 years[1,7-8]
- Sensor features demonstrated good clinimetric properties
  - Test-retest reliability, clinical validity, sensitivity to subtle manifestations[1,7-8]
- High overall satisfaction of daily testing over two years in the Phase II PASADENA study[9]



Data from Pasadena Ph2 with over two years of daily data collection[9]

Digital Biomarker Solution builds a pathway to the future

At Roche, we believe digital biomarkers provide a pathway to the future where trial sponsors and patients can benefit. Research findings demonstrate the preliminary reliability and validity of remote at-home collection of motor signs severity with the Roche Digital Biomarker Solution in individuals with early Parkinson's disease.[6] Evidence suggests digital biomarkers have the potential to speed up innovation through objective measurements and reduced trial duration.[1]

More than 14,000 months of Parkinson's disease data with extensive use in clinical trials and more than 50 scientific publications, posters, and presentations since 2015.* Researchers and clinical trial sponsors now have access to the Roche Digital Biomarker Solution to accelerate their own research.

*View the Publication table.

To preview the Roche Digital Biomarker solution, contact us today.

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