Digital Biomarker Deployment for Gait Analysis in Multiple Sclerosis

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Agenda

Multiple Sclerosis Gait Characteristics

"*Gait impairment represents one of the most common and disabling symptom of multiple sclerosis.*"
Lizrova Preiningerova et. al, J. Neuroeng Rehabil. 2015

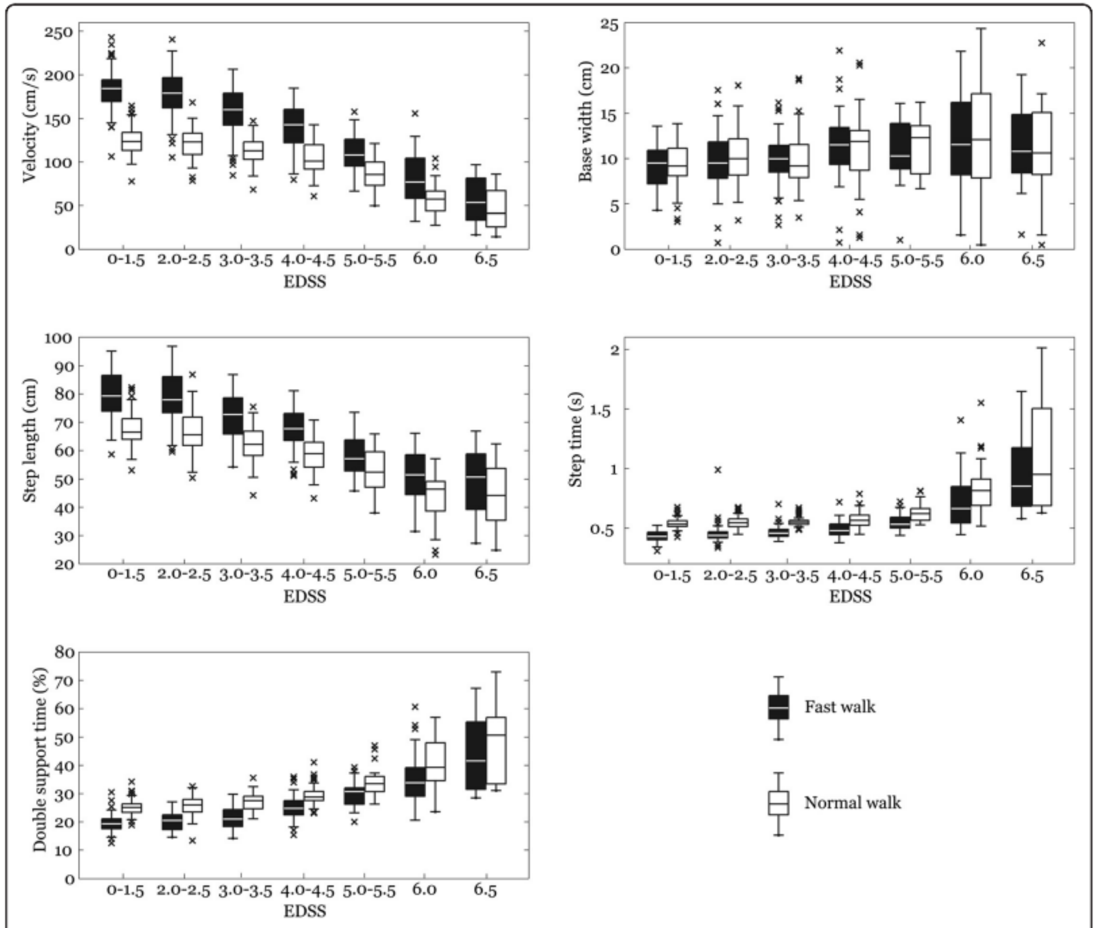
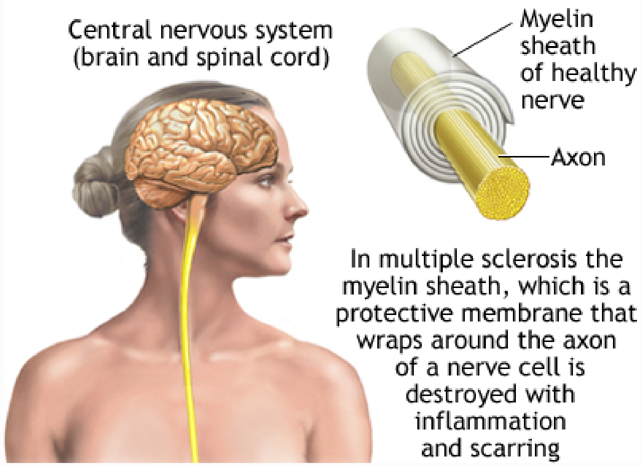


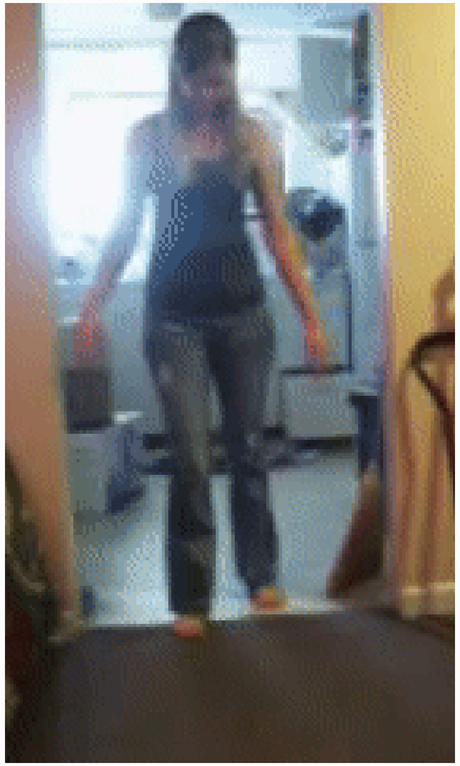
Figure 1 Comparison of gait measures for self-selected and fast walk speed across different EDSS levels.

Spatial and temporal characteristics of gait as outcome measures in multiple sclerosis (EDSS 0 to 6.5) – PMC

Gait impairment in persons with MS (PwMS):

- ↓ Slower gait speed
- ↓ Reduced cadence
- ↓ Shorter stride/step length
- ↑ Increased stride/step time
- ↑ Increased double support time





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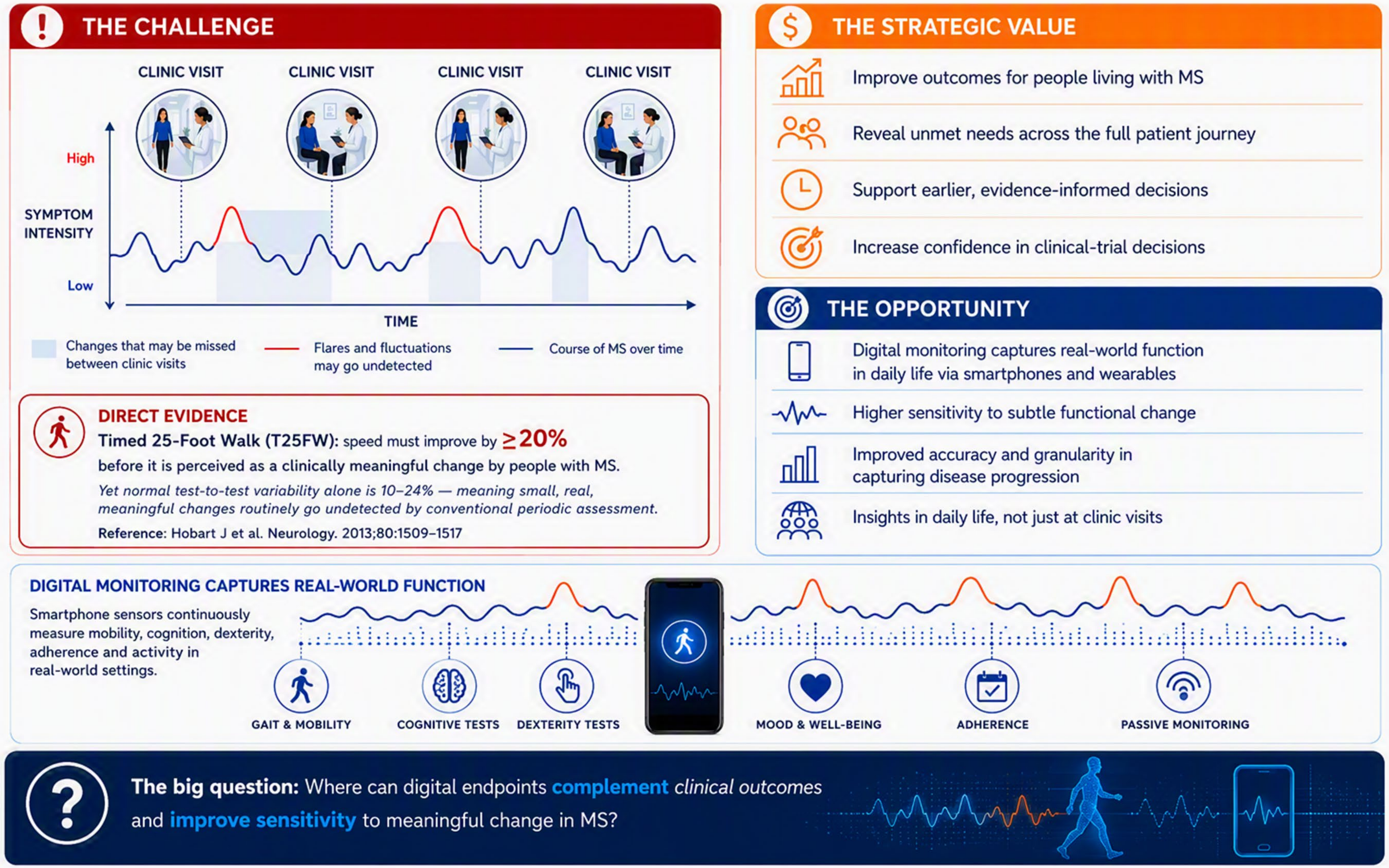
Why Digital Endpoints matter in Multiple Sclerosis

Better insights. Faster decisions, Better outcomes for people living with MS.



Commercial smartphone sensors

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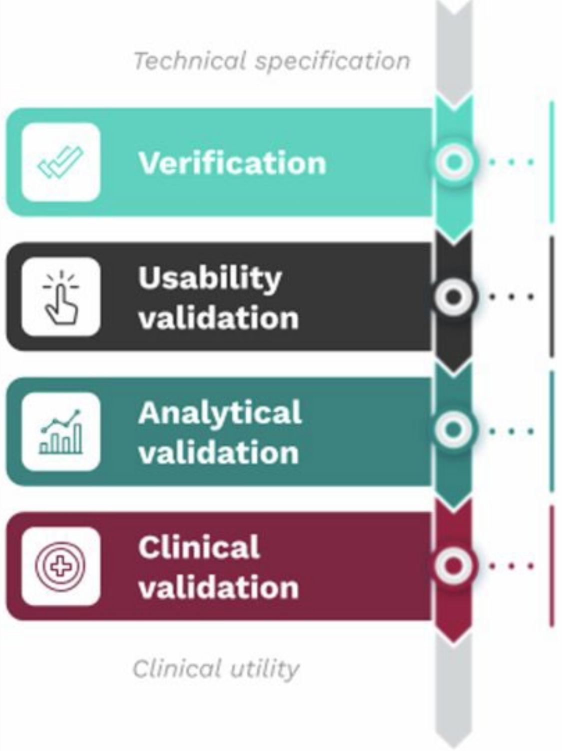
What evidence makes a Digital Health Technology fit for purpose?

V3+ separates four complementary evidence questions before a digital measure is used to evaluate an intervention.



Can the sensor and sample-level data meet pre-specified performance criteria? — Sensor performance

Can intended users achieve specified goals with ease, efficiency and satisfaction? — Use in context

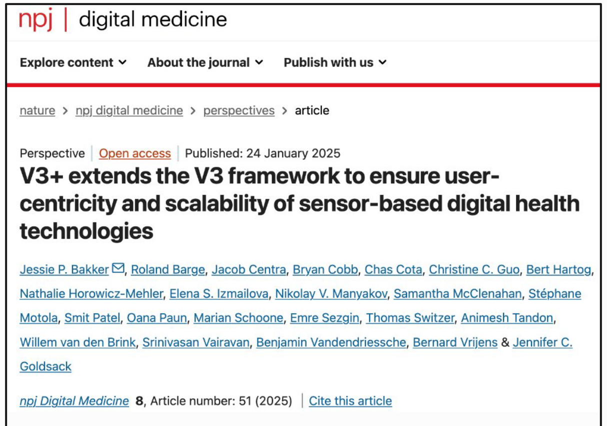
Can the algorithm measure, detect or predict the target metric accurately? — Algorithm performance

Does the measure reflect a meaningful clinical or functional state in the stated context of use? — Clinical meaning

For this talk, longitudinal sensitivity and MCID extend the evidence story beyond the four formal V3+ components.

FIT FOR PURPOSE = sufficient evidence for the specified context of use

Reference: Bakker JP et al. npj Digital Medicine. 2025;8:51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Perspective | Open access | Published: 24 January 2025

V3+ extends the V3 framework to ensure user-centricity and scalability of sensor-based digital health technologies

Jessie P. Bakker, Roland Barge, Jacob Centra, Bryan Cobb, Chas Cota, Christine C. Guo, Bert Hartog, Nathalie Horowicz-Mehler, Elena S. Izmailova, Nikolay V. Manyakov, Samantha McClenahan, Stéphane Motola, Smit Patel, Oana Paun, Marian Schoone, Emre Sezgin, Thomas Switzer, Animesh Tandon, Willem van den Brink, Srinivasan Vairavan, Benjamin Vandendriessche, Bernard Vrijens & Jennifer C. Goldsack

npj Digital Medicine 8, Article number: 51 (2025) | Cite this article

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Agenda

1 MS Gait Characteristics

2 Digital Endpoints

3 *V3+* Qualification Framework

4 Verification

5 Usability & Adherence

6 Analytical Validation

7 Clinical Validation

8 Longitudinal Sensitivity

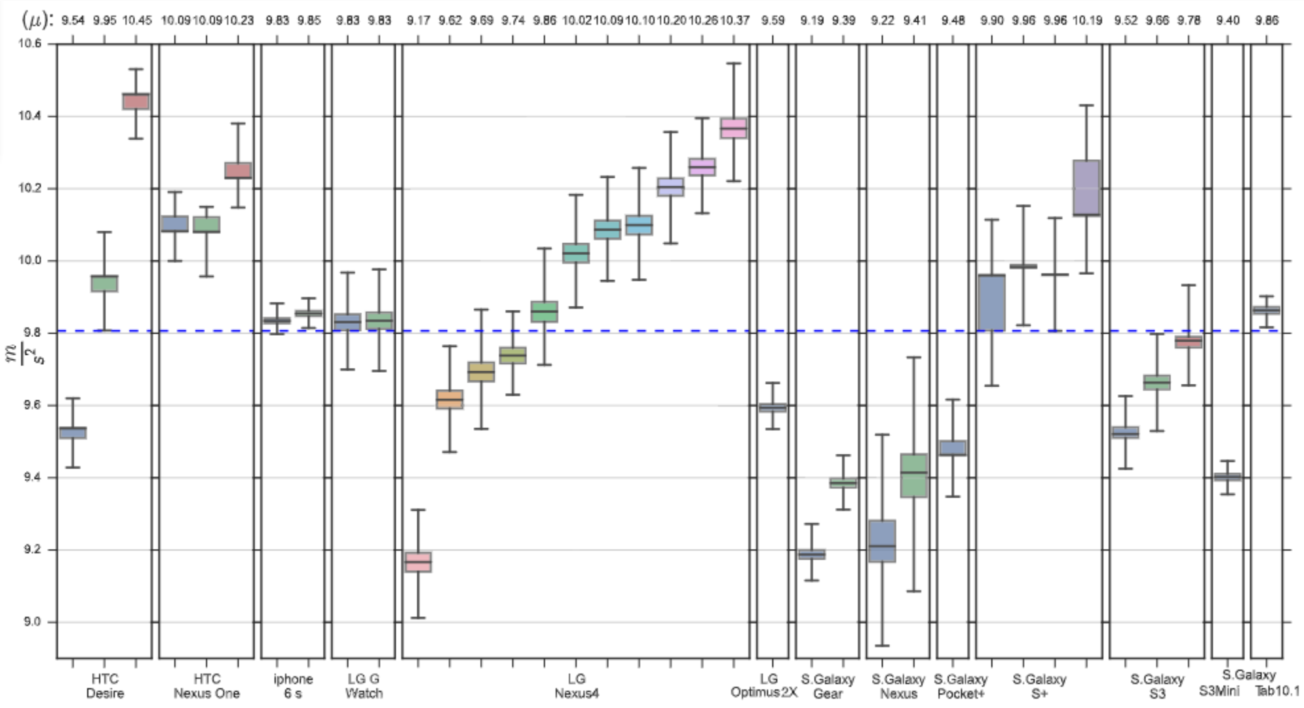
9 Clinical Interpretability (MCID)

10 Conclusion

Verification: Are Accelerometer Measurements Consistent Across Devices?

Device and sensor heterogeneity can introduce systematic error before the gait algorithm is applied.

Figure 1: Accelerometer biases of mobile devices in six different orientations under static conditions.



(a) Box plots of acceleration magnitudes and respective means (top) for investigated devices when lying on the back, with the whiskers indicating min/max values.

Reference: Stisen A et al. Smart Devices are Different. Proc. ACM SenSys. 2015;127–140.

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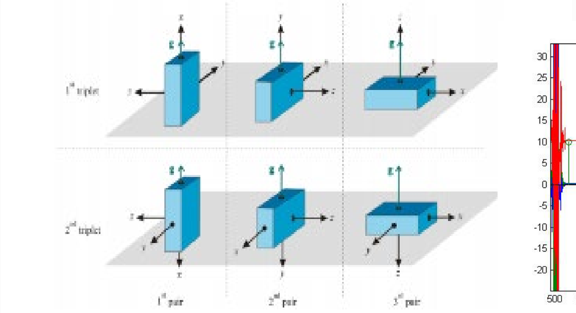
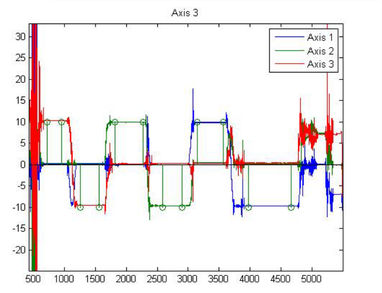
Accelerometer calibration techniques

Controlled six-position calibration:
Requires access to the device and accurate positioning

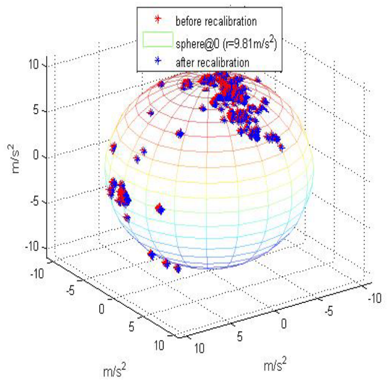


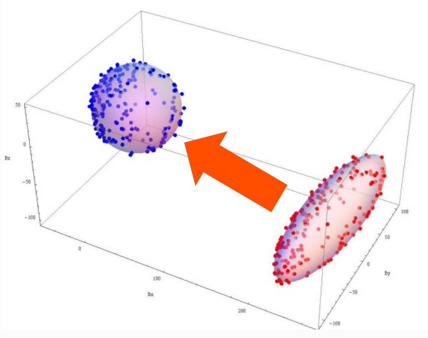


Ellipsoid fitting: Does not require known sensor orientations

Offset update = fitted ellipsoid center

Sensitivity update = fitted ellipsoid radii (sphere radius)





Ellipsoid or sphere fitting for sensor calibration: ST Microelectronics

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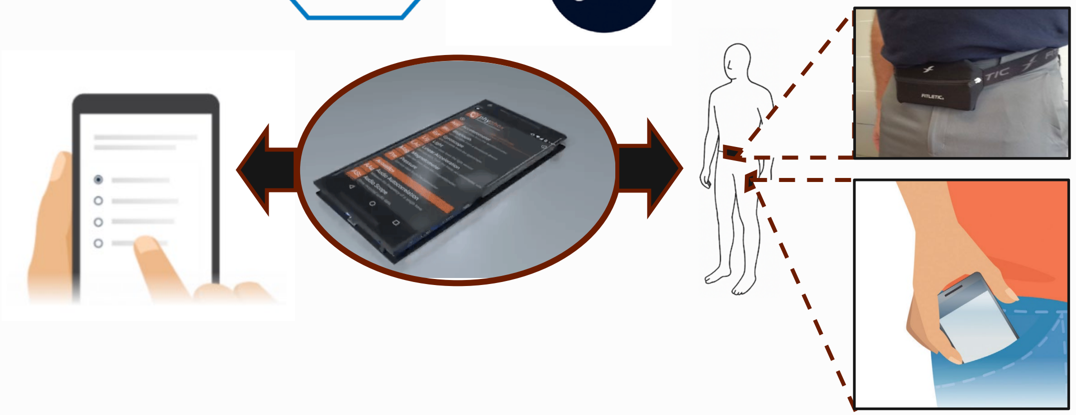
Artios study overview & adherence

ARTIOS is a **single arm**, prospective, multicentre and open-label, **96-week study** to **evaluate the treatment effectiveness of ofatumumab** in subjects with **relapsing multiple sclerosis** who had switched from commonly used oral disease-modifying therapies.

Bove R et al. J Neurol 273, 434 (2026).



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Alan Bourke | alan.bourke@novartis.com

P1952

Quantifying Adherence to Smartphone-Based Tests Over 96 Weeks in the ARTIOS Study: Monitoring Motor Function, Dexterity, Cognition and Patient-Reported Outcomes in People Living with Relapsing Multiple Sclerosis

Alan K. Bourke[1], Tobias Derfuss[2], Dawn Langdon[3], Laura Gaetano[1], Konstantinos Sechidis[1], Haoyi Fu[4], Hariprashanth Elangovan[1], Anamaria Rauh[1], Anil Abeyewickreme[5], Nikolaos Sfikas[1], Tim Woelfle[6], Ludwig Kappos[6], Riley Bove[7]

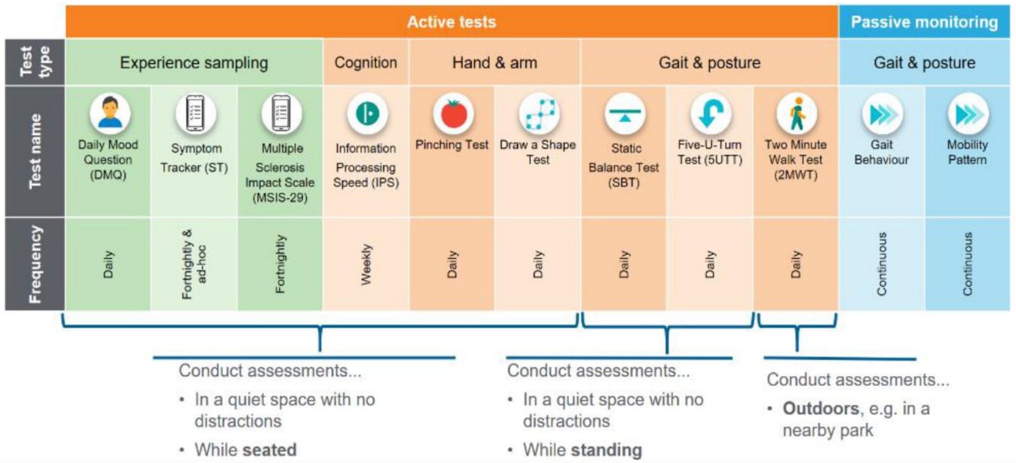
[1]Novartis Pharma AG, Basel, Switzerland; [2]Neurology Clinic and Policlinic and Research Center for Clinical Neuroimmunology and Neuroscience, Departments of Head Organs, Movement and Neuromedicine, and Biomedicine, University Hospital and University of Basel, Basel, Switzerland; [3]Royal Holloway, University of London, London, United Kingdom; [4]Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA; [5]Novartis Pharmaceuticals UK Ltd, London, United

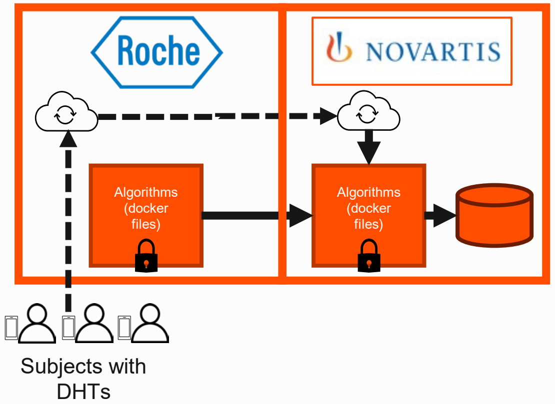
KEY FINDINGS AND CONCLUSIONS

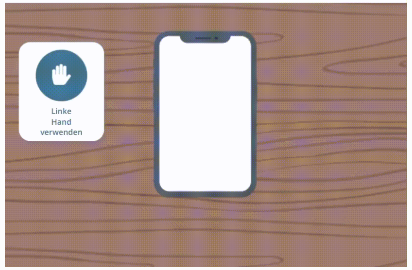
- We have collected a large volume of data through smartphone-based active tests and passive monitoring from plwRMS
- Our analysis provides insights into the adherence patterns for daily, weekly and fortnightly tests in plwRMS
- Further analysis will provide valuable insights into the daily impact of MS on patients' lives, enhancing the understanding of the disease dynamics

Reference: *Bourke AK et al. Quantifying adherence to smartphone-based tests over 96 weeks in the ARTIOS study: monitoring motor function, dexterity, cognition and patient-reported outcomes. ECTRIMS 2025; Poster P1952.*

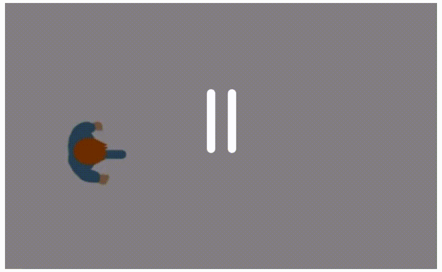
Figure 1: Overview of assessment suite for Roche FLOODLIGHT mobile app



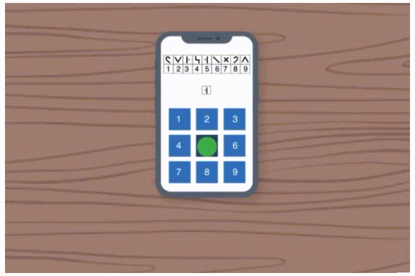




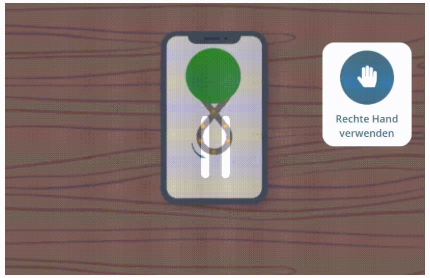
Pinching test



5 u-turn test

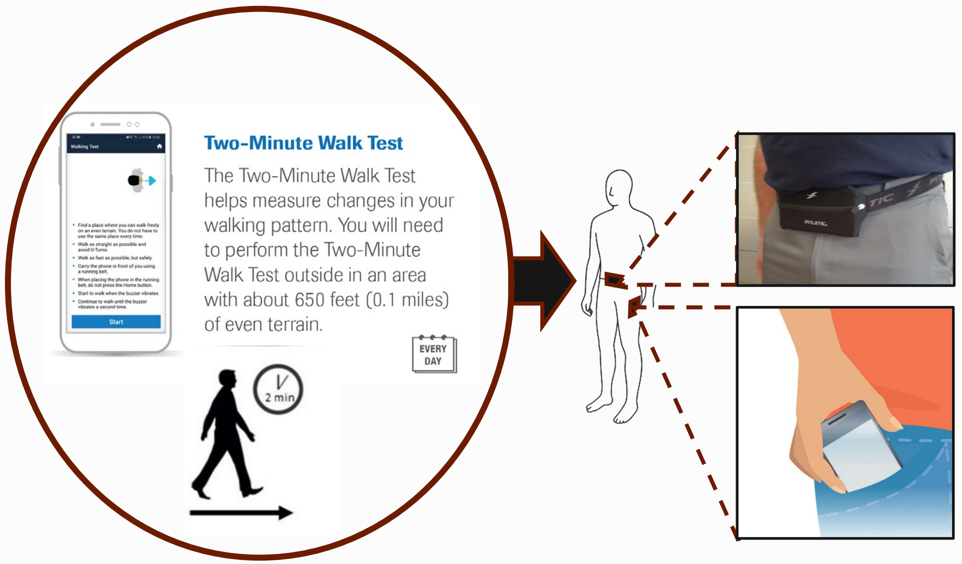


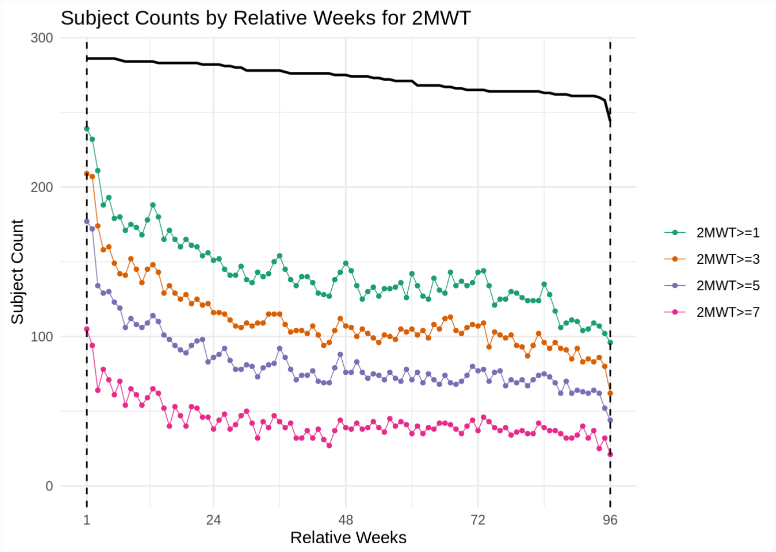
eSDMT
(Information processing speed)



Draw-a-shape test

Artios 2MWT summary adherence statistics





Characteristic	N = 454,696[1]
Total ACTIVE TESTS	454,696 (100%)
CATEGORY	
ACTIMETRY	434,915 (96%)
COGNITIVE TEST	19,781 (4.4%)
TEST	
Draw-a-shape	95,912 (21%)
2MWT	74,963 (16%)
eSDMT	19,781 (4.4%)
Pinching test	98,334 (22%)
static balance test	86,528 (19%)
5 U-Turn test	79,178 (17%)

Retention rates for daily tests

Threshold (number of tests) ≥1

PRO/Test	Week 1: Participant, n	Week 96: Participant, n	Retention rate (%)
DMQ	257	127	49.42
Draw-a-shape	254	120	47.24
Pinching test	254	120	47.24
SBT	250	113	45.2
5UTT	246	105	42.68
2MWT	239	96	40.17

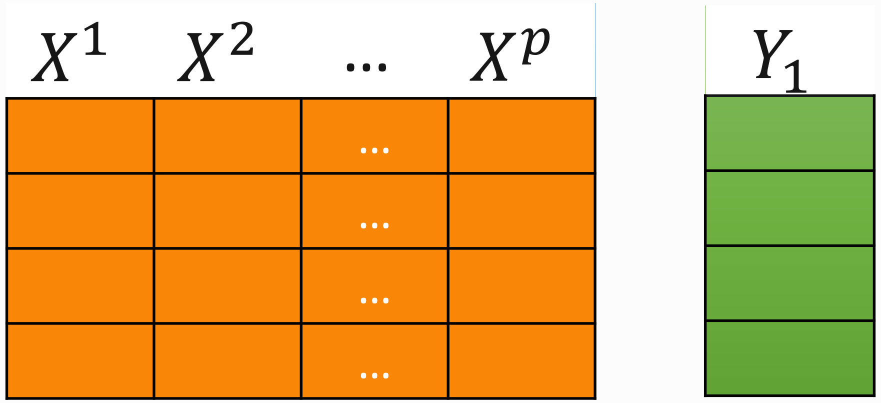
Threshold (number of tests) ≥3

PRO/Test	Week 1: Participant, n	Week 96: Participant, n	Retention rate (%)
DMQ	243	84	34.57
Draw-a-shape	239	77	32.22
Pinching test	240	77	32.08
SBT	232	69	29.74
5UTT	228	60	26.32
2MWT	209	62	29.67

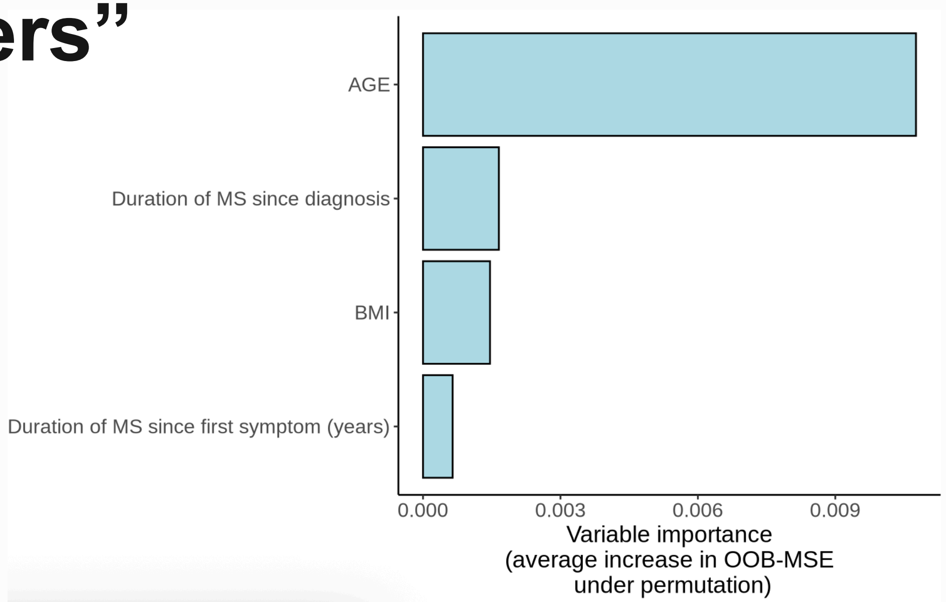
Threshold (number of tests) ≥7

PRO/Test	Week 1: Participant, n	Week 96: Participant, n	Retention rate (%)
DMQ	170	33	19.41
Draw-a-shape	161	27	16.77
Pinching test	162	28	17.28
SBT	141	26	18.44
5 U-Turn Test	129	22	17.05
2MWT	105	21	20

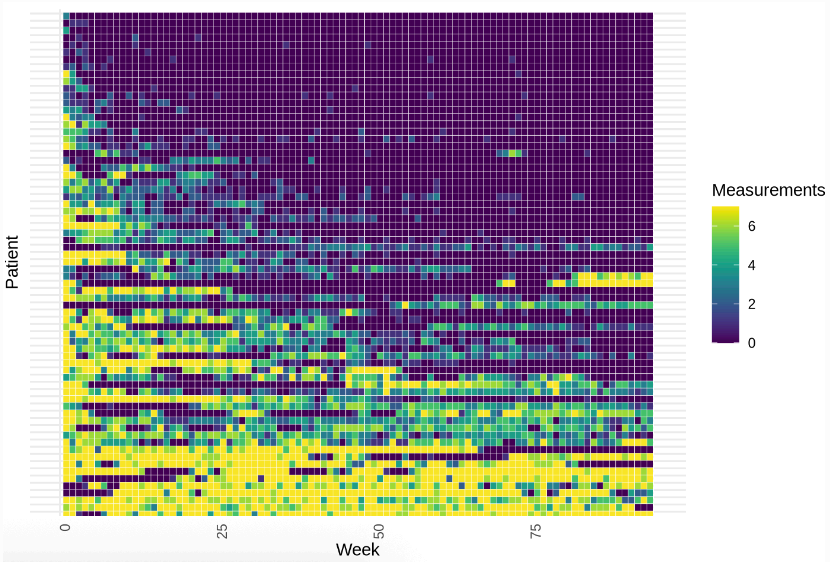
Adherence of 2MWT:
ML modelling to understand “drivers”



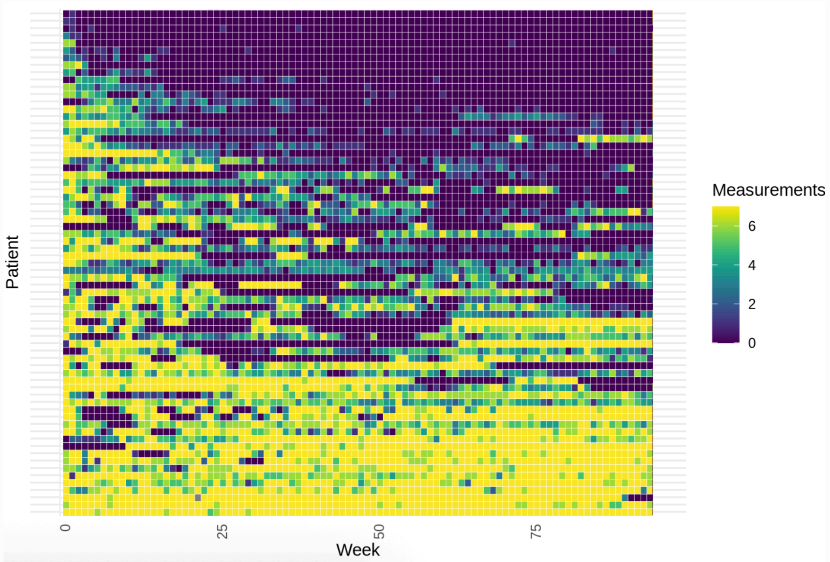
Baseline covariates



Younger participants (>28 years old)



Older participants (>45 years old)



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1	🚶 MS Gait Characteristics	6	🔬 Analytical Validation
2	📱 Digital Endpoints	7	🏥 Clinical Validation
3	***V3+*** Qualification Framework	8	📉 Longitudinal Sensitivity
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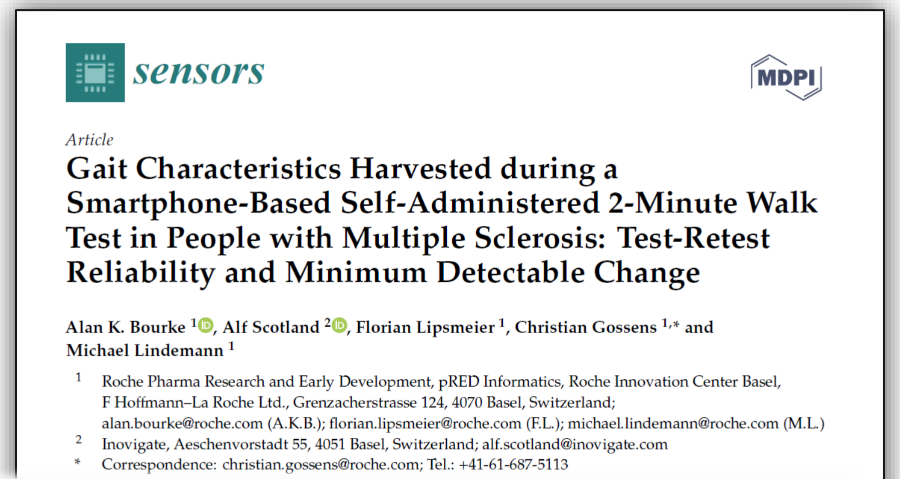
From Raw Sensor Data to Digital Gait Measures


sensors

MDPI

Article

Gait Characteristics Harvested during a Smartphone-Based Self-Administered 2-Minute Walk Test in People with Multiple Sclerosis: Test-Retest Reliability and Minimum Detectable Change

Alan K. Bourke [1], Alf Scotland [2], Florian Lipsmeier [1], Christian Gossens [1,*] and Michael Lindemann [1]

1 Roche Pharma Research and Early Development, pRED Informatics, Roche Innovation Center Basel, F Hoffmann–La Roche Ltd., Grenzacherstrasse 124, 4070 Basel, Switzerland; alan.bourke@roche.com (A.K.B.); florian.lipsmeier@roche.com (F.L.); michael.lindemann@roche.com (M.L.)

2 Inovigate, Aeschenvorstadt 55, 4051 Basel, Switzerland; alf.scotland@inovigate.com

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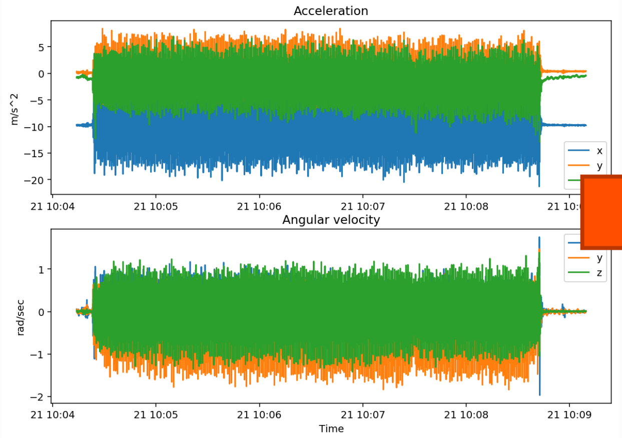
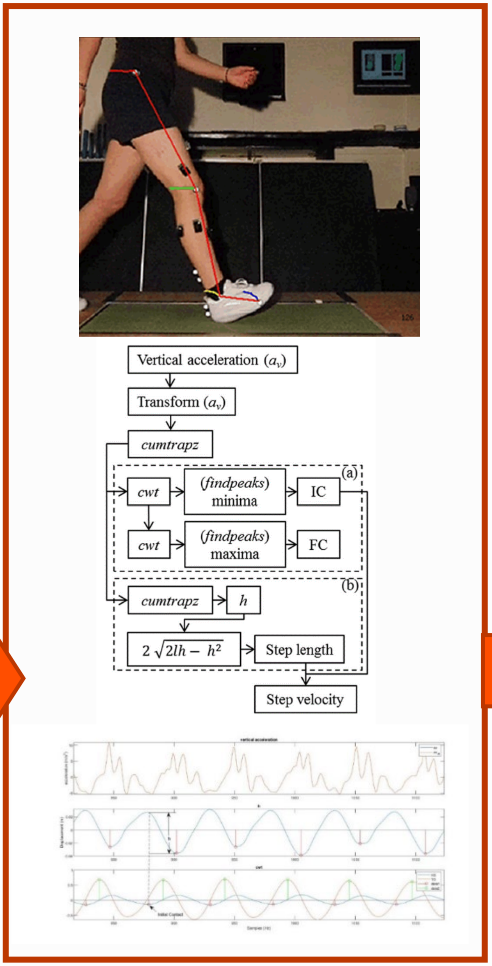
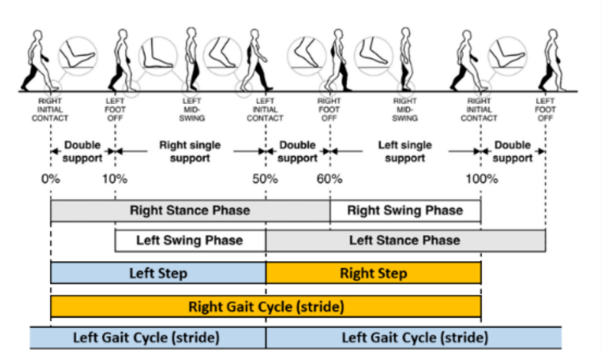
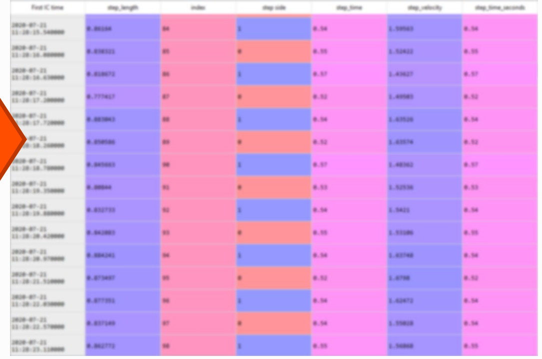
- Pre-processing steps applied to perform appropriate signal processing techniques (filtering, resampling, sensor frame alignment)
- Straight line gait bout extracted, initial and termination steps & turns removed
- Initial and final contact points extracted and pendulum h delta
- Temporal, spatial and spatiotemporal gait characteristics exported







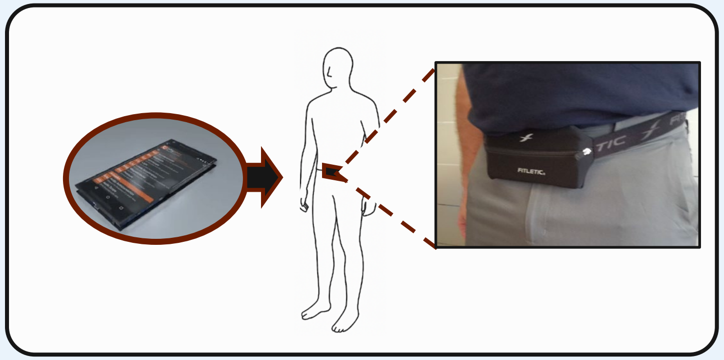


Analytical Validation: Reliability and Minimum detectable change

Remote smartphone-derived gait characteristics compared with established clinic-based walking tests

REMOTE SMARTPHONE 2MWT

Repeated, self-administered assessment at home



58 / 92 gait features had excellent (ICC>0.9) or good-to-excellent (ICC>0.75) test–retest reliability

Temporal 33/48 | Spatial 11/22 | Spatiotemporal 14/22

46 / 64* => MDC% <20%

13 / 64* => MDC% <11%

*Distribution features = percentiles (e.g. 95th percentile), min, mean and max

- **Most precise features (<11% MDC):** Step time, Stride time, Swing time, Stance time.
- **Notable features with MDC <20%:** Stride velocity, Step velocity, Step length, Stride length.

CLINIC-BASED WALKING TESTS

Periodic standardized assessment

T25FW	36%	MDC = 2.7 s
6MWT	20%	MDC = 88 m
6MWT, EDSS <4	11%	MDC = 58 m
6MWT, EDSS 4–6.5	39%	MDC = 120 m

Learmonth et al. 2013; n=82, assessments 6 months apart

Smartphone 2MWT characteristics were repeatable, and many had detectable-change thresholds below published walking-test benchmarks.

References: Bourke AK et al. Sensors. 2020;20(20):5906. Learmonth YC et al. Mult Scler J. 2013;19(13):1784–1791.

Analytical Validation

Smartphone-based assessment of gait with Floodlight in multiple sclerosis shows high operational robustness and analytical validity against reference tool.

Napiorkowski N et al. ECTRIMS 2024; Poster P781.

Key Question

Can a waist-worn smartphone measure gait speed accurately and reproducibly?

Key Findings:

✅ **High agreement with the GaitUp reference system**

- ICC(3,1)=0.91–0.96 across locations

✅ **Minimal systematic bias**

- Remote front-belt bias: 0.03 m/s

✅ **Excellent reliability across six smartphone locations**

- Belt: Front, Back | Pocket: Right front, Left front, Right back, Left back

✅ **Reliability improves with aggregation**

- ICC increased from 0.88 (single test) to 0.98 (6 aggregated tests)

✅ **Supports robust unsupervised remote assessment**

- High analytical validity in both laboratory and remote settings

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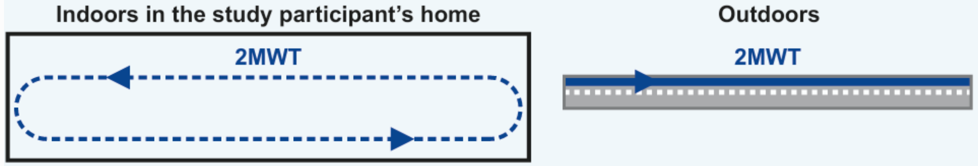
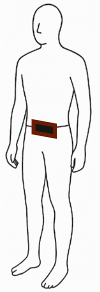
Remote setting: Floodlight 2MWT performed remotely every day in a home environment for a 14-day period





Floodlight 2MWT

- Front belt

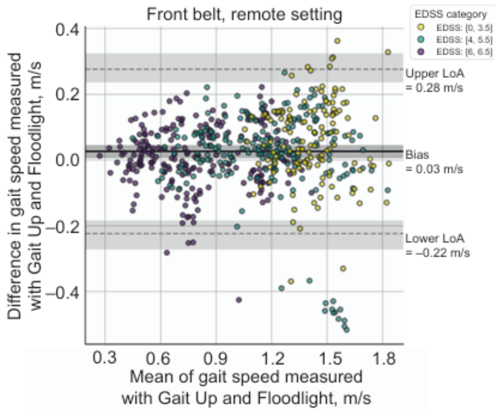
Reference system (Gait Up)

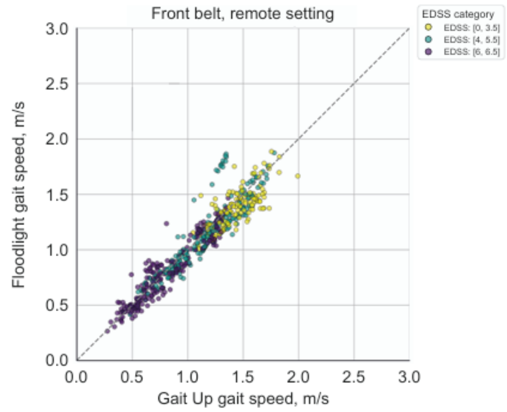
- Right shoe
- Left shoe

n=74, EDSS 4.8 ± 1.4

What is the Agreement Between Gait Speed Measured with the Floodlight 2MWT and Gait Speed Measured with Gait Up IMU Sensors in the Remote Setting?

- In the remote setting, the agreement between gait speed measured with the 2MWT and simultaneously with Gait Up IMU sensors remains high with minimal systematic bias





	Analytical validity in the remote setting[a]
Floodlight gait speed, m/s, median (IQR)	1.12 (0.54)
Gait Up gait speed, m/s, median (IQR)	1.15 (0.58)
ICC(3,1) (95% CI)	0.94 (0.91; 0.96)
Bias (95% CI)	0.03 (0.00; 0.05)
Lower LoA (95% CI)	−0.22 (−0.27; −0.18)
Upper LoA (95% CI)	0.28 (0.24; 0.33)

[a]Analytical validity was assessed for the front belt smartphone wear location only.2MWT, Two-Minute Walk Test; EDSS, Expanded Disability Status Scale; ICC, intraclass correlation coefficient; IMU, inertial measurement unit; IQR, interquartile range; LoA, limits of agreement.

High level of absolute agreement and minimal systematic bias in the remote setting

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Clinical Validation

Key Question

Can smartphone-derived gait features measure meaningful disability and gait impairment in multiple sclerosis?

Key Findings:

✅ **Strong correlation with:**

- T25FW speed
- EDSS
- Ambulation Score

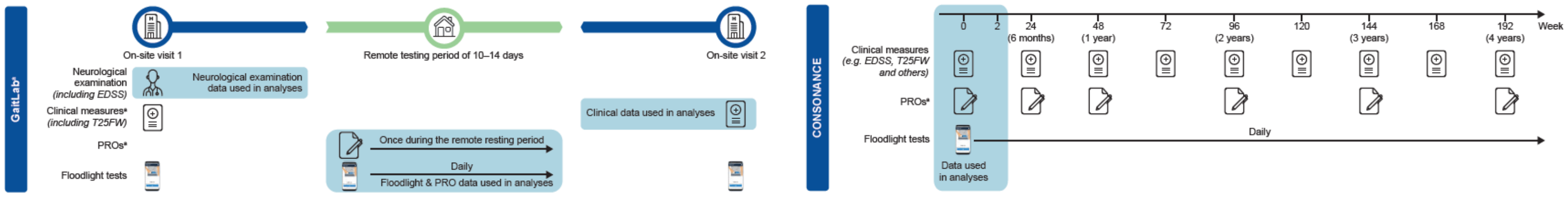
✅ **Differentiates disability severity groups**

Smartphone-Based Assessment of Gait with Floodlight Shows Association with Clinical Measures of Disability and Gait Impairment in Multiple Sclerosis.

Festanti A et al. ECTRIMS 2024; Poster P786.

	GaitLab (n=87)	CONSONANCE (n=363)
Female, n (%)	56 (64)	191 (53)
Age, years, mean (SD)	54.3 (12.8)	48.5 (9.4)
EDSS, mean (SD)	4.8 (1.5)	5.0 (1.3)
MSWS-12 transformed total score, mean (SD)	47.2 (31.7)	62.7 (25.2)
T25FW time, s, mean (SD)	7.3 (5.2)	14.5 (16.4)

What is the Schedule of Assessments in the GaitLab and CONSONANCE Studies?

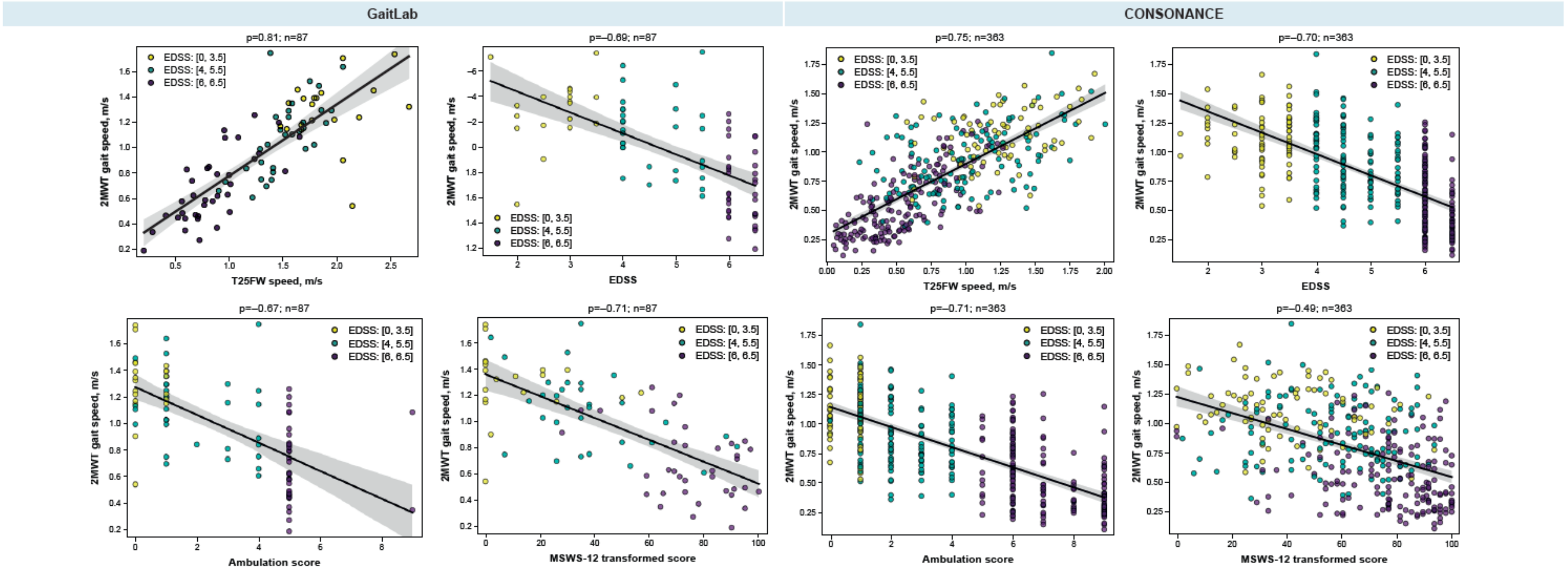


*Includes only assessments on gait; assessments of other domains, including hand motor function and cognition, are not shown.

*Includes only assessments on gait; assessments of other domains, including hand motor function and cognition, are not shown.

What Are the Correlations Between the Floodlight 2MWT and Clinical Measures of MS-Related Disability and Gait Impairment?

- In both studies, cross-sectional correlations between gait speed measured during remote 2MWTs and in-clinic T25FW speed, EDSS, MSWS-12 transformed score, as well as Ambulation score were moderate to strong, and in the expected direction



*The strength of the correlations were defined as follows: |ρ|: 0.80–1.00 = very strong; |ρ|: 0.60–0.79 = strong; |ρ|: 0.40–0.59 = moderate; |ρ|: 0.20–0.39 = weak; |ρ|: 0.00–0.19 = very weak.[8]

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Clinical Validation

Key Question

Can smartphone-derived gait speed differentiate clinically meaningful levels of disability and gait impairment?

Key Findings:

Distinguishes EDSS disability groups in GaitLab

- EDSS 0–3.5 | EDSS 4–5.5 | EDSS 6–6.5

Distinguishes Ambulation groups in GaitLab

- No gait imp.| Mod. gait imp. | Sev gait imp.

Replicated in CONSONANCE

- Same pattern observed in larger progressive-MS cohort

  n = 363 PwPMS at baseline

Known-groups validity demonstrated

- Lower gait speed consistently associated with higher disability and greater walking impairment

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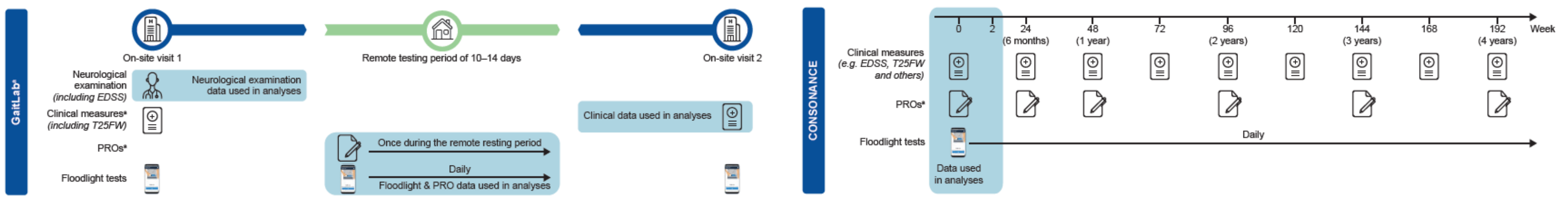
Smartphone-Based Assessment of Gait with Floodlight Shows Association with Clinical Measures of Disability and Gait Impairment in Multiple Sclerosis.

Festanti A et al. ECTRIMS 2024; Poster P786.

	GaitLab (n=87)	CONSONANCE (n=363)
Female, n (%)	56 (64)	191 (53)
Age, years, mean (SD)	54.3 (12.8)	48.5 (9.4)
EDSS, mean (SD)	4.8 (1.5)	5.0 (1.3)
MSWS-12 transformed total score, mean (SD)	47.2 (31.7)	62.7 (25.2)
T25FW time, s, mean (SD)	7.3 (5.2)	14.5 (16.4)

What is the Schedule of Assessments in the GaitLab and CONSONANCE Studies?

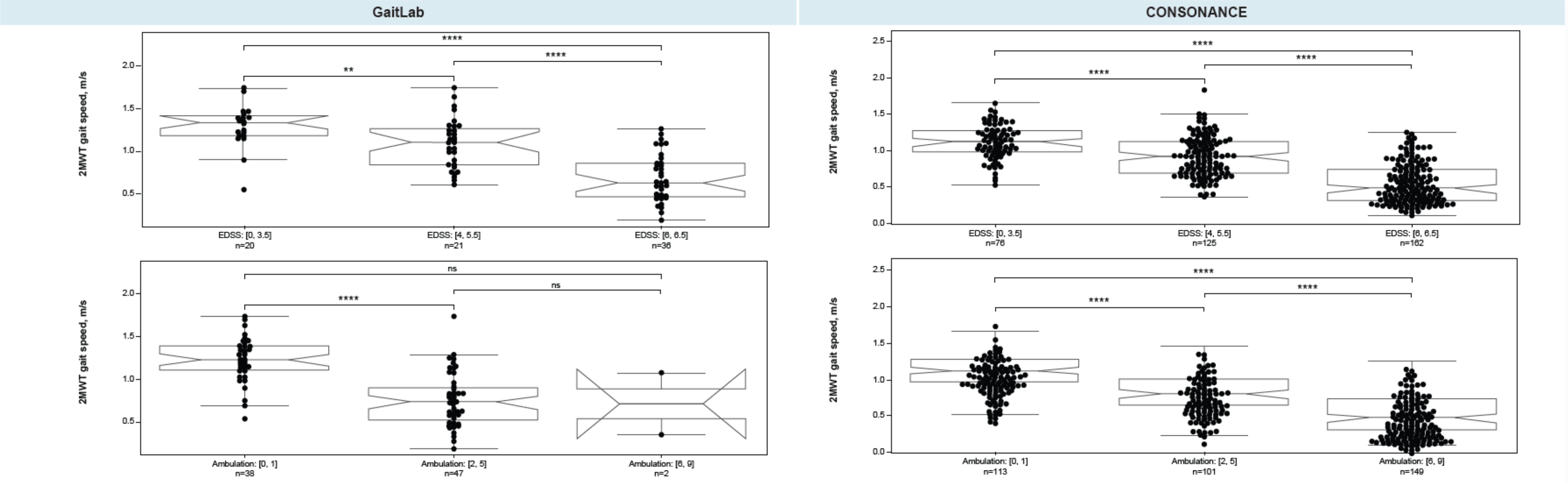


*Includes only assessments on gait; assessments of other domains, including hand motor function and cognition, are not shown.

*Includes only assessments on gait; assessments of other domains, including hand motor function and cognition, are not shown.

Can the Floodlight 2MWT Differentiate Between PwMS with Different Levels of MS-Related Disability and Gait Impairment?

- In GaitLab, gait speed measured during remote 2MWTs showed differentiation between PwMS subgroups defined by EDSS or Ambulation scores
  - The small sample size of PwMS with an Ambulation score between 6–9 (n=2) likely explains the lack of a statistical significance to difference between these subgroups and the other Ambulation score subgroups
- The CONSONANCE study confirms the discrimination of gait speed



** p<0.01; *** p<0.001; **** p<0.0001.

Agenda

1 MS Gait Characteristics
2 Digital Endpoints
3 *V3+* Qualification Framework
4 Verification
5 Usability & Adherence
6 Analytical Validation
7 Clinical Validation
8 Longitudinal Sensitivity
9 Clinical Interpretability (MCID)
10 Conclusion

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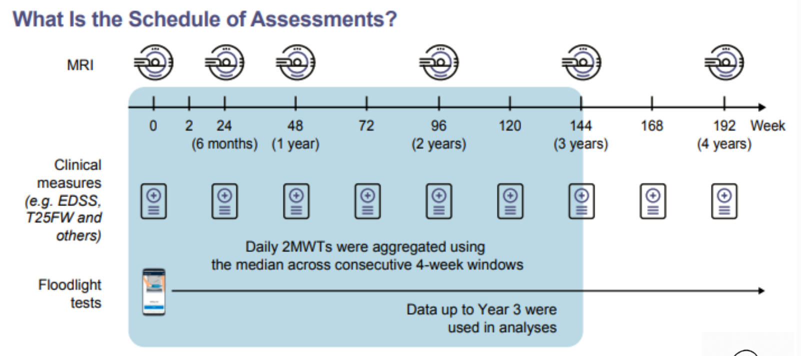
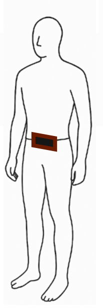
Sensitivity to Longitudinal Change

Smartphone-Based Assessment of Gait with Floodlight in Multiple Sclerosis Shows Sensitivity to Change Over a Follow-Up Period of 3 Years.

Rodrigues J et al. ECTRIMS 2024; Poster P1559.

	Matched population at baseline n=368
Female, n (%)	193 (52)
Age, mean (SD), years	48.5 (9.5)
Diagnosis, n (%)	
PPMS	175 (48)
SPMS	193 (52)
EDSS score, mean (SD)	5.0 (1.3)
MSWS-12 transformed total score, mean (SD)	62.7 (25.2)
T25FW time, mean (SD), s	14.5 (16.3)





Key Question

Can remote smartphone-derived 2MWT gait measures distinguish groups with and without EDSS progression compared to the In-Clinic T25FW?

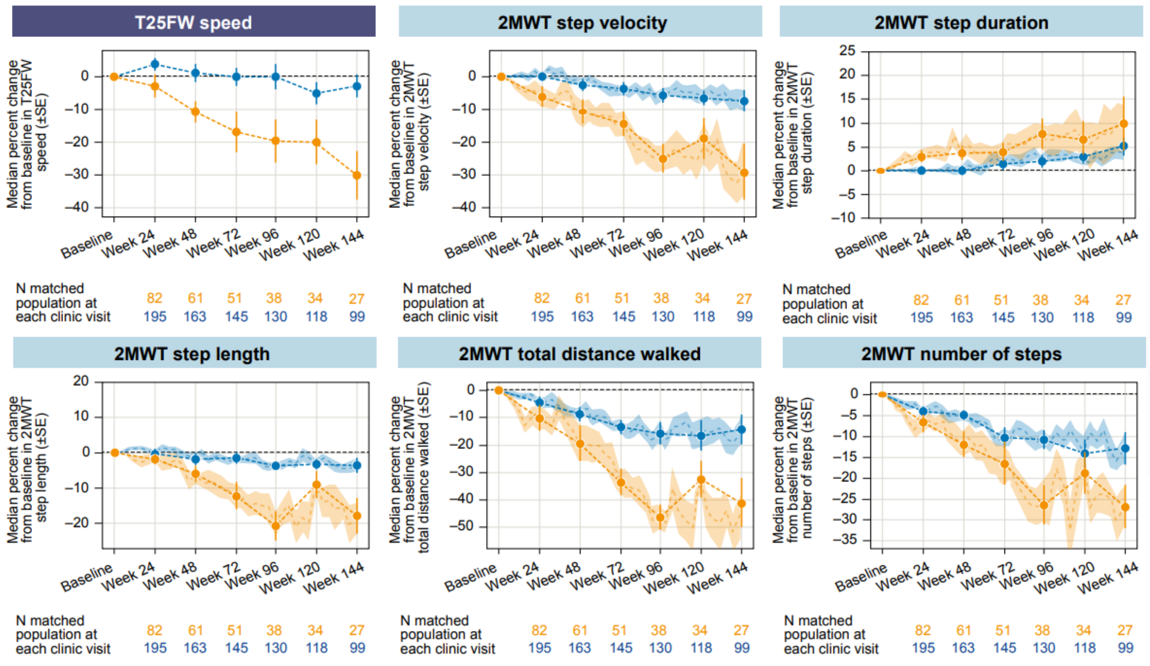
Key Findings:

- ✅ **Comparable discrimination to the in-clinic T25FW**
- ✅ **Captures changes in ambulation beyond gait speed**
- ✅ **Detects subtle worsening among EDSS non-progressors**
- Year 3: 2MWT gait measures **−3% to −13%**
- T25FW speed: **<5% change**
- ✅ **May be sensitive to change in PwMS with stable EDSS**

Future work:

Supports further evaluation as a progressive-MS trial outcome

Progressor versus non-progressor trajectories over 3 years



[a]The non-matched population includes all PwPMS for whom 2MWT data at baseline period and at the respective clinic visit period are available, regardless whether or not T25FW data are available.

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Agenda

1	MS Gait Characteristics	6	Analytical Validation
2	Digital Endpoints	7	Clinical Validation
3	***V3+*** Qualification Framework	8	Longitudinal Sensitivity
4	Verification	9	Clinical Interpretability (MCID)
5	Usability & Adherence	10	Conclusion

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Clinical Interpretability:
From Detectable Change to Meaningful Change

The **MDC** is the minimum magnitude of change required to be 95% confident that the observed change between measurements is **true change** and **not measurement error**

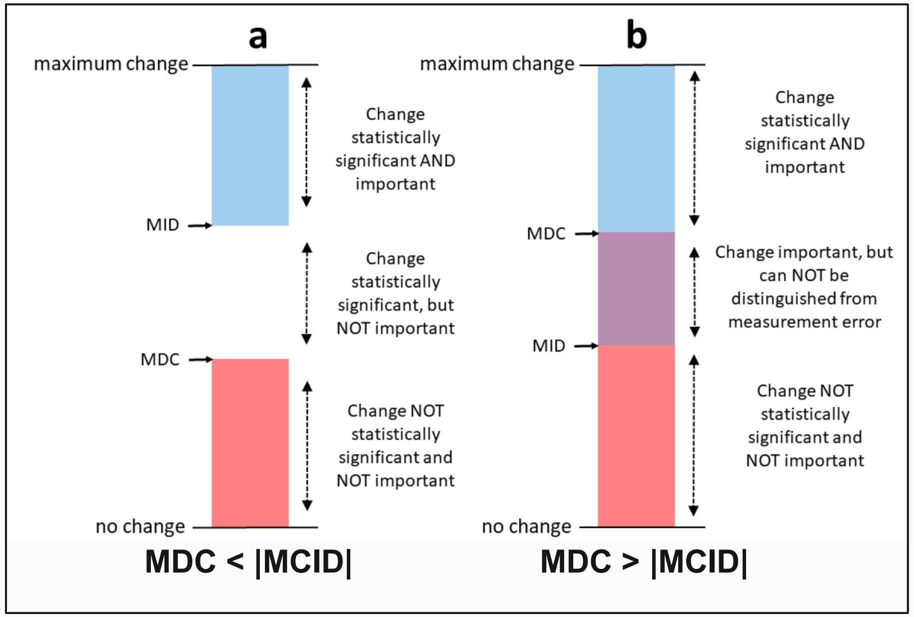
The **MCID (MID)** is defined as the smallest change in the score of the construct to be measured, which is perceived as important by patients, clinicians, or relevant others

Establishing the Minimal Clinically Important Difference (MCID) for Smartphone-Derived Gait Measures in Multiple Sclerosis.
Rinderknecht MD et al. arXiv. 2026

Anchor	Threshold
T25FW	≥20% worsening
Ambulation Score	≥1 point
EDSS	≥1 / 0.5 point
MSWS-12	≥8 points

Digital gait measure	MCID for worsening *Rinderknecht,2026,arXiv*	MDC_{50th} magnitude Bourke,2020,Sensors	Relationship
Step Velocity	**−0.16 m/s**	**0.152 m/s**	**MDC < |MCID|**
Step Velocity Scaled to Walk Time	**−0.18 m/s**	**0.152 m/s**	**MDC < |MCID|**
Step Duration / Time	**+0.06 s**	**0.045 s**	**MDC < |MCID|**
Step Length	**−0.07 m**	**0.082 m**	**MDC > |MCID|**
Total Number of Steps	**−28**	-	
Total Distance Walked	**−24 m**	-	

MCID signs indicate the direction of worsening; MDC is an unsigned measurement-error threshold. Comparisons therefore use absolute magnitudes.



References: Bourke AK et al. Sensors. 2020;20(20):

Take-home message

Bourke,2020,Sensors quantified detectable change (MDC). *Rinderknecht,2026,arXiv* quantified meaningful change (MCID). Together they provide the foundation for clinically interpretable digital gait endpoints.

Algorithm code: **GitHub - matt002/GaitPy**

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From measurement to meaning.

A V3+-informed evidence pathway for smartphone-derived gait measures in MS

1 POTENTIAL
Frequent, remote, multidimensional measurement

Real-world 2MWTs in daily life

2 VERIFICATION
Trustworthy sensor configuration and data quality

Waist-front or pocket placement Quality checked data

3 USABILITY & ADHERENCE
Sustained participation and sufficient data density

Your progress
M T W T F S S
This week
7 / 7 tests

High adherence Over months to years

4 ANALYTICAL VALIDATION
Accurate and repeatable gait characteristics

Excellent reliability Low measurement error (MDC)

Bourke et al. Sensors. 2020

5 CLINICAL VALIDATION
Association with disability and gait impairment

Correlates with T25FW, EDSS, Ambulation Score, MSWS-12

Festanti et al. ECTRIMS 2024

6 LONGITUDINAL SENSITIVITY
Change over time and EDSS-progression groups

Baseline Year 3

Detects progression and subtle change in non-progressors

Rodrigues et al. ECTRIMS 2024

7 CLINICAL INTERPRETABILITY (MCID)
MDC and MCID connect detectable with meaningful change

MCIDs define *meaningful thresholds* for progression

Rinderknecht et al. arXiv. 2026

The evidence shows that smartphone-derived gait measures can be **usable**, **reliable**, **clinically valid**, **sensitive to progression** and **interpretable**.

Waist-front or pocket placement enables frequent, real-world measurement.

Less noise.
More signal.
Better decisions.

KEY ENABLERS

- Secure & scalable infrastructure
- Patient-centered design
- Robust analytics & QA
- Regulatory-aligned frameworks (V3+)
- Cross-sector collaboration
- Advancing digital gait endpoints together for people living with MS

References: Bourke AK et al. Sensors. 2020;20(20):5906. Festanti A et al. ECTRIMS 2024; Poster P786. Rodrigues J et al. ECTRIMS 2024; Poster P1559. Bakker JP et al. npj Digital Medicine. 2025;8:51. Rinderknecht MD et al. arXiv. 2026;2606.28449.

Thank you

A shout-out to the wider digital health technology community in Basel

CONSORTIUM

Mobilise-D

Developing and validating real-world digital mobility outcomes across conditions, including MS, with a pathway toward regulatory and clinical endorsement.

CONTINUED COLLABORATION

RC2NB

For continued collaboration in developing and validating digital biomarkers to characterize MS progression and support clinical translation.

BASEL ECOSYSTEM

Indivi

A Basel-based technology partner providing smartphone measurement platforms for neuroscience research and clinical development.

FOUNDATIONAL COLLABORATION

Roche - Digital Biomarkers

For Floodlight, gait algorithms, validation studies and the scientific foundation supporting this evidence journey.

CURRENT COLLABORATION

Novartis – AQS Neuroscience

For advancing analytics and quantitative science, and translating digital-measure evidence into fit-for-purpose drug-development applications.

Advancing digital biomarkers requires collaboration across academia, healthcare, technology and biopharma. Thank you to everyone helping move the field forward.

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Backup: Key References

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