MSCopilot® digital biomarkers obtained in a real-world setting correlated with their clinical counterparts in the MS-DETECT study

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INTRODUCTION

Multiple Sclerosis (MS), a long-lasting immune-mediated neurodegenerative disorder, is characterized by multiple phenotypes and a variability of disease courses among patients[1,2]. **Standardized, quantitative and multidimensional clinical tools and technologies** have been and are being developed to assess and monitor Multiple Sclerosis symptoms and disease progression thus supporting clinicians in providing the best personalized care[3-6]. Among the most widespread clinical tools are the Expanded Disability Status Scale (EDSS)[7] which assesses disability and the **revised 4-component MS Functional Composite (MSFC-4)**[8,9] which allows objective measures of four functional parameters.

Inspired by the MSFC-4, **MSCopilot®** is a clinically validated **software-as-a-medical-device (SaMD)** facilitating **real life self-assessment of MS through digital biomarkers (dBMKs)**. MSCopilot® assesses **walking capacity, low-contrast visual acuity, cognitive processing, and dexterity** in people with MS and its composite scores have been shown to significantly correlate with EDSS and MSFC scores[5,6].

To determine MSCopilot®'s ability to **monitor disability worsening**, 336 people with MS have been recruited across 7 countries to be followed over a period of 18 to 24 months in the ongoing, prospective, longitudinal MS-DETECT study (NCT05816122).

OBJECTIVE

This interim analysis reports baseline socio-demographic and clinical data, comparing MSCopilot® digital biomarkers with individual MSFC-4 scores in the first 243 recruited patients.

METHODS

Baseline demographic and clinical data, including the MSFC-4 assessments, were collected in PwMS with relapsing or progressive MS during the in-clinic inclusion visit. Subsequently, the four MSCopilot® tests were self-administered at home within the following week. The association between the digital scores and their clinical counterparts was assessed using Pearson correlation coefficients.

RESULTS

Figure 1 . MS-DETECT (NCT05816122) is an ongoing international, multi-site, prospective, longitudinal study. To evaluate MSCopilot® ability to detect disability progression over a period of 18 to 24 months, patients with Multiple Sclerosis were recruited across two continents and seven countries notably the United States of America, Canada, Denmark, France, Germany, Italy and Spain. This analysis includes the first 243 out of 336 patients to have been recruited.

	Patients N = 243
Female, n (%)	167 (68.7)
Age, mean (SD)	49.1 (8.7)
Age at disease onset, mean (SD)	31.6 (9.0)
Disease duration, mean (SD)	17.6 (8.0)
EDSS score, mean (SD)	3.8 (1.3)

	Patients N = 243
MS phenotype	
RRMS, n (%)	204 (83.9)
Non-active SPMS, n (%)	32 (13.2)
Active SPMS	7 (2.9)

Table 1 . Baseline socio-demographics and disease characteristics of patients. This interim analysis focuses on the first 243 patients recruited in the MS-DETECT study.

MSCopilot® digital biomarkers	Digital test description	MSFC-4 equivalent	Number of evaluations at baseline, n	Percent of evaluations analyzable, %
Mobile Walking Perimeter Test	30-min walk	T25-FW	219	100
Mobile Cognitive Test	Cognitive Processing Speed Test	SDMT	216	98.2
Mobile Dexterity Test	Upper-limb fine dexterity	9HPT	220	100
Mobile Vision Test	Low-contrast visual acuity	SLCLA	215	99.1

Table 2 . MSCopilot® digital biomarkers allowed collection of good quality evaluations. The digital tests, inspired by the MSFC-4, were performed by patients, at-home, two weeks following their in-clinic inclusion.

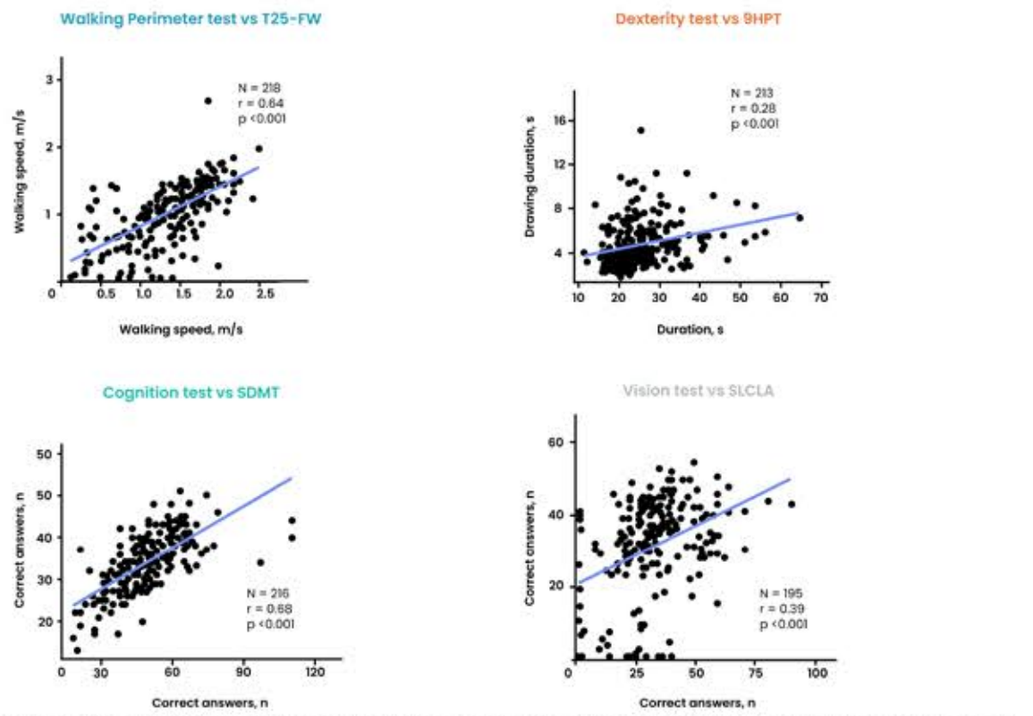

Figure 2 . Significant correlations were found at baseline between MSCopilot® digital tests taken at home and their equivalent MSFC-4 clinical assessments. Clinicians measured patients' MSFC-4 scores during the in-clinic inclusion visit which correlation with digital biomarkers was assessed with Pearson correlation coefficients.

CONCLUSIONS

- MSCopilot® digital biomarkers demonstrated high data coverage, excellent quality criteria, and strong correlations with their clinical counterparts.
- These findings emphasize the potential value of digital biomarkers for remote monitoring of people with Multiple Sclerosis and their possible use in detection of disease progression.

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