Title

Interim Analysis From FLOODLIGHT: A Prospective Pilot Study to Evaluate the Feasibility of Conducting Remote Patient Monitoring With the Use of Digital Technology in Patients With Multiple Sclerosis

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Introduction

Sensor-based, high-yield active and passive monitoring may be more sensitive and specific than periodic in-clinic assessments to measure progression in multiple sclerosis (MS). We present correlations between smartphone-based and in-clinic assessments of cognitive and physical measures in patients with MS.

Objective

To report interim analysis of correlations between smartphone-based and in-clinic tests from FLOODLIGHT (NCT02952911).

Methods

Patients with MS (McDonald 2010 criteria; 18–55 years; Expanded Disability Status Scale [EDSS]=0–5.5; n=80) and healthy controls (n=40) received a preconfigured smartphone and smartwatch that prompt the user to perform the FLOODLIGHT test battery, comprising 'active tests' and 'passive monitoring', for 24 weeks. The primary endpoint assessed participants' adherence. In-clinic tests (e.g. EDSS, 9-Hole Peg Test, Symbol Digit Modalities Test (SDMT), Timed 25-Foot Walk (T25FW)) and brain MRI assessments

were performed. The secondary endpoint explored whether data collected using the smartphone- and smartwatch-based remote monitoring are significantly different between MS and healthy controls and correlate with in-clinic outcomes. The correlation between smartphone-based and in-clinic tests was reported using Spearman's correlation coefficient (SCC).

Results

As of 27 March 2017, the first baseline cross-sectional interim analysis of 30 patients showed correlation between the number of correct responses in the smartphone-based SDMT vs the oral SDMT (SCC=0.73, $p<0.001$) and MS Impact Scale (MSIS)-29 total score (SCC=–0.52, $p=0.003$). Turning speed measured with the smartphone-based Five U-Turn Test correlated with the T25FW (n=28, SCC=–0.62, $p<0.001$) as well as the ambulation items of the MSIS-29 (n=29, SCC=–0.64, $p<0.001$). A longitudinal interim analysis of adherence and further correlations between baseline FLOODLIGHT sensor-based and in-clinic testing data will be presented.

Conclusions

Initial analysis of data from FLOODLIGHT indicates smartphone-based assessments are consistently correlated with in-clinic tests. FLOODLIGHT will further inform on the feasibility of integrating minimally intrusive and self-administered digital technologies into patients' daily routines for enhanced precision monitoring of MS disease.

Disclosures

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X Montalban has received speaking honoraria and travel expense reimbursement for participation in scientific meetings, and has been a steering committee member or participated in advisory boards of clinical trials for Actelion, Almirall, Bayer, Biogen, Genzyme, Merck, Novartis, Octapharma, Receptos, F. Hoffmann-La Roche Ltd, Sanofi, Teva and Trophos.

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L Julian is an employee of Genentech, Inc., and a shareholder of F. Hoffmann-La Roche Ltd.

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M Lindemann has nothing to disclose.