Title

FLOODLIGHT: Smartphone-Based Self-Monitoring is Accepted by Patients and Provides Meaningful,

Continuous Digital Outcomes Augmenting Conventional In-Clinic Multiple Sclerosis Measures

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Introduction

Sensor-based, active and passive smartphone-based self-monitoring (SSM) may be more sensitive and

specific than periodic in-clinic assessments to measure progression in MS.

Objective

To report an analysis of adherence, patient satisfaction questionnaire results, and correlations between

in-clinic tests and FLOODLIGHT SSM measures (NCT02952911).

Methods

Patients with MS (18-55 years; EDSS score 0-5.5; n=76) and healthy controls (n=25) received a

smartphone and smartwatch prompting FLOODLIGHT SSM, comprising 'active tests' and 'passive

monitoring' for 24 weeks. Primary analysis assessed participants' adherence (proportion of weeks with

≥3 days completed testing and ≥4 hours/day passive monitoring) and patient satisfaction with the

FLOODLIGHT SSM solution. In-clinic tests and brain MRI assessments were performed. Secondary

analyses compared FLOODLIGHT SSM outcomes 1) between patients with MS and healthy controls and

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2) with in-clinic outcomes in patients with MS. The correlation between FLOODLIGHT SSM outcomes and in-clinic tests was reported using Spearman's correlation coefficient (SCC).

Results

Interim analysis of adherence of 61 patients who completed the study showed 76.5% adherence to active tests and 83.2% to passive monitoring. Satisfaction amongst patients with MS who completed the study (n=61) was good to excellent (termination visit average score: 73.33/100). Correlations between FLOODLIGHT SSM and conventional in-clinic assessments at baseline were as follows: Correct responses from smartphone-based Symbol Digit Modalities Test (SDMT) vs oral SDMT: SCC=0.635, p<0.001, n=53; Time between two consecutive pinch attempts in the FLOODLIGHT Pinching Test vs 9-Hole Peg Test: SCC=0.508, p<0.001, n=54; Turning speed measured with the FLOODLIGHT Five-U-Turn Test vs Timed 25-Foot Walk test: SCC=-0.524, p<0.001, n=55. Further comparisons (baseline FLOODLIGHT SSM vs inclinic testing MS outcomes) will be presented.

Conclusions

Patients' adherence and satisfaction plus correlations observed between in-clinic assessments and digital outcomes show potential for the FLOODLIGHT SSM solution to capture meaningful outcomes augmenting the clinical picture in patients with MS.

Disclosures

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X Montalban has received speaker honoraria and travel expense reimbursement for participation in scientific meetings, been a steering committee member of clinical trials or served on advisory boards of clinical trials for Actelion, Biogen, Celgene, Merck, Novartis, Oryzon, Roche, Sanofi Genzyme and Teva Pharmaceutical.

P Mulero has nothing to disclose.

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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.