Electronic Neurostatus-EDSS increases quality of Expanded Disability Status Scale (EDSS) assessments: first experience from two phase 3 clinical trials with ofatumumab in relapsing multiple sclerosis using the Web Diary

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Background

Neurostatus-EDSS is the most widely used tool for assessing impairment and disability in MS clinical trials (1). It summarizes the assessment of 7 Functional Systems (FS) and ambulation (ambulation score, AS), and finally the determination of the EDSS step, according to rules described in the Neurostatus Definition Booklet (2). Neurostatus-eEDSS® was developed to improve data quality by detecting inconsistencies in the scores assigned by the examiner (4). The “Web Diary” (TriallMax Web™) was developed by CRF Health (CRFH) in collaboration with the University Hospital Basel, providing the Neurostatus-eEDSS® electronically.

Objectives

To analyse the first experiences with the Web Diary in two global multicentre phase 3 studies.

Methods

Study population

ASCLEPIOS I and II are Phase 3, randomised, double-blind, double-dummy, active comparator-controlled, parallel-group, multicentre trials conducted in parallel (Figure 6). A total of 1882 patients have been randomised across 385 centres in 37 countries.

Results

Table 1: Number of assessments with inconsistencies in FSS, AS or EDSS after each algorithm feedback round. Also the number of assessments that were sent off after each feedback round with their respective split between inconsistent and consistent. Table 2: % of assessments with inconsistencies in each chapter after each feedback round.

Conclusion

The web diary providing Neurostatus-eEDSS®

- increases quality of the data especially based on the feedback-function

- leads to reduced number of queries

- provides data electronically for analyses of data consistency at any time

References


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