Neurostatus-eEDSS results in high consistency of Expanded Disability Status Scale assessments: Experience from 13 clinical trials

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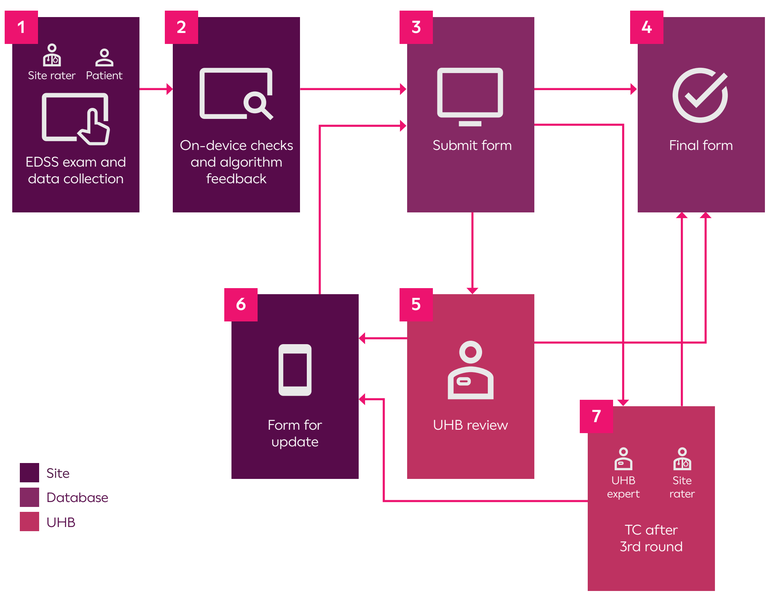
Background

In the setting of multiple sclerosis (MS) randomized clinical trials (RCT), Neurostatus-eEDSS is increasingly implemented as the preferred method to quantify disability. When implemented, the Neurostatus-eEDSS provides both an algorithm-based real-time feedback on the tablet and interaction with expert neurologists from the University Hospital Basel (UHB) to improve consistency in scoring.

Figure 1. Neurostatus-EDSS data collection and form workflow



Objective

To analyze the operational performance of the Neurostatus-eEDSS in 13 global clinical MS trials implemented into the Clario system.

Methods

Assessments captured using the Neurostatus-eEDSS in 13 global clinical trials with four different sponsors from 25 January 2019 until 25 April 2022 were analyzed. Assessments which triggered the expert review were included in this analysis only.

Results and discussion

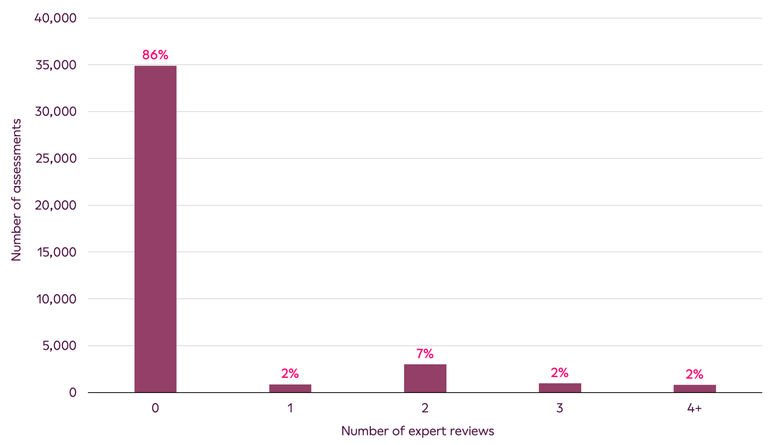
Trials included patients with relapsing MS (eight trials), primary progressive MS (four trials), and non-relapsing secondary progressive MS (one trial). The analysis included 41,874 Neurostatus-eEDSS assessments. At the time of analysis, 96.8% had the status "Final," 0.3% had the status "For Review" and 2.9% had the status "For Update" [Table 1].

Table 1. Summary of data

Studies	13
Total EDSS assessments	41,874
Final EDSS assessments ([%])	40,539 [96.8%]
Final EDSS assessments that underwent the review process ([%])	5,648 [13.5%]
EDSS assessments for review ([%])	140 [0.3%]
EDSS assessments for update ([%])	1,195 [2.9%]

Of the final assessments obtained after 1-4 rounds of on-device feedback, 86% were immediately stored as final and required no expert review [Figure 2]. Because the Clario system functions completely offline during data entry and initial on-device feedback, we cannot track what data changes raters may have made before form submission, as a result of the round(s) of on-device feedback. We can say that, in 86% of cases, raters either entered a form without any inconsistencies the first time, or used the on-device feedback to resolve all inconsistencies before form submission.

Figure 2. Number of review cycles for final assessments (n = 40,539)



Of the final assessments that underwent expert review (n = 5,648), EDSS Step was ultimately changed by the rater in 31% of these assessments [Figure 3]. Raters were more likely to change the EDSS Step in assessments when the original EDSS Step value was 3.5 or lower [Figure 4].

After EDSS Step, the Pyramidal functional system score (FSS) had the greatest number of changes; in 20% of final assessments that underwent expert review, the raters ultimately changed the Pyramidal FSS [Figure 3]. This is consistent with results found in previous Neurostatus-EDSS research.

Figure 3. Overall changes in EDSS step and functional system scores (n = 5,648)

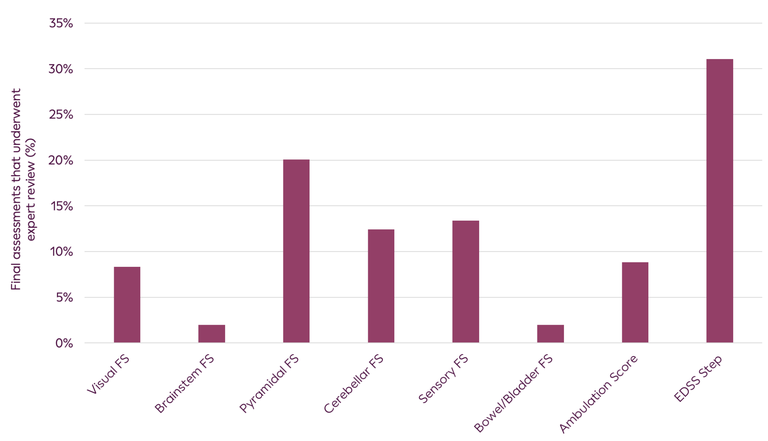
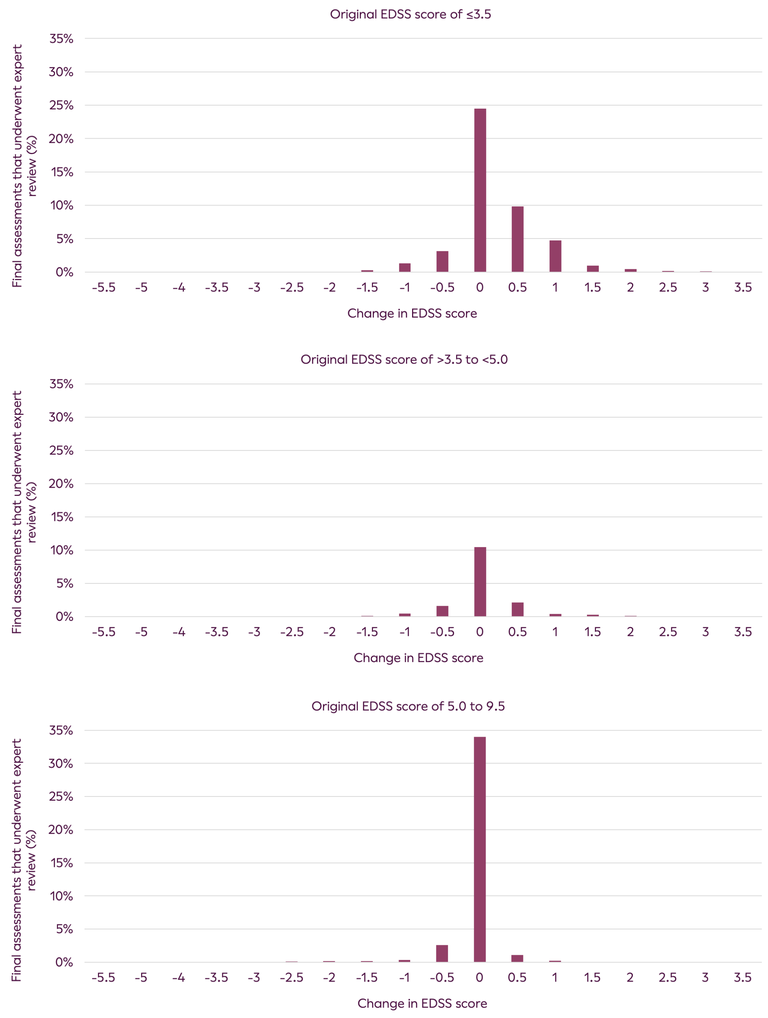


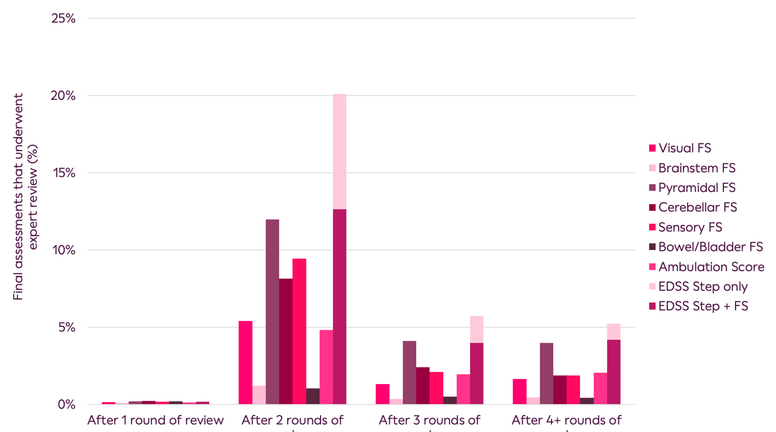
Figure 4. Impact of the expert review process on changes in the final EDSS Step score (n = 5,648)



This trend is also consistent when considering at which point in the review process these data changes occurred; EDSS Step and Pyramidal FSS saw the highest number of changes, regardless of the number of review rounds required for the form to be finalized [Figure 5]. In most cases where the rater changed the EDSS Step value during the review process, that change was also accompanied by an FSS change.

NOTE: The fatigue subscore in the Cerebral functional system can be either included or excluded in the scoring algorithm, depending on the requirements of the respective study protocol. In four of these 13 studies, the system configuration for the fatigue subscore was incorrect for a period of time, and led to a higher-than-normal number of inconsistencies in the Cerebral functional system. For this reason, data from the Cerebral functional system has been excluded from our analysis.

Figure 5. FS and EDSS scores changed compared to total number of review cycles (n = 5,648)



Conclusion

Clario's Neurostatus-eEDSS system results in a high consistency of EDSS scoring through real-time, on-device feedback on scoring inconsistencies and by assuring completeness of assessment data. The system allows further improvement and individualized patient evaluation based on timely remote feedback and interaction between users at sites and expert neurologists.

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