

# NEUROSTATUS-EXPANDED DISABILITY STATUS SCALE (EDSS)

## OVERVIEW

Primary endpoints in multiple sclerosis (MS) clinical trials are often derived from the Expanded Disability Status Scale (EDSS). Paper implementation of this complex clinician assessment scale is associated with inter- and intra-rater variability, complex scoring, and slow review and resolution processes.

Quality evidence generation is paramount. As a leading electronic Clinical Outcome Assessment (eCOA) provider for CNS studies, Signant Health worked with University Hospital Basel's clinical research group to develop an electronic Neurostatus-Expanded Disability Status Scale (EDSS) instrument with an aim to provide a solution to ensure standardized assessment and enable timely rating feedback from central rating experts to drive evidence quality.

In this study, we evaluated how the electronic Neurostatus-EDSS data capture compared to the EDSS raters' traditional, paper assessment.

## GOALS



Produce higher quality of data



Drive consistent rating for enhanced inter- and intra-rater reliability



Reduce site & patient burdens



Streamline & accelerate data collection

## CHALLENGES

1. Identify and reconcile inconsistencies between scores faster.
2. Examine 120 signs and symptoms in real time for inconsistencies.
3. Implement individual review process if inconsistencies cannot be reconciled.
4. Improve communication between the EDSS rater and EDSS expert reviewer (UHB).
5. Provide easy navigation for accurate assessment performance.

## SOLUTION

We used our flexible design environment to implement the EDSS assessment using a tablet computer. This included the rating of 120 signs and symptoms with associated scoring of sub-scores and the total EDSS step (a total disease severity score), logic and assessment instructions to simplify rater workflow.

We extended our web-based solution to enable real-time oversight of investigator ratings by central expert raters from University Hospital Basel. Central raters were able to provide timely in-solution feedback on individual ratings, accounting for the interdependencies between signs and symptoms that could not be achieved by simple in-solution edit checks. Our solution included management of the rating adjudication workflow to ensure quality endpoint data in a timely manner throughout the study.

## RESULTS

We performed 3 studies using the electronic EDSS solution (study 1: 150 patients, 28 countries; study 2: 1,311 patients, 34 countries, study 3: 1,323 patients, 36 countries). Combined, these studies generated 311,808 EDSS assessments. The usability features of the electronic Neurostatus-EDSS made it easier for study teams to track inconsistencies, assist raters, transfer real-time data, and create reports for review. Overall, the electronic scale streamlined data collection process, enhanced data quality, and reduced burdens for all.

## WHO IS SIGNANT HEALTH?

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