GUIDE TO BEST PRACTICES

COLLECTING eCOA IN MULTIPLE SCLEROSIS

ERT develops comprehensive solution for collecting the Expanded Disability Status Scale (EDSS)

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CONFIDENCE
AT EVERY TURN

The Expanded Disability Status Scale (EDSS) is a highly subjective and variable clinician-reported outcome. Standardized implementation and training for this assessment is crucial as the EDSS is the most widely used tool for assessing MS-related disability. ERT has considerable experience with multiple sclerosis (MS) and the EDSS, and a longstanding relationship with relevant stakeholders. Produced in collaboration with the University Hospital of Basel (UHB), ERT's electronic clinician reported outcome (eClinRO) EDSS system is the industry's only solution to include complete edit checks and algorithms from the original Neurostatus EDSS. From training investigative site raters on how to effectively capture the EDSS electronically/best practices, to enabling clinical data query resolution via an interface with UHB central reviewers, sponsors can improve data quality while significantly improving MS trial efficiencies. This eBook will describe how ERT's complete, electronic solution for capturing the EDSS eClinRO coupled with a comprehensive rater training platform and central review system enables collection of high quality data for more effective data analyses.

ERT AND THE EDSS - HOW THE ERT EDSS SYSTEM WORKS

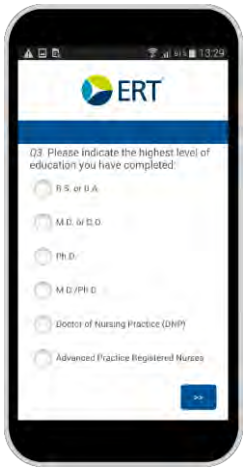
ERT recommends a comprehensive approach to address errors, data discrepancies, and inter-/intra-rater variability that is inherent to the subjective nature of neurological exams. Our system includes several integrated components designed to streamline workflow for sites and study sponsors. ERT has developed a world-class, state-of-the-art electronic EDSS System in collaboration with University Hospital Basel (UHB)/Neurostatus. The ERT EDSS System provides a comprehensive, reliable solution for use in MS trials and is comprised of three parts: rater qualification/training, streamlined data collection and central data review.

RATER TRAINING

Rater Pre-Qualification

ERT's comprehensive and streamlined solution begins by qualifying raters electronically using pre-defined criteria. The ERT rater qualification platform automatically qualifies site raters and routes waiver requests directly to the sponsor. ERT's system reduces time delays by eliminating the need for review of paper forms.

- Clinical raters complete the qualification questionnaire on their own smartphones. ERT provides a quick response (QR) code and/or link for clinical raters to easily access the qualification assessment.
- If a clinician is eligible to complete rater training, they will automatically receive email instructions on how to access their assigned training in ERT's study portal.



Electronic Rater Training and Certification

Qualified raters have on-demand access to the interactive multimedia training content through ERT's study portal. Our single sign-on platform allows site raters to access rater training materials and eCOA data/study reports in one central location. ERT's EDSS training includes electronic navigation (error messages, branching logic, missing data, etc) and best practices for interviewing subjects undergoing the EDSS assessment. A training certificate is provided to each site rater upon successful completion of applicable training materials and a comprehension quiz. The ongoing status of all certified, pending and failed site raters is always available in a report for access by sponsors, CROs and ERT clinical scientists.

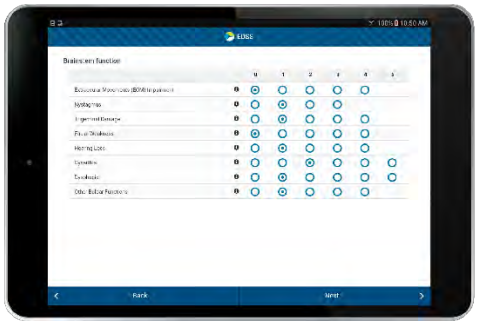
Gating: Monitoring the Bridge from Training to Data Collection

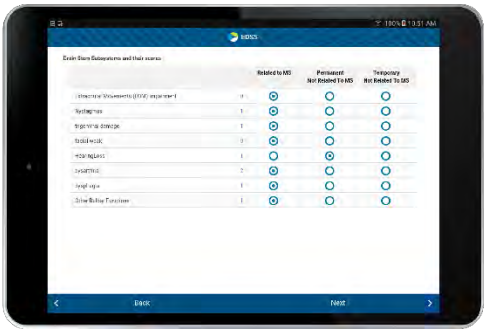
ERT leverages our robust eCOA system to reliably gate between rater training and the eClinRO environment. Only qualified, trained site raters can access the appropriate eCOA assessments and provide key endpoint data. Once site raters complete the necessary training steps they will receive a unique code that is entered on the tablet device to unlock the EDSS assessment. Prior to entry of this code, a rater will not be able to enter data for this assessment.

DATA COLLECTION

EDSS Data Collection

Based on best practices gleaned from more than 2,000 eCOA clinical trials conducted over the past 20 years, ERT designed its electronic EDSS system with a comprehensive approach to improving MS clinical trial data quality. ERT's electronic EDSS solution leverages built-in edit checks and programming logic to reduce errors and data discrepancies. Our platform includes a user-friendly, intuitive application programmed on a provisioned tablet device that allows site raters to easily enter data as they progress through the assessment. As a result, data discrepancies are reduced, as is the burden of data verification and query resolution typically placed on site raters, UHB expert reviewers and trial sponsors.





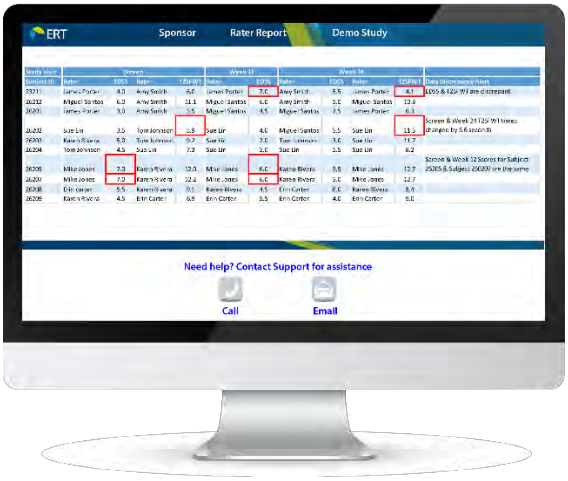
ERT Algorithmic Review/Rating

ERT's EDSS system incorporates Neurostatus/UHB-approved programming logic and scoring algorithms for real-time review and remediation of scoring and tracking of data discrepancies. EDSS data are remediated in two phases: First, prior to assessment completion, the site rater is provided an immediate report on-device that highlights any data discrepancies. Site raters can choose to go back and resolve the discrepancy or override the recommendation and complete the assessment. Second, additional feedback on data discrepancies is provided by UHB central reviewers for every EDSS assessment performed.

CENTRAL DATA REVIEW

UHB Expert Review

ERT clinical scientists and UHB expert reviewers use ERT's study portal to review completed data collection forms and query site raters for any remaining data discrepancies. Site raters can respond to queries and initiate data change requests as needed using the same portal system.



Site Data Monitoring

ERT clinical scientists review data discrepancy reports daily, interact with UHB expert reviewers and provide updates in weekly project calls with the eCOA Project Manager.

Advantages of ERT Algorithm-Based Central Monitoring

- Consistent standards/algorithms applied to all raters across all sites, resulting in global consistency of scores
- Near real-time inter-/intra-rater assessment discrepancy alerts
- No streaming required; no technical problems with internet connections during interviews/exams
- No patient health information (PHI) concerns
- Mitigates audio/visual technology issues (often recordings are unusable, leading to missing data)
- Audit trail for scoring modifications

CONCLUSION

ERT's electronic implementation strategy, rater qualification & training, and central review system is uniquely designed to reduce errors and data discrepancies for the EDSS. Based on best practices and 20 years of experience, ERT's EDSS system ensures a streamlined solution from rater qualification & training, to eCOA data collection and data discrepancy resolution, providing an optimal system for capturing high-quality EDSS data.

Learn how ERT accelerates your research with eCOA technology that doesn't get in the way.

ABOUT THE AUTHORS

Laura Khurana, MPH

Ms. Khurana has over 9 years of experience working in public health and clinical research. As a Scientific Advisor at ERT, she is responsible for providing scientific guidance on trial design and strategy, outcomes services and data analysis. Prior to ERT, she worked as a Senior Research Associate at Quintiles and as a Senior Site Management Associate at Outcome Sciences, Inc., where she was responsible for hiring and training the site management team for their office in Geneva, Switzerland.

Ms. Khurana earned her BA from the University of Georgia and her MPH from Boston University School of Public Health. At BUSPH she helped to design the curriculum for a new master's level course focused on mHealth, "Using Mobile Technology to Improve Health Outcomes."

Susan M. Dallabrida, PhD

Dr. Susan Dallabrida has over 23 years of experience leading clinical instrument development and psychometric validation and conceptual equivalence/ content validity studies and rater training for eCOA/COA. She interacts with regulatory agencies such as the FDA to support development and use of PRO's for labeling claims. She is expert in eCOA/COA design for clinical trials and optimizing data quality via incorporation of outcomes reliability training for site raters, subjects and caregivers, clinical data surveillance and clinical data validation. She conducts research to determine how to optimize eCOA/COA data quality and capture including strategies for optimized engagement, compliance, training and preferences.

She earned a B.A. in Chemistry and a B.S. in Biology, both cum laude, from Bloomsburg University; and a Ph.D. in Biochemistry and Molecular Biology from Pennsylvania State University. Dr. Dallabrida has significant regulatory experience in the US and internationally for biologics and small molecules. She has a broad background in scientific presentations and writing with 21 publications, 14 grants, 3 patents, 20 awards, 50 conference presentations, and 80 abstracts.

ABOUT ERT

ERT is a global data and technology company that minimizes uncertainty and risk in clinical trials so that customers can move ahead with confidence. With nearly 50 years of clinical and therapeutic experience, ERT balances knowledge of what works with a vision for what's next, so we can adapt without compromising standards.

Powered by the company's EXPERT® technology platform, ERT's solutions enhance trial oversight, enable site optimization, increase patient engagement and measure the efficacy of new clinical treatments while ensuring patient safety. Since 2014, more than half of all FDA drug approvals came from ERT-supported studies. Pharma companies, biotechs and CROs have relied on ERT solutions in 10,000+ studies spanning more than three million patients to date. By identifying trial risks before they become problems, ERT enables customers to bring clinical treatments to patients quickly — and with confidence.