ERT ELECTRONIC RATER TRAINING

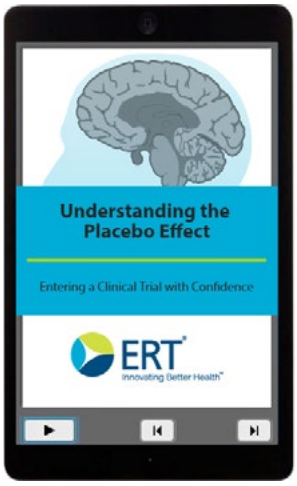
Minimize data quality risk with on-device instruction for caregiver, patients, clinicians and site staff

IMPROVE THE QUALITY OF YOUR CLINICAL TRIAL DATA

Uniform administration of assessments or completion of patient health status reports in clinical trials is required to reduce rater variability and minimize data risk with clinical outcome assessment implementations as well as to meet recommendations. Furthermore, effective assessment training remains a key determinant of whether a therapy attains efficacy and/or safety. The Food and Drug Administration (FDA), European Medicines Agency (EMA), and International Society for Pharmacoeconomics and Outcomes Research (ISPOR) recommend that site raters, patients and caregivers capturing assessment data receive training in the correct use of the instrument and of the electronic data capture element.

ELECTRONIC SYSTEMS FOR >50% OF ALL DRUG APPROVALS SINCE 2013

106 LANGUAGES SUPPORTED



CUSTOMIZED PLACEBO EFFECT TRAINING GENERATES HIGHER QUALITY DATA IMAGE

ERT ELECTRONIC RATER TRAINING

To help ensure uniformity, ERT Electronic Rater Training provides customized instruction for clinicians, caregivers, patients and site staff. Data integrity is preserved throughout the study duration through rater remediation, refresher training and gating between training and the eCOA environment. Rater qualification, training and certification are always accessible on ERT eCOA devices via a single login. ERT Electronic Rater Training improves inter-rater reliability, reduces unnecessary data variance, facilitates signal detection and improves compliance and engagement — providing confidence at every turn.

Built on experience

We combine instructional and interactive learning methods with electronic assessments to reduce rater variability. Our clinical psychologists, neuroscientists, psychometricians, eCOA scientists and instructional design experts customize all rater trainings. In addition, we have a global network of subject matter experts to strengthen training rigor and deploy the most complex studies.

Adaptive to your needs

Interactive and customized modular training components including role-play scenarios, interactive video quizzes and gold scoring (where applicable) improve rater retention and study compliance. Rater remediation, refresher training and gating ensure that only certified raters complete eCOA assessments.

Ensures regulatory compliance

In addition to the recommendation for training in the correct use of instruments, with documentation in the study archive, regulators recommend training to enhance understanding, compliance and engagement. To fully comply with regulatory guidelines, we combine instrument instructions and scoring standardization, instrument navigation for each device and best practices for clinical interviews and clinical trial expectations of patients, caregivers and site staff, including strategies to minimize the placebo effect. Every training session is date- and time-stamped, with each training record mapped to regulatory guidelines to provide accountability.

ELIMINATE eCOA COMPLEXITY SO YOU CAN MOVE AHEAD QUICKLY

Not all eCOA are created equal. We have over 50 years of combined clinical, therapeutic and regulatory experience as well as technology and process-related insights. We have provided electronic systems for more than half of all drug approvals since 2014.

ERT eCOA

Accelerate your research with eCOA technology that doesn't get in the way. For more information, email sales@ert.com or visit ert.com.

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