ERT®
Confidence at every turn™

ERT C-SSRS SUICIDE RISK ASSESSMENT

Ensure patient safety with improved signal detection and data quality for suicide risk assessment

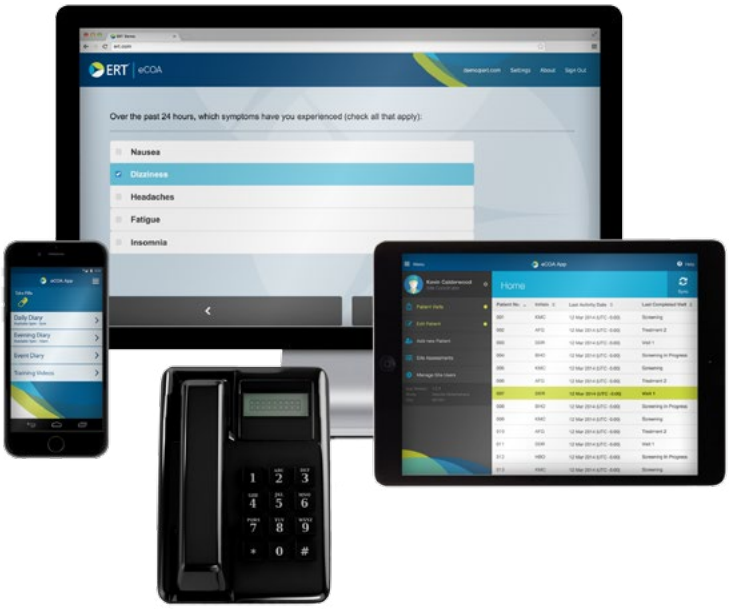
ENSURE PATIENT SAFETY WITH EFFECTIVE EVALUATION OF SUICIDAL IDEATION AND BEHAVIORS

Treatment-emergent suicidal ideation and behaviors (SIB) threaten efficacy and patient safety. The FDA's latest guidance on SIB in clinical trials recommends prospective assessment for a wide variety of indications, especially psychiatric and central nervous system drug trials.[1] The Columbia-Suicide Severity Rating Scale (C-SSRS) is the gold standard for assessing SIB, and the FDA considers the instrument and electronic C-SSRS implementation as a suitable instrument to deliver the expected level of data quality. Electronic data collection of SIB presents many benefits over paper collection, including improved signal detection and data quality; reduction in data noise because of missing, illegible or illogical entries; and access to near real-time reporting and safety alerts.

GOLD-STANDARD SIB ASSESSMENT

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

114 LANGUAGES SUPPORTED



THE RISK OF SUICIDE IS ASSESSED CONSISTENTLY REGARDLESS OF MODALITY

SCIENTIFICALLY-PROVEN ELECTRONIC C-SSRS ASSESSMENTS

We provide both interviewer-reported and patient-reported options for electronically implementing the C-SSRS, to facilitate trial workflow and reduce patient burden.

Interviewer-reported digital C-SSRS

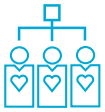
The interviewer-reported digital C-SSRS enhances data collection by enabling a trained interviewer to complete the semi-structured assessment via a tablet device during the patient's site visit. This reduces the burden, reduces transcription errors and enables access to near real-time reporting and automated safety alerts.

Patient-reported eC-SSRS

With the self-reported electronic C-SSRS (eC-SSRS), patients can comfortably and privately complete the systematic structure of logically branching questions via handheld, tablet, web or interactive voice response (IVR) during their site visit. This patient-reported approach increases patient candor and eliminates inter-rater variability and bias.[3]

Alerts for positive reports

If the patient assessment generates a positive report, the site is alerted immediately enabling staff to take quick and appropriate action per the trial protocol, even if the assessment was abandoned before completion. Patient safety and risk evaluations are available near real-time on the 24/7 study portal, in addition to eCOA operational and clinical data.



Prospective assessments

The prospective C-SSRS conforms to C-CASA[2] and provides more information than retrospective assessments. This comprehensive process ensures consistency and safety across all patients, at all sites, in the clinical trial.

Reduced burden

The patient-reported eC-SSRS removes the burden of specialized training for site staff who are not mental health professionals. This enables investigative sites to optimize trial resources and allows efficient and effective implementation of suicidal ideation screening in any study.

CONFIDENCE AT EVERY TURN

We have over 50 years of combined clinical, therapeutic and regulatory experience as well as technology and process-related insights. We use our 20 years of expertise in collecting eCOA data to develop assessments that you can confidently use to collect reliable, real-time data, helping you to ensure patient safety. With our electronic C-SSRS products, you can prospectively assess and be alerted about potential patient safety issues.

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.

[1]FDA Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials. 2012.
[2]Columbia Classification Algorithm for Suicide Assessment
[3]Hesdorffer, D., French, J., Posner, K., et al. Suicidal Ideation and Behavior Screening in Intractable Focal Epilepsy Eligible for Drug Trials. Epilepsia 2013; 54(5): 879-87.