

2018 Training Sessions Offered at NEALS

NEALS ALS OUTCOMES MEASURES TRAINING SESSION

Gale Kittle, RN, MPH (BNI)

Tuesday, October 2nd from 08:30 am – 12:30 pm

A training session developed for NEALS Clinical Trials Evaluators, this session can serve as a review for current evaluators and training for new evaluators for the Outcome Measure Assessments currently being done in ALS Clinical Trials.

MEDICAL MONITORING TRAINING SESSION

Jinsy Andrews, MD, MSc (Columbia); Christopher Coffey, PhD (Univ. of Iowa)

Tuesday, October 2nd from 1:30pm – 3:30pm

The Medical Monitor Training course will provide a general overview on the basic components of monitoring a clinical trial in patients with ALS.

SITE MANAGEMENT I

Tuesday, October 2nd from 2:00pm – 3:30pm

Study Site Start-Up: Getting from point A to E(nrollment)

Daniela Grasso Walker, Sara Thrower, Rebecca Randall, Taylor Pitts, Eric Tustison

Join us as we cover topics focused on protocol development and selection of database, site feasibility & site selection, cIRB related regulatory documentation, overall study start-up, including trainings, site initiation visits (SIVs), direct data entry/eSource, use of mobile technology (apps), to enrolling your first subject.

SITE MANAGEMENT II

Tuesday, October 2nd from 3:45pm – 5:15pm

Central IRB: So that's the cIRB's Role in my study!

Melissa Ricker

20 Minutes

The NCRI Central IRB Liaison is back again to discuss the role of the Central IRB (cIRB) in NEALS studies and provide an overview of the submission types that the cIRB handles. The presentation will include cIRB metrics, frequently asked questions and provide an opportunity for Q & A.

Study Maintenance: What Makes a Great Site

Meghan Hall, Emily Engel

40 Minutes

This session will include an interactive panel discussion on what makes a great enrolling site. We'll also share some recruitment and retention tools and tips and how to keep your study files in order during the course of the study.

Study Closeout: And That's a Wrap!

Lindsay Pothier, Armineuza Evora, Rebecca Randall, Taylor Pitts, Eric Tustison

30 Minutes

Join us as we cover topics on overall study closeout, including conducting your last patient last visit, EDC data entry and PI sign-off, and reconciliation of regulatory documentations.