



Revised ALS Clinical Trials Consensus Guidelines Modernize Trial Practices

The ALS Association is proud to be a longtime supporter of the Airlie House ALS Clinical Trials Consensus Guidelines, which have been revised and published in *Neurology*, the most widely read and highly cited peer-reviewed neurology journal.

The goal of the Guidelines is to improve research to test cures for ALS. We believe they will pave the way to decrease clinical trial burden for people with ALS and help contribute innovative designs to clinical trials.

The Guidelines review nine key areas of need within ALS clinical trials, including: (1) preclinical studies, (2) biological and phenotypic variation in ALS, (3) outcome measures, (4) disease-modifying and symptomatic interventions, (5) recruitment and retention, (6) biomarkers, (7) clinical trial phases, (8) beyond traditional trial designs, and (9) statistical considerations.

The project originated over two years ago during a workshop at the Airlie House in Virginia, in which over 140 international experts from more than 10 countries attended to discuss how to globally improve the existing set of clinical trial guidelines. The original version of the Guidelines came about in 1999.

The Guidelines build off the work The ALS Association has accomplished in the ALS regulatory space, including the Guidance for Industry from The ALS Association, the ALS Community Workshop: Therapy Development and Regulatory Pathways, and subsequent recommendations on how to improve the FDA's Guidance: Amyotrophic Lateral Sclerosis: Developing Drugs for Treatment Guidance for Industry.

The clinical trial Guidelines show potential to accelerate the development of effective ALS treatments by modernizing ALS clinical trial practices.

You can find the published paper summarizing 112 guidelines, including their associated backgrounds and rationales [here](#).

Citation: Leonard H. van den Berg, et al. Revised Airlie House consensus guidelines for design and implementation of ALS clinical trials. *Neurology*. 2019;92:e1610-e1623.
<https://doi.org/10.1212/WNL.0000000000007242> (Article is OPEN ACCESS.)