

Press Release

From March 17-19, 2016, 140 international thought leaders in the field of ALS from North America (Canada and USA), Europe (Belgium, France, Germany, Ireland, Italy, Netherlands, Portugal, Sweden, Switzerland and United Kingdom) and Asia-Pacific (Australia and Japan), a sub-committee of the World Federation of Neurology Research Group on Motor Neuron Diseases Research Group convened at the Airlie Conference Center in Warrenton, Virginia. This multinational group comprised neurologists, basic scientists, statisticians, patient advocates, representatives from the pharmaceutical industry, as well as regulatory agencies and patients with ALS.

The working group revised, updated and expanded the Guidelines for Clinical Trials in ALS/MND that were last revised in 1998.

The working group utilized an innovative evidence-informed and modified Delphi processes to develop revised Guidelines that represents a major advance from the existing document, including recommendations on gene therapy and stem cell therapy, not previously addressed. Many scientific and methodological advances are reflected in the new Guidelines, which have the potential to make future clinical trials including pragmatic clinical trials more efficient and productive.

The initial draft of the Guidelines will be released for public comments on August 1, 2016 for a period of one month (until August 31, 2016). It can be viewed on the website, <http://alsclinicaltrialsguidelines2016.ning.com/>. Public comments are welcomed to ensure that all interested persons and stakeholders have an opportunity to provide input. If you wish to make any comments, please email: guidelines.public.comments@gmail.com. There are eight major Sections containing multiple recommendations. Please specify to which Section and recommendations you are referring so we can respond accordingly. We appreciate your patience, as all investigators must reach a consensus addressing your comment or concern.

We look forward to hearing from you.
Clinical Trials Guidelines Investigators