

Washington DC, November 8, 2017 – The Liver Forum is pleased to announce the publication of its first manuscript, *Baseline Parameters in Clinical Trials for Nonalcoholic Steatohepatitis: Recommendations From the Liver Forum*, published as a Commentary in the September 2017 volume of the peer-reviewed journal *Gastroenterology*. The development of this manuscript included input and contributions from key opinion leaders in the field of NASH, and was led by Dr. Yuval Patel (Duke University), Dr. Andrew Muir (Duke University), and Dr. Joanne Imperial (Conatus Pharmaceuticals). The published article is available at: <https://doi.org/10.1053/j.gastro.2017.07.024>.

Dr. Veronica Miller, Executive Director of the Forum for Collaborative Research and The Liver Forum, commented on the significance of this article, noting that “the publication of this article is significant because although there are many drugs in various stages of development, there are currently no approved therapies to treat NASH. Drug development for NASH has been challenging in part due to the inconsistent measurement of baseline parameters, which makes trial data difficult to interpret and compare. The purpose of this article was to address this challenge by creating recommendations to standardize data collected in clinical trials.”

To accomplish this goal and develop consensus recommendations for standardized baseline parameters for NASH clinical trials, the Liver Forum created the Data Standardization Working Group, and invited experts from academia, regulatory agencies, the pharmaceutical and medical diagnostics industries, and patient advocacy organizations to participate in a consensus building process. The end result of this process was the development of parameters to recommend for baseline data collection, including demographics and genetics; diet and activity; concomitant medications; laboratory tests; and histology.

“Our expectation is that these standardized baseline parameters for NASH clinical trials will be adopted by pharmaceutical sponsors and thus facilitate the regulatory agencies’ efforts to determine efficacy and safety. This is only a first step in advancing regulatory science in this important area of unmet clinical need of great public health significance”, commented Dr. Arun Sanyal, academic co-chair of the Liver Forum and Professor of Medicine at Virginia Commonwealth University.

About the Liver Forum

The Liver Forum is an initiative of the Forum for Collaborative Research, part of the University of California, Berkeley School of Public Health. The Liver Forum was launched in 2014 in response to *The Trial Designs and Endpoints for Liver Disease Secondary to Nonalcoholic Fatty Liver Disease (NAFLD)* meeting sponsored in 2013 by the U.S. Food and Drug Administration (FDA) and the American Association for the Study of Liver Disease (AASLD).

The Liver Forum aims to advance the regulatory sciences for the treatment of Non-Alcoholic Steatohepatitis and liver fibrosis by providing an independent and neutral venue for ongoing multi-stakeholder dialogue to identify and address gaps in the field. Neutrality and objectivity is ensured through representation and active engagement of scientific experts from all stakeholder groups, including academia, industry, patient community and regulatory agencies.

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