DIA Research

Currently Launching!

**Understanding and measuring treatment tolerability of immune-oncology (IO) treatment in selected cancers**

DIA is currently seeking industry leaders to participate and support in a research study that contributes to the understanding of the tolerability definition of I-O in selected cancers, and discuss the potential development of a tolerability PRO instrument(s). Understanding tolerability as part of the development and delivery of I-O therapies is an integral part of including patient preference as mandated by the 21st Century Cures Act into programs and clinical decision-making. However, there are significant challenges with collecting information about tolerability from patients. For example, current definitions of tolerability are incomplete and there is little if any consensus about its definition. Furthermore, tools that can adequately measure patient-reported data are needed to facilitate the collection of robust, reliable, valid, interpretable tolerability data in clinical development.

To bridge this gap, DIA is establishing a Working Group to develop a guidance on:

- Endpoint definitions related to tolerability
- The use of tolerability data to inform healthcare provider/patient decision-making, benefit-risk appraisal, and product labeling
- Analytical methods to quantify tolerability, and
- The design of trials to measure comparative differences in tolerability Develop a predictive model for Immune-related adverse events using EHR and ML

This effort will establish a multidisciplinary collaboration including pharmaceutical organizations, contract research organizations, regulatory representatives, patient advocacy representatives, oncologists, healthcare providers, researchers, and academia, among other subject matter experts. Working Group members will have the opportunity to:

- ✓ Drive outputs and influence the direction of the project and overall understanding and acceptance of tolerability to incorporate patient preference
- ✓ Gain first access to novel thinking and research findings
- ✓ Network with our regulatory partners, researchers, patients, and other industry leaders from CROs, pharmaceutical companies, and other solution providers
- ✓ Share best practices and case studies with other leading experts in an intimate and neutral setting
- ✓ Amplify/share the research findings in their own networks and/or meetings
- ✓ Gain acknowledgment as a funding source in all peer-reviewed manuscripts or presentations and webinars resulting from this study

A participation fee of USD 150,000 will allow appointed Working Group Members to take part in all these aspects of the research. We hope that you can join us in this innovative work to shape the future of tolerability as an endpoint in clinical trials and research.

If you are interested in joining the study working group, learning more, or have any other questions about the research study**,** please contact science@diaglobal.org.