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ITN Achieves Scientific Manuscript First - Provides Open, Interactive Access to Clinical Trial Data

Immune Tolerance Network (ITN) researchers published data of their "Rituximab for the Treatment of Wegener's Granulomatosis and Microscopic Polyangiitis (RAVE)" clinical trial using ITN TrialShare, a clinical trial data and analysis portal that provides open, unprecedented access to clinical trial data, analyses and specimens.

WA, Seattle (July 26, 2013) – In an article reporting the 18-month results of the ITN's RAVE clinical trial, published August 1st in the *New England Journal of Medicine,* the ITN is providing unfettered access to the underlying clinical data and analysis code via the new clinical trials research portal, ITN TrialShare (itntrialshare.org). TrialShare is a significant advance in data sharing and transparency, allowing for collaborative hypothesis generation and specimen sharing between the ITN and the broader scientific community. TrialShare gives researchers the ability to access raw study data, confirm published conclusions and interactively perform their own exploratory analyses using this data.

"Direct access to raw clinical trial data will change the landscape of collaborative research" said Peter C. Grayson, MD, MSc of Boston University Medical Center, a collaborator with the ITN. "TrialShare creates unfettered opportunities to explore and understand the intricacies of clinical trial data. Better understanding of primary data leads to better downstream applications of that data."

The FDA has announced that it intends to consider making de-identified and masked subject level data widely available to improve the efficiency and effectiveness of medical product development, recognizing that external experts should become actively engaged in the research. ITN TrialShare was created precisely to address this need, enabling researchers to share the results of the clinical trial data in an open and transparent manner, while protecting the privacy and anonymity of study participants by fully de-identifying the data. TrialShare provides tools that allow external researchers to confirm results while providing access to the underlying data, ensuring that nothing is missed or overlooked. TrialShare also provides access to the ITN specimen repository catalog, allowing users external to the trial to request specimens for follow-up experiments based on the data and available samples.

"TrialShare allows researchers from around the world to have direct access to ITN's clinical trial data" said Gerald T. Nepom, MD, PhD, director of the ITN. "This will enhance scientific collaboration and greatly speed the sharing of the results of our studies."

In recognition of the system's approach to analytic transparency, ITN Trial Share was recently awarded "Best Practices Award – Honorable Mention" at the April, 2013 Bio-IT World Conference in Boston. The Bio-IT World's Best Practices Awards "recognize organizations for their outstanding innovations and excellence in the use of technologies that advance biomedical and translational research, and clinical trials." (http://www.bio-itworld.com/2013/4/10/best-practices-winners.html).

With the addition to TrialShare of the data from today's publication, ITN TrialShare currently has data associated with six published manuscripts available to the public in the therapeutic areas of transplant, allergy, auto-immunity and diabetes. ITN will make the underlying data from all published studies, regardless of outcome, available through TrialShare. ITN TrialShare uses the open source LabKey server software. TrialShare can be accessed at ITNTrialShare.org.

About The Immune Tolerance Network

The Immune Tolerance Network (ITN) is a research consortium sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health along with additional support from NIDDK and JDRF. The ITN develops and conducts clinical and mechanistic studies of immune tolerance therapies designed to prevent disease-causing immune responses, without compromising the natural protective properties of the immune system. Visit www.immunetolerance.org for more information.

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