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CDISC and Cohen Veterans Bioscience Partner to Establish the First Therapeutic Area Standard for PTSD

Creation of a Common "Dictionary" for PTSD Will Facilitate Research Data Exchange

Austin, TX – 23 September 2016 – The Clinical Data Interchange Standards Consortium (CDISC) and Cohen Veterans Bioscience today announced a collaboration to establish a new CDISC Therapeutic Area Data Standard for post-traumatic stress disorder (PTSD).

Approximately 7 to 8 out of every 100 people will experience PTSD at some point during their lives and about 8 million adults have PTSD in a given year, according to the U.S. Department of Veterans Affairs National Center for PTSD.

While there is a wealth of scientific research on PTSD—more than 100,000 peer-reviewed scientific articles have been published on the topic across the globe during the last 35 years—without a common "language" this valuable research cannot be effectively shared.

The CDISC and Cohen Veterans Bioscience collaboration will map the most common data elements and biomedical concepts used in PTSD to establish uniform clinical research and terminology standards. This will be accomplished by collecting, tabulating, analyzing and then standardizing data for PTSD medical research and clinical care, collected within the US National Institutes of Health, Department of Defense, Veterans Affairs and other key organizations.

To date, CDISC has developed and made publically available clinical data standards for more than 25 disease areas and disorders, including Traumatic Brain Injury (TBI), which are being implemented in clinical research studies and regulated clinical trials. CDISC standards are considered the gold standard for medical research around the world and are widely used in more than 90 countries for study planning and data collection, tabulation, and analysis. They are required by the U.S. FDA and other regulatory agencies internationally for evaluating new treatments for various diseases and afflictions.

"Building upon our work in TBI, we are pleased to be launching another project that can lead to a greater understanding of mental health and better care for those suffering from PTSD. Developing a data standard for PTSD is an important step for CDISC, and for the many patients and families that experience this condition, and we appreciate Cohen Veterans Bioscience's offer to fund the project," stated Bron Kisler, Vice President, Strategic Alliances & Development for CDISC. "The PTSD project is timely, as CDISC is also working on standards for PTSD & TBI comorbidity – Major Depressive Disorder, General Anxiety Disorder, and Bipolar Disorder – funded by FDA as well as donations from the Association of the US Army North Texas & the Golden Rule Family Foundation."

The sharing of information in the development of new therapeutics is a mounting problem. While billions of dollars are spent on clinical research, clinical trial data is frequently not shared – or is not collected in a standard, sharable format.

To address this practice of “siloes research,” the Clinical Data Interchange Standards Consortium (CDISC) – an Austin-based, global, non-profit organization – has led the charge for data synchronization, developing and supporting global data standards to help improve the quality and interoperability of medical research and healthcare.

“Establishing a suite of standards to support clinical research from protocol and data collection through analysis and reporting is an important tool that will accelerate the development of new and effective diagnostics and treatments for our service men and women and veterans that are affected by PTSD,” says Magali Haas, MD, PhD, CEO & President of Cohen Veterans Bioscience. “Empowering data collection and sharing makes the most of the valuable information offered by patients participating in research studies around the globe and saves time and resources to unlock cures sooner.”

About CDISC

CDISC is a 501(c)(3) global non-profit charitable organization that streamlines research and enables connections to healthcare through the development of clinical research data standards. CDISC has developed a suite of standards to support clinical research from protocol through analysis and reporting. CDISC standards make it possible for data to speak the same language, empowering simple data collection and private sharing that makes the most of the valuable information offered by patients participating in research studies around the globe. Using CDISC standards from the start of studies enables Smarter Research to Unlock Cures (www.unlockcures.org), saving 70-90% time in the start-up of clinical research studies and ~60% overall in terms of time and resources to conduct research. CDISC is the patient’s advocate, creating therapeutic area data standards for over 25 different disease areas that advance medical product development and various types of clinical research.

CDISC is funded through the generous support of over 400 member organizations, as well as through grants, Authorized Education courses and CDISC events. To find out more about how to support CDISC, please visit www.cdisc.org.

About Cohen Veterans Bioscience

Cohen Veterans Bioscience is the only 501(c)(3) non-profit research organization with a singular focus on PTSD and TBI research. We are dedicated to fast-tracking the development of diagnostic tests and personalized medicines for the millions of veterans and civilians who suffer the devastating effects of trauma on the brain. More information is available at www.cohenveteransbioscience.org