Proceedings from Huntington’s Disease Regulatory Science Consortium (HD-RSC) Kick-Off Meeting, Nov. 6-7, 2017

On November 6 and 7, 2017, in Silver Spring, MD, Critical Path Institute and CHDI Foundation welcomed participants from the pharmaceutical industry, academia, regulatory agencies, and advocacy groups to a kick-off meeting for the Huntington’s Disease Regulatory Science Consortium (HD-RSC). The meeting objectives were to solicit input from stakeholders on HD-RSC plans and deliverables, and to develop an understanding of 1) the value of a pre-competitive consortium model to advance regulatory science and enable drug development in HD; 2) the critical importance of data contributions in advancing regulatory science, and for the success of HD-RSC.

Meeting Agenda

The Vision: CHDI’s Dedication to Successful HD Treatments (R. Blumenstein)

Consortia-Based Strategies in Neurodegenerative Diseases:

Critical Path Institute’s Track Record in Collaborative Efforts (M. Brumfield)

Model Informed Drug Development (I. Zineh)

From Model-Based Clinical Trial Enrichment to Comprehensive Clinical Trial Simulation (B. Corrigan)

Success in Sharing Data from HD Natural History Studies (A. Mohan)

Rationale and Impact of Building a Comprehensive HD Clinical Database (C. Sampaio)

Biomarkers as Tools to Enable Decision-Making in HD Drug Development (E. Siemers)

Clinical Outcome Measures in HD: Beyond UHDRS (G. Stebbins)

The Operations: How HD-RSC Will Work (D. Stephenson)

Critical Path to TB Drug Regimens: Global Collaboration for Accelerating Novel TB Regimen Development (D. Hanna)

Presentation by Charles Sabine, Patient Advocate: “The Impact: Why This Matters to Patients”

Meeting Bios

Meeting Attendees

Meeting Summary