Bess Le Roy, The Critical Path Institute

“The goal of developing and implementing the formal TB Data Standard is to allow for standardization of clinical data acquisition enabling aggregation and analysis. At C-Path, we are very pleased to have been part of this important project. The effort to create the user guide started in earnest at the beginning of this year. Through support and collaboration with CDISC members, FDA, National Cancer Institute Enterprise Vocabulary Services, and the Critical Path to TB Drug Regimens (CPTR) work group members, we were able to complete this project on an accelerated schedule. It was a great team effort and a significant success.

We hope that this new data standard will help guide both new clinical trials and the conversion of legacy data. As part of CPTR, we plan to convert legacy data using this new standard to support our scientific research goals. The data, when appropriate, can be pooled to provide greater insight which will certainly contribute to research efforts in this area.

TB is one of the first therapeutic areas to go through the new CDISC process for therapeutic area standards development. This project provided some great lessons learned that can applied to future therapeutic area standards. One of the most important take away messages is to engage CDISC team members early. For this project we were able to receive key early input on many of our data modeling decisions. This allowed the Standards Review Committee (SRC) review to go much more smoothly and quickly than it would have otherwise.”