For the majority of drug development organizations, commercial functions are currently the primary users of real world evidence (RWE), whereas nearly 40% use RWE in R&D operations.

Headcount for the RWE function, which typically is centralized and supporting other functions, is projected to increase substantially within the next three years.

Although few companies report using social media, mobile health and wearable device data to support a new drug application at this time, these data areas are expected to be used by a much higher number of companies within three years.

Availability of data poses the greatest challenge in using RWE and real world data (RWD), followed by lack of external stakeholder trust in RWE and the cost of acquiring data.

The primary current electronic data capture (EDC) application is largely managing electronic case report form data.

The high cost and effort to collect, integrate, and use RWE today diminishes its utility.

The use of real world evidence and data is growing and taking on greater importance for pharmaceutical companies in drug development, patient safety, and commercialization, a trend spurred by the 21st Century Cures Act of 2016 that required the United States Food and Drug Administration (FDA) to implement a framework for RWE’s role in drug development within two years. The FDA has already developed guidance for the use of RWE for medical devices.

To better understand the role of RWE and RWD in the pharmaceutical industry, Tufts CSDD surveyed 30 drug companies to assess current and planned uses of RWE and RWD in drug development and post-marketing safety efforts. The study found that RWE poses a number of challenges associated with data availability and reliability, quality of data sources, the cost and effort of data integration, and acceptance by key stakeholders, including regulatory agencies and payers. However, new technology solutions that integrate disparate data sources, including RWE (e.g., HL7’s FHIR®), are expected to play an important role in addressing availability and cost issues.