eClinical data volume and diversity pose increasing challenges and delays

Data management cycle times are longer than those observed a decade ago

- Sponsors and CROs use an average of six applications to support clinical trial activities.
- 26% of sponsors and 52% of CROs report that they still use paper case report forms.
- Companies report taking 68.3 days, on average, to build and release a study database, with modest variation observed between companies.
- Protocol changes are the most common reason for delays in building study databases.
- Frequency of releasing the final study database after the first patient visit is associated with longer downstream delays and inefficiencies.
- Cycle time from last patient, last visit (LPLV) to database lock is 36 days on average, up from 33 days 10 years ago.
- 77% of sponsors and CROs cite difficulty loading data into their primary EDC system due to compatibility, technical demands, and integration challenges.

As the scope and complexity of global drug development programs continue to rise, data management functions must bear the burden of handling an ever larger amount of diverse clinical data. Electronic clinical outcome assessments, mobile devices, social media communities, and electronic health/medical records are but a few examples of new and diverse sources of data now captured during a clinical trial. The volume and diversity of data is presenting integration, compatibility, loading, and interoperability challenges that the pharmaceutical industry must address to optimize drug development performance.

To better understand the current data management operating environment, Tufts CSDD and Veeva Systems conducted a study including nearly 260 sponsor and CRO companies to obtain a baseline assessment of data management practices and experience, results of which are summarized in this report.