OBE update in CDISC

- OBE statistical reviewers can handle clinical trial data in most submissions.
- If the sponsor would like to submit RWE data to support a regulatory decision solely, the dataset is preferably organized similar to datasets created from clinical trials, especially if the RWE data were collected from multiple sources.
- The optimal time for the sponsor to communicate with FDA on the formats (which variables go to which domains, etc) should be considered.