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.