**CBER SEND Pilot 1 – Standardized data validation review**

Ref: Pilot Submission files and DataFit validation reports reviewed:

\\cbsfs03\CBER\_CASA-CV\Validation BLAs, supplements for 2020\SEND\_Pilot\pilot1

I. Comments for CBER Nonclinical Reviewers:

1. BW (Body Weight) dataset:

(1) As per SEND IG v3.1, variable BWBLFL should be populated as ‘Y’ or ‘Null’. But all **BWBLFL** values = blank. (Same observation for **LBBLFL** in LB dataset)

OVRR cares about the differences between scheduled body weight measurements rather than body weight change from the study initiation. According to WHO guidance, body weight measurements should be weekly with more frequent measurements occurring on the first week of each vaccination (daily).

For LB, they don’t care about baseline flag, only comparing control groups to treatment group.

CDISC Proposal: can xxBLFL be permissible instead of expected? Recommendation based on study type?

(2) The study Day number and label do not appear consistent / harmonious to each other. Is this commonly seen in submissions and/or considered acceptable?

**BWNOMDY** (Nominal Study Day) = ‘-8’ vs. **BWNOMLBL** (Label for Nomimal Study Day) = Pre-dose Day 1;

**BWNOMDY** (Nominal Study Day) = ‘-1’ vs. **BWNOMLBL** (Label for Nomimal Study Day) = Pre-dose Day 8;

The label is weird. Reviewers might not care about this.

This is based on the system, a statement in nsdrg to clarify is recommended.

2. LB (Lab Test) dataset: “Other” (“Other Urine Microscopic Findings”) is not part of CDISC controlled terminologies for laboratory tests. Should it be added to the CDISC standard terminologies?

Probably remapping to the right terminology “unspecified”