**CBER SEND Pilot 5 (Sanofi) – Standardized data validation review**

Ref: Pilot Submission files and DataFit validation reports reviewed:

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

**I. Comments for CBER Nonclinical Reviewers:**

1. CL dataset - CLTEST variable:

The CLTEST, CLTESTCD variables currently are not associated with standardized terminologies. Should there be one?

CLTESTCD: CLINOBS, CLNOB, CS

CLTEST: Clinical Observation, Clinical Signs, Clinical Observations

CLCAT: CLINICAL SIGNS

These terms might mean different things, they should be defined what exactly is evaluated.

These don’t have control terminology, only CLCAT has terminology. Recommend to have this be worked on.

1. CO – COVAL = “value under validated range” is noted for some lab records but not all relevant records, not sure if the numbers are made up, since it didn’t show consistency. See examples below:

SUBJID= RABBITV1-N30647, LBSEQ=155: Coagulation (Prothrombin Time) = 6.7 sec - Marked in CO

SUBJID= RABBITV1-N30729, LBSEQ=157: Coagulation (Prothrombin Time) =6.2 sec - not Marked in CO

SUBJID= RABBITV1-N30662 , LBSEQ=119: Coagulation (Prothrombin Time) =6.8 sec – Marked in CO

This is a method validation, not the lab reference range. How to indicate the validated range?

1. In Define.xml, DS – DSDECOD doesn’t list any codelist. But the actual DS dataset data seems fine =- compliant with SEND standard terminologies, codelist DSDECOD (C89968). Also define.xml doesn’t list any origin, derivation/comment information, miss links, it doesn’t have value level metadata for suppqual domain. It seems define.xml doesn’t follow the standards.

Need more discussion on how non-clinical define.xml should include and be used for.

1. In OM, the label variable (OMNOMLBL) is not included but OMNOMDY is present. Should those be associated?

OMNOMLBL is permissable

OMLAT “BILATERAL”, what does that mean? Does that mean the weight for “KIDNEY”, “TESTIS” and etc are the mean of weights for both side of kidney or …?

Usually it means the combined weight of left and right, it should be defined or clarified somewhere, in study report or footnote of the table.

1. There seems to be use of inconsistent study day labels:

IS.ISNOMLBL =’ Pretest’ for ISNOMDY=-11;

IS.ISNOMLBL =’Day 21’ for ISNOMDY=31

LB.LBNOMLBL =’Week 5’ for LBNOMDY=31

LB.LBNOMLBL =’ Predose’ for ISNOMDY=-12;

NOMLBL is designed to match the report. It is not supposed to be matched according to SENDIG.