Data Cutoff Date – Definition, Algorithm, and Application

1. Objective

The purpose of this guidance document is to provide the definition and algorithm used in determining data cutoff date, and to explain how they are applied in clinical datasets (as specified in Section 3) used for Regulatory submissions, publications, and other analysis purposes.

2. Definition

The data cutoff date (DCO) is defined as the date by which all data records in the clinical datasets will be included in or excluded from a prescribed set of analyses. For Part A End of Part A, the DCO is defined as below, if cutoff is based on unblinding/OL-D1 date, then the data prior to the date needs to be kept. If EOS date is used, the data up to EOS date needs to be kept.

1) For a subject, take the earliest date minus one day from the following dates as DCO date:

- Date of updated informed consent from "Unblinding" CRF page
- Date of unblinding from "Unblinding" CRF page
- Visit Date from "Visit Date" CRF page where Visit is "Participant Decision Visit / OL-D1"
- Treatment Date from "Exposure" CRF page where Visit is "Participant Decision Visit / OL-D1"
- Date of assessment from "Vital Signs - Dosing" CRF page where Visit is "Participant Decision Visit / OL-D1"
- Date of examination from "Physical Examination" CRF page where Visit is "Participant Decision Visit / OL-D1"
- Date of examination from "Pregnancy Test" CRF page where Visit is "Participant Decision Visit / OL-D1"
- Collection date from "Central Laboratory - Nasopharyngeal Swab and Blood Collection for SARS-CoV-2" CRF page where Visit is "Participant Decision Visit / OL-D1"
- Collection date from "Central Laboratory - Antibody-Mediated Immunogenicity" CRF page where Visit is "Participant Decision Visit / OL-D1"

2) If a subject discontinued prior to unblinding/OL-D1 (ie, unblinding/OL-D1 didn't occur), DCO is the date of study discontinuation.

A 'target date variable' is defined as the date variable from which the date is to be compared with the data cutoff date. The target date variable in each dataset is to be identified first (as described in Section 3 and 5). If the date from the identified target date variable (referred to as the 'target date' thereafter) is on or prior to the cutoff date, then the record containing the target date will be included in the post-cut dataset. If the target date is after the cutoff date, then the record containing the target date will be excluded from the post-cut dataset. In the disposition data set, the study status by DCO date will be reported.

3. Algorithm and Application

The following algorithm and rules are to be followed to identify the target date variable in each dataset to which the cutoff date is to be applied:

3.1 When there is only one date variable (eg, visit date) in the dataset, then that date variable serves as the target date variable, and the target date is to be compared with the cutoff date for all records in that dataset.

3.2 When there is a start date and an end date in a record in the dataset, the start date is used as the target date variable. If the start date is before the cutoff date and the end date is after the cutoff date, then the start date and the end date are kept as is, with the understanding that the entire record (including start and end dates) are cleaned and included in the data version with the specified data cut.

4. Data Handling Convention

When any of the identified target date variables involves partial or missing date, the following conventions are applied in order to determine whether such data records will be included in the post-cut datasets. Partial or missing target date variables are not to be imputed in any post-cut datasets.

Missing day only

When the month and year in the target date variable are the same as or before the month and year in the cutoff date, then the data record containing the partial target date variable with missing day will be included in the post-cut dataset.

Missing month

When the year in the target date variable is the same as or before the year in the cutoff date, then the data record containing the partial target date variable with missing month will be included in the post-cut dataset.

Missing year

When the year in the target date variable is missing, the target date for that data record is considered completely missing. The data record containing the missing year in the target date variable will be included in the post-cut dataset.

5. Data Cutoff Algorithm applying for EDC and non-EDC data

5.1 Exclude Part C subjects from EDC data

5.2 Exclude OL visits from EDC data execpt for UNBLND

5.3 Apply data cutoff algorithm per table below:

Dataset Name*	CRF Page/Data Description	Cutoff or Not?	If No, Specify Reason	Target Date Variable / Logic
SUBJECT	Participant Creation	No	Not Submitted	
VISIT	Visit Date	Yes		VISITDAT_RAW
UNS	Unscheduled Visit Assessment	Yes		Visit Date(VISITDAT_RAW) after merging with Raw VISIT dataset
DM	Demographics	No	Include all records	
ENROLL	Enrollment	No	Include all records	
A5ENR	Amendment 5 Enrollment	No	Include all records;	
IEYN	Inclusion/Exclusion Criteria Summary	No	Not Submitted	
IE	Inclusion/Exclusion Criteria	No	Include all records	
UNBLND	Unblinding	No	Include all records	
MHYN	Medical History Summary	No	Not Submitted	
MH	Medical History	No	Include all records	
VS	Vital Signs	Yes		VSDAT_RAW
VSDOSE	Vital Signs - Dosing	No	Include all records as OL visits were excluded in 5.2	
PE	Physical Examination	Yes		PEDAT_RAW
CLAB	Central Laboratory	Yes		LBDAT_RAW
CLAB_SER	Central Laboratory with Serology	Yes		LBDAT_RAW
CLAB_FSH	Central Laboratory with FSH/Serology	Yes		LBDAT_RAW
NASAL_SARS	Central Laboratory - Nasopharyngeal Swab	Yes		LBDAT_RAW
NASAL_SARS2	Central Laboratory - Nasopharyngeal Swab and Blood Collection for SARS-CoV-2	Yes		LBDAT_RAW
CLAB_UNS	Central Laboratory - Unscheduled	Yes		LBDAT_RAW
CB	Childbearing Potential	No	Include all records	
PT	Pregnancy Test	Yes		PTDAT_RAW
RAND	Randomization	No	Include all records	
EX	Exposure	Yes		EXSAT_DAT
CLAB_SR	Central Laboratory - Serology	Yes		LBDAT_RAW
CLABIM_ANT	Central Laboratory - Antibody-Mediated Immunogenicity	Yes		LBDAT_RAW
SC	Safety Call	Yes		SCCONDAT (Date of Contact or Contact Attempt);
COVID_ASSESS	SARS-CoV-2 or COVID-19 Exposure Assessment	Yes		Visit Date(VISITDAT_RAW) after merging with Raw VISIT dataset ; or Date of Contact or Contact Attempt (SCCONDAT_RAW) after merging with Raw SC dataset
COVID_ASSESS2	SARS-CoV-2 or COVID-19 Symptoms Assessment	Yes		Visit Date(VISITDAT_RAW) after merging with Raw VISIT dataset ; or Date of Contact or Contact Attempt (SCCONDAT_RAW) after merging with Raw SC dataset

Dataset Name*	CRF Page/Data Description	Cutoff or Not?	If No, Specify Reason	Target Date Variable / Logic
SR	Solicited Rash	No	Include all records as OL visits were excluded in 5.2	
LYMPH	Lymphadenopathy	No	Include all records as OL visits were excluded in 5.2	
LDT	Local Diagnostic Test	Yes		LDTDAT_RAW
CMYN	Prior/Concomitant Medication and Vaccination Summary	No	Not Submitted	
CM	Prior/Concomitant Medication and Vaccination	Yes		CMSTDAT_RAW
CPYN	Concomitant Procedures Summary	No	Not Submitted	
CP	Concomitant Procedures	Yes		CPDAT_RAW
AEYN	Adverse Events Summary	No	Not Submitted	
AE	Adverse Events	Yes		AESTDAT_RAW
EOT	Dosing Discontinuation	Yes		DSSTDAT
DS	End of Study / Study Discontinuation	Yes		DSSTDAT; For early termination prior to Unblinding/OL-D1, If subject don't have Unblinding/OL-D1 then keep the record for this subject
CONT	Continuing	No	Not Submitted	
COVID	COVID-19 Impact	Yes		COVSTDAT (Date of missed or out of window visit or assessment)
DIARY7	Temp	No	Include all records as OL visits were excluded in 5.2	
DIARY7RXT	Inj Site	No	Include all records as OL visits were excluded in 5.2	
DIARY7OBS	General	No	Include all records as OL visits were excluded in 5.2	
PAIN	Inj Pain	No	Include all records as OL visits were excluded in 5.2	
RED	Redness	No	Include all records as OL visits were excluded in 5.2	
SWELL	Swelling	No	Include all records as OL visits were excluded in 5.2	
HEAD	Headache	No	Include all records as OL visits were excluded in 5.2	
FATIGUE	Fatigue	No	Include all records as OL visits were excluded in 5.2	
MUSCLE	MuscleAche	No	Include all records as OL visits were excluded in 5.2	
JOINT	JointsAche	No	Include all records as OL visits were excluded in 5.2	
NAUSEA	Nausea	No	Include all records as OL visits were excluded in 5.2	
CHILLS	Chills	No	Include all records as OL visits were excluded in 5.2	
RASH	Rash	No	Include all records as OL visits were excluded in 5.2	
OTHER	MedAtten	No	Include all records as OL visits were excluded in 5.2	

Dataset Name*	CRF Page/Data Description	Cutoff or Not?	If No, Specify Reason	Target Date Variable / Logic
GLAND	UnderarmGland	No	Include all records as OL visits were excluded in 5.2	
ESCDIARY	Safety Follow Up Diary	Yes		ESCDIARYTMP (Date Part only)
LAB*	PPD Central Lab Data	Yes		LBDTM (Date Part only)
GCL_TRACKING*	PPD GCL Sample Tracker	No	Merged by other vendor data to get sample collection date and visit per subject and assession	
IG_BAB*	PPD Vaccine ~~(ELISA, VAC58)~~	Yes		DRAWDATE~~; Keep only VAC58 test~~
IG_NAB*	Battelle	No~~Yes~~	Include all records	~~Merge with GCL_TRACKING by subject and assession number; Keep records where COLLECTION_DATE is prior to or on Cut off date. If records in Battlle, but not in GCL Tracker, then keep those records in post-cut dataset~~
BIOFIRE*	Viracor	Yes		Merge with GCL_TRACKING by subject and assession number; Keep records where COLLECTION_DATE is prior to or on Cut off date. If records in Viracro, but not in GCL Tracker, then keep those records in post-cut dataset
SUBJECT_IRT_UNM*	Unblinded PPD IRT data	No	Include all records	
MRNA1273P201_ACT02*	Actual Randomization Schedule	No	Include all records	
DOSE_ERR*	Dosing Error	No	Include all records	
DOSE_ERR_B*	Dosing Error Part B	NA	Include all records	
DV*	Protocol Deviation	Yes		OCCURRED or IA Part contains 'Part A'
SYMP*	CEDECOD and CETERM	No	Include all records	

Note: * refers to non-EDC data;