

COVID-19 Proposed EDC Changes:

- Addition of Protocol Deviation Report to collect delayed treatment, delayed and missed investigations and missed/delayed follow up visits.
- Addition of COVID-19 screening form (to be completed with consent addendum)

Rationale:

- Current CRFs can capture the following data:
Treatment omissions, treatment delays (but not in real-time; if treatment held for extended time, reporting would be delayed), missed disease assessments, missed QOL /PRO, missed correlatives

But current CRFs do not capture the following data:

Missed or delayed labs, delayed disease assessment, delayed QOL/PRO, delayed correlatives, Missed or delayed Follow-Up visits and alternate assessments.

- FDA, EMA and HC COVID Guidance specifies that information must be documented (FDA specifically mentions captured in CRF) that explains basis for missing data including the relationship to COVID. This information will be summarized in the clinical study report.

New CRFs:

Protocol Deviation Report

Folder – Add Event rolling log, one time

COVID_DEV_Q *note to IT: this is the “confirmation” form for this folder; load other forms if answer “yes”*

Protocol Deviations Related to COVID-19 - Question

Have there been any deviations to the protocol (e.g. extended delays in study treatment or response evaluations or missed investigations or visits etc.) for this patient that have occurred as a result of COVID-19 virus infection or COVID-19 outbreak?

Yes No

Note:

- If a COVID-19 deviation has already been documented on another CRF (e.g. treatment omission as a result of COVID-19 outbreak reported on the Dose Modifications Table), it does not need to also be reported in this folder.
- Protocol non-compliance for reasons unrelated to COVID should not be documented on this form.

COVID_DEV_Q
Required
If yes, load COVID_DEV_RL

COVID_DEV_RL

COVID-19 Protocol Deviation Log			
Please record ALL protocol deviations related to COVID-19 virus infection/ COVID-19 outbreak by adding a log line for each deviation.			
Deviation Type	Timing (i.e. cycle 2 day 1)	Reason for Deviation	Comments

DEV_TYP <DEV_TYPE_D> Required	DEV_TMG Free text \$50 Required	DEV_REAS <DEV_REAS_D> Required	SCHED_COM \$500
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<DEV_TYPE_D>

- Anticipated extended delay
- Delayed response assessment
- Delayed lab
- Missed lab
- Delayed QOL completion
- Delayed PRO completion
- Delayed correlative collection
- Delayed study visit
- Missed study Visit
- Alternate patient assessment (Phone or virtual visit)
- Other (specify box)

<DEV_REAS_D>

- COVID-19 Outbreak
- COVID-19 virus infection
- Other (specify)

COVID_SCREEN_Q

COVID-19 Screening
Has patient been tested for COVID-19? <input type="radio"/> Yes <input type="radio"/> No

COVID_SCREEN_Q Required If yes, load COVID_SCREEN form
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COVID_SCREEN

COVID-19 Screening
COVID-19 Test Result: Date of Testing: dd-mm-yyyy Specimen Type: Name of Lab: _____ Free text Load additional screening form? Y/N

COVID_RESULT <COVID_RESULT_D> Required	COVID_TEST_DT Required Can't be in the future Can't be prior to 01NOV2019	COVID_SPEC_TYP <COVID_SPEC_TYP_D> Required	COVID_LAB_NAME Required	COVID_LOAD_Q Required If yes, load additional form
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<COVID_RESULT_D>
 Positive
 Negative
 Indeterminate

<COVID_SPEC_TYP_D>
 nasopharyngeal swab,
 viral throat swab
 sputum
 BAL
 Bronch wash
 pleural fluid
 lung tissue
 Other, specify