Dear **CDM community**,

We understand you all are feeling the impact of **COVID-19** personally and in your professional lives. Our clinical trials are not immune to this massive disruption. We understand Clinical trial teams actively are assessing the risks to their milestones and interruptions to the overall trial execution.

In this time of change, as the Data Management Leads and the stewards of good quality clinical data, we need to ensure the impact of **COVID-19** on the data collection and management is methodically assessed. This is critical not only to safeguard Data Integrity, but more importantly ensuring the mitigations adopted by the teams also address the reliability of the data to make scientific conclusions at the end of the study. Patient safety is always at the top of what we do, it is even more important at this juncture.

Through this brief communication, we wanted to highlight the major risk-categories and the impact on the practices of clinical data collection and management due to **COVID-19** as well as invite you to share your thoughts on the SCDM Community Platform. Data Managers should evaluate these areas working with the cross-functional Clinical Trial Team and be an active partner in developing specific mitigation strategies.

Risk-areas and potential impact to clinical data

1) **Patients/Study participants are unable to travel to the sites, resulting in-**
   - Missed visits – need to flag visits due to COVID-19 and associated Protocol Deviations
   - Missed procedures – need to flag assessments missed due to COVID-19 and associated Protocol Deviations
   - Unable to use the central lab
   - Compliance with site-based Clinical Outcome Assessment (COA) measures
   - Use of Telehealth to perform parts of the patients visits
   - Needing to ship IP to the Patients' home
   - Overall enrollment and screening impacts – option to screen-fail now and rescreen later in the year an option?
   - Potentially higher number of discontinued patients
   - ….
2) **Site staff unable to commute to work or need to go on leave, resulting in-**
   - Delays in data entry into EDC
   - Delays in data queries resolution
   - Delays in site initiations and enrollments
   - Delays in processing of lab samples
   - Unable to receive IP shipment – bulk dispensation an option?

3) **CRAs unable to perform site visits, resulting in-**
- Unable to perform traditional on-site SDV
- Delays in cohort-data reviews
- Impact on milestones such as DB Lock.
- …

4) **Vendors (Labs, eCOA, ECGs, IxRS etc.) face staff shortage or facilities shutdowns, resulting in-**
- Delays in sample analysis
- Delays in data transfers and reconciliations
- Delays in shipment of eCOA – paper and web-backup an option?
- …

Each of these risk-areas will require thoughtful mitigations, and in cases where (unfortunately), there are no good options, clinical trial may have to be extended out or additional patients may need to be recruited, or trial start-up delayed. In some cases, it may be required to put the clinical study on hold especially where the NME being studied uses immuno-suppressant mechanism given the spread of COVID-19. While each team or individual organization may decide on a strategy that is unique to their needs, we are pleased to share some high-level strategies to consider –

- **Critical to summarize missing data**
  - Focus on critical endpoint supporting items as defined by SAP and Biostatistics partners
  - Align with organization on definition of permanently missing vs delayed.
  - Consider how many missing visits = patient discontinued
  - Consider practical options of capturing cause of missing visits/procedures vs post production eCRF changes of every single trial
- **Assessment procedures that cannot be done centrally**
  - For non-specialty labs, local lab options may be more feasible or a local branch of a central lab
  - Additional work for confirmation of local lab qualification, but may be necessary
  - While same approach could apply for imaging, however in cases when Imaging is a primary endpoint, assess the scientific validity of the trial if the image is not captured, how many missed images would cause impact to the analysis.
  - Study EDC designs need to be flexible to account for manual local lab data capture vs central lab collection
- **Protocol Deviations**
  - Existing edit checks/derivations will report extremely high number
  - Advisable to leave these in place to capture all, however more intelligent filtering as well as flagging of COVID-19 related PDs via reporting may be necessary
- **RBM Practices**
  - Consider increasing the frequency of the cross-functional data review
  - Standard KRIs can remain in place and monitored but additional ones should be identified based on current risks
  - Organizational-wide updates to KRI's can mitigate how many trial-specific ones may be necessary
  - A decision tree to filter high volume of "false positives" and follow up actions needed

REGULATORY AGENCIES EASY-ACCESS

- **FDA**
- **EMA**
- **MHRA**
- **Denmark**
- **Austrian**
- **Belgian**
- **ECDC**

Hope you find this information useful as you plan for specific mitigations in your respective clinical trials and assess the impact on clinical data integrity. We want to hear from you and invite you to share ideas and best practices: ***COVID-19 preparedness from a Clinical Data Management lens with your fellow SCDM members.***

Let's Start the conversation on the SCDM Community Platform

ACCESS NOW

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