DATA MANAGEMENT CENTER NEWSLINE

COVID-19 Virtual Visits and Data Management Guidance for Sites

Virtual visits during COVID-19

Due to the COVID-19 pandemic, sites should consider conducting virtual study visits when possible and per recommendations from individual protocol teams. In order to accommodate virtual visits and to collect information in accordance with recent guidance from the FDA, the visit tracking eCRF has been updated to include COVID-19 specific reasons for a missed visit or a virtual visit.

Virtual Visit:

Subject: Subject Page: ADM10006: Visit Tracking ?	G
INSTRUCTIONS: • Complete and update this form as needed to document the study v specified in the protocol. • This form should also be completed for unscheduled/visits occurrin.	isit contacts as outlined in the protocol. This includes any telephon g outside of visit window.
Did the visit/contact occur?	● Yes ◯ No ◯
If No, indicate the primary reason for the missed visit/contact:	····
If Other, specify [70]:	G
Type of visit/contact:	Virtual visit due to COVID-19
Missed Visit: Subject: Subject Page: ADM10006: Visit Tracking?	
INSTRUCTIONS: • Complete and update this form as needed to document the study v specified in the protocol. • This form should also be completed for unscheduled/visits occurrin	risit contacts as outlined in the protocol. This includes any telephor ng outside of visit window.
Did the visit/contact occur?	O Yes No
If No, indicate the primary reason for the missed visit/contact:	Participant unable to come to clinic due to COVID-19

If a visit is conducted virtually, all eCRFs expected for that visit will roll out in *Rave*. Since it will likely be impossible to collect all of the expected visit information, such as labs, sites should complete the leading questions on each eCRF to indicate which evaluations were unable to be performed. *(cont'd on next page)*



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SUBMIT AN ARTICLE TO THE DMC NEWSLINE

The DMC Newsline encourages readers to submit articles, news releases, and event listings. Materials submitted are subject to editorial review. Please email information in Microsoft® Office Word format to the Editor, Mary Wojcik-Cross (wojcik@frontierscience.org).

COVID-19 Virtual Visits and Data Management Guidance for Sites (cont'd)

How will data collection differ during virtual visits?

It will likely not be possible to collect all required data. The study event tracking eCRF and leading questions will allow sites to record which data were not collected. In the case of eCRF completion problems, data will be reviewed by the DMC as soon as possible and errors regarding missing data will be resolved.

In certain *eData* and *Rave* studies that have a free text box for including "Reason not collected," enter "Not collected due to COVID-19 virtual visit."

Will this affect my site performance?

The DMC will work closely with network evaluation groups to ensure that site performance will not be negatively affected. Individual networks will likely be sending separate communications regarding adjustments to site and laboratory metrics as a result of the COVID-19 pandemic.

My site is shut down during the pandemic and site staff may be unable to respond to queries. Will this reflect poorly on the performance reports?

Site closure due to the COVID-19 pandemic will be taken into account on performance reports and delays in query response will not reflect negatively on your site or lab. Sites should not be concerned with data management metrics during this time. The safety of site and laboratory staff and participants is the immediate concern.

Will the DMC continue to send queries during this time?

The DMC will be implementing a new approach to queries during the COVID-19 pandemic. The DMC will continue to review data and will identify queries needed. Queries for high risk data, such as safety-related data, will continue to be sent. However, other lower priority data queries will be queued to be sent at a later date.

If a Site from System query occurs for missing data due to the visit being a COVID-19 virtual visit, or for some other COVID-19 related reason, sites must indicate in their query response that the data are missing due to COVID-19, so DMC staff can resolve the query:



How should I report a COVID-19 diagnosis or SAE on a CRF?

For a confirmed, positive test result, be sure to enter "COVID-19" in the description field of the eCRF so the diagnosis can be properly coded at the DMC.

What if I have an in-person visit, but all the data cannot be collected due to logistical issues related to the COVID-19 pandemic?

If you cannot collect all the data expected at an in-person visit and are unable to document this within a "Reason not obtained/collected" field or in response to a system generated query, then issue a Site to DM query noting that the missing data are due to the COVID-19 pandemic.

Importance of LDMS Collection and Processing Fields

In the LDMS, there are a number of fields used to show the timeline of a specimen between its collection and freezing. These fields are used by the networks to assess the efficiency of laboratories, based on the amount of time between each process. The networks want to be able to identify where improvements can be made if a sample took over a certain amount of time from collection to freeze. Below are a number of fields in the LDMS and their meaning:

Collection date/time = when participant was stuck with a needle

Received date/time = when the primary sample arrived at the processing bench

Processing date/time = when the primary tube was opened up to be aliquoted

Frozen date/time = when the aliquot was put into the freezer

In the past, labs have misinterpreted these fields. In cases where the sample was processed by a separate lab down the hall and the LDMS lab receives the already processed aliquot to log in, the LDMS lab enters the received date/time as the moment they took ownership of the already processed aliquot. The received date/time should be the time at which it was received by the other lab down the hall. Otherwise, these records have a progression of dates/times where it appears the sample was processed before it was received. When this error occurs, the evaluation on how long it took on each step from collection to freeze cannot be performed.

The LDMS runs various data validation checks upon initial entry of specimen records to ensure that these various date/time fields are entered in a logical order. These same data integrity checks run when a lab ships records and/or imports new records via the shipping module.



Additional resources and information about how information should be entered into these fields can be found online on our LDMS website (www.ldms.org) and accessing the user manual.

LDMS Training Schedule

LDMS Introductory Workshops are scheduled to take place at the Frontier Science office in Amherst, New York on the following dates:

•May 29, 2020

•August 21, 2020

•November 13, 2020

The one-day training will include a full demonstration of all functions within the web application, with a hands-on component for participants. Ad hoc training requests to fit your laboratory's needs can be submitted via the LDMS website: <u>https://www.ldms.org/training/</u>

Hain GenoType® Result eCRF Equivalencies to Reflect GLI Reporting Guidelines

The Global Laboratory Initiative (GLI) recently released a publication in which updated result language has been provided for TB Hain GenoType® assays in response to literature indicating that considering an organism as "susceptible" for drug resistance is no longer the best terminology.

The Data Management Center has received multiple questions about what result to choose on the current HAIN eCRF, since there is no exact match from what they are seeing on their result report from the testing laboratory. This article serves to provide clarification and instruction for the completion of Hain GenoType® result eCRFs. These clarifications and instructions reflect recent updates to the GLI reporting guidelines.

As laboratories adopt and implement these guidelines, site personnel may encounter additional language on TB result reports received from the testing laboratory. For sites/studies currently utilizing Hain GenoType® result eCRFs, please see below for instruction on how to accurately report results using the equivalent choice on your current eCRF.

OVERVIEW OF CHANGES/EQUIVALENCIES:

- Hain GenoType® MTBDR*plus* & MTBDR*sl* (Hain Lifescience, Nehren, Germany)
 - If the lab report indicates any of the below results, key these as "Resistant" on the eCRF:
 - \Rightarrow "Resistance Detected"
 - ⇒ "Resistance Inferred"
 - \Rightarrow "High level resistance detected"
 - \Rightarrow "High level resistance inferred"
 - \Rightarrow "At least low level resistance detected"
 - \Rightarrow "At least low level resistance inferred"
 - If the lab report indicates "Resistance Not Detected", key this as "Susceptible" on the eCRF.

We appreciate your cooperation with this transition. Moving forward, this language will be updated for all new studies utilizing these TB Hain GenoType® assays.

ACTG Protocol Data Manager: Thomas Miller



Thomas Miller joined the Data Management Center as an ACTG Protocol Data Manager in 2018. He is the primary data manager for several ACTG protocols: A5302, A5324, A5355, and A5383, provides assistance for A5345, A5347s, and A5377, and recently worked on the eData to Rave conversion for several studies.

Thomas holds a B.S. in Neuroscience from the University of Texas at Dallas and serves as the Data Management Center representative on the Neurology Collaborative Science Group. The thing that he likes most about his job is feeling like he is making a difference in people's lives, by fulfilling his role in the research that is taking place.

When not working, Thomas enjoys playing the cello, spending time with his wife and young daughter, and playing board games.

2020

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MARK YOUR CALENDARS

Upcoming Data Management Introductory Workshops

- April 22-23 (virtual format)
- October 21-22

Upcoming DMC Webinars

- April 9: Subject Enrollment System
- May 14: Adverse Event Log

See Frontier Science Portal Training Pages for additional information.

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