UT Health San Antonio
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Department of Population Health Sciences
Clinical Research Informatics Division

STANDARD OPERATING PROCEDURE

SOP Number: CRI.SOP.DMLC-004	**Title: Data Collection and Processing**	
Version No.: 0.0	**Effective Date: DRAFT**	**Page 1 of 16**
Supersedes Version: N/A **Dated:** N/A	REQUIRED APPROVALS BELOW	
CRI Director:	DocuSigned by: Meredith Zozus	**Date:** 3/13/2024
CISIL Approver 1:	DocuSigned by: Melanie Zuniga Rapp	**Date:** 4/3/2024
CISIL Approver 2:	DocuSigned by: Lori Erwin	**Date:** 4/3/2024

1.0 Purpose

This procedure specifies the process for data collection and processing performed by the Clinical Research Informatics (CRI) Division. The purpose of the procedure is to assure that data collection and processing operations comply with regulations and other requirements, are systematically identified and selected, are appropriate for the risk associated with the study, are consistently applied throughout the study, and yield the necessary outgoing quality.

2.0 Scope

This procedure applies to all clinical study data collected or processed by the CRI, and to all CRI faculty, staff, and contract informatics employees performing data collection and processing tasks.

3.0 Responsibility

3.1 The CRI Directors will ensure that all personnel who perform data collection and processing tasks are trained on and comply with this procedure.

3.2 The Clinical Research Informatics Specialist (CRIS) shall identify, discuss, and facilitate decision-making for all data collection and processing appropriate for the risk associated with the study.

3.3 The CRIS will document, implement and manage data collection and processing undertaken within the CRI Quality Management System (QMS), to ensure the necessary outgoing quality.

3.4 CRI faculty and staff who perform data collection and processing tasks shall adhere to this approved SOP.

4.0 References

4.1 CRI.SOP.DMLC-001 *Data Management Plan Creation and Maintenance*

5.0 **Definitions**

Data collection: Observation or measurement that generate data for a study or that select existing data for use in a study. Recording data on study data collection forms, electronic or otherwise, is often considered part of data collection.

Data processing: Operations performed on data including but not limited to entry into computerized systems, standardization, transformation, imputation, coding, cleaning, and linkage with other data.

Messaging data: Data about individuals or events pushed or pulled one-at-a-time, in real-time or near real-time, and on an ongoing basis from another system through an established interface.

External data: Data that originate or are managed outside the CRI QMS.

Data integration: Data integration is the process of aligning data according to attributes such as patient, site, study, visit, and timepoint identifiers, such as matching data from an external lab with study patients and the timepoints at which the samples from which data were obtained were collected.

Matching: the process of determining which data belong to the same entities, such as patients. Matching is usually required prior to record linkage.

Record linkage: establishing a persistent association between data such as between patient data and the visit at which it is collected, or patient data from two different data sources. The association serves as the mechanism through which the data are connected for reporting and analysis. Usually record linkage is used to associate patient data from one source with data on the same individuals from another data source.

Deterministic record linkage: use of an identifier such a patient number, study number, site number, visit number, or sample number to associate data. For example, CRF data and external lab data containing the patient identifier are “linked” by both being labeled with that identifier. In deterministic record linkages, the value of the data element used for the matching must be an exact match. Barring errors in the identifiers themselves, a deterministic match is an exact match.

Probabilistic record linkage: inexact matching by one or more data elements used when deterministic matching is not possible or the error rate in the corresponding identifiers is high. For example, matching text strings, such as for last name that phonetically sound the same or are less that one or two characters different. An example of inexact matching using multiple data elements, would be street address phonetically equivalent, last name phonetically

equivalent and two of either day, month or year of the date of birth match. As inexact matches, the accuracy of probabilistic record linkages must be measured and reported.

Traceability: documentation often, but not always generated automatically by information systems that enables operations on data to be reconstructed such that all changes to a data value can be sequentially inspected. Immutable audit trails containing such documentation are an expectation of traceability.

6.0 Procedures

6.1 As part of data management planning and in accordance with ICH E6 (R2) the CRIS identifies all data sources such as but not limited to study-specific site worksheets, electronic CRF, medical record, lab system, or mobile device, for a project will be identified and documented.

6.1.1 In accordance with ICH E6 (R2) data sources that vary by and within a site should be documented. The Site Data Sources form (Attachment 1) is used for this purpose.

6.1.1.1 If CRI is responsible for Site Management, the Site Data Sources form (Attachment 1) shall be completed with each site by the Monitor, Research Data Coordinator or CRIS.

6.1.1.2 A copy of the Site Data Sources form (Attachment 1) will be provided to the site to maintain with their copy of the Site Manual of Procedures (MOP) for the study or in their local Trial Master File (TMF) or regulatory binder. ICH E6(R2) requires documenting the source/s of data at sites.

6.1.1.3 A copy of the Site Data Sources form (Attachment 1) will be maintained in the Data Management Plan or Coordinating Center electronic Trial Master File (eTMF).

6.1.2 Data sources external to sites such as labs, provisioned devices, or electronic Patient Reported Outcome (ePRO) systems are documented on the Study Data Collection and Processing Plan form (Attachment 2). These data may originate outside or within the CRI QMS.

6.2 The CRIS and study team decide the data quality requirements for the project in accordance with the CRI Scope of Work for the study.

6.2.1 Data quality requirements for data generated or processed outside the CRI QMS and under contract or sub-award to UTHSA should be stated in the vendor or sub-awardee's scope of work. These may provide a planned quality level or provide for quality measurement during the study and where applicable, be used as an incoming quality level.

6.2.2 Data quality requirements for data generated or processed within the CRI QMS are stated in terms of the following.

6.2.2.1 Data quality dimensions important to the study (These commonly include accuracy, completeness, consistency and timeliness, but may include others where needed for a study.)

6.2.2.2 Specification of measurement methods for each data quality dimension

6.2.2.3 Specification of the acceptance or action criteria for each data quality dimension, such as average outgoing data quality level, or threshold at which corrective action should be taken

6.3 The Clinical Research Informatics Specialist (CRIS) shall identify all data collection and processing necessary for the study and suggest appropriate methods for collecting and processing the data, matching the methods and tools to the research and quality needs, the CRI scope of work, the available resources, applicable regulations and other requirements.

6.4 Data collection methods include human perception (direct observation), measurement of the phenomena of interest, or asking questions of humans.

6.4.1 The CRIS should explore with the study team use of objective rather than subjective measures where available unless patients themselves have been shown to be the best source of information.

6.4.2 Specification of data collection methods includes the step-by-step procedure and instrument, where applicable, for direct observations, measurements, and questionnaires.

6.4.3 Where data collection methods are not specified in sufficient detail in the protocol for their consistent application, the CRIS should suggest or provide further specification for the study site Manual of Procedures (SOP.DMLC.050 Site Manual of Study Procedures).

6.5 General types of data processing include the following and may be performed by humans, computers or hybrid methods relying on both.

Conversion Data to Electronic Form	Data Processing Tasks

• Key entry variants
  ○ single data entry
  ○ double data entry
• Key entry verification
  ○ blind verification
  ○ interactive verification
  ○ third person comparison
• Scan-based methods
  ○ One- and two-dimensional barcodes
  ○ Optical Mark Recognition (OMR)
  ○ Optical Character Recognition (OCR)
  ○ Intelligent Character Recognition (ICR)
• Verification for scan-based methods
• Voice recognition and corresponding text processing methods
• Direct electronic data acquisition
  ○ Extraction from existing databases
  ○ Medical or personal instrumentation
	• Fact extraction from narrative text
	• Data Mapping or Discretization
	• Classification
	• Data Standardization
	• Coding using controlled terminologies
	• Qualitative data coding
	• Data formatting
	• Structural transformations
	• Imputations
	• Conversions and calculations
	• Data cleaning
	• Data enhancement
	• Linkage or integration with other data

○ Direct from patient data capture via mobile devices	

6.6 The CRIS together with the study team decides which data collection and processing methods will be employed and by whom. Data collection and processing methods should be capable of achieving the necessary quality and achievable within the Scope of Work.

6.6.1 As the informaticist on the study team, the CRIS will comprehensively make recommendations for data collection and processing whether or not the work is performed by CRI.

6.6.2 Data collection and processing work undertaken and managed by CRI will be indicated on the Study Data Collection and Processing Plan form (Attachment 2).

6.7 The Study Data Collection and Processing Plan form (Attachment 2) is stored as part of the study Data Management Plan (SOP.DMLC.001).

6.8 To provide traceability between the data source and the locked database for all data values processed by CRI, additional detail may be needed such as algorithms for machine processed data and work instructions for human processed data. Work Instructions and algorithmic specifications will be indicated on the Study Data Collection and Processing Plan form (Attachment 2) and stored as part of the DMP.

6.9 To meet the intent of ICH E6 (R2) section 5.1.3, methods by which data quality will be ensured will be specified for each data source on the Study Data Collection and Processing Plan form (Attachment 2).

6.9.1 Data collected by asking questions of humans, such as those using questionnaires, require demonstration of reliability and validity ideally in the population and context of interest.

6.9.2 Data collection and processing processes involving humans benefit from process control. The DMP should specify procedures for process control.

6.9.3 Data collection and processing processes involving devices usually require calibration and those using computer algorithms require testing. Both benefit from monitoring over time to detect drift or unexpected interaction with odd data or data collection contexts. The DMP should specify procedures for calibration, testing and monitoring over time.

6.10 For each data acquisition and processing task, the DMP, through the study data collection and processing plan form (Attachment 2) and associated Work Instructions and algorithmic specifications, will describe or reference the following task components in detail such that a Research Data Coordinator or programmer can perform them without additional clarification.

6.10.1 Specifications for all operations performed on data by humans and computers will be sufficient for undertaking or programming the operations.

6.10.2 Testing plans and test data to assure that programmed algorithms used in processing tasks are working correctly. The author of the specifications or a

designee under their oversight writes the testing plans and test data. NOTE: in some cases it is not practical to test each logic condition through an algorithm. In cases where the number of test cases would be impractical or out of alignment with the risk, case-based testing will be balanced with post-production monitoring.

6.10.3 Description of the frequency with which the processing task is carried out including conditions that trigger or otherwise initiate the task.

6.10.4 Description of expected exceptions, exception monitoring and exception handling.

6.10.5 Description of how traceability is achieved and evidenced in the data, metadata or associated documentation.

6.11 Integration of data originating outside the CRI QMS are a special case of data processing. Procedures for integration of external data are specified in CRI.SOP. DMLC-003, Integration of External Data.

6.12 The study PI and Statistician will sign off on all data collection and processing procedures using the Study Data Collection and Processing Plan form (Attachment 2).

7.0 SOP Deviations

Deviations from this and all SOPs are handled according to CRI.POL.001 *Clinical Research Informatics Quality Management System (QMS)*.

8.0 Review & Revisions

Review and revisions of this and all SOPs are handled according to CRI.POL.001 *Clinical Research Informatics Quality Management System (QMS)*.

9.0 Attachments

Attachment 1 Site Data Sources form

Attachment 2 Study Data Collection and Processing Plan form

10.0 Revision History (Since Last Version)

The revision history will be documented using the table shown below:

Section	Revision Date	Description of Revision

Section	Revision Date	Description of Revision

Attachment 1: Site Data Sources form (CRI.SOP.DMLC-004.FRM-001)

Study: _____
Site #: _____

Section 1:

Action initiated with this form (check one):

☐ Initial version of this form Date: ___ ___ / ___ ___ ___ / ___ ___ ___
dd mon yyyy

☐ Amendment to the initial version Date: ___ ___ / ___ ___ ___ / ___ ___ ___
dd mon yyyy

If applicable, reason for amendment:

Section 2: Site Data Source Designation Table

The rows in the Site Data Sources Table should correspond to the data (rows) on Study Schedule of Events in the protocol. Indicate all sources of data at the site for the study and any contingencies such as different documentation for study participants that are not existing patients at the site prior to the study, different sources for follow-up visits, or different sources where pre-existing data are permitted.
→ *This list shall be comprehensive*. *Data will be monitored according to this list*.

Site Data Sources Table Column definitions:
Data: Items listed in the Data column should correspond to the rows of the Study Schedule of Events (SSE) in the protocol. Where data corresponding to one study schedule of events row are partitioned across multiple sources, add one row for each using SSE row name – specific data 1, SSE row name – specific data 2 format so that the rows in the Study Data Sources Table are easily mapped back to the protocol SSE.

Source: Where possible use the following standard picklist. (1) Site EHR, (2) Other site health information system, (3) Site-owned device, (4) paper chart at the site, (5) Study paper worksheet, (6) site CTMS, (7) site central or core lab, (8) study EDC system, (9) study-provided electronic Patient Reported Outcome (ePRO) or other study-provided system for collection of patient-reported data, (10) study-provided device, (11) Central or core lab designated for the study. Where appropriate, multiple sources may be noted. For example, where charting by different providers, different departments, or at different timepoints in a clinical encounter may dictate the source or specific location, a 1^{o}, 2^{o}, and 3^{o} source may be appropriate. NOTE: the location in the EHR or other clinical documentation is not necessary but may be specified to facilitate review and monitoring. The location in the clinical source at the site should not contradict any medical record abstraction guidelines for the study unless the abstraction guidelines are inappropriate due to clinical documentation practices at the site.

Contingencies: add a text description where the source will differ based on other events such as idiosyncrasies in clinical documentation across providers, differences in charting location by role charting, new versus existing patients, etc.

Data	Source	Contingencies

Section 3: Approvals

Signatures indicate review and agreement that all study data sources are listed and are appropriate.

CRIS, Monitor or Designee: _____

Signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

Site Study Coordinator: _____

Signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

Study PI and Statistician Signatures if required.

☐ If checked, study PI signature is required → Study PI: _____
or ☐ N/A

Signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

☐ If checked, study Statistician signature is required → Study Statistician: _____
or ☐ N/A

Signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

Attachment 2: Study Data Collection and Processing Plan Form (CRI.SOP.DMLC-004.FRM-002)

This form is used to document all data collection and processing for a study including data key entered into eCRFs by sites or other parties to a clinical study. The fillable form will be available as a job aid with example form data.

Section 1: Action initiated with this form (check one):

☐ Initial version of this form Date: ___ ___ / ___ ___ ___ / ___ ___ ___
dd mon yyyy

☐ Amendment to the initial version Date: ___ ___ / ___ ___ ___ / ___ ___ ___
dd mon yyyy

If applicable, reason for amendment:

Section 2: Data Sources Table

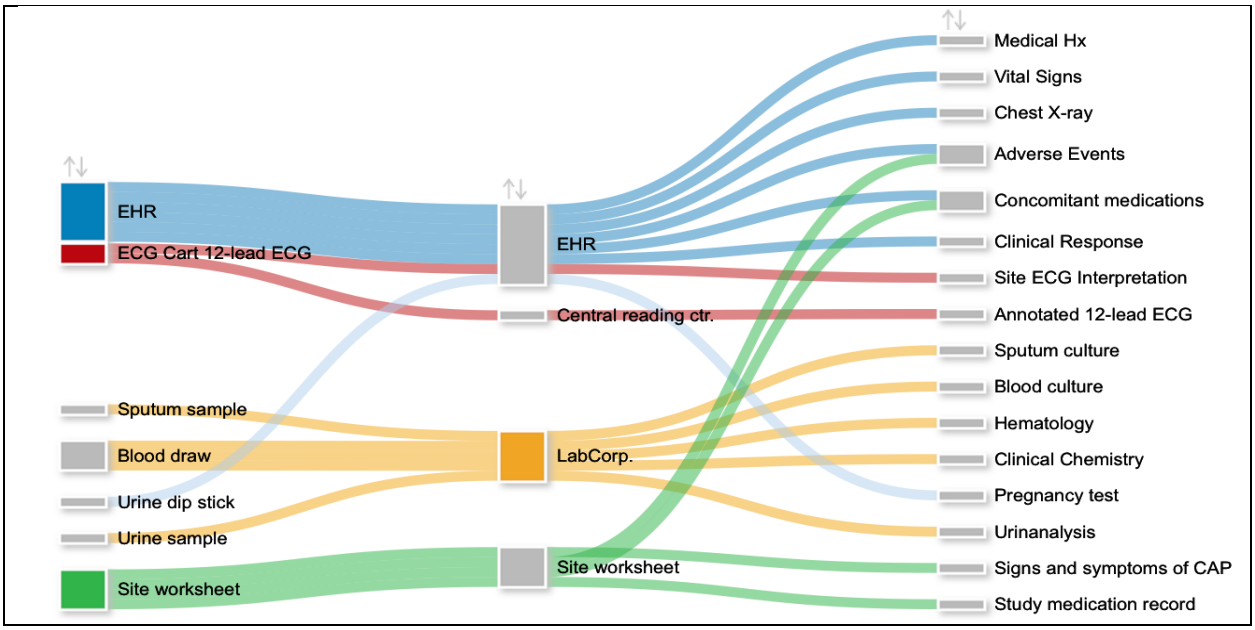
The rows in the Data Sources Table should correspond to the data (rows) on Study Schedule of Events in the protocol. Indicate all sources of data at the site for the study and any contingencies such as different documentation for study participants that are not existing patients at the site prior to the study, different sources for follow-up visits, or different sources where pre-existing data are permitted.
→ This list shall be comprehensive. Data will be monitored according to this list.

General Data Sources Table Column definitions:
Origination: Should indicate the initial collection of the data such as biological samples, imaging, devices, clinical observation, patient reported.

Source: Where possible use the following standard picklist. (1) EHR-abstracted, (2) EHR-FHIR, (3) paper chart, (4) Study paper worksheet, (5) study EDC system, (6) site CTMS, (7) name of external data provider followed by "data transfer". Where appropriate, multiple sources may be noted. For example, adverse events may be obtained from both the site EHR and a study site worksheet. NOTE: medical record abstraction guidelines may be needed for data manually abstracted from the EHR.

Study Data: Items listed in the Data column should correspond to the rows of the Study Schedule of Events (SSE) in the protocol and the Site Data Sources table.

Study data collection: Indicates how the data are collected at the study data management center, i.e., how the data come into the central coordinating center.



General* Study Data Source Disposition Diagram (Example)

*Data sources may differ by site. Site-specific data sources are documented on Site Data Sources form for each site.

Origination	Source	Study Data*	Study Data Collection	External
EHR	EHR-FHIR eSource	Medical History	eCRF	Partial FHIR® EHR-to-eCRF
EHR (site worksheet 2°)	EHR-FHIR eSource	Vital Signs		
Site PACS or Imaging	EHR-abstracted	Chest X-ray		
ECG Cart 12-lead ECG	EHR-FHIR eSource	Site ECG Interpretation		
	Central reading ctr.	Annotated 12-lead ECG	Reading Ctr. data transfer	External
Sputum sample	LabCorp.	Sputum culture	LabCorp. data transfer	External
Blood draw		Blood culture		
		Hematology		
		Clinical Chemistry		
Urine sample		Urinalysis		
Urine dip stick	EHR-FHIR eSource	Pregnancy test	eCRF	Partial FHIR® EHR-to-eCRF
Site worksheet	Site worksheet	Signs and symptoms CAP		
		Adverse Events		
EHR	EHR-abstracted	Adverse Events		
Site worksheet	Site worksheet	Concomitant medications		
EHR	EHR-FHIR eSource	Concomitant medications		
Site worksheet	Site worksheet	Study medication record		
EHR	EHR-abstracted	Clinical Response		

*At least one row should appear in this table for each row in the Study Schedule of Events.

Section 3: Data Collection and Processing Detail

For each data source in section 2, add and complete a row in the section 3.A Location of data generation and processing table, and complete sections 3.B and 3.C. Systematically addressing location of data generation and processing, procedures to be followed and quality control steps to be taken for each data source communicates that the researcher is in control of the data generation and processing and increases the likelihood that processes are in place to prevent errors or to detect and correct errors when they occur, and ultimately that the data will be capable of supporting conclusions.

3.A. Location of data generation and processing

	Outside the CRI QMS*				Within CRI QMS			
Data Source	Generated		Processed		Generated		Processed	
	Hum.	Mac.	Hum.	Mac.	Hum.	Mac.	Hum.	Mac.
eCRF (key entered)	EHR	EHR	MRA		SSWS	X	X	X
eCRF (FHIR®)	EHR	EHR		X			X	X
LabCorp. Central Lab		X	X	X				X
Quintiles ECG Reading Ctr.	X		X					X

*Data generated or processed outside the CRI QMS may have quality requirements stated in a vendor or sub-awardee scope of work or the vendor or sub-awardee scope of work may provide for quality measurement.
EHR indicates that the data originate in the EHR and are likely generated and processed by humans and machines for which no quality management was provided. Without a gold standard, their accuracy cannot be measured. **MRA** indicates that data are manually abstracted from medical records. Source Document Verification is required to measure their accuracy. **SSWS** indicates that site source worksheets are being used at one or more sites.

3.B. Procedures that will be followed for human-based operations such as Standard Operating Procedures (SOPs), guidelines or work instructions, instrumentation or system manuals, or a laboratory procedure performed within the CRI QMS; indicate whether study-specific Work Instructions will be generated for the study.

3.C. How data collection and processing performed within the CRI QMS will be quality controlled

a. for electronically generated and processed data state how the instrumentation is calibrated, such as use of standards or manufacturer-specified calibration procedures and how the testing processes are quality controlled such as running standards and confirming expected results, or monitoring measures of central tendency and dispersion over time.

b. for data that are generated or processed by humans, state how the processes involving humans are quality controlled, such as use of two raters with comparison and feedback, or measured Inter-rater reliability, whether performed for a sample of data or all data, the sample size where applicable, the timing of the checks such as quarterly or every 100 cases, and the action limits or criteria.

3.D. Statement of data quality requirements

Data Source	Quality Dimensions	Measurement	Acceptance Criterion
eCRF (key entered)	MRA/entry Accuracy Consistency Completeness	Error rate by SDV Edit checks Missing rate in Critical DEs	95% CI under 5% All discrepancies resolved < 5%
eCRF (FHIR®)	Mapping accuracy Consistency Completeness	3 case verification Edit checks Missing rate in Critical DEs	No systematic error All discrepancies resolved < 5%

LabCorp. Central Lab			
Reflects vendor SOW	Accuracy for each test	Se, Sp	--
Reflects vendor SOW	Internal consistency	Vendor edit checks	Extant discrepancies explained
Reflects vendor SOW	Completeness	% of samples missing data	< 5%
CRI SOW	Consistency w/study data	Post-integration Edit checks	All discrepancies resolved
CRI SOW	Completeness	Sample missing rate	< 5%
Quintiles ECG Reading Ctr.			
Reflects vendor SOW	ECG quality	% un-readable ECGs	< 5%
Reflects vendor SOW	Consistency of reading	Inter-rater reliability (IRR)	95% CI under 5%
Reflects vendor SOW	Internal consistency	Edit checks	All discrepancies resolved
CRI SOW	Completeness	ECG missing rate	< 5%

3.B. eCRF data collected on site source worksheets: Site worksheets are permitted for data collected by the study for which the EHR serves as the source. Sites may create such worksheets according to what will and will not be charted in the EHR for the study. The Site MOP requires the worksheets to mirror the eCRF screen with respect to eCRF question order and response format to minimize errors during entry. Site worksheets used as source will be documented on the Site Data Sources form (CRI.SOP.DMLC-004.FRM-001).

☐ A system interface will be used for data acquisition by CRI; algorithm specifications will be developed

☒ The data will be manually entered or imported and study-specific work instructions will be developed

☐ Computerized data processing will occur; study-specific algorithm specifications will be developed

☐ Human data processing will occur; study-specific work instructions will be developed

3.C.a Where site-owned instruments or devices are used to generate study data, the operating manuals and calibration documentation shall be available for monitoring which may include calibration and reliability verification.

3.C.b Key-entered eCRF data are expected to be entered within 24 hours of a study visit. These data are subject to computerized range, missing and consistency checking during data entry. Sites are expected to resolve discrepancies with in 24 hours of entry. Key-entered eCRF data are also subject to source data verification according to the study monitoring plan (SOP.DMLC.052 Study Monitoring).

3.B. eCRF data obtained through FHIR®: eCRF data obtained through FHIR® will be mapped to the site's EHR by the CRI informatics team. Data will be collected via FHIR® for successfully mapped fields.

☒ A system interface will be used for data acquisition by CRI; algorithm specifications will be developed

☐ The data will be manually entered or imported and study-specific work instructions will be used

☐ Computerized data processing will occur; study-specific algorithm specifications will be developed

☐ Human data processing will occur; study-specific work instructions will be developed

3.C.a The first three cases verified by full medical record review to identify and correct any systematic errors.

3.C.b The site study coordinator will review and initiate transfer of FHIR® based data to the eCRF. These data are subject to the same computerized range, missing and consistency checking as key entered data following receipt of the data in the eCRF. Sites are expected to resolve discrepancies with in 24 hours of entry. eCRF data obtained through FHIR® are copies of the source data and will not be subject to source data verification according to the FDA eSource and EHR Guidance's.

3.B. LabCorp. Central Lab Data: Acquisition and integration of the LabCorp. Central Lab Data is specified in the study Data Integration Form (CRI.SOP.DMLC-003.FRM-001). No processing other than that described on the study Data Integration Form and the study Database Lock Checklist will be performed.

☐ A system interface will be used for data acquisition by CRI; algorithm specifications will be developed

☒ The data will be manually entered or imported and study-specific work instructions will be used

☐ Computerized data processing will occur; study-specific algorithm specifications will be developed

☐ Human data processing will occur; study-specific work instructions will be developed

3.B. Quintiles ECG Reading Center Data: Acquisition and integration of the Quintiles ECG Reading Center Data is specified in the study Data Integration Form (CRI.SOP.DMLC-003.FRM-001). No processing other than that described on the study Data Integration Form and the study Database Lock Checklist will be performed.

☐ A system interface will be used for data acquisition by CRI; algorithm specifications will be developed

☒ The data will be manually entered or imported and study-specific work instructions will be used

☐ Computerized data processing will occur; study-specific algorithm specifications will be developed

☐ Human data processing will occur; study-specific work instructions will be developed

Repeat 3.B – 3.C for each data source indicated in Section 3.A.

Section 4: Data Quality Limitations

☒ Study data include data captured during routine care. In the absence of a gold standard, the accuracy of routine care data generally cannot be measured at the time of secondary data use. Unless plans for assessing the error rate of healthcare data are articulated herein, the absence of undetected errors in received routine healthcare data cannot be guaranteed by CRI.

☒ Study data include data generated or processed outside the CRI QMS (noted in Tables 3.a and 3.D). Vendor or sub-awardee versus CRI responsibilities for quality of data generated or processed outside the CRI QMS are articulated in Table 3.D. In the absence of a vendor audit, vendor or sub-awardee capability and process auditability was assessed by the PI and the vendor or sub-awardee was deemed capable and

auditable. Vendor or sub-awardee data quality reports will be taken at face value. Unless plans for assessing the error rate of incoming data are articulated herein, the accuracy and fitness for use of the data generated or processed outside the CRI QMS lie outside the scope and responsibility of CRI.

☒ Study data include data for which the CRI has agreed to data quality assurance or assessment activities in the project Scope of Work and described herein. The data quality assurance or assessment activities and their limitations are deemed capable of producing the needed quality by the PI and Statistician. All CRI standardized procedures are auditable. If repeated data quality assessment activities using the same method and on a random sample the size of which is agreed herein do not fall within the acceptance criteria agreed herein, where possible, the data will be remediated by CRI until the specified measures meet the specified acceptance criteria. Aspects of the fitness for use of the data not documented in Table 3.D lie outside the scope and responsibility of CRI.

Approvals:

CRIS: _____

Signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

Study Statistician: _____

Signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

Study PI: _____

Signature: _____ Date: ___ ___ / ___ ___ ___ / ___ ___
dd mon yy

Signatures indicate review and agreement that the information on the form is accurate; that all study data sources are listed on the form and approval of stated plans for data collection or processing undertaken by CRI.