UT Health San Antonio
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Clinical Research Informatics Division

STANDARD OPERATING PROCEDURE

SOP Number: CRI.SOP.DMLC-005	**Title: Study Surveillance and Operational Reporting**	
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1.0 Purpose

The purpose of this procedure is to outline the processes for surveillance and operational reporting for clinical studies managed by Clinical Research Informatics (CRI). Whereas data collection and processing (SOP.DMLC-003) act on and may alter individual data, study surveillance and reporting are read-only operations.

2.0 Scope

This procedure applies to all study surveillance and operational reporting performed by CRI. Study surveillance operational reporting are limited to data listings, automated alerts and related workflows, and descriptive statistics. The label operational reporting is used to emphasize that the reporting covered by this SOP does not include study analysis, results reporting and other statistical inference.

This procedure applies to all CRI faculty, staff, and contract informatics employees performing data surveillance and reporting tasks.

3.0 Responsibility

3.1 The CRI Directors will ensure that all personnel who perform study surveillance and operational reporting tasks are trained on and comply with this procedure.

3.2 The Clinical Research Informatics Specialist (CRIS) shall identify all data surveillance and study operational reporting needs and establish the tools and procedures necessary to undertake and document data surveillance and operational reporting activities.

3.3 CRI faculty and staff who perform data surveillance and reporting tasks shall adhere to this approved SOP.

4.0 References

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

4.2 SOP.DMLC-003 *Data Collection and Processing*

5.0 Definitions

Operational Reporting: Operational reporting includes structured data listings or tables that provide data, often aggregated in some way for operational decision-making during a study. Examples include but are not limited to lists of outstanding data forms and open data discrepancies for site managers, displays of screening, enrollment and retention, listings of coded terms to facilitate review of medical coding or safety events.

Data Surveillance: Data surveillance includes methods to look for outlying data values or outlying performance. The goal of data surveillance is to identify those data values, individuals or sites behaving differently from the rest and for which the observed variation is not likely due to natural variation. While these methods may detect misconduct, they more often detect population variation at sites, operational misunderstanding or lack of transfer of knowledge to new staff – all potentially impactful to study results. The goal of data surveillance is to systematically and proactively search data in real-time to identify significant threats to study validity early so that timely intervention can prevent future occurrence. Data surveillance is performed in collaboration with Statisticians and is used to inform risk-based monitoring and site communications. Data surveillance may be operationalized as data reports or alerts.

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

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.

6.0 Procedures

6.1 As part of data management planning, the CRIS works with the study Principal Investigator (PI), Clinical Operations, Project Manager, and Statistician to determine study surveillance and operational reporting needs.

6.2 Operational Reports

6.2.1 Standard reports use generic templates to provide specification to the report developer and require little customization.

6.2.1.1 Recruitment, enrollment and retention by site and overall.
6.2.1.2 Data status by participant, site and overall accompanied by lists of outstanding forms and discrepancies.
6.2.1.3 Coded term lists sorted by code and by participant.
6.2.1.4 Site payment milestones met by payment period by site.

6.2.2 Reporting needs may also include custom reports. Custom reports require the CRIS to draft a table shell and define data source and algorithm for each row, column and cell.

6.2.3 After reporting needs are decided, the CRIS drafts the specifications (table shells with data definition annotated on them) and provides them to the report developer.

6.2.4 Development of custom reports follows SOP.SDLC.003 Software Development Lifecycle. A risk-based approach is used to testing reports.

6.2.4.1 After the report/s are programmed, the CRIS or designee confirms the counts on the report based on the study database. Thus, reports are tested on early and limited data. Repeated confirmation may be performed if not accomplished as part of report use.

6.2.4.2 Study staff and sites are trained on the reports after the initial test.

6.2.5 Report users are instructed on how to review reports and actions expected following report review as well as reporting suspected problems with reports.

6.2.6 Site-level versions of reports may be made available to study sites.

6.2.7 An inventory of reports may be included in the Data Management Plan where the number of reports is large but is not required.

6.3 Data surveillance

6.3.1 Data surveillance usually utilizes clinical data tables or associated metadata tables.

6.3.2 The CRIS, Statistician, Clinical Operations team and PI decide which variables will be subject to data surveillance, which comparisons should be used to identify actionable data or events, what action limits should be applied, and whether the surveillance will be implemented as alerts or reports.

6.3.3 To safeguard the effectiveness of data surveillance, these decisions are often not revealed outside the data coordinating center during the trial.

6.3.4 Data surveillance reports

6.3.4.1 Data surveillance reports may require more complex programming and visualization and may be programmed by personnel in Biostatistics as decided by the CRIS and Statistician.

6.3.4.2 Data surveillance reports are tested in the same manner as regular data status reports.

6.3.4.3 Data surveillance reports are reviewed regularly by the CRIS, Statistician, and Clinical Operations personnel to decide course of action for outliers.

6.3.4.4 Data surveillance reports are usually not distributed outside the study Sponsor and operations team.

6.3.5 Data surveillance alerts

6.3.5.1 Alerts are specified and tested along with multivariate data cleaning rules following SOP.DMLC.003 Data Collection and Processing.

6.3.5.2 Workflow needed to take action on and resolve the alert should be specified at the time of the alert.

6.3.5.3 Alerts are implemented in the trial electronic data capture system.

6.3.6 An inventory of study surveillance algorithms and reports may be included in the Data Management Plan but is not required.

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

none

10.0 Revision History (Since Last Version)

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

Section	Revision Date	Description of Revision