Guidance document

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1. CPID_EDC_Metrics

Purpose:
This file provides a comprehensive overview of Electronic Data Capture (EDC) metrics for clinical data management. It helps study teams, data managers, and stakeholders monitor data quality, site performance, and operational bottlenecks across clinical trial sites and subjects.

Tab: Subject Level Metrics

Column Name	Description & Explanation
Project Name	Name of the clinical project or study.
Region	Geographical region (e.g., ASIA, EU, US) where the site is located.
Country	Country of the clinical site.
Site ID	Unique identifier for the clinical trial site.
Subject ID	Unique identifier for each subject enrolled in the study.
Latest Visit (SV) (Source: Rave EDC: BO4)	The most recent visit completed by the subject, as recorded in the EDC system.
Subject Status (Source: PRIMARY Form)	Current status of the subject (e.g., Ongoing, Discontinued, Screen Failure).
Input files	Number of input files or forms entered for the subject.
CPMD	Clinical Project Management Dashboard metric (custom metric, may refer to project-specific data points).
SSM	Site Status Metric (custom metric, may refer to site-specific status or performance).
Missing Visits	Number of scheduled visits that have not yet occurred or been entered.
Missing Page	Number of missing pages in the subject's case report forms (CRFs).
# Coded terms	Number of terms (e.g., adverse events, medications) that have been coded (e.g., MedDRA, WHO Drug).
# Uncoded Terms	Number of terms that remain uncoded and require coding for regulatory compliance.
# Open issues in LNR	Number of unresolved issues in the Lab Normal Range (LNR) module.

Column Name	Description & Explanation
# Open Issues reported for 3rd party reconciliation in EDRR	Number of open issues flagged for reconciliation with third-party data sources in the EDRR system.
Inactivated forms and folders	Count of forms or folders that have been inactivated (e.g., due to protocol deviations or subject withdrawal).
# eSAE dashboard review for DM	Number of Serious Adverse Event (SAE) dashboard reviews completed by Data Management.
# eSAE dashboard review for safety	Number of SAE dashboard reviews completed by the Safety team.
Visit status	Status of subject visits (e.g., Completed, Pending, Missed).
Page status (Source: (Rave EDC : BO4))	Status of data entry pages (e.g., Entered, Verified, Missing) in the EDC system.
Queries status (Source:(Rave EDC : BO4))	Status of data queries (e.g., Open, Answered, Closed) in the EDC system.
Page Action Status (Source: (Rave EDC : BO4))	Status of actions taken on data entry pages (e.g., Locked, Unlocked, Frozen).
Protocol Deviations (Source:(Rave EDC : BO4))	Number of protocol deviations recorded for the subject.
PI Signatures (Source: (Rave EDC : BO4))	Status of Principal Investigator (PI) signatures on required forms/pages.
# Expected Visits (Rave EDC : BO4)	Total number of visits expected for the subject as per protocol.
# Pages Entered	Total number of data entry pages completed for the subject.
# Pages with Non-Conformant data	Number of pages containing data that does not conform to protocol or data standards.
# Total CRFs with queries & Non-Conformant data	Number of case report forms (CRFs) that have either open queries or non-conformant data.
# Total CRFs without queries & Non-Conformant data	Number of CRFs that are clean (no queries, no non-conformant data).
% Clean Entered CRF	Percentage of CRFs that are clean (entered and verified without issues).
# DM Queries	Number of queries raised by Data Management.

Column Name	Description & Explanation
# Clinical Queries	Number of queries raised by Clinical team.
# Medical Queries	Number of queries raised by Medical team.
# Site Queries	Number of queries raised by the site.
# Field Monitor Queries	Number of queries raised by field monitors.
# Coding Queries	Number of queries related to coding (e.g., MedDRA, WHO Drug).
# Safety Queries	Number of queries related to safety data.
#Total Queries	Total number of queries (all types) for the subject.
# CRFs Require Verification (SDV)	Number of CRFs that require Source Data Verification (SDV).
# Forms Verified	Number of forms that have been verified.
# CRFs Frozen	Number of CRFs that are frozen (locked for further editing).
# CRFs Not Frozen	Number of CRFs that are not frozen (still open for editing).
# CRFs Locked	Number of CRFs that are locked (finalized and cannot be edited).
# CRFs Unlocked	Number of CRFs that are unlocked (editable).
# PDs Confirmed	Number of protocol deviations that have been confirmed.
# PDs Proposed	Number of protocol deviations that have been proposed but not yet confirmed.
# CRFs Signed	Number of CRFs that have been signed by the PI or authorized personnel.
CRFs overdue for signs within 45 days of Data entry	Number of CRFs overdue for signature within 45 days of data entry.
CRFs overdue for signs between 45 to 90 days of Data entry	Number of CRFs overdue for signature between 45 and 90 days.
CRFs overdue for signs beyond 90 days of Data entry	Number of CRFs overdue for signature beyond 90 days.
Broken Signatures	Number of CRFs with broken or invalid signatures.

Column Name	Description & Explanation
CRFs Never Signed	Number of CRFs that have never been signed.
Responsible LF for action	Responsible Lead Function (LF) for taking action on outstanding items.
Site/CRA, DM, CSE/CDD, CDMD/Medical Lead, Coder, Safety Team, Investigator	Various roles responsible for data entry, review, coding, and safety oversight.

2. Visit Projection Tracker

Purpose:

Lists all projected subject visits that have not yet occurred or been entered, including the number of days each visit is overdue. Used to track visit compliance and support proactive site and subject follow-up.

Tab: Missing Visits

Column Name	Description & Explanation
Country	Country where the clinical trial site is located.
Site	Unique identifier for the clinical trial site.
Subject	Unique identifier for each subject enrolled at the site.
Visit	Name of the scheduled visit (e.g., Cycle12Week1).
Projected Date	The planned date for the visit as per protocol schedule.
# Days Outstanding	Number of days since the projected visit date. Highlights overdue visits and supports timely follow-up.

3. Missing_Lab_Name_and_Missing_Ranges

Purpose:

Enumerates all instances where laboratory names or reference ranges/units are missing for local lab results. Used by data managers and CRAs to identify and resolve data gaps that could impact data quality and regulatory compliance.

Column Name	Description & Explanation
Country	Country where the clinical trial site is located.
Site number	Unique identifier for the clinical trial site.
Subject	Unique identifier for each subject enrolled at the site.
Visit	Name of the scheduled visit (e.g., 30 day Safety, Cycle 5 Week 5).
Form Name	Name of the data entry form in the EDC system (e.g., Chemistry - Local Lab Results).
Lab category	Category of the laboratory test (e.g., CHEMISTRY, HEMATOLOGY, COAGULATION).
Lab Name	Name of the laboratory performing the test. If missing, flagged for follow-up.
Lab Date	Date when the laboratory test was performed.
Test Name	Short name or code for the laboratory test (e.g., ALT, CK, HGB).
Test description	Full description of the laboratory test (e.g., Alanine aminotransferase, Hemoglobin).
Issue	Type of issue identified (e.g., “Ranges/ Units not entered”, “Missing Lab name”).
Comments	Recommended action or additional notes (e.g., “Action for CRA”, “Action for Site”).

4. SAE Dashboard

Purpose:

Tracks the status of Serious Adverse Event (SAE) discrepancies and reviews from a data management and safety team's perspective

Tab: SAE Dashboard_DM

Column Name	Description & Explanation
Discrepancy ID	Unique identifier for each discrepancy or issue tracked in the dashboard.
Study ID	Identifier for the clinical study.
Country	Country where the site is located.
Site	Unique identifier for the clinical trial site.
Patient ID	Unique identifier for the patient/subject.
Form Name	Name of the data entry form where the discrepancy was found.
Discrepancy Created Timestamp in Dashboard	Date and time when the discrepancy was created in the dashboard.
Review Status	Current review status (e.g., Review Completed, Pending for Review).
Action Status	Status of actions taken or required (e.g., No action required, Pending).

Tab: SAE Dashboard_Safety

Column Name	Description & Explanation
Discrepancy ID	Unique identifier for each discrepancy or issue tracked in the dashboard.
Study ID	Identifier for the clinical study.
Site	Unique identifier for the clinical trial site.
Patient ID	Unique identifier for the patient/subject.
Case Status	Status of the clinical case (e.g., Closed, Locked).
Discrepancy Created Timestamp in Dashboard	Date and time when the discrepancy was created in the dashboard.

Column Name	Description & Explanation
Review Status	Current review status (e.g., Review Completed, Pending for Review).
Action Status	Status of actions taken or required (e.g., No action required, Pending).

5. Inactivated Forms and Loglines

Purpose:

Logs all inactivated data pages and records in the clinical trial database, including the reason and context for inactivation.

Column Name	Description & Explanation
Country	Country where the site is located.
Site	Name or identifier of the clinical site.
Study Site Number	Numeric identifier for the site.
Subject	Unique identifier for the subject/patient.
Folder	Folder or module in the EDC system (e.g., Adverse Events, Disposition).
Form	Name of the data entry form (e.g., Adverse Events, Disposition).
Data on Form/Record	Indicates if data is present (Y/N).
RecordPosition	Position or sequence number of the record within the form/folder.
Audit Action	Description of the inactivation action (e.g., DataPage inactivated with code reason, Record Inactivated).

6. Global_Missing_Pages_Report

Purpose:

Details missing CRF pages at the individual visit level for each subject, enabling targeted follow-up and resolution of specific data gaps.

Column Name	**Description & Explanation**
Study Name	Name of the clinical study.
SiteGroupName(CountryName)	Country or region where the site is located.
SiteNumber	Unique identifier for the clinical trial site.
SubjectName	Unique identifier for the subject/patient.
Overall Subject Status	Status of the subject in the study (e.g., Survival, Discontinued, Follow-Up).
Visit Level Subject Status	Status of the subject at the visit level.
FolderName	Name of the folder/module in the EDC system.
Visit date	Date of the scheduled or actual visit.
Form Type (Summary or Visit)	Indicates if the missing page is from a summary or a specific visit.
FormName	Name of the form with missing pages.
No. #Days Page Missing	Number of days the page has been missing.

7. Compiled_EDRR

Purpose:

Summarizes the total number of unresolved data issues for each subject in the study for third party data, supporting prioritization of data cleaning and issue resolution.

Column Name	**Description & Explanation**
Study	Name of the clinical study.
Subject	Unique identifier for the subject/patient.
Total Open issue Count per subject	Number of unresolved issues for each subject.

8. GlobalCodingReport_MedDRA

Purpose:

Provides a detailed record of all medical terms (e.g., adverse events, medical history) that require or have undergone MedDRA coding

Column Name	Description & Explanation
MedDRA Coding Report	Indicates the type of coding report (MedDRA).
Study	Name or ID of the clinical study.
Dictionary	Name of the coding dictionary used (e.g., MedDRA).
Dictionary Version number	Version of the MedDRA dictionary used for coding.
Subject	Unique identifier for the subject/patient.
Form	Name of the data entry form (e.g., Adverse Events, Medical History).
Form OID	Object Identifier for the form in the EDC system.
Logline	Line number or sequence for the coded entry.
Field OID	Object Identifier for the specific field being coded.
Supplement Term Value1	Additional term or value supplementing the main coded term (if applicable).
Coding Status	Status of the coding (e.g., Coded Term, UnCoded Term).
Require Coding	Indicates if the term requires coding (Yes/No).

9. GlobalCodingReport_WHODRA

Purpose:

Provides a detailed record of all medications and therapies that require or have undergone WHO Drug dictionary coding

Column Name	Description & Explanation
WHODrug Coding Report	Indicates the type of coding report (WHO Drug).
Study	Name or ID of the clinical study.
Dictionary	Name of the coding dictionary used (e.g., WHODrug-Global-B3).
Dictionary Version number	Version of the WHO Drug dictionary used for coding.
Subject	Unique identifier for the subject/patient.
Form	Name of the data entry form (e.g., Antineoplastic Medications, Prior or Concomitant Medications).
Form OID	Object Identifier for the form in the EDC system.
Logline	Line number or sequence for the coded entry.
Field OID	Object Identifier for the specific field being coded.
Trade Name	Trade name of the medication (if available).
Coding Status	Status of the coding (e.g., Coded Term, UnCoded Term).
Require Coding	Indicates if the term requires coding (Yes/No).