

Qualification Report for the {gsm} R Package

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1 Introduction

Risk-Based Quality Monitoring (RBQM) is a proactive approach to clinical trial monitoring that focuses on identifying and addressing the most critical risks to the integrity of study data and patient safety. This approach aims to ensure that study data are accurate, reliable, and credible while optimizing the use of resources and minimizing the burden on study sites.

The `{gsm}` R package supports RBQM by performing risk assessments primarily focused on detecting differences in quality at the site level. This approach is intended to detect potential issues related to critical data or process(es) across the major risk categories of safety, efficacy, disposition, treatment, and general quality. Each category consists of one or more risk assessment(s). Each risk assessment analyzes the data to flag sites with potential outliers and provides a visualization to help the user understand the issue.

2 Scope

Qualification testing ensures that core functions execute as expected on a system-wide scale. Qualification includes executing various functional, performance, and usability testing. Qualification tests are designed to provide developers with a repeatable process that is easy to update and document. This document summarizes the qualification testing performed on `{gsm}` functions essential to the analytics workflow.

3 Process Overview

Each essential `{gsm}` workflow function is independently qualified using specifications and test cases compiled in this report. Details are provided below.

3.1 Specifications

Specifications capture the most critical use cases for a given function. Each function must have at least one (1) specification, and each specification must have at least one (1) associated test case. Multiple specifications may exist for a function, and multiple test cases may exist for a specification.

Each specification includes the following components:

- **Description:** outlines the use case for the specification
- **Risk Assessment**
 - **Risk Level:** assigned a value of “Low”, “Medium”, or “High”, corresponding to the risk associated with the specification failing
 - **Risk Impact:** assigned a value of “Low”, “Medium”, or “High”, corresponding to the severity of the impact associated with the specification failing
- **Test Cases:** lists measurable test cases associated with the specification

3.2 Test Cases

Test cases translate specifications into testable scripts to confirm that the package functions meet the established requirements. Test cases represent how a user may utilize the function to help identify code gaps and support testing automation.

Test cases for `{gsm}` are written using the standard `testthat` workflow. A single test script is saved for each test case and is named following the convention `test_qual_{TestID}.R`, where `TestID` is the test case number. Test code within these scripts is written clearly and concisely to facilitate quick execution and interpretability. Note that a single test case may be associated with multiple specifications.

4 Test Results: Overview

| Function Name | Number of Tests | Number Passed | Number Failed | Number Skipped |
|-------------------|-----------------|---------------|---------------|----------------|
| AE_Assess | 12 | 12 | 0 | 0 |
| AE_Map_Raw | 4 | 4 | 0 | 0 |
| Consent_Assess | 3 | 3 | 0 | 0 |
| DataChg_Assess | 12 | 12 | 0 | 0 |
| DataChg_Map_Raw | 4 | 4 | 0 | 0 |
| DataEntry_Assess | 12 | 12 | 0 | 0 |
| DataEntry_Map_Raw | 4 | 4 | 0 | 0 |
| Disp_Assess | 12 | 12 | 0 | 0 |
| Disp_Map_Raw | 8 | 8 | 0 | 0 |
| FilterDomain | 2 | 2 | 0 | 0 |
| Get_Enrolled | 3 | 3 | 0 | 0 |
| IE_Assess | 3 | 3 | 0 | 0 |
| LB_Assess | 12 | 12 | 0 | 0 |
| LB_Map_Raw | 4 | 4 | 0 | 0 |
| MergeSubjects | 1 | 1 | 0 | 0 |
| PD_Assess_Binary | 12 | 12 | 0 | 0 |
| PD_Assess_Rate | 12 | 12 | 0 | 0 |
| PD_Map_Raw_Binary | 4 | 4 | 0 | 0 |
| PD_Map_Raw_Rate | 4 | 4 | 0 | 0 |
| QueryAge_Assess | 12 | 12 | 0 | 0 |
| QueryAge_Map_Raw | 4 | 4 | 0 | 0 |
| QueryRate_Assess | 12 | 12 | 0 | 0 |
| QueryRate_Map_Raw | 6 | 6 | 0 | 0 |
| is_mapping_valid | 9 | 9 | 0 | 0 |

5 Test Results: Detailed

5.1 One Row Per Specification

| Spec ID | Spec Description | Risk | Impact | Associated Test IDs |
|---------|---|--------|--------|---|
| S1_1 | Given appropriate input data, an Adverse Event Assessment can be done using the Poisson method. | High | High | T1_1, T1_2, T1_3, T1_10 |
| S1_2 | Given appropriate input data, an Adverse Event Assessment can be done using the Identity method. | High | High | T1_4, T1_5, T1_6, T1_11 |
| S1_3 | Given appropriate input data, an Adverse Event Assessment can be done using the Normal Approximation method. | High | High | T1_7, T1_8, T1_9, T1_12 |
| S1_4 | Adverse Event Assessments can be done correctly using a grouping variable, such as Site or Country for KRIs, and Study for QTLs, when applicable. | Low | High | T1_1, T1_2, T1_3, T1_4, T1_5, T1_6, T1_7, T1_8, T1_9, T1_10, T1_11, T1_12 |
| S1_5 | Given appropriate input data, flag values can be correctly assigned to records that meet flagging criteria, including custom thresholding. | Medium | High | T1_1, T1_2, T1_3, T1_4, T1_5, T1_6, T1_7, T1_8, T1_9, T1_10, T1_11, T1_12 |
| S1_6 | Given an appropriate subset of input data, an Adverse Event Assessment can be done. | Medium | Medium | T1_1, T1_2, T1_4, T1_5, T1_7, T1_8 |

(continued)

| Spec ID | Spec Description | Risk | Impact | Associated Test IDs |
|---------|--|--------|--------|---|
| S1_7 | Given appropriate input data, flag values are correctly assigned as NA for sites with low enrollment. | | | T1_10, T1_11, T1_12 |
| S2_1 | Given appropriate input data, a Protocol Deviation Assessment can be done using the Poisson method. | High | High | T2_1, T2_2, T2_3, T2_10 |
| S2_2 | Given appropriate input data, a Protocol Deviation Assessment can be done using the Identity method. | High | High | T2_4, T2_5, T2_6, T2_11 |
| S2_3 | Given appropriate input data, a Protocol Deviation Assessment can be done using the Normal Approximation method. | High | High | T2_7, T2_8, T2_9, T2_12 |
| S2_4 | Protocol Deviation Assessments can be done correctly using a grouping variable, such as Site or Country for KRIs, and Study for QTLs, when applicable. | Low | High | T2_1, T2_2, T2_3, T2_4, T2_5, T2_6, T2_7, T2_8, T2_9, T2_10, T2_11, T2_12 |
| S2_5 | Given appropriate input data, flag values can be correctly assigned to records that meet flagging criteria, including custom thresholding. | Medium | High | T2_1, T2_2, T2_3, T2_4, T2_5, T2_6, T2_7, T2_8, T2_9, T2_10, T2_11, T2_12 |
| S2_6 | Given an appropriate subset of input data, a Protocol Deviation Assessment can be done. | Medium | Medium | T2_1, T2_2, T2_4, T2_5, T2_7, T2_8 |
| S2_7 | Given appropriate input data, flag values are correctly assigned as NA for sites with low enrollment. | | | T2_10, T2_11, T2_12 |
| S3_1 | Given appropriate input data, an Inclusion/Exclusion Criteria Assessment can be done using the Identity method. | High | High | T3_1, T3_2, T3_3 |
| S3_2 | Inclusion/Exclusion Criteria Assessments can be done correctly using a grouping variable, such as Site or Country for KRIs, and Study for QTLs, when applicable. | Low | High | T3_1, T3_2, T3_3 |
| S3_3 | Given appropriate input data, flag values can be correctly assigned to records that meet flagging criteria, including custom thresholding. | Medium | High | T3_1, T3_2, T3_3 |
| S3_4 | Given an appropriate subset of input data, an Inclusion/Exclusion Criteria Assessment can be done. | Medium | Medium | T3_2 |
| S4_1 | Given appropriate input data, a Consent Assessment can be done using the Identity method. | High | High | T4_1, T4_2, T4_3 |
| S4_2 | Consent Assessments can be done correctly using a grouping variable, such as Site or Country for KRIs, and Study for QTLs, when applicable. | Low | High | T4_1, T4_2, T4_3 |
| S4_3 | Given appropriate input data, flag values can be correctly assigned to records that meet flagging criteria, including custom thresholding. | Medium | High | T4_1, T4_2, T4_3 |
| S4_4 | Given an appropriate subset of input data, a Consent Assessment can be done. | Medium | Medium | T4_1, T4_2 |

(continued)

| Spec ID | Spec Description | Risk | Impact | Associated Test IDs |
|---------|---|--------|--------|---|
| S5_1 | Given appropriate input data, a Disposition Assessment can be done using the Fisher method. | High | High | T5_1, T5_2, T5_3, T5_10 |
| S5_2 | Given appropriate input data, a Disposition Assessment can be done using the Identity method. | High | High | T5_4, T5_5, T5_6, T5_11 |
| S5_3 | Given appropriate input data, a Disposition Assessment can be done using the Normal Approximation method. | High | High | T5_7, T5_8, T5_9, T5_12 |
| S5_4 | Disposition Assessments can be done correctly using a grouping variable, such as Site or Country for KRIs, and Study for QTLs, when applicable. | Low | High | T5_1, T5_2, T5_3, T5_4, T5_5, T5_6, T5_7, T5_8, T5_9, T5_10, T5_11, T5_12 |
| S5_5 | Given appropriate input data, flag values can be correctly assigned to records that meet flagging criteria, including custom thresholding. | Medium | High | T5_1, T5_2, T5_3, T5_4, T5_5, T5_6, T5_7, T5_8, T5_9, T5_10, T5_11, T5_12 |
| S5_6 | Given an appropriate subset of input data, a Disposition Assessment can be done. | Medium | Medium | T5_1, T5_2, T5_4, T5_5, T5_7, T5_8 |
| S5_7 | Given appropriate input data, flag values are correctly assigned as NA for sites with low enrollment. | | | T5_10, T5_11, T5_12 |
| S6_1 | Given appropriate input data, a Labs Assessment can be done using the Fisher method. | High | High | T6_1, T6_2, T6_3, T6_9 |
| S6_2 | Given appropriate input data, a Labs Assessment can be done using the Identity method. | High | High | T6_4, T6_5, T6_6, T6_10 |
| S6_3 | Given appropriate input data, a Labs Assessment can be done using the Normal Approximation method. | High | High | T6_7, T6_8, T6_9, T6_11 |
| S6_4 | Labs Assessments can be done correctly using a grouping variable, such as Site or Country for KRIs, and Study for QTLs, when applicable. | Low | High | T6_1, T6_2, T6_3, T6_4, T6_5, T6_6, T6_7, T6_8, T6_9, T6_10, T6_11, T6_12 |
| S6_5 | Given appropriate input data, flag values can be correctly assigned to records that meet flagging criteria, including custom thresholding. | Medium | High | T6_1, T6_2, T6_3, T6_4, T6_5, T6_6, T6_7, T6_8, T6_9, T6_10, T6_11, T6_12 |
| S6_6 | Given an appropriate subset of input data, a Labs Assessment can be done. | Medium | Medium | T6_1, T6_2, T6_4, T6_5, T6_7, T6_8 |
| S6_7 | Given appropriate input data, flag values are correctly assigned as NA for sites with low enrollment. | | | T6_10, T6_11, T6_12 |
| S7_1 | Given appropriate input data, a Data Change Rate Assessment can be done using the Identity method. | High | High | T7_4, T7_5, T7_6, T7_11 |
| S7_2 | Given appropriate input data, a Data Change Rate Assessment can be done using the Fisher method. | High | High | T7_1, T7_2, T7_3, T7_10 |
| S7_3 | Given appropriate input data, a Data Change Rate Assessment can be done using the Normal Approximation method. | High | High | T7_7, T7_8, T7_9, T7_12 |

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| Spec ID | Spec Description | Risk | Impact | Associated Test IDs |
|---------|--|--------|--------|---|
| S7_4 | Data Change Rate Assessments can be done correctly using a grouping variable, such as Site, Country, or Study, when applicable. | Low | High | T7_1, T7_2, T7_3, T7_4, T7_5, T7_6, T7_7, T7_8, T7_9, T7_10, T7_11, T7_12 |
| S7_5 | Given appropriate input data, flag values can be correctly assigned to records that meet flagging criteria, including custom thresholding. | Medium | High | T7_1, T7_2, T7_3, T7_4, T7_5, T7_6, T7_7, T7_8, T7_9, T7_10, T7_11, T7_12 |
| S7_6 | Given an appropriate subset of input data, a Data Change Rate Assessment can be done. | Medium | Medium | T7_1, T7_2, T7_4, T7_5, T7_7, T7_8 |
| S7_7 | Given appropriate input data, flag values are correctly assigned as NA for sites with low enrollment. | | | T7_10, T7_11, T7_12 |
| S8_1 | Given appropriate input data, a Data Entry Lag Assessment can be done using the Fisher method. | High | High | T8_1, T8_2, T8_3, T8_10 |
| S8_2 | Given appropriate input data, a Data Entry Lag Assessment can be done using the Identity method. | High | High | T8_4, T8_5, T8_6, T8_11 |
| S8_3 | Given appropriate input data, a Data Entry Lag Assessment can be done using the Normal Approximation method. | High | High | T8_7, T8_8, T8_9, T8_12 |
| S8_4 | Data Entry Lag Assessments can be done correctly using a grouping variable, such as Site, Country, or Study, when applicable. | Low | High | T8_1, T8_2, T8_3, T8_4, T8_5, T8_6, T8_7, T8_8, T8_9, T8_10, T8_11, T8_12 |
| S8_5 | Given appropriate input data, flag values can be correctly assigned to records that meet flagging criteria, including custom thresholding. | Medium | High | T8_1, T8_2, T8_3, T8_4, T8_5, T8_6, T8_7, T8_8, T8_9, T8_10, T8_11, T8_12 |
| S8_6 | Given an appropriate subset of input data, a Data Entry Lag Assessment can be done. | Medium | Medium | T8_1, T8_2, T8_4, T8_5, T8_7, T8_8 |
| S8_7 | Given appropriate input data, flag values are correctly assigned as NA for sites with low enrollment. | | | T8_10, T8_11, T8_12 |
| S9_1 | Given appropriate input data, a Query Age Assessment can be done using the Fisher method. | High | High | T9_1, T9_2, T9_3, T9_10 |
| S9_2 | Given appropriate input data, a Query Age Assessment can be done using the Identity method. | High | High | T9_4, T9_5, T9_6, T9_11 |
| S9_3 | Given appropriate input data, a Query Age Assessment can be done using the Normal Approximation method. | High | High | T9_7, T9_8, T9_9, T9_12 |
| S9_4 | Query Age Assessments can be done correctly using a grouping variable, such as Site, Country, or Study, when applicable. | Low | High | T9_1, T9_2, T9_3, T9_4, T9_5, T9_6, T9_7, T9_8, T9_9, T9_10, T9_11, T9_12 |
| S9_5 | Given appropriate input data, flag values can be correctly assigned to records that meet flagging criteria, including custom thresholding. | Medium | High | T9_1, T9_2, T9_3, T9_4, T9_5, T9_6, T9_7, T9_8, T9_9, T9_10, T9_11, T9_12 |
| S9_6 | Given an appropriate subset of input data, a Query Age Assessment can be done. | Medium | Medium | T9_1, T9_2, T9_4, T9_5, T9_7, T9_8 |

(continued)

| Spec ID | Spec Description | Risk | Impact | Associated Test IDs |
|---------|--|--------|--------|---|
| S9_7 | Given appropriate input data, flag values are correctly assigned as NA for sites with low enrollment. | | | T9_10, T9_11, T9_12 |
| S10_1 | Given appropriate input data, a Query Rate Assessment can be done using the Poisson method. | High | High | T10_1, T10_2, T10_3, T10_10 |
| S10_2 | Given appropriate input data, a Query Rate Assessment can be done using the Identity method. | High | High | T10_4, T10_5, T10_6, T10_11 |
| S10_3 | Given appropriate input data, a Query Rate Assessment can be done using the Normal Approximation method. | High | High | T10_7, T10_8, T10_9, T10_12 |
| S10_4 | Query Rate Assessments can be done correctly using a grouping variable, such as Site, Country, or Study, when applicable. | Low | High | T10_1, T10_2, T10_3, T10_4, T10_5, T10_6, T10_7, T10_8, T10_9, T10_10, T10_11, T10_12 |
| S10_5 | Given appropriate input data, flag values can be correctly assigned to records that meet flagging criteria, including custom thresholding. | Medium | High | T10_1, T10_2, T10_3, T10_4, T10_5, T10_6, T10_7, T10_8, T10_9, T10_10, T10_11, T10_12 |
| S10_6 | Given an appropriate subset of input data, a Query Rate Assessment can be done. | Medium | Medium | T10_1, T10_2, T10_4, T10_5, T10_7, T10_8 |
| S10_7 | Given appropriate input data, flag values are correctly assigned as NA for sites with low enrollment. | | | T10_10, T10_11, T10_12 |
| S11_1 | Given appropriate metadata, the raw data for an Adverse Event Assessment can be correctly mapped to an analysis-ready input dataset. | Medium | High | T11_1, T11_2, T11_3, T11_4 |
| S12_1 | Given appropriate metadata, the raw data for a Data Change Rate Assessment can be correctly mapped to an analysis-ready input dataset. | Medium | High | T12_1, T12_2, T12_3, T12_4 |
| S13_1 | Given appropriate metadata, the raw data for a Data Entry Lag Assessment can be correctly mapped to an analysis-ready input dataset. | Medium | High | T13_1, T13_2, T13_3, T13_4 |
| S14_1 | Given appropriate metadata, the raw data for a Disposition Assessment can be correctly mapped to an analysis-ready input dataset. | Medium | High | T14_1, T14_2, T14_3, T14_4, T14_5, T14_6, T14_7, T14_8 |
| S15_1 | Given appropriate metadata, the raw data for a Labs Assessment can be correctly mapped to an analysis-ready input dataset. | Medium | High | T15_1, T15_2, T15_3, T15_4 |
| S16_1 | Given appropriate metadata, the raw data for a Protocol Deviation Assessment can be correctly mapped to an analysis-ready input dataset. | Medium | High | T16_1, T16_2, T16_3, T16_4 |
| S17_1 | Given appropriate metadata, the raw data for a Query Age Assessment can be correctly mapped to an analysis-ready input dataset. | Medium | High | T17_1, T17_2, T17_3, T17_4 |

(continued)

| Spec ID | Spec Description | Risk | Impact | Associated Test IDs |
|---------|--|--------|--------|---|
| S18_1 | Given appropriate metadata, the raw data for a Query Rate Assessment can be correctly mapped to an analysis-ready input dataset. | Medium | High | T18_1, T18_2, T18_3, T18_4, T18_5, T18_6 |
| S19_1 | Input data can be correctly filtered on a specified key variable and key variable value. | Low | Medium | T19_1, T19_2 |
| S20_1 | Given appropriate input data and metadata, the correct number of enrolled participants per study can be derived. | Low | High | T20_1 |
| S20_2 | Given appropriate input data and metadata, the correct number of sites per study can be derived. | Low | High | T20_2 |
| S20_3 | Given appropriate input data and metadata, the correct number of enrolled participants per site can be derived. | Low | High | T20_3 |
| S21_1 | Given appropriate input data and key variable, domain-level data can be correctly merged with subject-level data. | Low | High | T21_1 |
| S22_1 | The structure of the input data can be correctly evaluated for validity of use in downstream assessment and workflow functions. | Low | Medium | T22_1, T22_2 |
| S22_2 | The structure of the mapping(s) can be correctly evaluated for validity of use in downstream assessment and workflow functions. | Low | Medium | T22_3, T22_4, T22_5 |
| S22_3 | The structure of the parameter specifications can be correctly evaluated for validity of use in downstream assessment and workflow functions. | Low | Medium | T22_5, T22_6, T22_7, T22_8, T22_9 |
| S23_1 | Given appropriate input data, a Protocol Deviation Assessment can be done using the Poisson method. | High | High | T23_1, T23_2, T23_3, T23_10 |
| S23_2 | Given appropriate input data, a Protocol Deviation Assessment can be done using the Identity method. | High | High | T23_4, T23_5, T23_6, T23_11 |
| S23_3 | Given appropriate input data, a Protocol Deviation Assessment can be done using the Normal Approximation method. | High | High | T23_7, T23_8, T23_9, T23_12 |
| S23_4 | Protocol Deviation Assessments can be done correctly using a grouping variable, such as Site or Country for KRIs, and Study for QTLs, when applicable. | Low | High | T23_1, T23_2, T23_3, T23_4, T23_5, T23_6, T23_7, T23_8, T23_9, T23_10, T23_11, T23_12 |
| S23_5 | Given appropriate input data, flag values can be correctly assigned to records that meet flagging criteria, including custom thresholding. | Medium | High | T23_1, T23_2, T23_3, T23_4, T23_5, T23_6, T23_7, T23_8, T23_9, T23_10, T23_11, T23_12 |
| S23_6 | Given an appropriate subset of input data, a Protocol Deviation Assessment can be done. | Medium | Medium | T23_1, T23_2, T23_4, T23_5, T23_7, T23_8 |
| S23_7 | Given appropriate input data, flag values are correctly assigned as NA for sites with low enrollment. | | | T23_10, T23_11, T23_12 |

(continued)

| Spec ID | Spec Description | Risk | Impact | Associated Test IDs |
|---------|--|--------|--------|----------------------------|
| S24_1 | Given appropriate metadata, the raw data for a Protocol Deviation Assessment can be correctly mapped to an analysis-ready input dataset. | Medium | High | T24_1, T24_2, T24_3, T24_4 |

5.2 One Row Per Test

| Function | Spec ID | Test ID | Test Description | Test Result |
|-----------|------------------------|---------|--|-------------|
| AE_Assess | S1_1, S1_4, S1_5, S1_6 | T1_1 | Given an appropriate subset of Adverse Event data, the assessment function correctly performs an Adverse Event Assessment grouped by the Site variable using the Poisson method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| AE_Assess | S1_1, S1_4, S1_5, S1_6 | T1_2 | Given an appropriate subset of Adverse Event data, the assessment function correctly performs an Adverse Event Assessment grouped by the Study variable using the Poisson method and correctly assigns Flag variable values. | Pass |
| AE_Assess | S1_1, S1_4, S1_5 | T1_3 | Given appropriate Adverse Event data, the assessment function correctly performs an Adverse Event Assessment grouped by a custom variable using the Poisson method and correctly assigns Flag variable values. | Pass |
| AE_Assess | S1_2, S1_4, S1_5, S1_6 | T1_4 | Given an appropriate subset of Adverse Event data, the assessment function correctly performs an Adverse Event Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| AE_Assess | S1_2, S1_4, S1_5, S1_6 | T1_5 | Given an appropriate subset of Adverse Event data, the assessment function correctly performs an Adverse Event Assessment grouped by the Study variable using the Identity method and correctly assigns Flag variable values. | Pass |
| AE_Assess | S1_2, S1_4, S1_5 | T1_6 | Given appropriate Adverse Event data, the assessment function correctly performs an Adverse Event Assessment grouped by a custom variable using the Identity method and correctly assigns Flag variable values. | Pass |
| AE_Assess | S1_3, S1_4, S1_5, S1_6 | T1_7 | Given an appropriate subset of Adverse Event data, the assessment function correctly performs an Adverse Event Assessment grouped by the Site variable using the Normal Approximation method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| AE_Assess | S1_3, S1_4, S1_5, S1_6 | T1_8 | Given an appropriate subset of Adverse Event data, the assessment function correctly performs an Adverse Event Assessment grouped by the Study variable using the Normal Approximation method and correctly assigns Flag variable values. | Pass |
| AE_Assess | S1_3, S1_4, S1_5 | T1_9 | Given appropriate Adverse Event data, the assessment function correctly performs an Adverse Event Assessment grouped by a custom variable using the Normal Approximation method and correctly assigns Flag variable values. | Pass |

(continued)

| Function | Spec ID | Test ID | Test Description | Test Result |
|----------------|------------------------|---------|---|-------------|
| AE_Assess | S1_1, S1_4, S1_5, S1_7 | T1_10 | Given appropriate Adverse Event data, the assessment function correctly performs an Adverse Event Assessment grouped by the Site variable using the Poisson method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| AE_Assess | S1_2, S1_4, S1_5, S1_7 | T1_11 | Given appropriate Adverse Event data, the assessment function correctly performs an Adverse Event Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| AE_Assess | S1_3, S1_4, S1_5, S1_7 | T1_12 | Given appropriate Adverse Event data, the assessment function correctly performs an Adverse Event Assessment grouped by the Site variable using the Normal Approximation method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| PD_Assess_Rate | S2_1, S2_4, S2_5, S2_6 | T2_1 | Given an appropriate subset of Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by the Site variable using the Poisson method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| PD_Assess_Rate | S2_1, S2_4, S2_5, S2_6 | T2_2 | Given an appropriate subset of Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by the Study variable using the Poisson method and correctly assigns Flag variable values. | Pass |
| PD_Assess_Rate | S2_1, S2_4, S2_5 | T2_3 | Given appropriate Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by a custom variable using the Poisson method and correctly assigns Flag variable values. | Pass |
| PD_Assess_Rate | S2_2, S2_4, S2_5, S2_6 | T2_4 | Given an appropriate subset of Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values when given a custom threshold. | Pass |

(continued)

| Function | Spec ID | Test ID | Test Description | Test Result |
|----------------|------------------------|---------|--|-------------|
| PD_Assess_Rate | S2_2, S2_4, S2_5, S2_6 | T2_5 | Given an appropriate subset of Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by a custom variable using the Identity method and correctly assigns Flag variable values. | Pass |
| PD_Assess_Rate | S2_2, S2_4, S2_5 | T2_6 | Given appropriate Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values. | Pass |
| PD_Assess_Rate | S2_3, S2_4, S2_5, S2_6 | T2_7 | Given an appropriate subset of Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by the Site variable using the Normal Approximation method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| PD_Assess_Rate | S2_3, S2_4, S2_5, S2_6 | T2_8 | Given an appropriate subset of Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by the Study variable using the Normal Approximation method and correctly assigns Flag variable values. | Pass |
| PD_Assess_Rate | S2_3, S2_4, S2_5 | T2_9 | Given appropriate Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by a custom variable using the Normal Approximation method and correctly assigns Flag variable values. | Pass |
| PD_Assess_Rate | S2_1, S2_4, S2_5, S2_7 | T2_10 | Given appropriate Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by the Site variable using the Poisson method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| PD_Assess_Rate | S2_2, S2_4, S2_5, S2_7 | T2_11 | Given appropriate Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| PD_Assess_Rate | S2_3, S2_4, S2_5, S2_7 | T2_12 | Given appropriate Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by the Site variable using the Normal Approximation method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |

(continued)

| Function | Spec ID | Test ID | Test Description | Test Result |
|----------------|------------------------|---------|---|-------------|
| IE_Assess | S3_1, S3_2, S3_3 | T3_1 | Given appropriate Inclusion/Exclusion data, the assessment function correctly performs an Inclusion/Exclusion Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values. | Pass |
| IE_Assess | S3_1, S3_2, S3_3, S3_4 | T3_2 | Given an appropriate subset of Inclusion/Exclusion data, the assessment function correctly performs an Inclusion/Exclusion Assessment grouped by the Study variable using the Identity method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| IE_Assess | S3_1, S3_2, S3_3 | T3_3 | Given appropriate Inclusion/Exclusion data, the assessment function correctly performs an Inclusion/Exclusion Assessment grouped by a custom variable using the Identity method and correctly assigns Flag variable values. | Pass |
| Consent_Assess | S4_1, S4_2, S4_3, S4_4 | T4_1 | Given an appropriate subset of Consent data, the assessment function correctly performs a Consent Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values. | Pass |
| Consent_Assess | S4_1, S4_2, S4_3, S4_4 | T4_2 | Given an appropriate subset of Consent data, the assessment function correctly performs a Consent Assessment grouped by the Study variable using the Identity method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| Consent_Assess | S4_1, S4_2, S4_3 | T4_3 | Given appropriate Consent data, the assessment function correctly performs a Consent Assessment grouped by a custom variable using the Identity method and correctly assigns Flag variable values. | Pass |
| Disp_Assess | S5_1, S5_4, S5_5, S5_6 | T5_1 | Given an appropriate subset of Disposition data, the assessment function correctly performs a Disposition Assessment grouped by the Site variable using the Fisher method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| Disp_Assess | S5_1, S5_4, S5_5, S5_6 | T5_2 | Given an appropriate subset of Disposition data, the assessment function correctly performs a Disposition Assessment grouped by the Country variable using the Fisher method and correctly assigns Flag variable values. | Pass |
| Disp_Assess | S5_1, S5_4, S5_5 | T5_3 | Given appropriate Disposition data, the assessment function correctly performs a Disposition Assessment grouped by a custom variable using the Fisher method and correctly assigns Flag variable values. | Pass |

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| Function | Spec ID | Test ID | Test Description | Test Result |
|-------------|------------------------|---------|--|-------------|
| Disp_Assess | S5_2, S5_4, S5_5, S5_6 | T5_4 | Given an appropriate subset of Disposition data, the assessment function correctly performs a Disposition Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| Disp_Assess | S5_2, S5_4, S5_5, S5_6 | T5_5 | Given an appropriate subset of Disposition data, the assessment function correctly performs a Disposition Assessment grouped by the Study variable using the Identity method and correctly assigns Flag variable values. | Pass |
| Disp_Assess | S5_2, S5_4, S5_5 | T5_6 | Given appropriate Disposition data, the assessment function correctly performs a Disposition Assessment grouped by a custom variable using the Identity method and correctly assigns Flag variable values. | Pass |
| Disp_Assess | S5_3, S5_4, S5_5, S5_6 | T5_7 | Given an appropriate subset of Disposition data, the assessment function correctly performs a Disposition Assessment grouped by the Site variable using the Normal Approximation method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| Disp_Assess | S5_3, S5_4, S5_5, S5_6 | T5_8 | Given an appropriate subset of Disposition data, the assessment function correctly performs a Disposition Assessment grouped by the Study variable using the Normal Approximation method and correctly assigns Flag variable values. | Pass |
| Disp_Assess | S5_3, S5_4, S5_5 | T5_9 | Given appropriate Disposition data, the assessment function correctly performs a Disposition Assessment grouped by a custom variable using the Normal Approximation method and correctly assigns Flag variable values. | Pass |
| Disp_Assess | S5_1, S5_4, S5_5, S5_7 | T5_10 | Given appropriate Disposition data, the assessment function correctly performs a Disposition Assessment grouped by the Site variable using the Fisher method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| Disp_Assess | S5_2, S5_4, S5_5, S5_7 | T5_11 | Given appropriate Disposition data, the assessment function correctly performs a Disposition Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |

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| Function | Spec ID | Test ID | Test Description | Test Result |
|-------------|------------------------|---------|--|-------------|
| Disp_Assess | S5_3, S5_4, S5_5, S5_7 | T5_12 | Given appropriate Disposition data, the assessment function correctly performs a Disposition Assessment grouped by the Site variable using the Normal Approximation method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| LB_Assess | S6_1, S6_4, S6_5, S6_6 | T6_1 | Given an appropriate subset of Labs data, the assessment function correctly performs a Labs Assessment grouped by the Site variable using the Fisher method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| LB_Assess | S6_1, S6_4, S6_5, S6_6 | T6_2 | Given an appropriate subset of Labs data, the assessment function correctly performs a Labs Assessment grouped by the Country variable using the Fisher method and correctly assigns Flag variable values. | Pass |
| LB_Assess | S6_1, S6_4, S6_5 | T6_3 | Given appropriate Labs data, the assessment function correctly performs a Labs Assessment grouped by a custom variable using the Fisher method and correctly assigns Flag variable values. | Pass |
| LB_Assess | S6_2, S6_4, S6_5, S6_6 | T6_4 | Given an appropriate subset of Labs data, the assessment function correctly performs a Labs Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| LB_Assess | S6_2, S6_4, S6_5, S6_6 | T6_5 | Given an appropriate subset of Labs data, the assessment function correctly performs a Labs Assessment grouped by the Study variable using the Identity method and correctly assigns Flag variable values. | Pass |
| LB_Assess | S6_2, S6_4, S6_5 | T6_6 | Given appropriate Labs data, the assessment function correctly performs a Labs Assessment grouped by a custom variable using the Identity method and correctly assigns Flag variable values. | Pass |
| LB_Assess | S6_3, S6_4, S6_5, S6_6 | T6_7 | Given an appropriate subset of Labs data, the assessment function correctly performs a Labs Assessment grouped by the Site variable using the Normal Approximation method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| LB_Assess | S6_3, S6_4, S6_5, S6_6 | T6_8 | Given an appropriate subset of Labs data, the assessment function correctly performs a Labs Assessment grouped by the Study variable using the Normal Approximation method and correctly assigns Flag variable values. | Pass |

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| Function | Spec ID | Test ID | Test Description | Test Result |
|----------------|------------------------|---------|--|-------------|
| LB_Assess | S6_1, S6_3, S6_4, S6_5 | T6_9 | Given appropriate Labs data, the assessment function correctly performs a Labs Assessment grouped by a custom variable using the Normal Approximation method and correctly assigns Flag variable values. | Pass |
| LB_Assess | S6_2, S6_4, S6_5, S6_7 | T6_10 | Given appropriate Labs data, the assessment function correctly performs a Labs Assessment grouped by the Site variable using the Fisher method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| LB_Assess | S6_3, S6_4, S6_5, S6_7 | T6_11 | Given appropriate Labs data, the assessment function correctly performs a Labs Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| LB_Assess | S6_4, S6_5, S6_7 | T6_12 | Given appropriate Labs data, the assessment function correctly performs a Labs Assessment grouped by the Site variable using the Normal Approximation method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| DataChg_Assess | S7_2, S7_4, S7_5, S7_6 | T7_1 | Given an appropriate subset of Data Change Rate data, the assessment function correctly performs a Data Change Rate Assessment grouped by the Site variable using the Fisher method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| DataChg_Assess | S7_2, S7_4, S7_5, S7_6 | T7_2 | Given an appropriate subset of Data Change Rate data, the assessment function correctly performs a Data Change Rate Assessment grouped by the Country variable using the Fisher method and correctly assigns Flag variable values. | Pass |
| DataChg_Assess | S7_2, S7_4, S7_5 | T7_3 | Given appropriate Data Change Rate data, the assessment function correctly performs a Data Change Rate Assessment grouped by a custom variable using the Fisher method and correctly assigns Flag variable values. | Pass |

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| Function | Spec ID | Test ID | Test Description | Test Result |
|----------------|------------------------|---------|--|-------------|
| DataChg_Assess | S7_1, S7_4, S7_5, S7_6 | T7_4 | Given an appropriate subset of Data Change Rate data, the assessment function correctly performs a Data Change Rate Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| DataChg_Assess | S7_1, S7_4, S7_5, S7_6 | T7_5 | Given an appropriate subset of Data Change Rate data, the assessment function correctly performs a Data Change Rate Assessment grouped by the Study variable using the Identity method and correctly assigns Flag variable values. | Pass |
| DataChg_Assess | S7_1, S7_4, S7_5 | T7_6 | Given appropriate Data Change Rate data, the assessment function correctly performs a Data Change Rate Assessment grouped by a custom variable using the Identity method and correctly assigns Flag variable values. | Pass |
| DataChg_Assess | S7_3, S7_4, S7_5, S7_6 | T7_7 | Given an appropriate subset of Data Change Rate data, the assessment function correctly performs a Data Change Rate Assessment grouped by the Site variable using the Normal Approximation method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| DataChg_Assess | S7_3, S7_4, S7_5, S7_6 | T7_8 | Given an appropriate subset of Data Change Rate data, the assessment function correctly performs a Data Change Rate Assessment grouped by the Study variable using the Normal Approximation method and correctly assigns Flag variable values. | Pass |
| DataChg_Assess | S7_3, S7_4, S7_5 | T7_9 | Given appropriate Data Change Rate data, the assessment function correctly performs a Data Change Rate Assessment grouped by a custom variable using the Normal Approximation method and correctly assigns Flag variable values. | Pass |
| DataChg_Assess | S7_2, S7_4, S7_5, S7_7 | T7_10 | Given appropriate Data Change Rate data, the assessment function correctly performs a Data Change Rate Assessment grouped by the Site variable using the Fisher method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| DataChg_Assess | S7_1, S7_4, S7_5, S7_7 | T7_11 | Given appropriate Data Change Rate data, the assessment function correctly performs a Data Change Rate Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |

(continued)

| Function | Spec ID | Test ID | Test Description | Test Result |
|------------------|------------------------|---------|--|-------------|
| DataChg_Assess | S7_3, S7_4, S7_5, S7_7 | T7_12 | Given appropriate Data Change Rate data, the assessment function correctly performs a Data Change Rate Assessment grouped by the Site variable using the Normal Approximation method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| DataEntry_Assess | S8_1, S8_4, S8_5, S8_6 | T8_1 | Given an appropriate subset of Data Entry Lag data, the assessment function correctly performs a Data Entry Lag Assessment grouped by the Site variable using the Fisher method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| DataEntry_Assess | S8_1, S8_4, S8_5, S8_6 | T8_2 | Given an appropriate subset of Data Entry Lag data, the assessment function correctly performs a Data Entry Lag Assessment grouped by the Country variable using the Fisher method and correctly assigns Flag variable values. | Pass |
| DataEntry_Assess | S8_1, S8_4, S8_5 | T8_3 | Given appropriate Data Entry Lag data, the assessment function correctly performs a Data Entry Lag Assessment grouped by a custom variable using the Fisher method and correctly assigns Flag variable values. | Pass |
| DataEntry_Assess | S8_2, S8_4, S8_5, S8_6 | T8_4 | Given an appropriate subset of Data Entry Lag data, the assessment function correctly performs a Data Entry Lag Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| DataEntry_Assess | S8_2, S8_4, S8_5, S8_6 | T8_5 | Given an appropriate subset of Data Entry Lag data, the assessment function correctly performs a Data Entry Lag Assessment grouped by the Study variable using the Identity method and correctly assigns Flag variable values. | Pass |
| DataEntry_Assess | S8_2, S8_4, S8_5 | T8_6 | Given appropriate Data Entry Lag data, the assessment function correctly performs a Data Entry Lag Assessment grouped by a custom variable using the Identity method and correctly assigns Flag variable values. | Pass |
| DataEntry_Assess | S8_3, S8_4, S8_5, S8_6 | T8_7 | Given an appropriate subset of Data Entry Lag data, the assessment function correctly performs a Data Entry Lag Assessment grouped by the Site variable using the Normal Approximation method and correctly assigns Flag variable values when given a custom threshold. | Pass |

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| Function | Spec ID | Test ID | Test Description | Test Result |
|------------------|------------------------|---------|--|-------------|
| DataEntry_Assess | S8_3, S8_4, S8_5, S8_6 | T8_8 | Given an appropriate subset of Data Entry Lag data, the assessment function correctly performs a Data Entry Lag Assessment grouped by the Study variable using the Normal Approximation method and correctly assigns Flag variable values. | Pass |
| DataEntry_Assess | S8_3, S8_4, S8_5 | T8_9 | Given appropriate Data Entry Lag data, the assessment function correctly performs a Data Entry Lag Assessment grouped by a custom variable using the Normal Approximation method and correctly assigns Flag variable values. | Pass |
| DataEntry_Assess | S8_1, S8_4, S8_5, S8_7 | T8_10 | Given appropriate Data Entry Lag data, the assessment function correctly performs a Data Entry Lag Assessment grouped by the Site variable using the Fisher method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| DataEntry_Assess | S8_2, S8_4, S8_5, S8_7 | T8_11 | Given appropriate Data Entry Lag data, the assessment function correctly performs a Data Entry Lag Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| DataEntry_Assess | S8_3, S8_4, S8_5, S8_7 | T8_12 | Given appropriate Data Entry Lag data, the assessment function correctly performs a Data Entry Lag Assessment grouped by the Site variable using the Normal Approximation method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| QueryAge_Assess | S9_1, S9_4, S9_5, S9_6 | T9_1 | Given an appropriate subset of Query Age data, the assessment function correctly performs a Query Age Assessment grouped by the Site variable using the Fisher method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| QueryAge_Assess | S9_1, S9_4, S9_5, S9_6 | T9_2 | Given an appropriate subset of Query Age data, the assessment function correctly performs a Query Age Assessment grouped by the Country variable using the Fisher method and correctly assigns Flag variable values. | Pass |
| QueryAge_Assess | S9_1, S9_4, S9_5 | T9_3 | Given appropriate Query Age data, the assessment function correctly performs a Query Age Assessment grouped by a custom variable using the Fisher method and correctly assigns Flag variable values. | Pass |

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| Function | Spec ID | Test ID | Test Description | Test Result |
|-----------------|------------------------|---------|--|-------------|
| QueryAge_Assess | S9_2, S9_4, S9_5, S9_6 | T9_4 | Given an appropriate subset of Query Age data, the assessment function correctly performs a Query Age Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| QueryAge_Assess | S9_2, S9_4, S9_5, S9_6 | T9_5 | Given an appropriate subset of Query Age data, the assessment function correctly performs a Query Age Assessment grouped by the Study variable using the Identity method and correctly assigns Flag variable values. | Pass |
| QueryAge_Assess | S9_2, S9_4, S9_5 | T9_6 | Given appropriate Query Age data, the assessment function correctly performs a Query Age Assessment grouped by a custom variable using the Identity method and correctly assigns Flag variable values. | Pass |
| QueryAge_Assess | S9_3, S9_4, S9_5, S9_6 | T9_7 | Given an appropriate subset of Query Age data, the assessment function correctly performs a Query Age Assessment grouped by the Site variable using the Normal Approximation method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| QueryAge_Assess | S9_3, S9_4, S9_5, S9_6 | T9_8 | Given an appropriate subset of Query Age data, the assessment function correctly performs a Query Age Assessment grouped by the Study variable using the Normal Approximation method and correctly assigns Flag variable values. | Pass |
| QueryAge_Assess | S9_3, S9_4, S9_5 | T9_9 | Given appropriate Query Age data, the assessment function correctly performs a Query Age Assessment grouped by a custom variable using the Normal Approximation method and correctly assigns Flag variable values. | Pass |
| QueryAge_Assess | S9_1, S9_4, S9_5, S9_7 | T9_10 | Given appropriate Query Age data, the assessment function correctly performs a Query Age Assessment grouped by the Site variable using the Fisher method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| QueryAge_Assess | S9_2, S9_4, S9_5, S9_7 | T9_11 | Given appropriate Query Age data, the assessment function correctly performs a Query Age Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |

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| Function | Spec ID | Test ID | Test Description | Test Result |
|------------------|----------------------------|---------|--|-------------|
| QueryAge_Assess | S9_3, S9_4, S9_5, S9_7 | T9_12 | Given appropriate Query Age data, the assessment function correctly performs a Query Age Assessment grouped by the Site variable using the Normal Approximation method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| QueryRate_Assess | S10_1, S10_4, S10_5, S10_6 | T10_1 | Given an appropriate subset of Query Rate data, the assessment function correctly performs a Query Rate Assessment grouped by the Site variable using the Poisson method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| QueryRate_Assess | S10_1, S10_4, S10_5, S10_6 | T10_2 | Given an appropriate subset of Query Rate data, the assessment function correctly performs a Query Rate Assessment grouped by the Study variable using the Poisson method and correctly assigns Flag variable values. | Pass |
| QueryRate_Assess | S10_1, S10_4, S10_5 | T10_3 | Given appropriate Query Rate data, the assessment function correctly performs a Query Rate Assessment grouped by a custom variable using the Poisson method and correctly assigns Flag variable values. | Pass |
| QueryRate_Assess | S10_2, S10_4, S10_5, S10_6 | T10_4 | Given an appropriate subset of Query Rate data, the assessment function correctly performs a Query Rate Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| QueryRate_Assess | S10_2, S10_4, S10_5, S10_6 | T10_5 | Given an appropriate subset of Query Rate data, the assessment function correctly performs a Query Rate Assessment grouped by the Study variable using the Identity method and correctly assigns Flag variable values. | Pass |
| QueryRate_Assess | S10_2, S10_4, S10_5 | T10_6 | Given appropriate Query Rate data, the assessment function correctly performs a Query Rate Assessment grouped by a custom variable using the Identity method and correctly assigns Flag variable values. | Pass |
| QueryRate_Assess | S10_3, S10_4, S10_5, S10_6 | T10_7 | Given an appropriate subset of Query Rate data, the assessment function correctly performs a Query Rate Assessment grouped by the Site variable using the Normal Approximation method and correctly assigns Flag variable values when given a custom threshold. | Pass |

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| Function | Spec ID | Test ID | Test Description | Test Result |
|------------------|----------------------------|---------|--|-------------|
| QueryRate_Assess | S10_3, S10_4, S10_5, S10_6 | T10_8 | Given an appropriate subset of Query Rate data, the assessment function correctly performs a Query Rate Assessment grouped by the Study variable using the Normal Approximation method and correctly assigns Flag variable values. | Pass |
| QueryRate_Assess | S10_3, S10_4, S10_5 | T10_9 | Given appropriate Query Rate data, the assessment function correctly performs a Query Rate Assessment grouped by a custom variable using the Normal Approximation method and correctly assigns Flag variable values. | Pass |
| QueryRate_Assess | S10_1, S10_4, S10_5, S10_7 | T10_10 | Given appropriate Query Rate data, the assessment function correctly performs a Query Rate Assessment grouped by the Site variable using the Poisson method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| QueryRate_Assess | S10_2, S10_4, S10_5, S10_7 | T10_11 | Given appropriate Query Rate data, the assessment function correctly performs a Query Rate Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| QueryRate_Assess | S10_3, S10_4, S10_5, S10_7 | T10_12 | Given appropriate Query Rate data, the assessment function correctly performs a Query Rate Assessment grouped by the Site variable using the Normal Approximation method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| AE_Map_Raw | S11_1 | T11_1 | Raw+ Adverse Event data can be mapped correctly to create an analysis-ready input dataset that has properly merged demographics and Adverse Event data with one record per subject, omitting subjects with zero days of treatment exposure. | Pass |
| AE_Map_Raw | S11_1 | T11_2 | Raw+ Adverse Event data can be mapped correctly to create an analysis-ready input dataset that has all required columns in the default Raw+ mapping specifications. | Pass |
| AE_Map_Raw | S11_1 | T11_3 | Raw+ Adverse Event data can be mapped correctly to create an analysis-ready input dataset which accurately calculates the number of Adverse Events and days of treatment exposure per subject. | Pass |
| AE_Map_Raw | S11_1 | T11_4 | A subset of Raw+ Adverse Event data can be mapped correctly to create an analysis-ready input dataset. | Pass |

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| Function | Spec ID | Test ID | Test Description | Test Result |
|-------------------|---------|---------|--|-------------|
| DataChg_Map_Raw | S12_1 | T12_1 | Raw data entry data can be mapped correctly to create an analysis-ready input dataset that has properly merged demographics and data point change counts with one record per subject, omitting subjects with no reported data points. | Pass |
| DataChg_Map_Raw | S12_1 | T12_2 | Raw data entry data can be mapped correctly to create an analysis-ready input dataset that has all required columns in the default EDC mapping specifications. | Pass |
| DataChg_Map_Raw | S12_1 | T12_3 | Raw data entry data can be mapped correctly to create an analysis-ready input dataset which accurately calculates the number of times any data point changed for a given data page and the total number of data points reported per subject. | Pass |
| DataChg_Map_Raw | S12_1 | T12_4 | A subset of raw data entry data can be mapped correctly to create an analysis-ready input dataset. | Pass |
| DataEntry_Map_Raw | S13_1 | T13_1 | Raw data entry data can be mapped correctly to create an analysis-ready input dataset that has properly merged demographics and data entry lag counts with one record per subject, omitting subjects with no reported data pages. | Pass |
| DataEntry_Map_Raw | S13_1 | T13_2 | Raw data entry data can be mapped correctly to create an analysis-ready input dataset that has all required columns in the default EDC mapping specifications. | Pass |
| DataEntry_Map_Raw | S13_1 | T13_3 | Raw data entry data can be mapped correctly to create an analysis-ready input dataset which accurately calculates the number of data entry lag counts and total number of data pages reported per subject. | Pass |
| DataEntry_Map_Raw | S13_1 | T13_4 | A subset of raw data entry data can be mapped correctly to create an analysis-ready input dataset. | Pass |
| Disp_Map_Raw | S14_1 | T14_1 | Raw+ Study Disposition data can be mapped correctly to create an analysis-ready input dataset that has properly merged demographics and Study Disposition data with one record per subject. | Pass |
| Disp_Map_Raw | S14_1 | T14_2 | Raw+ Study Treatment Disposition data can be mapped correctly to create an analysis-ready input dataset that has properly merged demographics and Study Treatment Disposition data with one record per subject. | Pass |
| Disp_Map_Raw | S14_1 | T14_3 | Raw+ Study Disposition data can be mapped correctly to create an analysis-ready input dataset that has all required columns in the default Raw+ mapping specifications. | Pass |

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| Function | Spec ID | Test ID | Test Description | Test Result |
|-----------------|---------|---------|--|-------------|
| Disp_Map_Raw | S14_1 | T14_4 | Raw+ Study Treatment Disposition data can be mapped correctly to create an analysis-ready input dataset that has all required columns in the default Raw+ mapping specifications. | Pass |
| Disp_Map_Raw | S14_1 | T14_5 | Raw+ Study Disposition data can be mapped correctly to create an analysis-ready input dataset which accurately calculates the number of subjects who discontinued from the study. | Pass |
| Disp_Map_Raw | S14_1 | T14_6 | Raw+ Study Treatment Disposition data can be mapped correctly to create an analysis-ready input dataset which accurately calculates the number of subjects who discontinued use of study treatment. | Pass |
| Disp_Map_Raw | S14_1 | T14_7 | A subset of Raw+ Study Disposition data can be mapped correctly to create an analysis-ready input dataset. | Pass |
| Disp_Map_Raw | S14_1 | T14_8 | A subset of Raw+ Study Treatment Disposition data can be mapped correctly to create an analysis-ready input dataset. | Pass |
| LB_Map_Raw | S15_1 | T15_1 | Raw+ Labs data can be mapped correctly to create an analysis-ready input dataset that has properly merged demographics and abnormal lab data with one record per subject, omitting subjects with no reported lab values. | Pass |
| LB_Map_Raw | S15_1 | T15_2 | Raw+ Labs data can be mapped correctly to create an analysis-ready input dataset that has all required columns in the default Raw+ mapping specifications. | Pass |
| LB_Map_Raw | S15_1 | T15_3 | Raw+ Labs data can be mapped correctly to create an analysis-ready input dataset which accurately calculates the number of abnormal lab values and total number of lab values reported per subject. | Pass |
| LB_Map_Raw | S15_1 | T15_4 | A subset of Raw+ Labs data can be mapped correctly to create an analysis-ready input dataset. | Pass |
| PD_Map_Raw_Rate | S16_1 | T16_1 | Raw+ Protocol Deviation data can be mapped correctly to create an analysis-ready input dataset that has properly merged demographics and Protocol Deviation data with one record per subject, omitting subjects with zero days on study. | Pass |
| PD_Map_Raw_Rate | S16_1 | T16_2 | Raw+ Protocol Deviation data can be mapped correctly to create an analysis-ready input dataset that has all required columns in the default Raw+ mapping specifications. | Pass |

(continued)

| Function | Spec ID | Test ID | Test Description | Test Result |
|-------------------|---------|---------|---|-------------|
| PD_Map_Raw_Rate | S16_1 | T16_3 | Raw+ Protocol Deviation data can be mapped correctly to create an analysis-ready input dataset which accurately calculates the number of Protocol Deviations and days on study per subject. | Pass |
| PD_Map_Raw_Rate | S16_1 | T16_4 | A subset of Raw+ Protocol Deviation data can be mapped correctly to create an analysis-ready input dataset. | Pass |
| QueryAge_Map_Raw | S17_1 | T17_1 | Raw data query data can be mapped correctly to create an analysis-ready input dataset that has properly merged demographics and data query age counts with one record per subject, omitting subjects with no reported data queries. | Pass |
| QueryAge_Map_Raw | S17_1 | T17_2 | Raw data query data can be mapped correctly to create an analysis-ready input dataset that has all required columns in the default EDC mapping specifications. | Pass |
| QueryAge_Map_Raw | S17_1 | T17_3 | Raw data query data can be mapped correctly to create an analysis-ready input dataset which accurately calculates the number of data query age counts and total number of data queries reported per subject. | Pass |
| QueryAge_Map_Raw | S17_1 | T17_4 | A subset of raw data query data can be mapped correctly to create an analysis-ready input dataset. | Pass |
| QueryRate_Map_Raw | S18_1 | T18_1 | Raw data query data can be mapped correctly to create an analysis-ready input dataset that has properly merged demographics, data query rates, and data point counts with one record per subject, omitting subjects with no reported data points. | Pass |
| QueryRate_Map_Raw | S18_1 | T18_2 | Raw data query data can be mapped correctly to create an analysis-ready input dataset that has all required columns in the default EDC mapping specifications. | Pass |
| QueryRate_Map_Raw | S18_1 | T18_3 | Raw data query data can be mapped correctly to create an analysis-ready input dataset which accurately calculates the query rate (i.e., the number of data queries over the total number of data points) per subject. | Pass |
| QueryRate_Map_Raw | S18_1 | T18_4 | A subset of raw data query data can be mapped correctly to create an analysis-ready input dataset. | Pass |
| QueryRate_Map_Raw | S18_1 | T18_5 | Raw data query data can be mapped correctly to create an analysis-ready input dataset where the sum of the variable Count is equivalent to the number of rows in the source 'edc_queries' dataset. | Pass |

(continued)

| Function | Spec ID | Test ID | Test Description | Test Result |
|-------------------|--------------|---------|--|-------------|
| QueryRate_Map_Raw | S18_1 | T18_6 | Raw data query data can be mapped correctly to create an analysis-ready input dataset where the sum of Count/Rate is equivalent to the number of rows in the original 'edc_data_points' dataset. | Pass |
| FilterDomain | S19_1 | T19_1 | Given pre-specified mapping, input data can be filtered to produce a data frame with the correct number of rows. | Pass |
| FilterDomain | S19_1 | T19_2 | Given pre-specified mapping, input data can be filtered to produce a data frame which retains all original source columns. | Pass |
| Get_Enrolled | S20_1 | T20_1 | Given correct input data and metadata, the correct number of enrolled participants per study can be derived. | Pass |
| Get_Enrolled | S20_2 | T20_2 | Given correct input data and metadata, the correct number of sites per study can be derived. | Pass |
| Get_Enrolled | S20_3 | T20_3 | Given correct input data and metadata, the correct number of enrolled participants per site can be derived. | Pass |
| MergeSubjects | S21_1 | T21_1 | Domain-level data can be correctly merged into subject-level data using subject ID as the key variable. | Pass |
| is_mapping_valid | S22_1 | T22_1 | The utility function can correctly evaluate that the input data is or is not a data frame. | Pass |
| is_mapping_valid | S22_1 | T22_2 | The utility function can correctly evaluate that the input data frame has or does not have the expected columns. | Pass |
| is_mapping_valid | S22_2 | T22_3 | The utility function can correctly evaluate that the input mapping(s) is(are) or is(are) not a list. | Pass |
| is_mapping_valid | S22_2 | T22_4 | The utility function can correctly evaluate that the elements of the input mapping(s) are or are not of character class. | Pass |
| is_mapping_valid | S22_2, S22_3 | T22_5 | The utility function can correctly evaluate that the input mapping(s) have or do not have all required parameters. | Pass |
| is_mapping_valid | S22_3 | T22_6 | The utility function can correctly evaluate that the input parameter specifications are or are not a list. | Pass |
| is_mapping_valid | S22_3 | T22_7 | The utility function can correctly evaluate if NA values are or are not acceptable in given columns depending on the vNACols component of the input parameter specifications. | Pass |
| is_mapping_valid | S22_3 | T22_8 | The utility function can correctly evaluate if empty string values are or are not acceptable in given columns depending on the vNACols component of the input parameter specifications. | Pass |

(continued)

| Function | Spec ID | Test ID | Test Description | Test Result |
|------------------|----------------------------|---------|---|-------------|
| is_mapping_valid | S22_3 | T22_9 | The utility function can correctly evaluate if duplicate values are or are not acceptable in given columns depending on the vUniqueCols component of the input parameter specifications. | Pass |
| PD_Assess_Binary | S23_1, S23_4, S23_5, S23_6 | T23_1 | Given an appropriate subset of Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by the Site variable using the Poisson method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| PD_Assess_Binary | S23_1, S23_4, S23_5, S23_6 | T23_2 | Given an appropriate subset of Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by the Study variable using the Poisson method and correctly assigns Flag variable values. | Pass |
| PD_Assess_Binary | S23_1, S23_4, S23_5 | T23_3 | Given appropriate Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by a custom variable using the Poisson method and correctly assigns Flag variable values. | Pass |
| PD_Assess_Binary | S23_2, S23_4, S23_5, S23_6 | T23_4 | Given an appropriate subset of Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values when given a custom threshold. | Pass |
| PD_Assess_Binary | S23_2, S23_4, S23_5, S23_6 | T23_5 | Given an appropriate subset of Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by a custom variable using the Identity method and correctly assigns Flag variable values. | Pass |
| PD_Assess_Binary | S23_2, S23_4, S23_5 | T23_6 | Given appropriate Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values. | Pass |
| PD_Assess_Binary | S23_3, S23_4, S23_5, S23_6 | T23_7 | Given an appropriate subset of Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by the Site variable using the Normal Approximation method and correctly assigns Flag variable values when given a custom threshold. | Pass |

(continued)

| Function | Spec ID | Test ID | Test Description | Test Result |
|-------------------|----------------------------|---------|--|-------------|
| PD_Assess_Binary | S23_3, S23_4, S23_5, S23_6 | T23_8 | Given an appropriate subset of Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by the Study variable using the Normal Approximation method and correctly assigns Flag variable values. | Pass |
| PD_Assess_Binary | S23_3, S23_4, S23_5 | T23_9 | Given appropriate Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by a custom variable using the Normal Approximation method and correctly assigns Flag variable values. | Pass |
| PD_Assess_Binary | S23_1, S23_4, S23_5, S23_7 | T23_10 | Given appropriate Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by the Site variable using the Poisson method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| PD_Assess_Binary | S23_2, S23_4, S23_5, S23_7 | T23_11 | Given appropriate Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by the Site variable using the Identity method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| PD_Assess_Binary | S23_3, S23_4, S23_5, S23_7 | T23_12 | Given appropriate Protocol Deviation data, the assessment function correctly performs a Protocol Deviation Assessment grouped by the Site variable using the Normal Approximation method and correctly assigns Flag variable values when given a custom threshold, and Flag variable values are set to NA for sites with low enrollment. | Pass |
| PD_Map_Raw_Binary | S24_1 | T24_1 | Raw+ Protocol Deviation data can be mapped correctly to create an analysis-ready input dataset that has properly merged demographics and Protocol Deviation data with one record per subject, omitting subjects with zero days on study. | Pass |
| PD_Map_Raw_Binary | S24_1 | T24_2 | Raw+ Protocol Deviation data can be mapped correctly to create an analysis-ready input dataset that has all required columns in the default Raw+ mapping specifications. | Pass |
| PD_Map_Raw_Binary | S24_1 | T24_3 | Raw+ Protocol Deviation data can be mapped correctly to create an analysis-ready input dataset, which accurately indicates if there are Protocol Deviations associated with each subject (0 = no associated Protocol Deviations, 1 = associated Protocol Deviations). | Pass |

(continued)

| Function | Spec ID | Test ID | Test Description | Test Result |
|-------------------|---------|---------|---|-------------|
| PD_Map_Raw_Binary | S24_1 | T24_4 | A subset of Raw+ Protocol Deviation data can be mapped correctly to create an analysis-ready input dataset. | Pass |

6 Unit Tests

6.1 Unit Testing Overview

Unit testing was performed in addition to qualification testing to help ensure that individual pieces of code within the R package function correctly and produce the expected results. By testing individual units of code in isolation, developers can identify and fix issues early in the development process before more significant and scaled problems arise.

6.2 Unit Test Coverage

The table below summarizes unit test coverage of each `{gsm}` function. This metric quantifies the extent of unit testing. The closer this measure is to 100%, the more unit testing that function has.

| Function | File Coverage |
|--|---------------|
| R/AE_Assess.R | 99.19 % |
| R/AE_Map_Adam.R | 97.73 % |
| R/AE_Map_Raw.R | 100.00 % |
| R/Analyze_Fisher.R | 100.00 % |
| R/Analyze_Identity.R | 100.00 % |
| R/Analyze_NormalApprox_PredictBounds.R | 94.64 % |
| R/Analyze_NormalApprox.R | 100.00 % |
| R/Analyze_Poisson_PredictBounds.R | 89.80 % |
| R/Analyze_Poisson.R | 100.00 % |
| R/Analyze_QTL.R | 100.00 % |
| R/barChart.R | 84.00 % |
| R/CheckSnapshotInputs.R | 100.00 % |
| R/Consent_Assess.R | 98.46 % |
| R/Consent_Map_Raw.R | 88.89 % |
| R/DataChg_Assess.R | 97.37 % |
| R/DataChg_Map_Raw.R | 100.00 % |
| R/DataEntry_Assess.R | 97.37 % |
| R/DataEntry_Map_Raw.R | 100.00 % |
| R/Disp_Assess.R | 96.77 % |
| R/Disp_Map_Raw.R | 100.00 % |
| R/ExportCode.R | 89.72 % |
| R/Flag_Fisher.R | 100.00 % |
| R/Flag_NormalApprox.R | 100.00 % |
| R/Flag_Poisson.R | 100.00 % |
| R/Flag_QTL.R | 100.00 % |
| R/Flag.R | 100.00 % |
| R/Get_Enrolled.R | 100.00 % |
| R/IE_Assess.R | 98.46 % |
| R/IE_Map_Raw.R | 100.00 % |
| R/is_workflow_valid.R | 100.00 % |
| R/LB_Assess.R | 97.37 % |
| R/LB_Map_Raw.R | 100.00 % |
| R/Make_Snapshot.R | 98.90 % |
| R/Overview_Table.R | 100.00 % |
| R/PD_Assess_Binary.R | 96.00 % |
| R/PD_Assess_Rate.R | 95.20 % |
| R/PD_Map_Raw_Binary.R | 100.00 % |
| R/PD_Map_Raw_Rate.R | 100.00 % |
| R/QueryAge_Assess.R | 97.37 % |

(continued)

| Function | File Coverage |
|-----------------------------------|---------------|
| R/QueryAge_Map_Raw.R | 100.00 % |
| R/QueryRate_Assess.R | 91.13 % |
| R/QueryRate_Map_Raw.R | 100.00 % |
| R/RunQTL.R | 100.00 % |
| R/SaveQTL.R | 90.48 % |
| R/scatterPlot.R | 84.00 % |
| R/Screening_Assess.R | 93.55 % |
| R/Screening_Map_Raw.R | 100.00 % |
| R/Study_Assess.R | 92.16 % |
| R/Study_AssessmentReport.R | 100.00 % |
| R/Study_Report.R | 0.00 % |
| R/Summarize.R | 100.00 % |
| R/tests-assess_helpers.R | 68.75 % |
| R/tests-map_raw_helpers.R | 85.19 % |
| R/Transform_Count.R | 100.00 % |
| R/Transform_Rate.R | 100.00 % |
| R/UpdateParams.R | 100.00 % |
| R/util-build_markdown.R | 0.00 % |
| R/util-CheckClindataMeta.R | 100.00 % |
| R/util-CheckInputs.R | 100.00 % |
| R/util-ConsolidateStrata.R | 100.00 % |
| R/util-FilterData.R | 96.67 % |
| R/util-FilterDomain.R | 100.00 % |
| R/util-generate_md_table.R | 0.00 % |
| R/util-is_mapping_valid.R | 100.00 % |
| R/util-kri_directionality_logo.R | 84.62 % |
| R/util-MakeDfConfig.R | 100.00 % |
| R/util-MakeStratifiedAssessment.R | 92.86 % |
| R/util-MakeWorkflowList.R | 100.00 % |
| R/util-MergeSubjects.R | 97.73 % |
| R/util-parse_data_mapping.R | 0.00 % |
| R/util-parse_data_spec.R | 0.00 % |
| R/util-ParseWarnings.R | 100.00 % |
| R/util-rank_chg.R | 100.00 % |
| R/util-RunStep.R | 100.00 % |
| R/util-RunStratifiedWorkflow.R | 90.91 % |
| R/util-RunWorkflow.R | 90.24 % |
| R/util-UpdateGSMVersion.R | 0.00 % |
| R/Visualize_Scatter.R | 100.00 % |
| R/Visualize_Score.R | 100.00 % |
| R/Visualize_Workflow.R | 98.44 % |
| Total Coverage | 92.93 % |

7 Qualification Testing Environment

7.1 Session Information

R version 4.2.0 (2022-04-22)

Platform: x86_64-pc-linux-gnu (64-bit)

locale: *LC_CTYPE=C.UTF-8, LC_NUMERIC=C, LC_TIME=C.UTF-8, LC_COLLATE=C.UTF-8, LC_MONETARY=C.UTF-8, LC_MESSAGES=C.UTF-8, LC_PAPER=C.UTF-8, LC_NAME=C, LC_ADDRESS=C, LC_TELEPHONE=C, LC_MEASUREMENT=C.UTF-8 and LC_IDENTIFICATION=C*

attached base packages: *stats, graphics, grDevices, utils, datasets, methods and base*

other attached packages: *gsm(v.1.5.0), riskmetric(v.0.2.0), gh(v.1.4.0), pander(v.0.6.5), knitr(v.1.42), lubridate(v.1.9.2), forcats(v.1.0.0), stringr(v.1.5.0), dplyr(v.1.1.0), purrr(v.1.0.1), readr(v.2.1.4), tidyr(v.1.3.0), tibble(v.3.2.0), ggplot2(v.3.4.1), tidyverse(v.2.0.0), rvest(v.1.0.3) and testthat(v.3.1.6)*

loaded via a namespace (and not attached): *colorspace(v.2.1-0), selectr(v.0.4-2), ellipsis(v.0.3.2), rprojroot(v.2.0.3), fs(v.1.6.1), rstudioapi(v.0.14), waldo(v.0.4.0), urltools(v.1.7.3), remotes(v.2.4.2), DT(v.0.27), bit64(v.4.0.5), fansi(v.1.0.4), xml2(v.1.3.3), R.methodsS3(v.1.8.2), cachem(v.1.0.7), pkgload(v.1.3.2), jsonlite(v.1.8.4), gt(v.0.8.0), broom(v.1.0.3), R.oo(v.1.25.0), shiny(v.1.7.4.9001), BiocManager(v.1.30.20), DiagrammeR(v.1.0.9), compiler(v.4.2.0), httr(v.1.4.5), tictoc(v.1.1), backports(v.1.4.1), lazyeval(v.0.2.2), assertthat(v.0.2.1), fastmap(v.1.1.1), cli(v.3.6.0), later(v.1.3.0), visNetwork(v.2.1.2), htmltools(v.0.5.4.9000), prettyunits(v.1.1.1), tools(v.4.2.0), gtable(v.0.3.1), glue(v.1.6.2), Rcpp(v.1.0.10), jquerylib(v.0.1.4), styler(v.1.9.1), vctrs(v.0.6.0), lamW(v.2.1.2), svglite(v.2.1.1), clindata(v.0.14.1), xfun(v.0.37), ps(v.1.7.2), brio(v.1.1.3), timechange(v.0.2.0), mime(v.0.12), miniUI(v.0.1.1.1), lifecycle(v.1.0.3), devtools(v.2.4.5), scales(v.1.2.1), hms(v.1.1.2), promises(v.1.2.0.1), rex(v.1.2.1), RColorBrewer(v.1.1-3), yaml(v.2.3.7), curl(v.5.0.0), memoise(v.2.0.1), sass(v.0.4.5), triebeard(v.0.4.1), stringi(v.1.7.12), desc(v.1.4.2), pkgbuild(v.1.4.0), systemfonts(v.1.0.4), rlang(v.1.1.0), pkgconfig(v.2.0.3), prompt(v.1.0.1), evaluate(v.0.20), data-pasta(v.3.1.0), fontawesome(v.0.5.0), htmlwidgets(v.1.6.1), bit(v.4.0.5), processx(v.3.8.0), tidyselect(v.1.2.0), here(v.1.0.1), magrittr(v.2.0.3), R6(v.2.5.1), generics(v.0.1.3), profvis(v.0.3.7), pillar(v.1.8.1), withr(v.2.5.0), crayon(v.1.5.2), utf8(v.1.2.3), tzdb(v.0.3.0), rmarkdown(v.2.20), urlchecker(v.1.0.1), usethis(v.2.1.6), grid(v.4.2.0), data.table(v.1.14.8), callr(v.3.7.3), cranlogs(v.2.1.1), webshot(v.0.5.4), reprex(v.2.0.2), digest(v.0.6.31), xtable(v.1.8-4), R.cache(v.0.16.0), covr(v.3.6.1), httpuv(v.1.6.9), R.utils(v.2.12.2), arrow(v.11.0.0.3), RcppParallel(v.5.1.7), munsell(v.0.5.0), viridisLite(v.0.4.1), kableExtra(v.1.3.4), bslib(v.0.4.2) and sessioninfo(v.1.2.2)*

7.2 Package List

The table below utilizes the `riskmetric` package, which quantifies the robustness of an R package. The `pkg_score` column captures the risk involved with using a package. The risk level ranges from 0 (low risk) to 1 (high risk).

| package | version | pkg_score |
|-------------|---------|-----------|
| broom | 1.0.3 | 0.387 |
| cli | 3.6.0 | 0.481 |
| DiagrammeR | 1.0.9 | 0.540 |
| dplyr | 1.1.0 | 0.451 |
| DT | 0.27 | 0.494 |
| fontawesome | 0.5.0 | 0.415 |
| fs | 1.6.1 | 0.411 |
| glue | 1.6.2 | 0.360 |
| gt | 0.8.0 | 0.509 |
| ggplot2 | 3.4.1 | 0.470 |
| htmlwidgets | 1.6.1 | 0.379 |
| here | 1.0.1 | 0.354 |
| knitr | 1.42 | 0.570 |
| lamW | 2.1.2 | 0.571 |
| lifecycle | 1.0.3 | 0.383 |
| magrittr | 2.0.3 | 0.349 |
| purrr | 1.0.1 | 0.448 |
| rmarkdown | 2.20 | 0.458 |
| rstudioapi | 0.14 | 0.407 |
| stringr | 1.5.0 | 0.436 |
| tibble | 3.2.0 | 0.435 |
| tidyr | 1.3.0 | 0.460 |
| yaml | 2.3.7 | 0.508 |
| rlang | 1.1.0 | 0.464 |

8 Pull Request History

8.0.1 Pull Request 1121: Fix 1079 - Updated Qual Report Rmd

Merging fix-1079 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1121>

| Requester | Date Requested | Reviewers | Review Status |
|-------------------|------------------------|-----------|-------------------|
| colleenmclaughlin | 2023-03-20 21:10:50 | | CHANGES_REQUESTED |

8.0.2 Pull Request 1119: Update protocol deviation mapping.

Merging fix-1096-pd into dev

<https://github.com/Gilead-BioStats/gsm/pull/1119>

| Requester | Date Requested | Reviewers | Review Status |
|-----------|------------------------|--|---------------|
| samussiah | 2023-03-16 17:24:22 | chelseadickens Zhongkai-Wang colleenmclaughlin | APPROVED |

8.0.3 Pull Request 1117: Fix 1096 Qualification - Aligning Qual. Tests with Updates

Merging fix-1096-qualification into fix-1096

<https://github.com/Gilead-BioStats/gsm/pull/1117>

| Requester | Date Requested | Reviewers | Review Status |
|-------------------|------------------------|---------------|---------------|
| colleenmclaughlin | 2023-03-16 16:39:09 | Zhongkai-Wang | APPROVED |

8.0.4 Pull Request 1115: Fix 1086 - Add Unit Tests/Code Coverage

Merging fix-1086 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1115>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|---------------|---------------|
| mattroumaya | 2023-03-14 22:02:17 | Zhongkai-Wang | COMMENTED |

8.0.5 Pull Request 1114: update qualification_analyze_normalapprox() in helper-qualification.R

Merging fix-1113 into fix-1107

<https://github.com/Gilead-BioStats/gsm/pull/1114>

| Requester | Date Requested | Reviewers | Review Status |
|----------------|------------------------|-----------|---------------|
| chelseadickens | 2023-03-14 20:22:08 | | APPROVED |

8.0.6 Pull Request 1112: Fix 1107 - Update Analyze_NormalApprox

Merging fix-1107 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1112>

| Requester | Date Requested | Reviewers | Review Status |
|---------------|------------------------|--------------------------------------|---------------|
| Zhongkai-Wang | 2023-03-13 14:15:05 | chelseadickens collleenmclaughlin | COMMENTED |

8.0.7 Pull Request 1104: Update domain and column mappings.

Merging fix-1096 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1104>

| Requester | Date Requested | Reviewers | Review Status |
|-----------|------------------------|---|---------------|
| samussiah | 2023-03-10 17:13:41 | chelseadickens Zhongkai-Wang collleenmclaughlin | APPROVED |

8.0.8 Pull Request 1103: Fix 1099, 1100, 1102

Merging fix-1100 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1103>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2023-03-09 20:53:15 | | APPROVED |

8.0.9 Pull Request 1093: Fix 1066 - update qualification test ordering

Merging fix-1066 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1093>

| Requester | Date Requested | Reviewers | Review Status |
|----------------|------------------------|--------------------|---------------|
| chelseadickens | 2023-03-02 18:53:34 | collleenmclaughlin | COMMENTED |

8.0.10 Pull Request 1090: Fix 1080

Merging fix-1080 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1090>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2023-02-28 22:32:51 | | |

8.0.11 Pull Request 1088: Fix 1083 - update meta_workflow

Merging fix-1083 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1088>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|---------------|---------------|
| mattroumaya | 2023-02-24 21:17:47 | Zhongkai-Wang | COMMENTED |

8.0.12 Pull Request 1087: Fix 1066 - Test Script Language Update

Merging fix-1066 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1087>

| Requester | Date Requested | Reviewers | Review Status |
|-------------------|------------------------|-----------|---------------|
| colleenmclaughlin | 2023-02-23 22:58:44 | | APPROVED |

8.0.13 Pull Request 1075: Fix 1074 - update data

Merging fix-1074 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1075>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2023-02-21 19:34:30 | | APPROVED |

8.0.14 Pull Request 1073: Fix 1035 - add badge to documentation

Merging fix-1035 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1073>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-------------------|---------------|
| mattroumaya | 2023-02-20 22:08:49 | colleenmclaughlin | APPROVED |

8.0.15 Pull Request 1072: Fix 1052 - util-is_mapping_valid() Qual. Tests

Merging fix-1052 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1072>

| Requester | Date Requested | Reviewers | Review Status |
|-------------------|------------------------|-----------|---------------|
| colleenmclaughlin | 2023-02-16 16:58:39 | | APPROVED |

8.0.16 Pull Request 1071: Fix 1070 - add flag counts to report

Merging fix-1070 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1071>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|---|---------------|
| mattroumaya | 2023-02-15 22:32:44 | jwildfire chelseadickens colleenmclaughlin | APPROVED |

8.0.17 Pull Request 1068: Fix 1061 - fix report error log

Merging fix-1061 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1068>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-------------------------------------|---------------|
| mattroumaya | 2023-02-14 17:58:44 | chelseadickens colleenmclaughlin | APPROVED |

8.0.18 Pull Request 1067: Fix 1065 - update is_mapping_valid

Merging fix-1065 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1067>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|---------------|---------------|
| mattroumaya | 2023-02-13 21:20:52 | Zhongkai-Wang | APPROVED |

8.0.19 Pull Request 1064: Add input data schema to {gsm}.

Merging fix-639 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1064>

| Requester | Date Requested | Reviewers | Review Status |
|-----------|------------------------|-------------|---------------|
| samussiah | 2023-02-08 17:43:58 | mattroumaya | |

8.0.20 Pull Request 1063: Sync dev and main

Merging main into dev

<https://github.com/Gilead-BioStats/gsm/pull/1063>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|------------------------|---------------|
| mattroumaya | 2023-02-07 21:52:21 | jwildfire samussiah | APPROVED |

8.0.21 Pull Request 1059: Fix 1057 - PD_Map_Raw() Qual. Tests Updates

Merging fix-1057 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1059>

| Requester | Date Requested | Reviewers | Review Status |
|--------------------|------------------------|-----------|---------------|
| collleenmclaughlin | 2023-02-02 22:35:08 | | APPROVED |

8.0.22 Pull Request 1056: Fix-1049: Update non-serious AE KRI to include all AEs

Merging fix-1049 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1056>

| Requester | Date Requested | Reviewers | Review Status |
|---------------|------------------------|-----------|---------------|
| Zhongkai-Wang | 2023-02-02 16:27:28 | | APPROVED |

8.0.23 Pull Request 1055: Release v1.5.0

Merging release-v1.5.0 into main

<https://github.com/Gilead-BioStats/gsm/pull/1055>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|----------------------------|---------------|
| mattroumaya | 2023-02-01 22:29:19 | samussiah Zhongkai-Wang | COMMENTED |

8.0.24 Pull Request 1054: Fix 929 - util-FilterDomain() Qual. Tests

Merging fix-929 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1054>

| Requester | Date Requested | Reviewers | Review Status |
|--------------------|------------------------|-----------|---------------|
| collleenmclaughlin | 2023-02-01 20:40:59 | | APPROVED |

8.0.25 Pull Request 1051: Fix 935 - util-MergeSubjects() Qual. Test

Merging fix-935 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1051>

| Requester | Date Requested | Reviewers | Review Status |
|-------------------|------------------------|-----------|---------------|
| colleenmclaughlin | 2023-02-01 19:40:33 | | APPROVED |

8.0.26 Pull Request 1048: Fix 932 - Get_Enrolled() Qual. Tests

Merging fix-932 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1048>

| Requester | Date Requested | Reviewers | Review Status |
|-------------------|------------------------|-----------|---------------|
| colleenmclaughlin | 2023-02-01 18:00:11 | | APPROVED |

8.0.27 Pull Request 1046: qualification specs management

Merging fix-1016 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1046>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------------------------|---------------|
| mattroumaya | 2023-01-30 23:21:19 | samussiah colleenmclaughlin | APPROVED |

8.0.28 Pull Request 1044: Fix 1034 - Qual Scraping Function

Merging fix-1034 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1044>

| Requester | Date Requested | Reviewers | Review Status |
|-------------------|------------------------|---------------------------------|---------------|
| colleenmclaughlin | 2023-01-30 21:22:42 | chelseadickens Zhongkai-Wang | APPROVED |

8.0.29 Pull Request 1042: tweaks

Merging fix-1003-review into fix-1003

<https://github.com/Gilead-BioStats/gsm/pull/1042>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2023-01-26 03:19:19 | | APPROVED |

8.0.30 Pull Request 1041: Fix 905 - Create stats vignette

Merging fix-905 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1041>

| Requester | Date Requested | Reviewers | Review Status |
|---------------|------------------------|--------------------------|---------------|
| Zhongkai-Wang | 2023-01-25 14:03:37 | jwildfire mattroumaya | APPROVED |

8.0.31 Pull Request 1040: Fix 1003 - Update IPD QTL

Merging fix-1003 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1040>

| Requester | Date Requested | Reviewers | Review Status |
|---------------|------------------------|-----------|---------------|
| Zhongkai-Wang | 2023-01-25 13:51:13 | samussiah | COMMENTED |

8.0.32 Pull Request 1039: Fix 967 - Check workflow list for Make_Snapshot

Merging fix-967 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1039>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2023-01-24 22:44:07 | jwildfire | DISMISSED |

8.0.33 Pull Request 1038: 987/1031 - resolve conflicts

Merging 987-subset-oriented-qualification-tests into 1031-qual-tests-for-nmindenominator

<https://github.com/Gilead-BioStats/gsm/pull/1038>

| Requester | Date Requested | Reviewers | Review Status |
|----------------|------------------------|-----------|---------------|
| chelseadickens | 2023-01-24 21:46:39 | | |

8.0.34 Pull Request 1037: Add Estimate to QTL output.

Merging fix-894 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1037>

| Requester | Date Requested | Reviewers | Review Status |
|-----------|------------------------|-----------|---------------|
| samussiah | 2023-01-24 14:40:21 | | APPROVED |

8.0.35 Pull Request 1036: Fix 1031; 987; 1058 - qual tests for nMinDenominator + subset-oriented tests + PD_Assess() updates

Merging 1031-qual-tests-for-nmindenominator into dev

<https://github.com/Gilead-BioStats/gsm/pull/1036>

| Requester | Date Requested | Reviewers | Review Status |
|----------------|------------------------|-----------|---------------|
| chelseadickens | 2023-01-23 20:48:23 | | COMMENTED |

8.0.36 Pull Request 1032: Fix 987 - subset oriented qualification tests

Merging 987-subset-oriented-qualification-tests into dev

<https://github.com/Gilead-BioStats/gsm/pull/1032>

| Requester | Date Requested | Reviewers | Review Status |
|----------------|------------------------|----------------------------|---------------|
| chelseadickens | 2023-01-20 21:43:35 | samussiah Zhongkai-Wang | |

8.0.37 Pull Request 1030: Update mappings to more easily integrate with safetyGraphics for gsmApp.

Merging consistent-mappings into dev

<https://github.com/Gilead-BioStats/gsm/pull/1030>

| Requester | Date Requested | Reviewers | Review Status |
|-----------|------------------------|-------------------------------------|---------------|
| samussiah | 2023-01-20 18:25:31 | chelseadickens colleenmclaughlin | APPROVED |

8.0.38 Pull Request 1028: Fix 988 even more tweaks

Merging fix-988-tweaks-tweak into fix-988-tweaks

<https://github.com/Gilead-BioStats/gsm/pull/1028>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2023-01-19 22:13:59 | | APPROVED |

8.0.39 Pull Request 1027: Reposition dropdown to remain visible throughout report.

Merging fix-988-tweaks into fix-988

<https://github.com/Gilead-BioStats/gsm/pull/1027>

| Requester | Date Requested | Reviewers | Review Status |
|-----------|------------------------|-------------|---------------|
| samussiah | 2023-01-19 19:15:45 | mattroumaya | |

8.0.40 Pull Request 1026: Fix 639; 1025 - fix barcharts + warning during rcmd check

Merging fix-639 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1026>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2023-01-18 20:42:30 | | COMMENTED |

8.0.41 Pull Request 1023: Fix 988 - report-level site dropdown

Merging fix-988 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1023>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2023-01-17 22:43:46 | | APPROVED |

8.0.42 Pull Request 1022: Fix 962 - clean up Make__Snapshot() merging

Merging fix-962 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1022>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2023-01-17 16:10:19 | samussiah | APPROVED |

8.0.43 Pull Request 1019: Fix 1018 - Minor Qual. Test Updates

Merging fix-1018 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1019>

| Requester | Date Requested | Reviewers | Review Status |
|-------------------|------------------------|-----------|---------------|
| colleenmclaughlin | 2023-01-13 17:54:14 | | APPROVED |

8.0.44 Pull Request 1017: Fix 941 - QueryRate_Map_Raw() Qual. Tests

Merging fix-941 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1017>

| Requester | Date Requested | Reviewers | Review Status |
|-------------------|------------------------|-----------|---------------|
| colleenmclaughlin | 2023-01-13 16:36:17 | | COMMENTED |

8.0.45 Pull Request 1015: Fix 1014 - update reporting functions

Merging fix-1014 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1015>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|---------------|---------------|
| mattroumaya | 2023-01-12 22:12:52 | Zhongkai-Wang | COMMENTED |

8.0.46 Pull Request 1013: Fix 966 - update rbm-viz function docs

Merging fix-966 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1013>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2023-01-12 20:48:55 | | APPROVED |

8.0.47 Pull Request 1011: Update rbm-viz to v1.0.0 .

Merging fix-1010 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1011>

| Requester | Date Requested | Reviewers | Review Status |
|-----------|------------------------|-----------|---------------|
| samussiah | 2023-01-11 20:14:47 | | APPROVED |

8.0.48 Pull Request 1009: Fix-1005 - Additional update to correct counting and merging logic

Merging fix-1005-more into dev

<https://github.com/Gilead-BioStats/gsm/pull/1009>

| Requester | Date Requested | Reviewers | Review Status |
|---------------|------------------------|-------------------|---------------|
| Zhongkai-Wang | 2023-01-11 15:30:02 | colleenmclaughlin | APPROVED |

8.0.49 Pull Request 1008: Fix 1006 - make flowchart optional

Merging fix-1006 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1008>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|----------------------------|---------------|
| mattroumaya | 2023-01-10 22:53:52 | jwildfire Zhongkai-Wang | APPROVED |

8.0.50 Pull Request 1007: Fix 1005 - QueryRate_Map_Raw Grouping

Merging fix-1005 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1007>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|------------------------------|---------------|
| mattroumaya | 2023-01-10 17:22:04 | samussiah collleenmclaughlin | APPROVED |

8.0.51 Pull Request 1004: Fix 520 - add ability to export code from workflow, IData, and IMapping

Merging fix-520 into dev

<https://github.com/Gilead-BioStats/gsm/pull/1004>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2023-01-09 22:10:48 | jwildfire | COMMENTED |

8.0.52 Pull Request 1002: fix 925 - qualify DataEntry_Assess

Merging 925-qualify-dataentry_assess into dev

<https://github.com/Gilead-BioStats/gsm/pull/1002>

| Requester | Date Requested | Reviewers | Review Status |
|----------------|------------------------|-----------|---------------|
| chelseadickens | 2023-01-06 15:44:35 | | APPROVED |

8.0.53 Pull Request 1001: fix 923 - qualify DataChg_Assess

Merging 923-qualify-datachg_assess into dev

<https://github.com/Gilead-BioStats/gsm/pull/1001>

| Requester | Date Requested | Reviewers | Review Status |
|----------------|------------------------|-----------|---------------|
| chelseadickens | 2023-01-06 15:23:23 | | APPROVED |

8.0.54 Pull Request 1000: fix 938 - qualify QueryAge_Assess

Merging 938-qualify-queryage_assess into dev

<https://github.com/Gilead-BioStats/gsm/pull/1000>

| Requester | Date Requested | Reviewers | Review Status |
|----------------|------------------------|-----------|---------------|
| chelseadickens | 2023-01-06 14:58:19 | | APPROVED |

8.0.55 Pull Request 999: fix 940 - qualify QueryRate_Assess

Merging 940-qualify-queryrate_assess into dev

<https://github.com/Gilead-BioStats/gsm/pull/999>

| Requester | Date Requested | Reviewers | Review Status |
|----------------|------------------------|-----------|---------------|
| chelseadickens | 2023-01-06 14:51:37 | | APPROVED |

8.0.56 Pull Request 998: Fix 965 - add missing unit tests

Merging fix-965 into dev

<https://github.com/Gilead-BioStats/gsm/pull/998>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2023-01-05 22:27:06 | | APPROVED |

8.0.57 Pull Request 997: Data model fixes

Merging data-model-fixes into dev

<https://github.com/Gilead-BioStats/gsm/pull/997>

| Requester | Date Requested | Reviewers | Review Status |
|-----------|------------------------|------------------------------------|---------------|
| samussiah | 2023-01-05 22:09:30 | Zhongkai-Wang colleenmclaughlin | APPROVED |

8.0.58 Pull Request 996: Fix 939 - QueryAge_Map_Raw() Qual. Tests

Merging fix-939 into dev

<https://github.com/Gilead-BioStats/gsm/pull/996>

| Requester | Date Requested | Reviewers | Review Status |
|-------------------|------------------------|-----------|---------------|
| colleenmclaughlin | 2023-01-05 22:04:51 | | APPROVED |

8.0.59 Pull Request 995: Fix 926 - DataEntry_Map_Raw() Qual. Tests

Merging fix-926 into dev

<https://github.com/Gilead-BioStats/gsm/pull/995>

| Requester | Date Requested | Reviewers | Review Status |
|-------------------|------------------------|-----------|---------------|
| colleenmclaughlin | 2023-01-05 14:58:53 | | APPROVED |

8.0.60 Pull Request 992: Fix 924 - DataChg_Map_Raw() Qual. Tests

Merging fix-924 into dev

<https://github.com/Gilead-BioStats/gsm/pull/992>

| Requester | Date Requested | Reviewers | Review Status |
|-------------------|------------------------|-----------|---------------|
| colleenmclaughlin | 2023-01-04 19:57:21 | | APPROVED |

8.0.61 Pull Request 991: Fix 924 - DataChg_Map_Raw() Qual. Tests

Merging fix-924 into dev

<https://github.com/Gilead-BioStats/gsm/pull/991>

| Requester | Date Requested | Reviewers | Review Status |
|-------------------|------------------------|-----------|---------------|
| colleenmclaughlin | 2023-01-04 19:20:45 | | |

8.0.62 Pull Request 990: multiple select

Merging fix-984-multiple into dev

<https://github.com/Gilead-BioStats/gsm/pull/990>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2023-01-03 18:30:48 | | |

8.0.63 Pull Request 989: Fix 986 - make unit tests faster

Merging fix-986 into dev

<https://github.com/Gilead-BioStats/gsm/pull/989>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|----------------------------|---------------|
| mattroumaya | 2023-01-03 14:28:03 | jwildfire Zhongkai-Wang | COMMENTED |

8.0.64 Pull Request 985: Add dropdown to widgets to highlight sites.

Merging fix-984 into dev

<https://github.com/Gilead-BioStats/gsm/pull/985>

| Requester | Date Requested | Reviewers | Review Status |
|-----------|------------------------|-----------|---------------|
| samussiah | 2022-12-22 21:34:46 | MayaGans | APPROVED |

8.0.65 Pull Request 983: Fix 961 - minify lData

Merging fix-961 into dev

<https://github.com/Gilead-BioStats/gsm/pull/983>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2022-12-22 20:03:27 | | APPROVED |

8.0.66 Pull Request 982: Fix 979 - remove unused functions and dependencies

Merging fix-979 into dev

<https://github.com/Gilead-BioStats/gsm/pull/982>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2022-12-22 19:16:40 | | APPROVED |

8.0.67 Pull Request 980: Fix 928 - Disp_Map_Raw() Qual. Tests

Merging fix-928 into dev

<https://github.com/Gilead-BioStats/gsm/pull/980>

| Requester | Date Requested | Reviewers | Review Status |
|-------------------|------------------------|----------------------------------|---------------|
| colleenmclaughlin | 2022-12-22 17:15:53 | samussiah gwu05 Zhongkai-Wang | COMMENTED |

8.0.68 Pull Request 978: Fix 934 - LB_Map_Raw() Qual. Tests

Merging fix-934 into dev

<https://github.com/Gilead-BioStats/gsm/pull/978>

| Requester | Date Requested | Reviewers | Review Status |
|-------------------|------------------------|----------------------------------|---------------|
| colleenmclaughlin | 2022-12-21 21:30:03 | samussiah gwu05 Zhongkai-Wang | APPROVED |

8.0.69 Pull Request 977: Fix 937 - PD_Map_Raw() Qual. Tests

Merging fix-937 into dev

<https://github.com/Gilead-BioStats/gsm/pull/977>

| Requester | Date Requested | Reviewers | Review Status |
|-------------------|------------------------|----------------------------------|---------------|
| colleenmclaughlin | 2022-12-21 19:26:15 | samussiah gwu05 Zhongkai-Wang | APPROVED |

8.0.70 Pull Request 976: Fix 953 - remove qualification YAML -> csv file

Merging fix-953 into dev

<https://github.com/Gilead-BioStats/gsm/pull/976>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|---|---------------|
| mattroumaya | 2022-12-20 22:52:52 | jwildfire chelseadickens Zhongkai-Wang collleenmclaughlin | APPROVED |

8.0.71 Pull Request 975: Fix 920 - AE_Map_Raw() Qual. Tests

Merging fix-920 into dev

<https://github.com/Gilead-BioStats/gsm/pull/975>

| Requester | Date Requested | Reviewers | Review Status |
|--------------------|------------------------|----------------------------------|---------------|
| collleenmclaughlin | 2022-12-20 21:44:00 | samussiah gwu05 Zhongkai-Wang | APPROVED |

8.0.72 Pull Request 974: Remove nStep argument in QueryRate_Assess() .

Merging fix-973 into dev

<https://github.com/Gilead-BioStats/gsm/pull/974>

| Requester | Date Requested | Reviewers | Review Status |
|-----------|------------------------|-----------|---------------|
| samussiah | 2022-12-20 19:04:44 | | APPROVED |

8.0.73 Pull Request 972: Sync dev and main

Merging main into dev

<https://github.com/Gilead-BioStats/gsm/pull/972>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2022-12-20 15:17:04 | samussiah | APPROVED |

8.0.74 Pull Request 971: Release v1.4.1

Merging release-v1.4.1 into main

<https://github.com/Gilead-BioStats/gsm/pull/971>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|--------------------|---------------|
| mattroumaya | 2022-12-19 22:03:35 | samussiah gwu05 | COMMENTED |

8.0.75 Pull Request 970: (targeted wrong branch) Release v1.4.1

Merging release-v1.4.1 into main

<https://github.com/Gilead-BioStats/gsm/pull/970>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2022-12-19 22:00:24 | | |

8.0.76 Pull Request 968: Sync main and dev for v1.4.0 release

Merging main into dev

<https://github.com/Gilead-BioStats/gsm/pull/968>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-------------------------------------|---------------|
| mattroumaya | 2022-12-19 15:25:32 | Zhongkai-Wang collleenmclaughlin | APPROVED |

8.0.77 Pull Request 964: Fix 614 - denominator requirement and score/flag rules

Merging fix-614 into dev

<https://github.com/Gilead-BioStats/gsm/pull/964>

| Requester | Date Requested | Reviewers | Review Status |
|---------------|------------------------|-----------|---------------|
| Zhongkai-Wang | 2022-12-15 15:50:53 | gwu05 | COMMENTED |

8.0.78 Pull Request 960: fix 936 - qualify PD_Assess for normal approximation

Merging 936-qualify-pd_assess into dev

<https://github.com/Gilead-BioStats/gsm/pull/960>

| Requester | Date Requested | Reviewers | Review Status |
|----------------|------------------------|-----------------|---------------|
| chelseadickens | 2022-12-14 15:48:01 | jwildfire gwu05 | APPROVED |

8.0.79 Pull Request 959: fix 933 - qualify LB_Assess for normal approximation

Merging 933-qualify-lb_assess into dev

<https://github.com/Gilead-BioStats/gsm/pull/959>

| Requester | Date Requested | Reviewers | Review Status |
|----------------|------------------------|-----------------|---------------|
| chelseadickens | 2022-12-14 14:50:59 | jwildfire gwu05 | APPROVED |

8.0.80 Pull Request 958: Release v1.4.0

Merging release-v1.4.0 into main

<https://github.com/Gilead-BioStats/gsm/pull/958>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2022-12-14 04:36:45 | jwildfire | APPROVED |

8.0.81 Pull Request 957: Add # of participants to overview table in KRI report.

Merging fix-954 into dev

<https://github.com/Gilead-BioStats/gsm/pull/957>

| Requester | Date Requested | Reviewers | Review Status |
|-----------|------------------------|---------------|---------------|
| samussiah | 2022-12-13 21:30:12 | Zhongkai-Wang | APPROVED |

8.0.82 Pull Request 956: fix 927 - qualify Disp_Assess for normal approximation

Merging 927-qualify-disp_assess into dev

<https://github.com/Gilead-BioStats/gsm/pull/956>

| Requester | Date Requested | Reviewers | Review Status |
|----------------|------------------------|-----------------|---------------|
| chelseadickens | 2022-12-13 20:57:14 | jwildfire gwu05 | DISMISSED |

8.0.83 Pull Request 955: fix 919 - qualify AE_Assess for normal approximation

Merging 919-qualify-ae_assess into dev

<https://github.com/Gilead-BioStats/gsm/pull/955>

| Requester | Date Requested | Reviewers | Review Status |
|----------------|------------------------|-----------------|---------------|
| chelseadickens | 2022-12-13 20:35:10 | jwildfire gwu05 | APPROVED |

8.0.84 Pull Request 952: Report tweaks

Merging report-tweaks into fix-950

<https://github.com/Gilead-BioStats/gsm/pull/952>

| Requester | Date Requested | Reviewers | Review Status |
|-----------|------------------------|---------------|---------------|
| samussiah | 2022-12-12 20:49:48 | Zhongkai-Wang | APPROVED |

8.0.85 Pull Request 951: Report updates

Merging fix-950 into dev

<https://github.com/Gilead-BioStats/gsm/pull/951>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|--------------------|---------------|
| mattroumaya | 2022-12-12 19:10:03 | samussiah gwu05 | APPROVED |

8.0.86 Pull Request 949: systime-based elementId

Merging fix-948 into dev

<https://github.com/Gilead-BioStats/gsm/pull/949>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2022-12-09 22:44:13 | | APPROVED |

8.0.87 Pull Request 947: Add screen fail assessment.

Merging fix-902 into dev

<https://github.com/Gilead-BioStats/gsm/pull/947>

| Requester | Date Requested | Reviewers | Review Status |
|-----------|------------------------|---------------|---------------|
| samussiah | 2022-12-09 16:50:14 | Zhongkai-Wang | APPROVED |

8.0.88 Pull Request 946: Release changes

Merging release-changes into dev

<https://github.com/Gilead-BioStats/gsm/pull/946>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2022-12-08 20:59:35 | | COMMENTED |

8.0.89 Pull Request 945: Fix 912 - Merge/join handling in mapping

Merging fix-912 into dev

<https://github.com/Gilead-BioStats/gsm/pull/945>

| Requester | Date Requested | Reviewers | Review Status |
|---------------|------------------------|-----------|---------------|
| Zhongkai-Wang | 2022-12-08 20:21:48 | | APPROVED |

8.0.90 Pull Request 917: Fix 915 - add rbm-viz widgets to new KRIs

Merging fix-915 into dev

<https://github.com/Gilead-BioStats/gsm/pull/917>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2022-12-06 19:56:59 | jwildfire | APPROVED |

8.0.91 Pull Request 913: Fix 837 report

Merging fix-837-report into dev

<https://github.com/Gilead-BioStats/gsm/pull/913>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2022-12-03 00:04:07 | jwildfire | COMMENTED |

8.0.92 Pull Request 910: Filter qt10004 workflow on important PDs.

Merging fix-909 into dev

<https://github.com/Gilead-BioStats/gsm/pull/910>

| Requester | Date Requested | Reviewers | Review Status |
|-----------|------------------------|-----------|---------------|
| samussiah | 2022-12-01 18:07:35 | | APPROVED |

8.0.93 Pull Request 908: fix-781-update-merge: update merge

Merging fix-781-update-merge into fix-781

<https://github.com/Gilead-BioStats/gsm/pull/908>

| Requester | Date Requested | Reviewers | Review Status |
|---------------|------------------------|-------------|---------------|
| Zhongkai-Wang | 2022-12-01 14:03:18 | mattroumaya | COMMENTED |

8.0.94 Pull Request 907: Tweak UpdateParams

Merging tweak-UpdateParams into fix-783

<https://github.com/Gilead-BioStats/gsm/pull/907>

| Requester | Date Requested | Reviewers | Review Status |
|-----------|------------------------|-----------|---------------|
| samussiah | 2022-11-30 23:11:58 | | APPROVED |

8.0.95 Pull Request 906: Fix 781 assess tests

Merging fix-781-assess-tests into fix-781

<https://github.com/Gilead-BioStats/gsm/pull/906>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2022-11-30 20:11:46 | | COMMENTED |

8.0.96 Pull Request 903: update tests + workflows

Merging fix-781-add-tests into fix-781

<https://github.com/Gilead-BioStats/gsm/pull/903>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2022-11-29 22:36:06 | | APPROVED |

8.0.97 Pull Request 899: Fix 769 - Add CheckSnapshotInputs()

Merging fix-769 into dev

<https://github.com/Gilead-BioStats/gsm/pull/899>

| Requester | Date Requested | Reviewers | Review Status |
|-------------|------------------------|-----------|---------------|
| mattroumaya | 2022-11-22 20:30:31 | jwildfire | APPROVED |