Validation Report for Centralized Statistical Monitoring R Package: clincsmr

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2022-11-28

Contents

1 1 Approval

1.1 1.1 Signatures

AUTHOR My signature designates authorship of this document.

Role	Name and Title	Signature	Date
Validation Lead, Creater	Feinan Lu, Statistician		

APPROVAL I have reviewed this document and approve its content.

Role	Name and Title	Signature	Date
tester	Val A XXX, Programmer II		

The effective date of this document is the last date of signature.

2 2 Release details

2.1 2.1 Package Information

2.1.1 2.1.1 Change Log

Version	Effective Date	Activity Description
0.0.0.9000	2022-11-16	Validation release notes for version 0.0.0.9000

2.1.2 2.1.2 Validation Environment

Type	Resource	Version Detail
system	OS	Windows 10 x64 (build 19042)
	R	4.2.1 (2022-06-23
package_req	ggplot2	3.4.0
	gplots	3.1.3
	knitr	1.40
	rmarkdown	2.18
	stats	4.2.1
	valtools	0.4.0
extended_req	devtools	2.4.5
	kableExtra	1.3.4
	magrittr	2.0.3
	testthat	3.1.5
session	usethis	2.1.6

2.2 2.2 Authors

2.2.1 2.2.1 Requirements

Requirement ID	Editor	Edit Date
Requirement_001	Feinan Lu	2022-11-16
Requirement_002	Feinan Lu	2022-11-16
Requirement_003	Feinan Lu	2022-11-16
Requirement_004	Feinan Lu	2022-11-16
Requirement_005	Feinan Lu	2022-11-16
Requirement_006	Feinan Lu	2022-11-16
Requirement_007	Feinan Lu	2022-11-16
Requirement_008	Feinan Lu	2022-11-16
Requirement_009	Feinan Lu	2022-11-16

2.2.2 2.2.2 Functions

2.2.3 2.2.3 Test Case Authors

2.2.4 2.2.4 Test Code Authors

2.3 2.3 Traceability

Function Name	Editor	Edit Date
cat_check	Feinan Lu	2022-11-16
correlation_check	Feinan Lu	2022-11-16
digit_preferece	Feinan Lu	2022-11-16
inlier_check	Feinan Lu	2022-11-16
integers_check	Feinan Lu	2022-11-16
mean_check	Feinan Lu	2022-11-16
outlier_check	Feinan Lu	2022-11-16
outlier_aedata	Feinan Lu	2022-11-16
var_check	Feinan Lu	2022-11-16

Test Case ID	Editor	Edit Date
Test_case_001	Feinan Lu	2022-11-16
Test_case_002	Feinan Lu	2022-11-16
Test_case_003	Feinan Lu	2022-11-16
Test_case_004	Feinan Lu	2022-11-16
Test_case_005	Feinan Lu	2022-11-16
Test_case_006	Feinan Lu	2022-11-16
Test_case_007	Feinan Lu	2022-11-16
Test_case_008	Feinan Lu	2022-11-21
Test_case_009	Feinan Lu	2022-11-21

Test Code ID	Editor	Edit Date
1,1	XXX	2022-11-16
1.2	XXX	2022-11-16
2,1	XXX	2022-11-16
2.2	XXX	2022-11-16
3,1	XXX	2022-11-16
3.2	XXX	2022-11-16
4,1	XXX	2022-11-16
4.2	XXX	2022-11-16
5,1	XXX	2022-11-16
5.2	XXX	2022-11-16
6,1	XXX	2022-11-16
6.2	XXX	2022-11-16
7,1	XXX	2022-11-16
7.2	XXX	2022-11-16
8,1	XXX	2022-11-16
8.2	XXX	2022-11-16
9,1	XXX	2022-11-16
9.2	XXX	2022-11-16

Requirement Name	Requirement ID	Test Case Name	Test Cases
Requirement 1	1.1	Test_case_001	1.1
	1.2		1.1
	1.3		1.1
	1.4		1.1
	1.1		1.2
	1.2		1.2
	1.3		1.2
	1.5		1.2
Requirement 2	2.1 2.2 2.3	Test_case_002	2.1
Requirement 3	3.1 3.2 3.3 3.4	Test_case_003	3.1
	3.1 3.2 3.3 3.5		3.2
Requirement 4	4.1 4.2 4.3 4.4	Test_case_004	4.1
Requirement 5	5.1 5.2 5.3 5.4	Test_case_005	5.1

Requirement 6	6.1 6.2	Test_case_006	6.1
Requirement 7	7.1 7.2 7.3 7.7	Test_case_007	7.1
	7.1 7.2 7.4 7.7		7.2
	7.1 7.2 7.5 7.7		7.3
	7.1 7.2 7.6 7.7		7.4
Requirement 8	8.1 8.2 8.3 8.7	Test_case_008	8.1
	8.1 8.2 8.4 8.7		8.2
	8.1 8.2 8.5 8.7		8.3
	8.1 8.2 8.6 8.7		8.4
Requirement 9	9.1 9.2	Test_case_009	9.1

3 3 Risk Assessment

Requirement Name	Requirement ID	Risk Assessment
Requirement_001	1.1	Low Risk, Small Impact
	1.2	Low Risk, Small Impact
	1.3	Low Risk, Small Impact
	1.4	Low Risk, Median Impact
	1.5	Low Risk, Median Impact
Requirement_002	2.1	Low Risk, Small Impact
	2.2	Low Risk, Small Impact
	2.3	Low Risk, Median Impact
Requirement_003	3.1	Low Risk, Small Impact
	3.2	Low Risk, Small Impact
	3.3	Low Risk, Small Impact
	3.4	Low Risk, Median Impact
	3.5	Low Risk, Median Impact
Requirement_004	4.1	Low Risk, Small Impact
	4.2	Low Risk, Small Impact
	4.3	Low Risk, Small Impact
	4.4	Low Risk, Small Impact
Requirement_005	5.1	Low Risk, Small Impact
	5.2	Low Risk, Small Impact
	5.3	Low Risk, Small Impact
	5.4	Low Risk, Small Impact
Requirement_006	6.1	Low Risk, Small Impact
	6.2	Low Risk, Small Impact
Requirement_007	7.1	Low Risk, Small Impact
	7.2	Low Risk, Small Impact
	7.3	Low Risk, Small Impact
	7.4	Low Risk, Small Impact
	7.5	Low Risk, Small Impact
	7.6	Low Risk, Small Impact
	7.7	Low Risk, Small Impact
Requirement_008	8.1	Low Risk, Small Impact
	8.2	Low Risk, Small Impact
	8.3	Low Risk, Small Impact
	8.4	Low Risk, Small Impact
	8.5	Low Risk, Small Impact
	8.6	Low Risk, Small Impact
	8.7	Low Risk, Small Impact
Requirement_009	9.1	Low Risk, Small Impact

4 4 Validation

4.1 4.1.1 Specification 1: cat_check

- 1.1 Categorical check result output table successfully displayed
- 1.2 Test information table showing variable and sites checked being correctly displayed
- 1.3 Frequencies and percentages for n by 2 tables are correctly tabulated and calculated
- 1.4 Fisher's exact test P-values are correctly calculated
- 1.5 Chi-square test P-values values are correctly calculated

4.2 4.1.2 Specification 2: correlation_check

- 2.1 The correlation plots for all sites are correctly displayed
- 2.2 The number of subjects for each site is correct
- 2.3 The p-value for each correlation check has been accurately calculated

4.3 4.1.3 Specification 3: digit_pref

- 3.1 P-value result output table successfully displayed
- 3.2 Frequency tables for digits are correctly displayed
- 3.3 Frequencies and percentages are correctly tabulated and calculated
- 3.4 Benford's law test P-values are correctly calculated
- 3.5 Comparison to all other sites P-values are correctly calculated

4.4 4.1.4 Specification 4: inlier_check

- 4.1 Information table is successfully displayed
- 4.2 Inlier plot is successfully displayed
- 4.3 The log(d) has been correctly calculated and plotted
- 4.4 Inlier is correctly detected by comparing to the lower bound

4.5 4.1.5 Specification 5: integer_check

- 5.1 Integer plots are successfully displayed
- 5.2 Information table of the tested variables are successfully displayed
- 5.3 The integer plots that indicate the number of non-integers are correct
- 5.4 The information table shows the correct number of sites and total number of sites

4.6 4.1.6 Specification 6: mean_check

- 6.1 Table of effect of variables are successfully displayed
- 6.2 The Chernoff face plots are successfully displayed has been properly arranged by sites and visits

4.7 4.1.7 Specification 7: outlier_aedata

- 7.1 The information table is successfully displayed
- 7.2 The outlier plot is successfully displayed
- 7.3 The AE incidence rate, along with the upper and lower bounds, using 'sd' method is correctly calculated and displayed

- 7.4 The AE incidence rate, along with the upper and lower bounds, using 'mahal' method is correctly calculated and displayed
- 7.5 The AE incidence rate, along with the upper and lower bounds, using 'IQR' method is correctly calculated and displayed
- 7.6 The AE incidence rate, along with the upper and lower bounds, using 'PCT' method is correctly calculated and displayed
- 7.7 The numbers in the information table are correctly calculated

4.8 4.1.8 Specification 8: outlier

- 8.1 The information table is successfully displayed
- 8.2 The outlier plot is successfully displayed
- 8.3 The AE incidence rate, along with the upper and lower bounds, using 'sd' method is correctly calculated and displayed
- 8.4 The AE incidence rate, along with the upper and lower bounds, using 'mahal' method is correctly calculated and displayed
- 8.5 The AE incidence rate, along with the upper and lower bounds, using 'IQR' method is correctly calculated and displayed
- 8.6 The AE incidence rate, along with the upper and lower bounds, using 'PCT' method is correctly calculated and displayed
- 8.7 The numbers in the information table are correctly calculated

4.9 4.1.9 Specification 9: var_check

- 9.1 The variance check result table is successfully displayed
- 9.2 The p-value of the variance check is correctly calculated
- Setup: DOCUMENT ANY SETUP THAT NEEDS TO BE DONE FOR TESTING

4.10 4.2.1 Test Case 1: cat_check

- 1.1 Test that the output tables and test information table have been correctly tabulated; p-values for Fisher's Exact Test are correctly calculated
- 1.2 Test that the output tables and test information table have been correctly tabulated; p-values for chi-square Test are correctly calculated
- Setup: DOCUMENT ANY SETUP THAT NEEDS TO BE DONE FOR TESTING

4.11 4.2.2 Test Case 2: correlation_check

- 2.1 Test that the correlation plots for all sites are properly displayed, the number of subjects for each site and p-value are correct
- Setup: DOCUMENT ANY SETUP THAT NEEDS TO BE DONE FOR TESTING

4.12 4.2.3 Test Case 3: digit_pref

- 3.1 Test that the frequency table with counts, percentages and p-values are correctly calculated using Benford's law

- 3.2 Test that the frequency table with counts, percentages and p-values of each site comparison to all other sites
- Setup: DOCUMENT ANY SETUP THAT NEEDS TO BE DONE FOR TESTING

4.13 4.2.4 Test Case 4: inlier_check

- 4.1 Test that the the log(d) has been correctly calculated and plotted, with inliers correctly detected by comparing to the lower bound
- Setup: DOCUMENT ANY SETUP THAT NEEDS TO BE DONE FOR TESTING

4.14 4.2.5 Test Case 5: integer_check

- 5.1 Test that the integer plot has been successfully and correctly displayed
- Setup: DOCUMENT ANY SETUP THAT NEEDS TO BE DONE FOR TESTING

4.15 4.2.6 Test Case 6: mean_check

- 6.1 Test that the Chernoff face plots are successfully displayed has been properly arranged by sites and visits
- Setup: DOCUMENT ANY SETUP THAT NEEDS TO BE DONE FOR TESTING

4.16 4.2.7 Test Case 7: outlier_aedata

- 7.1 Test that the outlier check for event type of data is accurately performed using 'sd' method
- 7.2 Test that the outlier check for event type of data is accurately performed using 'mahal' method
- 7.3 Test that the outlier check for event type of data is accurately performed using 'IQR' method
- 7.4 Test that the outlier check for event type of data is accurately performed using 'PCT' method
- Setup: DOCUMENT ANY SETUP THAT NEEDS TO BE DONE FOR TESTING

4.17 4.2.8 Test Case 8: outlier

- 8.1 Test that the outlier check for continuous data is accurately performed using 'sd' method
- 8.2 Test that the outlier check for continuous data is accurately performed using 'mahal' method
- 8.3 Test that the outlier check for continuous data is accurately performed using 'IQR' method
- 8.4 Test that the outlier check for continuous data is accurately performed using 'PCT' method
- Setup: DOCUMENT ANY SETUP THAT NEEDS TO BE DONE FOR TESTING

4.18 4.2.9 Test Case 9: var_check

- 9.1 Test that the variance and p-value have been accurately calculated

```
#> Warning: package 'testthat' was built under R version 4.2.2
```

Test	Results	Pass/Fail
1,1.1	As expected	Pass
1.2.1	As expected	Pass

Test	Results	Pass/Fail
2,1.1	As expected	Pass
2.2.1	As expected	Pass

Test	Results	Pass/Fail
3,1.1	As expected	Pass
3.2.1	As expected	Pass

Test	Results	Pass/Fail
4,1.1	As expected	Pass
4.2.1	As expected	Pass

Test	Results	Pass/Fail
5,1.1	As expected	Pass
5.2.1	As expected	Pass

Test	Results	Pass/Fail
6,1.1	As expected	Pass
6.2.1	As expected	Pass

Test	Results	Pass/Fail
7,1.1	As expected	Pass
7.2.1	As expected	Pass

Test	Results	Pass/Fail
8,1.1	As expected	Pass
8.2.1	As expected	Pass

Test	Results	Pass/Fail
9,1.1	As expected	Pass
9.2.1	As expected	Pass