

Validation Report for drugdevelopR

Johannes Cepicka

2022-08-23

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1 Certifications

1.1 Signatures

AUTHOR My signature designates authorship of this document.

Role	Name and Title	Signature	Date
Validation Lead, Responsible for Validation	Johannes Cepicka, BSc		

APPROVAL I have reviewed this document and approve its content.

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

2 Release details

2.1 Package Information

2.1.1 Change Log

Version	Effective Date	Activity Description
0.1.0	2022-08-21	Validation release notes for version 0.1.0

2.1.2 Validation Environment

Type	Resource	Version Detail
system	OS	macOS Big Sur ... 10.16
	R	4.2.1
package_req	cubature	2.0.4.4
	doParallel	1.0.17
	foreach	1.5.2
	iterators	1.0.14
	MASS	7.3.58
	msm	1.6.9
	mvtnorm	1.1.3
	parallel	4.2.1
	stats	4.2.1
extended_req	covr	3.5.1
	devtools	2.4.3
	kableExtra	1.3.4
	knitr	1.39
	magrittr	2.0.3
	rmarkdown	2.14
	testthat	3.1.4
session	usethis	2.1.6
	valtools	0.4.0

2.2 Authors

2.2.1 Requirements

Requirement ID	Editor	Edit Date
01_BasicSetting	Johannes Cepicka	2022-08-16
02_BiasAdjustment	Johannes Cepicka	2022-08-16
Multitrial_03	Johannes Cepicka	2022-08-16
Multiarm_04	Johannes Cepicka	2022-08-16
05_MultipleEndpoints	Johannes Cepicka	2022-08-16

2.2.2 Functions

2.2.3 Test Case Authors

Test Case ID	Editor	Edit Date
01_BasicSettingTestCases	Johannes Cepicka	2022-08-16
BiasAdjustment_02	Johannes Cepicka	2022-08-16
Multitrial_03	Johannes Cepicka	2022-08-16
Multiarm_04	Johannes Cepicka	2022-08-16
MultipleEndpoints_05	Johannes Cepicka	2022-08-16

2.2.4 Test Code Authors

2.3 Traceability

```
#> Warning in sort(as.numeric(unique(unlist(lapply(strsplit(out$req_title, : NAs
#> durch Umwandlung erzeugt
```

Requirement Name	Requirement ID	Test Case Name	Test Cases
	01.03	01_BasicSettingTestCases	01.01
	01.06		01.01
	01.12		01.01
	01.15		01.01
	01.03		01.02
	01.05		01.02
	01.14		01.02
	01.16		01.02
	01.10		01.03
	01.12		01.03
	01.09		01.04
	01.13		01.04
	01.11		01.05
	01.14		01.05
	01.15		01.05
	01.04		01.06
	01.07		01.07
	01.02		01.08
	01.05		01.08
	01.12		01.08
	01.02		01.09
	01.06		01.09
	01.01		01.10
	01.06		01.10
	01.01		01.11
	01.05		01.11
	01.15		01.11
	01.08		01.12
	REQUIREMENT	BiasAdjustment__02	TESTCASE
	REQUIREMENT	Multitrial__03	TESTCASE
	REQUIREMENT	Multiarm__04	TESTCASE
	REQUIREMENT	MultipleEndpoints__05	TESTCASE

3 Risk Assessment

Requirement Name	Requirement ID	Risk Assessment
01_BasicSetting	01.01	Low Risk, Very High Impact
	01.02	Low Risk, Very High Impact
	01.03	Low Risk, Very High Impact
	01.04	Medium Risk, Low Impact
	01.05	Low Risk, High Impact
	01.06	Medium Risk, High Impact
	01.07	Low Risk, Low Impact
	01.08	High Risk, Low Impact
	01.09	Low Risk, High Impact
	01.10	Low Risk, High Impact
	01.11	Low Risk, High Impact
	01.12	Low Risk, High Impact
	01.13	Low Risk, Medium Impact
	01.14	Low Risk, Medium Impact
	01.15	Low Risk, Medium Impact
	01.16	Low Risk, Medium Impact
02_BiasAdjustment	02.01	Medium Risk, High Impact
	02.02	Medium Risk, High Impact
	02.03	Low Risk, High Impact
	02.04	Medium Risk, High Impact
	02.05	High Risk, High Impact
	02.06	Medium Risk, High Impact
	02.07	Medium Risk, High Impact
	02.08	Medium Risk, High Impact
	02.09	High Risk, Low Impact
	02.10	Medium Risk, High Impact
	02.11	Medium Risk, High Impact
	02.12	Medium Risk, High Impact
	02.13	Medium Risk, High Impact
	02.14	Medium Risk, Medium Impact
	02.15	Medium Risk, Medium Impact
	02.16	Low Risk, Medium Impact
	02.17	Low Risk, Medium Impact
	02.18	Low Risk, Medium Impact
	02.19	Low Risk, Medium Impact
	02.20	Low Risk, Medium Impact
	03.01	Medium Risk, High Impact
	03.02	Medium Risk, High Impact
	03.03	Low Risk, High Impact
	03.04	Medium Risk, High Impact
	03.05	High Risk, High Impact
	03.06	Low Risk, High Impact
	03.07	Low Risk, High Impact
	03.08	Low Risk, High Impact
	03.09	High Risk, Low Impact
	03.10	Medium Risk, High Impact
	03.11	Medium Risk, High Impact
	03.12	High Risk, Low Impact
	03.13	Low Risk, Low Impact
	03.14	Very High Risk, Medium Impact
	03.15	Medium Risk, Medium Impact

	03.16	Low Risk, Medium Impact
	03.17	Low Risk, Medium Impact
	03.18	Low Risk, Medium Impact
	03.19	Low Risk, Medium Impact
	03.20	Low Risk, Medium Impact
	03.21	Low Risk, Medium Impact
Multiarm_04	04.01	Medium Risk, High Impact
	04.02	Medium Risk, High Impact
	04.03	Low Risk, High Impact
	04.04	Low Risk, High Impact
	04.05	Low Risk, High Impact
	04.06	Low Risk, High Impact
	04.07	High Risk, Low Impact
	04.08	Medium Risk, High Impact
	04.09	Medium Risk, High Impact
	04.10	Low Risk, Medium Impact
	04.11	Low Risk, Medium Impact
	04.12	Low Risk, Medium Impact
	04.13	Low Risk, Medium Impact
	04.14	Low Risk, Medium Impact
05_MultipleEndpoints	05.01	High Risk, High Impact
	05.02	High Risk, High Impact
	05.03	High Risk, High Impact
	05.04	Very High Risk, High Impact
	05.05	Low Risk, High Impact
	05.06	Low Risk, High Impact
	05.07	Low Risk, High Impact
	05.08	High Risk, Low Impact
	05.09	Low Risk, Medium Impact
	05.10	Low Risk, Medium Impact
	05.11	Low Risk, Medium Impact
	05.12	Low Risk, Medium Impact
	05.13	High Risk, High Impact
	05.14	High Risk, High Impact
	05.15	High Risk, High Impact

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