

CYNTEGRITY

MYRBQM PORTAL NEW VERSION RELEASE



NEW V6.8.1 | KEY FEATURES AT A GLANCE

- Significant database optimizations
- Data Connection | Data Mapping made easy
- New Privileges | Various useful privileges have been added
 - ▶ Incl. **maintained access to retired studies and data** for audits and risk history (lessons learned and metrics)
- New in Studies | Study type selection now part of study set up
- Enhanced print settings for IQRMP report
- Study thumbnail enhancements: active vs retired studies



And, coming soon... KRI Wiki!

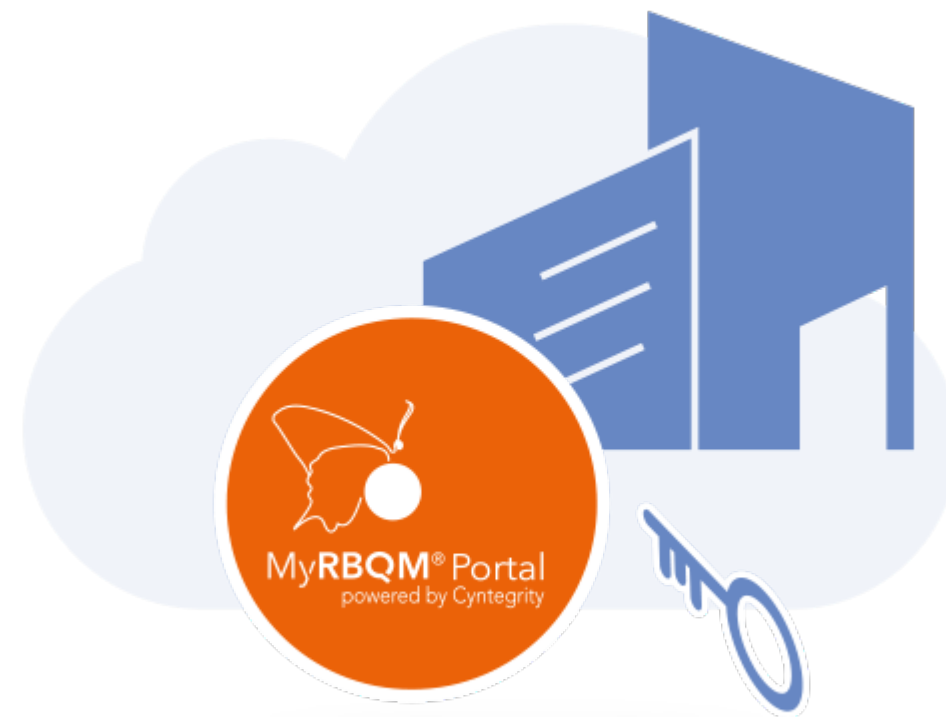


NEW V6.8.1 | DATABASE OPTIMIZATIONS

Database Upgrade

MyRBQM® Portal now handles larger volumes of data at an even higher speed.

The platform uses in-memory optimized cache and backs up data every 6 hours with a horizontally scale-out architecture, which means the Portal's databases can handle increased traffic by adding more nodes on the fly.



NEW V6.8.1 | WHEN DATA CONNECTION IS REQUIRED

Data mapping made easy

MyRBQM® Portal now recognizes the following data file types:

- Access DB
- Comma Separated Files (*.CSV)
- Excel (.xlsx)
- SAS files (.sas7bdat)



NEW V6.8.1 | NEW PRIVILEGES – VIEW RETIRED STUDIES

Access Retired Studies Data

Depending on the assigned user role, users can now:

- ▶ Access the Retired Studies Data in a read-only mode. This is particularly useful during **audits/inspections of already finished studies**.
- ▶ There is even an option to “unretire” a study to ensure **historical data (risk history!)** is **always at hand**.

The screenshot shows the 'Filter Studies' dialog box with the 'Display Retired Studies?' dropdown menu open, highlighting the 'Display only retired Studies' option. Below the dialog, two study cards are displayed. The first card, 'DemoVal1—Demo Study Val...', is highlighted with a red box around its details and has a 'View Data' button. The second card, 'DeS—Demo study', is also highlighted with a red box around its details and has a 'This Study has no data' message and an 'Unretire' button.

Filter Studies

Study Id or Name
Id or Name

Display Live Studies?
Display both Live and non-Live Studies

Display Retired Studies?
Display only retired Studies

Retired DemoVal1—Demo Study Val...

Investigational Product: Demo Investigational Product
Therapy Area: [Redacted]
Study Type: Unspecified
Study Phase: Phase III
Synopsis:
A double-blind, placebo-controlled, randomized multicenter study for the efficacy and safety of [Redacted] medication, in the dosage forms of intravenous solution and enteric-coated tablets used in elderly patients.

Retired At: January 10th 2022, 3:33:51 pm (UTC)

[Unretire](#) [View Data](#)

Retired DeS—Demo study

Investigational Product: Unspecified
Therapy Area: [Redacted]
Study Type: Interventional (Clinical Trial)
Study Phase: Unspecified
Synopsis:
N/A




This Study has no data





Retired At: July 21st 2021, 7:12:17 am (UTC)


[Unretire](#)

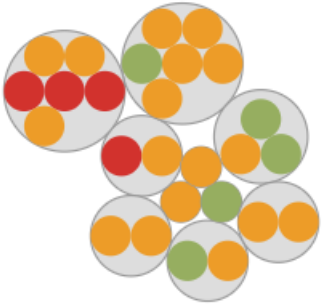


NEW V6.8.1 | STUDY THUMBNAIL ENHANCEMENTS



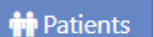

 Demo-Val1-220112—Demo Validatio...  


 RACT  Metrics  Mitigations  More

Total Risk Score :  7





Active RACT: Release 05-06-2019
MyRBQM Portal license: valid.


 RACT  CSM  Patients  Dashboard

 **Retired** DemoVal1—Demo Study Val...

Investigational Product: Demo Investigational Product
Therapy Area:
Study Type: Unspecified
Study Phase: Phase III
Synopsis:
A double-blind, placebo-controlled, randomized multicenter study for the efficacy and safety of
medication, in the dosage forms of intravenous solution and enteric-coated tablets used in elderly patients.

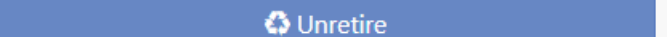
Retired At: January 10th 2022, 3:33:51 pm (UTC)

 Unretire  View Data

 **Retired** DeS—Demo study

Investigational Product: Unspecified
Therapy Area:
Study Type: Interventional (Clinical Trial)
Study Phase: Unspecified
Synopsis:
N/A

This Study has no data
Retired At: July 21st 2021, 7:12:17 am (UTC)

 Unretire

Active Study

Retired Study with Data

Retired Study without Data



NEW V6.8.1 | NEW PRIVILEGES – IQRMP REPORT

Various useful privileges have been added

Depending on the assigned user role, users can now:

- Download **IQRMP** report

IQRMP pdf report:
header/footer,
and print settings
optimizations

version	Date (UTC)	Released by
6/13/2021 19:42:05		fatemeh.sharifpanah@cynTEGRITY.com
7/6/2021 19:25:35		fatemeh.sharifpanah@cynTEGRITY.com
6/6/2021 17:39:50		fatemeh.sharifpanah@cynTEGRITY.com
5/6/2021 17:38:59		fatemeh.sharifpanah@cynTEGRITY.com
4/6/2021 15:00:00		fatemeh.sharifpanah@cynTEGRITY.com
3/5/2021 11:53:30		fatemeh.sharifpanah@cynTEGRITY.com
2/2/2021 15:51:46		fatemeh.sharifpanah@cynTEGRITY.com
1/2/2021 15:37:23		fatemeh.sharifpanah@cynTEGRITY.com

MyRBQM® Portal

EB-Val1-220112
Select another study

RACT Risks Actions CSM Patients Dashboard

RiskManagementOverview
Manage risk protocol versions

Go Back to Study Overview

Latest Release


Total Risk Score: 5

New Button
Download IQRMP Report



NEW V6.8.1 | NEW PRIVILEGES – IQRMP REPORT

IQRMP Excel report: print settings optimizations, e.g., autoscaling



Copies: 1

Print

Printer

Microsoft Print to PDF

Ready

[Printer Properties](#)

Settings

Print Entire Workbook

Print the entire workbook

Pages: to

Collated

1,2,3 1,2,3 1,2,3

Landscape Orientation

Letter

21,59 cm x 27,94 cm

Normal Margins

Top: 1,91 cm Bottom: 1,91 c...

Fit All Columns on One Page

Shrink the printout so that it...

[Page Setup](#)

Version Jun 13, 2021
MyRBQM Portal
EB-Val1-220112

Risk Version		Overall Risk level:		Medium		S	
Item	Item Name	Item ID	Item Description	Item Status	Item Risk	Item Score	Item Weight
1	Item 1	1.1	Item 1.1 Description	Item 1.1 Status	Item 1.1 Risk	Item 1.1 Score	Item 1.1 Weight
2	Item 2	2.1	Item 2.1 Description	Item 2.1 Status	Item 2.1 Risk	Item 2.1 Score	Item 2.1 Weight
3	Item 3	3.1	Item 3.1 Description	Item 3.1 Status	Item 3.1 Risk	Item 3.1 Score	Item 3.1 Weight
4	Item 4	4.1	Item 4.1 Description	Item 4.1 Status	Item 4.1 Risk	Item 4.1 Score	Item 4.1 Weight
5	Item 5	5.1	Item 5.1 Description	Item 5.1 Status	Item 5.1 Risk	Item 5.1 Score	Item 5.1 Weight
6	Item 6	6.1	Item 6.1 Description	Item 6.1 Status	Item 6.1 Risk	Item 6.1 Score	Item 6.1 Weight
7	Item 7	7.1	Item 7.1 Description	Item 7.1 Status	Item 7.1 Risk	Item 7.1 Score	Item 7.1 Weight
8	Item 8	8.1	Item 8.1 Description	Item 8.1 Status	Item 8.1 Risk	Item 8.1 Score	Item 8.1 Weight
9	Item 9	9.1	Item 9.1 Description	Item 9.1 Status	Item 9.1 Risk	Item 9.1 Score	Item 9.1 Weight
10	Item 10	10.1	Item 10.1 Description	Item 10.1 Status	Item 10.1 Risk	Item 10.1 Score	Item 10.1 Weight
11	Item 11	11.1	Item 11.1 Description	Item 11.1 Status	Item 11.1 Risk	Item 11.1 Score	Item 11.1 Weight
12	Item 12	12.1	Item 12.1 Description	Item 12.1 Status	Item 12.1 Risk	Item 12.1 Score	Item 12.1 Weight
13	Item 13	13.1	Item 13.1 Description	Item 13.1 Status	Item 13.1 Risk	Item 13.1 Score	Item 13.1 Weight
14	Item 14	14.1	Item 14.1 Description	Item 14.1 Status	Item 14.1 Risk	Item 14.1 Score	Item 14.1 Weight
15	Item 15	15.1	Item 15.1 Description	Item 15.1 Status	Item 15.1 Risk	Item 15.1 Score	Item 15.1 Weight
16	Item 16	16.1	Item 16.1 Description	Item 16.1 Status	Item 16.1 Risk	Item 16.1 Score	Item 16.1 Weight
17	Item 17	17.1	Item 17.1 Description	Item 17.1 Status	Item 17.1 Risk	Item 17.1 Score	Item 17.1 Weight
18	Item 18	18.1	Item 18.1 Description	Item 18.1 Status	Item 18.1 Risk	Item 18.1 Score	Item 18.1 Weight
19	Item 19	19.1	Item 19.1 Description	Item 19.1 Status	Item 19.1 Risk	Item 19.1 Score	Item 19.1 Weight
20	Item 20	20.1	Item 20.1 Description	Item 20.1 Status	Item 20.1 Risk	Item 20.1 Score	Item 20.1 Weight
21	Item 21	21.1	Item 21.1 Description	Item 21.1 Status	Item 21.1 Risk	Item 21.1 Score	Item 21.1 Weight
22	Item 22	22.1	Item 22.1 Description	Item 22.1 Status	Item 22.1 Risk	Item 22.1 Score	Item 22.1 Weight
23	Item 23	23.1	Item 23.1 Description	Item 23.1 Status	Item 23.1 Risk	Item 23.1 Score	Item 23.1 Weight
24	Item 24	24.1	Item 24.1 Description	Item 24.1 Status	Item 24.1 Risk	Item 24.1 Score	Item 24.1 Weight
25	Item 25	25.1	Item 25.1 Description	Item 25.1 Status	Item 25.1 Risk	Item 25.1 Score	Item 25.1 Weight
26	Item 26	26.1	Item 26.1 Description	Item 26.1 Status	Item 26.1 Risk	Item 26.1 Score	Item 26.1 Weight
27	Item 27	27.1	Item 27.1 Description	Item 27.1 Status	Item 27.1 Risk	Item 27.1 Score	Item 27.1 Weight
28	Item 28	28.1	Item 28.1 Description	Item 28.1 Status	Item 28.1 Risk	Item 28.1 Score	Item 28.1 Weight
29	Item 29	29.1	Item 29.1 Description	Item 29.1 Status	Item 29.1 Risk	Item 29.1 Score	Item 29.1 Weight
30	Item 30	30.1	Item 30.1 Description	Item 30.1 Status	Item 30.1 Risk	Item 30.1 Score	Item 30.1 Weight
31	Item 31	31.1	Item 31.1 Description	Item 31.1 Status	Item 31.1 Risk	Item 31.1 Score	Item 31.1 Weight
32	Item 32	32.1	Item 32.1 Description	Item 32.1 Status	Item 32.1 Risk	Item 32.1 Score	Item 32.1 Weight
33	Item 33	33.1	Item 33.1 Description	Item 33.1 Status	Item 33.1 Risk	Item 33.1 Score	Item 33.1 Weight
34	Item 34	34.1	Item 34.1 Description	Item 34.1 Status	Item 34.1 Risk	Item 34.1 Score	Item 34.1 Weight
35	Item 35	35.1	Item 35.1 Description	Item 35.1 Status	Item 35.1 Risk	Item 35.1 Score	Item 35.1 Weight
36	Item 36	36.1	Item 36.1 Description	Item 36.1 Status	Item 36.1 Risk	Item 36.1 Score	Item 36.1 Weight
37	Item 37	37.1	Item 37.1 Description	Item 37.1 Status	Item 37.1 Risk	Item 37.1 Score	Item 37.1 Weight
38	Item 38	38.1	Item 38.1 Description	Item 38.1 Status	Item 38.1 Risk	Item 38.1 Score	Item 38.1 Weight
39	Item 39	39.1	Item 39.1 Description	Item 39.1 Status	Item 39.1 Risk	Item 39.1 Score	Item 39.1 Weight
40	Item 40	40.1	Item 40.1 Description	Item 40.1 Status	Item 40.1 Risk	Item 40.1 Score	Item 40.1 Weight
41	Item 41	41.1	Item 41.1 Description	Item 41.1 Status	Item 41.1 Risk	Item 41.1 Score	Item 41.1 Weight
42	Item 42	42.1	Item 42.1 Description	Item 42.1 Status	Item 42.1 Risk	Item 42.1 Score	Item 42.1 Weight
43	Item 43	43.1	Item 43.1 Description	Item 43.1 Status	Item 43.1 Risk	Item 43.1 Score	Item 43.1 Weight
44	Item 44	44.1	Item 44.1 Description	Item 44.1 Status	Item 44.1 Risk	Item 44.1 Score	Item 44.1 Weight
45	Item 45	45.1	Item 45.1 Description	Item 45.1 Status	Item 45.1 Risk	Item 45.1 Score	Item 45.1 Weight
46	Item 46	46.1	Item 46.1 Description	Item 46.1 Status	Item 46.1 Risk	Item 46.1 Score	Item 46.1 Weight
47	Item 47	47.1	Item 47.1 Description	Item 47.1 Status	Item 47.1 Risk	Item 47.1 Score	Item 47.1 Weight
48	Item 48	48.1	Item 48.1 Description	Item 48.1 Status	Item 48.1 Risk	Item 48.1 Score	Item 48.1 Weight
49	Item 49	49.1	Item 49.1 Description	Item 49.1 Status	Item 49.1 Risk	Item 49.1 Score	Item 49.1 Weight
50	Item 50	50.1	Item 50.1 Description	Item 50.1 Status	Item 50.1 Risk	Item 50.1 Score	Item 50.1 Weight

Jan 25, 2022 02:59 PM UTC
Cyntegrity Confidential Information
Page 2 of 15

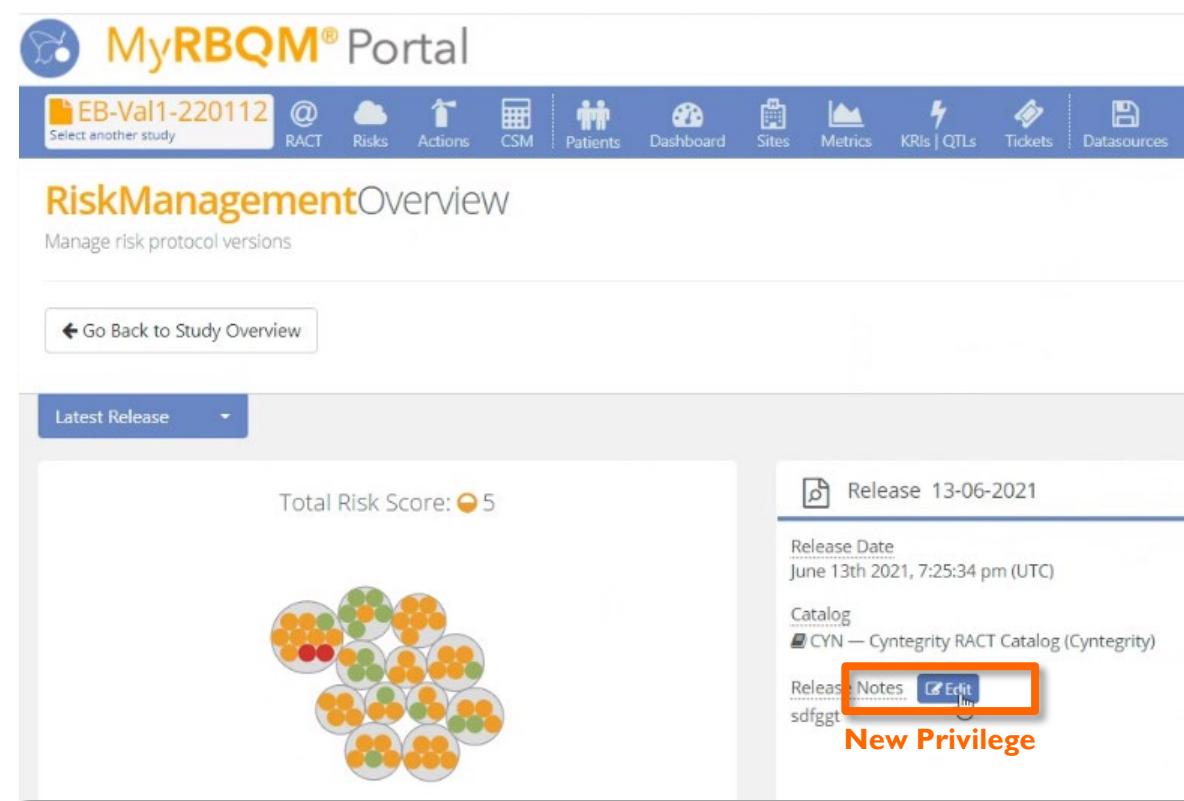


NEW V6.8.1 | NEW PRIVILEGES – RACT DRAFT

Various useful privileges have been added

Depending on the assigned user role, users can now:

- Release **RACT drafts**: user is now able to edit the “RACT Release Notes” for released RACT versions



The screenshot displays the MyRBQM Portal interface. The top navigation bar includes the portal logo and a list of menu items: RACT, Risks, Actions, CSM, Patients, Dashboard, Sites, Metrics, KRIs | QTLs, Tickets, and Datasources. The main content area is titled 'RiskManagementOverview' with the subtitle 'Manage risk protocol versions'. A 'Go Back to Study Overview' button is present. The 'Latest Release' section shows a 'Total Risk Score' of 5 and a cluster of colored dots. On the right, a 'Release 13-06-2021' details panel is visible, showing the release date, catalog, and release notes. The 'Release Notes' section has an 'Edit' button highlighted with a red box and labeled 'New Privilege'.



NEW V6.8.1 | NEW IN STUDIES

Study type selection now part of set up

The study wizard is now extended with “Select your study’s type .” If Study Types are pre-configured according to the user’s requirements, then the corresponding list will now be visible upon study set up.

The screenshot displays the StudyWizard interface for creating a study. It is divided into three steps:

- Step 1 — Name Your Study**: Includes a text input field for the Study Name.
- Step 2 — Select RAC Catalog**: Includes a list of catalogs under two groups: 'Cyntegrity' (OncoRACT, Ruka1001-RACT, Test Onco, Ruka Catalog) and 'No Group' (SimpleCat, Risks and mitigations).
- Step 3 — Select Your Study's Type (optional)**: Includes a list of study types. The 'demo' option is highlighted in blue, and an orange arrow points to it.



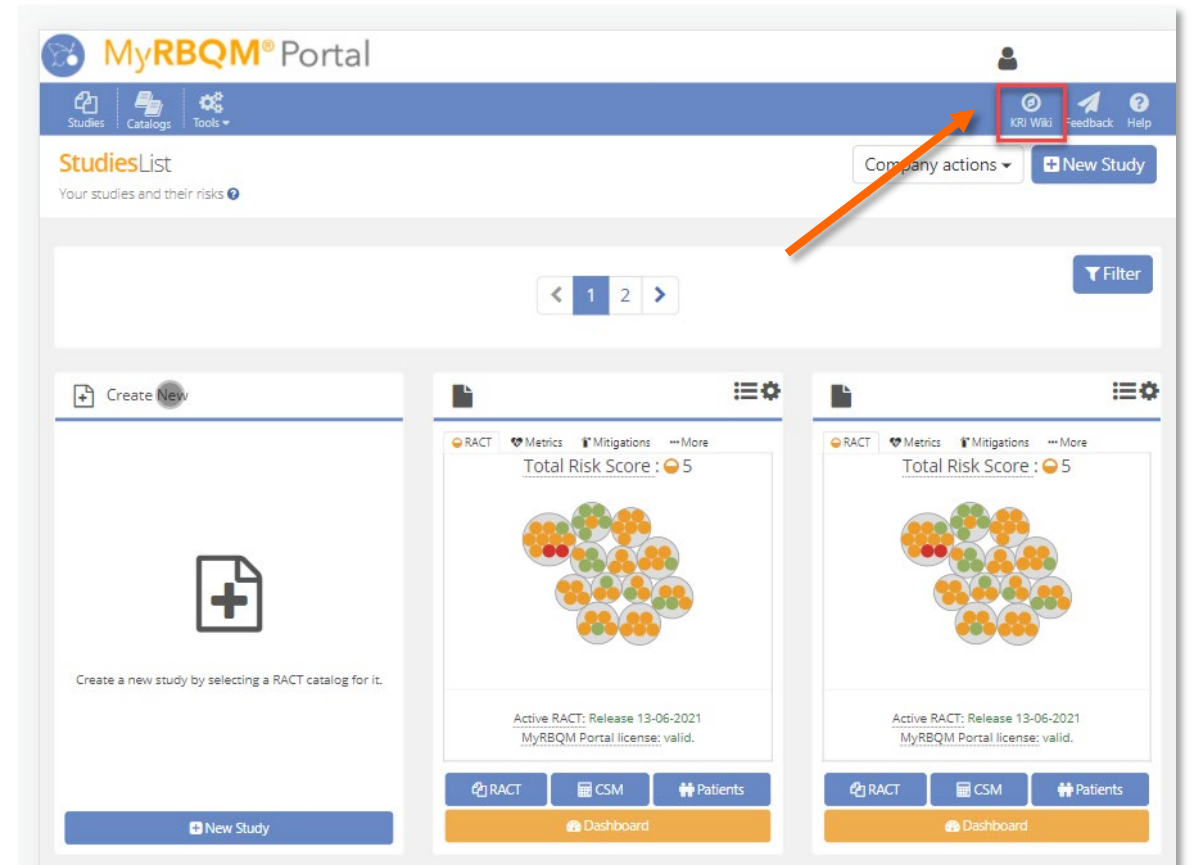
COMING SOON | ACCESS TO NEW RESOURCE

KRI Wiki – Knowledge Base

All users will get access to the robust and standardized knowledge base “*KRI Wiki*”. Besides filtering for **Cyntegrity’s Golden KRIs** and therapeutic area, the user can view the following information:

- Currently 28 KRIs, and their:
 - Risk Statements
 - Metrics and Associated Metrics
 - Thresholds

→ **Try it yourself:** [coming soon](#)



COMING SOON | ACCESS TO NEW RESOURCE

KRI Wiki

Search

Recent Changes Media Manager Sitemap

Trace: • start

start

Clear all filters

Golden KRI Yes ☐ No ☐

Therapeutic area Select all

KRI list

Category	KRI
data collection procedures	Critical data entry time is too long
data collection procedures	eCRF too many overdue monitoring pages
data collection procedures	eCRF too many unmonitored pages
subject population	High Percentage of Dropouts Due To Informed Consent Withdrawal
subject population	High Percentage of Lost To Follow-Up
data collection procedures	High Percentage of Missing CRF Entries/Pages
study endpoints	High Percentage of Missing Outcomes
data collection procedures	High Percentage of Total Overdue Queries
data collection procedures	High Percentage of Unverified Queries
safety	High Rate of concomitantly prescribed drugs
data collection procedures	High Rate of Delayed Query Responses
subject population	High Rate of DropOuts
safety	High Rate of Early Patient Deaths
technology	High Rate of Incorrect Patient Randomization

KRI →

KRI Wiki

Search

Recent Changes Media Manager Sitemap

Trace: • critical_data_entry_time_is_too_long • ecrf_too_many_overdue_monitoring_pages • start • high_rate_of_dropouts

kri:high_rate_of_dropouts

High Rate of DropOuts (kri)

Type of indicator	Risk
Risk Category	subject population
Golden KRI	YES
Therapeutic Area	General
IF Risk-Event	many patients drop out during the study
DUE TO Risk Causes	various reasons
THEN Risk Impact MAY RESULT	non-acceptance of the study result by health authorities
Risk Indicator	High Rate of DropOuts
Metric	Ratio of drop out cases
Parameter	%
What level should be measured	Study/Country/Site
Suggested Thresholds - High	>5 %
Suggested Thresholds - Medium	3 - 5 %
Suggested Thresholds - Low	<3 %
Associated Metric 1	Number of drop outs due to AEs
Associated Metric 2	Number of enrolled patients
Associated Metric 3	Number of lost to follow up
Associated Metric 4	Number of informed consent withdrawn

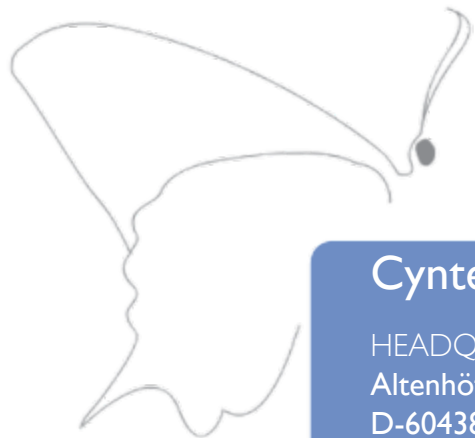
Risk Statement

Metric

Thresholds

Associated Metrics





Cyntegrity

HEADQUARTERS

Altenhöferallee 3

D-60438, Frankfurt am Main
GERMANY

t: +49 6192 - 470 - 113 - 50

f: +49 6192 - 470 - 113 - 59

US Office

t: +1 888.812.RBQM

Artem Andrianov, PhD
Managing Director

e: post@cyntegrity.com

w: www.cyntegrity.com



SEND
US
YOUR
FEEDBACK

