

Trust in Data

The journey from Excel to MyRBQM[®] Portal

TAKING RACT USABILITY TO THE NEXT LEVEL

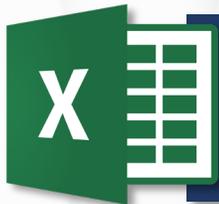
Product Management | January, 2022



Secure your
Information
and Process

9 BENEFITS





Usability

- 1 System elements are connected:**
 - Catalogs (incl. risks and mitigations suggestions)
 - Critical Process & Critical Data
 - Risk Indicators (RIs)
 - User or Group names
- 2 Clear status** of process and next steps:
 - Catalog – Category – Question statuses
 - Risks and Mitigation Action (MIT) statuses
- 3 User-friendly Risk Statement Constructor:**
 - **IF ... DUE TO ... THEN ... MAY RESULT**
- 4 Every mitigation for a Risk is presented separately** and has its own detailed description

Traceability

- 5 Company and Study Audits all changes tracked** in the Study/Company settings, actions made by user/system
- 6 Rationale for Change** system captures the reason for any change (captured in Audit)
- 7 Automatic versioning of the RACT** and ability to **compare** one of the past versions with the latest one secures “track changes”

Security & Accessibility



- 8 Privilege management system** allows adjusting MyRBQM Portal functionality for different Roles and safe process management
- 9 All information** needed for RBQM is available **in one compliant system**



9 Benefits Explained



1 System Elements are Connected

Example 1: Risk Statement

Critical Process and Critical Data can be selected from the pre-defined list

This risk is saved as 1_SAF: Safety risk for participants in the risk register.

If due to , then may result.

Impact	Low	Medium	High
Probability	Low	Medium	High
Detectability	Easy	Medium	Difficult

Risk Score: 4

Type of Risk: Please select an option risk

Associated Critical Process(es):
CRF development x Drug accountability x
Associate another Critical Process with this Risk
Add and associate a new Critical Process
Data entry
Eligibility
Endpoints

Associated Critical Data:
AE x CM x
Associate more Critical Data with this Risk

Add another Risk

Example 2: Add new Mitigation

Assigned users, associated Risk and Risk Indicators, Functional Plan can be selected from the pre-defined lists

Mitigations

Create New MIT_NEW

Owner: [dropdown]
Risk: 1_SAF: Safety risk for participants

Responsible: CRAs
Review Settings: Every 4 weeks

Associated Risk Indicators:
RI_T_26 - High Rate of PD Related to the IMP
RI_T_17 - High Rate of Queries
RI_T_32 - High Rate of Queries for Laboratory Analyses
RI_T_30 - High Percentage of Dropouts due to IC Withdrawal

Functional Plans:
Medical Monitoring Plan
Safety Plan
Data Plan
Statistical Analysis Plan

Study Plans: [text area]
Mitigation Actions: [text area]

Discard Save

Spelling standardization and pre-defined lists used for form filling **increase data integrity and administration time.**





2 Clear Status of Process and Next Steps

Example 1: RACT

RACT status overall readiness and details for each category question can easily be found in the RACT Tool

Category: Safety Total Risk Score: 0

Step 1 out of 13

Q1	Q2	Q3	Q4	Q5	Q6	Q7
...
...
...

Category: Safety Total Risk Score: 4

Step 1 out of 13

Q1	Q2	Q3	Q4
...
...
...
...

Example 2: Mitigation Actions

Status of each mitigation action (MIT) added to the Risk (New/Active/Closed) or Risk acceptance is presented in Risk Tab

Active MIT_121

Owner: Irina 01 GA

Responsible: Irina 01 GA

Risk: 3_POP: Failure to follow I/E criteria

Review Settings: Every 4 weeks

Mitigation Goal:

1. train sites during start up visits
2. retrain sites during all monitoring visits
3. Increase % of SDV\SDR
4. Additional MVs\co-MVs\audits

New MIT_120

Owner: Irina 01 GA

Responsible: Irina 01 GA

Risk: 3_POP: Failure to follow I/E criteria

Review Settings: Every 4 weeks

Mitigation Goal:

Central monitor - assess and identify trends, remote 100% listings review

Mitigation Actions:

1. Train sites\CRAS
2. Consider protocol amendment
3. Consider stop of recruitment
4. Consider study Newsletter



MyRBQM Portal allows study managers to **control the RACT process readiness.**





3 User-Friendly Risk Statement Constructor

Example:

MyRBQM RACT risk statements follow a clear template which makes them reusable in other Studies (Catalog principle). Users can set up Risk Scores and determine the impact of each element (Impact, Probability, Detectability). Subsequently, users can add Critical Process and Critical Data to the Risk.

Add this Risk's data to the Knowledge Base. Delete this risk

If due to , then may result.

Impact	<input type="button" value="Low"/>	<input type="button" value="Medium"/>	<input type="button" value="High"/>	Risk Score
Probability	<input type="button" value="Low"/>	<input type="button" value="Medium"/>	<input type="button" value="High"/>	...
Detectability	<input type="button" value="Easy"/>	<input type="button" value="Medium"/>	<input type="button" value="Difficult"/>	

Type of Risk: This is a risk

Associated Critical Process(es): *No Critical Processes are associated with this Risk*

Associated Critical Data: *No Critical Data is associated with this Risk*



Standardization is the key to **efficient future Cross-Study analytics.**



4 Distinct Risk Mitigation Actions and Detailed Description

Example: Every MIT attribute (owner, responsible person, action and other plans, goal, revision frequency, associated RIs) has its own field, which increases the level of Risk Management quality.

The screenshot displays a risk management interface. At the top, there's a header for '4. DAT: Data entry delay' with an 'Edit Risk Name' link. Below this, a descriptive text states: 'If Late data entry due to frequent study visits, then data integrity, study timelines may result.' To the right, a 'Risk Assessment Score' of 18 is shown, along with sub-scores for Impact (2), Probability (3), and Detectability (3).

The main section is titled 'Associated Risk Indicators' and contains a table with the following columns: 'Associated Risk Indicator', 'Likelihood of this Risk (in %) if this KRI fires?', and 'Add an Associated Risk Indicator'. One entry is visible: 'RI_T_29 - Long Mean Time for Data Entry' with a likelihood of 100%.

Below this is the 'Mitigations' section, which lists two mitigation actions:

- MIT_35 (Closed):** Risk: 4_DAT: Data entry delay. Review Settings: Once at Nov 30, 2017. Mitigation Goal: Payment dependency on eCRF completion (in contracts). Mitigation Actions: N/A.
- MIT_34 (Active):** Risk: 4_DAT: Data entry delay. Review Settings: Every 1 months. Mitigation Goal: MP - remote control of eCRF completion, phone contacts to re-train and push. Consider enrollment stop when issues identified. Mitigation Actions: N/A.



Clear Connection between Risk – MIT – Associated RI allows the team member to efficiently **control the Risk and react timely.**

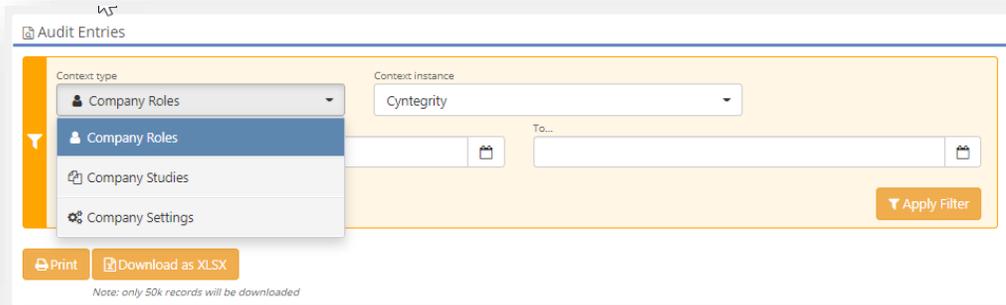


Limited MS Excel Track Changes: can show who had made what change in what cell/range before the moment file was saved with different name/reloaded to the SharePoint.

 **5** Company and Study Audits

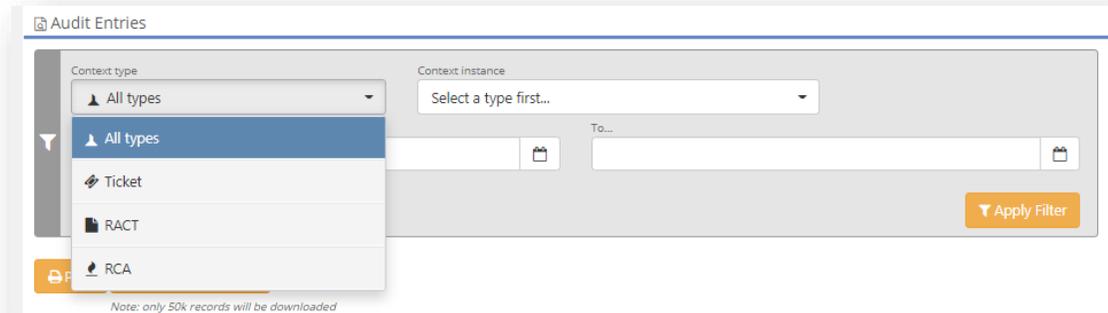
Example 1: Company Audit

Keep records of actions performed at the Company Level



Example 2: Study Audit

Keep records of actions performed at Study level



updated a role. Reason for change: test. DEC 14 2021, 6:27 AM (UTC) Hide details

Datapoint	Action	OldValue	NewValue
Role	Changed	{ "id": "61668a53e0e1161d4060bb3a", "companyId": "6049e66db3b3b22958740774", "DisplayName": "Central Monitor (CM)", "Privileges": ["access_csm", "create_csm_tickets", "create_generic_tickets", "create_kri_tickets", "create_site_tickets", "edic_auto_ticket_assignment", "edic_kri_threshold"] }	{ "id": "61668a53e0e1161d4060bb3a", "companyId": "6049e66db3b3b22958740774", "DisplayName": "Central Monitor (CM)", "Privileges": ["access_csm", "create_csm_tickets", "create_generic_tickets", "create_kri_tickets", "create_site_tickets", "edic_auto_ticket_assignment", "edic_kri_threshold"] }



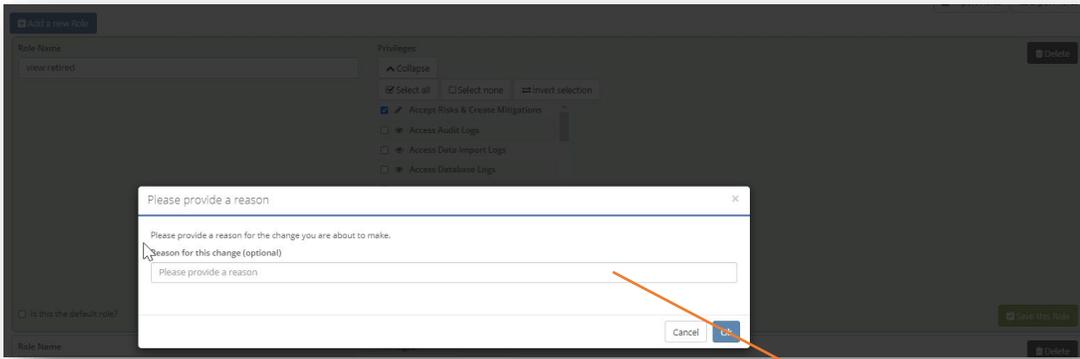
Limited MS Excel Track Changes: can show who had made what change in what cell/range before the moment file was saved with different name/reloaded to the SharePoint.



6 Rational for Change

Example: Company Audit – Role Change

When a change is made, In addition to the employee's name, date and time the system also captures the Rational for Change which will help to explain why this change was made in several months or years.



updated a role Reason for change: test: DEC 14 2021, 6:27 AM (UTC) Hide details

Context: Company User Roles

Datapoint	Action	OldValue	NewValue
Role	Changed	{ "id": "61668a53e0e1161d4060bb3a", "companyId": "6049e66db3b3b22958740774", "displayName": "Central Monitor (CM)", "Privileges": ["access_csm", "create_csm_tickets", "create_generic_tickets", "create_kri_tickets", "create_site_tickets", "edit_auto_ticket_assignment", "edit_kri_thresholds", "edit_tickets", "link_kris_to_risks", "manage_ias", "manage_migrations", "manage_reports", "view_catalogs", "view_dashboard", "view_data_logs", "view_kris", "view_metrics", "view_protocols", "view_reports", "view_sites", "view_tickets", "view_user_management"] } } }	{ "id": "61668a53e0e1161d4060bb3a", "companyId": "6049e66db3b3b22958740774", "displayName": "Central Monitor (CM)", "Privileges": ["access_csm", "create_csm_tickets", "create_generic_tickets", "create_kri_tickets", "create_site_tickets", "edit_auto_ticket_assignment", "edit_kri_thresholds", "edit_tickets", "link_kris_to_risks", "manage_ias", "manage_reports", "view_catalogs", "view_csm", "view_dashboard", "view_kris", "view_metrics", "view_protocols", "view_reports", "view_sites", "view_tickets"] } } }

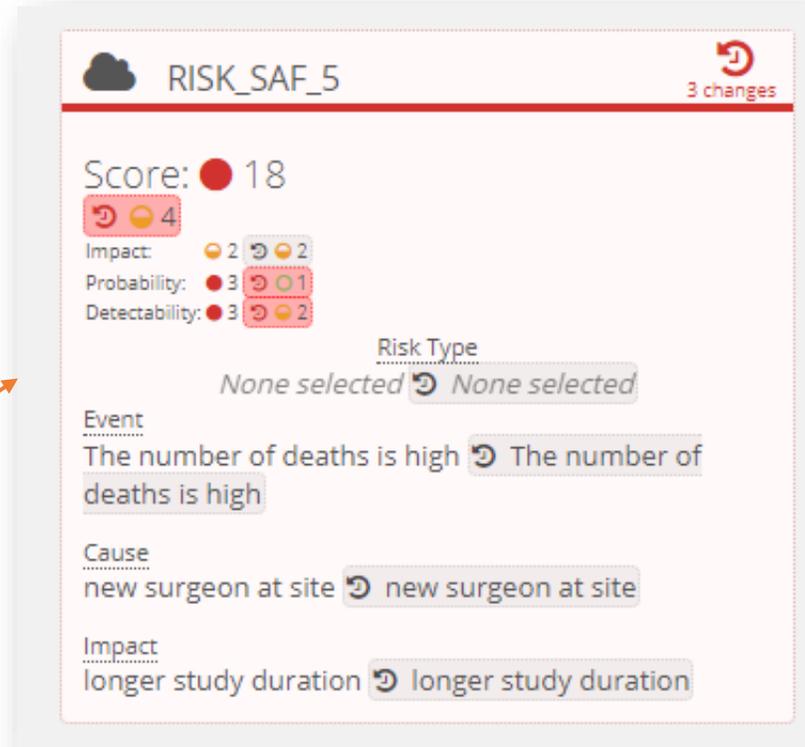
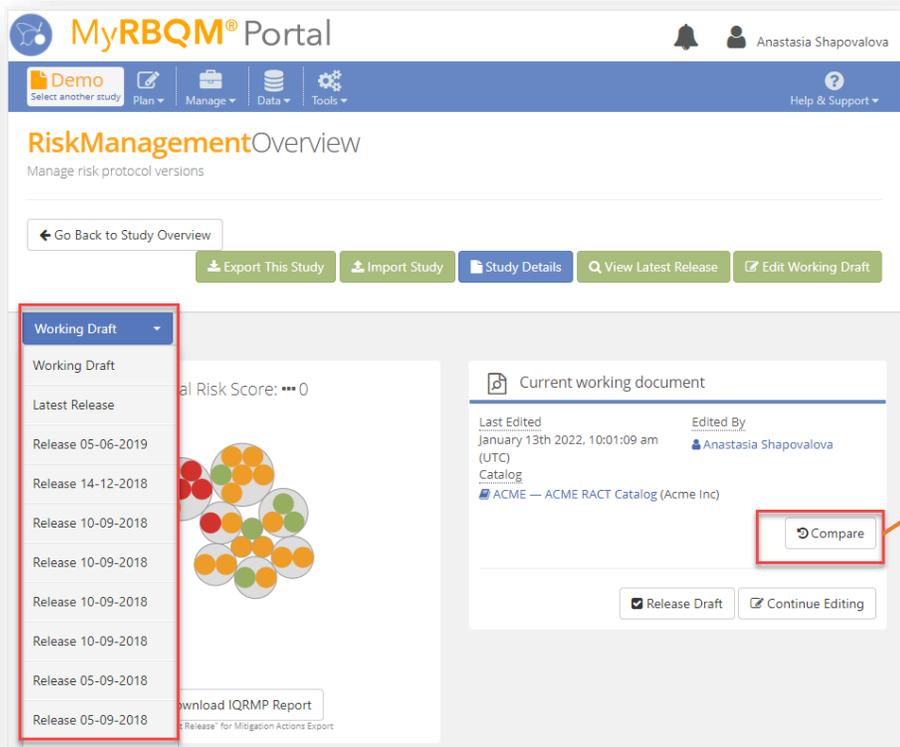


The ability to explain Who? When? and Why? performed certain actions is one of the basic Audit success criteria.



7 Automatic Versioning of the Secure RACT

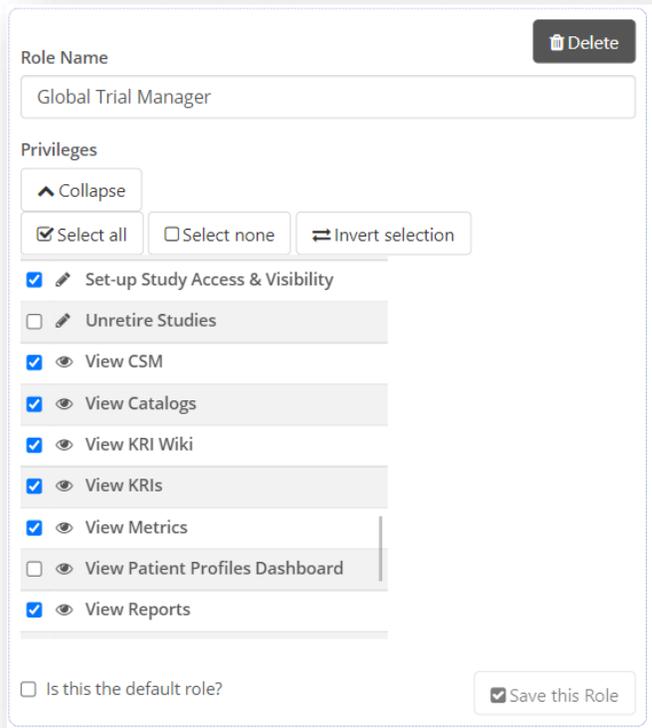
Example: All RACT version releases contain a unique, non-deletable version number. MyRBQM RACT facilitates version comparisons and highlights the changes.





8 Role-Based Access Control (w. Privilege System)

Example: The privilege system allows setting up different roles covering different functions that will enable you to keep the RBQM process under control and ensure that only authorized users perform the actions.



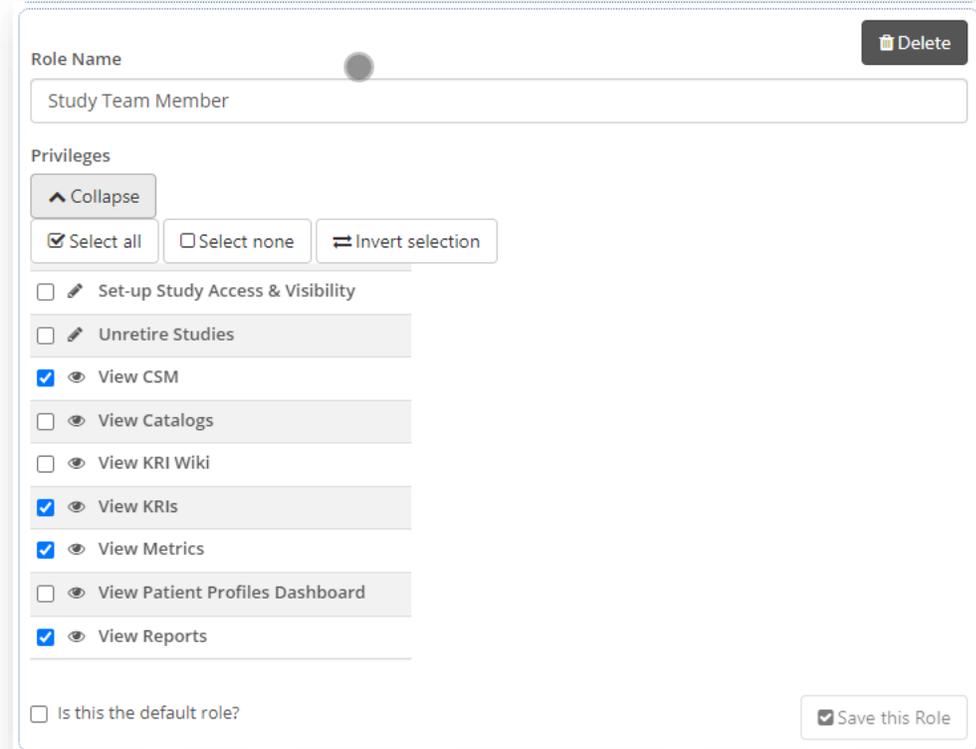
Role Name: Global Trial Manager Delete

Privileges

Select all Select none Invert selection

- Set-up Study Access & Visibility
- Unretire Studies
- View CSM
- View Catalogs
- View KRI Wiki
- View KRIs
- View Metrics
- View Patient Profiles Dashboard
- View Reports

Is this the default role? Save this Role



Role Name: Study Team Member Delete

Privileges

Collapse

Select all Select none Invert selection

- Set-up Study Access & Visibility
- Unretire Studies
- View CSM
- View Catalogs
- View KRI Wiki
- View KRIs
- View Metrics
- View Patient Profiles Dashboard
- View Reports

Is this the default role? Save this Role



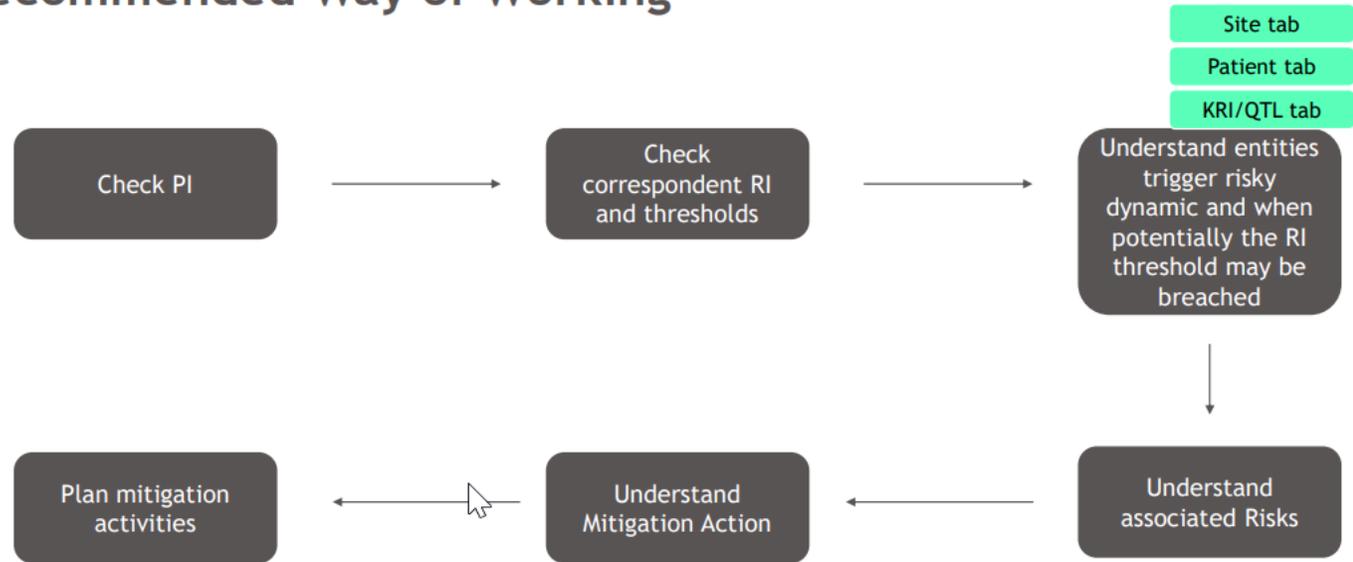


9 All Information Needed for RBQM is Available in One Place

Example:

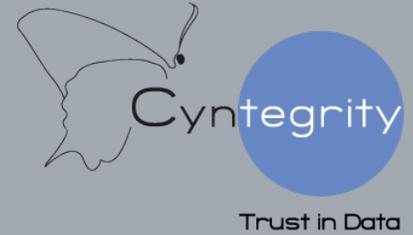
Keeping all information in one system allows the users to have a complete picture of the Risk status and root causes (which RIs and entities at what level drive the Risk to the "Red Zone"). In addition, the users can track improvements and understand the effectiveness of the mitigation, improvement/corrective, and preventive actions.

Recommended Way of Working



Sharing a synchronized data set and reporting (all available in one place for comprehensive analysis) **decreases the time of an action plan development and execution and secures the team alignment.**





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