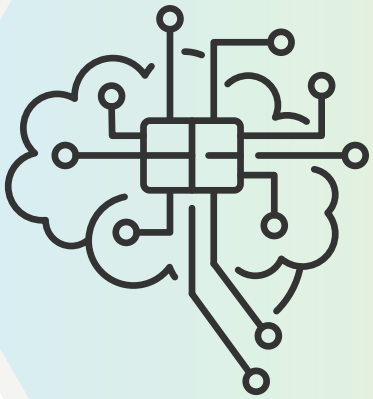
Julius Clinical

ONE-PAGER

RISK-BASED QUALITY MANAGEMENT (RBQM)



AN ADVOCATED APPROACH

Risk Based Quality Management (RBQM) is the ICH, EMA, and FDA advocated approach to manage risks for the entire lifecycle of a clinical project. However, widespread adoption of all RBQM components is still relatively low despite all proven benefits.

Julius Clinical is a strong believer of RBQM. As clinical projects are increasing in complexity and increasing in number of data points and external data sources, at the same time expanding their usage of external digital data-sources, centralized monitoring offers the best way to monitor these multiple data sources.

DEFINITION & BUILDING BLOCKS

RBQM is a change in the way clinical projects are performed that will enhance the overall quality of a clinical project. It consists of several components, that should be tailored to the clinical project design and scope to make most efficient use of resources and achieve the best outcome.

- Cross-functional risk assessment
- Centralized Monitoring
- Off-site/Remote monitoring strategy
- Targeted/Triggered monitoring strategy
- Reduced SDV/SDR Strategy
- Reduced/Targed Data Management reviews

QUALITY BY DESIGN

RBQM is known for safeguarding participants safety and well-being and, above and beyond it provides the best reliable clinical project results (quality by design). The implementation of RBQM leads to more efficient use of the resources available, increases the quality of the data, enhances the patient safety, and it gives us better oversight of the current state of a study. On top of that it allows us to act more decisively to possible changes, challenges, and additional risks within a clinical project. The primary goal of RBQM is not a reduction of costs.

THE #1 SYSTEM

In the current market we deem CluePoints offering, endorsed by the FDA, the best fitting and matured RBQM system. CluePoints offers a large set of methods to detect key risks, atypical data, and to monitor the study status for potential issues. Because CluePoints is integrated with our other clinical operation systems (i.e. Veeva CTMS and CDMS) and processes, the use of CluePoints will lead to the most efficient way to conduct your projects.

SCAN THE CODE
To read our full
RBQM One-pager

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SDV CASE STUDY

UNDERSTANDING THE IMPACT OF SDV IN NEURODEGENERATIVE STUDIES

To assess the impact of Source Data Verification (SDV) in our studies, we pooled data from three neurodegenerative studies and analyzed data changes between the electronic Case Report Form (eCRF) completion date and SDV completion date.

KEY FINDINGS

117,786
Total eCRFs Analyzed

83,229 (71%)
eCRFs Without SDV Changes

34,557 (29%)
eCRFs With SDV Changes

IMPACT OF REDUCING SDV ON DATA QUALITY

By gradually reducing SDV, we estimated its effect on data cleanliness:

- At 50% SDV, the percentage of clean eCRFs remains high at:
  - 92% (Study 1)
  - 97% (Study 2)
  - 90% (Study 3)

This means that cutting SDV efforts by half (saving ~3,000 hours) only results in a 7% decrease in clean eCRFs. No SDV at all still results in 71% clean eCRFs.

KEY TAKEAWAYS

✓ SDV requires significant resources, but its impact is limited

- Our findings align with other studies, which report SDV contributing to only 1-2% of data changes.
- The effect of SDV may be overestimated in our analysis, as not all data changes in the SDV timeframe are necessarily SDV-related.

✓ A tailor-made strategy for the study should be considered

- A risk assessment deterimining the CtQ and risk of a study needs to be carried out cross-functionaly.
- For each CtQ and risk an appropriate strategy should be implemented e.g. central monitoring, SDV, etc.