Quarterly Updates

Dear colleagues,

Since our last update, the Expert Working Group has made good progress on study-specific KRIs. Our discussions have focused on why standard KRI sets are not enough, how KRIs should link back to CTQs and prioritized risks, and what teams need to consider when designing indicators that are truly fit for purpose.

In this update, we share our latest thinking, key process challenges, news from SCOPE Europe, and an update on the RBQM Oversight resources.

Current Topic: Study-specific KRIs
Work continues apace on our new topic. We've been focusing on the challenges of determining and implementing study-specific KRIs.

Why have study-specific KRIs?
We decided it was important to articulate this as some organizations use only a standard set of KRIs across studies. The Expert Working Group sees this as a "one size fits all" approach which is explicitly discouraged in ICH E8(R1). A risk proportionate approach starts with CTQs (critical to quality factors) and prioritizes risks to those. For highly prioritized risks, the method of detection should be carefully considered and often leads to the need for study-specific KRIs. It is an important part of designing quality into the clinical trial and focusing resources on what matters.

Process map and process challenges
We have developed a generic process map and worked through each of the steps to consider common industry challenges and solutions. For example, **the generation of test data is time-consuming and often does not cover all possible scenarios**.

Possible causes of this challenge include:

- The data used to calculate the KRI has not been collected previously, and the likely data issues are unknown.
- Previous data is used but may not have the variation that occurs in the trial
- The impact of missing and "dirty" data is not considered
- It is difficult to think of all possible scenarios – the appropriate system experts may not input into the development e.g. ePRO
- Use of audit trail in KRI calculations can be challenging to test
- Constantly changing the standards

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And possible solutions:

- Have a standard set of scenarios to develop test data
- Focus on the risk and ensure test data is developed to test for the risk
- Use AI to generate test data for various scenarios
- Maintain a library of test data
- Adhere to CDISC standards, whenever possible
- As with the RBQM Oversight topic, we are considering what learning resources we can develop to assist with overcoming the identified challenges.

EWG Members on Panel at SCOPE Europe

We are excited to announce that members of the EWG will be part of a panel discussion at SCOPE Europe at 11:20 on October 14th in the **RBQM track**. The panel title is "Helping to ensure your study-specific KRIs are up to the job" and I will be moderating. Do come and have a chat with us if you're there!

Previous topic: RBQM Oversight

Use the "Resources" link on our website to download the resources for free. We'd love to hear your feedback no them. Our paper on this topic is in peer review with the journal, Therapeutic Innovation and Regulatory Science, and we hope it will be published soon.

Stay involved

If you'd like to follow updates, contribute to the discussion or join the Expert Working Group:

Website: https://www.minds-on.org/
LinkedIn Group: https://www.linkedin.com/groups/10088435/

As always, thank you for the open discussions, shared experience, and willingness to challenge assumptions.

Best wishes,

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