



Quarterly Updates

Happy New Year, and welcome to the first update of 2026!

Since our launch in 2025, the Expert Working Group has met on numerous occasions working to develop a best practice approach and learning resources for **RBQM oversight**. This is an area that has clearly gained attention with ICH E6(R3) and continues to prompt thoughtful discussion across the industry.

Where we are now

We are delighted to announce that we have made the learning resources available to the industry on our website <https://www.minds-on.org/>. The learning resources published are:

- **RBQM Oversight Process** which provides an overview
- **RBQM Oversight Trial Assessment** to help assess the intensity of oversight needed
- **RBQM Competency Questions** that can be used to assess process capability up-front
- **RBQM Oversight Mitigation Examples** which provides examples of different oversight intensity activities
- **RBQM Reflective Questions** which are designed to assist with oversight during a trial

The aim of these learning resources is to pull together knowledge from industry experts and make it available to support others – they are ready to be developed and built on and are not designed as rigid checklists or tools.

Sharing the work

We're pleased that the work of the group is starting to be shared more widely. Johann Proeve and Bethann Schrader-Giancarlo will be presenting at [SCOPE Florida in February](#), with a session titled:

"RBQM Needs Oversight – A Practical Approach"

If you're there, we hope you can join. We want to hear what our industry colleagues think. Thank you to members of the EWG who have contributed thought, time and effort to get us so far.

In parallel, we have developed a technical paper for publication which is in its final review stage. Thank you to everyone who has contributed time and careful feedback to get this over the line.



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What's next

Our immediate next steps are to:

- Socialise the **RBQM Oversight learning resources** with industry colleagues and gather feedback
- Finalise the **paper on RBQM Oversight** and submit to a journal
- Begin shaping our **next topic of focus**

We are currently proposing to look next at **KRI and QTL programming**, particularly how to ensure they do what they are intended to do in practice. We'll be testing this idea with the wider community and welcome early reactions. If this is an area of interest for you, please get in touch!

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. We're looking forward to building on this in 2026.

Best wishes,

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