

Risk Based Monitoring



Working Group Scope

Although Risk Based Monitoring is no longer considered a new way of working, it continues to stay an area that is constantly evolving. Changes in landscape due to the pandemic are accelerating this evolution.

This Working Group will identify innovative approaches in risk management and data analytics to proactively manage data quality and subject safety risks. The Working Group will support the pharmaceutical industry with change management challenges related to moving towards risk-based approaches.

Current Projects

[Quality Tolerance Limits](#)

Marion Wolfs: Working Group Lead

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Marion Wolfs is Head, Risk Management-Central Monitoring (RM-CM) within the Integrated Data Analytics and Reporting (IDAR) organisation from Janssen Pharmaceutical Companies of JnJ.

In this role Marion provides leadership and strategic direction for all activities in the RM-CM department and oversees enterprise wide implementation of ARBM at JnJ.

Marion joined the pharmaceutical industry in 2007 and worked in various clinical operations roles until joining the Risk Management-Central Monitoring Group in October 2014. She was the RBM TransCelerate Co-Lead from 2016 till 2019.

She holds a Master of Science degree in Biomedical Sciences from the Maastricht University and an International Certificate in Enterprise Risk Management from IRM in London.

Andy Lawton: Working Group Lead

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Andy Lawton is a consultant for Risk Based Approach Ltd, specialising in business changes related to ICH (E6 R2/3 and E8 R1), in particular QTL's, QbD and RBM.

Andy has been working in the clinical development arena for over 42 years and has covered most roles/tasks and was a Founding Committee Member of ACDM, Member of TransCelerate RBM, QTL, Data Transparency, eSource work streams and also a Member of EFPIA WG on Data Transparency.

In addition to the Working Group Lead role, Andy will be Co-Lead for the Quality Tolerance Limits Project.