

Dear RQA Member,

You are receiving this invitation to complete an online questionnaire as a member of the RQA and with experience related to GCP.

The purpose of this online questionnaire is to evaluate the role of Quality Assurance in clinical trials run under Risk-Based Monitoring model, as part of an independent research project for the MSc in Quality Management for Scientific Research and Development at Cranfield University, supported by the RQA.

This questionnaire has been designed to help answer the following research questions:

1. How does the Risk Based Monitoring strategy affect the various aspects of quality in clinical trials?
2. To what extent are Quality Assurance professionals involved in implementing Risk-Based Monitoring in their organizations?
3. Is there a need to amend the process of auditing investigator sites where the Risk-Based Monitoring approach is used?

This survey is not specifically targeted for individuals who have experience in Risk-Based Monitoring. However the respondents need to be familiar with the RBM approach and its differences from conventional monitoring process.

By responding to this questionnaire you will be contributing to a final thesis titled: *Evaluation of the Quality Assurance Role in Clinical Trials under a Risk Based Monitoring Model*. This is an independent research project and is not linked to any company or organisation. The outputs of this thesis may be made available in future RQA publications or presented at future Regional RQA forums.

It should take no more than 10 minutes to complete the survey which comprises 8 questions, which are mostly multiple choice questions. The survey is provided by Qualtrics electronic survey platform, through Cranfield University, and can be accessed via the attached link.

This research project is subject to ethics approval by Cranfield University. There is no signed consent for participants - completion of the questionnaire implies consent to take part. All questionnaire responses will be anonymous, confidential and no responses will be linked to any individual. You can at any time withdraw your participation in this questionnaire; any responses that you have provided up to the point of withdrawal will be included in the final analysis. Whilst you are requested to respond to all questions, you may choose not to respond to a particular question if you so wish.

**[Click here to access the Survey](#)**

Thank you for taking time to participate in this research. Your time and input is greatly appreciated.

If you have any queries, or you're interested in the outcome of this research, please don't hesitate to contact me.

Kind regards

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