CORA Cork Open Research Archive
Cartlann Taighde Oscailte Chorcaí

Title	Perceived barriers and facilitators to risk based monitoring in academic-led clinical trials: a mixed methods study
Authors	Hurley, Caroline;Sinnott, Carol;Clarke, Mike;Kearney, Patricia M.;Racine, Emmy;Eustace, Joseph A.;Shiely, Frances
Publication date	2017
Original Citation	Hurley, C., Sinnott, C., Clarke, M., Kearney, P., Racine, E., Eustace, J. and Shiely, F. (2017) 'Perceived barriers and facilitators to Risk Based Monitoring in academic-led clinical trials: a mixed methods study', Trials, 18, 423 (11pp). doi: 10.1186/s13063-017-2148-4
Type of publication	Article (peer-reviewed)
Link to publisher's version	https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-017-2148-4 - 10.1186/s13063-017-2148-4
Rights	© 2017, the Authors. Open Access This article is distributed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license, and indicate if changes were made. The Creative Commons Public Domain Dedication waiver (http://creativecommons.org/publicdomain/zero/1.0/) applies to the data made available in this article, unless otherwise stated. - https://creativecommons.org/licenses/by/4.0/
Download date	2026-10-10 14:16:10
Item downloaded from	https://hdl.handle.net/10468/4902

University College Cork, Ireland
Coláiste na hOllscoile Corcaigh

Study: Perceived barriers and facilitators to Risk Based Monitoring in academic-led clinical trials: a mixed methods study

Document: Interview Topic Guide

Hi (participant's name) , thank you for completing the Monitoring Survey. The questions I will ask you today will further explore your view and opinions on risk based monitoring. There are no right answers so please stop me if you want me to clarify any question.

---

1. To start could you tell me about the most recent clinical trial you worked on and your role in that trial?
2. At what stage is that trial- recruitment, close out?
3. How is/was that trial monitored?
4. Did you/team use on-site and/or centralised monitoring? Did you use an electronic clinical report form eCRF
5. Who developed the initial monitoring plan? *(You, monitor, PI)*
6. Were you involved in the development of the monitoring plan?
7. Why did you/they choose this type of monitoring? *(Cost, IT, staff)*
8. Was the monitoring plan reviewed and changes during the trial duration?
9. In November 2016, the ICH-GCP will launch the updated version of GCP which will recommend clinical trial Sponsors use risk based monitoring. Are you familiar with the new guidelines
10. If no we can review paragraph from 'participant sheet'?

11. Are you familiar with the term risk-based monitoring?

12. Have you ever conducted risk-based monitoring in a clinical trial?

13. Do you think risk based monitoring will change you monitor a clinical trial in the future?

14. Do you feel there are benefits associated with RBM?

15. Do you think there are limitations associated with RBM?

16. In future trials you work on, would you consider using risk-based monitoring?

17. In these trials, would you like to be involved in the development of a monitoring plan?

18. Do you feel you have the skills and knowledge base to conduct RBM?

19. What intervention or support would help you conduct risk based monitoring?

20. Who should lead this intervention?

21. How much commitment would you give to the intervention?

22. Do you have any additional information you would like to add?

23. Do you have any questions for me?