

BEING INSPECTION READY: TOP TIPS AND WARNINGS.

If you were handed with a notice for a clinical trial inspection plan right now, how would you react? - With a feeling of asserted confidence or a rush of slight concern? Wherever you think you would stand on this spectrum, use this infographic to learn from your peers' mistakes. Pharma IQ invites the expertise of Andy Fisher Senior GCP Inspector MHRA on a list of common TMF failings.

FACT

Alongside a number of other EU member states, Andy was recently involved in drafting guidance that the EMA is due to publish shortly. This draft guidance for TMF will replace what is currently in volume 10.



INTERACTIVE

Roll over the titles to see the tips  and Warnings 



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Resources

- 1 – trial Master File EU TMF Guideline http://ec.europa.eu/health/files/eudralex/vol-10/v10_chap5_en.pdf
- 2 – <http://www.wingspan.com/5-ways-to-improve-your-tmf-lessons-from-the-2015-tmf-summit/>
- 3 – Indepth article on how to prepare and be as GCP as possible with CTS <https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials>
- 4 – <https://tmfrefmodel.files.wordpress.com/2014/11/2014-tmf-survey-4-v1.pdf>
- 5 – <http://www.clinicalleader.com/doc/you-ve-gone-this-far-now-complete-your-tmf-0001>
- 6 – <http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodClinicalPractice/News/CON408249>
- 7 – <http://hallorancg.com/case-studies/tmf-inspection-readiness-strategy-needed-for-pivotal-clinical-trials/>
- 8 – <https://mhrainspectorate.blog.gov.uk/2015/07/30/inspecting-clinical-trials-the-trial-master-file/>
- 9 – <https://www.veeva.com/eu/wp-content/uploads/2015/12/Journal-of-Clinical-Trials-TMF-survey.pdf>
- 10 – EU discussion paper http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2013/02/WC500138893.pdf