BEING INSPECTION READY: TOP TIPS AND WARNINGS.

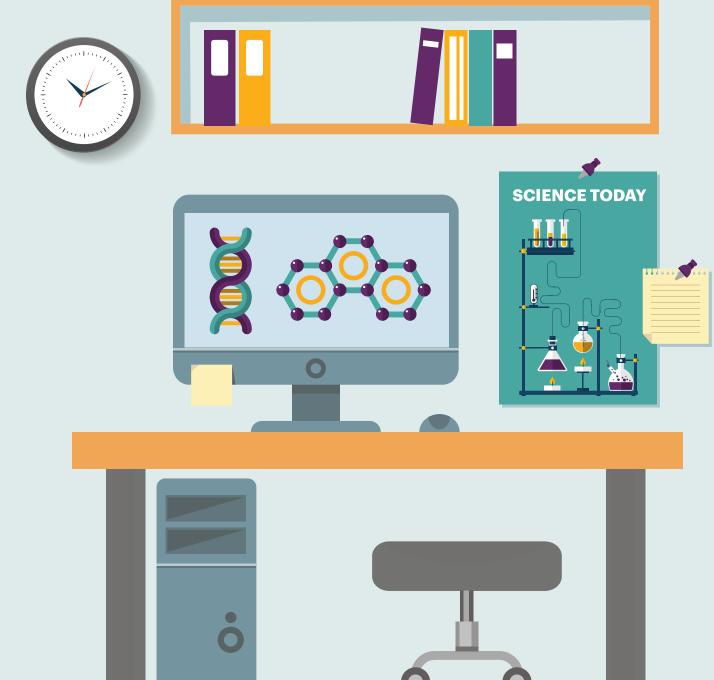
If you were handed with a notice for a clinical trial inspection plan right now, how would you react? - With a feeling of asserted confidence or a rush of slight concern? Wherever you think you would stand on this spectrum, use this infographic to learn from your peers' mistakes. Pharma IQ invites the 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 This draft guidance for TMF will replace what is currently in volume 10.









TRIAL MASTER FILES EUROPE 2016

12th -14th September • Barcelona

Exploit the opportunity to build on your peers' successes and learn how to effectively manage your TMFs.

This interactive, case study-driven event features TMF industry experts from the Pharma industry and regulatory landscape. The inspiring speaker panel will share real examples of TMF development and management, the challenges encountered and how they were overcome.

In September 2016, join 70+ industry experts in Barcelona to address the biggest challenges hindering the successful development and management of TMFs.

Reasons to attend

Live Inspection Simulation!

tmf-0001

Live Debate! CRO vs Sponsor Managed TMF

A regulatory body simulates a real inspection! The audience will get to watch as a 'real' inspection takes place before them.

Hear a CRO representative and a pharma TMF leader debate their unique benefits, and stir the pot with your own questions and points!

Visit: www.tmfeurope.com Email: enquire@iqpc.co.uk Call: +44 (0)207 036 1300

DOWNLOAD AGENDA

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 www.gov.uk/guidance/good-clinical-practice-for-clinical-trials
- 4 https://tmfrefmodel.files.wordpress.com/2014/11/2014-tmf-survey-4-v1.pdf
- http://www.clinicalleader.com/doc/you-ve-gone-this-far-now-complete-your-
- 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-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