

## Web Links from Today's H32 – Advanced Monitoring Course

### Resources –

- EMA GCP FAQ <https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-clinical-practice/ga-good-clinical-practice-gcp>
- MHRA GCP Forum & FAQ [http://forums.mhra.gov.uk/forumdisplay.php?1-Good-Clinical-Practice-\(GCP\)](http://forums.mhra.gov.uk/forumdisplay.php?1-Good-Clinical-Practice-(GCP))
- FDA GCP/Clinical Trial Guidance <https://www.fda.gov/science-research/guidance-documents-including-information-sheets-and-notice/selected-fda-gcp-clinical-trial-guidance-documents>
- UK TMN Guide to Efficient Clinical Trial Management [https://cdn.ymaws.com/www.tmn.ac.uk/resource/resmgr/tmn\\_guide/uktmng2.web.pdf](https://cdn.ymaws.com/www.tmn.ac.uk/resource/resmgr/tmn_guide/uktmng2.web.pdf)
- UK TMN Cancer Supplement [https://cdn.ymaws.com/www.tmn.ac.uk/resource/resmgr/tmn\\_guide/uktmn\\_cancer\\_supplement\\_firs.pdf](https://cdn.ymaws.com/www.tmn.ac.uk/resource/resmgr/tmn_guide/uktmn_cancer_supplement_firs.pdf)

### Key UK Legislation and Guidance which covers GCP –

- [The Medicines for Human Use \(Clinical Trials\) Regulations 2004](#)
- [The Medicines for Human Use \(Clinical Trials\) Amendment Regulations 2006](#)
- [The Medicines \(Advisory Bodies\) \(No. 2\) Regulations 2005](#)
- [The Medicines for Human Use \(Clinical Trials\) Amendment \(No.2\) Regulations 2006](#)
- [The Pharmacists and Pharmacy Technicians Order 2007](#)
- [The Medicines for Human Use \(Clinical Trials\) and Blood Safety and Quality \(Amendment\) Regulations 2008](#)
- [The Medicines for Human Use \(Miscellaneous Amendments\) Regulations 2009](#)
- [The Medicines for Human Use \(Advanced Therapy Medicinal Products and Miscellaneous Amendments\) Regulations 2010](#)
- [MHRA's guidance for clinical trial sponsors and host organisations on electronic health records](#)