



Medicines & Healthcare products
Regulatory Agency

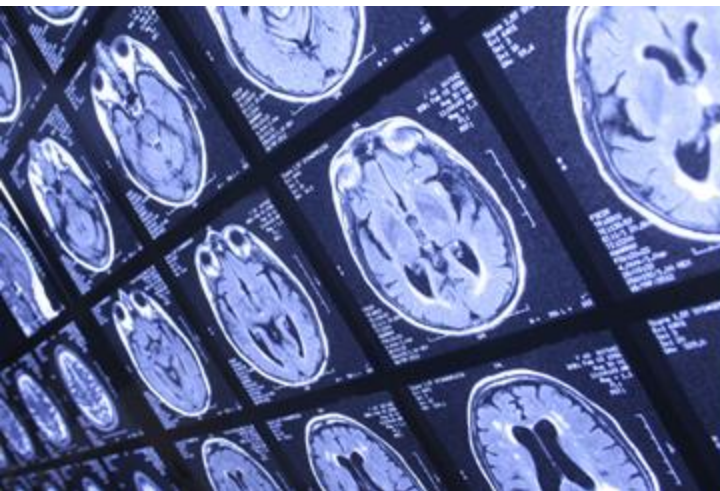


MHRA
Regulating Medicines and Medical Devices

MHRA Update

GCP StEM Meeting 18 March 2016

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Welcome



- 10.30-10.45 Intro and MHRA Update
- 10.45-11.15 TMF: MHRA Perspective
- 11.15-11.45 ePRO: MHRA Case Study
- 11.45-12.15 Reference Safety Information (RSI)
– Key Issues
- 12.15-12.30 StEM – Future Meetings



- CT Regulation delayed until ~October 2018
- EMA & Commission Guidance Updates
- Look out for (and respond to!) public consultations, including:
 - Risk proportionate approach ~June 2016
 - TMF



HRA Approval Process



- GCP inspectorate represented at HRA Collaboration & Development Forum to ensure inspectors are kept up to date with HRA approval process/ issues during implementation phase;
- Regular CTCG meetings with HRA;
- Inspectors aware of changes;
- Sponsor approval systems will need to be updated for implementation of new process.



Compliance Reports



- As of now, submission of GCP Compliance Reports to MHRA is no longer required
<https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials#compliance-report-requirements>
- Since 2009 used to provide intelligence in order to support the GCP inspection 'universe' and planning – thank you!
- Reduced regulatory burden;
- Inspection dossiers still provide up to date systems/ trials information at point of inspection.



Scoping Exercise



- Organisations inspected held within Sentinel;
- Parent – Organisation – Site;
- Aware that universe not up to date due to number of mergers/ acquisitions etc.
- Largest Pharma have been sent ‘scoping exercise’ to ensure information we hold in relation to inspected organisations is accurate, including:
 - Overarching company;
 - Business Units;
 - Quality Systems;
 - Therapeutic areas etc.



Scoping – future direction



- Scoping of largest pharma will help to ensure most appropriate focus of inspection notifications and split of organisation systems by e.g.:
 - Business Unit/ subsidiary;
 - Systems.
- You may be asked for additional information
- Potential to seek further info from CROs and large non-commercial organisations too
- Purpose is to further develop our RBIs and ensure regulatory burden is proportionate.



Communication Strategies



- ctdhelpline@mhra.gsi.gov.uk
 - for queries to MHRA - 14 day response;
- GCP Forum
 - For information sharing/ discussion with stakeholders;
 - Also MHRA FAQ answers ‘yellow stickies’
 - [http://forums.mhra.gov.uk/forumdisplay.php?1-Good-Clinical-Practice-\(GCP\)](http://forums.mhra.gov.uk/forumdisplay.php?1-Good-Clinical-Practice-(GCP))
- Inspectorate Blog
 - Communication of ‘hot topics’, common inspection issues etc. e.g. RSI!
 - <https://mhrainspectorate.blog.gov.uk>
- GCP Symposium 2016, 20-22 September.

