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

Regulatory Update

- 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)
- Inspectorate Blog
  - Communication of ‘hot topics’, common inspection issues etc. e.g. RSI!
  - https://mhrainspectorate.blog.gov.uk
- GCP Symposium 2016, 20-22 September.