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