Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Digital Topics

Discussion

Guidance and legislation

- Are there any new guidance/ legislation on the horizon? (eSignature, eConsent, BYOD etc.)
  - **Joint MHRA/HRA Guidance on eConsent**
  - **EMA Guideline on electronic systems and electronic data in clinical trials – comprehensive guidance – includes medical records, ePRO/outcome assessments, eCRF, IRT, eConsent, remote authentication & System Security, Validation, Data Integrity and Data Life Cycle etc.**
- Will device and traditional pharmaceutical legislation become more aligned?
  - **Opportunities to review this, but no formal plan; trials can include devices and medicines, joint inspection has been conducted**

Discussion

Recent experiences with digital studies

- How many digital/virtual studies have been inspected?
  - **Not seen any virtual trials**
  - **Seen a pilot eConsent**
  - **Almost all trials have a digital/electronic element**

Discussion

- How did the inspection technique differ and what was the focus?
  - **Technique does not differ but focus on control of the data; how are changes made and documented (lots of issues with ePRO), access to and control of data (sponsor/investigator), how is the system developed and validated (and updated)**
- With regard to sponsor inspections could you provide:
  - Level of focus on digital technologies
  - Lessons learned & suggestions on handling digital technology
- **Covered in next slide/questions**

Discussion

Level of ‘quality’ in digital health

- Can you describe any observations/trends regarding quality and digital health
  - **Look at electronic systems at Sponsor inspection – have had a focus on Vendors providing systems over the last 2 years to give a wide coverage**
  - **Most frequent findings Data Integrity Controls, CSV, Contracts (see EMA Q&A), Essential Documents, Project Management (due diligence/protocol amendments)**
- What have been the barriers to inspecting the technical aspects?
  - **Access, lack of audit trails, lack of documentation**
- What influence has ICH E6 R2 had on how you inspect/reference?
  - **Ratifies expectations, but principles have always applied to electronic data**