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

• 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