Human Intelligence Applied to Artificial Intelligence, Virtual Trials and GCP
Auditors’ Experience

- From a GCP perspective – not much!
  - Systems in development and pilot stages
  - Some experience from IT Systems Auditors in Vendor Support/Vendor Evaluation
Potential Challenges to Current GCP
Principal Investigator Responsibilities & Oversight

- Direct Patient Data Capture
  - No ‘traditional’ source
  - Direct to Sponsor systems a possibility or required 3rd party involvement?
- Patient remote from Site
- Site set-up may rely on centralised primary review (not a traditional PI/Patient relationship)
  - Medic may be a trial-appointed medic, not patient’s treating physician
- Is a decision made by computer acceptable?
  - What control and checks are made over algorithms used?
Record Integrity / Record-keeping

- Direct Patient Data Capture
  - Investigator/Sponsor divide non-traditional
  - Who is responsible for the quality of the data – the Patient?
  - Do patients need more education in their role and responsibility in data capture

- Are Virtual Trial methodologies/digital technologies suitable to all types of studies under appropriate risk management systems?
Record Integrity / Record-keeping

- Direct Patient Data Capture
  - Alarm/Alert & Warning sensitivities - are they static or dynamic? Robust and timely?
  - Follow-up to warnings/alerts may be critical to safeguarding patient safety

- What failsafes are in place?
  - What happens in the event of device error?
  - Downtime?
  - Poor connectivity/internet?
  - When to pull the plug?
GCP Training, Device & Technology Awareness

- IT Systems Developers responsible for development, scale-up of device(s)
  - Level of GCP training appropriate to responsibility greater than at present?
  - Science, compliance and safety integrated not isolated?
  - Maintenance of validated state? Sponsor ability to detect change?
  - Urgency in application of ‘bug fix’, ‘patch application’

- Auditors, Regulators, Ethics Committees
  - IT knowledge and skills to evaluate risks