



where science and ethics meet

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



where science and ethics meet

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