Experience of Digital Technology in GEP Trials in the UK

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Who am I?

- Studied Agriculture
- Practical experience working on research farms & field trials (Long Ashton)
- IT background – databases and software development
- Regulatory – Efficacy specialist, evaluating efficacy data
- Official Recognition – 15 years experience of Official Recognition (GEP) inspections
- Currently Head of GB/NI Official Recognition Scheme
- I therefore have experience in;
    - agriculture,
    - practical field trials,
    - regulatory efficacy evaluations,
    - GEP and
    - Technology / computers

GEP in GB/NI

- Currently 65 facilities which hold Official Recognition certification.
- Multi-site multi-national companies to sole owner/operators.
- There are no Official testing stations or facilities in the UK.

Certification available for:

Agriculture / Horticulture

Stored Crops

Biologicals and Semiochemicals

Vertebrate Control Agents

GEP managers/inspectors experience of the adoption of digital technology for data generation for the efficacy evaluation of PPPs.

Digital technology in GEP trials

This is very easy to answer from the GB/NI perspective

None to date

No facilities are currently using any digital technology in their assessment of GEP trials.

Digital technology in GEP trials

- Some facilities do use digital technologies but primarily for monitoring or environment control.
- Very few use laptops or tablets in the field for direct recording.
- Some switched to electronic recording, but then reverted back to paper.

- Why?

- Feedback revealed issues with:
  - Cost – outlay and maintenance
  - Reliability
  - Robustness
  - Short life

Digital technology in GEP trials

- The use of digital technology potentially offers new assessment methodologies
- But does raise challenges from a GEP compliance perspective.
- The following key requirements must still be met.
  - record keeping
  - staff training
  - equipment maintenance and calibration

Digital technology in GEP trials

Record keeping

Issues

Storage – location

amount

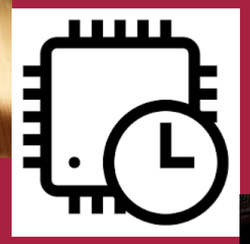
back-up

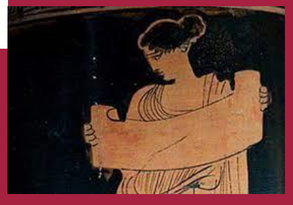
security

Compatibility – between systems

Retention

Historically readable





Digital technology in GEP trials

- Staff Training
    - Specialist training required for use?
    - Specialist training required for calibration/maintenance?
    - Specific certification?

Digital technology in GEP trials

- Equipment maintenance and calibration
- Will specialist equipment be required for
  - Maintenance
  - Calibration
  - Diagnostics

Digital technology in GEP trials

EPPO PP 1/181 states

“The primary aim of Good Experimental Practice (GEP) is to ensure that high-quality trials are conducted. This ensures that results can be used by different registration authorities. GEP is concerned with the management of efficacy evaluation trials and with the conditions under which trials should be planned, conducted, assessed, recorded and interpreted so that their results should be comparable and reliable. GEP relates to various aspects: staff qualifications, use of suitable equipment and facilities, protocols, modes of operation, recording of results.”

An important factor to the uptake of digital technology in regulatory Efficacy trials will be the willingness of the Efficacy evaluators to accept results from trials conducted using these techniques and tools.

Digital technology in GEP trials

- The development of a number of different digital and non-digital techniques or tools to assess the same parameter could potentially introduce variability into the results
- Therefore as far as possible standardisation is essential
- Validation and standardisation of the new technologies will be a pre-requisite!

- Role for ISO?

- Scope
  - Global standards?
  - EPPO defined?

Digital technology in GEP trials

- Not something that GEP managers *per se* should have a direct role in developing?
- Validation against the human eye (subjective though that is) will be required before this technology can be widely accepted
- Possible that this may be a new step in the GEP compliance check
- If the technology was adequately tested during development and certified this may not be necessary.

Digital technology in GEP trials

PROS

- In the UK the average age of people conducting Efficacy trials is rising.
    - There is an increasing difficulty in attracting younger people to the profession and also in retention.
    - Digital technology has the potential to address this issue
- Conducting a human assessment can be time consuming
    - Digital technology has the potential to address this issue
- Conducting a human assessment can produce variable results
    - Digital technology has the potential to address this issue

Digital technology in GEP trials

CONS

- Adoption and reliance on digital technology could “devalue” the current human skill in conducting assessments
- Humans will (reluctantly) do assessments in the rain/wind etc – what about digital technology?
- New tech is expensive – but usually reduces over time – or
- Remains expensive – with an increasing specification
- Robustness of technology
- How easy will it be to maintain and calibrate such equipment

Digital technology in GEP trials

- Digital technology has the potential to increase accuracy and consistency
  – how accurate do we need to be?
- Software and support
- Software upgrades – costs etc
- Hardware repair support
- Obsolescence

Digital technology in GEP trials

- Likely that initial uses will be to assess the more easily quantifiable parameters e.g.
  - Crop emergence/weed numbers
  - GAI (Green Area Index)
  - Ground cover

- The more complex areas of pest identification and severity/incidence assessments requiring much greater development and validation.

Timeframe?

Digital technology in GEP trials

Trials to demonstrate the effectiveness and crop safety of Plant Protection Products are required to be conducted in accordance with the principles of Good Experimental practice as defined in EPPO PP 1/181 and enshrined in PPP legislation.

Whilst GEP managers can strive to ensure that the adoption of digital assessment techniques and tools complies with the requirements of GEP, changes to some of the EPPO standards and to facility SOPs will be required.

Workshop provides opportunity to discuss what we need to do in the GEP arena

Thank You for Listening!