Medicines & Healthcare products Regulatory Agency

MHRA

MHRA Feedback on Regulated Bioanalysis

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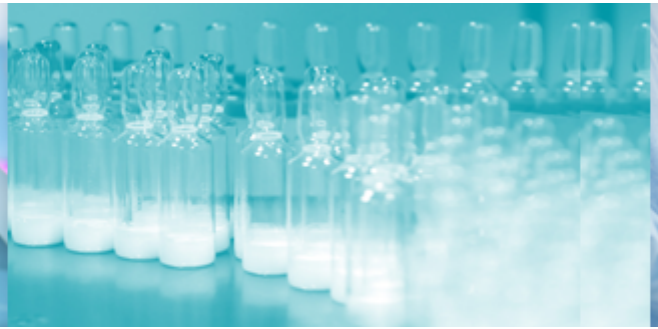
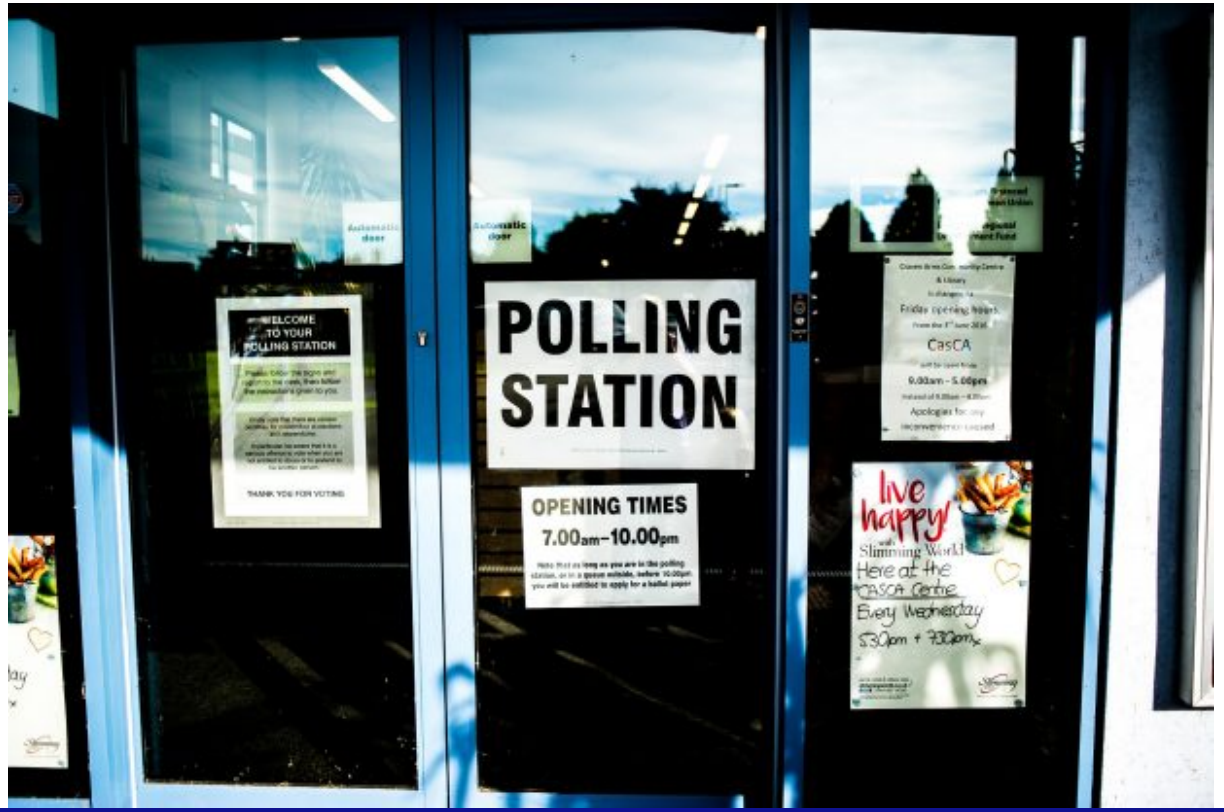
EBF 12th Open Symposium

20 November 2019


UK Pre-Election Period



ICH M10

Regulatory Collaboration

Continued interactions with other national regulators regarding:

- Inspection activities
- Information exchange
- Development of guidance
- Interpretation of guidance

International Fora

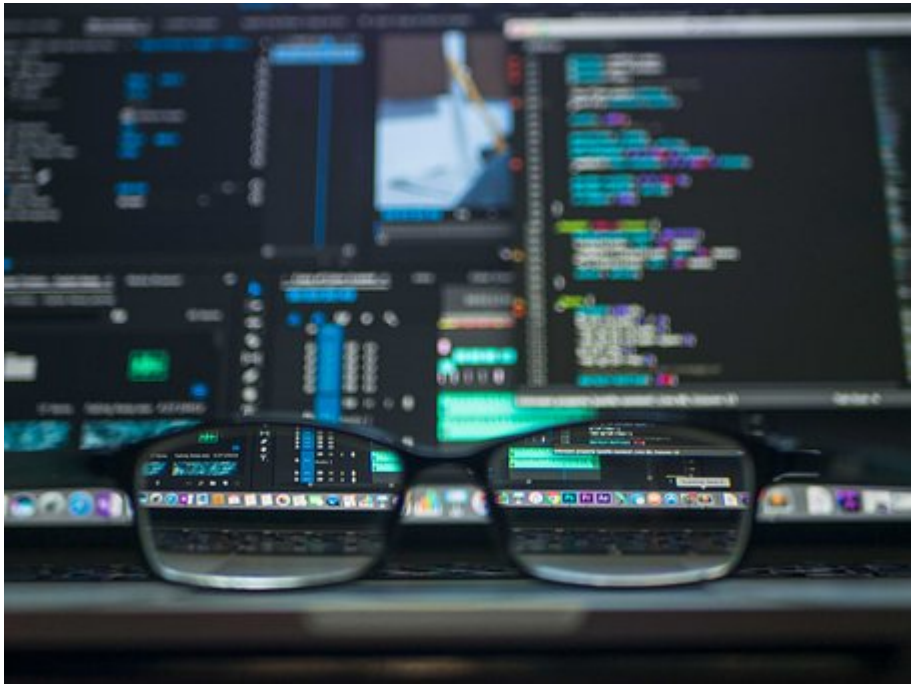
Keen to continue to support events such as EBF

- 2-Way opportunity for dialogue, learning, horizon scanning and networking
- Ability to input into discussions and to provide the regulator’s opinion

Areas of Regulatory Focus

- Data integrity
- E-Systems
- Method validation activities
- Clinical:Laboratory touchpoints
- Reporting
- Study plan compliance

Data Integrity



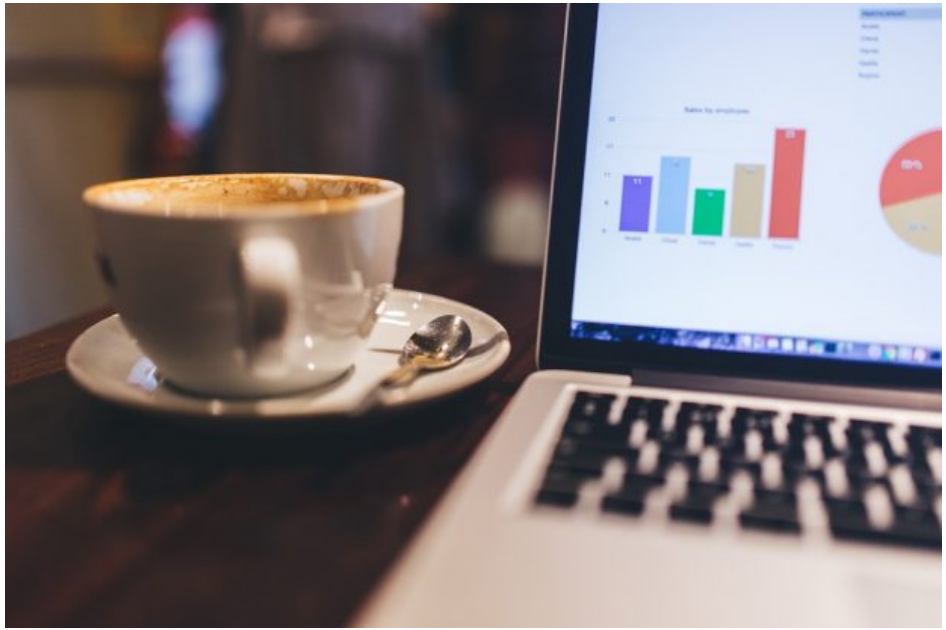
- Plenty of available guidance
- Lots of activity
- Issues:
  - Basics not covered
  - Risk based approach?
  - New kit
  - QA access

Laboratory: Clinical Site Interactions

Interactions

- Set-up
- Consent for tests
- Blinding considerations
- Communication
- Data provision

Reporting



- Accurate account of work undertaken?
- Suitable narrative?
- Compliance statement?

“Adequate long-term matrix stability to support sample storage time and conditions in this study has not been conducted”

Following the Plan?

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Any Questions?

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