U.S. FOOD & DRUG ADMINISTRATION

Day One: Wrap-up & Closing Remarks

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A Joint US-FDA | MHRA-UK | Health Canada Good Clinical Practice & Pharmacovigilance Compliance Workshop
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Medicines & Healthcare products Regulatory Agency

Health Canada Santé Canada

Overview

- Harmonization
- Digital Health Technology
- Innovations in Design
- Data Governance

Harmonization

- Updates to ICH E6, include
  - New *Data Governance* section
  - Appendices: IBs, protocol and amendments and essential records.
  - Deviation management (emphasis on impact to participant safety and data integrity)
  - Sponsor responsibility – inclusive trial design

Harmonization

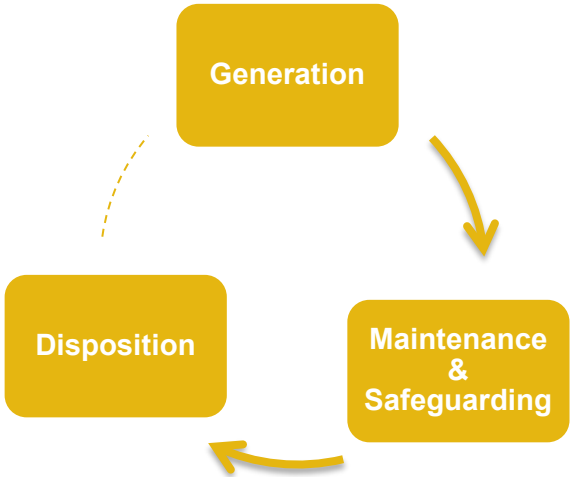
- Glossary terms/themes, to name a few…
  - Quality by design, risk proportionate, inclusive
  - Feasibility, fit-for-purpose
- Annex 2
  - Decentralized elements
  - Pragmatic elements
  - Real world data sources

Digital Health Technology

Mapping critical elements

Audit trail review

Digital or hybrid?



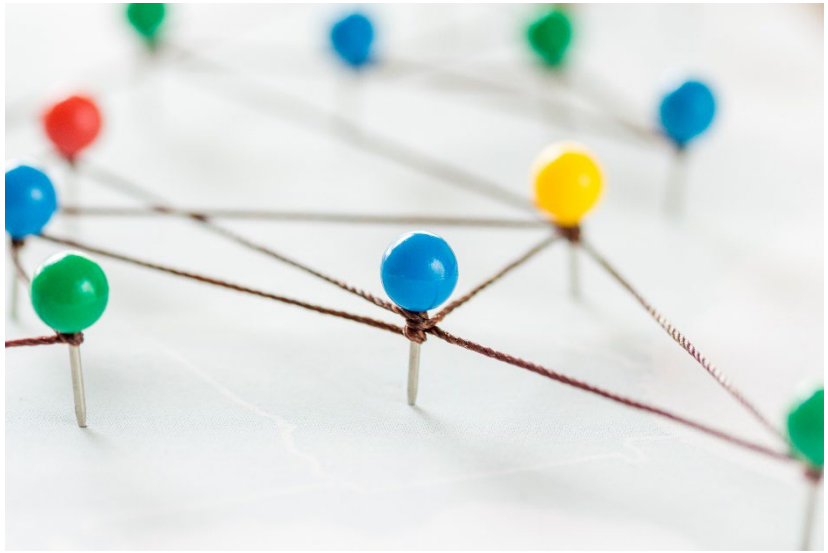
Validation

Risks to participants and data?

Devices

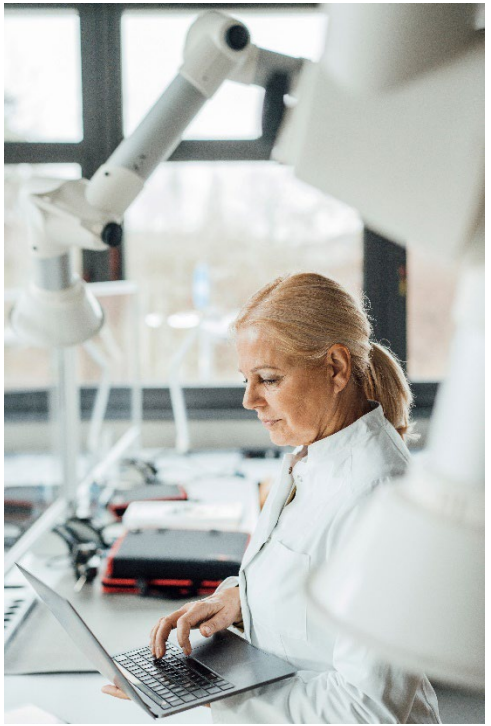
Innovations in design

- Decentralized elements offer flexibility
- Leveraging technology where appropriate
- Importance for sponsor oversight being maintained
- Proper planning is essential and includes the engagement of regulators



Data Governance

- Identify the critical-to-quality factors though each stage of the data life cycle
- Communication with all study personnel is key, and consider their input
- Risk-proportionate management of computerized systems and data governance processes
- Importance of validation – are systems purpose-fit?



Looking forward

- Sponsor Oversight
- Clinical Trials Post-Pandemic
- The Future of GCP Inspections
- Agency Updates
- Collaboration Between Agencies and Future Expectations

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