Breakout session summary:
Data Integrity

14 July 2020
14:30-15:30

Data integrity

• What do you understand the term ‘data integrity’ to mean?
• How do you ensure data integrity?
• Have there been any significant changes in regulatory/accreditation requirements in relation to ensuring/demonstrating data integrity?
• What are the challenges?
• What guidance/standards do you use – is further guidance needed?
• How do you distinguish between “data integrity” and “data quality”?
• Can “data integrity” be compromised by too much “data analysis”?
Data Integrity

Are you currently work/teach/supervise data integrity?
- 7 participants in the session
- 1 PhD student
- 2 teaching on either part-time or full-time basis
- 3 R&D staff
- 1 non-profit association
- Participants from 4 countries

- During the undergraduate and post graduate training not too much info related to the Data Integrity

Data integrity

- What do you understand the term ‘data integrity’ to mean?
- Consistency
- Accuracy
- Original
- Attributable
- From receiving stage of the samples
- Chain of custody
- Storage
- Traceability
Data integrity

• How do you ensure data integrity?

• Chain of custody
• Internal laboratory network – Limited/Authorized System Acces
• Double check
• Training of personnel
• Backup of raw data
• SOPs
• Audit Trails
• Validation
• Internal LIMS

Data integrity

• How do you distinguish between “data integrity” and “data quality”?

• Data quality – standards, proficiency test
  • Valid method
  • Staff training
• Data integrity – physical integrity of equipment and data
Data integrity

• Have there been any significant changes in regulatory/accreditation requirements in relation to ensuring/demonstrating data integrity?

  • No

Data integrity

• What guidance/standards do you use – is further guidance needed?

  • ISO 17025/2018
    • Collection, processing, recording, reporting, storage of data – SOPs
    • Quality Manual – describe the Management System

  • Can be needed for medical, clinical, forensic laboratory
Data integrity

- Can “data integrity” be compromised by too much “data analysis”?
  - Yes
  - No