



Breakout session summary: Data Integrity

**14 July 2020
14:30-15:30**

1



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”?

2



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

3



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

4



Data integrity

- How do you ensure data integrity?
- Chain of custody
- Internal laboratory network – Limited/Authorized System Access
- Double check
- Training of personnel
- Backup of raw data
- SOPs
- Audit Trails
- Validation
- Internal LIMS

5



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

6



Data integrity

- Have there been any significant changes in regulatory/accreditation requirements in relation to ensuring/demonstrating data integrity?
- No

7



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

8



Data integrity

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