National Institute of Diabetes and Digestive and Kidney Diseases

10-minute Refresher on Data Integrity

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National Institute of Diabetes and Digestive and Kidney Diseases

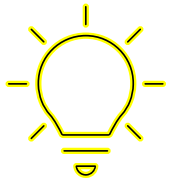
Costs of Data Integrity Failure

Rejection of data
Need for additional studies
Ethical issues
Reputational damage

Ongoing self-data review

Plan and follow “ongoing” self-data review

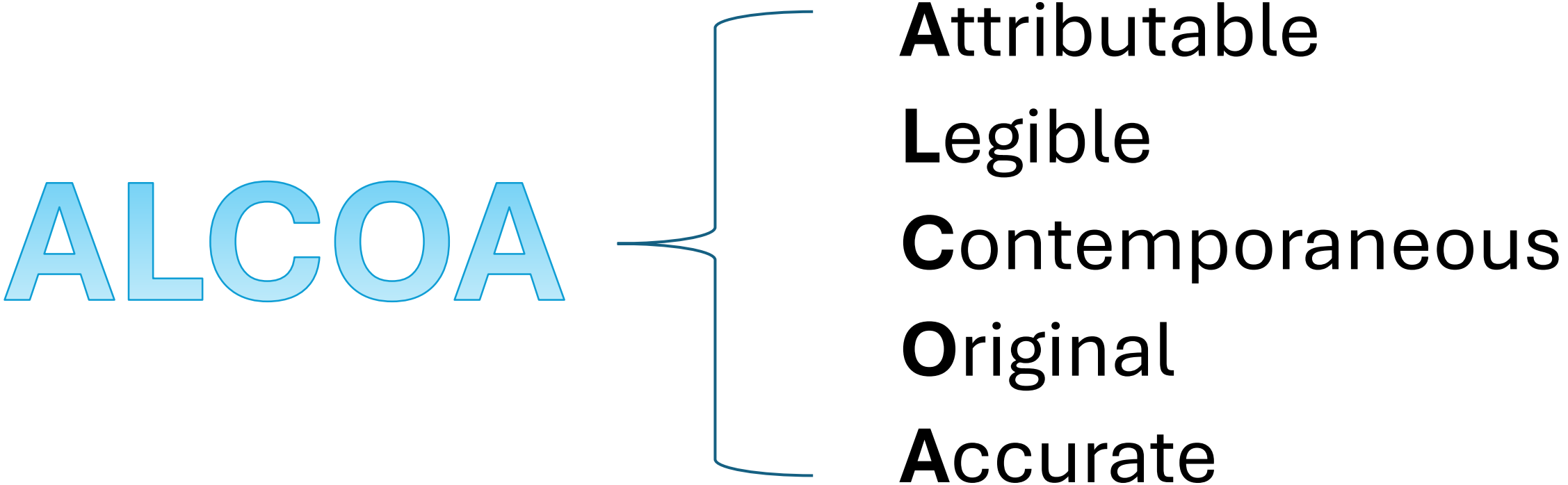
Check your data against ALCOA++



Act to mitigate identified risks

(e.g. update data management plan, clarify SOP, retrain staff)

Original Data Integrity Principles



Not **A**ttributable ☹

“For the first 196 subjects enrolled in the study between 6/26/2023 and 6/30/2023, entries in subjects’ source record forms did not include study staff initials, signatures, or any information identifying who completed the entries for protocol required activities.”

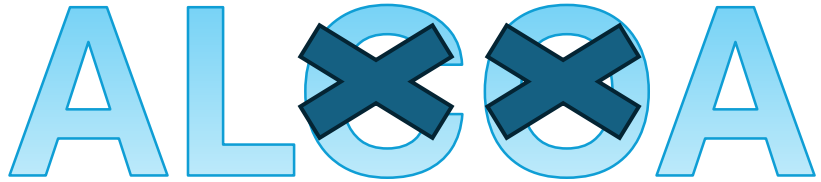
FDA Warning Letter: MARCS-CMS 719607

Not Legible ☹

“Some of the numbers written on the (histopathology) slides were no longer legible and it appeared some numbers had been wiped off and/or written over…… These slides therefore have no identification at all.”

FDA Warning Letter: MARCS-CMS 704332

Not **C**ontemporaneous & Not **O**riginal ☹



"Gaps between assessment end time and data entry ranged from seven minutes to 25 days with no source documentation of 144 assessment values for ….."

FDA Warning Letter: MARCS-CMS 671405

Not **A**ccurate ☹

ALCO~~A~~

“For Subject X, the time for obtaining informed consent was changed from 9:55 to 9:00 with no documentation or explanation for the change. It appears that the change was made to align with the study activities times which are documented as occurring between 09:00 and 09:55.”

FDA Warning Letter: MARCS-CMS 719607

Attributable
Legible
Contemporaneous
Original
Accurate

ALCOA

ALCOA

+

Complete
Consistent
Enduring
Available when needed

ALCOA +

ALCOA

+

Complete
Consistent
Enduring
Available when needed

+

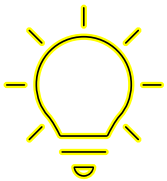
Traceable

ALCOA ++

Takeaway: Protect data integrity

Plan and follow “ongoing” self-data review

Check your data against ALCOA++



Act to mitigate identified risks

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References

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