DATA INTEGRITY IN SUBMISSIONS OF GLP STUDIES: CASE STUDIES

Dr. Labhu U. Sanghani
Director - Global QA, Jai Research Foundation, India

JAI RESEARCH FOUNDATION

INTRODUCTION

Data Integrity is the assurance that information is unchanged from its source to submission, and has not been accidentally or maliciously modified, altered or destroyed. It's a fact that without data integrity, data is no longer trustworthy and reliable and our products are considered adulterated. Data Integrity has become a HIGH focus area by the FDA and other regulatory agencies.

Assurance of Data Integrity at CRO:

- GLP quality system, raw data documentation, review, approval and archiving
- Independent QA audit of each study, raw data and reports
- GLP Inspection by GLP Monitoring Authority
- Report submission to Sponsor as approved paper copy and protected PDF

VS

What happens at Sponsor/Submitter's site?

- Review by Regulatory experts
- Submitted as Dossier or individual reports as per the procedure of regulatory authority. Paper or Electronic copy
- Data integrity assured?

CASE STUDY 1:

US EPA received GLP study reports on chemical properties of a pesticide with data integrity issues. The US EPA intimated to the National GLP Monitoring Authority. GLP Authority inspected the GLP CRO. Reports submitted to the US EPA and the reports available in the GLP Archives of CRO were compared along with raw data. Clear fraudulent case identified at Sponsor/submitter level. Detailed audit report submitted to US EPA by National GLP Monitoring Authority and subsequently the US EPA rejected the fraudulent reports.

Concerned Questions:

1. What CRO should do?
2. US EPA official site indicates inspection status as Report Rejected. What was the reason?
3. Can Regulatory Agencies provide guidance to CROs' to prevent such cases?

Our View:

1. Stop working with Client, Review of all works done for the particular Client
2. US EPA shall indicates the fact of inspection and reason for rejection of studies
3. YES, should have a forum to discuss this type of cases and guidance for CROs' to prevent fraudulent activities of submitter

CASE STUDY 2:

CRO received a query from Pesticide Regulatory body of Thailand for accuracy and integrity of Toxicity reports submitted by Sponsor. CRO scrutinized the reports and found that fraudulent reports were submitted by Sponsor using CRO's letter head, name, report template, and signature. The case was reported to the Regulatory Agency, which subsequently rejected the fraudulent reports.

Concerned Questions:

1. What CRO should do?
2. Does this type of cases shared and discussed among GLP authorities under MAD agreement?
3. Is there any steps taken or proposed to prevent such data integrity issues?

Our View:

1. Stop working with Client, Review of all works done for the particular Client
2. YES Cases should be shared and discussed among member countries
3. No, not in our knowledge

DATA INTEGRITY ISSUES NEEDS TO BE DEBATED AND DISCUSSED:

1. Link between regulatory agencies and GLP authorities, transfer of information and action
2. Information/certification to regulatory agencies by the CROs on submitted studies (in practice by some authorities)