

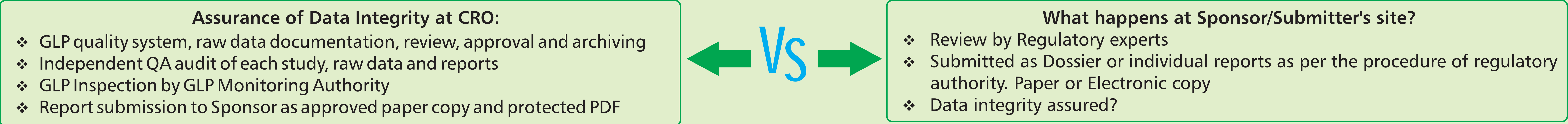


DATA INTEGRITY IN SUBMISSIONS OF GLP STUDIES: CASE STUDIES

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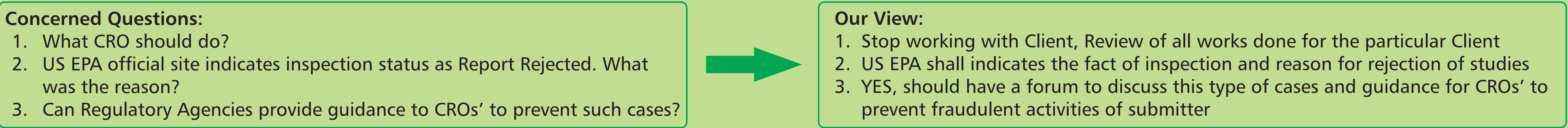
INTRODUCTION

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.



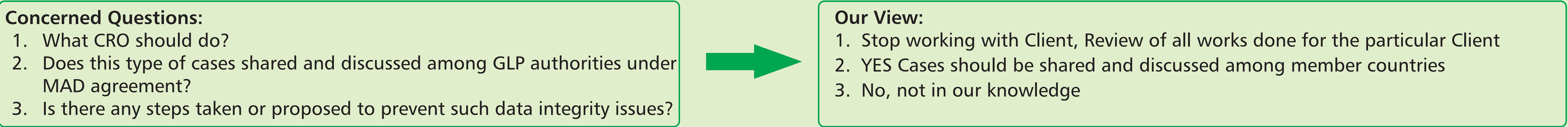
CASE STUDY 1:

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.



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.



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)