Reduced Sample Handling Errors

through Multiple Layers of Verification Process

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INTRODUCTION

SingHealth Investigational Medicine Unit specializes in Phase 1 clinical trials. During the initial phase of clinical research, accurate research data is essential to reflect the real drug profile of a research drug. Accuracy of data relies on the integrity of samples submitted for analysis. Errors in sample collection, processing, storage and shipment creates great impact on the integrity of data submitted for analysis.

Sample processing appears to be the most common source of errors. However, with proper planning, preparation and verification, potential errors could be minimized.

METHODOLOGY

Based on previous studies, there were isolated incidents of near misses where samples could have been mixed up. In order to avoid such mistakes, a more stringent verification process was implemented. A Phase I clinical trial involving 1303 samples was selected to measure the effectiveness of the verification process. Activities during the below mentioned steps were quantified and measured against errors that occurred.

Before start of trial

- ✓ Identify factors that may cause errors in sample handling before finalizing manuals
- ✓ Conduct dry run to mimic possible disruptions and challenges
- ✓ Trial specific training for all staff

Trial Commencement

Planning

Handwritten labels with subject codes affixed on sample collection tubes were verified against subject identifiers by another staff to prevent transcription errors. Subject identifiers were verified again before blood sample collection

Processing

The setting of each equipment would be verified by 2 CRCs prior to use

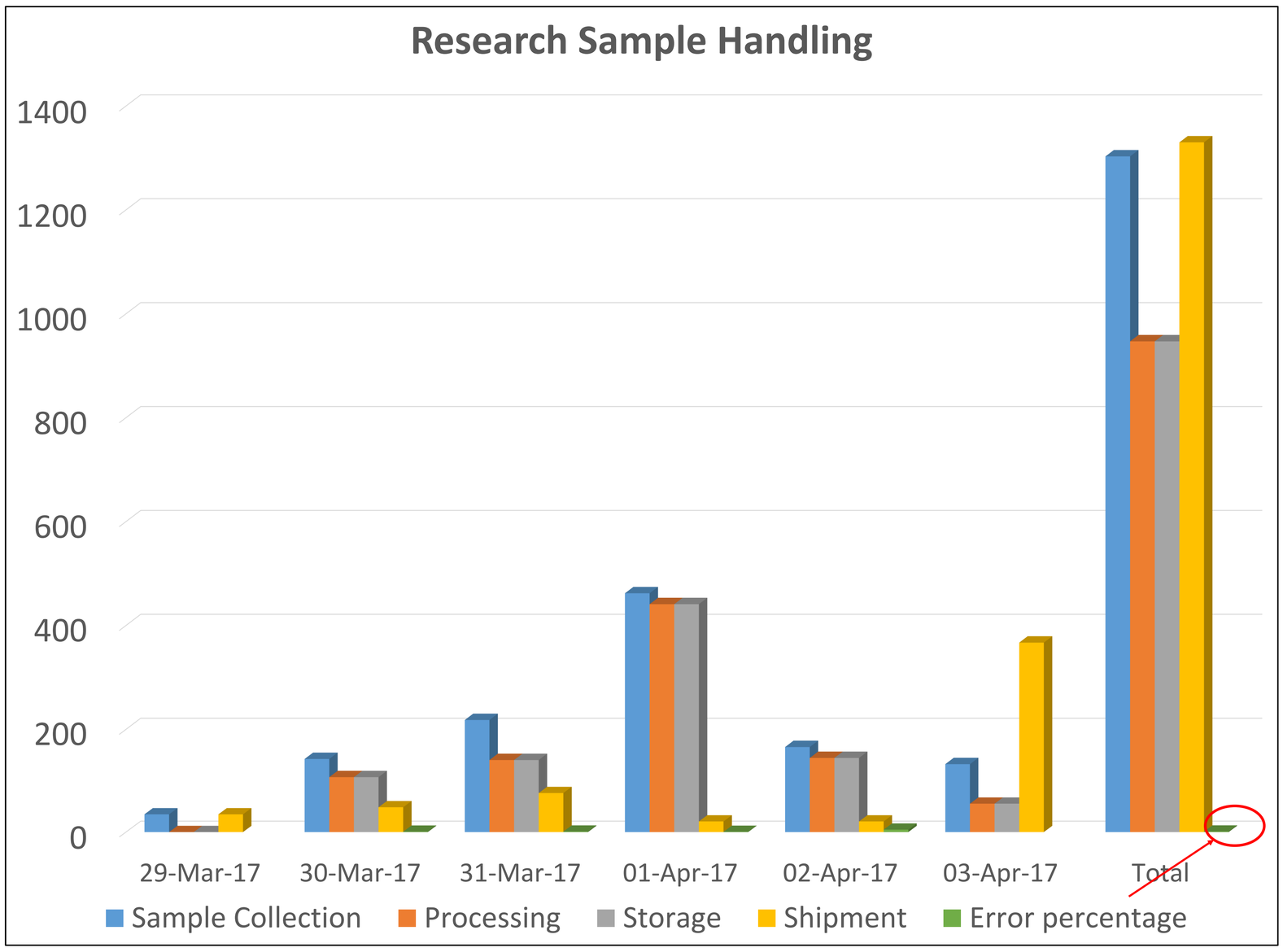
The identity of each sample would be verified by 2 CRCs prior to the transfer from blood collection tube to blood storage tube

Storage and Shipment

Samples would be sorted by 2 CRCs. Blood storage tubes were checked against the sample requisition forms and packed according to Biohazard Shipment Guidelines

RESULTS

- ✓ Identified challenges resolved before start of study
- ✓ Multiple layers of verification throughout the study reduced the occurrence of sample handling errors
- ✓ Total error percentage for sample processing, storage and shipment was 0%
- ✓ Less than 1% error for sample collection (delayed collection) reported. This can be attributed to poor patency of the cannula after 3 days, which is inevitable



CONCLUSION

Ensuring sample accuracy and maintaining sample viability plays a vital role in drug development. Therefore, stringent compliance to the multiple verification process during preparation, collection, processing, transferring, storage and shipment of research samples greatly reduced sample handling errors.